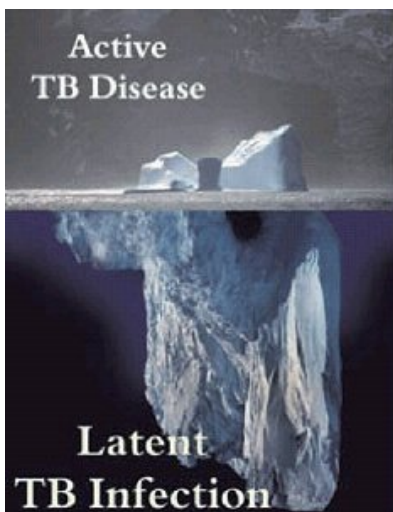


# Tuberculosis Policy and Procedure Manual

2012



Georgia Department of Public Health  
Division of Health Protection  
Tuberculosis Program  
<http://www.health.state.ga.us>

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## INTRODUCTION

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These guidelines were created to assist state, district and local health departments in controlling, monitoring, treating, notifying, and testing tuberculosis (TB) disease and infection for the State of Georgia. It is not possible for any guideline to address all situations for individuals; therefore, clinical judgment must always be exercised. Tuberculosis standards have been well established by nationally accepted scientific authorities, such as the American Thoracic Society (ATS), the Infectious Diseases Society of America (IDSA) and the U.S. Centers for Disease Control and Prevention (CDC), as well as generally recognized TB control experts such as the National Tuberculosis Nurse Coalition (NTNC) and National Tuberculosis Controllers Association (NTCA). The standards of care for the medical treatment and control of TB are published jointly by ATS, IDSA, and CDC. Georgia follows these national standards and recommendations and in addition, has state-specific standards for TB control and prevention. References to these standards are listed below:

*Nurse Protocols for Registered Professional Nurses in Public Health, current edition.* Located on the TB web pages at <http://www.health.state.ga.us/programs/nursing/publications.asp>

*Georgia Tuberculosis Reference Guide, current edition.* Located on the TB web pages at <http://www.health.state.ga.us/programs/tb/publications.asp>

NTCA, NTNC. *Tuberculosis Nursing: A Comprehensive Guide to Patient Care, Second Edition. 2011.* Each district health office and county health department was sent a copy in 2012. Additional copies may be purchased by contacting the National TB Controllers Association at <http://tbcontrollers.org/>

CDC. *Core Curriculum on Tuberculosis: What the Clinician Should Know, 2011.* Each district health office was sent a copy in 2012. It can also be ordered from CDC or downloaded at <http://www.cdc.gov/tb/education/corecurr/>

ATS, CDC, IDSA. "Treatment of Tuberculosis" (*MMWR* 2003;52[No. RR-11]). Available at: <http://www.cdc.gov/mmwr/PDF/rr/rr5211.pdf> .

CDC, NTCA. "Guidelines for the Investigation of Contacts of Persons with Infectious Tuberculosis: Recommendations from the National Tuberculosis Controllers Association and CDC" (*MMWR* 2005;54 [No. RR-15]). Available at: <http://www.cdc.gov/mmwr/pdf/rr/rr5415.pdf> .

CDC. "Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Healthcare Settings, 2005" (*MMWR* 2005;54[No. RR-17]). Available at: <http://www.cdc.gov/mmwr/pdf/rr/rr5417.pdf> .

CDC. "Targeted Tuberculin Testing and Treatment of Latent Tuberculosis Infection" (*MMWR* 2000;49[No. RR-6]). Available at: <http://www.cdc.gov/mmwr/PDF/rr/rr4906.pdf>.

ATS, CDC, IDSA. “Controlling Tuberculosis in the United States: Recommendations from the American Thoracic Society, CDC, and the Infectious Diseases Society of America” (*MMWR* 2005;54[No. RR-12]). Available at:  
<http://www.cdc.gov/MMWR/PDF/rr/rr5412.pdf>

ATS, CDC, IDSA. “Diagnostic Standards and Classification of Tuberculosis in Adults and Children” (*Am J Respir Crit Care Med* 2000;161[4 Pt 1]). Available at:  
<http://www.thoracic.org/statements/resources/archive/tbadult1-20.pdf>

### **Tuberculosis Program Contact Information:**

Georgia Department of Public Health  
Division of Health Protection  
Immunization and Infectious Disease Section  
Tuberculosis Program  
Two Peachtree Street, Northwest  
12<sup>th</sup> Floor  
Atlanta, Georgia 30303  
(P) 404-657-2634 (F) 404-463-3463  
[tb nurse@dhr.state.ga.us](mailto:tb nurse@dhr.state.ga.us)  
<http://www.health.state.ga.us/programs/tb/index.asp>

### **ACKNOWLEDGEMENTS**

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Kimberley Hazelwood, PharmD, Pharmacy Director, Georgia Department of Public Health

## **RESPONSIBILITIES FOR TB CONTROL**

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### **MISSION**

The mission of the Georgia Tuberculosis (TB) Program is to control transmission, prevent illness and ensure treatment of disease due to tuberculosis. This is accomplished by the following:

1. Identify and treat persons who have active TB disease
2. Locate, evaluate and treat contacts
3. Screen high-risk populations

The TB Program has the legal responsibility for all TB clients in Georgia regardless of who provides the direct services. TB Program services are available to all TB cases, suspects, contacts, converters, and children younger than five years old with latent TB infection; and they are not to be charged any fees for care. Clients who do not fall into the above mentioned categories may be billed for service according to local policy. However, no one can be denied service due to inability to pay at the time of service. If the client does not have the money on the day of service, the client can be billed. The state provides all TB medications and the purified protein derivative (PPD) solution for tuberculin skin testing; therefore no client should be charged for TB medications or the PPD solution.

Tuberculosis services in Georgia are provided on a cooperative basis by local county health departments, district health offices, the private medical sector, other public agencies and the Georgia Tuberculosis Program.

### **Legislative authority**

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Copies of the laws and regulations can be downloaded from these links:

- <http://www.lexisnexis.com/hottopics/gacode/> for the [Official Code of Georgia Annotated \(O.C.G.A.\) Sections 31-2-1, 31-12-2, 31-12-4, and 31-14](#)
- [http://rules.sos.state.ga.us/pages/DEPARTMENT\\_OF\\_HUMAN\\_SERVICES/PUBLIC\\_HEALTH/index.html](http://rules.sos.state.ga.us/pages/DEPARTMENT_OF_HUMAN_SERVICES/PUBLIC_HEALTH/index.html) for the [Rules and Regulations: Department of Human Services, Public Health Tuberculosis Control, Chapter 290-5-16](#)

## **RESPONSIBILITY OF THE STATE TB PROGRAM**

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### **State Medical Consultant**

Provide medical consultation to district contract physicians, local health departments, private physicians, other providers and agencies and provide recommendations for treatment of tuberculosis as requested.

Provide clinical updates to district contract TB physicians and district TB coordinators through official memoranda, conference calls, and other educational venues, as needed.

Review all cases and suspects to ensure quality and appropriate treatment regimens by attending local/district case reviews and state cohort reviews.

Monitor and approve all requests for use of second-line medications.

Review and update TB nurse protocols and the Georgia TB Reference Guide as requested by the Georgia TB Program.

### **Epidemiology**

Collect, manage, analyze and interpret TB surveillance and genotyping data to describe tuberculosis morbidity and mortality, trends, demographic characteristics and risk factors of TB cases, and the incidence of TB among high-risk populations. Interpret data to assist in development of program policies and procedures.

Manage state genotype database, notify districts of genotype clusters in their districts, conduct genotype cluster investigations, and recommend measures to control TB transmission.

Monitor resistance levels to anti-TB drugs.

Evaluate implementation of core TB program strategies and attainment of program outcome measures such as completion of therapy among active TB cases, directly observed therapy, completed contact evaluations, and completion of treatment for latent TB infection among contacts.

Conduct outbreak investigations, other epidemiologic studies and evaluation of special project interventions.

Review secondary data sources (e.g., hospital discharge summaries, AIDS registries, laboratory reports) to detect failure to report cases.

Review completeness, accuracy and timeliness of surveillance data.

Produce the annual Georgia TB Report, annual progress reports and program management reports. Respond to inquiries on TB statistics.

### **State Tuberculosis Program Staff**

Formulate and distribute state tuberculosis guidelines, procedures and protocols based on best practices.

Consult with district health departments, correctional facilities, hospitals, and all other health care providers on general concerns regarding tuberculosis management and/or specific tuberculosis cases. Provide consultation to the districts regarding the complete care of complex cases. Provide social service consultation and assessment on patients as needed.



Maintain listing of current educational materials and information on proper management and treatment of tuberculosis and act as a resource to provide these materials and information, as requested.

Maintain the tuberculosis web pages with current and accurate information on the Department of Public Health web site.

Conduct training for the district and local staff. Provide train-the-trainer courses to increase the local and district capacity for training. Maintain up-to-date training tool kits.

Provide program evaluation, technical consultation and support. Conduct site visits to local county health departments and district facilities to conduct technical consultation, quality assurance and quality improvement. Lead state case reviews and cohort reviews.

Maintain budget and financial data of all state funds and federal funds. Manages grant deliverables.

Establish, update and maintain charts for all tuberculosis suspects and tuberculosis cases. Maintain medical records on TB cases for at least 21 years. Information should include the following: Name, birth date, county of residence, medications, drug susceptibilities, and record of disposition.

Obtain documentation for out-of-state cases and/or contacts. Provide information to requesting district/county health departments.

Maintain the TB patient management module of the State Electronic Notifiable Disease Surveillance System (SENDSS) and monitor the status of immigrants and refugees in the Electronic Disease Notification System (EDN). Provide consultation and technical support to end users on these systems.

Monitor accuracy of data, establish files and internal databases, back up files, enter data and maintain tuberculosis documentation. Verify and count all cases of tuberculosis for the State of Georgia and transmit surveillance statistics to CDC.

Facilitate the process for court-ordered treatment/confinement.

## **RESPONSIBILITY OF THE DISTRICT TB PROGRAM**

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### **District Health Director**

Has the ultimate responsibility for ensuring appropriate TB management in their district. Implement TB guidelines, policies, procedures, and protocols in county health departments within the district. Provide supervision and delegate activities to staff and may delegate certain medical acts such as tuberculin skin testing, venipuncture and sputum collection to trained unlicensed public health staff.

Mediate between health care providers, the local health department, the contract TB physician and the state office to facilitate best practices for TB programs in the district. Produce and deliver health order directives as first legal step to ensure compliance for evaluation and/or treatment of tuberculosis.

Develop and maintain a working relationship with the county's attorney, the sheriff's office, hospitals and other community organizations in the district to facilitate access to needed resources, assist with patient adherence issues, and/or court-ordered therapy or confinement.

### **District Contract Physician/Consultant**

Provide for the overall medical management of clients in the county health department TB programs. Conduct and participate in regular, routine, case reviews and cohort reviews.

Remain knowledgeable on current recommendations regarding the clinical management of TB disease and infection.

Consult with the State TB Program when making recommendations for the treatment of multi-drug resistant (MDR) tuberculosis (TB resistant to at least isoniazid and rifampin) before prescribing secondary drug regimens.

Monitor the care and treatment of clients with TB disease and infection being followed by private physicians. Consult as needed with healthcare providers to ensure appropriate medical treatment.

Provide recommendations on the following clients within the specified time frame:

- Suspect/case within 48 hours.
- Close contact to TB cases/suspects and all children within 48 – 72 hours.
- All other clients within two weeks.

When contract physician is not available, provide backup physician for consultation.

### **District TB Coordinators**

Provide oversight, consultation and assistance to county health departments.

Provide consultation and assistance to other health care providers (e.g., hospitals, nursing homes, private physicians, correctional facilities, etc.).

Collaborate with physicians, hospitals, substance abuse centers, correctional facilities and community organizations to promote best practices, foster continuity of care, and provide needed social services for TB clients.

Facilitate hospitalization and/or discharge planning with social worker and/or infection control nurse.

Become a state certified TB Trainer and conduct TB Update & Skin Test (TST) Certification courses, Contact Investigation/DOT courses, TB Case Management courses and other classes

and education for the public health staff, correctional facilities and private sector within the district. Ensure TST certification is maintained by all public health staff who provide direct clinical services in TB. Submit all rosters, evaluation summaries and registration forms to the State TB Program within two weeks of each class.

Provide in-service training for tuberculosis to county health departments, local communities and other agencies.

Serve as the point of contact for counties needing emergency and long-term housing services for infectious, homeless or non-compliant clients. Identifies and establishes partnerships with local resources to provide placement as needed

Monitor the care and case management of all TB clients to ensure outcomes are obtained according to established state indicators and time frames.

Develop district policies, procedures and protocols to include infection control plan for health departments under direction of the Health Director.

Promote and conduct regular case reviews with local staff and contract physician.

Facilitate court-ordered treatment as needed.

Participate in all conference calls, in-person meetings, attend all state sponsored meetings and trainings, and disseminate the information obtained to the county health department TB staff.

Promote and conduct program evaluation activities. Perform chart audits and send summaries of findings to the state TB Office. Promote and attend state cohort reviews.

Maintain a current listing of all Public Health TB facilities that receive/participate in the *340B TB Drug Pricing Program*. Include the physical address of the facility and information regarding the contact person (e.g., name, title, phone/fax numbers, email address, etc.) who will verify 340B TB status during the state TB Office recertification period. Maintain records and ensure proper documentation of all clients receiving 340B TB drugs.

The district coordinators are to coordinate the submission of patient data to the state office. The state patient records should mirror the district patient records.

District Coordinators are to submit the following to the State TB office:

Client information on all cases and suspects including but not limited to the following:

- Consent and treatment plans
- Physicians' notes
- Progress reports
- Admission and discharge summaries
- Bacteriology results and laboratory reports
- Radiology results
- Any additional supporting documentation

District coordinators should refer to the case management timeline for a complete list of time-sensitive case management documents to report to the state office.

Grant-in-Aid quarterly reports are due to the state office on the 15<sup>th</sup> of the month following the end of each quarter. Grant-in-Aid annual report is due to the state office by July 15<sup>th</sup> of every year.

## **RESPONSIBILITY OF THE COUNTY TB PROGRAM**

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County Health Departments are responsible for the medical supervision and case management of all known cases and suspects in order to prevent the spread of tuberculosis within their county. Each county health department should have a designated TB nurse with the following responsibilities.

### **TB Nurse**

Collaborate with local physicians, local hospitals, substance abuse centers, correctional facilities and community organizations to promote TB education, best practices, foster continuity of care, and provide needed social services for TB clients. Facilitate hospitalization and/or discharge planning with social worker and/or infection control nurse. Provide tuberculin skin testing as requested. Collaborate with community organizations and facilities to perform targeted high risk TB screening and education about TB.

Ensure submissions of all isolates from local hospitals and laboratories to state laboratory for genotyping.

Upon notification of a case/suspect, a home visit within 24 – 48 hours is needed to assess the home environment for home isolation. If the patient is hospitalized, the home visit may be done within 24- 48 hours after discharge. Legal agreements and consents should be signed at this time.

Provide case management and follow-up of all known TB clients (cases, suspects, contacts, LTBI) to ensure timely and appropriate treatment. Appropriate treatment on the recommended four drug therapy should be started and completion of treatment should be within 12 months unless medically indicated otherwise. TB clients will be assessed for adverse reactions to medications at every encounter. Clinic visit, clinical status, and adherence shall be monitored and documented monthly. Directly observed therapy (DOT) is the standard of care for all cases, all children under the age of five with active TB disease or LTBI and for all HIV-infected persons with active TB disease or LTBI. Conversion of positive cultures to negative cultures will be documented. Drug susceptibilities will be completed on all initial specimens.

Cooperate with and assist private physicians treating tuberculosis clients. Obtain information from physicians assuring the private provider completes the “Initial Report on Clients with TB” form 3141 and “Follow-up Report on Clients” form 3142 monthly.

Facilitate the enforcement, when necessary, of tuberculosis laws and regulations to protect the health of the public.

Thorough contact investigations should be done to elicit and completely evaluate identified contacts. Infected contacts should be started on appropriate therapy with completion of treatment within 12 months.

Provide documentation for and participate in local, district and state case reviews, cohort reviews, chart audits and other program evaluation activities.

Receive reports of suspects/cases from other health care providers and promptly submit these reports (physicians' notes, progress notes, admission and discharge notes and bacteriology and radiology results) to the district TB Coordinator.

**Communicable Disease Specialist (CDS)/Outreach Worker (ORW)**

If the county does not have CDS/ORWs, the TB Nurse is responsible for these duties.

Assist with contact investigation on cases and suspects to elicit and completely evaluate identified contacts.

Trained CDS/ORW may provide tuberculin skin testing, venipuncture and sputum collection if these acts are delegated by the District Health Director.

Provide directly observed therapy (DOT). TB clients will be assessed for adverse reactions to medications at every encounter. In the event of an adverse reaction, medication should be discontinued and the TB Nurse contacted immediately.

Follow-up and locate TB clients who miss appointments.

Coordinate transportation for clinic appointments.

Educate communities, clients and families about tuberculosis.

Provide reports to TB nurse and/or to the district TB coordinator as requested.

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## TUBERCULOSIS MEDICAL RECORDS

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All tuberculosis records are confidential. Their release to health and non-health agencies (excluding agencies within DPH) and Quality Service Agreements should be made only with a signed authorization to release information. Health Insurance Portability and Accountability Act (HIPAA) guidelines must be followed. Public Health does have some exceptions. See letter from Commissioner of Public Health on following page. Additional information about HIPAA is available on the public health HIAA website:

<http://www.health.state.ga.us/programs/ohip/links.asp>.

The district TB coordinators are to coordinate the submission of patient data to the state office. The state patient records should mirror the district patient records.

### Retention of Medical Records

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The Georgia Archives maintains the record retention timelines and is located at [http://www.sos.ga.gov/archives/who\\_are\\_we/rims/retention\\_schedules/default.htm](http://www.sos.ga.gov/archives/who_are_we/rims/retention_schedules/default.htm)

<b>Record Title</b>	<b>Description</b>	<b>Retention</b>
(Cases/Treatment)	All documents relating to health services provided to tuberculosis patients; "cases" includes those clients with active TB infection and/or with latent TB infection (LTBI) and an abnormal chest x-ray	21 years from the date of the last service
Tuberculosis Records (Negative x-rays)		10 years from End of calendar year in which x-ray was taken
Tuberculosis Records (Positive x-rays)		10 years from end of calendar year in which x-ray was taken
Tuberculosis Records (Prophylaxis/Prevention)	All documents relating to health services provided to tuberculosis clients; "prophylaxis" includes those clients with LTBI and a normal chest x-ray	21 years from date of last service



Brenda Fitzgerald, MD, Commissioner

Nathan Deal, Governor

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RE **“Public Health” Exceptions to HIPAA**

Dear Colleague:

From time to time, we receive questions from physicians and other health care providers who are concerned that federal privacy regulations prevent them from reporting patient information to local health departments or to the Department of Public Health.

The “Health Insurance Portability and Accountability Act” (HIPAA), enacted by Congress in 1996, protects the confidentiality of the patient’s personal health information. However, HIPAA and its accompanying regulations strike a balance between a health care provider’s duty of confidentiality and the need to protect the public health. Federal HIPAA regulations provide that patient health information may be provided to state public health authorities, with or without the patient’s consent, in many different circumstances. Those circumstances include the following:

- A health care provider “may disclose protected health information for the public health activities and purposes described in this paragraph to a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions,” 45 C.F.R. § 164.512(b)(1)(i); and
- A health care provider “may, consistent with applicable law and standards of ethical conduct, use or disclose protected health information, if the [provider] in good faith believes the use or disclosure is necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public, and is to a person or persons reasonably able to prevent or lessen the threat, including the target of the threat,” 45 C.F.R. § 164.512(j)(1)(i).

I hope this information will facilitate your support of our unwavering efforts to protect the public health. If you have any questions, please feel free to contact our legal department.

With best regards, I am

Yours very truly,

A handwritten signature in black ink, appearing to read "Brenda Fitzgerald", is written over the typed name.

Brenda Fitzgerald, M.D.  
Commissioner of Public Health  
State Health Officer



## **SURVEILLANCE**

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### **Reporting requirements**

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In Georgia, physicians, hospitals, laboratories and other health care providers are required to report any of the following tuberculosis immediately to the local county health department:

- Any child younger than five years old diagnosed with latent TB infection
- Any confirmed case of TB
- Any suspected case of TB
- Any person being treated with two or more anti-tuberculosis drugs
- Any positive culture for *Mycobacterium tuberculosis*
- Any positive smear for acid-fast bacilli (AFB)

### **State Electronic Notification Disease Surveillance System (SENDSS)**

Approved users of the TB module in the State Electronic Notification Disease Surveillance System (SENDSS) can report the above conditions electronically at <http://sendss.state.ga.us>

Update the case verification status of all TB suspects in SENDSS as a verified TB case or not a TB case within 90 days from date of report.

### **Reporting and Counting Cases of *M. tuberculosis***

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The district TB coordinator or designee shall report new suspects/cases of tuberculosis within 24 hours of notification to the state TB Program office using the TB patient management module in SENDSS. The state TB program reviews each TB case to ensure that it meets CDC's surveillance case definition criteria. All cases that meet the surveillance definition of a verified TB case and cases whose TB diagnosis are certified by a licensed health provider are included in Georgia's annual TB morbidity count. Timely reporting of information is imperative to ensure that all verified cases are counted in the year the patient's diagnosis was verified.

Information concerning TB/HIV co-infected patients, MDR cases, airline flight exposures, clusters of TB cases, children suspected of, or diagnosed with TB, or any instance that might precipitate media attention, is to be immediately reported to the district TB Coordinator who will in turn, report it to the state TB program office.

### **Criteria for TB Suspect**

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TB suspects are persons for whom there is a high index of suspicion for active TB (e.g., a known contact to an active TB case or a person with signs or symptoms consistent with TB) who is being evaluated for TB disease. A TB suspect may be referred to as Class V TB. See Appendix 1: Classification System for Tuberculosis in *Tuberculosis Nursing: A Comprehensive Guide to Patient Care, 2<sup>nd</sup> Edition*.

The TB suspect will have a prescription for two or more TB drugs and one or more of the following:

- Signs/symptoms of tuberculosis
- Positive AFB smear
- Abnormal chest x-ray
- History of exposure to tuberculosis

Initial sputum reports, microbiology reports, prescriptions, chest x-ray reports and other provider notes are screened by the state medical consultant. If the client meets the above criteria, they will be placed on the State TB Program's active suspect list. TB suspects from districts with contract physicians are placed on the list based on recommendations from clinic notes. State TB program staff enter refugees and immigrants with a Class B1 or B2 (non-LTBI) status as TB suspects in SENDSS and county health departments should complete their evaluation within 90 days of arrival in Georgia to rule out TB.

## Case Definitions

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### 1. Laboratory confirmed case

Isolation of *M. tuberculosis* complex from clinical specimen, or  
Demonstration of *M. tuberculosis* from a clinical specimen by nucleic acid amplification test.

### 2. Clinical case

In the absence of a laboratory confirmation of *M. tuberculosis*, a person must meet **all** of the following criteria to be considered a clinical case of tuberculosis:

- Positive tuberculin skin test or IGRA
- Signs and symptoms compatible with TB (e.g., abnormal chest x-ray, abnormal chest CT scan, or clinical evidence of current disease such as fever, night sweats, cough, weight loss, hemoptysis)
- Receiving treatment with two or more anti-tuberculosis medications.

### 3. Provider Diagnosis

If a case does not meet the laboratory or clinical definition, the case may be counted as a verified case of tuberculosis by provider diagnosis if evidence of TB is present and a client shows clinical improvements with medications.

### 4. Recurrent TB cases

A new record in SENDSS should be created for all recurrent TB cases, whether the recurrent case occurred 12 months before or after treatment completion or closure from supervision by a county health department. However, a case should not be counted twice within a 12-month period. An active TB case diagnosed in a previously verified TB case within 12 months after completion of therapy or after being closed to supervision is not counted as a new case for surveillance purposes. Active TB diagnosed in a previously verified TB case should be counted as a new case if more than 12 months has elapsed since the patient completed treatment or was closed to supervision by the county health department.

### 5. Non-tuberculous Mycobacterial Disease (NTM)

- A person who has disease attributed to or caused by NTM only should not be counted or reported as a case of tuberculosis.
- A person who has tuberculosis disease diagnosed with both *M. tuberculosis* and other NTM shall be counted and reported as a case of tuberculosis.

### 6. Tuberculosis case diagnosed after death

Tuberculosis cases reported to health departments should be reported and counted as a case if evidence of current disease was present at time of death.

## **Reporting Latent TB Infection (LTBI)**

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The finding of LTBI in a child less than five years of age is a reportable disease. When LTBI in a child less than five years of age is reported, public health personnel will initiate a contact investigation to identify the source of the infection, recommend treatment for latent TB infection, follow-up the child to ensure completion of LTBI treatment by directly observed therapy, and monitor for development of active disease. Early identification of TB infection and treatment in children can prevent progression to active disease. The contact investigation of a young child with LTBI may identify a previously undiagnosed and untreated case of active TB.

## **SENDSS Reporting Requirements and Timelines**

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TB cases and TB suspects:

- Patient's basic demographic information (name, birth date, age, sex, race/ethnicity, address) will be entered in the Patient tab of the SENDSS within 24 hours after public health (county, district or state level) is notified of a TB suspect/case started on treatment for active TB. Other data in the Patient tab that are not available at time of notification will be updated in SENDSS within 24–72 hours after the missing data are received by the end user responsible for data entry in SENDSS.
- Data for the Assessment tab in SENDSS and the patient's initial drug regimen for the Medication tab in SENDSS will be entered within 24 hours after a patient is diagnosed as a verified case of TB by a county health department or within 24 hours after information of the patient's TB diagnosis is received by the end user responsible for data entry in SENDSS. Other data in the Assessment or Medication tab that are not available at time of diagnosis will be updated in SENDSS within 24–72 hours after the missing data are received.
- The Report of Verified Case of TB (RVCT) form should be generated (by clicking the Generate button) when data for the Patient, Assessment, and initial drug regimen in the Medication tab have been entered in SENDSS.
- Initial TST/IGRA, chest radiographs, chest CT scans, bacteriology and drug susceptibility test results will be entered in SENDSS within 24 hours after results are received. After entering the initial drug susceptibility test results, the end user should click the Generate button in SENDSS to generate the RVCT Follow-up 1 form.
- Information on whether the patient moved while on TB treatment and the reason for stopping TB treatment (found in the Medication tab) and DOT information (found in the DOT tab) will be entered in SENDSS within 24–72 hours after the client has completed therapy or within 24–72 hours after the county health department has determined that the patient can not complete therapy because patient died, is lost to follow-up or has moved, etc. After entering this information, the end user should click the Generate button in SENDSS to generate the RVCT Follow-up 2 form.

Contact Investigation and LTBI Treatment:

- Contact's basic demographic information will be entered in SENDSS within 72 hours after contacts are identified or 72 hours after the data are received by the end user responsible for data entry of contacts in SENDSS.
- Results of contact evaluations will be updated within 24 hours after receiving the first TST/IGRA result, within 24 hours after receiving the follow-up TST/IGRA results, and within 24 hours after the initial chest radiograph reading is obtained.

- The start date for LTBI treatment will be entered within 24 hours after contacts start LTBI therapy or within 24 hours after receipt of this information.
- The date LTBI treatment was stopped will be entered within 24–72 hours after contact stops treatment or within 24-72 hours after receipt of this information.

### **Other TB Program Reporting Requirements and Timelines**

District TB Coordinators for Health Districts receiving Grant-in-Aid (GIA) allocations from the Georgia TB Program should submit the GIA Quarterly Report to the state TB Office by the 15<sup>th</sup> of October, January, April, and July.

The GIA Annual Report is to be completed and submitted to the state TB Office by July 15 each year.

GIA District Education Reports are to be submitted quarterly.

Copies of all current contracts and memorandums of understanding/agreement (e.g., medical consultative, radiology, laboratory, etc.) funded with GIA dollars should be on file at the state TB Office.

Submit all TB program reports to the state TB program point of contact.

### **Interjurisdictional Transfers**

The district office should submit an Interjurisdictional Notification form to the state TB program’s point of contact when a TB patient who is still on TB treatment moves to another district or state. If the TB patient moves to another country while still on treatment, the district office should submit an International TB Notification form to the state TB program’s point of contact. The state office will send the Interjurisdictional or International TB Notification form to the TB program of the patient’s new state or country of residence, respectively. The state office will also refer patients who move to Mexico to CureTB and refer patients who move to countries other than Mexico to TBNNet, for treatment follow-up. The state office is responsible for following up treatment completion data from the state TB program of the patient’s new state of residence and entering the data in SENDSS. The state office will inform CDC’s Atlanta Quarantine Station of patients who have moved to another country to request their assistance to follow-up treatment abroad and/or request CDC to place the patient on a Do Not Board list.

The Interjurisdictional Notification form can be found on the Georgia TB program web pages at <http://www.health.state.ga.us/programs/tb/phclinicforms.asp>.

The International TB Notification form can be found on CDC’s Division of TB Elimination webpage at: [http://www.cdc.gov/tb/programs/international/internat\\_proces.htm](http://www.cdc.gov/tb/programs/international/internat_proces.htm)

Referral forms to TBNNet can be found at the Migrant Clinician’s Network website at: [http://www.migrantclinician.org/files/HN-Enrollment-Packet\\_English.pdf#](http://www.migrantclinician.org/files/HN-Enrollment-Packet_English.pdf#)

When patients move to another district, state or country, the District TB coordinator or their designee should document the move in SENDSS by the following procedure;

- Enter the patient’s new address in the Patient Information Tab in SENDSS
- Open the Meds tab and select “Yes” where it asks ““Did the patient move during

- TB therapy?”
- c. Enter the new county, state, or country where the patient has moved to

For foreign-born TB patients who have immigrated to the U.S. in the last five years, District TB coordinators and county health department nurses are encouraged to identify a patient's family member or point of contact from the patient's country of origin, to avoid the difficulty of locating patients that move back to their country of origin without a forwarding address.

### **1. District- to-District transfer**

When a TB patient plans to move (or has moved) from one District to another, District TB Coordinators or their designee should complete an Interjurisdictional Notification form and fax it to the Medical Records Operations Analyst at the state TB program office, inform the District TB Coordinator of the District the patient is moving to about the transfer, and document the transfer in SENDSS.

### **2. Out-of-State transfer**

When a TB patient plans to move (or has moved) from Georgia to another state, District TB Coordinators or their designee should complete an Interjurisdictional Notification form and fax it to the Medical Records Operations Analyst at the state office who will in turn notify the TB control program of the patient's new state of residence. The state office will fax all pertinent medical documents to that state and respond to any additional request for information. District offices or county health departments in Georgia should communicate directly with the county health department in the other state to provide detailed information on TB treatment, laboratory reports and clinical notes, to ensure continuity of care. District TB Coordinators or their designee should document the transfer in SENDSS.

### **3. Out-of-the-U.S. transfers**

When a TB patient plans to move (or has moved) to another country while still on treatment, or has moved before TB diagnosis was confirmed, or before TB treatment was started, District TB Coordinators should call or email the TB Program Director directly, or in the Director's absence, the TB epidemiology unit. Patient can travel internationally if they have three consecutively negative sputum AFB smears, have completed at least two weeks of appropriate TB medications, and do not have MDR-TB/XDR-TB. If these criteria are not met, the TB Program Director or TB epidemiologist will contact CDC's Division of Global Migration and Quarantine (DGMQ) to discuss whether the patient should be placed on a federal Do Not Board list or other means to restrict travel. For patients who move to Mexico, Districts should fill out an International TB notification form and fax it to the state TB program Medical Records Operations Analyst who will contact CureTB for follow-up. For countries other than Mexico, Districts should fill out both the International TB notification form and TBNNet referral forms and fax them to the state TB program Medical Records Operations Analyst who will contact TBNNet for follow-up. The Immigration and Customs Enforcement (ICE) agency is responsible for referring undocumented immigrants on TB treatment under ICE custody to CureTB or TBNNet on deportation.

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## **REFUGEE OR IMMIGRANT CLASS B1 OR B2**

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CDC notifies the Georgia State TB Program of aliens arriving in Georgia with a Class B1/B2 TB condition assessed during their screening abroad by U.S. Department of State panel physicians. Newly arrived immigrants, refugees and asylees with a B1/B2 TB classification should receive thorough and timely TB evaluations to ensure prompt detection of TB disease. Appropriate treatment should be completed to prevent future cases.

Class B Condition: A classification based on clinical evaluations performed abroad indicating findings consistent with a specific disease;

B-1 Tuberculosis, clinically active, not infectious

B-2 Tuberculosis, not clinically active, not infectious

B-2 Latent TB Infection

### **Instructions to County Health Departments on Class B1 or B2 notifications**

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1. Upon receipt of the Class B1/B2 notification from the state TB program, contact the refugee and immigrant immediately and instruct him/her to report to the county health department for a TB skin test and clinical evaluation.
2. Assess the alien for TB signs and symptoms.
3. Administer tuberculin skin test (TST) or Interferon Gamma Release Assay (IGRA)
4. Read TST after 48-72 hours
5. Order chest radiograph if TST is greater than or equal to 10 mm or the IGRA is positive
6. After TB evaluation is completed, treat appropriately if diagnosed with LTBI or active TB
7. Complete TB Follow-up Worksheet when evaluation is completed and fax the worksheet to District TB Coordinator who will submit the worksheet to the Georgia TB Program Office
8. If person was started on LTBI treatment, update the section on LTBI treatment on the same TB Follow-up Worksheet when the person completes LTBI treatment or stops treatment, and submit the worksheet to the District TB Coordinator who will submit the updated worksheet to the Georgia TB Program

### **B1/B2 SENDSS Processing Procedures for District TB Coordinators**

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Aliens with a B1 or B2 classification should be located and TB evaluation initiated within 30 days of arrival.

State TB Program staff enter all B1 and B2 (non-LTBI) aliens into SENDSS as TB suspects.

Some B2 aliens are classified as having LTBI (depending on their country of origin) and therefore are not entered in SENDSS as TB suspects, but should still be evaluated by the county health department.

Alien TB suspect status should be changed in SENDSS within 90 days of date reported.

### **SENDSS Data Entry for Class B1/B2**

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The case verification status of B1/B2 TB suspects should be updated in SENDSS when data on their final diagnosis become available.

To update the case verification status in SENDSS:

- Open the Diagnosis Tab
- Enter correct diagnosis from the Case Verification Status drop down box
- Click on the Add button
- Open the RVCT tab
- Click on the Generate button

### **TB Alien Follow-up Worksheet Completion**

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State TB program staff enters the TB Follow-up Worksheet data in CDC's Electronic Disease Notification (EDN) software.

DeKalb County TB Program staff enters their own data directly in EDN.

The highlighted fields in the follow-up worksheet are mandatory fields needed to successfully upload the data in EDN.

Submit the completed worksheet to state TB Medical Records with attention to Medical Records supervisor.

Resubmit the completed worksheet when the alien completes therapy, if applicable.

### **Electronic Disease Notification System Quality Improvement procedures**

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A monthly report of unsubmitted TB Alien Follow-up Worksheets and missing worksheet data is distributed by TB Epidemiology staff to District TB Coordinators.

A quarterly report of unclassified TB suspects greater than or equal to 90 days that include B1/B2 TB suspects is sent out to District TB Coordinators by Medical Records.



## NATIONAL TB INDICATORS

For tuberculosis (TB) programs, quality of care is measured by means of objectives and standards. Such objectives and standards are used as yardsticks to direct the program and measure its success. Objectives reflect outcomes or results and program desires. Programs require objectives to define expected outcomes and results for case management activities. Standards are an accepted set of conditions or behaviors that define what is expected and acceptable regarding job duties, performance, and provision of services. The TB control program works to achieve objectives through a series of standards.

### National TB Indicators with State Targets

Objective Categories	Objectives and Performance Targets
<b>1. Completion of Treatment</b>	For patients with newly diagnosed TB for whom 12 months or less of treatment is indicated, increase the proportion of patients who complete treatment within 12 months to 93.0%. <ul style="list-style-type: none"> <li>• <b>State target 88%</b></li> </ul>
<b>2. TB Case Rates</b> <ul style="list-style-type: none"> <li>• <b>U.S.-born Persons</b></li> <li>• <b>Foreign-born Persons</b></li> <li>• <b>U.S.-born non-Hispanic Blacks</b></li> <li>• <b>Children Younger than 5 Years of Age</b></li> </ul>	Decrease the TB case rate in U.S.-born persons to less than 0.7 cases per 100,000. Increase the average yearly decline in TB case rate in U.S.-born persons to at least 11.0%. <ul style="list-style-type: none"> <li>• <b>State target decrease by 8% per year</b></li> </ul> Decrease the TB case rate for foreign-born persons to less than 14.0 cases per 100,000. Increase the average yearly decline in TB case rate in foreign-born persons to at least 4.0%. <ul style="list-style-type: none"> <li>• <b>State target decrease by 11% per year</b></li> </ul> Decrease the TB case rate in U.S.-born non-Hispanic blacks to less than 1.3 cases per 100,000. <ul style="list-style-type: none"> <li>• <b>State target 4/100,000</b></li> </ul> Decrease the TB case rate for children younger than 5 years of age to less than 0.4 cases per 100,000. <ul style="list-style-type: none"> <li>• <b>State target 1/100,000</b></li> </ul>
<b>3. Contact Investigation</b> <ul style="list-style-type: none"> <li>• <b>Contact Elicitation</b></li> <li>• <b>Evaluation</b></li> <li>• <b>Treatment Initiation</b></li> <li>• <b>Treatment Completion</b></li> </ul>	Increase the proportion of TB patients with positive acid-fast bacillus (AFB) sputum-smear results who have contacts elicited to 100.0%. <ul style="list-style-type: none"> <li>• <b>State target 95%</b></li> </ul> Increase the proportion of contacts to sputum AFB smear-positive TB patients who are evaluated for infection and disease to 93.0%. <ul style="list-style-type: none"> <li>• <b>State target 80%</b></li> </ul> Increase the proportion of contacts to sputum AFB smear-positive TB patients with newly diagnosed latent TB infection (LTBI) who start treatment to 88.0%. <ul style="list-style-type: none"> <li>• <b>State target 80%</b></li> </ul> For contacts to sputum AFB smear-positive TB patients who start treatment for newly diagnosed LTBI, increase the proportion that complete treatment to 79.0%. <ul style="list-style-type: none"> <li>• <b>State target 75%</b></li> </ul>

Objective Categories	Objectives and Performance Targets
<p><b>4. Laboratory Reporting</b></p> <ul style="list-style-type: none"> <li>• <b>Turnaround Time</b></li> <li>• <b>Drug-susceptibility Result</b></li> </ul>	<p>Increase the proportion of culture-positive or nucleic acid amplification (NAA) test-positive TB cases with a pleural or respiratory site of disease that have the identification of <i>M. tuberculosis</i> complex reported by laboratory within N days from the date the initial diagnostic pleural or respiratory specimen was collected to n%.</p> <p>Increase the proportion of culture-positive TB cases with initial drug-susceptibility results reported to 100.0%.</p> <ul style="list-style-type: none"> <li>• <b>State target 98%</b></li> </ul>
<p><b>5. Treatment Initiation</b></p>	<p>Increase the proportion of TB patients with positive AFB sputum-smear results who initiate treatment within 7 days of specimen collection to n%.</p> <ul style="list-style-type: none"> <li>• <b>State target 88%</b></li> </ul>
<p><b>6. Sputum Culture Conversion</b></p>	<p>Increase the proportion of TB patients with positive sputum culture results who have documented conversion to sputum culture-negative within 60 days of treatment initiation to 61.5%.</p> <ul style="list-style-type: none"> <li>• <b>State target 62%</b></li> </ul>
<p><b>7. Data Reporting</b></p> <ul style="list-style-type: none"> <li>• <b>RVCT</b></li> <li>• <b>ARPEs</b></li> <li>• <b>EDN</b></li> </ul>	<p>Increase the completeness of each core Report of Verified Case of Tuberculosis (RVCT) data item reported to CDC, as described in the TB Cooperative Agreement announcement, to 99.2%.</p> <ul style="list-style-type: none"> <li>• <b>State target 95%</b></li> </ul> <p>Increase the completeness of each core Aggregated Reports of Program Evaluation (ARPEs) data items reported to CDC, as described in the TB Cooperative Agreement announcement, to 100.0%.</p> <ul style="list-style-type: none"> <li>• <b>State target 100%</b></li> </ul> <p>Increase the completeness of each core Electronic Disease Notification (EDN) system data item reported to CDC, as described in the TB Cooperative Agreements announcement, to n%.</p> <ul style="list-style-type: none"> <li>• <b>State target 75%</b></li> </ul>
<p><b>8. Recommended Initial Therapy</b></p>	<p>Increase the proportion of patients who are started on the recommended initial 4-drug regimen when suspected of having TB disease to 93.4%.</p> <ul style="list-style-type: none"> <li>• <b>State target 93%</b></li> </ul>
<p><b>9. Universal Genotyping</b></p>	<p>Increase the proportion of culture-confirmed TB cases with a genotyping result reported to 94.0%.</p> <ul style="list-style-type: none"> <li>• <b>State target 85%</b></li> </ul>
<p><b>10. Known HIV Status</b></p>	<p>Increase the proportion of TB cases with positive or negative HIV test result reported to 88.7%.</p> <ul style="list-style-type: none"> <li>• <b>State target 95%</b></li> </ul>

Objective Categories	Objectives and Performance Targets
<p><b>11. Evaluation of Immigrants and Refugees</b></p> <ul style="list-style-type: none"> <li>• <b>Evaluation Initiation</b></li> <li>• <b>Evaluation Completion</b></li> <li>• <b>Treatment Initiation</b></li> <li>• <b>Treatment Completion</b></li> </ul>	<p>For immigrants and refugees with abnormal chest x-rays read overseas as consistent with TB, increase the proportion who initiate medical evaluation within 30 days of arrival to n%.</p> <ul style="list-style-type: none"> <li>• State target 70%</li> </ul> <p>For immigrants and refugees with abnormal chest x-rays read overseas as consistent with TB, increase the proportion who complete medical evaluation within 90 days of arrival to n%.</p> <ul style="list-style-type: none"> <li>• State target 75%</li> </ul> <p>For immigrants and refugees with abnormal chest x-rays read overseas as consistent with TB and who are diagnosed with latent TB infection (LTBI) during evaluation in the U.S., increase the proportion who start treatment to n%.</p> <ul style="list-style-type: none"> <li>• State target 85%</li> </ul> <p>For immigrants and refugees with abnormal chest x-rays read overseas as consistent with TB, and who are diagnosed with latent TB infection (LTBI) during evaluation in the U.S. and started on treatment, increase the proportion who complete LTBI treatment to n%.</p> <ul style="list-style-type: none"> <li>• State target 75%</li> </ul>
<p><b>12. Sputum-culture Reported</b></p>	<p>Increase the proportion of TB cases with a pleural or respiratory site of disease in patients ages 12 years or older that have a sputum-culture result reported to 95.7%.</p> <ul style="list-style-type: none"> <li>• State target 95%</li> </ul>
<p><b>13. Program Evaluation</b></p> <ul style="list-style-type: none"> <li>• <b>Evaluation Focal Point</b></li> </ul>	<p>Increase program evaluation activities by monitoring program progress and tracking evaluation status of cooperative agreement recipients.</p> <p>Increase the percent of cooperative agreement recipients that have an evaluation focal point</p>
<p><b>14. Human Resource Development Plan</b></p>	<p>Increase the percent of cooperative agreement recipients who submit a program-specific human resource development plan (HRD), as outlined in the TB Cooperative Agreement announcement, to 100.0%.</p> <p>Increase the percent of cooperative agreement recipients who submit a yearly update of progress-to-date on HRD activities to 100.0%.</p>
<p><b>15. Training Focal Point</b></p>	<p>Increase the percent of cooperative agreement recipients that have a TB training focal point.</p>

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## **TUBERCULOSIS SERVICES**

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Active tuberculosis is a public health threat. Latent TB infection is a reservoir for future active TB cases. TB prevention and control programs need to address both active TB and LTBI to protect the health of the community. TB services must be rendered at the time of client presentation regardless of the client's ability to pay. All TB-related services including laboratory tests, clinic visits and chest radiographs are free of charge to TB suspects, confirmed TB cases, converters, contacts to TB suspects or cases, and children under five years of age with LTBI. For clients who fall outside these parameters (screening for employment, school, etc), TB services can be charged according to the county sliding fee scale. It may be possible for contracts or MOUs to be executed with local facilities that frequently send employees or students to the health department for TB screening as a way to generate funds to cover these services.

If the client does not have the money on the day of service, the client can be billed for service. If a client has Medicaid coverage, the county health department can bill Medicaid for a patient office visit to the county TB clinic, but should not bill Medicaid for TB medicines or the PPD solution which are purchased by the state at a discount from the federal 340B TB drug program and provided to all District TB programs.

Ideally, clients from high risk populations should only incur minimal charges from a county health department TB clinic because the benefit of providing TB services to them to prevent a future case far outweighs the cost of the service. An example would be a client who is enrolling in a substance abuse program and needs a TST or chest x-ray in order to be accepted to the program.

### **Medical Care**

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Each health district in Georgia has a District Health Director and a contract with a practicing physician for oversight in providing medical care to TB clients. The district varies widely in how the oversight is implemented. Some districts have the physician see every TB client, while in others; the physicians never see the clients but review the charts on a regular basis and provide consultation to the nurses. If the direct care is provided by a private physician, the county TB nurse is to obtain monthly reports to maintain oversight.

The nurse protocols describe the management of uncomplicated pulmonary TB and LTBI. Anything that falls outside of the protocols is to be managed by the contract physician and the nurse will work under those orders and will not be working under protocol. The district contract physician will write the order and sign off on the chart. The district pharmacy or contract pharmacy will dispense the medication. If a patient is being co-managed by a private physician in the community, the district contract physician will have to collaborate for care and write the orders for any health department involvement. This is especially important concerning medications. Public health nurses do not work under community physician's orders. They can only work under the Georgia Standard Nursing Protocol or the district contract physician's orders. A registered professional nurse or physician's assistant is only authorized to dispense pursuant to an order issued in conformity with a nurse protocol or job description, not a prescription or an order written on a chart or phoned in by a physician. For more information,

please see the “Drug Dispensing Procedure” in the *Nurse Protocols for Registered Professional Nurses in Public Health, current edition*. Located on the web pages at <http://www.health.state.ga.us/programs/nursing/publications.asp>

Diagnostics, treatment, clinical care, case management and infection control guidelines and standards should be available for reference by each TB staff member. Instead of repeating these guidelines in this document, please refer to the following sources:

*Nurse Protocols for Registered Professional Nurses in Public Health, current edition*. Located on the TB web pages at <http://www.health.state.ga.us/programs/nursing/publications.asp>

*Georgia Tuberculosis Reference Guide, current edition*. Located on the TB web pages at <http://www.health.state.ga.us/programs/nursing/publications.asp>

NTCA, NTNC. *Tuberculosis Nursing: A Comprehensive Guide to Patient Care, Second Edition. 2011*. Each district health office and county health department was sent a copy in 2012. Additional copies may be purchased by contacting the National TB Controllers Association at <http://tbcontrollers.org/>

CDC. *Core Curriculum on Tuberculosis: What the Clinician Should Know, 2011*. Each district health office was sent a copy in 2012. It can also be ordered from CDC or downloaded at <http://www.cdc.gov/tb/education/corecurr/>

ATS, CDC, IDSA. “Treatment of Tuberculosis” (*MMWR* 2003; 52[No. RR-11]). Available at: <http://www.cdc.gov/mmwr/PDF/rr/rr5211.pdf> .

CDC, NTCA. “Guidelines for the Investigation of Contacts of Persons with Infectious Tuberculosis: Recommendations from the National Tuberculosis Controllers Association and CDC” (*MMWR* 2005;54 [No. RR-15]). Available at: <http://www.cdc.gov/mmwr/pdf/rr/rr5415.pdf> .

CDC. “Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Healthcare Settings, 2005” (*MMWR* 2005;54[No. RR-17]). Available at: <http://www.cdc.gov/mmwr/pdf/rr/rr5417.pdf> .

CDC. “Targeted Tuberculin Testing and Treatment of Latent Tuberculosis Infection” (*MMWR* 2000;49[No. RR-6]). Available at: <http://www.cdc.gov/mmwr/PDF/rr/rr4906.pdf> .

ATS, CDC, IDSA. “Controlling Tuberculosis in the United States: Recommendations from the American Thoracic Society, CDC, and the Infectious Diseases Society of America” (*MMWR* 2005; 54[No. RR-12]). Available at: <http://www.cdc.gov/MMWR/PDF/rr/rr5412.pdf>

ATS, CDC, IDSA. “Diagnostic Standards and Classification of Tuberculosis in Adults and Children” (*Am J Respir Crit Care Med* 2000;161[4 Pt 1]). Available at: <http://www.thoracic.org/statements/resources/archive/tbadult1-20.pdf>

## **Office visits**

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TB suspects, confirmed TB cases, converters, contacts to TB suspects or cases, and children under five years of age with LTBI are not to be charged for office visits. Persons with LTBI who are not contacts but are being treated at the health department may be charged and/or billed for office visits. All fees should be based on the county sliding fee scale.

All legal forms are to be completed at the first office visit. This includes consent for treatment, treatment plan, medication information, DOT agreement and/or refusal of care.

Gather as much locating information as possible. Some examples would be emergency contact information, email address, cell phone number, screen name, face book or other social network. Upon evaluation of non-US born, "recent" (past 5 years) immigrants, please identify a family member or another close contact in their home of origin, as an emergency contact. This will assist in locating patients that are "lost" while infectious.

All persons on treatment are expected to have a clinic visit at least once a month. More frequent clinical visits may be needed depending on the complexity of the case.

## **Home visits**

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All active TB cases are expected to have at least one home visit to evaluate the living situation of the client to determine the suitability of home isolation, the presence of children and to educate and build rapport with the client and the client's family.

## **Administration of tuberculin skin tests (TST) or Interferon Gamma Release Assay (IGRA)**

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All health departments have the ability to administer and read TSTs. Persons who perform and/or interpret this test should have obtained initial TST certification when newly hired and have it maintained by completing the recertification requirements every two years.

TB suspects, cases and contacts to suspects and cases are not to be charged for the administration or reading of a TST. All others may be charged and/or billed for administrative services. No one is to be charged for the PPD solution.

Interferon Gamma Release Assay (IGRA) may be available through contracts with laboratories. If this is used in the course of a contact investigation, the contacts may not be charged. In all other instances, the person may be charged and/or billed.

## **Reading TSTs**

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When a client has a TST placed at an HIV clinic or a correctional facility and comes to the health department for it to be read, it would be advisable to read the TST without a fee as HIV and TB programs often collaborate in the case management of clients. Other facilities may place a TST and tell the client to go to the health department for it to be read. In these cases, collaboration with the facilities would be encouraged to assure proper placement and a possible MOU might be feasible.

## **Chest X-rays**

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Health districts and/or county health departments may have on-site x-ray services or the services may be provided through contracts with local facilities.

Chest x-rays should be performed on the following persons at no charge:

- Person with signs and/or symptoms of active TB regardless of TST or IGRA result
- Contacts with a positive reaction to a TST (greater than or = 5 mm induration) or IGRA
- Contacts to cases that have a previous positive TST
- Contacts with HIV infection
- Contacts for whom window period treatment is being considered
- Persons with documented evidence of converting from a negative TST to a positive TST within the past 2 years
- Persons on LTBI treatment that develop signs and/or symptoms of active TB
- Children under five years of age with a positive TST referred for a chest x-ray to diagnose LTBI or rule out TB

Chest x-rays for follow up of an initial positive skin test as a result of routine testing or in conjunction with employment, school, etc. may be provided through memorandums of agreement or at a nominal cost according to local health department policies. All fees should be based on the county sliding fee scale. Annual chest x-rays for previous TST positive clients are not recommended (although some facilities will still require them). The use of a clinical symptom screen is recommended to document the symptom screen. Education about signs and symptoms so that the person knows when to seek health care can be found at <http://www.health.state.ga.us/programs/tb/publications.asp>. This document can be signed and kept with the facility's annual screening paperwork.

A clinical symptom screen is required for all clients who have a lapse in LTBI treatment. A repeat chest x-ray evaluation is required for clients who are symptomatic or who have had a lapse in therapy for two months or more.

## **Other imaging and/or necessary medical procedures**

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The state TB Program is to be notified immediately of any necessary medical procedures that are not in the state nursing protocols. The state medical consultant must approve all procedures. The county will pay for the procedure at the current Medicaid rate.

## **Laboratory testing**

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TB suspects, confirmed TB cases, converters and contacts to TB suspects or cases are not to be charged for any laboratory tests. Persons with LTBI who are not contacts but are being treated at the health department may be charged and/or billed for laboratory tests. All fees should be based on the county sliding fee scale. Laboratory results not performed by the State Laboratory are done through a contract with a local laboratory and county and/or district. For more information about the state laboratory, please refer to the *2012 Laboratory Services Manual* found at <http://www.health.state.ga.us/programs/lab/manual.asp>. For more information on individual laboratory tests, please see the Laboratory Tests section.

HIV test results should be documented on all patients receiving TB care through the health departments. An opt-out approach is recommended. This means the patient is informed of the



laboratory tests that will be performed, including an HIV test. The patient can decline the HIV test; otherwise, the test will be performed. Documentation of a patient's refusal should be in the medical record. During the course of treatment, HIV testing should continue to be offered until results can be obtained. For more information and background on this approach, please refer to CDC's "*Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings*" at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm>.

## **Contact Investigation**

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The evaluation of contacts of cases of infectious TB is one of the most productive methods of identifying adults and children with LTBI who are at high risk for progression to TB disease and persons already in the early stages of TB disease. Contact investigations serve as an important means of preventing further TB transmission.

All active TB clients and children less than five years old with LTBI should have a contact investigation plan. Source case investigations for children less than age 5 with LTBI consist of household members receiving one TST/IGRA and a chest x-ray if indicated. Extrapulmonary TB patients (TB patients that do not pulmonary, or laryngeal, or pleural disease) are not infectious, however, they should always be asked if they have a household member with signs and symptoms of TB, in which case household members should receive one TST/IGRA and a chest x-ray if indicated. For all other investigations, follow the guidelines listed at the beginning of this section.

The TB Coordinator should review the contact investigation forms on a regular basis.

### Contact Investigations Across Health Districts

District TB Coordinators should notify other district TB coordinators of cross-district contact investigations and continue to monitor follow-up to ensure all contacts of cases from their district are identified and evaluated. Local health department TB nurses should complete the contact investigation form with full name and location information. This form should be forwarded to the receiving county health department for evaluation which should return the completed form to the originating health department. The district of the source case for the contacts is ultimately responsible for entering the contact investigation results in SENDSS, but may request help from other districts or the state epidemiology unit if the data entry task overwhelms their district's capacity to enter all contact information.

### Contact Investigations Across States

Contacts to Georgia cases that move out of state should be referred to that state for follow-up by submitting an interjurisdictional notification form to the State TB Program, which will notify the new state. When the follow-up information is received from the new state, the TB Program will forward the information to the District TB Coordinator. When the Georgia TB Program is notified of contacts entering Georgia from other states, the information is forwarded to the appropriate District TB Coordinator. When follow-up information is returned to the TB Program, it is forwarded to the original state that submitted the contact information.

## **Incentives and Enablers**

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Incentives and enablers for TB patients and contacts on LTBI treatment are available from the American Lung Association (ALA) of Georgia through a contract with the Georgia TB Program. Refer to the *Alternative Housing Project for Homeless Tuberculosis Patients in Georgia* brochure available from ALA, or call ALA at 770-434-5864 for current procedures to request and obtain incentives/enablers. Districts may request approval from the state TB program director or deputy director to use unexpended GIA funds to purchase incentives and enablers. On occasion, there may be incentive/enabler monies available from the state TB Program. Contact the TB program deputy director at 404-657-2634 to request these funds.

## **Medical Interpretation Services**

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The State of Georgia has a statewide contract with AT&T Language Line to provide medical interpretation services to the clients of Georgia. No person should be turned away because of the inability to speak or understand English. Family members of the client are not to be used to interpret for the client and staff. Information packets can be requested from AT&T free of charge by calling the customer service number 1-800-752-6096.

### Procedure for use of AT&T Language Line

- Place the non-English speaker on hold
- Dial 1-866-874-3972
- Enter your client ID [513565] on the keypad or stay on the line for assistance
- Press 1 for Spanish or
- Press 2 for all other languages
- Speak the name of the language at the prompt
- An interpreter will be connected to the call
- Brief the interpreter. Summarize what you wish to accomplish and give any special instructions.
- Add the non-English speaker to the line
- Conduct your business

## **Hospitalization**

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The state office TB Program is to be notified immediately of any pending hospitalization of a TB suspect/case. If the client has no insurance or Medicaid/Medicare, then the county is expected to negotiate with the local county hospital to use the hospital indigent care funds.

## **Court-ordered treatment and/or confinement of non-adherent TB patients**

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All court proceedings should be through the District TB Coordinator. The state office TB Program is to be notified immediately of any pending legal issue with a TB case. The county attorney, the client's attorney and all associated court fees are to be paid by the county health department.

The state office TB Program is to be notified immediately of any pending confinement case. Approval must be obtained from the TB Program Director. The health district is expected to pay the confinement facility. Paid invoices can then be submitted to the state office TB Program for reimbursement.

### Typical Court-Ordered Treatment Process:

1. District Health Officer or TB Coordinator sends a certified letter to non-adherent patient with specific instructions on TB treatment and isolation, e.g., wear a surgical mask in public.
2. If no letter has been sent, but the County Health Department (CHD) has documentation that they gave specific instructions to the patient, patient agreed and signed a treatment plan, patient did not comply with these instructions and is a public health threat because of potential disease transmission, the District or CHD can proceed to ask for court-ordered compliance with CHD instructions.
3. CHD should contact the county attorney's office for an Emergency Commitment Hearing Order (Form 3 in Commitment Templates). The county attorney will have a judge sign the order.
4. With this order, a court hearing is scheduled within 7 days from the day the order is signed. The county sheriff will pick-up the patient and confines him in a jail or hospital with respiratory isolation facilities until the court hearing. The sheriff's office can contact other counties to confine the patient if their county jail or local hospital does not have an appropriate isolation room.
5. The patient is assigned a lawyer, the county attorney represents the CHD, and CHD health providers appear in court to testify.
6. The judge can order the patient to follow very specific instructions, e.g., wear a mask in public until sputum smear negative 3x and until he has taken 2 weeks of medicines, and comply with DOT. The judge can state that if patient does not comply, he will be in contempt of court and can be detained/committed by court order to a facility approved by the state TB program like a county jail with respiratory isolation units or GeoCare (previously JustCare) in South Carolina.
7. If the county attorney does not have a lot of experience with these kinds of orders, s/he can consult with the county attorneys from Fulton, DeKalb, Gwinnett or Cobb, which do.

The Georgia Department of Public Health and GeoCare Inc. in South Carolina have a memorandum of understanding (MOA) regarding court-ordered non-adherent TB patients referred by county health departments to GeoCare for detention. The MOA has the following stipulations:

#### **Funding for admission of Georgia TB patients at GeoCare:**

Charges incurred by clients involuntarily committed will be invoiced to the client's county health department. The DPH TB Program will provide allocations to the respective district for charges incurred by the client(s) admitted to GeoCare. These allocations will be made within 30 days of receipt of an invoice.

- a) Services under this MOA will be invoiced to each district at a daily per person rate of \$260.00 while in isolation and \$189.00 out of isolation (2012 rates).
- b) After the first year of this MOA, on the anniversary date, the price will adjust for each additional year, in an amount equal to the most recently available annual change in the *Bureau of Labor Statistics Consumer Price Index for the South, Medical Care Component*, which is the most accurate measure of the cost increases CRCC experienced delivering services.
- c) The DPH TB Program will assist GeoCare, when requested, in collecting past due invoices from respective districts.

**Responsibilities of the DPH TB Program for GeoCare referrals:**

- a) The DPH TB Program will ensure that all clients referred for admission to GeoCare have a legal commitment order prior to admission.
- b) The DPH TB Program will ensure that GeoCare receives a completed *Medical Data Summary Sheet* on each pending admission.
- c) The DPH TB Program will ensure that each client will arrive with a signed *Medical Care Plan*, a copy of his/her current medical record along with a 3-month supply of prescribed TB medications.
- d) The DPH TB Program will ensure that the balance of prescribed TB medications to complete the client's treatment regimen will be provided.
- e) The DPH TB Program will routinely monitor the care, treatment and clinical status of each TB client committed from Georgia.
- f) The DPH TB Program will provide technical assistance, guidance, educational materials as requested.

**Responsibilities of GeoCare regarding Services and Deliverables:**

- a) GeoCare agrees to provide rooms that are secure and ensure safety at all times and that are appropriate for clients involuntarily committed to the facility for failure to adhere to a treatment regimen.
- b) GeoCare agrees to follow the *Medical Care Plan* which accompanies the client from Georgia.
- c) GeoCare agrees to consult the DPH TB Program Medical Consultant prior to any change in the prescribed treatment plan.
- d) GeoCare agrees to obtain prior approval from the DPH TB Program Medical Consultant or a designee before any referral to another facility for services, with the exception of a medical or life-threatening emergency. The DPH TB Program will be notified as soon as possible after the occurrence.
- e) GeoCare will provide monthly x-rays as ordered.
- f) GeoCare will provide *Monthly Medical Status Reports* to the DPH TB Program and local county health department.
- g) GeoCare will provide Airborne Infection Isolation (AII) rooms/special negative pressure rooms for the specific purpose of isolating persons who might have suspected or confirmed infectious TB disease.
- h) GeoCare will provide three nutritious meals along with snacks daily.
- i) GeoCare will provide opportunities for recreation in the courtyard.
- j) GeoCare will provide transportation for external medical appointments, if required.

**Special Circumstances:**

- a) In the event of the death of the TB client committed from Georgia, GeoCare shall notify the state TB Program Manager or designee as soon as possible after the event.
- b) The DPH TB Program will notify the county health department of the client's death.
- c) The DPH TB Program will discuss any burial plans with the respective county health department and with family members, if available.
- d) If the TB client is deemed homeless and after due diligence to identify family none is found, the client will be buried in accordance with the procedures of GeoCare.

- e) A statement to the effect of the above item d will be faxed to the GeoCare General Manager.
- f) The cost of burial will be included in the client's last invoice.

**Reporting Requirements:**

- a) GeoCare will submit monthly invoices for each client's charges to the respective District TB Coordinator by the 15<sup>th</sup> of each month for the preceding month.
- b) GeoCare will submit a *Monthly Medical Status Report* to the DPH TB Program's State Office for each TB client in their custody. Reports should be received by the 15<sup>th</sup> of each month for the preceding month.
- c) GeoCare will provide the DPH TB Program with a thorough *Discharge Summary* within two weeks after the client's discharge from their facility. The *Discharge Summary* will be inclusive of a synopsis of the hospital course, special procedures performed, consultations performed, abnormal laboratory studies and a complete list of medications prescribed at discharge.
- d) GeoCare will provide a 7-day supply of TB medications, if the patient is still under treatment at the time of discharge from the facility.

**Delinquent Reports:**

- a) GeoCare will submit reports/client updates as required by the DPH TB Program by the designated due dates as outlined in this MOA.
- b) DPH TB Program reserves the right to withhold payments for services performed under this MOA, after notice to GeoCare and an opportunity for a meeting with a DPH TB Program representative.

**Housing homeless clients**

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Each county and district should maintain a current listing of single occupancy motels in their area. The American Lung Association (ALA) has a contract to verify suitable housing for homeless clients. Refer to *Alternative Housing Project for Homeless Tuberculosis Patients in Georgia* available from ALA at 770-434-5864.

**State TB Social Services**

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Contact the state TB Program Social Services Provider for assistance with referrals and consultations on complicated clients.

What can the State TB Social Service Provider do?

1. Provide psychosocial assessments (to determine the problem(s), level of functioning and appropriate services and treatment plans for the patient)
2. Provide referral/linkage to appropriate resources
3. Provide direct services/counseling to patients and families
4. Provide phone consultation to districts on complex cases
5. Provide onsite consultation to districts on complex cases
6. Provide educational programs to District staff regarding social service issues
7. Provide assistance to districts with resource development and coordination by collaborating with local agencies and organizations
8. Provide assistance to districts by collaboration with ALA on complex patients
9. Provide assistance to districts on special projects

### Who can be referred to the State Social Service Provider?

1. Patients referred to ALA for services
2. Patients with complex psychosocial problems (homeless, uninsured, no income, substance abuse, mental health, undocumented, etc.)

### Items needed for referral to State Social Service Provider:

1. Georgia Department of Public Health Form 3121-R, Tuberculosis Services and Client Referral Form located on the TB web pages at <http://www.health.state.ga.us/programs/tb/phclinicforms.asp>
2. Social service referral form (completely filled out with relevant information i.e., infectious status, insurance type, family members, family support, next of kin, income, unemployment history, etc.)
3. Any other referrals or social services notes from hospital and/or community agencies  
It would also be very helpful to refer complex patients to the state social worker the same time they are referred to ALA for services. See American Lung Association section.

## **Program Evaluation**

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Program evaluation is a core activity of TB control. Self evaluation is needed in order to identify key intervention points during therapy in which action can be taken to promote optimal patient outcomes. The TB Program encourages participation in the Office of Nursing Quality Assurance/Quality Improvement initiative. During each grant cycle, an evaluation plan is developed and implemented. For more information, please refer to *Tuberculosis Program Evaluation Guidelines* available from the state office TB Nurses.

## **Directly Observed Therapy (DOT)**

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DOT is the standard of care in Georgia for TB patients to ensure completion of therapy. DOT entails the direct observation of the patient's self-administering and swallowing the correct dose of anti-tuberculosis medications at the proper time by a trained and responsible person, mutually agreed upon by the patient and public health authorities to provide DOT. However, DOT is not just providing medication. DOT involves personal interaction with the patient. The DOT worker has the opportunity to make genuine contributions not only to the patient's physical health but also to his or her well-being. Frequently, the DOT worker will identify adverse reactions, additional contacts or locations, and social service or personal needs that could interfere with completion of treatment. Helping the patient resolve these problems not only helps achieve program outcomes but also helps the patient find the assistance needed with their problems.

DOT is **required** for:

- All suspected and/or confirmed active cases of TB disease
- All children less than five (5) years of age being treated for active TB disease, LTBI or prophylactic treatment during the window period
- All persons being treated for LTBI who are co-infected with HIV
- All persons being treated for LTBI on an intermittent dosing regimen
- All persons on the combined Isoniazid and Rifapentine regimen for LTBI

If financial resources allow, DOT is **strongly recommended** for:

- Persons infected with TB that are at risk for active disease (e.g., close contacts, immunocompromised persons, converters)
- All children five to fifteen (5 – 15) years of age being treated for LTBI
- Any person being treated for LTBI that has adherence problems

Each person (or legal guardian) on DOT should sign and have a copy of a DOT agreement (form # DPH60/060W). DOT is considered to be given Monday through Friday except in the case of MDR-TB or XDR-TB. Only DOT doses are counted. DOT can be carried out at any site mutually agreed upon by the patient and DOT provider.

At each DOT visit, assessment for any adverse reactions or side effects to medication will be made and documented.

Personnel without a nursing license are not allowed to administer medications, e.g., pour medications from bottles, pour pills out of packets, crush pills, or mix pills with food or liquids. They are to support the patient in the self-preparation and self-administration of his/her own medications.

Any supervised and trained responsible person mutually agreed upon by the patient and the health department including (but not limited to) health care personnel, employers, school staff, clergy, staff of a drug treatment center, firemen or staff of a CBO may perform DOT. Training must be documented. DOT cannot be provided by a family member. For complex regimens including IV/IM medications or twice daily dosing, home care agencies may provide DOT or share responsibilities with the local health department.

Refer to the “Contact Investigation / DOT” Toolkit for training materials and procedures.

## **Medications**

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The state provides TB medications free of charge to all TB clients treated through the local health departments. Clients, Medicaid and insurance companies are not to be charged under any circumstance for TB medications or PPD solution. Any client receiving medications through the county health department must be clinically assessed at least monthly by a registered nurse, advance practice registered nurse, physician’s assistant or medical doctor for clinical improvement and adverse reactions to the medications. Each patient on TB medications should have a monthly clinical assessment.

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## PHARMACY

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For the current formulary, ordering procedures and storage considerations, please refer to *Division of Public Health, Office of Pharmacy, Pharmaceutical Supply Catalog, July 1, 2010* available from the Office of Pharmacy.

### Transport of dangerous drugs

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The DOT agreement signed by the client authorizes the DOT staff person to act as an agent of the client and gives permission for them to transport the client's medication.

### 340B Information and Drug Dispensing Procedure

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Refer to the *Nurse Protocols for Registered Professional Nurses in Public Health, current edition, "Georgia Department of Public Health Drug Dispensing Procedure."* Located on the Office of Nursing web page at <http://www.health.state.ga.us/programs/nursing/publications.asp>

### Medications requiring consultation with and approval by State Medical Consultant

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- Second line anti-TB medications
- Corticosteroids for patients with TB meningitis or pericarditis

#### Steps to complete to receive second-line TB drugs:

- Email the State Medical Consultant, the TB Program Manager and the State Office TB Nurses with a synopsis of the patient.
- Fax the following documentation to the State TB Office (404-463-3460):
  - 1) Copy of the prescription for all TB medications
  - 2) Progress Note stating the need for the alternate regimen
  - 3) The *Second-Line Therapy Authorization Form* can be found on the TB web pages at <http://www.health.state.ga.us/programs/tb/phclinicforms.asp>
- The state TB Nurse will verify the documentation and consult with the State Medical Consultant. Additional information may be requested.
- Once the State Medical Consultant has signed the approval, the State Office TB Nurse will supply a copy of the signed authorization to the state Office of Pharmacy and back to the requestor.
- The requestor will contact the district drug coordinator or pharmacy to have the order placed into Cardinal.com (district drug coordinator or pharmacist sends an e-mail to the State Pharmacy Section verifying the order was placed).
- Once the State Pharmacy Section receives the signed second-line approval form and the e-mail from the district drug coordinator/pharmacist, the pending order can be approved (if the product is not on hand locally). The pharmacist can dispense the order. If there is no district pharmacist, seek contracted pharmacy services to dispense since there is no nurse protocol for ordering and dispensing second-line drug treatment.

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## LABORATORY TESTS

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Alanine Aminotransferase (ALT/ SGPT)

Alkaline Phosphatase

Aspartate Aminotransferase (AST/ SGOT)

Bilirubin

Complete Blood count (CBC with differential)

Creatinine

Glucose

Helper T. CD4 (CD4)

Hemoglobin A1C (Hgb A1C)

Hepatic Function Panel (LFP)

Hepatitis B Profile

Hepatitis C Virus

Human Immunodeficiency Virus (HIV)

Quanti-FERON GIT (QFT)

T-Spot

Tuberculin Skin Test (TST)

Uric Acid

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<b>Alanine Aminotransferase (ALT/SGPT)</b>	
Specimen:	Serum (preferred) or plasma
Volume/Min. Vol.	1 ml/ 0.5 ml
Container:	Red-top tube, gel-barrier tube, green-top (heparin) tube, or lavender-top (EDTA) tube
Collection:	Separate serum or plasma from cells within 45 minutes of collection
Storage Instructions:	Maintain specimen at room temperature
Why run this test?	To screen for liver damage and/or to help diagnose liver disease
What is being tested?	Alanine aminotransferase (ALT) is an enzyme found mostly in the cells of the liver and kidney; much smaller amounts of it are also found in the heart and muscles. In healthy individuals, ALT levels in the blood are low. When the liver is damaged, ALT is released into the blood stream, usually before more obvious symptoms of liver damage occur, such as jaundice. This makes ALT a useful test for detecting liver damage.
How is this test used?	The alanine aminotransferase (ALT) blood test is typically used to detect liver injury. It is often ordered in conjunction with aspartate aminotransferase (AST) or as part of a liver panel to screen for and/or help diagnose liver disease. AST and ALT are considered to be two of the most important tests to detect liver injury, although ALT is more specific than AST. Sometimes AST is compared directly to ALT and an AST/ALT ratio is calculated. This ratio may be used to distinguish between different causes of liver damage. ALT values are often compared to the results of other tests such as alkaline phosphatase (ALP), total protein, and bilirubin to help determine which form of liver disease is present
What does the result mean?	Normally, levels of ALT in the blood are low, (per reported parameters). Very high levels (per reported parameters) of ALT (more than 10 times the highest normal level) are usually due to acute hepatitis, often due to a virus infection. In acute hepatitis, ALT levels usually stay high for about 1–2 months but can take as long as 3–6 months to return to normal. Levels of ALT may also be markedly elevated as a result of exposure to drugs or other substances that are toxic to the liver as well as in conditions that cause decreased blood flow (ischemia) to the liver. Other causes of moderate increases in ALT include obstruction of bile ducts, cirrhosis (usually the result of chronic hepatitis or bile duct obstruction), and with tumors in the liver.
How to order this test/cost	Order from your local contract laboratory. Cost: N/A
Comments(s)	Both Isoniazid and Rifampin can cause an elevation of hepatic enzymes (ALT and AST) ALT is less sensitive than is AST to alcoholic liver disease. Increased ALT is found with obesity.

<b>Alkaline Phosphatase</b>	
Specimen:	Serum (preferred) <b>or</b> plasma
Volume/Min.Vol.	2 ml / 0.5ml
Container:	Red-top tube, gel-barrier tube, or green-top (heparin) tube
Collection:	Separate serum or plasma from cells within 45 minutes of collection. If a red-top tube or green-top tube is used, transfer separated serum or plasma to a plastic transport tube.
Storage Instructions	Maintain specimen at room temperature or refrigerate
Why run this test?	To screen for or monitor treatment for a liver or bone disorder.
What is being tested?	Alkaline phosphatase (ALP) is an enzyme found in several tissues throughout the body, including liver, bone, kidney, bowel (intestine), and in the placenta of women who are pregnant. However, the highest concentrations ALP are present in the cells that comprise the bone and liver. ALP in bone is produced by special cells called "osteoblasts" that are involved in the formation of bone. Elevated levels of ALP in the blood are most commonly caused by liver disease or bone disorders. Levels of the enzyme can be greatly increased, for example, in cases where one or more bile ducts are blocked. Smaller increases of blood levels are seen in liver cancer and cirrhosis, with use of drugs toxic to the liver, and in hepatitis.
How is this test used?	The alkaline phosphatase test (ALP) is used to help detect liver disease or bone disorders. In conditions affecting the liver, damaged liver cells release increased amounts of ALP into the blood. This test is often used to detect blocked bile ducts because ALP is especially high in the edges of cells that join to form bile ducts. If one or more of them are obstructed, for example by a tumor, then blood levels of ALP will often be high. Any condition that affects bone growth or causes increased activity of bone cells can affect ALP levels in the blood. An ALP test may be used, for example, to detect cancers that have spread to the bone or to help diagnose Paget's disease. This test may also sometimes be used to monitor treatment of Paget's disease or other bone conditions, such as vitamin D deficiency. If ALP results are increased but it is not clear whether this is due to liver or bone disease, then tests for ALP isoenzyme tests may be done to determine the cause. A GGT test (Gamma-glutamyl Transferase) and/or a test for 5'-nucleotidase may also be done to differentiate between liver and bone disease. GGT and 5'-nucleotidase levels are increased in liver disease but not bone disorders.
What does the result mean?	High ALP usually means that either the liver has been damaged or a condition causing increased bone cell activity is present. If other liver tests such as bilirubin, aspartate aminotransferase (AST), or alanine aminotransferase (ALT) are also high, usually the ALP is coming from the liver. If calcium and phosphorus measurements are abnormal, usually the ALP is coming from bone. If a GGT or 5'-nucleotidase is also increased, and then the high ALP is likely due to liver disease. If either of these two tests is normal, then the high ALP is likely due to a bone condition.
How to order this test/cost	Order from your local contract laboratory. Cost: N/A
<b>Comment:</b> Some drugs: (clofibrate, azathioprine, estrogens and estrogens in combination with androgens) lower serum ALP activity. Hepatitis: Moderate increases in alkaline phosphatase occur in viral hepatitis, but greater elevations of the transaminases (AST (SGOT), ALT (SGPT)) are usually found. <i>Used alone, alkaline phosphatase may be misleading.</i>	

<b>Aspartate Aminotransferase (AST/SGOT)</b>	
Specimen:	Serum (preferred) <b>or</b> plasma
Volume/Min.Vol.	1 ml / 0.5 ml
Container:	Red-top tube, gel-barrier tube, green-top (heparin) tube, or lavender-top (EDT) tube
Collection:	Separate serum or plasma from cells within 45 minutes of collection
Storage Instruction	Maintain specimen at room temperature
Why run this test?	To detect liver damage and/or to help diagnose liver disease
What is being tested?	Aspartate aminotransferase (AST) is an enzyme found in cells throughout the body but mostly in the heart and liver, and to a lesser extent in the kidneys and muscles. In healthy individuals, levels of AST in the blood are low. When liver or muscle cells are injured, they release AST into the blood. This makes AST a useful test for detecting liver damage. A number of conditions can cause injury to liver cells and may cause increases in AST levels. The test is most useful in detecting liver damage due to hepatitis, drugs toxic to the liver, cirrhosis, and alcoholism. AST, however, it is not specific for the liver and may be increased in conditions affecting other parts of the body.
How is this test used?	The blood test for aspartate aminotransferase (AST) is usually used to detect liver damage. It is often ordered in conjunction with another liver enzyme, alanine aminotransferase (ALT), or as part of a liver panel to screen for and/or help diagnose liver disorders. AST and ALT are considered to be two of the most important tests to detect liver injury, although ALT is more specific than AST. Sometimes AST is compared directly to ALT and an AST/ALT ratio is calculated. This ratio may be used to distinguish between different causes of liver damage. AST levels are often compared with results of other tests, such as alkaline phosphatase (ALP), total protein, and bilirubin to help determine which form of liver disease is present. AST is often measured to monitor treatment of persons with liver disease and may be ordered either by itself or along with other tests for this purpose. Sometimes AST may be used to monitor people who are taking medications that are potentially toxic to the liver. If AST levels increase, then the person may be switched to another medication.
What does the result mean?	Normally, levels of AST in the blood are low. Very high levels (above reported parameters) of AST (more than 10 times the highest normal level) are usually due to acute hepatitis, often due to a virus infection. In acute hepatitis, AST levels usually stay high for about 1–2 months but can take as long as 3–6 months to return to normal. Levels of AST may also be markedly elevated as a result of exposure to drugs or other substances that are toxic to the liver as well as in conditions that cause decreased blood flow (ischemia) to the liver. When an increased AST is from the liver, it is more likely to relate to disease of the hepatocyte.
How to order this test/cost	Order from your local contract laboratory. Cost: N/A
<b>Comment: Drugs:</b> A large number of commonly used drugs have been reported to elevate AST: isoniazid, phenothiazines, erythromycin, progesterone, anabolic-androgenic steroids, halothane, methyldopa, opiates, indomethacin, salicylates in children, and other drugs. Hepatotoxicity from drugs may cause high aminotransferase activity with elevation of AST: ALT ratio.	

<b>Bilirubin, Direct</b>	
Specimen	Serum (preferred) <b>or</b> plasma
Volume/Min. Vol.	1 ml / 0.5 ml
Container:	Red-top tube, gel-barrier tube, or green-top (lithium heparin) tube
Collection:	Separate serum or plasma from cells within 45 minutes of collection
Storage Instructions	Refrigerate
Why run this test?	To screen for or monitor liver disorders or hemolytic anemia (increased destruction of RBCs)
What is being tested?	Bilirubin is an orange-yellow pigment, a waste product primarily produced by the normal breakdown of heme, a substance found mainly in the protein hemoglobin in red blood cells (RBCs). It is ultimately processed by the liver to allow its elimination from the body. This test measures the amount of bilirubin in the blood in order to evaluate liver function or to help diagnose anemia caused by the increased destruction of RBCs (hemolytic anemia). RBCs normally degrade after about 120 days in the circulation. As the heme in hemoglobin is broken down, it is converted into bilirubin; this form is also called <u>unconjugated bilirubin</u> . Unconjugated bilirubin is not very soluble in water, so it is carried by proteins to the liver, where sugars are attached (conjugated) to it to form water-soluble <u>conjugated bilirubin</u> . The breakdown products of bilirubin give stool its characteristic brown color.
How is this test used?	In adults and older children, bilirubin is measured to diagnose and/or monitor liver diseases, such as cirrhosis, hepatitis, or gallstones. It is also used to evaluate people with sickle cell disease or other causes of hemolytic anemia who may have episodes when excessive red blood cell destruction takes place, increasing bilirubin levels. Bilirubin can be measured as a total level and/or as conjugated and unconjugated levels for these purposes. More commonly, the laboratory uses a chemical test to detect water-soluble forms of bilirubin, termed direct bilirubin, which is an estimate of the amount of conjugated bilirubin. By subtracting this from the total bilirubin, an indirect estimate (indirect bilirubin) of unconjugated bilirubin is obtained.
What does the result mean?	<i>Adults and children:</i> Increased total bilirubin that is mainly unconjugated (indirect) bilirubin may be a result of: 1) Hemolytic or pernicious anemia, 2) Transfusion reaction, 3) Cirrhosis, 4) A common metabolic condition termed Gilbert syndrome, due to low levels of the enzyme that attaches sugar molecules to bilirubin. If conjugated (direct) bilirubin is elevated more than unconjugated (indirect) bilirubin, there typically is a problem associated with decreased elimination of bilirubin by the liver cells. Some conditions that may cause this include: 1) Viral hepatitis, 2) Drug reactions, 3) Alcoholic liver disease. Conjugated (direct) bilirubin is also elevated more than unconjugated (indirect) bilirubin when there is some kind of blockage of the bile ducts. This may occur, for example, with: 1) Gallstones getting into the bile ducts, 2) Tumors, 3) Scarring of the bile ducts
How to order this test/cost?	Order from your local contract laboratory. Cost: N/A
<b>Comment:</b> Drugs or infections that cause hepatotoxicity may alter bilirubin levels. Measurement of direct bilirubin is usually not necessary when the total bilirubin is <1.2 mg/dL.	



<b>Complete Blood Count (CBC) With Differential</b>	
Specimen:	Whole blood
Volume/Min. Vol.	Fill tube to capacity / 0.5 mL
Container:	Lavender-top (EDTA) tube
Collection:	Invert tube 8 to 10 times immediately after tube is filled at the time of collection.
Storage Instructions:	Maintain specimen at room temperature
Why run this test?	To determine general health status and to screen for and monitor a variety of disorders, such as anemia
What is being tested?	The Complete Blood Count (CBC) test is an automated count of the cells in the blood. A standard CBC includes the following: 1) number of white blood cells (WBC), 2) number of red blood cells (RBC), 3) hemoglobin content (Hgb), 4) hematocrit (Hct) , 5) mean corpuscular volume (MCV), 6) mean corpuscular hemoglobin (MCH), 7) mean corpuscular hemoglobin concentration (MCHC), 8) platelet count and volume
How is this test used?	The complete blood count or CBC test is used as a broad screening test to evaluate overall health, detect and/or identify a wide range of hematologic disorders such as <u>anemia</u> , infection, and many other diseases. It is actually a panel of tests that examines different parts of the blood and includes the following: 1) <u>White blood cell (WBC) count</u> is a count of the actual number of white blood cells per volume of blood. Both increases and decreases can be significant, 2) <u>White blood cell differential</u> looks at the types of white blood cells present. There are five different types of white blood cells, each with its own function in protecting us from infection. The differential classifies white blood cells into each type: <u>neutrophils</u> (also known as segs, PMNs, granulocytes, grans), <u>lymphocytes</u> , <u>monocytes</u> , <u>eosinophils</u> , and <u>basophils</u> , 3) <u>Red blood cell (RBC) count</u> is a count of the actual number of red blood cells per volume of blood. Both increases and decreases can point to abnormal conditions, 4) <u>Hemoglobin</u> measures the amount of oxygen-carrying protein in the blood, 5) <u>Hematocrit</u> measures the percentage of red blood cells in a given volume of whole blood, 6) The <u>platelet count</u> is the number of platelets in a given volume of blood. Both increases and decreases can point to abnormal conditions of excess bleeding or clotting.
What do the results mean?	Presence of one or more of the following may be indication for further investigation: hemoglobin <10 g/dL, hemoglobin >18 g/dL, MCV >100 fL, MCV <80 fL, MCHC >37%, WBC >20,000/mm <sup>3</sup> , WBC <2000/mm <sup>3</sup> , presence of sickle cells, spherocytes, Pappenheimer bodies, basophilic stippling, stomatocytes, schistocytes (fragmented RBCs), target cells, oval macrocytes, teardrop red blood cells, abnormal cell populations, nucleated red blood cells in other than the newborn..
How to order this test/cost	Order from your local contract laboratory
<b>Comment:</b> Rifampin is known to cause thrombocytopenia. Mean corpuscular volume (MCV) is a measurement of the average size of a RBC. Mean corpuscular hemoglobin (MCH) is a calculation of the average amount of oxygen-carrying hemoglobin inside a red blood cell. Mean corpuscular hemoglobin concentration (MCHC) is a calculation of the average concentration of hemoglobin inside a red blood cell. Red cell distribution width (RDW) is a calculation of the variation in the size of RBCs	

#### What does the test result mean?

The following table explains what increases or decreases in each of the components of the CBC may mean.

<b>Components of the CBC</b>		
<b>TEST</b>	<b>NAME</b>	<b>INCREASED/DECREASED</b>
WBC	White Blood Cell	May be increased with infections, inflammation, cancer, leukemia; decreased with some medications (such as methotrexate), some autoimmune conditions, some severe infections, bone marrow failure, and congenital marrow aplasia (marrow doesn't develop normally)
% Neutrophil	Neutrophil/Band/Seg/Gran	This is a dynamic population that varies somewhat from day to day depending on what is going on in the body. Significant increases in particular types are associated with different temporary/acute and/or chronic conditions. An example of this is the increased number of lymphocytes seen with lymphocytic leukemia. For more information, see Blood Smear and WBC.
Lymphs	Lymphocyte	
% Mono	Monocyte	
% Eos	Eosinophil	
% Baso	Basophil	
Neutrophil	Neutrophil/Ban/Seg/Gran	
Lymphs	Lymphocyte	
Mono	Monocyte	
Eos	Eosinophil	
Baso	Basophil	
RBC	Red Blood Cell	
Hgb	Hemoglobin	Mirrors RBC results
Hct	Hematocrit	Mirrors RBC results
MCV	Mean Corpuscular Volume	Increased with B12 and Folate deficiency; decreased with iron deficiency and thalassemia
MCH	Mean Corpuscular Hemoglobin	Mirrors MCV results
MCHC	Mean Corpuscular Hemoglobin Concentration	May be decreased when MCV is decreased; increases limited to amount of Hgb that will fit inside a RBC
RDW	RBC Distribution Width	Increased RDW indicates mixed population of RBCs; immature RBCs tend to be larger
Platelet	Platelet	Decreased or increased with conditions that affect platelet

TEST	NAME	INCREASED/DECREASED
		production; decreased when greater numbers used, as with bleeding; decreased with some inherited disorders (such as Wiskott-Aldrich, Bernard-Soulier), with Systemic lupus erythematosus, pernicious anemia, hypersplenism (spleen takes too many out of circulation), leukemia, and chemotherapy
MPV	Mean Platelet Volume	Vary with platelet production; younger platelets are larger

<b>Creatinine, Serum</b>	
Specimen:	Serum (preferred) <b>or</b> plasma
Volume/Min.Vol.	1 ml / 0.5 ml
Container:	Gel-barrier tube, red-top tube, green-top (heparin) tube, or lavender-top (EDTA) tube
Collection:	Separate serum or plasma from cells within 45 minutes of collection.
Storage Instructions	Maintain specimen at room temperature.
Why run this test?	Routinely as part of a comprehensive or basic metabolic panel to monitor kidney function
What is being tested?	This test measures the amount of creatinine in your blood and/or urine. Creatinine is a waste product produced in your muscles from the breakdown of a compound called creatine. Creatine is part of the cycle that produces energy needed to contract your muscles. Both creatine and creatinine are produced by the body at a relatively constant rate. Almost all creatinine is excreted by the kidneys, so blood levels are a good measure of how well your kidneys are working. Creatinine concentrations will be slightly higher in men than in women and children. Results from a blood creatinine test and a 24-hour urine creatinine test may be used to calculate creatinine clearance.
How is this test used?	The creatinine blood test is used along with a BUN (blood urea nitrogen) test to assess kidney function. Both are frequently ordered as part of a basic or comprehensive metabolic panel (BMP or CMP), groups of tests that are performed to evaluate the function of the body's major organs. BMP or CMP tests are used to screen healthy people during routine physical exams and to help evaluate acutely or chronically ill patients in the emergency room and/or hospital. If the creatinine and BUN tests are found to be abnormal or if you have an underlying disease, such as diabetes, that is known to affect the kidneys, then these two tests may be used to monitor the progress of kidney dysfunction and the effectiveness of treatment. Serum creatinine measurements (along with your age, weight, and gender) also are used to calculate the estimated glomerular filtration rate (eGFR), which is used as a screening test to look for evidence of kidney damage.
What does the result mean?	Increased creatinine levels in the blood suggest diseases or conditions that affect kidney function. These can include: 1) Damage to or swelling of blood vessels in the kidneys (glomerulonephritis) caused by, for example, infection or autoimmune diseases, 2) Bacterial infection of the kidneys (pyelonephritis), 3) Death of cells in the kidneys' small tubes (acute tubular necrosis) caused, for example, by drugs or toxins, 4) Prostate disease, kidney stone, or other causes of urinary tract obstruction, 5) Reduced blood flow to the kidney due to shock, dehydration, congestive heart failure, atherosclerosis, or complications of diabetes.
How to order this test/cost	Order from your local contract laboratory. Cost: N/A
Comment(s)	<b>Drugs:</b> If there is renal impairment dosage adjustment of EMB, PZA may be needed. <b>High</b> creatinine: Renal diseases and insufficiency with decreased glomerular filtration, urinary tract obstruction, reduced renal blood flow including congestive heart failure, shock, and dehydration; rhabdomyolysis can cause elevated serum creatinine. <b>Low</b> blood levels of creatinine are not common.

<b>Glucose, Plasma</b>	
Specimen:	Plasma
Volume/Min. Vol.	Entire collection / 0.5ml
Container:	Gray-top (sodium fluoride) tube
Collection:	Label specimen as plasma. Mix well
Storage Instructions	Maintain specimen at room temperature
Why run this test?	To determine if your blood glucose level is within a healthy range; to screen for, diagnose, and monitor high blood glucose ( <u>hyperglycemia</u> ) or low blood glucose ( <u>hypoglycemia</u> ), <u>diabetes</u> , and <u>pre-diabetes</u> ; to check for glucose in your urine
What is being tested?	This test measures the amount of glucose in the blood or urine. Glucose is the primary energy source for the body's cells and the only energy source for the brain and nervous system. A steady supply must be available for use, and a relatively constant level of glucose must be maintained in the blood. During digestion, fruits, vegetables, breads and other carbohydrates are broken down into glucose (and other nutrients); they are absorbed by the small intestine and circulated throughout the body. Using glucose for energy production depends on insulin, a hormone produced by the pancreas. Insulin facilitates transport of glucose into the body's cells and directs the liver to store excess energy as glycogen for short-term storage and/or as triglycerides in adipose (fat) cells.
How is this test used?	The blood glucose test may be used to: 1) Screen for both high blood glucose (hyperglycemia) and low blood glucose (hypoglycemia) 2) Help diagnose diabetes, 3) Monitor glucose levels in persons with diabetes. Depending on the purpose of testing, glucose may be measured on a fasting basis (collected after an 8- to 10-hour fast), randomly (anytime), post prandial (after a meal), and/or as part of an oral glucose challenge or tolerance test (OGTT/ GTT <i>Screening</i> : Blood glucose is often measured as part of a group of tests, such as a CMP (Comprehensive Metabolic Panel), during routine physicals. This is done to screen for diabetes, which often causes no symptoms early in its course, and for pre-diabetes – moderately increased blood glucose levels that indicate an increased risk of developing type 2 diabetes. For screening purposes, a CMP or blood glucose test is performed on a fasting basis (fasting blood glucose, FBG).
What does the result mean?	High levels (per reported parameters) of glucose most frequently indicate <u>diabetes</u> , but many other diseases and conditions can also cause elevated blood glucose.
How to order this test/cost	Order from your local contract laboratory
<b>Comment:</b> Blood should be drawn in the morning after an overnight fast (no caloric intake for at least eight hours), during which time the individual may consume water.	

## Helper T Lymphocyte Marker CD4

Specimen:	Whole blood
Volume	Fill tube(s) to capacity
Container:	Lavender-top (EDTA) tube and yellow-top (ACD-A) tube
Collection:	Invert tube 8 to 10 times immediately after collection. To preserve cellular viability, collect specimen so it will arrive in the laboratory Monday through Friday and within 48 hours of collection. Please indicate date and time of venipuncture on the tube(s) and on the test request form.
Storage Instructions	Maintain specimen at room temperature
Why run this test?	Most often, this test is done to measure the strength of your immune system if you have been diagnosed with <u>HIV</u> infection
What is being tested?	CD4 and CD8 cells are <u>lymphocytes</u> that have markers on the surfaces of the cells called CD4 and CD8. They are types of white blood cells that fight infection, and they play an important role in your immune system function. CD4 and CD8 cells are made in the spleen, lymph nodes, and thymus gland, and they circulate throughout the body in the bloodstream. CD4 cells are sometimes called T-helper cells. They help to identify, attack, and destroy specific bacteria, fungi, and viruses that affect the body. CD4 cells are a major target for HIV, which binds to the surface of CD4 cells, enters them, and either replicates immediately, killing the cells in the process, or remains in a resting state, replicating later. As the HIV virus gets into the cells and replicates, the number of CD4 cells in the blood gradually declines. The CD4 count decreases with HIV disease progression. This process may continue for several years before the number of CD4 cells drops to a low enough level that symptoms associated with AIDS begin to appear. As treatment reduces the amount of HIV present in the body and slows progression, the CD4 count will increase and/or stabilize.
How is this test used?	Monitor patient's helper/inducer T-cell status. If you have been diagnosed with HIV, a CD4 test by itself, a CD4 percent, or a CD4/CD8 ratio is used to help evaluate and track the progression of HIV infection and disease. CD4 cells are the main target of HIV, and the number of CD4 cells will decrease as HIV progresses. Since CD4 cells are usually destroyed more rapidly than other types of lymphocytes and because absolute counts can vary from day to day, it is sometimes useful to look at the number of CD4 cells compared to other types of lymphocytes.
What does the result mean?	In general, the CD4 count goes down as <u>HIV</u> disease progresses. Any single CD4 count value may differ from the last one even though your health status has not changed. According to public health guidelines, preventive therapy should be started when an HIV-positive person who has no symptoms registers a CD4 count under 200 cells per cubic millimeter of blood. Some physicians will opt to consider treatment earlier, at 350 cells/mm <sup>3</sup> . CDC considers HIV-infected persons who have CD4 counts below 200 cells/mm <sup>3</sup> to have AIDS, regardless of whether they have any signs or symptoms.
How to order this test/cost	Order from your local contract laboratory. Cost: N/A
<p><b>Comment:</b> For patients with CD4 counts &lt;50 cells/mm<sup>3</sup>, ART should be initiated within 2 weeks of starting TB treatment (<b>AI</b>) For patients with CD4 counts ≥50 cells/mm<sup>3</sup> with clinical disease of major severity as indicated by clinical evaluation (including low Karnofsky score, low body mass index [BMI], low hemoglobin, low albumin, organ system dysfunction, or extent of disease), the initiation of ART within 2 to 4 weeks of starting TB treatment (<b>BI</b> for CD4 count 50–200 cells/mm<sup>3</sup> and <b>BIII</b> for CD4 count &gt;200 cells/mm<sup>3</sup>). For other patients with CD4 counts ≥50 cells/mm<sup>3</sup>, ART can be delayed beyond 2 to 4 weeks but should be initiated by 8 to 12 weeks of TB therapy (<b>AI</b> for CD4 count 50–500 cells/mm<sup>3</sup>; <b>BIII</b> for CD4 count &gt;500 cells/mm<sup>3</sup>). Rating of Recommendations: A = Strong; B = Moderate; C = Optional</p>	

<b>Hemoglobin (Hbg) A1C</b>	
Specimen:	Whole blood
Volume/Min. Vol.	7 ml Pediatric EDTA whole blood tubes may be used. Please place the entire tube in a transport tube for shipment to the laboratory.
Container:	Lavender-top (EDTA) tube or green-top (lithium heparin) tube. Other anticoagulants have not been tested or found acceptable
Collection:	The usual precautions in the collection of venipuncture samples should be observed. The sample must be free of clots.
Storage Instructions	Maintain specimen at room temperature
Why run this test?	To monitor a person's <u>diabetes</u> and to aid in treatment decisions; to screen for and/or diagnose diabetes and prediabetes
What is being tested?	The A1c test evaluates the average amount of glucose in the blood over the last 2 to 3 months. It does this by measuring the concentration of glycated (also often called glycosylated) hemoglobin A1c. Hemoglobin is an oxygen-transporting protein found inside red blood cells (RBCs). Hemoglobin A can be further subdivided, with one of the subcomponents known as hemoglobin A1c. As glucose circulates in the blood, some of it spontaneously binds to hemoglobin A. The glucose-hemoglobin molecules formed are said to be glycated. The higher the concentration of glucose in the blood, the more glycated hemoglobin is formed. Once the glucose binds to the hemoglobin, it remains there for the life of the red blood cell - normally about 120 days. The combination of glucose and hemoglobin A is referred to as HbA1c or A1c. A1c is produced on a daily basis and slowly cleared from the blood as older RBCs die and younger RBCs (with non-glycated hemoglobin) take their place
How is this test used?	The A1c test and eAG calculation are used to monitor the glucose control of diabetics over time. The goal of those with <u>diabetes</u> is to keep their blood glucose levels as close to normal as possible. This helps to minimize the complications caused by <u>chronically</u> elevated glucose levels, such as progressive damage to body organs like the kidneys, eyes, cardiovascular system, and nerves. The A1c test and eAG result give a picture of the average amount of glucose in the blood over the last few months. A1c is frequently used to help newly diagnosed diabetics determine how elevated their uncontrolled blood glucose levels have been.
What does the result mean?	For monitoring glucose control, A1c is currently reported as a percentage, and it is recommended that diabetics aim to keep their A1c below 7%. The report for your A1c test also may include an estimated Average Glucose (eAG), which is a calculated result, based on your A1c levels. The purpose of reporting eAG is to help you relate your A1c results to your everyday glucose monitoring levels. The <u>formula</u> for eAG converts percentage A1c to units of mg/dL or mmol/L so that you can compare it to your glucose levels from home monitoring systems or laboratory tests. The closer a diabetic can keep their A1c to 6% without experiencing excessive <u>hypoglycemia</u> , the better their <u>diabetes</u> is in control. As the A1c and eAG increase, so does the risk of complication.
How to order this test/cost?	Order from your local contract laboratory. Cost: N/A
<b>Comment:</b> Any cause of shortened erythrocyte survival will reduce exposure of erythrocytes to glucose with a consequent decrease in Hb A <sub>1c</sub> (%). Causes of shortened erythrocyte lifetime might be hemolytic anemia or other hemolytic diseases, homozygous sickle cell trait, pregnancy, or recent significant or chronic blood loss.	

<b>Hepatic Function Panel ( LFP)</b>	
Specimen:	Serum (preferred) <b>or</b> plasma
Volume/Min.Vol.	1 ml / 0.5 ml ( <b>Note:</b> This volume does <b>not</b> allow for repeat testing)
Container	Red-top tube, gel-barrier tube, <b>or</b> green-top (heparin) tube
Collection:	Separate serum or plasma from cells within 45 minutes of collection
Storage Instructions	<b>Stable</b> at room temperature for up to seven days or refrigerated for up to 14 days.
Why run this test?	To screen for, detect, evaluate, and monitor for liver inflammation and damage
What is being tested?	A liver panel is a group of tests that are performed together to detect, evaluate, and monitor liver disease or damage. The liver is one of the largest organs in the body and is located in the upper right-hand part of the abdomen and behind the lower ribs. The liver metabolizes and detoxifies drugs and substances that are harmful to the body. It produces blood clotting factors, proteins, and enzymes; helps maintain hormone balances, and stores vitamins and minerals. Bile, a fluid produced by the liver, is transported through ducts directly to the small intestine to help digest fats or to the gallbladder to be stored and concentrated for later. The liver panel measures enzymes, proteins, and substances that are produced or excreted by the liver and are affected by liver injury. When performed together, these tests give a snapshot of the health of the liver, an indication of the potential severity of any liver injury, change in liver status over time, and a starting place for further diagnostic testing.
How is this test used?	A liver panel may be used to screen a person for liver damage, especially someone who has a condition, or is taking a drug, that may affect the liver. A Comprehensive Metabolic Panel (CMP) may be ordered instead of a liver panel for routine screening. This group of tests includes most of the liver panel as well as additional tests that evaluate other organs and systems within the body. Abnormal tests on a liver panel may prompt a repeat analysis to see if the elevation or decrease persists and/or may indicate the need for additional testing to determine the cause of the liver dysfunction.
What do the results mean?	The liver panel test results are not diagnostic of a specific condition; they indicate that there may be a problem with the liver. In a person who does not have symptoms or identifiable risk factors, abnormal liver test results may indicate a temporary liver injury or reflect something that is happening elsewhere in the body – such as in the skeletal muscles, pancreas, or heart. It may also indicate early <u>liver disease</u> and the need for further testing and/or periodic monitoring.
How to order this test/cost	Order from your local contract laboratory. Cost: N/A
<b>Comment:</b> Drugs: Isoniazid, Rifampin and Pyrazinamide have an adverse effect on the liver. Tests include: Alanine aminotransferase (ALT/SGPT); albumin, serum; alkaline phosphatase, serum; aspartate aminotransferase (AST/SGOT); bilirubin, direct; bilirubin, total; protein, total, serum.	



This table shows examples of some combinations of results that may be seen in certain types of liver conditions or diseases.

<b>Type of liver condition or disease</b>	<b>Bilirubin</b>	<b>ALT and AST</b>	<b>ALP</b>	<b>Albumin</b>	<b>PT</b>
Acute liver damage (due, for example, to infection, toxins or drugs, etc.)	Normal or increased usually after ALT and AST are already increased	Usually greatly increased; ALT is usually higher than AST	Normal or only moderately increased	Normal	Usually normal
Chronic forms of various liver disorders	Normal or increased	Moderately increased	Normal to slightly increased	Normal	Normal
Alcoholic Hepatitis	Normal or increased	AST is usually at least twice the level of ALT	Normal or moderately increased	Normal	Normal
Cirrhosis	May be increased but this usually occurs later in the disease	AST is usually higher than ALT but levels are usually lower than in alcoholic disease	Normal or increased	Usually decreased	Usually prolonged
Bile duct obstruction, cholestasis	Normal or increased; increased in complete obstruction	Normal to moderately increased	Increased; often greater than 4 times what is normal	Usually normal but if the disease is chronic, levels may decrease	Usually normal
Cancer that has spread to the liver (metastasized)	Usually normal	Normal or slightly increased	Usually greatly increased	Normal	Normal
Cancer originating in the liver (hepatocellular carcinoma, HCC)	May be increased, especially if the disease has progressed	AST higher than ALT but levels lower than that seen in alcoholic disease	Normal or increased	Usually decreased	Usually prolonged
Autoimmune	Normal or increased	Moderately increased	Normal or slightly increased	Normal or decreased	Normal

If a person is taking drugs that may affect their liver, then abnormal test results may indicate a need to re-evaluate the dosage or choice of medication. When a person with liver disease is being monitored, then the doctor will evaluate the results of the liver panel together to determine if liver function is worsening or improving. For example, increasingly abnormal bilirubin, albumin, and/or PT may indicate deterioration in liver function, while stable or improving results of these tests may indicate liver function preservation or improvement.

<b>Hepatitis B Routine Screen</b>	
Specimen:	Whole blood
Volume/Min. Vol.	6 ml
Container:	Red-top tube no additives
Collection:	Allow blood specimen to clot undisturbed at room temperature for at least 30 minutes. Transport immediately or place specimen in refrigerator until transporting. Do not hold over 7 days.
Storage Instructions:	Refrigerate
Why run this test?	To detect and diagnose an infection with a <u>hepatitis virus</u> .
What is being tested?	Hepatitis B is a liver infection caused by the hepatitis B virus (HBV). It is one of several various causes of hepatitis, a condition characterized by inflammation and enlargement of the liver. Other causes of hepatitis include, for example, certain drugs, inherited disorders, and autoimmune diseases. HBV is one of five "hepatitis viruses" identified so far. The other four are A, C, D, and E. The course of HBV infections can vary from a mild form that lasts only a few weeks to a more serious chronic form lasting years. Sometimes chronic HBV leads to serious complications such as cirrhosis or liver cancer. Some of the various stages or forms of hepatitis B include: 1) Acute infection - presence of typical signs and symptoms with positive screening test, 2) Chronic infection — persistent infection with the virus detected by lab tests accompanied by inflammation of the liver, 3) Carrier (inactive) state — persistent infection but no liver inflammation (a carrier is someone who may appear to be in good health but harbors the virus and can potentially infect others.
How is this test used?	Hepatitis B tests may be used for a variety of reasons. Some of the tests detect antibodies produced in response to HBV infection; some detect antigens produced by the virus, and others detect viral DNA. Generally, one set of tests is used to determine the cause of acute symptoms while another set of tests may be used after a diagnosis is made, to monitor possible progression of the disease, to detect chronic infection and/or carrier status. The following is a list the main uses for HBV tests: 1) To detect acute hepatitis B infection: hepatitis B surface antigen (HBsAg), hepatitis B core antibody (anti-HBc), IgM and sometimes hepatitis B e antigen (HBeAg), 2) To diagnose chronic HBV hepatitis: HBsAg, hepatitis B virus (HBV) DNA, and sometimes HBeAg , 3) To monitor chronic hepatitis B infection and its treatment: HBsAg, hepatitis B e antigen (HBeAg), hepatitis B surface antibody (anti-HBs) IgG, hepatitis B e antibody (anti-HBe) IgG and HBV DNA , 4) To detect previous exposure to hepatitis B, in a person who is immune compromised (when the virus can become reactivated): hepatitis B core antibody (anti-HBc) total and anti-HBs.
What does the result mean?	The tests for hepatitis B may be ordered individually, but are often ordered in some combination depending on the reason for testing. Results of the tests are typically evaluated together. Sometimes the meaning of one result depends on the result of another test.
How to order this test/cost	Order from the GPHL. The Ga. Public Health Laboratory does not charge the county health departments for this procedure.
<b>Comment:</b> Test includes: HBsAg; HBeAg; anti-HBc, total; anti-HBc, IgM; anti-HBe; anti-HBs	

The table below summarizes possible interpretations of some common patterns of results.

<b>Hep B surface antigen (HBsAg)</b>	<b>Hep B surface antibody (Anti-HBs)</b>	<b>Hep B core antibody (Anti-HBc IgM)</b>	<b>Hep B core antibody Total (Anti-HBc IgG+IgM)</b>	<b>Hep B e antigen (HBeAg)*See note</b>	<b>Hep B e antibody (Anti-HBe)</b>	<b>Interpretation / Stage of Infection</b>
Negative	Negative		Negative			No active or prior infection; not immune — may be good candidate for vaccine; possibly in the incubation stage
Positive	Negative	Negative	Negative	Positive	Negative	Early acute infection
Positive	Negative	Positive or Negative	Positive or Negative	Positive	Negative	Acute infection, usually with symptoms; contagious
Positive	Negative	Positive	Positive	Negative*	Positive	Late in the acute stage of infection (seroconversion)
Negative	Negative	Positive	Positive	Negative*	Positive	Acute infection is resolving (convalescent)
Positive	Negative	Negative	Positive	Positive	Negative	Usually indicates an active chronic infection (liver damage likely)
Positive	Negative	Negative	Positive	Negative*	Positive	Chronic infection but low risk of liver damage — carrier state
Negative	Positive	Negative	Positive	Negative*	Positive	Infection resolved (recovery); immunity due to natural infection
Negative	Positive		Negative			Immunity due to vaccination

\*Note: There are some types (strains) of HBV that do not make e-antigen. In areas where these strains of HBV are common (in the Middle East and Asia), testing for HBeAg is not very useful. In these cases, a negative HBeAg result does not necessarily mean that the antigen is not present or that the person is not infectious; it may be that the person is infected with a strain that does not make the e-antigen

<b>Hepatitis C Virus (HCV) Antibody</b>	
Specimen:	Whole blood
Volume/Min. Vol.	6 ml
Container	Red-top tube no additives
Collection:	Allow blood specimen to clot undisturbed at room temperature for at least 30 minutes. Transport immediately or place specimen in refrigerator until transporting. Do not hold over 7 days.
Storage Instructions:	Refrigerate
Why run this test?	To screen for and diagnose a hepatitis C virus (HCV) infection and to monitor treatment of the infection.
What is being tested?	Hepatitis C (HCV) is a virus that causes an infection of the liver that is characterized by liver inflammation and damage. It is one of five "hepatitis viruses" identified so far, including A, B, D, and E, that is known to cause the disease. HCV is spread by exposure to contaminated blood, primarily through the sharing of needles by intravenous drug users, but also by sharing personal items contaminated by blood such as razors, through sex with an infected person, via health care occupational exposure, and from mother to baby during childbirth. Before tests for HCV became available in the 1990s, HCV was often transmitted by blood transfusions. While HCV is not as contagious as Hepatitis B, there is currently no vaccine to prevent infection. Hepatitis C infection is a common cause of chronic liver disease in North America; about 2% of all adults in the United States have been exposed to the virus, and up to 85% of those who have it will become chronically infected after their acute infection resolves. According to the CDC, an estimated 3.2 million people in the U.S. have a chronic HCV infection. Many of those who are infected have no symptoms and are not aware of the condition.
How is this test used?	Hepatitis C tests are used to detect and diagnose an infection and/or to monitor the treatment of hepatitis C virus (HCV). Tests are used to detect the condition if a person: 1) Has been exposed to someone with HCV , 2) Participates in high risk behaviors such as injecting street drugs , 3) Has abnormal liver function tests, 4) Has symptoms associated with liver disease, such as jaundice, dark urine, nausea, or unexpected weight gain or loss , 5) Test blood safety
What do the results mean?	In general, if the HCV antibody test is strongly positive, then someone has likely been infected at some time with hepatitis C. If the HCV RNA test is positive, then the person has a current infection. If no HCV viral particles are detected, then the person either does not have an active infection or the virus is present in very low numbers.
How to order this test/cost?	Order from the GPHL. The GA Public Health Laboratory charges the county health department a fee of \$10 for this procedure.
<b>Comment:</b> Since as many as 90% of commercial intravenous immunoglobulin's test positive for hepatitis C antibody, an artifactual positive can result briefly after transfusion.	

### Human Immunodeficiency Virus 1 (HIV-1), Qualitative, RNA

Specimen:	Plasma <b>or</b> serum
Volume/Min. Vol.	1 ml 0.5 ml
Container:	Lavender-top (EDTA) tube, yellow-top (ACD) tube, red-top tube, or gel-barrier tube
Collection:	N/A
Storage Instructions	Refrigerate or Freeze
Why run this test?	To determine if you are infected with Human immunodeficiency virus (HIV)
What is being tested?	This test detects HIV antibodies in blood or other body fluids. HIV, human immunodeficiency virus, is the virus that causes AIDS (acquired immunodeficiency syndrome), which destroys the immune system and leaves the body vulnerable to debilitating infections. When HIV enters the body, such as through contact with an infected individual or contaminated needle, the immune system responds by producing antibodies directed against the virus. These antibodies can be detected about 3 to 8 weeks after exposure to the virus. If exposure to the virus is more recent, then antibody levels may be too low to detect. It may be necessary to perform a p24 antigen test or an HIV RNA (viral load) test in order to detect the virus.
How is this test used:	HIV antibody testing is used to screen for and diagnose HIV infections. Early treatment of HIV infection and immune system monitoring can greatly improve long-term health. Also, knowing your HIV status may help you change behaviors that would put you and others at risk.
What do the results mean?	A healthy individual has no antibodies to HIV. However, a negative screening test means only that there is no evidence of disease at the time of the test. It is important for those who are at increased risk of HIV infection to have screening tests performed on a regular basis to check for possible exposure to the virus. If you test positive for HIV antibodies on both the ELISA and the Western Blot tests, you are considered to be infected with HIV. HIV cannot be cured, but early diagnosis allows for treatment that can help to suppress levels of virus in your body (viral load) and slow progression of the disease.
How to order this test/cost	Order from the GPLH. The GA Public Health Laboratory charges the county health departments a fee of \$10 for this procedure.

**Comment:** Antibodies to the HIV virus are often detected by a screening test called an ELISA. The ELISA test is repeated if positive. The ELISA method is very sensitive but requires another test, a Western Blot, to confirm the results because false positives can occur. These tests can be done on blood, urine or oral sample in a local clinic. There are several rapid tests available in which results are generated in about 20 minutes. However, these too must have confirmatory testing before a final diagnosis can be made.

<b>QuantiFERON Gold-in-tube (Interferon-Gamma Release Assay or IGRA)</b>	
Specimen:	Whole blood
Volume/Min.Vol.	1 ml x three tubes (see Container) /0.8 ml x three tubes.
Container:	The QuantiFERON® collection kit contains instructions for the draw of three special QuantiFERON® collection tubes (one each): (1) gray-top (with white ring), uncoated (nil); (2) red-top (with white ring), TB antigen-coated; (3) purple-top (with white ring), mitogen-coated.
Collection:	<b>REFER TO COLLECTION INSTRUCTIONS INCLUDED WITH DRAW KIT.</b> Special specimen collection kit contains three gel-barrier tubes: gray-top/white ring (nil), red-top/white ring (TB antigens), and purple-top/white ring (mitogen). All three tubes are required for a single test result. Each tube is designed to draw only 1 ml and fill time may be longer than other blood collection tubes. Following proper fill, shake tubes vigorously for five seconds; frothing will occur. <b>Do not centrifuge or refrigerate</b> specimens. To preserve cellular viability, specimens should be collected and sent same day, at room temperature, so as to arrive at the lab as soon as possible and within 14 hours of draw. Please indicate date and time of venipuncture on the tubes and on the test request form.
Storage Instructions	Maintain specimen at room temperature (17°C to 27°C). <b>Do not</b> centrifuge, refrigerate, or ship tubes on ice.
Why run this test?	To help determine whether or not you may have a latent or active infection with the <i>Mycobacterium tuberculosis</i> bacteria.
What is being tested?	Tuberculosis (TB) screening tests help to determine whether a person has become infected with <i>Mycobacterium tuberculosis</i> bacteria, the cause of TB. The screening tests measure the body's immune response to antigens derived from the bacteria – either directly as a skin reaction to a tuberculin skin test (TST) or indirectly with an interferon gamma release assay (IGRA) blood test. TB, once called consumption, has been recognized as causing illness for thousands of years. This bacterial infection may affect many body organs, but it primarily targets the lungs. TB may cause an inactive (latent) infection or an active, progressive disease. The immune system of about 90% of the people who become infected with TB manage to control its growth and confine the TB infection to a few cells in the body. The bacteria in these cells are inactive but still alive. The person does not have any symptoms and they are not infectious, but they do have a "latent TB infection." If, after some time, the person's immune system becomes weakened (compromised), the mycobacterium may begin to grow again, leading to an active case of tuberculosis disease. Active TB does cause illness in the person and it can be passed to others through respiratory secretions such as sputum or aerosols released by coughing, sneezing, laughing, talking, singing or breathing.
How is this test used?	The QuantiFERON®-TB Gold test is an in vitro assay to aid in the diagnosis of both latent and active infection with <i>Mycobacterium tuberculosis</i> . TB screening tests are not used as a general population screens but are used to screen certain people who are at high risk for TB exposure.
What does the result mean?	Test results are reported either as: 1) <b>positive</b> , an indication of infection with <i>Mycobacterium tuberculosis</i> is likely, 2) <b>negative</b> , an indication of infection with <i>Mycobacterium tuberculosis</i> is unlikely, (however, in contact investigations, negative results obtained on recent contacts of persons with infectious tuberculosis prior to 8 weeks typically should be confirmed by repeat testing 8-10 weeks after the end of exposure), or 3) <b>indeterminate</b> , indicating an uncertain likelihood of <i>Mycobacterium tuberculosis</i> infection.
How to order this test/cost	Order from your local contract laboratory. Cost: N/A
<b>Comment:</b> QuantiFERON®-TB Gold test does not give a <b>false positive</b> response in people who have received bacilli Calmette-Guerin (BCG) as a vaccine or for cancer therapy. Since the test requires viable white blood cells, the IGRA blood sample must be received and tested by the laboratory within a designated window of time.	

<b>T-Spot (Interferon-Gamma Release Assay or IGRA)</b>	
Specimen:	Whole Blood
Volume/Min.Vol.	The guidelines for the volume of blood are: Adults and children 10 years old and over 6 ml, children 2 to 9 years old 4 ml, children up to 2 years old 2 ml
Container:	Collect the blood specimen(s) in a standard green top tube (lithium or sodium heparin). No special collection tubes are required
Collection:	<b>DO NOT USE</b> a blood collection tubes that contain the anti-coagulant EDTA. EDTA affects the secretion of interferon gamma. <i>Read package insert for complete instructions.</i>
Storage Instructions	Do <b>NOT</b> refrigerate or freeze blood samples. Blood samples to be processed with the T-SPOT.TB test must be used within 8 hours post venipuncture. Samples can be used up to 32 hours post venipuncture with the addition of the T-Cell <i>Xtend</i> reagent prior to running the T-SPOT.TB test. Whole blood samples should be maintained between 18°C and 25°C until processed. <i>Read package insert for complete instructions.</i>
Why run this test?	To help determine whether or not a person has latent TB infection or active TB disease with the <i>Mycobacterium tuberculosis</i> bacteria.
What is being tested?	The screening test measure the body's immune response to antigens derived from the bacteria. Peripheral blood mononuclear cells (PBMCs) are separated from a whole blood sample and washed to remove any sources of background interfering signal. The PBMCs are then counted so that a standardized cell number is used in the assay. This ensures that even those who have low T cell titers due to weakened immune systems (the immunocompromised and immunosuppressed) have adequate numbers of cells added to the microtitre wells.
How is this test used?	The T-SPOT TB test is a blood test, also known as an <b>Interferon Gamma Release Assay</b> , or IGRA, for TB infection. The test was approved by the FDA in 2008. The T-SPOT.TB test is an <i>in vitro</i> diagnostic test that enumerates the response of effector T cells that have been sensitized to <i>Mycobacterium tuberculosis</i> . The T-SPOT.TB test is an indirect test for <i>M. tuberculosis</i> infection (including disease) and is intended for use in conjunction with risk assessment, radiography and other medical and diagnostic evaluations.
What does the result mean?	Test results are reported either as: 1) <b>Positive</b> , = or > 8 spots, an indication of infection with <i>Mycobacterium tuberculosis</i> is <b>likely</b> , 2) <b>Borderline</b> , 5,6, or 7 spots, indicating an <b>uncertain likelihood</b> of infection with <i>Mycobacterium tuberculosis</i> , 3) <b>negative</b> , = or < 4 spots, indicating that <i>Mycobacterium tuberculosis</i> is <b>not likely</b> , (however, in contact investigations, negative results obtained on recent contacts of persons with infectious tuberculosis prior to 8 weeks typically should be confirmed by repeat testing 8-10 weeks after the end of exposure), or 4) <b>indeterminate</b> , indicating an <b>uncertain likelihood</b> of <i>Mycobacterium tuberculosis</i> infection.
How to order this test/cost	Order from Oxford Immunotec
<b>Comment:</b> The T-SPOT.TB assay should be used and interpreted only in the context of the overall clinical picture. A negative test result does not exclude the possibility of exposure to or infection with <i>M. tuberculosis</i> . There is no association with BCG vaccination and T-SPOT.TB test results. The test utilizes two <i>M. tuberculosis</i> specific antigens (ESAT-6 and CFP 10) that do not cross react with the BCG vaccine or most common non-tuberculosis mycobacteria (NTMs), with the exception of <i>M. kansasii</i> , <i>M. szulgai</i> , <i>M. marinum</i> <sup>3,4</sup> and <i>M. goodii</i> .	

<b>Tuberculin Skin Test, Mantoux (TST)</b>	
Specimen:	N/A
Volume:	N/A
Container:	N/A
Collection:	N/A
Storage Instructions:	Refrigerate
Why do this test?	To help determine whether or not you may have a <u>latent</u> or active infection with the <i>Mycobacterium tuberculosis</i> bacteria
What is being tested?	Tuberculosis (TB) screening tests help to determine whether a person has become infected with <i>Mycobacterium tuberculosis</i> bacteria, the cause of TB. The screening tests measure the body's immune response to antigens derived from the bacteria – either directly as a skin reaction to a tuberculin skin test (TST) or indirectly with an interferon gamma release assay (IGRA) blood test. The tuberculin skin test involves two steps: the injection of a small amount of purified protein derivative (PPD) solution under the first layer of skin of the forearm and an evaluation of the injection site conducted by a health care worker at 48 and/or 72 hours to see if a local skin reaction has occurred.
How is this test used?	TB screening tests are not used as a general population screens but are used to screen certain people who are at high risk for TB exposure such as: those who have <u>signs</u> and <u>symptoms</u> consistent with active tuberculosis, those with diseases or conditions that weaken the <u>immune system</u> , such as those with HIV or AIDS, that make them more vulnerable to a TB infection, those who are in confined living conditions such as homeless shelters, migrant farm camps, nursing homes, schools, and correctional facilities, health care workers and others whose occupations bring them in close contact with those who may have active TB, Those who have been in close contact with someone who has an active case of TB, those who come from or have lived for a period of time in a foreign country where TB may be more common, those who inject illegal drugs.
What does the result mean?	A health care worker will interpret your tuberculin skin test results by looking at the injection site on your forearm at 48 or 72 hours (in most cases). A <b>positive</b> result will form a red and swollen circle at the site of the injection. The size (diameter) of the swollen raised circle determines whether exposure to <u>TB</u> has occurred. Positive TST results are also commonly seen in those who have received a BCG vaccination. <b>Negative</b> results for may mean that a person has not been exposed to TB, that the person is not infected with tuberculosis, that their <u>immune system</u> has not responded to the <u>antigen</u> in the test, or that it is too early to detect exposure. It takes about 6 weeks after infection before a person demonstrates a positive reaction to TB screening tests. If you want to confirm a negative or indeterminate result, you may repeat the same test or do either the TST or IGRA as an alternate follow-up test.
How to order this test/cost?	N/A
<b>Comment:</b> Repeated TSTs do not produce hypersensitivity. TST does cause a false positive reaction in persons who has received BCG (Bacille Calmette-Guérin). Incorrect administrations of TST can produce negative result.	



<b>Uric Acid, Serum</b>	
Specimen:	Serum (preferred) <b>or</b> plasma
Volume/Min.Vol.	1ml 0.5ml
Container:	Red-top tube, gel-barrier tube, green-top (heparin) tube or lavender-top (EDTA) tube
Collection:	Separate serum or plasma from cells within 45 minutes of collection
Storage Instructions	Maintain specimen at room temperature
Why run this test?	To detect high levels of uric acid in the blood, which could be a sign of the condition gout or to monitor uric acid level
What is being tested?	Uric acid is produced by the breakdown of purines, which are nitrogen-containing compounds found in the body in substances such as DNA. Purines enter the blood primarily from the normal breakdown and turnover of cells in the body and to a lesser extent from the digestion of certain foods (such as liver, anchovies, mackerel, dried beans and peas) and drinks (alcoholic beverages like beer and wine). Most uric acid is removed from the body by the kidneys and is excreted in the urine; the remainder is eliminated in the stool. If too much uric acid is produced or not enough is excreted, it can accumulate in the body and cause increased levels in the blood (hyperuricemia). The presence of excess uric acid can cause gout, a condition characterized by inflammation that occurs in joints when crystals derived from uric acid form in the joint (synovial) fluid. Excess uric acid can also lead to kidney disease.
How is this test used?	The uric acid blood test is used to detect high levels of this compound in the blood in order to help diagnose gout. The test is also used to monitor uric acid levels in people undergoing chemotherapy or radiation treatment. Rapid cell turnover from such treatment can result in an increase in uric acid. The uric acid urine test is used to help diagnose the cause of recurrent kidney stones and to monitor people with gout for stone formation.
What does the result mean?	Higher than normal uric acid levels (per reported parameters) in the blood is called hyperuricemia and can be caused by the over-production of uric acid in the body or the inability of the kidneys to clear out enough uric acid. The doctor will need to investigate further to determine the cause of the overproduction or decreased excretion of uric acid. There are several genetic inborn errors that effect purine metabolism. Metastatic cancer, multiple myeloma, leukemias, and cancer chemotherapy can cause increased production of uric acid. Chronic renal disease, acidosis, toxemia of pregnancy, and alcoholism can cause decreased excretion.
How to order this test/cost?	Order from your local contract laboratory. Cost: N/A
Comment	Drugs causing increased uric acid concentration include diuretics, pyrazinamide, ethambutol, and nicotinic acid.

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## MYCOBACTERIOLOGY LABORATORY TESTS

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7H11 Agar Plate

Acid-Fast Stain (AFB)

Genotyping

Gen-Probe AccuProbe DNA Probe Test

High Performance Liquid Chromatography (HPLC)

Lowenstein-Jensen Agar (LJ Slants)

Mycobacteria Growth Indicator Tube (MGIT)

Nucleic Acid Amplification Test (NAAT) using the Amplified Mycobacteria Tuberculosis Direct Test (MTD)

NAAT using the Cepheid GeneXpert MTB/RIF Assay

Polymerase Chain Reaction (PCR)

Restrict Fragment Length Polymorphism (RFLP)

Drug Susceptibilities

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<b>7H11 Agar Plate</b>	
How does it work?	7H11 agar is a transparent agar-based media for the isolation and colony morphology of mycobacterium. Oleic acid, albumin, and pancreatic digest of casein are the key ingredients which aid in the growth of the tubercle bacilli.
When would this media be used?	When a broth culture exhibits growth, the laboratory uses this media to obtain growth of the mycobacterium on solid media.
How long before growth is obtained?	Visible growth can occur in as few as 3 to 5 days with the rapid-growing mycobacterium. With M. tuberculosis, and some of the other slow-growing bacteria, it can take up to 4 weeks before growth is obtained.
How are the results classified?	Positive for growth Negative for growth Contaminated
What do the results mean?	When growth is observed on the 7H11 media, the technologist determines if the growth is a mycobacterium or if it is some other organism. If the growth is a mycobacterium, HPLC is run to identify the mycobacterium. If the growth proves to be an organism other than a mycobacterium, then the plate is considered to be contaminated and no further studies are performed. If no growth is seen on the 7H11 agar, it is reported as negative.
Are other tests needed?	The TB Lab will initiate identification procedures if the growth is a mycobacterium species.
How would this test be ordered?	NA
How much would this test cost?	The GA Public Health Laboratory does not charge the county or the district for this procedure.

<b>Acid-Fast Stain (AFB Smear)</b>															
How does it work?	<p>Mycobacterium is able to form stable complexes within certain stains such as Auramine O. Although the exact nature of the acid-fast staining reaction is not completely understood, phenol in the primary stain allows the stain to penetrate into the cell wall. The cell wall mycolic acids retain this primary stain even after washing with acid-alcohol. This resistance to decolorization with acid-alcohol is what causes mycobacteria to be called “acid-fast.”</p> <ul style="list-style-type: none"> <li>• A drop of processed sputum is spread on microscope slide and placed on a 70° C slide warmer for 2 hours.</li> <li>• The slide is then moved to a staining rack and Auramine O stain is applied to the slide for 15 minutes.</li> <li>• The slide is washed with acid-alcohol for 2 minutes.</li> <li>• Acridine orange, a counterstain, is applied to the slide for 2 minutes.</li> <li>• The slide is then rinsed with distilled water, allowed to air dry and examined using a fluorescent microscope.</li> </ul> <p>Mycobacterium appears as green fluorescing bacilli against a red-orange background.</p>														
When is this test run?	Monday through Friday														
How long before results are ready?	Results are usually available within 24 hours.														
How are the results classified?	<table border="0"> <thead> <tr> <th style="text-align: left;"><u>Number of bacteria seen</u></th> <th style="text-align: left;"><u>Interpretation</u></th> </tr> </thead> <tbody> <tr> <td>No fluorescing bacteria seen</td> <td>No AFB found</td> </tr> <tr> <td>1-3 fluorescing bacteria seen on entire slide</td> <td>+/-</td> </tr> <tr> <td>4-36 fluorescing bacteria seen per 100 fields</td> <td>1+</td> </tr> <tr> <td>4-36 fluorescing bacteria seen per 10 fields</td> <td>2+</td> </tr> <tr> <td>4-36 fluorescing bacteria per field</td> <td>3+</td> </tr> <tr> <td>&gt;36 fluorescing bacteria per field</td> <td>4+</td> </tr> </tbody> </table>	<u>Number of bacteria seen</u>	<u>Interpretation</u>	No fluorescing bacteria seen	No AFB found	1-3 fluorescing bacteria seen on entire slide	+/-	4-36 fluorescing bacteria seen per 100 fields	1+	4-36 fluorescing bacteria seen per 10 fields	2+	4-36 fluorescing bacteria per field	3+	>36 fluorescing bacteria per field	4+
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What do the results mean?	<ul style="list-style-type: none"> <li>• The higher the number (4+), the higher the bacteria load.</li> <li>• The higher the number, the more infectious the patient is to others.</li> <li>• Begin TB treatment with 4 drugs until TB is confirmed or ruled out.</li> <li>• Any patient with a positive AFB smear needs to be on respiratory isolation.</li> </ul>														
Are other tests needed?	Yes, a culture and sensitivity if the culture grows MTB.														
When would this test be used?	<ul style="list-style-type: none"> <li>• To quickly determine if TB is a possibility.</li> <li>• To determine the degree of infectiousness.</li> </ul>														
How would this test be ordered?	This test is automatically done on all clinical specimens.														
How much would this test cost?	The GA Public Health Laboratory does not charge the county or district for this test.														

<b>Genotyping</b>	
How does it work?	<p>The genotype of an organism refers to the specific genetic makeup of that organism, usually in the DNA. This “internally coded, inheritable information” is used as a blueprint or set of instructions for building and maintaining a living creature. These instructions are written in a coded language (the genetic code) and they are copied at the time of cell division or reproduction and are passed from one generation to the next.</p> <p>Genotyping describes a great variety of techniques that are used to identify the primary localization and mapping of genes.</p>
When is this test run?	The State Lab does not perform this test. Isolates are sent to the Michigan State Genotyping Lab for analysis.
How long before results are ready?	Results are usually available 2 to 3 weeks after the Michigan State Genotyping Lab receives the isolate.
How are the results classified?	NA
What do the results mean?	The results show a mapping of the gene.
Are other tests needed?	NA
When would this test be used?	<ul style="list-style-type: none"> <li>• To rule out cross-contamination of specimens.</li> <li>• To determine reactivation vs. reinfection of a patient.</li> <li>• To determine if two or more patients are infected with strains of M. tuberculosis possessing identical genotypes.</li> </ul>
How would this test be ordered?	Isolates on all first-time MTB positive patients are automatically sent to Michigan for genotyping. Physicians can request this test by calling the Georgia Public Health TB Lab.
How much would this test cost?	There is no charge for this test.

<b>Gen-Probe AccuProbe DNA Probe Test</b>	
How does it work?	<ul style="list-style-type: none"> <li>The Gen-Probe identification test is rapid DNA probe test which uses nucleic acid hybridization for the identification of certain mycobacterium. Gen-Probe manufactures four Accuprobe kits to test for the following organisms: M. tuberculosis complex, M. avium complex, M. gordonae, and M. kansasii.</li> <li>Ribosomal RNA is released from the test organism by sonication. A single-stranded DNA probe (specific for the target* organism) with a chemiluminescent label combines with the ribosomal RNA to form a DNA: RNA hybrid. The hybrids are then measured in a luminometer. Results are measured in relative light units.</li> </ul>
When is this test run?	This test serves as a “back up” for HPLC testing and is only run when the HPLC instrument is “down” for maintenance.
How long before results are ready?	Results are available the day the test is run.
How are the results classified?	Positive, Negative, and Indeterminate for the target organism.
What do the results mean?	<p>Positive: The isolate is identified as one of the target organisms.</p> <p>Indeterminate: The test is inconclusive and must be repeated.</p> <p>Negative: The isolate is not one of the target organisms.</p>
Are other tests needed?	If the isolate is identified as M. tuberculosis, and if this is the first time the patient has had a positive MTB culture, drug susceptibility testing should be ordered. This is automatically done by the TB Lab.
When would this test be used?	To identify growth on solid media or growth in liquid media as M. tuberculosis complex, M. avium complex, M. kansasii, or M. gordonae.
How would this test be ordered?	This test is ordered by the TB laboratory technologists when it is indicated.
How much would this test cost?	The GA Public Health Laboratory does not charge the county or the district for this test.

\* The target organism is the organism the test kit is designed to identify. For example, if you were using the Accuprobe M. kansasii test kit, the target organism would be M. kansasii, or if you were using the Accuprobe M. tuberculosis complex test kit, the target organism would be M. tuberculosis complex.



<b>High-Performance Liquid Chromatography (HPLC)</b>	
How does it work?	HPLC is used to identify mycobacterium by analysis of mycolic acids. Mycobacterium contain large amounts of mycolic acids in their cell wall. The type and amount of the mycolic acids vary in each species of mycobacteria. HPLC testing generates chromatographs based on the mycolic acids that are present in the test organism. By comparing these graphs with known reference chromatograph patterns, the organism can be identified.
When is this test run?	Monday through Friday
How long before results are ready?	Results are available the day after the test is performed.
How are the results classified?	HPLC testing should identify the mycobacterium being tested.
What do the results mean?	The results identify the mycobacterium.
Are other tests needed?	If the organism is identified as <i>M. tuberculosis</i> , and if this is the first time MTB has been isolated from the patient, then a drug susceptibility test should be ordered. This is automatically done by the TB Lab.
When would this test be used?	To identify an isolate as a mycobacterium.
How would this test be ordered?	This test is ordered by the TB laboratory technologists when it is indicated.
How much would this test cost?	The GA Public Health Laboratory does not charge the county or the district for this test.

<b>Lowenstein-Jensen Agar (LJ Slants)</b>	
How does it work?	Lowenstein-Jensen agar is a relatively simple formulation that requires the addition of supplements in order to support the growth of mycobacterium. Glycerol and egg mixture are added to provide the fatty acids and protein which are required for the metabolism of mycobacterium.
When would this agar be used?	After undergoing the decontamination/concentration process, all specimens received in TB Lab for routine culture are inoculated onto this media.
How long before growth is obtained?	Visible growth can occur in as few as 3 to 5 days with the rapid-growing mycobacterium. With <i>M. tuberculosis</i> , and some of the other slow-growing bacteria, it can take up to 4 weeks before growth is obtained.
How are the results classified?	Positive for growth Negative for growth Contaminated
What do the results mean?	When growth is observed on the LJ slant, the technologist determines if the growth is a mycobacterium species or if it is some other organism. If the growth is a mycobacterium species, identification procedures are started. If the growth proves to be an organism other than a mycobacterium, then the LJ is considered to be contaminated and no further studies are performed. If no growth is seen on the LJ slant, it is reported as negative.
Are other tests needed?	The TB Lab will initiate identification testing. Susceptibilities will be ordered by the lab when indicated.
How would this test be ordered?	NA
How much would this test cost?	The GA Public Health Laboratory does not charge the county or the district for this test.

<b>Mycobacteria Growth Indicator Tube (MGIT)</b>	
How does it work?	<p>The MGIT Tube is intended for the detection and recovery of mycobacterium using the BACTEC 960 equipment. The tubes contain 7 ml of modified Middlebrook 7H9 broth and are flushed with 10% CO<sub>2</sub>.</p> <p>A fluorescent compound is embedded in silicone on the bottom of the round bottom MGIT tubes. The fluorescent compound is sensitive to the presence of oxygen dissolved in the broth. Initially, the large amount of dissolved oxygen quenches emissions from the compound and little fluorescence can be detected. Later, actively growing organisms consume the oxygen and allow the fluorescence to be detected.</p> <p>Tubes are monitored by the BACTEC 960 every 60 minutes for increasing fluorescence. Analysis of the fluorescence is used to determine if the tube is positive.</p>
When would this media be used?	MGIT tubes are inoculated each day that clinical specimens are received in the lab. After undergoing the decontamination/concentration process, all specimens received for routine culture are inoculated into this media.
How long before growth is obtained?	For mycobacterium, from 1 week to 6 weeks. Negative (no growth) MGITs are held for 6 weeks before reporting as negative.
How are the results classified?	Positive, Negative, or Contaminated
What do the results mean?	Positive: Growth noted. Identification procedures are started. Negative: No growth Contaminated: Growth other than mycobacterium is present.
Are other tests needed?	The TB Lab will initiate identification testing if the MGIT is positive. Susceptibilities will be ordered by the lab when indicated.
How would this test be ordered?	NA
How much would this test cost?	The GA Public Health Laboratory does not charge the county or the district for this test.

<b>Nucleic Acid Amplification Testing (NAAT) using the Amplified Mycobacteria Tuberculosis Direct Test (MTD)</b>	
How does it work?	<p>The Amplified <i>Mycobacterium tuberculosis</i> Direct Test (MTD) is a target-amplified nucleic acid probe test for the detection of <i>M. tuberculosis</i> complex rRNA in concentrated specimen sediments prepared from sputum, bronchial specimens (BAL or bronchial aspirates), or tracheal aspirates.</p> <p>The MTD test is intended for use only with specimens from patients showing signs and symptoms consistent with active pulmonary tuberculosis. Patients who have received no antituberculous therapy, or less than 7 days of such therapy, or have not received such therapy in the last 12 months may be evaluated with this test.</p> <p>MTD testing does not take the place of culture. A negative MTD test does not exclude the possibility of isolating <i>M. tuberculosis</i> from culture.</p>
When is this test run?	This testing serves as a backup for the Cepheid GeneXpert and is only run when the Cepheid GeneXpert is “down” for maintenance.
How long before results are ready?	Results are usually available the same day the test is run.
How are the results classified?	Positive, Negative, and Indeterminate.
What do the results mean?	<p>Positive: <i>M. tuberculosis complex</i> rRNA is detected.</p> <p>Negative: <i>M. tuberculosis complex</i> rRNA is not detected.</p> <p>Indeterminate: Equivocal results. Test must be repeated.</p>
Are other tests needed?	A culture for <i>M. tuberculosis</i> must be performed.
When would this test be used?	CDC Updated Guidelines for the Use of NAAT state: Nucleic acid amplification testing (NAAT) should be performed on at least one respiratory specimen from each patient with signs and symptoms of pulmonary TB for whom a diagnosis of TB is being considered but has not yet been established, and for whom the test result would alter case management or TB control activities.
How would this test be ordered?	By checking Nucleic Acid Amplification Testing (NAAT) on a TB Submission Form and sending the form and specimen to the State Lab.
How much would this test cost?	The GA Public Health Laboratory does not charge the county or the district for this test.

<b>Nucleic Acid Amplification Testing (NAAT) using the Cepheid GeneXpert MTB/RIF Assay</b>	
How does it work?	<p>The Cepheid GeneXpert MTB/RIF Assay is a diagnostic test that can identify <i>Mycobacterium tuberculosis</i> (MTB) in clinical specimens from respiratory sources. The GeneXpert purifies, concentrates, amplifies (by real-time PCR), and identifies targeted nucleic acid sequences in the TB genome.</p> <p>The GeneXpert MTB/RIF Assay does not take the place of culture. A negative MTB/RIF Assay does not exclude the possibility of isolating <i>M. tuberculosis</i> from culture.</p>
When is this test run?	Monday through Friday.
How long before results are ready?	Results are usually available the same day the test is run.
How are the results classified?	Positive, Negative, and Indeterminate.
What do the results mean?	<p>Positive: <i>M. tuberculosis</i> is detected.</p> <p>Negative: <i>M. tuberculosis</i> is not detected.</p> <p>Indeterminate: Equivocal results. Test must be repeated.</p>
Are other tests needed?	A culture for <i>M. tuberculosis</i> must be performed.
When would this test be used?	CDC Updated Guidelines for the Use of NAAT state: Nucleic acid amplification testing (NAAT) should be performed on at least one respiratory specimen from each patient with signs and symptoms of pulmonary TB for whom a diagnosis of TB is being considered but has not yet been established, and for whom the test result would alter case management or TB control activities.
How would this test be ordered?	By checking Nucleic Acid Amplification Testing (NAAT) on a TB Submission Form and sending the form and specimen to the State Lab.
How much would this test cost?	The GA Public Health Laboratory does not charge the county or the district for this test.

NOTE: This assay also detects rifampin resistance although we are not reporting those results at the present time. As soon as our validation studies are complete, we will begin reporting the rifampin results.

<b>Polymerase Chain Reaction (PCR)</b>	
What is PCR?	A technique for amplifying DNA sequences in vitro by separating the DNA into two strands and incubating it with oligonucleotide primers and DNA polymerase. It can amplify a specific sequence of DNA by as many as one billion times and is important in biotechnology, forensics, medicine and genetic research.
How does it work?	There three major steps are involved in a PCR. These three steps are repeated for 30 or 40 cycles. The cycles are done on an automated cycler, a device which rapidly heats and cools the test tubes containing the reaction mixture. Each step -- denaturation (alteration of structure), annealing (joining), and extension -- takes place at a different temperature: 1) <b>Denaturation:</b> At 94 C (201.2 F), the double-stranded DNA melts and opens into two pieces of single-stranded DNA. 2) <b>Annealing:</b> At medium temperatures, around 54 C (129.2 F), the primers pair up (anneal) with the single-stranded "template" (The template is the sequence of DNA to be copied.) On the small length of double-stranded DNA (the joined primer and template), the polymerase attaches and starts copying the template. 3) <b>Extension:</b> At 72 C (161.6 F), the polymerase works best, and DNA building blocks complementary to the template are coupled to the primer, making a double stranded DNA molecule.
Why run this test?	To do PCR, the original DNA that one wishes to copy need not be pure or abundant. It can be pure but it also can be a minute part of a mixture of materials. So, PCR has found widespread and innumerable uses -- to diagnose genetic diseases, do DNA fingerprinting, find bacteria and viruses, study human evolution, clone the DNA of an Egyptian mummy, establish paternity or biological relationships, etc.. Accordingly, PCR has become an essential tool for biologists, DNA forensics labs, and many other laboratories that study genetic material
How long before the results are ready?	N/A
What does the result mean?	There are thousands, millions or billions of copies of the original specimen submitted
How to order this test?	N/A
How much would this test cost?	The GA Public Health Laboratory does not charge for this service
Comment(s)	With one cycle, a single segment of double-stranded DNA template is amplified into two separate pieces of double-stranded DNA. These two pieces are then available for amplification in the next cycle. As the cycles are repeated, more and more copies are generated and the number of copies of the template is increased exponentially.

<b>Restriction Fragment Length Polymorphism (RFLP)</b>	
How does it work?	Restriction Fragment Length Polymorphism (RFLP) is a molecular technique in which organisms may be differentiated by analysis of patterns derived from cleavage of their DNA by restriction endonuclease. If two organisms differ in the distance between sites of cleavage of a particular restriction endonuclease, the length of the fragments produced will differ. The similarity or the difference of the patterns can be used to differentiate species of mycobacteria from one another.
When is this test run?	The State Lab does not perform this test. Isolates are sent to the Michigan State Genotyping Lab for analysis by PCR.
How long before results are ready?	Results are usually available within 3 weeks after the Michigan Genotyping Lab receives the isolate.
How are the results classified?	NA
What do the results mean?	The results show a mapping of the restriction fragment.
Are other tests needed?	No
When would this test be used?	<ul style="list-style-type: none"> <li>• To rule out cross-contamination of specimens.</li> <li>• To determine reactivation vs. reinfection of a patient.</li> <li>• To determine if two or more patients are infected with strains of <i>M. tuberculosis</i> possessing identical genotypes.</li> </ul>
How would this test be ordered?	Physicians can request this test if approved by the TB Program.
How much would this test cost?	There is no charge for this test.

<b>MTB Susceptibility Testing</b>	
How does it work?	<p><i>M. tuberculosis</i> isolates are tested for sensitivity/resistance to isoniazid, rifampin, and ethambutol using the BACTEC MGIT 960 susceptibility method. If resistance is detected in any of the three drugs, the susceptibility is repeated and streptomycin is added to the drug panel. All isolates showing resistance are submitted to CDC for confirmation.</p> <ul style="list-style-type: none"> <li>• A standardized suspension of MTB is added to 4 MGIT tubes. Tube 1 is a growth control (contains no antibiotics), Tube 2 contains isoniazid, Tube 3 contains rifampin, and Tube 4 contains ethambutol.</li> <li>• The MGIT tubes are placed in the BACTEC 960 which scans the tubes for growth once every hour.</li> <li>• When the growth control tube has reached 400 growth units, the BACTEC 960 performs a final scan on tubes 2, 3, and 4 to check for growth and then prints out a final report.</li> <li>• Based on growth units, it can be determined if the MTB isolate is sensitive or resistant to each of the drugs tested.</li> <li>• If the MTB is sensitive to a drug, there would be no growth in that MGIT tube. If the MTB is resistant to a drug, then the MTB would grow in the MGIT tube and the growth units would be registered on the BACTEC 960 report.</li> </ul>
When is this test run?	Monday through Friday
How long before results are ready?	4 to 13 days after the actual susceptibility testing is started. Isolates must meet certain criteria before susceptibility testing can be performed. This can add up to 7 days to the turn-around-time for the susceptibility results.
How are the results classified?	Sensitive, Resistant, or Contaminated
What do the results mean?	<p>Sensitive: The drug can be used to treat the MTB isolate.  Resistant: The drug has no effect on MTB isolate.  Contaminated: The susceptibility is contaminated with an organism other than MTB and will have to be repeated.</p>
Are other tests needed?	No, unless multi-drug resistance is demonstrated. Then the isolate is sent to CDC for an expanded panel of drug testing.
When would this test be used?	<ul style="list-style-type: none"> <li>• To determine the susceptibility of an MTB isolate to isoniazid, rifampin, ethambutol, and in some cases to streptomycin.</li> <li>• When a patient is not responding to treatment and the physician feels that the susceptibility should be checked again.</li> <li>• Every 3 months for as long as a patient's cultures remain MTB positive.</li> </ul>
How would this test be ordered?	Through the State TB Lab. Susceptibilities are automatically run on all first-time MTB positive cultures.
How much would this test cost?	The GA Public Health Laboratory does not charge the county or the district for this test.



## **COMMITMENT TEMPLATES**

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- 1. Commitment Order (p. 83)**
- 2. Consent Commitment Order (p. 87)**
- 3. Emergency Commitment Hearing Order (p. 89)**
- 4. Emergency Petition for Confinement of Tuberculosis Client (p. 93)**
- 5. Modification of Consent Commitment Order (p. 97)**
- 6. Physician's Certification for Tuberculosis Confinement (p. 99)**
- 7. Verification (p.101)**
- 8. Sample Medical Care Plan (p.103)**

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**COMMITMENT FOR TUBERCULOSIS TREATMENT**

**IN THE SUPERIOR COURT OF \_\_\_\_\_ COUNTY**

**STATE OF GEORGIA**

\_\_\_\_\_  
**COUNTY**  
**BOARD OF HEALTH**

\*  
\*

**Plaintiff,**

\*  
\*

\_\_\_\_\_

**CIVIL ACTION**

**v.**

\*

**FILE NO.**

\_\_\_\_\_

\*

**Defendant,**

\*

**COMMITMENT ORDER**

The Plaintiff having filed a Petition for Commitment to a hospital of a client with active tuberculosis on \_\_\_\_\_, 200\_\_, the Court having appointed a hearing officer to hear the Plaintiff's Petition and counsel to represent the Defendant, the Plaintiff and the Defendant having agreed to the following Consent Order for Confinement and the hearing officer having agreed to this Consent Order; the hearing officer finds the following:

The Defendant, \_\_\_\_\_, is a \_\_\_\_\_-year old male/female who has active tuberculosis as defined by O.C.G.A. 31-14-1. From 200\_\_, the Defendant was under the supervision of the \_\_\_\_\_ Board of Health's Tuberculosis Clinic for treatment of his/her active tuberculosis.

During this time, the Defendant did not comply with Board of Health orders to consistently take his/her medication and remain confined so that he/she would not spread the disease. The inconsistent treatment of tuberculosis poses the risk to \_\_\_\_\_

and the general public of creating a resistant tuberculosis strain that would not be treatable for the Defendant or for any person who might contract this resistant strain. Since the Defendant's involuntary confinement on \_\_\_\_\_, 200\_\_, at \_\_\_\_\_, the Defendant's tuberculosis has

responded to treatment and the level of bacteria in his/her sputum has reduced dramatically. Although he/she shortly will become non-infectious for active tuberculosis, he/she would subject himself/herself to a relapse if the tuberculosis treatment were not confined for the length of time as prescribed by his/her physician, which could result in a resistant or multi-resistant tuberculosis strain.

Based upon the above-described facts, the hearing officer hereby finds that the Defendant should remain confined to a facility that will ensure he/she consistently takes his/her medication for active tuberculosis. The period of confinement shall be for six (6) months unless an extension of the confinement is granted pursuant to O.C.G.A 31-14-8.1. The place of confinement shall be \_\_\_\_\_, a facility that has been approved by the Department of Human Resources for the care of tubercular clients. The Defendant's confinement at \_\_\_\_\_ shall begin only after the Defendant no longer has active tuberculosis as determined by his/her physician. While the client still has active tuberculosis, he/she shall remain confined at \_\_\_\_\_ under the \_\_\_\_\_ County Sheriff's supervision. When it is determined that he/she no longer has active tuberculosis, the Sheriff of \_\_\_\_\_ County or his/her deputies will transport the client to \_\_\_\_\_ in \_\_\_\_\_, \_\_\_\_\_, and release him/her into the custody of and care of \_\_\_\_\_.

SO FOUND this \_\_\_\_\_ day of \_\_\_\_\_, 200\_\_\_\_\_.

\_\_\_\_\_  
Hearing Officer appointed by

Superior Court Judge

\_\_\_\_\_  
Consented to and approved by:

\_\_\_\_\_  
Attorney for Defendant

\_\_\_\_\_  
Attorney for Plaintiff

\_\_\_\_\_  
Defendant

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IN THE SUPERIOR COURT OF \_\_\_\_\_ COUNTY

STATE OF GEORGIA

\_\_\_\_\_ COUNTY

\*

BOARD OF HEALTH

\*

Plaintiff

\*

CIVIL ACTION

v.

\*

FILE NO.

\_\_\_\_\_ ,

\*

Defendant,

\*

**CONSENT COMMITMENT ORDER**

The hearing officer that was appointed by this Court having approved a Consent Commitment Order for the confinement of the Defendant, this Court hereby approves the Commitment Order that was entered into by the hearing officer on the \_\_\_\_\_ day of \_\_\_\_\_, 200\_\_.

THEREFORE, the Defendant is ORDERED to be confined pursuant to **O.C.G.A. 31-14-1, et seq.**, and to \_\_\_\_\_ for a period of \_\_\_\_\_ (\_\_\_\_\_) months to ensure that he/she regularly takes his/her tuberculosis treatment. While at \_\_\_\_\_, the Defendant will comply with all the orders of \_\_\_\_\_ for the treatment of tuberculosis, Board of Health orders regarding his/her treatment for tuberculosis, and the orders of medical professional whose care he/she is under. The Defendant's confinement for the treatment and care for his/her disease shall not exceed \_\_\_\_\_ (\_\_\_\_) months, unless that time period is extended by hearing as provided in **O.C.G.A. 31-14-8.1.**

The Defendant's confinement at \_\_\_\_\_ shall begin only after he/she is negative for active tuberculosis. Until the Defendant is negative for active tuberculosis, he/she shall remain in the custody of the \_\_\_\_\_ County Sheriff or his/her lawful deputies at \_\_\_\_\_ Hospital.

SO ORDERED this \_\_\_\_\_ day of \_\_\_\_\_, 200\_\_.

\_\_\_\_\_

Judge

Superior Court \_\_\_\_\_ County

Prepared and presented by:

\_\_\_\_\_

Attorney for \_\_\_\_\_

Approved by:

\_\_\_\_\_

Attorney for \_\_\_\_\_

\_\_\_\_\_

Defendant



IN THE SUPERIOR COURT OF \_\_\_\_\_ COUNTY

STATE OF GEORGIA

\_\_\_\_\_ COUNTY

BOARD OF HEALTH

Plaintiff,

\* CIVIL ACTION

v.

\* FILE NO. \_\_\_\_\_

\_\_\_\_\_

\*

Defendant,

\*

**EMERGENCY COMMITMENT HEARING ORDER**

The plaintiffs' Emergency Petition for Confinement of Tuberculosis Client having come before this Court, and after hearing ex parte evidence presented by the Plaintiff, the Court finds the following:

1.

The Defendant, \_\_\_\_\_, has active tuberculosis

2.

The Defendant has violated the \_\_\_\_\_ County Board of Health orders to remain confined in the Defendant's residence and has further defied the Board of Health orders to consistently take his/her medicine.

3.

The Defendant poses a flight risk because (state documented basis for allegation – he/she does not have a stable address, has a drug problem, is used to living on the streets).

4.

Based upon the above listed conclusions, the evidence presented to the Court and the Physicians Certificate attached to the Plaintiff's Petition, and the verified Petition, the Court holds the following:

a. Because the Defendant may abscond or conceal himself/herself and because his/her violation of Board of Health orders makes him/her a substantial risk of exposing other person to an imminent danger of infection, the Court directs the Sheriff or his/her deputies to take the Defendant into custody pending the hearing that is required pursuant to **O.C.G.A. 31-14-3**. This shall be under the supervision of Board of Health personnel or other medical personnel to ensure the safety of the Sheriff's deputies.

b. The Defendant shall remain in custody until he/she has a full and fair hearing on the Plaintiff's Petition for Confinement. This initial confinement shall be at a facility appropriate for TB treatment.

c. The Court hereby sets a hearing date on the Plaintiff's Petition for the \_\_\_\_\_ day of \_\_\_\_\_, 200\_ at \_\_\_\_\_. The hearing shall be conducted at \_\_\_\_\_.

d. \_\_\_\_\_ is entitled to appointed counsel. The Court will appoint counsel unless \_\_\_\_\_ indicates in writing he/she does not want counsel. The Court will appoint counsel unless \_\_\_\_\_ indicates in writing he/she does not want counsel. The Court hereby appoints \_\_\_\_\_ as Counsel for the Defendant to represent him/her in this matter.

e. During the Defendant's initial confinement pursuant to this Order, the Defendant shall remain confined so that he/she does not infect the general public with tuberculosis and he/she shall take his/her medications as directed by the Board of Health and any health professional whose care he/she is under.

f. The Defendant shall further submit himself/herself to appropriate medical examinations to determine whether and when the tuberculosis is no longer active.

SO ORDERED this \_\_\_\_\_ day of \_\_\_\_\_, 200\_.

\_\_\_\_\_  
\_\_\_\_\_, Judge

**Superior Court of**

**County**

Prepared and Presented by:

\_\_\_\_\_

Attorney for Plaintiff

Ga. Bar No. \_\_\_\_\_

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IN THE SUPERIOR COURT OF \_\_\_\_\_ COUNTY

STATE OF GEORGIA

\_\_\_\_\_ COUNTY \*

BOARD OF HEALTH \*

Plaintiff, \*

CIVIL ACTION

v. \*

FILE NO. \_\_\_\_\_

\_\_\_\_\_ \*

Defendant, \*

**EMERGENCY PETITION FOR CONFINEMENT OF TUBERCULOSIS CLIENT**

COMES NOW, the \_\_\_\_\_ **COUNTY BOARD OF HEALTH** to file this Petition for Commitment of a Person with Active Tuberculosis pursuant to **O.C.G.A. 31-14-1, et seq.** and shows the Court as follows;

1.

The Defendant, \_\_\_\_\_, resides at \_\_\_\_\_ in \_\_\_\_\_ County, and is therefore subject to the jurisdiction of this Court.

2.

The Defendant has active tuberculosis as defined in **O.C.G.A. 31-14-1 (a)**.

3.

The Defendant is violating orders of the Department regarding treatment of his/her active tuberculosis having missed \_\_\_\_\_ (\_\_\_\_\_) out of his/her last \_\_\_\_\_ (\_\_\_\_\_) scheduled doses. The Defendant has also violated specific Board of Health orders by not confining himself/herself to his/her residence, thus exposing himself/herself to the general public. The Defendant, by violating these orders of the Board of Health presents a substantial

risk of exposing other persons to an imminent danger of infection. The Defendant was released from \_\_\_\_\_ Hospital on \_\_\_\_\_, 200\_, with active tuberculosis and was referred to the \_\_\_\_\_ County Board of Health Tuberculosis Clinic for follow-up treatment.

5.

The Defendant's chest x-ray and medical examinations and sputum examination confirm that the Defendant has active tuberculosis. The state medical lab has confirmed the sputum test.

6.

The general public's health requires commitment of this person to prevent exposing the general public to tuberculosis.

7.

The Defendant was formerly a homeless person, but since his/her release from \_\_\_\_\_ Hospital, has resided with \_\_\_\_\_ at \_\_\_\_\_. This person may be unaware of their risk for TB infection due to continued contact with the Defendant therefore screening may be necessary. Because he/she has no stable address, the Defendant presents a risk of concealing himself/herself from the \_\_\_\_\_ County Board of Health. He/She has also conducted himself/herself in a manner to expose the general public by disregarding the Board of Health orders to remain confined in \_\_\_\_\_'s house and to regularly take his/her medication.

8.

Because the Defendant is a flight risk and is conducting himself/herself in a manner to expose others to imminent danger of infection, emergency commitment is necessary to protect the general public.

**WHEREFORE**, the Plaintiff respectfully requests that this Court:

a. Direct the Sheriff or Sheriff's Deputies to take the Defendant into Custody pending a hearing on the Petition for Confinement so he/she will not endanger other persons pursuant to

**O.C.G.A 31-14-5.**

b. That the Court schedules a hearing no sooner than \_\_\_\_\_ ( ) days and no later than \_\_\_\_\_ ( ) days to determine whether the Defendant should be confined.

c. That the Court appoints the Defendant counsels to represent him/her at this hearing.

d. That the Court give the Plaintiff such further relief as the Court deems necessary.

Respectfully submitted,

\_\_\_\_\_

\_\_\_\_\_

Attorney for Plaintiff

Ga.Bar No. \_\_\_\_\_

Address

Phone Number

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IN THE SUPERIOR COURT OF \_\_\_\_\_ COUNTY

STATE OF GEORGIA

\_\_\_\_\_ COUNTY BOARD OF HEALTH, \* CIVIL ACTION

Petitioner \*

v. \* FILE NO. \_\_\_\_\_

\_\_\_\_\_, \*

Respondent. \*

**MODIFICATION OF CONSENT COMMITMENT ORDER**

The Plaintiff and the Defendant having come before this Court with a Consent Modification of this Court’s Consent Commitment Order dated \_\_\_\_\_, 200\_, the Court hereby amends its Order of \_\_\_\_\_, 200\_, as follows:

1.

The \_\_\_\_\_ County Sheriff is relieved of his/her responsibility of maintaining the Defendant in his/her custody at \_\_\_\_\_ Hospital until further order of this Court. The \_\_\_\_\_ County Sheriff or his/her lawful deputies are still responsible for transporting the Defendant to \_\_\_\_\_ in \_\_\_\_\_, \_\_\_\_\_. No other terms of the Consent Commitment Order or the Commitment Order of the hearing officer is altered or amended or superseded by this amendment.

\_\_\_\_\_  
Judge, \_\_\_\_\_ County Superior Court

(Signatures continued on following page.)

Consented to by:

\_\_\_\_\_  
Attorney for Plaintiff

Ga. Bar No. \_\_\_\_\_

\_\_\_\_\_  
Attorney for Defendant

Ga. Bar No. \_\_\_\_\_

IN THE SUPERIOR COURT OF \_\_\_\_\_ COUNTY

STATE OF GEORGIA

\_\_\_\_\_ COUNTY  
BOARD OF HEALTH

\*  
\*

Plaintiff,

\*  
\*  
\*

CIVIL ACTION

FILE NO. \_\_\_\_\_

\*

\_\_\_\_\_  
Defendant,

\*

**PHYSICIAN'S CERTIFICATION FOR TUBERCULOSIS CONFINEMENT**

COMES NOW, \_\_\_\_\_, M.D., who after being duly sworn states the following:

1.

Affiant is a Physician licensed to practice medicine in the State of Georgia and is the Primary Physician for the Defendant.

2.

The Defendant is a \_\_\_\_\_ year old man/woman with presumptive active Tuberculosis (TB). This diagnosis is based upon a physical examination of the client and reviewing \_\_\_\_\_'s medical records, including his/her chest x-ray, which shows an anomaly, and positive AFB sputum smears.

3.

The client should be strictly monitored to ensure that he/she takes his/her medication for the TB as prescribed to ensure his/her infection is not infectious and that he/she does not develop drug-resistant TB.

4.

Since \_\_\_\_\_'s TB is contagious, he/she should be confined so he/she does not come into contact with the general public.

FURTHER AFFIANT SAYETH NOT.

\_\_\_\_\_

**Print Physician Name**

**Sworn to and subscribed  
before me this \_\_\_\_\_  
day of \_\_\_\_\_, 200\_.**

\_\_\_\_\_  
**NOTARY PUBLIC**

[seal]

STATE OF \_\_\_\_\_

COUNTY OF \_\_\_\_\_

**VERIFICATION**

\_\_\_\_\_, **DIRECTOR, TB CLINIC,** \_\_\_\_\_ **COUNTY**

**BOARD OF HEALTH** being first duly sworn on oath, deposes and say that he/she is the **Coordinator of the TB Clinic for the** \_\_\_\_\_ **County Board of Health,** that he/she has read the foregoing **Emergency Petition for Confinement of Tuberculosis Client** and knows the contents thereof, and that the contents of the Petition are true and correct to the best of his/her knowledge.

\_\_\_\_\_  
**DIRECTOR OF \_\_\_\_\_ COUNTY  
BOARD OF HEALTH**

**Sworn to and subscribed  
before me this \_\_\_\_\_  
day of \_\_\_\_\_, 200 \_\_\_\_.**

\_\_\_\_\_  
**NOTARY PUBLIC**

**[SEAL]**

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## Sample Medical Care Plan for GeoCare Referral

(Type the Medical Care Plan on your County Health Department's letterhead/stationery)

**Current Date:**

**Patient's Name:**

**Patient's Date of Birth:**

**Patient's Social Security Number:**

**Diagnosis:** Laboratory-confirmed, active pulmonary TB

**Medications:**

(Provide detailed directions. For PRN medications, add reason for administration)

Initial TB drug regimen (for current weight = xx lbs.)

- Isoniazid 300 mg daily for 40 doses by DOT
- Rifampin 600 mg daily for 40 doses by DOT
- Ethambutol xxxx mg daily for 40 doses by DOT
- Pyrazinamide xxxx mg daily for 40 doses by DOT
- Pyridoxine 25 mg daily for 40 doses by DOT

Continuation TB drug regimen

- Isoniazid 900 mg biweekly for 36 doses by DOT
- Rifampin 600 mg biweekly for 36 doses by DOT
- Pyridoxine 50 mg biweekly for 36 doses by DOT

**Chest x-ray frequency:**

Only if indicated

**Laboratory Testing:** (Frequency of sputum examination, liver enzymes, vision tests, etc.)

- Monthly hepatic function panel, or as needed if signs or symptoms of hepatic toxicity
- Sputum AFB smear/culture daily x 3 then weekly until sputum conversion, then monthly

**Miscellaneous:**

(ID consult, negative pressure isolation room, frequency of recording patient's weight, social services referral if substance abuse counseling/drug rehabilitation is indicated, etc.)

- Baseline and monthly visual acuity testing and red/green color discrimination
- Negative pressure room needed until 3 consecutive negative sputum smears collected on different days, 2 weeks of TB medication and signs of clinical improvement
- Biweekly weight checks
- Refer to social services related to substance abuse

**Interchange:**

Please send monthly reports of normal findings re:

1. Medical evaluation
2. Laboratory results
3. General condition and miscellaneous

Please notify us as soon as possible re:

1. Abnormal laboratory findings
2. Adverse reactions to medications
3. Any other pertinent abnormal findings

**Physician's signature and date signed needed at end of sheet**

**Type physician's name and title underneath signature.**

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## **American Lung Association Forms**

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**Alternative Housing Program  
SOCIAL SERVICES REFERRAL**

**Patient's Name:** \_\_\_\_\_ **County/District:** \_\_\_\_\_  
 Age: \_\_\_\_\_ Race: \_\_\_\_\_ Gender:  Female  Male  
 Previous/Current Address: \_\_\_\_\_  
 Address Was:  Street  Shelter\*  Abandoned Building  Family/Friends  Home  
 \*Name of Shelter \_\_\_\_\_  
 Reason for services: \_\_\_\_\_

**Lab Status: (Must have lab work to process referral)**

Smear \_\_\_\_\_ Culture \_\_\_\_\_  
 Case 1+ 2+ 3+ 4+  No Growth  MTB  Atypical  
 Type of specimen: \_\_\_\_\_  
 Suspect 1+ 2+ 3+ 4+  Pending at \_\_\_\_\_ weeks

Expected TB Completion Date: \_\_\_\_/\_\_\_\_/\_\_\_\_ Site of TB \_\_\_\_\_

**Chest x-ray Status:**

Abnormal  Normal Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

**Physical Health Status**

Healthy  Diabetes  Hypertension  Other \_\_\_\_\_

**Mental Health Status**

Past Psychiatric History Yes No  
 Diagnosis (where, when, name of Doctor/Therapist) \_\_\_\_\_

**Income Status:**

Employment (Where) \_\_\_\_\_ \$ \_\_\_\_\_  
 Can Patient return to work  Yes  No  
 Food Assistance \$ \_\_\_\_\_  
 General Assistant \$ \_\_\_\_\_  
 SSI Disability \$ \_\_\_\_\_  
 TANF \$ \_\_\_\_\_  
 Veterans Benefits \$ \_\_\_\_\_  
**TOTAL MONTHLY INCOME** \$ \_\_\_\_\_

**Substance Abuse:**

Alcohol  Amphetamine  Cocaine  Crack  IV Drug  
 Marijuana  Denied

**Services Requested:**

Housing  Food  Funds for Rent/Utilities  Social Services

**Anticipated move-in date:** \_\_\_\_\_ **TB Representative:** \_\_\_\_\_  
 Date \_\_\_\_\_

\*\*\*\*\*

**For ALAG Use Only**

Approved  Denied \_\_\_\_\_  
 Signature and Date \_\_\_\_\_  
 Move in Date: \_\_\_\_\_

**All sections must be completed in its entirety to be processed.**

*It is the American Lung Association of the Southeast's (ALASE's) policy to ensure compliance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule by establishing sanctions for breaches of confidentiality. All employees are required to be aware of their responsibilities under ALASE privacy policies 7-10*

**Alternative Housing Program  
PATIENT-HEALTH DEPARTMENT AGREEMENT FOR TEMPORARY HOUSING**

I, \_\_\_\_\_ certify that I have no fixed, regular, and/or adequate residence at this time and I am unable to provide shelter for myself. I understand that I have (confirmed or suspected) active TB disease and treatment is necessary. I understand that, at this time, I am (infectious or not infectious) to others. I understand that District Public Health and the \_\_\_\_\_ will provide temporary housing during treatment and I must:

1. Be at \_\_\_\_\_ on \_\_\_\_\_ at \_\_\_\_\_ am/pm to take my medicine.
2. Keep clinic appointments and have laboratory tests as necessary.
3. Notify the TB nurse of any problems with TB medicine or other emergencies.
4. Avoid alcohol and/or other drug use.
5. Not to participate in any illegal activity at the residential facility.
6. Not visit with other people in the housing area or other indoor areas until the TB nurse tells me I am not infectious to others.
7. Follow lease conditions by not having anyone else stay overnight, unless pre-approved in the lease.
8. Not to make any charges to the housing; and not make any long distance phone calls charged to the housing.
9. Remove all personal items from housing at termination of lease. Neither the American Lung Association in Georgia, District Public Health, nor the residential facility will be responsible for personal items left after termination of lease.
10. Allow the Health Department to identify me by name to the housing agent if needed.
11. Will hold the \_\_\_\_\_ District Public Health, the American Lung Association in Georgia, and its agents, from **any and all liability**.

I understand that if I violate any of the above, I may lose the housing and I may be confined to another appropriate facility to complete my TB disease treatment.

Client: \_\_\_\_\_ TB Representative: \_\_\_\_\_

Date: \_\_\_\_\_

\*\*\*\*\*

The housing agent hereby agrees to comply with the following and thereby, will hold harmless the American Lung Association in Georgia and its agents from **any and all liability**.

**Infectious Patients:**

1. Provide housing that meets infection control guidelines.
2. Provide housing with an exit that leads directly to the outside or to a hallway that leads directly outside.
3. Provide single occupancy housing and will report TB patient violations to the TB representative and ALAG.
4. Allow no housing employee to enter the client's room until 24 hours after the client is determined to be noninfectious by the TB nurse. Housekeeping and linen supply arrangements are as follows:

**Non-Infectious Patients:**

1. Provide single occupancy housing and will report TB patient violations to the TB representative and ALAG.
2. Provide TB patient with clean linen at least once a week if patient is residing at a hotel, motel or a personal care home. Clients residing at a rooming house will be responsible for their own linen.

Housing Agent: \_\_\_\_\_ TB Representative: \_\_\_\_\_

Date: \_\_\_\_\_

*It is the American Lung Association of the Southeast's (ALASE's) policy to ensure compliance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule by establishing sanctions for breaches of confidentiality. All employees are required to be aware of their responsibilities under ALASE privacy policies.*

**Alternative Housing Program  
TEMPORARY HOUSING FUND APPLICATION**

Patient's Name: \_\_\_\_\_

Address: \_\_\_\_\_

\*\*\*\*\*

TB Coordinator Name: \_\_\_\_\_

District: \_\_\_\_\_ Health Department: \_\_\_\_\_

Address: \_\_\_\_\_

County: \_\_\_\_\_ Telephone #: \_\_\_\_\_

E-Mail: \_\_\_\_\_ Fax #: \_\_\_\_\_

\*\*\*\*\*

Housing Vendor: \_\_\_\_\_

Federal ID Number: \_\_\_\_\_

Contact Person: \_\_\_\_\_

Address: \_\_\_\_\_

County: \_\_\_\_\_ Telephone #: \_\_\_\_\_

E-Mail: \_\_\_\_\_ Fax #: \_\_\_\_\_

Charges for Housing	\$ _____	Monthly from _____ to _____
	\$ _____	Bi-weekly from _____ to _____
	\$ _____	Weekly from _____ to _____

\*\*\*\*\*

Signature of TB Representative: \_\_\_\_\_ Date: \_\_\_\_\_

Signature of Housing Vendor: \_\_\_\_\_ Date: \_\_\_\_\_

\*If there is not a vendor signature, Coordinator must provide official documentation of the amount and address.

**All Sections must be completed in its entirety to be processed.**

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**Alternative Housing Program  
PATIENT-PROVIDER THERAPEUTIC CONTRACT**

The following is a statement of what is expected of each patient who agrees to accept temporary housing paid for by the American Lung Association in Georgia. Please read guidelines carefully and if you agree to abide by the conditions listed, please sign at the bottom.

1. Lodging will be temporarily provided for you during your treatment for TB. The length of time the room will be made available to you will depend on your medical needs, your cooperation and continued participation with follow-up provided by District Public Health.
2. During your stay, you are expected to keep your room clean and undamaged. At the end of your stay, you must remove all personal items and the room must be left in good condition. Neither the American Lung Association in Georgia, District Public Health, nor the residential facility will be responsible for personal items left after termination of lease.
3. You should have **no** visitors at any time.
4. If it is determined that you need food assistance, food vouchers/certificates may be made available to you so that your family or friends may purchase food for you.
5. You must remain in your room until District Public Health informs you otherwise.
6. Your outreach worker or nurse will visit with you once a day, usually in the morning. Other unannounced visits will be made.
7. Participation in Directly Observed Therapy (DOT) is required in order to stay at the residential facility. DOT will be provided to you by a designated health care professional. Failure to participate in a scheduled DOT session, may lead to the immediate termination of your room rental. As a part of your treatment, you may be transported from time to time to the Health Department for test, or to see physicians.
8. Use of illegal drug or other illegal activities by you and/or any guest(s) in your room will result in the immediate termination of your room rental.
9. Any behavior deemed detrimental and or inappropriate (determined by ALAG, the District Public Health and/or the vendor) to your health, the health of others or the property will result in the immediate termination of your room rental.
10. If your room rental is terminated due to inappropriate behavior by you or your guest(s) or by your inability to comply with DOT, you must return the room key immediately to the outreach worker, TB nurse or designated staff and vacate the premises.
11. If you are diagnosed as **not** having TB, you will be released from the Program within 48 hours.
12. ALAG will seek, when possible, to involve and educate family and friends in your aftercare so that they will have a better understanding of how to assist you while you are in

the motel and later when you are able to find alternate housing.

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

*It is the American Lung Association of the Southeast's (ALASE's) policy to ensure compliance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule by establishing sanctions for breaches of confidentiality. All employees are required to be aware of their responsibilities under ALASE privacy policies.*

7-10

**Alternative Housing Program  
PATIENT-PROVIDER THERAPEUTIC CONTRACT  
For Financial Assistance**

The following is a statement of what is expected of each patient who agrees to accept financial assistance for (name services) \_\_\_\_\_ paid for by the American Lung Association in Georgia. Please read guidelines carefully and if you agree to abide by the conditions listed, please sign at the bottom.

1. The length of time that ALAG will provide financial assistance will be determined by any financial changes, your medical needs, your cooperation and continued participation with follow-up provided by District Public Health.
2. You should not have visitors until Public Health informs you that you are no longer infectious to others.
3. Your TB representative will visit with you weekly. Other unannounced visits will be made.
4. Participation in Directly Observed Therapy (DOT) is required in order to receive financial assistance. DOT will be provided to you by a designated health care professional. Failure to participate in a scheduled DOT session may lead to the immediate dismissal from the Program. As a part of your treatment, you may be transported from time to time to the Health Department or another site for tests or to see physicians.
5. Any behavior deemed detrimental to your health or the health of others will result in the immediate termination of the agreement.
6. ALAG will immediately cease to provide financial assistance if you fail to comply with DOT due to inappropriate behavior.
7. When you have completed the program and/or have **three negative smears**, ALAG will **immediately cease** from financial assistance.
8. If you are diagnosed as not having TB, ALAG will immediately cease financial assistance.
9. We will seek, when possible, to involve and educate family and friends in your aftercare so that they will have a better understanding of how to assist you while you are enrolled in the Program.

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

*It is the American Lung Association of the Southeast's (ALASE's) policy to ensure compliance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule by establishing sanctions for breaches of confidentiality. All employees are required to be aware of their responsibilities under ALASE privacy policies*

7-10

**Alternative Housing Program  
PATIENT AUTHORIZATION FOR USE OR DISCLOSURE  
OF HEALTH INFORMATION**

Completion of this document authorizes the disclosure and/or use of individually identifiable health information, as set forth below, consistent with Georgia and Federal law concerning the privacy of such information. **Failure to provide *all* information requested may invalidate this Authorization.**

**USE AND DISCLOSURE OF HEALTH INFORMATION**

I hereby authorize the use or disclosure of my health information as follows:

Member Name: \_\_\_\_\_

Persons/Organizations authorized to *use or disclose* the information: American Lung Association in Georgia

Persons/Organizations authorized to *receive* the information: \_\_\_\_\_  
\_\_\_\_\_  
(list vendors)

Purpose of requested use or disclosure: ii \_\_\_\_\_  
\_\_\_\_\_

This Authorization applies to the following information (select **only one** of the following):iii

All health information pertaining to any medical history, mental or physical condition and treatment received.

[Optional] **Except:** \_\_\_\_\_

**Only** the following records or types of health information (including any dates). This may consist of psychotherapy notes, if specifically authorized:

**EXPIRATION**

This Authorization expires [insert date or event]: iv \_\_\_\_\_  
\_\_\_\_\_

**NOTICE OF RIGHTS AND OTHER INFORMATION**

I may refuse to sign this Authorization.

I may revoke this authorization at any time. My revocation must be in writing, signed by me or on my behalf, and delivered to the following address: \_\_\_\_\_  
\_\_\_\_\_

My revocation will be effective upon receipt, but will not be effective to the extent that the Requestor or others have acted in reliance upon this Authorization.

I have a right to receive a copy of this authorization. v

Neither treatment, payment, enrollment or eligibility for benefits will be conditioned on my providing or refusing to provide this authorization.vi



Information disclosed pursuant to this authorization could be re-disclosed by the recipient and might no longer be protected by federal confidentiality law (HIPAA).

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Signature of Member or Authorized Representative / Date

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If Signed by Representative, State Relationship or Basis of Authority

- 
- i If the Authorization is being requested by the entity holding the information, this entity is the Requestor.
  - ii The statement "at the request of the individual" is a sufficient description of the purpose when the individual initiates the authorization and does not, or elects not to, provide a statement of the purpose.
  - iii This form may not be used to release both psychotherapy notes and other types of health information (see 45 CFR § 164.508(b)(3)(ii)). **If this form is being used to authorize the release of psychotherapy notes, a separate form must be used to authorize release of any other health information.**
  - iv If authorization is for use or disclosure of PHI for research, including the creation and maintenance of a research database or repository, the statement "end of research study," "none" or similar language is sufficient.
  - v Under HIPAA, the individual must be provided with a copy of the authorization when it has been requested by a covered entity for its own uses and disclosures (see 45 CFR § 164.508(d)(1), (e)(2)).
  - vi If any of the exceptions to this statement, as recognized by HIPAA apply, then this statement must be changed to describe the consequences to the individual of a refusal to sign the authorization when that covered entity can condition treatment, health plan enrollment, or benefit eligibility on the failure to obtain such authorization. A covered entity is permitted to condition treatment, health plan enrollment or benefit eligibility on the provision of an authorization as follows: (i) to conduct research-related treatment, (ii) to obtain information in connection with a health plan's eligibility or enrollment determinations relating to the individual or for its underwriting or risk rating determinations, or (iii) to create health information to provide to a third party or for disclosure of the health information to such third party. **Under no circumstances, however, may an individual be required to authorize the disclosure of psychotherapy notes.**

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