Georgia OEMS Update – COVID-19, etc

OEMS / Friday, 10/09/2020

Agenda

- Reminders
- Epidemiology Report – due to the amount of material we have to cover today, questions will be at the end.
- Operational Updates
  - BinaxNOW and CLIA
- Educational Updates
- Questions

Reminders

- As of 10/8/2020:
  - 3,668 (-120 in 2 weeks) Medics without email addresses!

- Renewal season is here!
- Agencies are being sent lists of all their medics who are on their roster but don't have email addresses.
- Agencies MUST have current rosters.

- There is NO excuse for having out-of-date rosters and NO excuse for saying "I didn't know that medic had expired"

Renewals Completed so far – 72 down, 15,925 to go!

Date	Count
10/1/2020	21
10/2/2020	11
10/3/2020	1
10/4/2020	5
10/5/2020	9
10/6/2020	11
10/7/2020	9
10/8/2020	5
TOTAL	**72**

Agencies who pay for renewals

- Application = **Agency - Indicate Medics for Renewal Payments**
  - Must be Authorized Agent or EMS Agency Admin
- Open now till 2/15/2021 – this deadline is **FIRM**
  - All moneys MUST be received by COB on March 1, 2021 – this deadline is **FIRM**!
    - This leaves the medic 30 day to renew their license.
- Medics will NOT see the "Georgia Medic Renewal – Agency Paid" application until AFTER the EMS Agency has paid for their application fees

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Epidemiology Report – Dr. Cherie Drenzek – graphs as of 10/8/2020
https://dph.georgia.gov/covid-19-daily-status-report

Confirmed Cases	Deaths	Hospitalizations	ICU Admissions
327,407	7,294	29,386	5,453

COVID-19 Testing

	Total PCR/ Molecular	PCR/Molecular Reported Today	Total Antibody (Serology)
Number of Tests	3,083,121	24,934	307,780
Number of Positive Tests	306,421	1,247	26,095
% Positive	9.9%	5.0%	8.5%

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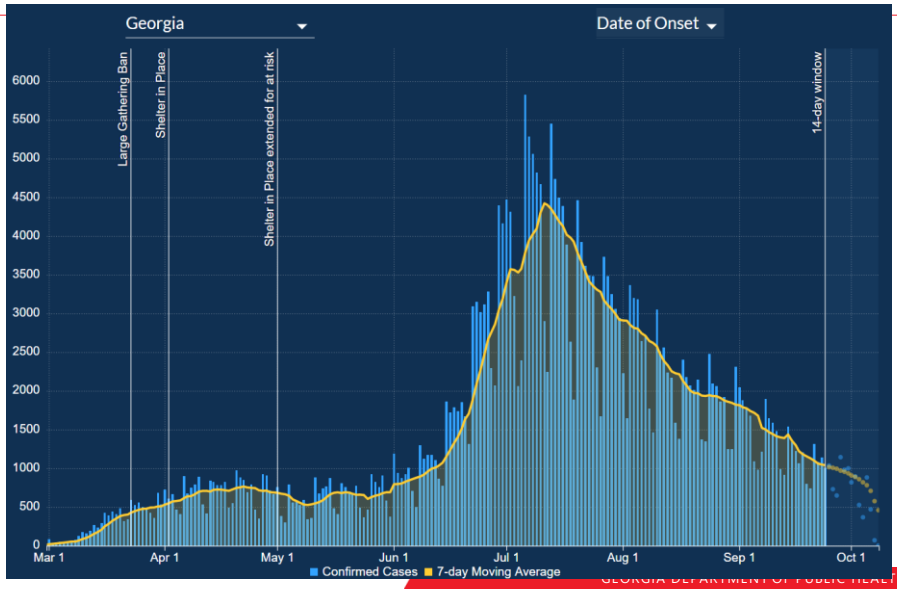
Cases Over Time (By date of onset)



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Reported cases per 100,000 people last 14 days - as of 10/08/2020

Georgia - October 08

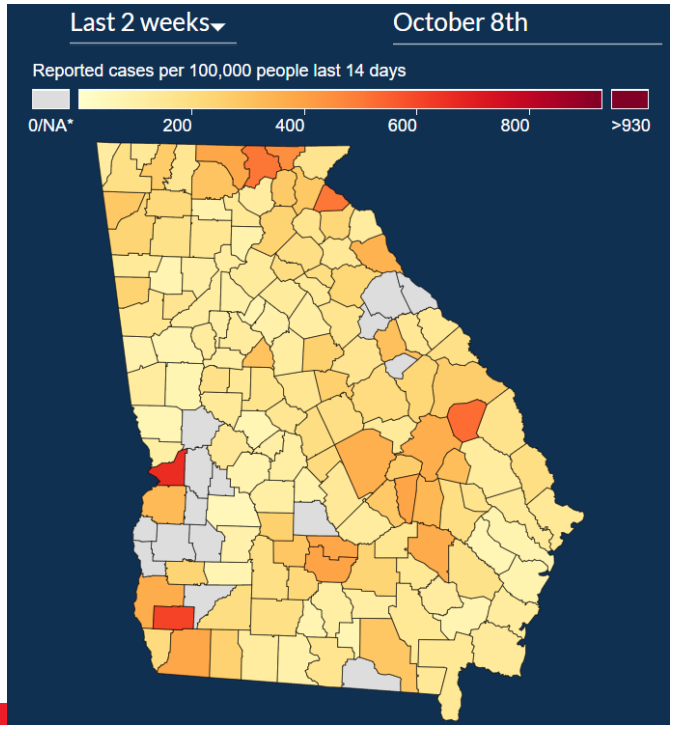
Cases (last 2 weeks): 16,792

Cases per 100k (last 2 weeks): 155

Cases (total): 327,407

Cases per 100k (total): 3022

Population: 10,833,472



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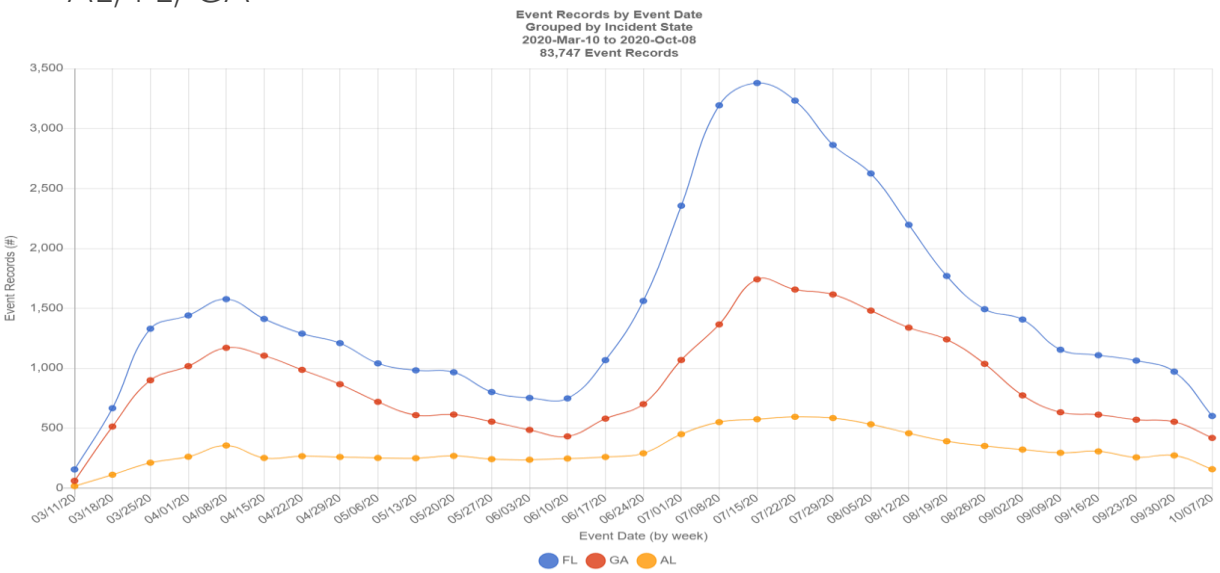
Calculated COVID-19 Syndrome – 3/10/2020 – 10/08/2020, AL, FL, GA



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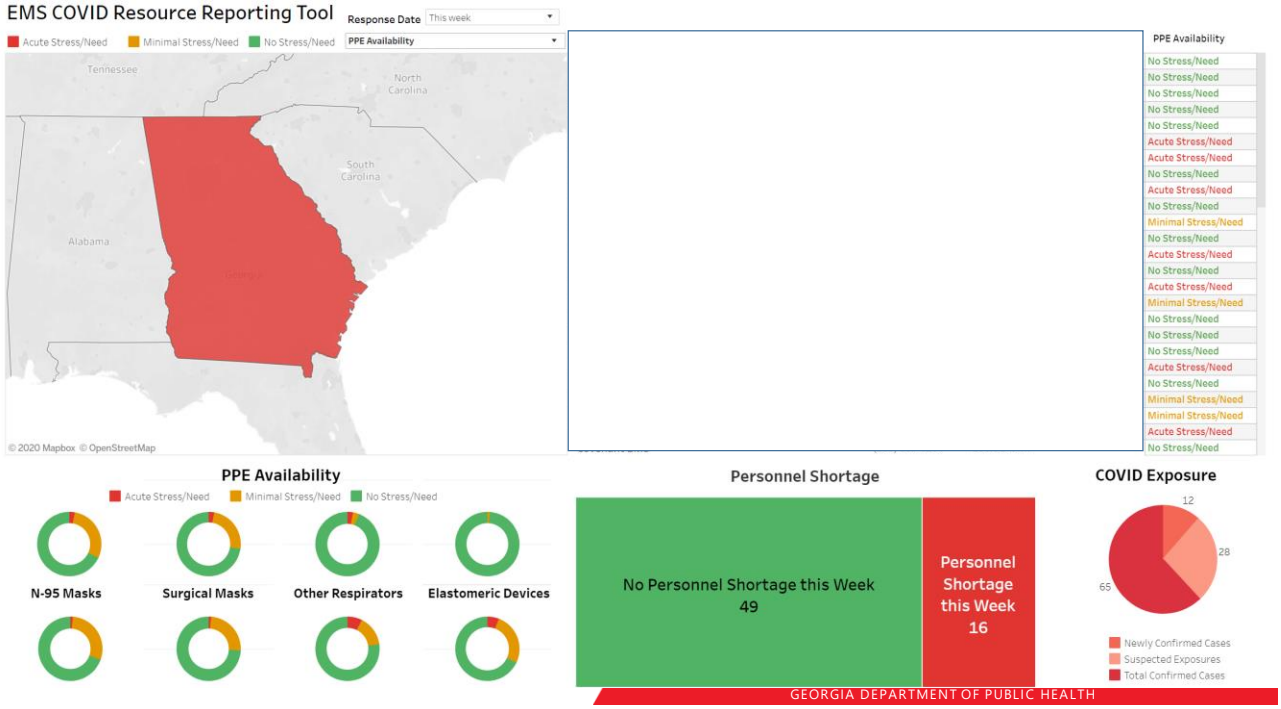

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2020 Word of the year = Adaptability

CLIA and BinaxNOW

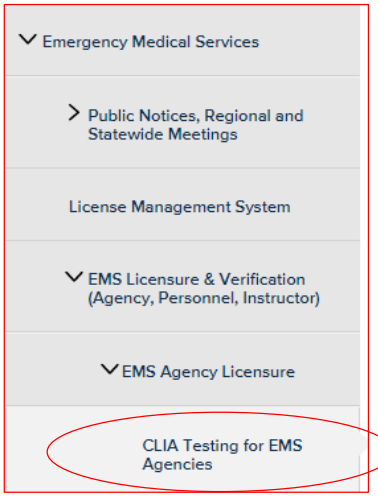
CLIA

- Congress passed the Clinical Laboratory Improvement Amendments (CLIA) in 1988, and under CLIA, a laboratory is defined as a facility that performs applicable testing on materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or assessment of the health of, human beings.
- Short info – if you do ANY testing of materials from human body (including glucose testing), you MUST have a CLIA Certificate of Waiver. (this is NOT a NEW requirement)

Rule 511-9-2-.18. Standards of Conduct for Licensees

- (31) A licensee shall not violate any statue or regulation, state or federal, which pertains to emergency medical services.

OEMS Website – ems.ga.gov



CLIA Testing for EMS Agencies

Since all EMS Agencies in Georgia are required to have devices that can check a patient's blood glucose, all EMS Agencies are required to have a CLIA Certificate of Waiver. Congress passed the Clinical Laboratory Improvement Amendments (CLIA) in 1988, and under CLIA, a laboratory is defined as a facility that performs applicable testing on materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or assessment of the health of, human beings.

To learn more about CLIA and how to apply for a CLIA Certificate of Waiver, please review the following:

- How to obtain a CLIA Certificate of Waiver - CMS
- Clinical Laboratory Improvement Amendments (CLIA) Website
- Laboratory Quick Start Guide to CMS CLIA Certification
- Waived Tests (CDC webpage with educational materials)

The State Agency for CLIA in Georgia is:

GEORGIA DEPARTMENT OF COMMUNITY HEALTH
Healthcare Facility Regulation
Division Diagnostic Services Unit
2 Peachtree Street, N.W., Suite 31-447
Atlanta, GA 30303-3142
(404) 657-5700
FAX: (404) 463-4398
Email: hfrd.diagnostic@dch.ga.gov

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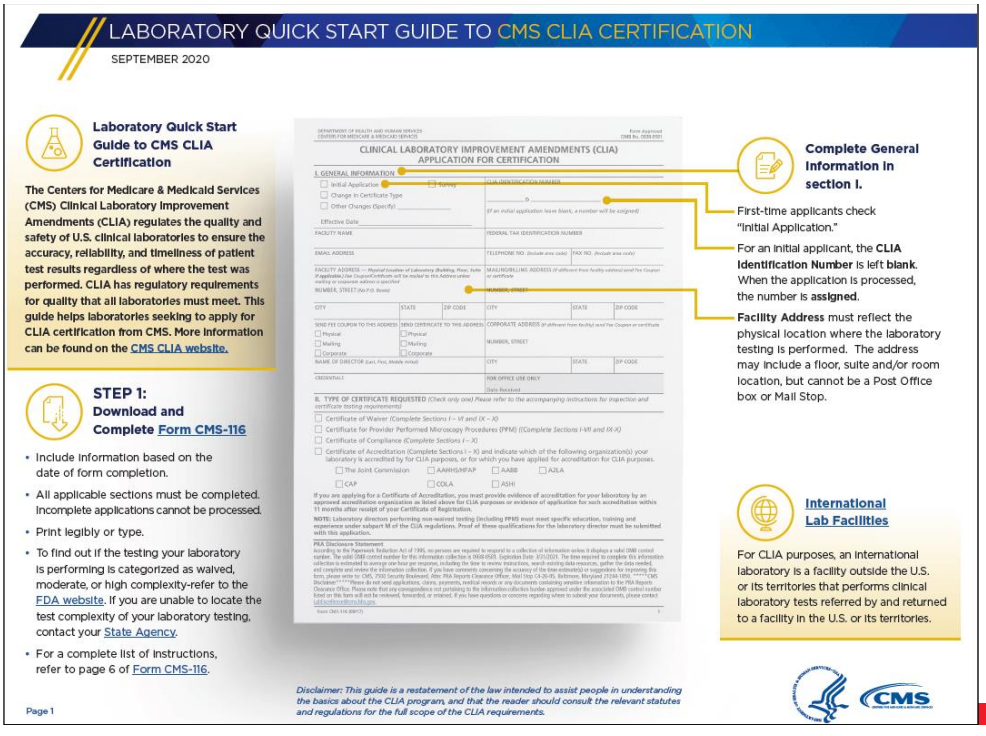

LABORATORY QUICK START GUIDE TO CMS CLIA CERTIFICATION

SEPTEMBER 2020

Laboratory Quick Start Guide to CMS CLIA Certification

The Centers for Medicare & Medicaid Services (CMS) Clinical Laboratory Improvement Amendments (CLIA) regulates the quality and safety of U.S. clinical laboratories to ensure the accuracy, reliability, and timeliness of patient test results regardless of where the test was performed. CLIA has regulatory requirements for quality that all laboratories must meet. This guide helps laboratories seeking to apply for CLIA certification from CMS. More information can be found on the CMS CLIA website.

STEP 1: Download and Complete Form CMS-116

- Include information based on the date of form completion.
- All applicable sections must be completed. Incomplete applications cannot be processed.
- Print legibly or type.
- To find out if the testing your laboratory is performing is categorized as waived, moderate, or high complexity-refer to the FDA website. If you are unable to locate the test complexity of your laboratory testing, contact your State Agency.
- For a complete list of instructions, refer to page 6 of Form CMS-116.

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA) APPLICATION FOR CERTIFICATION

Complete General Information in section I.

First-time applicants check "Initial Application."

For an initial applicant, the **CLIA Identification Number** is left **blank**. When the application is processed, the number is **assigned**.

Facility Address must reflect the physical location where the laboratory testing is performed. The address may include a floor, suite and/or room location, but cannot be a Post Office box or Mail Stop.

International Lab Facilities

For CLIA purposes, an international laboratory is a facility outside the U.S. or its territories that performs clinical laboratory tests referred by and returned to a facility in the U.S. or its territories.

Disclaimer: This guide is a restatement of the law intended to assist people in understanding the basics about the CLIA program, and that the reader should consult the relevant statutes and regulations for the full scope of the CLIA requirements.

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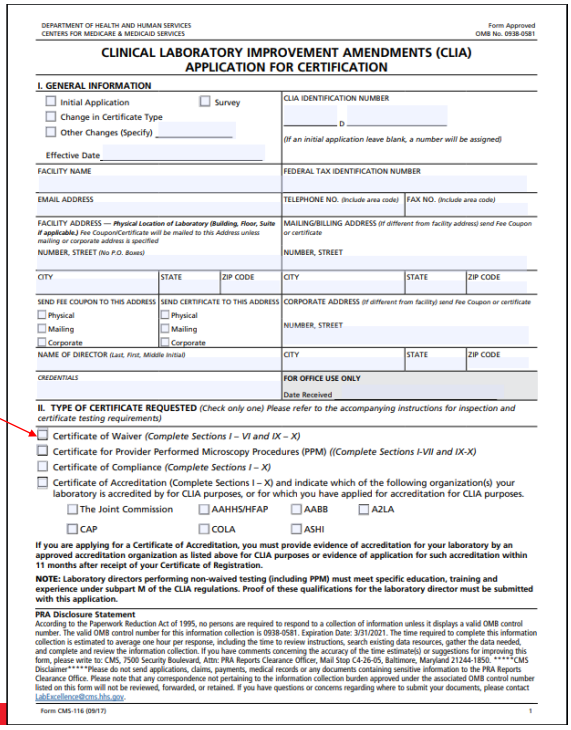
Select Certificate of Waiver



DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

Form Approved
OMB No. 0938-0581

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA)
APPLICATION FOR CERTIFICATION

I. GENERAL INFORMATION

- ☐ Initial Application ☐ Survey
- ☐ Change in Certificate Type
- ☐ Other Changes (Specify) _____

Effective Date _____

CLIA IDENTIFICATION NUMBER

_____ D _____

(If an initial application leave blank, a number will be assigned)

FACILITY NAME

FEDERAL TAX IDENTIFICATION NUMBER

EMAIL ADDRESS

TELEPHONE NO. *(Include area code)* FAX NO. *(Include area code)*

FACILITY ADDRESS — ***Physical Location of Laboratory (Building, Floor, Suite if applicable.)*** *Fee Coupon/Certificate will be mailed to this Address unless mailing or corporate address is specified*

NUMBER, STREET *(No P.O. Boxes)*

CITY | STATE | ZIP CODE

MAILING/BILLING ADDRESS *(If different from facility address) send Fee Coupon or certificate*

NUMBER, STREET

CITY | STATE | ZIP CODE

SEND FEE COUPON TO THIS ADDRESS
- ☐ Physical
- ☐ Mailing
- ☐ Corporate

SEND CERTIFICATE TO THIS ADDRESS
- ☐ Physical
- ☐ Mailing
- ☐ Corporate

CORPORATE ADDRESS *(If different from facility) send Fee Coupon or certificate*

NUMBER, STREET

NAME OF DIRECTOR *(Last, First, Middle Initial)*

CITY | STATE | ZIP CODE

CREDENTIALS

FOR OFFICE USE ONLY

Date Received

II. TYPE OF CERTIFICATE REQUESTED *(Check only one) Please refer to the accompanying instructions for inspection and certificate testing requirements)*

- ☐ Certificate of Waiver *(Complete Sections I – VI and IX – X)*
- ☐ Certificate for Provider Performed Microscopy Procedures (PPM) *((Complete Sections I-VII and IX-X)*
- ☐ Certificate of Compliance *(Complete Sections I – X)*
- ☐ Certificate of Accreditation (Complete Sections I – X) and indicate which of the following organization(s) your laboratory is accredited by for CLIA purposes, or for which you have applied for accreditation for CLIA purposes.
  - ☐ The Joint Commission ☐ AAHHS/HFAP ☐ AABB ☐ A2LA
  - ☐ CAP ☐ COLA ☐ ASHI

If you are applying for a Certificate of Accreditation, you must provide evidence of accreditation for your laboratory by an approved accreditation organization as listed above for CLIA purposes or evidence of application for such accreditation within 11 months after receipt of your Certificate of Registration.

NOTE: Laboratory directors performing non-waived testing (including PPM) must meet specific education, training and experience under subpart M of the CLIA regulations. Proof of these qualifications for the laboratory director must be submitted with this application.

PRA Disclosure Statement

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0581. Expiration Date: 3/31/2021. The time required to complete this information collection is estimated to average one hour per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850. *****CMS Disclaimer*****Please do not send applications, claims, payments, medical records or any documents containing sensitive information to the PRA Reports Clearance Office. Please note that any correspondence not pertaining to the information collection burden approved under the associated OMB control number listed on this form will not be reviewed, forwarded, or retained. If you have questions or concerns regarding where to submit your documents, please contact LabExcellence@cms.hhs.gov.

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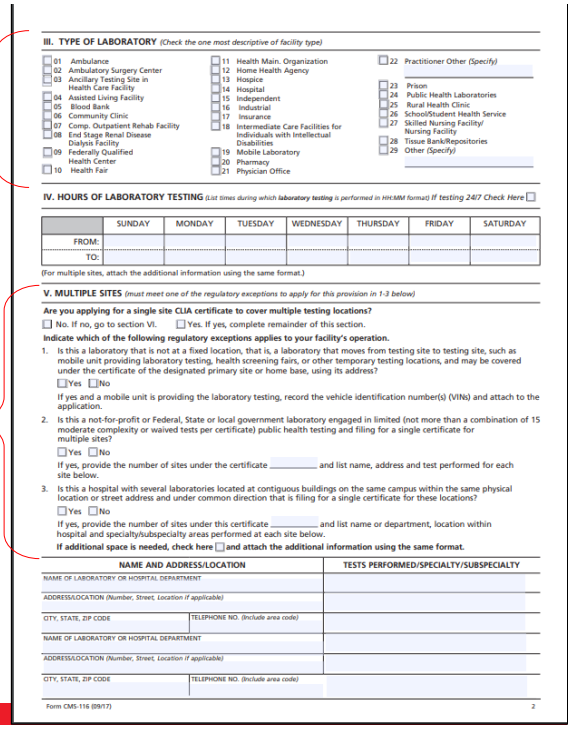
Type of Laboratory = Ambulance or Other ("Medical First Responder vehicle")

Multiples Site = YES

#1 = Yes (mobile)

#2 = Yes, if governmental agency

Must list ALL VINs for each vehicle on which a test will be performed. Attach as a document.



III. TYPE OF LABORATORY *(Check the one most descriptive of facility type)*

- ☐ 01 Ambulance
- ☐ 02 Ambulatory Surgery Center
- ☐ 03 Ancillary Testing Site in Health Care Facility
- ☐ 04 Assisted Living Facility
- ☐ 05 Blood Bank
- ☐ 06 Community Clinic
- ☐ 07 Comp. Outpatient Rehab Facility
- ☐ 08 End Stage Renal Disease Dialysis Facility
- ☐ 09 Federally Qualified Health Center
- ☐ 10 Health Fair
- ☐ 11 Health Main. Organization
- ☐ 12 Home Health Agency
- ☐ 13 Hospice
- ☐ 14 Hospital
- ☐ 15 Independent
- ☐ 16 Industrial
- ☐ 17 Insurance
- ☐ 18 Intermediate Care Facilities for Individuals with Intellectual Disabilities
- ☐ 19 Mobile Laboratory
- ☐ 20 Pharmacy
- ☐ 21 Physician Office
- ☐ 22 Practitioner Other *(Specify)*
- ☐ 23 Prison
- ☐ 24 Public Health Laboratories
- ☐ 25 Rural Health Clinic
- ☐ 26 School/Student Health Service
- ☐ 27 Skilled Nursing Facility/ Nursing Facility
- ☐ 28 Tissue Bank/Repositories
- ☐ 29 Other *(Specify)*

IV. HOURS OF LABORATORY TESTING *(List times during which **laboratory testing** is performed in HH:MM format)* *If testing 24/7 Check Here* ☐

	SUNDAY	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY
FROM:							
TO:							

(For multiple sites, attach the additional information using the same format.)

V. MULTIPLE SITES *(must meet one of the regulatory exceptions to apply for this provision in 1-3 below)*

Are you applying for a single site CLIA certificate to cover multiple testing locations?

☐ No. If no, go to section VI. ☐ Yes. If yes, complete remainder of this section.

Indicate which of the following regulatory exceptions applies to your facility's operation.

1. Is this a laboratory that is not at a fixed location, that is, a laboratory that moves from testing site to testing site, such as mobile unit providing laboratory testing, health screening fairs, or other temporary testing locations, and may be covered under the certificate of the designated primary site or home base, using its address?
   ☐ Yes ☐ No
   If yes and a mobile unit is providing the laboratory testing, record the vehicle identification number(s) (VINs) and attach to the application.
2. Is this a not-for-profit or Federal, State or local government laboratory engaged in limited (not more than a combination of 15 moderate complexity or waived tests per certificate) public health testing and filing for a single certificate for multiple sites?
   ☐ Yes ☐ No
   If yes, provide the number of sites under the certificate _____ and list name, address and test performed for each site below.
3. Is this a hospital with several laboratories located at contiguous buildings on the same campus within the same physical location or street address and under common direction that is filing for a single certificate for these locations?
   ☐ Yes ☐ No
   If yes, provide the number of sites under this certificate _____ and list name or department, location within hospital and specialty/subspecialty areas performed at each site below.

If additional space is needed, check here ☐ **and attach the additional information using the same format.**

NAME AND ADDRESS/LOCATION	TESTS PERFORMED/SPECIALTY/SUBSPECIALTY
NAME OF LABORATORY OR HOSPITAL DEPARTMENT	
ADDRESS/LOCATION (Number, Street, Location if applicable)	
CITY, STATE, ZIP CODE / TELEPHONE NO. (Include area code)	
NAME OF LABORATORY OR HOSPITAL DEPARTMENT	
ADDRESS/LOCATION (Number, Street, Location if applicable)	
CITY, STATE, ZIP CODE / TELEPHONE NO. (Include area code)	

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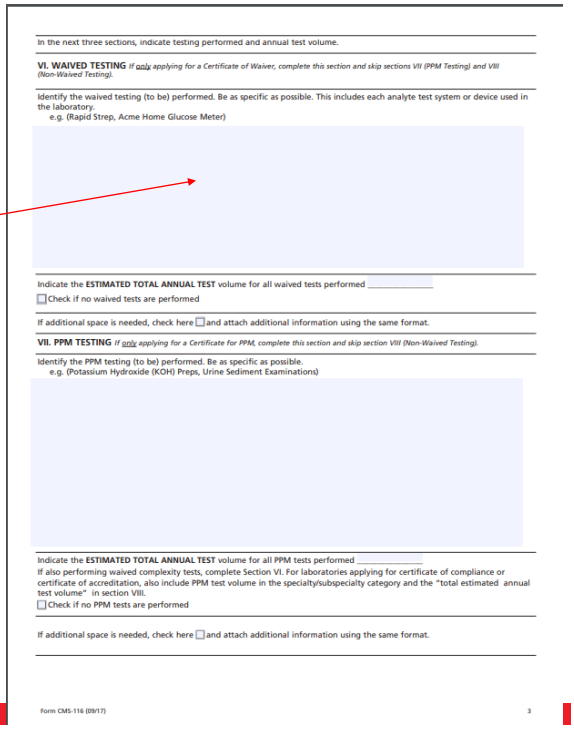
Be DESCRIPTIVE on which Glucose test(s) you use

Include **"Abbott BinaxNOW Rapid Antigen Test for COVID-19"**

- Even if you don't think you are going to need it now



In the next three sections, indicate testing performed and annual test volume.

VI. WAIVED TESTING *If only applying for a Certificate of Waiver, complete this section and skip sections VII (PPM Testing) and VIII (Non-Waived Testing).*

Identify the waived testing (to be) performed. Be as specific as possible. This includes each analyte test system or device used in the laboratory.
e.g. (Rapid Strep, Acme Home Glucose Meter)

Indicate the **ESTIMATED TOTAL ANNUAL TEST** volume for all waived tests performed _____
☐ Check if no waived tests are performed

If additional space is needed, check here ☐ and attach additional information using the same format.

VII. PPM TESTING *If only applying for a Certificate for PPM, complete this section and skip section VIII (Non-Waived Testing).*

Identify the PPM testing (to be) performed. Be as specific as possible.
e.g. (Potassium Hydroxide (KOH) Preps, Urine Sediment Examinations)

Indicate the **ESTIMATED TOTAL ANNUAL TEST** volume for all PPM tests performed _____
If also performing waived complexity tests, complete Section VI. For laboratories applying for certificate of compliance or certificate of accreditation, also include PPM test volume in the specialty/subspecialty category and the "total estimated annual test volume" in section VIII.
☐ Check if no PPM tests are performed

If additional space is needed, check here ☐ and attach additional information using the same format.

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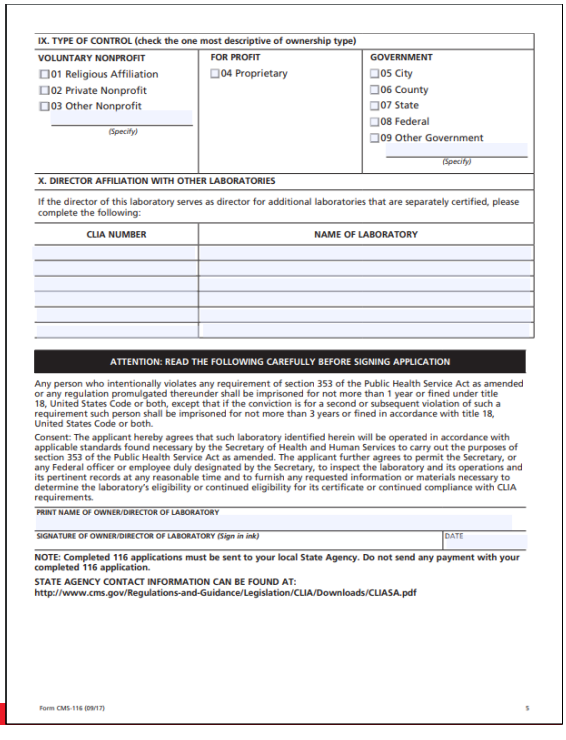
DCH HFR:

GEORGIA DEPARTMENT OF COMMUNITY HEALTH
Healthcare Facility Regulation
Division Diagnostic Services Unit
2 Peachtree Street, N.W., Suite 31-447
Atlanta, GA 30303-3142
(404) 657-5700
FAX: (404) 463-4398
Email: hfrd.diagnostic@dch.ga.gov



IX. TYPE OF CONTROL (check the one most descriptive of ownership type)

VOLUNTARY NONPROFIT	FOR PROFIT	GOVERNMENT
☐ 01 Religious Affiliation	☐ 04 Proprietary	☐ 05 City
☐ 02 Private Nonprofit		☐ 06 County
☐ 03 Other Nonprofit		☐ 07 State
_____ (Specify)		☐ 08 Federal
		☐ 09 Other Government _____ (Specify)

X. DIRECTOR AFFILIATION WITH OTHER LABORATORIES

If the director of this laboratory serves as director for additional laboratories that are separately certified, please complete the following:

CLIA NUMBER	NAME OF LABORATORY

ATTENTION: READ THE FOLLOWING CAREFULLY BEFORE SIGNING APPLICATION

Any person who intentionally violates any requirement of section 353 of the Public Health Service Act as amended or any regulation promulgated thereunder shall be imprisoned for not more than 1 year or fined under title 18, United States Code or both, except that if the conviction is for a second or subsequent violation of such a requirement such person shall be imprisoned for not more than 3 years or fined in accordance with title 18, United States Code or both.

Consent: The applicant hereby agrees that such laboratory identified herein will be operated in accordance with applicable standards found necessary by the Secretary of Health and Human Services to carry out the purposes of section 353 of the Public Health Service Act as amended. The applicant further agrees to permit the Secretary, or any Federal officer or employee duly designated by the Secretary, to inspect the laboratory and its operations and its pertinent records at any reasonable time and to furnish any requested information or materials necessary to determine the laboratory's eligibility or continued eligibility for its certificate or continued compliance with CLIA requirements.

PRINT NAME OF OWNER/DIRECTOR OF LABORATORY

SIGNATURE OF OWNER/DIRECTOR OF LABORATORY *(Sign in ink)* DATE

NOTE: Completed 116 applications must be sent to your local State Agency. Do not send any payment with your completed 116 application.

STATE AGENCY CONTACT INFORMATION CAN BE FOUND AT:
http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.pdf

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BinaxNOW™ COVID-19 Ag Card

- https://www.globalpointofcare.abbott/en/support/product-installation-training/navica-brand/navica-binaxnow-ag-training.html
- Training Webinars (Abbott)
  - Multiple in October
- Data Reporting Training (DPH)
  - Thursday, October 15th from 4-4:30pm
- Georgia Train-the-Trainer (Abbott):
  - Friday, October 16th from 9-10am

Allocations and Purchasing

- HHS spent $750 Million on 150 Million cards ($5/card)
- Georgia receiving~3.2 Million BinaxNOW Cards by end of 2020
  - DPH is doing allocations
- Cards will be available for purchase by private entities in early 2021

Allocations for EMS

- For EMS staff and medics
- NOT for patients or the general public
- Based on qualifications (CLIA, MD support) and based on number of rostered personnel (in LMS)
  - Keep your roster up-to-date!!

Product Insert

- Testing of Symptomatic persons within 7 days of symptom onset
- Positive tests are considered presumptive
- Negative tests in symptomatic persons should be followed up by PCR testing
- ALL results must be reported

BinaxNOW™ COVID-19 Ag Card Performance within 7 days of symptom onset against the Comparator Method

BinaxNOW™ COVID-19 Ag Card	Comparator Method		
	Positive	Negative	Total
Positive	34	1	35
Negative	1	66	67
Total	35	67	102
Positive Agreement: 34/35	97.1% (95% CI: 85.1% - 99.9%)		
Negative Agreement: 66/67	98.5% (95% CI: 92.0% - 100%)		

Patient Demographics

Patient demographics (gender, age, time elapsed since onset of symptoms) are available for the 102 samples used in the analysis. The table below shows the positive results broken down by age of the patient:

Age	BinaxNOW™ COVID-19 Ag Card		
	Total #	Positive	Prevalence
≤ 5 years	0		
6 to 21 years	0		
22 to 59 years	77	28	36.4%
≥ 60 years	25	7	28.0%

Positive results broken down by days since symptom onset:

Days Since Symptom Onset	Cumulative RT-PCR Positive (+)	Cumulative BinaxNOW™ COVID-19 Ag Card Positive (+)	PPA	95 % Confidence Interval	
1	4	4	100.0%	39.8%	100.0%
2	10	10	100.0%	69.2%	100.0%
3	15	15	100.0%	78.2%	100.0%
4	18	18	100.0%	81.5%	100.0%
5	23	22	95.7%	78.1%	99.9%
6	27	26	96.3%	81.0%	99.9%
7	35	34	97.1%	85.1%	99.9%

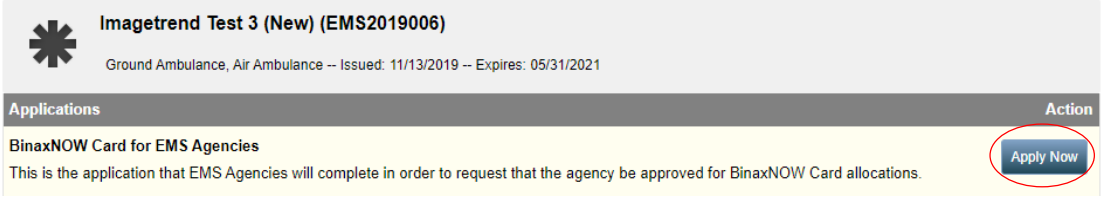
The following data is provided for informational purposes:

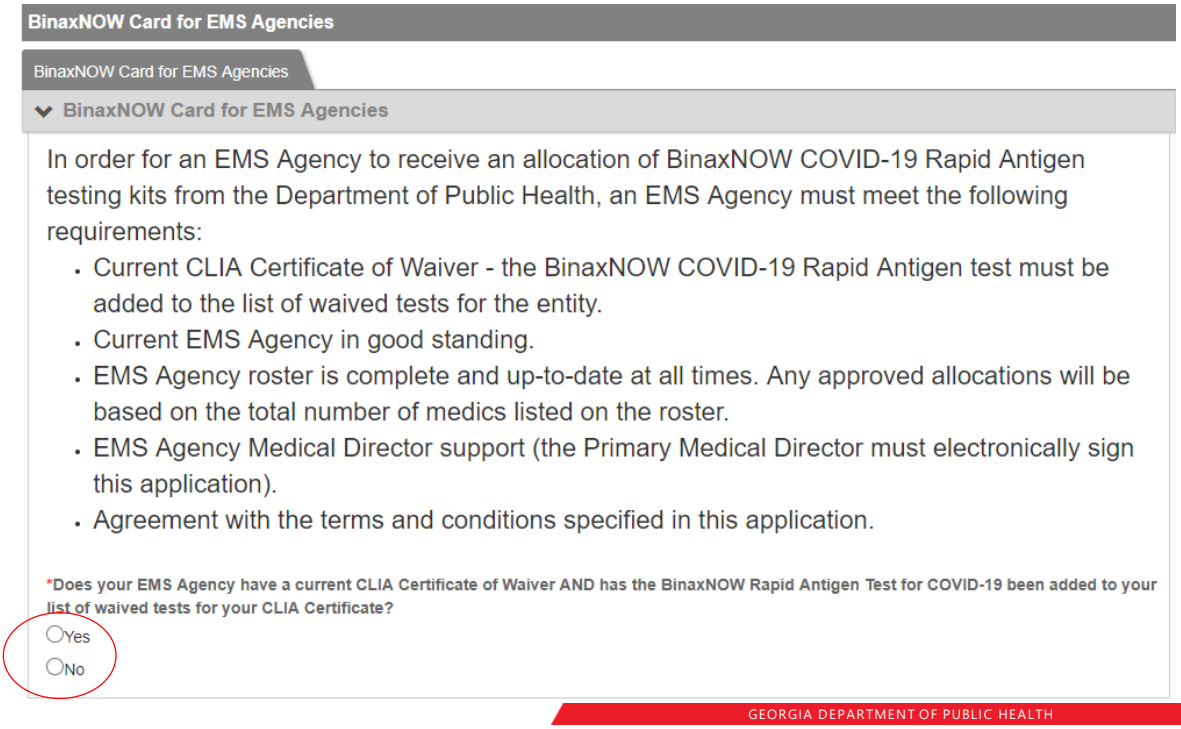
The performance of BinaxNOW COVID-19 Ag Card with positive results stratified by the comparator method cycle threshold (Ct) counts were collected and assessed to better understand the correlation of assay performance to the cycle threshold, estimating the viral titer present in the clinical sample. As presented in the table below, the positive agreement of the BinaxNOW COVID-19 Ag Card is higher with samples of a Ct count <33.

BinaxNOW™ COVID-19 Ag Card Performance against the Comparator Method – by Cycle Threshold Counts

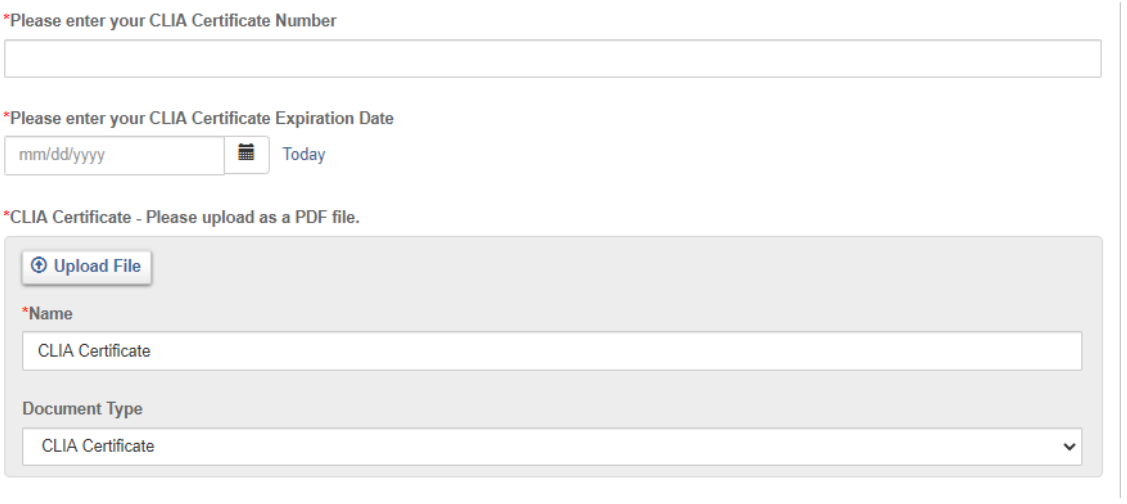
BinaxNOW™ COVID-19 Ag Card	Comparator Method (POS by Ct Category)	
	POS (Ct < 33)	POS (Ct ≥ 33)
Positive	29	5
Negative	0	1
Total	29	6
Positive Agreement (95% CI)	100.0 (88.1, 100.0)	83.3 (35.9, 99.6)

Request Allocation on LMS





CLIA Certificate



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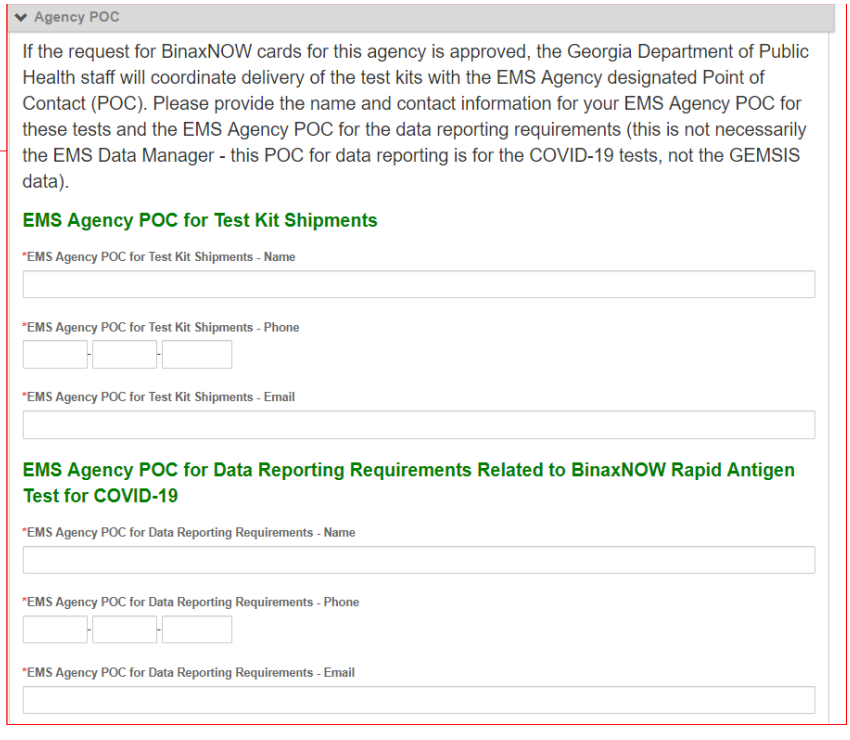
POCs



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If this request for BinaxNOW card allocation is approved, **the Georgia Department of Public Health responsibilities include:**

1. The Georgia Department of Public Health will procure and deliver Testing Devices (BinaxNOW Rapid Antigen test for COVID-19) to the EMS Agency. The amount of Testing Devices delivered to the EMS Agency and frequency of those deliveries will be based on the number of rostered personnel on the EMS Agency roster in this License Management System, and will be determined by the Georgia Department of Public Health. Any future allocations will also be based on the EMS Agency's compliance with these guidelines regarding data reporting requirements.
2. The Georgia Department of Public Health shall not be liable for any malfunction or defect in the Testing Devices.

Responsibilities of the EMS Agency:

1. The EMS Agency shall have appropriately trained and licensed personnel to perform the test. The EMS Agency shall maintain required licensures under applicable federal, state and municipal law, and certifies that it is operating under a CLIA Certificate. Documentation of such licensure shall be provided upon written request.
2. The EMS Agency shall report all results of COVID-19 testing, as well as demographic and clinical information, in accordance with the Official Code of Georgia § 31-12-2 and federal law, and with the following specifications and mechanisms:
    1. Results, demographic and clinical information shall be submitted to the Georgia Department of Public Health (GaDPH) through the Public Health Information Network Messaging System (PHINMS) using Health Level 7 International (HL7) standards. If HL7 is unavailable to the EMS Agency, a spreadsheet will be accepted in PHINMS as long as it adheres to the template and format provided by GaDPH. Results, demographic and clinical information may also be entered manually into the GaDPH State Electronic Notifiable Disease Surveillance System (SENDSS).
    2. Report all test results (including positive, negative and inconclusive test results) within 24 hours of testing.
    3. All results of the tests as well as demographic and clinical information must be provided. This includes, but is not limited to, patient first and last name, date of birth, demographics such as race and ethnicity, geographical identifiers such as address or county of residence, and contact information such as telephone number, and any additional information required by GaDPH.
    4. No confidential data collected, maintained, or used in the course of performance of these tests shall be disseminated except as authorized by law.
    5. No monies shall be exchanged pursuant to this agreement, and the EMS Agency is responsible for all costs associated with the activities under this agreement including but not limited to provision of the test site and testing personnel.

Test Limitations:

- If an allocation of BinaxNOW Rapid Antigen tests for COVID-19 is approved for this EMS Agency, the tests are to be used to test symptomatic (symptoms related to COVID-19) individuals who are employees of the EMS Agency. These test kits are NOT intended for routine screening of asymptomatic persons and are not intended to be used for the general public or for patients assessed or treated by the EMS Agency.
- The BinaxNOW Rapid Antigen tests for COVID-19 should be used within the first 7 days of symptom onset.
- More information on the test kits can be found here:
    - https://www.globalpointofcare.abbott/en/support/product-installation-training/navica-brand/navica-binaxnow-ag-training.html

Attestation Statement:

As the **Authorized Agent** for the EMS Agency listed below, and by electronically signing this application below, I hereby attest that I have read and understand the terms above and understand that failure to comply with the above terms will result in no future allocations of BinaxNOW Rapid Antigen Tests for COVID-19 for our EMS Agency. I also attest that our EMS Agency will follow all guidance providing by the Department of Public Health related to these tests, and all test results (positive, negative, inconclusive) will be reported to the Department of Public Health via electronic means and per the terms above within 24 hours of performing the test.

Attestation

Attestation Statement:

As the **Authorized Agent** for the EMS Agency listed below, and by electronically signing this application below, I hereby attest that I have read and understand the terms above and understand that failure to comply with the above terms will result in no future allocations of BinaxNOW Rapid Antigen Tests for COVID-19 for our EMS Agency. I also attest that our EMS Agency will follow all guidance providing by the Department of Public Health related to these tests, and all test results (positive, negative, inconclusive) will be reported to the Department of Public Health via electronic means and per the terms above within 24 hours of performing the test.

EMS Agency Name

Imagetrend Test 3 (New)

*As the Authorized Agent of the EMS Agency listed above, do you fully understand and agree to the terms and attestation statement above?

○ Yes
○ No

Submit

Signature

*As the Authorized Agent of the EMS Agency listed above, do you fully understand and agree to the terms and attestation statement above?

◉ Yes
○ No

You have indicated that you understand and agree with the terms above - please sign the attestation statement below.

*Authorized Agent Attestation Signature

Username: DNewton

Password:

After submitting this form, the Primary EMS Agency Medical Director will be notified that they need to come and sign the Medical Director Attestation form.

Submit

Medical Director gets an email

GEORGIA DEPARTMENT OF PUBLIC HEALTH

This email is being sent to the Primary Medical Director for the following EMS Agency:

Imagetrend Test 3 (New)

This email serves as notice that an Authorized Agent for the above EMS Agency has indicated that this agency is requesting to receive an allocation of BinaxNOW Rapid Antigen tests for COVID-19. This application requires the primary medical director to sign-off on the application.

To review and sign-off on the application:

1. Login to www.mygemsis.org/lms
2. Click on **Applications** on the left, and then on Review. You will see the application for **BinaxNOW Card for EMS Agencies.**
3. Click on **View PDF** to review the application that was submitted.
4. You will then need to click on the **Start** button next to the ***Medical Director Attestation for BinaxNOW*** form.
5. On the ***Medical Director Attestation for BinaxNOW*** form, you will be asked to approve or disapprove the agency's request for allocation.
6. Once you sign and Submit the form, the agency will be notified of your decision.

Should you have any questions, please contact the Office of EMS and Trauma at 770-996-3133

-Georgia Office of EMS and Trauma

Medical Director Reviews App and then clicks Start

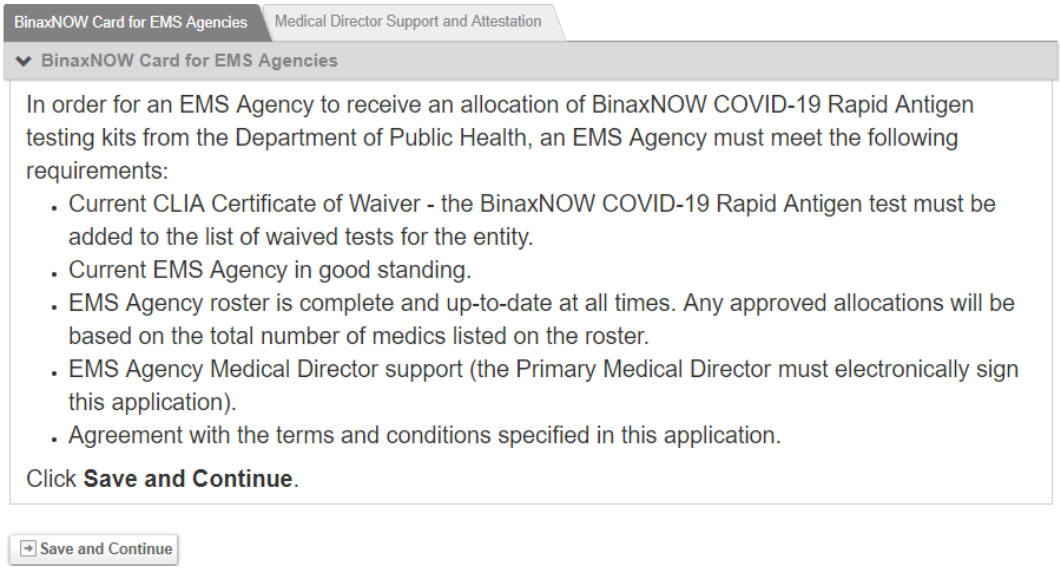
BinaxNOW Card for EMS Agencies - (Imagetrend Test 3 (New))

Status: Awaiting Medical Director Signature
Number: EMS2019006
Level(s): Air Ambulance, Ground Ambulance
Forms: 0 of 2 completed

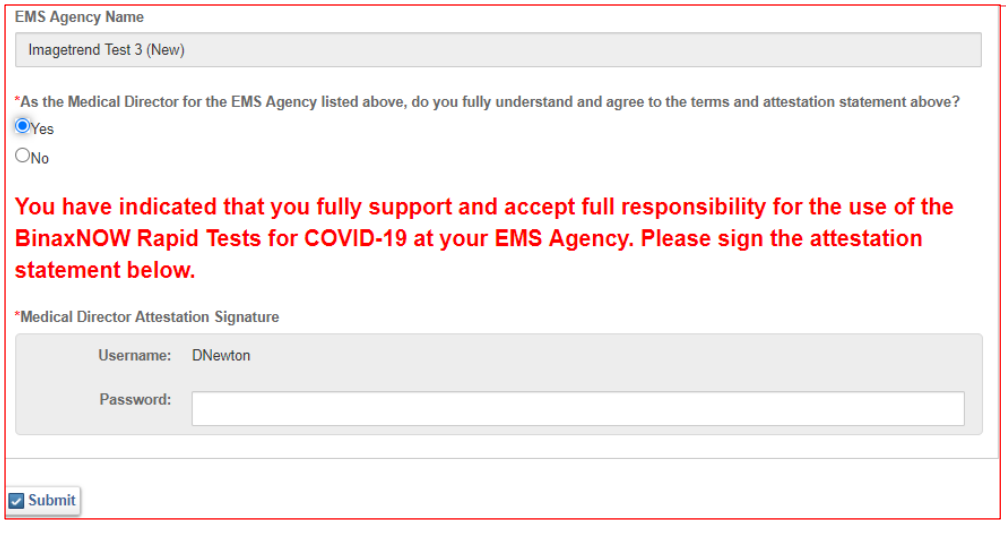
Initiated On: Oct 8, 2020
Issue Date:
Expiration Date:

Forms

Form	Requested	Completed	Action
BinaxNOW Card for EMS Agencies	Oct 8, 2020	Oct 8, 2020	View PDF
Medical Director Attestation for BinaxNOW	Oct 8, 2020		Start



Attestation



Next Steps

- OEMS will review your submitted information and accept or not accept.
- If accepted, DPH EP staff will contact you about allocations and where to ship the kits.
- Future allocations will be based on need, compliance with reporting, and available supply.

CMS Testing Requirements

CMS Testing Requirements

- Per HFRD, CMS clarified on a recent conference call that EMS personnel would not fall under the "routine" testing requirements of QSO 20-38-NH. EMS personnel should not be delayed access on the basis of testing. However, non-emergency transport, in most cases, will trigger the requirement as they are in the building on a more regular, scheduled basis.

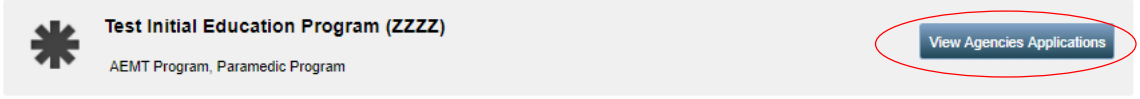
Schematron Updates

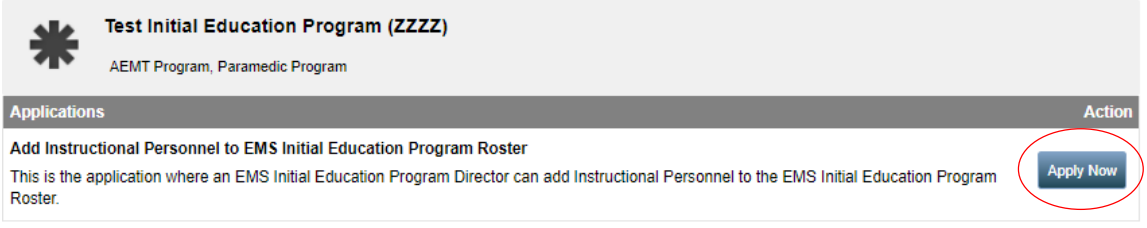
Schematron File has been corrected

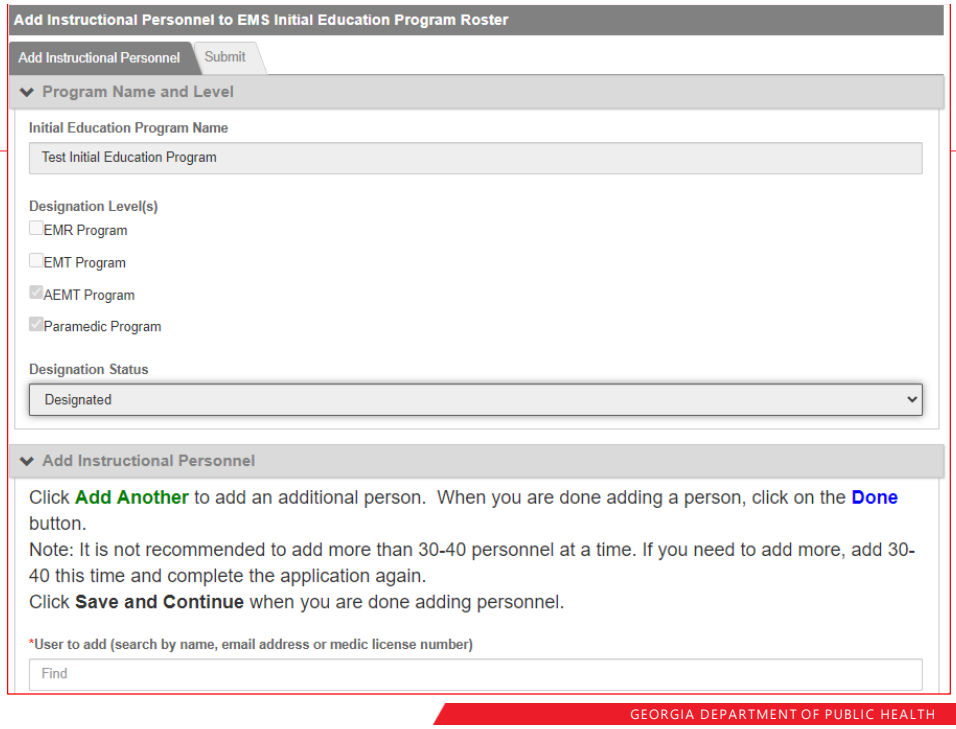
- Being sent to NEMSIS TAC today
- Email will be sent on Tuesday to all EMS Data Managers

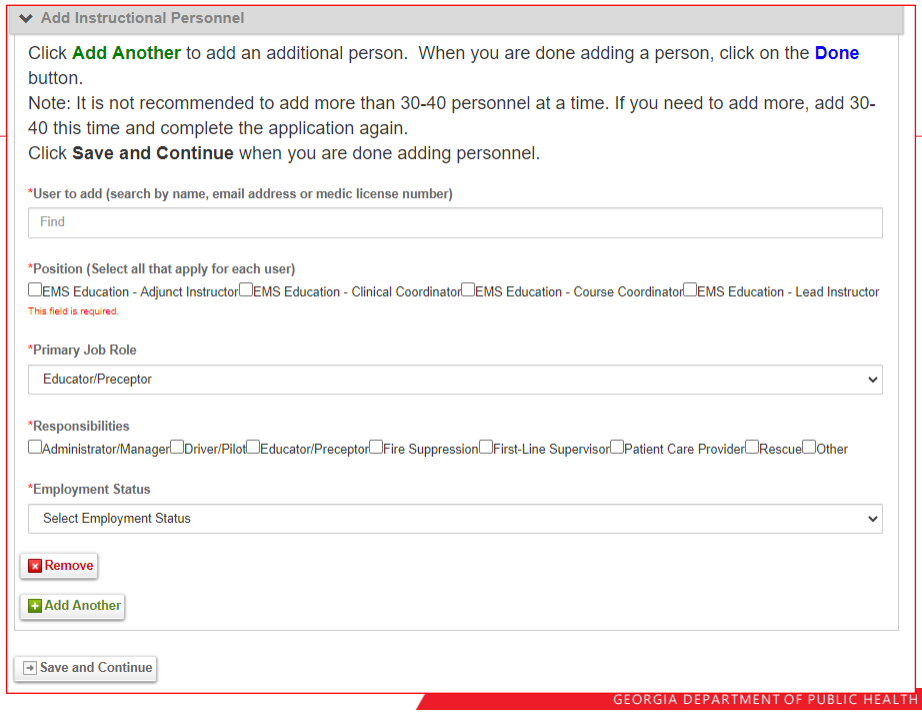
EMS Initial Education Programs

EMS Initial Education Program – Add Personnel
Click on Applications








Add Instructional Personnel
Click Add Another to add an additional person. When you are done adding a person, click on the Done button.
Note: It is not recommended to add more than 30-40 personnel at a time. If you need to add more, add 30-40 this time and complete the application again.
Click Save and Continue when you are done adding personnel.
*User to add (search by name, email address or medic license number)
Find
*Position (Select all that apply for each user)
EMS Education - Adjunct Instructor
EMS Education - Clinical Coordinator
EMS Education - Course Coordinator
EMS Education - Lead Instructor
This field is required.
*Primary Job Role
Educator/Preceptor
*Responsibilities
Administrator/Manager
Driver/Pilot
Educator/Preceptor
Fire Suppression
First-Line Supervisor
Patient Care Provider
Rescue
Other
*Employment Status
Select Employment Status
Remove
Add Another
Save and Continue

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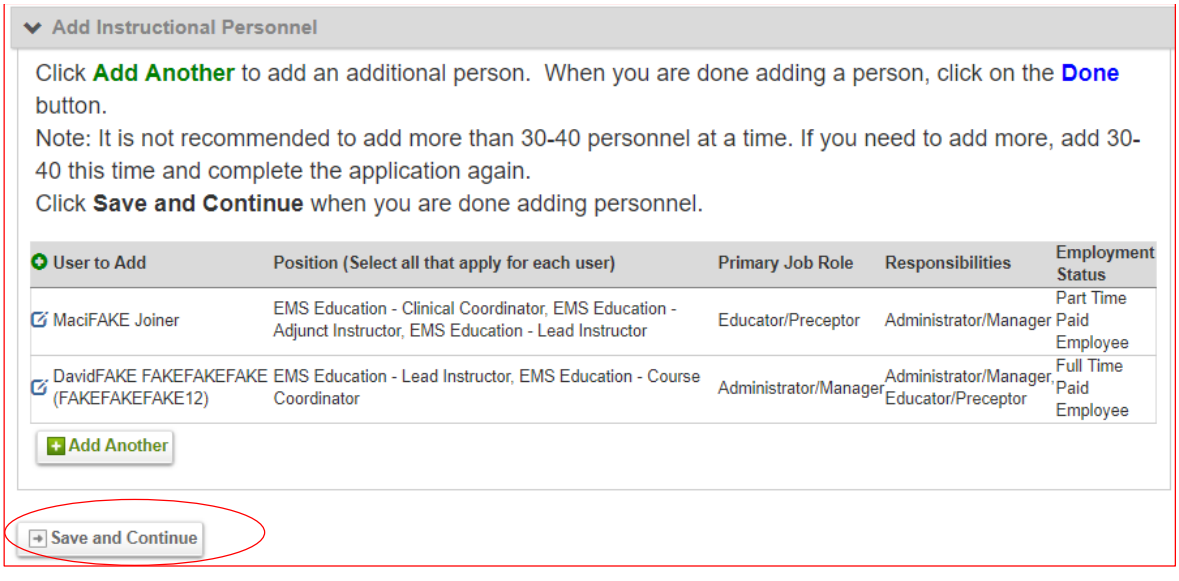
Add Instructional Personnel
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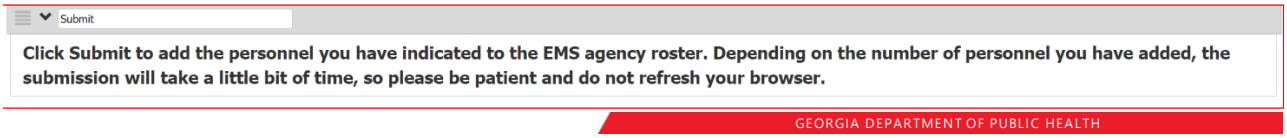
Note: It is not recommended to add more than 30-40 personnel at a time. If you need to add more, add 30-40 this time and complete the application again.
Click Save and Continue when you are done adding personnel.
User to Add
Position (Select all that apply for each user)
Primary Job Role
Responsibilities
Employment Status
MaciFAKE Joiner
EMS Education - Clinical Coordinator, EMS Education - Adjunct Instructor, EMS Education - Lead Instructor
Educator/Preceptor
Administrator/Manager
Part Time Paid Employee
DavidFAKE FAKEFAKEFAKE (FAKEFAKEFAKE12)
EMS Education - Lead Instructor, EMS Education - Course Coordinator
Administrator/Manager
Administrator/Manager, Educator/Preceptor
Full Time Paid Employee
Add Another
Save and Continue


Submit
Click Submit to add the personnel you have indicated to the EMS agency roster. Depending on the number of personnel you have added, the submission will take a little bit of time, so please be patient and do not refresh your browser.

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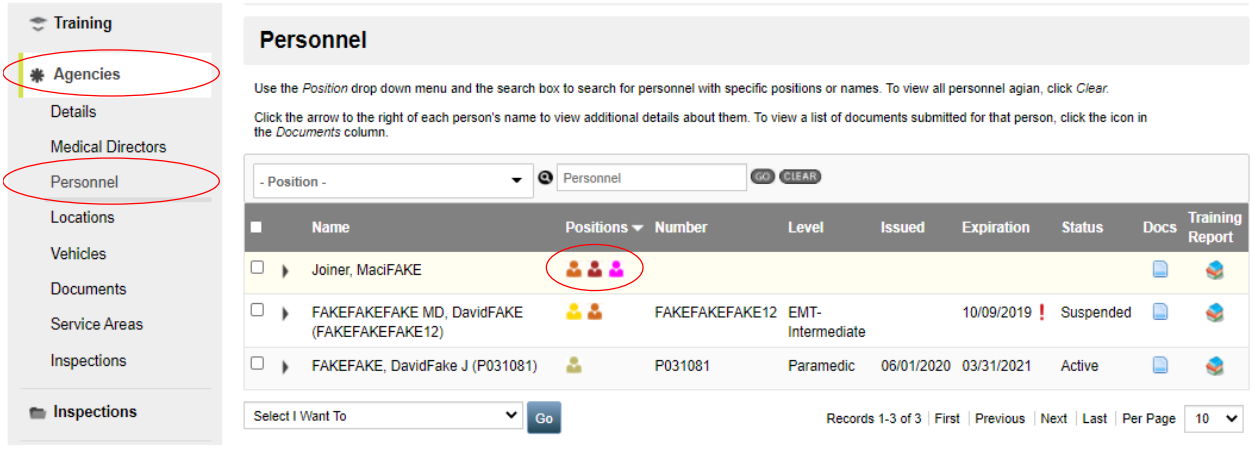
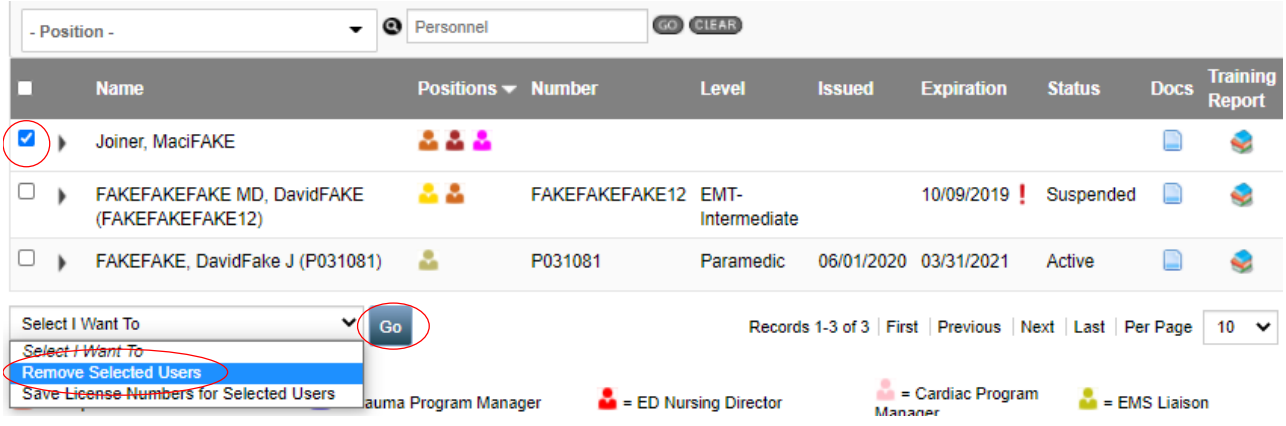
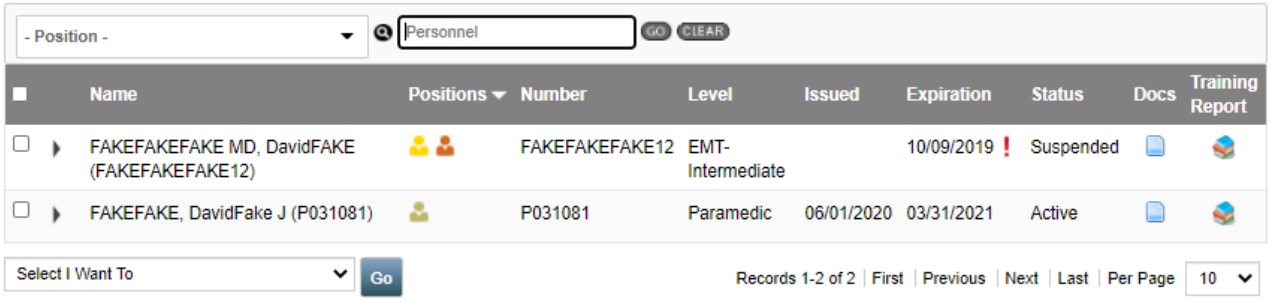


Removing Is Easier





Future OEMS Updates – Switching to Monthly in November 2020

- Next Meeting = Friday, 10/23/2020 @ 11am
- Subsequent meetings will be monthly unless more frequent meetings are needed…time for a poll!

Questions? And Open Discussion

Thanks for all that you do!

- Be safe
- Be prepared
- Watch your emails