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- There is NO excuse for having out-of-date rosters and NO excuse for saying “I didn’t know that medic had expired”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!

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<td><strong>TOTAL</strong></td>
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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
Cases Over Time (By date of onset)

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

Event Records by Event Date
Grouped by Incident State
2020-Mar-10 to 2020-Oct-08
03,741 Event Records

EMS COVID Resource Reporting Tool

PPE Availability

Personnel Shortage

COVID Exposure

No Personnel Shortage this Week
49

Personnel Shortage this Week
16
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 statute 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 1986, 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, NW, Suite 31-447
Atlanta, GA 30303-3142
Phone: (404) 657-3700
Fax: (404) 463-4398
Email: hfdl.diagnostics@dch.ga.gov

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 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 state 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 CMS 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.
Select Certificate of Waiver

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.
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
BinaxNOW™ COVID-19 Ag Card


- **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
Request Allocation on LMS

BinaxNOW Card for EMS Agencies

In order for an EMS Agency to receive an allocation of BinaxNOW COVID-19 Rapid Antigen testing kits from the Department of Public Health, an EMS Agency must meet the following requirements:

- Current CLIA Certificate of Waiver - the BinaxNOW COVID-19 Rapid Antigen test must be added to the list of waived tests for the entity.
- Current EMS Agency in good standing.
- EMS Agency roster is complete and up-to-date at all times. Any approved allocations will be based on the total number of medics listed on the roster.
- EMS Agency Medical Director support (the Primary Medical Director must electronically sign this application).
- Agreement with the terms and conditions specified in this application.

*Does your EMS Agency have a current CLIA Certificate of Waiver AND has the BinaxNOW Rapid Antigen Test for COVID-19 been added to your list of waived tests for your CLIA Certificate?

- Yes
- No
CLIA Certificate

*Please enter your CLIA Certificate Number

*Please enter your CLIA Certificate Expiration Date
[mm/dd/yyyy]  Today

*CLIA Certificate - Please upload as a PDF file.

Name
CLIA Certificate

Document Type
CLIA Certificate

POCs

If the request for BinaxNOW cards for this agency is approved, the Georgia Department of Public Health staff will coordinate delivery of the test kits with the EMS Agency designated Point of Contact (POC). Please provide the name and contact information for your EMS Agency POC for these tests and the EMS Agency POC for the data reporting requirements (this is not necessarily the EMS Data Manager - this POC for data reporting is for the COVID-19 tests, not the GEMSIS data).

EMS Agency POC for Test Kit Shipments

EMS Agency POC for Test Kit Shipments - Name

EMS Agency POC for Test Kit Shipments - Phone

EMS Agency POC for Test Kit Shipments - Email

EMS Agency POC for Data Reporting Requirements Related to BinaxNOW Rapid Antigen Test for COVID-19

EMS Agency POC for Data Reporting Requirements - Name

EMS Agency POC for Data Reporting Requirements - Phone

EMS Agency POC for Data Reporting Requirements - Email
Attestation

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

Inorganic 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

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

*Authorized Agent Attestation Signature

Username: DNavton

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

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

Imagetrack 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 BinxNOW 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.EMS210.org/ems
2. Click on Applications on the left, and then on Review. You will see the application for BinxNOW 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 BinxNOW form
5. On the Medical Director Attestation for BinxNOW 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 770-986-3133.

-Georgia Office of EMS and Trauma

Medical Director Reviews App and then clicks Start

![Screen shot of BinxNOW Card for EMS Agencies](image-url)

- Status: Awaiting Medical Director Signature
- Number: EMSS219006
- Level(s): Air Ambulance: Ground Ambulance
- Forms: 0 of 2 completed
- Initiated On: Oct 8, 2020
- Issue Date:
- Expiration Date:

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<td>Medical Director Attestation for BinxNOW</td>
<td>Oct 8, 2020</td>
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- EMS Agency Medical Director support (the Primary Medical Director must electronically sign this application).
- Agreement with the terms and conditions specified in this application.

Click Save and Continue.

**Attestation**

**EMS Agency Name**

*imagerend Test 3 (New)*

*As the Medical Director for 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 fully support and accept full responsibility for the use of the BinaxNOW Rapid Tests for COVID-19 at your EMS Agency. Please sign the attestation statement below.

*Medical Director Attestation Signature*

Username: DNewton
Password: [ ]

Submit
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

- 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 File has been corrected

- Being sent to NEMSIS TAC today
- Email will be sent on Tuesday to all EMS Data Managers
EMS Initial Education Program – Add Personnel

Click on Applications

Test Initial Education Program (ZZZZ)
AEMT Program, Paramedic Program

Add Instructional Personnel to EMS Initial Education Program Roster
This is the application where an EMS Initial Education Program Director can add Instructional Personnel to the EMS Initial Education Program Roster.

Add Instructional Personnel to EMS Initial Education Program Roster

- Initial Education Program Name
- Program Name and Level
- Designation Level(s)
- Designation Status

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)
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

Click **Add Another** to add an additional person. When you are done adding a person, click on the **Done** button.

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<th>Position (Select all that apply for each user)</th>
<th>Primary Job Role</th>
<th>Responsibilities</th>
<th>Employment Status</th>
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<tr>
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<td>EMS Education - Clinical Coordinator, EMS Education - Adjunct Instructor, EMS Education - Lead Instructor</td>
<td>Educator/Preceptor</td>
<td>Administrator/Manager</td>
<td>Part Time (Paid)</td>
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<tr>
<td>DavidFAKE FAKEFAKEFAKE (FAKEFAKEFAKE12)</td>
<td>EMS Education - Lead Instructor, EMS Education - Course Coordinator</td>
<td>Administrator/Manager</td>
<td>Administrator/Manager</td>
<td>Employee</td>
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</table>

- [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.
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