Navigating Coronavirus Series

Ask the Experts
September 29, 2020
This webinar series brought to you by

NORTH CAROLINA AHEC

COMMUNITY CARE PHYSICIAN NETWORK

NCAFP

NORTH CAROLINA Psychiatric Association

North Carolina Pediatric Society State Chapter of the American Academy of Pediatrics

Community Care of North Carolina
Today’s Emcees

- **Hugh Tilson**, JD, director of the North Carolina Area Health Education Centers (NC AHEC) Program

- **Tom Wroth**, M.D. MPH, president and CEO of Community Care of North Carolina (CCNC)
Today’s Presenters

- **Infectious diseases:** Ibukun C Akinboyo, M.D.
  Medical Director of Pediatric Infection Prevention, Duke University Hospital

- **Mental health:** Carrie Brown, M.D., MPH
  Chief Medical Officer, Behavioral Health, NCDHHS

- **Testing:** “Chip” Watkins, M.D., MPH, FAAFP
  Regional Medical Director, Community Care of North Carolina
COVID-19 in Children - Updates
Ibukun Akinboyo, M.D.
Assistant Professor
Pediatric Infection Prevention Medical Director
Duke University Hospital
Objectives

- Review updated COVID-19 epidemiology
- Summarize concerns about COVID-19 and Influenza
- Discuss approach to disseminating evidence and supporting public education
Cumulative Number of Child COVID-19 Cases: 9/24/20

- 624,890 total child COVID-19 cases (cumulative)
- Twenty-one states reported 10,000+ child cases
- Four states reported fewer than 1,000 child cases

See details in Appendix: Data from 48 states, NYC, DC, PR, and GU (TX excluded from figure)
All data reported by state/local health departments are preliminary and subject to change
Analysis by American Academy of Pediatrics and Children’s Hospital Association
Possible Case of Vertical Transmission of SARS-CoV-2

- In Newborn with Positive Placental In Situ Hybridization of SARS-CoV-2 RNA.

- 32 yo G2P0 at 35.6WGA had contractions and bleeding
  - Also with fevers, chills, fatigue, anosmia & dysgeusia
  - Partner worked as RT in ICU. Asymptomatic (-ve)

- Mother (+ve); Infant (+ve) at 24 and 48 HOL & 7D

- Mother masked during infant care.
  - Infant roomed in (isolette). Formula and breastfeeding

Alamar I. et al., JPIDS, 2020
Possible Case of Vertical Transmission of SARS-CoV-2

Placenta path showed:
- No inflammation
- Central infarct– bleeding placenta previa, fetal placental vascular rupture, villous necrosis
- Increased CD68

Alamar I. et al., JPIDS, 2020
A Case of Early Re-infection with SARS-CoV-2

Larson D. Brodniak SL. *Clinical Infectious Diseases*. 2020
COVID-19 and Influenza: Australia experience

Number of specimens tested and percentage testing positive for influenza, by year, using weeks 14 – 31

CDC. MMWR. Vol 69. 2020
COVID-19 & Influenza: Experience in South Africa

Number of specimens tested and percentage testing positive for influenza, by year, using weeks 14 – 31

CDC. MMWR. Vol 69. 2020
Are we heading into the “twin-demic” with COVID-19 and Influenza?

- COVID-19 and influenza have similar symptoms
- Efforts to curb COVID-19 may also curb influenza
- There are safe and available vaccines to prevent the flu
- There are approved flu antivirals
- Experience in the southern hemisphere suggests milder influenza season
We already mandate several vaccines
Strategies to reopen schools or keep them open may be predicated on this
The reproduction number $[R_0]$ is approximately 1 for the influenza virus but for SARS-CoV-2, the $R_0$ is 2 - 2.5
Is there evidence that a COVID-19 vaccine is safe for children with an acceptable level of risk?
Should We Mandate a COVID-19 Vaccine for Children?

Douglas J. Opel, MD, MPH\(^1\); Douglas S. Diekema, MD, MPH\(^1\); Lainie Friedman Ross, MD, PhD\(^2,3\)

Box. Criteria to Consider When Evaluating Antigens for Inclusion in Mandatory School Immunization Programs

1. *Vaccine related*: Experience to date with the vaccine containing this antigen indicates that it is safe and has an acceptable level of adverse effects.

2. *Vaccine related*: The antigen is effective as measured by immunogenicity and population-based prevention.

3. *Vaccine related*: The vaccine containing this antigen is as cost-effective from a societal perspective as other vaccines used to prevent disease.

4. *Vaccine related*: The vaccine containing this antigen should bear some relationship to increasing safety in the school environment.
Should We Mandate a COVID-19 Vaccine for Children?

Douglas J. Opel, MD, MPH\(^1\); Douglas S. Diekema, MD, MPH\(^1\); Lainie Friedman Ross, MD, PhD\(^2,3\)

Box. Criteria to Consider When Evaluating Antigens for Inclusion in Mandatory School Immunization Programs

5. *Disease related:* The vaccine containing this antigen prevents disease(s) with significant morbidity and/or mortality in at least some subset of the population.\(^a\)

6. *Disease related:* Vaccinating the infant, child, or adolescent against this disease reduces the risk of person-to-person transmission.\(^b\)

7. *Implementation related:* The vaccine is acceptable to the medical community and the public.

8. *Implementation related:* The administrative burdens of delivery and tracking of vaccine containing this antigen(s) are reasonable.

9. *Implementation related:* The burden of adherence for the vaccine containing this antigen is reasonable for the parent/caregiver.
The ABC Science Collaborative

Uniting science and schools for a data-driven solution to decision making and implementation
Proposed solution: A data-driven approach to support decision making

- Initiate a direct-to-family and community-engaged approach
- Promote existing guidance from state and local health departments, provide data, and interpret emerging scientific evidence to keep children, teachers, and the community healthy and safe during the COVID-19 pandemic.
- Deploy a three-tier approach
  - Educational outreach
  - Data to support decisions
  - Targeted research opportunities
Aim 1: Educational outreach

- Provide school administrators, teachers, staff, and parents access to real-time, data-driven information about COVID-19.
- Collect, synthesize, and interpret available data in collaboration with educational leaders.
- Cultivate trust and facilitate the delivery of culturally appropriate information and support to educational leaders and the school communities.
- Communicate in layperson terms to help build trust.
- Lead with empathy and commitment to children’s health.

DELIVERABLES

- **Webinars** for parents, administrators, teachers and staff
- **Newsletter content** for districts to share with teachers and staff
- Newsletter content for districts to share with families
- **Information included on public-facing website**, including an interactive map where communities can drill down to local data sets
Aim 2: Data to support school-specific decisions

- Provide weekly, customized, data-driven information to school administrators in pre-identified districts.
  - Person-level data derived from members of the school district, as well as data about rates of disease in the local, state, and national communities
- Provide detailed information about potential consequences of actions.
  - Discuss and assess possible scenarios under consideration by school leaders.
- Support for implementation of local public health guidance

**DELIVERABLES**

- Initially **identify and partner** with local and national school districts
- Establishment of **teams** to deliver prepared customized scorecards
- **Data “dashboards”** at the individual school district level
- Collection and summary of **up-to-date district-level data** if available, including de-identified comparison to other districts and characteristics of those districts
- **Customized risk assessments** with scenario modeling using district-specific data
- **Assessment of local impact** from best practices related to public health practice
Potential structure

THE ABC Science Collaborative members include scientists and clinicians with broad expertise across the life span.

SCHOOL BOARD

PROJECT LEADER
organizes meetings, minutes, timelines

DATA MANAGER
assembles data, organizes presentation to advisory team

Emerging research data
School system data
County data
State & USA data

Media & government data

State & USA data
Emerging research data
School system data
County data
Media & government data

Navigating COVID-19 Webinar Series
Program leadership team

COVID-related research experience, sponsored by NIH, and led by the team. For each project, a team member is the National Principal Investigator (PI)

Kanecia Zimmerman, MD
Co-chair
Associate Professor, Critical Care
2 children, Durham

Danny Benjamin, MD, PhD
Co-chair
Distinguished Professor, Epidemiology Therapeutics
4 children, CHCCS/college

Ibukun Akinboyo, MD
Assistant Professor,
Infectious Disease
No school-aged children

Gabriela Maradiaga Panayotti, MD
Assistant Professor, Primary Care, Latinx advocacy
2 children, Durham

Micky Cohen-Wolkowez, MD, PhD
Distinguished Professor, Infectious Disease
2 children, Durham

David Weber, MD, MPH
Assistant Chief Medical Officer
UNC Health Care
COVID-19: Managing Stress Today and Tomorrow

Carrie L. Brown, MD, MPH
Chief Medical Officer for Behavioral Health & IDD
North Carolina Department of Health and Human Services

Navigating COVID-19
September 29, 2020
“Daily news of large-scale COVID19 related disease and death in the community over months or years is almost certain to elevate psychiatric burden in the population. As such, the pattern of stress resembles that experienced by refugees or others exposed to chronic violence, rather than acute disasters like the September 11th terrorist attacks.”

-Dost Ongur et al. JAMA Vol 324, #12
NC Behavioral Health Impacts of COVID-19

• **Anxiety & Depression**
  - Existing unmet need: 1.5 million North Carolinians 18+ have a mental illness in a given year - 1 in 5 don’t receive care or treatment
  - Three-fold increase in reported symptoms of depression and/or anxiety disorders – 1 in 3, up from 1 in 9.
  - Younger cohorts (18-29) report higher prevalence of anxiety and depression, while prevalence among racial groups is relatively consistent.

• **Substance Use – Alcohol & Opioids**
  - Existing unmet need: 8 out of 9 North Carolinians with SUD don’t received treatment in a specialized SUD treatment facility
  - Liquor sales in North Carolina increased 12% in State Fiscal Year 2019-20
  - Recent nationwide survey found 1 in 4 respondents reported binge drinking at least once (up from 1 in 6)
  - In 2020, while NC experienced a 12% decrease in overall Emergency Department visits, we have seen a 19% increase in Medical/Drug Overdose ED visits – largely driven by a 21% increase in opioid overdose ED visits.

• **Suicide**
  - For every five-percentage point increase in the rate of unemployment, an additional 304 North Carolinians would be expected to die each year from suicide (126) and drug overdose (178).
Targeted Interventions

$116 M in funding from the CARES Act and $3.5 M from other federal sources have been allocated to address emerging issues – crisis, prevalence of specific disease, etc. -- targeted toward specific populations. These efforts are designed to leverage other programs for a coordinated response that drives systemic change.

<table>
<thead>
<tr>
<th>A. Congregant Care Settings</th>
<th>$17.6 M</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 months of temporary funding to support increased staffing and care costs at residential facilities and group homes</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>B. Managing Crisis, tying into Hope4NC and other programs</th>
<th>$13.5 M</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 months of community-based services and peer-warmline to stabilize crisis and reduce emergency department visits</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>C. Increased State Funded Services for Underinsured</th>
<th>$88 M</th>
</tr>
</thead>
<tbody>
<tr>
<td>15% increase of mental health and substance use services due to increased need or loss of health insurance</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>D. Substance Use Disorder - Prevention</th>
<th>$400K (+ $1.6M)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doses of naloxone for increased risk of accidental overdose stemming from both modified services and broader drivers</td>
<td></td>
</tr>
</tbody>
</table>
Evidence Based Behavioral Health Messaging Aimed at Prevention

The SCOOP on Managing Stress

S - Stay connected to family and friends.
   Social connections build resiliency.

C - Compassion for yourself and others.
   Self-compassion decreases trauma symptoms and stress.

O - Observe your use of substances.
   Early intervention can prevent problems.

O - Ok to ask for help.
   Struggling is normal. Asking for help is empowering.

P - Physical activity to improve your mood.
   Exercise boosts mood and lowers anxiety.

HOPE 4 NC HELPLINE 1-855-587-3463
Awareness, Managing Crisis, Building Resiliency

- **Hope4NC (1-855-587-3463)**
  - The Hope4NC Helpline connects North Carolinians to mental health and resilience supports
  - Available statewide, 24 hours a day, seven days a week during the COVID-19 crisis
  - Hope4NC includes a Crisis Counseling Program tailored for COVID-19, which will provide immediate crisis counseling services to individuals affected by the ongoing COVID-19 public health crisis.

- **Hope4Healers Helpline (919-226-2002)**
  - Partnership with the North Carolina Psychological Foundation
  - Provides mental health and resilience supports for health care professionals, emergency medical specialists, first responders, other staff who work in health care settings who are experiencing stress from being on the front lines of the state's COVID-19 response
  - Available 24 hours per day, seven days a week, staffed by licensed mental health professional for follow-up
CONTACT

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North Carolina Department of Health and Human Services
Phone: (984) 236-5011
Carrie.Brown@dhhs.nc.gov
COVID-19 Testing Update
R.W. “Chip” Watkins, M.D., MPH, FAAFP
Regional Medical Director, Community Care of North Carolina
Bio Page

- 3 years Medical Director – Genova Diagnostics, Asheville, NC
- 12 years CMO – NeuroLab, Inc., Asheville, NC
- 5 years AAFP appointee COLA Board of Directors
- Physician Member – CDC’s CLIAC (Clinical Laboratory Improvement Advisory Committee)
- COVID-19 Testing: Fundamentals & Application to Practice Webinar for AAFP (can get AAFP CME credit if member) – on CCPN website under Webinars for Providers
“You cannot fight a fire blindfolded. And we cannot stop this pandemic if we don’t know who is infected.”

World Health Organization Director-General

16 March 2020
Let’s Look at the Virus Time Course

![Graph showing the virus time course]

- **Window Period**
- **Decline**
- **Convalescence**

- Exposure
- Asymptomatic Stage
- Onset of symptoms
- IgM becomes detectable
- IgG production begins
- IgM disappears
- Patient begins to recover

**SARS-CoV-2 RNA and Antigen**
- **IgM antibody**
- **IgG antibody**

*IgG remains in blood and provides long-term immunity*

*Disclaimer: this chart is for illustrative purposes only*

Diazyme:MK 244 Rev.A
Testing Resources from CCNC/CCPN

- NCDHHS Provider Guidance on SARS-CoV-2 Testing
  - https://www.communitycarenc.org/provider-guide-to-sars-cov-2-testing
- Point of Care COVID-19 Testing: Guidance for Practicing Physicians
Let’s Take a More In-depth Look at the Tests
Diagnostic Testing

Testing Modalities

- Molecular (RT-PCR) tests that detect the virus’s genetic material (RNA)
- Antigen tests that detect specific proteins on the surface of the virus
- Diagnostic tests should be used when active viral infection is suspected, either because the patient is symptomatic and/or they have been in close contact (within 6 feet for 15 minutes or more) with someone with confirmed COVID-19 diagnosis, regardless of symptoms.
Here are the 5 PCR (Molecular) Tests that can be run in Labs that have a Certificate of Waiver.
Diagnostic Testing – Molecular

1. **Xpert Xpress SARS-CoV-2** test

   - Uses NP and nasal swabs. The test detects the current pandemic coronavirus SARS-CoV-2 in as soon as 30 minutes for positive results* with less than a minute of hands on time to prepare the sample.
   - Sensitivity 100%
   - 30/30 “spiked” samples

The ** denotes a test system that is portable and can be used outside the clinical laboratory like mobile, nursing homes, or temporary sites like a drive thru or health fair.
Diagnostic Testing – Molecular

2. Accula SARS-CoV-2 Test (Mesa Biotech Inc.): Using throat and nasal swabs, results are available in 30 minutes. Thirty (30) negative samples and 30 positive contrived samples were tested with the Accula SARS-CoV-2 Test. Positives were “spiked” samples of the negative samples collected from patients under IRB. Sensitivity 100%, Specificity 99.8%

The ** denotes a test system that is portable and can be used outside the clinical laboratory like mobile, nursing homes, or temporary sites like a drive thru or health fair.
Diagnostic Testing – Molecular

3. ID NOW COVID-19-PCR (Abbott Diagnostics Scarborough, Inc.): This testing platform can deliver a POSITIVE test result in 5 minutes and NEGATIVE test results in 13 minutes targeting the coronavirus (COVID-19) RdRp Gene. Direct sample types include: Nasal, Throat, and Nasopharyngeal swabs. Urgent care clinic study shows ID NOW test performance of ≥94.7% positive percent agreement (sensitivity) and ≥98.6% negative percent agreement (specificity) compared to lab-based PCR reference tests. The ** denotes a test system that is portable and can be used outside the clinical laboratory like mobile, nursing homes, or temporary sites like a drive thru or health fair.
Diagnostic Testing – Molecular

Cue COVID-19 Test – PCR (Cue Health Inc.) (waived, moderate and high complexity laboratories): The test is run using the Cue Health Monitoring System (Cue Cartridge Reader), the Cue COVID-19 Test Cartridge, the Cue Sample Wand, and the Cue Health App on the Apple® iPhone® 8+ or newer mobile smart device with iOS 13 (or higher).

Clinical Evaluation: The Cue COVID-19 Test was also evaluated with 45 frozen nasopharyngeal swab samples collected from patients suspected of SARS-CoV-2 infection and transported in viral transport media. The Cue COVID-19 Test result was positive for 100% of the 45 samples. They also tested 60 negative patient samples and spiked 30 of these with SARS-CoV-2. They were 30/30 on the negatives and were in agreement with expected results was ≥ 95% on the positives.
5. Cobas SARS-CoV-2 & Influenza A/B Nucleic Acid Test (Roche Molecular Systems, Inc.). (waived, moderate and high complexity laboratories) To be used with the cobas® Liat® Analyzer (P/N 07341920190) Including cobas® Liat® System Software (Core) Version 3.2 or higher and cobas® SARS CoV-2 & Influenza A/B Assay Script v1.0 or higher.

Just got EUA approval on September 14, 2020
### Table 22: Comparison of cobas® Liat® and RealTime PCR System

<table>
<thead>
<tr>
<th>Virus</th>
<th>Number of Samples</th>
<th>Percent Agreement (%)</th>
<th>95% CI (LCL, UCL)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>SARS-CoV-2*</td>
<td>36</td>
<td>96.4%</td>
<td>(87.7%, 99.0%)</td>
</tr>
<tr>
<td>Influenza A</td>
<td>36</td>
<td>98.0%</td>
<td>(95.6%, 99.1%)</td>
</tr>
<tr>
<td>Influenza B</td>
<td>30</td>
<td>100.0%</td>
<td>(94.0%, 100.0%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>99.6%</td>
<td>(98.0%, 99.9%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>100.0%</td>
<td>(90.6%, 100.0%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>99.7%</td>
<td>(98.2%, 99.9%)</td>
</tr>
</tbody>
</table>
Here are the 4 Antigen Tests that can be run in Labs that have a Certificate of Waiver
Diagnostic Testing – Antigen

1. Sofia 2 SARS Antigen FIA (Quidel Corporation) (waived, moderate and high complexity laboratories) using the Sofia 2 instrument. The assay demonstrated acceptable clinical sensitivity (80%) when compared to an EUA molecular device. The assay demonstrated excellent clinical specificity (100%). There was no demonstrable cross-reactivity with seventy-nine (79) specimens containing seasonal CoVs detected by the BioFire® FilmArray® Respiratory Panel.

July 17, 2020 Quidel updated the performance data for its Sofia® SARS Antigen FIA test on its package insert to 96.7% PPA using direct nasal swab specimens versus PCR as a result of further studies included in its amended Emergency Use Authorization (EUA) that were submitted to the U.S. Food and Drug Administration (FDA).
Diagnostic Testing – Antigen

BD Veritor System for Rapid Detection of SARS-CoV-2 (Becton Dickinson and Company [BD]) (waived, moderate, and high complexity laboratories) using the BD Veritor™ Plus Analyzer. BD clinical studies performed at more than 20 sites across the U.S. demonstrated that the test is capable of achieving 84% sensitivity and 100% specificity. Like all immunoassay tests, FDA recommends that negative test results be confirmed by a molecular method to confirm the result, if necessary, for patient management.
Diagnostic Testing – Antigen

- Lumira SARS-CoV-2 Ag Test (LumiraDX UK Ltd.) using the LumiraDx Instrument. This test combines a single use fluorescence immunoassay device with an instrument to provide a result within 12 minutes. That is roughly in line with Quidel and BD turnaround times. The test is touting 98% sensitivity and 97% specificity in pre-market analysis. NP swab.
Diagnostic Testing – Antigen

BinaxNow™ COVID-19 Ag Card (Abbott Diagnostics Scarborough, Inc.): (waived, moderate, and high complexity laboratories) Direct read card test. Simple test procedure using a direct nasal swab. Direct nasal swabs from individuals suspected of COVID-19 by their healthcare provider within the first seven days of symptom onset. Onboard extraction allows the swab to be directly inserted into the test card. Room temperature storage. Visually read results in 15 minutes—no instrument required. 97% sensitivity and 98.5% specificity in pre-market analysis.
Happy Thanksgiving!!
Antibody Testing

- Antibody tests should not be used to diagnose SARS-CoV-2 and cannot determine a person’s immunity to reinfection with SARS-CoV-2 and should not be used as an “immunity voucher” for work or daycare in an attempt to assure the safety of individuals.
Antibody Testing

On September 23rd, the U.S. Food and Drug Administration issued an emergency use authorization (EUA) for the first serology (antibody) point-of-care (POC) test for COVID-19.

The Assure COVID-19 IgG/IgM Rapid Test Device got an EUA in July 2020 to help identify individuals with antibodies to SARS-CoV-2.

That EUA is being reissued to authorize the test for POC use using fingerstick blood samples. This authorization means that fingerstick blood samples can now be tested in POC settings like doctor’s offices, hospitals, urgent care centers and emergency rooms rather than having to be sent to a central lab for testing.

Interpretation of Results:

A test is positive if Control Line (A) appears together with any of the two test lines.
Antibody Testing – Assure COVID-19 IgG/IgM Rapid Test Device

- Total of 42 positive and 113 negative fingerstick whole blood samples were collected and tested at 3 different POC sites. These samples were tested with both RT-PCR method for SARS-CoV-2 infection and Assure COVID-19 IgG/IgM Rapid Test device for antibodies. The PPA/sensitivity and NPA/specificity results are summarized in following tables.

<table>
<thead>
<tr>
<th>Site</th>
<th>Days from symptom</th>
<th># PCR Positive</th>
<th>IgG (Assure Device)</th>
<th>IgM (Assure Device)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Antibody Positive</td>
<td>PPA</td>
</tr>
<tr>
<td>Site 1+2+3</td>
<td>0-7 days</td>
<td>2</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td></td>
<td>8-14 days</td>
<td>12</td>
<td>10</td>
<td>83.3%</td>
</tr>
<tr>
<td></td>
<td>≥15 days</td>
<td>28</td>
<td>28</td>
<td>100%</td>
</tr>
</tbody>
</table>
Recent Guidance from CMS/AMA and NCDHHS on Antigen Testing


- NC Medicaid is adding the following code into NCTracks for medically necessary laboratory testing effective Sept. 1, 2020, as follows:
Recent Guidance from CMS/AMA and NCDHHS on Antigen Testing

- CPT 87426-Infectious agent antigen detection by immunoassay technique (e.g., enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative, multiple-step method; severe acute respiratory syndrome coronavirus (e.g., SARS-CoV, SARS-CoV-2 [COVID-19]).
Recent Guidance from CMS/AMA and NCDHHS on Antigen Testing

- **Positive** antigen tests should be considered an indication of likely SARS-CoV-2 infection, especially when pretest probability is high.

- **Negative** antigen test results should be considered in the context of a patient’s recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19, and confirmed with an FDA-authorized molecular assay, if necessary, for patient management.
Recent Guidance from CMS/AMA and NCDHHS on Antigen Testing

- All positive and negative antigen results must be reported as part of the required reporting of COVID-19 diagnostic tests. The methods of reporting for antigen tests are the same as for PCR tests.
- Guidance on Reporting can be found here:
Questions?