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Community Care OF NORTH CAROLINA

Navigating Coronavirus Series

Ask the Experts
September 29, 2020

1

This webinar series brought to you by

NORTH CAROLINA AHEC

COMMUNITY CARE PHYSICIAN NETWORK

NCAFP NORTH CAROLINA ACADEMY OF FAMILY PHYSICIANS

NORTH CAROLINA Psychiatric Association

ncpeds North Carolina Pediatric Society

Community Care OF NORTH CAROLINA

Navigating COVID-19 Webinar Series 2

2

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)

3

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

4

Logistics for today's COVID-19 Forum

Question during the live webinar

Technical assistance

technicalassistanceCOVID19@gmail.com

https://www.communitycarenc.org/newsroom/coronavirus-covid-19-information

5

COVID-19 in Children - Updates

Ibukun Akinboyo, M.D.
Assistant Professor
Pediatric Infection Prevention Medical Director
Duke University Hospital

6

6

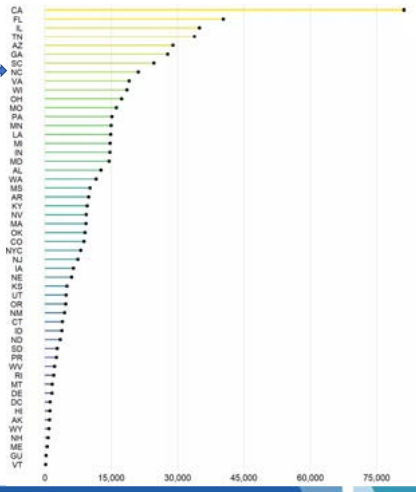
Objectives

- Review updated COVID-19 epidemiology
- Summarize concerns about COVID-19 and Influenza
- Discuss approach to disseminating evidence and supporting public education

7

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 detail 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

Children's Hospital Association · American Academy of Pediatrics

8

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

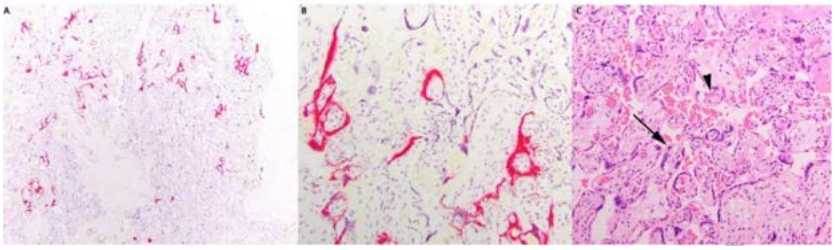
Alamar I. et al., *JPIDS*, 2020

9

Possible Case of Vertical Transmission of SARS-CoV-2

Placenta path showed:

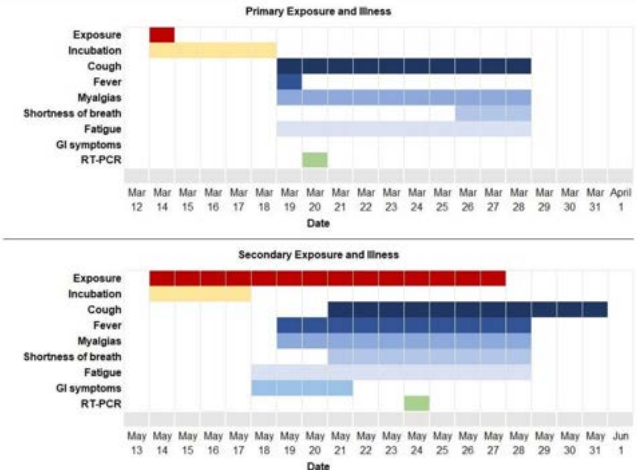
- No inflammation
- Central infarct– bleeding placenta previa, fetal placental vascular rupture, villous necrosis
- Increased CD68



Alamar I. et al., *JPIDS*, 2020

10

A Case of Early Re-infection with SARS-CoV-2

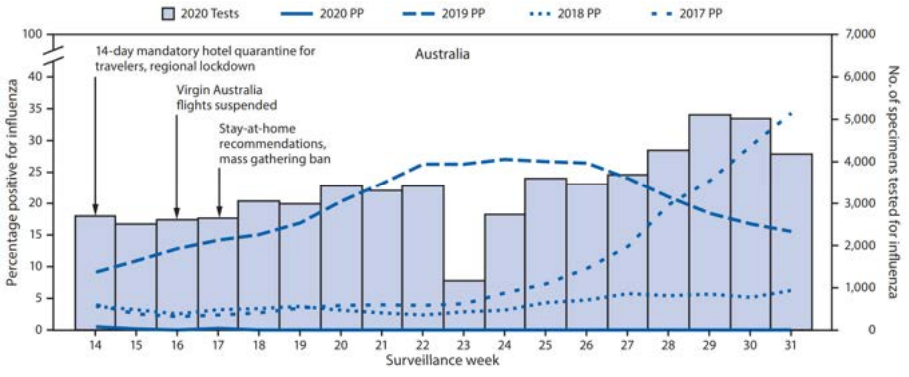


Larson D. Brodniak SL. *Clinical Infectious Diseases*. 2020

11

COVID-19 and Influenza: Australia experience

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

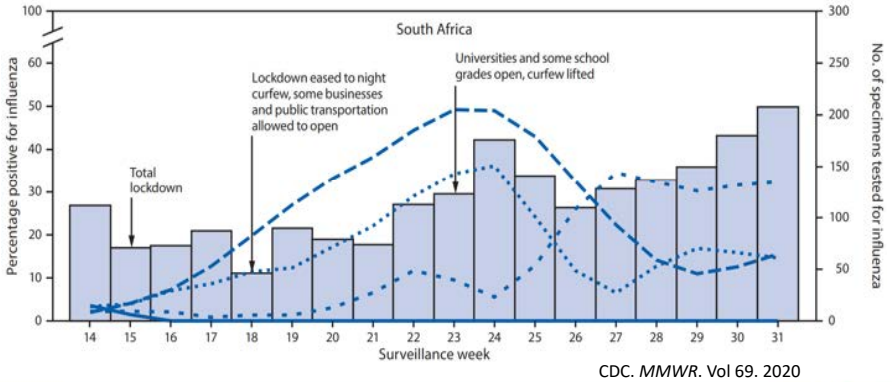


CDC. *MMWR*. Vol 69. 2020

12

COVID-19 & Influenza: Experience in South Africa

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

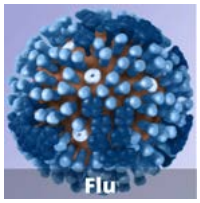


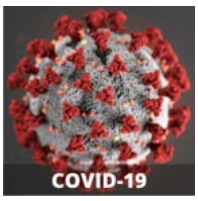
CDC. *MMWR*. Vol 69. 2020

13

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





14

Viewpoint

September 14, 2020

Should We Mandate a COVID-19 Vaccine for Children?

JAMA Pediatrics

Douglas J. Opel, MD, MPH[1]; Douglas S. Diekema, MD, MPH[1]; Lainie Friedman Ross, MD, PhD[2,3]

- 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?

15

Viewpoint

September 14, 2020

Should We Mandate a COVID-19 Vaccine for Children?

JAMA Pediatrics

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.

16

Viewpoint

September 14, 2020

Should We Mandate a COVID-19 Vaccine for Children?

JAMA Pediatrics

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.

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17

The ABC Science Collaborative

Uniting science and schools for a data-driven solution to decision making and implementation

THE ABC SCIENCE COLLABORATIVE

Learning | Informed Decision-Making | Research

18

18

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

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19

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

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20

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

THE ABC SCIENCE COLLABORATIVE

21

Potential structure

Project Leader organizes meetings, minutes, timelines

Data Manager assembles data, organizes presentation to advisory team

SCHOOL BOARD

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

THE ABC SCIENCE COLLABORATIVE

22

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-Wolkoweiz, MD, PhD
Distinguished Professor,
Infectious Disease
2 children, Durham

David Weber, MD, MPH
Assistant Chief Medical Officer
UNC Health Care

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23

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

24

"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

25

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).

26

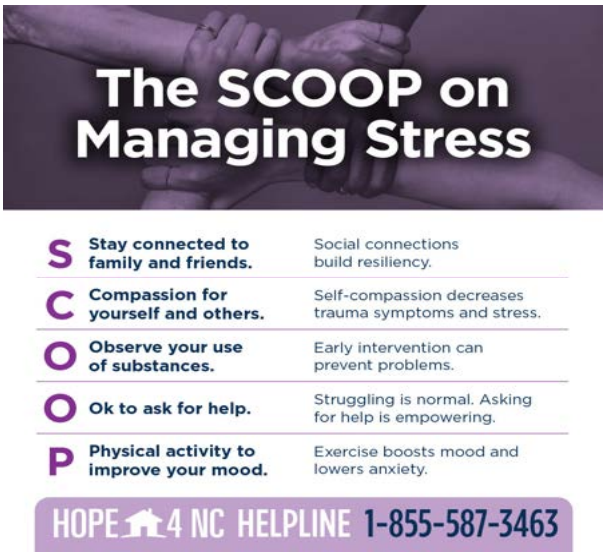
Targeted Interventions

$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.

A. Congregant Care Settings 3 months of temporary funding to support increased staffing and care costs at residential facilities and group homes	$17.6 M
B. Managing Crisis, tying into Hope4NC and other programs 6 months of community-based services and peer-warmline to stabilize crisis and reduce emergency department visits	$13.5 M
C. Increased State Funded Services for Underinsured 15% increase of mental health and substance use services due to increased need or loss of health insurance	$88 M
D. Substance Use Disorder - Prevention Doses of naloxone for increased risk of accidental overdose stemming from both modified services and broader drivers	$400K (+ $1.6M)

27

Evidence Based Behavioral Health Messaging Aimed at Prevention



28

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

29

CONTACT

Carrie L. Brown, MD, MPH

Chief Medical Officer for Behavioral Health & IDD

North Carolina Department of Health and Human Services

Phone: (984) 236-5011

Carrie.Brown@dhhs.nc.gov

30

COVID-19 Testing Update

R.W. "Chip" Watkins, M.D., MPH, FAAFP
Regional Medical Director, Community Care of North Carolina

31

31

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

32

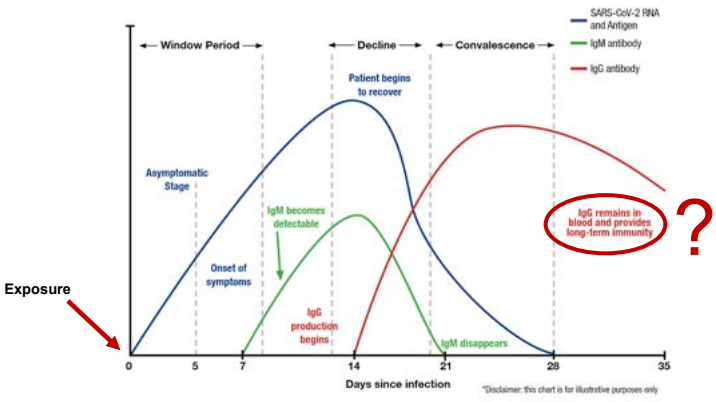
"You cannot fight a fire blindfolded. And we cannot stop this pandemic if we don't know who is infected."

World Health Organization Director-General

16 March 2020

33

Let's Look at the Virus Time Course



Diazyme:MK 244 Rev.A

34

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
- https://www.communitycarenc.org/point-of-care-covid-19-testing

35

Let's Take a More In-depth Look at the Tests

Community Care OF NORTH CAROLINA

36

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.

37

Here are the 5 PCR (Molecular) Tests that can be run in Labs that have a Certificate of Waiver

38

Diagnostic Testing – Molecular

1. Xpert Xpress S
swabs. The test
coronavirus SAF
with less than a
Sensitivity 100%
30/30 "spiked"

es NP and nasal
ent pandemic
positive results*
e sample.
amples and

Genexpert system with Xpert Xpress SARS-CoV-2 test. Credit: Cepheid Inc.

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-
and nasal swabs, resu
negative samples and
the Accula SARS-Co

Inc.): Using throat
es. Thirty (30)
les were tested with
ed" samples of the

Easy Work Flow Like

Tests

Combining molecular PCR acc

- PCR
- Cost Effective
- Easy to Use
- Room Temperature Storage
- Small Footprint
- CE Mark
- CLIA Waived

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

41

Diagnostic Testing – Molecular

Cue Health Monitoring System & COVID-19 Test Cartridge

42

Diagnostic Testing - Multianalyte

- 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

43

Diagr

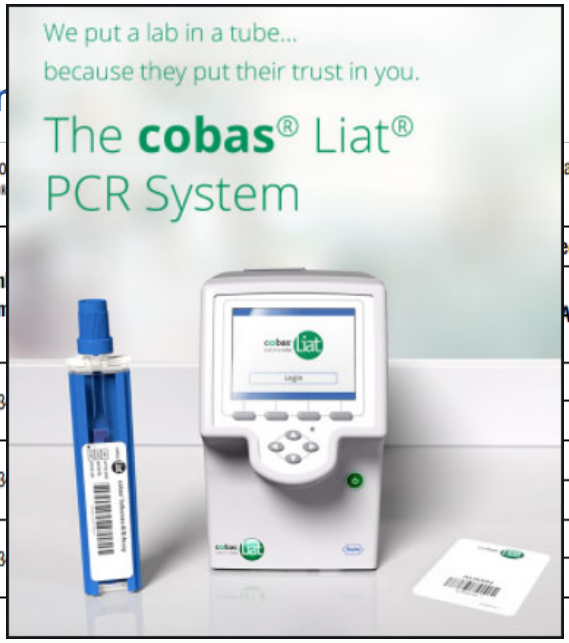


Table 22 Comparison o a A/B & RSV for use on the cobas® Liat®

Virus	Num Sam	eement Statistics	
		Percent Agreement (%)	95% CI (LCL, UCL)*
SARS-CoV-2†	3	96.4%	(87.7%, 99.0%)
		98.0%	(95.6%, 99.1%)
Influenza A	3	100.0%	(94.0%, 100.0%)
		99.6%	(98.0%, 99.9%)
Influenza B	3	100.0%	(90.6%, 100.0%)
		99.7%	(98.2%, 99.9%)

44

Here are the 4 Antigen Tests that can be run in Labs that have a Certificate of Waiver

45

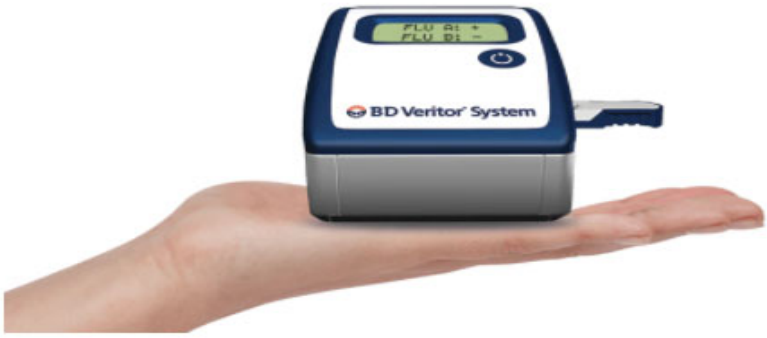
Diagnostic Testing – Antigen

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).

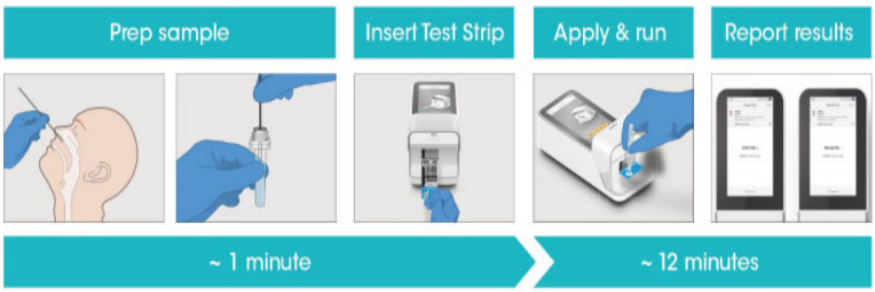
46

Diagnostic Testing – Antigen



47

Diagnostic Testing – Antigen



48

Diagnostic Testing – Antigen

49

Happy Thanksgiving!!

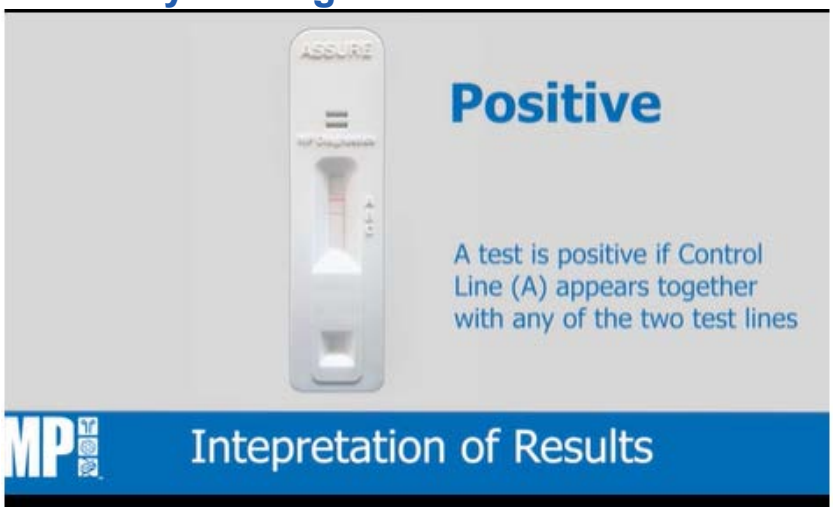
50

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.

51

Antibody Testing



52

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 5. IgG/IgM PPA for the Assure COVID-19 IgG/IgM Rapid Test Device

Site	Days from symptom	# PCR Positive	IgG (Assure Device)			IgM (Assure Device)		
			Antibody Positive	PPA	95%CI	Antibody Positive	PPA	95%CI
(Site 1+2+3)	0-7 days	2	0	0%	0%-57.5%	2	100%	42.5%-100%
	8-14 days	12	10	83.3%	55.2%-95.3%	10	83.3%	55.2%-95.3%
	≥15 days	28	28	100%	91.2%-100%	25	89.3%	72.8%-96.3%

53

Recent Guidance from CMS/AMA and NCDHHS on Antigen Testing

- https://medicaid.ncdhhs.gov/blog/2020/09/21/special-bulletin-covid-19-132-laboratory-codes-coronavirus-covid-19-testing
- NC Medicaid is adding the following code into NCTracks for medically necessary laboratory testing effective Sept. 1, 2020, as follows:

54

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]).

55

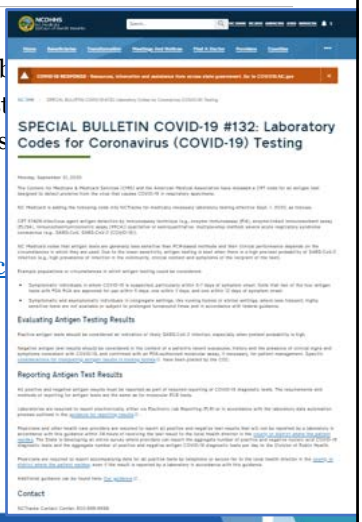
Recent Guidance from CMS/AMA and NCDHHS on Antigen Testing

- *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.

56

Recent Guidance from CMS/AMA and NCDHHS on Antigen Testing

- All positive and negative antigen results must b
  required reporting of COVID-19 diagnostic test
  methods of reporting for antigen tests are the s
  PCR tests.
- Guidance on Reporting can be found here:
- https://files.nc.gov/covid/documents/guidanc
  Order-Guidance-SL-2020-4-Sec.4.10.a.pdf



57

Questions?

58