Welcome to the

RHC COVID-19 Testing Technical Assistance Webinar

This webinar is brought to you by the National Association of Rural Health Clinics and is supported by cooperative agreement G27RH39211 from the Federal Office of Rural Health Policy, Health Resources and Services Administration (HRSA). It is intended to serve as a technical assistance resource based on the experience and expertise of independent consultants and guest speakers.

The contents of this webinar are solely the responsibility of the authors and do not necessarily represent the official views of HRSA.
SARS-CoV-2 Testing

Victoria Olson, Ph.D.
COVID-19 Laboratory Task Force
06/04/2020
## Testing Data in the United States

**Updated June 1, 2020**

<table>
<thead>
<tr>
<th>TOTAL TESTS REPORTED</th>
<th>POSITIVE TESTS REPORTED</th>
<th>% OF POSITIVE TESTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>17,612,125</td>
<td>2,140,439</td>
<td>12%</td>
</tr>
</tbody>
</table>

* Data reflect primarily viral testing; some states may include antibody testing numbers

- Totals compiled from different sources, and not all tests are reported to CDC
- U.S. laboratory testing by state including commercial, reference, public health, and hospital totals available through the CDC COVID Data Tracker
Two Test Types for COVID-19

Viral
- Provides information about a current infection
- Nucleic acid or antigen test

Antibody
- Provides evidence of a previous infection
- Screening for antibodies in blood
Viral Tests

- Many SARS-CoV-2 diagnostic tests granted U.S. FDA Emergency Use Authorization (EUA) are commercially available
  - Most are nucleic acid tests (i.e., detects genetic material of virus) with currently, one antigen test (EUA issued 5/9/2020)
    - High specificity - positive results are highly accurate
    - Different testing formats - laboratory-analyzed versus point-of-care
      - Laboratory-analyzed assays often require longer turnaround time for results
      - Point-of-care assays have rapid turnaround time but limitations on sensitivity (potential false negatives)
        - Negative results (presumptive) may require confirmatory testing
Considerations for Viral Tests

• Testing can be coordinated through public health, commercial, or clinical laboratories
  o Information on performance and intended use of EUAs available through FDA
    ➢ https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations
  o Laboratories performing testing should be certified by Clinical Laboratory Improvement Amendments (CLIA)
Specimen Types for Viral Testing

• Proper specimen collection and handling are key to a valid test result

• The following are acceptable diagnostic specimen types:
  o Nasopharyngeal (NP) specimen collected by a healthcare provider (HCP)
  o Oropharyngeal (OP) specimen collected by a HCP
  o Nasal mid-turbinate swab collected by a HCP or by a supervised onsite self-collection (using a flocked tapered swab)
  o Anterior nares (nasal swab) specimen collected by a HCP or self-collection onsite or at home (using a flocked or spun polyester swab)
  o Nasopharyngeal or nasal wash/aspirate (NW) specimen collected by a HCP
  o Lower respiratory tract specimens (e.g., sputum)

• Specimen collection guidance, including storage and safe handling practices, can be found on CDC’s coronavirus website
Priorities for COVID-19 Viral Testing

- **High Priority**
  - Hospitalized patients with symptoms
  - Healthcare facility workers, workers in congregate living settings, and first responders with symptoms
  - Residents in long-term care facilities or other congregate living settings, including prisons and shelters, with symptoms

- **Priority**
  - Persons with symptoms of potential COVID-19 infection, including:
    - Fever, cough, shortness of breath, chills, muscle pain, new loss of taste or smell, vomiting or diarrhea, and/or sore throat.
  - Persons without symptoms who are prioritized by health departments or clinicians, for any reason, including but not limited to:
    - Public health monitoring
    - Sentinel surveillance
    - Screening of other asymptomatic individuals according to state and local plans

Antibody Testing

- Types of serological tests
  - Binding tests detect antibodies reactive to SARS-CoV-2
  - Neutralizing tests detect antibodies that inhibit SARS-CoV-2 infection

- Used to detect presence of antibodies in blood indicating likely infection with SARS-CoV-2 at some time in the past
  - Antibodies start developing 1 to 3 weeks after infection

- Valuable in investigating transmission dynamics to inform prevention strategies

- Tool for conducting population seroprevalence surveys

- Not recommended for use in diagnosing acute infection
  - Use viral test for diagnostic purposes
Understanding Antibody Test Results

- Positive results indicate likely infection with SARS-CoV-2 at some time in the past
  - Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains
- Negative results do not preclude acute SARS-CoV-2 infection
  - If acute infection is suspected, viral testing for SARS-CoV-2 is necessary.
- Results from antibody testing should not be used to diagnose or exclude acute SARS-CoV-2 infection.
CDC is Conducting Seroprevalence Surveys to Gather Important Information

Questions CDC **wants to answer** through Serology Surveillance

- How much of the U.S. population has been infected with the virus causing COVID-19 (SARS-CoV-2)?
- How is this changing over time?
- Are there different characteristics, or risk factors, that are associated with SARS-CoV-2 infection, such as age, location, or underlying health conditions?
- How many U.S. residents experienced mild or asymptomatic COVID-19 illness?
- How long can antibodies be found after a COVID-19 infection?

Questions CDC **cannot answer** through Serology Surveillance

- How much of the U.S. population is immune to COVID-19 and not able to get infected again?
- How many antibodies are needed to protect someone from COVID-19?
- How long will someone with antibodies be protected from COVID-19?
- Can you be re-infected with COVID-19?
- Can people with antibodies return to work?

Status of Antibody Testing

- Currently 15 antibody tests with FDA EUA

- Tests can detect total antibody or immunoglobulin (Ig), different classes (e.g., IgG, IgM or IgA), or combinations

- FDA, CDC, BARDA, and NIH/National Cancer Institute (NCI) are collaborating to independently validate certain antibody tests

- Test performance characteristics of FDA EUA antibody tests are available

- Additional data are needed to determine correlation of antibody response with immunity and duration of antibody response
Interim Guidelines for COVID-19 Antibody Testing

- Last updated on May 23, 2020

- Summary:
  - Preferentially utilize assays with FDA EUA
    - Currently, no identified advantage of assays whether test detects IgG, IgM and IgG, or total antibody
  - Optimize positive predictive value and minimize false positive test results
    - Choose an assay with high specificity
    - Focus use on persons with high pre-test probability
    - Employ alternative orthogonal testing algorithm in which persons testing positive are tested with a second, different test
  - Can not use antibody testing to determine immune status in individuals until presence, durability, and duration of immunity is established
General Considerations on Test Performance

- Sensitivity and specificity are characteristics of the test.
- Predictive value of a test is related to prevalence of the disease in a population.
  - Positive predictive value is the probability that subjects with a positive test truly have (had) the disease.
  - Negative predictive value is the probability that subjects with a negative screening test truly do not have (had) the disease.
Predictive Value Examples

Assume 5% Disease Prevalence and a Test with 95% Sensitivity and 95% Specificity

<table>
<thead>
<tr>
<th>Disease</th>
<th>Present</th>
<th>Absent</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>TP: 95,000</td>
<td>FP: 95,000</td>
<td>190,000</td>
</tr>
<tr>
<td>Negative</td>
<td>FN: 5,000</td>
<td>TN: 1,805,000</td>
<td>1,810,000</td>
</tr>
<tr>
<td>Total</td>
<td>100,000</td>
<td>1,900,000</td>
<td>2,000,000</td>
</tr>
</tbody>
</table>

Positive Predictive Value (PPV) = 50%

Negative Predictive Value (NPV) = 99%

Test result: TP: true positive; FP: False Positive; TN: true negative; FN: false negative

PPV = (TP/TP + FP)  NPV = (TN/TN+FN)
Predictive Value Examples

Assume 20% Disease Prevalence and a Test with 95% Sensitivity and 95% Specificity

<table>
<thead>
<tr>
<th>Test Result</th>
<th>Disease</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Present</td>
<td>Absent</td>
<td>Total</td>
</tr>
<tr>
<td>Positive</td>
<td>TP 190,000</td>
<td>FP 40,000</td>
<td>230,000</td>
</tr>
<tr>
<td>Negative</td>
<td>FN 10,000</td>
<td>TN 760,000</td>
<td>770,000</td>
</tr>
<tr>
<td>Total</td>
<td>200,000</td>
<td>800,000</td>
<td>1,000,000</td>
</tr>
</tbody>
</table>

Positive Predictive Value (PPV) = 82.6%

Negative Predictive Value (NPV) = 98.7%

Test result: TP: true positive; FP: False Positive; TN: true negative; FN: false negative

\[
PPV = \frac{TP}{TP + FP} \quad NPV = \frac{TN}{TN + FN}
\]
# Interpreting Viral and Antibody COVID-19 Test Results

## Guidance on Interpreting COVID-19 Test Results

<table>
<thead>
<tr>
<th>RESULT</th>
<th>INTERPRETATION</th>
<th>RECOMMENDED ACTION</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>VIRAL TESTING:</strong> (testing for current infection)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive</td>
<td>Most likely you DO currently have an active COVID-19 infection and can give the virus to others.</td>
<td>Stay home* and follow CDC guidance on steps to take if you are sick. If you are a healthcare or critical infrastructure worker, notify your work of your test result.</td>
</tr>
<tr>
<td>Negative</td>
<td>Most likely you DO NOT currently have an active COVID-19 infection.</td>
<td>If you have symptoms, you should keep monitoring symptoms and seek medical advice about staying home and if you need to get tested again. If you don’t have symptoms, you should get tested again only if your medical provider and/or workplace tells you to. Take steps to protect yourself and others.</td>
</tr>
<tr>
<td><strong>ANTIBODY TESTING:</strong> (testing for past infection with the virus)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive:</td>
<td>You likely* have Had a COVID-19 infection.</td>
<td>You may be protected from re-infection (have immunity), but this cannot be said with certainty. Scientists are conducting studies now to provide more information. Take steps to protect yourself and others.</td>
</tr>
<tr>
<td>Negative</td>
<td>You likely* NEVER HAD (or have not yet developed antibodies to) COVID-19 infection.</td>
<td>You could still get COVID-19. Take steps to protect yourself and others.</td>
</tr>
<tr>
<td><strong>BOTH</strong> (antibody and viral testing)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Viral Positive, Antibody Positive</td>
<td>Most likely you DO currently have an active COVID-19 infection and can give the virus to others.</td>
<td>Stay home* and follow CDC guidance on steps to take if you are sick. If you are a healthcare or critical infrastructure worker, notify your work of your test result.</td>
</tr>
<tr>
<td>Viral Positive, Antibody Negative</td>
<td>Most likely you DO currently have an active COVID-19 infection and can give the virus to others.</td>
<td>Stay home* and follow CDC guidance on steps to take if you are sick. If you are a healthcare or critical infrastructure worker, notify your work of your test result.</td>
</tr>
<tr>
<td>Viral Negative, Antibody Positive</td>
<td>You likely* have Had and RECOVERED FROM a COVID-19 infection.</td>
<td>You may be protected from re-infection (have immunity), but this cannot be said with certainty. Scientists are conducting studies now to provide more information. You should get tested again only if your medical provider and/or workplace tells you to. Take steps to protect yourself and others.</td>
</tr>
<tr>
<td>Viral Negative, Antibody Negative</td>
<td>You likely* have NEVER HAD a COVID-19 infection.</td>
<td>You could still get COVID-19. You should get tested again only if your medical provider and/or workplace tells you to. Take steps to protect yourself and others.</td>
</tr>
</tbody>
</table>

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*Stay home* means not to return to work unless there are steps you can take to protect yourself and others.
SARS-CoV-2 Testing is Evolving

• Additional specimen types and collection methods
  o FDA has approved at home collection kits and tests for self-collected nasal swabs and saliva

• Modified CDC EUA assay to allow additional nucleic acid extraction and amplification technologies to broaden options across the supply chain

• Examining approaches to test for SARS-CoV-2 and other pathogens at the same time
  o CDC is developing a multiplex assay that can be used to test for Influenza A, Influenza B and SARS-CoV-2.

• Antibody testing is increasing and being refined
Final Thoughts

- All testing for SARS-CoV-2 should be conducted in consultation with a healthcare provider.
- Appropriate public health authorities should be notified of all positive test results.
- Regardless of test, proper specimen collection and handling is critical.
Submit Questions to:

https://wwwn.cdc.gov/dcs/ContactUs/Form

800-CDC-INFO
COMMUNITY-BASED TESTING SITES (CBTS) OVERVIEW

National Association of Rural Health Clinics (NARHC)

Sean M. Crawford, CBTS Deputy TF lead
6/04/2020
AGENDA

- Overview – CBTS 1.0 Program
- Overview – CBTS 2.0 Program
- Social Vulnerability Index
- Nasal Self-Swab Concept of Operations (ConOps)
- Recommended Supplies for Rural Testing
- Rural Testing CONOPS
CBTS 1.0 - Program

CBTS 1.0 Key Metrics Dashboard

**Statuses**
- 41 Community Based Testing Sites
  - 13 Live
  - 0 In Progress
  - 20 Transitioned
  - 8 Closed

**Throughput**
- 236,328 Samples Collected

**Samples Collected Yesterday (06/02/2020)**
- 10 sites were OPEN yesterday, 10 of them have REPORTED
- 2,637 Samples Collected Yesterday

**Diagnostics**
- 228,925 Samples Resulted
  - 31,456 Positives
  - 2,852 Indeterminates
  - 194,717 Negatives

**Samples Resulted Yesterday (06/02/2020)**
- 2,496 Samples Resulted
  - 251 Positives
  - 327 Indeterminates
  - 1,918 Negatives

**Daily Sample Results**
- Display data for the last seven days. Data label is total daily resulted samples which includes positive, indeterminate, and negative results
Nasal Self-Swab ConOps

- When the CBTS 1.0 program began, the sites were using nasopharyngeal swabs.
- Mid April, the FDA authorized use of the nasal foam self-swabbing method; CBTS 1.0 revised ConOps to utilize the nasal foam self-swabbing method in alignment with the FDA
  - Significantly less invasive swabbing of the anterior nares, rather than the nasopharyngeal.
  - **Risk Reduction to Health Care workers** - Allows for greater physical distancing,
  - **90% PPE Reduction**
Nasal Self-Swab Quick Reference Guide

- A healthcare professional will verify each individual's identification and prior registration.
- While maintaining a proper distance of six feet or greater to reduce virus exposure, a healthcare professional will place a pre-labeled self-swabbing kit on a nearby table.
- The tests are easily self-administered. Within a safe distance, a healthcare professional will provide a brief demonstration of the test and answer any questions.

1. Open the wrapper on the swab. Handle only the plastic end. Use care to not touch the soft end.
2. Place the soft end of the swab midway in the nose, rotate twice, and hold it inside for 15 seconds.
3. Repeat in the other nostril.
4. Open the tube and put the soft end of the swab down inside.
5. Break off the top of the swab stick and replace the tube cap.
6. When finished, place the kit, packaging and broken end of the swab back on the table.

*Due to the limited supplies at the time of this quick-reference guide, a nasopharyngeal swab is used in the photos. However, the swab used for self-swab testing is a nasal foam swab that goes just inside the nose.

Use QR Code or visit: https://youtu.be/vsQVxsQY3jc
Drive-Through or Walk-Through Self-Swab Testing

**STEP 1 (Pre-Arrival – Unobserved)**
Patient registration and consent retrieval conducted remotely via online platform/app

**Step 2 (Pre-arrival or Onsite - Observed)**
Onsite patient registration and consent verification conducted by testing site personnel or via telehealth platform (lab ordered in this step)

- 1. Testing site personnel protection requirements - gloves and surgical mask (min. 6-foot distancing)

**Step 3 (Onsite – Observed)**
Patient obtains testing kit

**Step 4 (Onsite – Observed)**
Patient initiates self-swab

1. Patient conducts swab in accordance with kit instructions
2. Patient places swab into proper collection tube and breaks swab as needed
3. Patient caps sample tube
4. Patient places sealed tube in corresponding sample bag

**Step 5 (Onsite – Observed)**
Patient drops completed test into a sample collection bin

- 1. Site testing personnel collect final samples and performs QAQC
- 2. Sample is deposited in the refrigerator and then transferred/shipped in temperature-controlled packaging

**Step 6 (Offsite – Unobserved)**
Lab testing conducted

**Step 7 (Offsite – Unobserved)**
Patient notified of results
Drive-Through or Walk-Through Self-Swab Testing

**STATIONS FOR 1 LANE PROCESS**

**Step 1: Self Registration and Consent:**
Individual self-registers on approved App min 24 hours prior to testing
**LAB Test Order** (Telehealth)

**Step 2: LAB Test Order:**
(Telehealth or Onsite) Registration Confirmation
Arrive at test site
Present Identification and confirm registration
**Staff PPE: Gloves and Mask**

**Station 3: Self Pick up Test Kit and move**

**Station 4: Observed self-swab process**
1) Unpack kit
   a) Conduct Self-Test
   b) Re-Pack Kit
2) Validate Test process is followed
   **Staff PPE: Gloves and Mask at site location discretion**

**Station 5: Test Drop Off and Site Packaging**
Drop packaged on table
Site Support package bulk shipment
Shipment to Labs
**Staff PPE: Gloves and Mask**

**Step 6: Lab processing**

**Step 7 Result Notification**
Individual receives call from Results Center

**Cold Zone**

**Hot Zone**

**ENTER**

**EXIT**
CBTS 2.0 Testing Program

FEMA CBTS Public-Private Partnership Sites Dashboard

437 CBTS Public-Private Partnership Sites

484,740 Samples Resulted

36,900 Positives

1,536 Indeterminates

446,304 Negatives

Percent and Count Positive by Age Group

Daily Sample Results

Percent Positive by Patient County of Residence

United States

Top Counties by % and Count Positive:

- Essex County, MA: 16.73% 1826
- Kane County, IL: 17.93% 61
- Will County, IL: 17.00% 953
- PA: 16.60% 138
- Suffolk County, MA: 15.51% 382

1. Includes results reported as invalid, blank, or test not performed.
2. Data labels in columns are the total samples resulted for the day and include positive, negative, and indeterminate.
3. Only includes counties that have at least 100 sample results. Location data is not available for 9400 sample results.

June 4, 2020
CBTS 2.0 – Drive Thru
CDC’s Social Vulnerability Index (SVI)

https://svi.cdc.gov/

What is the SVI?

The SVI measures the resilience of communities when confronted by external stressors along four main themes:

1. Socioeconomic Status
2. Household Composition & Disability
3. Minority Status
4. Housing Type
# Recommended Supplies for Rural Testing

<table>
<thead>
<tr>
<th>Weekly Re-Supply</th>
<th>Per Kit</th>
<th>Unit of Measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polyester Spun Swabs</td>
<td>2,500</td>
<td>Each</td>
</tr>
<tr>
<td>Transport Media (Viral Transport Media, Universal Transport Media, or Normal Saline)</td>
<td>2,500</td>
<td>Each</td>
</tr>
<tr>
<td>Disposable individual, single-use bags</td>
<td>2,500</td>
<td>Each</td>
</tr>
<tr>
<td>Matched standard code-128 barcodes with unique numbers</td>
<td>2,500</td>
<td>Pairs</td>
</tr>
<tr>
<td>Gloves (Nitrile) (Sizes: S/M/L)</td>
<td>20,000</td>
<td>Each</td>
</tr>
<tr>
<td>Surgical Masks</td>
<td>150</td>
<td>Each</td>
</tr>
<tr>
<td>Biohazard Bags</td>
<td>50</td>
<td>Boxes</td>
</tr>
<tr>
<td>Specimen Transport Bag with requisition pouch. 6x9” polyethylene specimen bags case of 100</td>
<td>25</td>
<td>Case</td>
</tr>
<tr>
<td>Insulated Foam Shipping Kit – 30 ¾ x 14 ½ x 16”</td>
<td>25</td>
<td>Each</td>
</tr>
<tr>
<td>Single-Use Cold Packs – 12 oz (24 pack x2)</td>
<td>10</td>
<td>Pack</td>
</tr>
<tr>
<td>UN3373 Biological Substance, Category B Air labels (roll of 500)</td>
<td>8</td>
<td>Pack</td>
</tr>
<tr>
<td>Tamper-Evident Tape, 3” x 110 yards</td>
<td>12</td>
<td>Pack</td>
</tr>
<tr>
<td>Telatemp Heat Indicator – 6 windows in 10° increments (pack of 25)</td>
<td>5</td>
<td>Carton</td>
</tr>
<tr>
<td>Cavicide wipes</td>
<td>50</td>
<td>Containers</td>
</tr>
<tr>
<td>Care Touch Sterile Alcohol Prep Pads (2-Ply) – Alcohol Wipes 600 (weekly)</td>
<td>5</td>
<td>Boxes</td>
</tr>
<tr>
<td>Bleach, spray or wipe disinfectant (from Environmental Protection Agency—EPA—List N)</td>
<td>100</td>
<td>Containers</td>
</tr>
<tr>
<td>4.5” x 9” x 2.5 mil 18 oz Whirl-Pak Sampling Bags case of 500</td>
<td>5</td>
<td>Case</td>
</tr>
</tbody>
</table>

**One-time purchase items (no weekly re-supply)**

<table>
<thead>
<tr>
<th>Per Initial Kit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sharps containers – 2 gallon or larger</td>
</tr>
<tr>
<td>Red Uline Garbage Can (32 gallon)</td>
</tr>
</tbody>
</table>
Rural Testing ConOps

Concept of Operation:

- With increased flexibility, mobile vans/bus/RV rotates throughout the rural counties, alternating locations each day, but always beginning and ending in the same location to pick up/drop off personnel and supplies.
- Counties are targeting based on the needs of the state and the local population.
- Rotations for the mobile testing groups are looped together based on geographic location.
- Operating hours will vary by day based on the needs of the specific location for that day.

Benefits:

- Reduced resource requirements:
  - Reduces the number of medical professionals away from their corporate duties.
  - Coordinating for state owned property, solves security concerns and reduces complexity of resource demands from a physical fixture perspective.
  - Single shipping site for supporting resources.
  - Increased ability to support the state:
    - Ability to support Governor desired locations.
    - Reduced State and local negotiating requirements.
  - Allows private partners to expand more rapidly to serve more people in underserved areas.
Alabama Routes

Single location each day based out of Montgomery. Three cities on a rotational basis Sunday off.

- **Monday:** Selma 10-3, Lunch 12:30pm-1pm
- **Tuesday:** Demopolis 10-3, Lunch 12:30pm-1pm
- **Wednesday:** Thomasville 10-3, Lunch 12:30pm-1pm
- **Thursday:** Thomasville 10-3, Lunch 12:30pm-1pm
- **Friday:** Selma 10-3, Lunch 12:30pm-1pm
Georgia Routes

Single location each day based out of Evans. Three cities on a rotational basis with Saturday and Sunday off.

- **Monday/Tuesday:** Augusta 10-3, Lunch 12:30pm-1pm
- **Wednesday/Saturday:** Milledgeville 10-3, Lunch 12:30pm-1pm
- **Thursday/Friday:** Tifton 10-3, Lunch 12:30pm-1pm
Dallas Walk up ConOps
Submit Questions to:

For more information:

Contact CBTS RFI
fema-cbts-rfi@fema.dhs.gov
QUESTIONS?