

Welcome to the

RHC COVID-19 Testing

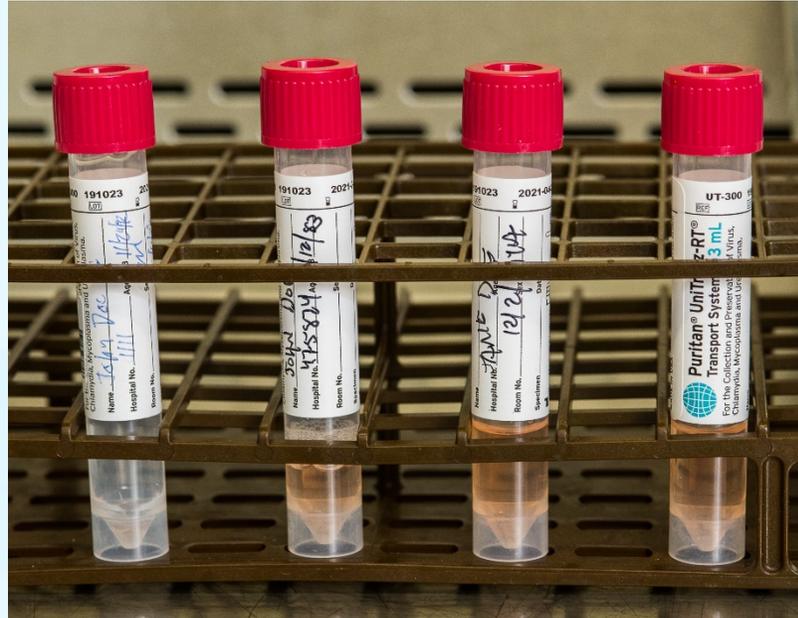
Technical Assistance Webinar

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.

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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*

TOTAL TESTS REPORTED

17,612,125

POSITIVE TESTS REPORTED

2,140,439

% OF POSITIVE TESTS

12%

* 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
 - <https://www.cdc.gov/covid-data-tracker/index.html>

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

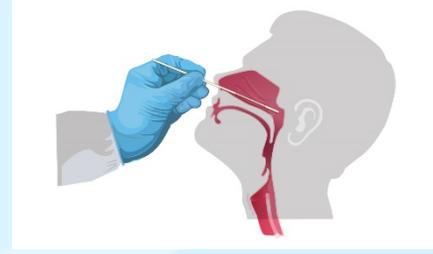
Viral Tests

- 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
 - Information on performance and intended use of EUAs available through FDA
 - <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>
 - 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:
 - Nasopharyngeal (NP) specimen collected by a healthcare provider (HCP)
 - Oropharyngeal (OP) specimen collected by a HCP
 - Nasal mid-turbinate swab collected by a HCP or by a supervised onsite self-collection (using a flocked tapered swab)
 - Anterior nares (nasal swab) specimen collected by a HCP or self-collection onsite or at home (using a flocked or spun polyester swab)
 - Nasopharyngeal or nasal wash/aspirate (NW) specimen collected by a HCP
 - Lower respiratory tract specimens (e.g., sputum)
- Specimen collection guidance, including storage and safe handling practices, can be found on CDC's coronavirus website
 - <https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html>

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
 - <https://www.cdc.gov/coronavirus/2019-ncov/covid-data/serology-surveillance/index.html>
- 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
 - <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ivd>
- 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
 - <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/eua-authorized-serology-test-performance>
- 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
 - <https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antibody-tests-guidelines.html>
- 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

		Disease		Total
		Present	Absent	
Test Result	Positive	TP 95,000	FP 95,000	190,000
	Negative	FN 5,000	TN 1,805,000	1,810,000
Total		100,000	1,900,000	2,000,000

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

		Disease		
		Present	Absent	Total
Test Result	Positive	TP 190,000	FP 40,000	230,000
	Negative	FN 10,000	TN 760,000	770,000
Total		200,000	800,000	1,000,000

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

$PPV = (TP / (TP + FP))$ $NPV = (TN / (TN + FN))$

Interpreting Viral and Antibody COVID-19 Test Results



GUIDANCE ON INTERPRETING COVID-19 TEST RESULTS

	RESULT	INTERPRETATION	RECOMMENDED ACTION
VIRAL TESTING: (testing for current infection)	Positive	<i>Most likely*</i> you DO currently have an active COVID-19 infection and can give the virus to others.	<u>Stay home*</u> and follow <u>CDC guidance</u> on steps to take if you are sick. *If you are a healthcare or critical infrastructure worker, notify your work of your test result.
	Negative	<i>Most likely*</i> you DO NOT currently have an active COVID-19 infection.	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. <u>Take steps to protect yourself and others.</u>
ANTIBODY TESTING: (testing for past infection with the virus)	Positive:	You <i>likely*</i> have HAD a COVID-19 infection.	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. <u>Take steps to protect yourself and others.</u>
	Negative	You <i>likely*</i> NEVER HAD (or have not yet developed antibodies to) COVID-19 infection.	You could still get COVID-19. <u>Take steps to protect yourself and others.</u>
BOTH (antibody and viral testing)	Viral Positive, Antibody Positive:	<i>Most likely*</i> you DO currently have an active COVID-19 infection and can give the virus to others.	<u>Stay home*</u> and follow <u>CDC guidance</u> on steps to take if you are sick. *If you are a healthcare or critical infrastructure worker, notify your work of your test result.
	Viral Positive, Antibody Negative	<i>Most likely*</i> you DO currently have an active COVID-19 infection and can give the virus to others.	<u>Stay home*</u> and follow <u>CDC guidance</u> on steps to take if you are sick. *If you are a healthcare or critical infrastructure worker, notify your work of your test result.
	Viral Negative, Antibody Positive	You <i>likely*</i> have HAD and RECOVERED FROM a COVID-19 infection.	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. <u>Take steps to protect yourself and others.</u>
	Viral Negative, Antibody Negative	You <i>likely*</i> have NEVER HAD a COVID-19 infection.	You could still get COVID-19. You should get tested again only if your medical provider and/or workplace tells you to. <u>Take steps to protect yourself and others.</u>

SARS-CoV-2 Testing is Evolving

- Additional specimen types and collection methods
 - 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
 - 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.
 - <https://www.cdc.gov/coronavirus/2019-ncov/lab/reporting-lab-data.html>
- 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

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June 4, 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

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For inquiries, please reach out to: FEMA-CBTS-RFI@fema.dhs.gov



FEMA

CBTS 1.0 Key Metrics Dashboard



Statuses

41

Community Based Testing Sites

13
Live

0
In Progress

20
Transitioned

8
Closed

CBTS Live and In Progress Sites

Site	Status
CO State Fairgrounds, Pueblo	Live
IL EPA Emissions Testing Facility	Live
IL Peoria	Live
NJ Bergen Community College	Live
NJ PNC Arts Center	Live
PA Montgomery Community College	Live
TX American Airlines Center	Live
TX Butler Stadium	Live
TX Cargo Force - El Paso Airport	Live
TX Delmar Stadium	Live
TX Ellis Davis Field House	Live
TX Pridgeon Stadium	Live
TX San Jacinto College Central	Live

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

Samples Collected Yesterday by Site¹

Site	Samples Collected
TX Prigeon Stadium	424
TX Ellis Davis Field House	412
TX Delmar Stadium	393
TX American Airlines Center	316
TX Butler Stadium	302
TX San Jacinto College Stadium	216
PA Montgomery Community College	192
NJ Bergen Community College	181
CO State Fairgrounds, Pueblo	120
TX Cargo Force - El Paso Airport	81
Total	2,637

¹ Two NJ sites and five TX sites are approved to collect up to 500 samples/day, all other sites are approved to collect up to 250 samples/day.

Diagnostics

228,925

Samples Resulted

31,456

2,852

194,717

Positives Indeterminates Negatives

Samples Resulted Yesterday (06/02/2020)²

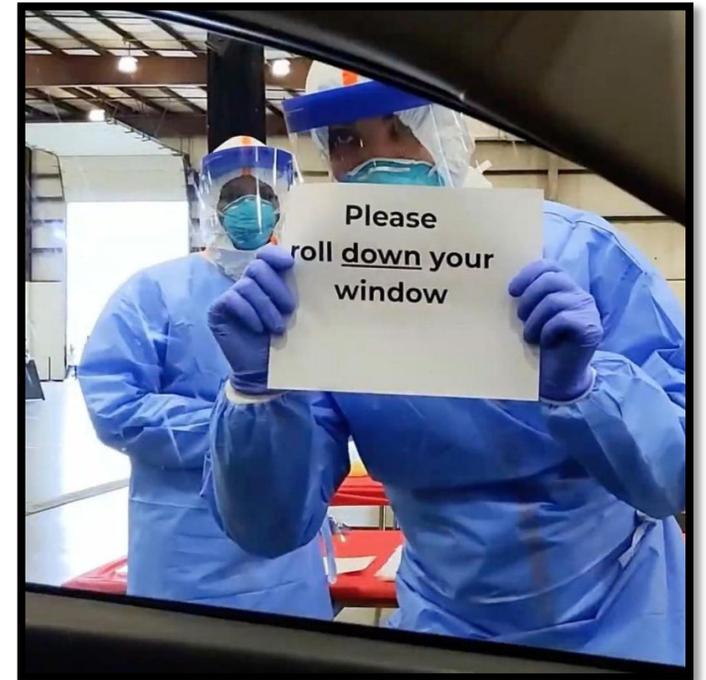
Samples Resulted	Positives	Indeterminates	Negatives
2,496	251	327	1,918

Daily Sample Results³

² Sample results are reported on the date results were received, not the date the sample was collected.
³ Displays data for the last seven days. Data label is total daily resulted samples which includes positive, indeterminate, and negative results

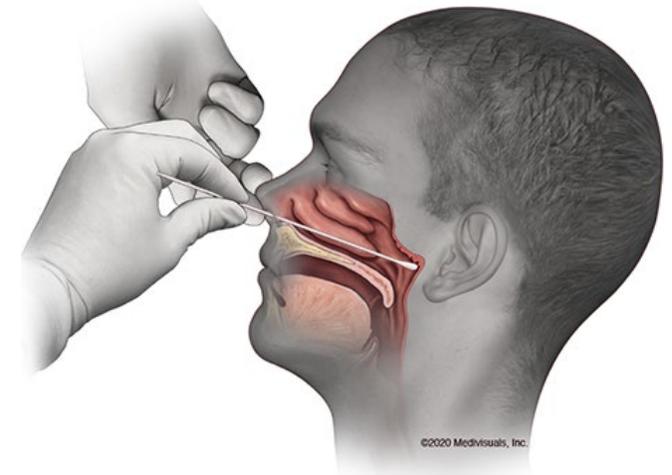


CBTS 1.0 - Drive Thru

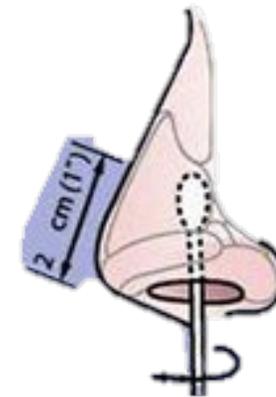


Nasal Self-Swab ConOps

- 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**



Nasopharyngeal Swab



Nasal Self-Swab



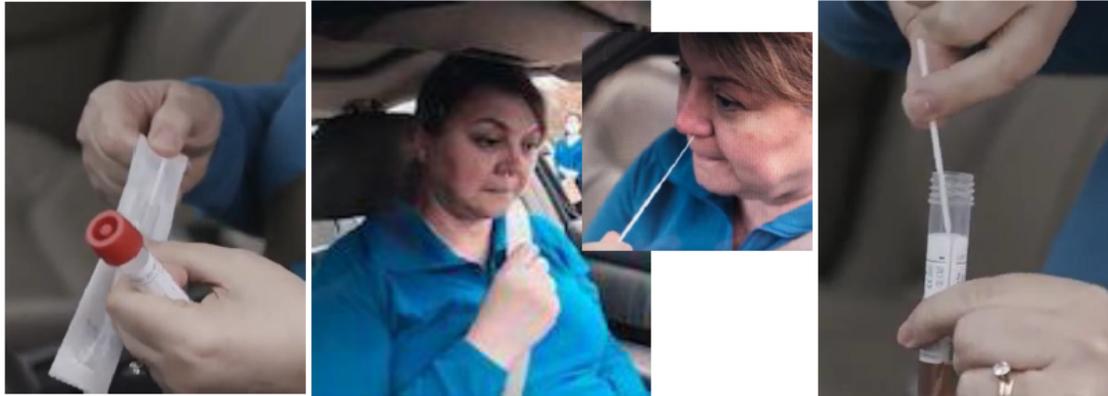
Nasal Self-Swab ConOps

Nasal Self-Swab Quick Reference Guide

- A healthcare professional will verify each individual's identification and prior registration.
- While maintaining 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.

Use QR Code or visit:

<https://youtu.be/vsQVxsQY3jc>



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 making 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.



FEMA

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**

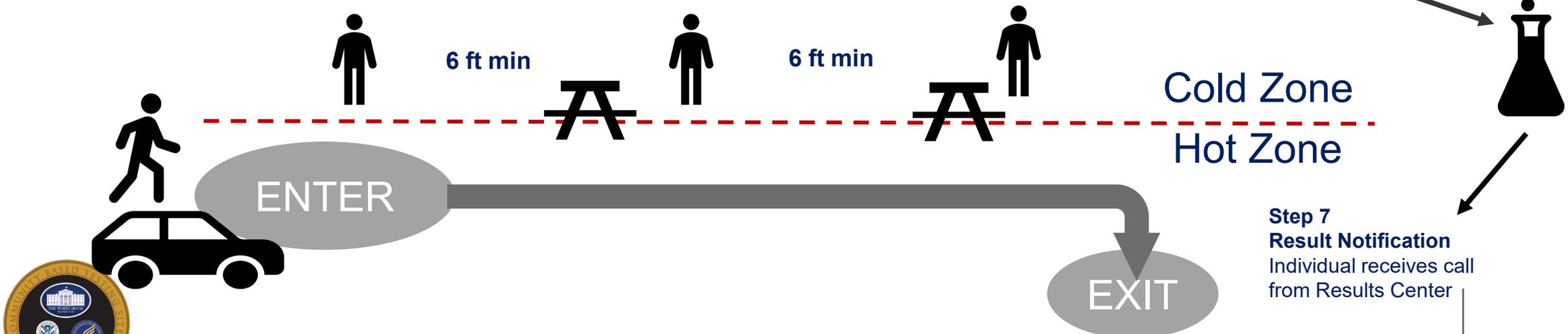
Station 5: Test Drop Off and Site Packaging

Drop packaged on table
 Site Support package bulk shipment
 Shipment to Labs
Staff PPE: Gloves and Mask

Station 6: Lab processing

Cold Zone
 Hot Zone

Step 7 Result Notification
 Individual receives call from Results Center



CBTS 2.0 Testing Program

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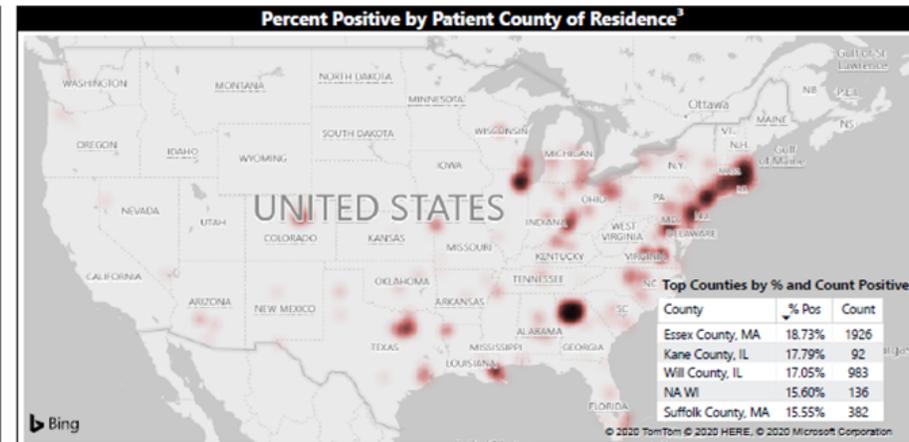
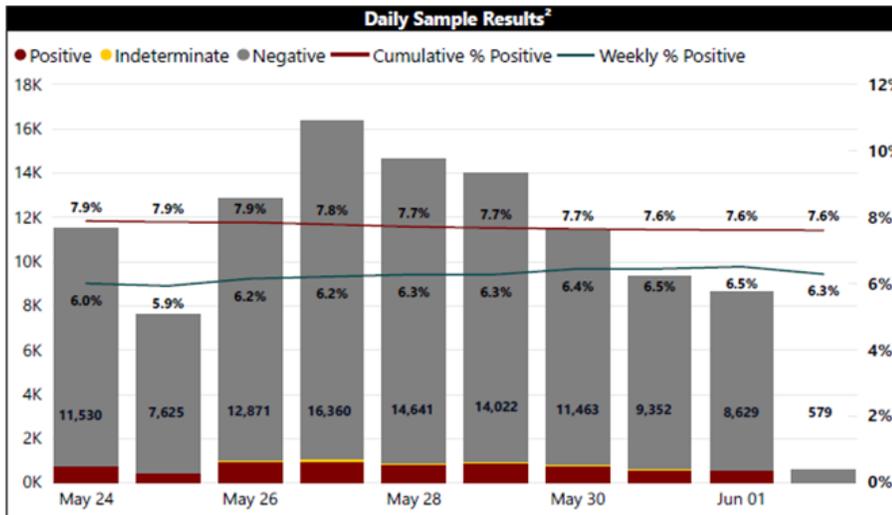
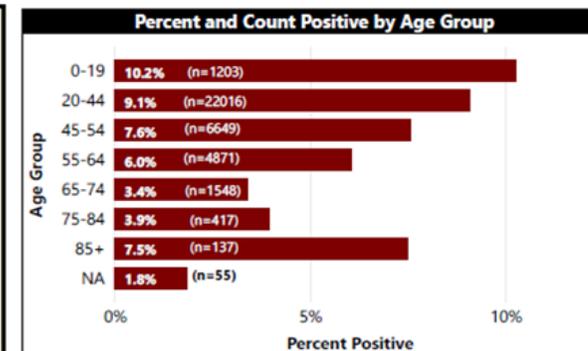
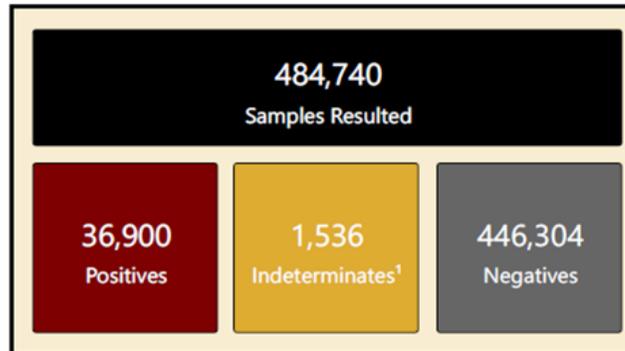
For inquiries, please reach out to: FEMA-CBTS-RFI@fema.dhs.gov



CBTS Public-Private Partnership Sites Dashboard



437 CBTS Public-Private Partnership Sites



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.

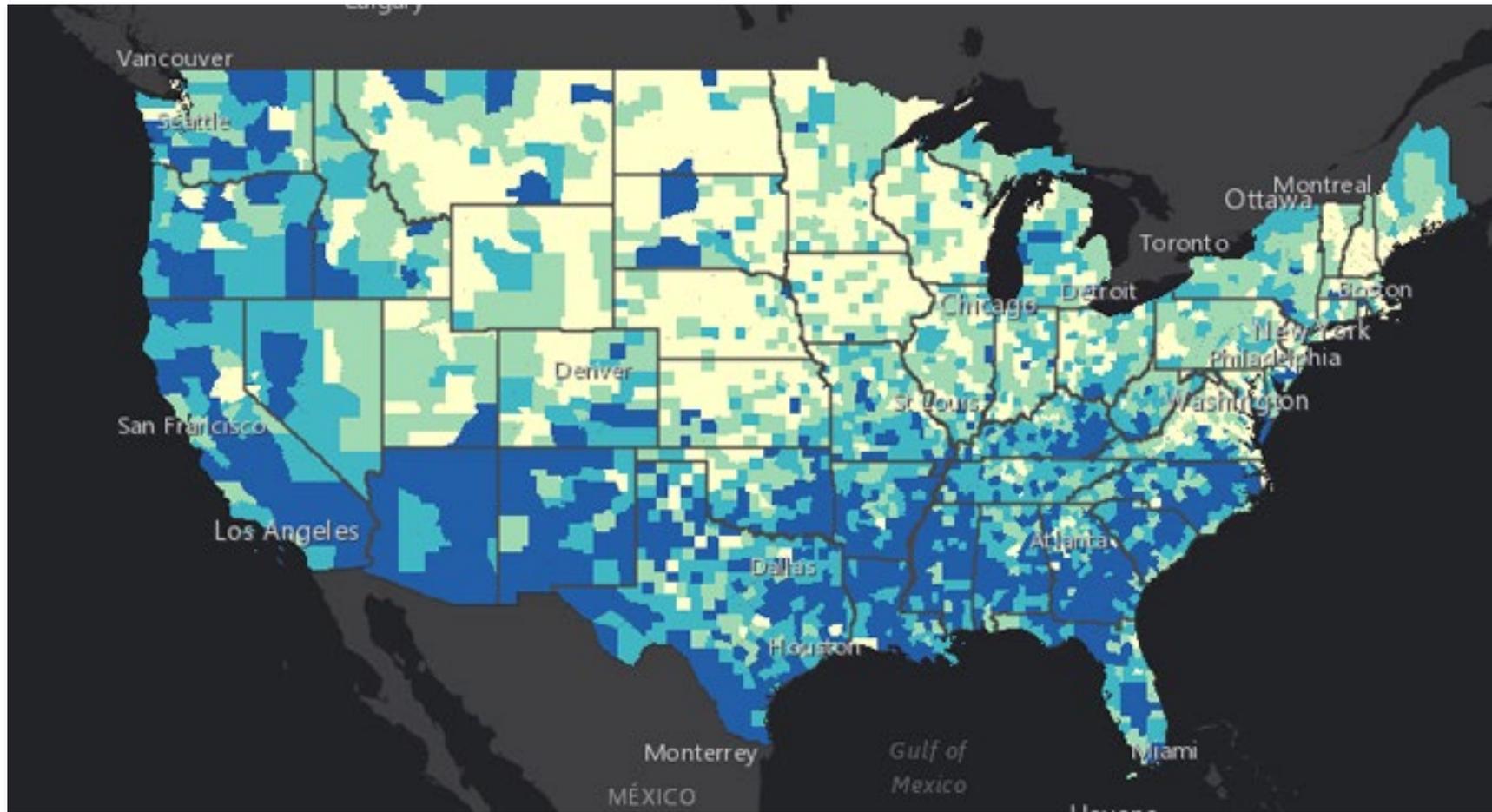
³ Only includes counties that have at least 100 sample results. Location data is not available for 9400 sample results.



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

Weekly Re-Supply	Per Kit	Unit of Measure
Polyester Spun Swabs	2,500	Each
Transport Media (Viral Transport Media, Universal Transport Media, or Normal Saline)	2,500	Each
Disposable individual, single-use bags	2,500	Each
Matched standard code-128 barcodes with unique numbers	2,500	Pairs
Gloves (Nitrile) (Sizes: S/M/L)	20,000	Each
Surgical Masks	150	Each
Biohazard Bags	50	Boxes
Specimen Transport Bag with requisition pouch. 6x9" polyethylene specimen bags case of 100	25	Case
Insulated Foam Shipping Kit – 30 ¼ x 14 ½ x 16"	25	Each
Single-Use Cold Packs – 12 oz (24 pack x2)	10	Pack
UN3373 Biological Substance, Category B Air labels (roll of 500)	8	Pack
Tamper-Evident Tape, 3" x 110 yards	12	Pack
Telatemp Heat Indicator – 6 windows in 10°F increments (pack of 25)	5	Carton
Cavicide wipes	50	Containers
Care Touch Sterile Alcohol Prep Pads (2-Ply) – Alcohol Wipes 600 (weekly)	5	Boxes
Bleach, spray or wipe disinfectant (from Environmental Protection Agency—EPA—List N)	100	Containers
4.5" x 9" x 2.5 mil 18 oz Whirl-Pak Sampling Bags case of 500	5	Case
One-time purchase items (no weekly re-supply)	Per Initial Kit	
Sharps containers – 2 gallon or larger	10	
Red Uline Garbage Can (32 gallon)	10	



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:

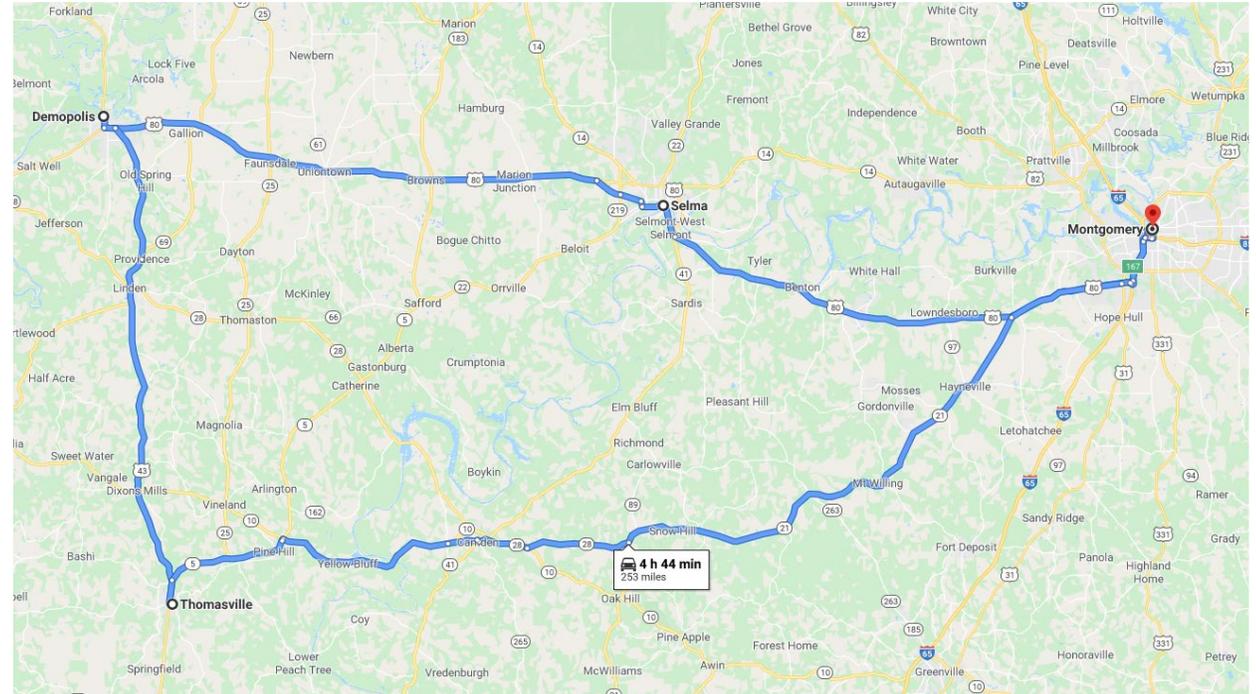
- Reduced resource requirements:
- Reduces the number of medical professionals away from their corporate duties.
- Coordinating for state owned property, solves security concerns and reduces complexity of resource demands from a physical fixture perspective.
- Single shipping site for supporting resources.
- 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.

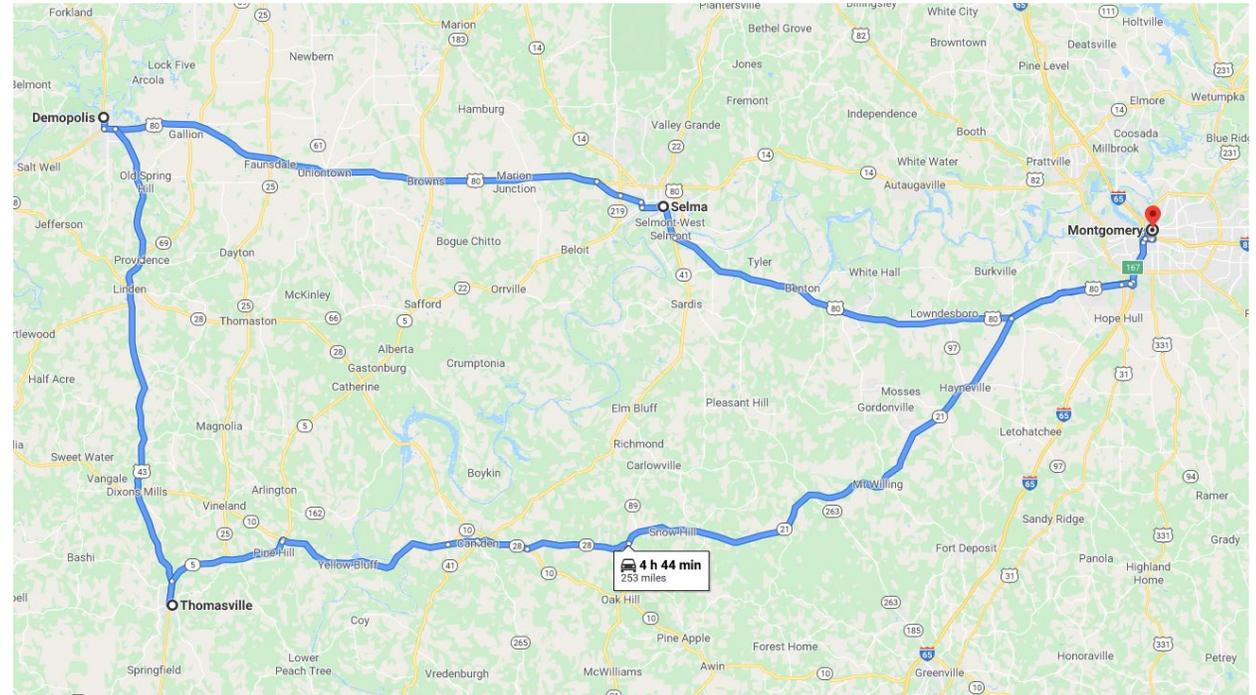
- **Monday:** Selma 10-3, Lunch 12:30pm-1pm
- **Tuesday:** Demopolis 10-3, Lunch 12:30pm-1pm
- **Wednesday:** Thomasville 10-3, Lunch 12:30pm-1pm
- **Thursday:** Thomasville 10-3, Lunch 12:30pm-1pm
- **Friday:** Selma 10-3, Lunch 12:30pm-1pm



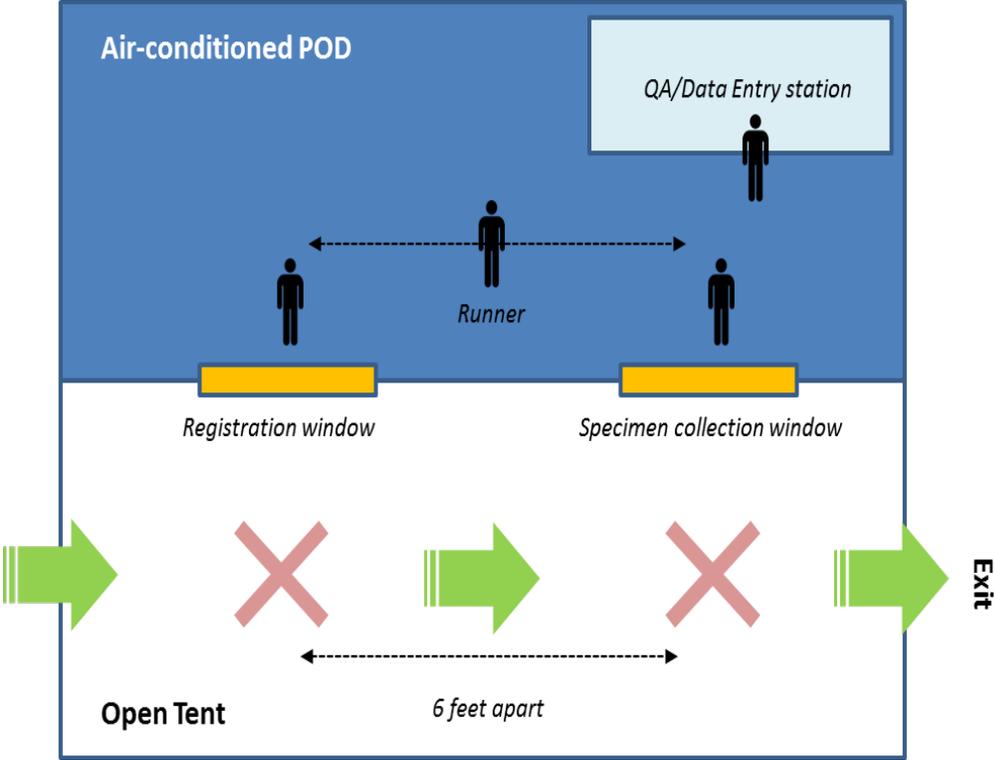
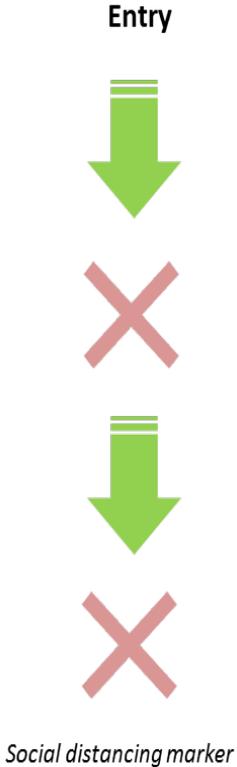
Georgia Routes

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?

