Medical Reserve Corps

COVID-19 Testing Operations Overview
August 21, 2021
Presenters:

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COVID-19 Point-of-Care Testing
August 21, 2021
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A brief history of SARS-CoV-2 testing

• In 2020, main focus was on Covid-19 diagnostic testing using molecular (nucleic acid amplification or “NAA”) tests = collect swab and send to outside lab

• PCR is just one type of molecular or NAA test

• FDA issued hundreds of Emergency Use Authorizations (EUAs) – vast majority are for molecular tests. FDA continues to authorize tests under EUA

• In May & July 2020, Covid-19 antigen tests first became available and received FDA EUAs

• These “rapid tests” detect protein antigen around RNA of SARS-CoV-2 virus

• In August 2020, first lateral flow antigen test granted EUA by FDA = Abbott BinaxNOW COVID-19 Ag Card – uses a test strip, sample wicks its way along the strip – no need for analyzer device
A brief history of SARS-CoV-2 testing – 2

• Multiple benefits of antigen testing:
  • Tests can be done at the point of care – not a send out test
  • “CLIA waived” test = can do in office setting
  • Easy to perform
  • Results available in about 15 minutes

• Limitations of antigen testing:
  • Lack sensitivity of PCR testing, therefore, may have more false negative results compared to PCR
A brief history of Covid-19 testing – 3

• In November 2020, FDA grants first EUA for a molecular test to be performed completely at home = the Lucira COVID-19 All-In-One Test Kit – a prescription item – person follows directions to complete test

• Abbott BinaxNOW COVID-19 Ag Card and Lucira molecular test help pave the way for “at-home” antigen and molecular tests. More diagnostic lab companies enter the “at-home” Covid-19 test market
Point-of-care (POC) lab testing

• Lab testing completed where the patient is = specimen collected AND test performed onsite (examples of office-based tests: rapid influenza test, rapid strep test, and many others)

• Conventional lab testing = specimen taken from patient and sent to reference lab. Results reported back to ordering clinician

• **POC tests can also be done at home** (examples = urine pregnancy test, fingerstick glucose testing, and now Covid-19 tests). May be referred to as “self-administered tests”

• POC tests typically are easy to perform and CLIA-waived – in office setting, need a CLIA certificate

• POC tests meant for home use are different than home specimen collection kits. Home collection kits = sample obtained at home and mailed to lab for testing.

• POC tests (whether at home or in office) have advantages and drawbacks
Types of COVID-19 Tests

Covid-19 Molecular tests (example: PCR testing)
- Used to diagnose current Covid-19 infections – typically a nasal swab (or saliva) is collected as specimen
- Test detects genetic material from the virus itself
- Some tests are point-of-care

Covid-19 Antigen tests (example: Abbott BinaxNOW Covid-19 Antigen Card)
- Also used to diagnose current Covid-19 infections – nasal swab typically obtained as specimen
- Test detects whether a SARS-CoV-2 viral protein is present or not
- Most antigen tests are point-of-care – some meant for medical office use & some for home use
- Point of care tests provide results in 10-15 minutes, depending on the test

Covid-19 antibody tests (also referred to as serology tests)
- A blood test that looks for antibodies to the SARS-CoV-2 virus – if antibodies are present, it MAY indicate PAST infection with Covid-19
- Antibody test NOT designed to diagnose current Covid-19
- HOWEVER, some important caveats: (1) POSSIBLE cross reactivity with other coronaviruses, (2) if antibody test is positive, does not indicate duration of immunity
POC tests & general indications – self-administered tests

• Points below are generalities – need to review package insert for specific test

1. Single antigen test (one point in time) = generally for symptomatic people within specific time frame after illness onset
   • Exception = Ellume (can be used for symptomatic or asymptomatic people)

2. Single molecular test (one point in time) = generally for symptomatic OR asymptomatic people, OR for people who have a reason to suspect COVID-19 infection or no reason to suspect COVID-19 infection
   • Can be used on anyone
   • Exception = Lucira COVID-19 All-In-One Test Kit (only for symptomatic people)

3. Serial antigen tests (2 tests done over a 2-3 day period) = for symptomatic or asymptomatic people, OR for people who have a reason to suspect COVID-19 infection or no reason to suspect COVID-19 infection
   • Can be used on anyone
New over-the-counter (OTC) at-home antigen tests

Over-the-counter COVID-19 rapid tests to be sent to major pharmacies this week

1 day ago

Store shelves at pharmacies across the county will soon be filled with affordable, quick, at-home coronavirus test kits.
# Self-administered point-of-care Covid-19 molecular tests as of 8/21/2021

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Test brand name</th>
<th>Date of original FDA EUA</th>
<th>Type of test</th>
<th>Rx or non-Rx test</th>
<th>What type of sample needs to be collected</th>
<th>Age range for test</th>
<th>Link to most recent FDA EUA letter</th>
<th>Test indication</th>
<th>Can test be mailed to person’s home?</th>
<th>Additional information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lucira Health Inc.</td>
<td>Lucira CHECK-IT COVID-19 Test Kit</td>
<td>4/9/2021</td>
<td>molecular</td>
<td>non-Rx</td>
<td>anterior nasal turbinate swab</td>
<td>age ≥ 2</td>
<td><a href="http://www.fda.gov/media/147492/download">www.fda.gov/media/147492/download</a></td>
<td>with or without COVID-19 symptoms or epi reason to suspect COVID-19</td>
<td>yes</td>
<td>For more information about test or to order, see <a href="http://www.lucirahc.com">www.lucirahc.com</a>. Smartphone or smart device not needed for test. Result available between 11 and 30 minutes.</td>
</tr>
<tr>
<td>Lucira Health Inc.</td>
<td>Lucira COVID-19 All-In-One Test Kit</td>
<td>11/17/2020</td>
<td>molecular</td>
<td>Rx</td>
<td>anterior nasal turbinate swab</td>
<td>age ≥ 14</td>
<td><a href="http://www.fda.gov/media/143810/download">www.fda.gov/media/143810/download</a></td>
<td>individuals suspected of having COVID-19</td>
<td>no</td>
<td>For more information, see <a href="https://shop.lucirahc.com/">https://shop.lucirahc.com/</a>. Result available between 11 and 30 minutes.</td>
</tr>
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</table>

- Lucira tests do not require a smartphone to perform test. However, if person wants an official test result, this can be sent to phone.
- Cue Health test does require a smartphone to perform test
## Self-administered point-of-care Covid-19 antigen tests as of 8/21/2021

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<tr>
<td>Access Bio, Inc.</td>
<td>CareStart COVID-19 Antigen Home Test</td>
<td>8/2/2021</td>
<td>serial antigen testing</td>
<td>non-Rx</td>
<td>anterior nares swab</td>
<td>age ≥ 2</td>
<td><a href="https://www.accessbiodiagnostics.net">www.fda.gov/media/151245/download</a></td>
<td>with or without COVID-19 symptoms or epidemiologic reason to suspect COVID-19</td>
<td>unknown</td>
<td>Specimen collection not observed. A lateral flow test. No analyzer device needed. Results must be read between 10-15 minutes after test started. According to the package labeling, a smartphone is needed; however, the FDA EUA letter states a smartphone can be used, but is not required. For more information, see <a href="https://accessbiodiagnostics.net">https://accessbiodiagnostics.net</a></td>
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<tr>
<td>Abbott Diagnostics Scarborough Inc.</td>
<td>BinaxNOW COVID-19 Antigen Self Test</td>
<td>4/1/2021</td>
<td>serial antigen testing</td>
<td>non-Rx</td>
<td>anterior nares swab</td>
<td>age ≥ 2</td>
<td><a href="http://www.fda.gov/media/147251/download">www.fda.gov/media/147251/download</a></td>
<td>with or without COVID-19 symptoms or epi reason to suspect COVID-19</td>
<td>yes</td>
<td>For more information, see <a href="http://www.abbott.com/BinaxNOW-Test-NAVICA-App.html">www.abbott.com/BinaxNOW-Test-NAVICA-App.html</a>. Test available at CVS, Walmart, and other stores or online. Result available in 15 minutes.</td>
</tr>
<tr>
<td>Quidel Corp.</td>
<td>QuickVue At-Home OTC COVID-19 Test</td>
<td>3/31/2021</td>
<td>serial antigen testing</td>
<td>non-Rx</td>
<td>anterior nares swab</td>
<td>age ≥ 2</td>
<td><a href="http://www.fda.gov/media/147247/download">www.fda.gov/media/147247/download</a></td>
<td>with or without COVID-19 symptoms or epi reason to suspect COVID-19</td>
<td>unknown</td>
<td>For more information, see <a href="https://quickvueathome.com/">https://quickvueathome.com/</a>. Result in 10 minutes. Will be available at Walgreens in near future.</td>
</tr>
<tr>
<td>Abbott Diagnostics Scarborough Inc.</td>
<td>BinaxNOW COVID-19 Ag Card 2 Home Test</td>
<td>3/31/2021</td>
<td>serial antigen testing</td>
<td>non-Rx</td>
<td>anterior nares swab</td>
<td>age ≥ 2</td>
<td><a href="http://www.fda.gov/media/147256/download">www.fda.gov/media/147256/download</a></td>
<td>with or without COVID-19 symptoms or epi reason to suspect COVID-19</td>
<td>unknown</td>
<td>Unclear if test currently available. Test uses telehealth proctor. Must have a smart device or computer. Result available in 15 minutes.</td>
</tr>
<tr>
<td>Quidel Corp.</td>
<td>QuickVue At-Home COVID-19 Test</td>
<td>3/1/2021</td>
<td>single antigen test</td>
<td>Rx</td>
<td>anterior nares swab</td>
<td>age ≥ 8</td>
<td><a href="http://www.fda.gov/media/146309/download">www.fda.gov/media/146309/download</a></td>
<td>within first 6 days after symptom onset</td>
<td>unknown</td>
<td>Unclear if test currently available. Result in 10 minutes.</td>
</tr>
<tr>
<td>Ellume Limited</td>
<td>Ellume COVID-19 Home Test</td>
<td>12/15/2020</td>
<td>single antigen test</td>
<td>non-Rx</td>
<td>mid nasal turbinate swab</td>
<td>age ≥ 2</td>
<td><a href="http://www.fda.gov/media/144457/download">www.fda.gov/media/144457/download</a></td>
<td>with or without COVID-19 symptoms or epi reason to suspect COVID-19</td>
<td>yes</td>
<td>For more information, see <a href="http://www.ellumecovidtest.com">www.ellumecovidtest.com</a>. Available at CVS Pharmacy or <a href="http://www.cvs.com">www.cvs.com</a>. Result in 15 minutes. Smartphone and app required as part of test.</td>
</tr>
</tbody>
</table>
Common questions/issues about POC COVID-19 Tests

• Can a point-of-care molecular test be used as a confirmatory test for an antigen test? This is not the intended use of a POC molecular test; preference is to use an NAA test done in a high-complexity lab.

• Are antigen tests accurate? Yes, but depends on the study. Greatest utility is in symptomatic people → if positive antigen test, no further testing needed. Overall, a small # of antigen tests will be recommended to have NAA test confirmation.

• Are POC molecular tests as good as those done in high-complexity labs? Based on a study with one specific POC molecular test, no. But, varies by specific molecular POC test.

COVID-19 Point-of-care tests – helpful websites


Thank you for your attention and for your service during this pandemic!

Questions?

If you have questions later, please email testinginfo@vdh.virginia.gov
Presenters:

Suzie Trotter, RN, BSN, MA
VDH Covid-19 Testing Project Manager
What does COVID-19 Testing Event look like at the facility site?

PRIOR TO THE EVENT:
- Planning
- Logistics
- Workforce
- Training

AT THE EVENT:
- Vendors/LHD/Volunteers will arrive approximately 1 hour early to review action plan for the testing that day and start the set-up process for: Registration, Specimen Collection location, Traffic control, etc.
- MRC Volunteers will work with the Testing Lead at the location
- Specimen Collection will occur and kits will be packaged and transported to the Lab by the LHD/Vendor or by commercial courier.
- Results will be reported by the Lab/Vendor to the facility POC and LHD
Community Testing Overview

★ As a Volunteer, you play a significant role for integrity and reliability of the tests.
★ The tests modality will be chosen for the event but the integrity of the tests, the timeliness including proper test disposal are key factors for the success of these events.
What is a Community Testing Event?

★ Community Testing Events are testing events open to local community members, which are organized by local health departments and community partners.
What is a Community Testing Event?

★ Community Testing Events vary in size - some LHDs choose to hold smaller (50 person) events each day in the same location, while other LHDs hold larger events (250 person) in different locations throughout their District.
What is a Community Testing Event?

★ Community Testing Events can be walk-up/drive-up and can require pre-registration.
What is a Community Testing Event?

★ Community Testing Events are often planned and overseen by the Local Health Emergency Coordinator in each district.
Testing Summary

★ Different Testing Platforms
★ Different Roles needed
★ Training Required
★ Valuable Service to the community

Thank you for your service!
Thank YOU

for choosing to volunteer with the Virginia Medical Reserve Corps!

YOU are the force multiplier that makes Virginia better prepared and resilient!