The NCPA Innovation Center thanks Compliant Pharmacy Alliance for its generous support of additional informational webinars during these extraordinary times.
Opportunities for Pharmacy Testing During COVID-19

Rx Clinic Pharmacy/Avant Institute
Overview

Types of Testing

Vetting Your Testing Partner & The FDA’s Role

How Pharmacists Should Position Themselves For These Opportunities

www.ncpa.org/coronavirus-information
Coronavirus COVID-19 Global Cases by the Center for Systems Science and Engineering (CSSE) at Johns Hopkins University (JHU)

Total Confirmed
379,965

Confirmed Cases by Province/State/Dependency
- 3,485 deaths
  - New York City, New York US
- 881 deaths
  - Nassau, New York US
- 436 deaths
  - Wayne, Michigan US
- 282 deaths
  - King, Washington US
- 211 deaths
  - Westchester, New York US
- 209 deaths
  - Cook, Illinois US
- 200 deaths
  - Bergen, New Jersey US

Total Deaths
11,851

Total Recovered
20,090

Last Updated at (M/DD/YYYY)
4/7/2020, 1:14:58 PM

184 countries/regions


Data sources: WHO, CDC, ECDC, NHG, DXY, 1snot2sers, Worldometers.info, BNO, state and national government health departments, and local media reports. Read more in this blog.

www.ncpa.org/coronavirus-information

https://coronavirus.jhu.edu/map.html
So many lab tests....
Types of COVID-19 Tests

PCR (NASAL)

ANTIGEN (NASAL)

ANTIBODY (SEROLOGY/BLOOD)

Image adapted from: https://www.youtube.com/watch?v=1mbmVqbZ4oA&feature=youtu.be
Types of COVID-19 Tests

- PCR/Molecular Testing
  - Nasal or throat swab test which utilizes a process to analyze molecular breakdown to determine results
  - Best to be used before or during when you have symptoms
  - Virus is easily detectable within 7-10 days of illness
  - Difficult to perform in a provider office (Abbott test kit)

Image adapted from: https://www.youtube.com/watch?v=1mbmVqbZ4oA&feature=youtu.be
Types of COVID-19 Tests

• Antigen Testing
  • Nasal/throat swab
  • Coating of Virus being detected
  • Not reliable until symptoms exist
  • 3-5 days is peak testing time
  • Can be performed in a provider office

Image adapted from: https://www.youtube.com/watch?v=1mbmVqb4oA&feature=youtu.be
Types of COVID-19 Tests

- Antibody Testing
  - Blood sample
  - Test focuses on immunity response to the virus
  - 10 days to detect immunity (IgM – first antibody response)
  - 10-14 days of infection

Image adapted from: https://www.youtube.com/watch?v=1mbmVqbZ4oA&feature=youtu.be
Types of COVID-19 Tests

• Antibody
  • 2-3 weeks later, we can detect IgG
  • 21-30 days later
  • IgG has become higher than IgM which means maximum immunity response has occurred

Image adapted from: https://www.youtube.com/watch?v=1mbmVqbZ4oA&feature=youtu.be
Antibody tests are an effective way to evaluate immunity (yes/no)
- Make behavior recommendations (Work?)
- Point of Care Test (POCT) - simple finger prick
- ~ 10-15 min for results
- COVID-19 knowledge is constantly in flux

These are CONSERVATIVE Recommendations
- Sars-CoV comparison research
- H1N1 Antibody Distributions

Tests should be performed on completely asymptomatic individuals
- (At least 7 days since last symptom or NEVER symptomatic)
- If tested earlier, clinical reliability may be compromised

Once test is completed, no need to run a PCR/Viral RNA test
- If Positive, likely shows you had immunity to virus

https://www.alphabiolabs.co.uk/workplace-testing-services/coronavirus-testing-kit/
www.ncpa.org/coronavirus-information
Sensitivity & Specificity

- **Sensitivity** ("true positive rate") measures how often a test correctly generates a positive result for people who have the condition that is being tested for.
  - A highly sensitive test will identify almost everyone who has the disease and is less likely to generate many false-negative results.
  - (Example: a test with 90% sensitivity will correctly return a positive result for 90% of people who have the disease but will return a negative result — a false-negative — for 10% of the people who have the disease and should have tested positive.)

- **Specificity** ("true negative rate") measures a test’s ability to correctly generate a **negative** result for people who do not have the condition that is being tested for.
  - A test with high-specificity will correctly rule out nearly everyone who does not have the disease and will not generate many false-positive results.
  - (Example: a test with 90% specificity will correctly return a negative result for 90% of people who don’t have the disease, but will return a positive result — a false-positive — for 10% of the people who do not have the disease and should have tested negative.)

The following slide will show specific decision process analysis with information that has been researched from multiple sources and from our own internal discussions. We are sharing to provide insight into what information may be presented in the near future.

However this is NOT a standard recommendation and we advise that you follow the FDA, CDC, and any state, local and/or healthcare, employer/organization guidance and/or guidelines.
**COVID-19 ANTIBODY TESTING DECISION TABLE**

Does the Patient Have Symptoms?

<table>
<thead>
<tr>
<th>Test is (-) Negative</th>
<th>Test is (+) Positive</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>IgG (-) &amp; IgM (-)</strong> • Patient is likely healthy and has not encountered COVID-19 • May recommend social distancing</td>
<td></td>
</tr>
<tr>
<td><strong>IgG (+) &amp; IgM (+)</strong> • Recent infection • Immune system is functional • May consider returning to work</td>
<td></td>
</tr>
<tr>
<td><strong>IgG (-) &amp; IgM (+)</strong> • Response is in early stages • Possible carrier of virus • May recommend social distancing</td>
<td></td>
</tr>
<tr>
<td><strong>IgG (+) &amp; IgM (-)</strong> • Past infection • Immune system is functional • May consider returning to work</td>
<td></td>
</tr>
</tbody>
</table>

**Does the Patient Have Symptoms?**

**Recommend PPE, Not Required**

**Perform Test**

**Test is (-) Negative**

**Test is (+) Positive**

**Does the Patient Have Symptoms?**

**Require patient wear PPE**

**Perform Test**

**Test is (-) Negative**

**Test is (+) Positive**

**Is Patient High Risk?**

**Yes**

**No**

Determine How Long since patient has been symptomatic?

**Less than 1 week**

**Greater than 1 week**

- Potential to be COVID-19
- May recommend self quarantine and monitor symptoms

- Other infecting agent, not COVID-19
- Allergic Response

Call your health care provider for next steps.

May Recommend Self-Quarantine

www.ncpa.org/coronavirus-information

[https://www.alphabiolabs.co.uk/workplace-testing-services/coronavirus-testing-kit/](https://www.alphabiolabs.co.uk/workplace-testing-services/coronavirus-testing-kit/) fda.gov/media/136624/download
Who Are We Communicating With

- OUR PATIENTS
- OUR TEAM
- OUR PROVIDERS
- OUR HEALTH DEPARTMENT
GROWING CONCERNS ABOUT "CRAPPY" ANTIBODY TESTS ON THE MARKET
What is the FDA’s Role in the “Vetting” Process
## Policy/Recommendation Highlights

<table>
<thead>
<tr>
<th>Applicable Technologies</th>
<th>Validation?</th>
<th>Notification to FDA</th>
<th>EUA to FDA after testing initiated?</th>
<th>Location of Testing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Policy A</td>
<td>Yes</td>
<td>From high complexity lab</td>
<td>Yes</td>
<td>High complexity labs only</td>
</tr>
<tr>
<td>molecular, antigen, antibody</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Policy B</td>
<td>Yes</td>
<td>From State; encouraged from labs</td>
<td>Not required</td>
<td>High complexity labs in certain states only</td>
</tr>
<tr>
<td>molecular, antigen, antibody</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Policy C</td>
<td>Yes</td>
<td>From manufacturer</td>
<td>Yes</td>
<td>Clinical labs or point of care; not for home use</td>
</tr>
<tr>
<td>molecular, antigen, antibody</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Policy D</td>
<td>Yes</td>
<td>From developer (manufacturer or high complexity lab)</td>
<td>Not required</td>
<td>Clinical labs or point of care; not for home use</td>
</tr>
<tr>
<td>antibody</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

NOTE: EUA = Emergency Use Authorization
• All tests without an EUA are considered high complexity
DO I NEED A CLIA WAIVER TO PERFORM THIS TEST?

- Awaiting clarification
  - PREP Act currently offers immunity in performing service during this time
  - Best Practice would be to get a CLIA Waiver
- CLIA/CMS is working with FDA to classify these products to establish billing codes
- When a product receives an EUA, they are then granted CLIA Waiver status
- Even if you plan to offer these tests for a cash price, we recommend looking for one that has an EUA or pursuing an EUA (that will then allow the test to be CLIA waived)
- Keep in mind that products that obtain an EUA may have specific instructions for use and where the tests can be administered and how to allow for a test (ie POCT, by prescription only, etc.)
- Every state has specifics around CLIA waived tests, so please know your state rules and regulations

FDA Statements on Serology

Contains Nonbinding Recommendations

Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency

Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff


• Applies to developers of serology tests that identify antibodies (e.g., IgM, IgG) to SARS-CoV-2 from clinical specimens

• Limited to such testing in laboratories or by healthcare workers at the point-of-care

• DOES NOT APPLY TO IN HOME-TESTING
FDA Statements on Serology

• Considering that serology tests are less complex than molecular tests and are solely used to identify antibodies to the virus, FDA does not intend to object to the development and distribution by commercial manufacturers or development and use by laboratories of serology tests to identify antibodies to SARS-CoV-2...

• where the test has been **VALIDATED**,  
• **NOTIFICATION** is provided to FDA,  
• and information along the lines of the following is **INCLUDED IN THE TEST REPORTS**:  
  • This test has not been reviewed by the FDA.  
  • Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.  
  • Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.  
  • Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.
FDA RECOMMENDS that developers planning to submit an EUA for serological testing as the sole basis to diagnose or inform infection status, include information along the lines of the statements above in their test reports until data is submitted and an EUA is authorized for additional uses.
### FDA Statement Policy on Validation Studies for Each Test

<table>
<thead>
<tr>
<th>Molecular Diagnostic (ie PCR)</th>
<th>Antigen Detection</th>
<th>Serological Diagnostics (ie Antibody Tests)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Limit of Detection</td>
<td>Limit of Detection/Analytical Sensitivity</td>
<td>Cross-Reactivity/Analytical Specificity</td>
</tr>
<tr>
<td>Clinical Evaluation</td>
<td>Cross-Reactivity/Analytical Specificity</td>
<td>Class Specificity</td>
</tr>
<tr>
<td>Inclusivity</td>
<td>Microbial Interference</td>
<td>Clinical Agreement Study</td>
</tr>
<tr>
<td>Cross-Reactivity</td>
<td>Clinical Agreement (performance characteristics)</td>
<td></td>
</tr>
</tbody>
</table>

[https://www.fda.gov/media/135659/download](https://www.fda.gov/media/135659/download)
FDA Update as of 4/7 – Serological Tests

Summary

- FDA issued a policy in March to allow developers of certain tests (qualitative)
- Developers can market their tests without prior FDA review
- Goal to allow early patient access
- FDA has authorized one EUA for serological testing intended for clinical labs
- Over 70 test developers have notified FDA of their availability for use
- Some firms are falsely claiming their tests are FDA approved

www.ncpa.org/coronavirus-information
Coronavirus (COVID-19) Update: FDA Alerts Consumers About Unauthorized Fraudulent COVID-19 Test Kits

For Immediate Release: March 20, 2020

Statement From: Commissioner of Food and Drugs - Food and Drug Administration
Stephen M. Hahn M.D.
Associate Commissioner for Regulatory Affairs - Office of Regulatory Affairs
Judith A. McMeekin Pharm.D.

“Watch Your 6!”

www.ncpa.org/coronavirus-information
<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Registration Number</th>
<th>Current Registration Yr</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABBOTT MOLECULAR, INC.</td>
<td>3005248192</td>
<td>2020</td>
</tr>
<tr>
<td>CODIAGNOSTICS</td>
<td>3014214006</td>
<td>2020</td>
</tr>
<tr>
<td>ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO., LTD.</td>
<td>3016447251</td>
<td>2020</td>
</tr>
</tbody>
</table>

**Reagents, 2019-Novel Coronavirus Nucleic Acid**

**CODIAGNOSTICS**


**ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO., LTD.**

- Reagents, 2019-Novel Coronavirus Nucleic Acid - COVID-19(SARS-CoV-2)lgG Antibody Test Kit(Colloidal Gold); COVID-19(SARS-CoV-2)lgM/lgG Antibody Test Kit(Colloidal Gold); COVID-19(SARS-CoV-2)lgG Antibody Test Kit(Colloidal Gold)
Photoshop Magic

This certifies that:
Name: ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO., LTD.
Add: 4th Floor, D-1# Zone, Pearl Industrial Park, 106 Innovation Avenue,
High-Tech Development Zone Hefei Anhui, CN 230088

The Owner/ Operator Number for this Registration is: 3013482554
This certifies that:
Name: **ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO., LTD.**
Add: 4th Floor, D-1# Zone, Pearl Industrial Park, 106 Innovation Avenue, High-Tech Development Zone Hefei Anhui, CN 230088

<table>
<thead>
<tr>
<th>Establishment Name</th>
<th>Registration Number</th>
<th>Current Registration Yr</th>
</tr>
</thead>
<tbody>
<tr>
<td>XUZHOU YONGKANG ELECTRONIC SCIENCE TECHNOLOGY CO., LTD.</td>
<td>3013482554</td>
<td>2020</td>
</tr>
</tbody>
</table>

The Owner/Operator Number for this Registration is **3013482554**.
Feds seize 100 fraudulent COVID-19 test kits shipped from China, addressed to Portland man with prior ties to cannabis industry

Updated Mar 27, 2020; Posted Mar 27, 2020

Package of 100 fraudulent COVID-19 tests seized
At Present, The FDA has not approved direct to consumer or an in-home testing kit

www.ncpa.org/coronavirus-information
VETTING YOUR PRODUCTS IS A MUST...
Even the Shiny New Toy!

- Requires Venus-puncture
- Must be performed in a lab
- Not recommended for pharmacies
How Do You Do Your Due Diligence?

**Step 1:** Look up the company with the FDA

**Step 2:** Identify if the company is registered with the FDA

**Step 3:** Have the company provide the legal and clinical validation of their test

- Determine that first (-) tests and first (+) tests were validated with PCR per FDA recommendation
- ELISA validation may have value but PCR is considered “Gold Standard

**Step 4:** Determine what they validated their results with (upon request)
- Determine that first (-) tests and first (+) tests were validated with PCR per FDA recommendation

**Step 5:** To comply with the FDA, product/kits must have the following per the policy guidelines:
- This test has not been reviewed by the FDA
- Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus.
- Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
- Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status
- Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E
Why Does This All Matter?

• Education = Appropriate Expectations

• We need to focus around healthy individuals that may be exposed but are not sick
  • Remember the first slide?
    • What if 1,000,000 had the virus? How do we impact what the story will be with COVID-19?
  • As the most accessible healthcare provider, pharmacists have an opportunity to be a major player in this space
    • We have an opportunity to support identifying epidemiology & public health measures
    • Widespread testing allows us to determine if a large number of mild infections have gone unnoticed and this will allow many people to return to work faster

• Testing on both ends have their place and can be an effective combination

www.ncpa.org/coronavirus-information

Patients who have recently recovered from COVID-19 have high levels of immunity in the form of antibodies in their blood that can be transfused into very sick COVID-19 patients who do not yet have immunity. This treatment is known as “human convalescent plasma” and has been used in previous pandemics.

If you have recently recovered from COVID-19, please volunteer to have your blood tested to see if you have high levels of antibodies. You may be qualified to donate plasma at The Mount Sinai Hospital and save a life!

To volunteer, please send an email to: COVIDSerumTesting@mountsinai.org

#StayHome #SaveLives
So What Is the Opportunity?

- 320+ Million people in the US.
- As of 4/7 – nearly 400,000 confirmed cases of COVID-19
- According to data analyzed by NCPA, there are 14,866 zip codes in the United States with at least one pharmacy. In 3,057 of those, or roughly 21 percent, the only pharmacies are independently owned pharmacies
- Antibody testing can potentially aid in helping get individuals back to work safely
- Pharmacy has an opportunity to support in surveillance of this pandemic and collect data for public health and epidemiological statistics
- Pharmacy can be a stronghold for vaccination against this virus when it is developed

www.ncpa.org/coronavirus-information
Payment Models

• Cash only!!!
  • FOR NOW

• Stay tuned to see what CMS and FDA establish in the near future regarding CLIA and EUA Tests
Things to Consider Before Starting

- PPE Equipment – consider CDC recommendations
- Staff Education
- CLIA Waiver (Stay Tuned)
- Understanding the FDA Guidelines around the test and what an EUA means
- Types of Tests and what works for your setting
- Additional Guidance from US DHHS or other governing bodies

*STAY UP TO DATE ON INFORMATION!!!! MAY CHANGE DAILY!*
• OASH wants to support expansion of testing for COVID-19

• Pharmacists – most accessible

• Under the Public Readiness & Emergency Preparedness Act (PREP)
  • OASH issues guidance for ordering and authorizing licensed pharmacists to order and administer COVID-19 tests
    • Serology tests
    • Including serology tests that FDA has authorized
    • Pharmacists qualify as “Covered Persons” under PREP Act
    • May receive immunity with respect to all claims for loss from the administration and use of FDA-authorized COVID-19 tests
### COVID-19 Symptoms: Fever, Cough, and Shortness of Breath

<table>
<thead>
<tr>
<th>PRIORITY 1</th>
<th>Ensures optimal care options for all hospitalized patients, lessen the risk of healthcare-associated infections, and maintain the integrity of the U.S. healthcare system</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospitalized patients</td>
<td>Healthcare facility workers with symptoms</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PRIORITY 2</th>
<th>Ensures those at highest risk of complication of infection are rapidly identified and appropriately triaged</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients in long-term care facilities with symptoms</td>
<td>Patients 65 years of age and older with symptoms</td>
</tr>
<tr>
<td>Patients with underlying conditions with symptoms</td>
<td>First responders with symptoms</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PRIORITY 3</th>
<th>As resources allow, test individuals in the surrounding community of rapidly increasing hospital cases to decrease community spread, and ensure health of essential workers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Critical infrastructure workers with symptoms</td>
<td>Individuals who do not meet any of the above categories with symptoms</td>
</tr>
<tr>
<td>Healthcare facility workers and first responders</td>
<td>Individuals with mild symptoms in communities experiencing high numbers of COVID-19 hospitalizations</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>NON-PRIORITY</th>
<th>NON-PRIORITY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Individuals without symptoms</td>
<td></td>
</tr>
</tbody>
</table>

For more information visit: coronavirus.gov

• FDA ([www.fda.gov](https://www.fda.gov))

• CDC ([www.cdc.gov](https://www.cdc.gov))
  - [https://www.cdc.gov/hai/pdfs/ppe/ppe-sequence.pdf](https://www.cdc.gov/hai/pdfs/ppe/ppe-sequence.pdf)


The expectations of life depend upon diligence; the mechanic that would perfect his work must first sharpen his tools.

- Confucius