COVID-19 Testing Opportunity & Quality Validation

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TheComplianceTeam™
Exemplary Provider® Accreditation

AGENDA

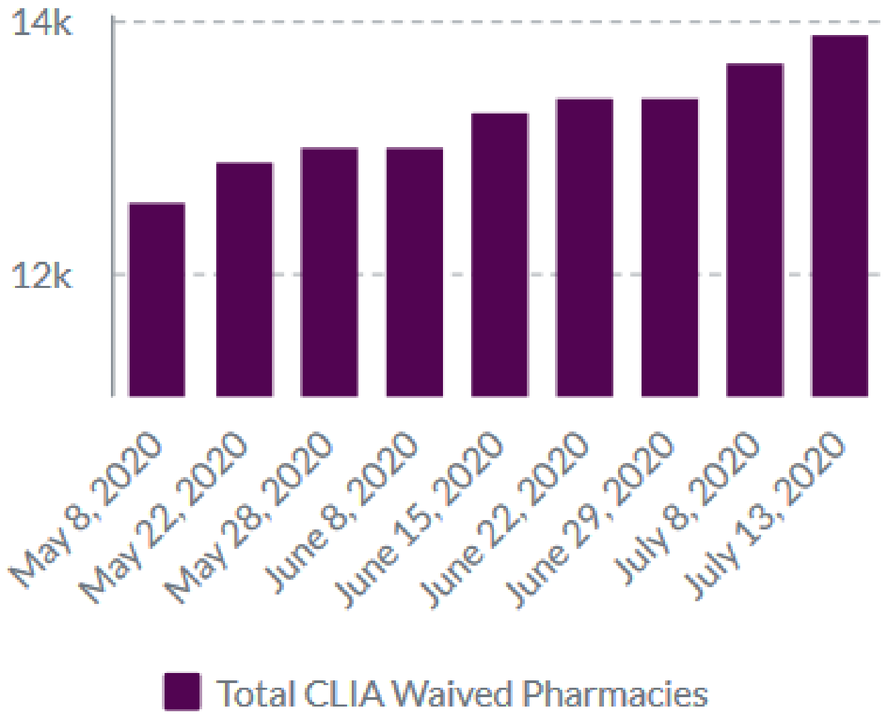
- **Why Test?**
- **Pharmacist / Pharmacy Authorization**
- **Types of Testing**
- **Emergency Use Authorization**
- **Tests that a Pharmacy may Perform**
- **Billing & Reimbursement**
- **TCT Pharmacy Testing Certification Program**
  - **Timeline and Process**
- **Q & A**

Why Test?

- Pharmacists are the most accessible healthcare providers for most people. In 21% of ZIP codes independent pharmacies are the only pharmacies for patients to seek help from in uncertain times.
- The more widespread testing is, the quicker people can return to work and help restart our economy
- Your Pharmacy can establish itself as a coronavirus resource center in the community
- To create a value-added revenue opportunity for Pharmacies
- To give assurances to pharmacy customers and payers that their Pharmacy testing quality has been validated by a third party
    - TCT Pharmacy Testing Certification program provides independent third- party validation of pharmacy processes.

Pharmacist Authorization

- **National Alliance of State Pharmacy Associations (NASPA)**
  - https://naspa.us/resource/covid-19-testing/
  - Provides state by state actions regarding testing
  - Pharmacies that have CLIA Waiver certificates



1,329

Number of Pharmacy Waivers Approved Since May 8, 2020

Types of COVID-19 Testing

- Two kinds of tests are available for COVID-19: viral tests (Molecular) and antibody tests (Serology).
  - A viral test tells you if you have a current infection.
  - An antibody test tells you if you had a previous infection.

- **Polymerase Chain Reaction (PCR) or Molecular Testing:** A molecular diagnostic testing technique that detects the genetic material from the virus. These tests are performed with a nasal or throat swab test, and they are best used before a patient starts exhibiting symptoms or while they are still exhibiting symptoms.

- **Antigen Testing:** Antigen tests are also performed with a nasal or throat swab. They generally can't detect the virus before patients show symptoms, so they should only be used on patients that are currently symptomatic. It can be easily performed in your pharmacy. Antigen tests are very specific for the virus but are not as sensitive as molecular PCR tests. This means that positive results from antigen tests are highly accurate, but there is a higher chance of false negatives, so negative results do not rule out infection. Negative results from an antigen test may need to be confirmed with a PCR test prior to making treatment decisions or to prevent the possible spread of the virus due to a false negative.

- **Antibody Testing:** Sometimes known as a **serology** test, antibody tests use a blood sample (typically a finger stick) to look for an immunity response to the virus. This kind of test starts being useful 10 to 14 days after infection, and patients receiving this kind of test should be asymptomatic — either they are over their symptoms or they never had them.

- www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/testing.html
- www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-first-antigen-test-help-rapid-detection-virus-causes

Emergency Use Authorizations

- The Emergency Use Authorization (EUA) authority allows FDA to help strengthen the nation's public health protections against Chemical, Biological, Radiological & Nuclear (CBRN) threats by facilitating the availability and use of Medical Counter Measures (MCMs) needed during public health emergencies.
- Under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), the FDA Commissioner may allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by CBRN threat agents when there are no adequate, approved, and available alternatives.
- Authorized Settings for Testing:

  H - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform **high complexity tests**.

  M - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform **moderate complexity tests**.

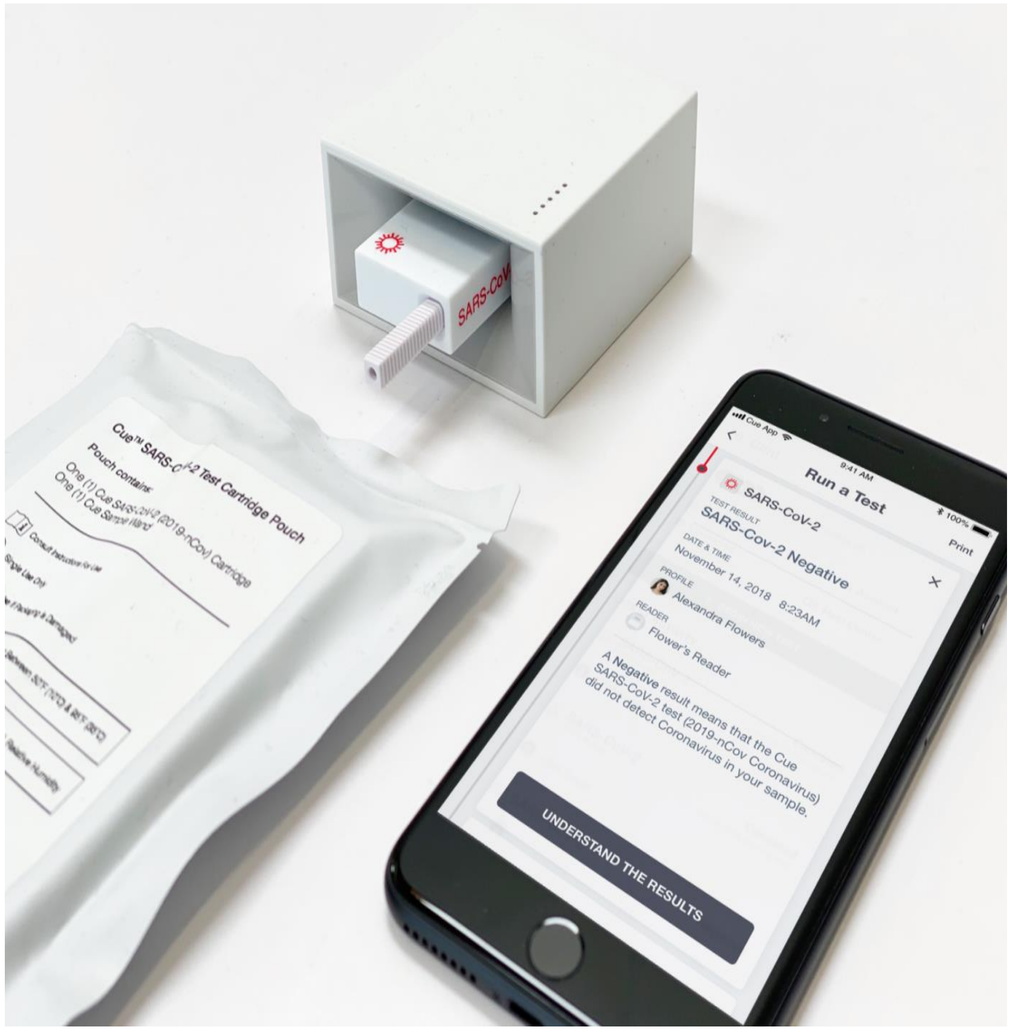
  W - Patient care settings operating under a CLIA Certificate of Waiver.
- Currently, 111 EUA's for testing kits, 6 have a Certificate of Waiver (W) designation.
- www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization

Date EUA Issued	Manufacturer	Diagnostic (Letter of Authorization)	Technology	Authorized Setting(s)
7/02/2020	Becton, Dickinson (BD	BD Veritor System for Rapid Detection of SARS-CoV-2	Antigen, NP, NS	H, M, W
6/10/2020	Cue Health, Inc	Cue COVID-19 Test	Molecular NS	H, M, W
5/8/2020	Quidel Corporation	Sofia 2 SARS Antigen FIA	Antigen NP, NS	H, M, W
3/27/2020	Abbott Diagnostics Scarborough	ID NOW COVID-19	Molecular NP, NS, Throat	H, M, W
3/23/2020	Mesa Biotech, Inc.	Accula SARS-Cov-2 Test	Molecular NS, Throat	H, M, W
3/20/2020	Cepheid	Xpert Express SARS-CoV-2-test	Molecular NP, Nasal Wash/Aspirate	H, M, W

BD Veritor System for SARS-CoV-2 – Becton, Dickinson & Co. (BD)

- Displays easy-to-read digital results for SARS-CoV-2 in 15 minutes.
- Easy operation and 1-button functionality may help reduce the potential for procedural errors.
- www.bd.com

Cue Covid-19 Test -Cue Health, Inc.

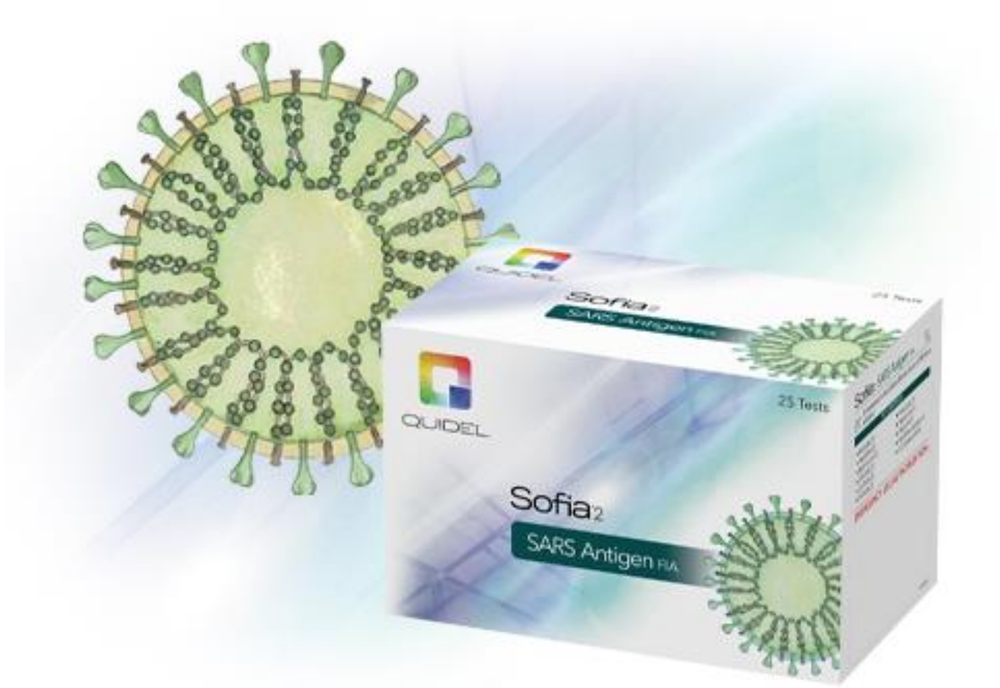


Cue COVID-19 Test is a molecular test that detects the RNA of SARS-CoV-2,

in 25 minutes using a nasal swab sample taken from the lower part of the nose

www.cuehealth.com

Sofia 2 SARS Antigen FIA – Quidel Corporation



Healthcare professionals can purchase the Sofia 2 SARS Antigen FIA through distribution representatives for Cardinal Health, Fisher Healthcare, Henry Schein, or McKesson.

Catalog # : 20374 **Kit Size / Case Size : 25/12**

Description: Test Kit

For use with Sofia 2 - FDA Emergency Use Authorization; Results within 15 mins. **www.quidel.com**

ID NOW COVID-19 – Abbott Laboratories Scarborough, Inc.

- Positive results may be detected in as little as 5 minutes
- Negative results in 13 minutes
- To purchase must contact Abbott Sales or your local Abbott Sales representative

https://www.alere.com/en/home/product-details/id-now-covid-19.html#widgetOverlay

Accula SARS-Cov-Test – Mesa Biotech, Inc.

- This product detects SARS-CoV-2 in throat and nasal swabs and provides results in only 30 minutes.
- The testing device fits in the palm.
- www.mesabiotech.com/coronavirus

Parties in the U.S can purchase this test through Sekisui Diagnostics. They must email covid-19testing@sekisui-dx.com.

Xpert Express SARS-CoV-2-test - Cepheid

It offers compatibility with nasopharyngeal swabs and nasal wash/aspirate specimens collected in patient care settings.

The test can provide rapid detection of the current pandemic coronavirus SARS-CoV-2 in as soon as 30 minutes for positive results

Laboratories must have Cepheid's GeneXpert Dx or GeneXpert Infinity system to use this testing option.

This test is utilized as an Observed and Collect the specimen, then send to laboratory that has the GeneXpert Infinity system. www.cepheid.com

Molecular Test Fact Sheet for Patients

https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas

FACT SHEET FOR PATIENTS

Molecular Laboratory Developed Test (LDT) COVID-19 Authorized Tests

Coronavirus Disease 2019 (COVID-19)

You are being given this Fact Sheet because your sample(s) was tested for the Coronavirus Disease 2019 (COVID-19) using a Molecular Laboratory Developed Test (LDT) COVID-19 Authorized Test (Molecular LDT COVID-19 Authorized Test) that has been issued an Emergency Use Authorization (EUA) by FDA.

This Fact Sheet contains information to help you understand the risks and benefits of using this test for the diagnosis of COVID-19. After reading this Fact Sheet, if you have questions or would like to discuss the information provided, please talk to your healthcare provider.

- **For the most up to date information on COVID-19 please visit the CDC Coronavirus Disease 2019 (COVID-19) webpage:**
- **https://www.cdc.gov/COVID19**

What is COVID-19?
COVID-19 is caused by the SARS-CoV-2 virus. The virus, which can cause mild to severe respiratory illness, was first identified in Wuhan, China, and has now spread globally, including the United States. There is limited information available to characterize the spectrum of clinical illness associated with COVID-19 but it likely spreads to others when a person shows signs or symptoms of being sick (e.g., fever, coughing, difficulty breathing, etc.).

What is the Laboratory Developed Test?
The Molecular LDT COVID-19 Authorized Test is designed, for use in a since laboratory, to detect the virus that causes COVID-19 in respiratory specimens, for example nasal or oral swabs.

Why was my sample tested?
You were tested because your healthcare provider believes you may have been exposed to the virus that causes COVID-19 based on your signs and symptoms (e.g., fever, cough, difficulty breathing), and/or because:

- You live in or have recently traveled to a place where transmission of COVID-19 is known to occur, and/or
- You have been in close contact with an individual suspected of or confirmed to have COVID-19.

Testing of the samples will help find out if you may have COVID-19.

What are the known and potential risks and benefits of the test?

Potential risks include:

- Possible discomfort or other complications that can happen during sample collection.
- Possible incorrect test result (see below for more information).

Potential benefits include:

- The results, along with other information, can help your healthcare provider make informed recommendations about your care.
- The results of this test may help limit the spread of COVID-19 to your family and others in your community.

Reimbursement & Billing for Tests

- If you want to bill for testing, you must have a CLIA or CLIA Waiver CLIA Waiver Application (CMS 116):
  - Processed and approved by each state
  - Each state may have different fees, guidelines, instructions, and forms to complete
  - CMS certification fees are $180 (generally payable once the application is complete)
- Enrolling with Medicare
  - Two sides of **Medicare Part B – Clinical 855B / DME 855S**
- Electronic Billing Services (EBS) offerings:
  - http://www.ebsservice.com/Resources.aspx
    - Access to CMS 116 CLIA Waiver application
    - Access to CLIA Waiver state contacts
    - Access to CLIA Waiver test and fee schedules
    - Access to CMS 855 applications

Reporting COVID-19 Laboratory Data

- Identify your local and state public health departments for direction in reporting

  https://www.naccho.org/membership/lhd-directory Local Health departments

- CDC is working with state health departments to collect SARS-CoV-2 laboratory testing data that they already receive from most clinical laboratories.
- CDC also receives SARS-CoV-2 testing data directly from state and local public health laboratories, a few large commercial laboratories, and its own laboratories.

  For assistance with reporting SARS-CoV-2 testing results, please send an email to DLSinquiries@cdc.gov.

TCT Pharmacy Testing Certification Program

- Application to TCT for program enrollment
- CLIA Waiver and CMS Part B application completion (provided through EBS contracting). Beyond COVID-19, Flu (A/B), RSV, Strep, Glucose, A1C
- Preparation tools to include recorded educational webinars, Live Q&A, Policy & Procedure templates and self-assessment checklists
- Medical Billing / Reimbursement services and payer credentialing assistance available (contracted by EBS)
- Assessment of pharmacy ability to meet criteria for administering/collecting/transporting
- Desk review and validation of standards
- Documentation of successful program completion

Pharmacy Testing Certification Timeline

Immediately

1. Apply to TCT for Pharmacy Testing Certification

2. Sign-up With EBS for assistance with Medical Enrollment and Billing

3. Apply to CMS for a CLIA-Waiver (CMS-116)

Initial 20-Days

1. Attend TCT Educational Webinars and Q&A

2. Policies and Procedures (Use templates provided if needed)

3. Review TCT Self-Assessment Checklist

20-40 Days

1. Receive CMS CLIA-Waiver

2. Submit CMS 855B to CMS/PECOS for Enrollment and Connection

3. Submit required documentation to TCT Portal for Desk Review

End Phase

1. Successfully complete TCT Pharmacy Testing Desk Review and Real-Time Remote™ Process

2. Begin Testing

3. Claims Processing typically 17-20 days

4. Credentialing with 3rd Party Insurers

Steps to Testing Certification

Step 1 - Training can begin immediately. Do not wait for your CLIA waiver to start.

- Apply to The Compliance Team for Pharmacy Testing Certification. For application form, call 215-654-9110.
- Determine if you will be doing Point of Care testing (requires CLIA waiver) or Observe, Collect and Transfer (does not require CLIA waiver). Our program supports both forms of testing.
- Apply to CMS for a CLIA waiver (CMS-116). If you already have a CLIA waiver for other testing services, you should add Covid-19 to your waiver.
- Pharmacy testing is different from normal pharmacy billing, which is why we recommend you investigate a billing services, such as Electronic Billing Services, Inc. www.ebsservice.com. They can walk you through the process of enrollment, billing, and credentialing.

Step 2 – This process can take 20 days or more, depending on your commitment to the process

- Once your Compliance Team application is approved, you will be assigned an advisor who will answer questions and guide you through the certification process. You will also be given access to our providers-only portion of our website.
- Log into The Compliance Team website with your login and password and begin watching educational webinars.
- One of our advisors will schedule a live Q&A call with you.
- Utilize The Compliance Team's Self-Assessment Checklist, available on our website, to assure your pharmacy has all of the proper policy and procedures and steps in place for the certification program.
- Download our policy and procedure templates, if needed, to begin reviewing and/or creating to verify you have the necessary program documentation. Once completed, you can upload it to our portal.

Step 3 – This process can take 10 to 20 days, depending on your commitment to the process and receipt of your CLIA waiver.

- Receive CMS CLIA waiver.
- Submit CMS 855B to CMS/PECOS for Enrollment Connection.
- Finish submitting all required documentation to The Compliance Team for desk review.

Step 4 – This phase can be scheduled at your convenience once all documentation has been submitted.

- Successfully complete The Compliance Team's Pharmacy Testing Desk Review and Real-Time Remote™ Process.
- Receive certificate from The Compliance Team.
- Begin testing.

Notes:

1. The Compliance Team's Pharmacy Testing Certificate is valid for two years.
2. This entire certification can take less than 30 days to complete if you already have a CLIA waiver or if you are doing Observe, Collect and Transfer.

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Questions

We will continue to bring you weekly webinars on this ever-evolving topic

THANK YOU

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