STAY SAFE MN

Cue Testing Information

1/11/2023

Test description

Cue Health offers a diagnostic, rapid molecular COVID-19 test that uses a nasal swab. Results are available within 20 minutes. The Minnesota Department of Health (MDH) has received a limited supply of Cue tests through the U.S. Department of Health and Human Services. These tests will be made available to approved test sites at no cost.

Cue has two tests: one sold over the counter (OTC) and a professional version. They are the same test but have different packaging. The Cue COVID-19 test for over the counter (OTC) is authorized for nonprescription home use.

Federal guidance indicates that any care facility, test site, or other setting assisting with the administration or interpretation of a Cue professional or OTC test must operate under a CLIA certificate of waiver, certificate of compliance, or certificate of accreditation.

Considerations for use

Test sites must agree to and meet several core requirements to receive the Cue tests.

General information

- Cue tests must be administered according to the requirements in the manufacturer instructions and in the applicable FDA emergency use authorization (refer to the **Vendor information** section below for these resources).
- Test sites should follow MDH and Centers for Disease Control and Prevention (CDC) guidance.
  - Cue tests may be considered when rapid results are needed.
  - Cue tests may be used on people with symptoms or without symptoms.
  - Cue tests may be used on people 2 years of age or older.
- The person administering the test uses a Cue Reader (included with a test order) to process and read test results, which are typically available within 20 minutes.
- The person administering the test must report the test result to the person being tested.
- Positive results must be reported to MDH. Refer to the **Reporting results to MDH** section below for more information.

- Test sites are strongly encouraged to advise people who test positive to follow MDH general isolation guidance or the relevant setting-specific guidance. General isolation guidance is at If you test positive or have symptoms (www.health.state.mn.us/diseases/coronavirus/sick.html#positive).
- Even if a test result is negative, additional measures (e.g., testing, isolation) may be recommended, depending on the setting where the patient lives, works, or attends. Refer to setting-specific guidance for additional details at Guidance Library: COVID-19 (www.health.state.mn.us/diseases/coronavirus/guidance.html).

Training

Test sites must review and follow all applicable training standards in the test manufacturer instructions, available below. Training videos, product information, and frequently asked questions are at Cue Health Help & Support (www.cuehealth.com/help-and-support/).

CLIA requirements

- Test sites must operate under a Clinical Laboratory Improvement Amendment (CLIA) certificate of waiver, certificate of compliance, or certificate of accreditation to order and conduct the Cue test, including a Cue over the counter (OTC) test.
  - organization may apply for and obtain a CLIA certificate of waiver from the Centers for Medicare and Medicaid Services (CMS). CMS: Clinical Laboratory Improvement Amendments (CLIA) (www.cms.gov/regulations-and-guidance/legislation/clia).

Individual test site CLIA certificate of waiver

- Some organizations may have an existing CLIA waiver that can be used to administer the Cue test.
- Organizations may obtain their own CLIA certificate of waiver. Test sites can learn more about the CLIA certificate of waiver application process at Minnesota Clinical Laboratory Improvement Amendment (CLIA) (www.health.state.mn.us/facilities/regulation/clia/index.html).
  - For questions about CLIA, contact health.clia@state.mn.us or call 651-201-4120.
  - CLIA application forms may be submitted to health.clia@state.mn.us. Once the form is submitted, it takes MDH approximately three days to process the application. Once MDH processes the application, test sites may choose to receive instructions to pay online with a credit card ($180 every two years), or to wait two to three weeks to receive an invoice in the mail. While this entire process takes about four to six weeks, testing may begin as soon as the test site has been assigned a CLIA certificate of waiver number, which is typically issued approximately three days after MDH receives the application.
- Additional information about waived testing is in a booklet developed by CDC and CMS, Ready? Set? Test! Patient Testing is Important. Get the right results (www.cdc.gov/labquality/images/waived-tests/RST-Booklet_Dec-2019.pdf).

Ordering provider requirements

- An ordering provider is not required to order the Cue OTC test. Please check to ensure that test kits received are OTC tests.
- An ordering medical provider is required to perform the professional version of the Cue test.

Preparing the test area

- The area chosen for testing should provide enough room to safely administer the test, offer privacy, and have surfaces that can hold testing materials and it should include convenient methods to dispose of test material (use biohazard bags).
- Disinfect surfaces within 6 feet of the specimen collection and handling area at these times: before testing begins each day; between each specimen collection; at least hourly during testing; when visibly soiled, in the event of a specimen spill or splash; and at the end of every testing day. Refer to CDC: Guidance for SARS-CoV-2 Rapid Testing Performed in Point-of-Care Settings (www.cdc.gov/coronavirus/2019-ncov/lab/point-of-care-testing.html).
- For information about COVID-19 disinfectants, refer to EPA About List N: Disinfectants for Coronavirus (COVID-19) (www.epa.gov/coronavirus/about-list-n-disinfectants-coronavirus-covid-19-0).

Using personal protective equipment

- Test sites must follow any personal protective equipment (PPE) requirements in the manufacturer instructions and the applicable FDA emergency use authorization.
- Test sites should ensure that adults administering the test understand and implement appropriate infection prevention measures, including the proper use of PPE for the tasks they are performing. For example, personnel collecting specimens or working within 6 feet of someone suspected to be infected with SARS-CoV-2 should maintain proper infection control and use recommended PPE, which could include an N95 respirator or higher-level respirator (or face mask if a respirator is not available), eye protection, gloves, and a lab coat or gown. For more detailed information on standard and transmission-based infection prevention precautions, visit CDC: Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19) Pandemic (https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html).
- Depending on the setting, federal or state law may also impose PPE requirements. For example, the Occupational Health and Safety Administration impose standards relating to the use of respirators, depending on whether respirators are mandatory, voluntary, or employer distributed.
  - For more information, refer to DLI: Voluntary Use of Filtering Facepiece Respirators (N95) for COVID-19 (www.dli.mn.gov/sites/default/files/pdf/fact_voluntry_use_filtering_facepiece_respirators_for_COVID-19.pdf) and CDC: Types of Masks and Respirators (www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/types-of-masks.html).
  - You may also contact:
    Minnesota OSHA Workplace Safety Consultation
    651-284-5060 or 800-657-3776
- For information on standard and transmission-based infection prevention precautions, refer to CDC: COVID-19 Overview and Infection Prevention and Control Priorities in non-U.S. Healthcare Settings (www.cdc.gov/coronavirus/2019-ncov/hcp/non-us-settings/overview/).

Technology needs and considerations

- The Cue test requires the administrator of the test to download the free Cue Health app and to connect to a Cue Reader device, which is included with the test order.

- The free Cue Health app[1] must be installed on a compatible mobile device issued by the test site – personal devices may not be used. Visit Cue Health App Compatible Devices & System Requirements (www.cuehealth.com/help-and-support/compatible-devices/). Test sites should ensure the most up-to-date app is installed. The app is available on commercial application platforms:
  - Apple App Store - Cue Health (apps.apple.com/us/app/id1448897162)
  - Google Play - Cue Health (play.google.com/store/apps/details?id=com.cuehealth.healthapp)
- Up to six Cue Reader devices can be connected to each mobile device.
- The person administering the test, who may be a staff person or an outside provider, will be able to see the test results. MDH recommends against storing health information in the app directly. Refer to the legal and consent section below.

Test performance and technical considerations

Information on test accuracy and any risks or side effects is available in the manufacturer instructions, COVID-19 Cue™ COVID-19 Test Instructions For Use (www.fda.gov/media/138826/download) and The Cue™ COVID-19 Test for Home and Over The Counter (OTC) Use (www.fda.gov/media/146470/download).

If there are technical difficulties when using the Cue test, test sites should contact the vendor for further guidance.

Specimen collection

- Adults must test children 2 years of age or older. Information on training is in the **Vendor information** section below.
- MDH recommends that people administering tests be evaluated first by a registered nurse or health care provider for competency in administering a test.

Reporting results to MDH

- Reporting cases and test results relating to infectious diseases is a vital step in controlling and preventing the spread of communicable disease. Test sites have two different COVID-19 reporting obligations under federal and state law.
  - Test sites operating under a CLIA certificate of waiver must report **positive Cue test results** through one of the methods identified at COVID-19 Test Reporting Requirements (www.health.state.mn.us/diseases/coronavirus/hcp/reportlab.html).
    - All organizations that report through MDH RePortal must use the specific Cue spreadsheet template available at MDH COVID-19 Lab Results Reporting File Template - for Cue Testing (www.health.state.mn.us/diseases/coronavirus/hcp/labcue.xlsx).
    - For templates and guidance specific to schools and child care, refer to COVID-19 Testing in K-12 Schools and Child Care: Reporting (www.health.state.mn.us/diseases/coronavirus/schools/testing.html).

1 Reference to any specific commercial products, process, or service by trade name, trademark, manufacturer, or otherwise, does not constitute or imply its endorsement, recommendation, or favoring by the State.

- **Cases:** Minnesota law also requires reports of **cases** of infectious disease, including COVID-19, regardless of whether the case was identified on-site or elsewhere (e.g., at home test, external test site, provider diagnosis, etc.). Refer to Reportable Disease Rule (www.health.state.mn.us/diseases/reportable/rule/index.html) for more information.

Facilities that do not report test results to MDH as required will not receive additional test kits until reporting issues are resolved.

Legal and consent

- The State of Minnesota makes no representations or warranties, express or implied, regarding these tests, including the use, condition, and effectiveness of tests, or the accuracy of test results. The persons ordering and taking a test accept the test as-is and assume all risks associated with the test. The State of Minnesota assumes no responsibility for actual, consequential, incidental, special, or exemplary damages resulting from, caused by, or associated with any test.
- The person administering the test must ensure that the person taking a test has given informed consent to take the test. The person should work with a parent or guardian, as necessary, to ensure they understand and fully complete any informed consent requirements.
- Test sites must determine how to manage consent. This includes ensuring each person being tested completes the necessary informed consent and may include consent to sharing information with the person administering the test and, if applicable, test sites before the test is performed.
- Test sites may be subject to federal and state laws and are responsible for complying with all applicable legal obligations, including those that govern data privacy and health records.
- Test sites are strongly encouraged to consult with legal counsel. The State of Minnesota cannot provide legal advice to test sites and this document should not be relied on as legal advice.

Cost

The Minnesota Department of Health (MDH) has received a limited supply of Cue tests through a grant by the U.S. Department of Health and Human Services. These tests will be made available at no cost.

Vendor information

For any questions about the Cue test, please contact the Cue team at 833-283-8378 or support@cuehealth.com.

Training

More information is at Cue Health (www.cuehealth.com). Information available includes:

- Cue's COVID-19 Diagnostic Test (www.cuehealth.com/products/how-cue-detects-covid-19/)
- Cue Health Help & Support (www.cuehealth.com/help-and-support/)
  Product documentation, frequently asked questions, and training videos.

- Cue Health COVID-19 Training Webinar (cuehealth.zoom.us/webinar/register/WN_QMOm36oxRVemyBdapAoTxQ)
  A Cue product demo webinar; register for webinar in advance.
- Cue Health COVID-19 Dashboard Webinar (cuehealth.zoom.us/webinar/register/WN_WuvtX8OtR2Khf0ErTCTXvQ)
  Bi-weekly Friday dashboard webinar.

Cue professional test resources

Before administering the Cue professional test, it is critical that test sites and all staff involved in administering the test understand the following information:

- FDA emergency use authorization (EUA):
  DHHS Letterhead: Cue COVID-19 Test (www.fda.gov/media/138823/download).
- FDA instructions for use:
  COVID-19 Cue™ COVID-19 Test Instructions For Use (www.fda.gov/media/138826/download).
- FDA fact sheet for patients:
  Patient FS: Fact Sheet for Patients | Cue COVID-19 Test (www.fda.gov/media/138825/download).

Cue OTC test resources

Before administering the Cue OTC test, it is critical that test sites and all staff involved in administering the test understand the following information:

- FDA emergency use authorization (EUA): Cue COVID-19 Test for Home and Over The Counter (OTC) Use - Letter of Authorization (www.fda.gov/media/146467/download).
- FDA instructions for use: Cue COVID-19 Test for Home and Over The Counter (OTC) Use - Instructions for Use (www.fda.gov/media/146470/download).
- FDA FAQ: Cue COVID-19 Test for Home and Over The Counter (OTC) Use - FAQ (www.fda.gov/media/146472/download).
- FDA fact sheet for individuals: Cue COVID-19 Test for Home and Over The Counter (OTC) Use - Fact Sheet for Individuals (www.fda.gov/media/146469/download).

How to order tests

- A CLIA certificate of waiver number for each test site is required to place an order. Orders received without a CLIA certificate of waiver number will not be processed. Refer to the **CLIA requirements** section above for information on obtaining a CLIA waiver number.
- Ordering test kits requires a lead time of up to two weeks.
- Order Cue test materials at Information for Organizations Requesting Cue Rapid Molecular Tests (www.health.state.mn.us/diseases/coronavirus/hcp/cue.html) (order form is near the bottom of the page).
- Test sites will need test cartridges, test readers, and test control swab packs. There will be:
  - One test cartridge per test.
  - One test reader per 200 test cartridges ordered.

  - One test control swab kit per 100 tests for each test reader.
- Minnesota has a limited supply of free Cue tests and devices available for test sites.
- The Cue test cartridges and test control swab packs you receive may have a printed expiration date on the box that is past the current date (expired). These tests have had their expiration date extended by the FDA. Documentation will be sent with our order confirmation.

For more information

For more information on Cue tests, contact: health.test.help@state.mn.us.

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