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# **COUNTY OF DUTCHESS**

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Office of the Assistant Commissioner

## **COVID-19 Testing Procedure for Dutchess County Schools**

#### Background

COVID-19 remains a serious public health threat to the residents of Dutchess County, NY. Recently, the Governor of New York State has approved that both public and private K-12 schools will be able to open for the upcoming school year and was given guidance documents to develop plans to safely re-open with many COVID-19 mitigations. One of those mitigations is to have a plan for COVID-19 testing for individuals in a school setting. Information about testing in Dutchess County is described below.

#### **Symptoms of COVID-19**

Symptoms of COVID-19 may appear 2-14 days after exposure and include: fever or chills, cough, shortness of breath or difficulty breathing, fatigue, muscle or body aches, headache, new loss of taste or smell, sore throat, congestion or runny nose, nausea or vomiting, and diarrhea. For complete list of symptoms visit: <a href="mailto:cdc.gov/coronavirus">cdc.gov/coronavirus</a>.

#### Types of COVID-19 tests

There are two different types of tests – diagnostic tests and antibody tests.

- A <u>diagnostic test</u> can show if you have an active coronavirus infection and should take steps to quarantine or isolate yourself from others. Currently there are two types of diagnostic tests which detect the virus molecular tests, such as RT-PCR tests, that detect the virus's genetic material, and antigen tests, commonly used as a POC or "Point of Care" test, that detect specific proteins on the surface of the virus. Saliva tests are also becoming available and offers a rapid response option.
- An <u>antibody test</u> looks for antibodies that are made by your immune system in response to a threat, such as a specific virus. Antibodies can help fight infections. Antibodies can take several days or weeks to develop after you have an infection and may stay in your blood for several weeks or more after recovery. Because of this, antibody tests should not be used to diagnose an active coronavirus infection. At this time researchers do not know if the presence of antibodies means that you are immune to the coronavirus in the future.

### How to be Tested for COVID-19

- 1. Contact your primary care provider to receive a prescription to visiting a testing site; or
- 2. Contact a testing site to schedule an appointment.

## **Dutchess County Plan to Support Testing for Schools**

Dutchess County has embarked on a four-prong approach to support the testing needs of local schools as part of their re-opening process. The Dutchess County Department of Behavioral Health (DBCH) seeks to act as a resource to local school districts by defining and outlining testing programs and creating a

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plan for ensure the testing demands of the school community can be met in an effective manner. DBCH is not a direct care provider and does not directly provide COVID-19 testing to residents.

#### 1. Testing Site Resource Guide

Dutchess County maintains an active list of all available testing sites located throughout the county. The most up to date list of providers offering testing and the specific criteria for testing at each site is and will be maintained on Dutchess County's website at <a href="dutchessny.gov/coronavirustesting">dutchessny.gov/coronavirustesting</a>.

Thanks to established relationships with testing sites, Dutchess County is able to provide detailed test site information including test site locations, methods of contacting each site, hours of operation, methods of testing, and types of tests available. The county is updating our resource guide to include information regarding cost and insurance coverage, age restrictions, and average test result turnaround time.

Local testing sites offering diagnostic and/or antibody testing include:

- CareMount Medical Group
- Emergency One Urgent Care
- MidHudson Regional Hospital
- Nuvance Health
- Pulse-MD Urgent Care
- Rite Aid Pharmacy

Residents are directed to review and understand the full list of requirements for each site **BEFORE** visiting.

### 2. Preferred Student and Staff Testing

Dutchess has established a preferred client relationship with Pulse MD Urgent Care to offer rapid testing for students and school staff with preliminary results in approximately 15 minutes. Pulse MD will offer a separate virtual scheduling que for school nurses to directly schedule visits for testing. These virtual scheduling portals will be established for each interested school district. For individuals without insurance coverage, who meet income eligibility criteria may be able to receive these services at a reduced cost.

Rapid antigen tests can provide a positive result within 15 minutes confirming a positive case and allowing for DBCH to partner with schools on rapid response contact tracing to control potential spread. This type of rapid test is known to provide false negative results, therefore traditional swab tests are used to confirm all negative rapid test results. The traditional swab test result is used to confirm a negative result or overturn the initial rapid test result. Individual who receive a negative rapid test result are required to continue isolating until this diagnosis is confirmed by a traditional swab test.

At this time, there is limited availability for rapid test kits, however testing capacity and efficacy is expected to improve in the coming months as Pulse MD expands onsite rapid tests through improved technology.

#### 3. Supply Chain for Rapid Test Kits

Dutchess County is pursuing bulk purchase of rapid testing supplies to make these test kits available for schools to purchase and administer by medical personnel on site as needed. Creation of this distribution channel for schools will provide the benefit of quantity pricing and offer test kits validated for efficacy. Many rapid test kits have historically proven to be both inconclusive and unreliable, thus Dutchess County will require a validation study prior to committing to bulk purchase of these test kits. Ulster County has requested to piggyback upon any distribution channels identified by Dutchess County for acquiring reliable and proven rapid test kits. NOTE: Partnership with a lab with a Clinical Laboratory Improvement Amendments (CLIA) waiver would be essential to properly administer these tests.

### 4. Experimental Sample Pooling or Pool Testing

Pooling of tests is being explored to address capacity for testing. Local schools may be able to take advantage of pool testing technology. Sample pooling allows for more people to be tested quickly using fewer testing resources. Sample pooling does this by allowing multiple people to be tested at once. The samples collected are then tested in a pool or "batch" using one test, rather than running each individual sample on its own test. If the pool is positive, it means that one or more of the individuals tested in that pool may be infected, so each of the samples in that pool are tested again individually. Because the samples are pooled, it is expected that fewer tests are run overall, meaning fewer testing supplies are used and more tests can be run at the same time allowing patients to receive their results more quickly in most cases. This testing strategy is most efficient in areas with low prevalence, meaning most results are expected to be negative.

A sample pooling or pool testing protocol is being used or will be used by a number of colleges and universities in New York State, including Onondaga Community College and Syracuse University. It may potentially be used in grade schools throughout Onondoga County as well. It is important to note that sample pooling is still experimental and it is under review to determine the possible benefits and accessibility for local schools.

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#### **ADDENDUM: Testing of Dutchess County School Population**

Generally, viral testing for SARS-CoV-2 is diagnostic when conducted among individuals with symptoms consistent with COVID-19 or among asymptomatic individuals with known or suspected recent exposure to SARS-CoV-2 to control transmission, or to determine resolution of infection. Viral testing is screening when conducted among asymptomatic individuals without known or suspected exposure to SARS-CoV-2 for early identification, and surveillance when conducted among asymptomatic individuals to detect transmission hot spots or characterize disease trends.

CDC does not currently recommend using antibody testing as the sole basis for diagnosis of acute infection, and antibody tests are not authorized by FDA for such diagnostic purposes. In certain situations, serologic assays may be used to support clinical assessment of persons who present late in their illnesses when used in conjunction with viral detection tests. Serologic assays for SARS-CoV-2, now broadly available, can play an important role in understanding the transmission dynamic of the virus in the general population and identifying groups at higher risk for infection.

Certain tests to detect COVID-19 may be performed at the **point-of-care, or POC**, meaning that the process of medical diagnostic testing occurs at the time and place of patient care, e.g. bedside, physician's office, etc. POC testing offers additional benefits including speed of diagnosis, and simplicity of use (push button, single cassette, etc.). Various types of technologies may be utilized in POC tests, such as:

- nucleic acid amplification (molecular) tests that detect the presence of a pathogen;
- antigen tests that also detect the presence of a pathogen; and
- serological tests that can determine whether an individual has immunological evidence of exposure to a pathogen. (Note that there are currently no FDA authorized serological point of care tests; however, they may become available in the future.) POC tests are a useful component of the diagnostic strategy in response to the SARS-CoV-2 (COVID-19) outbreak.

## **Nucleic Acid Amplification POC Tests**

Mobile platforms Mobile platforms are small and portable, and are optimal for deployment to remote, outbreak and crisis situations. These POC instruments are lower throughput (i.e., process fewer samples in a specified timeframe) than other platforms (instruments), and typically run one sample at a time in 5-30 minutes. For this reason, it may not be feasible to test, for example, an entire manufacturing facility of thousands of employees for COVID-19 with a POC platform. In such a situation, the POC instrument could be used to test the highest priority (symptomatic) individuals, while test orders for asymptomatic individuals could be sent out for processing at an offsite laboratory using high throughput platforms. The Abbott ID NOW is an example of a mobile molecular POC device for COVID-19.

Facility-based platforms are larger POC platforms, such as the Cepheid GeneXpert® Xpress, another example of a POC device that can be used for COVID-19, are often based in hospitals and medical centers. They have higher throughput than the mobile platforms, but still return results in less than an hour. The components are often self-contained, requiring fewer laboratory resources (i.e., hands-on personnel) than other laboratory-based instruments. Using a rapid, facility based POC platform to test

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healthcare providers and symptomatic patients enables maintenance of workforce (rapid return to work), reduces PPE usage, and rapid diagnosis for critically ill patients.

# **Antigen POC tests**

These diagnostic tests quickly detect fragments of proteins found on or within the virus by testing samples collected from the nasal cavity using swabs. The Quidel Corporation's Sofia 2 SARS Antigen FIA received an EUA from the FDA on May 8, 2020 and is approved for point-of-care-testing by facilities operating under a CLIA Certificate of Waiver.

The antigen test can provide results in minutes; however, antigen tests may not detect all active infections, based on their mechanism of action. These tests are very specific for the virus but are not as sensitive as molecular PCR tests. **Therefore, 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.** With this in mind, 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.

# Proposed Uses of Point-of-Care Diagnostic Tests for SARS-CoV-2 (COVID-19)

POC rapid tests are envisioned to supplement laboratory testing, enabling testing to be available for communities and populations that cannot readily access laboratory testing or need to quickly address emerging outbreaks. Laboratory testing remains the primary testing mechanism for the nation because of the ability to perform a high volume of tests at one time.

#### Requirement for establishing POC in school setting

- Medical director/provider to order and interpret results
- CLIA wavered lab to run the POC test
- Trained staff to administer the test
- Staff to document and maintain results in a database (protected medical information)
- Communicate positive results with DOH staff
- The positive cases of POC testing should be validated with the gold standard test