Revised 12/27/2022

OASAS Guidance Regarding SARS-CoV-2 Point of Care (POC) Antigen (Ag) Testing in Inpatient and Residential Settings and Opioid Treatment Programs (OTPs)

This guidance provides information on SARS-CoV-2 (COVID-19) POC Ag testing for New York State (NYS) Office of Addiction Services and Supports (OASAS) licensed, funded, and operated inpatient and residential programs and OTPs.

General Information

There are many waived POC SARS-CoV-2 diagnostic tests available. The test must be ordered by a qualified healthcare provider (including physicians, physician assistants, and nurse practitioners).

Most of these tests can be done via an anterior nares swab. Some may also utilize a nasopharyngeal swab option.

Some possible SARS-CoV-2 POC Ag tests include the Abbott BinaxNOW, the Quidel QuickVue, the Meridian Bioscience GenBody, the iHealth Labs iHealth, the Access Bio CareStart, and the Siemens Healthineers Clinitest.

See specific instructions for use of the tests specified above available at:
https://www.fda.gov/media/141570/download (Abbott BinaxNOW),
https://www.fda.gov/media/150788/download (Meridian Bioscience GenBody),
https://www.fda.gov/media/144668/download (Quidel QuickVue),
https://www.fda.gov/media/153923/download (iHealth Labs iHealth),
https://www.fda.gov/media/151248/download (Access Bio CareStart), and
https://www.fda.gov/media/155175/download (Siemens Healthineers Clinitest).

For additional information on the Abbott BinaxNOW test, also see https://www.globalpointofcare.abbott/en/product-details/navica-binaxnow-covid-19-us.html under Helpful Documents). None of these tests require a separate instrument to run the test; it is performed similarly to a urine pregnancy test with a "card".

On November 1, 2022, the U.S. Food and Drug Administration (FDA) informed developers of SARS-CoV-2 antigen tests that they are revising the authorized use of SARS-CoV-2 antigen tests. **Serial testing will now be required when testing both symptomatic and asymptomatic individuals.**

- For symptomatic individuals, SARS-CoV-2 antigen tests will now be authorized for use on symptomatic individuals when tested at least twice over three (3) days with at least 48 hours between tests. Serial (repeat) testing on symptomatic individuals is a new requirement.

- For asymptomatic individuals, SARS-CoV-2 antigen tests will now be authorized for use on asymptomatic individuals when tested at least three (3) times over five (5) days with at least 48 hours between tests. Performing serial (repeat) testing 3 times is a new requirement.

Manufacturers will be updating instructions to reflect these new serial testing requirements. See FDA guidance here.

Ag levels in specimens collected beyond 7 days of the onset of symptoms may drop below the limit of detection of the test. This may result in a negative test result, while a more sensitive laboratory-based SARS-CoV-2 molecular (PCR) test may produce a positive result on the same specimen. Therefore, negative results from symptomatic patients should be treated as presumptive negative and confirmed with a laboratory-based SARS-CoV-2 molecular (PCR) assay**. See below for additional information on interpreting SARS-CoV-2 POC Ag test results when testing symptomatic or asymptomatic individuals.**

In addition, some brands of the COVID-19 POC Ag test may be less sensitive overall at detecting SARS-CoV-2 or may be less sensitive to detecting certain variants or subvariants of SARS-CoV-2. For this reason, the testing strategy must involve serial testing (see FDA guidance above) to increase the overall sensitivity of the tests' performance. See the IFU for the brand of POC Ag test you are using for recommendations on the use of serial testing for that particular test.

SARS-CoV-2 (COVID-19) POC Ag Testing:

SARS-CoV-2 (COVID-19) POC Ag tests are being provided to NYS OASAS licensed, funded, and operated programs who have requested them at no charge, pending availability of testing supplies.

See FDA guidance here.

Algorithm for Interpreting Serial POC Ag Test Results:

Manufacturers will also be required to update instructions on how test results are interpreted test when serial testing is performed.

Status on first day of Testing	First Result Day 1	Second Result Day 3	Third Result Day 5	Interpretation
With Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	N/A	Negative for COVID-19
Without Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	Positive	Positive for COVID-19
	Negative	Negative	Negative	Negative for COVID-19

There are several key considerations when planning to implement SARS-CoV-2 POC Ag testing in OASAS settings, including safety and training, in house laboratory issues, testing supplies, reporting of results, maintenance of records, interpretation and application of test results, linking patients to SARS-CoV-2 molecular (PCR) diagnostic testing when indicated, and recommendations on the frequency of testing in your individual setting. Programs should work with their

medical and nursing leadership to develop policies, procedures, and protocols to reflect these key considerations.

Safety and Training

1. All healthcare personnel collecting nasal (anterior nares) swab samples should utilize appropriate PPE, including a fit-tested N95 or higher-level respirator (or face mask if a respirator is not available), eye protection (goggles or a face shield that covers the front and sides of the face), gowns, and gloves if testing is done by a tester and within 6 feet of the patient. If the patient self-swabs and the observing, trained healthcare personnel is not within 6 feet of the patient, then only a face mask (preferably a KN95 or a non-fit-tested N95), eye protection (goggles or a face shield that covers the front and sides of the face), and gloves are indicated for the observing healthcare personnel. See Training for Sample Collection Procedure for SARS-CoV-2 Diagnostic Testing (slides 16 thru 22 and slide 32), and CDC guidance here, and here.
2. The laboratory director (or designee) at your institution should read the Instructions for Use (IFU) for any SAR-CoV-2 POC Ag test utilized (Abbot BinaxNOW: https://www.fda.gov/media/141570/download, Meridian Bioscience GenBody: https://www.fda.gov/media/150788/download, Quidel QuckVue: https://www.fda.gov/media/144668/download, iHealth Labs iHealth: https://www.fda.gov/media/153923/download), Access Bio Care Start (https://www.fda.gov/media/151248/download), and Siemens Healthineers Clinitest (https://www.fda.gov/media/155175/download). Any staff performing testing need to be properly trained and their competency assessed. Competency assessment is a process to make sure that staff are following the proper test procedure after initial training, should be performed at least annually, and should be documented.
   Abbott BinaxNOW training: Training videos, modules, helpful documents, and frequently asked questions for the BinaxNOW™ test can be accessed on Abbott's website: https://www.globalpointofcare.abbott/en/support/product-installation-training/navica-brand/navica-binaxnow-ag-training.html. All training modules must be completed. Observation of proper specimen collection and test performance and interpretation, using a positive and negative control, must be completed prior to testing patients. Sites not using the NAVICA app QR code (*see below) to identify the card as corresponding to a specific tested individual must have a means to uniquely identify the patient's card to avoid a test mix-up.
   Watch Abbott BinaxNOW sample collection technique video here (under Helpful Documents->Videos)

   For questions regarding the BinaxNOW™ test, please call Abbott Technical Services at 1-800-257-9525 or email ts.scr@abbott.com.

   Quidel QuickVue training: A training PowerPoint, video, and test (with printable certificate of training completion) can be accessed at Quidel's website: https://www.quidel.com/immunoassays/quickvue-sars-antigen-test.

   For questions regarding QuickVue and other Quidel diagnostic solutions contact 800-847-1517 or visit **quidel.com**.

   For technical support on this training portal, please contact us at **support@digitellinc.com** or by phone at 1-716-338-0332. Phone support is available Monday to Friday from 9:00 am to 5:00 pm ET.

   Meridian Bioscience GenBody training: Review information on the Meridian Bioscience GenBody website: https://www.meridianbioscience.com/diagnostics/disease-areas/respiratory/coronavirus/genbody-covid-19-ag/?country=US and the GenBody Instructions for Use (IFU): https://www.fda.gov/media/150788/download

   For technical support regarding the diagnostics of the GenBody test: call 1-800-543-1980 or email: CustomerService@meridianbioscience.com

iHealth Labs iHealth training: Review information on the iHealth Labs iHealth website: https://ihealthlabs.com/pages/support-ihealth-covid-19-antigen-rapid-test and the iHealth Instructions for Use (IFU): https://www.fda.gov/media/153923/download

For technical support regarding the diagnostics of the iHealth test: submit a support ticket on their website (https://ihealthlabs.com/pages/contact-us) or call 1-855-816-7705, M-F, 8:30 AM-5:30 PM PST.

Access Bio CareStart training: Review information on the Access Bio CareStart website: https://accessbio.net/products/covid-19-detection-kits/carestart-covid-19-antigen-home-test and the Access Bio CareStart Instructions for USE (IFU): https://www.fda.gov/media/151248/download

For technical support regarding the CareStart test: send Access Bio a direct message through their website: https://accessbio.net/contact-us, email Access Bio at info@accessbio.net or call them at 732-873-4040.

Siemens Healthineers Clinitest Training: Review information on the Siemens Healthineers Clinitest website: https://www.clinitest.siemens-healthineers.com/usa and the Siemens Healthineers Clinitest Instructions for Use (IFU): https://www.fda.gov/media/155175/download

FAQ on the Clinitest: https://www.clinitest.siemens-healthineers.com/en/rapid-antigen-safety-faq

For a video on administering the Clinitest: https://www.youtube.com/watch?v=7Xu01IuPNUM

For technical questions or concerns, you can reach the regional support center here: covidselftest-USA.dl@siemens-heathineers.com or 833-933-2340.

a. Staff should be trained in the proper donning and doffing of PPE. See CDC Using Personal Protective Equipment and Training for Sample Collection Procedure for SARS-CoV-2 Diagnostic Testing (slides 24 and 25).
b. Programs should contact their local health department and/or their OASAS Regional Office (RO) or State Opioid Treatment Authority (SOTA) if they need assistance in identifying existing resources for fit testing for respirator masks.

All staff collecting samples should be properly trained in safe sample collection techniques. See Training for Sample Collection Procedure for SARS-CoV-2 Diagnostic Testing (slides 26 thru 37).

***NAVICA app:**
Abbott offers a phone app reporting system. The patient downloads the consumer app and the testing site can use the NAVICA Administrator App to pair a patient to a test card and to communicate encrypted BinaxNOW™ COVID-19 Ag Card test results to participants. The NAVICA Administrator app is designed to be used on a computer tablet. See the Abbott website for details.

It is not required that the NAVICA app be used. The results of the test can be recorded manually, and the report provided to the individual tested as per state requirements and your laboratory's procedures. All results must also be reported to the NYS Department of Health (see page 5 below).

3. Non-medical, unlicensed staff may collect anterior nares specimens if properly trained. See DOH Specimen Collection Training for Unlicensed Individuals.
4. Test samples should be handled properly and transported to the in-house laboratory or otherwise designated area for processing. Please note that the COVID-19 Ag Card Instructions for Use for each brand of test state that direct nasal swabs should be tested as soon as possible after collection and provide instructions on the transport and handling specimens if they cannot be tested immediately.

5. The physical space where test samples are collected should have adequate ventilation, which should be discussed with and approved by the local department of health (or infection control department for hospital-based programs) before beginning test sample collection. Test samples can also be collected safely outdoors. Sample collection should never be done in shared client rooms.
6. Policies, procedures, and protocols should be in place to ensure that the number of health care personnel present during the procedure should be limited only to those essential for patient care and procedure support (i.e., the person collecting the sample) during sample collection, and that the room is properly sanitized afterwards. Visitors should not be present for specimen collection. **Non-aerosol-generating procedures (e.g., interviewing) should be performed before any procedures that may lead to coughing or sneezing. Collecting NP/OP/anterior nares specimens should be the last activity performed just before leaving the room**. The potential for aerosolization exists with nasal (anterior nares) swabs as the procedure may generate a cough or sneeze. As indicated above, if a staff member is doing the nasal (anterior nares) swab, full PPE must be worn. If the patient self-swabs and the observing, trained healthcare personnel is not within 6 feet of the patient, then only a face mask (preferably a KN95 or non-fit-tested N95), eye protection (goggles or a face shield that covers the front and sides of the face), and gloves are indicated for the observing healthcare personnel.
7. Patients should not be transported by staff or be accompanied on public transit solely for the purposes of test sample collection, as this could increase exposure to COVID-19 for staff, other patients, and the community.
8. See CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens for COVID-19, Training for Sample Collection Procedure for SARS-CoV-2 Diagnostic Testing, and here (slides 18-43).

Limited Services Lab (LSL) Issues

- Only facilities that have, at a minimum, an LSL certification may perform SARS-CoV-2 POC Ag testing. The LSL certificate for the facility must be current. For more information on becoming an LSL, see the OASAS FAQ here. See LSL application materials here. To determine if your facility is an LSL, check here.
- If your facility already has a current LSL, you must add the SARS-CoV-2 POC Ag test to your LSL registration. The Laboratory Director or designee at your facility, must fill out and submit the Change Test Request Form immediately so that your use of the test is not delayed. Information on adding COVID-19 test to an existing LSL can be found here. Click on "COVID-19 Response for Limited Service Laboratory Registration Requests and Additions" and follow the instructions provided. The NYS DOH has agreed to accept an email with an attachment of a high-quality scan of the signed change request form (instead of using the US mail) to submit the form. The email address is clepltd@health.ny.gov. See here.
- To assist the DOH Clinical Laboratory Evaluation Program (CLEP) to triage incoming emails, please provide the following information in the Subject Line of your email: your PFI# and the test(s) that you wish to add, for example: **PFI#: ____ - Request to Add COVID-19 Abbott BinaxNOW COVID-19 Ag Cards**
- For general information on SARS-CoV-2 (COVID-19) testing and the LSL, see the CLEP page here.
  If testing will occur at a location other than the address shown on the LSL registration, the LSL must request approval to perform Community Screening. Next to test procedure name, indicate "request Off-Site Community Screening approval."

  If an LSL wants to do testing at off-site Community Screening events, they must request Community Screening approval. Laboratory staff bring testing equipment from the registered LSL to an off-site location where specimen collection and testing will occur. At the end of the event, staff, equipment and records return to the registered LSL location. If a facility does not want to perform testing using the SARS-CoV-2 POC Ag Test Cards, the facility can partner with another facility that has NYS approval to use this test for community screening.

Testing Supplies

OASAS will be purchasing the SARS-CoV-2 POC Ag testing supplies on behalf of the OASAS programs that have requested them. Testing supplies will be distributed to programs, and more information about this will be provided to your designated LSL point of contact.

Receipt and Storage of Kits:

Note the expiration date on each kit. All kits coming in a shipment should be noted as quality control testing is required for each shipment. Please note that there are a variable number of tests provided in each kit depending on the brand of COVID-19 POC Ag test.

The kits should be stored at the temperature indicated on the instructions. Most kits are stored at room temperature (2-30^0 C = 35.6 - 86-30^{0}F).

Disposal of Test Card:

The card should be disposed of as regulated medical waste (using a biohazard red bag).

Interpretation and Application of Test Results

All tests have limitations, including false positive and false negative rates. Results should be used in conjunction with other clinical data including symptoms and history of COVID-19 contacts to inform clinical decision-making.

As with any test, the prior probability of infection should be considered (e.g., symptomology, prevalence in the region, history of contact with a positive person, travel history, presence at an event associated with an outbreak, etc.). For detailed information regarding SARS-CoV-2 POC Ag testing, see FDA guidance here, which includes the requirements for serial testing with POC Ag tests.

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	Negative	Negative	N/A	Negative for COVID-19
Without Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	Positive	Positive for COVID-19
	Negative	Negative	Negative	Negative for COVID-19

Each testing site should have a plan for obtaining confirmatory laboratory-based molecular (PCR) testing when it is indicated and should consult a healthcare provider if questions arise in interpretation of a test result. Note, there is limited data on the performance of this test in asymptomatic individuals infected with the virus.

Important considerations in the context of using serial SARS-CoV-2 POC Ag testing include the following: Is a COVID-19 outbreak occurring in the general public? Is an outbreak occurring in my facility (i.e., is there a positive COVID-19 case in patients or staff members within the facility)? Is the person being tested symptomatic (with COVID-19 like symptoms) or asymptomatic? Where will I refer the patient for molecular testing if indicated to do so by the FDA algorithm?

Reporting of Results:

All facilities with an LSL who are performing SARS-CoV-2 Ag tests are required to report test results to the Commissioner through the Electronic Clinical Laboratory Reporting System (ECLRS). As noted in guidance that OASAS issued with the NYS Office of Mental Health, OMH and OASAS Ambulatory and Residential Program COVID-19 Testing, Record Keeping, and Notification Instructions, all consent forms must be updated to include the possibility of reporting confirmed or suspected COVID-19 to the NYS DOH and local health departments. Please note that one signed patient consent is sufficient for serial testing as the patient consent form indicates that any brand of POC Ag test may be utilized and that serial testing is required.

What information needs to be reported?

According to updated CDC/HHS guidance (found here), reporting of negative results for non-NAAT tests (rapid or antigen test results) is no longer required. No COVID-19 Antibody results, either positive or negative are reportable. See the CDC informational page on reporting here. Positive and indeterminate results need to be reported.

In addition, facilities performing SARS-CoV-2 Ag testing are required to report:

- test type;
- test result including positive and negative results;
- test result date;
- accession number;
- patient age;
- patient race;
- patient ethnicity;
- patient sex;
- patient name;
- patient's complete phone number;
- patient date of birth;
- full patient address where currently residing;
- county;
- ordering provider name;
- ordering provider address with zip;
- ordering provider phone number;
- performing facility name and CLIA number;
- performing facility zip code (full address);
- specimen source;
- date specimen collected;
- patient's occupation;
- patient's employer name;
- patient's work address;
- patient's employer phone number;
- whether the person being tested attends, works or volunteers in a school and if so, the name and location of the school. This includes elementary, secondary and post-secondary/higher education. For minors, the detailed information can be entered in the occupation and employment fields.

How often are test results reported?
All facilities performing testing for COVID-19 must report test results immediately within 24 hours through ECLRS.

How are test results reported?
Results can be reported to ECLRS by file upload or by manual entry into ECLRS. Please contact the ECLRS Help Desk at (866) 325–7743 or eclrs@health.ny.gov with any technical questions.

Maintenance of Records:

Any records associated with the use of this test must be maintained until otherwise notified by the FDA. Such records will be made available to the FDA for inspection upon request (see the instructions provided by the manufacturer of the COVID-19 POC Ag Card).

Linking Patients Who Need SARS-CoV-2 Molecular (PCR) Diagnostic Testing When Indicated:

If your facility does not have the capacity to do SARS-CoV-2 molecular (PCR) diagnostic testing on site when indicated (see here, here, and here for indications), then there need to be policies, procedures, and linkage agreements in place for patients to receive appropriate testing in a timely manner. See here to locate a COVID-19 test site near you. Your local health department may have further COVID-19 testing resources available.

Recommendations on Frequency of Testing:

The guidance regarding use of SARS-COV2 POC Ag testing continues to evolve. There is no clear precedent on how and when to utilize SARS-CoV-2 POC Ag testing in substance use disorder (SUD) treatment settings. The following recommendations will be used to determine the amount of testing supplies that programs are allocated. Each individual facility or OTP should develop policies and procedures that address their unique practice setting.

Recommendations for inpatient rehabilitation and detoxification settings, and in 820 stabilization and rehabilitation programs: For inpatient rehabilitation and medically managed or medically supervised withdrawal settings, and in 820 stabilization and rehabilitation programs, **use the POC Ag test to test serially (three times)** all patients at admission , anyone who develops symptoms consistent with COVID-19, those who have been exposed to a known COVID-19 case (close exposure within the facility and/or outside of the facility). See FDA guidance here. If there is a confirmed case of COVID-19 within the facility among either a patient or a staff member, immediate isolation of the positive individual(s) will need to occur. In addition, facilities will need to conduct a case investigation to identify direct (close) contacts to the case(s) in need of serial testing and quarantine and will need to restrict movement within the impacted facility unit(s) or facility-wide, as appropriate, in consultation with the OASAS RO and the local health department. The same process will occur again if any breach in infection control protocols occurs while individuals are under isolation protocol.

Recommendations for longer term residential settings (i.e., all 819 and 820 reintegration programs): For longer term residential settings (i.e., all 819 and 820 reintegration programs), test serially in outbreak situations only. If the facility has a confirmed COVID-19 case within the facility among either a resident or a staff member, then serially test all residents in the facility. The OASAS RO should be contacted in either situation to request that testing supplies are deployed to the residential facility, if indicated. See FDA guidance here.

Recommendations for OTPs: In the absence of active community spread of COVID-19, OTPs can consider using SARS-CoV-2 POC Ag testing in twice monthly testing events on randomly selected days. The frequency of the testing events may be informed by how many patients come on any given day, i.e., if fewer patients attend on a given day, then perhaps schedule testing events more frequently. This strategy might include selecting different days of the week to do testing events in order to offer testing to individuals on different dosing/pick-up days. On selected days, testing should be offered to any patient who presents to the OTP. This is an attempt to capture as many different patients over time without depleting testing supplies/resources or creating undue OTP staff burden. Other approaches might be considered and discussed with OASAS (RO and SOTA) for input. If using POC Ag testing, then it is required to do serial testing. See FDA guidance here.

If there is a confirmed case of COVID-19 that impacts the OTP among either a patient or a staff member, contact tracing efforts will inform testing recommendations for patients and staff at the OTP.

OTPs should not BRING patients in FOR TESTING when there is an outbreak at the OTP. In the context of an outbreak at the OTP, the OTP should focus on reducing visits to the OTP as appropriate and per previous guidance (i.e., through increased use of take-home doses, telehealth, designated others, and, if available, methadone delivery system (MDS).