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| **Administrative Policy and Procedure** | **Subject: Covid 19 Testing**  |
| **Approved by:**  |  |
| **Effective: 5**/11/2020 | **Revised:** 1/7/2021; 6/14/2021; 7/14/2021; 9/16/2021; 10/27/2021; 1/5/2022, 3/16/2022, 6/8/22, 10/14/22  |

**POLICY**

The facility will test all staff and residents for COVID-19 in accordance with both State and Federal regulations and as indicated to prevent the spread of Covid-19 infection and to ensure appropriate clinical treatment. The facility will utilize both Point of Care (POC) Antigen tests and PCR tests, as applicable, to promote expedited results as needed. The facility will adjust testing requirements as per State and Federal regulations based on community transmission and potential outbreaks.

**DEFINITION(S)**

**Outbreak**: a new Covid-19 infection in any healthcare personnel (HCP) or any nursing home-onset Covid-19 infection in a resident.

**Fully Vaccinated**: ≥2 weeks following receipt of the 2nd dose in a 2-dose series, or ≥2 weeks following receipt of 1 dose of a single-dose vaccine

**“Up To Date” Covid Vaccination**: a person has received all recommended Covid 19 vaccines including any booster dose(s) when eligible

**Close Contact**: refers to someone who has been within 6 feet of a Covid-19 positive person for a cumulative total of 15 minutes or more over a 24-hour period.

**Higher-risk Exposure**: refers to exposure of an individual’s eyes, nose, or mouth to material potentially containing SARS-CoV-2, particularly if present in the room for an aerosol-generating procedure (AGP).

**Level of Community Transmission**: refers to a facility’s level of Covid-19 transmission. This metric uses two indicators for categorization: (1) total number of new cases per 100,000 persons within the last 7 days and (2) percentage of positive diagnostic and screening nucleic acid amplification tests (NAAT) during the past 7 days.

**PROCEDURE:**

1. The Facility will contract with a certified lab to provide testing as needed and in accordance with NYSDOH and FDA approved testing to provide test results for all tests in a timely manner (within 48 hours of specimen collection)
2. The facility will utilize POC Antigen tests and/or PCR tests via contracted lab(s) and facility “lab” (if facility - has a CLIA waiver) for testing in accordance with CMS/NYSDOH recommendations as needed to ensure appropriate diagnosis, management, and cohorting are implemented
	* Facility will follow manufacturer’s instruction for use (MIFU) for each type Covid-19 test kit used for outbreak testing (e.g., Abbott Binax or iHealth OTC tests)
3. Staff will utilize all PPEs (gown, N95 mask (if fit-tested) otherwise procedure mask, eye protection and gloves) while performing nasal/nasopharyngeal swabs
4. The facility will test or arrange for the testing for Covid-19 according to CMS QSO-20-38-NH (REVISED 9/23/22)
5. Staff with signs/symptoms of Covid 19, regardless of vaccination status, will be tested as soon as possible and will be restricted from the facility pending results.
6. Residents that have signs/symptoms of Covid 19, regardless of vaccination status, will be tested as soon as possible and placed on Contact and Droplet Transmission Based Precautions pending results
7. The Facility will not perform routine testing of asymptomatic staff
8. In accordance with CMS testing requirements, in the event of a new positive Covid 19 case, the facility will conduct outbreak testing.
	* An outbreak investigation will **not** be triggered if a resident admitted with Covid 19 and placed on TBPs or when a resident is a close contact with someone Covid positive is placed on immediately on TBPS and develops Covid 19 while on TBPs
	* The facility will identify close contacts of the individual with COVID-19 and conduct focused testing based on known close contacts rather than testing all staff and all residents.
	* If a facility does not have the expertise, resources, or ability to identify all close contacts, the facility will instead investigate the outbreak at a facility-wide or group-level (e.g., unit, floor, or other specific area(s) of the facility).
9. When contact tracing reveals that the infected resident/staff member had close contact with a specific group of residents and/or unit, the serial testing will be limited to the identified residents/staff members who had close contact and subsequently have been exposed to COVID-19.
10. The facility will document on the line listing for all positive staff/residents what the contact tracing revealed and how the determination was made to proceed with limited testing versus facility wide testing.
11. All staff and residents that are negative will be tested every 3-7days until there are no new cases identified for 14 days since the most recent positive result.
	* For individuals (staff or residents) who tested positive for Covid-19 within 30 days, repeat testing is not necessary
	* Testing should be considered for those who have recovered in the prior 31-90 days.
		+ However, if testing is performed on these people, an antigen test instead of a nucleic acid amplification test (NAAT) is recommended.

**TABLE 1**

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| --- | --- | --- |
| **Testing Trigger** | **Staff** | **Residents** |
| Symptomatic individual identified | Staff, regardless of vaccination status, with signs or symptoms must be tested. | Residents, regardless of vaccination status with signs and symptoms must be tested |
| Newly identified Covid-19 positive staff or resident in a facility that can identify close contacts | Test staff, regardless of vaccination status, that had a higher-risk exposure with a Covid-19 positive individual. | Test residents, regardless of vaccination status, that had close contact with a Covid-19 positive individual. |
| Newly identified Covid-19 positive staff or resident in a facility that is unable to identify close contacts | Test all staff, regardless of vaccination status, facility-wide or at a group level if staff are assigned to a specific location where the new case occurred (e.g., unit, floor, or other specific area(s) of the facility).  | Test all residents regardless of vaccination status, facility-wide or at a group level (e.g., unit, floor, or other specific area(s) of the facility). |
| Routine testing | Not generally recommended | Not generally recommended |

1. Residents and Resident Representatives can exercise their right to refuse testing in accordance with 42CFR&483.109c) (6). Staff will discuss the importance of testing and document any refusals. Any resident with symptoms will be placed on Transmission-Based Precautions (TBPs) until the criteria for discontinuing TBPs have been met.
2. In addition to providing Covid testing at the facility, a list of easily accessible testing centers will be made available for staff. Off premises test site locations list will be maintained by department heads and staff shall be informed to check with their departments if they do not, or cannot, utilize the facility testing.
* Staff are required to submit to Employee/Occupational Health Services or Designee proof of Covid test(s) done outside of facility and provide record of result(s) promptly.
* Facility will offer testing to their personnel through the contracted lab.
* Facility shall accept documentation of testing conducted by an individual’s healthcare provider.
* Staff with previous positive COVID-19 test who were already furloughed do not require additional furlough if subsequent positive test(s) are <30 days of the first and staff is asymptomatic.
	+ If positive test is >30 days of first positive test, this is considered a new case and furlough is required
	+ In general testing is not necessary for asymptomatic people who have recovered from SARS-CoV-2 in the prior 30 days, however if testing performed/needed an antigen test instead of a nucleic acid amplification test (NAAT) is recommended
	+ Healthcare personnel who have signs or symptoms of Covid-19 and refuse testing will be prohibited from entering the building until the return-to-work criteria are met
	+ If an outbreak testing has been triggered and a staff member refuses testing, the staff member will be restricted from the facility until they produce a Covid-negative test or until the procedures for outbreak testing have been completed.
1. Staff and residents with signs or symptoms of Covid-19, regardless of vaccination status, must receive a Covid-19 test immediately, along with any other medically appropriate testing (e.g., viral respiratory pathogens)
* Staff will be restricted from the facility pending the results of a confirmatory Covid-19 test by PCR if facility is not experiencing an outbreak; otherwise, result from an antigen test is acceptable
* If Covid-19 is confirmed, facility will follow CDC return to work criteria (*refer to P/P specific to Covid-19*)
* Residents will be placed on transmission-based precautions until receipt of confirmatory Covid-19 test by PCR if facility is not experiencing an outbreak; otherwise, result from an antigen test is acceptable
* The facility will take appropriate actions based on the results (*refer to P/P specific to Covid-19*)
1. Per NYS Code 415, whenever a person expires while in a nursing home, where in the professional judgment of the nursing home clinician there is a clinical suspicion that COVID-19 was a cause of death, but no such tests were performed in the 14 days before death, the nursing home shall administer both a COVID-19 test within 48 hours after death, along with any other clinically appropriate testing. Such COVID-19 test shall be performed using rapid testing methodologies to the extent available. The facility shall report the death to the Department immediately after and only upon receipt of such test results through the Health Emergency Response Data System (HERDS). Notwithstanding the foregoing, no test shall be administered if the next of kin objects to such testing. Should the nursing home lack the ability to perform such testing expeditiously, the nursing home should request assistance from the State Department of Health.

**Documentation of Testing**:

The facility will document all COVID-19 testing for staff and residents.

1. A spreadsheet will be utilized to track the testing of all personnel, including all employees, contract staff, medical staff, operators, and administrators, for COVID-19.
2. For any outbreak, the facility IP/Designee will document the date case identified, the dates and results of all testing.
3. Point of Care Antigen positive results of Covid 19 testing performed at the facility will be reported to NYSDOH ECLRS as directed by NYSDOH by 1:00PM of the day following receipt of the results
4. All staff and residents testing positive shall be documented on the log and the results will be reported on all required submissions to the CDC via NHSN (at least weekly) and NYSDOH via HERDS (daily reporting)
* Currently NHSN does not require reporting **individual** POC tests, but requires a cumulative number via the Covid-19 Pathway Report.
1. All staff will receive Inservice Education on the NH COVID-19 Testing policies/procedures, including all updates in accordance with NYSDOH and Federal guidance.

**RESOURCES:**

NYSDOH (5/11/2020). ACF DAL #20-14, NH-20-07. Required Covid19 Testing for all Nursing Home and Adult Care Facility Personnel <https://www.health.ny.gov/professionals/hospital_administrator/letters/2020/docs/dal_20-14_covid_required_testing.pdf>

CMS (8/26/2020). Ref: QSO-20-38-NH. Interim Final Rule, Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency related to Long Term Care Facility Testing Requirements and Revised COVID-19 Focused Survey Tool. Retrieved from <https://www.cms.gov/files/document/qso-20-38-nh.pdf>

NYSDOH Health Advisory Covid 19 Updated 10 13 22 [https://commerce.health.state.ny.us/hpn/ctrldocs/alrtview/postings/Health\_Advisory\_\_Nursing\_Home\_Testing,\_Cohorting\_and\_Visita\_1665772061063\_0.pdf](https://commerce.health.state.ny.us/hpn/ctrldocs/alrtview/postings/Health_Advisory__Nursing_Home_Testing%2C_Cohorting_and_Visita_1665772061063_0.pdf)**.**

CMS QSO 20-38 (revised 9 /23/2022) <https://www.cms.gov/medicareprovider-enrollment-and-certificationsurveycertificationgeninfopolicy-and-memos-states-and/interim-final-rule-ifc-cms-3401-ifc-additional-policy-and-regulatory-revisions-response-covid-19-0>.

CDC (revised 9/23/22) <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html>.

**Policy and Procedure: Covid-19 Point of Care Testing**

**Policy**:

The facility will use Point of Care testing approved by the Food and Drug Administration (FDA) as needed to assist with early identification of COVID-19 in residents and staff as well as ensure compliance with State and Federal regulations.

**Procedure**:

1. Licensed personnel will be trained in utilization of available Point of Care Test Kits for rapid detection of COVID-19.
2. Upon completion of training, licensed personnel will follow procedures outlined in the competency in the use of available POC antigen test kits. (See attached competencies for BD Veritor and Abbott BinaxNOW)
3. Facility may choose to use POC Antigen tests kits to fulfill bi-weekly staff testing.
4. Facility may choose to use POC Antigen test kits to satisfy requirements for serial testing when there is an outbreak. (\*Refer to NYSDOH POC Testing Algorithm for when to follow up PCR test is required).
5. When a resident displays symptom of COVID-19 and/or Influenza, an order will be obtained for both Covid and Influenza.
* If there is a roommate, same will be done for roommate.
1. Residents and roommates (when applicable) who are tested for Covid-19 or Influenza will be placed on appropriate transmission-based precautions pending the test results.
2. The facility shall comply with all requirements as set forth in CDC Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Covid-19 including:
* Utilizing required/recommended PPE not limited to face shield or other eye protection, N95 mask (fit tested) or surgical mask if not available, isolation gown, and disposable gloves.
* Maintaining social distancing of at least 6 feet apart
* Using equipment in the specified area/location as associated with current CLIA Waiver certificate.
* Following standard precautions when handling specimens, including hand hygiene, correct usage of PPE, and proper specimen/device disposal in biohazardous container
1. The results of all POC antigen tests will be documented and reported to NYSDOH daily via the HERDS Survey and the Electronic Clinical Laboratory Reporting System (ECRLS).

**COMPETENCY: Collecting and Analyzing SARS-CoV-2 Specimen Using the**

**BD Veritor System**

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| **TASKS** | **TASK** **COMPLETED** **(YES/NO)** | **COMMENTS** |
| 1. Ensure clean work surface with adequate lighting
 |  |  |
| 1. Gather supplies
2. BD Veritor Analyzer
3. Reader Verification Cartridge (orange & white)
4. SARS-CoV-2 Device (blue & white)
5. Swab stick
6. Extraction Reagent Tube (yellow top)
7. Biohazard waste container
8. PPEs (gown, gloves, N95 respirator, eye/face shield)
9. Alcohol-based hand sanitizer (ABHS)
 |  |  |
| 1. Perform hand hygiene
 |  |  |
| 1. Don PPEs
 |  |  |
| 1. Before testing patient specimens, perform a system verification check
2. Using Analyze Now Test Mode, insert reader verification cartridge (orange & white) into the test device slot
* A distinct click indicates when the cartridge is fully inserted
1. After 3 seconds, VERIFY PASS, appears on the screen to indicate the device is ready for use
2. Remove and store the verification cartridge in the orange zip-loc pouch for use every time the device is used for testing specimens
 |  |  |
| 1. Collect specimen via nasal swab
2. Insert swab into anterior aspect of one nostril
3. Swirl the swab about 5 times along the mucosa inside the nostrils (*rationale*: to ensure that both mucus & cells are collected)
4. Using the same swab, repeat this process for the other nostril
5. Withdraw swab from the nasal cavity.
 |  |  |
| 1. Insert patient sample swab in reagent tube and vigorously plunge the swab up and down for 15 secs
 |  |  |
| 1. Remove swab and dispose in biohazard container
 |  |  |
| 1. Close cap on reagent tube and mix sample by swirling the bottom of the tube.
 |  |  |
| 1. Label reagent tube with patient identifier – first and last initials
 |  |  |
| 1. Add 3 drops of the processed sample to the test device sample well (blue & white cartridge)
 |  |  |
| 1. Label test device with patient identifier – first and last initials
 |  |  |
| 1. Allow sample to sit/incubate for 15 mins
 |  |  |
| 1. Turn on analyzer (press blue power button)
 |  |  |
| 1. Await prompt – Insert Test Device OR Double-Click Button for Walk Away Mode
 |  |  |
|  |  |  |
| 1. **ANALYZE NOW MODE**: Specimen incubates for 15 mins outside of the device
2. Insert cartridge (blue & white) with specimen
3. Result will display on screen
4. Record result and remove test device
5. Discard device in biohazard container
 |  |  |
| 1. **WALK AWAY MODE**: Specimen incubates for 15 mins inside of the device
2. Double click power button to enter Walk-Away Mode; Ensure power plug is plugged in to power
3. Follow steps #6-11
4. 3-min countdown timer displays time remaining for test device insertion
5. Insert device with specimen to start assay timing and analysis
6. Result will appear on the screen after analysis is complete (15 mins)
7. Record result and remove test device
8. Discard device in biohazard container
 |  |  |

PASS (YES/NO): \_\_\_\_\_ FAIL (YES/NO: \_\_\_\_\_

EMPLOYEE’s NAME (PRINT): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

EMPLOYEE’S SIGNATURE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

EVALUATOR’S SIGNATURE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ DATE\_\_\_\_\_\_\_\_\_\_\_\_\_

COMPLETED BD CERTIFICATION: YES/NO

**COMPETENCY: Collecting and Analyzing SARS-CoV-2 Specimen Using the Abbott BinaxNOW COVID-19 Ag Card**

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| **TASKS** | **TASK** **COMPLETED** **(YES/NO)** | **COMMENTS** |
| 1. Ensure clean work surface with adequate lighting
 |  |  |
| 1. Gather supplies
2. BinaxNOW COVID-19 Ag Card
3. Extraction Reagent bottle
4. Swab stick
5. Biohazard waste container
6. PPEs (gown, gloves, N95 respirator (fit tested) or surgical mask, eye/face shield)
7. Alcohol-based hand sanitizer (ABHS)
 |  |  |
| 1. Perform hand hygiene
 |  |  |
| 1. Don PPE
 |  |  |
| 1. Label new BinaxNOW card with patient identifier (e.g., name, DOB, etc.)
 |  |  |
| 1. Prep BinaxNOW COVID-19 Ag Card with extraction reagent solution
2. Open card and lay flat
3. Hold extraction reagent bottle vertically, hovering about ½ inch above the top hole
4. Slowly **add 6 drops to the top hole** of the swab well

\*DO NOT touch the card with the dropper tip while dispensing |  |  |
| 1. Collect specimen via nasal swab
2. Insert swab into anterior aspect of one nostril
3. Swirl the swab about 5 times along the mucosa inside the nostrils (*rationale*: to ensure that both mucus & cells are collected)
4. Using the same swab, repeat this process for the other nostril
5. Withdraw swab from the nasal cavity.
 |  |  |
| 1. Insert sample swab into **bottom hole** and firmly push upwards so that the swab tip is visible in the top hole.
 |  |  |
| 1. Rotate (twirl) swab shaft 3 times **clockwise** (to the right). Do not remove swab.
 |  |  |
| 1. Peel off adhesive line from the right edge of the test card, close and securely seal the card
 |  |  |
| 1. **Read result** in the window **15 minutes after** closing the card.

**\***Result should not be read after 30 mins |  |  |
| 1. Interpret result
2. Negative: a single pink/purple Control Line in the top half of the window
3. Positive: two pink/purple lines
 |  |  |
| 1. Record result and discard used BinaxNOW COVID-19 Ag Card in biohazard container
 |  |  |
| 1. Perform hand hygiene
 |  |  |

PASS (YES/NO): \_\_\_\_\_ FAIL (YES/NO: \_\_\_\_\_

EMPLOYEE’s NAME (PRINT): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

EMPLOYEE’S SIGNATURE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

EVALUATOR’S SIGNATURE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ DATE\_\_\_\_\_\_\_\_\_\_\_\_\_

**COMPETENCY: Collecting and Analyzing SARS-CoV-2 Specimen Using the**

**Sofia/Sofia 2 System**

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| **TASKS** | **TASK** **COMPLETED** **(YES/NO)** | **COMMENTS** |
| 1. Ensure clean work surface with adequate lighting
 |  |  |
| 1. Gather supplies
2. Sofia 2 Analyzer
3. Test Cassette
4. Reagent tube
5. Reagent solution
6. Swab stick
7. Biohazard waste container
8. PPEs (gown, gloves, N95 respirator, eye/face shield)
9. Alcohol-based hand sanitizer (ABHS)
 |  |  |
| 1. Perform hand hygiene
 |  |  |
| 1. Don PPEs
 |  |  |
| 1. Before testing patient specimens, perform a system calibration check (every 30 days)
2. Enter Zip Code of the facility (only required the very 1st time machine is turned on)
3. Enter supervisor code 1234, then select “Run”
4. Follow prompts, insert calibration cassette into drawer
 |  |  |
| 1. Prepare the reagent by dispensing all the reagent solution into the reagent tube
 |  |  |
| 1. Collect specimen via nasal swab
2. Insert swab into anterior aspect of one nostril
3. Swirl the swab about 5 times along the mucosa inside the nostrils (*rationale*: to ensure that both mucus & cells are collected)
4. Using the same swab, repeat this process for the other nostril
5. Withdraw swab from the nasal cavity.
 |  |  |
| 1. Place the patient swab sample into the reagent tube. Roll the swab at least 3 times while pressing the head against the bottom and side of the reagent tube (**let swab sit in tube for at least 1 minute**)
 |  |  |
| 1. Roll the swab head inside of the reagent tube as you remove it
 |  |  |
| 1. Dispose of the used swab in a biohazardous waste container
 |  |  |
| 1. Fill the 120 µL fixed volume pipette with patient sample from reagent tube
 |  |  |
| 1. Firmly squeeze the top bulb to empty the contents of the pipette into the Test Cassette sample well

**\*\*Do not pour sample from reagent tube; use the small, clear 120 µL fixed volume pipette** |  |  |
| 1. **READ NOW MODE**: Specimen incubates for 15 mins outside of the Sofia/Sofia 2
2. Insert cassette into device
3. Result will display on screen in approx. 11 secs
4. Record result and remove sample cassette
5. Allows for multiple tests to be run with high throughput (~ 40 – 50 tests/hr.)
 |  |  |
| 1. **WALK AWAY MODE**: Specimen incubates for 15 mins inside of the device
2. Pipette sample onto Test Cassette and insert into Sofia/Sofia 2
3. Sofia/Sofia 2 will automatically time the test and report results in 15 mins
 |  |  |

**Resources**: <https://www.quidel.com/sites/default/files/product/documents/EF1439004EN01.pdf>

 <https://www.youtube.com/watch?v=BOrPGjtgHyE>

PASS (YES/NO): \_\_\_\_\_ FAIL (YES/NO: \_\_\_\_\_

EMPLOYEE’s NAME (PRINT): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

EMPLOYEE’S SIGNATURE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

EVALUATOR’S SIGNATURE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ DATE\_\_\_\_\_\_\_\_\_\_\_\_\_