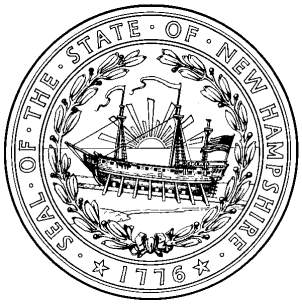

NEW HAMPSHIRE COVID-19 ANTIGEN SCREENING PROGRAM GUIDANCE AND RECOMMENDATIONS

November 20, 2020

New Hampshire Department of Health and Human Services

TABLE OF CONTENTS

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EXECUTIVE SUMMARY

This guidance establishes guidelines for routine COVID-19 screening for asymptomatic individuals using antigen testing. Antigen screening programs aim to identify asymptomatic individuals with COVID-19 for early intervention of mitigation strategies.

Participating organizations must have CLIA certification in order to utilize rapid antigen testing. For questions about obtaining a CLIA certificate, contact CovidTesting@dhhs.nh.gov. Participating organizations must have an internal guideline, covering all aspects of the program implementation and operational guidelines, compliant with this guideline. Note that participation is optional and flexible, with a range of acceptable strategies according to program goals.

Given that most antigen tests has some chance of false positive result, one of the most important operative principles of an asymptomatic screening program is that any asymptomatic individual who tests antigen-positive should be isolated and undergo a reflex anterior nares or nasopharyngeal (NP) RT-PCR test immediately, ideally within 24 hours, but no later than 48 hours after the positive antigen test. If the RT-PCR test is positive, NH DHHS and the participating organization will enact COVID-19 infection control strategies, including isolation, quarantine, contact tracing, testing of close contacts, and other protective measures. If the RT-PCR test is negative, and the person remains asymptomatic, the individual can return to work and resume all normal activities.

NOTE: Antigen screening programs utilize antigen testing for asymptomatic screening, in accordance with CDC guidance for utilizing antigen testing for asymptomatic screening purposes, such as among high-density critical infrastructure workers and non-healthcare workplaces. Therefore, these programs operates in accordance with State recommendations to only use antigen testing for diagnostic purpose among symptomatic individuals. The required confirmatory RT-PCR for positive antigen test results will limit unnecessary and potentially disruptive response to false positive antigen results.

I. BACKGROUND

Rapid Antigen Testing

Rapid antigen tests are commonly used in the diagnosis of respiratory pathogens, including influenza viruses and respiratory syncytial virus (RSV). The FDA has granted emergency use authorization (EUA) for antigen tests that can identify SARS-CoV-2 [1]. Antigen tests are relatively inexpensive and can be used at the point-of-care. The currently authorized devices for COVID-19 return results in approximately 15 minutes. The sensitivity and specificity of rapid antigen tests is generally lower than RT-PCR (nucleic acid amplification tests) [1].

The clinical performance of rapid antigen diagnostic tests largely depends on the circumstances in which they are used. Rapid antigen tests perform best when the person is tested in the early stages of infection with SARS-CoV-2 when viral load is generally highest [1]. **There are limited data to guide the use of rapid antigen tests as screening tests on asymptomatic persons to detect or exclude COVID-19** [1]. It is important for clinicians and testing personnel to understand the performance characteristics, including analytic sensitivity and specificity, of the particular rapid antigen test being used, and to follow the manufacturer's instructions and package insert [1].

For NH specific recommendations on antigen testing, see HAN #23.

Definition of Screening

Antigen screening programs use antigen tests for screening, not diagnostic, purposes, following CDC guidelines for testing asymptomatic individuals without known or suspected exposure to SARS-CoV-2 for early identification in special settings. The CDC definition of screening testing is as follows:

> "Screening testing for SARS-CoV-2 is intended to identify infected persons who are asymptomatic and without known or suspected exposure to SARS-CoV-2. Screening testing is performed to identify persons who may be contagious so that measures can be taken to prevent further transmission. Examples of screening include testing in congregate settings, such as a long-term care facility or a correctional facility, a workplace testing its employees, or a school testing its students, faculty, and staff. See CDC's Overview of Testing for SARS-CoV-2…Considerations for Non-Healthcare Workplaces…FDA's FAQs on Testing for SARS-CoV-2 also address screening testing for SARS-CoV-2. [1]"

Testing asymptomatic individuals without known or suspected exposure to SARS-CoV-2 for early identification in special settings

Antigen screening programs for asymptomatic persons may be useful to detect COVID-19 early and stop transmission quickly, particularly in areas with moderate to substantial community transmission. Routine and recurrent testing of asymptomatic individuals in an identified target population also serves a surveillance function and helps identify and track spread of COVID-19 in communities. A screening program may be considered in settings such as:

1. Workplace settings where physical distancing is difficult and workers are in close contact with co-workers or the public;
2. Where continuity of operations is a high priority (e.g., critical infrastructure sectors)" [2]; and
3. Visitors to long-term care facilities.

II. LOGISTICS

Eligibility

Organizations that meet inclusion criteria have the option to implement an antigen screening program. For best results, however, up to 100% of their eligible participants should be tested monthly. Inclusion criteria are shown below:

Table 2.1 Inclusion Criteria

Organization Inclusion Criteria
○ Must have clinical staff onsite trained and willing to perform specimen collection, and adequate personal protective equipment ○ Must have a CLIA certificate[1] ○ Should have an individual plan for the program, guided by this document
Individual Participant Inclusion Criteria
○ Elects to participate with no coercion ○ Asymptomatic ○ Not tested positive for COVID-19 in the prior 3 months ○ Agrees to obtain RT-PCR within 48 hours if the antigen test is positive

Note Regarding Symptomatic Individuals

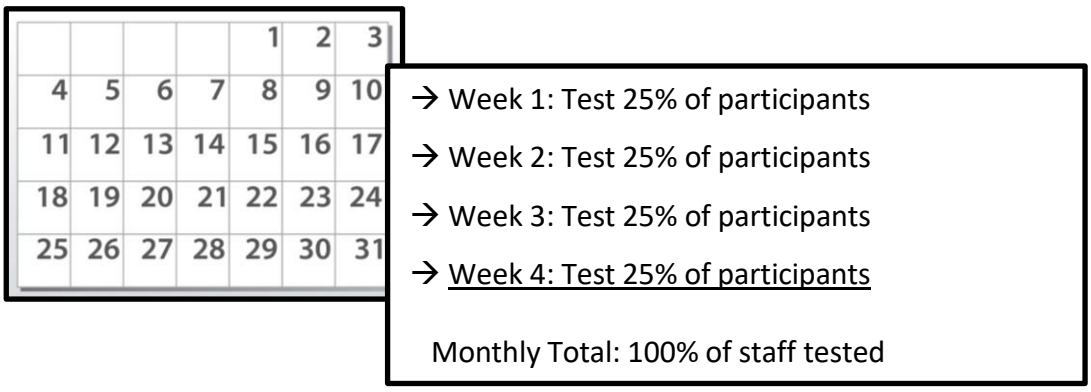
Antigen screening programs are intended to test asymptomatic individuals. Individuals who develop any new and unexplained symptoms compatible with COVID-19 should consult their healthcare provider and be tested under appropriate infection control procedures. Healthcare providers should follow DHHS testing recommendations to determine the appropriate testing strategy and location.

Repeat Testing and Sampling

Organizations should develop their own schedule for testing. For one example of a workplace screening program, the organization might divide eligible participants into four approximately equal groups. These groupings can be achieved according to job type, usual shift, or randomly such as quarter of birth year or alphabetically. Test one group each week so that at the end of the month, 100% of eligible participants have been tested. Another example is to simply test 100% of eligible staff once a month. As another example, for a long term care facility visitor screening program, essential support visitors might be tested weekly, or occasional social visitors tested once.

[1] Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform moderate, high or waived complexity tests.

Figure 2.2 Sample Calendar



Specimen Collection

Follow manufacturer guidelines for specimen collection depending on the antigen-testing machine being used. The testing will need to be performed by an organization that has Clinical Laboratory Improvement Amendments (CLIA) certification and appropriately trained personnel to perform the test.

The direct nasal swab should be collected in accordance with the package insert for the antigen-testing machine. It can be self-collected under supervision by a trained staff member. Review and follow CDC's Guidance for SARS-CoV-2 Point-of-Care Testing.

Personal Protective Equipment (PPE)

The trained staff member collecting the nasal swab on an employee and those running the test should wear appropriate PPE consisting of: surgical face mask, eye protection (goggles or face shield that protect the front and side of the eyes), gown, and gloves. Gloves should be changed between patients, but if no physical contact and no contamination of PPE occurred during a patient encounter, then face mask, eye protection, and gown can be re-used. Hand hygiene should be conducted at a minimum before donning gloves, after glove removal, and in-between patients. For trained staff member overseeing self-collection of a nasal swab collection, maintain 6ft of distance and wear a surgical facemask. For individuals performing self-swabbing, no PPE is needed. See CDC guidance for Handling and Processing Specimens Associated with COVID-19.

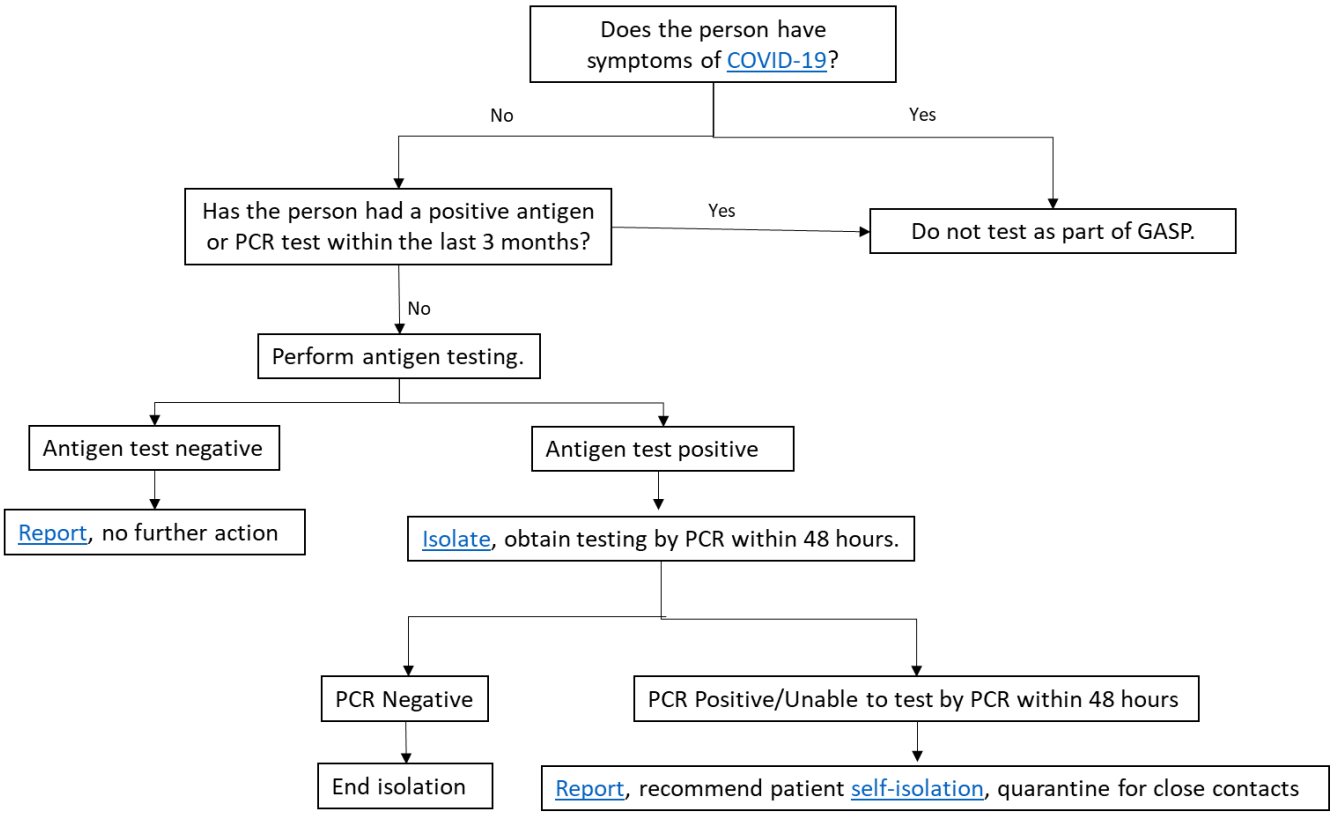
Informed Assent

Individuals who elect to participate in testing should receive clear information on:

- The manufacturer and name of the test, the type of test (antigen test), the purpose of the test (to identify NH individuals who are asymptomatically infected with COVID-19), the reliability of the test (i.e., risk of false positive and false negative test results), any limitations associated with the test, who will pay for the test, and how the test will be performed (i.e., anterior nares swab), and
- How to understand what the results mean, actions associated with negative or positive results (isolation while seeking PCR within 48 hours of antigen test), who will receive the results (NH DHHS), how the results may be used (see algorithm below), and any consequences for declining to be tested (e.g., work restrictions if a private business or disallowed visitation in the long term care facility).

Individuals tested are required to receive patient fact sheets as part of the test's emergency use authorization." [2] See employee FAQs and informational sheet in Appendix A.

III. TESTING ALGORITHM



IV. RESPONSE TO A POSITIVE ANTIGEN TEST RESULT[2]

Antigen tests are less accurate than PCR-based tests and may give false positive results when used in areas of low-prevalence of COVID-19 and in asymptomatic individuals. If the antigen test is positive as part of the antigen screening program, the next steps are critical to unnecessarily avoid mental anguish or disruption of your organization's services if the test is false positive, but also respond to minimize transmission if the test is true positive:

1. If the antigen test is positive, the participant whose test is positive should immediately
    a. put on a surgical mask (if not already),
    b. be dismissed from the facility, and
    c. instructed to self-isolate pending RT-PCR results.
2. The individual should acquire follow-up RT-PCR testing as soon as possible (ideally same day) but no later than 48 hours following the positive antigen test. This confirmatory test is necessary due to the fact that antigen tests may return false positive results when performed on asymptomatic individuals, such as in a screening program. The follow-up PCR test can be arranged by through primary care providers or the existing community testing sites.

[2] This guidance is specific for an asymptomatic antigen screening program. Other guidance may apply for other uses of antigen testing, such as use for symptomatic persons or in long term care facilities.

3. The organization that collected the RT-PCR specimen is responsible for providing the person tested with a written test result. When RT-PCR results are available:
    a. If the RT-PCR test collected within 48 hours is negative, and the person remains asymptomatic, the individual should be considered to not have SARS-CoV-2 infection and the antigen test result should be considered false positive.
    b. If the RT-PCR test is positive, the individual should continue to follow instructions for isolation. Consult with DHHS regarding any need for cleaning, additional testing, quarantine of close contacts, and to advise the individual duration of isolation (e.g., return to work criteria).

What is a False Positive?

A false positive is a test result indicating the infection is present when it is not. Communities where there is a lower incidence of COVID-19 have a higher likelihood of antigen tests returning false positive results. For example, the antigen test BinaxNOW's specificity is such that if used among persons where <1% actually have disease, <40% of positive test results are true positive. Therefore, all positive antigen tests in a screening program must be confirmed with an RT-PCR test within 48 hours. If the PCR test is negative, and the person remains asymptomatic, the antigen test result will be considered a false positive, meaning the individual likely does not have COVID-19. If the individual is unable to obtain a PCR test within 48 hours, they will be treated as a true positive.

For more information on understanding antigen tests, review CDC's Interim Guidance for Rapid Antigen Testing for SARS-CoV-2.

Table 4.1 COVID-19 Prevention and Response Resources NH DHHS

Prevention

- Using Cloth Face Coverings to Help Slow the Spread of COVID-19
- Employee Travel and Quarantine Guidance
- Health Alert Network (HAN) messages to provide new guidance and information regarding COVID-19.

  (To sign up email health.alert@nh.gov)
- Public Health Partner Calls, Thursdays at 12:00pm
    - Zoom link: https://zoom.us/s/94841259025
    - Call-in phone number: (646) 558-8656
    - Meeting ID: 948 4125 9025
    - Password: 003270
- For individual consultations, contact 603-271-4496 (after-hours: 603-271-5300)

Response

- Self-Isolation Guidance
- Self-Quarantine Guidance
- What are isolation, quarantine, and self-observation?
- Return to Work Criteria and Crisis Staffing Guidelines

Various translated documents can be found at https://www.nh.gov/covid19/resources-guidance/residents.htm

CDC Guidance
○ https://www.cdc.gov/coronavirus/2019-ncov/index.html ○ Contact Tracing: Do your part to keep your family, friends, and community safe ○ Critical Infrastructure Workers Who May Have Been Exposed to COVID-19 ○ Environmental Cleaning and Disinfection for Community Facilities

V. TESTING COORDINATION

Test Results – Notification Process

Antigen test results must be reported to the NH Division of Public Health Services (DPHS). Reporting all personally identifiable information for COVID-19 test results is required by federal and state law. This includes reporting positive, negative, and invalid results. Results must be submitted at least daily and within 24 hours of the result being available. Organizations performing point-of-care testing have two options to submit results:

POSITIVE ANTIGEN REPORT:

- Complete Asymptomatic Antigen Screening COVID-19 Case Reporting Form (Appendix B)
  - Fax to 603-271-0545

NEGATIVE ANTIGEN REPORT:

- Enter test results for each patient tested via an online form.
- Submit daily results for multiple patients via a specially formatted file submitted through a secure file transfer solution. Instructions for this method are online.

RT-PCR Access

For the RT-PCR tests following a positive screening antigen test, individuals should utilize their primary care provider or obtain testing at one of the statewide community testing sites. Depending on the setting, the DHHS Congregate Settings Investigation Unit will determine if additional testing is warranted (e.g. mobile testing, referral to fixed testing sites, etc.).

Roles and Responsibilities

Individual organizations are responsible for managing agreements, obtaining antigen testing machines or kits, CLIA waiver verification, and monitoring participation rates. NH DHHS will investigate confirmed positive cases to perform contact tracing per routine protocols.

VI. REFERENCES

1. https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html
2. https://www.cdc.gov/coronavirus/2019-ncov/community/organizations/testing-non-healthcare-workplaces.html

APPENDIX A

[SAMPLE INFORMATION SHEET FOR BINAXNOW]
Information for Participants

Information to know before you get tested:

- The BinaxNOW COVID-19 Ag Card made by Abbott Diagnostics will be used
- The purpose of this test is to detect parts of SARS-CoV-2, the virus that causes COVID-19 infection. The test can be used to diagnose COVID-19 in symptomatic persons, but for this program, will be used among asymptomatic persons.
- The test requires a nasal swab.
- Especially when used in asymptomatic persons, the BinaxNOW COVID-19 Ag Card test sometimes can give false positive results, which could result in: recommendation to isolate, monitoring of close contacts for symptoms, and temporarily limit your ability to work.
- If you test positive using the antigen card, you must obtain a PCR test within 48 hours.
- The purpose of the PCR test is to determine whether the initial positive was a true positive.
- All results will be reported to the New Hampshire Department of Health and Human Services.
- The cost of the BinaxNOW COVID-19 Ag Card will be covered by the federal government, whereas the cost of test coordination will be covered by the State of New Hampshire.
- You do not have to participate in this program, and if you choose not to, there are no negative consequences

Other important information:
FDA Emergency Use Authorization: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas

BinaxNOW COVID-19 Ag Card Diagnostic (Most Recent Letter of Authorization) and Date EUA Originally Issued: https://www.fda.gov/media/141567/download
BinaxNOW COVID-19 Ag Card Fact Sheet: https://www.fda.gov/media/141569/download

APPENDIX B

New Hampshire Confidential COVID-19 Case Report Form v 11/3/2020

For Reporting Asymptomatic Antigen Screening Test Results

This form should only be used to report test results from an Asymptomatic Antigen Screening Program

Report Date: ____/_____/_____

Patient Information

Name _____
(Last) (First) (M.I.)

Date of Birth _____/_____/_____ Age _____ Sex: ☐ Male ☐ Female ☐ Other

Address _____City/Town _____ State _____ Zip _____

Phone: Cell_____ Home _____ Work _____

Race: ☐ White ☐ Black ☐ Asian ☐ Pacific Islander ☐ Native Am./Alaskan Nat ☐ Unknown ☐ Other: _____

Ethnicity: ☐ Hispanic ☐ Not Hispanic ☐ Unknown

Occupation/Employment (select all that apply): ☐ Fire ☐ Police ☐ EMS ☐ Healthcare ☐ Other: _____

Employer/Institution (name and location [City, State): _____

Test Information

Does the patient have symptoms of COVID-19? ☐ Yes ☐ No ☐ Unknown If yes, onset: _____/_____/_____

Test Results: ☐ Positive/detected ☐ Negative ☐ Indeterminate/Inconclusive ☐ Invalid

Antigen Test Type: ☐ BinaxNOW ☐ Other: _____ Specimen Source: ☐ Nasal ☐ Other: _____

Specimen Collection Date: _____/_____/_____ Was appropriate PPE used: ☐ Yes ☐ No ☐ Unknown

Location where specimen tested: _____

Risk Factors (check all that apply within the 14 days prior to diagnosis or specimen collection if asymptomatic)

International/Domestic Travel: ☐ Yes ☐ No ☐ Not asked ☐ Unknown Details:_____

Contact to a case: ☐ Yes ☐ No ☐ Not asked ☐ Unknown Details: _____

No known risk factors: ☐ Yes ☐ No ☐ Not asked ☐ Unknown

Additional Details (e.g., including names, relationship of contact and venue):_____

_____

Health Care Provider Reporting Information

Person Reporting: _____ Phone _____

Provider Facility/Practice Name _____

City/Town_____ State_____

Fax to: (603) 271-0545
Office Phone: 603-271-4496

For NH DHHS Use Only ☐ **Entered in NHEDSS** ☐ **Assigned to Investigator**
☐ **Confirmed** ☐ **Probable** ☐ **Suspect** ☐ **Not a case**