



NARA COVID-19 Response

Fact Sheet #12, version 4: Vaccine documentation and COVID-19 Testing Program

March 7, 2022

This fact sheet provides guidance to help protect NARA staff and reduce the spread of the 2019 novel coronavirus disease (COVID-19) in the workplace. This version has been updated to lift the testing requirement for facility occupants in Low community levels. This fact sheet supersedes all previous versions.

Confidentiality requirement: This guidance requires individuals to report on their vaccination status and, in some cases, provide the results of COVID-19 tests. **NARA employees and contractors who collect or view this information must protect vaccination status or COVID-19 test results of employees, contractors, or public visitors from unauthorized disclosure and will use this information only for legitimate business purposes that are consistent with the authorized uses of the data under [Office of Personnel Management \(OPM\) System of Records Notice \(SORN\) GOVT-10](#).**

1. Vaccination documentation for NARA employees.

- a. All NARA employees and prospective employees (new hires) who are fully vaccinated are required to provide documentation of proof of vaccination. Employees and prospective employees who are not fully vaccinated are not required to be vaccinated due to the nationwide preliminary injunction against the vaccine mandate for Federal employees in Executive Order 14043. Employees and prospective employees who do not provide acceptable documentation of proof of vaccination will be treated as if they are not fully vaccinated.
- b. Employees who are not fully vaccinated for COVID-19 must provide weekly COVID-19 test results when they work on-site in periods of High and Medium community levels. Employees are not required to provide COVID-19 test results in Low community levels, regardless of vaccination status. The Centers for Disease Control and Prevention (CDC) provides county-level community transition levels weekly at <https://www.cdc.gov/coronavirus/2019-ncov/science/community-levels.html>. NARA will not prevent employees from working on-site at NARA facilities based solely on vaccination status.
- c. NARA determines an employee's vaccination status based on their documented proof of vaccination. NARA maintains a repository of documentation of proof of vaccination submitted by NARA employees. The Office of Human Capital collects documentation of proof of vaccination from prospective employees

through the new hire orientation process. In High and Medium community levels, employees who have not submitted documentation of proof of vaccination are issued weekly emails that include a link where they can submit documentation if they become fully vaccinated.

- d. In facilities with a security force, NARA employees will not be required to display vaccination attestation forms or COVID-19 test results in order to access the building. NARA supervisors are responsible for verifying their employees' vaccination status and COVID-19 test results according to the procedures in this fact sheet.

2. COVID-19 testing for NARA employees.

- a. In High and Medium community levels, employees who are not fully vaccinated are required to provide a new, negative COVID-19 test at least once in each week that they work on-site. Employees are not required to test when they are not working on-site and are not required to test in Low community levels, regardless of vaccination status.
 - i. Employees requiring testing who provided a negative COVID-19 test result in the previous week may provide a new, negative COVID-19 test result at any time during the current week.
 - (1) These employees may work on site the entire week until they submit a test result if: (a) they are not experiencing COVID-19 symptoms; and (b) they are not waiting on the results of a diagnostic test (due to exposure, illness, etc.).
 - (2) Employees requiring testing who do not provide a new, negative COVID-19 test result for an entire week will not be permitted to return to the work site the following week until they provide a new, negative COVID-19 test result.
 - ii. Employees requiring testing who did not produce a new COVID-19 test result in the previous week must provide a new, negative COVID-19 test result when they first return to the workplace. The specimen collection date on the test results must be no more than seven calendar days before the date of entry into the facility. If an employee requiring testing does not produce a new COVID-19 test result when required:
 - (1) If the employee has not used duty time to obtain a COVID-19 test in the current week, the employee will be immediately sent for testing on duty time. The employee will not be permitted to return to the worksite without a new, negative COVID-19 test result.

- (2) If the employee has already used duty time to obtain a COVID-19 test in the current week, the employee will be permitted to use personal leave to obtain a test, or else the employee will be placed on enforced leave until they produce a new, negative COVID-19 test result.
 - (3) Employees who are required to test but refuse to provide the required COVID-19 test result or repeatedly fail to provide a COVID-19 test result when required will be placed on mandatory telework or investigative leave, will be barred from NARA facilities until they provide a new COVID-19 test result, and will be subject to disciplinary action.
 - iii. If at any time an employee receives a positive COVID-19 test result, the employee must not report to the work site. The employee must report their test result to their supervisor (or designee) by telephone, text, or email. The supervisor, in coordination with the Designated Official, will place the employee on home isolation and initiate contact tracing procedures, in accordance with [COVID-19 Fact Sheet #8, Contact Tracing](#).
- b. In High and Medium community levels, employees requiring testing must provide a new, negative COVID-19 test result – from an acceptable COVID-19 test – to their supervisor every week that they work on-site.
 - i. Employees requiring testing must obtain an acceptable COVID-19 test from an acceptable source.
 - (1) Employees must obtain a *viral* COVID-19 test administered by a pharmacy, health care provider, laboratory, clinic, government testing site, or similar facility. NARA will not accept the results of antibody tests or at-home or self-test kits.
 - (2) The U.S. Department of Health and Human Services (HHS) maintains a nation-wide list of COVID-19 testing sites [here](#). Employees who want to obtain a COVID-19 test from a location not listed on the HHS site must receive supervisory approval in advance.
 - (3) NARA determines acceptable COVID-19 tests based on testing guidance from the [Safer Federal Workforce Taskforce](#), the [U.S. Food and Drug Administration \(FDA\)](#), and the [Centers for Disease Control and Prevention \(CDC\)](#).
 - ii. Employees who require testing are responsible for submitting their COVID-19 test results to their supervisor each week, as required. Employees who did not provide a new COVID-19 test result in the

previous week must coordinate their arrival with their supervisor, since they must produce a new, negative COVID-19 test result when they first return to the worksite.

- iii. Supervisors must ensure that all of their employees requiring testing provide a negative COVID-19 test result each week. Each week, the Office of Human Capital will provide each supervisor with a list of their employees who require testing (if they work on site that week). Supervisors must have procedures in place to ensure timely validation of COVID-19 test results for their employees who require testing.
- iv. Supervisors must ensure that their employees who require testing provide COVID-19 test results that meet the following requirements. Supervisors should accept COVID-19 test results in electronic or paper format, as long as the test results meet all of these standards.
 - (1) **Test type.** Test results must indicate they are from a *viral* COVID-19 test. NARA does not accept the results of antibody tests.
 - (2) **Issuing entity.** Test results must include the name of the pharmacy, health care provider, laboratory, clinic, government testing site, or similar facility that administered the test. The results of at-home or self-test kits – or test results that do not clearly identify the entity that performed the test – are not acceptable.
 - (3) **Test date.** The date that the specimen was collected must be no more than seven days before the date the test result is provided to the supervisor. The age of a test is based on the *specimen collection date*, not the date the lab received the specimen or the date the result was reported. If an employee is testing weekly, the date the specimen was collected for the new report must be any time after the specimen collection date on the previous week’s report.
 - (4) **Identification.** The test result must include the employee’s name. Supervisors must be able to readily determine that the employee presenting the COVID-19 test result is the individual who took the test.
 - (5) **Results.** Test results must be negative, or “not detected”. An employee who presents a positive COVID-19 test result must be sent home immediately, and contact tracing procedures must be initiated.
- v. Supervisors must retain copies of employee COVID-19 test results in a secure environment (locked filing cabinet or personal “My Drive” location

not shared with others). Test results must be stored separately from employee personnel folders. When results are provided by an app, the employee should provide a screen shot to the supervisor. COVID-19 test results must be retained in accordance with SORN OPM/GOVT-10 and GRS 2-7, Employee Health and Safety Records.

- c. Employees who require COVID-19 testing will be provided duty time to obtain a test and will be reimbursed for the costs of obtaining an acceptable COVID-19 test, including reasonable travel expenses, if travel expenses are approved in advance.
 - i. Employees requiring testing will be provided up to one hour of duty time per week to obtain a COVID-19 test. Duty time used to obtain a COVID-19 test will be reported on timesheets as “Regular time” (pay code 010)
 - (1) When employees are testing on a regular basis, supervisors are recommended to work with employees to schedule duty time for COVID-19 testing on the same date and approximate time each week.
 - (2) If no schedule is established, the use of duty time for COVID-19 testing must be requested by the employee and approved by the supervisor in advance, similar to procedures for requesting annual leave.
 - (3) Employees requiring testing who are teleworking or on weather and safety leave will not be required to test unless they return to the facility. These employees must request (and will be granted) duty time during telework periods or in lieu of weather and safety leave to obtain a test in the week prior to returning to the facility.
 - (4) Supervisors may disapprove a request for duty time to obtain a COVID-19 test if there is a legitimate business need for the employee to be working (on-site or remotely) during the time requested.
 - (5) Employees who want to use a COVID-19 testing site that is not on the HHS list of testing sites [here](#) or who plan to request reimbursement of reasonable travel expenses should request approval when they coordinate the use of duty time with their supervisor.
 - (a) Supervisors may approve the use of an alternative site, not on the HHS list, at their discretion if the site is a pharmacy, health care provider, laboratory, clinic, government testing site, or similar facility that will produce test results that

meet all of the requirements for COVID-19 test results in paragraph 2b.iv.

- (b) NARA will not reimburse travel expenses that are not approved in advance.
- (6) In general, employees will be provided the duty time necessary to travel to a COVID-19 testing site, obtain a test, and return, up to one hour per week. An employee who takes more than one hour to obtain a COVID-19 test must submit a written explanation to their supervisor. Supervisors will not approve duty time in excess of one hour without written documentation and may, at their discretion, disapprove duty time in excess of one hour if delays are caused by reasons that are within the employee's control.
- ii. Employees requiring testing will be reimbursed for the costs of obtaining COVID-19 tests using the existing procedure for local travel reimbursement.
- (1) Employees seeking reimbursement must submit a local travel voucher through the government-wide travel system, Concur. At the end of each fiscal quarter (December 31, March 31, June 30, and September 30), employees may request reimbursement for all COVID-19 costs incurred in the previous quarter.
 - (2) Employees may request reimbursement for the costs of any COVID-19 tests that were required by NARA to access the worksite. Employees seeking reimbursement must retain all receipts for COVID-19 tests and upload them into Concur. NARA will not reimburse the costs of COVID-19 tests that are not supported by receipts.
 - (3) Employees may request reimbursement for reasonable travel costs necessary to obtain a test, provided that travel expenses were approved in advance. In general, reasonable travel costs refers to mileage to and from the testing site. If the employee begins or ends the trip from a location other than the worksite, ordinary commuting mileage will be deducted. Employees seeking reimbursement for travel costs to obtain a COVID-19 test must include these expenses with their quarterly request for reimbursement for the costs of the tests.
- iii. Supervisors will not accept, will not grant duty time, and will not reimburse employee costs to obtain COVID-19 tests that do not meet all of the requirements for COVID-19 test results in paragraph 2b.iv. If an employee uses duty time to obtain a COVID-19 test result that does not

meet NARA requirements, the duty time used will be changed to personal leave or, if no personal leave is available, leave without pay.

- d. NARA will provide COVID-19 testing for all employees who require testing in order to conduct official government business, regardless of vaccination status.
 - i. NARA will provide diagnostic testing for employees who are exposed to COVID-19 at work, if they choose to obtain COVID-19 testing. Exposed employees are not required to obtain COVID-19 testing after an exposure.
 - (1) Employees will be granted duty time and will be reimbursed for the costs of obtaining a COVID-19 test if they have had a close contact (within 6 feet for a total of 15 minutes over a 24 hour period) in the workplace with a person who has been diagnosed with COVID-19 or who has received a positive COVID-19 test result, provided that the close contact occurred during the two calendar days before the sick person first experienced symptoms or received a positive COVID-19 test.
 - (2) Exposed employees must obtain their own COVID-19 test and will be granted duty time and reimbursed for the costs of obtaining a COVID-19 test according to all of the procedures and requirements in paragraph 2c, above. Employees must obtain a COVID-19 test that meets all of the requirements for COVID-19 test results in paragraph 2b.iv in order to receive duty time and reimbursement.
 - ii. NARA will provide COVID-19 testing for employees who require a COVID-19 test for official business travel or to access a site, if the site visit is for official business. Employees must obtain their own COVID-19 test and will be granted duty time and reimbursed for the costs of obtaining a COVID-19 test according to all of the procedures and requirements in paragraph 2c, above. Employees must obtain a COVID-19 test that meets all of the requirements for COVID-19 test results in paragraph 2b.iv in order to receive duty time and reimbursement.
 - iii. In general, NARA will not provide routine COVID-19 testing for fully vaccinated employees or employees who are not reporting to the worksite unless they are exposed to COVID-19 in the workplace or require a COVID-19 test to conduct official business. NARA may provide routine testing for certain employees, regardless of vaccination status, as a test pilot to assess the viability of changes in NARA's testing program. NARA will not provide for diagnostic testing of employees who are exposed to COVID-19 outside of work.
- e. An employee with a disability or religious objection to COVID-19 testing should request a reasonable accommodation. An employee requiring testing who requests

a reasonable accommodation should be placed on full-time telework or, if remote work is not available, weather and safety leave, while their reasonable accommodation request is adjudicated.

3. Vaccination attestations and COVID-19 testing for contractors.

- a. All contractors must present an attestation of their vaccination status in order to access any NARA facility. In High and Medium community levels, contractors who are not fully vaccinated must also present a new, negative COVID-19 test result. Contractors will present their vaccination attestation or COVID-19 test results for visual inspection, but NARA employees and security officers will not collect or record contractors' vaccination status or COVID-19 test results.
 - i. In facilities with security officers, security officers will only verify that the contractor has completed an attestation form and has the required paperwork before allowing access to the facility. Security officers will not review attestation forms or verify COVID-19 test results.
 - ii. The Contracting Officer's Representative (COR) for the contract, responsible program managers, and the Designated Official must coordinate to develop local procedures to ensure that on-site contractors have vaccination attestation forms and produce a new, negative COVID-19 test result when required.
- b. In High and medium community levels, contractors who are not fully vaccinated or who do not report their vaccination status must provide a negative COVID-19 test result that is no more than three calendar days old in order to access NARA facilities.
 - i. CORs, program managers, and Designated Officials are responsible for ensuring that contractor-provided COVID-19 test results meet all NARA requirements for COVID-19 test results.
 - ii. Contractor-provided COVID-19 test results must meet all of the requirements for COVID-19 test results in paragraph 2b.iv, except that the date that the specimen was collected must be no more than three whole calendar days before the date the contractor seeks entry to a NARA facility. Three whole calendar days may exceed 72 hours; for example, a test of a specimen collected on Monday morning is valid through Thursday evening.
 - iii. Contractors who require testing but do not provide a negative COVID-19 test result that meets NARA standards for COVID-19 test results will be barred from NARA facilities.

- c. NARA will not provide COVID-19 testing, will not provide duty time, and will not reimburse contractor employees for COVID-19 tests.
- d. The Chief Acquisition Officer (CAO) may grant exceptions to allow certain contractors to enter NARA facilities without carrying vaccination attestations or COVID-19 test results. In order to receive an exception, the vendor must establish a vaccination attestation and COVID-19 testing program for their own employees that meets or exceeds NARA standards for contractor COVID-19 testing. Vendors who are granted exceptions under this authority must provide regular compliance reports in order to remain covered.

4. Vaccination attestations and COVID-19 testing for visitors.

- a. **Museum visitors** will not be required to attest to their vaccination status and will not be required to produce negative COVID test results in order to access NARA museums and associated public spaces.
- b. **Researchers.**
 - i. All visitors to NARA public research rooms must present an attestation that they are fully vaccinated. In High and Medium community levels, researchers who are not fully vaccinated or do not disclose their vaccination status must present a negative COVID-19 test result in order to access NARA research rooms.
 - (1) NARA staff will provide researchers with guidance and an electronic vaccination attestation form during the virtual consultation. NARA staff will not ask for vaccination status information and will not collect or record vaccination status information that is volunteered by the researcher.
 - (2) Fully vaccinated researchers must bring a completed vaccination attestation form to the research room on the day of their appointment. In High and Medium community levels, researchers who are not fully vaccinated or do not report their vaccination status must bring both a vaccination attestation form and a negative COVID-19 test result.
 - (3) Researcher-provided COVID-19 test results must meet all of the requirements for COVID-19 test results in paragraph 2b.iv, except that the date that the specimen was collected must be no more than three whole calendar days before the date the researcher seeks entry to a NARA facility. Three whole calendar days may exceed 72 hours; for example, a test of a specimen collected on Monday morning is valid through Thursday evening.

- ii. Research room staff must review researchers' vaccination attestations and, as applicable, negative COVID-19 test results before allowing researchers to access any NARA records.
 - (1) In facilities with a security force, security officers will only verify that the researcher has completed an attestation form and has the required paperwork for entry into the facility. Security officers will not review attestation forms or verify COVID-19 test results.
 - (2) Researchers will retain all documentation and will only present copies to NARA security officers and staff for visual inspection. NARA security officers and staff will not collect or record researcher attestation forms or COVID-19 test results.
- iii. Researchers who are not fully vaccinated or who do not report their vaccination status will be removed from NARA facilities for up to seven calendar days and may be considered for banning if they refuse to provide a valid, negative COVID-19 test result when required or if they fail to follow NARA procedures for face coverings and physical distancing.

c. Other categories of visitors and facility occupants.

- i. All visitors and facility occupants who are not NARA employees are required to provide a vaccination attestation in order to access NARA facilities or NARA-occupied space.
- ii. In High and Medium community levels, individuals who are not fully vaccinated for COVID-19 or who do not disclose their vaccination status must provide COVID-19 test results – from an acceptable COVID-19 test – that are no more than three whole calendar days old in order to access NARA facilities or NARA-controlled space.
- iii. NARA officials who host, sponsor, or are responsible for the underlying program or purpose of the visit must verify that the individual has a vaccination attestation form and, if required, a negative COVID-19 test result.
 - (1) COVID-19 test results must meet all of the requirements for COVID-19 test results in paragraph 2b.iv, except that the date that the specimen was collected must be no more than three whole calendar days before the date the individual seeks entry to a NARA facility.
 - (2) In facilities with a security force, security officers will only verify that the individual has completed an attestation form and has the

required paperwork for entry into the facility. Security officers will not review attestation forms or verify COVID-19 test results.

- (3) Individuals will present their vaccination attestation or COVID-19 test results for visual inspection, but NARA employees and security officers will not collect or record their vaccination status or COVID-19 test results.
- iv. The following categories of visitors and facility occupants are not NARA employees for the purposes of this policy.
- (1) **NARA volunteers** are not employees as defined by 5 U.S.C. § 2105. These individuals must present a vaccination attestation and, if applicable, a negative COVID-19 test result to the NARA volunteer coordinator or a responsible program manager in order to access NARA facilities.
 - (2) **NARA students** who do not have civil service appointments and who do not otherwise meet the definition of employee under 5 U.S.C. § 2105 must present a vaccination attestation and, if applicable, a negative COVID-19 test result to the NARA student coordinator or a responsible program manager in order to access NARA facilities. Pathways interns are employees and should follow to the procedures for vaccination attestations and COVID-19 testing for NARA employees.
 - (3) Members of the **National Historical Publications and Records Commission (NHPRC), Public Interest Declassification Board (PIDB), and members of other boards or commissions** who are NARA employees only when performing the duties of the board or commission, with or without compensation, must present a vaccine attestation and, if applicable, negative COVID-19 test result to the NARA employee who serves as executive secretary or related role, in order to access a NARA facility.
 - (4) **Foundation Board Members and employees.** Board members and employees of the National Archives Foundation (NAF) and Presidential Library Foundations must present a vaccine attestation and, if applicable, negative COVID-19 test result to the NARA Designated Official or designee in order to gain access to NARA facilities (including the Hoover, Roosevelt, Truman, Eisenhower, Kennedy, and Johnson Libraries, the Ford Library and Museum, and the Carter and Obama Libraries) or NARA-controlled space (at the Nixon, Reagan, George H.W. Bush, Clinton, and George W. Bush Libraries).

- (5) Department of Veterans Affairs (VA) **Compensated Work Therapy (CWT) workers** are not employees of NARA or the VA and must present a vaccination attestation and, if applicable, a negative COVID-19 test result to their NARA supervisor in order to access NARA facilities.
 - (6) **GSA employees, contractors, and sub-contractors** in NARA-occupied GSA facilities with no on-site GSA building manager must present a vaccination attestation and, if applicable, a negative COVID-19 test result to the NARA Designated Official or designee in order to access NARA facilities.
 - (7) **Federal tenants in National Personnel Records Center (NPRC) building** at 1 Archives Drive are tenants of GSA and will follow their home agency's procedures for vaccine attestations and COVID-19 testing.
 - (8) **Delivery drivers**, including mail carriers, couriers, and package delivery services, should be directed to the loading dock as much as possible. If the bay doors are open, the loading dock may be treated as outdoor space for face covering, attestation, and testing purposes. As much as possible, drivers should stay in their cabs when records shipments are loaded or unloaded. Delivery drivers who must enter the facility (e.g. vending machine service, armored car service) must present a vaccination attestation and, if applicable, a negative COVID-19 test.
 - (9) **All other visitors** for meetings, on-site work, or other purposes, including employees and contractors of other Federal agencies (**including agency declassification reviewers**) must present a vaccination attestation and, if applicable, a negative COVID-19 test result to the NARA official who hosts or sponsors the individual's site visit or on-site work in order to access NARA facilities.
- v. NARA will not provide COVID-19 testing to visitors and will not reimburse visitors for COVID-19 tests that are required for access to NARA facilities.

Point of Contact: If you have questions or comments, please contact the Office of Human Capital at labor.relations@nara.gov.

Summary of NARA Requirements for COVID-19 Test Results
 March 7, 2022


1. Summary of requirements.

	ACCEPTABLE	NOT ACCEPTABLE
Test Type	Supervisors must positively identify or confirm that test results are from viral tests.	Supervisors must ensure that test results are <u>not</u> from antibody tests.
	Results of viral tests typically include words like: <ul style="list-style-type: none"> • Viral • NAAT or NAA • PCR or RT-PCR • Molecular • Antigen • RNA 	Antibody tests are not acceptable. Antibody test results include words like: <ul style="list-style-type: none"> • Serology • Antibody • IgG • IgM
	Results must be from a test administered by a pharmacy, health care provider, laboratory, clinic, or similar facility.	Test results that do not indicate the type of test or do not include enough information to search the FDA list of approved tests are not acceptable.
Issuing entity	Test results must clearly indicate the pharmacy, health care provider, laboratory, clinic, or similar facility that performed the test.	Test results that do not indicate the entity that performed the are not acceptable. Self-tests are not acceptable.
Specimen collection date (employees only)	Employees who regularly participate in NARA’s screening testing program (they produced a test result in the previous week) must produce a new test result every week. <ul style="list-style-type: none"> • The date that the specimen was collected or the date of the procedure must be no more than seven days before the date the test result is provided to the supervisor. 	If an employee is not regularly testing through NARA’s screening testing program (they did not produce a test result in the previous week), they must provide a test result that is no more than seven days before their date of entry to the building. <ul style="list-style-type: none"> • Seven days is seven whole calendar days.

	ACCEPTABLE	NOT ACCEPTABLE
	<ul style="list-style-type: none"> If there is any dispute, the date the specimen was collected for the new report must be any time after the specimen collection date for the previous week's report. 	
Specimen collection date (contractors and visitors)	<p>Contractors and visitors who require testing must provide a test result that is dated no more than three days before the date of entry at a NARA facility.</p> <ul style="list-style-type: none"> The three day limit is based on the date that the specimen was collected or the date of the procedure. Three days is three whole calendar days, which may exceed 72 hours. A test of a specimen collected on Monday morning is valid through Thursday evening. 	<p>A test result more than three whole calendar days old is not acceptable.</p> <ul style="list-style-type: none"> The <i>date received by the lab</i> or <i>date reported</i> are not acceptable for determining the age of the test result.
Identification	The test result must include the individual's name.	Test result does not identify the individual's name as the "patient" or person who was tested.
Results	Results must be negative, or "not detected".	Positive, equivocal, or invalid results are not acceptable.

2. Examples of acceptable test results.

Example A1: Molecular / NAAT, “negative” result.



S. Fargahi, M.D. Medical Director
K. Mehraein, M.D. Medical Co-Director

Client Information
Client ID: [REDACTED]
Xpress Urgent Care
17612 E. 17th St.
Tustin, CA 92780

Ordering Provider
[REDACTED]
Phone: [REDACTED]
Fax: [REDACTED]

Patient Information
Name: **Your Name**
MRN/ID: [REDACTED] Sex: M
DOB: [REDACTED] Age: [REDACTED]

Specimen Information
Order No: [REDACTED]
Collection Date/Time: 12/23/2020 00:00
Received Date: 12/23/2020 03:15

Report Information
Issue Date/time: 12/23/2020 08:24
Status: Complete
Page: 1

Fasting: No

Molecular	OUT OF RANGE	IN RANGE	REF. RANGE	UNITS
SARS-CoV-2 Qual NAAT		Negative	Negative	

Diagnostic tests for detection of SARS-CoV-2 RNA, PCR or TMA, are the most commonly used NAAT tests and both have FDA Emergency use Authorization (EUA). These tests are very sensitive and accurate for detection of SARS-CoV-2 viral RNA. These assays are based on amplifying the viral RNA to detect the presence of the viral RNA. Most assays use some form of PCR to amplify the virus RNA, to convert viral RNA to cDNA with reverse transcriptase PCR before amplification and detection.

The Aptima SARS-CoV-2 assay is a nucleic acid amplification in vitro diagnostic test (NAAT) intended for the qualitative detection of RNA from SARS-CoV-2 isolated and purified from nasopharyngeal (NP), nasal, and oropharyngeal (OP) swab specimens obtained from individuals who meet COVID-19 clinical and/or epidemiological criteria. The Aptima SARS-CoV-2 assay combines the technologies of target capture, Transcription Mediated Amplification (TMA) and Dual Kinetic Assay (DKA). For more information, see:
Fact Sheet for Healthcare Providers: www.fda.gov/media/138095/download
Fact Sheet for Patients: <https://www.fda.gov/media/138098/download>

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information. CDC's clinical criteria for Covid-19 testing is frequently updated as additional information becomes available. The most recent information on the Covid-19 can be found at: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-overview.html>

The CDC approves this methodology for traveling purposes. Please see CDC website: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-overview.html>

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Example A2: NAA, COVID-19 “not detected”

Patient Report

Specimen ID: [REDACTED]
Control ID: [REDACTED]

Acct #: [REDACTED] Phone: [REDACTED] Rte: 00
Xpress Urgent Care
Medical Center [REDACTED]
131 E 17th St [REDACTED]
COSTA MESA CA 92627

Your Name

Patient Details
DOB: [REDACTED]
Age(y/m/d): [REDACTED]
Gender: M [REDACTED]
Patient ID: [REDACTED]

Specimen Details
Date collected: 01/02/2021 1100 Local
Date received: 01/03/2021
Date entered: 01/03/2021
Date reported: 01/04/2021 0906 ET

Physician Details
Ordering: B. LINTON
Referring:
ID: [REDACTED]
NPI: [REDACTED]

General Comments & Additional Information
Alternate Control Number: [REDACTED] Alternate Patient ID: [REDACTED]

Ordered Items
SARS-CoV-2, NAA; SARS-CoV-2, NAA 2 DAY TAT

TESTS	RESULT	FLAG	UNITS	REFERENCE INTERVAL	LAB
SARS-CoV-2, NAA	Not Detected			Not Detected	01

This nucleic acid amplification test was developed and its performance characteristics determined by LabCorp Laboratories. Nucleic acid amplification tests include PCR and TMA. This test has not been FDA cleared or approved. This test has been authorized by FDA under an Emergency Use Authorization (EUA). This test is only authorized for the duration of the time the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostic tests for detection of SARS-CoV-2 virus and/or diagnosis of COVID-19 infection under section 564(b)(1) of the Act, 21 U.S.C. 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.
When diagnostic testing is negative, the possibility of a false

Example A3: Molecular / RT-PCR, “negative” result

DANNER LABORATORY
5230 Carroll Canyon Rd., Suite 114
San Diego, California 92121
(858) 552-1508
Fax: (858) 552-1453

Nancy Barr, M.D.
Medical Director
CLIA:

PATIENT: **Your Name**
CLINICIAN/
REQUESTING
DOCTOR:
PATIENT ID #:
[REDACTED]

DATE OF PROCEDURE: 12/23/2020
DATE RECEIVED IN LAB: 12/24/2020
DATE OF REPORT: 12/24/2020
DATE OF BIRTH: **00/00/0000**
AGE: SEX:

MOLECULAR REPORT

MOLECULAR ACCESSION #:



PROCEDURE	OUTSIDE OF REFERENCE	WITHIN RANGE	REFERENCE RANGE
COVID-19		Negative	Negative

Negative results do not preclude 2019-nCoV infection and should not be used as the sole basis for treatment or other patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

Danner Laboratory utilizes an FDA permitted, **RT-PCR-based, molecular platform** on all nasopharyngeal, oropharyngeal and nasal swabs for COVID-19 testing.

3. Examples of unacceptable test results

Example U1: Serology / IgG / antibody, not FDA approved

 		Report Status: Final TEST, C19	
Patient Information TEST, C19 ← Your Name DOB: Not Given AGE: 56 Gender: M Fasting: N Phone: NG Patient ID: NG		Specimen Information Specimen: KP615943B Requisition: 2224204 Collected: 04/20/2020 / 08:00 EDT Received: 04/20/2020 / 19:48 EDT Reported: 04/20/2020 / 19:59 EDT	
Client Information Client #: 97502840 H0990000 TESTING, DOC TEST CLIENT (HQ) Attn: ATTN:TEST DEPARTMENT 30 JACKSON RD MEDFORD, NJ 99999			
Test Name SARS CoV 2 (COVID 19) AB (IGG), IA SARS CoV 2 AB IGG		In Range Out Of Range Reference Range Lab QTE NEGATIVE	
Reference range: Negative		Your Test Results: Positive Negative Equivocal	
<p>Detection of IgG antibodies may indicate exposure to SARS-CoV-2 (COVID-19). It usually takes at least 10 days after symptom onset for IgG to reach detectable levels. An IgG positive result may suggest an immune response to a primary infection with SARS-CoV-2, but the relationship between IgG positivity and immunity to SARS-CoV-2 has not yet been firmly established. Antibody tests have not been shown to definitively diagnose or exclude SARS-CoV-2 infection. Diagnosis of COVID-19 is made by detection of SARS-CoV-2 RNA by molecular testing methods, consistent with a patient's clinical findings.</p> <p>This test has not been reviewed by the FDA. Negative results do not rule out SARS-CoV-2 infection particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals. Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status. Positive results could also be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus</p>			

Example U2: Antibody test

SUMMIT MEDICAL GROUP				
1 Diamond Hill Road Berkeley Heights, NJ 07922 LABORATORY DEPARTMENT				
				31D0116144 Gordana Katava, DO
Name/DOB: TESTPATIENT, MARGUERITE (6/14/1995)		Provider: Provider Test		
Patient ID: EH3	Sex: F Fasting:	Draw Location: BH_1Diamond_LAB		
Phone number: (908) 273-4344	Age: 24	Case Number: 2016202006		
Procedure Date: 6/10/2020 4:23 PM	Home Chart Location:	Technician: Kahul Patel		
Approval date: 6/10/2020 4:26 PM	Encounter ID:	Entered by: Kahul Patel		
TEST NAME	RESULT	UNITS	REFERENCE RANGE	
	IN RANGE	OUT OF RANGE		
COVID-19 Total Antibody			KP	
COVID-19 Total Antibody	Positive			
06/10/20 4:25 PM	<p>A negative test result does not rule out the possibility of an infection with SARS-CoV-2. Serum or plasma samples from the early (pre-seroconversion) phase of illness can yield negative findings. Therefore, this test cannot be used to diagnose an acute infection. Testing with molecular diagnostic should be performed to evaluate for active infection in symptomatic individuals. It is not known at this time if the presence of antibodies to SARS-CoV-2 confers immunity to reinfection. False positive results for the test may occur due to cross-reactivity. The Siemens Covid-19 Total Antibody test was developed, and its performance characteristics determined by Siemens for the Vista 1500. The FDA has authorized this test for EUA.</p>			

Example U3: Self-tests are not acceptable