

**EMERGENCY USE AUTHORIZATION (EUA) SUMMARY
FOR THE QUEST DIAGNOSTICS HA SARS-COV-2 ASSAY**

For *In vitro* Diagnostic Use

Rx Only

For use under Emergency Use Authorization (EUA) only

INTENDED USE

The Quest Diagnostics HA SARS-CoV-2 Assay is intended for the qualitative detection of nucleic acid from SARS-CoV-2 in anterior nasal swab specimens collected using the Quest Diagnostics Collection Kit for COVID-19 when used consistent with its authorization.

Testing is limited to laboratories designated by Quest Diagnostics that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meet the requirements to perform high complexity tests.

Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in anterior nasal swabs during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

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. Specimens that are collected will not be tested with an internal control to confirm that the specimen was properly collected. Collected specimens from SARS-CoV-2 positive individuals may yield negative results if the specimen was not collected properly.

Testing with the Quest Diagnostics HA SARS-CoV-2 Assay is intended for use by qualified and trained laboratory personnel specifically instructed and trained in the molecular testing and *in vitro* diagnostic procedures. The Quest Diagnostics HA SARS-CoV-2 Assay and the Quest Diagnostics Collection Kit for COVID-19 are only for use under the Food and Drug Administration's Emergency Use Authorization.

DEVICE DESCRIPTION AND TEST PRINCIPLE

1) **Device Description:**

The Quest Diagnostics HA SARS-CoV-2 Assay for use with the Quest Diagnostics Collection Kit for COVID-19 which enables the collection of an anterior nasal swab specimen when used consistent with its authorization. This specimen is then transported to a laboratory designated by Quest Diagnostics for SARS-CoV-2 testing using the Quest Diagnostics HA SARS-CoV-2 Assay.

2) ***Test Principle:***

The Quest Diagnostics HA SARS-CoV-2 Assay is only used for patients who have been previously qualified by their healthcare provider as needing SARS-CoV-2 testing based on the provider's medical judgement regarding symptoms, exposure, and risk factors. A healthcare provider qualifies a patient for testing using anterior nasal swab specimens collected using the Quest Diagnostics Collection Kit for COVID-19 when used consistent with its authorization.

Specimens received at the laboratory designated by Quest Diagnostics will undergo review for integrity of packaging, adequacy of sample, verification of patient information, and acceptable time window between specimen collection and receipt at the laboratory prior to acceptance for testing.

Laboratories designated by Quest Diagnostics are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meet the requirements to perform high complexity tests using an FDA authorized NAAT test per the Instructions for Use.

3) ***Medical Oversight and Process to be Used:***

Medical oversight of the process is provided by the healthcare provider who is ordering the test.

4) ***Test results and interpretation***

CONTROLS TO BE USED WITH QUEST DIAGNOSTICS HA SARS-COV-2 ASSAY

Quest Diagnostics and laboratories designated by Quest Diagnostics will use the controls used with the Quest Diagnostics HA SARS-CoV-2 Assay performed using the Hologic Aptima SARS-CoV-2 assay, which include an internal control, positive control and negative control, will be used in accordance with the package insert.

The Hologic Aptima SARS-CoV-2 assay provides the positive controls and negative controls as part of the kit, and the controls are ready-to-use. The instrument assesses the validity of the run and will not run patient samples until valid results are achieved.

INTERPRETATION OF RESULTS

All test controls should be examined prior to interpretation of patient results. If the controls are not valid, the patient results cannot be interpreted. Results are reported as Positive, Negative, or Invalid.

The Quest Diagnostics HA SARS-CoV-2 Assay will use the result interpretation displayed in the table below:

| SARS-CoV-2 Result | IC Result | Interpretation |
|--------------------------|------------------|---|
| Neg | Valid | SARS-CoV-2 not detected. |
| POS | Valid | SARS-CoV-2 detected. |
| Invalid | Invalid | Invalid. There was an error in the generation of the result; retest sample. |

Note: Detection of internal control is not required for samples that are positive for SARS-CoV-2.

If a result is invalid, then the assay will be repeated if adequate specimen is available. If on repeat the specimen is still invalid, then Quest Diagnostics will offer the patient at least one of the following options: the opportunity to collect a second specimen at no additional cost and/or a refund of their purchase minus the ordering provider's fee.

All results are delivered electronically to the healthcare provider and the participant.

PERFORMANCE EVALUATION

1) **Quest Diagnostics Collection Kit for COVID-19 Studies:**

The Quest Diagnostics HA SARS-CoV-2 Assay is performed using anterior nasal swabs collected with the Quest Diagnostics Collection Kit for COVID-19 when used consistent with its authorization. The Quest Diagnostics Collection Kit for COVID-19 was authorized as a standalone EUA on October 8, 2021. Sample stability studies, human usability studies and studies to support removal of the RNase P control are described in the Quest Diagnostics Collection Kit for COVID-19 submission authorized on October 8, 2021.

2) **Quest Diagnostics HA SARS-CoV-2 Assay Analytical and Clinical Performance Evaluation:**

The Quest Diagnostics HA SARS-CoV-2 Assay is performed on the Hologic Aptima SARS-CoV-2 assay using anterior nasal swabs collected with the Quest Diagnostics Collection Kit for COVID-19. The analytical and clinical performance of the Hologic Aptima SARS-CoV-2 assay has been demonstrated by Hologic in the Emergency Use Authorization submission originally authorized on 05/14/2020. The details of the performance of the authorized Hologic Aptima SARS-CoV-2 assay can be found here: <https://www.fda.gov/media/138096/download>. Hologic granted Right of Reference to Quest Diagnostics for Hologic's authorized Hologic Aptima SARS-CoV-2 assay.

Limitation:

- The performance of this test was established based on the evaluation of a limited number of clinical specimens. Clinical performance has not been established with all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the

time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.

Warnings:

- This product has not been FDA cleared or approved, but has been authorized by FDA under an EUA for use by authorized laboratories; laboratories designated by Quest Diagnostics that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meet the requirements to perform high complexity tests;
- This product has been authorized only for the detection of nucleic acid from SARS- CoV-2, not for any other viruses or pathogens; and
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.