

**EMERGENCY USE AUTHORIZATION (EUA) SUMMARY FOR THE
QUEST DIAGNOSTICS PF SARS-COV-2 ASSAY**
For *In vitro* Diagnostic Use
Rx Only
For use under Emergency Use Authorization (EUA) only

The Quest Diagnostics PF SARS-CoV-2 Assay will be performed at laboratories designated by Quest Diagnostics that are certified under the Clinical Laboratory Amendments of 1988 (CLIA), 42 U.S.C. §263a and meet the requirements to perform high complexity tests as described in the Laboratory Standard Operating Procedures that were reviewed by FDA under this EUA.

INTENDED USE

The Quest Diagnostics PF SARS-CoV-2 Assay is intended for the qualitative detection of nucleic acids from SARS-CoV-2 from nasopharyngeal (NP) and oropharyngeal (OP) swab specimens, nasopharyngeal washes/aspirates or nasal aspirates, and bronchoalveolar lavage specimens (collected by a healthcare provider) and anterior nasal (nasal) and mid-turbinate nasal swab specimens (collected under observation of or by a healthcare provider) from individuals who meet COVID-19 clinical and/or epidemiological criteria, as well as NP and OP swab specimens (collected by a healthcare provider) and nasal and mid-turbinate nasal swab specimens (collected under observation of or by a healthcare provider) from any individual, including from individuals without symptoms or other reasons to suspect COVID-19.

The Quest Diagnostics PF SARS-CoV-2 Assay is also intended for the qualitative detection of nucleic acids from SARS-CoV-2 in anterior nasal swab specimens collected using the Quest Diagnostics Collection Kit for COVID-19 or the Quest COVID-19 Nucleic Acid Test Collection Kit when used consistent with their respective authorizations.

The Quest Diagnostics PF SARS-CoV-2 Assay is also intended for the qualitative detection of nucleic acids from SARS-CoV-2 in pooled samples containing up to five individual NP or OP swabs (collected by a healthcare provider), nasal, or mid-turbinate nasal swabs (collected under observation of or by a healthcare provider), or anterior nasal swab specimens collected using the Quest Diagnostics Collection Kit for COVID-19 or the Quest COVID-19 Nucleic Acid Test Collection Kit when used consistent with their respective authorizations.

Testing is limited to laboratories designated by Quest Diagnostics which are also 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. SARS-CoV-2 RNA is generally detectable in respiratory specimens 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.

Quest Diagnostics PF SARS-CoV-2 Assay EUA Summary:
Updated: March 10, 2023

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.

Negative results from pooled testing should not be treated as definitive. If a patient's clinical signs and symptoms are inconsistent with a negative result or if the results are necessary for patient management, then the patient should be considered for individual testing. Specimens included in pools with a positive or invalid result must be tested individually prior to reporting a result. Specimens with low viral loads may not be detected in sample pools due to the decreased sensitivity of pooled testing.

The Quest Diagnostics PF SARS-CoV-2 Assay is only intended for use by qualified clinical laboratory personnel specifically instructed and trained in the techniques of real-time RT-PCR assays and in vitro diagnostic procedures. The Quest Diagnostics PF SARS-CoV-2 Assay is only for use under the Food and Drug Administration's Emergency Use Authorization.

SPECIAL CONDITIONS OF USE STATEMENTS

For *in vitro* diagnostic use
For Emergency Use only
For Prescription Use only

This assay can be used with the Quest Diagnostics Collection Kit for COVID-19 and Quest COVID-19 Nucleic Acid Test Collection Kit when used consistent with their respective authorizations.

DEVICE DESCRIPTION AND TEST PRINCIPLE

1) Device Description:

The Quest Diagnostics PF SARS-CoV-2 Assay is a real-time reverse transcription polymerase chain reaction (RT-PCR) that contains primers and probes designed for the detection of specific nucleic acid sequences within the SARS-CoV-2 ORF1 a/b gene.

The Quest Diagnostics PF SARS-CoV-2 Assay is intended for use with certain upper and lower respiratory specimens and anterior nasal swab specimens collected using the Quest Diagnostics Collection Kit for COVID-19 or the Quest COVID-19 Nucleic Acid Test Collection Kit when used consistent with their respective authorizations.

This assay is also intended for the qualitative detection of nucleic acids from SARS-CoV-2 in pooled samples containing up to five individual respiratory specimens, including anterior nasal swab specimens collected using the Quest Diagnostics Collection Kit for COVID-19 or the Quest COVID-19 Nucleic Acid Test Collection Kit when used consistent with their respective authorizations.

2) ***Test Principle:***

The Quest Diagnostics Collection Kit for COVID-19 is for use by 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.

The Quest COVID-19 Nucleic Acid Test Collection Kit, is for use by any individual, including individuals without symptoms or other reasons to suspect COVID-19 when determined to be appropriate by a healthcare provider.

Specimens collected under observation of or by a healthcare provider, or anterior nasal swab specimens collected using either the Quest Diagnostics Collection Kit for COVID-19 or the Quest COVID-19 Nucleic Acid Test Collection Kit, are transported to a laboratory designated by Quest Diagnostics for SARS-CoV-2 testing using the Quest Diagnostics PF SARS-CoV-2 Assay. Specimens received at the laboratory will undergo review for integrity of packaging, liquid volume, verification of patient information, and acceptable interval between specimen collection and receipt at the laboratory prior to acceptance for testing.

Testing with the Quest Diagnostics PF SARS-CoV-2 Assay is performed by laboratories designated by Quest Diagnostics and that are also certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meet the requirements to perform high complexity tests.

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 Procedure:***

Quest Diagnostics and laboratories designated by Quest Diagnostics will perform the procedure as described in the manufacturer's instructions (Hologic Inc.) for the Hologic Panther Fusion SARS-CoV-2 Assay.

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

Controls for the Quest Diagnostics PF SARS-CoV-2 Assay include an internal control, positive control, and negative control, that are used in accordance with the package insert for the Hologic Panther Fusion SARS-CoV-2 Assay.

The Hologic Panther Fusion SARS-CoV-2 Assay provides the positive controls and negative controls with the kit, and the controls are ready-to-use. The instrument assesses the validity of the run and will not run patient specimens 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 PF SARS-CoV-2 Assay will follow the result interpretation algorithm

Quest Diagnostics PF SARS-CoV-2 Assay EUA Summary:
Updated: March 10, 2023

displayed in the table below:

Specimen Result Interpretation for Unpooled Specimens

SARS-CoV-2 Result	IC Result	Interpretation
Neg	Valid	SARS-CoV-2 notdetected.
Pos	Valid	SARS-CoV-2 detected.
Invalid	Invalid	Invalid. There was an error in the generation of the result; retest specimen.

If a result for a specimen collected using the Quest Diagnostics Collection Kit for COVID-19 or the Quest COVID-19 Nucleic Acid Test Collection Kit is invalid, then the assay will be repeated if adequate specimen is available. If on repeat the result is still reported as invalid, then Quest Diagnostics will offer the patient a one or both 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.

Specimen Result Interpretation for Pooled Samples

Negative—Negative results from pooled samples testing should not be treated as definitive. If the patient's clinical signs and symptoms are inconsistent with a negative result and if results are necessary for patient management, then the patient should be considered for individual testing. The use of sample pooling should be indicated in the test report for any specimens with reported negative results.

Positive—Samples with a positive sample pool result must be tested individually prior to reporting a result. Specimens with low viral loads may not be detected in sample pools due to the decreased sensitivity of pooled testing.

Invalid—Samples with an invalid pool result must be tested individually prior to reporting a result. However, in instances of an invalid run, repeat testing of pooled samples may be appropriate depending on laboratory workflow and required result reporting time.

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

PERFORMANCE EVALUATION

Quest Diagnostics PF SARS-CoV-2 Assay Analytical and Clinical Performance Evaluation:

The Quest Diagnostics PF SARS-CoV-2 Assay is performed on the Hologic Panther Fusion System by testing anterior nasal swab specimens collected using the Quest Diagnostics Collection Kit for COVID-19 or the Quest COVID-19 Nucleic Acid Test Collection Kit with the Hologic Panther Fusion SARS-CoV-2 Assay on the Panther Fusion System. The analytical and clinical performance of the Quest Diagnostics PF SARS-CoV-2 Assay are supported by the validation studies that were performed by Hologic Inc. for the Hologic Panther Fusion SARS-CoV-2 Assay (EUA200014; originally authorized on March 16, 2020). The EUA for the Hologic Panther Fusion SARS-CoV-2 Assay was re-authorized to allow testing of pools of up to 5 samples, and to allow testing of any individual, including individuals without signs and symptoms or other reasons to suspect COVID-19 on September 24, 2020. The EUA for the Hologic Panther Fusion SARS-CoV-2 Assay was most recently re-authorized on March 23, 2022.

Hologic Inc. granted a Right of Reference to Quest Diagnostics for the data submitted in support of the Hologic Panther Fusion SARS-CoV-2 Assay EUA. The details of the Hologic Panther Fusion SARS-CoV-2 Assay can be found at <https://www.fda.gov/media/136156/download>.

LIMITATIONS

- 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.
- Samples should only be pooled when testing demand exceeds laboratory capacity and/or when testing reagents are in short supply.
- Samples with low viral loads may not be detected in sample pools due to the decreased sensitivity of pooled testing.
- Asymptomatic individuals infected with COVID-19 may not shed enough virus to reach the limit of detection of the test, giving a false negative result.

WARNINGS

- For in vitro diagnostic use.
- For Emergency Use Authorization only.
- This product has not been FDA cleared or approved but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories.
- This product has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.
- 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.