EMERGENCY USE AUTHORIZATION (EUA) SUMMARY
THE LABCORP SARS-COV-2 & INFLUENZA A/B ASSAY
(LABORATORY CORPORATION OF AMERICA)

For *In vitro* Diagnostic Use
Rx Only
For use under Emergency Use Authorization (EUA) only

(The Labcorp SARS-CoV-2 & Influenza A/B Assay will be performed at the Center for Esoteric Testing in Burlington, North Carolina, or other laboratories designated by Labcorp 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, as described in the Standard Operating Procedures that were reviewed by the FDA under this EUA.)

INTENDED USE

The Labcorp SARS-CoV-2 & Influenza A/B Assay is a real-time RT-PCR assay intended for the simultaneous qualitative detection and differentiation of SARS-CoV-2, influenza A virus, and/or influenza B virus RNA in anterior nasal swab specimens collected at home by individuals suspected of respiratory viral infection consistent with COVID-19 by a healthcare provider (HCP). The Labcorp SARS-CoV-2 & Influenza A/B Assay is intended for use as an aid in differential diagnosis of SARS-CoV-2, influenza A, and influenza B in human and is not intended to detect influenza C. Clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2 and influenza can be similar.

This test is for use with anterior nasal swab specimens that are collected by individuals age 18 years and older (self-collected), 14 years and older (self-collected under adult supervision), or 2 years and older (collected with adult assistance) using either the Labcorp COVID-19 + Flu Test Home Collection Kit or the Pixel by Labcorp COVID-19 + Flu Test Home Collection Kit when ordered directly by an HCP. Specimens collected using the Labcorp COVID-19 + Flu Test Home Collection Kit or the Pixel by Labcorp COVID-19 + Flu Test Home Collection Kit can be transported at ambient temperature for testing.

Testing is limited to the Center for Esoteric Testing, Burlington, NC, or other laboratories designated by Labcorp 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.

RNA from SARS-CoV-2, influenza A, and influenza B is generally detectable in anterior nasal swab specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2, influenza A and/or influenza B 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 pathogens not detected by the test. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all SARS-CoV-2 results to the appropriate public health authorities.

Negative results do not preclude SARS-CoV-2, influenza A, and/or influenza B infection and should not be used as the sole basis for diagnosis, treatment, or other patient management decisions. Negative results must be combined with clinical observations, patient history, and/or epidemiological information.

The Labcorp SARS-CoV-2 & Influenza A/B Assay is intended for use by qualified laboratory personnel specifically instructed and trained in the techniques of real-time PCR and in vitro diagnostic procedures.

The Labcorp SARS-CoV-2 & Influenza A/B Assay is only for use under the Food and Drug Administration's Emergency Use Authorization.

DEVICE DESCRIPTION AND TEST PRINCIPLE

The Labcorp SARS-CoV-2 & Influenza A/B Assay is a real-time RT-PCR test for the qualitative detection of SARS-CoV-2, Influenza A, and/or Influenza B RNA in anterior nasal swab samples collected in 0.9% physiological saline and is based on the fully automated cobas SARS-CoV-2 & Influenza A/B assay (EUA202635) performed on the cobas 6800/8800 Systems. The cobas 6800/8800 Systems consist of the sample supply module, the transfer module, the processing module, and the analytic module.

For detection of SARS-CoV-2, forward and reverse primer sets and probes for the ORF1ab gene region (which is unique to SARS-CoV-2 virus), and for the E gene region (which is common for all members under the subgenus Sarbecovirus) are used. For detection of influenza A and influenza B viruses, selective amplification of target nucleic acid from the sample is achieved using target-specific forward and reverse primers for the matrix proteins 1 and 2 (M1/M2) for influenza A and the nuclear export protein (NEP) / nonstructural protein 1 (NS1) genes for influenza B. Selective amplification of an RNA Internal Control is achieved using non-competitive sequence specific forward and reverse primers which have no homology with the coronavirus or influenza genomes.

Either the Labcorp COVID-19 + Flu Test Home Collection Kit or the Pixel by Labcorp COVID-19 + Flu Test Home Collection Kit will be used for collection of anterior nasal swab specimens at home by patients suspected by their healthcare provider of respiratory viral infection consistent with COVID-19, for testing with the Labcorp SARS-CoV-2 & Influenza A/B Assay.

Collection Kit Components

In addition to specific Instructions for Use and applicable kit registration card or specimen confirmation form, both the Labcorp COVID-19 + Flu Test Home Collection Kit and the Pixel by Labcorp COVID-19 + Flu Test Home Collection Kit will have the following components.

Table 1: Kit Components

Reagent	Manufacturer	Catalog #
Shipping box	Therapak	23586G
Return envelope	FedEx	163034
Specimen biohazard bag	Therapak	16019G
Nasal swab	Super Brush	59-1187-BULK
Saline and tube [1]	Sarstedt	51.550.123

[1] For the Pixel by Labcorp COVID-19 Test Home Collection Kit, a unique registration code is applied to each tube

The above kit components are the same as those in the previously authorized "Labcorp At Home COVID-19 Test Home Collection Kit" (EUA200011) and "Pixel by Labcorp COVID-19 Test Home Collection Kit" (EUA203057) for home collection of anterior nasal swabs specimens for detection of SARS-CoV-2 using the Labcorp COVID-19 RT-PCR Test.

Collection Device Stability

Both the Labcorp COVID-19 + Flu Test Home Collection Kit and the Pixel by Labcorp COVID-19 + Flu Test Home Collection Kit have a three-year expiration date from the date of manufacture of the saline tube or swab, whichever is earlier. Because the saline tubes and swabs remain in their original form from their respective manufacturers and are not repackaged during kit assembly, the manufacturer's assigned expiration date for the saline (3 years) and the swabs (3 years) are used to determine the expiration date of the collection kit.

Home Collection Kit ordering and distribution

a) The Labcorp COVID-19 + Flu Test Home Collection Kit: The kit is dispensed to patients when prescribed by their physician using the Labcorp provider interface to order diagnostic tests. The kit is intended for use by individuals to collect nasal swab specimens at home, when determined to be appropriate by a healthcare provider (HCP), to aid in the diagnosis of SARS-CoV-2, Influenza A, and/or Influenza B infection. Once the physician order is placed, Labcorp will mail the home collection kit to the patient, who will perform the sample collection at home and mail the sample back to Labcorp for testing.

b) The Pixel by Labcorp COVID-19 + Flu Test Home Collection Kit: Individuals having symptoms of respiratory viral infections consistent with COVID-19 will visit the Pixel online portal (www.pixel.Labcorp.com) to order the Pixel Labcorp COVID-19 + Flu Test Home Collection Kit. To place an order, an individual must answer a screening questionnaire provided by the Physician Wellness Network (PWN). If the patient is determined to be eligible for testing based on their responses to the questionnaire, an HCP from PWN will issue a prescription order to Labcorp to ship the Pixel home collection kit to the individual's home address. After receiving the Pixel home collection kit, the individual will perform the sample collection at home and ship the sample back to Labcorp for testing.

Home Collection Kit Use

As indicated in Table-1, both the Labcorp COVID-19 + Flu Test Home Collection Kit and the Pixel Labcorp COVID-19 + Flu Test Home Collection Kit are composed of a shipping box, pre-labeled return envelope, Instructions For Use, specimen collection materials (nasal swab and saline tube), and a specimen biohazard bag. The sample collection and shipping instructions are also included in the kit to direct users on how to collect an anterior nasal swab specimen appropriately, place it in the saline transport tube, properly package the specimen and mail it back to the laboratory using the pre-labeled FedEx return envelope. Return shipment should be performed on the same day as specimen collection.

Laboratory Processing (Sample accessioning)

When specimens collected using the Labcorp COVID-19 + Flu Test Home Collection Kit or the Pixel Labcorp COVID-19 + Flu Test Home Collection Kit arrive at the testing laboratory they will be accessioned as per the laboratory's SOP. The specimens will be rejected for testing if they meet one or more of the following criteria:

- No saline collection tube included
- No swab included within saline collection tube
- No registration code attached to the Pixel saline collection tube
- Saline collection tube leaked resulting in no sample for testing

- Accession date is greater than 1 calendar day from the specimen collection date

Results reporting:
For samples collected with the Labcorp COVID-19 + Flu Test Home Collection Kit, Labcorp will report test results back to the ordering physician and to the patient via the Labcorp patient portal. Upon receiving the result, the physician will also follow up all positive, negative and indeterminate results by contacting the individuals.

For Samples collected with the Pixel Labcorp COVID-19 + Flu Test Home Collection Kit, all test results will be delivered to the user via their Pixel by Labcorp account. The PWN will follow up all positive, negative and indeterminate results by contacting the individuals.

REAGENTS, AND MATERIALS
The Labcorp SARS-CoV-2 & Influenza A/B Assay is conducted with the same kits, reagents, and control materials authorized for use with the cobas SARS-CoV-2 & Influenza A/B Assay (EUA202635). The following tables list all the reagents and materials that will be used for running the Labcorp SARS-CoV-2 & Influenza A/B Assay.

Table 2: Kits and Reagents

Item	Storage Temp	Vendor	Catalog Number
cobas SARS-CoV-2 & Influenza A/B & Influenza A/B	2°C to 8°C	Roche	09233474190
cobas SARS-CoV-2 & Influenza A/B & Influenza A/B Control Kit	2°C to 8°C	Roche	09233482190
cobas Buffer Negative Control Kit	2°C to 8°C	Roche	07002238190
cobas omni Lysis Reagent	2°C to 8°C	Roche	06997538190
cobas omni MGP Reagent	2°C to 8°C	Roche	06997546190
cobas omni Specimen Diluent	2°C to 8°C	Roche	06997511190
cobas omni Wash Reagent	15°C to 30°C	Roche	06997503190

Reagents expire per manufacturer specification

Table 3: Materials and consumables for cobas 6800/8800

Item	Vendor	Part Number
Processing Plate	Roche	05534917001
Amplification Plate	Roche	05534941001
Pipette Tips	Roche	05534925001
Liquid Waste Container	Roche	07094388001
Solid Waste Bag	Roche	07435967001
Solid Waste Container	Roche	07094361001
Tubes for clot racks	Sarstedt	55.466
Wypall All-Purpose Wipers	Fisher Healthcare	0667771

Table 4: Materials and consumables for preparing specimen aliquot

Item	Vendor	Part Number
1ml Disposable Pipets		201CS30
Tube PP RND Base 7ml 82x13 HDPE With SCRW Cap	Sarstedt	60.550.034
	OR both of	
Tube 7ml SC 13x82 RB PP NO CAP	Sarstedt	60.550.030
Replacement cap		
Microplate Film Roll Or adhesive card, etc	USA Scientific	2920-3500

INSTRUMENT AND SOFTWARE

Cobas 6800 or 8800 System and associated software v1.4
Sample Supply Module

Instrument Gateway (IG) server
Dedicated PC for Data Innovation interface and Remote User Interface

CONTROLS

The Labcorp SARS-CoV-2 & Influenza A/B Assay will use the positive, negative, and internal controls that were previously authorized for use with the cobas SARS-CoV-2 & Influenza A/B assay (EUA202635). Briefly, SARS-CoV-2 & Influenza A/B Positive Control (SCoV2-FluA/B (+) C) and cobas Buffer Negative Control (BUF (-) C) will be included in every test batch and must produce a positive and negative result respectively for a run to be valid. There is also an RNA internal control (noninfectious MS2 bacteriophage RNA) that is added to every sample prior to processing to monitor specimen preparation and PCR amplification/detection.

INTERPRETATION OF RESULTS

The Labcorp SARS-CoV-2 & Influenza A/B Assay is modified from the FDA-authorized cobas SARS-CoV-2 & Influenza A/B assay (EUA202635). The result interpretation algorithm of the Labcorp SARS-CoV-2 & Influenza A/B Assay is described in the chart below.

Table 5: Result interpretation algorithm

Target 1 Influenza A*	Target 2 SARS-CoV-2	Target 3 Pan-Sarbecovirus	Target 4 Influenza B*	Interpretation
Negative	Negative	Negative	Negative	No target RNA Detected.
Negative	Negative	Negative	Positive	Influenza B RNA Detected.
Positive	Negative	Negative	Negative	Influenza A RNA Detected.
Positive	Negative	Negative	Positive	Influenza A and Influenza B RNA Detected.
Negative	Negative	Positive	Negative	Indeterminate for SARS-CoV-2.
Negative	Negative	Positive	Positive	Indeterminate for SARS-CoV-2. Influenza B RNA Detected.
Positive	Negative	Positive	Negative	Influenza A RNA Detected. Indeterminate for SARS-CoV-2.
Positive	Negative	Positive	Positive	Influenza A and Influenza B RNA Detected. Indeterminate for SARS-CoV-2.
Negative	Positive	Negative	Negative	SARS-CoV-2 RNA Detected.
Negative	Positive	Negative	Positive	SARS-CoV-2 and Influenza B RNA Detected.
Positive	Positive	Negative	Negative	Influenza A and SARS-CoV-2 RNA Detected.
Positive	Positive	Negative	Positive	Influenza A, SARS-CoV-2 and Influenza B RNA Detected.
Negative	Positive	Positive	Negative	SARS-CoV-2 RNA Detected.
Negative	Positive	Positive	Positive	SARS-CoV-2 and Influenza B RNA Detected.
Positive	Positive	Positive	Negative	Influenza A and SARS-CoV-2 RNA Detected.
Positive	Positive	Positive	Positive	Influenza A, SARS-CoV-2 and Influenza B RNA Detected.

If any individual target result is invalid, the presence or absence of that individual target cannot be determined. Other initial valid target results can be interpreted as described in the table.

Invalid results may occur due to the presence of PCR inhibitor(s) in the specimen. If retesting does not resolve the issue, recollection of the specimen is recommended for individuals if clinically indicated.

For samples with indeterminate results, if clinically indicated, additional sample collection is recommended for retesting.

* Results (positive and negative) for influenza should be interpreted with caution. If an influenza result is inconsistent with clinical presentation and/or other clinical and epidemiological information, FDA-cleared Influenza NAATs are available for confirmation if clinically indicated.

PERFORMANCE EVALUATION

The Labcorp SARS-CoV-2 & Influenza A/B Assay uses the same reagents and instrumentation as the previously authorized cobas SARS-CoV-2 & Influenza A/B assay (EUA202635). Labcorp obtained a Right of Reference from Roche Molecular Systems, Inc. (RMS, Inc.) to the information contained in the EUA submission for the cobas SARS-CoV-2 & Influenza A/B assay, including the evaluation of analytical sensitivity, inclusivity, cross-reactivity and clinical performance. Please refer to the Instructions For Use of the cobas SARS-CoV-2 & Influenza A/B assay for details.

1. Shipping Sample Stability:

Labcorp conducted a stability study to validate the shipping stability of the anterior nasal swab specimens that will be collected and transported using the Labcorp COVID-19 + Flu Test Home Collection Kit and the Pixel by Labcorp COVID-19 + Flu Test Home Collection Kit. In this study, a SARS-CoV-2 positive remnant patient sample, a live Influenza A culture (A/Nebraska/14/2018) and a live Influenza B culture (B/Colorado/06/2017) were separately diluted into negative individual anterior nasal swab samples, resulting in concentrations of virus corresponding to approximately 2X the LoD (low positive) and 10X the LoD (high positive). Twenty low-positive samples and 20 high-positive samples (separately containing each viral type) and 10 negative samples were independently subjected to the summer and winter profiles in accordance with FDA's recommended sample stability study design for home collection kits.

Samples were tested with the Labcorp SARS-CoV-2 & Influenza A/B Assay at 0-hour and after the 56-hour temperature excursion. The mean Ct values at T=56 hours were compared to the mean Ct values at time 0. All samples containing viral RNA remained positive after the temperature excursion and all samples without virus remained negative. The mean Ct values at T=56 hours for all viral targets were within 3.0 Ct compared to time 0, indicating acceptable specimen stability under the conditions tested.

Together, these data support the stability of anterior nasal swab samples collected with either the Labcorp COVID-19 + Flu Test Home Collection Kit or the Pixel Labcorp COVID-19 + Flu Test Home Collection Kit for up to 56 hours in an ambient temperature shipping environment.

2. Clinical Study:

Labcorp obtained a Right of Reference from RMS, Inc. to the results from the clinical evaluation for the cobas SARS-CoV-2 & Influenza A/B Assay (EUA202635). While Labcorp uses a modified algorithm to interpret SARS-CoV-2 results as shown in Table 5, the performance of the Labcorp SARS-CoV-2 & Influenza A/B Assay recalculated as per the result algorithm meets the criteria recommended in the FDA

Molecular Diagnostic Template.

3. Usability Study:

Under EUA200011, Labcorp conducted a Usability Study to evaluate the ease-of-use of the Labcorp At Home COVID-19 Collection Kit for collection of anterior nasal swab specimens from the Intended Use population, including from patients <18 years of age. The components of the Labcorp and Pixel by Labcorp COVID-19 + Flu Test Home Collection Kits and instructions for sample collection and shipment are the same as those for the Labcorp At Home COVID-19 Collection Kit and therefore the results of the Usability Study performed under EUA200011 are applicable to the current submission for the Labcorp At Home COVID-19 + Flu Home Collection Kit and the Pixel Labcorp COVID-19 + Flu Test Home Collection Kit. Please refer to the EUA Summary for the Labcorp COVID-19 RT-PCR Assay for additional details.

Additional Requirements:

In addition to the usability data provided in EUA200011, Labcorp will submit to FDA a summary report within 30 calendar days of authorization summarizing the results of any testing performed using specimens collected with the Labcorp COVID-19 + Flu Test Home Collection Kit and the Pixel by Labcorp COVID-19 + Flu Test Home Collection Kit during that timeframe, including how many specimens were received, how many specimens had to be rejected during accessioning and the main reasons for rejection, and the positivity rate for specimens collected with the authorized self-collection kits.

Labcorp will also solicit post-collection usability feedback from parents/guardians performing collection on very young children 2-4 years old to assess the ease of use of the kit in this age group further and submit a 30-day report to FDA. Monthly reporting must continue until FDA informs Labcorp that the cumulative data submitted within the monthly reports has sufficiently assessed the home collection kit for use with younger children.

WARNINGS

- For In Vitro Diagnostic Use.
- For Emergency Use Authorization Only.
- For Rx Only.
- Do not use reagents past their expiration date.
- For Use by individuals 18 years of age and older when self-collected.
- For Use by individuals 14 years of age and older when self-collected under adult supervision.
- For Use by individuals 2 years of age and older when collected with adult assistance.
- 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 and differentiation of nucleic acid from SARS-CoV-2, influenza A and/or influenza B, 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 Cosmetics Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

LIMITATIONS

- The clinical performance has not been established in all circulating variants of SARS-CoV-2 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.
- The Labcorp SARS-CoV-2 & Influenza A/B Assay has been evaluated only for use in combination with the cobas SARS-CoV-2 & Influenza A/B Control Kit, cobas Buffer Negative Control Kit, cobas omni MGP Reagent, cobas omni Lysis Reagent, cobas omni Specimen Diluent, and cobas omni Wash Reagent for use on the cobas 6800/8800 Systems.
- Reliable results depend on proper sample collection, storage and handling procedures.
- This test is intended to be used for the detection of SARS-CoV-2, Influenza A, and Influenza B RNA in anterior nasal swab samples collected with the Labcorp COVID-19 + Flu Test Home Collection Kit or with the Pixel Labcorp COVID-19 + Flu Test Home Collection Kit.
- Detection of SARS-CoV-2 and Influenza A/B RNA may be affected by sample collection methods, patient factors (e.g., presence of symptoms), and/or stage of infection.
- As with any molecular test, mutations within the target regions of the Labcorp SARS-CoV-2 & Influenza A/B Assay could affect primer and/or probe binding resulting in failure to detect the presence of virus.
- Due to inherent differences between technologies, it is recommended that, prior to switching from one technology to the next, users perform method correlation studies in their laboratory to qualify technology differences. One hundred percent agreement between the results should not be expected due to aforementioned differences between technologies. Users should follow their own specific policies/procedures.
- False negative or invalid results may occur due to interference. The Internal Control is included in the Labcorp SARS-CoV-2 & Influenza A/B Assay to help identify the specimens containing substances that may interfere with nucleic acid isolation and PCR amplification.
- The addition of AmpErase enzyme into the PCR Master Mix reagent enables selective amplification of target RNA; however, good laboratory practices and careful adherence to the procedures specified in this Instructions For Use document are necessary to avoid contamination of reagents.
- Results (positive and negative) for influenza should be interpreted with caution. If an influenza result is inconsistent with clinical presentation and/or other clinical and epidemiological information, FDA-cleared Influenza NAATs are available for confirmation if clinically indicated.
- Specimens that are collected at home will not be tested with a specimen adequacy control to confirm that the specimen was properly collected. Specimens collected at home from SARS-CoV-2 positive individuals may yield negative results if the specimen was not collected properly.