

**EMERGENCY USE AUTHORIZATION (EUA) SUMMARY
PIXEL BY LABCORP COVID-19 TEST HOME COLLECTION KIT
(LABORATORY CORPORATION OF AMERICA)**

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

(Anterior nasal swab specimens collected by individuals using the Pixel by Labcorp COVID-19 Test Home Collection Kit will be tested with the Labcorp COVID-19 RT-PCR Test 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 laboratory procedures that were reviewed by the FDA under this EUA.)

INTENDED USE

The Pixel by Labcorp COVID-19 Test Home Collection Kit is a direct to consumer product for collection of anterior nasal swab specimens at home by any individual 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), including individuals without symptoms or other reasons to suspect COVID-19, for testing with Labcorp's COVID-19 RT-PCR Test.

Anterior nasal swab specimens collected with the Pixel by Labcorp COVID-19 Test Home Collection Kit are also authorized to be tested with the COVID-19 RT-PCR Test, for the qualitative detection of nucleic acid from the SARS-CoV-2 in pooled samples, using a matrix pooling strategy (i.e., group pooling strategy), containing up to five individual upper respiratory swab specimens (nasopharyngeal, mid-turbinate, anterior nasal or oropharyngeal swabs collected using individual vials containing transport media) per pool and 25 specimens per matrix. Negative results from pooled testing should not be treated as definitive and may need follow up testing if inconsistent with an individual's signs and symptoms. Specimens included in pools where the positive sample cannot be identified using the matrix 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.

Anterior nasal swab specimens collected with the Pixel by Labcorp COVID-19 Test Home Collection Kit are authorized to be tested with the Labcorp COVID-19 RT-PCR Test. 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.

All test results are delivered to the user via an online portal. Additionally, individuals with positive or invalid/indeterminate results will be contacted by a healthcare provider. The direct to consumer home collection system is intended to enable users to access information about their COVID-19 infection status that could aid with determining if self-isolation or quarantine is appropriate and to assist with healthcare decisions after

discussion with a healthcare provider.

Results are for the identification of SARS-CoV-2 RNA. The 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 medical history and other diagnostic information is necessary to determine 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. Negative results do not preclude SARS-CoV-2 infection. Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

The Pixel by Labcorp COVID-19 Test Home Collection Kit with the Labcorp COVID-19 RT-PCR Test is not a substitute for visits to a healthcare provider. The information provided by this kit should not be used to start, stop, or change any course of treatment unless advised by your healthcare provider.

Testing with the COVID-19 RT-PCR Test is intended for use by trained clinical laboratory personnel specifically instructed and trained in the techniques of real-time PCR and *in vitro* diagnostic procedures. The Pixel by Labcorp COVID-19 Test Home Collection Kit with the COVID-19 RT-PCR Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

DEVICE DESCRIPTION AND TEST PRINCIPLE

The Pixel by Labcorp COVID-19 Test Home Collection Kit will be available direct to consumer (DTC) without a prescription and online direct to consumer for any individual 18 years and older to purchase. The Pixel by Labcorp COVID-19 Test Home Collection Kits will be available for purchase at retail locations and through the Pixel by Labcorp website.

Individuals will be asked screening questions through the Pixel website COVID-19 questionnaire, when registering their kit or ordering the kit online. When ordering the kit online, after verifying that the individual is 18 years or older, any answer will result in a kit being distributed. All test results are then delivered to the user via their Pixel by Labcorp account created during registration. Positive and invalid/indeterminate results are delivered to the user via a healthcare provider. The Physician Wellness Network (PWN) will follow up all positive and indeterminate or invalid test results by contacting the individuals (also see Interpretation of Results section below). For purposes of this EUA, a healthcare provider includes any healthcare professional with prescribing abilities including, but not limited to, physicians, nurses, pharmacists, technologists, laboratory directors, and epidemiologists. The healthcare provider contacting individuals with test results will have prescribing privileges for that individual, should medication be indicated for treatment.

The Pixel by Labcorp COVID-19 Test Home Collection Kit is composed of a shipping box, pre-labeled return envelope, directions, specimen collection materials (nasal swab and saline tube), specimen biohazard bag with absorbent pad, and the Individual Fact Sheet for the Pixel by Labcorp COVID-19 Test Home Collection Kit. Instructions are included in the kit to direct the home users on how to appropriately collect the nasal

swab specimen and place it in the saline transport tube, how to properly package the specimen and how to mail the specimen back to the laboratory using the pre-labeled FedEx return envelope.

Anterior nasal swab specimens collected with the Pixel by Labcorp COVID-19 Test Home Collection Kit are authorized to be tested with the COVID-19 RT-PCR Test, a real-time reverse transcription polymerase chain reaction (rRT-PCR) test. The test can be run in a singleplex format (three individual assays for each of the three SARS-CoV-2 targets) or multiplexed into a single reaction (containing all 3 SARS-CoV-2 targets) and amplification set up. In a singleplex format, the test uses three primer and probe sets to detect three regions in the SARS-CoV-2 nucleocapsid (N) gene and one primer and probe set to detect human RNase P (RP) in a clinical sample. When multiplexed into a single reaction, the test uses two primer and probe sets to detect two regions in the SARS-CoV-2 N gene and one primer and probe set to detect RP. RNA isolated from upper and lower respiratory specimens (such as nasal, nasopharyngeal or oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate) is reverse transcribed to cDNA and subsequently amplified using Applied Biosystems QuantStudio7 Flex (QS7) instrument with software version 1.3. During the amplification process, the probe anneals to a specific target sequence located between the forward and reverse primers. During the extension phase of the PCR cycle, the 5' nuclease activity of Taq polymerase degrades the bound probe, causing the reporter dye to separate from the quencher dye, generating a fluorescent signal. Fluorescence intensity is monitored at each PCR cycle by QS7.

DESCRIPTION OF POOLING

Traditionally, pooling employs a 2-stage approach where samples are tested as pools and then any positive pools are retested at a later time to determine which individual was positive. While this approach saves reagents, it is not practical to implement in a high throughput testing environment where many thousands of samples would need to be pulled and retested every day. Matrix based pooling strategies allow the lab to test samples as pools while preventing the need to retest individual samples as long as the expected (and observed) number of positive samples per matrix is less than or equal to 1 as indicated in the table below. To combat the retest problem, Labcorp will employ a matrix pooling strategy where samples will be tested twice in pools of 4 samples which increases lab efficiency by a factor of 2 if the tested population prevalence remains < 6% (Table below).

Prevalence (%)	Expected Positives			
	3x3	4x4	5x5	10x10
0.1	0.009	0.016	0.025	0.1
0.5	0.045	0.08	0.125	0.5
1	0.09	0.16	0.25	1
3	0.27	0.48	0.75	3
5	0.45	0.8	1.25	5
10	0.9	1.6	2.5	10
15	1.35	2.4	3.75	15
Throughput	1.5	2	2.5	5

Matrix Based Pooling Strategies Increase Throughput Without Requiring Retesting.
 Green - <1 positive per matrix at indicated prevalence, red - >1 positive per matrix at indicated prevalence

INSTRUMENTS USED WITH TEST

The details of the instruments used with Labcorp’s COVID-19 RT-PCR Test are available in the FDA EUA for Labcorp’s COVID-19 RT-PCR Test (EUA200011).

COLLECTION KITS USED WITH LABCORP’S COVID-19 RT-PCR TEST

- This test can be used with the Pixel by Labcorp COVID-19 Test Home Collection Kit available without a prescription (Direct to consumer, DTC) to collect nasal swab specimens at home.¹

REAGENTS AND MATERIALS

The details of the reagents and materials used with Labcorp’s COVID-19 RT-PCR Test are available in the FDA EUA for Labcorp’s COVID-19 RT-PCR Test (EUA200011).

PATIENT INCLUSION/EXCLUSION CRITERIA:

Home collection with the Pixel by Labcorp Home Collection Kit is intended for the collection of anterior nasal swabs from individuals 18 years and older (self-collected), 14 years and older (self-collected under adult supervision), or 2 years and older (collected with adult assistance). There are no additional inclusion or exclusion criteria for the Pixel by Labcorp Home Collection Kit as this product is authorized for over the counter/direct to consumer use. However, when registering the collection kit online, individuals with severe symptoms will be directed to seek immediate care.

INSPECTION OF SPECIMENS

Applies to specimens received from patients using home collection kit

Specimen received through the Pixel by Labcorp Home Collection Kit should be

¹ This test is also authorized for use under EUA 200011 to test specimens collected using the Labcorp At Home COVID-19 Test Home Collection Kit when directly ordered by a HCP.

checked for the following criteria before entering the workflow:

- No saline collection tube included
- No swab included within saline collection tube
- No registration code attached to the saline collection tube
- Saline collection tube leaked resulting in no sample for testing
- Kit not registered on Pixel platform (would have to freeze the sample until Pixel customer service contacts customer)
- Accession date is greater than 1 calendar day from the specimen collection date

CONTROLS TO BE USED WITH THE COVID-19 RT-PCR

The details of the controls used with Labcorp's COVID-19 RT-PCR Test are available in the FDA EUA for Labcorp's COVID-19 RT-PCR Test (EUA200011).

INTERPRETATION OF RESULTS

The details of the interpretation of results used with Labcorp's COVID-19 RT-PCR Test are available in the FDA EUA for Labcorp's COVID-19 RT-PCR Test (EUA200011).

PERFORMANCE EVALUATION

The performance of the Pixel by Labcorp COVID-19 Test Home Collection Kit (EUA203057) for use with Labcorp's COVID-19 RT-PCR Test is the same data used to support the previous authorization of the Labcorp COVID-19 RT-PCR Test (EUA200011) - which represent the same real-time RT-PCR test used for different indications of use.

1) Analytical Sensitivity

The details of the LoD study for both the singleplex and multiplex formats, as well as the authorized extraction methods are available in the FDA EUA for Labcorp's COVID-19 RT-PCR Test (EUA200011).

2) Analytical Sensitivity

This test is using the primers and probes published by CDC and used in the CDC COVID-19 Diagnostic Panel without sequence modifications. This test has Right of Reference to the [2019-nCoV Real-Time RT-PCR Diagnostic Panel \(CDC\)](#) and the information on *in silico* inclusivity analysis are contained in that assay EUA summary. Based on publicly available information there are no significant concerns that reactivity of the CDC reagents have been impacted by the emergence of SARS-CoV-2 genetic variants.

3) Analytical Specificity

The details of the cross-reactivity studies (*in silico* analysis and wet testing) are available in the FDA EUA for Labcorp's COVID-19 RT-PCR Test (EUA200011).

4) **Clinical Evaluation**

The details of the clinical evaluation are available in the FDA EUA for Labcorp's COVID-19 RT-PCR Test (EUA200011).

5) **Comparison Between Singleplex and Multiplex COVID-19 RT-PCR Test**

The details of the comparison between the singleplex and multiplex platforms are available in the FDA EUA for Labcorp's COVID-19 RT-PCR Test (EUA200011).

6) **Validation of the ThermoFisher MagMAX Viral/Pathogen Nucleic Acid Isolation Kit using the Low Volume MagMax procedure (200uL Extraction Volume)**

The details of the validation of the ThermoFisher MagMAX Viral/Pathogen Nucleic Acid Isolation Kit using the low volume MagMax procedure are available in the FDA EUA for Labcorp's COVID-19 RT-PCR Test (EUA200011).

7) **Usability Study - Self-Collection Validation (Labcorp At Home COVID-19 Test Home Collection Kit OR Pixel by LabCorp COVID-19 Test Home Collection Kit)**

The details of the usability study to support collection with at home collection kits are available in the FDA EUA for Labcorp's COVID-19 RT-PCR Test (EUA200011).

8) **Sample shipping stability study (Summer and Winter Profiles) – Labcorp At Home COVID-19 Test Home Collection Kit**

The details of the sample shipping stability study are available in the FDA EUA for Labcorp's COVID-19 RT-PCR Test (EUA200011).

9) **Validation of New Foam Swabs for Shipping Stability**

The details of the validation of new foam swabs for shipping stability are available in the FDA EUA for Labcorp's COVID-19 RT-PCR Test (EUA200011).

10) **Clinical Concordance Validation for Asymptomatic Positive and Negative Samples**

The details of the clinical concordance validation for asymptomatic positive and negative samples are available in the FDA EUA for Labcorp's COVID-19 RT-PCR Test (EUA200011).

11) **Sample Pooling – Limit of Detection Validation**

The details of the LoD validation for sample pooling are available in the FDA EUA for Labcorp's COVID-19 RT-PCR Test (EUA200011).

12) Sample Pooling – Clinical Concordance Evaluation of Pooled Samples

The details of the clinical concordance evaluation of pooled samples are available in the FDA EUA for Labcorp’s COVID-19 RT-PCR Test (EUA200011).

13) Support for Pooling Unobserved Self-Collected Samples

The details to support pooling of unobserved self-collected samples are available in the FDA EUA for Labcorp’s COVID-19 RT-PCR Test (EUA200011).

14) Validation of New Extraction Method (CERES Nanosciences Nanotrap Virus Capture Kit):

The details of the validation with the CERES Nanosciences Nanotrap Virus Capture Kit are available in the FDA EUA for Labcorp’s COVID-19 RT-PCR Test (EUA200011).

15) Validation of New Extraction Method (ThermoFisher MagMAX Viral/Pathogen II (MVP II) Nucleic Acid Isolation Kit using the Hamilton MicroLab STAR and ThermoFisher KingFisher Flex instruments)

The details of the validation with the ThermoFisher MagMAX Viral/Pathogen II (MVP II) Nucleic Acid Isolation Kit using the Hamilton MicroLab STAR and ThermoFisher KingFisher Flex instruments are available in the FDA EUA for Labcorp’s COVID-19 RT-PCR Test (EUA200011).

WARNINGS

- 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; 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.

LIMITATIONS

- The clinical performance has not been established in 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.
- Performance with specimens collected from individuals 18 years and older by an adult in the home has not been evaluated.