

**EMERGENCY USE AUTHORIZATION (EUA) SUMMARY
THE KROGER HEALTH COVID-19 TEST HOME COLLECTION KIT**

For *In vitro* Diagnostic Use

Rx Only

For use under Emergency Use Authorization (EUA) only

Home self-collected nasal swabs collected with the Kroger Health COVID-19 Test Home Collection Kit will be sent to High Complexity Laboratories that have been designated by The Kroger Co. All laboratories will be certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a and meet requirements to perform high complexity tests and run the specimens collected from the Kroger Health COVID-19 Test Home Collection Kit on an in vitro diagnostic (IVD) molecular test that is indicated for use with the Kroger Health COVID-19 Test Home Collection Kit for self-collection of nasal swab specimens.

INTENDED USE

The Kroger Health COVID-19 Test Home Collection Kit is intended for use by individuals to self-collect nasal swab specimens at home, video-observed by a healthcare provider, when determined by a healthcare provider to be appropriate based on results of a COVID-19 questionnaire and for use only with in vitro diagnostic (IVD) molecular tests for the detection of SARS-CoV-2 RNA that are indicated for use with the Kroger Health COVID-19 Test Home Collection Kit. Specimens collected using the Kroger Health COVID-19 Test Home Collection Kit can be transported at ambient temperature for testing at a laboratory. SARS-CoV-2 RNA from the nasal swab specimen is maintained in the specimen packaging.

Testing is limited to laboratories designated by The Kroger Co. that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meet requirements to perform high complexity tests and that run the specimens collected from the Kroger Health COVID-19 Test Home Collection Kit on an in vitro diagnostic (IVD) molecular test that is indicated for use with the Kroger Health COVID-19 Test Home Collection Kit for self-collection of nasal swab specimens as described above.

The Kroger Health COVID-19 Test Home Collection Kit is only for use under the Food and Drug Administration's Emergency Use Authorization.

SPECIAL CONDITIONS FOR USE STATEMENTS

For Emergency Use Authorization (EUA) only

For prescription use only

For in vitro diagnostic use

For use by people 18 years of age or older.

The Kroger Health COVID-19 Test Home Collection Kit is only authorized for use in conjunction with in vitro diagnostic (IVD) test for the detection of SARS-CoV-2 that is indicated for use with nasal swab specimens collected with a Home Collection Kit, that includes the Kroger Health COVID-19 Test Home Collection Kit.

DEVICE DESCRIPTION AND TEST PRINCIPLE

Individuals may request the Kroger Health COVID-19 Test Home Collection Kit from the Kroger Health website (<http://www.krogerhealth.com/covidtestkit>). As part of the registration process, individuals must complete a health survey. The survey is first reviewed by a pre-screen algorithm then sent for review and approval by healthcare providers whom the Kroger Co. employs or contracts (KHCP), based on specific criteria, prior to shipment of the Kroger Health COVID-19 Test Home Collection Kit. Following testing, the physicians at KHCP will review and approve the test results with appropriate follow up actions. Negative results will be delivered either via email, text, or through the patient portal. Positive results will be delivered by phone call, informing patients of their results and providing education and a recommended course of care; in the event a patient cannot be reached after 3 call attempts, a letter is sent. Laboratories designated by The Kroger Co. will report positive findings to the appropriate public health authorities.

The Kroger Health COVID-19 Test Home Collection Kit collects and stabilizes viral RNA from nasal swab specimens in saline; it can also be used for the transportation and short room temperature storage of a sample. The Kroger Health COVID-19 Test Home Collection Kit is a readily accessible alternative for collecting viral RNA by/from individuals who are suspected of COVID-19 by their healthcare provider.

The Kroger Health COVID-19 Test Home Collection Kit consists of sample registration instructions, sample collection instructions, sample preparation and shipping instructions, nasal swab, saline in a tube, shipping materials and return labels. Detailed instructions for collection and shipping will be provided, over video, by a health care provider. The individual using the Kroger Health COVID-19 Test Home Collection Kit performs the steps to collect the initial specimen, as video-guided by a healthcare provider. After the Kroger Health COVID-19 Test Kit nasal swab specimen is collected, the swab is inserted into a tube with saline, the top of the swab shaft is broken off, and the cap is sealed tightly. The tube is then placed in the biohazard bag, the bag is sealed, and then wiped with the provided alcohol wipe.

Each Kroger Health COVID-19 Test Home Collection Kit is intended to be returned via UPS next day Air at ambient conditions on the same day or the following day after sample collection in accordance with the standards as put forth by the CDC and WHO for the transport of suspected COVID-19 samples.

Specimens received at laboratories, designated by The Kroger Co., will undergo review and accessioning prior to acceptance for testing.

The COVID-19 molecular testing will be performed at laboratories designated by The Kroger Co., that are certified under CLIA, 42 U.S.C. §263a, and meet requirements to

perform high complexity tests using a NAAT test indicated to process nasal swabs per the Instructions for Use.

REAGENTS AND MATERIALS

Kroger Health COVID-19 Test Home Collection Kit consists of the items listed in the table below.

Kit box (6"x7"x2")
Patient ID label (barcoded)
Medium alcohol prep pads (2)
Biohazard bag (6"x9")
Absorbent sheet
Nasal Swab
3 mL transport medium (0.85% saline) in tube
Patient Instruction Insert
Return shipping lab pack with prepaid, addressed return label applied

MEDICAL OVERSIGHT AND PROCESS TO BE USED:

Medical Oversight of the process is provided by KHCP. KHCP designed the initial COVID-19 questionnaire based on CDC guidance to determine the appropriateness for patient testing. The digital platform allows the patient to submit the questionnaire only once. In addition, patients must input a unique code given to them by their organization, or their identity must be validated against an eligibility file provided by their organization in order to submit their request for testing. KHCP reviews all information and, if in their clinical judgment the patient is a candidate for testing, they will issue a prescription for the test. The prescription for the test is written before the kit is shipped to the patient's home. Before the self-collected specimen can be processed at the CLIA lab, KHCP generates the lab test requisition, if appropriate, based on the identified eligibility criteria. This occurs during the Telehealth Visit. This deters patients from submitting specimens directly to the lab without completing the Telehealth Visit. Specimens received at the lab without an order will be monitored and those patients will be contacted to determine remediation. After the self-collected specimen is processed, KHCP reviews and approves the test results, and recommends follow-up action and education to the end-user of the Kroger Health COVID-19 Test Home Collection Kit.

Kroger Health, the healthcare arm of The Kroger Co., employs over 22,000 healthcare professionals. The Kroger Co. employs or contracts with healthcare providers (KHCP) licensed in the states in which they provide patient care in person or via telehealth, healthcare professionals, and non-clinical patient care technicians as support staff.

The KHCP COVID-19 care program is highlighted below:

- A. Eligibility for testing is based on CDC published guidelines in conjunction with HHS priority levels. This eligibility formula is changed accordingly as new updates are presented.
- B. Eligibility assessment hinges on four main characteristics:
 1. Symptoms: Includes initial triage of severely ill to in-person or emergency care while further segmenting into those with mild/non-limiting symptoms and no symptoms at all
 2. Exposure
 - a. Delineation based on any form of exposure including workplace, etc.
 - b. Exposure also covers specific elements of CDC criteria
 3. Medical and Personal History
 - a. Factors that assist in risk stratification, including age, pregnancy status, comorbidities, and recent hospitalization
 - b. All individuals taking the test will receive education and information both before and after the test on symptom monitoring including when to seek in-person or emergency care, isolation precautions, health hygiene, and other critical points to limit the spread of the disease and to optimize outcome
 - c. Brief review of history of present illness (HPI) and medical history of chronic illness
 4. Exclusion Criteria
 - a. Live outside the states in which KHCP are licensed to provide telehealth services
 - b. Patients without access to the internet, preventing them from receiving telehealth services
 - c. Patients without symptoms or no known exposure risks
 - d. Patients with severe enough symptoms to be directed to receive immediate medical attention

INSPECTION OF SPECIMENS:

Applies to specimens received from patients using home collection kit

Specimens received through the Kroger Health COVID-19 Test Home Collection Kit should be checked for the following criteria before entering the work flow:

- **Physical Damage** - Any damage to the tube, or alternate container, allowing exposure of the specimen will be cause for rejection.
- **Sufficient Transport media** – specimens without sufficient transport media (200 µL) will be rejected.

- **Labeling** - Improperly labeled or shipped specimens that cannot be resolved are rejected. Name on the tube does not match a corresponding electronic order or test request form will be rejected
- **Electronic order** - If the specimen does not have complete information on the electronic order or test request form, the specimen may be rejected. Required information will usually be obtained by Lab customer service personnel, which will allow acceptance of specimens that initially lacked all the required information.
- **Expired shipping time** - If a specimen is received ≥ 48 hours from the collection date, the specimen is rejected.
- Specimens holding for incomplete information are considered expired when the collection date is ≥ 7 days. These specimens are held at 2-8°C.

CONTROLS TO BE USED WITH THE COVID-19 MOLECULAR TEST

All test controls should be examined prior to interpretation of patient results. If the controls are not valid, the patient results cannot be interpreted.

- 1) A negative (no template) control is needed to eliminate the possibility of sample contamination on the assay run and is used on every assay plate. This control is molecular grade, nuclease-free water.
- 2) A positive template control is needed to verify that the assay run is performing as intended and is used on every assay plate starting at master mix. The positive template control does not include RNase P target and will result as “undetermined” for that marker.
- 3) An internal control targeting RNase P is needed to verify that nucleic acid is present in every sample and is used for every sample processed. This also serves as the extraction control to ensure that samples resulting as negative contain nucleic acid for testing.
- 4) A negative extraction control (optional) is a previously characterized negative patient sample. It serves both as a negative extraction control to monitor for any cross-contamination that occurs during the extraction process, as well as an extraction control to validate extraction reagents and successful RNA extraction.

INTERPRETATION OF RESULTS

The Kroger Co.’s protocol provides for real-time communication throughout the testing process. Patients are provided education for before and after the test on symptom monitoring, including when to seek immediate medical attention, physical distancing precautions, and other points to limit the spread of the disease and to optimize the patient’s outcome. The collection of the nasal swab sample is guided by video-observation by a healthcare provider. Clinical and non-clinical support is available via

KHCP and The Kroger Co. staff, seven days per week via a toll-free phone number. Patients will be connected to a healthcare provider to address clinical support needs and to answer questions or to receive other information/education.

In the case of positive results:

- Patients will receive a call informing them of their results and providing education and a recommended course of care; in the event a patient cannot be reached after three call attempts, a letter is sent.
- Patient calls are made promptly after receiving results from the lab.
- Patient calls cover: result of the test, provide education and a recommended course of care, depending on symptomology and patient risk factors. Course of care may include medical attention/referral to emergency department, medical attention via outpatient care, or isolation and symptom management.
- Laboratories designated by The Kroger Co. to process samples collected using the Kroger Health COVID-19 Test Kit are responsible for reporting positive test results to health authorities except where state law dictates that both lab and provider report.

PERFORMANCE EVALUATION

1) Kroger Health COVID-19 Test Home Collection Kit Sample Stability Studies:

The stability study described below was conducted by Quantigen Biosciences, with support from The Gates Foundation and UnitedHealth Group. Quantigen Biosciences has granted a right of reference to any sponsor wishing to pursue an EUA to leverage their COVID-19 swab sample stability data as part of that sponsor's EUA request.

Two SARS-CoV-2-positive pools (2x LoD and 10x LoD) were contrived by combining SARS-CoV-2- negative human/porcine matrix with previously confirmed, high-positive patient samples.

The 2x LoD and 10x LoD pools were added directly to swabs through a procedure that mimics a nasal swabbing action: swabs were submerged into a reservoir of either 2x LoD or 10x LoD mixture and “abraded” against the side of the (Eppendorf style) tube while the viral solution absorbs into the swab (whether foam or polyester). The 20 low-positive samples and the 10 intermediate-positive samples used with each test condition did not come from individual patients. Rather, for each of the two concentrations, a single preparation of virus + media or virus + matrix was prepared, from which technical replicates were prepared.

The human/porcine negative matrix swabs were prepared by spiking them into negative porcine nasal mucous using the same procedure described above. Swabs were then placed into 1 mL saline.

Samples were tested using an EUA authorized assay at time 0, 30 hours, and 54 hours post incubation. Samples were held at 40°C for 12 hours, then 32°C for 18 or 42 hours, respectively. Samples were allowed to equilibrate to room temperature for 2 hours before testing.

The acceptance criteria laid out for the study was a 95% agreement or greater for positives samples. Both time points met this criteria and supported sample shipping stability, using a drop box, with over-night or 48-hour shipping.

Average Ct Values for Each time point for both sample dilutions.

Swab	Time Point	N	Internal Control	Target 1	Target 2	Target 3
2xLoD swab in Saline	0h	5	23.74	32.23	30.03	31.80
10xLoD swab in Saline	0h	5	23.27	29.46	27.58	28.67
2xLoD swab in Saline	30h	20	26.00	32.69	31.33	34.59
10xLoD swab in Saline	30h	10	26.19	29.54	28.37	28.69
2xLoD swab in Saline	54h	20	25.70	32.03	31.09	32.10
10xLoD swab in Saline	54h	10	26.11	28.73	27.25	25.09

2) Self-Collection Validation:

A human usability study was conducted by Kroger Health for the home-collection and mailing of the sample to Gravity Diagnostics, LLC for testing. The study included 37 participants who registered for the test, received the test kit, initiated and participated in the telehealth visit, completed the HCP-observed collection of a nasal swab sample, and shipped the sample to Gravity Diagnostics, LLC. A breakdown of the age and education level of the participants is given in Table 2. Thirty five out of 37 participants completed each step in the process.

Table 2. Human Usability Study Participant Demographics.

Age Group	Count	Education	Count
18-34	6	High School	15
35-49	7	College	14
50-64	8	Greater than college	8
65+	16		

At the conclusion of the patient portion of the study, a questionnaire was administered to each participant. One of the questionnaires was not included in the analysis due to data entry error. For the purpose of acceptance criteria, answers “neutral”, “agree”, and “strongly agree” are considered acceptable responses. Of the 34 available surveys, there

was > 90% acceptance rate for each process step. Three individual questions scored under 90%. All three were related to provider instructions given during the telehealth visit and did not impact specimen collection. Provider training will be enhanced as a future mitigating strategy. A virtual training session will be conducted for providers and a provider checklist was created to ensure every item is discussed.

Samples were received by Gravity Diagnostics, LLC. Samples were evaluated according to rejection criteria and were tested for RNase P in order to determine if sufficient sample was collected. One sample was not received and one electronic order was not completed. All other samples tested positive for RNase P, demonstrating that human sample was collected by each participant.

At launch of the Kroger Health COVID-19 Test Home Collection Kit, The Kroger Co. will implement a usability assessment to identify and characterize user success and error rates with at-home collection of samples which will be shared with the Agency. This will be a prospective assessment of error rate by type and overall success for samples received at the laboratory to identify potential areas for improvement in user instructions and experience. Specifically, Kroger Health will evaluate user error rate on an aggregating basis for the first 2-weeks post-launch up to 1,000 samples. At each 100-sample receipt increment, they will calculate error rates (by type and overall) as well as overall success metrics. User error rates will be calculated as an overall error rate (# of total errors over total number of samples received) and for each error rate type (number of specific errors over total number of samples received). User success rate will be calculated as the number of samples received with no errors divided by the total number of samples. Kroger Health will use the acceptance criteria of 10% for error rate type and 90% success as thresholds for implementing corrective actions (e.g. modifications to user instructions). Corrective action will be undertaken in the event a specific error rate type exceeds the criterion or if the success rate falls below the user success acceptance criteria.

Conclusion: The Kroger Health COVID-19 Test Home Collection Kit has demonstrated sample stability and usability that is acceptable to the FDA.

WARNINGS:

- This home sample collection kit has not been FDA cleared or approved.
- This home sample collection kit has been authorized by FDA under an EUA. This home sample collection kit has been authorized only for the home collection and maintenance of nasal swab specimens as an aid in detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.
- This home sample collection kit in combination with the authorized test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner