

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

For *In vitro* Diagnostic Use

For use under Emergency Use Authorization (EUA) only

(A direct to consumer (DTC) product for home self-collecting anterior nasal swabs by individuals 16 or older (either observed or video-observed) with the Kroger Health COVID-19 Test Home Collection Kit. Specimens 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 anterior nasal swab specimens.)

INTENDED USE

The Kroger Health COVID-19 Test Home Collection Kit is a direct to consumer product for self-collecting anterior nasal swab specimens by individuals 16 or older at home (either unobserved or video-observed) and sending that specimen for testing with 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 anterior nasal swab specimens, that is indicated for testing any individuals, including individuals without symptoms or other reasons to suspect COVID-19 and has been issued an EUA for use with Home Collection Kits, that includes the Kroger Health COVID-19 Test Home Collection Kit.

Testing is limited to laboratories designated by Kroger Health 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.

All test results are delivered to the user via their Kroger Health patient portal created through the registration process. Patients with positive and invalid/indeterminate results additionally will receive a phone call from 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.

The Kroger Health COVID-19 Test Home Collection Kit is for use by individuals 16 years and older, to self-collect anterior nasal swab specimens either unobserved or video-observed, including for use by such individuals without symptoms or other reasons to suspect COVID-19.

The Kroger Health COVID-19 Test Home Collection Kit 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.

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 in vitro diagnostic use

For use by people 16 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, and that is indicated for the detection of SARS-CoV-2 RNA from any individual, including individuals without symptoms or other reasons to suspect COVID-19.

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 will complete a health survey. All individuals will receive a home collection kit regardless of the answers given and the health survey serves as a means for data collection. Negative results will be delivered either via email, text, or through the patient portal. Positive results will be delivered by a health care provider (HCP) 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 all results 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 any individual, including those without symptoms or other reasons to suspect COVID-19.

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 with the instructions for use. Individuals will have the option of video-observed self-collection or unobserved self-collection by selecting this option prior to kit receipt. The appropriate instructions for use will be included with the kit depending on the option selected. 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 no later than 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.

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")
Fact Sheet for Individuals
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

PROCESS AND MEDICAL OVERSIGHT

Any individual may purchase a Kroger Health COVID-19 Test Home Collection Kit at Kroger.com. During the purchase, an individual will enter their email address and select their preference for video-observed self-collection by a health care provider or unobserved self-collection. One of two sets of instructions for use will be provided with the kit depending on the option selected. Upon completion of the purchase the individual receives an email containing a voucher code and a link to the patient pre-screen questionnaire (www.krogerhealth.com/covidtestkit). The individual completes the questionnaire and inputs their voucher code, which creates an account for the Kroger Health patient portal. Upon completion of the questionnaire, the individual receives a registration email to activate their patient portal. After activation of the patient portal, the patient is shipped a Kroger Health COVID-19 Test Home Collection Kit. All individuals who purchase a Kroger Health COVID-19 Test Home Collection Kit at Kroger.com will

receive one. The individual collects an anterior nasal specimen and ships it back to the lab. Negative results will be delivered either via email, text, or through the patient portal. Positive results will be delivered by Kroger healthcare provider (KHCP) 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.

Kroger Health, the healthcare arm of The Kroger Co., employs over 22,000 healthcare professionals. The Kroger Co. employs or contracts with healthcare providers 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.

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 at the High Complexity Laboratory:

- **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 μ L) 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 > 96 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 EUA SARS-COV-2 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.

PERFORMANCE EVALUATION

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

A stability study was conducted by Gravity Diagnostics, LLC, to support shipping of nasal swabs, collected in 0.9% saline, for up to 96 hours. A right of reference was obtained by Kroger to leverage the Gravity Diagnostics COVID-19 swab stability data to extend the shipping time for nasal swabs, collected in 0.9% saline, from 48 hours to 96 hours.

The stability study was conducted by subjecting contrived SARS-CoV-2 samples to either a winter shipping temperature profile and summer shipping temperature profile. Following storage at each of these conditions, sample integrity was assessed using an EUA authorized SARS-CoV-2 assay. The results of the EUA authorized SARS-CoV-2 assay indicated that there was no evidence of degradation of target RNA when compared with the control condition. The results of this study have been reviewed by FDA and support the shipping of nasal swabs collected in 0.9% saline for up to 96 hours, year-round.

2) **Video-observed Self-Collection Validation:**

An option for HCP video-observed collection is available for the Kroger Health COVID-19 Test Home Collection Kit. The option for video-observed collection will be selected prior to kit receipt and the corresponding instructions for use will be provided. To support this option, a human usability study was conducted by Kroger Health for the video-observed 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 1. Thirty five out of 37 participants completed each step in the process.

Table 1. Human Usability Study Participant Demographics for Video-Observed Self-Collection.

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		

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 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. Kroger Health formulated mitigations and revised their instructions for use for video-observed collection of nasal samples based on the results of this study. The revised instructions for use for video-observed collection of nasal samples using the Kroger Health COVID-19 Test Home Collection Kit have been reviewed by FDA and appear to be acceptable.

To fulfill their post-authorization condition, Kroger Health evaluated the user error rate on an aggregating basis for the first 30 days post-launch. In this time period 283 samples were returned, and error rates were calculated as the number of samples received with errors divided by the total number of samples. The acceptance criterion was an error rate of a given type of less than 10% as the threshold before implementing corrective actions. A total of 266 out of 283 samples were returned without any defect, yielding an overall success rate of 94.0%.

3) Unobserved Self-Collection Validation:

An option for unobserved self-collection is available for the Kroger Health COVID-19 Test Home Collection Kit. The option for unobserved self-collection will be selected prior to kit receipt and the corresponding instructions for use will be provided. To support self-collection of specimens without observation by a healthcare provider, a study was performed to assess the usability of the Kroger Health COVID-19 Test Home Collection Kit for unobserved self-collection of nasal swab specimens. The study included 37 participants (age and education ranges are broken down in Table 2). The study was designed to assess each participant’s ability to receive a test kit, collect a nasal sample, ship the test kit to the clinical lab, and have the lab receive the test kit with no defects. User error rates (by type and overall) were calculated from the 37 samples that were returned to the lab. Error rates were calculated as the number of samples received with errors divided by the total number of samples. The acceptance criterion was an error rate

of less than 10% as the threshold before implementing corrective actions. A total of 32 out of 37 samples were returned without any defect, yielding an overall success rate of 86%. Two of the 37 samples were rejected due to insufficient labeling information. Three of the 37 samples were returned with no box, however, as the integrity of the samples was still maintained, they were still accessioned and processed for RNase P detection. Of the 35 samples accessioned by Gravity Diagnostics, all samples tested positive for RNase P, demonstrating that human samples were collected by each participant.

Table 2. Human Usability Study Participant Demographics for Unobserved Self-Collection.

Age Group	Count	Education	Count
16-17	2	< High School	3
18-34	9	High School	12
35-49	12	College	14
50-64	8	Greater than College	8
65+	4		
Missing information	2		

Each self-collection was observed by an HCP to evaluate sample collection technique and to note any issues; the HCP did not intervene to provide guidance. The HCP-observations showed that each step scored a greater than 90% positive assessment by the observer. In addition to the written instructions provided with the kit, 73% (19/26 participants who completed the post-study questionnaire) participants who returned a survey also viewed video instructions¹ prior to sample collection.

At the conclusion of the patient self-collection portion of the study, a questionnaire was administered to each participant. For the purposes of acceptance criteria, answers “neutral”, “agree”, and “strongly agree” are considered positive responses. Of the 26 available surveys, there was > 90% positive response rate for each process step. Of the individual questions that scored < 90%, all were related to instructions and none impacted sample collection technique nor ability of the samples to be processed successfully. Kroger Health formulated mitigations and revised their instructions for use for unobserved self-collection based on the results of this study. The revised instructions for use for unobserved collection of nasal samples using the Kroger Health COVID-19 Test Home Collection Kit have been reviewed by FDA and appear to be acceptable.

Kroger Health will implement a second usability assessment to identify and characterize user success and error rates with unobserved at-home collection of samples which will be shared with FDA. This will be a prospective assessment of error rate by type and overall success for samples received at the laboratory to identify potential

¹ The video instructions (krogerhealth.com/services/covidtesting/instructions) were reviewed by FDA and found to be acceptable.

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 after re-issuance of the letter of authorization 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. These metrics should include the accessioning data from Gravity Diagnostics, LLC, as well as a tally of customer complaints and inquiries to the customer service hotline. 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 criterion.

4) Kit stability:

Saline Tube (Reagent) Stability

The pre-filled saline tubes used in the Kroger Health COVID-19 Test Home Collection Kit are manufactured at Sarstedt. Each batch of product is quality controlled before release into saleable inventory and is sterile according to Sarstedt manufacturing specifications and ISO 11137: “Sterilization of Health Care Products Package”. The manufacturer is providing the product with dating not beyond one year. The expiration date of the Kroger Health COVID-19 Test Home Collection Kit will correspond with the kit component that has the earliest expiration date, which will likely be the saline.

WARNINGS:

- This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA.
- This product 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.
- 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 medical devices 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.