

EMERGENCY USE AUTHORIZATION (EUA) SUMMARY
Kwokman Diagnostics COVID-19 Home Collection Kit
Kwokman Diagnostics, LLC.

For *In vitro* Diagnostic Use
Rx Only

For use under Emergency Use Authorization (EUA) only

Anterior nasal swab specimens collected at home using the Kwokman Diagnostics COVID-19 Home Collection Kit will be sent to laboratories that have been designated by Kwokman Diagnostics, LLC. 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. Specimens collected with the Kwokman Diagnostics COVID-19 Home Collection Kit will be tested with an in vitro diagnostic (IVD) molecular test for the detection of SARS-CoV-2 RNA that is indicated for use with the Kwokman Diagnostics COVID-19 Home Collection Kit.

INTENDED USE

The Kwokman Diagnostics COVID-19 Home Collection Kit is intended for use to collect anterior nasal (nasal) swab specimens at home from individuals age 18 years or older (self-collected, unsupervised), when determined to be appropriate by a healthcare provider.

Nasal swab specimens collected using the Kwokman Diagnostics COVID-19 Home Collection Kit are transported at ambient temperature for testing at an authorized laboratory. SARS-CoV-2 RNA from the nasal swabs is maintained in the specimen packaging and is only for use in molecular diagnostic testing performed using an in vitro diagnostic (IVD) test for the detection of SARS-CoV-2 RNA that is indicated for use with the Kwokman Diagnostics COVID-19 Home Collection Kit.

Testing is limited to laboratories designated by Kwokman Diagnostics, LLC 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 with the Kwokman Diagnostics COVID-19 Home Collection Kit on an IVD molecular test that is indicated for use with the Kwokman Diagnostics COVID-19 Home Collection Kit when used consistent with its authorization.

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

DEVICE DESCRIPTION AND TEST PRINCIPLE

The Kwokman Diagnostics COVID-19 Home Collection Kit is for prescription use only for individuals 18 years and older. The Kwokman Diagnostics COVID-19 Home Collection Kit is for the self-collection of anterior nasal swab specimens and stabilization of SARS-CoV-2 RNA in saline for shipping to a clinical laboratory. When ordering a kit online, individuals must verify

they are 18 years or older and complete a screening questionnaire. The questionnaire is reviewed by a physician and if deemed appropriate a prescription is issued and a kit is shipped to the patient.

After the anterior nasal swab specimen is collected, the swab is inserted into the transportation liquid (0.9% saline), and the swab shaft is broken off at the score. Upon contacting the medium, the viral particles are stabilized for transportation. For specimen shipping, the individual must place the tube in the biohazard bag. The bag with the specimen is placed into a primary box, which is then placed into a secondary box and finally placed in the supplied UPS UN3373 Pak. The individual drops off the package at a UPS drop box for shipping.

Specimens received at the testing lab designated by Kwokman Diagnostics will undergo accessioning prior to acceptance for testing. All acceptable samples are processed by the laboratory. All rejected specimens are disposed of and the individual is contacted for potential recollection.

Testing will be performed at CLIA-certified laboratories that meet requirements to perform high complexity tests using an IVD molecular test that is indicated for use with the Kwokman Diagnostics COVID-19 Home Collection Kit.

All test results are delivered to the user via encrypted email. Additionally, individuals with positive and invalid/inconclusive results are contacted by a healthcare provider.

REAGENTS AND MATERIALS

The product will be distributed by Kwokman Diagnostics and they will ship orders as they are received. Table 1 lists the components included in the Kwokman Diagnostics COVID-19 Home Collection Kit.

Table 1. Components Included with the Kwokman Diagnostics COVID-19 Home Collection Kit.

Name	Supplier	Catalog Number
Pre-labeled shipping pack	UPS	NA
Outer box	ULINE	S-17917
Inner box	ULINE	S-18151
IFU	Kwokman Diagnostics	NA
Biohazard specimen transport bag and absorbent sheet	Path-Tec	NA

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Name	Supplier	Catalog Number
Flocked Polyester nasal swab	BD	25-3606-H
Sample tube (containing 0.9% saline)	Sarstedt	51.540.387

MEDICAL OVERSIGHT AND PROCESS TO BE USED

Kwokman Diagnostics contracts with individual physicians, Physician assistants, and Nurses responsible for medical oversight. The resident physician maintains oversight over the physician network.

1) Ordering a Kit

Individuals may request the Kwokman Diagnostics COVID-19 Home Collection Kit by filling out the form at www.kwokmandiagnostics.com titled “Contact us to find out how you can deploy our testing for your business.” The patient is then sent an intake form, which includes a questionnaire to determine eligibility and verification of age. The questionnaire is reviewed by a physician to determine eligibility. The Kwokman Diagnostics COVID-19 Home Collection Kit is used to self-collect anterior nasal swab specimens at home, when determined by a healthcare provider to be appropriate (prescription use).

2) Kit receipt, sample collection, and shipping

When a prescription for a test is issued, the order is sent to the fulfillment center and a kit is shipped to the patient. The patient information is also sent to the testing lab. After collection, samples are shipped to the testing lab. Specimens received at the clinical laboratory for testing undergo an accessioning procedure.

3) Process for Results Reporting and Interpretation

After the self-collected sample is processed at the CLIA laboratory, a physician contracted with Kwokman Diagnostics reviews and approves the test results. All results are delivered via encrypted email and patients with positive and inconclusive results will receive a phone call from a health care provider licensed in the state in which the patient resides.

INSPECTION OF SPECIMENS

Specimens collected using the Kwokman Diagnostics COVID-19 Home Collection Kit will be checked for the following criteria before entering the workflow 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 medium – specimens without sufficient transport medium (200 µL) will be rejected.
- Labeling - Improperly labeled or shipped specimens that cannot be resolved are rejected.

- Expired shipping time - If a specimen is received > 96 hours from the collection date, the specimen is rejected.

Note: Specimens holding for incomplete information are considered expired 48 h after receipt. These specimens are held at 2-8°C.

CONTROLS TO BE USED WITH THE TEST

1. **Positive Control (PC):** The positive control is run on every plate. The positive control is a diluted mix of Thermo Fisher TaqPath COVID-19 Control (25 copies/uL) with Hs-RPP30 Positive Control (Integrated DNA Technologies, CAT#: 10006626; 2,000 copies/uL). The TaqPath COVID-19 control contains the sequence for the three SARS-CoV-2-specific targets, while the Hs-RPP30 control contains the sequence for the human RNase P target. This control monitors amplification and signal production and ensures the integrity of the PCR reagents.
2. **Negative (No Template) Control (NTC):** The negative control is run on every plate. The negative control comprises extraction reagents without target nucleic acid that are extracted and processed in the real time RT-PCR along with the patient samples. This control monitors for contamination during the extraction process and in the real time RT-PCR reagents.
3. **Internal Control 1 (MS2):** The MS2 internal control RNA is added to each sample prior to nucleic acid isolation and is run for every sample. The MS2 is a bacteriophage RNA target included in the TaqPath COVID-19 Combo Kit (Applied Biosystems, CAT #: A47814). This control monitors for nucleic acid extraction, reverse transcription, amplification and signal production in each sample.
4. **Internal Control 2 (RNase P):** This internal control is human RNase P gene and is run with every sample. This control monitors for nucleic acid extraction and ensures sample integrity of the human specimen collected for testing.

PERFORMANCE EVALUATION

1) Shipping and Sample stability:

The stability study was conducted by Gravity Diagnostics to support shipping of nasal swabs collected in 0.9% saline for up to 96 hours. A right of reference was obtained by Kwokman Diagnostics to leverage the Gravity Diagnostics COVID-19 swab stability data as part of that sponsor's EUA request to support the shipping time for nasal swabs collected in saline of 96 hours. This study is identical to the study recorded in the Kroger Health COVID-19 Test Home Collection Kit authorization (EUA201373) to support year-round shipping of up to 96 hours.

2) Self-Collection Validation:

A human usability study was conducted by Kwokman Diagnostics for the home-collection and mailing of the sample to Gravity Diagnostics, LLC for testing. The study included 31 participants

who ordered a test kit¹, received the test kit, completed the observed collection² of a nasal swab sample, and shipped the sample, via UPS, to Gravity Diagnostics, LLC. Gravity Diagnostics received and processed samples using the Gravity Diagnostics SARS-CoV-2 RT-PCR assay (EUA202301).

User error rates were calculated from the 31 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 or equal to 10% as the threshold before implementing corrective actions. If any of the process steps experience < 90% success rate, a mitigation was put in place to address that failure point.

The moderators documented observations during each participant session. Moderators noted that three out of the 31 participants encountered difficulty packaging the specimen tubes appropriately for shipping.

The accessioning and sample processing results showed that Gravity Diagnostics accepted all 31 samples for processing and that all 31 samples tested positive for RNase P, demonstrating that human specimen was collected.

At the conclusion of the patient portion of the study, a questionnaire was administered to each participant. Twenty-nine of the 31 participants returned a survey. If any of the survey questions received < 90% positive response rate, a mitigation was formulated to address the failure to that response. Additional mitigations were also formulated based on participant written responses and observer notes. A summary of the failure points identified by the usability study, and associated mitigations is given in Table 2.

Table 2. Summary of Failure Points and Mitigations.

Failure point	Question Score, comment, or moderator note	Area for Mitigation	Summary of Mitigation
Specimen Packaging	Three participants did not perform this critical task successfully. The participants put the biohazard bag into the white box and then into the UPS bag. Thus the kit in this case still had one rigid outer layer to comply with DOT standards.	IFU change: The wording describing the placement of the biohazard bag into the brown box is confusing.	The sponsor changed the wording in the IFU to clarify this placement, stating “Place the sealed specimen biohazard bag within the brown box and close it.”

¹ Each participant followed the steps for ordering a kit as described in “Medical Oversight”.

² Each participant was video-observed. No training was provided to the patient.

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Did you properly read and follow the entire instructions for use for the home collection kit?	This question failed to meet the acceptance threshold of 90%.	IFU change: There are too many steps	
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Kwokman Diagnostics conducted a second usability study to test the modifications made to the Kwokman Diagnostics COVID-19 Home Collection Kit IFU. This study included 10 participants who registered for the test, received the test kit, completed the observed collection of a nasal swab sample, and shipped the sample, via UPS, to Gravity Diagnostics, LLC. Gravity Diagnostics received and processed samples using the Gravity Diagnostics SARS-CoV-2 RT-PCR assay (EUA202301).

User error rates were calculated from the 10 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 or equal to 10% as the threshold before implementing corrective actions. If any of the process steps experience < 90% success rate, a mitigation was put in place to address that failure point.

The moderators documented observations during each participant session. Moderators noted no difficulties among any of the 10 participants.

The accessioning and sample processing results showed that Gravity Diagnostics accepted all 10 samples and that all 10 samples tested positive for RNase P, demonstrating that human specimen was collected.

At the conclusion of the patient portion of the study, a questionnaire was administered to each participant. Nine of the ten participants returned a survey. If any of the survey questions received < 90% positive response rate, a mitigation was formulated to address the failure to that response.

All questions scored 100%, and no participant comments or observer notes were provided which might indicate difficulty in using the Kwokman Diagnostics COVID-19 Home Collection Kit. Therefore, no additional mitigations or changes to the IFU were made.

At launch of the Kwokman Diagnostics COVID-19 Home Collection Kit, Kwokman Diagnostics will submit to FDA a summary report within 30 calendar days of authorization summarizing the results of any testing performed using anterior nasal swab specimens collected with the Kwokman Diagnostics COVID-19 Home Collection Kit during that timeframe and stratified by age group, including how many kits were requested and sent for home collection to individuals, how many kits were distributed and returned according to the instructions, how many specimens had to be rejected during accession and the main reasons for rejection, and the positivity rate for the Kwokman Diagnostics COVID-19 Home Collection Kit. Thereafter, monthly reporting must continue until FDA informs you that the cumulative data submitted within the monthly reports has sufficiently assessed updates made to your collection kit.

WARNINGS:

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- 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 anterior nasal swab specimens as an aid in 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 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.