



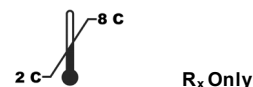
Revogene SARS-CoV-2 assay

For Emergency Use Authorization (EUA) Only

For use with the Revogene®

REF 410700

IVD For *in vitro* Diagnostic Use



INTENDED USE

The Revogene® SARS-CoV-2 assay is a real-time RT-PCR test intended for the qualitative detection of RNA from SARS-CoV-2 in nasopharyngeal, oropharyngeal, anterior nasal, and mid-turbinate nasal swab specimens from individuals suspected of COVID-19 by their healthcare provider. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, that meet requirements to perform high or moderate complexity tests.

Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in nasopharyngeal, oropharyngeal, anterior nasal, and mid-turbinate nasal swab specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 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 viruses. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all test results to the appropriate public health authorities.

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

The Revogene SARS-CoV-2 assay is a single-use test intended for use by qualified laboratory personnel specifically instructed and who are proficient in performing testing using the Revogene instrument. The Revogene SARS-CoV-2 assay is only for use under the Food and Drug Administration's Emergency Use Authorization.

SUMMARY AND EXPLANATION OF THE TEST

The World Health Organization (WHO) received a report of an outbreak of respiratory illness on December 31, 2019¹. The source of this outbreak was Wuhan City, Hubei Province, China¹. Authorities identified this outbreak as coronavirus disease 2019 (COVID-19). On March 11, 2020, the COVID-19 outbreak was characterized as a pandemic by the WHO². The virus was subsequently named SARS-CoV-2 by the International Committee for Taxonomy of Viruses (ICTV)³. The coronaviruses are a group of enveloped, non-segmented positive-sense RNA viruses which may cause illness in animals or humans⁴. In humans, coronaviruses are known to cause a variety of clinical outcomes, including asymptomatic infection, mild upper respiratory infection, severe lower respiratory disease including pneumonia and respiratory failure, and in some cases, death. The availability of specific and sensitive assays for the detection of the virus is essential for accurate diagnosis of cases, assessment of the extent of the outbreak, monitoring of intervention strategies, and surveillance studies.

The Revogene SARS-CoV-2 assay is a rRT-PCR *in vitro* diagnostic test designed to identify nucleic acid from SARS-CoV-2 associated with respiratory tract infection, from a single swab specimen. The Revogene SARS-CoV-2 reagents of Revogene SARS-CoV-2 assay contain primers and probes targeting RNA from the nucleocapsid protein (N) gene of the SARS-CoV-2 coronavirus. Two (2) controls are also incorporated in the system, one (1) Microfluidic Control and one (1) Internal Control. The assay minimizes operator intervention from the time the single-use microfluidic cartridge (named PIE hereafter) containing the sample is placed in the Revogene carousel until results are available. Each patient specimen (nasopharyngeal swab, oropharyngeal swab, anterior nasal swab (nasal), or mid-turbinate nasal swab specimens) collected in authorized transport media (see the Storage and Stability section) is directly transferred into the Revogene SARS-CoV-2 PIE using a Disposable Transfer Tool (DTT). The PIE is designed to perform viral lysis and the homogenized sample is automatically delivered by centrifugation to sample wells containing dried master mix.

PRINCIPLE OF THE PROCEDURE

The Revogene automates sample homogenization, dilution, cell lysis, conversion of RNA templates into DNA using reverse transcription, nucleic acid amplification and detection of the amplified PCR products. User intervention is only required to transfer the sample into the PIE and insert the PIEs into the Revogene carousel.

Each PIE is a fully integrated closed device into which a sample is dispensed and processed through different microfluidic chambers and channels which allow for the sample processing (i.e., sample homogenization, sample dilution and cell lysis) and subsequent rRT-PCR steps (**Figure 1**). The liquid from a single sample is transferred by centrifugation from one chamber to the next in sequence. All reagents specific for the PCR reaction are incorporated and dried within the PCR well. An Internal Control is incorporated into each PIE to verify RNA transcription/amplification/detection steps including the verification of potential inhibitory substances as well as reagent failure. A Microfluidic Control is also incorporated into each PIE to verify the fluidic properties of the PIE. The amplified products are detected in real-time using target-specific TaqMan® chemistry-based probes. No operator intervention is necessary once a PIE is loaded into the Revogene.



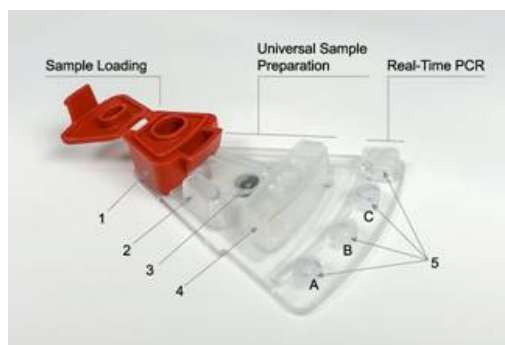


Figure 1. Top View of a PIE.
1: Sample Loading Chamber, 2: Overflow Chamber,
3: Homogenization Chamber containing the Microfluidic Control, 4: Dilution/Lysis Chamber,
5: Three (3) PCR Wells (A to C from left to right) and one (1) Waste Chamber (at the right end).

The Revogene can process from one (1) up to eight (8) samples simultaneously in the same run. The carousel must contain eight (8) PIEs to maintain thermodynamic balance within the run. During the run and at run completion, the results are computed by the system from measured fluorescent signals and embedded calculation algorithms. Results are displayed on the touchscreen and may be printed or transferred to a USB flash drive or transmitted to the laboratory information system.

An Early Positive Result Outcome (E-PRO) feature provides a positive result if the signal from the SARS-CoV-2 target reaches a predetermined threshold before the full PCR cycles have been completed. With E-PRO, a positive result could be obtained as early as 47 minutes after run start for samples with a high viral load. For negative samples, the time to result is approximately 85 minutes.

REAGENTS AND MATERIALS PROVIDED

Revogene SARS-CoV-2 kit contains sufficient reagents and materials to process 24 samples. Each kit contains the following materials:

1. Twenty-four (24) **Disposable Transfer Tools (DTT)**: Plastic pipette with minimal and maximal volume marks for transferring the sample into the PIE.
2. Twenty-four (24) individual pouches, each pouch containing one (1) **Revogene SARS-CoV-2 microfluidic cartridge (PIE)**: Integrated device which comprises dried reagents allowing sample process and rRT-PCR steps for transcription, amplification and detection of SARS-CoV-2 RNA. Each PIE contains an Internal Control (IC), IC-specific primers and probe, SARS-CoV-2 target-specific primers and probes, a Microfluidic Control, dNTPs, buffer and DNA polymerase displaying reverse transcriptase activity.

MATERIALS REQUIRED BUT NOT PROVIDED

- Revogene® Instrument (cat# 610210)
- Revogene® System RNA Software Upgrade Kit⁵ (cat# 610240; must be installed prior to running the Revogene SARS-CoV-2 assay. Please contact Technical Support at 1-800-343-3858 to ensure the appropriate software has been installed on your instrument.
- Disposable powderless gloves
- MOCK PIE(s) (cat# 610208; optional)
- Positive external control (for example: viral transport media or saline spiked with well characterized SARS-CoV-2 virus)
- Negative external control (viral transport media or saline)

WARNING AND PRECAUTIONS

1. For *in vitro* diagnostic (IVD) use under Emergency Use Authorization only.
2. For prescription use only.
3. Positive results are indicative of presence of SARS-CoV-2 RNA.
4. This product has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.
5. Laboratories within the United States and its territories are required to report all test results to the appropriate public health authorities.
6. 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.
7. 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.
8. The Revogene SARS-CoV-2 assay can only be used on the Revogene instrument.
9. Always handle specimens as if they are infectious and in accordance with Good Laboratory Practices such as those described in Biosafety in Microbiological and Biomedical Laboratories⁶ and in Clinical and Laboratory Standards Institute (CLSI) Document M29-A4⁷. Only personnel proficient in handling infectious materials and the use of Revogene SARS-CoV-2 should perform this procedure.
10. If infection with SARS-CoV-2 is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions. Refer to the CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19)⁸ for more information. <https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html>
11. Wear disposable powderless gloves while handling specimens and thoroughly wash hands afterwards.
12. Do not use the kit if the label that seals the outer box is broken upon arrival.
13. Do not use PIEs if the protective pouches are open or broken upon arrival.

14. Each single-use DTT and PIE are used to process one (1) specimen. Do not reuse DTT or PIE.
15. The PIE contains dried reagents. The protective pouch should not be opened until ready to perform the test.
16. Dispose of unused reagents and waste in accordance with country, federal, provincial, state and local regulations.
17. Do not open or break apart the PIE after use. The cap and the seals in the PIE prevent contamination with amplification products and/or infectious particles.
18. Do not use a PIE that has been dropped, shaken or inverted after the specimen has been loaded as this may cause invalid results.
19. Do not use a kit that has passed its stated expiration date.
20. Do not refrigerate the loaded PIE.
21. Each run must be performed with eight (8) PIEs in the Revogene carousel to maintain thermodynamic and mechanical balance within the run. Place MOCK PIEs or assay PIEs loaded with viral transport media or saline in empty positions if less than eight (8) specimens are tested.
22. Do not modify assay reagents, assay protocols, or instrumentation.

HAZARD AND PRECAUTIONARY STATEMENTS

There are no known hazards associated with this product.

STORAGE AND STABILITY

1. Swab specimens collected in VTM/UTM can be stored at 2-8 C for up to seven (7) days before being tested with the Revogene SARS-CoV-2 assay. Specimens collected in CDC media, MicroTest™ M4RT® (Remel) or saline may be stored up to 72 hours at 2-8 C before use.
2. Store the Revogene SARS-CoV-2 kit at 2-8 C. The expiration date is indicated on the kit box label.
3. Do not open a pouch until ready to perform testing. Use the PIE within one (1) hour after opening the pouch.

SPECIMEN COLLECTION

Nasopharyngeal, anterior nasal, mid-turbinate nasal, or oropharyngeal swab specimens should be collected according to standard technique and placed in 3 mL of transport media according to manufacturer's instructions. Patient samples that have visible blood in the collection media after addition of the patient specimen should not be used, as whole blood may interfere with the detection of positive samples.

Refer to the Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19)⁸ <https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html>.

INSTRUCTION FOR USE

PIE PREPARATION FOR PATIENT SPECIMEN TESTING

NOTE 1: One (1) pouch is required for each specimen to be tested.

NOTE 2: Process one (1) specimen at a time.

NOTE 3: The loaded PIE should be tested within one (1) hour of opening the protective pouch.

1. Mix the vial containing the specimen by inversion five (5) times before loading into the PIE.
2. Unseal the pouch containing the PIE, removing it from the pouch.
3. Place the PIE on a flat surface.
4. Using a DTT, aspirate the specimen by squeezing the entire bulb. The liquid level in the DTT must be anywhere between the two (2) marks (**Figure 2**). If the liquid level is not between the two (2) marks, discharge the specimen volume completely into the specimen tube by squeezing the entire bulb and repeat step 4.
5. Insert the tip of the DTT vertically into the sample loading chamber of the PIE and discharge completely the specimen (Figures 3A and 3B). Make sure not to touch the outer edges or the bottom of the sample loading chamber with the DTT. In case of contact with the outer edge or the bottom of the sample loading chamber, load a new PIE.
6. Close the cap of the PIE tightly. Do not refrigerate the loaded PIE. Make sure that only one (1) PIE is open at once. The PIE should not be inverted or shaken after the patient specimen has been added.
7. Prepare all additional specimens for testing by repeating steps 1 to 6 then proceed to step 1 of the **Revogene System Operation** section.

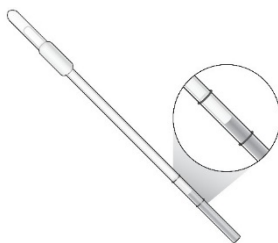


Figure 2.
Representation of an Appropriate Sample Level Using the Disposable Transfer Tool (DTT).





Figure 3A. Adequate Insertion Angle of the DTT into the Sample Loading Chamber of the PIE

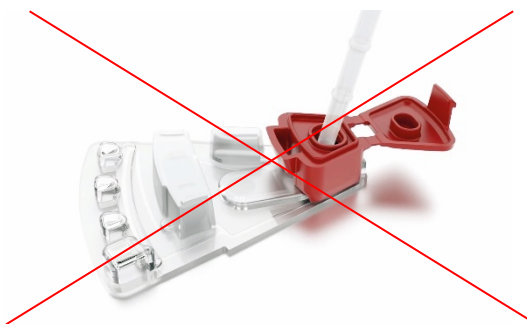


Figure 3B. Inadequate Insertion Angle of the DTT into the Sample Loading Chamber of the PIE

REVOGENE SYSTEM OPERATION

NOTE 1: A maximum of eight (8) specimens can be processed simultaneously in a single run using the Revogene.

NOTE 2: Each run must be performed with eight (8) PIEs in the Revogene. When less than eight (8) specimens are processed, the empty places must be filled with MOCK PIEs*.

NOTE 3: Refer to the Revogene Operator's Manual⁹ for further information regarding Revogene set-up and operation.

NOTE 4: Refer to Section - Materials Required But Not Provided for software requirements.

1. Ensure the Revogene is powered on.
2. Log in by entering the <Username> and <Password> and tap <Login>. The main menu will appear automatically.
3. Tap <Setup Run>.
4. Enter the specimen identification using either the barcode scanner or manual entry. Manual entry can be done by tapping the **pencil** icon of the <Scan or Enter Sample ID> line.
5. Enter the PIE barcode using the Revogene barcode scanner. Gently position the PIE almost vertically in front of the scanner. Alternatively, PIE barcode may be entered manually (tap the **pencil** icon of their respective lines). Handle the PIE carefully without dropping, shaking or inverting it.
6. (Optional) Tap the **pencil** icon of the <Add Comments> line and type to add a comment.
7. Insert the PIE into the Revogene, at any position of the carousel. The software will automatically associate specimen to the correct PIE.
8. Confirm that the PIE is inserted into the instrument by tapping <OK> on the <insert PIE into instrument> line and repeat steps 4 to 8 for all specimens. If less than eight (8) PIEs are being tested, load MOCK PIEs* in the carousel remaining positions. No scan is required when inserting MOCK PIEs into the Revogene.
9. When all PIEs and MOCK PIEs (when necessary) are inserted into the instrument, tap <Next>.
10. If you have entered MOCK PIEs into the carousel, check the box to confirm that they were inserted.
11. Scan the retention ring and place it on the carousel.
12. Gently rotate carousel around to check all PIEs are loaded correctly with no friction or resistance to rotation. Close the instrument lid with both hands and hold on until you hear the lock activate. Then gently pull up on the lid to guarantee that the lock is engaged.
13. Initiate the test run by tapping <Start>.

*If MOCK PIEs are not available, use unused assay PIEs filled with un-inoculated viral transport media or saline (blank). An unused PIE, which was used as a balance within the instrument, can no longer be used for patient samples.

VIEWING AND EXPORTING RESULTS

NOTE 1: Refer to the Revogene Operator's Manual⁹ for further information regarding the acquisition of test results.

1. During the run

- a. If the lights indicating run progression on the Revogene lid start to blink, this is a notification for an Early-Positive Result Outcome (E-PRO). An icon will also appear on the title bar of the screen. The **E-PRO** icon includes the "+" symbol and a number representing the number of positive results available at this time. The number will increase if additional positive results become available.
- b. Enter <Username> and <Password> and tap <Login> if the user's session has logged-out.
- c. Tap the **E-PRO** icon.
- d. Results from the current run are automatically listed on the screen. For each specimen line, there will be either a positive symbol or an in-progress symbol. The in-progress symbol, consisting of a rotating animation, is displayed until a positive result is obtained or the run is completed.
- e. Select the desired specimen by tapping on its position number, then tap either on the positive result symbol or on the Report button to open the interim report.
- f. (Optional) Tap <Export> and save the interim report where appropriate (e.g., USB flash drive). Once the results screen has been consulted, the E-PRO notifications will disappear. New E-PRO notifications will appear upon the detection of an additional early positive result. Any specimen result displayed in the interim report is final and will remain unchanged in the final assay result report.



2. At the End of the Run

- a. Once the run is completed, the lid opens automatically.
- b. Enter **<Username>** and **<Password>** and tap **<Login>** if the user's session has logged-out.
- c. Tap **Results** icon.
- d. Results from the last run are automatically listed on the screen.
- e. Select specimens for which results report(s) has (have) to be exported:
 - All specimens can be selected simultaneously by checking the box on the upper left corner of the screen.
- f. Tap **<Report>** to see the specific result for each specimen. Refer to the **Results Interpretation** section to confirm if any additional action needs to be taken according to the result obtained.
- g. Tap **<Export>** and save where appropriate (e.g., USB flash drive or via connectivity option).
- h. Alternatively:
 - Tap **<Search>** to find a specific specimen and its result.
 - Tap **<Run Report>** to group the results of multiple samples together in a single report if they were processed in the same run.
- i. Remove the retention ring and retain for future use.
- j. Remove all the assay PIEs and MOCK PIEs from the Revogene after each run:
 - Dispose of the assay PIEs according to your institution's standard practices.
 - Do not discard MOCK PIEs as they can be reused.

QUALITY CONTROL

Quality control procedures monitor the accuracy and precision of the analytical process. Each laboratory must establish the number, type and frequency of testing control materials per applicable regulations or accrediting agencies. The procedure described below may be employed, if appropriate, based on local policies and procedures.

INTERNAL CONTROL

The PIE contains an Internal Control (IC) that verifies RNA transcription/amplification/detection, nucleic acid amplification inhibition and assay reagents failure.

MICROFLUIDIC CONTROL

The PIE contains a Microfluidic Control (MFC) to verify the fluidic properties of the PIE.

EXTERNAL CONTROLS

Clinical laboratories are responsible for running quality control material when using the Revogene SARS-CoV-2 assay. External Controls should be run in accordance with laboratory protocols, local regulatory requirements, or accrediting organizations as applicable. For example, Positive and Negative External Controls should be tested with each new lot and/or shipment of reagents. Viral transport media or saline can be used as the Negative Control. The Positive External Control must be a commercially available control. This control should be prepared at a concentration that is known to be detectable by this assay; for example, not more than 5X LoD (e.g., at approximately 22800 copies/mL). A positive external control that is not more than 5X LoD is recommended to ensure the instrument and assay are detecting the viral RNA at clinically relevant concentrations.

REPEAT TESTING PROCEDURE

UNEXPECTED POSITIVE OR UNEXPECTED NEGATIVE RESULT FOR AN EXTERNAL CONTROL

When an unexpected Negative result is obtained for the Positive External Control or when an unexpected Positive result is obtained for the Negative External Control, the run is invalid. A repeat test of the External Controls must be performed with new External Control materials as described in the **External Controls** section. Handling and preparation techniques should be reviewed.

In addition, a repeat test must be performed for all specimens included in the run.

Load new PIEs using the remaining specimens within the timeframe defined in the **Storage and Stability** section. Follow the **PIE Preparation** section from step 1, then follow the **Revogene System Operation** section.

INDETERMINATE OR UNRESOLVED RESULT FOR A SPECIMEN

When an Indeterminate (IND) or an Unresolved (UNR) result is obtained for a specimen, a repeat test from the corresponding specimen must be performed within the specified timeframe described in the **Storage and Stability** section.

If an IND/UNR result is obtained on the repeat test, it is recommended that a second specimen be requested and the test be repeated on the new specimen. If an IND/UNR result is obtained on the new specimen, please contact Technical Support.

INDETERMINATE OR UNRESOLVED RESULT FOR AN EXTERNAL CONTROL

When an Indeterminate (IND) or an Unresolved (UNR) result is obtained for an External Control, the run is invalid. A repeat test of the External Controls must be performed.

In addition, a repeat test must be performed for the specimens included in the same run within the specified timeframe defined in the **Storage and Stability** section.

Load new PIEs using the corresponding External Controls and specimen(s). Follow the **PIE Preparation** section from step 1, then follow the **Revogene System Operation** section.



RESULTS INTERPRETATION

The results are computed by the Revogene from measured fluorescent signals and embedded calculation algorithms and are available on the "Results" window. Possible reported results are listed below.

Sample	Symbol displayed on user screen	Reported Result	Interpretation
Positive External Control		Positive	Valid Positive External Control result.
		Negative	A Positive External Control that yields a negative result is indicative of a specimen handling/preparation problem. The run is invalid. Review the specimen handling/preparation technique. Repeat testing must be performed (refer to the Repeat Testing Procedure section).
		Unresolved	Incorrect Positive External Control result. The run is invalid. Repeat testing must be performed (refer to the Repeat Testing Procedure section).
		Indeterminate	Incorrect Positive External Control result. The run is invalid. Repeat testing must be performed (refer to the Repeat Testing Procedure section).
		In progress	Results not available yet.
Negative External Control		Positive	A Negative External Control that yields a positive result is indicative of a specimen handling/preparation problem or contamination event. The run is invalid. Repeat testing must be performed (refer to the Repeat Testing Procedure section).
		Negative	Valid Negative External Control result.
		Unresolved	Incorrect Negative External Control result. The run is invalid. Repeat testing must be performed (refer to the Repeat Testing Procedure section).
		Indeterminate	Incorrect Negative External Control result. The run is invalid. Repeat testing must be performed (refer to the Repeat Testing Procedure section).
		In progress	Results not available yet.

Sample	Symbol displayed on user screen	Reported Result	Interpretation
Patient Specimen		Positive	SARS-CoV-2 target RNA detected.
		Negative	SARS-CoV-2 target RNA not detected.
		Unresolved	Amplification/detection failure of the Internal Control as well as for the SARS-CoV-2 target RNA. Could be caused by inhibitory specimens or reagent failure. Repeat testing must be performed (refer to the Repeat Testing Procedure section).
		Indeterminate	No reportable result due to possible Revogene detection error during the assay processing, the data analysis, or due to an error code, a microfluidic failure or if the run is interrupted by the user. Repeat testing must be performed (refer to the Repeat Testing Procedure section).
		In progress	Results not available yet.

LIMITATIONS OF THE PROCEDURE

- Performance of the Revogene SARS-CoV-2 assay has been established with nasopharyngeal swab specimens collected in 3 mL of viral transport media, only. Testing with oropharyngeal, anterior nasal, and mid-turbinate nasal swabs is also acceptable, although performance with these specimen types has not been established with the Revogene SARS-CoV-2 assay.
- The Revogene SARS-CoV-2 assay should not be run together with any other Revogene assay.
- Positive results are indicative of the presence of SARS CoV-2 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 viruses. The agent detected may not be the definite cause of disease.
- Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.
- Erroneous test results may occur from improper specimen collection, handling or storage, technical error, specimen mix-up or because the specimen does not contain a sufficient viral load for detection by the assay. Careful compliance with the instructions of these Instructions for Use, the Revogene Operator's Manual⁹ and established guidelines is necessary to avoid erroneous results.
- Contamination or unexpected positive results may occur if a PIE cap is incorrectly closed or if a droplet has been dropped on the edges of the sample loading chamber.
- Whole blood or Tobramycin may interfere with the Revogene SARS-CoV-2 assay when either of these substances is present in a nasopharyngeal swab specimen at a concentration of > 0.22% (v/v) or > 2.16 mg/mL, respectively.
- Salinex[®] nasal spray or Oseltamivir may interfere with the Revogene SARS-CoV-2 assay when either of these substances is present in a nasopharyngeal swab specimen at a concentration of > 0.22% (v/v) or > 0.013 mg/mL, respectively.
- Based on *in silico* analysis, there is a risk for the Revogene SARS-CoV-2 assay to detect a bat coronavirus sequence. The risk is considered low as this organism should normally not be found in a human sample.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens. The clinical performance has not been established with 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.



11. As with any molecular test, mutations within the target regions of SARS-CoV-2 could affect primer and/or probe binding resulting in failure to detect the presence of virus.
12. The performance of this device has not been assessed in a population vaccinated against COVID-19.
13. Revogene SARS-CoV-2 assay has not been evaluated for patients receiving intranasally administered influenza vaccine.

Conditions of Authorization for Labs

The Revogene SARS-CoV-2 assay Letter of Authorization, along with the authorized labeling are available on the FDA website: <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas>. However, to assist clinical laboratories using the Revogene SARS-CoV-2 assay, the relevant Conditions of Authorization are listed below.

- A. Authorized laboratories¹ using the Revogene SARS-CoV-2 assay must include with result reports of the Revogene SARS-CoV-2 assay, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
- B. Authorized laboratories using the Revogene SARS-CoV-2 assay must use Revogene SARS-CoV-2 assay as outlined in the authorized labeling. Deviations from the authorized procedures, including the authorized instruments, authorized extraction methods, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to perform the Revogene SARS-CoV-2 assay are not permitted.
- C. Authorized laboratories that receive the Revogene SARS-CoV-2 assay must notify the relevant public health authorities of their intent to run the test prior to initiating testing.
- D. Authorized laboratories using the Revogene SARS-CoV-2 assay must have a process in place for reporting test results to health care providers and relevant public health authorities, as appropriate.
- E. Authorized laboratories must collect information on the performance of the Revogene SARS-CoV-2 assay and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and Meridian (via email: MBI-TechService@meridianbioscience.com) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the test of which they become aware.
- F. All laboratory personnel using the Revogene SARS-CoV-2 assay must be appropriately trained in RT-PCR techniques and use appropriate laboratory and personal protective equipment when handling this kit and use the test in accordance with the authorized labeling.
- G. Meridian Biosciences, its authorized distributor(s) and authorized laboratories using the Revogene SARS-CoV-2 assay must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

¹ The letter of authorization refers to, "Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high or moderate complexity tests" as "authorized laboratories".

PERFORMANCE CHARACTERISTICS

CLINICAL EVALUATION

The performance of the Revogene SARS-CoV-2 assay was evaluated against an EUA authorized highly sensitive SARS-CoV-2 RT-PCR assay (Comparator) in a head-to-head comparison using frozen samples from retrospectively collected nasopharyngeal swab (NPS) specimens in 3 mL of viral transport media.

A total of 43 SARS-CoV-2 positive and 43 SARS-CoV-2 negative de-identified NPS samples, collected from patients suspected of COVID-19 by their healthcare provider, were included in the study and tested with Revogene SARS-CoV-2 assay and Comparator Method in a randomized and blinded fashion. The sample population included in the study represents a broad clinical range of SARS-CoV-2 viral loads including low positives based on Ct values of the Comparator.

RESULTS

Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA) were calculated from the results of these 86 retrospective NPS samples as shown in **Table 1**. The positive samples showed a 97.7% (95% CI: 87.9% - 99.6%) agreement with the Comparator results, and the negative samples showed 97.7% (95% CI: 87.9% - 99.6%) agreement. The clinical performance of the Revogene SARS-CoV-2 assay against the Comparator Method is presented in **Table 1**.

Table 1. Revogene SARS-CoV-2 Clinical Comparison with an EUA authorized SARS-CoV-2 rRT-PCR assay

		Comparator Result		
		Positive	Negative	Total
Revogene SARS-CoV-2 assay	Positive	42	1	43
	Negative	1	42	43
	Total	43	43	86
Positive Percent Agreement		97.7% [95% CI: 87.9% - 99.6%]		
Negative Percent Agreement		97.7% [95% CI: 87.9% - 99.6%]		

The overall initial unresolved rate was 0.0% (0/86). The overall initial indeterminate rate was 0.0% (0/86). No repeat testing was required.



ANALYTICAL PERFORMANCE CHARACTERISTICS

ANALYTICAL SENSITIVITY (LIMIT OF DETECTION)

The Limit of Detection (LoD) for the Revogene SARS-CoV-2 assay was determined as the lowest concentration of SARS-CoV-2 RNA where the detection rate is consistently $\geq 95\%$. It was determined using quantified SARS-CoV-2 heat-inactivated culture fluid (USA-WA1/2020 strain, ZeptoMetrix Corporation, 0810587CFHI) diluted into pooled negative nasopharyngeal (NP) matrix over six (6) dilutions ranging from 0.9 to 14.1 TCID₅₀/mL. The preliminary LoD was determined by testing each concentration with a total of 12 replicates across three (3) lots of Revogene SARS-CoV-2 assay reagents. The LoD was confirmed using two (2) preparations of SARS-CoV-2 diluted into pooled negative nasopharyngeal (NP) matrix over three (3) dilutions ranging from 3.52/14.1 TCID₅₀/mL. A total of 20 replicates for each concentration was tested across three (3) lots of Revogene SARS-CoV-2 reagents (**Table 2**). The LoD of the Revogene SARS-CoV-2 assay is 7 TCID₅₀/mL inVTM which is equivalent to 4,575 copies/mL in VTM.

Table 2. LoD Confirmation Results for the Revogene SARS-CoV-2 Assay

Concentration (TCID ₅₀ /mL of VTM)	Positive/Total Results			Mean Ct values
	Pooled NP Matrix 1	Pooled NP Matrix 2	Overall Positive/ Total Results (% positivity)	
14.1	10/10	10/10	20/20 (100%)	34.2
7.0	10/10	10/10	20/20 (100%)	35.3
3.5	9/10	9/10	18/20 (90.0%)	36.5
0	0/10	0/10	0/20 (0.0%)	N/A

INCLUSIVITY

The inclusivity of Revogene SARS-CoV-2 was evaluated using *in silico* analysis of the assay primers and probes to confirm the detection of the N gene of SARS-CoV-2 strains. The *in silico* analysis was performed on all sequences available as of May 6, 2021 in the National Center for Biotechnology Information (NCBI) database and as of May 4, 2021 in the Global Initiative on Sharing All Influenza Data (GISAID) database. A total of 1 724 784 sequences were identified.

Of the 1 724 784 sequences, 50 908 sequences were excluded either because they presented ambiguous nucleotides in the regions targeted by the primers and probes of the Revogene SARS-CoV-2 assay, were incomplete or were not isolated from human specimen. Of the remaining 1 673 876 sequences, 98.22% (1 644 150 sequences) are 100% homologous to the Revogene SARS-CoV-2 primers and probe(s) and 3 835 (0.23%) sequences had one or more critical mismatches that could impact the revogene SARS-CoV-2 test performance. Overall, the *in silico* analysis revealed that 99.77% of the SARS-CoV-2 sequences assessed are deemed to have a high probability of being detected by the Revogene SARS-CoV-2 assay.

CROSS-REACTIVITY

The cross-reactivity of the Revogene SARS-CoV-2 assay was assessed through bench testing using a diverse set of commensal and pathogenic microorganisms, which are listed in Table 3. The study included nine (9) bacteria, two (2) yeasts, 13 infectious or inactivated viruses (**Table 3**). Two (2) bacteria, three (3) viruses, and human genomic DNA were tested as extracted or synthetic DNA or RNA. Each analyte was tested in triplicate (3) across three (3) Revogene SARS-CoV-2 reagent lots. Under the conditions of the study, none of the 32 non-targeted analytes tested were reactive with the Revogene SARS-CoV-2 assay.

The cross-reactivity with primers and probes of the Revogene SARS-CoV-2 assay was evaluated by an *in silico* analysis performed on sequences contained in the NCBI database as of May 5, 2021 for the analytes listed in **Table 3** as well as for coronavirus target found in bats and civets. The sequence #MN996532 (Bat coronavirus RATG13) presents $\geq 90\%$ homology with primers and probes of the Revogene SARS-CoV-2 assay. No other sequences were found to have significant level of homology with the Revogene SARS-CoV-2 primers and probes.



Table 3. Cross-Reactivity Results with the Revogene SARS-CoV-2 Assay

Analyte	Identification	Concentration	Positive Results/Total
Bacteria and Yeasts			
<i>Bordetella pertussis</i>	ATCC [®] 9797 [™]	1.20 x 10 ⁸ CFU/mL	0/3
<i>Candida albicans</i>	ATCC [®] 10231 [™]	5.98 x 10 ⁶ CFU/mL	0/3
<i>Chlamydomonas pneumoniae</i>	ATCC [®] VR-1435 [™]	8.79 x 10 ⁶ IFU/mL	0/3
<i>Haemophilus influenzae</i>	ATCC [®] 33533 [™]	1.53 x 10 ⁸ CFU/mL	0/3
<i>Legionella pneumophila</i>	ATCC [®] 33152 [™]	1.36 x 10 ⁷ CFU/mL	0/3
<i>Mycobacterium tuberculosis</i> (genomic DNA)	ATCC [®] 25618DQ [™]	2.08 x 10 ⁵ cp/mL	0/3
<i>Mycoplasma pneumoniae</i> (genomic DNA)	ATCC [®] 15531D [™]	2.11 x 10 ⁴ cp/mL	0/3
<i>Pseudomonas aeruginosa</i>	ATCC [®] 35554 [™]	7.45 x 10 ⁷ CFU/mL	0/3
<i>Staphylococcus epidermidis</i>	ATCC [®] 14990 [™]	3.78 x 10 ⁷ CFU/mL	0/3
<i>Streptococcus pneumoniae</i>	ATCC [®] 49619 [™]	4.23 x 10 ⁷ CFU/mL	0/3
<i>Streptococcus pyogenes</i>	ATCC [®] 12344 [™]	8.50 x 10 ⁷ CFU/mL	0/3
<i>Streptococcus salivarius</i>	ATCC [®] 13419 [™]	6.88 x 10 ⁷ CFU/mL	0/3
<i>Pneumocystis jirovecii</i> (PJP) (formerly known as <i>Pneumocystis carinii</i>)	ATCC [®] PRA-159 [™]	6.10 x 10 ⁶ nuclei/mL	0/3
Viruses, Human DNA, and Negative NP matrix pool			
Human Coronavirus 229E	0810229CFHI	1.00 x 10 ⁵ TCID ₅₀ /mL	0/3
Human Coronavirus OC43	0810024CFHI	1.00 x 10 ⁵ TCID ₅₀ /mL	0/3
Human Coronavirus NL63	0810228CFHI	1.00 x 10 ⁵ TCID ₅₀ /mL	0/3
Human Coronavirus HKU1 (synthetic RNA)	ATCC [®] VR-3262SD [™]	2.26 x 10 ⁵ cp/mL	0/3
NATtrol [™] Coronavirus-SARS Strain 2003-00592	NATSARS-ST	Undiluted*	0/3
MERS-Coronavirus (genomic RNA)	NR-45843	4.31 x 10 ⁵ cp/mL	0/3
Enterovirus 68 (genomic RNA)	ATCC [®] VR-1826DQ [™]	4.64 x 10 ⁵ cp/mL	0/3
Rhinovirus 1A	0810012CFN	1.00 x 10 ⁵ TCID ₅₀ /mL	0/3
Adenovirus C1 Ad. 71	ATCC [®] VR-1 [™]	1.34 x 10 ⁶ TCID ₅₀ /mL	0/3
Human Metapneumovirus (hMPV-16 Type A1)	0810161CF	1.93 x 10 ⁵ TCID ₅₀ /mL	0/3
Parainfluenza virus type 1	ATCC [®] VR-94 [™]	9.77 x 10 ⁵ TCID ₅₀ /mL	0/3
Parainfluenza virus type 2	0810504CF	1.34 x 10 ⁵ TCID ₅₀ /mL	0/3
Parainfluenza virus type 3	0810016CF	2.07 x 10 ⁶ TCID ₅₀ /mL	0/3
Parainfluenza virus type 4A	0810060CF	2.07 x 10 ⁵ TCID ₅₀ /mL	0/3
Influenza A H1N1 (Swine/ Iowa/15/30)	ATCC [®] VR-333 [™]	5.43 x 10 ⁷ CEID ₅₀ /mL	0/3
Influenza B Nevada/03/2011 (Victoria Lineage)	NR-44023	1.71 x 10 ⁷ CEID ₅₀ /mL	0/3
Respiratory Syncytial Virus (RSV) A2/Australia/1961	ATCC [®] VR-1540 [™]	3.36 x 10 ⁶ PFU/mL	0/3
Human genomic DNA	N/A	2.54 x 10 ⁵ cp/mL	0/3
Pooled nasopharyngeal negative matrix	N/A	N/A	0/3

* Highest concentration available. Concentration is unknown.

MICROBIAL INTERFERENCE

NATtrol[™] Coronavirus-SARS strain 2003-00592, a non-targeted analyte for which the *in silico* analysis has revealed a sequence homology ≥ 80% with the Revogene SARS-CoV-2 probes, was tested for microbial interference. In addition, the potential microbial interference of pooled nasopharyngeal matrix collected from patients symptomatic for respiratory infection but negative for the SARS-CoV-2 target was also evaluated. One (1) heat-inactivated strain of SARS-CoV-2 (USA-WA1/2020, ZeptoMetrix Corporation, 0810587CFHI) was tested at a load of 3xLoD in VTM (21 TCID₅₀/mL or 13 725 cp/mL of VTM) in the absence of non-targeted analyte (control without interference), as well as in combination with each individual non-targeted analyte. Each sample type (SARS-CoV-2 strain with/without potential interferents) was tested in triplicate with three (3) Revogene SARS-CoV-2 reagent lots. Neither of the analytes tested interfered with detection of SARS-CoV-2.

Table 4: Results for the Control and Analytes tested with the Revogene SARS-CoV-2 Assay

Analyte	Concentration	Positive Results/Total
NATtrol [™] Coronavirus-SARS Strain 2003-00592	Undiluted*	3/3
Pooled nasopharyngeal negative matrix	N/A	3/3
Control without interference	3xLoD (21 TCID ₅₀ /mL or 13 725 cp/mL of VTM)	3/3

* Highest concentration available. Concentration is unknown.



INTERFERING SUBSTANCES

Thirteen (13) potentially interfering substances (endogenous and exogenous) that may be found in nasopharyngeal swab (NPS) specimens were evaluated. For each substance, three (3) replicates were tested in negative NP matrix in the presence of the SARS-CoV-2 strain (USA-WA1/2020 strain, ZeptoMetrix Corporation, 0810587CFHI) (at three (3) times its LoD, i.e., 21.09 TCID₅₀/mL or 13 725 cp/mL of VTM) and three (3) SARS-CoV-2-negative replicates (negative NP matrix only) were also tested. Nine (9) substances did not show interference with the Revogene SARS-CoV-2 assay when tested at their potentially highest concentration that could be found in a NPS specimen. Four (4) substances, including whole blood, Salinex[®] nasal spray, Oseltamivir, and Tobramycin did interfere with detection of SARS-CoV-2, the internal control (IC) or the Microfluidic Control (MFC) when tested at their initial concentrations. These substances showed no reportable interference with the Revogene SARS-CoV-2 assay when tested at 0.22% (v/v) for whole blood and Salinex[®] nasal spray, or at 0.013 mg/mL and 2.16 mg/mL for Oseltamivir and Tobramycin respectively (**Table 5**). The highest concentration at which the potentially interfering substances do not show interference on the Revogene SARS-CoV-2 assay is shown in **Table 5**.

Table 5: Overview of the Endogenous and Exogenous Interfering Substances Concentrations without Interference on the Revogene SARS-CoV-2 Assay

Substance	Commercial Name	Composition / Active Ingredient(s)	Concentration in VTM without Interference observed ¹	Concentration in VTM with Interference observed
Blood	Whole blood	Glucose, hormones, enzymes, ions, iron, etc.	0.22 % (v/v)	2.2 % (v/v) ²
Mucin	Mucin from bovine submaxillary glands	Purified mucin protein	2.2 % (w/v)	n/a
Nasal sprays	Dristan [®] nasal spray	Oxymetazoline	2.2 % (v/v)	n/a
	Salinex [®] nasal spray	Sodium chloride with preservatives	0.22 % (v/v)	2.2 % (v/v) ³
	Neo-Syneprine [®]	Phenylephrine hydrochloride	2.2 % (v/v)	n/a
	Triamcinolone	Triamcinolone	2.2 % (v/v)	n/a
Nasal corticosteroids	Flonase [®] spray	Fluticasone	2.2 % (v/v)	n/a
	Budesonide	Budesonide (glucocorticoid)	133.3 µg/mL	n/a
Nasal gel / Homeopathic allergy and analgesic	Zicam [®] allergy relief nasal gel	Luffa operculata, sulfur, Galphimia glauca, Histaminum hydrochloricum	2.2 % (w/v)	n/a
Throat lozenges	Cepacol [®] Extra Strength	Benzocaine, Menthol	2.2 % (w/v)	n/a
Anti-viral drugs	Zanamivir	Zanamivir	3.3 mg/mL	n/a
	Oseltamivir	Oseltamivir phosphate	0.013 mg/mL	0.13 mg/mL ⁴
Antibacterial, systemic	Tobramycin	Tobramycin sulfate	2.16 mg/mL	21.6 mg/mL ⁴

v/v: Volume/Volume; w/v: Weight/Volume; n/a: not applicable

¹ 3/3 positive replicates yielded expected results. 3/3 negative replicates yielded expected results.

² One false negative obtained out of 3 positive replicates. 3/3 negative replicates yielded expected results.

³ One false positive obtained out of 3 negative replicates. 3/3 positive replicates yielded expected results.

⁴ One indeterminate due to an error code and two false negatives obtained out of 3 positive replicates. 3/3 negative replicates yielded expected results.

E-LABELING

Documentation related to this product can be accessed online at www.meridianbioscience.com/pi. Additionally, paper copies are available free of charge upon request by contacting your local distributor or via the phone number listed on the kit box.

REFERENCES

- World Health Organization. Q&A on coronaviruses (COVID-19). April 17, 2020. World Health Organization Web site <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/question-and-answers-hub/q-a-detail/coronaviruse-disease-covid-19>. Accessed October 16th, 2020.
- World Health Organization. Timeline: WHO's COVID-19 response. <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/interactive-timeline>. Accessed September 27th, 2020
- Boni, M.F., Lemey, P., Jiang, X. et al. Evolutionary origins of the SARS-CoV-2 sarbecovirus lineage responsible for the COVID-19 pandemic. Nat Microbiol (2020).
- Mahendra Pal, Gemechu Berhanu, Chaltu Desalegn, and Venkataramana Kandi. Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2): An Update. Cureus (2020) Mar; 12(3): e7423.
- SN11290 Revogene[®] System RNA Software Upgrade Kit
- Public Health Service, Centers for Disease Control and Prevention, National Institutes of Health. Biosafety in microbiological and biomedical laboratories-5th Edition. HHS Publication No. (CDC) 21-1112. Revised December 2009
- CLSI M29-A4, 2014, Protection of laboratory workers from occupationally acquired infections; Approved Guideline-Fourth Edition
- Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19) <https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html>
- SN134822 Revogene[®] Operator's Manual





INTERNATIONAL SYMBOL USAGE

You may see one or more of these symbols on the labelling/packaging of this product:

Key guide to symbols

	Use-by date		Humidity Limitation
	Batch Code		Prescription Use Only
	In vitro diagnostic medical device		Do not use if package is damaged
	CE Mark		Keep away from sunlight
	Catalog number		Revogene Test Device
	Consult Instructions for use		Sample Buffer Tube
	Manufacturer		Disposable Transfer Loop
	Contains sufficient for <n> tests		Disposable Transfer Tool
	Temperature limit		Contains 24 Disposable Transfer Loops (DTL)
	Authorized representative in the European Community		For Emergency Use Authorization Only
	Do not reuse		Revogene Test Device
	Keep dry		
	Contains # pouches: 1 Disposable Transfer Tool (DTT), 1 Sample Buffer Tube (SBT), 1 PIE		

For technical assistance, call Technical Support Services at 800-343-3858 between the hours of 8AM and 6PM, USA Eastern Standard Time. To place an order call Customer Service Department at 800-543-1980.

TaqMan is a registered trademark of Roche Molecular Systems, Inc.

ATCC is a registered trademark of the American Type Culture Collection.

BD is a trademark of Becton, Dickinson and Company.

Copan UTM is a trademark of Copan.

NATtrol is a trademark of ZeptoMetrics Corporation.

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IMPORTANT PRODUCT NOTIFICATION

revogene®

Revogene SARS-CoV-2 assay

IVD

For *in vitro* Diagnostic Use

R_x Only

For Emergency Use Authorization (EUA) Only

Electronic copies of Revogene Package Inserts are available at our designated internet website:

www.meridianbioscience.com/pi

- 410700, Revogene SARS-CoV-2

This product information card does not contain the full instructions.

Please contact Technical Support at 1-800-343-3858 or meridianbioscience.com if you require a printed copy of the full instructions, free of charge.

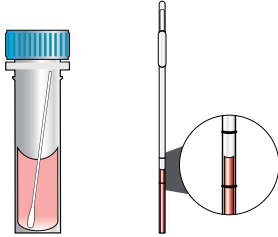
- This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories;
- This product has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and
- The emergency 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.



TEST PROCEDURE

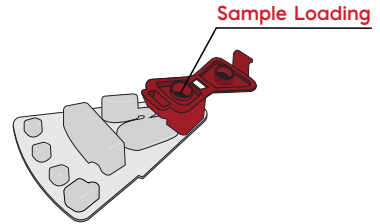
How to perform the test

1.



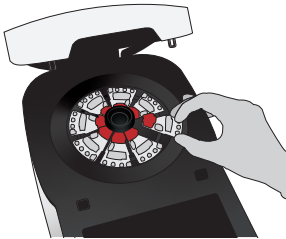
- Invert the specimen 5 times.
- Unseal the pouch containing the Revogene® SARS-CoV-2 PIE.
- Using the disposable transfer tool (DTT), squeeze the bulb while the tip is in the patient sample and release the bulb when the liquid level is between the two lines on the DTT.

2.



- Discharge the specimen completely into the sample loading chamber of the PIE.
- Close the cap of the Sample Loading Chamber tightly.

3.



- Start the test run by navigating to the <Setup Run> menu. Select Revogene® SARS-CoV-2. Follow the on screen instructions to load the patient test PIE.
- Load the remaining patient tests. If less than eight (8) PIEs are being tested, load MOCK PIEs in the carousel in the remaining positions.

4.



- Close the instrument lid with both hands and ensure the lid lock engages.
- Select <Start> to initiate the test and walk away.
- The lid opens when the run is complete.
- Tap the <Results> icon to see test results.

Note: The E-PRO feature may display positive results as early as 47 minutes.

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.

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.



This illustration is representative of the current Package Insert at the time of publication. Please refer to the most current version of the Package Insert for complete instructions.

USA/CORPORATE OFFICE

3471 River Hills Drive
Cincinnati, Ohio 45244 USA
Telephone: 513-271-3700

MERIDIAN BIOSCIENCE EUROPE

Belgium/Luxembourg Tel: +32 (0)6789 5959
France Tel: +33 (0)1 4256 0440
Germany Tel: +49 (0)3371 60 222 31
Italy Tel: +39 (0)331 43 3636
Netherlands Tel: +31 (0)411 62 11 66
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INTENDED USE

The Revogene® System RNA Software Upgrade Kit is a single-use qualitative test utilizing automated real-time Reverse Transcription Polymerase Chain Reaction (rRT-PCR) to confirm that the parameters of the Revogene® instrument are within specifications for testing with an RNA-based assay. It is intended for use by qualified laboratory personnel who have been trained and are proficient in performing testing on the Revogene instrument or by Meridian Bioscience, Inc. service personnel. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, that meet the requirements to perform high or moderate complexity tests. The Revogene System RNA Software Upgrade Kit is only for use under the Food and Drug Administration's Emergency Use Authorization.

PRINCIPLE OF THE PROCEDURE

The Revogene System RNA Software Upgrade Kit is used to install the Revogene System Software version 4.2.0, import the Revogene Instrument Control Protocol file for RNA-based assay, and install the Assay Definition File (ADF) file. The correct installation of the software, Instrument Control Protocol, and ADF files are verified by running the four (4) microfluidic cartridges (named PIE hereafter) enclosed in the kit. Confirmation of successful installation is accomplished by sending a troubleshooting report to Meridian Bioscience Technical Support to confirm the appropriate installation. The instrument is ready to run specimens once the verification password has been entered into the instrument to import the Revogene® SARS-CoV-2 ADF. An Internal Control (IC) is incorporated into each PIE to verify RNA transcription/amplification/detection steps including the verification of reagent failure. A Microfluidic Control (MFC) is also incorporated into each PIE to verify the fluidic properties of the PIE. Revogene automates nucleic acid amplification and detection of the Internal Control (IC) amplified PCR product by using reverse transcription (conversion of RNA templates into DNA). User intervention is only required to transfer sample buffer from the Sample Buffer Tube (SBT) into the PIE and insert the PIE into the Revogene carousel.

Each Revogene System RNA Software Upgrade Kit PIE is a fully integrated closed device into which sample buffer is dispensed and processed through different microfluidic chambers and channels, which allows for the IC real-time RT-PCR steps (Figure 1). The sample buffer is transferred by centrifugation from one chamber to the next in sequence. All reagents specific for the PCR reaction are incorporated and dried within one of the PCR wells. The amplified product is detected in real-time using a target-specific TaqMan® chemistry-based probe. No operator intervention is necessary once a PIE is loaded into the Revogene.

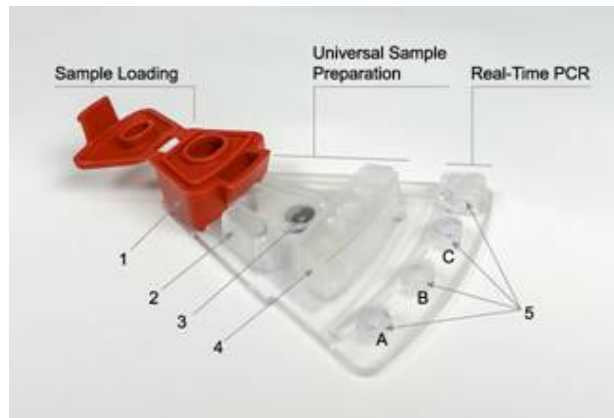


Figure 1. Top View of a PIE.
1: Sample Loading Chamber, 2: Overflow Chamber, 3: Homogenization Chamber containing the Microfluidic Control, 4: Dilution/Lysis Chamber, 5: Three (3) PCR Wells (A to C from left to right) and one (1) Waste Chamber (at the right end).

The Revogene carousel must contain eight (8) PIEs to maintain thermodynamic balance within the run. At run completion, the results are computed by the system from measured fluorescent signals and embedded calculation algorithms. The results are displayed on the touchscreen and may be printed. Results have to be transferred to a USB flash drive and provided to Meridian for analysis and confirmation on the software, Instrument Control protocol and ADF upgrade.

REAGENTS AND MATERIALS PROVIDED

Revogene System RNA Software Upgrade USB flash drive is required to perform the upgrade. The USB flash drive contains the following files:

1. Revogene System Software version 4.2.0
2. Instrument Control Protocol specific for RNA-based assays which include the reverse transcription step
3. Revogene System RNA Software Upgrade kit ADF
4. Password protected Revogene SARS-CoV-2 ADF
5. Revogene Operator's Manual

Revogene System RNA Software Upgrade kit contains sufficient reagents and materials to execute one (1) software upgrade. The kit contains four (4) individual pouches, and each pouch contains the following materials:

1. One (1) **RNA Software Upgrade Kit Sample Buffer Tube (SBT)**: Tube containing Tris-HCl pH 8.0/EDTA Na₂ (TE 1X) buffered solution as a dilution buffer for the IC.
2. One (1) **Disposable Transfer Tool (DTT)**: Plastic pipette with minimal and maximal volume marks for transferring the SBT into the PIE.
3. One (1) **RNA Software Upgrade Kit microfluidic cartridge (PIE)**: Integrated device which comprises dried reagents allowing real-time RT-PCR steps for transcription, amplification and detection of the IC. Each PIE contains an Internal Control (IC), IC-specific primers and probe, a Microfluidic Control, dNTPs, buffer and DNA polymerase displaying reverse transcriptase activity.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Revogene® (cat# 610210)
2. Disposable powderless gloves
3. Vortex mixer
4. MOCK PIEs (cat# 610208)

WARNINGS AND PRECAUTIONS

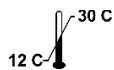
1. For *in vitro* diagnostic (IVD) use under Emergency Use Authorization only.
2. This product has not been FDA cleared or approved but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories.
3. This product has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.
4. 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.
5. The Revogene System RNA Software Upgrade Kit can only be used on the Revogene instrument.
6. The Revogene System RNA Software Upgrade Kit must run all four PIEs (4) in a single run on the Revogene.
7. Do not use the kit if the label that seals the outer box is broken upon arrival.
8. Do not use Revogene System RNA Software Upgrade Kit PIEs if the protective pouches are open or broken upon arrival.
9. Do not interchange DTT, SBT, PIE between kit lots.
10. Each single-use DTT and PIEs included in the kit are used to execute one (1) test. Do not reuse DTT or PIE.
11. Wear disposable powderless gloves while handling PIEs and thoroughly wash hands afterwards.
12. The PIE contains dried reagents. The protective pouch should not be opened until ready to perform the test.
13. Dispose of unused materials, reagents and waste in accordance with country, federal, provincial, state and local regulations.
14. Do not open or break apart the PIE after use to avoid contamination with amplification product.
15. Do not use a PIE that has been dropped, shaken or inverted after the sample has been loaded as this may cause invalid results.
16. Do not use a kit that has passed its stated expiration date.
17. Do not refrigerate the loaded PIE.
18. Each run must be performed with four (4) RNA Software Upgrade Kit PIEs and four (4) MOCK PIEs in the Revogene carousel to maintain thermodynamic and mechanical balance within the run.

STORAGE AND STABILITY

1. Store the Revogene System RNA Software Upgrade Kit at 2-25 C. The expiration date is indicated on the box kit's label and on each pouch.



2. Store the Revogene System RNA Software Upgrade USB flash drive at 12-30 C.



3. Do not open a pouch until ready to perform testing. Use the PIE within one (1) hour after opening the pouch.

INSTRUCTION FOR USE

NOTE: The contents of the Revogene System RNA Software Upgrade Kit of four (4) pouches and one (1) USB drive must be used to perform each software upgrade.

SOFTWARE VERSION 4.2.0 UPGRADE

1. Log on to the Revogene with a "supervisor" account (*admin* is a supervisor account).
2. Insert the USB flash drive into the Revogene.
3. Tap on the <revogene>/<GenePOC> tab on the top left corner of the screen.
4. Tap the <Upgrades> tab on the bottom right (Figure 2).

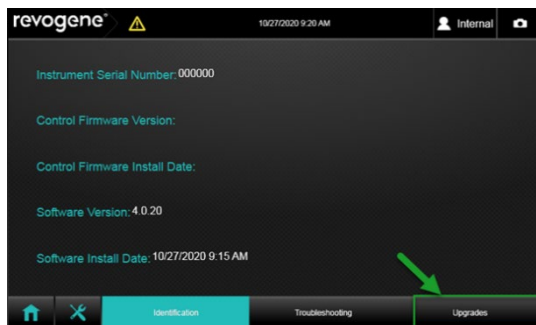


Figure 2. Upgrade Button Location

5. Tap the <...> button (Figure 3).

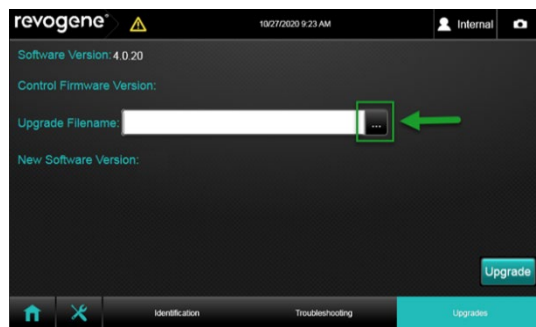


Figure 3. Installer File Selection Button

6. A window will appear. Select the USB drive (D:). The default format should be .msi. If not, change the format of the file to .msi (MSI files). (Figure 4)

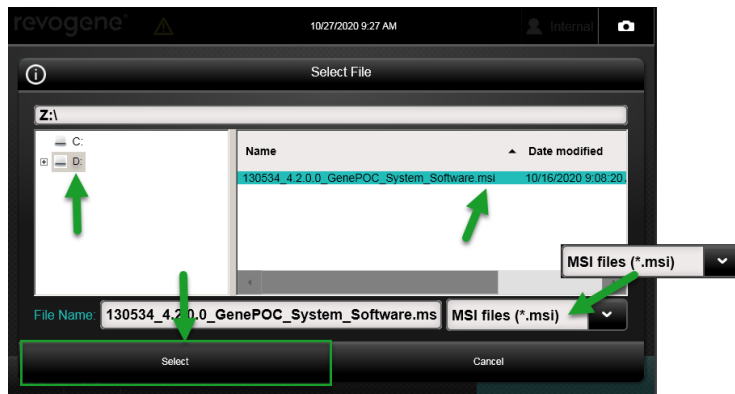


Figure 4. Installer File Selection Window

7. In the USB drive, select the 130534_4.2.0.0_GenePOC_System_Software.msi. Tap the <Select> button.

8. The window will close and the <Upgrade> button on the right bottom corner will be available. Tap on the <Upgrade> button (Figure 5)

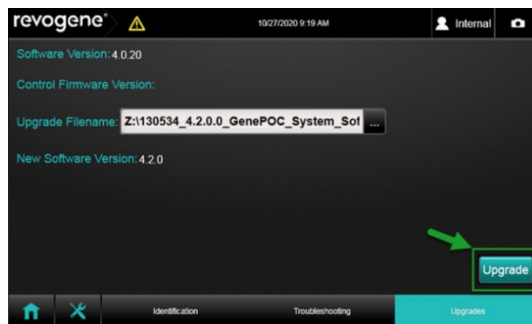


Figure 5. Upgrade Button Location

9. A window will appear. Tap <OK>. (Figure 6)

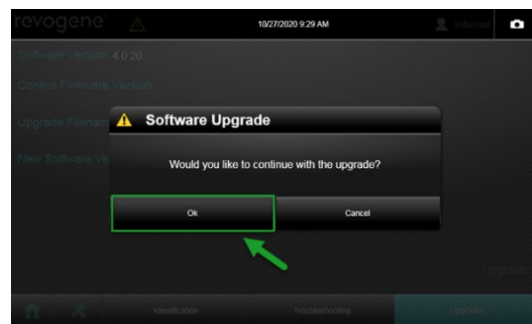


Figure 6. Upgrade Confirmation

10. The Revogene will process the software upgrade. Once the software upgrade is completed, the Revogene will restart. This step takes about 1-2 minutes (including restart).
11. Log on to the Revogene using a "supervisor" account (*admin* is a supervisor account).
12. Press on the <revogene>/<GenePOC> tab on the top left corner of the screen.
13. Verify that the software version has been updated to version 4.2.0. (Figure 7)

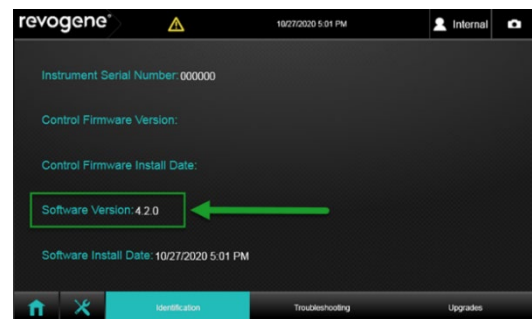


Figure 7: Version Confirmation

INSTRUMENT CONTROL PROTOCOL (XML) IMPORT (Revogene specific)

1. Tap on the <Tools> menu right to the "Setup run" main button.
2. Tap on the <Assay> menu on the bottom right corner of the sub-menu window.
3. Tap on the <Import> tab at the bottom right corner. (Figure 8)

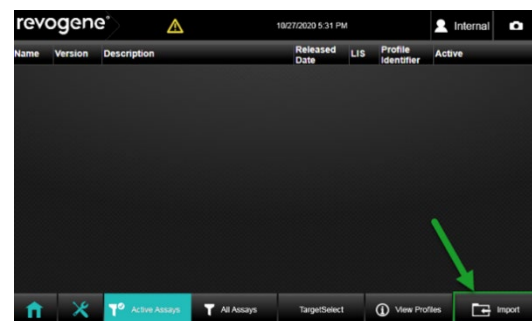


Figure 8. Assay Import Button

4. A window will appear:
 - a. Select the USB drive (D:).
 - b. Change the format of the file to .xml (Profile files, *.xml).
 - c. In USB drive, select the Instrument Control Protocol (.xml) file that has the correct serial number (example: 135580_XXXXXX_instrument_Control_Protocol_ARN_IVD_V_1_0_0YYYYYYY) where the XXXXXX corresponds to the Revogene's serial number and YYYYYYY is a randomized number different for each xml file.
 - d. Tap on the <Select> button. (Figure 9)

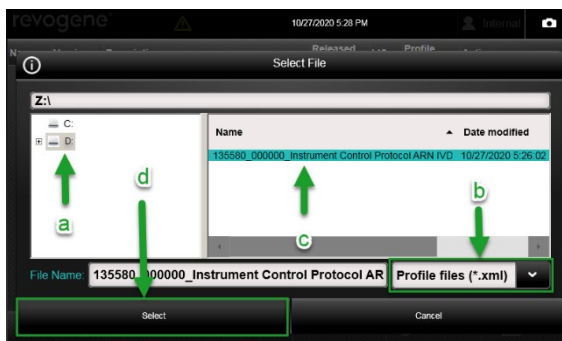


Figure 9. Instrument Control Protocol (.xml) Selection Window

5. A window will appear stating that the Instrument Control Protocol also named Thermocycler Profile (.xml) file was imported successfully. Tap <OK>. (Figure 10)

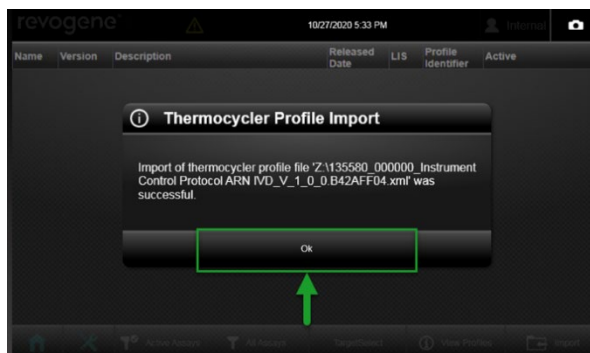


Figure 10. Instrument Control Protocol (.xml) Import Confirmation

6. Tap on the <View Profiles> tab. The new Instrument Control Protocol ARN IVD (.xml) (identifier 135580) should be listed with version 1.0.0. (Figure 11)

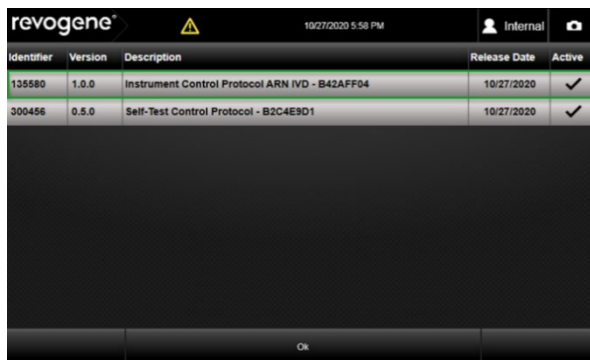


Figure 11. Instrument Control Protocol Window

7. Tap <OK>.

ADF IMPORT

1. Tap the <Import> button.
2. A window will appear. Select the USB drive (D:). The default format should be .adf. If not, change the format of the file to .adf (ADF files) and select the ADF file named: RNA SW Upgrade-135632_1.0.1.74D421CB.adf (Figure 12)

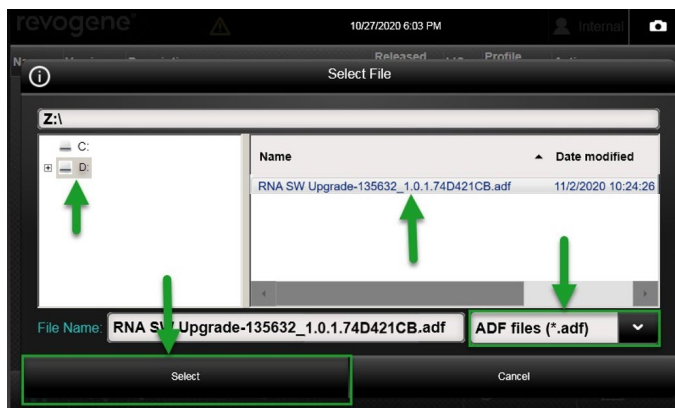


Figure 12: ADF Selection Window

3. Tap the <Select> button.
4. A window will appear stating that the ADF was imported successfully. Tap <OK>. (Figure 13)

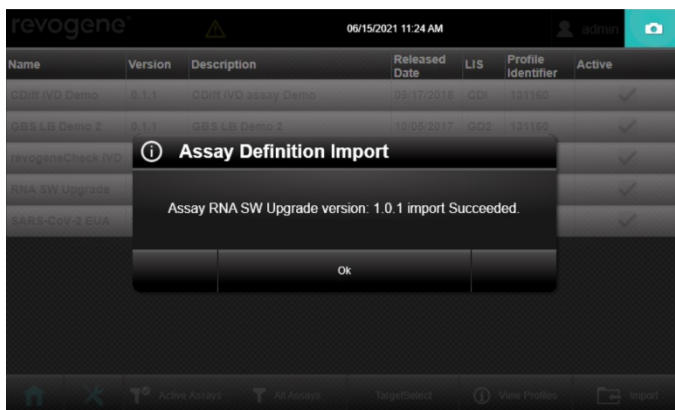


Figure 13: ADF Import Confirmation

TEST RUN

SBT PREPARATION

1. Open the kit box and remove the four (4) pouches from the box.
2. Unseal the right side of the pouch (when facing label) containing DTT and SBT and remove only the SBT from the pouch.
3. Identify (or label) the SBT with the appropriate identification. Place the SBT on a sample rack, if used.

PIE PREPARATION

4. Mix the SBT for a minimum of 15 seconds at maximal speed using a vortex mixer.
5. Unseal the left side of the pouch (when facing label) containing the PIE, removing it from the pouch. Once unsealed, the PIE must be used within one (1) hour.
6. Remove the DTT from the right side of the pouch and use it to aspirate the sample buffer (SB) by squeezing the entire bulb. The liquid level into the DTT must be anywhere between the two (2) marks (Figure 14). If the liquid level is not between the two (2) marks, discharge the SB completely into the SBT and repeat this step.
7. Insert the tip of the DTT vertically into the sample loading chamber of the PIE and discharge completely the SB (Figures 15A and 15B). Make sure not to touch the outer edges or the bottom of the sample loading chamber with the DTT.
8. Close the cap of the PIE tightly. Place the PIE on a sample rack, if used. Do not refrigerate the loaded PIE.
9. Prepare all additional PIEs for testing by repeating steps 2 to 8 then proceed to step 1 of the **Start Run** section

NOTE: Hold the PIE by the dilution chamber or by its sides to avoid smearing on PCR wells.

NOTE: Be cautious when manipulating a loaded PIE. Do not invert, shake or drop it.

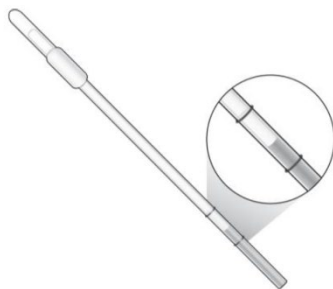


Figure 14. Representation of an Appropriate Sample Buffer (SB) Level using the Disposable Transfer Tool (DTT).

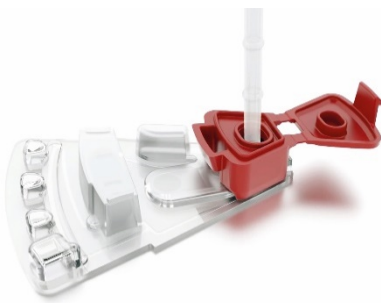


Figure 15A. Adequate Insertion of the DTT into the Sample Loading Chamber of the PIE



Figure 15B. Inadequate Insertion of the DTT into the Sample Loading Chamber of the PIE

START RUN

Required Software version, Instrument Control Protocol (.XML) and ADF must be installed prior run execution. Please refer to Software version 4.2.0 Upgrade section for more information.

NOTE 1: Each run must be performed with the four (4) Revogene System RNA Software Upgrade KitPIEs in the Revogene. Insert a MOCK PIE into each of the remaining four (4) positions in the carousel. Each of the eight (8) positions in the carousel must be filled.

NOTE 2: Refer to the Revogene Operator's Manual¹ for further information regarding Revogene set-up and operation.

1. Power on the Revogene (if not already done). The software will launch automatically.
2. Log in by entering <Username> and <Password> and tap <Login>. The main menu will appear automatically.
3. Tap <Setup Run>.
4. In the scanning menu:



Figure 16. Sample ID Button

- a. Enter a sample identification (Ex: 1 for first PIE, 2 for second etc.) manually. Manual entry can be done by tapping the pencil icon of the <Scan or Enter Sample ID> line (Figure 16).
 - b. Enter PIE barcodes using the barcode scanner by gently positioning the PIE almost vertically in front of the scanner. Alternatively, PIE barcodes may be entered manually (tap the pencil icon of their respective lines). Handle the PIE carefully without shaking, dropping it, or inverting it.
 - c. Insert the PIE into the Revogene at any position of the carousel.
 - d. Confirm that the PIE is inserted by tapping <OK> on the <Insert PIE into instrument> line.
 - e. Repeat steps "a" to "d" for the three (3) other PIEs.
 - f. When all PIEs are inserted into the carousel, tap <Next> and follow the instructions on the screen.
5. Because less than eight (8) PIEs are being tested, load MOCK PIEs in the carousel remaining positions. No scan is required when inserting MOCK PIEs into the Revogene. Check the box to confirm that they were inserted.
 6. Scan the retention ring and place it on the carousel.
 7. Gently rotate the carousel around to check all PIEs are loaded correctly with no friction or resistance to rotation. Close the instrument lid with both hands and hold on until you hear the lock activate. Then gently pull up on the lid to guarantee that the lock is engaged.
 8. Initiate the test run by tapping <Start>.
 - A timer on the screen and lights on the Revogene lid will show the progression of the test.

VIEWING AND EXPORTING RESULTS

NOTE: You must complete this step to be able to use the Revogene SARS-CoV-2 assay.

1. Once the run is completed, the lid opens automatically.
2. Enter <Username> and <Password> and tap <Login> if the user's session has logged-out.
3. Results from the last run are automatically shown on the screen.
4. Make sure **all** the results obtained are **Negative (-)** (Figure 17).
 - a. If one (1) or more results is (are) not negative, contact Meridian Bioscience Technical Support Services at MBI-techsupport@meridianbioscience.com or 1-800-343-3858 and follow their instructions for a repeat

Sample ID	Patient ID	Started	Assay	LIS Status	Result
QAS-PC 9-15-20		09/15/2020 07:15	RNA SW Upgrade	Not Released	
QAS-NC 9-15-20		09/15/2020 07:15	RNA SW Upgrade	Not Released	
QAS-PC 9-15-20		09/15/2020 07:15	RNA SW Upgrade	Not Released	
QAS-NC 9-15-20		09/15/2020 07:15	RNA SW Upgrade	Not Released	

Figure 17. All Negative Results

5. Next, export the troubleshooting package:
 - a. Tap on the <revogene>/<GenePOC> logo on the upper left corner of the screen (Figure 18).
 - b. Tap the "Troubleshooting" menu at the bottom of the screen (Figure 19).
 - c. Select the date range that covers the period in which the runs were executed. **Note:** If a repeat was executed, make sure the date range covers the initial run and the repeat run (Figure 20, c).
 - d. Tap all the checkboxes so they are checked (Figure 20, d).
 - e. Tap the "Create Package" button (Figure 20, e).
 - f. Save the package on the same USB key (D:) by pressing select. **Note:** Another zip file will appear on the key, do not select it before pressing select (Figure 21).

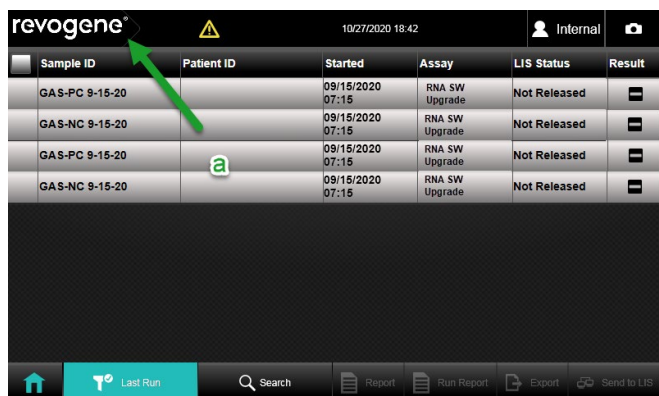


Figure 18. Revogene Logo

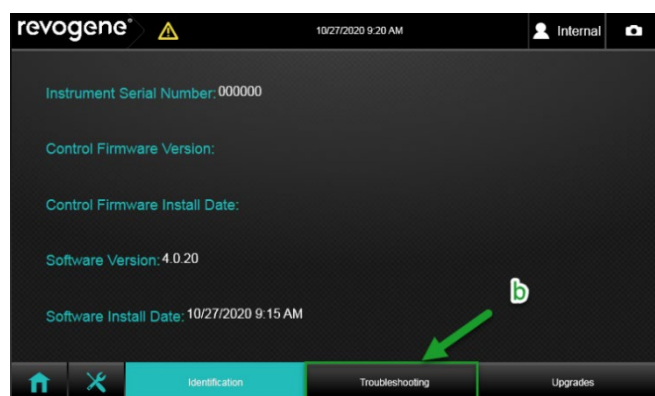


Figure 19. Troubleshooting Button

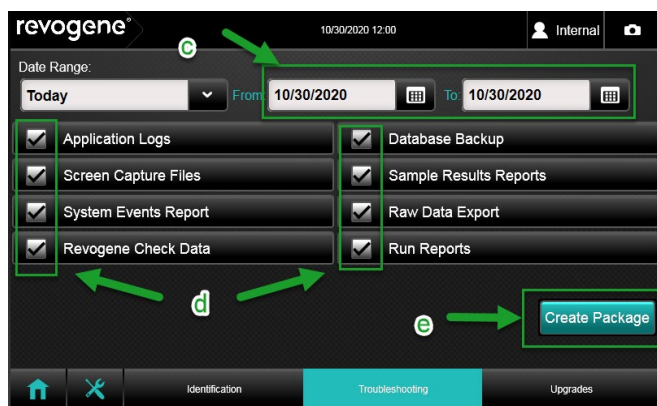


Figure 20. Troubleshooting Package Parameters

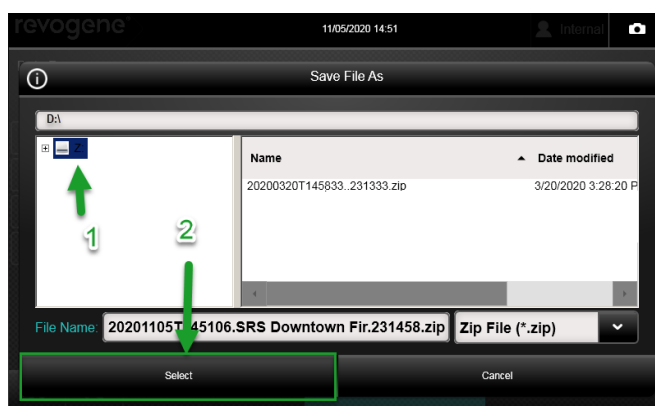


Figure 21. Saving Troubleshooting Package

6. Contact Meridian Bioscience Technical Support Services at MBTechsupport@meridianbioscience.com or 1-800-343-3858 and follow their instructions to send the troubleshooting package.
7. Keep the USB flash drive.

NOTE: It is only possible to proceed to the next steps once the reply from Meridian Bioscience Technical Support Services has been received.

COMPLETION OF UPGRADE

NOTE: This step must be completed to be able to use the Revogene SARS-CoV-2 assay. The goal of this step is to extract the password protected ADF into the root of the USB key to allow the import into the Revogene instrument.

1. Meridian Bioscience will send an email confirmation of the upgrade. This email will contain the password to unzip the ADF to run the Revogene SARS-CoV-2 assay.
2. **Plug the USB key into a computer** and open the file explorer (**Window key + E**):
 - a. To unzip the file, right-click on the SARS-CoV-2 EUA zip file and tap <Extract All...> (Figure 22).

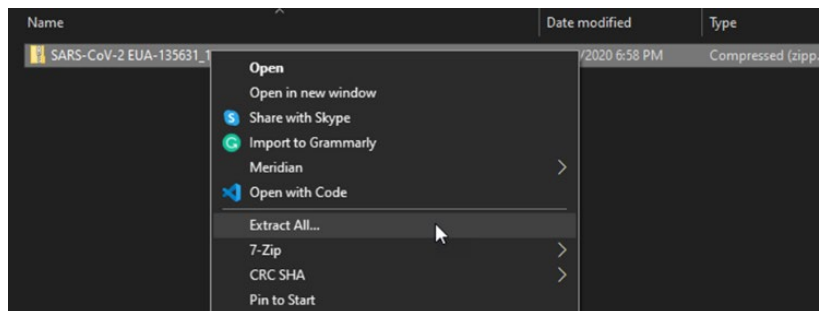


Figure 22. Extract Menu

- b. A window will appear to extract the content on the USB flash drive. **Note the USB letter (Figure 23).**
- c. Erase the text after the USB letter you noted (here: E:\, yours can be different). Tap <Extract> (Figure 24).

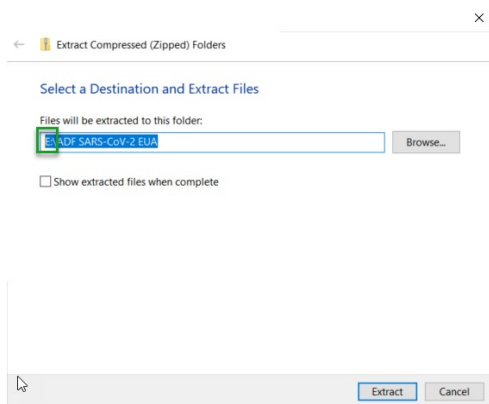


Figure 23. Window with Full Text

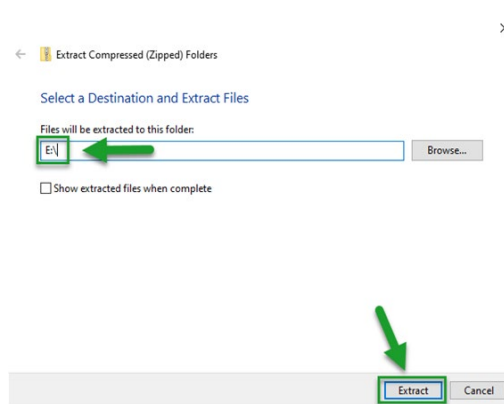


Figure 24. Modified Text and Extract Button

- d. Enter the provided password in the window when prompted and tap <OK> (Figure 25).

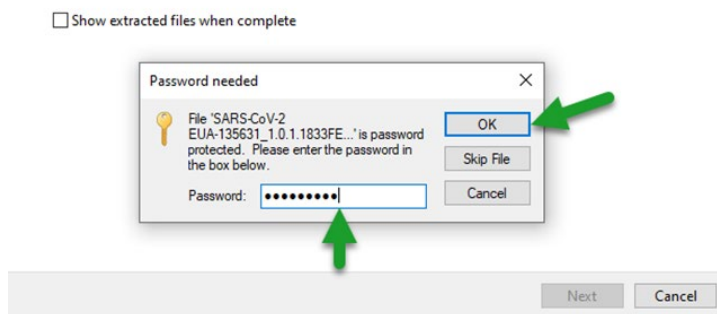


Figure 25. Password Window

3. Unplug the USB key from the computer. Plug it in the Revogene.
4. Log on to the Revogene with a "supervisor" account (*admin* is a supervisor account).
5. Select the **Tools** menu.
6. Select the **Assay** menu, then select **Import** on the bottom right corner of the sub-menu window.
7. A window will appear. Select the USB drive (D:). The default format should be .adf. If not, change the format of the file to .adf (ADF files).
8. In the USB drive files listed, select the ADF file: **SARS-CoV-2 EUA-135631_2.0.1.D1B4A50C.adf**
9. Tap the <Select> button (Figure 26).

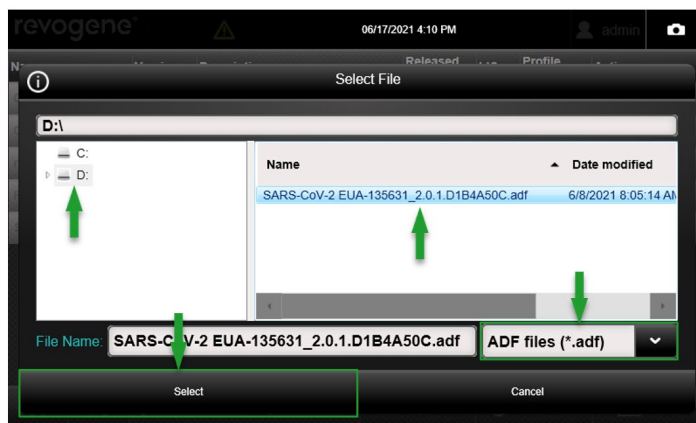


Figure 26. ADF Selection Window

10. A window will appear stating that the ADF was imported successfully. Tap <OK>.

The Revogene System RNA Software upgrade is now completed and the Revogene SARS-CoV-2 assay may now be used.

LIMITATIONS OF THE PROCEDURE

1. The Revogene System RNA Software Upgrade Kit must only be used with the Revogene by trained personnel.
2. Only the Revogene System RNA Software Upgrade Kit PIEs can be used within a single run. PIEs from other Revogene assays are not compatible with the Revogene System RNA Software Upgrade Kit and should not be used.

E-LABELING

Documentation related to this product can be accessed online at www.meridianbioscience.com/nj. Additionally, paper copies are available upon request by contacting your local distributor or via the phone number listed on the kit box.

REFERENCES

1. SN134822 Revogene® Operator's Manual



Manufactured By

Meridian Bioscience, Inc.
Corporate Office
3471 River Hills Drive
Cincinnati, Ohio 45244 USA
Telephone: 513.271.3700
Orders/Customer Service:
800.543.1980
Technical Support Center:
800.343.3858
Information Fax: 513.272.5432
Ordering Fax: 513.271.0124



INTERNATIONAL SYMBOLS USAGE

You may see one or more of these symbols on the labeling/packaging of this product:
Key guide to symbols

	Use-by date		Humidity Limitation
	Batch Code		Prescription Use Only
	In vitro diagnostic medical device		Do not use if package is damaged
	CE Mark		Keep away from sunlight
	Catalog number		Revogene Test Device
	Consult Instructions for use		Sample Buffer Tube
	Manufacturer		Disposable Transfer Loop
	Contains sufficient for <n> tests		Disposable Transfer Tool
	Temperature limit		Contains 24 Disposable Transfer Loops (DTL)
	Authorized representative in the European Community		For Emergency Use Authorization Only
	Do not reuse		Revogene Test Device
	Keep dry		
	Contains # pouches: 1 Disposable Transfer Tool (DTT), 1 Sample Buffer Tube (SBT), 1 PIE		

For technical assistance, call Technical Support Services at 800-343-3858 between the hours of 8AM and 6PM, USA Eastern Standard Time. To place an order, call Customer Service Department at 800-543-1980.

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Revogene and associated logos are registered trademarks of Meridian Bioscience, Inc.
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Upgrade Procedure

How to perform the software 4.2.0 upgrade

This product is only for use under FDA's Emergency Use Authorization (EUA).

1. SOFTWARE 4.2.0 UPGRADE

1. Log on to Revogene as "supervisor".
2. Insert the USB drive into the Revogene.
3. Tap **<Revogene/GenePOC>**
4. Tap **<Upgrades>**.
5. Tap the ellipsis button **<"...">** in the middle of the screen.
6. Tap **<USB drive (D:)>**. The default format should be .msi. If not, change the format of the file to .msi (MSI files).
7. In the USB drive, select the file named **<130534_4.2.0_GenePOC_System_Software.msi>**
Tap **<Select>**.
8. The window will close and the Upgrade button on the right bottom corner will be available. Tap **<Upgrade>**.
9. A window will appear. Tap **<OK>**.
10. Upgrade will begin and Revogene will restart when the upgrade is complete (1-2 minutes).
11. Log on to Revogene as "supervisor".
12. Tap **<Revogene/GenePOC>**.
13. Verify on the screen that the software version has been updated to version 4.2.0

NOTE: Software 4.2.0 upgrade complete. Move to XML file import.

2. XML FILE IMPORT

NOTE: Make note of the serial number of your instrument for this procedure.

1. Tap **<Tools>**.
2. Tap **<Assay>**.
3. Tap **<Import>**.
4. Tap **<USB drive (D:)>**. Change the format file to .xml (Profile files, *.xml).
5. In USB drive select the Instrument Control Protocol (.xml) file that contains the serial number that corresponds to the instrument.
6. Tap **<Select>**.
7. A window will appear stating the Instrument Control Protocol also named Thermocycler Profile (.xml file) was imported successfully. Tap **<OK>**.
8. Tap **<View Profiles>**. The new Instrument Control Protocol ARN IVD (.xml) (identifier 135580) file should be listed with version 1.0.0.
9. Tap **<OK>**.

NOTE: XML successfully completed. Move to ADF file import.

3. ADF FILE IMPORT

1. Tap **<Import>**.
2. Tap **<USB drive (D:)>**. The default format should be .adf. If not change the format to .adf (ADF files).
3. Tap the ADF file named **<RNA SW Upgrade-135632_1.0.1.74D421CB.adf>**.
4. Tap **<Select>**.
5. A window will appear stating the ADF file was imported successfully. Tap **<OK>**.

NOTE: ADF file import successfully completed. Move to PIE preparation.

4. PIE PREPARATION

1. Open the kit box and remove the 4 PIE pouches.
2. Unseal the pouch containing the DTT and SBT. Remove only the SBT from the pouch. Label the SBT.
3. Vortex the SBT. Unseal the left side of the pouch and remove the PIE.
4. Remove a sample buffer tube (SBT) and disposable transfer tool (DTT). Using the DTT, squeeze the bulb while the tip is in the SBT and release the bulb when the liquid level is between the two lines on the DTT.
5. Insert the tip of the DTT vertically into the sample loading chamber of the PIE and discharge completely.
6. Close the cap of the sample loading chamber tightly.
7. Repeat steps 1-6 for the remaining 3 PIEs.

NOTE: Move to Start Run (see back page).



FLIP OVER TO BACK



The instructions provided are representative of the current Package Insert at the time of publication. Please refer to the most current version of the Package Insert for complete instructions.

USA/CORPORATE OFFICE

3471 River Hills Drive
Cincinnati, Ohio 45244 USA
Telephone: 513-271-3700

SN11291 rev. 11/21
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Orders / Customer Service: 1-800-543-1980
Technical Support: 1-800-343-3858
Information Fax: 513-272-5432
Ordering Fax: 513-271-0124
meridianbioscience.com



Upgrade Procedure

How to perform the software 4.2.0 upgrade

This product is only for use under FDA's Emergency Use Authorization (EUA).

5. START RUN

NOTE: Software 4.2.0, XML, and ADF must be installed prior to run execution.

1. Log in by entering **«User name»** and **«Password»** and tap **«Login»**. The main menu will appear.
2. Tap **«Setup Run»**.
3. Enter the sample ID number (i.e. PIEs 1-4).
4. Scan the PIE barcode and insert the PIE into the Revogene carousel. Select **«OK»**.
5. Repeat Steps 3-4 for the remaining 3 PIEs.
6. Insert a MOCK PIE into each of the remaining four (4) positions in the carousel.
7. Tap **«Next»**.
8. Scan the retention ring and place on the carousel.
9. Rotate carousel to check PIEs are properly loaded with no resistance to rotation.
10. Close the instrument lock with both hands and hold until the lock activates.
11. Tap **«Start»** to initiate the test run.
12. The lid opens automatically when the run is complete.
13. Results may be viewed or exported at this time.

6. VIEWING / EXPORTING FILES

1. Enter **«Username»** and **«Password»** and tap **«Login»** if the user's session has timed out.
2. Results from the last run are shown on the screen.
3. Make sure all results obtained are Negative. If one (1) or more results is (are) not negative, contact Meridian Bioscience Technical Support Services at MBI-techservice@meridianbioscience.com or 1-800-343-3858 for instructions.
4. Export the troubleshooting package.
 - a. Tap **«Revogene/GenePOC»**
 - b. Tap **«Troubleshooting»**
 - c. Select the date range that covers the period in which the runs were executed.
 - d. Tap all checkboxes so they are checked.
 - e. Tap **«Create Package»**
 - f. Save the package on the same USB drive (D:) by pressing **«Select»**
5. Contact Meridian Bioscience Technical Support Services at MBI-techservice@meridianbioscience.com or 1-800-343-3858 for instructions to send the troubleshooting package.

NOTE: You must receive a reply from Meridian Bioscience Technical Support Services to proceed to Completion of Upgrade.

Keep the USB drive.

7. COMPLETION OF UPGRADE

1. Meridian Bioscience will send an e-mail confirmation of the upgrade. This e-mail will contain the password to unzip the ADF to run the Revogene SARS-CoV-2 assay.
2. Insert the USB drive into a computer to download the file explorer (Window drive + E).
3. To unzip the file, right-click on the SARS-CoV-2 EUA zip file and tap **«Extract All...»**.
4. A window will appear to extract the content on the USB drive. Note the USB letter. Change the text in the box so the content is only the USB drive letter (ex E:\) and tap **«Extract»**.
5. Type the provided password into the window when prompted and tap **«OK»**.
6. Insert the USB drive into the Revogene instrument.
7. Log on to Revogene as "supervisor".
8. Tap **«Tools»**.
9. Tap **«Assay»**. Select **«Import»**.
10. Select **«USB drive (D:)»**. The default format should be .adf. If not, change the file format to .adf (ADF files).
11. In the USB drive select the **«ADF file: SARS-CoV-2 EUA-135631_2.0.1.D1B4A50C.adf»**.
12. Tap **«Select»**.
13. Tap **«OK»**.

The Revogene System RNA Software upgrade is now complete.

The Revogene SARS-CoV-2 assay can now be run.

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.

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.

