

Upgrade Procedure

How to perform the software 4.2.0 upgrade

This test 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.

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meridianbioscience.com

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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.