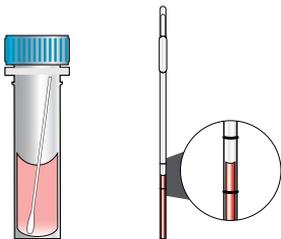


TEST PROCEDURE

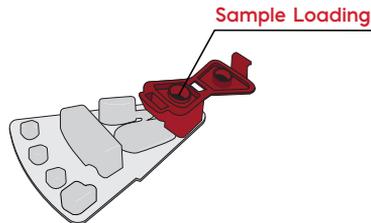
How to perform the test

1.



- Invert the specimen 5 times.
- Unseal the pouch containing the Revogene® SARS-CoV-2 assay 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.



- Follow the onscreen 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.
- Scan the retention ring and place it on the carousel.

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.
- Remove all PIEs including MOCK PIEs after the run.
- 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 0331 43 3636
Netherlands Tel: +31 (0)411 62 11 66
United Kingdom Tel: +44 (0)20 8453 7970

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