TEST PROCEDURE

How to perform the test

1. Using the Disposable Transfer Tool (DTT), aspirate the Sample Buffer (SB) by squeezing the entire bulb until the liquid level is anywhere between the two lines on the DTT.

2. Discharge the specimen completely into the Sample Loading Chamber of the PIE.

3. Close the cap of the Sample Loading Chamber tightly.

4. Using the Disposable Transfer Tool (DTT), aspirate the Sample Buffer (SB) by squeezing the entire bulb until the liquid level is anywhere between the two lines on the DTT.

   - Vortex the stool specimen at high speed for 15 seconds.
   - Using the provided Disposable Transfer Loop (DTL), transfer approximately 5 µL of specimen into the provided Sample Buffer Tube (SBT).
   - Vortex the SBT at high speed for 15 seconds.
   - Unseal the pouch containing the Revogene® C. difficile PIE.

   - Start the test run by navigating to the <Setup Run> menu.
   - Select Revogene® C. difficile. 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.

   - 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.

For the detection of the toxin B (tcdB) gene of toxigenic Clostridium difficile (C. difficile) in unformed (liquid or soft) stool specimens. For use with the Revogene® instrument. Please refer to the current complete instructions for proper external controls testing and results interpretation.