MDx-Chex® for BC-GP and BC-GN Best Practices Guide

For use with the VERIGENE® Blood Culture Gram Positive (BC-GP) and Blood Culture Gram Negative (BC-GN) tests on the Luminex VERIGENE® System

Step 1

Prepare Test Cartridge and Consumables

1. Thoroughly sanitize the work area, vortex mixers, centrifuges, pipettes and any other equipment used for sample processing with a lint-free decontamination cloth before and after sample preparation.
2. Press the OPEN/CLOSE Button on the VERIGENE **Processor**. **Figure 1**. This opens the **Drawer Assembly**. Sanitize with a lint-free decontamination cloth.
3. Remove the **Test Cartridge**, **Extraction Tray**, **Utility Tray** and **Tip Holder Assembly** from the refrigerator. Test run must begin within 30 minutes or store **Utility Tray** at < 8 °C until ready for testing.
    a. **Note**: The **Test Cartridges** and other consumables are color coded for each specific test.
        i. **BC-GP** consumables are coded **Purple.**
        ii. **BC-GN** consumables are coded **Red.**
4. Check the expiration dates. Do not use expired cartridges or other consumables.

Figure 1.

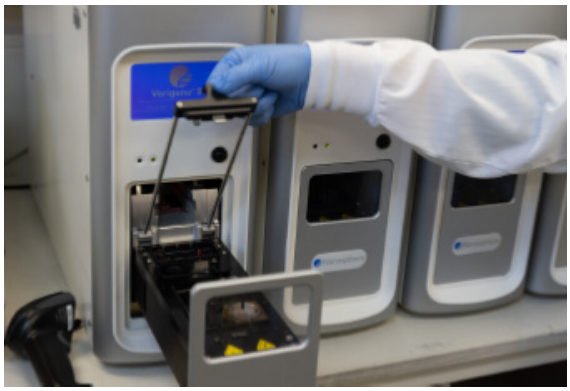

Figure 2.

Step 2

Load Consumables onto the Processor

1. Open the **Drawer Clamp** by pressing the silver latch and then lift the latch prior to loading. **Figure 2**.
2. Load the **Extraction Tray** into the **Drawer Assembly** in the space closest to the **Drawer Door**. **Figure 3**. This tray can only be loaded in one direction and, when loaded correctly, the sample well is in the front right-hand corner. Press the tray down on all four corners to ensure it is secure and level.
3. Load the **Tip Holder Assembly**. This is placed just above the **Extraction Tray**. **Figure 4**. The **Tip Holder Assembly** can only be inserted in one direction. Ensure that the **O-Rings** on both pipette tips and that the **Tip Seal** are secure prior to insertion.
4. Load the **Utility Tray**.
   BC-GP Control Test Only: Remove and save the cap from the *B. subtilis* **Process Control (PC) Tube** and fully insert the PC tube in to the **Utility Tray**. Insert the **Utility Tray** into the **Drawer Assembly**. This can be loaded in only one direction. Make sure the tray is flat.

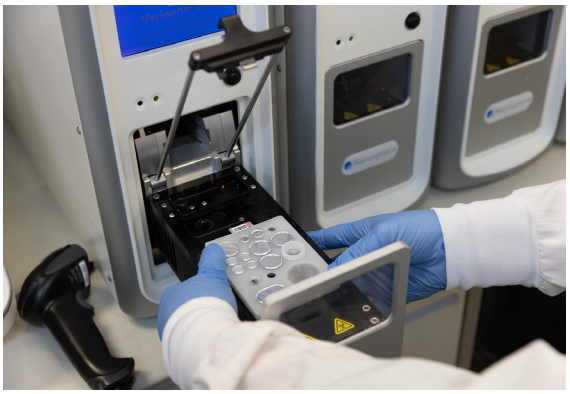

Figure 3.

5. Lower and latch the **Drawer Clamp** without pushing the silver latch. **Figure 5**.

Step 3

Prepare Control Mix

1. Remove the vial from the box. If stored in the refrigerator, warm controls to room temperature before use.
2. Mix each control vial by vortexing for 30 seconds or by inversion until all cellular material is visibly resuspended. **Figure 6**.
3. Verify resuspension of the control by checking the bottom of the tube and ensuring there is no visible cellular material settled.
4. Immediately prior to loading the control sample, mix by pipetting the controls 5 to 10 times. No visible cellular material should be settled at the bottom of the vial.

Step 4

Load Control Mix

1. **Loading the controls onto the Extraction Tray. Figure 7 (BC-GP shown).**
   - BC-GP Control Tests Only: Pipette 350 uL of control from the vial into the bottom of the **Sample Well** in the **Extraction Tray**.
   - BC-GN Test: Pipette 700 uL of control from the vial into the bottom of the **Sample Well** in the **Extraction Tray**. Cover the **Sample Well** with a **Sample Cap** and snap into place. **Figure 8**.

Figure 4.

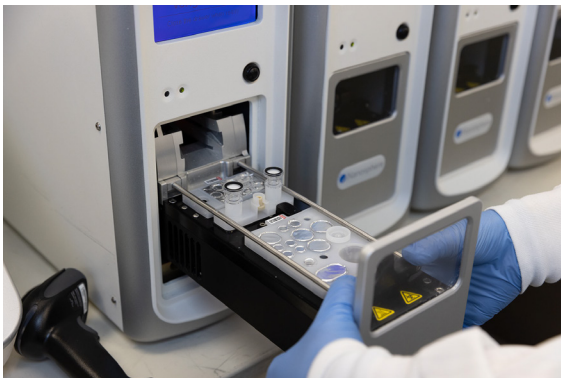

Figure 5.

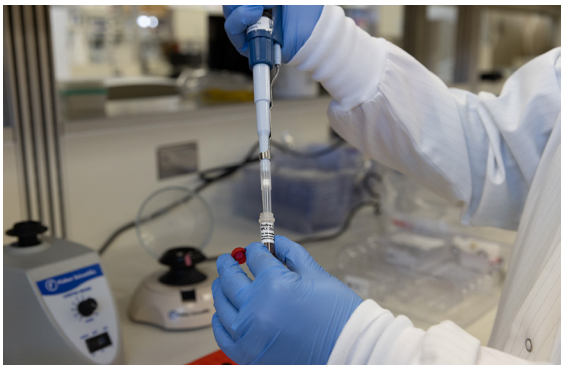

Figure 6.

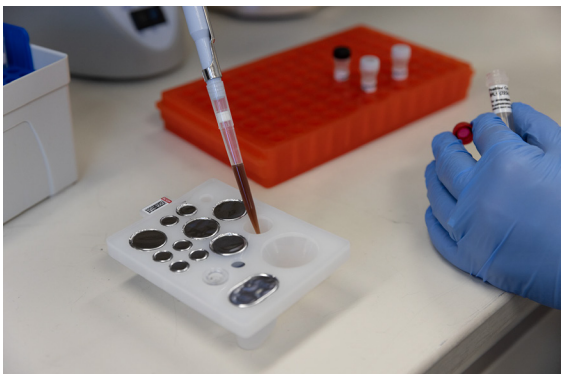

Figure 7.

Step 5

Preparing and Loading the Test Cartridge

1. All tests must be ordered through a VERIGENE® **Reader** that is connected to a VERIGENE **Processor**. Follow the instructions in the VERIGENE System Quick Reference Guide for the VERIGENE Blood Culture Nucleic Acid Test (BC-GP or BC-GN).
2. Enter the **Test Cartridge ID** by scanning the barcode with the handheld scanner attached to the reader or manually entering this information. **Figure 9**.
3. Scan the **Test Cartridge Cover** 2D barcode using the scanner. **Figure 10**.
4. Hold the **Test Cartridge** by the handle with one hand and use the other hand to bend away the cartridge cover. **DO NOT REMOVE** until immediately prior to inserting the **Test Cartridge** into the **Processor**.
5. Insert the **Test Cartridge** into the **Hybridization Module** or the VERIGENE **Processor** until it reaches its stopping point. **Figure 11**.
6. Close the **Processor Drawer** by pressing the OPEN/CLOSE Button.
7. At the **Reader** either scan the control information using the barcode reader or enter the information manually on the touch screen.
8. **Run test in QC Mode**.

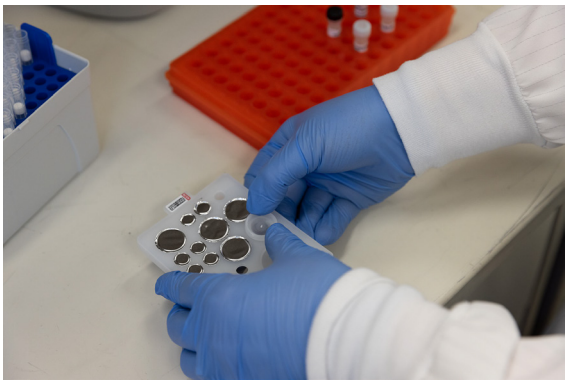

Figure 8.

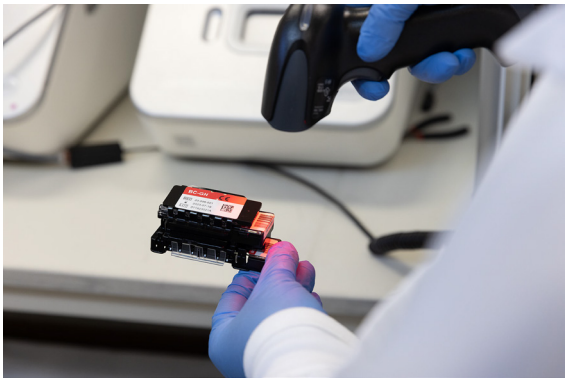

Figure 9.

Figure 10.

Figure 11.

Step 6

Post Test Run Analysis

1. The VERIGENE® **Reader** will ring to notify the user when the test is completed and the **Processor** will display a test completion message.
2. Open the **Drawer Assembly** by pressing the OPEN/CLOSE button. **If testing BC-GP Control Test Only**: Cap the PC tube for disposal.
3. Remove the **Test Cartridge** and immediately orient it on its side.
4. While keeping test cartridge on its side, separate the **Reagent Pack** from the **Substrate Holder**. **Figure 12.**
5. Remove the protective tape from the back of the **Substrate Holder**. **Figure 13.**
6. Scan the **Substrate Holder** barcode and immediately insert it into the **Reader**. **Figure 14**.
7. The barcode will be scanned again in the **Reader**, and the analysis will begin.

Please refer to these IFUs for more information:
Streck MDx-Chex® for BC-GP, #350787
Streck MDx-Chex® for BC-GN, #350788

Figure 12.

Figure 13.

Figure 14.