

MDx-Chex[®] for BCID2 Best Practices Guide

For Use with the BIOFIRE[®] Blood Culture Identification 2 (BCID2) Panel on the FilmArray[®] 2.0 and Torch Systems

Step 1

Prepare Pouch

1. Thoroughly clean the work area and the Pouch Loading Station with freshly prepared 10% bleach (or suitable disinfectant) followed by a distilled water rinse.
2. Remove the pouch from its vacuum-sealed package by tearing or cutting the notched outer packaging and opening the protective canister. **Figure 1.**
3. Check the expiration date on the pouch. Do not use expired pouches.
4. Insert the pouch into the Pouch Loading Station, aligning the red and blue labels on the pouch with the red and blue arrows on the Pouch Loading Station, **Figure 2.**
5. Place a red-capped Sample Injection Vial into the red well of the Pouch Loading Station.
6. Place a blue-capped Hydration Injection Vial into the blue well of the Pouch Loading Station.

Step 2

Hydrate Pouch

1. Unscrew the Hydration Injection Vial from the blue cap.
2. Remove the Hydration Injection Vial, leaving the blue cap in the Pouch Loading Station.
3. Insert the Hydration Injection Vial's cannula tip into the pouch hydration port located directly below the blue arrow of the Pouch Loading Station, **Figure 3.**
4. Forcefully push down in a firm and quick motion to puncture seal until a faint "pop" is heard and there is an ease in resistance. Wait as the correct volume of Hydration Solution is pulled into the pouch by vacuum.
 - If the hydration solution is not automatically drawn into the pouch, repeat #4 to verify that the seal of the pouch hydration port was broken. If hydration solution is again not drawn into the pouch, discard the current pouch, retrieve a new pouch, and repeat from *Step 1: Prepare Pouch.*
5. Verify that the pouch has been hydrated.
 - Flip the barcode label down and check to see that fluid has entered the reagent wells (located at the base of the rigid plastic part of the pouch). Small air bubbles may be seen.
 - If the pouch fails to hydrate (dry reagents appear as white pellets), repeat Step 4 to verify that the seal of the pouch hydration port was broken. If hydration solution is still not drawn into the pouch, discard the current pouch, retrieve a new pouch, and repeat from *Step 1: Prepare Pouch.*



Figure 1



Figure 2



Figure 3

Step 3

Mix the Controls

1. Remove the vials from the box. If stored in the refrigerator, warm controls to room temperature before use.
2. Vortex each for 30 seconds, **Figure 4**.
3. Invert them 10 times to complete mixing, **Figure 5**. Alternatively, mix by pipetting the controls 5 to 10 times.
4. Verify resuspension of the control by checking the bottom of the tube and ensuring there is no visible cellular material settled.
5. Flash spin the controls in a microfuge for a few seconds.

Step 4

Prepare Control Mix

1. Add Sample Buffer to the Sample Injection Vial.
 - Hold the Sample Buffer ampoule with the tip facing up and facing away from user.
 - Firmly pinch at the textured plastic tab on the side of the ampoule until the seal snaps.
 - Invert the ampoule over the red-capped Sample Injection Vial and dispense Sample Buffer using a slow, forceful squeeze followed by a second squeeze, taking care to avoid squeezing bubbles into the sample injection vial on the second squeeze. **Figure 6**.
2. Using a pipette, withdraw 200 μ L of the Streck MDx-Chex for BCID2 control mix, 1 or 2, from the vial, taking care to avoid the formation of bubbles.



Figure 4



Figure 5



Figure 6

Please refer to the Streck MDx-Chex for BCID2 Instructions for Use, #350766.

3. Add control mix directly to Sample Buffer in the Sample Injection Vial. Discard pipette tip in an appropriate biohazard container and tightly close the lid of the Sample Injection Vial, **Figure 7**.
4. Remove the Sample Injection Vial from the Pouch Loading Station and invert the vial at least 10 times to mix.
5. Return the Sample Injection Vial to the red well of the Pouch Loading Station.

Step 5

Load Control Mix

1. Slowly twist to unscrew the Sample Injection Vial from the red cap and wait for 5 seconds with the vial resting in the cap.
2. Lift the Sample Injection Vial, leaving red cap in the well of the Pouch Loading Station, and insert the Sample Injection Vial cannula tip into the pouch sample port located directly below the red arrow of the Pouch Loading Station, **Figure 8**.
3. Forcefully push down in a firm and quick motion to puncture seal (a faint “pop” is heard) and sample is pulled into the pouch by vacuum, **Figure 9**.
4. Verify that the sample has been loaded.
 - Check to see that fluid has entered the reagent well next to the sample loading port.
 - If the pouch fails to pull sample from the Sample Injection Vial, the pouch should be discarded. Retrieve a new pouch and repeat from *Step 1: Prepare Pouch*.
5. Discard the Sample Injection Vial and the Hydration Injection Vial in the appropriate biohazard sharps container.
6. Record the Control Vial ID (Control 1 or Control 2) in the provided area on the pouch label and remove the pouch from the Pouch Loading Station.

Step 6

Run Pouch

1. Follow the BIOFIRE® FilmArray® Operating Instructions for scanning the control label barcode.
2. Insert the pouch into the Instrument as described and start run.



Figure 7



Figure 8



Figure 9