1: Add 50 μL of Assay Control II into Lysis Tube.

2: Add 150 μL of sample to Lysis Tube containing Assay Control II.

3: Perform specimen extraction per package insert. Collect extracted DNA in Elution Tube.

4: Heat the Elution Tube at 95 C for 10 minutes. Centrifuge for 10 seconds.

5: Add 75 μL of Reaction Buffer II to a clean Screw-top Tube.

6: Add 75 μL of heat treated DNA to Screw-top Tube. Vortex for 10 seconds.

7: Using a new pipette tip for each, transfer 50 μL of the diluted specimen to the TEST and CONTROL chambers of the illumigene® Test Device.

8: Close and fasten the latch securely. Gently tap device to remove air bubbles trapped on the bottom of the tubes. Carefully examine reaction tubes to ensure that there are no air bubbles left in tube.

9: Insert illumigene® Test Device into the illumipro-10™ and initiate amplification reaction and detection.