

MOBILEDETECT BIO

BCC19 Test Quick Start Guide

All items included in the testing kit are color coded to match the steps below.

NOTE: This guide is NOT a replacement for reading the User Manual.

1

COLLECT SAMPLE

- NOTE: Items used in all steps are color coded for ease of use.
- Utilize proper Personal Protective Equipment (PPE) in accordance with federal, state and local restrictions.
- Using a viral sample collection kit, collect sample(s) utilizing CDC Guidelines for sample collection on their website at www.cdc.gov.*
- Place collected swab sample(s) in viral transfer medium (VTM) fluid container, break swab off and close top tightly.



STEP 1

* The MD-Bio BCC19 Assay has been validated with NP swabs.

2

PREPARE TEST

- Place tube strip and Reagents 1&2 in prep stand for this step.
 - Dispense 12.5µL of Reagent 1 into test tube(s). *Throw away tip after every dispensation.*
 - Dispense 11.5µL of Reagent 2 into test tube(s). *Throw away tip after every dispensation.*
- NOTE: You will now apply patient samples; it is recommended to do this in an entirely different room from where Reagent 1 & 2 were deposited.**
- Lightly agitate then dispense 1µL of VTM from collected sample into test tube. *Throw away tip after every dispensation.*
 - NOTE: Each collected sample must be dispensed in one tube only for unique test results, replacing pipette tip between each unique VTM sample.
 - Firmly place tube strip lid on tube(s) after collected samples have been dispensed.



STEP 2

** Refer to IFU document for recommended test controls.

3

RUN TEST

- Place test tube(s) in the MD-Bio Heater or Approved Thermal Cycler and close the lid.
 - Press SELECT button on MD-Bio Heater to begin test. (Press twice if device is in sleep mode).
- NOTE: If using an alternate thermal cycler, use the following settings:
- Cycle time: 30 minutes
 - Sample Temperature: 65°C
 - Lid Temperature: 95-105°C
 - Sample Volume: 25µL
- Test is finished on MD-BIO Heater when device emits a continual series of beeps and green and amber lights are blinking. Press SELECT button to return heater to standby mode.

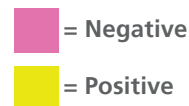


STEP 3

4

ANALYZE RESULTS

- Open lid on MD-Bio Heater and remove the test tube strip.
- Place test tube strip in MD-Bio Analysis Station, making sure to fully insert it into the stand.
- Review color change(s) on each individual test tube.



For Automated Detection, download the MobileDetect App on the Apple App or Google Play store and follow the on screen instructions and tutorials.



STEP 4