

Sample

- Whole blood or plasma
- EDTA – Purple Top Tube
- Perform test within **24 hours** of sample draw.
If this is not possible, spin down and store plasma –20°C until tested.
- Avoid short draws** – fill tube 90% full – within 10% of draw line.
- DO NOT use a blood sample that contains clots.
- DO NOT use a severely hemolyzed sample.

Test

- Test devices are stored refrigerated at 2°C to 8°C. Once removed from refrigerator, the test is stable for up to **14 days** at room temperature, but not beyond expiration date.
- Prior to performing test, allow a minimum of **15 minutes** for test to reach room temperature, while sealed in foil pouch.
- Remove test device from foil pouch **JUST PRIOR** to performing test.
- Write **Patient ID** and **Time** of Inoculation on the device.
- Aspirate **EDTA whole blood or plasma** into the pre-measured transfer pipette. Fill pipette completely with some sample going into smaller (lower bulb).
- Add sample to the sample port of the device. Allow sample to absorb into the filter.
- After sample is added to the port, the device must be inserted into the meter within **30 minutes**.

Meter

- Select RUN TEST from meter main menu ↩
- Enter USER ID ↩
- Select PATIENT SAMPLE ↩
- Enter PATIENT ID ↩
- Confirm PATIENT ID ↩
- If an error is made when entering either USER ID or PATIENT ID, press DELETE key 🗑 and re-enter.
- Insert device into the meter until you hear a “click” and feel resistance. ↩
- Results are displayed on LCD screen and printed in 15-20 minutes.
Abnormal results will be highlighted in black and a “Results Abnormal” message will appear.
- Results can be recalled and printed from the meter.

QC

- QC Device
 - Run daily (every 24 hours)
- External Controls (2)
 - Run on every new lot, every new shipment, and every 30 days thereafter.
- Calibration Verification Controls (5)
 - If needed, typically every 6 months



Code Chips Modules

- Provided with each test kit and each external control.
- Insert code chip module into meter for every new lot of test kits and for every new lot of external controls.

Please refer to Package Insert for complete product procedure.