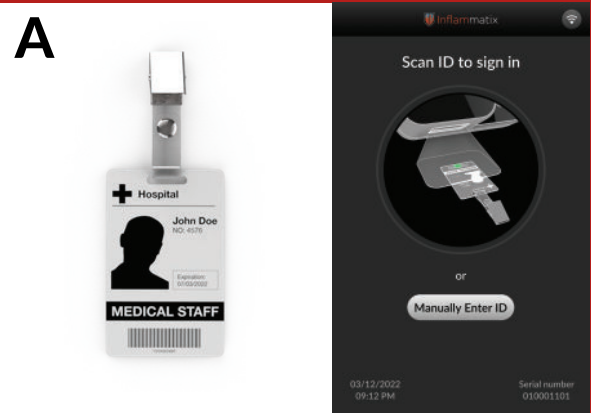
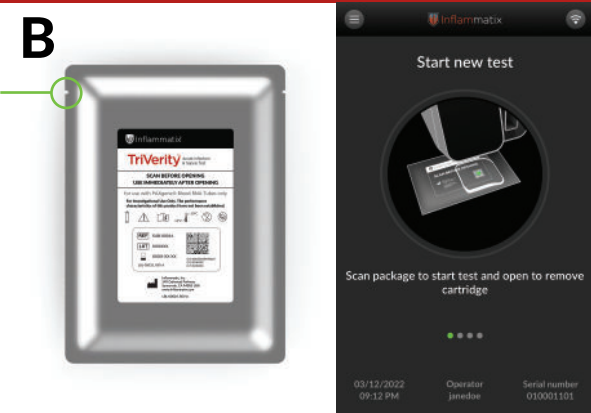


I. Test Procedure

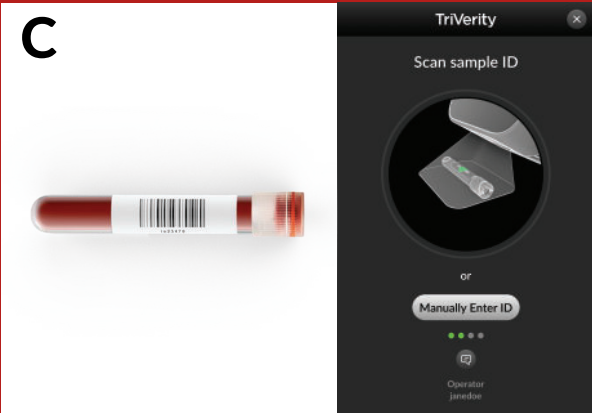
Approx. 2 minutes



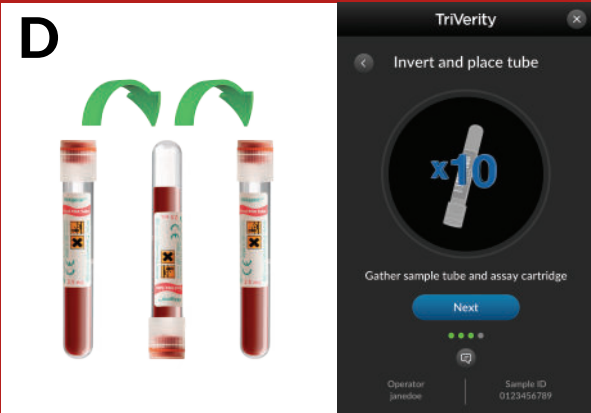
To be granted access to the software on the instrument, enter a user ID either manually or by scanning an ID badge via the front-facing instrument scanner.



Scan the TriVerity Cartridge foil pouch barcode via the front-facing instrument scanner to register the test type on the Inflammatrix Instrument. Using the tear notch, carefully open the cartridge foil pouch and remove the cartridge.



Enter sample ID either manually or by scanning a previously applied barcode label on the PAXgene Blood RNA Tube via the front-facing instrument scanner.



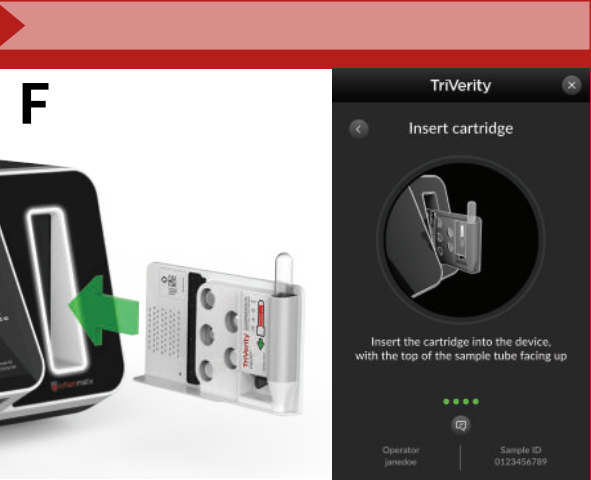
Gently invert the PAXgene Blood RNA Tube 10 times to ensure a good mixture of whole blood and PAXgene buffer.

Note: the figure above depicts a single inversion that needs to be repeated 10 times.

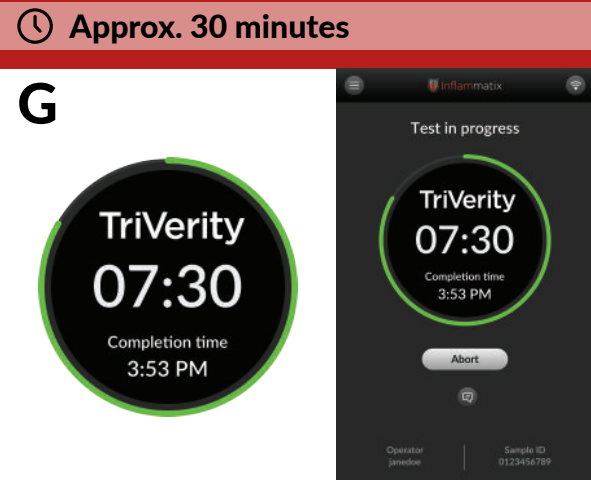


Insert the PAXgene Blood RNA Tube into the cartridge opening, cap side first, applying pressure until a click is heard and felt.

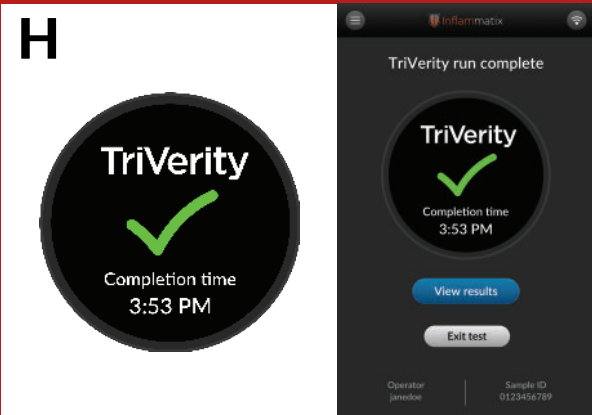
Press the NEXT button on the instrument screen.



When the instrument is ready, the door will open, and the solid white light will flash. Place the cartridge into the doorway of the instrument with the label side facing the screen, as shown in the figure above. Gently advance the cartridge until the instrument pulls it in.

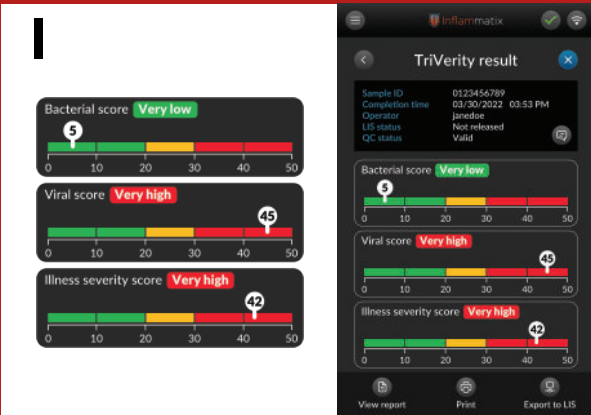


A countdown (approximately 30 minutes) is shown onscreen to provide time remaining until the completion of the test. Fully automated extraction and processing of the sample from the PAXgene Blood RNA Tube takes place within the instrument at this time.



Once a test is complete, a completion confirmation screen is presented. The green light pulses to signify test complete.

Select VIEW RESULTS.



Results are available on the instrument screen for reporting and will be output to a printer for study records.

To exit the test and eject the TriVerity Cartridge from the Inflammatrix Instrument:

1. Select the blue X (exit) button in the upper-right corner -or-
2. Press the back arrow button in the upper-left corner to return to the Test Complete screen then select the EXIT TEST button.



When EXIT TEST is selected, the light pulses white while the cartridge is ejected. Gently remove the cartridge from the Inflammatrix Instrument. The light returns to static white.

II. Post-Test Procedure

1. Remove the PAXgene Blood RNA tube from the TriVerity Cartridge.
2. As soon as immediately possible (in accordance with PAXgene labeling from time of collection) freeze leftover sample upright in a wire rack at approximately -80°C, for later shipment to sponsor.
3. **Do not freeze tubes upright in a Styrofoam tray as this may cause the tubes to crack.**
4. Treat the TriVerity Cartridge as biohazardous waste and disposed of in accordance with local and federal regulations.

Quality Control

The TriVerity External Quality Control is run in a similar manner as the subject sample but requires a TriVerity External Quality Control Kit. Refer to the TriVerity External Quality Control Kit Quick Reference Guide for the exact procedure and for more information on running and discarding external quality controls.



Run external controls one time per month or per cartridge lot; whichever comes first. For more information refer to the full TriVerity Instructions for Use.



If an external control fails, run a new test with a fresh control kit and cartridge. If the repeat test fails, please contact your Study Coordinator.



Inflammatix™

TriVerity™

Acute Infection
& Sepsis Test

Quick Reference Guide

Thoroughly review this entire document before proceeding.



For Investigational Use Only. The performance characteristics of this product have not been established.



Inflammatix™



For more information refer to the full TriVerity Instructions for Use.



Inflammatix, Inc
540 Oakmead Parkway
Sunnyvale, CA 94085, USA
www.inflammatix.com

Materials Supplied
in Test Kit



TriVerity™ Cartridge

Additional Materials
Required



PAXgene® Blood
RNA Tube



Inflammatix™ Instrument

Materials Required
but Not Supplied



Medical Gloves



Biohazardous
Waste Bin

Warnings ⚠

1. For investigational use only.
2. Always wear gloves while handling samples and cartridges. Change gloves that come in contact with any specimen or that appear to be wet, to avoid contaminating other specimens.
3. Change gloves before leaving work areas and upon entry into work areas.
4. Prepare the sample and TriVerity Cartridge on a clean, level surface.
5. Keep the work area clean according to your institution's policies.
6. Do not use the TriVerity Cartridge past its expiration date.
7. The TriVerity Cartridge is for single use only; do not reuse.
8. Leave the TriVerity Cartridge sealed in the foil pouch until just before use.
9. Do not use the PAXgene Blood RNA Tube and/or TriVerity Cartridge if either appears damaged or opened.
10. Do not use the TriVerity Cartridge if its foil pouch has been ripped or pierced.
11. Do not use the PAXgene Blood RNA Tube and/or TriVerity Cartridge if either has been dropped.
12. Do not tamper with the TriVerity Cartridge.
13. Do not stick fingers or other foreign objects into the TriVerity Cartridge openings.
14. Do not shake or tilt the TriVerity Cartridge after adding a sample.
15. The TriVerity Cartridges should only be used with PAXgene Blood RNA Tubes and TriVerity External Quality Control Kit Tubes.
16. Do not place any type of barcode on the cartridge.
17. When the Inflammatix Instrument cartridge door is open, do not insert objects other than a TriVerity Cartridge. Doing so can damage the Inflammatix Instrument.

Storage & Handling

1. Store TriVerity Cartridges between 59°F and 86°F (15°C and 30°C), 20% to 80% relative humidity. Do not freeze. In case of exposure to cold temperatures, ensure that the TriVerity Cartridge is allowed to fully come to at least minimum operating temperature of 59°F (15°C) prior to use.
2. Biohazardous waste containers for used cartridges should be located near the test area.
3. Keep the work area clean and dry to prevent contamination.
4. Ensure the PAXgene Blood RNA Tube cap is secure prior to inverting the specimen.
5. Run the TriVerity Test at room temperature between 59°F and 86°F (15°C and 30°C), and at a humidity level between 20-80%.
6. Remove the PAXgene Blood RNA Tube from the used cartridge and store remaining sample according to the instructions in Section II: Post-Test Procedure.
7. TriVerity Cartridges should be disposed of in accordance with local and federal regulations.
8. Treat all biological specimens, including used TriVerity Cartridges and PAXgene Blood RNA Tubes as capable of transmitting infectious agents. Because it is often impossible to know which may be infectious, all biological specimens should be treated with standard bloodborne pathogen precautions.