Inflammatix™

TriVerity™

Acute Infection
& Sepsis Test

External Quality Control

Quick Reference Guide

Thoroughly review this entire document before proceeding.

CONTROL

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

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

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LBL-00018, REV B

Materials Supplied in Test Kit

TriVerity™ External Quality Control Kit Pouch

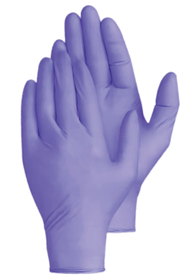
TriVerity™ External Quality Control Tube

Additional Materials Required

TriVerity™ Cartridge

Inflammatix™ Instrument

Materials Required but Not Supplied



Medical Gloves

Warnings

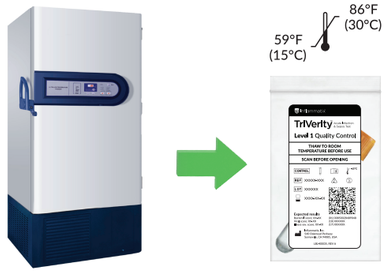
1. For investigational device use only.
2. Always wear gloves while handling samples and cartridges. Change gloves that come in contact with any specimen or appear to be wet, to avoid contaminating other specimens.
3. Change gloves before leaving work areas and upon entry into work areas.
4. Prepare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

Storage & Handling

1. Store TriVerity Quality Control Kits at -112°F (-80°C).
2. Allow TriVerity Quality Control Kits to thaw to room temperature for a minimum of 1 hour, but for no more than 24 hours.
3. Keep the work area clean and dry to prevent contamination.
4. Run the TriVerity External Quality Control Kit at room temperature between 59°F and 86°F (15°C and 30°C) and at a humidity level between 20-80%.
5. Ensure that the TriVerity External Quality Control Kit Tube cap is secure prior to inverting.
6. If the TriVerity External Quality Control Tube is dropped, examine the tube carefully before use. If the TriVerity External Quality Control Kit Tube appears damaged or soiled, discard, prepare a fresh kit, and restart the test setup workflow.
7. TriVerity External Quality Control Kits do not contain any material of human or animal origin.
8. The TriVerity Cartridge and TriVerity External Quality Control Tube should be disposed of in accordance with local and federal regulations.

I. Pre-Test Prep

Minimum 1 hour

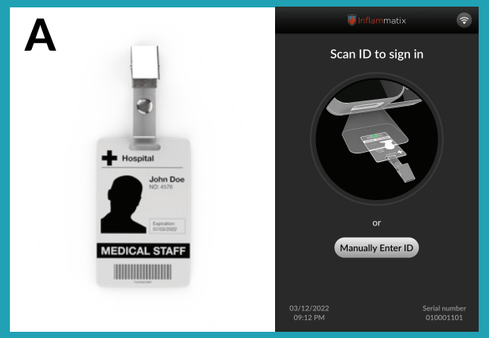


Retrieve the appropriate level of quality control kit from -112°F (-80°C) storage and allow it to thaw to room temperature for a minimum of 1 hour, but for no more than 24 hours. The sample should not be run until it reaches 59°C (15°C).
Note: The procedure should be repeated if more than one level of control is to be processed.

II. Test Procedure

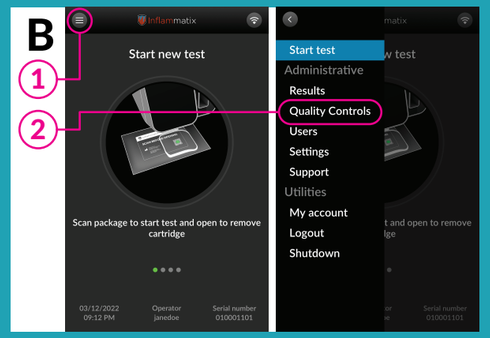
Approx. 2 minutes

A



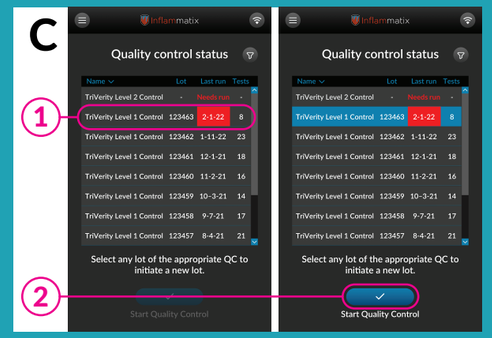
To be granted access to the software on the instrument, enter a user ID either manually or by scanning an ID badge via the front-facing instrument scanner.

B



1. Select the menu button in the upper left corner of the screen.
2. Select QUALITY CONTROLS from the list of options to navigate to the Quality Controls menu.

C

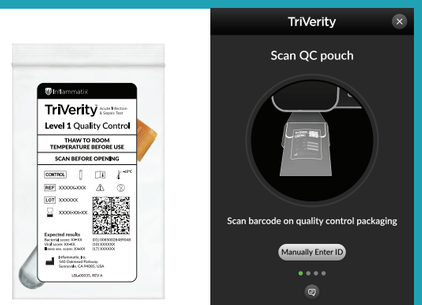


1. Select the desired quality control from the list shown.
2. Select the START QUALITY CONTROL button.

D

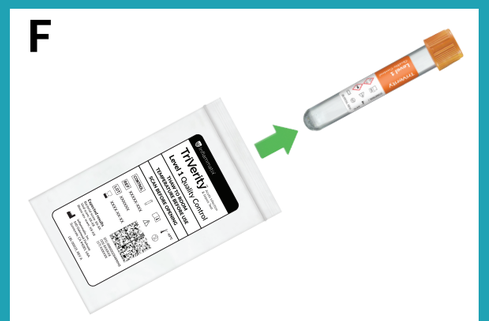
Scan the TriVerity Cartridge foil pouch barcode via the front-facing instrument scanner to register the test type on the Inflammatix Instrument. Using the tear notch, carefully open the cartridge foil pouch and remove the cartridge.

E



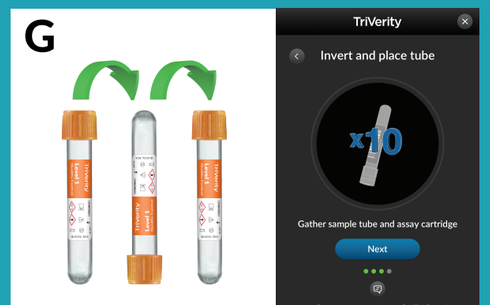
Scan the TriVerity External Quality Control Pouch barcode via the front-facing instrument scanner to register the level of external quality control on the Inflammatix Instrument.

F



Open the TriVerity External Quality Control Kit Pouch and remove the TriVerity External Quality Control Tube. Visually inspect the tube to ensure that the contents are fully thawed to room temperature.

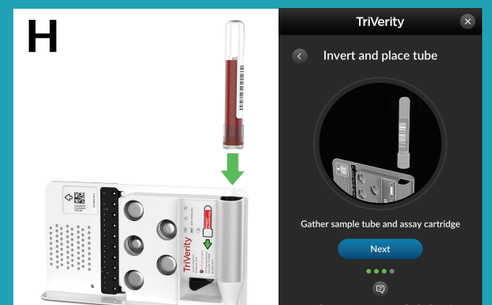
G



Gently invert the TriVerity External Quality Control Tube 10 times to ensure that the contents are completely mixed.

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

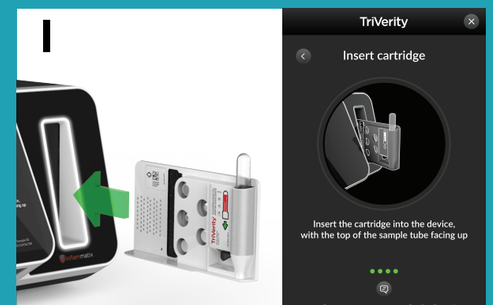
H



Insert the TriVerity External Quality Control 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.

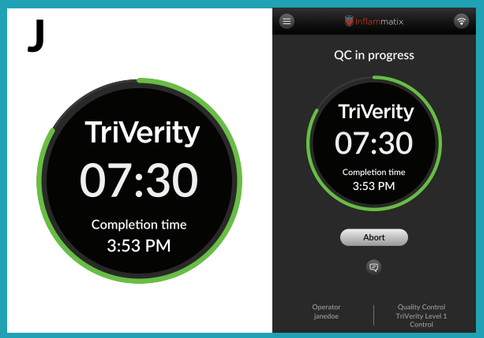
I



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

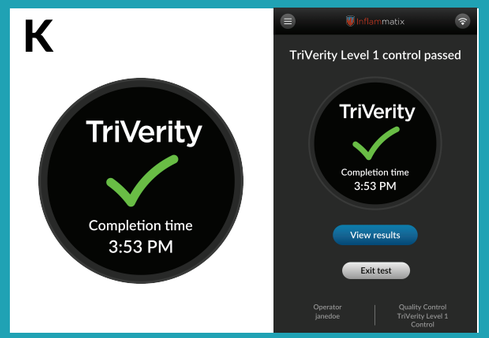
Approx. 30 minutes

J



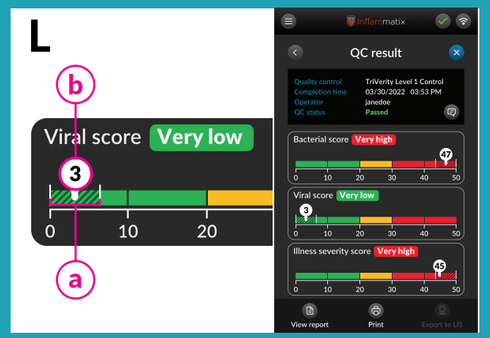
A countdown (approximately 30 minutes) is shown onscreen. Fully automated extraction and processing of the sample from the TriVerity External Quality Control Tube takes place within the instrument at this time.

K



Once a quality control procedure is complete, a completion confirmation screen is presented. The green light pulses to signify test complete.
Select VIEW RESULTS.

L



Results are available at the instrument screen. A passing range (a), 0-6 in the example, is shown within which a score (b) must fall to qualify as passing.

M

Press EXIT TEST. The light pulses white while the cartridge is ejected.
Gently remove the cartridge from the Inflammatix Instrument. The light returns to static white.

III. Post-Test Procedure

1. The procedure should be repeated if more than one level of control needs to be processed.
2. The TriVerity Cartridge containing the TriVerity External Quality Control Tube is not biohazardous waste and does not need to be treated or disposed of as such.
3. Dispose of TriVerity Cartridge containing the TriVerity External Quality Control Tube per local and federal regulations.
4. Run external controls one time per month or per cartridge lot; whichever comes first. For more information refer to the TriVerity IFU.
5. If an external control fails, re-run with a fresh QC kit and cartridge. If this repeat test fails, contact your Inflammatix Study Coordinator.