Inflammatix

TriVerity™ Acute Infection & Sepsis Test

INSTRUCTIONS FOR USE

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

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

Test Name

Inflammatix™ TriVerity™ Acute Infection & Sepsis Test

Common or Usual Name
TriVerity™

1. Main Characteristics of TriVerity Acute Infection & Sepsis Test

Investigational TriVerity Overview	
Manufacturer	Inflammatix, Inc 540 Oakmead Parkway Sunnyvale, CA 94085 USA
CE-marked	No
Sample Input	1 PAXgene® Blood RNA Tube (IVD)* (single patient sample per test)
Cartridge Expiration	As stated on Cartridge packaging
Instrument Size and weight	Dimensions: 520mm L x 292mm W x 267mm H Weight: 42 lbs.
Cartridge Size and Weight	Dimensions: 195mm L x 26mm W x 109mm H Weight: 5.3 oz. (~150 g)
Calibration scheme	None

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2. Intended Use

The TriVerity Acute Infection and Sepsis Test is an automated, semi-quantitative in vitro diagnostic test that measures the relative expression levels of host response genes in RNA isolated from whole blood collected in the PAXgene Blood RNA tube using reverse transcription loop-mediated isothermal amplification (RT-LAMP) on the Myrna instrument. The results are generated using two fixed classifiers.

The TriVerity Test is indicated for use in conjunction with clinical assessments and other laboratory findings as an aid to differentiate bacterial infections, viral infections, and non-infectious illness, as well as the likelihood of disease progression in adult patients with suspected acute infection or sepsis presenting to the emergency department. The test generates three scores that fall within one of five discrete interpretation bands based on the likelihood of:
1) bacterial infection,
2) viral infection, and
3) severe illness, as defined by the need for critical care within seven days, including mechanical ventilation, vasopressors, or renal replacement therapy (RRT).

The Myrna system is intended for use by trained health professionals in the emergency department or clinical Laboratory setting.

3. Summary and Explanation of the Procedure

The TriVerity system uses automated sample preparation from whole blood collected in PAXgene Blood RNA Tubes cleared by the FDA. The PAXgene Blood RNA Tube is inserted into the single-use, disposable TriVerity Cartridge and together they are loaded into the Inflammatix Instrument. PAXgene blood is automatically pulled from the PAXgene Blood RNA Tube into the TriVerity Cartridge. The TriVerity Cartridge contains everything necessary to perform RNA isolation from the sample and subsequent RT-LAMP detection. The assay is processed only by the Inflammatix Instrument and all waste and amplified material remain sealed within the cartridge after the test is performed. Full sample traceability is maintained through GS1 DataMatrix barcodes.

4. Principles of the Procedure

TriVerity is an in vitro diagnostic test for the simultaneous amplification and detection of 29 mRNA host response genes, 3 housekeeping genes, and 2 process controls using total RNA extracted from human whole blood samples collected in PAXgene Blood RNA Tubes.

TriVerity is performed with a TriVerity Cartridge, a single-use, disposable, multi-chambered fluidic cartridge that has been designed, manufactured, and validated for use only on the Inflammatix Instrument. Following the addition of the sample, all processing steps are automated and occur within the TriVerity Cartridge, including sample extraction/purification, and RT-LAMP for the detection and relative quantification of 29 informative and 3 internal control genes RNA from the entire sample is purified and then split into a series of real-time reaction chambers to enable parallel singleplex reactions. The TriVerity Cartridge contains all the necessary reagents to perform RNA isolation from the sample and subsequent RT-LAMP detection.

Test results are available in approximately 30 minutes. TriVerity produces three clinical scores computed by two classifiers to differentiate bacterial infections, viral infections, and non-infectious illness, as well as the likelihood of a severe clinical outcome. The range of each score is 0 to 50 and is divided into five (5) bands. Test results are available onscreen, can be configured to be output to a local printer, and can be transmitted to a lab information system (LIS).

5. Materials

a. Materials Provided

- Inflammatix Instrument
- TriVerity Cartridge
- PAXgene Blood RNA Tube (with study-specific sample labels)
- TriVerity External Quality Control Kits (Level 1 and Level 2)
- Quick Reference Guide
- Device Description/Profile
- Instructions for Adding a New User

b. Materials Required but Not Supplied

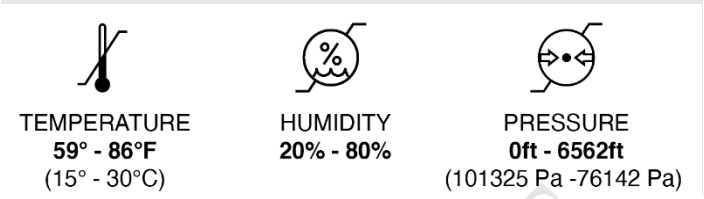
Note: Clinical Study Sites will defer to their Standard Operating Procedures (SOPs) for materials needed to perform a blood draw outside of what is provided by Inflammatix, Inc.

- Suggested Collection kit including the following:
  - Blood collection set such as the BD Vacutainer® Push Button Blood Collection Set or the BD Vacutainer Safety-Lok™ Blood Collection Set
  - Vacutainer Needle Holder to ensure proper function
  - A “Discard Tube” if the PAXgene Blood RNA Tube is the only tube being drawn
  - Alcohol swab for cleansing site
  - Dry sterile gauze
  - Tourniquet
  - Needle disposal container for used needle or needle/holder combination
- Biohazardous waste disposal bin for used cartridges
- Medical gloves

6. Storage and Stability

a. Storage Conditions

Store TriVerity Cartridges between 59°F and 86°F (15°C and 30°C), 20% to 80% relative humidity, non-condensing. 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.



b. Specimen Collection

Use freshly collected specimens for optimal test performance. Inadequate specimen collection or improper sample handling/storage/transport/dilution may yield erroneous results.

Note: Testing should occur within 12 hours of collection.

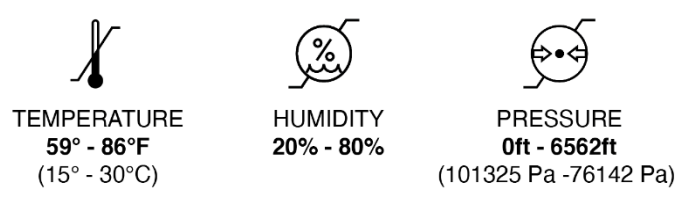
7. Warnings and Precautions

a. General

1. For investigational 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 area 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.

b. The Inflammatix Instrument

6. Operating Conditions: The Inflammatix Instrument should be used between 59°F and 86°F (15°C and 30°C), 20% to 80% humidity, and 0-6562 feet (0 to 2000m, 101325 Pa – 76142 Pa) elevation. Failure to do so may yield invalid results.



7. Use the Inflammatix Instrument only as directed.
8. The Inflammatix Instrument is best used in a room with adequate lighting and away from glare. Failure to do so may result in difficulty during setup and in seeing the test results on screen.
9. Place the Inflammatix Instrument on a level surface and do not move during operation. Failure to do so may yield invalid or inaccurate results.

10. A grounded power outlet is required for operation. In addition, a local surge protector is recommended if the installation site is not set up site-wide for surge protection.
    Note: the internal instrument power supply specifications are as follows ~ Line 100-240 VAC, 50/60 Hz, 9A MAX
11. Do not touch or move the Inflammatix Instrument power cable while a test is running.
12. Do not unplug the Inflammatix Instrument during operation.
13. While color-blind users may be unable to differentiate the Inflammatix Instrument red, green, and white status lights, they can consult the light behavior and information on the screen to determine test status. When interpreting results, the user can consult the location of a colored band and the value presented.
14. If a spill occurs on the Inflammatix Instrument or power cord, power down the instrument, unplug the unit, and wipe it down with 70% ethyl or isopropyl alcohol. Allow the Inflammatix Instrument or power cord to completely dry before continued use.
    The instrument may also be cleaned with:
    - Quaternary ammonium and isopropyl alcohol (e.g., Super Sani-Cloth Wipes)
    - Sodium hypochlorite (5.2% household bleach) up to a 1:10 dilution. Wipe down with water afterward.

    Caution: Do not spray cleaning solution directly onto the instrument.
    Caution: Wipe the exterior of the instrument only; do not attempt to clean the interior of the instrument.

c. TriVerity Cartridge

15. Operating Conditions: TriVerity Cartridges should be stored and used between 59°F and 86°F (15°C and 30°C), 20% to 80% humidity, and 0-6562 feet (0 to 2000m, 101325 Pa – 76142 Pa) elevation. Failure to do so may yield invalid results.

16. Do not freeze TriVerity Cartridges. In case of refrigeration or other exposure to cold temperatures, ensure that they allowed to fully come to at least minimum operating temperature of 59°F (15°C) prior to use.
17. Do not use the TriVerity Cartridge past its expiration date.
18. Use TriVerity Cartridges only as directed.
19. The TriVerity Cartridge is for single use only; do not reuse.
20. The TriVerity Cartridge should only be used with PAXgene Blood RNA Tubes when testing patient samples and with TriVerity External Quality Control Kit Tubes when verifying performance.

21. Leave the TriVerity Cartridge sealed in the foil pouch until just before use.
22. Do not use the PAXgene Blood RNA Tube and/or TriVerity Cartridge if either appears damaged or opened.
23. Do not use the TriVerity Cartridge if its foil pouch has been ripped or pierced.
24. Do not use the PAXgene Blood RNA Tube, TriVerity Cartridge, and/or the external quality control kit if it has been dropped.
25. Do not tamper with the TriVerity Cartridge.
26. Do not stick fingers or other foreign objects into the TriVerity Cartridge openings.
27. Do not shake or tilt the TriVerity Cartridge after adding a sample.
28. Do not place any type of barcode on the cartridge.
29. When the Inflammatix Instrument cartridge door is open, do not insert objects other than the TriVerity Cartridge.
30. Biohazardous waste containers for used cartridges should be located near the test area.
31. Remove the PAXgene Blood RNA Tube from the used TriVerity Cartridge and store remaining sample according to the instructions in Section 9b, Step 14.
32. The TriVerity Cartridge should be disposed of in accordance with local and federal regulations.
33. Treat all biological specimens, including used TriVerity Cartridges, 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 precautions. Follow the guidelines for specimen handling from the Centers for Disease Control (CDC) and Prevention and the Clinical Laboratory Standards Institute and dispose of in the appropriate specimen waste containers according to the Institution's standard practices.
34. If a spill occurs with the TriVerity Cartridge, soak up material with a disposable absorbent pad. Ensure that all liquid has been removed from the spill site before proceeding; failure to do so may result in injury. Dispose of contents/container to an appropriate treatment and disposal facility in accordance with applicable laws and regulations. Change gloves before proceeding.

    Caution: do not mix TriVerity cartridge or TriVerity External Quality control tube contents with bleach.

    Next, apply 10% bleach on the contaminated area and materials and let it rest for at least 15 minutes. Re-wipe down the surface with 70% ethyl or isopropyl alcohol to remove bleach residual. Dispose of contaminated materials such as the absorbent pad, medical gloves, test tube holder, and the TriVerity Cartridge in accordance with applicable laws and regulations according to the Institution's standard practices.

d. Specimen and PAXgene Blood RNA Tube

1. Follow the CDC's guidelines and the Institution's safety procedures for working with chemicals and handling biological samples.
2. Ensure the PAXgene Blood RNA Tube cap is secure prior to inverting the specimen.
3. The PAXgene Blood RNA Tube must be fully inserted into the TriVerity Cartridge, or the test may yield invalid results.
4. Do not use the PAXgene Blood RNA Tube more than 3 times with separate TriVerity Cartridges.
5. Do not use the PAXgene Blood RNA Tube if it appears to be damaged or opened.
6. Follow study lab manual instructions for specimen storage.

e. TriVerity External Quality Control Kit

1. Store TriVerity External Quality Control Kits in a -112°F (-80°C) freezer.
2. Allow the TriVerity Quality Control Kit to thaw to room temperature for a minimum of 1 hour, but for no more than 24 hours.
3. The TriVerity External Quality Control Kit should not be run until it reaches 59°C (15°C).
4. Do not use the TriVerity External Quality Control Kit past its expiration date.
5. The TriVerity External Quality Control Kit is for single use only; do not reuse.
6. Do not use the TriVerity Quality Control Kit if it appears damaged or opened.
7. Ensure that the TriVerity External Quality Control Kit Tube cap is secure prior to inverting.
8. 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.
9. TriVerity External Quality Control Kits do not contain any material of human or animal origin.
10. Use TriVerity External Quality Control Kits only as directed.
11. The TriVerity External Quality Control procedure should be repeated if more than one level of control is to be processed.

8. Inflammatix Instrument Orientation

The parts of the Inflammatix Instrument that a user will need to be acquainted with to successfully perform a test are identified in *Figure 1*.

A. Touchscreen display
B. USB port
C. Power button
D. Scanner beam exit window
E. Cartridge opening
F. LED light ring

Figure 1

9. TriVerity System Instructions for Use

Prior to initial use, ensure operating conditions are met and maintained; workstation is set up on a clean, level surface; and the materials shown in *Figure 2* are present. Follow the instructions carefully and in the order described.

Figure 2

a. Collect the specimen

1. Ensure that the PAXgene Blood RNA Tube is at 59−86° F (18−25° C) prior to use and properly labeled with specimen identification.
2. Collect 2.5ml whole blood directly into the PAXgene Blood RNA Tube using standard phlebotomy practice and institutional standard operating procedures.
3. Immediately after blood collection, gently invert the PAXgene Blood RNA Tube 10 times and follow the instructions for running a test. *Figure 3* depicts a single inversion that needs to be repeated 10 times.

   Note: Testing should occur within 12 hours of collection.

Figure 3

b. <u>TriVerity workflow on the Inflammatix Instrument</u>

The Inflammatix Instrument software guides the user in performing the steps required to start a test.

Step 1. 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.

Figure 4

Step 2. 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 cartridge foil pouch and remove the cartridge.

Figure 5

Step 3. 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.
Note: Testing should occur within 12 hours of collection.

Figure 6

Step 4. Gently invert the PAXgene Blood RNA Tube 10 times to ensure a good mixture of whole blood and PAXgene buffer.
Note: Figure 7 depicts a single inversion that needs to be repeated 10 times.

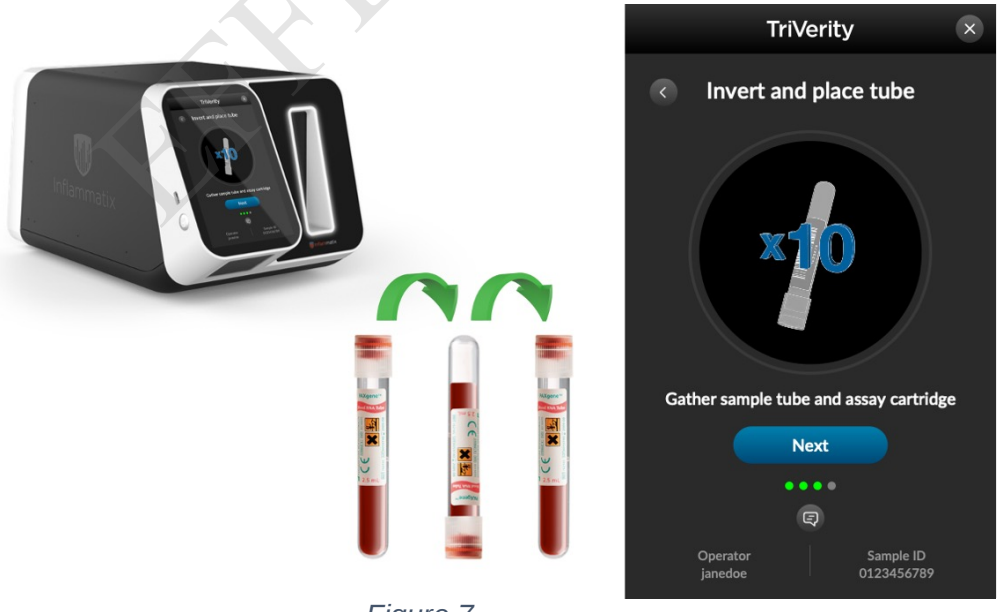


Figure 7

Step 5. 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.

Figure 8

Step 6. 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, as shown in *Figure 9*. Gently advance the cartridge until the instrument pulls it in.

Figure 9

Step 7. 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 during this time.

Figure 10

Step 8. Once a test is complete, a completion confirmation screen is presented. The green light pulses to signify test complete.

Press VIEW RESULTS.

Figure 11

Step 9. Results are available on the instrument screen for reporting and will be printed for study records.

Figure 12

Step 10. To exit the test and eject the TriVerity Cartridge from the Inflammatix Instrument:

A. Press the blue X (exit) button in the upper-right corner
   or
B. Press the back arrow button in the upper-left corner to return to the Test Complete screen then press the EXIT TEST button (as shown in *Figure 11*).

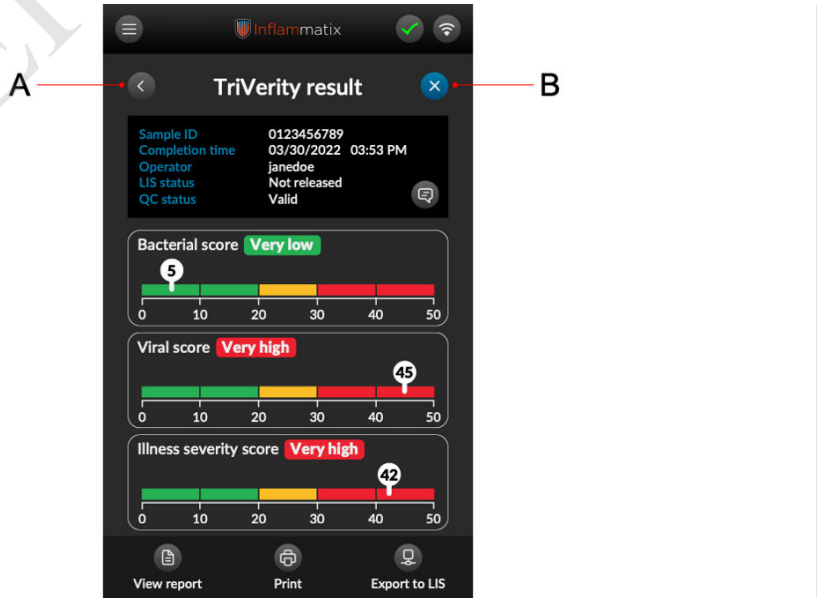


Figure 13

Step 11. The light pulses white while the cartridge is ejected. Gently remove the cartridge from the Inflammatix Instrument. The light returns to static white.

Figure 14

Step 12. Remove the PAXgene Blood RNA Tube from the TriVerity Cartridge.

Figure 15

Step 13. Dispose of the cartridge in an appropriate biohazardous waste disposal bin.

Figure 16

Step 14. Remaining sample within the PAXgene Blood RNA Tube should be immediately stored upright in an approximately -112°F (-80°C) freezer for later shipment to the sponsor.

Do not freeze tubes upright in a Styrofoam tray as this may cause the tubes to crack.

10. Interpretation of Sample Results

TriVerity generates three scores that fall within one of five discrete interpretation bands based on the likelihood of

1) bacterial infection,
2) viral infection, and
3) severe illness, as defined by the need for critical care within seven days, including mechanical ventilation, vasopressors, or renal replacement therapy (RRT).

Information displayed on the instrument test result screen is shown in *Figure 17*.

A. Return to Main Menu
B. Test type
C. Data for this test event
D. External quality control status
E. Likelihood of a bacterial infection
F. Likelihood of a viral infection
G. Likelihood of severe illness
H. View full test results report
I. Return to the Test Complete screen
J. Exit test and trigger ejection of the cartridge
K. Displays (optional) comments entered by the operator
L. Likelihood indicator for a test result
M. Marker displaying the exact numerical score within the range of 0 to 50
N. Five (5) interpretation bands within which a score will fall
O. Export test results to a local printer

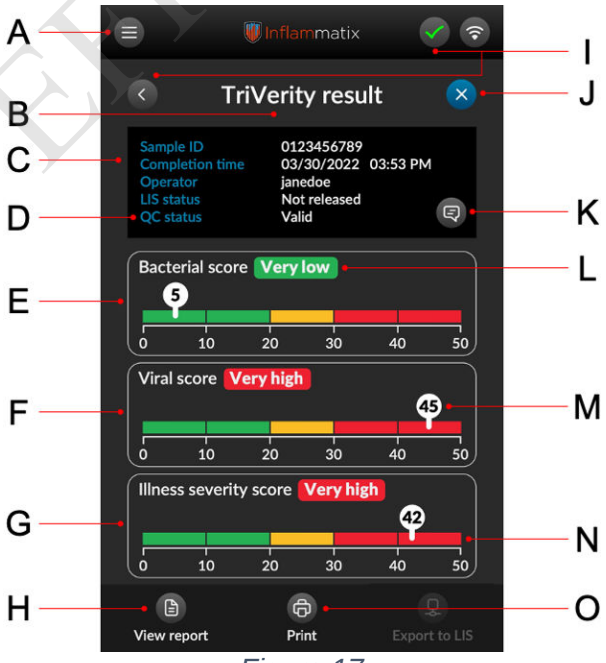


Figure 17

11. Error Handling

Various errors may manifest during interaction with the instrument. The touchscreen display provides indication of the cause and troubleshooting instructions.

Although errors may vary in level of severity and specific type, they are presented to the user in the same manner through the graphical user interface. Errors that arise may require the following actions:

A. Re-start the test with a new cartridge.
B. Reboot the system to start a test.
C. Reboot the system and re-start the test with a new cartridge.
D. Insufficient RNA - check IFU for instructions.
    i. Remove tube, perform the 10x inversion step again (see *Figure 3*), and rerun with a new cartridge.
    ii. Redraw sample and run with new cartridge.
    iii. If the error persists, contact your Study Coordinator.
E. Wait for the instrument to be ready before running the next test.
F. Contact customer support.

Figure 18

Additional indication of an error state is provided by the LED light ring surrounding the cartridge opening, which will illuminate red in color and pulse.

12. Quality Controls

Quality controls ensure that the instrument and cartridges are operating as expected. The TriVerity system has two types of quality controls:

1. **Process Controls**
   Each cartridge has two internal process controls that verify that the RNA extraction and RT-LAMP amplification steps are performing as expected.

2. **External Controls**
   External quality controls ensure that the instrument and cartridges are operating as expected. At the time of use, users will remove a TriVerity External Quality Control Kit from -80°C storage, allow it to thaw to room temperature, and test the mixture in the same way as with a PAXgene blood tube sample. Refer to the TriVerity External Quality Control workflow for additional information on running external quality controls and interpreting results.

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

3. **External Control Types**
   There are two types of external controls (TriVerity External Control Level 1 and Level 2) that need to be run to fully verify instrument performance. Both must be valid to run a test.

4. **External Control Frequency**
   Run external controls one time per month or with each new cartridge lot; whichever comes first.

13. <u>Pre-test Prep</u>

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.

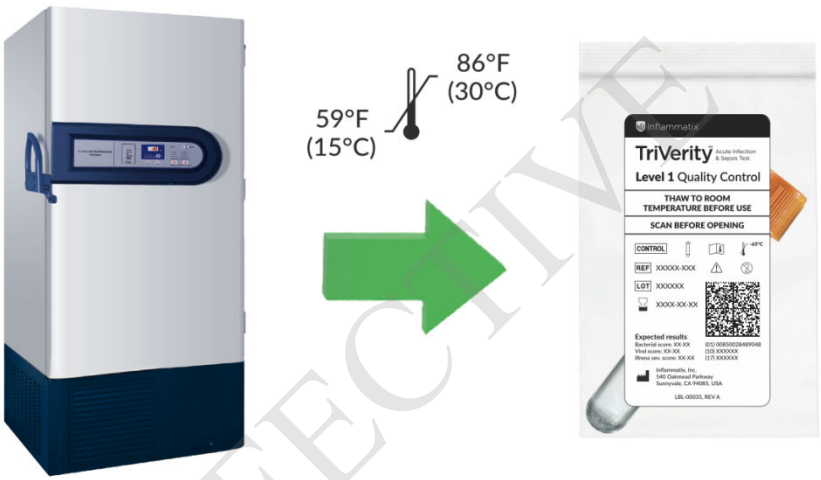


Figure 19

14. External Quality Control workflow

The procedure for running an external quality control is similar to the steps required to run a PAXgene blood sample.

Step 1. Start a Quality Control workflow by doing to following:

A. Select the MENU button in the upper left corner of the screen.
B. Select QUALITY CONTROLS from the list of options.

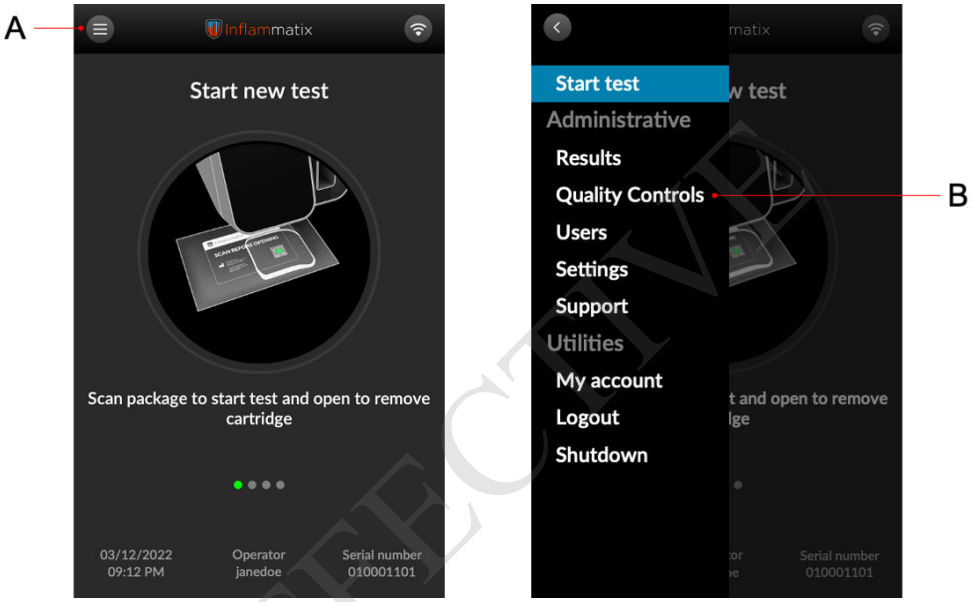


Figure 20

Step 2. Select the desired external quality control:

A. Select the desired quality control from the list shown.
B. Select the START QUALITY CONTROL button.

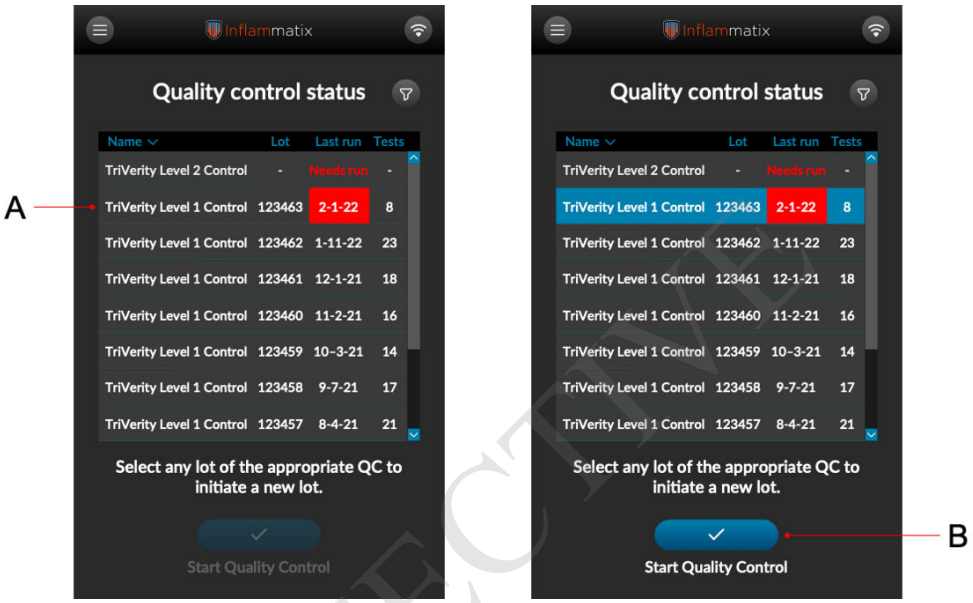


Figure 21

Step 3. 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 cartridge foil pouch and remove the cartridge.

Figure 22

Step 4. 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.

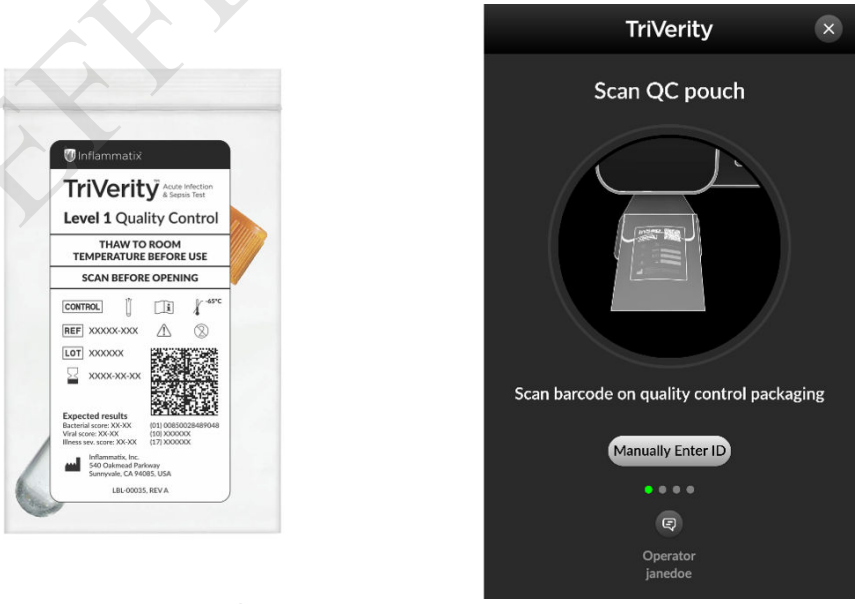


Figure 23

Step 5. 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.

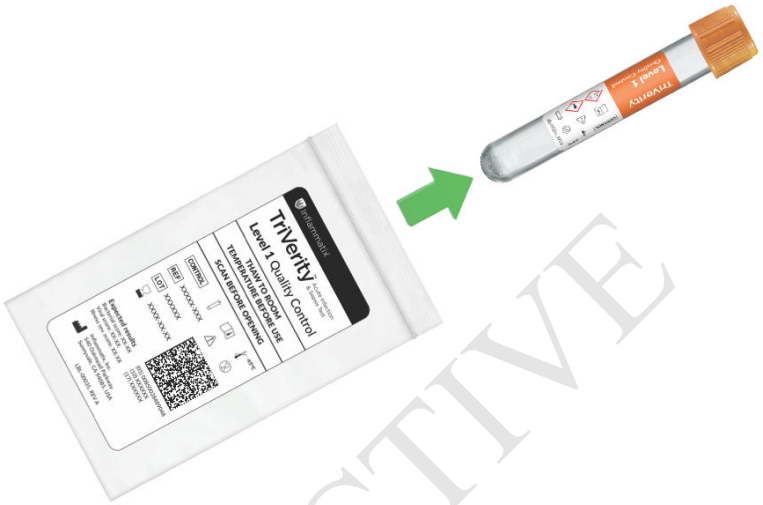


Figure 24

Step 6. Gently invert the TriVerity External Quality Control Tube 10 times to ensure that the contents are completely mixed.

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

Figure 25

Step 7. 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.

Step 8. 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 *Figure 9*. Gently advance the cartridge until the instrument pulls it in.

Step 9. 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 TriVerity External Quality Control Tube takes place within the instrument at this time.

Step 10. Once a quality control procedure is complete, a completion confirmation screen is presented. Select VIEW RESULTS.

A. If an external quality control passes, the sequence of screens in *Figure 26* will be displayed.

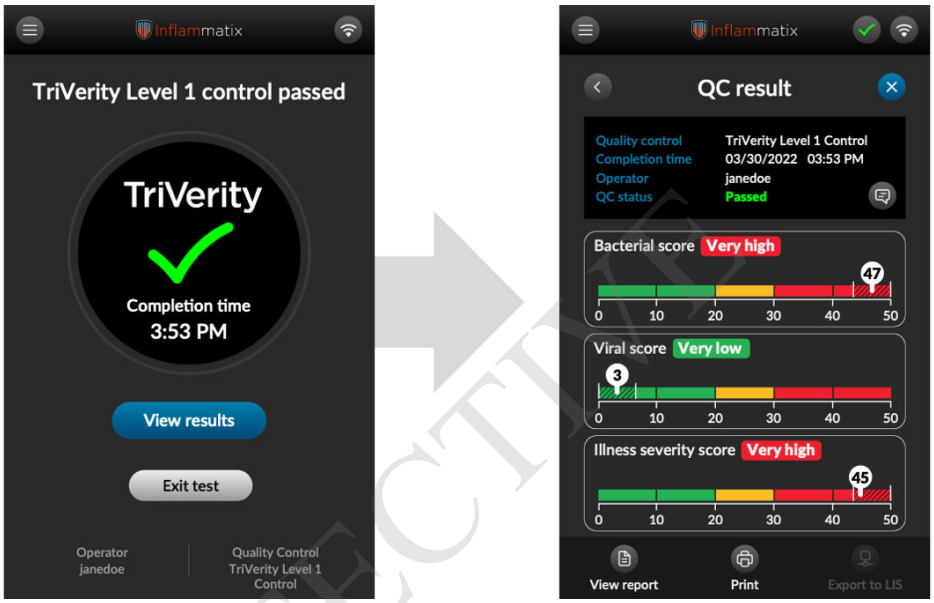


Figure 26

B. If an external quality control fails, the sequence of screens in *Figure 27* will be displayed. Instructions on how to proceed will be provided in the results screen.

Note: If an external quality control test fails repeatedly, contact your Study Coordinator.

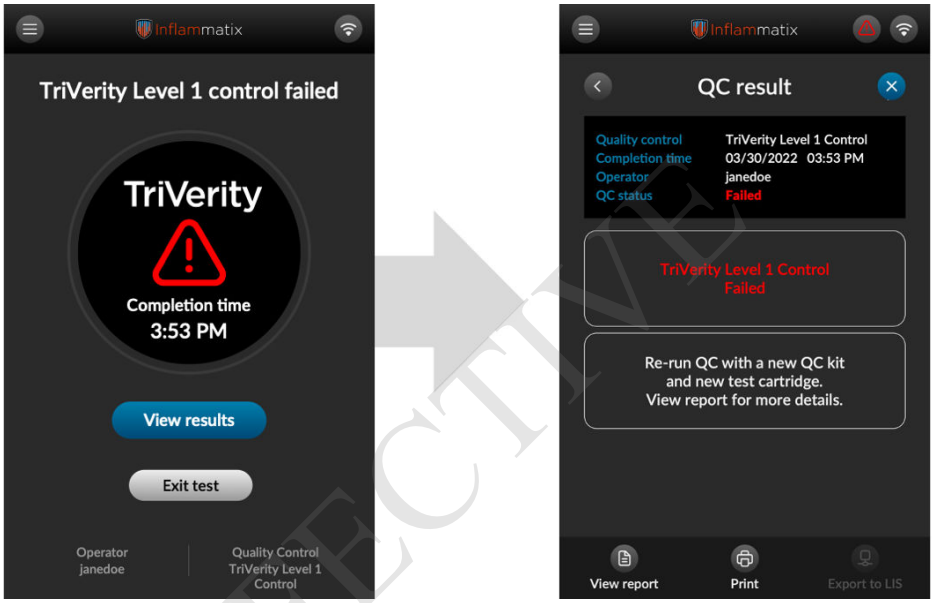


Figure 27

Step 10. To exit the test and eject the TriVerity Cartridge from the Inflammatix Instrument:

A. Press the blue X (exit) button in the upper-right corner
or
B. Press the back arrow button in the upper-left corner to return to the Test Complete screen then press the EXIT TEST button (as shown in Figure 26).

Step 11. The 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.

Step 12. Dispose of TriVerity Cartridge containing the TriVerity External Quality Control Tube per local and federal regulations. 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.

Note: The cartridge does contain a blunt end needle and should be disposed of accordingly.

15. Interpretation of External Control Results

The TriVerity Quality External Quality Control Test result is presented as an acceptable range of score to pass. A TriVerity Quality External Quality Control Test whose results fall outside of this range must be rerun with a fresh TriVerity External Quality Control Tube and Cartridge. *If the repeat test fails, contact your Study Coordinator.*

Information shown for the instrument test result screen is shown in Figure 28.

A. Test type
B. External Quality Control result status
C. Marker displaying the exact numerical score within the range of 0 to 50
D. Acceptable range within which a result must fall to pass

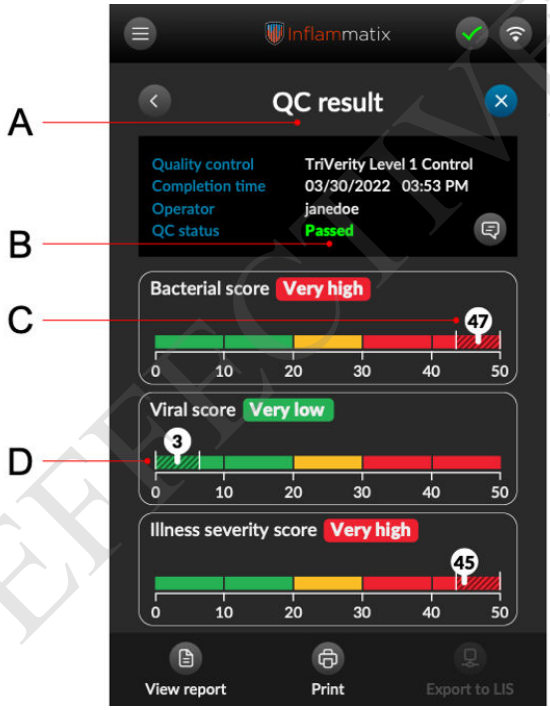


Figure 28

16. Limitations

A. This test has not been FDA cleared or approved;
B. Products in development, are not for sale, and do not have marketing approval or clearance from regulatory authorities in any jurisdiction.

17. Conditions of Authorization for the Laboratory

The TriVerity System, consisting of the Inflammatix Instrument, TriVerity Cartridge, and TriVerity External Quality Control Kit is authorized for investigational use only. The system may be housed and operated in a non-CLIA laboratory, however prior to use, all operators must have both study-specific device training and the Principal Investigator's delegation of operation documented and filed, available for sponsor review/collection.

18. Important Information

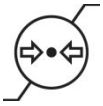
a. Analytical Performance
For Investigational Use Only. The performance characteristics of this product have not been established.

b. Analytical Sensitivity (Limit of Detection)
For Investigational Use Only. The performance characteristics of this product have not been established.

c. Analytical Specificity (Interfering Substances)
For Investigational Use Only. The performance characteristics of this product have not been established.

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

19. Index of Symbols

Symbol	Meaning	Symbol	Meaning
	Atmospheric pressure limitation		Date of manufacture
	Batch code		Do not re-use
	Biological risks		Do not use if package is damaged and consult *instructions for use*
	Catalog number		For IVD performance evaluation only
	Caution		Humidity limitation
	Consult *instructions for use* or consult electronic *instructions for use*		Manufacturer
	Contains sufficient for <*n*> tests		Temperature limit
	Control		Use by date

20. References

1. Centers for Disease Control and Prevention. https://www.cdc.gov/niosh/topics/bbp/
2. Centers for Disease Control and Prevention. *Biosafety in Microbiological and Biomedical laboratories* (refer to latest edition). http://www.cdc.gov/biosafety/publications/
3. Clinical and Laboratory Standards Institute. *Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline*. Document M29 (refer to latest edition).

Revision History

Rev.	DCO	Originator	Effective Date	Description of Change
A	DCO-00378	C. Wilson	06-Feb-2023	Initial release
B	DCO-00650	C. Wilson	See header	Updated all references to the external quality control kit. In particular, Section 8. This, in addition to small requests made in the quick reference guides (LBL-00017 and LBL-00018) to match.
Note: For previous versions, contact Document Control personnel.				