SPECTRUM
MEDICAL DIAGNOSTICS

# MONO Rapid Test

QUICK REFERENCE INSTRUCTIONS

Please refer to the Package Insert for complete instructions. Read the complete test procedure before performing the test.

## Before Running The Test

- Before running the test, please ensure that you have read all the information in this package insert.
- The MONO Rapid Test Cassette (Whole Blood/Serum/Plasma) is an in vitro diagnostic test designed for professional use only. It is used to qualitatively detect Infectious Mononucleosis (IM) heterophile antibodies in whole blood, serum, or plasma, aiding in the diagnosis of Infectious Mononucleosis.

## Intended Use

- The MONO Rapid Test Cassette (Whole Blood/Serum/Plasma) is intended for professional in vitro diagnostic use only.
- It is a rapid chromatographic immunoassay designed to qualitatively detect Infectious Mononucleosis (IM) heterophile antibodies in whole blood, serum, or plasma.
- The test aids in the diagnosis of Infectious Mononucleosis, a condition caused by the Epstein-Barr virus, by detecting the presence of IM heterophile antibodies.

## Warnings & Precautions

1. For professional in vitro diagnostic use only: The test should only be used by trained professionals who are familiar with the procedures and precautions associated with diagnostic testing.
2. Do not use after expiration date: Ensure that the test has not expired before use. Using an expired test may lead to inaccurate results.
3. Handle specimens and kits with caution: Treat all specimens and kits as if they contain infectious agents. Follow established precautions against microbiological hazards throughout the testing process.
4. Do not use damaged pouches: If the pouch containing the test cassette is damaged, do not use it. Using a damaged pouch may compromise the integrity and accuracy of the test.
5. Wear protective clothing and follow proper handling procedures: When handling specimens and performing the test, wear appropriate protective clothing such as laboratory coats, disposable gloves, and eye protection. Follow standard procedures for handling and disposal of specimens and controls.
6. Caution with positive and negative controls: The positive and negative controls included in the kit have been tested for specific viruses, but caution should still be exercised when handling and disposing of these items.
7. Humidity and temperature can affect results: Be aware that humidity and temperature can have an impact on the accuracy of test results. Store the test as packaged in the sealed pouch at the recommended temperature range and avoid exposing it to extreme humidity or temperature conditions.

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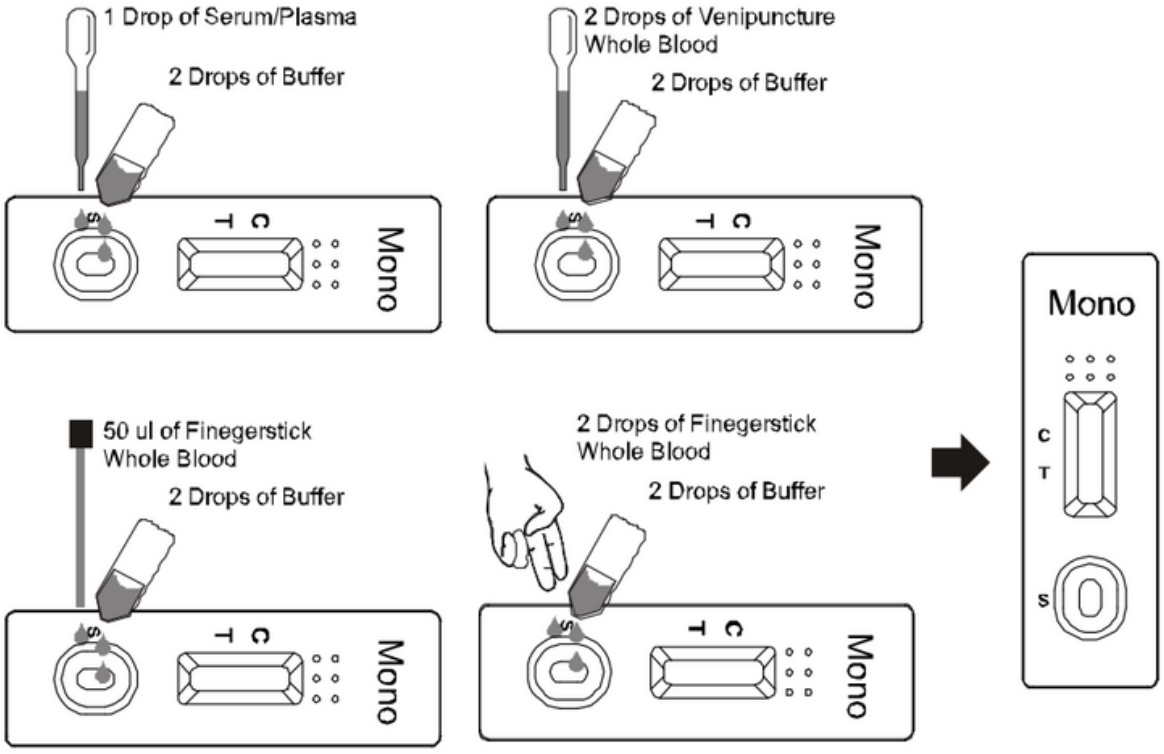
## Test Procedure

1. Remove the Test Cassette from the foil pouch and use it as soon as possible. Twist off the tab of the buffer vial without squeezing.
2. Place the Test Cassette on a clean and level surface.
3. **For fingerstick whole blood specimens:**

- Fill a capillary tube with approximately 50 µL of fingerstick whole blood.
- Transfer the blood from the capillary tube to the specimen well (S) of the Test Cassette.
- Add 2 drops of buffer (approximately 55 µL) to the specimen well.
- Start the timer.
- Wait for the colored lines to appear. Read the results at 5 minutes. Do not interpret the result after 10 minutes.




## QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that a positive control and a negative control be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

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## Positive Result:

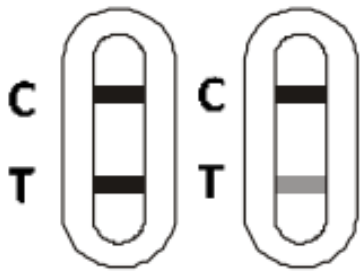
- A positive result indicates the presence of Infectious Mononucleosis (IM) heterophile antibodies.
- The appearance of two coloured lines, one in the control line region (C) and another in the test line region (T), confirms a positive result.
- Any shade of colour in the test line region should be considered positive. This suggests a likelihood of IM infection.

## Negative Result:

- A negative result indicates the absence of IM heterophile antibodies.
- When only one coloured line appears in the control line region (C) and no line appears in the test line region (T), it suggests that IM infection is unlikely or not present at the time of testing.
- However, a negative result does not completely rule out the possibility of IM infection, particularly if clinical symptoms persist.

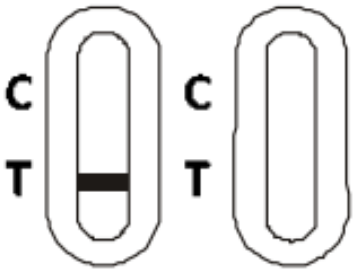
## Invalid Result:

- An invalid result is indicated **when the control line fails to appear.**
- This can be due to insufficient specimen volume or incorrect procedural techniques.
- It is advised to review the procedure, repeat the test with a new kit, and ensure proper specimen volume.
- If the problem persists, discontinue using the test kit and contact us at (866) 287-2425 or info@spectrummdx.com



Positive

Negative



Invalid

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# MONO Rapid Test Training Quiz

**What is the intended use of the MONO Rapid Test Cassette?**
a) To diagnose Influenza
b) To detect Infectious Mononucleosis heterophile antibodies
c) To screen for HIV
d) To monitor cholesterol levels

**True or False: The MONO Rapid Test Cassette can be used for self-testing at home.**
a) True
b) False

**What class of antibodies do Infectious Mononucleosis heterophile antibodies belong to?**
a) IgG
b) IgA
c) IgM
d) IgE

**What is the purpose of the control line in the MONO Rapid Test Cassette?**
a) It indicates the presence of IM heterophile antibodies.
b) It confirms that the specimen volume is sufficient and the test is functioning correctly.
c) It detects the presence of other viral infections.
d) It determines the antibody concentration.

**When should the MONO Rapid Test Cassette be stored?**
a) In the freezer
b) At room temperature or refrigerated (2-30°C)
c) In direct sunlight
d) In a humid environment

**What does a positive result on the MONO Rapid Test Cassette indicate?**
a) Presence of Infectious Mononucleosis heterophile antibodies
b) Absence of Infectious Mononucleosis heterophile antibodies
c) Positive for other viral infections
d) Invalid test result