

INTEX[®]-Mononukleose Test

Instructions for use

**A rapid test for the diagnosis of Infectious Mononucleosis (IM)
to detect infectious mononucleosis heterophile antibodies qualitatively
in whole blood, serum or plasma**

1. INTENDED USE

The INTEX[®]-Mononukleose Test (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of Infectious Mononucleosis heterophile antibodies in whole blood, serum or plasma as an aid in the diagnosis of Infectious Mononucleosis.

Infectious Mononucleosis (IM) is caused by the Epstein-Barr virus, which is a member of the herpesvirus family. Symptoms of IM are fever, sore throat and swollen lymph glands. In very rare cases, heart or central nervous system problems may occur. Diagnosis of IM is made based on the presence of heterophile antibodies. Infectious Mononucleosis heterophile antibodies belong to the IgM class. They are present in 80-90% of acute IM cases and can be detected in 60-70% of patients during the first week of clinical illness.^{1,2,3,4}

The INTEX[®]-Mononukleose Test (Whole Blood/Serum/ Plasma) is a simple test that utilizes an extract of bovine erythrocytes to qualitatively and selectively detect Infectious Mononucleosis heterophile antibodies in whole blood, serum or plasma in just 5 minutes.

2. TEST PRINCIPLE

The INTEX[®]-Mononukleose Test (Whole Blood / Serum / Plasma) is a qualitative membrane strip based immunoassay for the detection of IM heterophile antibodies in whole blood, serum or plasma. In this test procedure, bovine erythrocyte extracted antigen is immobilized in the test line region of the device. The specimen reacts with bovine erythrocyte extracted antigen coated particles that have been applied to the label pad. This mixture migrates chromatographically along the length of the test strip and interacts with the immobilized bovine erythrocyte extracted antigen. If the specimen contains IM heterophile antibodies, a colored line will appear in the test line region indicating a positive result. If the specimen does not contain IM heterophile antibodies, a colored line will not appear in this region indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

3. REAGENTS

The test device contains bovine erythrocyte extracted antigen-coated particles and bovine erythrocyte extracted antigen-coated membrane.

4. PRECAUTIONS

- *For professional in vitro diagnostic use only. Do not use after expiration date.*
- *Do not eat, drink or smoke in the area where the specimens or kits are handled.*
- *Do not use test if pouch is damaged*
- *Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow standard procedures for proper disposal of specimens.*

- *Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.*
- *Humidity and temperature can adversely affect results.*

5. STORAGE AND STABILITY

Store as packaged in the sealed pouch at room temperature or refrigerated (2-30°C). The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. DO NOT FREEZE.

6. SPECIMEN COLLECTION AND PREPARATION

- The INTEX[®]-Mononukleose Test (Whole Blood / Serum / Plasma) can be performed using whole blood (from venipuncture or fingerstick), serum or plasma.
- To collect Venipuncture Whole Blood specimens: Collect anti-coagulated blood specimen (sodium or lithium heparin, potassium or sodium EDTA, sodium oxalate, sodium citrate) following standard laboratory procedures.
- To collect Fingerstick Whole Blood specimens:
 - Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
 - Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
 - Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
 - Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
 - Add the Fingerstick Whole Blood specimen to the test device by using a capillary tube:
 - Touch the end of the capillary tube to the blood until filled to approximately 50 µL. Avoid air bubbles.
 - Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood to the specimen well (S) of the test device.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long-term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
- If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

7. MATERIALS

Materials Provided

- Test devices
- Disposable specimen droppers
- Disposable capillary tubes and dispensing bulb
- Positive control (Diluted human plasma containing IM heterophile antibodies, 0.1% sodium azide)

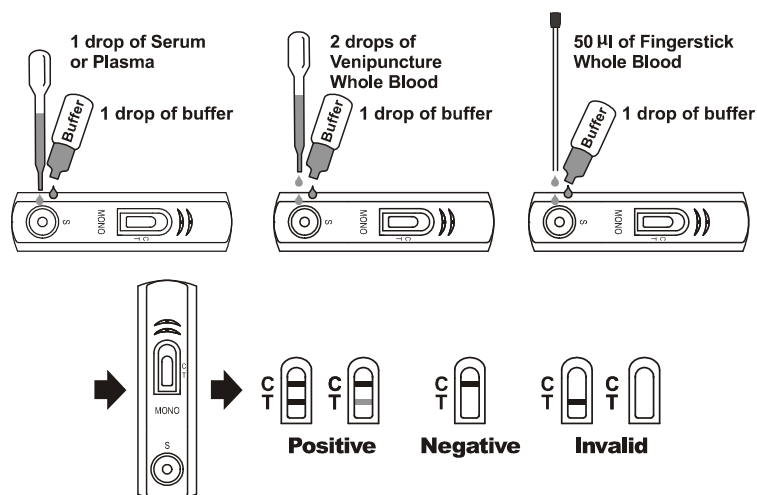
- Negative control (Diluted human plasma, 0.1% sodium azide)
- Buffer
- Package insert

Materials Required But Not Provided

- Specimen collection containers (for venipuncture whole blood)
- Lancet (for fingerstick whole blood only)
- Centrifuge (for plasma only)
- Timer

8. DIRECTIONS FOR USE

1. Allow the test device, specimen, buffer, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.
2. Remove the test device from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
3. Place the test device on a clean and level surface.
4. For Serum or Plasma specimens:
Hold the dropper vertically and transfer 1 drop of serum or plasma (approximately 25 µL) to the specimen well (S) of the test device, and add 1 drop of buffer (approximately 55 µL), then start the timer. See illustration below.
5. For Venipuncture Whole Blood specimens:
Hold the dropper vertically and transfer 2 drops of whole blood (approximately 50 µL) to the specimen well (S) of the test device, and add 1 drop of buffer (approximately 55 µL), then start the timer. See illustration below.
6. For Fingerstick Whole Blood specimens:
To use a capillary tube: Fill the capillary tube and transfer approximately 50 µL of fingerstick whole blood specimen to the specimen well (S) of the test device, then add 1 drop of buffer (approximately 55 µL) and start the timer. See illustration below.
7. Wait for the red line(s) to appear. The result should be read at 5 minutes. Do not interpret the result after 10 minutes.



INTERPRETATION OF RESULTS

POSITIVE: * Two distinct red lines appear. One line should be in the control line region (C) and another line should be in the test line region (T).

***NOTE:** The intensity of the red color in the test line region (T) will vary depending on the concentration of IM heterophile antibodies present in the specimen. Therefore, any shade of red in the test line region (T) should be considered positive.

NEGATIVE: One red line appears in the control line region (C). No apparent red or pink line appears in the test line region (T).

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

9. QUALITY CONTROL

Internal procedural controls are included in the test. A red line appearing in the control line region (C) is considered an 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 positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

10. LIMITATIONS

The INTEX[®]-Mononukleose Test (Whole Blood / Serum / Plasma) is for in vitro diagnostic use only. The test should be used for the detection of Infectious Mononucleosis antibodies in whole blood, serum or plasma specimens only. Neither the quantitative value nor the rate of increase in Infectious Mononucleosis antibody concentration can be determined by this qualitative test.

The INTEX[®]-Mononukleose Test (Whole Blood / Serum / Plasma) will only indicate the presence of infectious mononucleosis antibodies in the specimen and should not be used as the sole criteria for the diagnosis of Infectious Mononucleosis infection.

As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.

If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of Infectious Mononucleosis infection.

11. EXPECTED VALUES

Epstein-Barr virus infection during adolescence or young adulthood causes Infectious Mononucleosis in 35% to 50% of reported cases.^{1,5}

The incidence of EBV-associated Infectious Mononucleosis in the USA has been estimated at 45 per 100,000 and is highest in adolescent and young adults-about 2 out of 1,000. No seasonal pattern of EBV infection exists. The incubation period is 10 to 60 days, though 7 to 14 days is common for children and adolescents.

12. PERFORMANCE CHARACTERISTICS

Sensitivity

The INTEX[®]-Mononukleose Test (Whole Blood / Serum / Plasma) has been evaluated with specimens confirmed by a leading commercial latex agglutination test. The latex agglutination test served as the reference method for the INTEX[®]-Mononukleose Test (Whole Blood / Serum / Plasma). The result shows that the sensitivity of the INTEX[®]-Mononukleose Test (Whole Blood / Serum / Plasma) is >99.9% relative to the latex agglutination test.

Specificity

The INTEX[®]-Mononukleose Test (Whole Blood / Serum / Plasma) uses an antigen that is highly specific for IM antibodies in whole blood, serum or plasma. The results show that the specificity of the INTEX[®]-Mononukleose Test (Whole Blood / Serum / Plasma) is 98.6% relative to the latex agglutination test.

INTEX[®] Diagnostika

INTEX[®]-Mononukleose Test vs. Latex Agglutination

Method	Latex-Agglutination			Total
	results	positive	negative	
INTEX [®] -Mononukleose Test	positive	52	1	53
	negative	0	69	69
	Total results	52	70	122

Relative Specificity: 98.6% (92.3%-100.0%)* – Accuracy: 99.2% (95.5%-100.0%)*

* 95% Confidence Intervals

Precision

- Intra-Assay

Within-run precision has been determined by using 15 replicates of three specimens: a negative, a low positive and a high positive. The negative, low positive and high positive values were correctly identified >99% of the time.

- Inter-Assay









Between-run precision has been determined by 15 independent assays on the same three specimens: a negative, a low positive and a high positive. Three different lots of the



The INTEX[®]-Mononukleose Test (Whole Blood / Serum / Plasma) has been tested using negative, low positive and high positive specimens. The specimens were correctly identified > 99% of the time.

13. LITERATURE

1. Hickey SM, Strasburger VC. What Every Pediatrician Should Know About Infectious Mononucleosis In Adolescents. *Pediatr Clin North Am.* 1997; 44(6):1541-56.
2. Omori M. Mononucleosis. 2002. <http://www.emedicine.com/EMERG/topic309.htm>
3. Linde A. Diagnosis of Epstein-Barr virus-related diseases. *Scand J Infect Dis Suppl.* 1996; 100:83-8.
4. Papesch M, Watkins R. Epstein-Barr virus infectious mononucleosis. *Clin Otolaryngol.* 2001; 26(1):3-8.
5. CDC National Center for Infectious Diseases. EBV & IM: <http://www.cdc.gov/ncidod/diseases/ebv.htm>

14. SYMBOLS

	Article number		For single use only
	Lot number		Expiry date
	Storage		Content
	For in vitro diagnostics only		Instructions for use

INTEX[®]-Mononukleose Test		
	5 Test cassettes	SMO4405
	20 Test cassettes	SMO4420



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