

INTEX[®] Mononucleosis Test

Rapid test for the diagnosis of Infectious Mononucleosis to detect infectious mononucleosis heterophile antibodies

Fast and reliable diagnosis for rapid treatment!

The INTEX[®] - Mononucleosis Test 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 is caused by the Epstein-Barr virus (EBV), which is a member of the herpes virus family. Symptoms of Infectious Mononucleosis are fever, sore throat and swollen lymph glands. In very rare cases heart or central nervous system problems may occur.

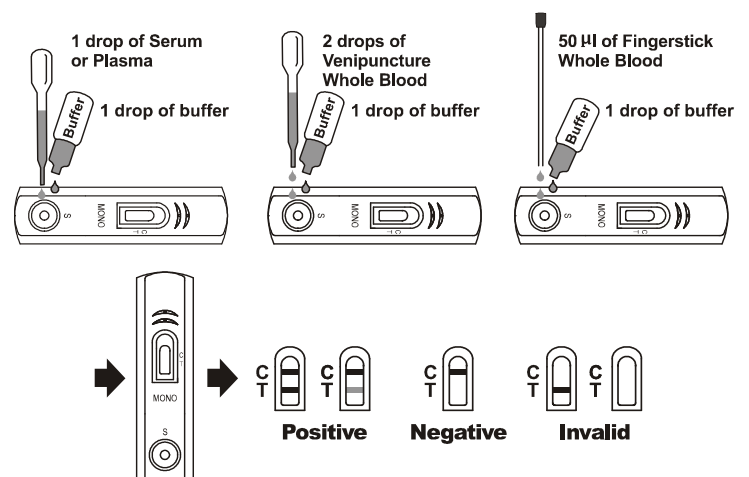
Test characteristics

- **Qualitative one step rapid test**
- **Simple handling**
- **To be accomplished with whole blood, serum- or plasma**
- **Reliable results in 5 minutes**
- **High diagnostic sensitivity and specificity**
- **Storage at room temperature up to 2 years**



Test procedure

- ① Remove the test device from the foil pouch and place it on a clean and level surface.
- ② Drop the indicated amount of serum, plasma or whole blood to the specimen well of the test device.
- ③ Read the result after 5-10 minutes.



Diagnostic sensitivity and specificity

The test characteristics of the INTEX[®]- Mononucleosis Test have been compared with a Latex Agglutination test. Here the INTEX[®]- Mononucleosis Test showed a diagnostic sensitivity of >99.9% and a diagnostic specificity of 98.6%.

INTEX[®]-Mononukleose Test vs. Latex Agglutination test:

Method	Latex Agglutination test			Total results
	Results	Positive	Negative	
INTEX [®] - Mononukleose Test	Positive	52	1	53
	Negative	0	69	69
Total results		52	70	122

Diagnostic Sensitivity: >99.9% (93.2%-100%) – diagnostic Specificity: 98.6% (92.3%-100%) – Precision: 99.2% (95.5%-100%)

Precision

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.

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 INTEX-Mononucleosis test (Whole Blood/Serum/ Plasma) have been tested using negative, low positive and high positive specimens. The specimens were correctly identified >99% of the time.

INTEX [®] - Mononucleosis Test	▼	REF
	5 test cassettes	SMO4405
	20 test cassettes	SMO4420



INTEX[®] Pharmazeutica AG

Hofackerstrasse 77
CH-4132 Muttenz
Tel. (0041) 61 465 90 70
Fax (0041) 61 465 90 71
service.ch@intex-diagnostika.com

INTEX[®] Diagnostika GmbH

Hauptstrasse 435
DE-79576 Weil am Rhein
Tel. (0049) 7621 940 90 80
Fax (0049) 7621 940 90 84
service@intex-diagnostika.com

IDSAN[®] Kft.

Árpád u. 3/b. fsz. 1
HU-1195 Budapest
Tel. (0036) 1 357 65 98
Fax (0036) 1 357 65 99
intex@t-online.hu

www.intex-diagnostika.com