Mononucleosis Rapid Test Device
(Whole blood/Serum/Plasma)

INTENDED USE

The MONO Mononucleosis Rapid Test Device (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay , that utilizes an extract of bovine erythrocytes to qualitatively and selectively detect Infectious Mononucleosis heterophile antibodies in whole blood, serum or plasma as an aid in the diagnosis of Infectious Mononucleosis.

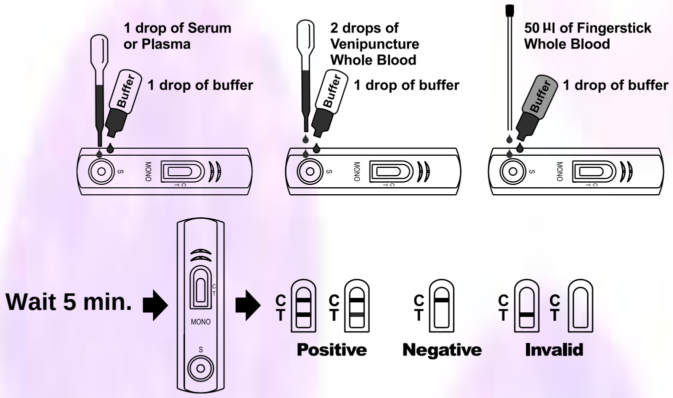
SUMMARY

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.

PRINCIPLE

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.

PROCEDURE



PERFORMANCE

Method		Latex Agglutination		Total Results
	Results	Positive	Negative	
MONO Test Device	Positive	52	1	53
	Negative	0	69	69
Total Results		52	70	122

Relative Sensitivity: >99.9% (93.2%-100.0%)*
Relative Specificity: 98.6% (92.3%-100.0%)*
Accuracy: 99.2% (95.5%-100.0%)*
95% Confidence Intervals

REFERENCE CODE	DESCRIPTION	TESTS PER KIT
8514308	Mononucleosis	20

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