MONONUCLEOSIS ema kit

Qualitative and semiquantitative determination
by slide agglutination
of heterophyl antibodies related to
Infectious Mononucleosis

100 tests **REF 6005**

PRINCIPLE

Infectious Mononucleosis (IM) is an acute pathology caused by Epstein-Barr Virus (EBV). The most frequent symptoms are fatigue, pharyngitis, fever, linphoadenopatia, splenomegaly and hepatitis.
Heterophyl antibodies are the primary antibodies which appear in the patient serum, usually from one to three weeks after the beginning of the symptoms and in 85-95% of the cases. These antibodies are principally represented by IgM class and may be detected the in the patient serum more than a year after the disease arising. A reliable IgM diagnosis is based on the heterophyl antibody determination. These antibodies can react with the membrane antigens of the erythrocytes infected by several mammals species. The test is based on the immunological reaction of the heterophyl antibodies associated to mononucleosis and to sensitized latex particles. These particles are stabilized to avoid any cross reaction with Forssman heterophyl antibodies. The agglutinate is easily visible with the naked eye.

REAGENTS

Kit components: **REF 6005**
REAGENT 1 (liquid, white cap) **1 x 5 ml**
Latex particles in suspension sensitized against heterophyl antibodies, ready to use.
REAGENT 2 (liquid, red cap) **1 x 1 ml**
Positive control, ready to use.
REAGENT 3 (liquid, blue cap) **1 x 1 ml**
Negative control, ready to use.
WARNING: the reagents contain sodium azide (< 0.1%) as preservative. Handle with caution and avoid ingestion and contact with skin.
SLIDE **17 pieces**
STIRRER **100 pieces**

STABILITY: sealed and stored at 2-8°C, reagents are stable up to the expiration date printed on the label.

SAMPLE

Serum.
STABILITY: 2 days at 2-8°C, 1 month at -20°C.

PREPARATION OF THE REAGENTS

Let the reagents reach the test temperature before use. Shake the Reagent 1 accurately before use. Make sure all latex particles are in suspension and not deposited on the bottom of the vial.

MANUAL PROCEDURE OF THE QUALITATIVE TEST

Pour the reagents in the proper areas of the slide, as the following table:

	Sample	Pos. Control	Neg. Control
Sample Reagent 2 Reagent 3	50 µl	1 drop	1 drop
Reagent 1	1 drop	1 drop	1 drop

Mix to spread the liquid on the whole area of the slide. Shake the slide gently (round movement) for 5 minutes and then read the results.

READING OF THE RESULTS

An evident agglutination within 2 minutes means positivity. Anyhow, for patients with infectious mononucleosis symptoms and negative results, it is recommended to repeat the test diluting the sample 1:10.

SEMI-QUANTITATIVE TEST PROCEDURE

Dilute the sample with saline solution as follows:

Dilution	1:2	1:4	1:8	1:16
Sensitivity equal to mg/l	12	24	48	96

Proceed on each dilution same as the qualitative test.

RESULTS

The last dilution which shows any agglutination corresponds to the sample titer.

NOTES

1. Longer reaction times may give false positive results.
2. Always compare the results with the controls.
3. All reagents have been deactivated and tested for HIV, HBsAg and HCV antibodies. However, they should be treated as potentially infectious.
4. Patients with pathologies like hepatitis, rubella, leukemia and Burkett lymphoma may give false positive results.

REFERENCES

Forssman J., Biochem. Z. ,78, 37,1911
Paul G.R. and Bunnell W.W., Amer. J. Med. Sci., 183, 90-104, 1932

KEY SYMBOLS

IVD	In Vitro diagnostic medical device
LOT	batch number
REF	catalog number
	temperature limits
	use by
	caution
	read instructions for use

IVD CE Ed. 02 - Mar 2015 MS

MANUFACTURER

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