

Immunoglobulin M – Instructions for use

R1: 1x 50 mL **REF** A-R1100003601
R2: 1x 6,5 mL



SUMMARY AND EXPLANATION OF THE TEST

IgM is important in early response to infections. The measurement of IgM is important for typing immunodeficiencies and myelomas. IgM plays an important role in the humoral defense of the body. Serum levels may be increased in all kind of acute infections. Elevated levels in cord serum suggest clinical infection in the newborn.

PRINCIPLE OF THE TEST

Measurement of antigen-antibody reaction by the end-point method.

IgM Reagent Kit

Code ADA-R1100003601

Reagent 1 (R1) - Buffer - 1 x 48.5 mL/vial

Reagent 2 (R2) - Antiserum - 1 x 6.0 mL/vial

Each vial is ready to use and contains:

Reagent 1:	Conc.	U.M.
Saline Solution	9	g/L
Accelerator	/	/
Sodium azide	0,95	g/L
Reagent 2:	Conc.	U.M.
Phosphate buffered saline (pH 7.43)	/	/
Polyclonal goat anti-human IgM (variable)	/	/
Sodium azide	0,95	g/L

Reagent Preparation:

Liquids reagents ready for use.

Storage and Stability:

If stored at 2 - 8°C avoiding direct light, the reactants remain stable until the expiration date printed on the label.

Stability in the instrument is at least 4 weeks if contamination is avoided. Do not freeze.

Do not freeze the reagents.

EQUIPMENT / ACCESSORIES REQUIRED AND NOT SUPPLIED

General laboratory equipment

Saline (9 g/L)

Calibrators and/or Control

(Pooleed human serum, liquid and stabilized. Contains 0.95 g/L sodium azide. Value is stated in the insert)

PRECAUTIONS AND LIMITATIONS

For *in vitro* diagnostic use.

Only experienced laboratory personnel should use this test and handling should be in agreement with Good Laboratory Practice (GLP).

Reagents from different lots must not be interchanged.

Safety Precautions

- Each donor unit used in the preparation of the reagents, standards and controls was found to be negative for the presence of HIV1 and HIV2 antibodies, as well as for the hepatitis B surface antigen and anti-hepatitis C antibodies, using a method approved by the FDA
- Do not pipet by mouth.
- Do not smoke, eat or apply cosmetics in areas in which patients' samples or kit reagents are handled.
- Cuts, abrasions, and other skin lesions should be properly protected with an appropriate waterproof dressing.
- Take care to avoid self-inoculation, splashing of mucous membranes or generation of aerosols.
- Laboratory gloves should be worn while handling patients' samples or disposing of solid or liquid wastes.
- In addition to the eventual risk indications regarding the active components, the reagents contain inactive components such as preservatives (e.g. sodium azide or others) and detergents. The total concentrations of these components is lower than the limits reported by the current directive and following modification and amendments. However, it is recommended to handle reagents carefully, to avoid ingestion and contact with eyes, skin and mucus membranes and to use laboratory reagents according to good laboratory practice.
- All human samples must be handled and disposed of as potentially infectious materials.
- For information about safe handling, read carefully the Material Safety Data Sheet (MSDS).

Disposal of Reagents

Disposal of reagents must be performed in accordance with the EC regulations regarding waste, or the local national or regional legislation.

SPECIMEN COLLECTION AND STORAGE

Use fresh serum.

If the test can not be carried out on the same day, the serum may be stored at 2 - 8°C for 48 hours.

If stored for a longer period, the sample should be frozen.

ASSAY PROCEDURE

Allow reagents to reach working temperature before using.

Quality control

It's necessary, each time the kit is used, to perform the quality controls and to check that values obtained are within the acceptance range provided in the insert. Each laboratory should establish its own mean and standard deviation and adopt a quality control program to monitor laboratory testing.

Automation

All applications not explicitly approved by I.S.E S.r.l. cannot be guaranteed in terms of performance, and must therefore be established by the operator.

Procedures

Sample/Control/standard: dilute 1:2 in saline 9g/L

Reference curve: generate a reference curve by diluting the standard high level
Ref R1300002501 1:1, 1:2, 1:4, 1:8, 1:16 in saline 9 g/L. Use saline 9 g/L as zero point.

Method for automated instrumentation

Analyzer:	Miura Family		
Analyte Name :	IGM	Ref.:	A-R1100003601
Method Code:	IGM		
Type:	Different. Sample Blk.		
Unit:	mg/dL		
Filter F1:	340 nm		
Blank in calculation:	Not Used		
Step	Reaction volume	U.M.	
Sample volume:	3	µL	
Volume Reagent 1:	250	µL	
Volume Reagent 2:	30	µL	
Incubation Time	60	Sec.	
Reading Time:	300	Sec.	
Calibration	See Reference Curve		

EXPECTED VALUES

Men: 34 - 214 mg/dL (IFCC)

Woman: 40 - 250 mg/dL

Reference values are considered indicative since each laboratory should establish reference ranges for its own patient population. The analytical results should be evaluated with other information coming from patient's clinical history.

PERFORMANCE CHARACTERISTICS

The performance characteristics for the Immunoglobulin IgM reagents were measured on a clinical chemistry analyzer.

Measuring Range: 0 - 500 mg/dL

Detection Limit: 6.0 mg/dL

Hook effect: No Risk

Sensitivity: 6.7 ABS units/concentration unit

Precision: [%CV]		Low	Medium	High
		Intra-Run	1.43	1.59
	Inter-Run	3.17	3.65	2.49
Accuracy: [mg/dL]	Control	Assigned	Measured	
	Bio-Rad 1	67 (54 - 81)	75	
	Bio-Rad 2	129 (103 - 155)	153	

Specificity: Monospecific

Interferences: No interference for:
Hemoglobin (1000 mg/dL), Na-citrate (1000 mg/dL), Heparin (50 mg/dL), Bilirubin (20 mg/dL), Triglyceride (2500 mg/dL), EDTA (5 mg/dL), Turbidity (5%)

Limitations: None

Comparison with Behring Nephelometry: $y = 0.9875x - 8.2224$ / $r = 0.9966$

Stability at 2...8°C: at least 3 years after production

BIBLIOGRAPHY

- Naito, H.K., J. Clin. Immunoassay, **9**, 155 (1986)
- Kottke, B.A., et al., Mayo Clin. Proc., **61**, 313 (1986)
- Dati, F. et al., Lab. Med. **13**, 87 (1989)



Numero lotto / Lot numer



Consultare la metodica operativa / consult instructions for use



Per uso diagnostico in-vitro / For in-vitro diagnostic use



Prodotto da / manufactured by



Data di scadenza / expiry date



Temp. Di Conservazione / storage temperature

