IGM (IMMUNOGLOBULIN M)

TURBIDIMETRY

Intended use:

Immunoglobulin M in the sample precipitates in the presence of anti-human immunoglobulin M antibodies. The light scattering of the antigen-antibody complexes is proportional to the immunoglobulin M concentration and can be measured by turbidimetry[1,2].

Test principle:

Immunoglobulins M (IgM) selectively react with an antiIgM antibody and form an immunocomplex. The produced turbidity is proportional to the concentration of IgM in the sample, and can be measured at the wavelenght of 340 nm.

Reagent concentration:

R1: Buffer pH 7.50, PEG ≥ 2%, stabilizers and preservatives.
R2: Anti-human IgM antibody ≥ 2%, stabilizers and preservatives

Preparation and stability:

R1: Reagent is provided ready to use.
R2: Reagent is provided ready to use.
The Reagent is stable until the expiry date shown on the label when stored tightly closed and if contaminations are prevented during its use. Up to the expiration date at 2^0 to 8^0C

On board stability: R1: 28 days
R2: 28 days

Specimen:

Serum, plasma. Keep specimens away form direct light sources. Samples are stable 7 days when stored at 2-8°C and 1 month at -20°C.

Limitations - interference:

Criterion: Recovery within ±10% of initial value.
Icterus: No significant interference up to an index I of 45(approximate conjugated and unconjugated bilirubin concentration: 45mg/dl).
Hemolysis: No significant interference up to an index H of 1000 (approximate haemoglobin concentration: 1000 mg/dl).
Lipemia (Intralipid): No significant interference up to an index L of 770 (approximate triglycerides concentration: 1000. Rheumatoid factors <630 IU/l do not interfere.

Expected values:

Adults: 40 - 230 mg/dL
Newborns 5 – 30 mg/dL
Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference range. For diagnostic purposes the test results should always be assayed in conjunction with the patient's medical history, clinical examinations and other findings.

Measuring/reportable range:

1,6 - 300 mg/dL
At higher concentrations, dilute the sample with 0.9% NaCl (e.g. 1 + 4). Multiply the result by the appropriate factor (e.g. 5).

Testing procedure:

Applications for automated systems are available on request.

Materials provided
· Working solutions as described above *Additional materials required*
· Calibrators and controls as indicated below
· 0.9% NaCl

Manual procedure:		
Wavelength:	340 nm	
Temperature:	+37°C	
Cuvette:	1 cm	
Zero adjustment:	against reagent blank	
	Blank	Sample/ Calibrator
Sample/Calibrator	-- --	7,5 µl
R1	600 µl	600 µl
Mix, incubate at 37^0C for 5 minutes.Read against reagent blank the absorbances of calibrator and Sample		
R2	150 µl	150 µl
Mix ,incubate at 37^0C for 5 minutes. Read against reagent blank the absorbances of calibrator and Sample		
Calculation:		
A = [(A) sample or Calibrator] - [(A) blank]		
The concentration of IgM in patient sera has to be calculated from A using linear method For zero value is recommended to use saline solution (0.9%)		

Imprecision:

İntra -assay(n=10)	Mean (mg/dl)	S.D(mg/dl)	C.V%
Sample 1	70	0,5	0,69
Sample 2	140	0,9	0,66
İnter -assay(n=20)	Mean (mg/dl)	S.D(mg/dl)	C.V%
Sample 1	70	2,4	3,38
Sample 2	140	6,1	4,32

Methods comparison:

A comparison between BIOANALYTIC and a commercially available product gave the following results:
IgM competitor = x IgM BIOANALYTIC = y
n = 20
y = 1,186x – 5,8 mg/dl
r2 = 0.99

Quality Control:

Human Control Serum:

BIOANALYTIC Protein Control Serum L2	1 x 1 ml	# B10844
BIOANALYTIC Protein Control Serum L1	1 x 1 ml	# B10845

The control intervals and limits must be adapted to the individual laboratory and country-specific requirements. Values obtained should fall within established limits. Each laboratory should establish corrective measures to be taken if values fall outside the limits.

Calibration:

BIOANALYTIC Protein Calibrators. The set contains 5 different levels of IgM concentration and it should be used to prepare the calibration curve. The calibrators are supplied ready to use.
S1: BIOANALYTIC PROTEIN CALIBRATOR

Literature:

1. Narayanan S. Method-comparison studies on immunoglobulins. *Clin Chem* 1982; 28: 1528-1531.
2. Price CP, Spencer K and Whicher J. Light-scattering immunoassay of specific proteins: a review. *Ann Clin Biochem* 1983; 20: 1-14.
3. Dati F et al. Consensus of a group of professional societies and diagnostic companies on guidelines for interim reference range for 14 proteins in serum based on the standarization against the IFCC/CAP reference material (CRM 470). *Eur J Clin Chem Clin Biochem* 1996; 34: 517-520.
4. Young DS. Effects of drugs on clinical laboratory tests, 5th ed. AACC Press, 2000.
5. Friedman and Young. Effects of disease on clinical laboratory tests, 4th ed. AACC Press, 2001.

Order information (Cat No.) :

CR439	B24205	B27206	B30206	B33206	B37205
B21205	B25205	B28205	B31205	B34205	B80205
B21206	B25206	B28206	B32205	B35205	
B22205	B27205	B30205	B33205	B36205	

Manufacturer

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SYMBOLS

IVD	for in vitro diagnostic use only
LOT	lot of manufacturing
REF	code number
	storage at temperature interval
	expiration date (year/month)
	warning, read enclosed documents
	Read the directions

ISO 9001:2015
ISO 13485:2016