

IMMUNOGLOBULIN M

(IgM Turbidimetric)

Diagnostic reagent for determination of IgM concentration.

Liquid. Mono Reagents. Store at 2°C - 8°C. For in Vitro Diagnostic Use. Do not freeze

Ref No	Pack	Ref No	Pack	Ref No	Pack
TA160	5 x 25 mL	DMT160	990 Tests	MAB160	1515 Tests
TA161	5 x10 mL	RAB160	1000 Tests	MAB161	758 Tests
TAB160	1115 Tests	SAB161	545 Tests	NAB160	848 Tests
TA160B1	1000 mL	BY161	2652 Tests	DAB160	892 Test

INTENDED USE

The test is applied for the quantitative determination of IgM (Immunoglobulin M) in human serum or plasma.

Plasma IgM concentration is decreased in inherited or acquired deficiencies of immunoglobulin production.

Clinical diagnosis should not be made on the findings of a single test result, but should integrate both clinical and laboratory data.

TEST PRINCIPLE

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.

TEST PARAMETERS

Method : Turbidimetric
Wavelength : 340 nm
Temperature : 37°C
Sample : Serum / Plasma
Linearity : 2 mg/dL - 300 mg/dL

REAGENT COMPOSITION

Reagent 1:
Imidazole buffer ≤ 0.2 mol/L,
Goat anti-human IgM antibodies,
Sodium azide ≤ 1.00 g/L, pH 7.5.

REAGENT PREPARATION

Reagents are ready for use.

REAGENT STABILITY AND STORAGE

Store at 2-8°C.

The Reagent is stable until the expiry date shown on the label when stored tightly closed and if contaminations are prevented during its use.

Once opened vials (reagent 1) are stable minimum 30 days at 2-8°C at optimum conditions. On board stability is strongly related to auto analyzers cooling specification and carry-over values.

SAMPLE

Serum or plasma collected by standard procedures. Use heparin or EDTA as anticoagulants. Lipemic samples are not suitable for testing.

IgM in serum or plasma IgM is stable for 5 days at 2-8°C, 6 Months at -20°C

For reagents which are related antigen antibody interaction, do not shake the sample, just gently mix.

TEST PROCEDURE

Sample Start

There have many ready application procedures dedicated to different kind of photometers and ready manual working process can be supplied on request.

There have many ready application procedures dedicated to different kind of biochemistry auto analyzers can be supplied on request.

CALCULATION

Calibration curve: Plot the absorbance values of each calibrator against its IgM concentration. Use the Blank as the calibrator of 0 concentration. IgM concentration in the sample is calculated by interpolation of its absorbance on the calibration curve.

REFERENCE INTERVAL (NORMAL VALUES)*

Serum, adults: 40 - 230 mg/dL

*It is recommended that each laboratory establish its own reference range.

QUALITY CONTROL AND CALIBRATION

It is recommended to use the Protein Control Serum level I (PCN01) and II (PCN05) to verify the

performance of the measurement procedure. Protein Calibrators (ARCHEM). The set contains 5 different levels of IgM concentration and they should be used to prepare the calibration curve. The calibrators are supplied ready to use.

*Calibration Stability: It is strongly depend of application to auto analyzers and auto analyzers specification. Calibration stability is 30 days.

*Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if controls do not recover within the acceptable tolerances.

Quality control is recommended every morning. Calibration is not recommended if QC control values are acceptable. Reagent should be calibrated after lot changes.

PERFORMANCE CHARACTERISTICS

Low linearity: 2 mg/dL IgM

High Linearity: 300 mg/dL. For higher values dilute sample 1/5 with distilled water and repeat measurement.

Linearity may considerably vary depending on the instrument used.

Precision Studies (Based on CLSI EP5 Doc.):

Repeatability (within run) (Intra-assay)

Mean concentration	CV	n
83 mg/dL	2.1%	20
205 mg/dL	2.0%	20

Reproducibility (run to run) (Inter-assay)

Mean concentration	CV	n
83 mg/dL	4.5%	25
205 mg/dL	3.1%	25

Trueness: Results obtained with this reagent did not show systematic differences when compared with reference reagents. Details of the comparison experiments are available on request.

Prozone effect: Falsely low values are obtained when IgM is present in the sample at a concentration higher than 1400 mg/dL.

Interferences: Bilirubin (20 mg/dL), hemoglobin (20 g/L) and rheumatoid factors (150 IU/mL) do not interfere. Lipemia (triglycerides > 4.4 g/L) may affect the results. Other drugs and substances may interfere.

These performance characteristics have been obtained using an analyzer. Results may vary if a different instrument or a manual procedure is used.

NOTES

1. For in vitro diagnostic use only. Do not pipette by mouth. Avoid contact with skin and mucous membranes.
2. All the calibrators, controls and some reagents must be considered as human & animal sample, so potentially infectious; all the protection actions must be applied to avoid any potential biological risk.
3. Material safety data sheet will be supplied on request.
4. Exercise the normal precautions required for handling laboratory reagents.
5. After measurements are taken, reagent bottles should cap and kept at 2-8°C. Caps of the reagents bottles cannot be used between two different kind of reagent and between R1 & R2.
6. Reagents with different lot numbers should not be interchanged or mixed.
7. The reagents contain sodium azide (< 0.1%) as a preservative.
8. The linearity limit depends on the sample to reagent ratio.
- 9.

PRECAUTIONS AND WASTE DISPOSAL

This product is made to be used in professional laboratories and by professional operators. Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.

R36/38 : Irritating to eyes and skin.

S20/21 : When using, do not eat, drink or smoke.

S26 : In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S28 : After contact with skin wash immediately with plenty of water.

S36/37/39: Wear suitable protective clothing, gloves and eye/face protection.

S45 : In case of accident or if you feel unwell, seek medical advice immediately.

S56 : Dispose of this material and its container at hazardous or special waste collection point.

S57 : Use appropriate container to avoid environmental contamination.

S61 : Avoid release in environment. Refer to special instructions/safety data sheets.

Please consult local regulations for a correct waste disposal.

ABBREVIATIONS

CV% : Coefficient of Variation Percentage

GLP : Good Laboratory Practice

IgM : Immunoglobulin G

IU : International Unit

mA : milliabsorbance

mL : milliliter

NCCLS : National Committee for Clinical Laboratory Standards



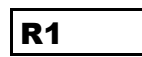




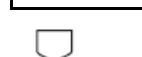



QC : Quality Control

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SYMBOLS

	Only for invitro diagnostic use
	Lot of manufacturing
	Reagent 1
	Concentration
	Reagent Ingredients
	Reference Number (Catalog No)
	Serial Number
	Expiration date
	Storage temperature interval
	Read the directions
	Biological risk



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