Immunoglobulin M (IgM)
(Immunoturbidimetric Method)

- **Kit Specifications:**

	Reagent/Quantity	Storage
Cat. No.: **IM0011**	R.1: 1 x 50 ml R.2: 1 x 10 total 60 ml	2-8°C
Cat. No.: **IM0017**	R.1: 1 x 50 ml R.2: 1 x 10 total 60 ml	2-8°C

- **Intended Use:**

In Vitro Diagnostic reagent pack for the quantitative determination of Immunoglobulin M (IgM) in human serum/plasma on automated and semi-automated photometric systems.

- **Summary and Explanation:**

The all antibodies have different classes (IgG, IgA, IgM, IgE and IgD). They have different function and structure. The IgM produce by B-Cell in plasma, this antibody encloses 5 percent of all soluble immunoglobulins. The molecular weight is 970 Kilo Dalton (kDa) which contain two same light chains and two same heavy chains. This immunoglobulin has five subunits in Y shape with monomeric structure and peptide binding and finally make pentamer complex. This immunoglobulin responsible of ABO blood groups and the rheumatoid factor. However, in all immunoglobulins IgA and IgM also perform polymorphism. The monomers of each immunoglobulin attached via j-chain which has a glycoprotein structure with 15 kDalton molecular weight. The disulfide bond near to the carboxy terminal in heavy chain make connection.

The IgM antibody is a dominant to response immunity initially. This antibody is an exclusively and first, appear in serum against infection. Also, to compare IgM with IgG the speed of reduction is high. So this scenario can guide us to diverse diagnostic of chronic or acute infection. Meanwhile, if the amount and titration of IgM is high, means the infection is at acute stage unlike IgG is high so the infection is at chronic stage. The main action of IgM is attached to new antigens, activate complement systems and active others reaction to catabolism the antigen.

The reduction of this antibody observed in secondary and initial deficiency auto immune syndrome, hyperproteinemia (nephrotic syndrome, enteropathy and burning), consume auto immune drug suppressor, multiple myeloma (IgG and IgM), and agammaglobulinemic. The increase of IgM is reported on acute infection, auto immune diseases, inflammation bowl disease and liver disorders such as biliary cirrhosis. Therefore, the quantitative measuring of IgM is essential and necessary for diversity diagnostic in all auto immune diseases.

Principle of the Method:

This method is based on reaction between anti-gen and anti-body. The IgM exist on the sample become sensitive by anti-body against human IgM and finally make turbid complex. The intensity of turbidity is directly related to amount of IgM in the sample which measuring at 340 nm.

IgM antigen + Anti-IgM antibody → Antigen/Antibody Complex

- **Reagent Preparation and Stability:**

Reagent is ready for use.
Before use, mix reagent by gently inverting each bottle.
Reagent is stable until the expiration date on the label when stored tightly closed at 2-8°C, protected from light and contaminations prevented during their use.
Do not use reagents over the expiration date.
Do not freeze and protect from light.
R1 is transparent and colorless.
R2 light beige color.
The following table is the preparation of calibrator with normal saline.
The normal saline 0.9%NaCl use as a zero.

Dilution	Neat	1:2	1:4	1:8	1:16
Dilution Factor	1	0.5	0.25	0.125	0.063

Waste Management:

Refer to local legal requirements for chemical disposal regulations.
Warning: Handle waste as potentially biohazardous material.
Dispose of waste according to accepted laboratory instructions and procedures.

- **Warnings and Precautions:**

For In Vitro Diagnostics Use Only.
For Professional Use Only.
Carefully read instructions for use.
In case of serious damage to the bottle or cap, resulting in product leakage or contamination, do not use the reagent pack and contact your distributor.
Take all necessary precautions required when handling laboratory reagents.
Do not use components past the expiry date stated on the Bottles.
Do not interchange caps among components as contamination may occur and compromise test results. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
Any serious incident related to the product must be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is located.

- **Type of Specimen:**

Use fresh serum, non-hemolysis and or heparinized, EDTA plasma collected. The stability of IgM serum/plasma samples at 2-8°C in 90 days and at -20°C in 6 months. Avoid contamination the samples.

Required but not Supplied:

Specific Protein calibrator from TKS or other valid calibrators.
Specific Protein Control Level 1 & 2 from TKS or other valid controls.
Saline solution 0.9 % NaCl
General laboratory equipments

- **Notes:**

Carefully read instructions for use.
It is recommended to use disposable material. If glassware is used the material should be scrupulously cleaned with hydrochloric acid 1 N and then thoroughly rinsed it with distilled water.
Use clean disposable pipette tips for its dispensation.
Disposable and glassware material used must be free of metals, ions and detergents.

Performance Characteristics:

Performance results can vary with the instrument used.
Data obtained in each individual laboratory may differ from these values.

The Maximum concentration will be obeying base of calibrator

LOD: 5 mg/dl

For samples with a higher concentration (base on maximum concentration of your calibrator), dilute 1:1 with 0.9 % NaCl and re-assay. Multiply result by 2.

Prozone:

In this assay till ۲۰00mg/dl concentration no prozone will not be observed.

Precision:

Intra Assay-Within run IgM

Sample	n	Mean (mg/dl)	SD (mg/dl)	CV (%)
1	20	65	1.0	1.53
2	20	99	1.0	1.01

Inter Assay-Between run IgM

Sample	n	Mean (mg/dl)	SD (mg/dl)	CV (%)
1	20	71	4.0	5.63
2	20	106	5.0	4.71

- **Accuracy:**

Results obtained using BIOMEDIC reagents (y) did not show systematic differences when compared with other commercial reagents (x).
Correlation coefficient (r): 0.997
Regression equation: Y = 0.908 (X) - 0.025 mg/dl
The results of the performance characteristics depend on the analyzer used.

- **Interfering Substances:**

Bilirubin (mixed isomer)	Less than 10% interference up to 600 µmol/L Bilirubin
Lipaemia	Less than 10% interference up to 5 g/L intralipid
Haemolysis	Less than 10% interference up to 5 g/L Hemoglobin.

Manufactured by: TOSE'E KIMIA SA'ADAT, No.5, 32nd Alley, Asadabadi St. Yousef abad, Tehran-IRAN
Factory Address: No.18, Niloufar 6, Toska Blvd., Nakhl Blvd., Paytakht Industrial Town, 54 km of Tehran-Semnan Road
Tel/Fax: +98 (0)21 88549754-9
www.tksmed.com - info@tksmed.com

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- **Reference Values:**

Adults	**40-230 mg/dl**	**0.41-2.37 µmol/L**
Children 10-13	**40-150 mg/dl**	**0.41-1.55 µmol/L**
Children 6-9	**40-160 mg/dl**	**0.41-1.65 µmol/L**
Children 3-5	**40-180 mg/dl**	**0.41-1.85 µmol/L**
Children 1-2	**40-140 mg/dl**	**0.41-1.44 µmol/L**
Infants 7-12 months	**30-100 mg/dl**	**0.31-1.03 µmol/L**
Infants 4-6 months	**20-100 mg/dl**	**0.21-1.03 µmol/L**
Infants 1-3 months	**10-70 mg/dl**	**0.10-0.72 µmol/L**
Infants <1 month	**10-30 mg/dl**	**0.10-0.31 µmol/L**

Each laboratory should establish its own expected values. The IgM results should always be reviewed with the patient's medical examination and history.

- **Assay Procedure:**

Allow reagents to reach working temperature before using.

A proportional variation of the reaction volumes indicated does not change the result

Assay conditions:

340 nm	**Wavelengths**
37 °C	**Incubation Temperature**
1 cm	**Cuvette**

Adjust the instrument to zero with distilled water.

Control/Sample/Calibrator	**Blank**	
1000 µl	1000 µl	**R1**
10 µl	-	**Control/Sample/Calibrator**
Gently mix and incubate for 5 minutes at 37°C. the first absorbance OD1 of sample measurement. Then added R2		

Control/Sample/Calibrator	**Blank**	
200 µl	200 µl	**R2**
Gently mix and incubate for 10 minutes at 37°C. The second absorbance OD2 of sample measurement.		

- **Calculations:**

Δ Abs= OD2 – OD1

The changes of absorbance Δ Abs should be followed by first absorbance and second absorbance respectively. Formerly, the second one should minus to the first one. Then the changes for all different calibrators should put in the logarithmic table so by this principal the concentration of control and samples should be determine.

Conversion units:

g/L = mg/dl x 0.01

TOSE'E KIMIA SA'ADAT has instruction sheets for several automatic analyzers. Instructions for many of them are available on request.

- **References:**

1-Gitlin D, Edelhoch HJ. Immunol. 1951, 66, 76-78.

2-Burtis CA, Ashwood ER. Tietz Fund. Of Clin. Chem. 5th ed. 30-54 and 462-494.

3-Guder WG, Narayanan S, Wisser H, Zawta B. List of Analytes; Preanalytical Variables. Brochure in: Samples: From the Patient to the Laboratory. Darmstadt: GIT Verlag, 1996.

4-Consensus values of the Deutsche Gesellschaft fur Laboratoriums-medizin, the Deutsche Gesellschaft fur Klinische Chemie and the Verband der Diagnostica-Industrie.V. (VDGH). DG Klinische Chemie Mitteilungen 1995; 41:743-748.

Symbols:

The following symbols are used in the labelling of TOSE'E KIMIA SA'ADAT systems:

IVD	In Vitro Diagnostics	Σ	Contains sufficient for <n> tests
LOT	Batch Code		Temperature limit
REF	Catalogue No.		Consult instruction for use
	Expiry Date		Caution
	Date of Manufacture		Keep dry
	Manufactured by		This way up
	Biological Risks		Keep away from sunlight

Rev 01: Issued on 20 February 2023

ISO 13485:2016
ISO 9001:2015

IVD

Revised:20231129

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