Immunoglobulin G (IgG)
(Immunoturbidimetric Method)

- **Kit Specifications:**

	Reagent/Quantity	Storage
Cat. No.: **IG0011**	R.1: 1 x 50 ml R.2: 1 x 10 total 60 ml	2-8°C
Cat. No.: **IG0017**	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 G (IgG) 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. This antibody, encloses 75 percent of all antibodies. The molecular weight is 150 KDalton which contain two same light chains and two same heavy chains. All chain attached to each other by disulfide binding and finally the Y form appear.

The IgG exist on internal and external of vascular space. This category of immunoglobulin produces by B-cells in plasma. The main function of immunoglobulins is secondary response in immunity. The critical role of antibodies is attached to the antigens to active some components and reactions to catabolism antigens. In the base of biological and functional characteristics IgG divided into 4 subclasses: IgG1, IgG2, IgG3 and IgG4.

The reduction of IgG is reported on secondary and initial deficiency auto immune syndrome (expulsion of all proteins and immunoglobulins), mal nutrition, bowl enteropathy, leukemia and consume auto immune drug suppressor.

In multiple myeloma, IgG will increase in monoclonal or polyclonal. The severe increase of one class in immunoglobulin leading the all reduction on other immunoglobulin classes. Also, IgG will rise on chronic liver disease, granulomatosis infection such as tuberculosis, wegneres syndrome and sarcoidosis. Furthermore, IgG will increase in autoimmune diseases including rheumatoid arthritis, systemic erythromatosis lupus, and sjogrens syndrome. Therefore, the quantitative measurement of IgG is crucial to diverse diagnostic in above diseases.

Principle of the Method:

This method is based on reaction between anti-gen and anti-body. The IgA exist on the sample become sensitive by anti-body against human IgG and finally make turbid complex. The intensity of turbidity is directly related to amount of IgG in the sample which measuring at 700 nm.

IgG antigen + Anti-IgG 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, plasma collected by EDTA. The stability of IgA serum/plasma samples at 2-8°C in 90 days and at -20°C in 6 months. The serum/plasma should be collected maximum till 2 hours after blood collection. Avoid the samples contamination.

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: 9 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 ٥٥٠0mg/dl concentration no prozone will not be observed.

Precision:

Intra Assay-Within run IgG

Sample	n	Mean (mg/dl)	SD (mg/dl)	CV (%)
1	20	660	13.0	1.96
2	20	1020	22.0	2.15

Inter Assay-Between run IgG

Sample	n	Mean (mg/dl)	SD (mg/dl)	CV (%)
1	20	670	15.0	2.23
2	20	1050	31.0	2.95

- **Accuracy:**

Results obtained using BIOMEDIC reagents (y) did not show systematic differences when compared with other commercial reagents (x).
Correlation coefficient (r): 0.909
Regression equation: Y = 0.930 (X) + 1.285 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.

- **Reference Values:**

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
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Adults	**700-1600 mg/dl**
Children 10-13	**700-1400 mg/dl**
Children 6-9	**600-1300 mg/dl**
Children 3-5	**500-1300 mg/dl**
Children 1-2	**350-1000 mg/dl**
Infants 7-12 months	**300-1000 mg/dl**
Infants 4-6 months	**180-800 mg/dl**
Infants 1-3 months	**250-750 mg/dl**
Infants <1 month	**700-1600 mg/dl**

Each laboratory should establish its own expected values. The IgG 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:

600-700 (700) 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**
5 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