Immunoglobulins M (IGM) – Immunoturbidimetric method
For Konelab - Indiko® systems

Instructions for Use (IFU)

IVD CE

ORDERING INFORMATION

Format	Code	Composition
Kit 2 x 40 mL – 2 x 6 mL	REF B78182266	n° 2 vials x 40 mL R.A n° 2 vials x 6 mL R.B n°1 vial x 60 mL R.C*

* In case of use on Indiko Analyser transfer the content into the additional empty vial

INTENDED USE
Diagnostic immunoturbidimetric test for the quantitative determination IVD of Immunoglobulins G (IGM) in human serum and plasma. All results must be interpreted in conjunction with the clinical context. FOR PROFESSIONAL USE ONLY

CLINICAL SIGNIFICANCE
Immunoglobulins constitute the main defense mechanism of the organism against infections, by promoting phagocytosis. Of these proteins, immunoglobulin M (IgM) are the first to be formed against a new antigen, especially the polysaccharide type, thus constituting the primary response of the organism to infection.
Higher than average IgM levels are seen in Waldenström's macroglobulinemia and in parasitic diseases.
Lower than average IgM levels are seen in agammaglobulinemia, in hypogammaglobulinemia, in disgammaglobulinemia, and in protein-dependent enteropathies.

PRINCIPLE OF THE METHOD
Immunoturbidimetric method. IgM contained in the test sample react with the specific antibodies, forming immunocomplexes, which cause a degree of turbidity which can be detected photometrically and is proportional to the IgM concentration in the sample. The quantitative analysis is obtained by interpolation of this photometric value with those found by testing known concentrations of IgM

Storage and stability

= **Storage temperature 2-8 °C**

If stored at 2-8°C avoiding direct light, the intact reagents remain stable until the expiration date, printed on the label. Slight variations in composition among batches will not affect test results.

Concentrations

Reagent A			
		Conc.	**U.M.**
Protein Buffer	TRIS	0.05	mol/L
	PEG	5	%
	NaN$_3$	< 0.1	%
Reagent B			
IgM Goat antiserum	NaN$_3$	< 0.1	%
Reagent C			
Sample Diluent	PBS	0,015	mol/L
	NaN$_3$	< 0,1	%

Materials included in the kit
Reagent as described above.
Necessary materials not included in the kit
Controls and calibrators.

PRECAUTIONS and WARNINGS
1. Reagents and waste materials shall be disposed of in accordance with Community waste provisions or national or regional provisions.
2. Reagents may contain non-active components such as preservatives and detergents. The total concentration of these components is below the limits set out in Regulation 1272/2008 EC and subsequent amendments and additions.
3. It is recommended that the reagent be handled in accordance with the rules of good laboratory practice and that appropriate personal protective equipment be used.
4. Do not use the reagent if it is visibly degraded (e.g. presence of corpuscles).
5.All human samples shall be handled and disposed of as potentially infectious material.
6. The kit should only be used by qualified and properly trained technical personnel.
7. Diagnoses shall be carried out exclusively by authorised and qualified personnel.
8. Comply with national directives on occupational safety and quality assurance.
9. Use equipment that complies with current regulations.

Reporting of serious incidents
In the event of a serious incident in relation to the use of the device, please inform the manufacturer (via your distributor) and the competent authority of the European Union member state where the incident occurred. For other jurisdictions, reporting must be made in accordance with regulatory requirements. Reporting serious incidents helps provide more information about the safety of the diagnostic medical device.

PREPARATION OF THE REAGENT
The Reagents are liquid, ready for use. After opening, the Reagents are stable until the expiry date if kept as indicated in "Storage and stability".

PROCEDURE
Quality Control
Use the Sclavo Diagnostics Int. Control Sera for specific Proteins Low REF B47182064 and High REF B47182065 for your quality control purposes at least once a day. Repeat the analysis also after calibration. Obtained values must be within the range of acceptability.

ANALYTICAL TECHNIQUE
For automatic procedures, consult the instruction manual and applicable notes for the Konelab® - Indiko®. analyzers. All applications not specifically approved by Sclavo Diagnostics Int. cannot be guaranteed in terms of performance and must be evaluated by the user.

Calibration
For calibration, use the Sclavo Diagnostics Int. Specific Proteins Single Level Calibrator REF B47182273, in accordance with methodology applying to Konelab® - Indiko® series.

Traceability
The IGM value has been determined according to the IRMM using the reference material ERM®-DA470k/IFCC.

SAMPLE
Sample types and storage
Serum or plasma obtained by normal medical techniques can be used. No special preparation of the patient is necessary.
The samples must be pre-diluted 1:10 before analysis.
Strongly lipemic samples or those which present a high degree of turbidity or precipitates must be clarified by centrifugation (10 min. at 15,000xg), before testing.

Calculation of results on Konelab® - Indiko® systems
Results are automatically calculated by analyzer based on the calibration curve. The analyzer automatically performs serial dilutions from a primary standard according to the method protocol. The calibration curve is obtained by interpolating the values obtained with an appropriate algorithm.

REFERENCE RANGE
The typical reference range (g/L) is:
0- 5 months	0.26 – 1.22
5 -- 9 months	0.32 – 1.32
9 - 15 months	0.40 – 1.43
15 - 24 months	0.46 – 1.52
2 - 4 years	0.37 – 1.84
4 – 7 years	0.37 – 2.24
7 – 10 years	0.38 – 2.51
10 - 13 years	0.41 – 2.55
13 – 16 years	0.45 – 2.44
16-18 years	0.49 – 2.01
18 years	0.37 – 2.86

As sex, age, geographical location and other factors can influence the normal values found in the population, each laboratory should determine its own normal, medium and pathological values for its own population.

CHARACTERISTICS/PERFORMANCE
Analytical Range – Antigen excess
The analytical range was tested using a strongly positive sample and serial dilutions of this serum in saline solution. The method guarantees a correct response throughout the minimal detectable measurement range and the calibrator higher concentration.
The present method does not show Antigen Excess until 23.60 g/L.

Trueness
The Trueness of the analytical results has been determined according to the CLSI EP15-A2 guideline, using commercial control sera. The data obtained are shown in the following table (confidence interval 95%).

Level	Replicates	Mean (g/L)	SD	CV%
Low	25	0.608	0.0127	2.1
High	25	1.784	0.0688	3.9

Specificity
The method is 100% specific for human IGM.

Interferences
The influence of the following substances on the analytical response was tested up to the concentrations reported below:

Bilirubin 50 mg/dL, Ascorbic Acid 50 mg/dL, EDTA 10 mM, Hemoglobin 500 mg/dL, Sodium citrate 1000 mg/dL, Sodium Heparin 40 mg/mL, Triglycerides 2%, Rheumatoid Factor 2000 IU/mL.

No appreciable interference was found in any case, and the variations observed were within the expected precision range. Higher concentrations were not tested.

However, in view of the wide heterogeneity of potentially interfering substances and pharmaceuticals, for diagnostic purposes the results of this test must always be taken into consideration in conjunction with the clinical history of the patient, other clinical tests and medical investigations.

Precision
The Precision of the analytical results has been determined as Repeatability and Total Precision according to the CLSI EP15-A2 guideline, using commercial control sera. The data obtained are shown in the following table (confidence interval 95%).

Within-run Precision – Repeatability				
Level	Replicates	Mean (g/L)	DS	CV%
Low	25	0.608	0.008	1.3
High	25	1.784	0.020	1.1
Total Precision (Within-lab Precision)				
Level	Replicates	Mean (g/L)	DS	CV%
Low	25	0.608	0.013	2.2
High	25	1.784	0.075	4.2

Limits of sensitivity
The Sensitivity limit has been measured using serial dilutions of a high concentrated serum. The smallest measurable concentration is 0.07 g/L.

Comparison between methods
The present method was compared with another commercially available method following the guidelines of the CLSI EP09-A2-IR, analyzing 59 human sera with a concentration between 0.36 e 2.49 g/L. The correlation data between the two methods are reported in the table below.

Parameter	Estimation
Intercept	0.0059
Slope	0.958
Correlation Coeff. (R)	0.993

Symbols used in IFU and Packaging	
IVD In vitro diagnostic medical device vitro	Manufacturer
REF Catalogue Number	i Instruction for use
LOT Lot Number	Temperature limitation
Expiration date	

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REVISION	DATE	CHANGE
Rev.E	06/2024	New Issue for IVDR Regulation (UE) 2017/746 compliance