Urinary Proteins Multilevel Calibrator

6 x 1 mL • REF B47282215

IVD

ORDERING INFORMATION

Format (Test/kit)	Code	Composition
-	REF B47282215	6 vials x 1 ml

Intended use

For calibration purposes in the quantitative determination of proteins (IgG, KLC, LLC, mALB, B2M, TRF, A1M) in human urine in association with immunoturbidimetric kits and applications procedures established by Sclavo Diagnostics International. FOR PROFESSIONAL USE ONLY.

Characteristics of the calibrator

The calibrator is composed of highly purified human proteins which have been added in variable amounts to a stabilized proteic buffer solution in order to obtain adequate concentrations.

Composition of the kit

The calibration set is composed of a series of five calibrators containing increasing concentrations of the analyte, plus a standard corresponding to "zero".
The analyte concentrations were determined by the immunoturbidimetric methods using Sclavo Diagnostics Int. reagents.
The analyte concentrations are batch-dependent, the true values are reported in the table below and are expressed in "mg/L".

Assigned values and traceability

The analyte concentration was determined by the immunoturbidimetric methods using Sclavo Diagnostics Int. reagents.
The KLC, LLC, IGG, TRF, mALB values were determined using spectrophotometric methods applied to the pure proteins.
The B2M values were determined with reference to the NIBSC "1st International Standard BETA-2 MICROGLOBULIN Code: B2M".
The A1M values were determined using the Sclavo Diagnostics Int. standard reference preparation.
The analyte concentration is batch-dependent and the true value is reported in the table below.

Preparation, conservation and stability

The calibrator is liquid, ready for use. It is stable up to the expiry date reported on the vials if closed and stored at a temperature ranging between 2 and 8°C.

PRECAUTIONS and WARNINGS

1. Reagents and waste materials shall be disposed of in accordance with Community waste provisions or national or regional provisions.
2. In addition to any risk claims relating to active components, 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) After reconstitution
5. All human samples shall be handled and disposed of as potentially infectious material. The sera have been tested and proved negative for the presence of HbsAg, and also for anti-HIV 1 and 2 and anti-HCV antibodies. As no known method can completely guarantee the absence of infective agents, these reagents must be handled following all precautions required for potentially infected serum or blood samples (Biosafety level: 2).
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.

Warnings

Do not use the calibrator in the case that anomalies or evident alterations are observed.
Mix by inversion before use.
The sera contain sodium azide 0.09% which can react with lead and copper to form explosive deposits of metal azides. Dilute with large amounts of water before elimination.

Procedure

The calibrator is treated in the same way as the test samples and in accordance with the recommended test protocol. Variations in the test procedures or in the composition of the reagents can cause significant alterations in the accuracy of the reagent.

Reporting of serious incidents

Please inform the manufacturer (through your distributor) and the competent authority of the member state of the European Union in which the user and/or patient is established, of cases of serious incident that has occurred in relation to the device. For other jurisdictions, reports of serious incidents must be made in accordance with the regulatory requirements of the home Member State. By reporting serious incidents, you help provide more information about the safety of your in vitro medical diagnostic device.

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

REVISION	DATE	CHANGE
Rev. D	09/2023	Revision for compliance with IVDR Regulation (UE) 2017/746

Concentration of the multicalibrator

Calibrator	Volume	IGG	Light Chains (Free & Bound)		m-ALB	B2M	TRF	A1M
			KAPPA	LAMBDA				
		mg/L	mg/L	mg/L	mg/L	mg/L	mg/L	mg/L
Standard 0	1 ml	0	0	0	0	0	0	0
Standard 1	1 ml	35	24	12	54	0.18	4	18
Standard 2	1 ml	88	59	29	134	0.44	11	45
Standard 3	1 ml	176	118	58	269	0.88	21	91
Standard 4	1 ml	264	177	87	403	1.32	32	136
Standard 5	1 ml	352	236	116	537	1.76	43	181

LOT 24/001

2026/05/13

+2 +8 °C

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