Urinary Proteins High Control

IVD

3 x 1 mL • REF B47282224

INFORMATION FOR ORDER

Format (Test/kit)	Code	Composition
-	REF B47282224	3 vials x 1 ml

Introduction

Control samples are reference materials to be used to determine accuracy and precision in urinary protein determinations. The use of control materials is part of normal laboratory activity as specified in the "*Good Laboratory Practice*". The Sclavo Diagnostic Urinary Protein Control High is a control reagent containing High levels of urinary proteins (Kappa and Lambda Light Chains, Immunoglobulin G, Microlbuminuria, Beta 2 Microglobulin, Transferrin and Alpha 1 Microglobulin).

Intended use

For control purposes in the determination of proteins in human urine, in association with the immunoturbidimetric kits and instrumental applications established by Sclavo Diagnostics International. FOR PROFESSIONAL USE ONLY

Characteristics of the control

The control sera are produced from a pool of stabilized human sera from which lipid content has been removed, and containing high concentrations of the analytes.

Composition of the kit

The Urinary Proteins control set is composed of three 1ml vials containing high concentrations of the analytes. Controls are liquid ready to use.

Assigned values and traceability

The concentration of the analytes was determined by immunoturbidimetric methods using Sclavo Diagnostics International reagents and calibrators. The concentrations indicated are batch dependent and their values and acceptability ranges are specified in the table below and are expressed in "mg/L".

The assigned values for CLK, CLL, IGG, ALB, TRF were determined by spectrophotometric analysis of pure proteins.

The value of B2M refers to the international reference standard NIBSC "1st International Standard BETA-2 MICROCLOBULIN Code: B2M".

The value of A1M refers to the standard reference preparation for A1M of Sclavo Diagnostics Int.

Preparation, storage and stability

The sera are liquid, ready for use and are stable up to the expiry date reported on each vial if stored at 2-8°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 control sera if any anomaly or evident alteration is observed.
Mix by inversion before use.
The sera contain sodium azide 0.09% which can react with lead and copper, forming highly explosive metal azides. Dilute with large volumes of water before disposal.

Procedure

The controls are 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.

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	10/2024	Chemilab Line Deletion

Assigned values

KONELAB – INDIKO – OPEN Systems	Urinary Proteins High Control		
Analyte	Units	Average	Range
Kappa light chains (free and bound)	mg/L	**193**	145 – 241
Lambda light chains (free and bound)	mg/L	**95**	71 – 119
Immunoglobulin G	mg/L	**288**	216 – 360
Microalbuminuria	mg/L	**391**	293 – 489
β-2 Microglobulin	mg/L	**1.46**	1.09 – 1.82
Transferrin	mg/L	**28**	21 – 35
Alfa-1 Microglobulin	mg/L	**143**	107 – 178

LOT **24/002**

2026/10/07

+2 +8 °C

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