Specific Proteins High Control

IVD

3 x 1 mL • REF B47182065

INFORMATION FOR ORDER

Format (Test/kit)	Code	Composition
-	REF B47182065	3 vials x 1 ml

Introduction

Control samples are reference materials to be used to determine accuracy and precision in specific protein determinations. The use of control materials is part of normal laboratory activity as specified in the "*Good Laboratory Practice*". The Sclavo Diagnostic Specific Protein Control High is a control reagent containing High levels of specific proteins.

Intended use

For control purposes in the determination of specific proteins in human serum and plasma, in association with immunoturbidimetric kits and the 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, delipidated human sera, and containing high concentrations of the analytes.

Composition of the kit

The Specific 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 analyte concentrations are batch-dependent and were determined by the immunoturbidimetric methods using Sclavo Diagnostics Int. reagents and calibrators.

The analyte concentrations are batch-dependent, the values and the acceptable range are reported in the table below.

The declared values were with reference to the international standard IFCC/RPPHS (RPPHS/CRP 470) and are expressed in "g/L".

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	04/2025	Chemilab Line Deletion

Assigned values

KONELAB – INDIKO – OPEN Systems			"High" Control	
Analyte	Abbr.	units	Average	Range
Alfa 1 Acid Glycoprotein	AGP	g/L	**1.90**	1.43 - 2.38
Alfa 1 Antitrypsin	AAT	g/L	**3.31**	2.48 - 4.14
Alfa 2 Macroglobulin	A2M	g/L	**5.33**	4.00 - 6.66
Haptoglobin	HPT	g/L	*	*
Ceruloplasmin	CER	g/L	*	*
C1 Esterase Inhibitor	CEI	g/L	*	*
C3 Complement	C3	g/L	**3.77**	2.83 - 4.71
C4 Complement	C4	g/L	**0.65**	0.48 - 0.81
Immunoglobulin A	IgA	g/L	**5.63**	4.22 - 7.04
Immunoglobulin G	IgG	g/L	**25.7**	19.3 - 32.1
Immunoglobulin M	IgM	g/L	**1.90**	1.43 - 2.38
Kappa Light Chains	CLK	g/L	**7.41**	5.56 - 9.27
Lambda Light Chains	CLL	g/L	**3.65**	2.74 - 4.56
Prealbumin	PAL	g/L	*	*
Transferrin	TRF	g/L	**6.87**	5.15 - 8.59

***Available upon request**

LOT **25/002**

2027/01/13

+8 +2 °C

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