Single Level Calibrator CRP

3 x 1 mL • REF B47182290

ORDERING INFORMATION

Format (Test/kit)	Code	Composition
-	REF B47182290	3 vials x 1 ml

Intended use
For calibration purposes in the quantitative determination of C-reactive protein in human serum and plasma in association with immunoturbidimetric kits and applications procedures established by Sclavo Diagnostics International. FOR PROFESSIONAL USE ONLY.

Characteristics of the calibrator
The calibrator is produced from a pool of stabilized human sera, which may be enriched with highly purified proteins in order to obtain adequate concentrations.

Composition of the kit
The calibration set is composed of three vials of calibrator containing a single concentration level.

Assigned values and traceability
The analyte concentration was determined by the immunoturbidimetric methods using Sclavo Diagnostics Int. reagents.
The results of the concentrations obtained are to be referred to the use of international reference standards. The assigned value for C-Reactive Protein is referred to the IRMM "ERM-DA470" international standard.
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. F	10/2024	Chemilab line deletion

Calibration values for the parameter

Description	Code	Value	Unit
C-REACTIVE PROTEIN	CRP	**240**	mg/L

LOT **24/001**

2026/10/04

+2 +8 °C

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METHODS FOR SINGLE INSTRUMENTATION LINE

KONELAB - INDIKO SYSTEM

DESCRIPTION	Code	Value	Unit	Conc.1	Conc.2	Conc.3	Conc.4	Conc.5
C REACTIVE PROTEIN	CRP	**240**	mg/L	1+9	1+5	1+2	1+1	1+0

OPEN SYSTEM

DESCRIPTION	Code	Value	Unit	Conc.1	Conc.2	Conc.3	Conc.4	Conc.5
C REACTIVE PROTEIN	CRP	**240**	mg/L	1/8	1/4	1/3	1/2	1/1

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