

SERUMPROTEIN CALIBRATOR 7 PARAMETERS

(CALIBRATOR FOR IMMUNOCHEMICAL REACTIONS)

AAG - C3 - C4 - IgA - IgG - IgM - TRF

Titred human serum useful as calibrator or control in immuno turbidimetric and radial immunodiffusion reactions

PRINCIPLE

The evaluation of suitable material in the sequence analysis, allows to verify the global inaccuracy of procedure adopted in.

The use of human serum as a control material, guarantees commutability of results obtained in the Quality Control process with similar samples.

The serum is calibrated, against ERM-DA470k/IFCC, for the following proteins:

alpha-1-acid glycoprotein (AAG), C3 Complement (C3), C4 Complement (C4), Immunoglobulin A (IgA), Immunoglobulin G (IgG), Immunoglobulin M (IgM) and Transferrin (TRF).

REAGENTS

Treated and titred human serum ready to use.

STORAGE AND STABILITY

Calibrator is stored at 2-8°C and is stable until expiration date on label if not contaminated during use.

Before opening wait and bring the vial at room temperature and shake delicately avoiding foam formation.

VALUES CALIBRATION

The calibration values are specified for each lot and are indicated in the attached sheet values.

The concentration of each protein was determined by the average of the tests performed with immunoturbidimetric methods and radial immunodiffusion using as calibrator ERM-DA470k/IFCC.

The extended uncertainty is calculated with $k = 2$ corresponds to a confidence level of 95%.

CALIBRATION CURVE

To obtain a calibration curve, dilute the calibrator with saline solution at different concentrations.

For radial immunodiffusion plates it is possible to run a two points calibration curve using saline as a point at 0 mg/dl and the undiluted calibrator as second point.

The 0 mg/dl point must not show any halos, therefore the measurement to take into consideration is the diameter of the hole.

Calibrators must be treated as if they were samples and test as indicated by the analytical procedure required by the reagent used.

REFERENCE INTERVALS

Reference ranges for protein for healthy individuals.

alpha-1-acid glycoprotein	50 – 120 mg/dl
C3	90 – 180 mg/dl
C4	10 – 40 mg/dl
IgA	70 – 400 mg/dl
IgG	700 – 1600 mg/dl
IgM	40 – 230 mg/dl
Transferrin	200 – 360 mg/dl

Each laboratory should establish appropriate reference intervals related to its population.

PRECAUTIONS

- Contains Sodium Azide 0.09 g/l.
- Each serum or plasma donor unit used in this product has been tested and found to be negative for HbsAg, HCV, HIV antibody, HCV-PCR and HIV-PCR by an FDA approved method.
- Considering that no known test can offer complete certainty that products derived from human blood will not transmit hepatitis, HIV or other infectious agents, must be taken all the

necessary precautions for handling potentially infectious materials.

NOTE

- Inaccurate results, or changes of color reagent could indicate a deterioration of the product. In any case, poor performance of the calibrator may also be due to other factors related to the dosage system.
- For in vitro diagnostic use only.

WASTE DISPOSAL

Waste products must be handled as per relevant security cards and local regulations.

PACKAGING

CODE IC00200

Calibrator 1 x 1 ml (liquid)









MANUFACTURER

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REFERENCES

1. Blirup-Jensen S, Johnson AM, Larsen M. Protein standardization V: value transfer. A practical protocol for the assignment of serum protein values from a reference Material to a Target Material. Clin Chem Lab Med 2008;46:1470-79.
2. Zegers I, Keller T, Schreiber W, Sheldon J, Albertini R, Blirup-Jensen S, Johnson M, Trapmann S, Emons H, Merlini G, Schimmel H. Characterization of the New Serum Protein Reference Material ERM-DA470k/IFCC: Value Assignment by Immunoassay. Clin Chem 2010;56:12:1880-88.
3. Blirup-Jensen S, Johnson AM, Larsen M. Protein standardization IV: value transfer. Procedure for the assignment of serum protein values from a reference preparation to a target material. Clin Chem Lab Med 2001;39:1110-22.

SYMBOLS

-  Only for IVD use
-  Lot of manufacturing
-  Code number
-  Storage temperature interval
-  Expiration date (year, month)
-  Warning, read enclosed documents
-  Read the directions
-  Biological risk

NOTE: MODIFICATIONS HIGHLIGHTED WITH GRAY BACKGROUND

Mod. 01.06 (ver. 02 – 19/03/2024)

