

LIQUID PROTEIN CALIBRATORS (SP CAL (LIQ))

FOR NEAT SAMPLE ASSAYS

CATALOGUE NO. IT 269I
LOT NOS. 1748IT - 1752IT
EXPIRY: 2019-09-28
PRESENTATION: Liquid
SIZE: 5 x 1.0 ml
GTIN: 05055273204032

INTENDED USE

Liquid Protein Calibrators are an *in vitro* diagnostic product used for the calibration of ASO, Complement C3, Complement C4, Ceruloplasmin, CRP, Ferritin, Haptoglobin, IgA, IgG, IgM, Prealbumin, RF and Transferrin assays.

CHARACTERISTICS

The calibration material is derived from normal serum obtained from volunteer donors.

Assignment of IT269I has been performed at Randox by immunoturbidimetry, with reference to material standardised against appropriate International Reference Preparations. The assigned values for the batch are listed below.

PREPARATION

These Calibrators are supplied ready for use.

STABILITY

The material is stable to expiry, when stored at +2°C to +8°C in the original capped containers. Open vials are stable for 30 days in the absence of bacterial contamination. Only the required amount of product should be removed. After use, any residual product should NOT BE RETURNED to the original vial.

SAFETY PRECAUTIONS AND WARNINGS

Human source material, from which this product has been derived, has been tested at donor level for the Human Immunodeficiency Virus (HIV 1, HIV 2) antibody, Hepatitis B Surface Antigen (HbsAg), and Hepatitis C Virus (HCV) antibody and found to be NON-REACTIVE. FDA approved methods have been used to conduct these tests.

However, since no method can offer complete assurance as to the absence of infectious agents, this material and all patient samples should be handled as though capable of transmitting infectious diseases and disposed of accordingly.

For **IN VITRO** diagnostic use only.

MATERIALS REQUIRED BUT NOT PROVIDED

Randox Saline Diluent, (Cat. No. SA 3854).

| | REFERENCE MATERIAL | Units | Calibrator 1 | Calibrator 2 | Calibrator 3 | Calibrator 4 | Calibrator 5 |
|-------------------|--------------------|-------|--------------|--------------|--------------|--------------|--------------|
| ASO | NIBSC 97/662 | IU/ml | - | - | - | - | 742 |
| Complement C3 | ERM®-DA470k/IFCC | mg/dl | 32.3 | 64.7 | 129.3 | 258.7 | 517.3 |
| | | g/l | 0.32 | 0.65 | 1.29 | 2.59 | 5.17 |
| Complement C4 | ERM®-DA470k/IFCC | mg/dl | 9.0 | 18.0 | 36.0 | 72.0 | 143.9 |
| | | g/l | 0.09 | 0.18 | 0.36 | 0.72 | 1.44 |
| Ceruloplasmin | ERM®-DA470k/IFCC | mg/dl | 3.5 | 7.0 | 14.1 | 28.1 | 56.2 |
| | | g/l | 0.04 | 0.07 | 0.14 | 0.28 | 0.56 |
| CRP multipoint | ERM®-DA474/IFCC | mg/l | 13.4 | 26.8 | 53.7 | 107.3 | 214.6 |
| | | g/l | 0.0134 | 0.0268 | 0.0537 | 0.1073 | 0.2146 |
| Ferritin | NIBSC 94/572 | ng/ml | 35.5 | 52.6 | 103.2 | 227 | 453.6 |
| Haptoglobin | ERM®-DA470k/IFCC | mg/dl | 23.3 | 46.6 | 93.1 | 186.2 | 372.4 |
| | | g/l | 0.23 | 0.47 | 0.93 | 1.86 | 3.72 |
| Ig A single point | ERM®-DA470k/IFCC | mg/dl | - | - | - | - | 663 |
| | | g/l | - | - | - | - | 6.63 |
| IgG single point | ERM®-DA470k/IFCC | mg/dl | - | - | - | - | 3833 |
| | | g/l | - | - | - | - | 38.33 |
| IgM single point | ERM®-DA470k/IFCC | mg/dl | - | - | - | - | 391 |
| | | g/l | - | - | - | - | 3.91 |
| IgA multipoint | ERM®-DA470k/IFCC | mg/dl | 41.4 | 82.9 | 165.8 | 331.5 | 663 |
| | | g/l | 0.41 | 0.83 | 1.66 | 3.32 | 6.63 |
| IgG multipoint | ERM®-DA470k/IFCC | mg/dl | 239.6 | 479.1 | 958.3 | 1916.5 | 3833 |
| | | g/l | 2.40 | 4.79 | 9.58 | 19.17 | 38.33 |
| IgM multipoint | ERM®-DA470k/IFCC | mg/dl | 24.4 | 48.9 | 97.8 | 195.5 | 391 |
| | | g/l | 0.24 | 0.49 | 0.98 | 1.96 | 3.91 |
| Prealbumin | ERM®-DA470k/IFCC | mg/dl | 4.74 | 9.47 | 18.95 | 37.90 | 75.79 |
| | | g/l | 0.05 | 0.09 | 0.19 | 0.38 | 0.76 |
| Rheumatoid Factor | NIBSC 64/002 | IU/ml | 8.2 | 19.5 | 44.5 | 66.8 | 84.3 |
| Transferrin | ERM®-DA470k/IFCC | mg/dl | 31.3 | 62.5 | 125.1 | 250.1 | 500.2 |
| | | g/l | 0.31 | 0.63 | 1.25 | 2.50 | 5.00 |

CALIBRATOR VALUES FOR RX SUZUKA

| | REFERENCE MATERIAL | Units | Calibrator 1 | Calibrator 2 | Calibrator 3 | Calibrator 4 | Calibrator 5 |
|-----|--------------------|-------|--------------|--------------|--------------|--------------|--------------|
| IgA | ERM®-DA470k/IFCC | mg/dl | 1.97 | 3.95 | 7.89 | 15.79 | 31.57 |
| | | g/l | 0.020 | 0.039 | 0.079 | 0.158 | 0.316 |
| IgG | ERM®-DA470k/IFCC | mg/dl | 11.41 | 22.82 | 45.63 | 91.26 | 182.52 |
| | | g/l | 0.114 | 0.228 | 0.456 | 0.913 | 1.825 |
| IgM | ERM®-DA470k/IFCC | mg/dl | 1.16 | 2.33 | 4.65 | 9.31 | 18.62 |
| | | g/l | 0.012 | 0.023 | 0.047 | 0.093 | 0.186 |

Please note that 0.9% NaCl is required as the zero calibrator for ALL assays. We recommend Randox Saline Diluent, (Cat. No. SA 3854).

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