

## LIQUID ASSAYED SPECIFIC PROTEIN CONTROL - LEVEL I (SP CONTROL I)

|                 |                |                |            |
|-----------------|----------------|----------------|------------|
| <b>CAT. NO.</b> | PS2682         | <b>LOT NO.</b> | 675LPC     |
| <b>SIZE</b>     | 3 x 1 ml       | <b>EXPIRY:</b> | 2025-06-28 |
| <b>GTIN:</b>    | 05055273204896 |                |            |

### INTENDED USE

This product is intended for *in vitro* diagnostic use, in the quality control of serum on clinical chemistry and immunoassay systems. The Assayed Liquid Protein Controls are for the control of accuracy.

### DEVICE DESCRIPTION

The Liquid Protein Controls are supplied at 3 levels, level 1, 2 and 3. Target values and ranges are supplied for the analytes listed in the values table. Note: Free Lambda light chains are not for use in the U.S.

### SAFETY PRECAUTIONS AND WARNINGS

For *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

#### Pictogram



#### Warning

#### Hazard statement(s)

H317 May cause an allergic skin reaction.

#### Precautionary statement(s)

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.  
 P272 Contaminated work clothing should not be allowed out of the workplace.  
 P280 Wear protective gloves/protective clothing/eye protection/face protection.

#### Supplemental Hazard Information (EU)

P302+P352 If on skin: Wash with plenty of water.  
 P321 Specific treatment (see on this label).  
 P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

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.

Health and Safety Data Sheets are available on request.

### STORAGE AND STABILITY

OPENED: Store refrigerated (+2°C to +8°C). Protein control material is stable for 30 days at +2°C to +8°C, if kept capped in original container and free from contamination. Only the required amount of product should be removed. After use, any residual product should NOT BE RETURNED to the original vial.

UNOPENED: Store refrigerated (+2°C to +8°C). Stable to expiration date printed on individual vials.

Note: Free Kappa Light Chains is present in the Liquid Assayed Specific Protein Control material but no claim is made for the expected value or stability of this analyte.

### PREPARATION

The Liquid Protein Controls are supplied ready for use. Allow the control to come to room temperature before analysis.

### MATERIALS PROVIDED

Liquid Protein Control - Level I 3 x 1 ml

**MATERIALS REQUIRED BUT NOT PROVIDED**

Not applicable.

**LIMITATIONS**

RF: Please note that the dilution of multi-controls on certain systems can result in the over recovery of R.F. compared to the undiluted control. This is due to complex Immunoglobulin interactions.

**ASSIGNED VALUES**

Each batch of Protein Control is submitted to approximately 100 laboratories and values are assigned from a consensus of results obtained by these laboratories. With each batch, a control range is provided for individual parameters and each parameter method.

If a method is unavailable, contact Randox Laboratories - Technical Services, Northern Ireland, tel: +44 (0) 28 9445 1070 or email [Technical.Services@randox.com](mailto:Technical.Services@randox.com).

The presence of a vertical bar in the margin indicates a technical update from the previous revision

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## LIQUID ASSAYED SPECIFIC PROTEIN CONTROL - LEVEL 1 (SP CONTROL 1)

Cat. No. PS2682 Lot. No. 675LPC

Size 3 x 1 ml Expiry 2025-06-28

| Analyte                   | unit          | Target | Range |                                  | methods                           |
|---------------------------|---------------|--------|-------|----------------------------------|-----------------------------------|
|                           |               |        | low   | high                             |                                   |
| Albumin                   | g/l           | 20.3   | 17.3  | 23.3                             | Bromocresol Green (IFCC Cal.)     |
|                           | g/dl          | 2.03   | 1.73  | 2.33                             |                                   |
|                           | g/l           | 19.0   | 16.2  | 21.9                             | Bromocresol Purple (IFCC Cal.)    |
|                           | g/dl          | 1.90   | 1.62  | 2.18                             |                                   |
|                           | g/l           | 19.3   | 16.4  | 22.2                             | Nephelometric (IFCC Cal.)         |
|                           | g/dl          | 1.93   | 1.64  | 2.22                             |                                   |
|                           | g/l           | 20.8   | 17.7  | 23.9                             | Bromocresol Green (Non IFCC Cal.) |
|                           | g/dl          | 2.08   | 1.77  | 2.39                             |                                   |
| g/l                       | 20.0          | 17.0   | 23.0  | Turbidimetric Assays (IFCC Cal.) |                                   |
| g/dl                      | 2.00          | 1.70   | 2.30  |                                  |                                   |
| Alpha-1-Acid Glycoprotein | g/l           | 0.547  | 0.438 | 0.656                            | Turbidimetric (IFCC Cal.)         |
|                           | mg/dl         | 54.7   | 43.8  | 65.6                             | Nephelometric (IFCC Cal.)         |
|                           | g/l           | 0.580  | 0.464 | 0.696                            |                                   |
|                           | mg/dl         | 58.0   | 46.4  | 69.6                             |                                   |
| Alpha-1-Antitrypsin       | g/l           | 0.537  | 0.430 | 0.644                            | Turbidimetric (Non IFCC Cal.)     |
|                           | mg/dl         | 53.7   | 43.0  | 64.4                             |                                   |
|                           | g/l           | 0.502  | 0.402 | 0.602                            | Turbidimetric (IFCC Cal.)         |
|                           | mg/dl         | 50.2   | 40.2  | 60.2                             |                                   |
| Alpha-1-Antitrypsin       | g/l           | 0.571  | 0.457 | 0.685                            | Nephelometric (IFCC Cal.)         |
|                           | mg/dl         | 57.1   | 45.7  | 68.5                             |                                   |
|                           | g/l           | 0.498  | 0.398 | 0.598                            | Turbidimetric (Non IFCC Cal.)     |
|                           | mg/dl         | 49.8   | 39.8  | 59.8                             |                                   |
| Alpha-2-Macroglobulin     | g/l           | 1.12   | 0.896 | 1.34                             | Nephelometric (IFCC Cal.)         |
|                           | mg/dl         | 112    | 89.6  | 134                              |                                   |
| Alphafoetoprotein         | KIU/l = IU/ml | 14.0   | 11.2  | 16.8                             | Chemiluminescence (IFCC Cal.)     |
|                           | ng/ml         | 16.9   | 13.6  | 20.2                             |                                   |
|                           | KIU/l = IU/ml | 14.3   | 11.4  | 17.2                             | Chemiluminescence (Non IFCC Cal.) |
|                           | ng/ml         | 17.3   | 13.8  | 20.8                             |                                   |
| Anti Streptolysin O       | IU/ml         | 97.7   | 78.2  | 117                              | Turbidimetric (Non IFCC Cal.)     |
|                           | IU/ml         | 97.2   | 77.8  | 117                              | Neph. others (Non IFCC Cal.)      |
|                           | IU/ml         | 64.4   | 51.5  | 77.3                             | Neph. Beckman (IFCC Cal.)         |
|                           | IU/ml         | 66.6   | 53.3  | 79.9                             | Neph. Beckman (Non IFCC Cal.)     |
| Beta-2-microglobulin      | µg/ml = mg/l  | 1.19   | 0.952 | 1.43                             | Nephelometric (IFCC Cal.)         |
|                           | µg/ml = mg/l  | 1.24   | 0.992 | 1.49                             | Nephelometric (Non IFCC Cal.)     |
|                           | µg/ml = mg/l  | 1.42   | 1.14  | 1.70                             | Turbidimetric (IFCC Cal.)         |
|                           | µg/ml = mg/l  | 1.38   | 1.10  | 1.66                             | Turbidimetric (Non IFCC Cal.)     |
| C-Reactive Protein        | mg/l          | 28.6   | 22.9  | 34.3                             | Vitros (IFCC Cal.)                |
|                           | mg/l          | 24.2   | 19.4  | 29.0                             | Turbidimetric (IFCC Cal.)         |
|                           | mg/l          | 22.7   | 18.2  | 27.2                             | Nephelometric (IFCC Cal.)         |
|                           | mg/l          | 29.7   | 23.8  | 35.6                             | Vitros (Non IFCC Cal.)            |
|                           | mg/l          | 23.5   | 18.8  | 28.2                             | Nephelometric (Non IFCC Cal.)     |
|                           | mg/l          | 24.4   | 19.5  | 29.3                             | Turbidimetric (Non IFCC Cal.)     |

## LIQUID ASSAYED SPECIFIC PROTEIN CONTROL - LEVEL 1 (SP CONTROL 1)

Cat. No. PS2682 Lot. No. 675LPC

Size 3 x 1 ml Expiry 2025-06-28

| Analyte                  | unit         | Target | Range |       | methods                                   |
|--------------------------|--------------|--------|-------|-------|---|
|                          |              |        | low   | high  |   |
| C-Reactive Protein       | mg/l         | 24.9   | 19.9  | 29.9  | Agappe - Nephelometry                     |
|                          | mg/l         | 23.4   | 18.7  | 28.1  | Roche Turbidimetric Gen 3 (IFCC Cal.)     |
|                          | mg/l         | 22.9   | 18.3  | 27.5  | Roche Turbidimetric Gen 3 (non-IFCC Cal.) |
|                          | mg/l         | 23.9   | 19.1  | 28.7  | Roche Turbidimetric Latex (IFCC Cal.)     |
|                          | mg/l         | 23.9   | 19.1  | 28.7  | Roche Turbidimetric Latex (non-IFCC Cal.) |
|                          | mg/l         | 23.3   | 18.6  | 28.0  | Beckman Turb Latex (IFCC Cal)             |
|                          | mg/l         | 23.3   | 18.6  | 28.0  | Roche Turbidimetric CRP4 (IFCC Cal.)      |
| Caeruloplasmin           | g/l          | 0.234  | 0.176 | 0.293 | Nephelometric (IFCC Cal.)                 |
|                          | mg/dl        | 23.4   | 17.6  | 29.3  |   |
|                          | g/l          | 0.193  | 0.145 | 0.241 | Nephelometric (Non IFCC Cal.)             |
|                          | mg/dl        | 19.3   | 14.5  | 24.1  |   |
|                          | g/l          | 0.162  | 0.122 | 0.203 | Turbidimetric (Non IFCC Cal.)             |
| Complement C3            | mg/dl        | 16.2   | 12.2  | 20.3  |   |
|                          | g/l          | 1.03   | 0.876 | 1.18  | Turbidimetric (IFCC Cal.)                 |
|                          | mg/dl        | 103    | 87.6  | 118   |   |
|                          | g/l          | 0.990  | 0.842 | 1.14  | Nephelometric (IFCC Cal.)                 |
|                          | mg/dl        | 99.0   | 84.2  | 114   |   |
|                          | g/l          | 1.02   | 0.867 | 1.17  | Nephelometric (Non IFCC Cal.)             |
|                          | mg/dl        | 102    | 86.7  | 117   |   |
|                          | g/l          | 1.06   | 0.901 | 1.22  | Turbidimetric (Non IFCC Cal.)             |
| Complement C4            | mg/dl        | 106    | 90.1  | 122   |   |
|                          | g/l          | 1.02   | 0.867 | 1.17  | Vitros 5.1 FS microtip assay              |
|                          | mg/dl        | 102    | 86.7  | 117   |   |
|                          | g/l          | 0.190  | 0.162 | 0.219 | Turbidimetric (IFCC Cal.)                 |
|                          | mg/dl        | 19.0   | 16.2  | 21.9  |   |
|                          | g/l          | 0.200  | 0.170 | 0.230 | Nephelometric (IFCC Cal.)                 |
|                          | mg/dl        | 20.0   | 17.0  | 23.0  |   |
|                          | g/l          | 0.200  | 0.170 | 0.230 | Nephelometric (Non IFCC Cal.)             |
| Ferritin                 | mg/dl        | 20.0   | 17.0  | 23.0  |   |
|                          | ng/ml = µg/l | 85.9   | 73.0  | 98.8  | Turbidimetric (IFCC Cal.)                 |
|                          | ng/ml = µg/l | 71.8   | 61.0  | 82.6  | Turbidimetric (Non IFCC Cal.)             |
|                          | ng/ml = µg/l | 109    | 92.7  | 125   | Chemiluminescence (IFCC Cal.)             |
| Free Lambda Light Chains | ng/ml = µg/l | 100    | 85.0  | 115   | Chemiluminescence (Non IFCC Cal.)         |
|                          | mg/L         | 8.78   | 7.02  | 10.5  | Nephelometric - Binding Site              |
|                          | mg/L         | 8.41   | 6.73  | 10.1  | Nephelometric - Siemens                   |
| Haptoglobin              | mg/L         | 7.37   | 5.90  | 8.84  | Turbidimetric                             |
|                          | g/l          | 0.620  | 0.496 | 0.744 | Nephelometric (IFCC Cal.)                 |
|                          | mg/dl        | 62.0   | 49.6  | 74.4  |   |
|                          | g/l          | 0.650  | 0.520 | 0.780 | Turbidimetric (IFCC Cal.)                 |
|                          | mg/dl        | 65.0   | 52.0  | 78.0  |   |
| Haptoglobin              | g/l          | 0.660  | 0.528 | 0.792 | Turbidimetric (Non IFCC Cal.)             |
|                          | mg/dl        | 66.0   | 52.8  | 79.2  |   |

## LIQUID ASSAYED SPECIFIC PROTEIN CONTROL - LEVEL 1 (SP CONTROL 1)

Cat. No. PS2682 Lot. No. 675LPC Size 3 x 1 ml Expiry 2025-06-28

| Analyte            | unit          | Target | Range |       | methods                           |
|--------------------|---------------|--------|-------|-------|-----------------------------------|
|                    |               |        | low   | high  |                                   |
| Immunoglobulin A   | g/l           | 1.74   | 1.31  | 2.18  | Turbidimetric (IFCC Cal.)         |
|                    | mg/dl         | 174    | 131   | 217   |                                   |
|                    | g/l           | 1.82   | 1.37  | 2.28  | Nephelometric (IFCC Cal.)         |
|                    | mg/dl         | 182    | 137   | 227   |                                   |
|                    | g/l           | 1.82   | 1.37  | 2.28  | Nephelometric (Non IFCC Cal.)     |
|                    | mg/dl         | 182    | 137   | 227   |                                   |
|                    | g/l           | 1.73   | 1.30  | 2.16  | Turbidimetric (Non IFCC Cal.)     |
|                    | mg/dl         | 173    | 130   | 216   |                                   |
| Immunoglobulin E   | KIU/l = IU/ml | 82.8   | 66.2  | 99.0  | Chemiluminescence (Non IFCC Cal.) |
|                    | KIU/l = IU/ml | 73.1   | 58.5  | 87.7  | Nephelometric (Non IFCC Cal.)     |
|                    | KIU/l = IU/ml | 67.1   | 53.7  | 80.5  | Turbidimetric (Non IFCC Cal.)     |
| Immunoglobulin G   | g/l           | 8.87   | 7.27  | 10.5  | Turbidimetric (IFCC Cal.)         |
|                    | mg/dl         | 887    | 727   | 1047  |                                   |
|                    | g/l           | 8.89   | 7.29  | 10.5  | Nephelometric (IFCC Cal.)         |
|                    | mg/dl         | 889    | 729   | 1049  |                                   |
|                    | g/l           | 8.88   | 7.28  | 10.5  | Nephelometric (Non IFCC Cal.)     |
|                    | mg/dl         | 888    | 728   | 1048  |                                   |
|                    | g/l           | 8.87   | 7.27  | 10.5  | Turbidimetric (Non IFCC Cal.)     |
|                    | mg/dl         | 887    | 727   | 1047  |                                   |
| Immunoglobulin M   | g/l           | 0.750  | 0.600 | 0.900 | Turbidimetric (IFCC Cal.)         |
|                    | mg/dl         | 75.0   | 60.0  | 90.0  |                                   |
|                    | g/l           | 0.790  | 0.632 | 0.948 | Nephelometric (IFCC Cal.)         |
|                    | mg/dl         | 79.0   | 63.2  | 94.8  |                                   |
|                    | g/l           | 0.780  | 0.624 | 0.936 | Nephelometric (Non IFCC Cal.)     |
|                    | mg/dl         | 78.0   | 62.4  | 93.6  |                                   |
|                    | g/l           | 0.750  | 0.600 | 0.900 | Turbidimetric (Non IFCC Cal.)     |
|                    | mg/dl         | 75.0   | 60.0  | 90.0  |                                   |
| Kappa Light Chain  | g/l           | 2.13   | 1.70  | 2.56  | Nephelometric - Siemens           |
|                    | mg/dl         | 213    | 170   | 256   |                                   |
|                    | g/l           | 2.14   | 1.71  | 2.57  | Turbidimetric                     |
|                    | mg/dl         | 214    | 171   | 257   |                                   |
| Lambda Light Chain | g/l           | 1.19   | 0.950 | 1.43  | Turbidimetric                     |
|                    | mg/dl         | 119    | 95.0  | 143   |                                   |
|                    | g/l           | 1.19   | 0.950 | 1.43  | Nephelometric - Siemens           |
|                    | mg/dl         | 119    | 95.0  | 143   |                                   |
| Prealbumin         | g/l           | 0.110  | 0.088 | 0.132 | Nephelometric (IFCC Cal.)         |
|                    | mg/dl         | 11.0   | 8.80  | 13.2  |                                   |
|                    | g/l           | 0.100  | 0.080 | 0.120 | Turbidimetric (IFCC Cal.)         |
|                    | mg/dl         | 10.0   | 8.00  | 12.0  |                                   |
|                    | g/l           | 0.100  | 0.080 | 0.120 | Turbidimetric (Non IFCC Cal.)     |
|                    | mg/dl         | 10.0   | 8.00  | 12.0  |                                   |

## LIQUID ASSAYED SPECIFIC PROTEIN CONTROL - LEVEL 1 (SP CONTROL 1)

Cat. No. PS2682 Lot. No. 675LPC Size 3 x 1 ml Expiry 2025-06-28

| Range                   |       |        |       |      |                               |
|-------------------------|-------|--------|-------|------|-------------------------------|
| Analyte                 | unit  | Target | low   | high | methods                       |
| Protein Total           | g/l   | 38.8   | 31.0  | 46.6 | Biuret reaction end point     |
|                         | g/dl  | 3.88   | 3.10  | 4.66 |                               |
| Retinol Binding Protein | mg/l  | 20.5   | 16.4  | 24.6 | Nephelometric (IFCC Cal.)     |
| Rheumatoid Factor       | U/ml  | 16.5   | 12.4  | 20.6 | Turbidimetric (Non IFCC Cal.) |
|                         | U/ml  | 17.0   | 12.8  | 21.3 | Latex (Non-IFCC Cal.)         |
| Transferrin             | g/l   | 1.29   | 1.03  | 1.55 | Turbidimetric (IFCC Cal.)     |
|                         | mg/dl | 129    | 103   | 155  |                               |
|                         | g/l   | 1.29   | 1.03  | 1.55 | Turbidimetric (Non IFCC Cal.) |
|                         | mg/dl | 129    | 103   | 155  |                               |
|                         | g/l   | 1.24   | 0.992 | 1.49 | Nephelometric (IFCC Cal.)     |
|                         | mg/dl | 124    | 99.2  | 149  |                               |