

LIQUID ASSAYED SPECIFIC PROTEIN CONTROL - LEVEL 2 (SP CONTROL 2)

CAT. NO. PS2683 **LOT NO.** 588LPC
SIZE: 3 x 1ml **EXPIRY:** 2022-02-28
GTIN: 05055273204902

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.

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 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.

MATERIALS PROVIDED

Liquid Protein Control - Level 2 3 x 1 ml

MATERIALS REQUIRED BUT NOT PROVIDED

N/A

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 94451070 or email Technical.Services@randox.com.

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LIQUID ASSAYED SPECIFIC PROTEIN CONTROL LEVEL 2 (SP CONTROL 2)

Cat. No. PS2683 Lot. No. 588LPC Size 3 x 1 ml Expiry 2022-02-28

| Analyte | unit | Target | Range | | methods |
|---------------------------|---------------|--------|-------|--------------------------------------|------------------------------------|
| | | | low | high | |
| Albumin | g/l | 38.9 | 33.1 | 44.7 | Bromocresol Green (IFCC Cal.) |
| | g/dl | 3.89 | 3.31 | 4.47 | |
| | g/l | 40.0 | 34.0 | 46.0 | Bromocresol Purple (IFCC Cal.) |
| | g/dl | 4.00 | 3.40 | 4.60 | |
| | g/l | 38.0 | 32.3 | 43.7 | Nephelometric (IFCC Cal.) |
| | g/dl | 3.80 | 3.23 | 4.37 | |
| | g/l | 40.0 | 34.0 | 46.0 | Bromocresol Green (Non IFCC Cal.) |
| | g/dl | 4.00 | 3.40 | 4.60 | |
| | g/l | 39.1 | 33.2 | 45.0 | Bromocresol Purple (Non IFCC Cal.) |
| | g/dl | 3.91 | 3.32 | 4.50 | |
| | g/l | 37.8 | 32.1 | 43.5 | Turbidimetric Assays (IFCC Cal.) |
| | g/dl | 3.78 | 3.21 | 4.35 | |
| g/l | 38.3 | 32.6 | 44.0 | Turbidimetric Assays (Non IFCC Cal.) | |
| g/dl | 3.83 | 3.26 | 4.40 | | |
| Alpha-1-Acid Glycoprotein | g/l | 0.905 | 0.724 | 1.09 | Turbidimetric (IFCC Cal.) |
| | mg/dl | 90.5 | 72.4 | 109 | |
| | g/l | 0.914 | 0.731 | 1.10 | Nephelometric (IFCC Cal.) |
| | mg/dl | 91.4 | 73.1 | 110 | |
| Alpha-1-Antitrypsin | g/l | 0.920 | 0.736 | 1.10 | Turbidimetric (Non IFCC Cal.) |
| | mg/dl | 92.0 | 73.6 | 110 | |
| | g/l | 1.65 | 1.32 | 1.98 | Turbidimetric (IFCC Cal.) |
| | mg/dl | 165 | 132 | 198 | |
| Alpha-1-Antitrypsin | g/l | 1.77 | 1.42 | 2.12 | Nephelometric (IFCC Cal.) |
| | mg/dl | 177 | 142 | 212 | |
| | g/l | 1.61 | 1.29 | 1.93 | Nephelometric (Non IFCC Cal.) |
| | mg/dl | 161 | 129 | 193 | |
| Alpha-1-Antitrypsin | g/l | 1.66 | 1.33 | 1.99 | Turbidimetric (Non IFCC Cal.) |
| | mg/dl | 166 | 133 | 199 | |
| | g/l | 1.94 | 1.55 | 2.33 | Turbidimetric (IFCC Cal.) |
| | mg/dl | 194 | 155 | 233 | |
| Alpha-2-Macroglobulin | g/l | 2.00 | 1.60 | 2.40 | Nephelometric (IFCC Cal.) |
| | mg/dl | 200 | 160 | 240 | |
| | g/l | 1.93 | 1.54 | 2.32 | Turbidimetric (Non IFCC Cal.) |
| | mg/dl | 193 | 154 | 232 | |
| Alphafoetoprotein | KIU/l = IU/ml | 36.5 | 29.2 | 43.8 | Chemiluminescence (IFCC Cal.) |
| | ng/ml | 44.2 | 35.3 | 53.1 | |
| | KIU/l = IU/ml | 36.3 | 29.0 | 43.6 | Chemiluminescence (Non IFCC Cal.) |
| Anti Streptolysin O | ng/ml | 43.9 | 35.1 | 52.7 | |
| | IU/ml | 231 | 185 | 277 | Turbidimetric (IFCC Cal.) |
| | IU/ml | 237 | 190 | 284 | Turbidimetric (Non IFCC Cal.) |
| | IU/ml | 153 | 122 | 184 | Neph. Beckman (IFCC Cal.) |
| | IU/ml | 153 | 122 | 184 | Neph. Beckman (Non IFCC Cal.) |

LIQUID ASSAYED SPECIFIC PROTEIN CONTROL LEVEL 2 (SP CONTROL 2)

Cat. No. PS2683 Lot. No. 588LPC Size 3 x 1 ml Expiry 2022-02-28

| Range | | | | | |
|----------------------|--------------|--------|-------|-------|-----------------------------------|
| Analyte | unit | Target | low | high | methods |
| Anti Streptolysin O | IU/ml | 232 | 186 | 278 | Neph. Behring (IFCC Cal.) |
| | IU/ml | 231 | 185 | 277 | Neph. Behring (Non IFCC Cal.) |
| Beta-2-microglobulin | µg/ml = mg/l | 3.89 | 3.11 | 4.67 | Nephelometric (IFCC Cal.) |
| | µg/ml = mg/l | 4.41 | 3.53 | 5.29 | Nephelometric (Non IFCC Cal.) |
| | µg/ml = mg/l | 4.33 | 3.46 | 5.20 | Turbidimetric (IFCC Cal.) |
| | µg/ml = mg/l | 4.22 | 3.38 | 5.06 | Turbidimetric (Non IFCC Cal.) |
| C-Reactive Protein | mg/l | 47.9 | 38.3 | 57.5 | Vitros (IFCC Cal.) |
| | mg/l | 46.0 | 36.8 | 55.2 | Turbidimetric (IFCC Cal.) |
| | mg/l | 40.9 | 32.7 | 49.1 | Nephelometric (IFCC Cal.) |
| | mg/l | 45.8 | 36.6 | 55.0 | Turbidimetric (Non IFCC Cal.) |
| | mg/l | 46.9 | 37.5 | 56.3 | Beckman Turb Latex (IFCC Cal) |
| Caeruloplasmin | g/l | 0.432 | 0.324 | 0.540 | Nephelometric (IFCC Cal.) |
| | mg/dl | 43.2 | 32.4 | 54.0 | |
| | g/l | 0.377 | 0.283 | 0.471 | Turbidimetric (IFCC Cal.) |
| | mg/dl | 37.7 | 28.3 | 47.1 | |
| | g/l | 0.308 | 0.231 | 0.385 | Nephelometric (Non IFCC Cal.) |
| | mg/dl | 30.8 | 23.1 | 38.5 | |
| | g/l | 0.356 | 0.267 | 0.445 | Turbidimetric (Non IFCC Cal.) |
| | mg/dl | 35.6 | 26.7 | 44.5 | |
| Complement C3 | g/l | 1.46 | 1.17 | 1.75 | Turbidimetric (IFCC Cal.) |
| | mg/dl | 146 | 117 | 175 | |
| | g/l | 1.45 | 1.16 | 1.74 | Nephelometric (IFCC Cal.) |
| | mg/dl | 145 | 116 | 174 | |
| | g/l | 1.49 | 1.19 | 1.79 | Nephelometric (Non IFCC Cal.) |
| | mg/dl | 149 | 119 | 179 | |
| | g/l | 1.45 | 1.16 | 1.74 | Turbidimetric (Non IFCC Cal.) |
| | mg/dl | 145 | 116 | 174 | |
| Complement C4 | g/l | 0.367 | 0.294 | 0.440 | Turbidimetric (IFCC Cal.) |
| | mg/dl | 36.7 | 29.4 | 44.0 | |
| | g/l | 0.388 | 0.310 | 0.466 | Nephelometric (IFCC Cal.) |
| | mg/dl | 38.8 | 31.0 | 46.6 | |
| | g/l | 0.378 | 0.302 | 0.454 | Nephelometric (Non IFCC Cal.) |
| | mg/dl | 37.8 | 30.2 | 45.4 | |
| | g/l | 0.347 | 0.278 | 0.416 | Turbidimetric (Non IFCC Cal.) |
| | mg/dl | 34.7 | 27.8 | 41.6 | |
| Ferritin | ng/ml = µg/l | 184 | 147 | 221 | Turbidimetric (IFCC Cal.) |
| | ng/ml = µg/l | 204 | 163 | 245 | Turbidimetric (Non IFCC Cal.) |
| | ng/ml = µg/l | 198 | 158 | 238 | Chemiluminescence (IFCC Cal.) |
| | ng/ml = µg/l | 202 | 162 | 242 | Chemiluminescence (Non IFCC Cal.) |
| Free Lambda Light | mg/L | 21.4 | 17.1 | 25.7 | Nephelometric - Binding Site |

LIQUID ASSAYED SPECIFIC PROTEIN CONTROL LEVEL 2 (SP CONTROL 2)

Cat. No. PS2683 Lot. No. 588LPC Size 3 x 1 ml Expiry 2022-02-28

| Range | | | | | |
|--------------------------|---------------|--------|------|------|-----------------------------------|
| Analyte | unit | Target | low | high | methods |
| Free Lambda Light Chains | mg/L | 15.8 | 12.6 | 19.0 | Nephelometric - Siemens |
| | mg/L | 20.7 | 16.6 | 24.8 | Turbidimetric |
| Haptoglobin | g/l | 1.41 | 1.13 | 1.69 | Nephelometric (IFCC Cal.) |
| | mg/dl | 141 | 113 | 169 | |
| | g/l | 1.51 | 1.21 | 1.81 | Turbidimetric (IFCC Cal.) |
| | mg/dl | 151 | 121 | 181 | |
| | g/l | 1.40 | 1.12 | 1.68 | Nephelometric (Non IFCC Cal.) |
| | mg/dl | 140 | 112 | 168 | |
| Immunoglobulin A | g/l | 2.41 | 1.81 | 3.01 | Turbidimetric (IFCC Cal.) |
| | mg/dl | 241 | 181 | 301 | |
| | g/l | 2.51 | 1.88 | 3.14 | Nephelometric (IFCC Cal.) |
| | mg/dl | 251 | 188 | 314 | |
| | g/l | 2.52 | 1.89 | 3.15 | Nephelometric (Non IFCC Cal.) |
| | mg/dl | 252 | 189 | 315 | |
| Immunoglobulin E | g/l | 2.41 | 1.81 | 3.01 | Turbidimetric (Non IFCC Cal.) |
| | mg/dl | 241 | 181 | 301 | |
| | g/l | 2.41 | 1.81 | 3.01 | Vitros 5.1 FS Microtip (IFCC) |
| | mg/dl | 241 | 181 | 301 | |
| | KIU/l = IU/ml | 162 | 130 | 194 | Chemiluminescence (Non IFCC Cal.) |
| | KIU/l = IU/ml | 157 | 126 | 188 | Nephelometric (Non IFCC Cal.) |
| Immunoglobulin G | KIU/l = IU/ml | 146 | 117 | 175 | Turbidimetric (Non IFCC Cal.) |
| | g/l | 13.7 | 11.2 | 16.2 | Turbidimetric (IFCC Cal.) |
| | mg/dl | 1370 | 1120 | 1620 | |
| | g/l | 14.0 | 11.5 | 16.5 | Nephelometric (IFCC Cal.) |
| | mg/dl | 1400 | 1150 | 1650 | |
| | g/l | 13.7 | 11.2 | 16.2 | Nephelometric (Non IFCC Cal.) |
| | mg/dl | 1370 | 1120 | 1620 | |
| | g/l | 13.9 | 11.4 | 16.4 | Turbidimetric (Non IFCC Cal.) |
| mg/dl | 1390 | 1140 | 1640 | | |
| Immunoglobulin M | g/l | 13.7 | 11.2 | 16.2 | Vitros 5.1 FS Microtip (IFCC) |
| | mg/dl | 1370 | 1120 | 1620 | |
| | g/l | 1.66 | 1.33 | 1.99 | Turbidimetric (IFCC Cal.) |
| | mg/dl | 166 | 133 | 199 | |
| | g/l | 1.72 | 1.38 | 2.06 | Nephelometric (IFCC Cal.) |
| | mg/dl | 172 | 138 | 206 | |
| | g/l | 1.66 | 1.33 | 1.99 | Nephelometric (Non IFCC Cal.) |
| | mg/dl | 166 | 133 | 199 | |
| Kappa Light Chain | g/l | 1.67 | 1.34 | 2.00 | Turbidimetric (Non IFCC Cal.) |
| | mg/dl | 167 | 134 | 200 | |
| | g/l | 1.68 | 1.34 | 2.02 | Vitros 5.1 FS Microtip (IFCC) |
| | mg/dl | 168 | 134 | 202 | |
| | g/l | 10.6 | 8.46 | 12.7 | Nephelometric - Beckman |
| | mg/dl | 1057 | 846 | 1270 | |
| Kappa Light Chain | g/l | 3.47 | 2.78 | 4.16 | Nephelometric - Siemens |
| | mg/dl | 347 | 278 | 416 | |

LIQUID ASSAYED SPECIFIC PROTEIN CONTROL LEVEL 2 (SP CONTROL 2)

Cat. No. PS2683 Lot. No. 588LPC Size 3 x 1 ml Expiry 2022-02-28

| Range | | | | | |
|-------------------------|-------|--------|-------|-------|-------------------------------|
| Analyte | unit | Target | low | high | methods |
| Kappa Light Chain | g/l | 3.60 | 2.88 | 4.32 | Turbidimetric |
| | mg/dl | 360 | 288 | 432 | |
| Lambda Light Chain | g/l | 5.45 | 4.36 | 6.54 | Nephelometric - Beckman |
| | mg/dl | 545 | 436 | 654 | |
| | g/l | 1.83 | 1.46 | 2.20 | Nephelometric - Siemens |
| | mg/dl | 183 | 146 | 220 | |
| | g/l | 1.77 | 1.42 | 2.12 | Turbidimetric |
| mg/dl | 177 | 142 | 212 | | |
| Prealbumin | g/l | 0.428 | 0.342 | 0.514 | Nephelometric (IFCC Cal.) |
| | mg/dl | 42.8 | 34.2 | 51.4 | |
| | g/l | 0.391 | 0.313 | 0.469 | Turbidimetric (IFCC Cal.) |
| | mg/dl | 39.1 | 31.3 | 46.9 | |
| Protein Total | g/l | 67.1 | 53.7 | 80.5 | Biuret reaction end point |
| | g/dl | 6.71 | 5.37 | 8.05 | |
| Retinol Binding Protein | mg/l | 63.3 | 50.6 | 76.0 | Nephelometric (IFCC Cal.) |
| | mg/l | 68.1 | 54.5 | 81.7 | Nephelometric (Non IFCC Cal.) |
| Rheumatoid Factor | U/ml | 75.1 | 60.1 | 90.1 | Turbidimetric (Non IFCC Cal.) |
| | U/ml | 76.7 | 61.4 | 92.0 | Latex (Non-IFCC Cal.) |
| | U/ml | 69.6 | 55.7 | 83.5 | Neph. Beckman (Non IFCC Cal.) |
| | U/ml | 66.3 | 53.0 | 79.6 | Neph. Behring (Non IFCC Cal.) |
| Transferrin | g/l | 2.55 | 2.04 | 3.06 | Turbidimetric (IFCC Cal.) |
| | mg/dl | 255 | 204 | 306 | |
| | g/l | 2.58 | 2.06 | 3.10 | Turbidimetric (Non IFCC Cal.) |
| | mg/dl | 258 | 206 | 310 | |
| Transferrin | g/l | 2.51 | 2.01 | 3.01 | Nephelometric (IFCC Cal.) |
| | mg/dl | 251 | 201 | 301 | |