# LIQUID ASSAYED SPECIFIC PROTEIN CONTROL - LEVEL 3 (SP CONTROL 3)

**CAT. NO.** PS2684 **LOT NO.** 539LPC
**SIZE:** 3 x 1 ml **EXPIRY:** 2021-03-28

**GTIN:** 05055273204919

## 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°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.

## MATERIALS PROVIDED
Liquid Protein Control - Level 3 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 94451070 or email Technical.Services@randox.com.

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**Cat. No. PS2684 Lot No. 539LPC Size: 3 x 1 ml Expiry: 2021-03-28**

| | | | Range | | |
|---|---|---|---|---|---|
| **Analyte** | **unit** | **Target** | **low** | **high** | **methods** |
| Albumin | g/l | 55.4 | 47.1 | 63.7 | Bromocresol Green (IFCC Cal.) |
| | g/dl | 5.54 | 4.71 | 6.37 | |
| | g/l | 55.6 | 47.3 | 63.9 | Bromocresol Purple (IFCC Cal.) |
| | g/dl | 5.56 | 4.73 | 6.39 | |
| | g/l | 55.4 | 47.1 | 63.7 | Nephelometric (IFCC Cal.) |
| | g/dl | 5.54 | 4.71 | 6.37 | |
| | g/l | 55.5 | 47.2 | 63.8 | Bromocresol Green (Non IFCC Cal.) |
| | g/dl | 5.55 | 4.72 | 6.38 | |
| | g/l | 55.4 | 47.1 | 63.7 | Bromocresol Purple (Non IFCC Cal.) |
| | g/dl | 5.54 | 4.71 | 6.37 | |
| | g/l | 55.2 | 46.9 | 63.5 | Turbidimetric Assays (IFCC Cal.) |
| | g/dl | 5.52 | 4.69 | 6.35 | |
| | g/l | 57.1 | 48.5 | 65.7 | Turbidimetric Assays (Non IFCC Cal.) |
| | g/dl | 5.71 | 4.85 | 6.57 | |
| Alpha-1-Acid Glycoprotein | g/l | 1.40 | 1.12 | 1.68 | Turbidimetric (IFCC Cal.) |
| | mg/dl | 140 | 112 | 168 | |
| | g/l | 1.44 | 1.15 | 1.73 | Nephelometric (IFCC Cal.) |
| | mg/dl | 144 | 115 | 173 | |
| | g/l | 1.39 | 1.11 | 1.67 | Turbidimetric (Non IFCC Cal.) |
| | mg/dl | 139 | 111 | 167 | |
| Alpha-1-Antitrypsin | g/l | 2.12 | 1.70 | 2.54 | Turbidimetric (IFCC Cal.) |
| | mg/dl | 212 | 170 | 254 | |
| | g/l | 2.36 | 1.89 | 2.83 | Nephelometric (IFCC Cal.) |
| | mg/dl | 236 | 189 | 283 | |
| | g/l | 2.09 | 1.67 | 2.51 | Turbidimetric (Non IFCC Cal.) |
| | mg/dl | 209 | 167 | 251 | |
| Alpha-2-Macroglobulin | g/l | 3.02 | 2.42 | 3.62 | Turbidimetric (IFCC Cal.) |
| | mg/dl | 302 | 242 | 362 | |
| | g/l | 3.20 | 2.56 | 3.84 | Nephelometric (IFCC Cal.) |
| | mg/dl | 320 | 256 | 384 | |
| | g/l | 2.86 | 2.29 | 3.43 | Turbidimetric (Non IFCC Cal.) |
| | mg/dl | 286 | 229 | 343 | |
| Alpha-fetoprotein | KIU/l = IU/ml | 56.3 | 45.0 | 67.6 | Chemiluminescence (IFCC Cal.) |
| | ng/ml | 68.1 | 54.5 | 81.7 | |
| | KIU/l = IU/ml | 57.0 | 45.6 | 68.4 | Chemiluminescence (Non IFCC Cal.) |
| | ng/ml | 69.0 | 55.2 | 82.8 | |
| Anti Streptolysin O | IU/ml | 360 | 288 | 432 | Turbidimetric (IFCC Cal.) |
| | IU/ml | 348 | 278 | 418 | Turbidimetric (Non IFCC Cal.) |
| | IU/ml | 237 | 190 | 284 | Neph. Beckman (IFCC Cal.) |
| | IU/ml | 228 | 182 | 274 | Neph. Beckman (Non IFCC Cal.) |
| | IU/ml | 384 | 307 | 461 | Neph. Behring (IFCC Cal.) |
| | IU/ml | 383 | 306 | 460 | Neph. Behring (Non IFCC Cal.) |

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## LIQUID ASSAYED SPECIFIC PROTEIN CONTROL - LEVEL 3 (SP CONTROL 3)

**Cat. No. PS2684 Lot No. 539LPC Size: 3 x 1 ml Expiry: 2021-03-28**

| | | | Range | | |
|---|---|---|---|---|---|
| **Analyte** | **unit** | **Target** | **low** | **high** | **methods** |
| Antithrombin III | mg/l | 381 | 286 | 476 | Turbidimetric (IFCC Cal.) |
| | mg/dl | 38.1 | 28.6 | 47.6 | |
| Beta-2-microglobulin | µg/ml = mg/l | 5.55 | 4.44 | 6.66 | Chemiluminescence (Non IFCC Cal.) |
| | µg/ml = mg/l | 5.69 | 4.55 | 6.83 | Nephelometric (IFCC Cal.) |
| | µg/ml = mg/l | 5.95 | 4.76 | 7.14 | Nephelometric (Non IFCC Cal.) |
| | µg/ml = mg/l | 6.06 | 4.85 | 7.27 | Turbidimetric (IFCC Cal.) |
| | µg/ml = mg/l | 5.98 | 4.78 | 7.18 | Turbidimetric (Non IFCC Cal.) |
| C-Reactive Protein | mg/l | 53.8 | 43.0 | 64.6 | Vitros (IFCC Cal.) |
| | mg/l | 67.6 | 54.1 | 81.1 | Turbidimetric (IFCC Cal.) |
| | mg/l | 68.2 | 54.6 | 81.8 | Nephelometric (IFCC Cal.) |
| | mg/l | 69.2 | 55.4 | 83.0 | Nephelometric (Non IFCC Cal.) |
| | mg/l | 66.9 | 53.5 | 80.3 | Turbidimetric (Non IFCC Cal.) |
| | mg/l | 71.8 | 57.4 | 86.2 | Beckman Turb Latex (IFCC Cal) |
| Caeruloplasmin | g/l | 0.555 | 0.416 | 0.694 | Nephelometric (IFCC Cal.) |
| | mg/dl | 55.5 | 41.6 | 69.4 | |
| | g/l | 0.509 | 0.382 | 0.636 | Turbidimetric (IFCC Cal.) |
| | mg/dl | 50.9 | 38.2 | 63.6 | |
| | g/l | 0.534 | 0.401 | 0.667 | Nephelometric (Non IFCC Cal.) |
| | mg/dl | 53.4 | 40.1 | 66.7 | |
| | g/l | 0.474 | 0.356 | 0.592 | Turbidimetric (Non IFCC Cal.) |
| | mg/dl | 47.4 | 35.6 | 59.2 | |
| | g/l | 0.404 | 0.303 | 0.505 | Neph. Beckman (IFCC Cal.) |
| | mg/dl | 40.4 | 30.3 | 50.5 | |
| Complement C3 | g/l | 1.83 | 1.46 | 2.20 | Turbidimetric (IFCC Cal.) |
| | mg/dl | 183 | 146 | 220 | |
| | g/l | 1.81 | 1.45 | 2.17 | Nephelometric (IFCC Cal.) |
| | mg/dl | 181 | 145 | 217 | |
| | g/l | 1.80 | 1.44 | 2.16 | Nephelometric (Non IFCC Cal.) |
| | mg/dl | 180 | 144 | 216 | |
| | g/l | 1.87 | 1.50 | 2.24 | Turbidimetric (Non IFCC Cal.) |
| | mg/dl | 187 | 150 | 224 | |
| | g/l | 1.82 | 1.46 | 2.18 | Vitros 5.1 FS Microtip (Non IFCC) |
| | mg/dl | 182 | 146 | 218 | |
| Complement C4 | g/l | 0.442 | 0.354 | 0.530 | Turbidimetric (IFCC Cal.) |
| | mg/dl | 44.2 | 35.4 | 53.0 | |
| | g/l | 0.475 | 0.380 | 0.570 | Nephelometric (IFCC Cal.) |
| | mg/dl | 47.5 | 38.0 | 57.0 | |
| | g/l | 0.474 | 0.379 | 0.569 | Nephelometric (Non IFCC Cal.) |
| | mg/dl | 47.4 | 37.9 | 56.9 | |
| | g/l | 0.421 | 0.337 | 0.505 | Turbidimetric (Non IFCC Cal.) |
| | mg/dl | 42.1 | 33.7 | 50.5 | |
| | g/l | 0.429 | 0.343 | 0.515 | Vitros 5.1 FS Microtip (Non IFCC) |
| | mg/dl | 42.9 | 34.3 | 51.5 | |
| Ferritin | ng/ml = µg/l | 288 | 230 | 346 | Turbidimetric (IFCC Cal.) |
| | ng/ml = µg/l | 298 | 238 | 358 | Turbidimetric (Non IFCC Cal.) |
| | ng/ml = µg/l | 314 | 251 | 377 | Chemiluminescence (IFCC Cal.) |

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| | | | Range | | |
|---|---|---|---|---|---|
| **Analyte** | **unit** | **Target** | **low** | **high** | **methods** |
| Ferritin | ng/ml = µg/l | 324 | 259 | 389 | Chemiluminescence (Non IFCC Cal.) |
| | ng/ml = µg/l | 290 | 232 | 348 | Nephelometric (IFCC Cal.) |
| Free Lambda Light Chains | mg/L | 22.1 | 17.7 | 26.5 | Nephelometric - Siemens |
| | mg/L | 27.8 | 22.2 | 33.4 | Nephelometric - Binding Site |
| | mg/L | 25.7 | 20.6 | 30.8 | Turbidimetric |
| Haptoglobin | g/l | 1.87 | 1.50 | 2.24 | Nephelometric (IFCC Cal.) |
| | mg/dl | 187 | 150 | 224 | |
| | g/l | 1.88 | 1.50 | 2.26 | Turbidimetric (IFCC Cal.) |
| | mg/dl | 188 | 150 | 226 | |
| | g/l | 1.87 | 1.50 | 2.24 | Nephelometric (Non IFCC Cal.) |
| | mg/dl | 187 | 150 | 224 | |
| | g/l | 1.88 | 1.50 | 2.26 | Turbidimetric (Non IFCC Cal.) |
| | mg/dl | 188 | 150 | 226 | |
| Immunoglobulin A | g/l | 3.49 | 2.62 | 4.36 | Turbidimetric (IFCC Cal.) |
| | mg/dl | 349 | 262 | 436 | |
| | g/l | 3.69 | 2.77 | 4.61 | Nephelometric (IFCC Cal.) |
| | mg/dl | 369 | 277 | 461 | |
| | g/l | 3.91 | 2.93 | 4.89 | Nephelometric (Non IFCC Cal.) |
| | mg/dl | 391 | 293 | 489 | |
| | g/l | 3.44 | 2.58 | 4.30 | Turbidimetric (Non IFCC Cal.) |
| | mg/dl | 344 | 258 | 430 | |
| | g/l | 3.58 | 2.69 | 4.48 | Vitros 5.1 FS Microtip (Non IFCC) |
| | mg/dl | 358 | 269 | 447 | |
| Immunoglobulin E | KIU/l = IU/ml | 193 | 154 | 232 | Fluorimetric (Non IFCC Cal.) |
| | KIU/l = IU/ml | 184 | 147 | 221 | Chemiluminescence (Non IFCC Cal.) |
| | KIU/l = IU/ml | 179 | 143 | 215 | Nephelometric (Non IFCC Cal.) |
| | KIU/l = IU/ml | 171 | 137 | 205 | Enzyme Immunoassay (Non IFCC Cal.) |
| | KIU/l = IU/ml | 191 | 153 | 229 | Turbidimetric (Non IFCC Cal.) |
| Immunoglobulin G | g/l | 18.0 | 14.8 | 21.2 | Turbidimetric (IFCC Cal.) |
| | mg/dl | 1800 | 1480 | 2120 | |
| | g/l | 18.3 | 15.0 | 21.6 | Nephelometric (IFCC Cal.) |
| | mg/dl | 1830 | 1500 | 2160 | |
| | g/l | 18.8 | 15.4 | 22.2 | Nephelometric (Non IFCC Cal.) |
| | mg/dl | 1880 | 1540 | 2220 | |
| | g/l | 17.9 | 14.7 | 21.1 | Turbidimetric (Non IFCC Cal.) |
| | mg/dl | 1790 | 1470 | 2110 | |
| | g/l | 18.9 | 15.5 | 22.3 | Vitros 5.1 FS Microtip (Non IFCC) |
| | mg/dl | 1890 | 1550 | 2230 | |
| Immunoglobulin M | g/l | 2.63 | 2.10 | 3.16 | Turbidimetric (IFCC Cal.) |
| | mg/dl | 263 | 210 | 316 | |
| | g/l | 2.74 | 2.19 | 3.29 | Nephelometric (IFCC Cal.) |
| | mg/dl | 274 | 219 | 329 | |
| | g/l | 2.81 | 2.25 | 3.37 | Nephelometric (Non IFCC Cal.) |
| | mg/dl | 281 | 225 | 337 | |
| | g/l | 2.63 | 2.10 | 3.16 | Turbidimetric (Non IFCC Cal.) |
| | mg/dl | 263 | 210 | 316 | |

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|---|---|---|---|---|---|
| **Analyte** | **unit** | **Target** | **low** | **high** | **methods** |
| Immunoglobulin M | g/l | 2.53 | 2.02 | 3.04 | Vitros 5.1 FS Microtip (Non IFCC) |
| | mg/dl | 253 | 202 | 304 | |
| Kappa Light Chain | g/l | 15.2 | 12.2 | 18.2 | Nephelometric - Beckman |
| | mg/dl | 1520 | 1220 | 1820 | |
| | g/l | 4.98 | 3.98 | 5.98 | Turbidimetric |
| | mg/dl | 498 | 398 | 598 | |
| | g/l | 4.62 | 3.70 | 5.54 | Nephelometric - Siemens |
| | mg/dl | 462 | 370 | 554 | |
| Lambda Light Chain | g/l | 2.62 | 2.10 | 3.14 | Turbidimetric |
| | mg/dl | 262 | 210 | 314 | |
| | g/l | 7.89 | 6.31 | 9.47 | Nephelometric - Beckman |
| | mg/dl | 789 | 631 | 947 | |
| | g/l | 2.48 | 1.98 | 2.98 | Nephelometric - Siemens |
| | mg/dl | 248 | 198 | 298 | |
| Prealbumin | g/l | 0.516 | 0.413 | 0.619 | Nephelometric (IFCC Cal.) |
| | mg/dl | 51.6 | 41.3 | 61.9 | |
| | g/l | 0.458 | 0.366 | 0.550 | Turbidimetric (IFCC Cal.) |
| | mg/dl | 45.8 | 36.6 | 55.0 | |
| | g/l | 0.472 | 0.378 | 0.566 | Nephelometric (Non IFCC Cal.) |
| | mg/dl | 47.2 | 37.8 | 56.6 | |
| | g/l | 0.459 | 0.367 | 0.551 | Turbidimetric (Non IFCC Cal.) |
| | mg/dl | 45.9 | 36.7 | 55.1 | |
| Protein Total | g/l | 90.4 | 72.3 | 108 | Biuret reaction end point |
| | g/dl | 9.04 | 7.23 | 10.8 | |
| Retinol Binding Protein | mg/l | 69.5 | 55.6 | 83.4 | Nephelometric (IFCC Cal.) |
| | mg/l | 69.7 | 55.8 | 83.6 | Nephelometric (Non IFCC Cal.) |
| Rheumatoid Factor | U/ml | 80.0 | 64.0 | 96.0 | Turbidimetric (Non IFCC Cal.) |
| | U/ml | 83.2 | 66.6 | 100 | Latex (Non-IFCC Cal.) |
| | U/ml | 97.7 | 78.2 | 117 | Neph. Beckman (Non IFCC Cal.) |
| | U/ml | 63.8 | 51.0 | 76.6 | Neph. Behring (Non IFCC Cal.) |
| | U/ml | 108 | 86.2 | 129 | Randox Immunoturbidimetric |
| Transferrin | g/l | 3.35 | 2.68 | 4.02 | Turbidimetric (IFCC Cal.) |
| | mg/dl | 335 | 268 | 402 | |
| | g/l | 3.38 | 2.70 | 4.06 | Turbidimetric (Non IFCC Cal.) |
| | mg/dl | 338 | 270 | 406 | |
| | g/l | 3.21 | 2.57 | 3.85 | Nephelometric (IFCC Cal.) |
| | mg/dl | 321 | 257 | 385 | |
| | g/l | 3.12 | 2.50 | 3.74 | Nephelometric (Non IFCC Cal.) |
| | mg/dl | 312 | 250 | 374 | |

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