

## HUMAN ASSAYED MULTI-SERA - LEVEL 2 (HUM ASY CONTROL 2)

**CAT. NO.** HN1530      **GTIN:** 05055273203783      **SIZE:** 20 x 5ml  
**CAT. NO.** HS2611      **GTIN:** 05055273203813      **SIZE:** 5 x 5ml  
**LOT NO.** 1561UN      **EXPIRY:** 2025-11-28

### INTENDED USE

This product is intended for in vitro diagnostic use, in the quality control of diagnostic assays. The Human Assayed Multi-sera is for the control of accuracy.

### DEVICE DESCRIPTION

The Human Assayed Multi-sera is supplied at 2 levels, level 2 and 3. Target values and ranges are supplied for the analytes listed in the values section at both levels.

### 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 NONREACTIVE. 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). Reconstituted serum is stable for 8 hours at +15°C to +25°C or 7 days at +2°C to +8°C, and 28 days when frozen once at -18°C to -24°C. (See Limitations)

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

### LIMITATIONS

For Total & Prostatic Acid Phosphatase, the material should be stabilised by adding 1 drop (25µl - 30µl) of 0.7M Acetic acid solution to 1ml of the serum exactly 30 minutes after reconstitution. After stabilisation Total and Prostatic Acid Phosphatase is stable for 2 hours at +15°C to +25°C, 2 days at +2°C to +8°C, and 28 days when frozen once at -18°C to -24°C.

Alkaline Phosphatase levels in the reconstituted serum will rise over the stability period. It is recommended that the reconstituted serum is allowed to stand for 1 hour at +15°C to +25°C before measurement.

Bilirubin in the serum is light sensitive and it is recommended that the serum is stored in the dark. Stored in the dark, it is stable for 4 days at +2°C to +8°C. Do not store at +15°C to +25°C. Do not freeze.

GLDH is stable for 2 days at 2-8°C.

NEFA is stable for 1 day at +2°C to +8°C.

Total PSA is stable for 4 days at +2°C to +8°C, or 28 days in aliquots frozen at -18°C to -24°C.

Bacterial contamination of the reconstituted serum will cause reductions in the stability of many components.

Different lot numbers of this control should not be interchanged, as the values assigned to the controls vary from lot to lot.

The control should not be used as a calibration material.

Due to the zinc content in some batches of rubber stoppers, the QC and calibrator material should be aliquoted into polypropylene tubes and stored at +2°C to +8°C to ensure stable zinc levels throughout the stability period.

### PREPARATION FOR USE

The Human Assayed Multi-sera is supplied lyophilised.

1. Carefully reconstitute each vial of lyophilised serum with exactly 5ml of distilled water at +15°C to +25°C. Close the bottle and allow to stand for 30 minutes before use. Ensure contents are completely dissolved by swirling gently. Avoid formation of foam. Do not shake.

2. Refer to the Control section of the individual analyser application.

3. Refrigerate any unused material. Prior to reuse, mix contents thoroughly.

### MATERIALS PROVIDED

Human Assayed Multi-sera - Level 2 20 x 5ml / 5 x 5ml

### MATERIALS REQUIRED BUT NOT PROVIDED

Volumetric pipette

### ASSIGNED VALUES

Due to the variation caused by test equipment, test reagents and laboratory technique, the quoted ranges are provided for guidance. It is recommended that these ranges are used until each laboratory has established its own ranges, based on individual laboratory requirements.

Each batch of assayed human serum is submitted to reference laboratories for assignment against international Reference Standards.

Where international Reference Standards are unavailable, Reference Methods are used. Values are also collected from approx. 3000 laboratories worldwide and using a unique statistical analysis, a value is assigned.

With each batch, a control range is provided for individual parameters and each parameter method. The control range is equivalent to the assigned mean  $\pm$ 2S.D.

If an instrument specific value is not available, refer to the Method section. If necessary, contact Randox Laboratories - Technical Services, Northern Ireland, tel: +44 (0) 28 9445 1070 or email Technical.Services@randox.com.

### NOTES

\* All trademarks recognised.

(1) Applies only in Germany. Ranges established according to the Guidelines of the Federal Chamber of Physicians in Germany.

(2) Values established by reference laboratories officially recognised by the Federal Chamber of Physicians in Germany.

(3) DGKC: German Society for Clinical Chemistry.

(4) IFCC: International Federation of Clinical Chemistry.

(5) SCE: Scandinavian Committee on Enzymes.

**METHOD**
**HUMAN ASSAYED MULTI-SERA - LEVEL 2**

| Lot. No.             | 1561UN | EXPIRY: | 2025-11-28 | Cat. No. | HN1530 / HS2611 |       |   |  |
|----------------------|--------|---------|------------|----------|-----------------|-------|---|--|
| Analyte              | unit   | Target  | low        | high     | 1SD             | 2SD   | methods   |  |
| Albumin              | g/dl   | 4.08    | 3.468      | 4.69     | 0.306           | 0.612 | Bromocresol Green                                   |  |
| Alkaline Phosphatase | U/L    | 268     | 228        | 308      | 20              | 40    | Diethanolamine buffer DEA 37°C                      |  |
| ALT (GPT)            | U/L    | 39      | 31         | 47       | 4               | 8     | Tris buffer without P5P 37°C                        |  |
| AST (GOT)            | U/L    | 32      | 26         | 38       | 3               | 6     | Tris buffer without P5P 37°C                        |  |
| Amylase Total        | U/L    | 92      | 78         | 106      | 7               | 14    | pNP Maltotrioxide substrates 37°C                   |  |
| Apolipoprotein A-1   | mg/dl  | 120     | 98.4       | 141.6    | 10.8            | 21.6  | Immunoturbidimetric                                 |  |
| Apolipoprotein B     | mg/dl  | 52.9    | 43.4       | 62.4     | 4.75            | 9.5   | Immunoturbidimetric                                 |  |
| Bilirubin Direct     | mg/dl  | 1.08    | 0.85       | 1.31     | 0.113           | 0.226 | Dichlorophenyl Diazonium (DPD)                      |  |
|                      | mg/dl  | 1.09    | 0.86       | 1.32     | 0.115           | 0.23  | Diazo with Dichloroaniline (DCA)                    |  |
| Bilirubin Total      | mg/dl  | 1.57    | 1.236      | 1.90     | 0.167           | 0.334 | Dichlorophenyl Diazonium (DPD)                      |  |
|                      | mg/dl  | 1.61    | 1.27       | 1.95     | 0.17            | 0.34  | Diazo with Dichloroaniline (DCA)                    |  |
| Calcium              | mg/dl  | 8.9     | 8.02       | 9.78     | 0.44            | 0.88  | Arsenazo III  |  |
|                      | mg/dl  | 8.66    | 7.82       | 9.50     | 0.42            | 0.84  | Cresolphthalein complexone (CPC)                    |  |
| Cholesterol          | mg/dl  | 158     | 138        | 178      | 10              | 20    | Cholesterol Oxidase                                 |  |
| Chloride             | mmol/l | 99.2    | 91.3       | 107      | 3.95            | 7.9   | Colorimetric  |  |
| CK Total             | U/L    | 213     | 175        | 251      | 19              | 38    | CK-NAC (IFCC) 37°C                                  |  |
| Copper               | µg/dl  | 104     | 83.3       | 125      | 10.35           | 20.7  | Colorimetric  |  |
| Creatinine           | mg/dl  | 1.54    | 1.228      | 1.85     | 0.156           | 0.312 | Jaffe rate blanked                                  |  |
|                      | mg/dl  | 1.56    | 1.24       | 1.88     | 0.16            | 0.32  | Enzymatic UV method                                 |  |
| gamma-GT             | U/L    | 52      | 44         | 60       | 4.0             | 8.0   | Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 37°C |  |
| Glucose              | mg/dl  | 111     | 94.4       | 128      | 8.3             | 16.6  | Glucose oxidase                                     |  |
| HDL - Cholesterol    | mg/dl  | 58.3    | 49.4       | 67.2     | 4.45            | 8.9   | Direct HDL PPD                                      |  |
| Immunoglobulin A     | mg/dl  | 187     | 140        | 234      | 23.5            | 47    | Immunoturbidimetric                                 |  |
| Immunoglobulin G     | mg/dl  | 662     | 543        | 781      | 59.5            | 119   | Immunoturbidimetric                                 |  |
| Immunoglobulin M     | mg/dl  | 85      | 68         | 102      | 8.5             | 17    | Immunoturbidimetric                                 |  |
| Iron                 | µg/dl  | 108     | 88.3       | 128      | 9.85            | 19.7  | Colorimetric without ppt.                           |  |
| Lactate              | mg/dl  | 13.9    | 11.4       | 16.4     | 1.25            | 2.5   | Colorimetric Lactate Oxidase                        |  |
| LD (LDH)             | U/L    | 423     | 359        | 487      | 32              | 64    | P->L German methods 37°C                            |  |
| Lipase               | U/L    | 38      | 30.0       | 46.0     | 4               | 8     | Other Colorimetric 37°C                             |  |
| Lithium              | mmol/l | 0.98    | 0.86       | 1.10     | 0.06            | 0.12  | Ion selective electrode                             |  |
|                      | mg/dl  | 0.678   | 0.596      | 0.760    | 0.041           | 0.082 |   |  |
| Magnesium            | mg/dl  | 2.22    | 1.95       | 2.49     | 0.14            | 0.27  | Xylidyl Blue  |  |
| NEFA                 | mmol/l | 1.44    | 1.15       | 1.73     | 0.146           | 0.29  | Colorimetric  |  |
| Phosphorus           | mg/dl  | 4.25    | 3.6        | 4.9      | 0.33            | 0.65  | Phosphomolybdate UV                                 |  |
| Potassium            | mmol/l | 3.93    | 3.61       | 4.25     | 0.16            | 0.32  | ISE method - direct                                 |  |
|                      | mmol/l | 4.01    | 3.69       | 4.33     | 0.16            | 0.32  | ISE method - indirect                               |  |
| Sodium               | mmol/l | 140     | 133        | 147      | 3.5             | 7.0   | ISE method - direct                                 |  |
|                      | mmol/l | 143     | 136        | 150      | 3.5             | 7.0   | ISE method - indirect                               |  |
| Protein Total        | g/dl   | 5.77    | 4.61       | 6.93     | 0.58            | 1.16  | Biuret reaction end point                           |  |
| TIBC                 | µg/dl  | 231     | 183        | 279      | 24              | 48    | Direct Colorimetric                                 |  |
| Transferrin          | mg/dl  | 185     | 148        | 222      | 18.5            | 37.0  | Immunoturbidimetric                                 |  |
| Triglycerides        | mg/dl  | 98.2    | 82.8       | 114      | 7.7             | 15.4  | Lipase/GPO-PAP                                      |  |
| UIBC                 | µg/dl  | 111     | 90.6       | 131.4    | 10.2            | 20.4  | Direct Colorimetric                                 |  |
| Uric Acid (Urate)    | mg/dl  | 5.81    | 5.06       | 6.56     | 0.38            | 0.75  | Uricase Peroxidase with ascorbate oxidase @ 546nm   |  |
| Urea                 | mg/dl  | 45      | 38.2       | 51.8     | 3.4             | 6.8   | Urease kinetic                                      |  |
|                      | mg/dl  | 21      | 17.9       | 24.1     | 1.55            | 3.10  | BUN   |  |
| Zinc                 | µg/dl  | 132     | 106        | 158      | 13              | 26    | Colorimetric  |  |