

## IMMUNOASSAY SPECIALITY I - LEVEL 3 (IA SPECIALITY I LEV 3)

|                |                |                |            |
|----------------|----------------|----------------|------------|
| <b>CAT NO.</b> | IAS3115        | <b>LOT NO.</b> | 2220EC     |
| <b>SIZE</b>    | 5 x 2 ml       | <b>EXPIRY:</b> | 2024-11-28 |
| <b>GTIN:</b>   | 05055273207316 |                |            |

### INTENDED USE

This product is intended for *in vitro* diagnostic use, in the quality control of the accuracy of Immunoassays on clinical chemistry systems. This material can be used to monitor the control of accuracy or the control of reproducibility of immunoassays.

### 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). Reconstituted serum is stable for 5 days at +2°C to +8°C if kept capped in original container and free from contamination, or 4 weeks frozen once at -20°C. Anti-TG is stable for 3 days at +2°C to +8°C.

C-Peptide and Procalcitonin are stable for 1 day at +2°C to +8°C. IGF-1 is stable for 8 hours at +2°C to +8°C.

Osteocalcin is stable for 4 hours at +2 to +8°C. Parathyroid Hormone (PTH) should be tested within 4 hours of reconstitution when stored at +2°C to +8°C, or within 2 weeks when stored below -20°C.

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.

Bacterial contamination of the reconstituted serum will cause reductions in the stability of many components. If bacterial contamination is suspected, the vial should be discarded and a fresh vial reconstituted.

### PREPARATION

The Immunoassay Speciality I Control is supplied lyophilised.

- Carefully reconstitute each vial of lyophilised serum with exactly 2 ml 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.
- Refer to the Control section of the individual analyser application.
- Refrigerate any unused material. Prior to reuse, mix contents thoroughly.

### MATERIALS PROVIDED

Immunoassay Speciality I - Level 3 5 x 2 ml

### MATERIAL REQUIRED BUT NOT PROVIDED

Volumetric pipette

### VALUE ASSIGNMENT

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 Immunoassay Speciality I Control is submitted to a number of reference laboratories and values are assigned from a consensus of results obtained by these laboratories, using a unique statistical analysis. With each batch, a control range is provided for individual parameters and each parameter method. The control range is equivalent to the assigned mean  $\pm 2$  S.D.

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).

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Cat. No. IAS3115 Lot. No. 2220EC Size 5 x 2 ml Expiry 2024-11-28

| Analyte                          | unit   | Target | Range |       | methods                                 |
|----------------------------------|--------|--------|-------|-------|---|
|                                  |        |        | low   | high  |   |
| 1-25 (OH) <sub>2</sub> Vitamin D | pmol/l | 317    | 222   | 412   | Diasorin Liaison XL                     |
| 25-OH Vitamin D                  | nmol/l | 84.7   | 63.5  | 106   | Roche Vitamin D Total                   |
|                                  | nmol/l | 94.0   | 70.5  | 118   | Diasorin Liaison                        |
|                                  | nmol/l | 92.9   | 69.7  | 116   | Abbott Architect (3L52)                 |
|                                  | nmol/l | 124    | 93.0  | 155   | Siemens Centaur XP/XPT/Classic          |
|                                  | nmol/l | 85.8   | 64.4  | 107   | BioMerieux Vidas                        |
|                                  | nmol/l | 84.9   | 63.7  | 106   | Beckman Dxl 600/800                     |
|                                  | nmol/l | 96.2   | 72.2  | 120   | Abbott Architect (5P02)/ Alinity (8P45) |
|                                  | nmol/l | 94.8   | 71.1  | 119   | Diasorin Liaison XL                     |
|                                  | nmol/l | 91.7   | 68.8  | 115   | Roche Vitamin D Total II                |
|                                  | nmol/l | 121    | 90.8  | 151   | Siemens Atellica IM                     |
|                                  | nmol/l | 89.4   | 67.1  | 112   | Roche Vitamin D Total II e801           |
|                                  | nmol/l | 90.0   | 67.5  | 113   | Roche Vitamin D Total III               |
| Anti TG                          | kU/l   | 359    | 269   | 449   | Siemens Immulite 2000/2500              |
|                                  | kU/l   | 696    | 522   | 870   | Abbott Architect / Alinity              |
|                                  | kU/l   | 1903   | 1427  | 2379  | Roche Cobas 4000/E411                   |
|                                  | kU/l   | 2006   | 1505  | 2508  | Roche Cobas e601/602                    |
|                                  | kU/l   | 813    | 610   | 1016  | Beckman Dxl 600/800                     |
|                                  | kU/l   | 795    | 596   | 994   | Siemens Centaur XP/XPT/Classic          |
|                                  | kU/l   | 725    | 544   | 906   | BioMerieux Vidas                        |
|                                  | kU/l   | 859    | 644   | 1074  | Siemens Atellica IM                     |
|                                  | kU/l   | 1738   | 1304  | 2173  | Roche Cobas e402/e801                   |
|                                  | kU/l   | 851    | 638   | 1064  | Siemens Atellica IM aTgII               |
|                                  | kU/l   | 903    | 677   | 1129  | Siemens Centaur XP/XPT aTgII            |
| Anti TPO                         | kU/l   | 117    | 87.8  | 146   | Abbott Architect / Alinity              |
|                                  | kU/l   | 147    | 110   | 184   | Siemens Immulite 2000/2500              |
|                                  | kU/l   | 81.2   | 60.9  | 102   | Roche Cobas 4000/E411                   |
|                                  | kU/l   | 78.4   | 58.8  | 98.0  | Roche Cobas c501/502 e601/602           |
|                                  | kU/l   | 63.7   | 47.8  | 79.6  | Beckman Dxl 600/800                     |
|                                  | kU/l   | 414    | 311   | 518   | Siemens Centaur XP/XPT/Classic          |
|                                  | kU/l   | 90.7   | 68.0  | 113   | BioMerieux Vidas                        |
|                                  | kU/l   | 103    | 77.3  | 129   | Roche Cobas e402/e801                   |
|                                  | kU/l   | 411    | 308   | 514   | Siemens Atellica IM                     |
| C-Peptide                        | nmol/l | 1.860  | 1.400 | 2.330 | Roche Cobas e601/602                    |
|                                  | ng/ml  | 5.62   | 4.23  | 7.01  |   |
|                                  | nmol/l | 1.710  | 1.280 | 2.140 | Abbott Architect / Alinity              |
|                                  | ng/ml  | 5.16   | 3.86  | 6.46  |   |
|                                  | nmol/l | 1.710  | 1.280 | 2.140 | Siemens Immulite 2000/2500              |
|                                  | ng/ml  | 5.16   | 3.86  | 6.46  |   |
|                                  | nmol/l | 1.830  | 1.370 | 2.290 | Roche Cobas 4000/E411                   |
|                                  | ng/ml  | 5.52   | 4.14  | 6.90  |   |
|                                  | nmol/l | 2.110  | 1.580 | 2.640 | Diasorin Liaison XL                     |
|                                  | ng/ml  | 6.37   | 4.77  | 7.97  |   |

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| Analyte                   | unit   | Target | Range |                             | methods                            |
|---------------------------|--------|--------|-------|-----------------------------|------------------------------------|
|                           |        |        | low   | high                        |                                    |
| C-Peptide                 | nmol/l | 1.810  | 1.360 | 2.260                       | Roche Cobas e402/e801              |
|                           | ng/ml  | 5.46   | 4.11  | 6.81                        |                                    |
|                           | nmol/l | 1.550  | 1.160 | 1.940                       | Siemens Atellica IM                |
|                           | ng/ml  | 4.68   | 3.50  | 5.86                        |                                    |
| IGF 1                     | µg/l   | 492    | 369   | 615                         | Siemens Immulite 2000/2500         |
|                           | µg/l   | 214    | 161   | 268                         | Diasorin Liaison                   |
|                           | µg/l   | 123    | 92.3  | 154                         | Roche Cobas 6000/8000              |
|                           | µg/l   | 114    | 85.5  | 143                         | Roche Elecsys                      |
| Insulin                   | mU/l   | 33.6   | 25.2  | 42.0                        | Abbott Architect                   |
|                           | µU/ml  | 33.6   | 25.2  | 42.0                        |                                    |
|                           | mU/l   | 45.3   | 34.0  | 56.6                        | Roche Cobas 6000/8000              |
|                           | µU/ml  | 45.3   | 34.0  | 56.6                        |                                    |
|                           | mU/l   | 43.8   | 32.9  | 54.8                        | Siemens Centaur XP/XPT/Classic     |
|                           | µU/ml  | 43.8   | 32.9  | 54.7                        |                                    |
|                           | mU/l   | 37.7   | 28.3  | 47.1                        | Beckman Dxl 600/800                |
|                           | µU/ml  | 37.7   | 28.3  | 47.1                        |                                    |
|                           | mU/l   | 46.8   | 35.1  | 58.5                        | Roche Cobas 4000/E411              |
|                           | µU/ml  | 46.8   | 35.1  | 58.5                        |                                    |
|                           | mU/l   | 41.4   | 31.1  | 51.8                        | Siemens Atellica IM                |
|                           | µU/ml  | 41.4   | 31.1  | 51.7                        |                                    |
| Osteocalcin               | µg/l   | 49.9   | 37.4  | 62.4                        | Siemens Immulite 2000/2500         |
|                           | µg/l   | 148    | 111   | 185                         | Roche Cobas 6000/8000              |
|                           | µg/l   | 147    | 110   | 184                         | Roche Cobas 4000/E411              |
| Parathyroid Hormone (PTH) | pmol/l | 108    | 81.0  | 135                         | Abbott Architect / Alinity         |
|                           | pg/ml  | 1026   | 769   | 1283                        |                                    |
|                           | pmol/l | 77.1   | 57.8  | 96.4                        | Beckman Dxl 600/800                |
|                           | pg/ml  | 732    | 549   | 915                         |                                    |
|                           | pmol/l | 67.8   | 50.9  | 84.8                        | Roche Cobas e601/602 PTH           |
|                           | pg/ml  | 644    | 483   | 805                         |                                    |
|                           | pmol/l | 73.8   | 55.4  | 92.3                        | Roche Cobas 4000/e411 PTH/PTH STAT |
|                           | pg/ml  | 701    | 526   | 876                         |                                    |
|                           | pmol/l | 99.0   | 74.3  | 124                         | Siemens Centaur XP/XPT/Classic     |
|                           | pg/ml  | 940    | 706   | 1174                        |                                    |
|                           | pmol/l | 63.7   | 47.8  | 79.6                        | Roche Cobas e601/602 PTH (1-84)    |
|                           | pg/ml  | 605    | 454   | 756                         |                                    |
|                           | pmol/l | 69.4   | 52.1  | 86.8                        | Roche Cobas 4000/E411 PTH (1-84)   |
|                           | pg/ml  | 659    | 495   | 823                         |                                    |
|                           | pmol/l | 97.0   | 72.8  | 121                         | Siemens Atellica IM                |
|                           | pg/ml  | 921    | 691   | 1151                        |                                    |
| pmol/l                    | 66.3   | 49.7   | 82.9  | Roche Cobas e801 PTH        |                                    |
| pg/ml                     | 630    | 472    | 788   |                             |                                    |
| pmol/l                    | 60.5   | 45.4   | 75.6  | Roche Cobas e801 PTH (1-84) |                                    |
| pg/ml                     | 575    | 431    | 719   |                             |                                    |

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| Analyte                   | unit   | Target | Range |      | methods                               |
|---------------------------|--------|--------|-------|------|---------------------------------------|
|                           |        |        | low   | high |                                       |
| Parathyroid Hormone (PTH) | pmol/l | 64.4   | 48.3  | 80.5 | Roche Cobas e801 PTH STAT             |
|                           | pg/ml  | 612    | 459   | 765  |                                       |
|                           | pmol/l | 62.8   | 47.1  | 78.5 | Roche Cobas e601/602 PTH STAT         |
|                           | pg/ml  | 596    | 447   | 745  |                                       |
| Procalcitonin             | µg/l   | 9.67   | 7.25  | 12.1 | Brahms Kryptor                        |
|                           | µg/l   | 20.8   | 15.6  | 26.0 | BioMerieux Vidas                      |
|                           | µg/l   | 15.0   | 11.3  | 18.8 | Roche Elecsys/Cobas/Modular           |
|                           | µg/l   | 20.3   | 15.2  | 25.4 | Siemens Centaur XP/XPT/Classic        |
|                           | µg/l   | 20.1   | 15.1  | 25.1 | Siemens Centaur CP 10378883           |
|                           | µg/l   | 14.8   | 11.1  | 18.5 | Abbott Architect / Alinity Brahms PCT |
|                           | µg/l   | 14.8   | 11.1  | 18.5 | Roche Cobas e402/e801                 |
|                           | µg/l   | 19.4   | 14.6  | 24.3 | Siemens Atellica IM 10995651          |
|                           | µg/l   | 19.0   | 14.3  | 23.8 | Beckman Access PCT                    |
|                           | µg/l   | 19.3   | 14.5  | 24.1 | Siemens Centaur XP/XPT 11202697       |
|                           | µg/l   | 20.9   | 15.7  | 26.1 | Siemens Centaur CP 11202697           |
|                           | µg/l   | 18.6   | 14.0  | 23.3 | Siemens Atellica IM 11202699          |