

IMMUNOASSAY SPECIALITY I - LEVEL 2 (IA SPECIALITY I LEV 2)

CAT. NO. IAS3114

LOT NO. 1988EC

SIZE: 5 x 2 ml

EXPIRY: 2022-06-28

GTIN: 05055273207309

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, IGF-I and Procalcitonin are stable for 1 day at +2°C to +8°C. Osteocalcin is stable for 4 hours at +2°C 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.

1. 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.
2. Refer to the Control section of the individual analyser application.
3. Refrigerate any unused material. Prior to reuse, mix contents thoroughly.

MATERIALS PROVIDED

Immunoassay Speciality I - Level 2 5 x 2 ml

MATERIAL REQUIRED BUT NOT PROVIDED

Volumetric pipette

VALUE ASSIGNMENT

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 ± 2 S.D. This results in extremely accurate values, which may be confidently used by laboratories to ensure the accuracy of their methods.

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



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| Range | | | | | |
|----------------------------------|--------|--------|-------|-------|---|
| Analyte | unit | Target | low | high | methods |
| 1-25 (OH) ₂ Vitamin D | pmol/l | 218 | 153 | 283 | Diasorin Liaison XL |
| 25-OH Vitamin D | nmol/l | 60.5 | 45.4 | 75.6 | Roche Vitamin D Total |
| | nmol/l | 69.0 | 51.8 | 86.3 | Diasorin Liaison |
| | nmol/l | 60.3 | 45.2 | 75.4 | Abbott Architect |
| | nmol/l | 89.7 | 67.3 | 112 | Siemens Centaur XP/XPT/Classic |
| | nmol/l | 67.6 | 50.7 | 84.5 | BioMerieux Vidas |
| | nmol/l | 64.4 | 48.3 | 80.5 | Beckman Dxl 600/800 |
| | nmol/l | 71.8 | 53.9 | 89.8 | Beckman Access 25 OH Vitamin D Total |
| | nmol/l | 60.8 | 45.6 | 76.0 | Abbott Architect (5P02)/ Alinity (8P45) |
| | nmol/l | 74.9 | 56.2 | 93.6 | Diasorin Liaison XL |
| | nmol/l | 65.6 | 49.2 | 82.0 | Roche Vitamin D Total II |
| | nmol/l | 91.4 | 68.6 | 114 | Siemens Atellica IM |
| Anti-TG | kU/l | 153 | 115 | 191 | Siemens Immulite 2000/2500 |
| | kU/l | 145 | 109 | 181 | Abbott Architect |
| | kU/l | 801 | 601 | 1001 | Roche Cobas E411 |
| | kU/l | 753 | 565 | 941 | Roche Cobas 6000/8000 |
| | kU/l | 311 | 233 | 389 | Beckman Dxl 600/800 |
| | kU/l | 498 | 374 | 623 | Siemens Centaur XP/XPT/Classic |
| | kU/l | 285 | 214 | 356 | Beckman Access/LXi725 |
| | kU/l | 313 | 235 | 391 | BioMerieux Vidas |
| | kU/l | 539 | 404 | 674 | Siemens Atellica IM |
| Anti-TPO | kU/l | 112 | 84.0 | 140 | Abbott Architect |
| | kU/l | 130 | 97.5 | 163 | Siemens Immulite 2000/2500 |
| | kU/l | 76.6 | 57.5 | 95.8 | Roche Cobas E411 |
| | kU/l | 78.2 | 58.7 | 97.8 | Roche Cobas 6000/8000 |
| | kU/l | 88.1 | 66.1 | 110 | Beckman Dxl 600/800 |
| | kU/l | 368 | 276 | 460 | Siemens Centaur XP/XPT/Classic |
| | kU/l | 96.7 | 72.5 | 121 | BioMerieux Vidas |
| | kU/l | 364 | 273 | 455 | Siemens Atellica IM |
| C-Peptide | nmol/l | 1.050 | 0.788 | 1.310 | Siemens Centaur XP/XPT/Classic |
| | ng/ml | 3.17 | 2.38 | 3.96 | |
| | nmol/l | 1.420 | 1.070 | 1.780 | Roche Cobas 6000/8000 |
| | ng/ml | 4.29 | 3.23 | 5.35 | |
| | nmol/l | 1.480 | 1.110 | 1.850 | Diasorin Liaison |
| | ng/ml | 4.47 | 3.35 | 5.59 | |
| | nmol/l | 1.240 | 0.930 | 1.550 | Abbott Architect |
| | ng/ml | 3.74 | 2.81 | 4.67 | |
| | nmol/l | 1.260 | 0.945 | 1.580 | Siemens Immulite 2000/2500 |
| | ng/ml | 3.80 | 2.85 | 4.75 | |
| | nmol/l | 1.410 | 1.060 | 1.760 | Roche Cobas E411 |
| | ng/ml | 4.26 | 3.20 | 5.32 | |
| | nmol/l | 0.967 | 0.725 | 1.210 | Siemens Atellica IM |
| ng/ml | 2.92 | 2.19 | 3.65 | | |

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| Analyte | unit | Target | Range | | methods |
|---------------------------|--------|--------|-------|--------------------------------|------------------------------------|
| | | | low | high | |
| IGF-1 | µg/l | 225 | 169 | 281 | Siemens Immulite 2000/2500 |
| | µg/l | 169 | 127 | 211 | Diasorin Liaison |
| | µg/l | 106 | 79.5 | 133 | Roche Cobas 6000/8000 |
| Insulin | mU/l | 10.9 | 8.18 | 13.6 | Abbott Architect |
| | µU/ml | 10.9 | 8.18 | 13.6 | |
| | mU/l | 12.9 | 9.68 | 16.1 | Roche Cobas 6000/8000 |
| | µU/ml | 12.9 | 9.68 | 16.1 | |
| | mU/l | 13.8 | 10.4 | 17.3 | Siemens Centaur XP/XPT/Classic |
| | µU/ml | 13.8 | 10.4 | 17.2 | |
| | mU/l | 4.92 | 3.69 | 6.15 | Siemens Immulite 2000 |
| | µU/ml | 4.92 | 3.69 | 6.15 | |
| | mU/l | 11.0 | 8.25 | 13.8 | Beckman Dxl 600/800 |
| | µU/ml | 11.0 | 8.25 | 13.8 | |
| | mU/l | 12.8 | 9.60 | 16.0 | Roche Cobas E411 |
| | µU/ml | 12.8 | 9.60 | 16.0 | |
| | mU/l | 14.4 | 10.8 | 18.0 | Diasorin Liaison XL |
| µU/ml | 14.4 | 10.8 | 18.0 | | |
| mU/l | 12.8 | 9.60 | 16.0 | Siemens Atellica IM | |
| µU/ml | 12.8 | 9.60 | 16.0 | | |
| Osteocalcin | µg/l | 38.0 | 28.5 | 47.5 | Siemens Immulite 2000/2500 |
| | µg/l | 69.4 | 52.1 | 86.8 | Roche Elecsys |
| | µg/l | 70.7 | 53.0 | 88.4 | Roche Cobas 6000/8000 |
| | µg/l | 69.0 | 51.8 | 86.3 | Roche Cobas E411 |
| | µg/l | 83.6 | 62.7 | 105 | Diasorin Liaison |
| Parathyroid Hormone (PTH) | pmol/l | 45.6 | 34.2 | 57.0 | Abbott Architect |
| | pg/ml | 433 | 325 | 541 | |
| | pmol/l | 31.4 | 23.6 | 39.3 | Beckman Dxl 600/800 |
| | pg/ml | 298 | 224 | 372 | |
| | pmol/l | 50.6 | 38.0 | 63.3 | Siemens Immulite 2000/2500 |
| | pg/ml | 481 | 361 | 601 | |
| | pmol/l | 28.9 | 21.7 | 36.1 | Roche Cobas 6000/8000 |
| | pg/ml | 274 | 206 | 342 | |
| | pmol/l | 29.7 | 22.3 | 37.1 | Roche Cobas 4000/e411 PTH/PTH STAT |
| | pg/ml | 282 | 212 | 352 | |
| pmol/l | 38.4 | 28.8 | 48.0 | Siemens Centaur XP/XPT/Classic | |
| pg/ml | 365 | 274 | 456 | | |
| pmol/l | 38.2 | 28.7 | 47.8 | Siemens Atellica IM | |
| pg/ml | 363 | 273 | 453 | | |
| Procalcitonin | µg/l | 2.30 | 1.73 | 2.88 | Brahms Kryptor |
| | µg/l | 4.10 | 3.08 | 5.13 | BioMerieux Vidas |
| | µg/l | 2.82 | 2.12 | 3.53 | Roche Elecsys/Cobas/Modular |
| | µg/l | 3.50 | 2.63 | 4.38 | Siemens Centaur XP/XPT/Classic |
| | µg/l | 3.57 | 2.68 | 4.46 | Siemens Centaur CP |
| | µg/l | 5.99 | 4.79 | 7.18 | Diazyme PCT |
| µg/l | 2.95 | 2.21 | 3.69 | Abbott Architect Brahms PCT | |

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Range

| Analyte | unit | Target | low | high | methods |
|---------------|------|--------|------|------|------------|
| Procalcitonin | µg/l | 8.18 | 6.95 | 9.41 | Nexus IB10 |