

IMMUNOASSAY PREMIUM - LEVEL 2 (IA PREMIUM 2)

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|------------------------|-----------------------------|-----------------------|
| CAT. NO. IA2639 | GTIN: 05055273203851 | SIZE 12 x 5 ml |
| CAT. NO. IA2633 | GTIN: 05055273203837 | SIZE 4 x 5 ml |
| LOT NO. 2276EC | EXPIRY: 2026-04-28 | |

INTENDED USE

This product is intended for *in vitro* diagnostic use, as assayed quality control material to monitor the accuracy and reproducibility of analytes listed in the package insert.

This device is for prescription use only.

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 7 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. C-Peptide is stable for 1 day at +2°C to +8°C. Thyroglobulin should be tested within 4 hours of reconstitution when stored at +2°C to +8°C, or within 2 weeks when stored at -20°C.

ACTH should be tested immediately after the 30-minute reconstitution period. No frozen stability claim is made for ACTH, Aldosterone and C-Peptide. 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

Immunoassay Premium is supplied lyophilised.

- Carefully reconstitute each vial of lyophilised serum with exactly 5 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 Premium - Level 2: 12 x 5 ml Tri-Level: 4 x 5 ml

MATERIAL REQUIRED BUT NOT PROVIDED

Volumetric pipette

VALUE ASSIGNMENT

Each batch of Immunoassay Premium is submitted to a number of external laboratories. Values are assigned from a consensus of results obtained by these laboratories, using a unique statistical analysis. Average values should normally fall within the listed ranges for analytes in the instruments specified in this product insert. However, variations may be caused by instrument reagents and laboratory technique. Therefore, the range produced herein should only be considered as a reference and it is recommended that each laboratory establish its own mean and acceptable ranges. Parathyroid Hormone (PTH) is present in the control, but no claim is made for the expected value or stability of this analyte.

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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| EC | REP |
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IMMUNOASSAY PREMIUM - LEVEL 2 (IA PREMIUM 2)

Cat. No. IA2639 / IA2633 Lot. No. 2276EC Size 12 x 5ml / 4 x 5ml Expiry 2026-04-28

| Analyte | unit | Target | Range | | methods |
|--------------------|---------------|--------|-------|---------------------|---|
| | | | low | high | |
| 17-OH-Progesterone | nmol/l | 13.0 | 9.75 | 16.3 | DIAsource ELISA |
| | ng/ml | 4.30 | 3.23 | 5.37 | |
| | nmol/l | 11.4 | 8.55 | 14.3 | SNIBE Maglumi Analysers |
| | ng/ml | 3.77 | 2.83 | 4.71 | |
| 25-OH Vitamin D | nmol/l | 97.9 | 73.4 | 122 | Siemens Centaur XP/XPT/Classic |
| | nmol/l | 63.4 | 47.6 | 79.3 | Roche Vitamin D Total |
| | nmol/l | 74.3 | 55.7 | 92.9 | Abbott Architect (3L52) |
| | nmol/l | 115 | 86.3 | 144 | Vitros ECi |
| | nmol/l | 81.5 | 61.1 | 102 | BioMerieux Vidas |
| | nmol/l | 89.3 | 67.0 | 112 | Beckman Dxl 600/800 |
| | nmol/l | 75.9 | 56.9 | 94.9 | Abbott Architect (5P02)/ Alinity (8P45) |
| | nmol/l | 59.0 | 44.3 | 73.8 | Roche Vitamin D Total II |
| | nmol/l | 77.3 | 58.0 | 96.6 | Abbott Alinity i |
| | nmol/l | 93.0 | 69.8 | 116 | Siemens Atellica IM |
| | nmol/l | 65.4 | 49.1 | 81.8 | Roche Vitamin D Total II e801 |
| | nmol/l | 66.0 | 49.5 | 82.5 | Roche Vitamin D Total III |
| ACTH | pmol/l | 9.43 | 7.07 | 11.8 | Siemens Immulite 2000/2500 |
| | pg/ml | 42.9 | 32.1 | 53.7 | |
| | pmol/l | 8.82 | 6.62 | 11.0 | Roche Cobas 4000/E411 |
| | pg/ml | 40.1 | 30.1 | 50.1 | |
| | pmol/l | 8.96 | 6.72 | 11.2 | Roche Cobas e601/602 |
| | pg/ml | 40.7 | 30.5 | 50.9 | |
| | pmol/l | 9.26 | 6.95 | 11.6 | Siemens Immulite 1000 |
| | pg/ml | 42.1 | 31.6 | 52.6 | |
| | pmol/l | 13.1 | 9.83 | 16.4 | Diasorin Liaison XL |
| | pg/ml | 59.5 | 44.7 | 74.3 | |
| Aldosterone | pmol/l | 410 | 308 | 513 | Diasorin Liaison XL |
| | pg/ml | 148 | 111 | 185 | |
| Alphafoetoprotein | KIU/l = IU/ml | 43.9 | 35.1 | 52.7 | Abbott Architect |
| | ng/ml | 53.1 | 42.5 | 63.7 | |
| | KIU/l = IU/ml | 42.8 | 34.2 | 51.4 | Beckman DxI800 |
| | ng/ml | 51.8 | 41.4 | 62.2 | |
| | KIU/l = IU/ml | 47.9 | 38.3 | 57.5 | Roche Cobas e601/602 |
| | ng/ml | 58.0 | 46.3 | 69.7 | |
| | KIU/l = IU/ml | 48.5 | 38.8 | 58.2 | Roche Cobas 4000/E411 |
| | ng/ml | 58.7 | 46.9 | 70.5 | |
| KIU/l = IU/ml | 52.0 | 41.6 | 62.4 | Siemens Atellica IM | |
| | ng/ml | 62.9 | 50.3 | 75.5 | |
| KIU/l = IU/ml | 43.9 | 35.1 | 52.7 | Abbott Alinity i | |
| | ng/ml | 53.1 | 42.5 | 63.7 | |

IMMUNOASSAY PREMIUM - LEVEL 2 (IA PREMIUM 2)

Cat. No. IA2639 / IA2633 Lot. No. 2276EC Size 12 x 5ml / 4 x 5ml Expiry 2026-04-28

| Analyte | unit | Target | Range | | methods |
|--------------------------------|---------------|--------|-------|------------------|--------------------------------|
| | | | low | high | |
| Alphafoetoprotein | KIU/l = IU/ml | 47.5 | 38.0 | 57.0 | Roche Cobas e402/e801 |
| | ng/ml | 57.5 | 46.0 | 69.0 | |
| Amikacin | µmol/l | 15.2 | 12.2 | 18.2 | Gravimetric |
| | µg/ml | 8.90 | 7.14 | 10.7 | |
| Androstenedione | nmol/l | 13.9 | 10.4 | 17.4 | Siemens Immulite 2000 |
| | ng/ml | 3.99 | 2.98 | 5.00 | |
| Beta-2-microglobulin | µg/ml = mg/l | 2.58 | 2.06 | 3.10 | Siemens Immulite 2000/2500 |
| | µg/ml = mg/l | 2.96 | 2.37 | 3.55 | Roche Cobas 6000/8000 |
| C-Peptide | nmol/l | 1.820 | 1.370 | 2.280 | Roche Cobas e601/602 |
| | ng/ml | 5.49 | 4.14 | 6.84 | |
| | nmol/l | 1.920 | 1.440 | 2.400 | Roche Cobas 4000/E411 |
| | ng/ml | 5.80 | 4.35 | 7.25 | |
| Carbamazepine | nmol/l | 1.710 | 1.280 | 2.140 | Roche Cobas e402/e801 |
| | ng/ml | 5.16 | 3.86 | 6.46 | |
| | µmol/l | 39.7 | 31.8 | 47.6 | Abbott Architect (CMIA) |
| | µg/ml | 9.39 | 7.52 | 11.3 | |
| Carbamazepine | µmol/l | 40.2 | 32.2 | 48.2 | Roche Cobas 6000/8000 |
| | µg/ml | 9.50 | 7.61 | 11.4 | |
| | µmol/l | 38.5 | 30.8 | 46.2 | Gravimetric |
| | µg/ml | 9.10 | 7.28 | 10.9 | |
| Carcinoembryonic Antigen (CEA) | ng/ml = µg/l | 26.5 | 21.2 | 31.8 | BioMerieux Vidas |
| | ng/ml = µg/l | 25.4 | 20.3 | 30.5 | Vitros ECi |
| | ng/ml = µg/l | 25.1 | 20.1 | 30.1 | Beckman Access |
| | ng/ml = µg/l | 29.6 | 23.7 | 35.5 | Siemens Centaur XP/XPT/Classic |
| | ng/ml = µg/l | 29.8 | 23.8 | 35.8 | Abbott Architect |
| | ng/ml = µg/l | 25.0 | 20.0 | 30.0 | Beckman Dxl800 |
| | ng/ml = µg/l | 22.6 | 18.1 | 27.1 | Roche Cobas e601/602 |
| | ng/ml = µg/l | 24.6 | 19.7 | 29.5 | Roche Cobas 4000/E411 |
| | ng/ml = µg/l | 29.3 | 23.4 | 35.2 | Siemens Atellica IM |
| | ng/ml = µg/l | 23.6 | 18.9 | 28.3 | Roche Cobas e402/e801 |
| ng/ml = µg/l | 29.3 | 23.4 | 35.2 | Abbott Alinity i | |
| Cortisol | nmol/l | 743 | 557 | 929 | Siemens Centaur XP/XPT/Classic |
| | µg/dl | 26.7 | 20.1 | 33.3 | |
| | nmol/l | 587 | 440 | 734 | Siemens Immulite 2000/2500 |
| | µg/dl | 21.1 | 15.8 | 26.4 | |
| | nmol/l | 582 | 437 | 728 | Vitros ECi |
| | µg/dl | 21.0 | 15.7 | 26.3 | |
| | nmol/l | 573 | 430 | 716 | Abbott Architect |
| | µg/dl | 20.6 | 15.5 | 25.7 | |
| | nmol/l | 593 | 445 | 741 | Beckman Dxl800 |
| | µg/dl | 21.3 | 16.0 | 26.6 | |
| Cortisol | nmol/l | 678 | 509 | 848 | Roche Cobas e601/602 |
| | µg/dl | 24.4 | 18.3 | 30.5 | |
| | nmol/l | 676 | 507 | 845 | Roche Cobas 4000/E411 |
| | µg/dl | 24.3 | 18.3 | 30.3 | |
| Cortisol | nmol/l | 646 | 485 | 808 | Roche Cobas 4000/e411 Gen II |
| | µg/dl | 23.3 | 17.5 | 29.1 | |

IMMUNOASSAY PREMIUM - LEVEL 2 (IA PREMIUM 2)

Cat. No. IA2639 / IA2633 Lot. No. 2276EC Size 12 x 5ml / 4 x 5ml Expiry 2026-04-28

| Analyte | unit | Target | Range | | methods |
|--------------|--------------|--------|-------|---|---|
| | | | low | high | |
| Cortisol | nmol/l | 640 | 480 | 800 | Roche Cobas e601/602 Gen II |
| | µg/dl | 23.0 | 17.3 | 28.7 | |
| | nmol/l | 786 | 590 | 983 | Siemens Atellica IM |
| | µg/dl | 28.3 | 21.2 | 35.4 | |
| | nmol/l | 628 | 471 | 785 | Roche Cobas e402/e801 |
| | µg/dl | 22.6 | 17.0 | 28.2 | |
| DHEA-S | nmol/l | 633 | 475 | 791 | Roche Cobas e801 Gen II |
| | µg/dl | 22.8 | 17.1 | 28.5 | |
| | nmol/l | 577 | 433 | 721 | Abbott Alinity i |
| | µg/dl | 20.8 | 15.6 | 26.0 | |
| | µmol/l | 11.2 | 8.96 | 13.4 | Siemens Immulite 2000/2500 |
| | µmol/l | 12.2 | 9.76 | 14.6 | Abbott Architect |
| Digoxin | µmol/l | 9.73 | 7.78 | 11.7 | Beckman DxI800 |
| | µmol/l | 14.6 | 11.7 | 17.5 | Roche Cobas 4000/E411 |
| | µmol/l | 14.1 | 11.3 | 16.9 | Roche Cobas e601/602 |
| | µmol/l | 13.9 | 11.1 | 16.7 | Roche Cobas e402/e801 |
| | µmol/l | 12.1 | 9.68 | 14.5 | Abbott Alinity i |
| | Ethosuximide | µmol/l | 360 | 288 | 432 |
| µg/ml | | 51.0 | 40.8 | 61.3 | |
| nmol/l | | 3.35 | 2.68 | 4.02 | Roche Cobas e402/e801 |
| ng/ml | | 2.62 | 2.09 | 3.15 | |
| Ferritin | nmol/l | 2.71 | 2.17 | 3.25 | Abbott Architect (CMIA) |
| | ng/ml | 2.12 | 1.69 | 2.54 | |
| | nmol/l | 3.07 | 2.46 | 3.68 | Gravimetric |
| | ng/ml | 2.40 | 1.92 | 2.87 | |
| | ng/ml = µg/l | 96.0 | 76.8 | 115 | BioMerieux Vidas |
| | ng/ml = µg/l | 132 | 106 | 158 | Roche Elecsys/Cobas e411 |
| | ng/ml = µg/l | 80.9 | 64.7 | 97.1 | Beckman Access |
| | ng/ml = µg/l | 79.1 | 63.3 | 94.9 | Vitros ECI |
| | ng/ml = µg/l | 87.7 | 70.2 | 105 | Siemens Centaur XP/XPT/Classic |
| | ng/ml = µg/l | 131 | 105 | 157 | Abbott Architect |
| ng/ml = µg/l | 128 | 102 | 154 | Roche Modular E170 / Roche Cobas e601/602 | |
| ng/ml = µg/l | 76.5 | 61.2 | 91.8 | Beckman DxI800 | |
| ng/ml = µg/l | 117 | 93.6 | 140 | Roche Cobas c501/502/503/701/702 | |
| ng/ml = µg/l | 134 | 107 | 161 | Abbott Alinity i | |
| ng/ml = µg/l | 86.1 | 68.9 | 103 | Siemens Atellica IM | |
| ng/ml = µg/l | 124 | 99.0 | 149 | Roche Cobas e402/e801 | |
| Folate | nmol/l | 8.57 | 6.51 | 10.6 | Siemens Immulite 2000 |
| | ng/ml | 3.78 | 2.87 | 4.69 | |
| | nmol/l | 7.39 | 5.62 | 9.16 | Vitros ECI |
| | ng/ml | 3.26 | 2.48 | 4.04 | |
| | nmol/l | 11.2 | 8.51 | 13.9 | Abbott Architect |
| | ng/ml | 4.94 | 3.75 | 6.13 | |
| Folate | nmol/l | 25.8 | 19.6 | 32.0 | Siemens Centaur XP/XPT/Classic (enhanced kit) |
| | ng/ml | 11.4 | 8.64 | 14.2 | |

IMMUNOASSAY PREMIUM - LEVEL 2 (IA PREMIUM 2)

Cat. No. IA2639 / IA2633 Lot. No. 2276EC Size 12 x 5ml / 4 x 5ml Expiry 2026-04-28

| Range | | | | | | |
|---------|---------|--------|-------|-----------------------------|---------------------------------------|----------------|
| Analyte | unit | Target | low | high | methods | |
| Folate | nmol/l | 13.5 | 10.3 | 16.7 | Beckman Dxl 600 / 800 - A98032 | |
| | ng/ml | 5.95 | 4.54 | 7.36 | | |
| | nmol/l | 12.9 | 9.80 | 16.0 | Roche Elecsys Folate | |
| | ng/ml | 5.69 | 4.32 | 7.06 | | |
| | nmol/l | 13.1 | 9.96 | 16.2 | Roche Folate III - 07559992 | |
| | ng/ml | 5.78 | 4.39 | 7.17 | | |
| | nmol/l | 21.8 | 16.6 | 27.0 | Siemens Atellica IM | |
| | ng/ml | 9.61 | 7.32 | 11.9 | | |
| | nmol/l | 12.5 | 9.50 | 15.5 | Abbott Alinity i | |
| | ng/ml | 5.51 | 4.19 | 6.83 | | |
| | nmol/l | 12.8 | 9.73 | 15.9 | Roche Folate 07027290 e801 | |
| | ng/ml | 5.64 | 4.29 | 6.99 | | |
| | Free T3 | pmol/l | 10.7 | 8.03 | 13.4 | Beckman Access |
| | | ng/dl | 0.696 | 0.522 | 0.870 | |
| pg/ml | | 6.97 | 5.23 | 8.71 | | |
| pmol/l | | 30.8 | 23.1 | 38.5 | Vitros ECI | |
| ng/dl | | 2.00 | 1.50 | 2.50 | | |
| pg/ml | | 20.1 | 15.0 | 25.2 | | |
| pmol/l | | 13.4 | 10.1 | 16.8 | Siemens Centaur XP/XPT/Classic | |
| ng/dl | | 0.871 | 0.657 | 1.09 | | |
| pg/ml | | 8.72 | 6.58 | 10.9 | | |
| pmol/l | | 11.5 | 8.63 | 14.4 | Abbott Architect, 2 point calibration | |
| ng/dl | | 0.748 | 0.561 | 0.935 | | |
| pg/ml | | 7.49 | 5.62 | 9.36 | | |
| pmol/l | | 9.68 | 7.26 | 12.1 | Beckman Dxl800 | |
| ng/dl | | 0.629 | 0.472 | 0.786 | | |
| pg/ml | | 6.30 | 4.73 | 7.87 | | |
| pmol/l | | 14.6 | 11.0 | 18.3 | Roche Cobas 4000/E411 | |
| ng/dl | | 0.949 | 0.715 | 1.18 | | |
| pg/ml | | 9.50 | 7.16 | 11.8 | | |
| pmol/l | | 14.7 | 11.0 | 18.4 | Roche Cobas e601/602 | |
| ng/dl | | 0.956 | 0.715 | 1.20 | | |
| pg/ml | | 9.57 | 7.16 | 12.0 | | |
| pmol/l | | 14.3 | 10.7 | 17.9 | Siemens Atellica IM | |
| ng/dl | | 0.930 | 0.696 | 1.16 | | |
| pg/ml | | 9.31 | 6.97 | 11.7 | | |
| pmol/l | | 11.7 | 8.78 | 14.6 | Abbott Architect, 6 point calibration | |
| ng/dl | | 0.761 | 0.571 | 0.951 | | |
| pg/ml | | 7.62 | 5.72 | 9.52 | | |
| pmol/l | | 14.7 | 11.0 | 18.4 | Roche Cobas e402/e801 | |
| ng/dl | 0.956 | 0.715 | 1.20 | | | |
| pg/ml | 9.57 | 7.16 | 12.0 | | | |
| pmol/l | 11.8 | 8.85 | 14.8 | Abbott Alinity, 6 point cal | | |
| ng/dl | 0.767 | 0.575 | 0.959 | | | |
| pg/ml | 7.68 | 5.76 | 9.60 | | | |
| Free T4 | pmol/l | 25.0 | 18.8 | 31.3 | Beckman Access | |
| | ng/dl | 1.95 | 1.47 | 2.43 | | |
| | pg/ml | 19.5 | 14.7 | 24.3 | | |

IMMUNOASSAY PREMIUM - LEVEL 2 (IA PREMIUM 2)

Cat. No. IA2639 / IA2633 Lot. No. 2276EC Size 12 x 5ml / 4 x 5ml Expiry 2026-04-28

| Analyte | unit | Target | Range | | methods |
|---------------------|--------|--------|-------|-----------------------|--------------------------------|
| | | | low | high | |
| Free T4 | pmol/l | 68.3 | 51.2 | 85.4 | Vitros ECI |
| | ng/dl | 5.33 | 3.99 | 6.67 | |
| | pg/ml | 53.3 | 39.9 | 66.7 | |
| | pmol/l | 21.8 | 16.4 | 27.3 | Siemens Centaur XP/XPT/Classic |
| | ng/dl | 1.70 | 1.28 | 2.12 | |
| | pg/ml | 17.0 | 12.8 | 21.2 | |
| | pmol/l | 31.2 | 23.4 | 39.0 | Siemens Immulite 2000/2500 |
| | ng/dl | 2.43 | 1.83 | 3.03 | |
| | pg/ml | 24.3 | 18.3 | 30.3 | |
| | pmol/l | 22.8 | 17.1 | 28.5 | Abbott Architect |
| | ng/dl | 1.78 | 1.33 | 2.23 | |
| | pg/ml | 17.8 | 13.3 | 22.3 | |
| | pmol/l | 25.4 | 19.1 | 31.8 | Beckman Dxl800 |
| | ng/dl | 1.98 | 1.49 | 2.47 | |
| | pg/ml | 19.8 | 14.9 | 24.7 | |
| | pmol/l | 29.9 | 22.4 | 37.4 | Roche Cobas e601/602 |
| | ng/dl | 2.33 | 1.75 | 2.91 | |
| | pg/ml | 23.3 | 17.5 | 29.1 | |
| | pmol/l | 29.3 | 22.0 | 36.6 | Roche Cobas 4000/E411 |
| | ng/dl | 2.29 | 1.72 | 2.86 | |
| pg/ml | 22.9 | 17.2 | 28.6 | | |
| pmol/l | 23.0 | 17.3 | 28.8 | Siemens Atellica IM | |
| ng/dl | 1.79 | 1.35 | 2.23 | | |
| pg/ml | 17.9 | 13.5 | 22.3 | | |
| pmol/l | 21.5 | 16.1 | 26.9 | Abbott Alinity i | |
| ng/dl | 1.68 | 1.26 | 2.10 | | |
| pg/ml | 16.8 | 12.6 | 21.0 | | |
| pmol/l | 30.9 | 23.2 | 38.6 | Roche Cobas e402/e801 | |
| ng/dl | 2.41 | 1.81 | 3.01 | | |
| pg/ml | 24.1 | 18.1 | 30.1 | | |
| FSH | mU/ml | 26.0 | 20.8 | 31.2 | BioMerieux Vidas |
| | mU/ml | 29.5 | 23.6 | 35.4 | Beckman Access |
| | mU/ml | 29.7 | 23.8 | 35.6 | Siemens Centaur XP/XPT/Classic |
| | mU/ml | 21.3 | 17.0 | 25.6 | Siemens Immulite 2000/2500 |
| | mU/ml | 24.2 | 19.4 | 29.0 | Abbott Architect |
| | mU/ml | 26.8 | 21.4 | 32.2 | Beckman Dxl800 |
| | mU/ml | 25.4 | 20.3 | 30.5 | Roche Cobas 4000/E411 |
| | mU/ml | 24.3 | 19.4 | 29.2 | Roche Cobas e601/602 |
| | mU/ml | 26.8 | 21.4 | 32.2 | Siemens Atellica IM |
| | mU/ml | 24.7 | 19.8 | 29.6 | Abbott Alinity i |
| | mU/ml | 24.6 | 19.7 | 29.5 | Roche Cobas e402/e801 |
| Gentamicin | µmol/l | 8.16 | 6.53 | 9.79 | Gravimetric |
| | µg/ml | 3.90 | 3.12 | 4.68 | |
| Growth Hormone (GH) | µU/ml | 18.5 | 14.8 | 22.2 | Siemens Immulite 2000/2500 |
| | ng/ml | 6.16 | 4.93 | 7.39 | |

IMMUNOASSAY PREMIUM - LEVEL 2 (IA PREMIUM 2)

Cat. No. IA2639 / IA2633 Lot. No. 2276EC Size 12 x 5ml / 4 x 5ml Expiry 2026-04-28

| Analyte | unit | Target | Range | | methods |
|--------------------------|---------------|--------|-------|--------------------------------------|---|
| | | | low | high | |
| Growth Hormone (GH) | µU/ml | 17.6 | 14.1 | 21.1 | Roche Cobas e601/602 |
| | ng/ml | 5.86 | 4.70 | 7.02 | |
| | µU/ml | 15.4 | 12.3 | 18.5 | Diasorin Liaison XL |
| | ng/ml | 5.13 | 4.10 | 6.16 | |
| | µU/ml | 17.5 | 14.0 | 21.0 | Roche Cobas e402/e801 |
| | ng/ml | 5.83 | 4.66 | 7.00 | |
| Immunoglobulin E | KIU/I = IU/ml | 98.0 | 78.4 | 118 | BioMerieux Vidas |
| | KIU/I = IU/ml | 102 | 81.6 | 122 | Siemens Centaur XP/XPT/Classic |
| | KIU/I = IU/ml | 106 | 84.8 | 127 | Siemens Immulite 2000/2500 |
| | KIU/I = IU/ml | 94.3 | 75.4 | 113 | Abbott Architect |
| | KIU/I = IU/ml | 120 | 96.0 | 144 | Roche Cobas 4000/E411 |
| | KIU/I = IU/ml | 113 | 90.4 | 136 | Roche Cobas e601/602 |
| | KIU/I = IU/ml | 113 | 90.4 | 136 | Siemens Atellica IM |
| | KIU/I = IU/ml | 121 | 96.8 | 145 | Roche Cobas e402/e801 |
| Insulin | KIU/I = IU/ml | 88.7 | 71.0 | 106 | Abbott Alinity |
| | mU/l | 17.5 | 13.1 | 21.9 | Siemens Centaur XP/XPT/Classic |
| | µU/ml | 17.5 | 13.1 | 21.9 | |
| | mU/l | 13.8 | 10.4 | 17.3 | Abbott Architect |
| | µU/ml | 13.8 | 10.4 | 17.2 | |
| | mU/l | 19.1 | 14.3 | 23.9 | Roche Cobas 4000/E411 |
| | µU/ml | 19.1 | 14.3 | 23.9 | |
| | mU/l | 18.0 | 13.5 | 22.5 | Roche Cobas 6000/8000 |
| | µU/ml | 18.0 | 13.5 | 22.5 | |
| | mU/l | 14.4 | 10.8 | 18.0 | Beckman Dxl 600/800 |
| | µU/ml | 14.4 | 10.8 | 18.0 | |
| Luteinising Hormone (LH) | mU/l | 12.7 | 9.53 | 15.9 | Abbott Alinity i |
| | µU/ml | 12.7 | 9.53 | 15.9 | |
| | mU/ml | 31.0 | 24.8 | 37.2 | Beckman Access |
| | mU/ml | 35.4 | 28.3 | 42.5 | BioMerieux Vidas |
| | mU/ml | 34.7 | 27.8 | 41.6 | Siemens Centaur XP/XPT/Classic |
| | mU/ml | 51.9 | 41.5 | 62.3 | Siemens Immulite 2000 |
| | mU/ml | 29.9 | 23.9 | 35.9 | Abbott Architect |
| | mU/ml | 29.3 | 23.4 | 35.2 | Beckman DxI800 |
| | mU/ml | 38.9 | 31.1 | 46.7 | Roche Cobas 4000/E411 |
| | mU/ml | 37.9 | 30.3 | 45.5 | Roche Cobas e601/602 |
| | mU/ml | 35.5 | 28.4 | 42.6 | Siemens Atellica IM |
| mU/ml | 28.3 | 22.6 | 34.0 | Abbott Alinity i | |
| mU/ml | 40.7 | 32.6 | 48.8 | Roche Cobas e402/e801 | |
| Oestradiol | pmol/l | 1997 | 1598 | 2396 | BioMerieux Vidas |
| | pg/ml | 543 | 435 | 651 | |
| | pmol/l | 795 | 636 | 954 | Abbott Architect |
| | pg/ml | 216 | 173 | 259 | |
| | pmol/l | 1252 | 1002 | 1502 | Siemens Centaur XP/XPT/Classic Enhanced (eE2) |
| | pg/ml | 341 | 273 | 409 | |
| pmol/l | 954 | 763 | 1145 | Roche Cobas e601/602 (Estradiol III) | |
| pg/ml | 259 | 208 | 310 | | |

IMMUNOASSAY PREMIUM - LEVEL 2 (IA PREMIUM 2)

Cat. No. IA2639 / IA2633 Lot. No. 2276EC Size 12 x 5ml / 4 x 5ml Expiry 2026-04-28

| Analyte | unit | Target | Range | | methods |
|---------------|--------|--------|-------|-------|---------------------------------------|
| | | | low | high | |
| Oestradiol | pmol/l | 960 | 768 | 1152 | Roche Elecsys (Estradiol III) |
| | pg/ml | 261 | 209 | 313 | |
| | pmol/l | 957 | 766 | 1148 | Roche Cobas 4000/E411 (Estradiol III) |
| | pg/ml | 260 | 208 | 312 | |
| | pmol/l | 758 | 606 | 910 | Beckman Dxl600/800 Sensitive B84493 |
| | pg/ml | 206 | 165 | 247 | |
| | pmol/l | 1369 | 1095 | 1643 | Siemens Atellica IM |
| | pg/ml | 372 | 298 | 446 | |
| Paracetamol | pmol/l | 780 | 624 | 936 | Abbott Alinity i |
| | pg/ml | 212 | 170 | 254 | |
| | pmol/l | 933 | 746 | 1120 | Roche Cobas e801 (Estradiol III) |
| | pg/ml | 254 | 203 | 305 | |
| Phenobarbital | mmol/l | 0.310 | 0.248 | 0.372 | Roche Cobas c501/502/503/701/702 |
| | mg/l | 46.9 | 37.5 | 56.3 | |
| | mmol/l | 0.348 | 0.280 | 0.420 | Gravimetric |
| | mg/l | 52.7 | 42.1 | 63.3 | |
| Phenytoin | µmol/l | 79.9 | 63.9 | 95.9 | Abbott Architect (CMIA) |
| | µg/ml | 18.5 | 14.8 | 22.2 | |
| | µmol/l | 79.6 | 63.7 | 95.5 | Siemens Immulite 2000/2500 |
| | µg/ml | 18.5 | 14.8 | 22.2 | |
| | µmol/l | 79.0 | 63.2 | 94.8 | Beckman AU400/600/640/2700/5400 |
| | µg/ml | 18.3 | 14.7 | 21.9 | |
| | µmol/l | 75.7 | 60.6 | 90.8 | Roche Cobas C303/501/502/503/701 |
| | µg/ml | 17.6 | 14.1 | 21.1 | |
| Phenytoin | µmol/l | 77.6 | 62.1 | 93.1 | Gravimetric |
| | µg/ml | 18.0 | 14.4 | 21.6 | |
| | µmol/l | 66.7 | 53.4 | 80.0 | Abbott Architect |
| | µg/ml | 16.8 | 13.5 | 20.1 | |
| Phenytoin | µmol/l | 70.3 | 56.2 | 84.4 | Roche Cobas 6000/8000 |
| | µg/ml | 17.8 | 14.2 | 21.4 | |
| | µmol/l | 71.3 | 57.0 | 85.6 | Gravimetric |
| | µg/ml | 18.0 | 14.4 | 21.6 | |
| Primidone | µmol/l | 22.5 | 18.0 | 27.0 | Gravimetric |
| | µg/ml | 4.91 | 3.93 | 5.89 | |
| Progesterone | nmol/l | 31.7 | 25.4 | 38.0 | BioMerieux Vidas |
| | ng/ml | 9.92 | 7.95 | 11.9 | |
| | nmol/l | 24.9 | 19.9 | 29.9 | Siemens Centaur XP/XPT/Classic |
| | ng/ml | 7.79 | 6.23 | 9.35 | |
| | nmol/l | 24.6 | 19.7 | 29.5 | Siemens Immulite 2000/2500 |
| | ng/ml | 7.70 | 6.17 | 9.23 | |
| | nmol/l | 29.3 | 23.4 | 35.2 | Abbott Architect |
| | ng/ml | 9.17 | 7.32 | 11.0 | |
| Progesterone | nmol/l | 29.2 | 23.4 | 35.0 | Beckman Dxl Prog Cal 33555 |
| | ng/ml | 9.14 | 7.32 | 11.0 | |
| | nmol/l | 32.7 | 26.2 | 39.2 | Roche Cobas 4000/e411 (Prog. II) |
| | ng/ml | 10.2 | 8.20 | 12.2 | |

IMMUNOASSAY PREMIUM - LEVEL 2 (IA PREMIUM 2)

Cat. No. IA2639 / IA2633 Lot. No. 2276EC Size 12 x 5ml / 4 x 5ml Expiry 2026-04-28

| Analyte | unit | Target | Range | | methods |
|----------------|--------------|--------|-------|------|--|
| | | | low | high | |
| Progesterone | nmol/l | 22.3 | 17.8 | 26.8 | Beckman Dxl Prog DE Cal A80773 |
| | ng/ml | 6.98 | 5.57 | 8.39 | |
| | nmol/l | 31.9 | 25.5 | 38.3 | Roche Cobas e601/602 (Prog. III) |
| | ng/ml | 9.98 | 7.98 | 12.0 | |
| | nmol/l | 31.7 | 25.4 | 38.0 | Roche Cobas 4000/e411 (Prog. III) |
| | ng/ml | 9.92 | 7.95 | 11.9 | |
| | nmol/l | 26.3 | 21.0 | 31.6 | Abbott Alinity i |
| | ng/ml | 8.23 | 6.57 | 9.89 | |
| Prolactin | nmol/l | 25.5 | 20.4 | 30.6 | Siemens Atellica IM |
| | ng/ml | 7.98 | 6.39 | 9.57 | |
| | nmol/l | 32.2 | 25.8 | 38.6 | Roche Cobas e801 (Prog. III) |
| | ng/ml | 10.1 | 8.08 | 12.1 | |
| | µU/ml | 666 | 533 | 799 | BioMerieux Vidas |
| | µU/ml | 494 | 395 | 593 | Vitros ECi |
| | µU/ml | 434 | 347 | 521 | Siemens Centaur XP/XPT/Classic |
| | µU/ml | 554 | 443 | 665 | Abbott Architect |
| PSA Free | µU/ml | 496 | 397 | 595 | Beckman DxI800 |
| | µU/ml | 697 | 558 | 836 | Roche Cobas 4000/E411 |
| | µU/ml | 642 | 514 | 770 | Roche Cobas e601/602 |
| | µU/ml | 407 | 326 | 488 | Siemens Atellica IM |
| | µU/ml | 579 | 463 | 695 | Abbott Alinity i |
| | µU/ml | 634 | 507 | 761 | Roche Cobas e801 PRL II |
| | ng/ml = µg/l | 12.0 | 9.00 | 15.0 | Abbott Architect |
| | ng/ml = µg/l | 12.5 | 9.38 | 15.6 | Beckman DXI standardised to Hybritech |
| PSA Total | ng/ml = µg/l | 9.67 | 7.25 | 12.1 | Roche Cobas 4000/E411 |
| | ng/ml = µg/l | 9.37 | 7.03 | 11.7 | Roche Cobas e601/602 |
| | ng/ml = µg/l | 11.8 | 8.85 | 14.8 | Siemens Atellica IM |
| | ng/ml = µg/l | 11.8 | 8.85 | 14.8 | Abbott Alinity i |
| | ng/ml = µg/l | 9.06 | 6.80 | 11.3 | Roche Cobas e402/e801 |
| | ng/ml = µg/l | 13.7 | 10.3 | 17.1 | Beckman Access standardised to Hybritech |
| | ng/ml = µg/l | 11.2 | 8.40 | 14.0 | Siemens Centaur XP/XPT/Classic |
| | ng/ml = µg/l | 9.56 | 7.17 | 12.0 | Abbott Architect |
| Salicylic Acid | ng/ml = µg/l | 15.5 | 11.6 | 19.4 | Beckman Access standardised to WHO IRP96/670 |
| | ng/ml = µg/l | 13.5 | 10.1 | 16.9 | Beckman Dxl standardisd to Hybritech |
| | ng/ml = µg/l | 10.5 | 7.88 | 13.1 | Beckman DxI800 standardised to WHO IRP96/670 |
| | ng/ml = µg/l | 13.4 | 10.1 | 16.8 | Roche Cobas 4000/E411 |
| | ng/ml = µg/l | 13.0 | 9.75 | 16.3 | Roche Cobas e601/602 |
| | ng/ml = µg/l | 13.3 | 9.98 | 16.6 | Ortho Vitros 3600/5600/ECi PSA II |
| | ng/ml = µg/l | 12.3 | 9.23 | 15.4 | Siemens Atellica IM |
| | ng/ml = µg/l | 9.74 | 7.31 | 12.2 | Abbott Alinity i |
| | ng/ml = µg/l | 12.5 | 9.38 | 15.6 | Roche Cobas e402/e801 |
| | mmol/l | 1.22 | 0.980 | 1.46 | Gravimetric |
| | mg/dl | 16.9 | 13.5 | 20.2 | |
| SHBG | nmol/l | 36.3 | 29.0 | 43.6 | Siemens Immulite 2000/2500 |
| | nmol/l | 40.6 | 32.5 | 48.7 | Abbott Architect |

IMMUNOASSAY PREMIUM - LEVEL 2 (IA PREMIUM 2)

Cat. No. IA2639 / IA2633 Lot. No. 2276EC Size 12 x 5ml / 4 x 5ml Expiry 2026-04-28

| Range | | | | | |
|-----------------------------|---------------|--------|------|--------------------------|--|
| Analyte | unit | Target | low | high | methods |
| SHBG | nmol/l | 36.1 | 28.9 | 43.3 | Roche Cobas e801 - 413429 |
| | nmol/l | 38.3 | 30.6 | 46.0 | Roche analysers - 413417/15 |
| | nmol/l | 41.5 | 33.2 | 49.8 | Abbott Alinity i |
| T Uptake | %U | 31.9 | 26.2 | 37.6 | Siemens Immulite 2000 |
| Testosterone | nmol/l | 17.4 | 13.9 | 20.9 | Siemens Immulite 2000/2500 |
| | ng/ml | 5.01 | 4.00 | 6.02 | |
| | ng/dl | 501 | 400 | 602 | |
| | nmol/l | 16.3 | 13.0 | 19.6 | Abbott Architect |
| | ng/ml | 4.69 | 3.74 | 5.64 | |
| | ng/dl | 469 | 374 | 564 | |
| | nmol/l | 13.5 | 10.8 | 16.2 | Beckman DxI800 |
| | ng/ml | 3.89 | 3.11 | 4.67 | |
| | ng/dl | 389 | 311 | 467 | |
| | nmol/l | 16.9 | 13.5 | 20.3 | Roche Cobas 4000/e411 Test II |
| | ng/ml | 4.87 | 3.89 | 5.85 | |
| | ng/dl | 487 | 389 | 585 | |
| | nmol/l | 16.9 | 13.5 | 20.3 | Roche Cobas e601/602 Test II |
| | ng/ml | 4.87 | 3.89 | 5.85 | |
| | ng/dl | 487 | 389 | 585 | |
| | nmol/l | 16.4 | 13.1 | 19.7 | Abbott Architect 2nd Generation |
| | ng/ml | 4.72 | 3.77 | 5.67 | |
| | ng/dl | 472 | 377 | 567 | |
| | nmol/l | 16.9 | 13.5 | 20.3 | Siemens Centaur TST II |
| | ng/ml | 4.87 | 3.89 | 5.85 | |
| | ng/dl | 487 | 389 | 585 | |
| nmol/l | 17.2 | 13.8 | 20.6 | Siemens Atellica IM | |
| ng/ml | 4.95 | 3.97 | 5.93 | | |
| ng/dl | 495 | 397 | 593 | | |
| nmol/l | 16.3 | 13.0 | 19.6 | Roche Cobas e801 Test II | |
| ng/ml | 4.69 | 3.74 | 5.64 | | |
| ng/dl | 469 | 374 | 564 | | |
| nmol/l | 16.8 | 13.4 | 20.2 | Abbott Alinity i | |
| ng/ml | 4.84 | 3.86 | 5.82 | | |
| ng/dl | 484 | 386 | 582 | | |
| Theophylline | µmol/l | 83.8 | 67.0 | 101 | Gravimetric |
| | µg/ml | 15.1 | 12.1 | 18.2 | |
| Thyroglobulin | ng/ml | 18.0 | 13.5 | 22.5 | Siemens Immulite 2000 |
| | ng/ml | 32.2 | 24.2 | 40.3 | Beckman DxI800 |
| | ng/ml | 35.1 | 26.3 | 43.9 | Roche Cobas e601/602 |
| | ng/ml | 37.4 | 28.1 | 46.8 | Abbott Architect 2000i |
| | ng/ml | 34.6 | 26.0 | 43.3 | Roche Cobas e601/602 Tg II |
| | ng/ml | 35.5 | 26.6 | 44.4 | Roche Cobas 4000/E411 TGII |
| | ng/ml | 34.3 | 25.7 | 42.9 | Roche Cobas e801 Tg II |
| | ng/ml | 36.6 | 27.5 | 45.8 | Abbott Alinity i |
| Thyroid Stimulating Hormone | µU/ml = mIU/l | 2.31 | 1.85 | 2.77 | Beckman Access hyperTSH 3rd Generation |
| | µU/ml = mIU/l | 2.34 | 1.87 | 2.81 | Vitros ECI |

IMMUNOASSAY PREMIUM - LEVEL 2 (IA PREMIUM 2)

Cat. No. IA2639 / IA2633 Lot. No. 2276EC Size 12 x 5ml / 4 x 5ml Expiry 2026-04-28

| Analyte | unit | Target | Range | | methods |
|-----------------------------|---------------|--------|-------|----------------------|---|
| | | | low | high | |
| Thyroid Stimulating Hormone | µU/ml = mIU/l | 2.37 | 1.90 | 2.84 | Siemens Centaur XP/XPT/Classic |
| | µU/ml = mIU/l | 2.11 | 1.69 | 2.53 | Siemens Immulite 2000/2500 |
| | µU/ml = mIU/l | 1.91 | 1.53 | 2.29 | Abbott Architect |
| | µU/ml = mIU/l | 2.51 | 2.01 | 3.01 | Roche Cobas 4000/E411 |
| | µU/ml = mIU/l | 2.48 | 1.98 | 2.98 | Roche Cobas e601/602 |
| | µU/ml = mIU/l | 2.36 | 1.89 | 2.83 | Siemens Centaur XP/XPT/Classic TSH3-Ultra |
| | µU/ml = mIU/l | 2.16 | 1.73 | 2.59 | Beckman Dxl 600/800 Access (3rd IS) |
| | µU/ml = mIU/l | 2.36 | 1.89 | 2.83 | Siemens Atellica IM |
| | µU/ml = mIU/l | 1.92 | 1.54 | 2.30 | Abbott Alinity i |
| Tobramycin | µmol/l | 7.16 | 5.73 | 8.59 | Gravimetric |
| | µg/ml | 3.35 | 2.68 | 4.02 | |
| Total Beta hCG | mU/ml=IU/l | 47.1 | 37.7 | 56.5 | BioMerieux Vidas |
| | IU/ml | 0.047 | 0.038 | 0.056 | |
| | mU/ml=IU/l | 48.6 | 38.9 | 58.3 | Vitros ECi |
| | IU/ml | 0.049 | 0.039 | 0.059 | |
| | mU/ml=IU/l | 28.0 | 22.4 | 33.6 | Siemens Centaur XP/XPT/Classic |
| | IU/ml | 0.028 | 0.022 | 0.034 | |
| | mU/ml=IU/l | 58.0 | 46.4 | 69.6 | Siemens Immulite 2000 |
| | IU/ml | 0.058 | 0.046 | 0.070 | |
| | mU/ml=IU/l | 27.4 | 21.9 | 32.9 | Abbott Architect |
| | IU/ml | 0.027 | 0.022 | 0.032 | |
| | mU/ml=IU/l | 30.2 | 24.2 | 36.2 | Roche hCG+Beta |
| | IU/ml | 0.030 | 0.024 | 0.036 | |
| | mU/ml=IU/l | 30.7 | 24.6 | 36.8 | Beckman Dxl Total BhCG (5th IS) |
| | IU/ml | 0.031 | 0.025 | 0.037 | |
| | mU/ml=IU/l | 31.0 | 24.8 | 37.2 | Siemens Atellica IM |
| IU/ml | 0.031 | 0.025 | 0.037 | | |
| mU/ml=IU/l | 27.8 | 22.2 | 33.4 | Abbott Alinity i | |
| IU/ml | 0.028 | 0.022 | 0.034 | | |
| mU/ml=IU/l | 29.5 | 23.6 | 35.4 | Roche hCG+Beta e801 | |
| IU/ml | 0.030 | 0.024 | 0.036 | | |
| Total T3 | nmol/l | 3.96 | 2.97 | 4.95 | Siemens Centaur XP/XPT/Classic |
| | ng/ml | 2.58 | 1.93 | 3.23 | |
| | ng/dl | 258 | 193 | 323 | |
| | nmol/l | 3.35 | 2.51 | 4.19 | Abbott Architect |
| | ng/ml | 2.18 | 1.63 | 2.73 | |
| | ng/dl | 218 | 163 | 273 | |
| | nmol/l | 4.28 | 3.21 | 5.35 | Vitros ECi |
| | ng/ml | 2.79 | 2.09 | 3.49 | |
| | ng/dl | 279 | 209 | 349 | |
| | nmol/l | 3.99 | 2.99 | 4.99 | Roche Cobas 4000/E411 |
| | ng/ml | 2.60 | 1.95 | 3.25 | |
| | ng/dl | 260 | 195 | 325 | |
| nmol/l | 4.09 | 3.07 | 5.11 | Roche Cobas e601/602 | |
| ng/ml | 2.66 | 2.00 | 3.32 | | |
| ng/dl | 266 | 200 | 332 | | |

IMMUNOASSAY PREMIUM - LEVEL 2 (IA PREMIUM 2)

Cat. No. IA2639 / IA2633 Lot. No. 2276EC Size 12 x 5ml / 4 x 5ml Expiry 2026-04-28

| Analyte | unit | Target | Range | | methods | |
|---------------|--------|--------|-------|-------------------------|--------------------------------|------|
| | | | low | high | | |
| Total T3 | nmol/l | 3.38 | 2.54 | 4.23 | Abbott Alinity i | |
| | ng/ml | 2.20 | 1.65 | 2.75 | | |
| | ng/dl | 220 | 165 | 275 | | |
| | nmol/l | 4.11 | 3.08 | 5.14 | Siemens Atellica IM | |
| | | ng/ml | 2.68 | 2.01 | | 3.35 |
| | | ng/dl | 268 | 201 | | 335 |
| | nmol/l | 4.24 | 3.18 | 5.30 | Roche Cobas e402/e801 | |
| | | ng/ml | 2.76 | 2.07 | | 3.45 |
| | | ng/dl | 276 | 207 | | 345 |
| Total T4 | nmol/l | 122 | 91.5 | 153 | Vitros ECI | |
| | µg/dl | 9.52 | 7.14 | 11.9 | | |
| | ng/ml | 95.2 | 71.4 | 119 | | |
| | nmol/l | 128 | 96.0 | 160 | Beckman Access | |
| | | µg/dl | 9.98 | 7.49 | | 12.5 |
| | | ng/ml | 100 | 74.9 | | 125 |
| | nmol/l | 127 | 95.3 | 159 | Siemens Centaur XP/XPT/Classic | |
| | | µg/dl | 9.91 | 7.43 | | 12.4 |
| | | ng/ml | 99.1 | 74.3 | | 124 |
| | nmol/l | 114 | 85.5 | 143 | Siemens Immulite 2000/2500 | |
| | | µg/dl | 8.89 | 6.67 | | 11.1 |
| | | ng/ml | 88.9 | 66.7 | | 111 |
| | nmol/l | 116 | 87.0 | 145 | Abbott Architect | |
| | | µg/dl | 9.05 | 6.79 | | 11.3 |
| | | ng/ml | 90.5 | 67.9 | | 113 |
| | nmol/l | 115 | 86.3 | 144 | Roche Cobas 4000/E411 | |
| | | µg/dl | 8.97 | 6.73 | | 11.2 |
| | | ng/ml | 89.7 | 67.3 | | 112 |
| | nmol/l | 112 | 84.0 | 140 | Roche Cobas e601/602 | |
| | | µg/dl | 8.74 | 6.55 | | 10.9 |
| | | ng/ml | 87.4 | 65.5 | | 109 |
| | nmol/l | 108 | 81.0 | 135 | Abbott Alinity i | |
| | | µg/dl | 8.42 | 6.32 | | 10.5 |
| | | ng/ml | 84.2 | 63.2 | | 105 |
| | nmol/l | 138 | 104 | 173 | Siemens Atellica IM | |
| | | µg/dl | 10.8 | 8.11 | | 13.5 |
| | | ng/ml | 108 | 81.1 | | 135 |
| nmol/l | 106 | 79.5 | 133 | Roche Cobas e402/e801 | | |
| | µg/dl | 8.27 | 6.20 | | 10.3 | |
| | ng/ml | 82.7 | 62.0 | | 103 | |
| Valproic Acid | µmol/l | 525 | 420 | 630 | Abbott Architect (CMIA) | |
| | µg/ml | 75.8 | 60.6 | 91.0 | | |
| | µmol/l | 539 | 431 | 647 | Roche Cobas 6000/8000 | |
| | | µg/ml | 77.8 | 62.2 | | 93.4 |
| µmol/l | 525 | 420 | 630 | Abbott Alinity (PETINA) | | |
| | µg/ml | 75.8 | 60.6 | | 91.0 | |

IMMUNOASSAY PREMIUM - LEVEL 2 (IA PREMIUM 2)

Cat. No. IA2639 / IA2633 Lot. No. 2276EC Size 12 x 5ml / 4 x 5ml Expiry 2026-04-28

| Range | | | | | |
|---------------|--------|--------|------|-------------------------|--------------------------------|
| Analyte | unit | Target | low | high | methods |
| Valproic Acid | µmol/l | 638 | 510 | 766 | Gravimetric |
| | µg/ml | 92.1 | 73.6 | 111 | |
| Vancomycin | µmol/l | 8.17 | 6.54 | 9.80 | Abbott Architect (CMIA) |
| | µg/ml | 12.1 | 9.72 | 14.5 | |
| | µmol/l | 7.26 | 5.81 | 8.71 | Roche Cobas 6000/8000 |
| | µg/ml | 10.8 | 8.63 | 13.0 | |
| | µmol/l | 7.10 | 5.68 | 8.52 | Gravimetric |
| Vitamin B12 | pmol/l | 366 | 293 | 439 | Beckman Access |
| | pg/ml | 496 | 397 | 595 | |
| | pmol/l | 473 | 378 | 568 | Siemens Centaur XP/XPT/Classic |
| | pg/ml | 641 | 512 | 770 | |
| | pmol/l | 431 | 345 | 517 | Abbott Architect |
| | pg/ml | 584 | 467 | 701 | |
| | pmol/l | 454 | 363 | 545 | Vitros Eci |
| | pg/ml | 615 | 492 | 738 | |
| | pmol/l | 353 | 282 | 424 | Beckman DxI800 |
| | pg/ml | 478 | 382 | 574 | |
| | pmol/l | 482 | 386 | 578 | Roche Cobas 4000/e411 Gen II |
| | pg/ml | 653 | 523 | 783 | |
| | pmol/l | 484 | 387 | 581 | Roche Cobas e601/602 Gen II |
| | pg/ml | 656 | 524 | 788 | |
| | pmol/l | 487 | 390 | 584 | Siemens Atellica IM |
| pg/ml | 660 | 528 | 792 | | |
| pmol/l | 455 | 364 | 546 | Abbott Alinity i | |
| pg/ml | 617 | 493 | 741 | | |
| pmol/l | 484 | 387 | 581 | Roche Cobas e801 Gen II | |
| pg/ml | 656 | 524 | 788 | | |

IMMUNOASSAY PREMIUM - LEVEL 2 (IA PREMIUM 2)

| | | |
|------------------------|-----------------------------|------------------------|
| CAT. NO. IA2639 | GTIN: 05055273203851 | SIZE: 12 x 5 ml |
| CAT. NO. IA2633 | GTIN: 05055273203837 | SIZE: 4 x 5 ml |
| LOT NO. 2276EC | EXPIRY: 2026-04-28 | |

INTENDED USE

This product is intended for in vitro diagnostic use, as assayed quality control material to monitor the accuracy and reproducibility of analytes listed in the package insert.

This device is for prescription use only.

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 7 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. C-Peptide is stable for 1 day at +2°C to +8°C.

Thyroglobulin should be tested within 4 hours of reconstitution when stored at +2°C to +8°C, or within 2 weeks when stored at -20°C.

ACTH should be tested immediately after the 30-minute reconstitution period. No frozen stability claim is made for ACTH, Aldosterone and C-Peptide. 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

Immunoassay Premium is supplied lyophilised.

- Carefully reconstitute each vial of lyophilised serum with exactly 5 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 Premium - Level 2: 12 x 5 ml Tri-Level: 4 x 5 ml

MATERIAL REQUIRED BUT NOT PROVIDED

Volumetric pipette

VALUE ASSIGNMENT

Each batch of Immunoassay Premium is submitted to a number of external laboratories. Values are assigned from a consensus of results obtained by these laboratories, using a unique statistical analysis. Average values should normally fall within the listed ranges for analytes in the instruments specified in this product insert. However, variations may be caused by instrument reagents and laboratory technique. Therefore, the range produced herein should only be considered as a reference and it is recommended that each laboratory establish its own mean and acceptable ranges. Parathyroid Hormone (PTH) is present in the control, but no claim is made for the expected value or stability of this analyte.

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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| EC | REP |
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Randox Teoranta, Meenmore,
Dungloe, Donegal,
F94 TV06, Ireland

07 Nov '24 me

IMMUNOASSAY PREMIUM - LEVEL 2 (IA PREMIUM 2)

Cat. No. IA2639 / IA2633 Lot. No. 2276EC Size 12 x 5ml / 4 x 5ml Expiry 2026-04-28

| Analyte | unit | Target | Range | | methods |
|--------------------------------|--------|--------|-------|------|---|
| | | | low | high | |
| Cortisol | µg/dL | 22.6 | 16.5 | 28.7 | Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i |
| | | 22.6 | 16.5 | 28.7 | Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i |
| C-Peptide | ng/mL | 4.50 | 3.29 | 5.72 | Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i |
| | | 4.50 | 3.29 | 5.72 | Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i |
| DHEA-S | µg/dL | 466 | 340 | 591 | Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i |
| | | 466 | 340 | 591 | Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i |
| Insulin | µIU/mL | 18.2 | 12.4 | 24.0 | Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i |
| | | 20.1 | 13.6 | 26.5 | Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i |
| Alphafoetoprotein | ng/ml | 55.6 | 40.6 | 70.6 | Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i |
| | | 55.6 | 40.6 | 70.6 | Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i |
| Carcinoembryonic Antigen (CEA) | ng/ml | 19.3 | 14.1 | 24.5 | Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i |
| | | 19.3 | 14.1 | 24.5 | Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i |
| Ferritin | ng/mL | 119 | 87.2 | 152 | Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i |
| | | 119 | 87.2 | 152 | Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i |
| PSA Free | ng/mL | 12.1 | 8.83 | 15.4 | Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i |
| | | 12.1 | 8.83 | 15.4 | Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i |
| PSA Total | ng/mL | 12.6 | 9.19 | 16.0 | Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i |
| | | 12.6 | 9.19 | 16.0 | Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i |
| Oestradiol | pg/mL | 314 | 229 | 398 | Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i <= Lot 230501 |
| | | 314 | 229 | 398 | Wiener Lab CLIA Series & Mindray CL 900i <= Lot 230501 |
| | | 354 | 241 | 467 | Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i >= Lot 231001 |
| | | 354 | 241 | 467 | Wiener Lab CLIA Series & Mindray CL 900i >= Lot 231001 |
| FSH | mIU/mL | 29.2 | 21.3 | 37.0 | Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i <= Lot 231101 |
| | | 29.2 | 21.3 | 37.0 | Wiener Lab CLIA Series & Mindray CL 900i <= Lot 231101 |
| | | 25.3 | 15.2 | 35.4 | Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i >= Lot 240401 |
| | | 25.3 | 15.2 | 35.4 | Wiener Lab CLIA Series & Mindray CL 900i >= Lot 240401 |
| Total Beta hCG | mIU/mL | 27.4 | 18.6 | 36.1 | Wiener Lab CLIA Series & Mindray hCG 8000/6000/2000/1200/1000i |
| | | 24.5 | 16.7 | 32.3 | Wiener Lab CLIA Series & Mindray hCG CL 900i/920i/960i/980i |
| | | 56.2 | 33.7 | 78.6 | Wiener Lab CLIA Series & Mindray hCG2 8000/6000/2000/1200/1000i |
| | | 56.2 | 33.7 | 78.6 | Wiener Lab CLIA Series & Mindray hCG2 CL 900i |
| Luteinising Hormone (LH) | mIU/mL | 40.6 | 29.7 | 51.6 | Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i |
| | | 40.6 | 29.7 | 51.6 | Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i |
| Prolactin | ng/mL | 29.8 | 20.3 | 39.4 | Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i |
| | | 29.8 | 20.3 | 39.4 | Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i |
| Progesterone | ng/mL | 11.7 | 8.56 | 14.9 | Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i |
| | | 11.7 | 8.56 | 14.9 | Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i |
| | | 9.16 | 6.23 | 12.1 | Wiener Lab CLIA Series & Mindray PROG II CL 8000i/6000i/2000i/1200i/1000i |
| | | 9.16 | 6.23 | 12.1 | Wiener Lab CLIA Series & Mindray PROG II CL 900i |

IMMUNOASSAY PREMIUM - LEVEL 2 (IA PREMIUM 2)

Cat. No. IA2639 / IA2633 Lot. No. 2276EC Size 12 x 5ml / 4 x 5ml Expiry 2026-04-28

| Analyte | unit | Target | Range | | methods |
|-----------------------------|--------|--------|-------|------|--|
| | | | low | high | |
| Testosterone | ng/mL | 6.58 | 4.80 | 8.35 | Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i Ref: TESTO 11X |
| | | 6.58 | 4.80 | 8.35 | Wiener Lab CLIA Series & Mindray CL 900i Ref: TESTO 11X |
| | | 5.62 | 4.10 | 7.13 | Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i Ref 105-0025XX-00 |
| | | 5.62 | 4.10 | 7.13 | Wiener Lab CLIA Series & Mindray CL 900i Ref 105-0025XX-00 |
| | | 4.31 | 2.93 | 5.69 | Wiener Lab CLIA Series & Mindray TESTO II CL 8/6/2/12/1000i |
| | | 4.31 | 2.93 | 5.69 | Wiener Lab CLIA Series & Mindray TESTO II CL 900i |
| Folate | ng/mL | 14.2 | 9.63 | 18.7 | Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i |
| | | 14.2 | 9.63 | 18.7 | Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i |
| Vitamin B12 | pg/mL | 689 | 469 | 910 | Wiener Lab CLIA Series & Mindray CL 8000i/6000i/2000i/1200i/1000i |
| | | 689 | 469 | 910 | Wiener Lab CLIA Series & Mindray CL 900i/920i/960i/980i |
| Free T3 | pg/mL | 7.96 | 5.41 | 10.5 | Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i Ref: FT3 11X |
| | | 7.96 | 5.41 | 10.5 | Wiener Lab CLIA Series & Mindray CL 900i Ref: FT3 11X |
| | | 7.96 | 5.41 | 10.5 | Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i FT3 105-0042XX-00 |
| | | 7.96 | 5.41 | 10.5 | Wiener Lab CLIA Series & Mindray CL 900i FT3 105-0042XX-00 |
| Free T4 | ng/dL | 2.27 | 1.54 | 2.99 | Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i Ref: FT4 11X |
| | | 2.27 | 1.54 | 2.99 | Wiener Lab CLIA Series & Mindray CL 900i Ref: FT4 11X |
| | | 2.76 | 2.02 | 3.51 | Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i FT4 105-0042XX-00 |
| | | 2.76 | 2.02 | 3.51 | Wiener Lab CLIA Series & Mindray CL 900i FT4 105-0042XX-00 |
| Total T3 | ng/mL | 2.05 | 1.39 | 2.70 | Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i Ref: T3 11X |
| | | 2.05 | 1.39 | 2.70 | Wiener Lab CLIA Series & Mindray CL 900i Ref: T3 11X |
| | | 2.05 | 1.39 | 2.70 | Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i T3 105-0042XX-00 |
| | | 2.05 | 1.39 | 2.70 | Wiener Lab CLIA Series & Mindray CL 900i T3 105-0042XX-00 |
| Total T4 | µg/dL | 9.84 | 6.69 | 13.0 | Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i Ref: T4 11X |
| | | 9.84 | 6.69 | 13.0 | Wiener Lab CLIA Series & Mindray CL 900i Ref: T4 11X |
| | | 8.97 | 6.55 | 11.4 | Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i T4 105-0042XX-00 |
| | | 8.97 | 6.55 | 11.4 | Wiener Lab CLIA Series & Mindray CL 900i T4 105-0042XX-00 |
| Thyroid Stimulating Hormone | µIU/mL | 2.84 | 2.07 | 3.61 | Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i Ref: TSH 11X |
| | | 2.84 | 2.07 | 3.61 | Wiener Lab CLIA Series & Mindray CL 900i Ref: TSH 11X |
| | | 2.12 | 1.55 | 2.69 | Wiener Lab CLIA Series & Mindray CL 8/6/2/12/1000i TSH105-0042XX-00 |
| | | 2.12 | 1.55 | 2.69 | Wiener Lab CLIA Series & Mindray CL 900i TSH 105-0042XX-00 |