# PRODUCT INFORMATION

AU2352

1248UC

Please note that while Copper is present in 1248UC – Assayed Urine Control Level 2, targets and ranges are not provided for this analyte.

INC1995



FORM NO. 8373-GP
REVISION (2)
2 Aug 2019

# ASSAYED URINE CONTROL - LEVEL 2 (URN ASY CONTROL 2)

**CAT. NO.** AU 2352 **LOT NO.** 1248UC

**SIZE:** 12 x 10 ml **EXPIRY:** 2026-11-28

**GTIN:** 05055273200539

## INTENDED USE
This product is intended for *in vitro* diagnostic use, in the quality control of urine on clinical chemistry systems. The Assayed Urine Controls are for the control of accuracy.

## DEVICE DESCRIPTION
The Urine Controls are supplied at 2 levels, level 2 and 3. Target values and ranges are supplied for the following analytes at both levels; amylase, calcium, chloride, copper, cortisol, creatinine, dopamine, epinephrine, glucose, 5-Hydroxyindoleacetic acid, magnesium, metanephrine, microalbumin, norepinephrine (noradrenalin), normetanephrine, osmolality, oxalate, phosphorous inorganic, potassium, total protein, sodium, urea, uric acid and vanillylmandelic acid (VMA).

## 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 urine is stable for 8 hours at +15°C to +25°C and 5 days at +2°C to +8°C if kept capped in original container and free from contamination, or 14 days at –20°C. No stability claims are made for copper. Only the required amount of product should be removed. After use, any residual product should NOT BE RETURNED to the original vial.

## PREPARATION AND STABILITY OF SAMPLES FOR Catecholamines, Vanillylmandelic Acid (VMA), Oxalate and 5-Hydroxyindole Acetic Acid (5-HIAA):

These analytes are unstable in urine samples and no claims are made on the stability. Samples should be prepared according to the standard procedures within each laboratory.

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

## PREPARATION FOR USE
The Assayed Urine Control is supplied lyophilised.

1. Carefully reconstitute each vial of lyophilised urine with exactly 10 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
Assayed Urine Control - Level 2 12 x 10 ml

## 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 Urine Control is submitted to a number of external 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. The control range is equivalent to the assigned mean ± 2SD.

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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Rev. 05 May '23 me

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# ASSAYED URINE CONTROL LEVEL 2 (URN ASY CONTROL 2)

**Cat. No. AU 2352 Lot. No. 1248UC Size 12 x 10ml Expiry 2026-11-28**

| | | | Range | | |
|---|---|---|---|---|---|
| **Analyte** | **unit** | **Target** | **low** | **high** | **methods** |
| 5-HIAA | µmol/l | 30.8 | 24.6 | 37.0 | HPLC |
| Amylase | U/l | 121 | 96.8 | 145 | Vitros |
| | U/l | 236 | 189 | 283 | Siemens - blocked pNPG7 |
| | U/l | 226 | 181 | 271 | Randox Liquid Ethylidene pNPG7 |
| | U/l | 198 | 158 | 238 | Roche liquid pNPG7 |
| | U/l | 202 | 162 | 242 | Roche Integra 2-chloro-pNPG7 |
| | U/l | 219 | 175 | 263 | Beckman Coulter - blocked pNPG7 |
| | U/l | 261 | 209 | 313 | Siemens 2-chloro-pNPG3 |
| | U/l | 243 | 194 | 292 | Other 2-chloro-pNPG3 |
| | U/l | 244 | 195 | 293 | Abbott Architect / Alinity cal factor 3431 |
| | U/l | 249 | 199 | 299 | Abbott Architect / Alinity cal factor 3806 |
| Calcium | mmol/l | 1.65 | 1.49 | 1.82 | Vitros |
| | mg/dl | 6.61 | 5.97 | 7.25 | |
| | mmol/l | 1.59 | 1.43 | 1.75 | Cresolphthalein complexone |
| | mg/dl | 6.37 | 5.73 | 7.01 | |
| | mmol/l | 1.56 | 1.40 | 1.72 | Arsenazo III |
| | mg/dl | 6.25 | 5.61 | 6.89 | |
| | mmol/l | 1.59 | 1.43 | 1.75 | NM-BAPTA |
| | mg/dl | 6.37 | 5.73 | 7.01 | |
| Chloride | mmol/l | 81.6 | 69.4 | 93.8 | Vitros |
| | mmol/l | 79.5 | 67.6 | 91.4 | ISE indirect |
| | mmol/l | 77.2 | 65.6 | 88.8 | ISE direct |
| Cortisol | nmol/l | 108 | 81.0 | 135 | Chemiluminescence (+ solvent extraction.) |
| | µg/dl | 3.89 | 2.92 | 4.86 | |
| | nmol/l | 104 | 78.0 | 130 | Chemiluminescence (direct) |
| | µg/dl | 3.74 | 2.81 | 4.67 | |
| Creatinine | mmol/l | 6.74 | 5.39 | 8.09 | Alkaline picrate no deproteinization |
| | mg/dl | 76.2 | 60.9 | 91.5 | |
| | mmol/l | 7.13 | 5.70 | 8.56 | Creatinine PAP method |
| | mg/dl | 80.6 | 64.4 | 96.8 | |
| | mmol/l | 7.05 | 5.64 | 8.46 | Enzymatic UV method |
| | mg/dl | 79.7 | 63.7 | 95.7 | |
| | mmol/l | 7.03 | 5.62 | 8.44 | Other enzymatic methods |
| | mg/dl | 79.4 | 63.5 | 95.3 | |
| | mmol/l | 7.30 | 5.84 | 8.76 | Roche Creatinine Plus |
| | mg/dl | 82.5 | 66.0 | 99.0 | |
| | mmol/l | 6.70 | 5.36 | 8.04 | Jaffe rate blanked |
| | mg/dl | 75.7 | 60.6 | 90.8 | |
| | mmol/l | 6.87 | 5.50 | 8.24 | Jaffe rate blanked comp. (-26 µmol/l) |
| | mg/dl | 77.6 | 62.2 | 93.0 | |
| | mmol/l | 6.93 | 5.54 | 8.32 | Vitros IDMS Traceable |
| | mg/dl | 78.3 | 62.6 | 94.0 | |



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# ASSAYED URINE CONTROL LEVEL 2 (URN ASY CONTROL 2)

**Cat. No. AU 2352 Lot. No. 1248UC Size 12 x 10ml Expiry 2026-11-28**

| | | | Range | | |
|---|---|---|---|---|---|
| **Analyte** | **unit** | **Target** | **low** | **high** | **methods** |
| Creatinine | mmol/l | 7.12 | 5.70 | 8.54 | IDMS traceable |
| | mg/dl | 80.5 | 64.4 | 96.6 | |
| | mmol/l | 6.83 | 5.46 | 8.20 | Jaffe rate blanked compensated (-18 µmol/l) |
| | mg/dl | 77.2 | 61.7 | 92.7 | |
| Dopamine | nmol/l | 570 | 456 | 684 | HPLC |
| Epinephrine | nmol/l | 71.8 | 57.4 | 86.2 | HPLC |
| Glucose | mmol/l | 2.55 | 2.17 | 2.93 | Vitros |
| | mg/dl | 46.0 | 39.1 | 52.9 | |
| | mmol/l | 2.76 | 2.35 | 3.17 | Glucose oxidase |
| | mg/dl | 49.7 | 42.3 | 57.1 | |
| | mmol/l | 2.72 | 2.31 | 3.13 | Hexokinase |
| | mg/dl | 49.0 | 41.6 | 56.4 | |
| Magnesium | mmol/l | 3.75 | 3.30 | 4.20 | Vitros |
| | mg/dl | 9.11 | 8.02 | 10.2 | |
| | mmol/l | 3.06 | 2.69 | 3.43 | Xylidyl Blue |
| | mg/dl | 7.44 | 6.54 | 8.34 | |
| | mmol/l | 3.11 | 2.74 | 3.48 | Arsenazo III |
| | mg/dl | 7.56 | 6.66 | 8.46 | |
| | mmol/l | 3.11 | 2.74 | 3.48 | Chlorphosphonazo III |
| | mg/dl | 7.56 | 6.66 | 8.46 | |
| | mmol/l | 3.16 | 2.78 | 3.54 | Methylthymol blue |
| | mg/dl | 7.68 | 6.76 | 8.60 | |
| | mmol/l | 3.16 | 2.78 | 3.54 | Enzymatic |
| | mg/dl | 7.68 | 6.76 | 8.60 | |
| Metanephrine | µmol/l | 0.234 | 0.187 | 0.281 | HPLC |
| Microalbumin | mg/l | 32.4 | 25.9 | 38.9 | Immunoturbidimetric |
| Norepinephrine | nmol/l | 240 | 192 | 288 | HPLC |
| Normetanephrine | µmol/l | 1.16 | 0.928 | 1.39 | HPLC |
| Osmolality | mOsm/kg | 439 | 351 | 527 | Freezing point depression |
| | mOsm/kg | 343 | 274 | 412 | Calculated |
| Oxalate | mmol/l | 0.090 | 0.072 | 0.108 | Oxalate oxidase |
| Phosphate Inorganic | mmol/l | 10.4 | 8.84 | 12.0 | Vitros |
| | mg/dl | 32.2 | 27.4 | 37.0 | |
| | mmol/l | 9.11 | 7.74 | 10.5 | Phosphomolybdate UV |
| | mg/dl | 28.2 | 24.0 | 32.4 | |
| | mmol/l | 9.41 | 8.00 | 10.8 | Phosphomolybdate enzymatic |
| | mg/dl | 29.2 | 24.8 | 33.6 | |
| Potassium | mmol/l | 30.9 | 26.3 | 35.5 | Vitros |
| | mmol/l | 31.7 | 26.9 | 36.5 | ISE direct |
| | mmol/l | 30.1 | 25.6 | 34.6 | ISE indirect |
| Protein Total | g/l | 0.130 | 0.104 | 0.156 | Biuret reaction - direct |
| | mg/dl | 13.0 | 10.4 | 15.6 | |
| | mg/l | 130 | 104 | 156 | |
| | g/l | 0.110 | 0.088 | 0.132 | Turbidimetry |
| | mg/dl | 11.0 | 8.80 | 13.2 | |
| | mg/l | 110 | 88.0 | 132 | |

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# ASSAYED URINE CONTROL LEVEL 2 (URN ASY CONTROL 2)

**Cat. No. AU 2352 Lot. No. 1248UC Size 12 x 10ml Expiry 2026-11-28**

| | | | Range | | |
|---|---|---|---|---|---|
| **Analyte** | **unit** | **Target** | **low** | **high** | **methods** |
| Protein Total | g/l | 0.170 | 0.136 | 0.204 | Pyrogallol Red |
| | mg/dl | 17.0 | 13.6 | 20.4 | |
| | mg/l | 170 | 136 | 204 | |
| | g/l | 0.200 | 0.160 | 0.240 | Vitros |
| | mg/dl | 20.0 | 16.0 | 24.0 | |
| | mg/l | 200 | 160 | 240 | |
| | g/l | 0.230 | 0.184 | 0.276 | Siemens UCFP Reagent |
| | mg/dl | 23.0 | 18.4 | 27.6 | |
| | mg/l | 230 | 184 | 276 | |
| Sodium | mmol/l | 66.0 | 58.1 | 73.9 | Vitros |
| | mmol/l | 63.4 | 55.8 | 71.0 | ISE direct |
| | mmol/l | 62.7 | 55.2 | 70.2 | ISE indirect |
| Urea | mmol/l | 152 | 129 | 175 | Vitros |
| | mg/dl | 914 | 775 | 1053 | |
| | mmol/l | 156 | 133 | 179 | Urease kinetic |
| | mg/dl | 938 | 799 | 1077 | |
| | mmol/l | 156 | 133 | 179 | Urease end point |
| | mg/dl | 938 | 799 | 1077 | |
| Uric Acid (Urate) | mmol/l | 0.750 | 0.653 | 0.848 | Ortho Vitros Microslide Systems |
| | mg/dl | 12.6 | 11.0 | 14.2 | |
| | mmol/l | 0.740 | 0.644 | 0.836 | Uricase peroxidase no ascorbate oxidase |
| | mg/dl | 12.4 | 10.8 | 14.0 | |
| | mmol/l | 0.780 | 0.679 | 0.881 | Spectrophotometric at 280-290 |
| | mg/dl | 13.1 | 11.4 | 14.8 | |
| | mmol/l | 0.710 | 0.618 | 0.802 | Uricase Peroxidase with ascorbate oxidase @ 546nm |
| | mg/dl | 11.9 | 10.4 | 13.4 | |
| | mmol/l | 0.720 | 0.626 | 0.814 | Uricase peroxidase with ascorbate oxidase |
| | mg/dl | 12.1 | 10.5 | 13.7 | |
| Vanillylmandelic Acid (VMA) | µmol/l | 31.1 | 24.9 | 37.3 | Column test |
| | µmol/l | 28.1 | 22.5 | 33.7 | HPLC |

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