

## URINALYSIS CONTROL - LEVEL 2 (URNAL CONTROL 2)

**CAT NO.** UC5034                      **LOT NO.** 1193UC  
**SIZE:** 12 x 12 ml                      **EXPIRY:** 2023-04-28  
**GTIN:** 05055273207590

### INTENDED USE

This product is intended for *in vitro* diagnostic use in the quality control of urine test strips.

### DEVICE DESCRIPTION

The Urinalysis Controls are supplied at 2 levels, level 1 and level 2. Ranges are supplied for the following analytes: Albumin, Bilirubin, Blood, Creatinine, Glucose, hCG, Ketones, Leukocytes, Nitrite, pH, Protein, Specific Gravity and Urobilinogen.

### 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). The Urinalysis Control is stable for 30 days at +2°C to +25°C or 20 immersions if kept capped in original container and free from contamination. Do not freeze.

Prior to 20 immersions, there may be a loss of sensitivity resulting in a negative reading for blood. Should this occur, it is recommended that the Urinalysis Control is transferred directly onto the dipstick rather than immersing the dipstick in the control.

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

### PREPARATION FOR USE

The Urinalysis Control is supplied ready for use.

### MATERIALS PROVIDED

Urinalysis Control - Level 2    12 x 12 ml

### ASSIGNED VALUES

Each batch of Urinalysis 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.

**\*\*Negative results (or Normal in the case of Urobilinogen) may be observed due to different test strip / analyser combinations. In this instance the control is not suitable for use.\*\***

| MANUFACTURER / METHOD   | ANALYTE            | RANGE   |
|-------------------------|--------------------|---|
| 77 Elektronika kft      | Albumin            | 1+ – 3+ (30 – 500 mg/dl) (0.3 – 5 g/l)                        |
|                         | Bilirubin          | 1+ – 3+ (1 – 6 mg/dl) (17 – 100 µmol/l)                       |
|                         | Blood              | 1+ – 3+ ((5-10) – 300 Ery/µl)                                 |
|                         | Glucose            | 2+ – 4+ (150 – 1000 mg/dl) (10 – 50 mmol/l)                   |
|                         | Ketones            | TRACE – 2+ (5 – 50 mg/dl) (0.5 – 5 mmol/l)                    |
|                         | Leukocytes         | 1+ – 3+ (25 – 500 Leu/µl)                                     |
|                         | Nitrite            | POSITIVE  |
|                         | pH                 | 7 – 8   |
|                         | Protein            | 1+ – 3+ (30 – (300-500) mg/dl) (0.3 – (3-5) g/l)              |
|                         | Specific Gravity   | 1 – 1.015 RATIO   |
|                         | Urobilinogen       | 2+ – 4+ (70 – 200 µmol/l) (4 – 12 mg/dl) (4 – 12 EU/dl)       |
| Abbott IMx (intact hCG) | hCG                | POSITIVE  |
| Abon hCG One Step Ultra | hCG                | POSITIVE  |
| Acon Laboratories       | hCG                | POSITIVE  |
| Acon Mission            | Bilirubin          | 1+ – 3+ (1 – 4 mg/dl) (17 – 70 µmol/l)                        |
|                         | Blood              | 1+ – 3+ (25 – 200 Ery/µl)                                     |
|                         | Glucose            | +/- – 2+ (100 – 500 mg/dl) (5 – 30 mmol/l)                    |
|                         | Ketones            | +/- – 2+ (5 – 40 mg/dl) (0.5 – 4 mmol/l)                      |
|                         | Nitrite            | POSITIVE  |
|                         | pH                 | 7.5 – >8.5  |
|                         | Protein            | 2+ – 4+ (100 – >1000 mg/dl) (1 – >10 g/l)                     |
|                         | Specific Gravity   | 1.005 – 1.015 RATIO   |
| Analyticon Combiscreen  | Bilirubin          | 1+ – 3+ (1 – 4 mg/dl) (15 – 70 µmol/l)                        |
|                         | Blood              | 1+ – 3+ ((5-10) – 300 Ery/µl)                                 |
|                         | Glucose            | 3+ – 5+ (250 – 1000 mg/dl) (14 – 56 mmol/l)<br>(2.5 – 10 g/l) |
|                         | Ketones            | TRACE – 3+ (10 – 300 mg/dl) (1 – 30 mmol/l)                   |
|                         | Leukocytes         | 1+ – 3+ (25 – 500 Leu/µl)                                     |
|                         | Nitrite            | POSITIVE  |
|                         | pH                 | 7.5 – >8.5  |
|                         | Protein            | 1+ – 3+ (30 – 500 mg/dl) (0.3 – 5 g/l)                        |
|                         | Specific Gravity   | 1 – 1.01 RATIO  |
|                         | Urobilinogen       | 1+ – 4+ (2 – 12 mg/dl) (35 – 200 µmol/l)                      |
| CTK Biotech Onsite hCG  | hCG                | POSITIVE  |
| DFI -Cybow              | Bilirubin          | 1+ – 3+   |
|                         | Blood              | 1+ – 3+ (10 – 250 Ery/µl)                                     |
|                         | Glucose            | +/- – 2+ (100 – 500 mg/dl) (5.5 – 28 mmol/l)                  |
|                         | Ketones            | +/- – 2+ (5 – 40 mg/dl) (0.5 – 3.9 mmol/l)                    |
|                         | Nitrite            | POSITIVE  |
|                         | pH                 | 7.5 – >8.5  |
|                         | Protein            | 2+ – 4+ (100 – 1000 mg/dl) (1 – 10 g/l)                       |
| Specific Gravity        | 1.005 – 1.02 RATIO |   |

| MANUFACTURER / METHOD              | ANALYTE  | RANGE   |
|------------------------------------|--|---|
| Dirui H Series                     | Albumin  | (0.03 – 0.15 g/l) (3 – 15 mg/dl) (30 – 150 mg/l)                      |
|                                    | Bilirubin  | SMALL – LARGE / 1+ – 3+ (17 – >103 µmol/l)<br>(1 – >6 mg/dl)          |
|                                    | Blood  | SMALL – LARGE / 1+ – 3+ (25 – 200 Ery/µl)<br>(0.1 – 0.6 mg/dl)        |
|                                    | Glucose  | 1+ – 4+ (5.6 – >56 mmol/l) (100 – >1000 mg/dl)<br>(1 – 10 g/l)        |
|                                    | Ketones  | +/- – 2+ ((0.5-1.0) – (3.9-6.0) mmol/l)<br>((5-10) – (40-60) mg/dl)   |
|                                    | Leukocytes                                       | TRACE – MODERATE / +/- – 2+ (15 – 125 Leu/µl)                         |
|                                    | Nitrite  | POSITIVE  |
|                                    | pH   | 7 – >8.5  |
|                                    | Protein  | 1+ – 3+ (0.3 – 3 g/l) (30 – 300 mg/dl)                                |
|                                    | Specific Gravity                                 | 1.005 – 1.015 RATIO   |
| EKF Diagnostics QuPID / QuPID Plus | hCG  | POSITIVE  |
| Erba Lachema                       | Bilirubin  | 1+ – 3+ (17 – 103 µmol/l) (1 – 6 mg/dl)                               |
|                                    | Blood  | 1+ – 3+ ((5-10) – 250 Ery/µl)   |
|                                    | Glucose  | 2+ – 4+ (5.5 – 55 mmol/l) (100 – 1000 mg/dl)                          |
|                                    | Ketones  | +/- – 2+ (5 – (31-52) mg/dl) (0.5 – (3-5) mmol/l)                     |
|                                    | Leukocytes                                       | 1+ – 3+ ((10-25) – 500 Leu/µl)  |
|                                    | Nitrite  | POSITIVE  |
|                                    | pH   | 7.5 – >8.5  |
|                                    | Protein  | 1+ – 3+ (30 – 500 mg/dl) (0.3 – 5 g/l)                                |
| Specific Gravity                   | 1 – 1.01 RATIO                                   |   |
| Human Combina                      | Albumin  | 30 – 150 mg/dl  |
|                                    | Creatinine                                       | (4.4 – 17.7 mmol/l) (50 – 200 mg/dl)                                  |
| IND Diagnostic hCG                 | hCG  | POSITIVE  |
| Iris Velocity                      | Blood  | 1+ – 3+ ((0.06-0.1) – >1.0 mg/dl) (1 – >10 mg/l)<br>(25 – 300 Ery/µl) |
|                                    | Glucose  | 2+ – 4+ (100 – >1000 mg/dl) (5.6 – >56 mmol/l)<br>(0.1 – >1 g/dl)     |
|                                    | Ketones  | 1+ – 3+ (10 – (60-80) mg/dl) (1 – (6-8) mmol/l)                       |
|                                    | Leukocytes                                       | 1+ – 3+ (75 – 500 Leu/µl)   |
|                                    | Nitrite  | POSITIVE / 1+ – 2+ (0.1 – 0.2 mg/dl)                                  |
|                                    | pH   | 7.5 – >8.5  |
|                                    | Protein  | 1+ – 3+ (50 – 300 mg/dl) (0.5 – 3 g/l)                                |
| Specific Gravity                   | 1.005 – 1.015 RATIO                              |   |
| Urobilinogen                       | 1+ – 3+ ((2-3) – 8 mg/dl) ((34-50) – 140 µmol/l) |   |
| LifeSign BioSign hCG               | hCG  | POSITIVE  |
| Nova Century Scientific            | hCG  | POSITIVE  |
| Quidel Quickvue / Rapidvue         | hCG  | POSITIVE  |

| MANUFACTURER / METHOD         | ANALYTE  | RANGE  |
|-------------------------------|--|--|
| Roche Cobas U601/ Urisys 2400 | Bilirubin  | 1+ – 3+ (1 – 6 mg/dl) (17 – 100 µmol/l)                        |
|                               | Blood  | 3+ – 5+ (50 – 250 Ery/µl)                                      |
|                               | Glucose  | 2+ – 4+ (100 – 1000 mg/dl) (6 – 56 mmol/l)                     |
|                               | Ketones  | 2+ – 4+ (15 – 150 mg/dl) (1.5 – 15 mmol/l)                     |
|                               | Leukocytes                                       | 1+ – 3+ (25 – 500 Leu/µl)                                      |
|                               | Nitrite  | POSITIVE   |
|                               | pH   | 7.5 – >8.5   |
|                               | Protein  | 2+ – 4+ (75 – 500 mg/dl) (0.75 – 5 g/l)                        |
|                               | Specific Gravity                                 | 1.005 – 1.015 RATIO  |
|                               | Urobilinogen                                     | 1+ – 3+ (1 – 8 mg/dl) (17 – 135 µmol/l)                        |
|                               | Roche Cobas U411 / Urisys 1100 / 1800 / Miditron | Bilirubin  |
| Blood                         |  | 2+ – 5+ (25 – 250 Ery/µl)                                      |
| Glucose                       |  | 2+ – 4+ (100 – 1000 mg/dl) (6 – 56 mmol/l)                     |
| Ketones                       |  | 2+ – 4+ (15 – 150 mg/dl) (1.5 – 15 mmol/l)                     |
| Leukocytes                    |  | 1+ – 3+ (25 – 500 Leu/µl)                                      |
| Nitrite                       |  | POSITIVE   |
| pH                            |  | 7.5 – >8.5   |
| Protein                       |  | 2+ – 4+ (75 – 500 mg/dl) (0.75 – 5 g/l)                        |
| Specific Gravity              |  | 1.005 – 1.02 RATIO   |
| Urobilinogen                  |  | 1+ – 3+ (1 – 8 mg/dl) (17 – 140 µmol/l)                        |
| Roche Combur                  |  | Albumin  |
|                               | Bilirubin  | 1+ – 3+ (1 – 6 mg/dl) (17 – 100 µmol/l)                        |
|                               | Blood  | 2+ – 4+ (25 – 250 Ery/µl) (0.1 – 1 mg/dl)                      |
|                               | Glucose  | 2+ – 4+ (100 – 1000 mg/dl) (5.5 – 56 mmol/l)                   |
|                               | Ketones  | 1+ – 3+ (10 – 150 mg/dl) (1 – 15 mmol/l)                       |
|                               | Leukocytes                                       | 1+ – 3+ ((10-25) – 500 Leu/µl)                                 |
|                               | Nitrite  | POSITIVE   |
|                               | pH   | 7.5 – >8.5   |
|                               | Protein  | 1+ – 3+ (30 – 500 mg/dl) (0.3 – 5 g/l)                         |
|                               | Specific Gravity                                 | 1 – 1.01 RATIO   |
|                               | Urobilinogen                                     | 1+ – 3+ (1 – 8 mg/dl) (17 – 135 µmol/l) (1 – 8 Eu/dl)          |
| Siemens Clinitek Microalbumin | Albumin  | (3 – 15 mg/dl) (30 – 150 mg/l) (20.8 – 103.5 mmol/l)           |
| Siemens Clinitek Novus        | Albumin  | (30 – 150 mg/l)  |
|                               | Blood  | SMALL – LARGE / 1+ – 3+ (25 – 200 Ery/µl)<br>(0.1 – 0.8 mg/dl) |
|                               | Creatinine                                       | (0.9 – 8.8 mmol/l) (10 – 100 mg/dl)                            |
|                               | Glucose  | 1+ – 3+ (5.5 – 28 mmol/l) (100 – 500 mg/dl)                    |
|                               | Ketones  | TRACE – 2+ (TRACE – 3.9 mmol/l) (TRACE – 40 mg/dl)             |
|                               | Leukocytes                                       | SMALL – LARGE / 1+ – 3+ (70 – 500 Leu/µl)                      |
|                               | Nitrite  | POSITIVE   |
|                               | pH   | 7.5 – >8.5   |
|                               | Protein  | 2+ – 4+ (1 – >10 g/l) (100 – >1000 mg/dl)                      |
|                               | Specific Gravity                                 | <1.005 – 1.015 RATIO   |
|                               | Urobilinogen                                     | (3.2 – 33 µmol/l) (0.2 – 2 EU/dl) (0.2 – 2 mg/dl)              |
| Siemens Clinitest hCG         | hCG  | POSITIVE   |

| MANUFACTURER / METHOD            | ANALYTE          | RANGE  |   |
|----------------------------------|------------------|--|---|
| Siemens Multistix                | Bilirubin        | SMALL – LARGE / 1+ – 3+  |   |
|                                  | Blood            | SMALL – LARGE / 1+ – 3+ (25 – 200 Ery/ $\mu$ l)<br>(800 – 6000 $\mu$ g/l) (0.08 – 0.6 mg/dl) |   |
|                                  | Glucose          | TRACE – 2+ (100 – 500 mg/dl) (5.5 – 28 mmol/l)<br>(1 – 5 g/l)                                |   |
|                                  | Ketones          | SMALL – LARGE / 1+ – 3+ (15 – 80 mg/dl) (1.5 – 8 mmol/l) (0.015 – 0.8 g/l)                   |   |
|                                  | Leukocytes       | TRACE – MODERATE / TRACE – 2+ (15 – 125 Leu/ $\mu$ l)  |   |
|                                  | Nitrite          | POSITIVE   |   |
|                                  | pH               | 7.5 – >8.5   |   |
|                                  | Protein          | 2+ – 4+ (100 – 1000 mg/dl) (1 – 10 g/l) (0.1 – 1 g/dl)                                       |   |
|                                  | Specific Gravity | 1.005 – 1.02 RATIO   |   |
|                                  |                  |  |   |
| Sysmex Meditape UC 9A & 11A      | Albumin          | (30 – 150 mg/l) (0.03 – 0.15 g/l)  |   |
|                                  | Blood            | 1+ – 3+ (20 – 250 Ery/ $\mu$ l) (0.06 – 0.75 mg/dl)  |   |
|                                  | Creatinine       | (50 – 200 mg/dl) (0.5 – 2 g/l)   |   |
|                                  | Glucose          | 2+ – 4+ (250 – 2000 mg/dl) (14 – 111 mmol/l)   |   |
|                                  | Ketones          | 1+ – 3+ (10 – 80 mg/dl) (0.93 – 7.4 mmol/l)  |   |
|                                  | Leukocytes       | 1+ – 3+ (25 – 500 Leu/ $\mu$ l)  |   |
|                                  | Nitrite          | POSITIVE   |   |
|                                  | pH               | 7.5 – >8.5   |   |
|                                  | Protein          | 1+ – 3+ (30 – 300 mg/dl) (0.3 – 3 g/l)   |   |
|                                  | Specific Gravity | 1.005 – 1.015 RATIO  |   |
|                                  | Urobilinogen     | 1+ – 3+ (2 – 8 mg/dl) (34 – 135 $\mu$ mol/l)   |   |
|                                  |                  |  |   |
| Sysmex Meditape UC 10S & 12S     | Blood            | 1+ – 3+ (20 – 250 Ery/ $\mu$ l) (0.06 – 0.75 mg/dl)  |   |
|                                  | Glucose          | 2+ – 4+ (250 – 2000 mg/dl) (14 – 111 mmol/l)   |   |
|                                  | Ketones          | 1+ – 3+ (10 – 80 mg/dl) (0.93 – 7.4 mmol/l)  |   |
|                                  | Leucocytes       | 1+ – 3+ (25 – 500 Leu/ $\mu$ l)  |   |
|                                  | Nitrite          | POSITIVE   |   |
|                                  | pH               | 7.5 – >8.5   |   |
|                                  | Protein          | 1+ – 3+ (30 – 300 mg/dl) (0.3 – 3 g/l)   |   |
|                                  | Specific Gravity | 1 – 1.015 RATIO  |   |
|                                  |                  | Urobilinogen   | 1+ – 3+ (2 – 8 mg/dl) (34 – 135 $\mu$ mol/l)  |
|                                  |                  |  |   |
| Urit Medical Electronic          | Blood            | 1+ – 3+ (25 – >200 Ery/ $\mu$ l)   |   |
|                                  | Glucose          | 1+ – 3+ (100 – 500 mg/dl) (5.5 – 28 mmol/l)  |   |
|                                  | Ketones          | +/- – 2+ (5 – 40 mg/dl) (0.5 – 4 mmol/l)   |   |
|                                  | pH               | 7 – 8  |   |
|                                  | Protein          | 1+ – 3+ (30 – >300 mg/dl) (0.3 – >3.0 g/l)   |   |
|                                  | Specific Gravity | 1 – 1.015 RATIO  |   |
|                                  |                  | Urobilinogen   | 1+ – 3+ (2 – 8 mg/dl) (33 – >131 $\mu$ mol/l) |
|                                  |                  |  |   |
| WH Accu Test hCG Pregnancy Test  | hCG              | POSITIVE   |   |
|                                  |                  |  |   |
| YD Diagnostics/ Biosys / Genesis | Albumin          | 1+ – 3+ (30 – 150 mg/l)  |   |
|                                  | Blood            | 1+ – 3+ (10 – 250 Ery/ $\mu$ l)  |   |
|                                  | Creatinine       | (0.9 – 8.8 mmol/l) (10 – 100 mg/dl)  |   |
|                                  | Glucose          | 1+ – 3+ (250 – >1000 mg/dl) (14 – >55 mmol/l)  |   |
|                                  | Ketones          | TRACE – 2+ (5 – 50 mg/dl) (0.5 – 5 mmol/l)   |   |
|                                  | Nitrite          | POSITIVE   |   |
|                                  | pH               | 7.5 – >8.5   |   |
|                                  | Protein          | 1+ – 3+ (30 – 300 mg/dl) (0.3 – 3 g/l)   |   |
|                                  | Specific Gravity | 1 – 1.015 RATIO  |   |
|                                  |                  | Urobilinogen   | 1+ – 3+ (1 – 8 mg/dl) (17 – 140 $\mu$ mol/l)  |

| The presence of a vertical bar in the margin indicates a technical update from the previous revision. |

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| EC | REP |
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10 Feb '22 me