

## URINALYSIS CONTROL - LEVEL 1 (URNAL CONTROL I)

**CAT. NO.** UC5033**LOT NO.** 1109UC**SIZE:** 12 x 12 ml**EXPIRY:** 2021-09-28**GTIN:** 05055273207583

### 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.

**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 1 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.

| MANUFACTURER / METHOD   | ANALYTE          | RANGE                                                                    |
|-------------------------|------------------|--------------------------------------------------------------------------|
| 77 Elektronika kft      | Bilirubin        | NEGATIVE                                                                 |
|                         | Blood            | NEGATIVE                                                                 |
|                         | Glucose          | NEGATIVE – NORMAL                                                        |
|                         | Ketones          | NEGATIVE                                                                 |
|                         | Leucocytes       | NEGATIVE                                                                 |
|                         | Nitrite          | NEGATIVE                                                                 |
|                         | pH               | <5 – 6                                                                   |
|                         | Protein          | NEGATIVE                                                                 |
|                         | Specific Gravity | 1.02 – 1.03 RATIO                                                        |
| Abon hCG One Step Ultra | hCG              | NEGATIVE                                                                 |
|                         |                  |                                                                          |
|                         |                  |                                                                          |
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|                         |                  |                                                                          |
| Acon Laboratories       | hCG              | NEGATIVE                                                                 |
|                         |                  |                                                                          |
|                         |                  |                                                                          |
|                         |                  |                                                                          |
|                         |                  |                                                                          |
|                         |                  |                                                                          |
|                         |                  |                                                                          |
|                         |                  |                                                                          |
|                         |                  |                                                                          |
| Acon Mission            | Bilirubin        | NEGATIVE                                                                 |
|                         | Blood            | NEGATIVE                                                                 |
|                         | Glucose          | NEGATIVE                                                                 |
|                         | Ketones          | NEGATIVE                                                                 |
|                         | Leucocytes       | NEGATIVE                                                                 |
|                         | Nitrite          | NEGATIVE                                                                 |
|                         | pH               | 5.5 – 6                                                                  |
|                         | Protein          | NEGATIVE                                                                 |
|                         | Specific Gravity | 1.02 – 1.03 RATIO                                                        |
| Analyticon Combiscreen  | Bilirubin        | NEGATIVE                                                                 |
|                         | Blood            | NEGATIVE                                                                 |
|                         | Glucose          | NEGATIVE – NORMAL                                                        |
|                         | Ketones          | NEGATIVE                                                                 |
|                         | Leucocytes       | NEGATIVE                                                                 |
|                         | Nitrite          | NEGATIVE                                                                 |
|                         | pH               | <5 – 6                                                                   |
|                         | Protein          | NEGATIVE                                                                 |
|                         | Specific Gravity | 1.02 – 1.03 RATIO                                                        |
| Arkray/Menarini         | Urobilinogen     | NORMAL                                                                   |
|                         |                  |                                                                          |
|                         | Bilirubin        | NEGATIVE                                                                 |
|                         | Blood            | NEGATIVE                                                                 |
|                         | Glucose          | NEGATIVE – NORMAL (0 – 0.1 g/l) (0 – 10 mg/dl)<br>(0 – 0.6 mmol/l)       |
|                         | Ketones          | NEGATIVE                                                                 |
|                         | Leucocytes       | NEGATIVE                                                                 |
|                         | Nitrite          | NEGATIVE                                                                 |
|                         | pH               | <5 – 6                                                                   |
| DFI – Cybow             | Protein          | NEGATIVE                                                                 |
|                         | Specific Gravity | 1.015 – 1.025 RATIO                                                      |
|                         | Urobilinogen     | NEGATIVE – NORMAL (0.2 – 1 EU/dl)<br>(0.2 – 1.0 mg/dl) (3.2 – 16 µmol/l) |
|                         |                  |                                                                          |
|                         | Bilirubin        | NEGATIVE                                                                 |
|                         | Blood            | NEGATIVE                                                                 |
|                         | Glucose          | NEGATIVE                                                                 |
|                         | Ketones          | NEGATIVE                                                                 |
|                         | Leucocytes       | NEGATIVE                                                                 |
|                         | Nitrite          | NEGATIVE                                                                 |
|                         | pH               | <5-6                                                                     |
|                         | Protein          | NEGATIVE                                                                 |
|                         | Specific Gravity | 1.02 – 1.03 RATIO                                                        |
|                         | Urobilinogen     | NORMAL / 0.1 EU/dl / 0.1 mg/dl / 1.6 µmol/l                              |

| MANUFACTURER / METHOD             | ANALYTE          | RANGE                                          |
|-----------------------------------|------------------|------------------------------------------------|
| DIAsource, RIA                    | Albumin          | NEG – 0.01 g/l / NEG – 1 mg/dl / NEG – 10 mg/l |
|                                   | pH               | <5 – 6                                         |
|                                   |                  |                                                |
| Dirui H Series                    | Bilirubin        | NEGATIVE                                       |
|                                   | Blood            | NEGATIVE                                       |
|                                   | Glucose          | NEGATIVE                                       |
|                                   | Ketones          | NEGATIVE                                       |
|                                   | Leucocytes       | NEGATIVE                                       |
|                                   | Nitrite          | NEGATIVE                                       |
|                                   | Protein          | NEGATIVE                                       |
|                                   | Specific Gravity | 1.015 – 1.025 RATIO                            |
|                                   | Urobilinogen     | NORMAL / +/- / 3.4 – 17.0 µmol/l               |
|                                   |                  |                                                |
| EKF Diagnostics QuPID/ QuPID Plus | hCG              | NEGATIVE                                       |
|                                   |                  |                                                |
| Erba Lachema                      | Bilirubin        | NEGATIVE                                       |
|                                   | Blood            | NEGATIVE                                       |
|                                   | Glucose          | NEGATIVE                                       |
|                                   | Ketones          | NEGATIVE                                       |
|                                   | Leucocytes       | NEGATIVE                                       |
|                                   | Nitrite          | NEGATIVE                                       |
|                                   | pH               | <5 – 6                                         |
|                                   | Protein          | NEGATIVE                                       |
|                                   | Specific Gravity | 1.02 – 1.03 RATIO                              |
|                                   | Urobilinogen     | NORMAL                                         |
|                                   |                  |                                                |
| Human Combina                     | Albumin          | NEGATIVE – 10 mg/l                             |
|                                   | Creatinine       | 0.9 mmol/l / 10 mg/dl                          |
|                                   |                  |                                                |
| IND Diagnostic hCG                | hCG              | NEGATIVE                                       |
|                                   |                  |                                                |
| Iris Velocity                     | Bilirubin        | NEGATIVE                                       |
|                                   | Blood            | NEGATIVE                                       |
|                                   | Glucose          | NEGATIVE                                       |
|                                   | Ketones          | NEGATIVE                                       |
|                                   | Leucocytes       | NEGATIVE                                       |
|                                   | Nitrite          | NEGATIVE                                       |
|                                   | pH               | <5 – 6                                         |
|                                   | Protein          | NEGATIVE                                       |
|                                   | Specific Gravity | 1.015 – 1.025 RATIO                            |
|                                   | Urobilinogen     | NORMAL                                         |
|                                   |                  |                                                |
| LifeSign BioSign hCG              | hCG              | NEGATIVE                                       |
|                                   |                  |                                                |
| Nova Century Scientific           | hCG              | NEGATIVE                                       |
|                                   |                  |                                                |
| Quidel Quickvue                   | hCG              | NEGATIVE                                       |
|                                   |                  |                                                |
| Randox One-Step                   | hCG              | NEGATIVE                                       |

| MANUFACTURER / METHOD               | ANALYTE          | RANGE                                         |
|-------------------------------------|------------------|-----------------------------------------------|
| Roche Combur                        | Bilirubin        | NEGATIVE                                      |
|                                     | Blood            | NEGATIVE                                      |
|                                     | Glucose          | NEGATIVE / NORMAL                             |
|                                     | Ketones          | NEGATIVE                                      |
|                                     | Leucocytes       | NEGATIVE                                      |
|                                     | Nitrite          | NEGATIVE                                      |
|                                     | pH               | <5 – 6                                        |
|                                     | Protein          | NEGATIVE                                      |
|                                     | Specific Gravity | 1.01 – 1.02 RATIO                             |
|                                     | Urobilinogen     | NORMAL / 0.2 EU/dl                            |
| Roche Mditron/u411/u601             | Bilirubin        | NEGATIVE                                      |
|                                     | Blood            | NEGATIVE                                      |
|                                     | Glucose          | NORMAL                                        |
|                                     | Ketones          | NEGATIVE                                      |
|                                     | Leucocytes       | NEGATIVE                                      |
|                                     | Nitrite          | NEGATIVE                                      |
|                                     | pH               | <5 – 6                                        |
|                                     | Protein          | NEGATIVE                                      |
|                                     | Specific Gravity | 1.01 – 1.02 RATIO                             |
|                                     |                  |                                               |
| Roche Urisys 1100/1800/2400         | Bilirubin        | NEGATIVE                                      |
|                                     | Blood            | NEGATIVE                                      |
|                                     | Glucose          | NORMAL                                        |
|                                     | Ketones          | NEGATIVE                                      |
|                                     | Leucocytes       | NEGATIVE                                      |
|                                     | Nitrite          | NEGATIVE                                      |
|                                     | pH               | <5 – 6                                        |
|                                     | Protein          | NEGATIVE                                      |
|                                     | Specific Gravity | 1.015 – 1.025 RATIO                           |
|                                     | Urobilinogen     | NORMAL                                        |
| Siemens Clinitek Novus              | Albumin          | NEGATIVE – 10 mg/l                            |
|                                     | Bilirubin        | NEGATIVE                                      |
|                                     | Blood            | NEGATIVE                                      |
|                                     | Creatinine       | NEGATIVE                                      |
|                                     | Glucose          | NEGATIVE                                      |
|                                     | Ketones          | NEGATIVE                                      |
|                                     | Leucocytes       | NEGATIVE                                      |
|                                     | Nitrite          | NEGATIVE                                      |
|                                     | pH               | <5 – 6                                        |
|                                     | Protein          | NEGATIVE                                      |
|                                     | Specific Gravity | 1.02 – >1.03 RATIO                            |
|                                     | Urobilinogen     | NEGATIVE / 0.2 EU/dl / 3.2 µmol/l / 0.2 mg/dl |
|                                     |                  |                                               |
|                                     |                  |                                               |
| Roche Clinitest hCG                 | hCG              | NEGATIVE                                      |
| Siemens/Bayer Clinitek Microalbumin | Albumin          | 1 mg/dl / 10 mg/l / 6.9 mmol/l                |
| Siemens Multistix                   | Bilirubin        | NEGATIVE                                      |
|                                     | Blood            | NEGATIVE                                      |
|                                     | Glucose          | NEGATIVE                                      |
|                                     | Ketones          | NEGATIVE                                      |
|                                     | Leucocytes       | NEGATIVE                                      |
|                                     | Nitrite          | NEGATIVE                                      |
|                                     | pH               | <5 – 6                                        |
|                                     | Protein          | NEGATIVE                                      |
|                                     | Specific Gravity | 1.02 – >1.03 RATIO                            |
|                                     | Urobilinogen     | NEGATIVE / 0.2 EU/dl / 3.2 µmol/l / 0.2 mg/dl |

| MANUFACTURER / METHOD             | ANALYTE          | RANGE                                 |
|-----------------------------------|------------------|---------------------------------------|
| Sysmex Meditape UC Series Tests   | Bilirubin        | NEGATIVE                              |
|                                   | Blood            | NEGATIVE                              |
|                                   | Glucose          | NEGATIVE                              |
|                                   | Ketones          | NEGATIVE                              |
|                                   | Leucocytes       | NEGATIVE                              |
|                                   | Nitrite          | NEGATIVE                              |
|                                   | pH               | <5 – 6                                |
|                                   | Protein          | NEGATIVE                              |
|                                   | Specific Gravity | 1.02 – 1.03 RATIO                     |
|                                   | Urobilinogen     | NORMAL                                |
| Urit Medical Electronic           | Bilirubin        | NEGATIVE                              |
|                                   | Blood            | NEGATIVE                              |
|                                   | Glucose          | NEGATIVE                              |
|                                   | Ketones          | NEGATIVE                              |
|                                   | Leucocytes       | NEGATIVE                              |
|                                   | Nitrite          | NEGATIVE                              |
|                                   | pH               | <5 – 6                                |
|                                   | Protein          | NEGATIVE                              |
|                                   | Specific Gravity | 1.015 – 1.025 RATIO                   |
|                                   | Urobilinogen     | NEGATIVE                              |
| WH Accu Test hCG Pregnancy Test   | hCG              | NEGATIVE                              |
| YD Diagnostics / Biosys / Genesis | Bilirubin        | NEGATIVE                              |
|                                   | Blood            | NEGATIVE                              |
|                                   | Glucose          | NEGATIVE                              |
|                                   | Ketones          | NEGATIVE                              |
|                                   | Leucocytes       | NEGATIVE                              |
|                                   | Nitrite          | NEGATIVE (0.00 – 0.04 mg/dl)          |
|                                   | pH               | <5 – 6                                |
|                                   | Protein          | NEGATIVE                              |
|                                   | Specific Gravity | 1.02 – 1.03 RATIO                     |
|                                   | Urobilinogen     | NORMAL / +/- / 0.1 mg/dl / 1.7 µmol/l |

06 Aug '20 ne