

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

**CAT NO.** UC5034

**LOT NO.** 1113UC

**SIZE:** 12 x 12 ml

**EXPIRY:** 2021-11-28

**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.

MANUFACTURER / METHOD	ANALYTE	RANGE
77 Elektronika kft	Bilirubin	1+ – 3+ (1 – 6 mg/dl) (17 – 100 µmol/l)
	Blood	1+ – 3+ (10 – 300 Ery/µl)
	Glucose	2+ – 4+ (150 – 1000 mg/dl) (10 – 50 mmol/l)
	Ketones	1+ – 3+ (15 – 150 mg/dl) (1.5 – 15 mmol/l)
	Leukocytes	1+ – 3+ (25 – 500 Leu/µl)
	Nitrite	POSITIVE
	pH	7 – 8
	Protein	1+ – 3+ (0.3 – (3-5) g/l) (30 – (300-500) mg/dl)
	Specific Gravity	1 – 1.015 RATIO
	Urobilinogen	2+ – 4+ (70 – 200 µmol/l) (4 – 12 mg/dl) (4 – 12 EU/dl)
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	1+ – 3+ (30 – 300 mg/dl) (0.3 – 3 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) (2.5 – 10 g/l)
	Ketones	TRACE – 2+ (10 – 100 mg/dl) (1 – 10 mmol/l)
	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+ (2 – 8 mg/dl) (35 – 140 µmol/l)
Arkray / Menarini	Blood	1+ – 3+ / SMALL – LARGE ((0.06-1) – >1 mg/dl) ((20-30) – >300 Ery/µl) ((0.6-1) – >10 mg/l)
	Glucose	2+ – 4+ ((150-200) – >1000 mg/dl) ((8.4-11.2) – >56 mmol/l) ((1.5-2) – >10 g/l)
	Ketones	1+ – 3+ ((10-20) – (60-80) mg/dl) ((1-2) – (6-8) mmol/l)
	Nitrite	POSITIVE / 1+ – 2+
	pH	7.5 – >8.5
	Protein	1+ – 3+ ((30-70) – (250-400) mg/dl) ((0.3-0.7) – (2.5-4) g/l)
	Specific Gravity	1.005 – 1.015 RATIO
DFI – Cybow	Bilirubin	1+ – 3+
	Blood	1+ – 3+ (10 – 250 Ery/µl)
	Ketones	+/- – 2+ (5 – 40 mg/dl) (0.5 – 3.9 mmol/l)
	pH	7.5 – >8.5
	Protein	2+ – 4+ (100 – 1000 mg/dl) (1 – 10 g/l)
	Specific Gravity	1.005 – 1.02 RATIO
DIAsource RIA	Albumin	(0.03 – 0.15 g/l) (3 – 15 mg/dl) (30 – 150 mg/l)
	pH	7.5 – >8.5

MANUFACTURER / METHOD	ANALYTE	RANGE
Dirui H Series	Bilirubin	1+ – 3+ / SMALL – LARGE (17 – >103 µmol/l) (1 – >6 mg/dl)
	Blood	1+ – 3+ / SMALL – LARGE (25 – 200 Ery/µl) (0.1 – 0.6 mg/dl)
	Glucose	2+ – 4+ (14 – >56 mmol/l) (250 – >1000 mg/dl) (2.5 – 10 g/l)
	Nitrite	POSITIVE
	Protein	1+ – 3+ (0.3 – 3 g/l) (30 – 300 mg/dl)
	Specific Gravity	1 – 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/l
	Creatinine	(8.8 – 26.5 mmol/l) (100 – 300 mg/dl)
IND Diagnostic hCG	hCG	POSITIVE
Iris Velocity	Blood	1+ – 3+ ((0.06-0.1) – >1.0 mg/dl) ((20-40) – >300 Ery/µl) (1 – >10 mg/l)
	Glucose	2+ – 4+ (100 – >1000 mg/dl) (5.6 – >56 mmol/l) (0.1 – >1 g/dl)
	Ketones	1+ – 3+ (10 – (60-80) mg/dl) (1 – (6-8) mmol/l)
	Leukocytes	TRACE – 2+ (25 – 250 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	hCG	POSITIVE
Randox One-Step	hCG	POSITIVE
Roche Combur	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) (6 – 55 mmol/l)
	Ketones	1+ – 3+ (15 – 150 mg/dl) (1.5 – 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	1.005 – 1.02 RATIO
	Urobilinogen	1+ – 3+ (1 – 8 mg/dl) (17 – 140 µmol/l) (1 – 8 EU/dl)

MANUFACTURER / METHOD	ANALYTE	RANGE
Roche Miditron/u411/u601	Bilirubin	1+ – 3+ (17 – 100 µmol/l) (1 – 6 mg/dl)
	Blood	3+ – 5+ (50 – 250 Ery/µl)
	Glucose	2+ – 4+ (6 – 56 mmol/l) (100 – 1000 mg/dl)
	Ketones	2+ – 4+ (1.5 – 15 mmol/l) (15 – 150 mg/dl)
	Leukocytes	1+ – 3+ (25 – 500 Leu/µl)
	Nitrite	POSITIVE
	pH	7.5 – >8.5
	Protein	2+ – 4+ (0.75 – 5 g/l) (75 – 500 mg/dl)
	Specific Gravity	1.005 – 1.02 RATIO
	Urobilinogen	1+ – 3+ (17 – 135 µmol/l) (1 – 8 mg/dl) (1 – 8 EU/dl)
Roche Urisys 1100/1800/2400	Bilirubin	1+ – 3+ (17 – 100 µmol/l) (1 – 6 mg/dl)
	Blood	2+ – 4+ (25 – 250 Ery/µl)
	Glucose	2+ – 4+ (6 – >56 mmol/l) (100 – >1000 mg/dl)
	Ketones	1+ – 3+ (1.5 – 15 mmol/l) (15 – 150 mg/dl)
	Leukocytes	1+ – 3+ (25 – 500 Leu/µl)
	Nitrite	POSITIVE
	pH	7.5 – >8.5
	Protein	2+ – 4+ (0.75 – 5 g/l) (75 – 500 mg/dl)
	Specific Gravity	1.005 – 1.015 RATIO
	Urobilinogen	1+ – 3+ (17 – 140 µmol/l) (1 – 8 mg/dl)
Siemens/Bayer Clinitek Microalbumin	Albumin	(3 – 15 mg/dl) (30 – 150 mg/l) (20.8 – 103.5 mmol/l)
Siemens Clinitek Novus	Blood	1+ – 3+ / SMALL – LARGE (25 – 200 Ery/µl) (0.1 – 0.8 mg/dl)
	Glucose	2+ – 4+ (14 – >55 mmol/l) (250 – >1000 mg/dl)
	Ketones	TRACE – 2+ (TRACE – 3.9 mmol/l) (TRACE – 40 mg/dl)
	Leukocytes	TRACE – 2+ / TRACE – MOD (15 – 125 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 Clintest hCG	hCG	POSITIVE
Siemens Multistix	Bilirubin	1+ – 3+ / SMALL – LARGE
	Blood	1+ – 3+ / SMALL – LARGE (25 – 200 Ery/µl) (800 – 6000 µg/l) (0.08 – 0.6 mg/dl)
	Glucose	TRACE – 2+ (100 – 500 mg/dl) (5.5 – 28 mmol/l) (1 – 5 g/l)
	Ketones	TRACE – 2+ / TRACE – MOD (0.5 – 4 mmol/l) (5 – 40 mg/dl) (0.05 – 0.4 g/l)
	Leukocytes	TRACE – 2+ / TRACE – MOD (15 – 125 Leu/µl)
	Nitrite	POSITIVE / 1+ – 2+
	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 Series Tests	Blood	1+ – 3+ (20 – 250 Ery/µl) (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)
	Leukocytes	1+ – 3+ (25 – 500 Leu/µl)
	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 µmol/l)

MANUFACTURER / METHOD	ANALYTE	RANGE
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	1.005 – 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	Blood	1+ – 3+ (10 – 250 Ery/ $\mu$ l)
	Glucose	TRACE – 2+ (100 – 500 mg/dl) (5.5 – 28 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	1.005 – 1.015 RATIO

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

EC REP

Randox Teoranta, Meenmore,  
Dungloe, Donegal,  
F94 TV06, Ireland

Revised 23 Feb 21 pl

**THIS PAGE IS INTENTIONALLY BLANK**