URINALYSIS CONTROL - LEVEL 2 (URNAL CONTROL 2)

Cat. No. UC5034 **Lot No.** 789UC
Size: 12 x 12 ml **Expiry:** 2017-02

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	Albumin	POSITIVE / 1+ – 3+ (30 – 500 mg/dl) (0.3 – 5 g/l)
	Bilirubin	POSITIVE / 1+ – 3+ (1 – 6 mg/dl) (17 – 100 µmol/l)
	Blood	2+ – 3+ (50 – 300 Ery/µl)
	Glucose	POSITIVE / 1+ – 4+ (50 – 1000 mg/dl) (3 – 50 mmol/l)
	Ketones	POSITIVE / 1+ – 3+ (15 – 150 mg/dl) (1.5 – 15 mmol/l)
	Leukocytes	1+ – 3+ (25 – 500 Leu/µl)
	Nitrite	POSITIVE
	pH	7 – 8
	Protein	POSITIVE / (+) – 3+ (15 – (300-500) mg/dl) (0.15 – (3-5) g/l)
	Specific Gravity	1 – 1.02 RATIO
	Urobilinogen	POSITIVE / 1+ – 4+ (35 – 200 µmol/l) (2 – 12 mg/dl)
Abon hCG One Step Ultra	hCG	POSITIVE
Acon Laboratories	Bilirubin	1+ – 3+ (1 – 4 mg/dl) (17 – 70 µmol/l)
	Blood	+/- – 3+ (10 – 200 Ery/µl)
	Glucose	POSITIVE / +/- – 3+ (100 – >1000 mg/dl) (5 – >60mmol/l)
	hCG	POSITIVE
	Ketones	POSITIVE / +/- – 3+ (5 – 80 mg/dl) (0.5 – 8 mmol/l)
	Leukocytes	+/- – 3+ (15 – 500 Leu/µl)
	Nitrite	POSITIVE
	pH	7 – >8.5
	Protein	1+ – 3+ (30 – 300 mg/dl) (0.3 – 3 g/l)
	Specific Gravity	1.005 – 1.02 RATIO
	Urobilinogen	POSITIVE / +/- – 3+ (0.2 – 8 mg/dl) (3.5 – 140 µmol/l) (0.2 – 8 EU/dl)
Alere hCG Cassette	hCG	POSITIVE
Analyticon Combiscreen	Bilirubin	1+ – 3+ (1 – 4 mg/dl) (15 – 70 µmol/l)
	Blood	2+ – 3+ (50 – 300 Ery/µl)
	Glucose	2+ – 5+ (100 – 1000 mg/dl) (5.6 – 56 mmol/l)
	Ketones	TRACE – 3+ (10 – 300 mg/dl) (1 – 30 mmol/l)
	Leukocytes	2+ – 3+ (75 – 500 Leu/µl)
	Nitrite	POSITIVE
	pH	7 – 8
	Protein	1+ – 3+ (30 – 500 mg/dl) (0.3 – 5 g/l)
	Specific Gravity	1 – 1.015 RATIO
	Urobilinogen	1+ – 4+ (2 – 12 mg/dl) (35 – 200 µmol/l)
Arkray / Menarini	Albumin	POSITIVE
	Bilirubin	POSITIVE / +/- – 2+ / SMALL – MODERATE (0.2 – (2-4) mg/dl) (3.2 – (32-64) µmol/l)
	Blood	1+ – 3+ / SMALL – LARGE ((0.06-0.1) – >1 mg/dl) ((20-30) – >300 Ery/µl) ((0.6-1) – >10 mg/l)
	Glucose	1+ – 4+ ((70-100) – >1000 mg/dl) ((3.9-5.6) – >56 mmol/l) ((0.7-1) – >10 g/l)
	Ketones	1+ – 4+ ((10-20) – >80 mg/dl) ((1-2) – >8 mmol/l)
	Leukocytes	TRACE – LARGE (25 – 500 Leu/µl)
	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 – 1.02 RATIO
	Urobilinogen	+/- – 4+ ((0.2-1) – >12 mg/dl) ((3.2-16) – >192 µmol/l) ((0.2-1) – >12 EU/dl)

MANUFACTURER / METHOD	ANALYTE	RANGE
Bio Chemical Technology Co Ltd	hCG	POSITIVE
BioMaxima BM Uri Strip	Bilirubin	1+ – 2+ (8.6 – 33 µmol/l) (0.5 – 2 mg/dl)
	Blood	1+ – 3+ (25 – 200 Ery/µl)
	Glucose	1+ – 3+ (5.5 – 28 mmol/l) (100 – 500 mg/dl)
	Ketones	1+ – 3+ (1.5 – >8 mmol/l) (15 – >80 mg/dl)
	Leukocytes	+/- – 2+ (15 – 125 Leu/µl)
	Nitrite	POSITIVE
	pH	7 – 8
	Protein	1+ – 3+ (0.3 – 3 g/l) (30 – 300 mg/dl)
	Specific Gravity	1.005 – 1.02 RATIO
	Urobilinogen	1+ – 3+ (33 – >131 µmol/l) (2 – >8 mg/dl)
Biomerieux	hCG	POSITIVE
CTK Biotech Onsite hCG	hCG	POSITIVE
DFI - Cybow	Bilirubin	1+ – 3+
	Blood	2+ – 3+ (50 – 250 Ery/µl)
	Glucose	+/- – 3+ (100 – 1000 mg/dl) (5.5 – 55 mmol/l)
	Ketones	1+ – 3+ (15 – 100 mg/dl) (1.5 – 10 mmol/l)
	Leukocytes	2+ – 3+ (75 – 500 Leu/µl)
	Nitrite	POSITIVE
	pH	6 – >8.5
	Protein	1+ – 3+ (30 – 300 mg/dl) (0.3 – 3 g/l)
	Specific Gravity	1 – 1.015 RATIO
	Urobilinogen	0.1 – 8 mg/dl / 1.6 – 131 µmol/l
Dirui H Series	Albumin	0.15 g/l / 15 mg/dl / 150 mg/l
	Bilirubin	POSITIVE / 1+ – 3+ (17 – >103 µmol/l) (1 – >6mg/dl)
	Blood	1+ – 3+ (25 – 200 Ery/µl) (0.1 – 0.6 mg/dl)
	Glucose	1+ – 4+ (5.6 – >56 mmol/l) (100 – >1000 mg/dl) (1 – 10 g/l)
	Ketones	POSITIVE / +/- – 3+ ((0.5-1.0) – >10 mmol/l) ((5-10) – >103 mg/dl)
	Leukocytes	+/- – 3+ (15 – 500 Leu/µl)
	Nitrite	POSITIVE
	pH	6.5 – >8.5
	Protein	1+ – 4+ (0.3 – 3 g/l) (30 – 300 mg/dl)
	Specific Gravity	1.005 – 1.025 RATIO
	Urobilinogen	+/- – 3+ ((3.4-17) – 135 µmol/l) (NORM – >8 mg/dl) (NORM – >8 EU/dl)
Dutch Diagnostics Uri-Screen	Blood	2+ – 3+ (50 – 300 Ery/µl)
	Glucose	2+ – 3+ (500 – 1000 mg/dl) (28 – 55 mmol/l)
	Leukocytes	1+ – 3+ (25 – 500 Leu/µl)
	Nitrite	POSITIVE
	pH	7.5 – 8
	Specific Gravity	1 – 1.015 RATIO

MANUFACTURER / METHOD	ANALYTE	RANGE
Erba Lachema	Bilirubin	POSITIVE / 2+ – 3+ (51 – 103 µmol/l) (3 – 6 mg/dl)
	Blood	POSITIVE / 2+ – 3+ (50 – 250 Ery/µl)
	Glucose	2+ – 4+ (5.5 – 55 mmol/l) (100 – 1000 mg/dl)
	Ketones	2+ – 3+ ((31-52) – 78 mg/dl) ((3-5) – 7.5 mmol/l)
	Leukocytes	2+ – 3+ (75 – 500 Leu/µl)
	Nitrite	POSITIVE
	pH	7 – 8
	Protein	1+ – 3+ (30 – 500 mg/dl) (0.3 – 5 g/l)
	Specific Gravity	1 – 1.01 RATIO
	Urobilinogen	1+ – 3+ (1 – 6 mg/dl) (17 – 102 µmol/l)
Erba Mannheim Uro-Dip	Bilirubin	POSITIVE / 2+ – 3+
	Blood	1+ – 3+ (25 – 200 Ery/µl)
	Glucose	1+ – 3+ (250 – 1000 mg/dl) (2.5 – 10 g/l) (14 – 55 mmol/l)
	Ketones	1+ – 3+ (15 – 80 mg/dl)
	Leukocytes	1+ – 3+ (70 – 500 Leu/µl)
	Nitrite	POSITIVE
	pH	7 – 8
	Protein	1+ – 3+ (30 – 300 mg/dl) (0.3 – 3 g/l)
	Specific Gravity	1 – 1.015 RATIO
	Urobilinogen	POSITIVE / 1+ – 3+ (1 – 4 mg/dl) (16 – 66 µmol/l)
Gabmed beta 10 hCG Cassette	hCG	POSITIVE
Greats Medtech hCG Strip	hCG	POSITIVE
Hangzhou Clongene hCG Test	hCG	POSITIVE
Human Combina	Bilirubin	1+ – 3+ / SMALL – LARGE (17 – 103 µmol/l) (1 – 6 mg/dl)
	Blood	2+ – 3+ / MODERATE – LARGE (50 – (200-300) Ery/µl)
	Glucose	1+ – 3+ (14 – 55 mmol/l) (250 – 1000 mg/dl)
	Ketones	1+ – 3+ (15 – 100 mg/dl) (1.5 – 10 mmol/l)
	Leukocytes	2+ – 3+ / MODERATE – LARGE ((70-75) – 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 – 1.015 RATIO
	Urobilinogen	NORMAL – 2+ (NORM – 4 mg/dl) (NORM – (66-70) µmol/l)
Human Rapid Pregnancy Tests	hCG	POSITIVE
IND Diagnostic hCG	hCG	POSITIVE
Innovacon hCG Pregnancy Test	hCG	POSITIVE (>25 mU/ml)

MANUFACTURER / METHOD	ANALYTE	RANGE
Iris Velocity	Bilirubin	NEGATIVE – 1+ (NEG – 1 mg/dl) (NEG – 17 µmol/l)
	Blood	1+ – 3+ ((0.06-0.1) – >1.0mg/dl) (1 – >10 mg/l)
	Glucose	1+ – 4+ (50 – >1000 mg/dl) (2.8 – >56 mmol/l)
	Ketones	1+ – 3+ (10 – (60-80) mg/dl) (1 – (6-8) mmol/l)
	Leukocytes	2+ – 3+ (250 – 500 Leu/µl)
	Nitrite	POSITIVE / 1+ – 2+ (0.1 – 0.2 mg/dl)
	pH	7 – 8
	Protein	1+ – 2+ (50 – 100 mg/dl) (0.5 – 1 g/l)
	Specific Gravity	1.01 – 1.02 RATIO
	Urobilinogen	NORMAL – 3+ (NORM – 8 mg/dl) (NORM – 140 µmol/l)
Macherey-Nagel	Bilirubin	POSITIVE / 1+ – 3+ (1 – 4 mg/dl) (17 – 70 µmol/l)
	Blood	POSITIVE (50 – 250 Ery/µl)
	Glucose	POSITIVE (150 – >1000 mg/dl) (8.3 – >55.5 mmol/l)
	Ketones	POSITIVE / 1+ – 2+ (25 – 100 mg/dl) (2.5 – 10 mmol/l)
	Leukocytes	POSITIVE (25 – 500 Leu/µl)
	Nitrite	POSITIVE
	pH	7 – >8.5
	Protein	POSITIVE (30 – 500 mg/dl) (0.3 – 5 g/l)
	Specific Gravity	1 – 1.01 RATIO
	Urobilinogen	POSITIVE (2 – 8 mg/dl) (34 – 140 µmol/l)
Menarini	Bilirubin	+/- – 2+ (0.2 – (2-4) mg/dl)
	Blood	2+ – 3+ ((0.2-0.5) – >1 mg/dl) ((60-150) – >300 Ery/µl)
	Glucose	2+ – 4+ ((150-200) – >1000 mg/dl)
	Ketones	2+ – 3+ ((30-45) – (60-80) mg/dl)
	Leukocytes	250 – 500 Leu/µl
	Nitrite	2+
	Protein	1+ – 3+ ((30-70) – (250-400) mg/dl)
	Specific Gravity	1.01 – 1.02 RATIO
	Urobilinogen	+/- / 0.2 – 1 mg/dl
Nal von Minden Nadal hCG	hCG	POSITIVE
Neopharma Sensatest	hCG	POSITIVE
Nova Century Scientific	hCG	POSITIVE
Premier Diagnostics	hCG	POSITIVE
Quidel Quickvue / Rapidvue	hCG	POSITIVE
Randox One-Step	hCG	POSITIVE
Roche Combur	Albumin	POSITIVE
	Bilirubin	POSITIVE / 1+ – 3+ (1 – 6 mg/dl) (17 – 100 µmol/l)
	Blood	POSITIVE / 3+ – 4+ (50 – 250 Ery/µl) (0.2 – 1 mg/dl)
	Glucose	2+ – 4+ (100 – 1000 mg/dl) (6 – 55 mmol/l)
	Ketones	POSITIVE / 1+ – 3+ (15 – 150 mg/dl) (1.5 – 15 mmol/l)
	Leukocytes	POSITIVE / 1+ – 3+ (25 – 500 Leu/µl)
	Nitrite	POSITIVE
	pH	8 – >8.5
	Protein	POSITIVE / 1+ – 3+ (25 – 150 mg/dl) (0.25 – 1.5 g/l)
	Specific Gravity	1 – 1.02 RATIO
	Urobilinogen	POSITIVE / NORMAL – 3+ (NORM – 8 mg/dl) (NORM – 140 µmol/l) (0.2 – 8 EU/dl)

MANUFACTURER / METHOD	ANALYTE	RANGE
Roche Miditron / u411 / u601	Bilirubin	POSITIVE / 1+ – 3+ (17 – 100 µmol/l) (1 – 6 mg/dl)
	Blood	POSITIVE / 3+ – 5+ (50 – 250 Ery/µl)
	Glucose	POSITIVE / 2+ – 4+ (6 – 56 mmol/l) (100 – 1000 mg/dl)
	Ketones	POSITIVE / 2+ – 4+ (1.5 – 15 mmol/l) (15 – 150 mg/dl)
	Leukocytes	POSITIVE / 2+ – 3+ (100 – 500 Leu/µl)
	Nitrite	POSITIVE
	pH	7.5 – >8.5
	Protein	POSITIVE / 1+ – 3+ (0.25 – 1.5 g/l) (25 – 150 mg/dl)
	Specific Gravity	1.005 – 1.02 RATIO
	Urobilinogen	POSITIVE / 1+ – 4+ (17 – 203 µmol/l) (1 – 12 mg/dl) (1 – 12 EU/dl)
Roche Urisys 1100 / 1800 / 2400	Bilirubin	POSITIVE / 1+ – 3+ (17 – 100 µmol/l) (1 – 6 mg/dl)
	Blood	POSITIVE / 2+ – 4+ (25 – 250 Ery/µl)
	Glucose	POSITIVE / 2+ – 4+ (6 – >56 mmo/l) (100 – >1000mg/dl)
	Ketones	POSITIVE / 2+ – 3+ (5 – 15 mmol/l) (50 – 150 mg/dl)
	Leukocytes	POSITIVE / 2+ – 3+ (100 – 500 Leu/µl)
	Nitrite	POSITIVE
	pH	7.5 – >8.5
	Protein	POSITIVE / 2+ – 4+ (0.75 – 5 g/l) (75 – 500 mg/dl)
	Specific Gravity	1.01 – 1.02 RATIO
	Urobilinogen	POSITIVE / 1+ – 3+ (17 – 140 µmol/l) (1 – 8 mg/dl)
Siemens/Bayer Clinitek	Albumin	8 – 15 mg/dl / 80 – 150 mg/l / 55.2 – 103.5 mmol/l
	Creatinine	100 – 300 mg/dl / 8.8 – 26.5 mmol/l
Siemens Multistix	Albumin	3 – 15 mg/dl / 30 – 150 mg/l / 20.7 – 103.5 mmol/l
	Bilirubin	POSITIVE / 1+ – 3+ / SMALL – LARGE
	Blood	POSITIVE / MODERATE – LARGE / 2+ – 3+ (80 – 200 Ery/µl) (2500 – 6000 µg/l) (0.25 – 0.6 mg/dl)
	Creatinine	100 – 300 mg/dl / 8.8 – 26.5 mmol/l
	Glucose	POSITIVE / TRACE – 3+ (100 – 1000 mg/dl) (5.5 – 55 mmol/l) (1 – 10 g/l)
	Ketones	POSITIVE / 1+ – 4+ / SMALL – LARGE (15 – >160 mg/dl) (1.5 – 16 mmol/l)
	Leukocytes	POSITIVE / TRACE – 3+ / TRACE – LARGE (15 – 500 Leu/µl)
	Nitrite	POSITIVE / 1+ – 2+
	pH	7.5 – >8.5
	Protein	POSITIVE / 2+ – 4+ (100 – 1000 mg/dl) (1 – 10 g/l) (0.1 – 1 g/dl)
	Specific Gravity	1.005 – 1.02 RATIO
	Urobilinogen	POSITIVE (0.2 – >8 EU/dl) (3.2 – 131 µmol/l) (0.2 – >8 mg/dl)
Standard Diagnostics	hCG	POSITIVE
Standard Diagnostics Urocolor	Bilirubin	POSITIVE / 2+ – 3+ (1 – 3 mg/dl) (17 – 51 µmol/l)
	Blood	2+ – 3+ (50 – 250 Ery/µl)
	Glucose	+/- – 3+ (100 – >1000mg/dl) (5.5 – >55 mmol/l)
	Ketones	1+ – 3+ (10 – 100 mg/dl) (1 – 10 mmol/l)
	Leukocytes	1+ – 2+ (25 – 75 Leu/µl)
	Nitrite	POSITIVE
	pH	7 – >8.5
	Protein	1+ – 3+ (30 – 300 mg/dl) (0.3 – 3 g/l)
	Specific Gravity	1.005 – 1.01 RATIO
	Urobilinogen	+/- – 1+ (0.1 – 1 mg/dl) (1.6 – 16 µmol/l)

MANUFACTURER / METHOD	ANALYTE	RANGE
Teco Diagnostics	Albumin	POSITIVE
	Bilirubin	NEGATIVE – 1+ / NEG – SMALL
	Blood	2+ – 3+ / MODERATE – LARGE (60 – 200 Ery/µl)
	Glucose	1+ – 2+ (250 – 500 mg/dl) (14 – 28 mmol/l)
	Ketones	1+ – 3+ (15 – >80 mg/dl) (1.5 – >7.8 mmol/l) (0.15 – >0.8 g/l)
	Leukocytes	TRACE – 3+ / TRACE – LARGE (15 – 500 Leu/µl)
	Nitrite	POSITIVE
	pH	7 – >8.5
	Protein	1+ – 3+ (30 – >300 mg/dl) (0.3 – >3 g/l)
	Specific Gravity	1.01 – 1.025 RATIO
	Urobilinogen	2 – >8 EU/dl / 32 – 126 µmol/l / 2 – >8 mg/dl
True BioScience	hCG	POSITIVE
Uritest Medical	Bilirubin	1+ – 2+ (8.8 – 33 µmol/l)
	Blood	2+ – 3+ (80 – 200 Ery/µl)
	Glucose	1+ – 2+ (5.5 – 14 mmol/l)
	Ketones	1+ – 3+ (1.5 – 78 mmol/l)
	Leukocytes	1+ – 3+ (70 – 500 Leu/µl)
	Nitrite	POSITIVE
	pH	7.5 – >8.5
	Protein	2+ – 3+ (1 – 3 g/l)
	Specific Gravity	1.005 – 1.015 RATIO
	Urobilinogen	1+ – 3+ (33 – >131 µmol/l)
WH Accu Test hCG Pregnancy Test	hCG	POSITIVE
Wondfo hCG	hCG	POSITIVE
YD Diagnostics / Biosys / Genesis	Bilirubin	NEGATIVE – 1+ (NEG – 0.5 mg/dl) (NEG – 9 µmol/l)
	Blood	1+ – 3+ (10 – 250 Ery/µl)
	Glucose	1+ – 3+ (250 – >1000 mg/dl) (14 – >55 mmol/l)
	hCG	POSITIVE
	Ketones	1+ – 3+ (10 – 100 mg/dl) (1 – 10 mmol/l)
	Leukocytes	1+ – 3+ (25 – 500 Leu/µl)
	Nitrite	POSITIVE (>0.5 mg/dl)
	pH	7 – >8.5
	Protein	1+ – 3+ (30 – 300 mg/dl) (0.3 – 3 g/l)
	Specific Gravity	1.005 – 1.02 RATIO
	Urobilinogen	1+ – 3+ (1 – 8 mg/dl) (17 – 140 µmol/l)

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