

URINALYSIS CONTROL - LEVEL 2 (URNAL CONTROL 2)

CAT NO. UC5034**LOT NO.** 1158UC**SIZE:** 12 x 12 ml**EXPIRY:** 2022-10-28**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.

****Please note that due to the differences present between different dipstick manufacturers and the reactions involved, in some cases negative or normal (for Urobilinogen) readings may occur for certain analytes on some test strip/analyser combinations. In these instances, the Urinalysis control is not suitable for controlling that analyte.****

MANUFACTURER / METHOD	ANALYTE	RANGE
77 Elektronika kft	Bilirubin	TRACE – 2+ (0.5-3 mg/dl) (8.5-50 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	1.005 – 1.015 RATIO
	Urobilinogen	1+ – 3+ (35 – 140 µmol/l) (2 – 8 mg/dl) (2 – 8 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+ (10 – 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 – >8.5
	Protein	1+ – 3+ (30 – 300 mg/dl) (0.3 – 3 g/l)
	Specific Gravity	1.005 – 1.015 RATIO
	Urobilinogen	+/- – 2+ (0.2 – 2 mg/dl) (3.5 – 35 µmol/l) (0.2 – 2 EU/dl)
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)
	Leukocytes	1+ – 3+ (25 – 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+ – 4+ (2 – 12 mg/dl) (35 – 200 µmol/l)
Arkray / Menarini	Blood	1+ – 3+ / SMALL – LARGE ((0.01-0.1) – >1 mg/dl) ((20-30) – >300 Ery/µl) ((0.6-1) – >10 mg/l)
	Glucose	2+ – 4+ ((150-200) – >1000mg/dl) ((8.4-11.2) – >56 mmol/l) ((1.2-2) – >10 g/l)
	Ketones	1+ – 3+ ((10-20) – (60-80) mg/dl) ((1-2) – (6-8) mmol/l)
	Leukocytes	TRACE – MODERATE / 25 – 250 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	1.005 – 1.015 RATIO

MANUFACTURER / METHOD	ANALYTE	RANGE
DFI -Cybow	Blood	1+ – 3+ (10 – 250 Ery/ μ l)
	Glucose	+/- – 2+ (100 – 500 mg/dl) (5.5 – 28 mmol/l)
	Ketones	+/- – 2+ (5 – 40 mg/dl) (0.5 – 3.9 mmol/l)
	Leukocytes	1+ – 3+ (25 – 500 Leu/ μ 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
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 μ mol/l) (1 – >6 mg/dl)
	Blood	SMALL – LARGE / 1+ – 3+ (25 – 200 Ery/ μ l) (0.1 – 0.6 mg/dl)
	Glucose	2+ – 4+ (14 – >56 mmol/l) (250 – >1000 mg/dl) (2.5 – 10 g/l)
	Ketones	+/- – 2+ ((0.5-1.0) – (3.9-6.0) mmol/l) ((5-10) – (40-60)) mg/dl)
	Leukocytes	SMALL – LARGE / 1+ – 3+ (70 – 500 Leu/ μ 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
EKF Diagnostics QuPID / QuPID Plus	hCG	POSITIVE
Erba Lachema	Bilirubin	1+ – 3+ (17 – 103 μ mol/l) (1 – 6 mg/dl)
	Blood	1+ – 3+ ((5-10) – 250 Ery/ μ l)
	Glucose	2+ – 4+ (100 – 1000 mg/dl) (5.5 – 55 mmol/l)
	Ketones	+/- – 2+ (5 – (31-52) mg/dl) (0.5 – (3-5) mmol/l)
	Leukocytes	1+ – 3+ ((10-25) – 500 Leu/ μ 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
Human Combina	Albumin	30 – 150 mg/l
	Bilirubin	SMALL – LARGE / 1+ – 3+ (17 – 103 μ mol/l) (1 – 6 mg/dl)
	Blood	SMALL – LARGE / 1+ – 3+ ((5-10) – (200-300) Ery/ μ l)
	Creatinine	(8.8 – 26.5 mmol/l) (100 – 300 mg/dl)
	Glucose	+/- – 2+ ((5.5-8.3) – 28 mmol/l) ((100-150) – 500 mg/dl)
	Ketones	+/- – 2+ (5 – 40 mg/dl) (0.5 – 4 mmol/l)
	Leucocytes	SMALL – LARGE / 1+ – 3+ ((10-25) – 500 Leu/ μ 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
IND Diagnostic hCG	hCG	POSITIVE

MANUFACTURER / METHOD	ANALYTE	RANGE
Iris Velocity	Blood	1+ – 3+ ((0.06-0.1) – >1 mg/dl) (1 – >10 mg/dl) (25 – 300 Ery/ μ l)
	Glucose	1+ – 3+ (50 – 500 mg/dl) (2.8 – 28 mmol/l) (0.05 – 0.5 g/l)
	Ketones	1+ – 3+ (10 – (60-80) mg/dl) (1 – (6-8) mmol/l)
	Leukocytes	1+ – 3+ (75 – 500 Leu/ μ l)
	Nitrite	POSITIVE
	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 μ mol/l)
LifeSign BioSign hCG	hCG	POSITIVE
Nova Century Scientific	hCG	POSITIVE
Quidel Quickvue / Rapidvue	hCG	POSITIVE
Roche Cobas U411 / Uriscys 1100 / 1800 / Miditron	Bilirubin	1+ – 3+ (1 – 6 mg/dl) (17 – 100 μ mol/l)
	Blood	3+ – 5+ (50 – 250 Ery/ μ l)
	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/ μ l)
	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 μ mol/l)
Roche Cobas U601/ Uriscys 2400	Bilirubin	1+ – 3+ (1 – 6 mg/dl) (17 – 100 μ mol/l)
	Blood	3+ – 5+ (50 – 250 Ery/ μ l)
	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/ μ l)
	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 μ mol/l)
Roche Combur	Bilirubin	1+ – 3+ (1 – 6 mg/dl) (17 – 100 μ mol/l)
	Blood	2+ – 4+ (25 – 250 Ery/ μ l) (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/ μ 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
Siemens Clinitek Microalbumin	Albumin	(3 – 15 mg/dl) (30 – 150 mg/l) (20.8 – 103.5 mmol/l)

MANUFACTURER / METHOD	ANALYTE	RANGE
Siemens Clinitek Novus	Albumin	30 – 150 mg/l
	Blood	SMALL – LARGE / 1+ – 3+ (25 – 200 Ery/ μ l) (0.1 – 0.8 mg/dl)
	Creatinine	(0.9 – 8.8 mmol/l) (10 – 100 mg/dl)
	Glucose	1+ – 4+ (100 – >1000 mg/dl) (5.5 – >55 mmol/l)
	Ketones	TRACE – 2+ (TRACE – 40 mg/dl) (TRACE – 3.9 mmol/l)
	Leukocytes	SMALL – LARGE / 1+ – 3+ (70 – 500 Leu/ μ 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
	Urobilinogen	(3.2 – 33 μ mol/l) (0.2 – 2 EU/dl) (0.2 – 2 mg/dl)
Siemens Clinitest hCG	hCG	POSITIVE
Siemens Multistix	Bilirubin	SMALL – LARGE / 1+ – 3+
	Blood	SMALL – LARGE / 1+ – 3+ (25 – 200 Ery/ μ l) (800 – 6000 μ g/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 – MODERATE (5 – 40 mg/dl) (0.05 – 0.4 g/l)
	Leukocytes	TRACE – 3+ / TRACE – LARGE (15 – 500 Leu/ μ 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 – 1.015 RATIO
Standard Diagnostics	hCG	POSITIVE
Sysmex Meditape UC 9A & 11A	Blood	1+ – 3+ (20 – 250 Ery/ μ l) (0.06 – 0.75 mg/dl)
	Creatinine	(10 – 100 mg/dl) (0.1 – 1 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/ μ 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 μ mol/l)
Sysmex Meditape UC 10S & 12S	Blood	1+ – 3+ (20 – 250 Ery/ μ 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)
	Leukocytes	1+ – 3+ (25 – 500 Leu/ μ 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 μ mol/l)

MANUFACTURER / METHOD	ANALYTE	RANGE
Urit Medical Electronic	Blood	1+ – 3+ (25 – >200 Ery/ μ l)
	Glucose	1+ – 3+ (100 – 500 mg/dl) (5.5 – 28 mmol/l)
	Ketones	+/- – 2+ (5 – 40 mg/dl) (0.5 – 4 mmol/l)
	Leukocytes	1+ – 3+ (15 – 500 Leu/ μ l)
	pH	7 – 8
	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) (33 – >131 μ 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/ μ 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 – 50mg/dl) (0.5 – 5 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
	Urobilinogen	1+ – 3+ (1 – 8 mg/dl) (17 – 140 μ mol/l)

EC REP

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