

URINALYSIS CONTROL - LEVEL 2 (URNAL CONTROL 2)

CAT NO. UC5034**LOT NO.** 1135UC**SIZE:** 12 x 12 ml**EXPIRY:** 2022-05-28**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+ (30 – (300-500) mg/dl) (0.3 – (3-5) g/l)	
	Specific Gravity	1 – 1.02 RATIO	
	Urobilinogen	1+ – 4+ (35 – 200 µmol/l) (2 – 12 mg/dl) (2 – 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	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	7.5 – >8.5	
	Protein	1+ – 3+ (30 – 500 mg/dl) (0.3 – 5 g/l)	
	Specific Gravity	1 – 1.01 RATIO	
Urobilinogen	Urobilinogen	1+ – 4+ (2 – 12 mg/dl) (35 – 200 µmol/l)	
	Arkray / Menarini	Blood	1+ – 3+ / SMALL – LARGE ((0.06-0.1) – >1 mg/dl) ((20-30) – >300 Ery/µl) ((0.6-1) – >10 mg/l)
		Glucose	2+ – 4+ ((1.2-2) – >10 g/l) ((150-200) – >1000 mg/dl) ((8.4-11.2) – >56 mmol/l)
		Ketones	1+ – 3+ ((10-20) – (60-80) mg/dl) ((1-2) – (6-8) mmol/l)
		Leukocytes	TRACE – MOD (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	
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
DIAsource, RIA	Albumin	0.03 – 0.15 g/l / 3 – 15 mg/dl / 30 – 150 mg/l
	pH	6 – >8.5
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	1+ – 4+ (5.6 – >56 mmol/l) (100 – >1000 mg/dl) (1 – 10 g/l)
	Ketones	+/- – 2+ ((0.5-1.0) – (3.9-6.0) mmol/l) ((5-10) – (40-60) mg/dl)
	Leucocytes	+/- – 2+ / TRACE – MOD (15 – 125 Leu/µl)
	Nitrite	POSITIVE
	Protein	+/- – 3+ (TRACE – 3 g/l) (TRACE – 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/l
	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) ((20-40) – >300 Ery/µl) (1 – >10 mg/l)
	Glucose	1+ – 3+ (50 – 500 mg/dl) (2.8 – 28 mmol/l) (0.05 – 0.5 g/dl)
	Ketones	1+ – 4+ (10 – >150 mg/dl) (1 – 15 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	hCG	POSITIVE
Roche Cobas u60/Urisys 2400	Specific Gravity	1.005 – 1.02 RATIO
Roche Cobas u411/Urisys 1100/1800/Miditron	Specific Gravity	1.005 – 1.02 RATIO

MANUFACTURER / METHOD	ANALYTE	RANGE
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) (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	1.005 – 1.02 RATIO
	Urobilinogen	1+ – 3+ (1 – 8 mg/dl) (17 – 135 µmol/l) (1 – 8 EU/dl)
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)
	Urobilinogen	1+ – 3+ (17 – 135 µmol/l) (1 – 8 mg/dl) (1 – 8 EU/dl)
	Roche Urisys 1100/1800/2400	Bilirubin
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)
Urobilinogen		1+ – 3+ (17 – 135 µmol/l) (1 – 8 mg/dl)
Siemens Clinitek Novus		Albumin
	Blood	1+ – 3+ / SMALL – LARGE (25 – 200 Ery/µl) (0.1 – 0.8 mg/dl)
	Creatinine	0.9 – 8.8mmol/l / 10 – 100 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	1+ – 3+ / SMALL – LARGE (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
Urobilinogen	3.2 – 33 µmol/l / 0.2 – 2 EU/dl / 0.2 – 2 mg/dl	
Siemens Clinitest hCG	hCG	POSITIVE
Siemens/Bayer Clinitek Microalbumin	Albumin	3 – 15 mg/dl / 30 – 150 mg/l / 20.8 – 103.5 mmol/l

MANUFACTURER / METHOD	ANALYTE	RANGE
Siemens Multistix	Bilirubin	1+ – 3+ / SMALL – LARGE
	Blood	1+ – 3+ / SMALL – LARGE (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 – MOD (0.5 – 4 mmol/l) (5 – 40 mg/dl) (0.05 – 0.4 g/l)
	Leucocytes	TRACE – 2+ / TRACE – MOD (15 – 125 Leu/ μ l)
	Nitrite	POSITIVE / 1+ – 2+
	pH	7.5 – >8.5
	Protein	1+ – 3+ (0.3 – 3 g/l) (0.03 – 0.3 g/dl) (30 – 300 mg/dl)
	Specific Gravity	1.005 – 1.015 RATIO
Systemx Meditape UC Series Tests	Blood	1+ – 3+ (20 – 250 Ery/ μ 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)
	Leucocytes	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)
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)
	Leucocytes	+/- – 2+ (15 – 70 Leu/ μ 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 μ mol/l)
WH Accu Test hCG Pregnancy Test	hCG	POSITIVE
YD Diagnostics / Biosys / Genesis	Blood	1+ – 3+ (10 – 250 Ery/ μ 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
	Urobilinogen	1+ – 3+ (1 – 8 mg/dl) (17 – 140 μ mol/l)

EC REP

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

16 Apr '21 ne

THIS PAGE IS INTENTIONALLY BLANK