

URINALYSIS CONTROL - LEVEL 2 (URNAL CONTROL 2)

CAT NO. UC5034 **LOT NO.** 1259UC
SIZE: 12 x 12 ml **EXPIRY:** 2024-05-28
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+ ((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 – 1.015 RATIO
	Urobilinogen	2+ – 4+ (70 – 200 µmol/l) (4 – 12 mg/dl) (4 – 12 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+ (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)
	Leukocytes	+/- – 3+ (15-500 Leu/µl)
	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
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	1+ – 3+ (25 – 300 mg/dl) (2.5 – 30 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	2+ – 4+ (4 – 12 mg/dl) (70 – 200 µmol/l)
Arkray/Menrini	Blood	1+ – 3+ (SMALL – LARGE) ((20-30) – >300 Ery/µl) ((0.06-0.1) – >1 mg/dl) ((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	SMALL – LARGE (25 – 500 Leu/µl)
	Nitrite	POSITIVE (1+ – 2+)
	pH	7.5 – >8.5
	Protein	1+ – 3+ ((0.3-0.7) – (2.5 – 4) g/l) ((30-70) – (250-400) mg/dl)
	Specific Gravity	1.005-1.015 RATIO
	Urobilinogen	1+ – 3+ ((2-3) – (8-10) EU/dl) ((2-3) – (8-10) mg/dl) ((32-48) – (128-160) µmol/l)
CTK Biotech Onsite hCG	hCG	POSITIVE

MANUFACTURER / METHOD	ANALYTE	RANGE
DFI -Cybow	Bilirubin	1+ – 3+
	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 – 1.02 RATIO
Dirui H Series-	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	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)
	Leukocytes	TRACE – LARGE / +/- – 3+ (15 – 500 Leu/ μ l)
	Nitrite	POSITIVE
	pH	7 – >8.5
	Protein	1+ – 3+ (0.3 – 3 g/l) (30 – 300 mg/dl)
	Specific Gravity	1.005 – 1.015 RATIO
EKF Diagnostics QuPID / QuPID Plus	hCG	POSITIVE
Erba Lachema	Blood	1+ – 3+ ((5-10) – 250 Ery/ μ l)
	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+ ((10-15) – 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/dl) (0.03 – 0.15 g/l)
	Creatinine	(4.4 – 17.7 mmol/l) (50 – 200 mg/dl)
Human Rapid Pregnancy Tests	hCG	POSITIVE
IND Diagnostic hCG	hCG	POSITIVE
Iris Velocity	Blood	1+ – 3+ (25 – 300 Ery/ μ l) ((0.06-0.1) – >1.0 mg/dl) (1 – >10 mg/l)
	Glucose	2+ – 4+(0.1 – >1 g/dl) (100 – >1000 mg/dl) (5.6 – >56 mmol/l)
	Ketones	1+ – 3+ (10 – (60-80) mg/dl) (1 – (6-8) mmol/l)
	Leukocytes	1+ – 3+ (75 – 500 Leu/ μ l)
	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 μ mol/l)

MANUFACTURER / METHOD	ANALYTE	RANGE
Mindray	Bilirubin	1+ – 3+ (1 – 4 mg/dl) (17 – 70 μ mol/l)
	Blood	1+ – 3+ (50 – (250-300) Ery/ μ l)
	Glucose	+/- – 2+ (100 – 500 mg/dl) (6 – 30 mmol/l)

	Ketones	+/- - 2+ (5 – 40 mg/dl) (0.5 – 4 mmol/l)
	Nitrite	POSITIVE
	pH	7.5 - >8.5
	Protein	2+ - 4+ (1 - 20 g/l) (100 - 2000 mg/dl)
	Specific Gravity	1.005 – 1.015 RATIO
Nova Century Scientific	hCG	POSITIVE
Quidel Quickvue / Rapidvue	hCG	POSITIVE
Roche Cobas U601/ Urisys 2400	Bilirubin	1+ – 3+ (1 – 6 mg/dl) (17 – 100 µmol/l)
	Blood	3+ – 5+ (50 – 250 Ery/µl)
	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/µl)
	Nitrite	POSITIVE
	pH	7.5 – >8.5
	Protein	2+ – 4+ (75 – 500 mg/dl) (0.75 – 5 g/l)
	Specific Gravity	1.01 – 1.02 RATIO
	Urobilinogen	2+ – 4+ (4 - 12 mg/dl) (68 – 203 µmol/l)
Roche Cobas U411 / Urisys 1100 / 1800 / Miditron	Bilirubin	1+ – 3+ (1 – 6 mg/dl) (17 – 100 µmol/l)
	Blood	2+ – 5+ (25 – 250 Ery/µl)
	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/µl)
	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	2+ – 4+ (4 - 12 mg/dl) (70 – 203 µmol/l)
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 – 1.01 RATIO
	Urobilinogen	1+ – 3+ (1 – 8 mg/dl) (1 – 8 EU/dl) (17 – 135 µmol/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+ (5.5 – >55 mmol/l) (100 – >1000 mg/dl)
	Ketones	TRACE – 2+ (TRACE – 3.9 mmol/l) (TRACE – 40 mg/dl)
	Leukocytes	SMALL – LARGE / 1+ – 3+ (70 – 500 Leu/ μ l)
	Nitrite	POSITIVE
	pH	7.5 – >8.5
	Protein	2+ – 4+ (1 – >10 g/l) (100 – >1000 mg/dl)
	Specific Gravity	1.01 – 1.02 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 – LARGE / TRACE – 3+ (5 – 80 mg/dl) (0.5 – 8 mmol/l) (0.05 – 0.8 g/l)
	Leukocytes	TRACE – LARGE / TRACE – 3+ (15 – 500 Leu/ μ l)
	Nitrite	POSITIVE
	pH	7.5 – >8.5
	Protein	1+ – 4+ (0.03-1 g/dl) (0.3 - 10 g/l) (30 – 1000 mg/dl)
	Specific Gravity	1.005 – 1.015 RATIO
	Urobilinogen	(0.2 – 2 EU/dl) (0.2 – 2 mg/dl) (3.2 - 33 μ mol/l)
Sysmex Mediatpe UC 9A & 11A	Albumin	(30 – 150 mg/l) (0.03 – 0.15 g/l)
	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)
	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 Mediatpe UC 10S & 12S	Blood	1+ – 3+ (20 – 250 Ery/ μ l) (0.6 – 7.5 mg/l) (0.06-0.75mg/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)
	Leucocytes	1+ – 3+ (25 – 500 Leu/ μ l)
	Nitrite	POSITIVE (0.1 – 0.3 mg/dl)
	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)
	Leucocytes	1+ – 3+ (15 – 500 Leu/ μ l)
	pH	7 – >8.5
	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	Albumin	1+ – 3+ (30 – 150 mg/l)
	Blood	1+ – 3+ (50 – 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 – 50 mg/dl) (0.5 – 5 mmol/l)
	Nitrite	POSITIVE (>0.5 mg/dl)
	pH	7.5 – >8.5
	Protein	1+ – 3+ (30 – 300 mg/dl) (0.3 – 3 g/l)
	Specific Gravity	1 – 1.01 RATIO
	Urobilinogen	2+ – 4+ (4 – 12 mg/dl) (70 – 200 μ mol/l)

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