

URINALYSIS CONTROL - LEVEL I (URNAL CONTROL I)

Cat. No. UC5033 **Lot No.** 788UC
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.

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 I 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	NEGATIVE
	Bilirubin	NEGATIVE
	Blood	NEGATIVE
	Glucose	NEGATIVE – NORMAL
	Ketones	NEGATIVE
	Leukocytes	NEGATIVE
	Nitrite	NEGATIVE
	pH	5.5 – 7
	Protein	NEGATIVE
	Specific Gravity	1.01 – 1.03 RATIO
	Urobilinogen	NEGATIVE / NORMAL
Abon hCG One Step Ultra	hCG	NEGATIVE
Acon Laboratories	Bilirubin	NEGATIVE
	Blood	NEGATIVE
	Glucose	NEGATIVE
	hCG	NEGATIVE
	Ketones	NEGATIVE
	Leukocytes	NEGATIVE
	Nitrite	NEGATIVE
	pH	5.5 – 7.5
	Protein	NEGATIVE
	Specific Gravity	1.01 – 1.03 RATIO
	Urobilinogen	NEG – 0.2 mg/dl / NEG – 0.2 EU/dl / NEG – 3.5 µmol/l
Alere hCG Cassette	hCG	NEGATIVE
Analyticon Combiscreen	Bilirubin	NEGATIVE
	Blood	NEGATIVE
	Glucose	NEGATIVE – NORMAL
	hCG	NEGATIVE
	Ketones	NEGATIVE
	Leukocytes	NEGATIVE
	Nitrite	NEGATIVE
	pH	5.5 – 7.5
	Protein	NEGATIVE
	Specific Gravity	1.02 – 1.03 RATIO
	Urobilinogen	NORMAL
Arkray / Menarini	Albumin	NEGATIVE
	Bilirubin	NEGATIVE
	Blood	NEGATIVE
	Glucose	NEGATIVE / NORMAL (0 – 0.1 g/l) (0 – 10 mg/dl) (0 – 0.6 mmol/l)
	Ketones	NEGATIVE
	Leukocytes	NEGATIVE
	Nitrite	NEGATIVE
	pH	6 – 7
	Protein	NEGATIVE
	Specific Gravity	1.015 – 1.03 RATIO
	Urobilinogen	+/- / NORMAL / 0.2 – 1 mg/dl / 0.2 – 1 EU/dl / 3.2 – 16 µmol/l
Bio Chemical Technology Co Ltd	hCG	NEGATIVE

MANUFACTURER / METHOD	ANALYTE	RANGE
BioMaxima BM Uri Strip	Bilirubin	NEGATIVE
	Blood	NEGATIVE
	Glucose	NEGATIVE
	Ketones	NEGATIVE
	Leukocytes	NEGATIVE
	Nitrite	NEGATIVE
	pH	5.5 – 6.5
	Protein	NEGATIVE – +/- / NEG – 0.15 g/l / NEG – 15 mg/dl
	Specific Gravity	1.02 – 1.03 RATIO
	Urobilinogen	NORMAL
Biomerieux	hCG	NEGATIVE
CTK Biotech Onsite hCG	hCG	NEGATIVE
DFI - Cybow	Bilirubin	NEGATIVE
	Blood	NEGATIVE
	Glucose	NEGATIVE
	Ketones	NEGATIVE
	Leukocytes	NEGATIVE
	Nitrite	NEGATIVE
	pH	5.5 – 6.5
	Protein	NEGATIVE – TRACE
	Specific Gravity	1.02 – 1.03 RATIO
	Urobilinogen	NORMAL / 0.1 mg/dl / 0.1 EU/dl / 1.6 µmol/l
Dirui H Series	Albumin	NEGATIVE
	Bilirubin	NEGATIVE
	Blood	NEGATIVE
	Glucose	NEGATIVE
	Ketones	NEGATIVE
	Leukocytes	NEGATIVE
	Nitrite	NEGATIVE
	pH	5.5 – 7
	Protein	NEGATIVE
	Specific Gravity	1.015 – 1.03 RATIO
	Urobilinogen	+/- / NORMAL / 3.4 – 17 µmol/l
Dutch Diagnostics Uri-Screen	Blood	NEGATIVE
	Glucose	NEGATIVE
	Leukocytes	NEGATIVE
	Nitrite	NEGATIVE
	pH	6 – 8
	Specific Gravity	1 – 1.02 RATIO
Erba Lachema	Bilirubin	NEGATIVE
	Blood	NEGATIVE
	Glucose	NEGATIVE
	Ketones	NEGATIVE
	Leukocytes	NEGATIVE
	Nitrite	NEGATIVE
	pH	5 – 6.5
	Protein	NEGATIVE
	Specific Gravity	1.02 – 1.03 RATIO
	Urobilinogen	NORMAL

MANUFACTURER / METHOD	ANALYTE	RANGE
Erba Mannheim Uro-Dip	Bilirubin	NEGATIVE
	Blood	NEGATIVE
	Glucose	NEGATIVE
	Ketones	NEGATIVE
	Leukocytes	NEGATIVE
	Nitrite	NEGATIVE
	pH	5.5 – 6.5
	Protein	NEGATIVE
	Specific Gravity	1.02 – 1.03 RATIO
	Urobilinogen	NORMAL
Gabmed beta 10 hCG Cassette	hCG	NEGATIVE
Greats Medtech hCG Strip	hCG	NEGATIVE
Hangzhou Clongene hCG Test	hCG	NEGATIVE
Human Combina	Bilirubin	NEGATIVE
	Blood	NEGATIVE
	Glucose	NEGATIVE
	Ketones	NEGATIVE
	Leukocytes	NEGATIVE
	Nitrite	NEGATIVE
	pH	5.5 – 6.5
	Protein	NEGATIVE
	Specific Gravity	1.02 – 1.03 RATIO
	Urobilinogen	NORMAL
Human Rapid Pregnancy Tests	hCG	NEGATIVE
IND Diagnostic hCG	hCG	NEGATIVE
Innovacon hCG Pregnancy Test	hCG	NEGATIVE
Iris Velocity	Bilirubin	NEGATIVE
	Blood	NEGATIVE
	Glucose	NEGATIVE
	Ketones	NEGATIVE
	Leukocytes	NEGATIVE
	Nitrite	NEGATIVE
	pH	5 – 7
	Protein	NEGATIVE
	Specific Gravity	1.01 – 1.03 RATIO
	Urobilinogen	NORMAL

MANUFACTURER / METHOD	ANALYTE	RANGE
Macherey-Nagel	Bilirubin	NEGATIVE
	Blood	NEGATIVE
	Glucose	NEGATIVE
	Ketones	NEGATIVE
	Leukocytes	NEGATIVE
	Nitrite	NEGATIVE
	pH	5.5 – 6.5
	Protein	NEG – 0.3 g/l / NEG – 30 mg/dl
	Specific Gravity	1.015 – 1.03 RATIO
	Urobilinogen	0 – 1 mg/dl / 0 – 17 µmol/l
Menarini	Bilirubin	NEGATIVE
	Blood	NEGATIVE
	Glucose	NEGATIVE
	Ketones	NEGATIVE
	Leukocytes	NEGATIVE
	Nitrite	NEGATIVE
	pH	5.5 – 6.5
	Protein	NEGATIVE
	Specific Gravity	1.015 – 1.025 RATIO
	Urobilinogen	+/- / 0.2 – 1 mg/dl
Nal von Minden Nadal hCG	hCG	NEGATIVE
Neopharma Sensatest	hCG	NEGATIVE
Nova Century Scientific	hCG	NEGATIVE
Quidel Quickvue / Rapidvue	hCG	NEGATIVE
Randox One-Step	hCG	NEGATIVE
Roche Combur	Albumin	NEGATIVE
	Bilirubin	NEGATIVE
	Blood	NEGATIVE
	Glucose	NEGATIVE – NORMAL
	Ketones	NEGATIVE
	Leukocytes	NEGATIVE
	Nitrite	NEGATIVE
	pH	5 – 7
	Protein	NEGATIVE
	Specific Gravity	1.01 – 1.02 RATIO
	Urobilinogen	NORMAL / 0.2 EU/dl
Roche Mditron/u411/u601	Bilirubin	NEGATIVE
	Blood	NEGATIVE
	Glucose	NORMAL
	Ketones	NEGATIVE
	Leukocytes	NEGATIVE
	Nitrite	NEGATIVE
	pH	5 – 6.5
	Protein	NEGATIVE
	Specific Gravity	1.01 – 1.025 RATIO
	Urobilinogen	NEGATIVE – NORMAL

MANUFACTURER / METHOD	ANALYTE	RANGE
Roche Urisys 1100/1800/2400	Bilirubin	NEGATIVE
	Blood	NEGATIVE
	Glucose	NEGATIVE – NORMAL
	Ketones	NEGATIVE
	Leukocytes	NEGATIVE
	Nitrite	NEGATIVE
	pH	5 – 7.5
	Protein	NEGATIVE
	Specific Gravity	1.015 – 1.025 RATIO
	Urobilinogen	NEGATIVE - NORMAL
Siemens/Bayer Clinitek	Albumin	1 – 3 mg/dl / 6.9 – 20.8 mmol/l / 10 – 30 mg/l
	Creatinine	4.4 – 17.7 mmol/l / 50 – 200 mg/dl
Siemens Multistix	Albumin	NEGATIVE
	Bilirubin	NEGATIVE
	Blood	NEGATIVE
	Creatinine	4.4 – 17.7 mmol/l / 50 – 200 mg/dl
	Glucose	NEGATIVE
	Ketones	NEGATIVE
	Leukocytes	NEGATIVE
	Nitrite	NEGATIVE
	pH	5.5 – 7
	Protein	NEGATIVE
	Specific Gravity	1.02 – >1.03 RATIO
	Urobilinogen	NEGATIVE / 3.2 µmol/l / 0.2 EU/dl / 0.2 mg/dl
Standard Diagnostics	hCG	NEGATIVE
Standard Diagnostics Urocolor	Bilirubin	NEGATIVE
	Blood	NEGATIVE
	Glucose	NEGATIVE
	Ketones	NEGATIVE
	Leukocytes	NEGATIVE
	Nitrite	NEGATIVE
	pH	5 – 6.5
	Protein	NEGATIVE
	Specific Gravity	1.02 – 1.03 RATIO
	Urobilinogen	+/- / 0.1 – 1 mg/dl / 1.6 µmol/l
Teco Diagnostics	Bilirubin	NEGATIVE
	Blood	NEGATIVE
	Glucose	NEGATIVE
	Ketones	NEGATIVE
	Leukocytes	NEGATIVE
	Nitrite	NEGATIVE
	pH	5 – 6.5
	Protein	NEGATIVE
	Specific Gravity	1.02 – 1.03 RATIO
	Urobilinogen	3.2 µmol/l / 0.2 EU/dl / 0.2 mg/dl
True BioScience	hCG	NEGATIVE

MANUFACTURER / METHOD	ANALYTE	RANGE
Uritest Medical	Bilirubin	NEGATIVE
	Blood	NEGATIVE
	Glucose	NEGATIVE
	Ketones	NEGATIVE
	Leukocytes	NEGATIVE
	Nitrite	NEGATIVE
	pH	5.5 – 6.5
	Protein	NEGATIVE – +/- / 0 – 0.15 g/l
	Specific Gravity	1.02 – 1.03 RATIO
	Urobilinogen	NEGATIVE
WH Accu Test hCG Pregnancy Test	hCG	NEGATIVE
Wondfo hCG	hCG	NEGATIVE
YD Diagnostics / Biosys / Genesis	Bilirubin	NEGATIVE
	Blood	NEGATIVE
	Glucose	NEGATIVE
	hCG	NEGATIVE
	Ketones	NEGATIVE
	Leukocytes	NEGATIVE
	Nitrite	NEGATIVE
	pH	5 – 6
	Protein	NEGATIVE – TRACE / NEG – 0.1 g/l / NEG – 10 mg/dl
	Specific Gravity	1.02 – 1.03 RATIO
	Urobilinogen	+/- / NORMAL / 0.1 mg/dl / 1.7 µmol/l

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