

URINALYSIS CONTROL - LEVEL 1 (URNAL CONTROL I)

CAT. NO.	UC5033	LOT NO.	I310UC
SIZE	12 x 12 ml	EXPIRY:	2024-10-28
GTIN:	05055273207583		

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 1 12 x 12 ml

ASSIGNED VALUES

Due to the variation caused by test equipment, test reagents and laboratory technique, the quoted ranges are provided for guidance. It is recommended that these ranges are used until each laboratory has established its own ranges, based on individual laboratory requirements.

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	NEGATIVE
	Blood	NEGATIVE
	Ketones	NEGATIVE
	Leukocytes	NEGATIVE
	Nitrite	NEGATIVE
	pH	<5 – 6
	Protein	NEGATIVE
	Specific Gravity	1.02-1.03 RATIO
	Urobilinogen	NORMAL
Abbott IMx (intact hCG)	hCG	NEGATIVE
Abon hCG One Step Ultra	hCG	NEGATIVE
Acon Mission	Bilirubin	NEGATIVE
	Blood	NEGATIVE
	Glucose	NEGATIVE
	Ketones	NEGATIVE
	Leukocytes	NEGATIVE
	Nitrite	NEGATIVE
	pH	<5 – 6
	Protein	NEGATIVE
	Specific Gravity	1.02-1.03 RATIO
Analyticon Combiscreen	Bilirubin	NEGATIVE
	Blood	NEGATIVE
	Ketones	NEGATIVE
	Leukocytes	NEGATIVE
	Nitrite	NEGATIVE
	pH	<5 – 6
	Protein	NEGATIVE
	Specific Gravity	1.02-1.03 RATIO
	Urobilinogen	NORMAL
Arkray / Menarini	Bilirubin	NEGATIVE
	Blood	NEGATIVE
	Ketones	NEGATIVE
	Leukocytes	NEGATIVE
	Nitrite	NEGATIVE
	pH	<5 – 6
	Protein	NEGATIVE
	Specific Gravity	1.02 – 1.03 RATIO
	Urobilinogen	NORMAL (0.2 – 1 mg/dl) (3.2 – 16 µmol/l) (0.2 – 1 EU/dl)
DFI - Cybow	Bilirubin	NEGATIVE
	Blood	NEGATIVE
	Glucose	NEGATIVE
	Ketones	NEGATIVE
	Leukocytes	NEGATIVE
	Nitrite	NEGATIVE
	pH	<5 – 6
	Protein	NEGATIVE
	Specific Gravity	1.02 – 1.03 RATIO
	Urobilinogen	NORMAL (0.1 – 1 mg/dl) (1.6 – 16) µmol/l) (0.1 – 1 EU/dl)

MANUFACTURER / METHOD	ANALYTE	RANGE
Dirui H Series	Albumin	NEGATIVE
	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 / +/- / 3.4 – 17 µmol/l / 0.2mg/dl
EKF Diagnostics QuPID / QuPID Plus	hCG	NEGATIVE
Erba Lachema	Bilirubin	NEGATIVE
	Blood	NEGATIVE
	Glucose	NEGATIVE
	Ketones	NEGATIVE
	Leukocytes	NEGATIVE
	Nitrite	NEGATIVE
	pH	<5 – 6
	Protein	NEGATIVE
	Specific Gravity	1.02 – 1.03 RATIO
	Urobilinogen	NORMAL
IND Diagnostic hCG	hCG	NEGATIVE
Iris Velocity	Bilirubin	NEGATIVE
	Blood	NEGATIVE
	Glucose	NEGATIVE
	Ketones	NEGATIVE
	Leukocytes	NEGATIVE
	Nitrite	NEGATIVE
	pH	<5 – 6
	Protein	NEGATIVE
	Specific Gravity	1.015 – 1.025 RATIO
	Urobilinogen	NORMAL
LifeSign BioSign hCG	hCG	NEGATIVE
Mindray	Bilirubin	NEGATIVE
	Blood	NEGATIVE
	Glucose	NEGATIVE
	Ketones	NEGATIVE
	Leukocytes	NEGATIVE
	Nitrite	NEGATIVE
	pH	<5 – 6
	Protein	NEGATIVE
	Specific Gravity	1.02-1.03 RATIO
	Urobilinogen	NORMAL / 0.2 mg/dl / 3.2 µmol/l
Nova Century Scientific	hCG	NEGATIVE

MANUFACTURER / METHOD	ANALYTE	RANGE
Roche Cobas U601 / Urisys 2400	Bilirubin	NEGATIVE
	Blood	NEGATIVE
	Ketones	NEGATIVE
	Leukocytes	NEGATIVE
	Nitrite	NEGATIVE
	pH	<5 – 6
	Protein	NEGATIVE
	Specific Gravity	1.015-1.025 RATIO
	Urobilinogen	NEGATIVE / NORMAL
Roche Cobas U411 / Urisys I 100/1800/Miditron	Bilirubin	NEGATIVE
	Blood	NEGATIVE
	Ketones	NEGATIVE
	Leukocytes	NEGATIVE
	Nitrite	NEGATIVE
	pH	<5 – 6
	Protein	NEGATIVE
	Specific Gravity	1.015-1.025 RATIO
	Urobilinogen	NEGATIVE / NORMAL
Roche Combur	Bilirubin	NEGATIVE
	Blood	NEGATIVE
	Glucose	NEGATIVE
	Ketones	NEGATIVE
	Leukocytes	NEGATIVE
	Nitrite	NEGATIVE
	pH	<5 – 6
	Protein	NEGATIVE
	Specific Gravity	1.01-1.02 RATIO
	Urobilinogen	NORMAL
Siemens Clinitek Novus	Bilirubin	NEGATIVE
	Blood	NEGATIVE
	Glucose	NEGATIVE
	Ketones	NEGATIVE
	Leukocytes	NEGATIVE
	Nitrite	NEGATIVE
	pH	<5 – 6
	Protein	NEGATIVE
	Specific Gravity	1.02 - >1.03 RATIO
	Urobilinogen	3.2 µmol/l / 0.2 EU/dl / 0.2 mg/dl
Siemens Clinitest hCG	hCG	NEGATIVE
Siemens Multistix	Bilirubin	NEGATIVE
	Blood	NEGATIVE
	Glucose	NEGATIVE
	Ketones	NEGATIVE
	Leukocytes	NEGATIVE
	Nitrite	NEGATIVE
	pH	<5 – 6
	Protein	NEGATIVE
	Specific Gravity	1.02 - >1.03 RATIO
	Urobilinogen	3.2 µmol/l / 0.2 EU/dl / 0.2 mg/dl

MANUFACTURER / METHOD	ANALYTE	RANGE
Sysmex Meditape UC 10S & 12S	Bilirubin	NEGATIVE
	Blood	NEGATIVE
	Glucose	NEGATIVE
	Ketones	NEGATIVE
	Leukocytes	NEGATIVE
	Nitrite	NEGATIVE
	pH	<5 – 6
	Protein	NEGATIVE
	Specific Gravity	1.02 – 1.03 RATIO
	Urobilinogen	NORMAL
Sysmex Meditape UC 9A & 11A	Bilirubin	NEGATIVE
	Blood	NEGATIVE
	Glucose	NEGATIVE
	Ketones	NEGATIVE
	Leukocytes	NEGATIVE
	Nitrite	NEGATIVE
	pH	<5 – 6
	Protein	NEGATIVE
	Specific Gravity	1.02 - 1.03 RATIO
	Urobilinogen	NORMAL
Urit Medical Electronic	Bilirubin	NEGATIVE
	Blood	NEGATIVE
	Glucose	NEGATIVE
	Ketones	NEGATIVE
	Leukocytes	NEGATIVE
	Nitrite	NEGATIVE
	pH	<5 – 6
	Protein	NEGATIVE
	Specific Gravity	1.015 - 1.025 RATIO
	Urobilinogen	NORMAL
YD Diagnostics / Biosys / Genesis	Bilirubin	NEGATIVE
	Blood	NEGATIVE
	Glucose	NEGATIVE
	Ketones	NEGATIVE
	Leukocytes	NEGATIVE
	Nitrite	NEGATIVE (0.00 – 0.04 mg/dl)
	pH	<5 – 6
	Protein	NEGATIVE
	Specific Gravity	1.02 - 1.03 RATIO
	Urobilinogen	NORMAL / +/- / 0.1 mg/dl / 1.7 µmol/l

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