

## **URINALYSIS CONTROL - LEVEL I (URNAL CONTROL I)**

**CAT. NO.** UC5033**LOT NO.** 1109UC**SIZE:** 12 x 12 ml**EXPIRY:** 2021-09-28**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 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	Bilirubin	NEGATIVE
	Blood	NEGATIVE
	Glucose	NEGATIVE – NORMAL
	Ketones	NEGATIVE
	Leucocytes	NEGATIVE
	Nitrite	NEGATIVE
	pH	<5 – 6
	Protein	NEGATIVE
	Specific Gravity	1.02 – 1.03 RATIO
	Urobilinogen	NORMAL
Abon hCG One Step Ultra	hCG	NEGATIVE
Acon Laboratories	hCG	NEGATIVE
Acon Mission	Bilirubin	NEGATIVE
	Blood	NEGATIVE
	Glucose	NEGATIVE
	Ketones	NEGATIVE
	Leucocytes	NEGATIVE
	Nitrite	NEGATIVE
	pH	<5 – 6.5
	Protein	NEGATIVE
	Specific Gravity	1.02 – 1.03 RATIO
Analyticon Combiscreen	Bilirubin	NEGATIVE
	Blood	NEGATIVE
	Glucose	NEGATIVE – NORMAL
	Ketones	NEGATIVE
	Leucocytes	NEGATIVE
	Nitrite	NEGATIVE
	pH	<5 – 6
	Protein	NEGATIVE
	Specific Gravity	1.02 – 1.03 RATIO
	Urobilinogen	NORMAL
Arkray/Menarini	Bilirubin	NEGATIVE
	Blood	NEGATIVE
	Glucose	NEGATIVE – NORMAL (0 – 0.1 g/l) (0 – 10 mg/dl) (0 – 0.6 mmol/l)
	Ketones	NEGATIVE
	Leucocytes	NEGATIVE
	Nitrite	NEGATIVE
	pH	<5 – 6
	Protein	NEGATIVE
	Specific Gravity	1.015 – 1.025 RATIO
	Urobilinogen	NEGATIVE – NORMAL (0.2 – 1 EU/dl) (0.2 – 1.0 mg/dl) (3.2 – 16 µmol/l)
DFI – Cybow	Bilirubin	NEGATIVE
	Blood	NEGATIVE
	Glucose	NEGATIVE
	Ketones	NEGATIVE
	Leucocytes	NEGATIVE
	Nitrite	NEGATIVE
	pH	<5-6
	Protein	NEGATIVE
	Specific Gravity	1.02 – 1.03 RATIO
	Urobilinogen	NORMAL / 0.1 EU/dl / 0.1 mg/dl / 1.6 µmol/l

MANUFACTURER / METHOD	ANALYTE	RANGE
DIAsource, RIA	Albumin	NEG – 0.01g/l / NEG – 1 mg/dl / NEG – 10 mg/l
	pH	<5 – 6
Dirui H Series	Bilirubin	NEGATIVE
	Blood	NEGATIVE
	Glucose	NEGATIVE
	Ketones	NEGATIVE
	Leucocytes	NEGATIVE
	Nitrite	NEGATIVE
	Protein	NEGATIVE
	Specific Gravity	1.015 – 1.03 RATIO
	Urobilinogen	NORMAL / +/- / 3.4 – 17.0 µmol/l
EKF Diagnostics QuPID/ QuPID Plus	hCG	NEGATIVE
Erba Lachema	Bilirubin	NEGATIVE
	Blood	NEGATIVE
	Glucose	NEGATIVE
	Ketones	NEGATIVE
	Leucocytes	NEGATIVE
	Nitrite	NEGATIVE
	pH	<5 – 6
	Protein	NEGATIVE
	Specific Gravity	1.02 – 1.03 RATIO
	Urobilinogen	NORMAL
Human Combina	Albumin	NEGATIVE – 10 mg/l
	Creatinine	0.9 mmol/l / 10 mg/dl
IND Diagnostic hCG	hCG	NEGATIVE
Iris Velocity	Bilirubin	NEGATIVE
	Blood	NEGATIVE
	Glucose	NEGATIVE
	Ketones	NEGATIVE
	Leucocytes	NEGATIVE
	Nitrite	NEGATIVE
	pH	<5 – 6
	Protein	NEGATIVE
	Specific Gravity	1.015 – 1.025 RATIO
	Urobilinogen	NORMAL
LifeSign BioSign hCG	hCG	NEGATIVE
Nova Century Scientific	hCG	NEGATIVE
Quidel Quickvue	hCG	NEGATIVE
Randox One-Step	hCG	NEGATIVE

MANUFACTURER / METHOD	ANALYTE	RANGE
Roche Combur	Bilirubin	NEGATIVE
	Blood	NEGATIVE
	Glucose	NEGATIVE / NORMAL
	Ketones	NEGATIVE
	Leucocytes	NEGATIVE
	Nitrite	NEGATIVE
	pH	<5 – 6
	Protein	NEGATIVE
	Specific Gravity	1.01 – 1.025 RATIO
	Urobilinogen	NORMAL / 0.2 EU/dl
Roche Miditron/u411/u601	Bilirubin	NEGATIVE
	Blood	NEGATIVE
	Glucose	NORMAL
	Ketones	NEGATIVE
	Leucocytes	NEGATIVE
	Nitrite	NEGATIVE
	pH	<5 – 6
	Protein	NEGATIVE
	Specific Gravity	1.01 – 1.025 RATIO
Roche Urisys 1100/1800/2400	Bilirubin	NEGATIVE
	Blood	NEGATIVE
	Glucose	NORMAL
	Ketones	NEGATIVE
	Leucocytes	NEGATIVE
	Nitrite	NEGATIVE
	pH	<5 – 6
	Protein	NEGATIVE
	Specific Gravity	1.015 – 1.025 RATIO
	Urobilinogen	NORMAL
Siemens Clinitek Novus	Albumin	NEGATIVE – 10 mg/l
	Bilirubin	NEGATIVE
	Blood	NEGATIVE
	Creatinine	NEGATIVE
	Glucose	NEGATIVE
	Ketones	NEGATIVE
	Leucocytes	NEGATIVE
	Nitrite	NEGATIVE
	pH	<5 – 6
	Protein	NEGATIVE
	Specific Gravity	1.02 – >1.03 RATIO
	Urobilinogen	NEGATIVE / 0.2 EU/dl / 3.2 µmol/l / 0.2 mg/dl
Roche Clinitest hCG	hCG	NEGATIVE
Siemens/Bayer Clinitek Microalbumin	Albumin	1 mg/dl / 10 mg/l / 6.9 mmol/l
Siemens Multistix	Bilirubin	NEGATIVE
	Blood	NEGATIVE
	Glucose	NEGATIVE
	Ketones	NEGATIVE
	Leucocytes	NEGATIVE
	Nitrite	NEGATIVE
	pH	<5 – 6
	Protein	NEGATIVE
	Specific Gravity	1.02 – >1.03 RATIO
	Urobilinogen	NEGATIVE / 0.2 EU/dl / 3.2 µmol/l / 0.2 mg/dl

MANUFACTURER / METHOD	ANALYTE	RANGE
Sysmex Meditape UC Series Tests	Bilirubin	NEGATIVE
	Blood	NEGATIVE
	Glucose	NEGATIVE
	Ketones	NEGATIVE
	Leucocytes	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
	Leucocytes	NEGATIVE
	Nitrite	NEGATIVE
	pH	<5 – 6
	Protein	NEGATIVE
	Specific Gravity	1.015 – 1.025 RATIO
	Urobilinogen	NEGATIVE
WH Accu Test hCG Pregnancy Test	hCG	NEGATIVE
YD Diagnostics / Biosys / Genesis	Bilirubin	NEGATIVE
	Blood	NEGATIVE
	Glucose	NEGATIVE
	Ketones	NEGATIVE
	Leucocytes	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

The presence of a vertical bar in the margin indicates a technical update from the previous revision.

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