

Cat. No.: REG00053

Store at (+2 to +8) °C

Specifications:

URINORM control urines are a liquid synthetic material with concentrations within the normal (URINORM N) and pathological (URINORM P) ranges.

Usage: URINORM control urines are designed for verification and confirmation of precision and accuracy of PHAN (Uro-dip 10e) diagnostic strips as well as LAURA, LAURA Smart, Uro-dipcheck 240e, Uro-dip-check 400e, LAURA M urine analysers (for the visual and objective evaluation).
URINORM control urines are designed for direct usage (*ready to use*). This product is to be treated in the same manner as patient specimen and used in accordance with the instructions for PHAN diagnostic strips and LAURA, LAURA Smart, Uro-dipcheck 240e, Uro-dipcheck 400e, LAURA M analysers.

Reagents:

URINORM N – normal (negative) level 3×15 ml

URINORM P – pathological (positive) level 3×15 ml

URINORM control urines contain preservatives added to ensure the required stability and avoid microbial growth. **URINORM control urines do not contain human urine.**

Stability:

This product will be stable until the expiration date when stored unopened at (+2 to +8) °C; the product is to be protected against direct light and contamination.

Once opened, URINORM control urines remain stable for 30 days (blood analyte is stable for 20 days) or 10 measurements (whichever occurs first). Such used control urines are to be stored at (+2 to +8) °C – in a closed container and protected against direct light and contamination.

Mark the date of the first opening of vials on the appropriate place on the label of the vial (see cell **Opened**) containing control urines. Do not store this product in freezing appliances.

Preparation:

1. Allow the control urines to reach the room temperature (+18 to +25) °C;
2. Shake up a vial containing control urine (homogenization);
3. Open the vial carefully;
4. Immerse a PHAN - Uro-dip 10e diagnostic strip in the vial (1–2 seconds);
5. Remove excess urine from the strip (wipe the rim of the strip on the vial);
6. Perform a measurement (using LAURA, LAURA Smart, Uro-dipcheck 240e, Uro-dipcheck 400e, LAURA M analysers or visually);
7. Perform an evaluation (comparison with the target ranges listed in the table);
8. Close the vial containing control urine;
9. Store at (+2 to +8) °C.

Values: Values for LAURA, LAURA Smart, Uro-dipcheck 240e, Uro-dipcheck 400e, LAURA M urine analysers and for visual evaluation.

Analyte	URINORM N Scale 1 & 2	URINORM P Scale 1	URINORM P Scale 2	Units
Specific gravity	1.020–1.030	1.000–1.020	1.000–1.020	
Leucocytes	negative	25–500 / 1+ – 3+	Traces - 500 / ± - 3+	Leu/μl / ARB
Nitrites	negative	positive	positive	
pH	5–6.5	8–9	7–9 (LAURA) 8–9 (LAURA SMART)	
Protein	negative	1–5 / 100–500 / 2+ – 3+	1–5 / 100–500 / 2+ – 3+	g/l / mg/dl / ARB
Glucose	negative	17–55 / 300–1000 / 3+ – 4+	15–55 / 250–1000 / 1+ – 3+	mmol/l / mg/dl / ARB
Ketones	negative	1.5–15 / 16–156 / 1+ – 3+	1.5–15 / 16–156 / 1+ – 3+	mmol/l / mg/dl / ARB
Urobilinogen	normal	17–203 / 1–12 / 1+ – 4+	17–203 / 1–12 / 1+ – 4+	μmol/l / mg/dl / ARB
Bilirubin	negative	17–102 / 1–6 / 1+ – 3+	17–102 / 1–6 / 1+ – 3+	μmol/l / mg/dl / ARB
Blood	negative	10–250 / 1+ – 3+	10–250 / 1+ – 3+	Ery/μl / ARB
Creatinine	0.9 / 0.1	2.2 – >26.5 / 0.25 - >3	2.2 – >26.5 / 0.25 - >3	mmol/l / g/l
Microalbumine	0.01 / 10	0.03–5 / 30–5000	0.03–5 / 30–5000	g/l / mg/l

Limitations:

- This product may not be used after the expiration date specified on the package and it is not intended to be used as the standard.
- This product is not to be used after the elapse of 30 days from the day of first opening or after 10 measurements (whichever occurs first).
- If there is evidence of microbial contamination or excessive turbidity in the product, discard the vial.

Health protection:

For *in vitro* diagnostic use. To be handled solely by an authorized, trained personnel.

URINORM N control urines contains reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H -isothiazol-3-one (3:1).

**Warning****Hazard statement:**

H317 May cause an allergic skin reaction.

Precautionary statement:

P280 Wear protective gloves/protective clothing/eye protection.

P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower.

P333+P313: If skin irritation or rash occurs: Get medical advice/attention

URINORM P control urines are not classified as hazardous.

First aid: In case of an accidental ingestion wash up the mouth and drink approximately 0.5 l of water. In case of eye contact rinse the eye quickly and thoroughly using a stream of clean water. Contaminated skin is to be washed using warm water and soap. Consult a physician in all serious cases of health damage.

Waste disposal: Residues of control urines, which are not classified as infectious material, are to be disposed of in accordance with the internal regulations and by-laws. Paper and other packaging materials are to be discarded in the form of sorted waste (paper, glass, plastic).

Date of revision: 18. 2. 2025

USED SYMBOLS

REF Catalogue number **LOT** Lot number **IVD** In Vitro Diagnostics Manufacturer Storage temperature Expiry date See instructions for use