Medi-Test Control

en | REF 93038 | CONTROL | IVD

Negative and positive control solutions for the Medi-Test urine test strips

Intended Purpose:
Medi-Test Control is a control solution for functionality control of the Medi-Test Urine test strips and the URYXXON® Relax and URYXXON® 500 devices. Solution N simulates a urine sample with all values in the negative or normal range. Solution P provides a positive color reaction on the Medi-Test urine test strips. After dipping into the control solutions the urine test strips can be evaluated visually with the color scale or can be read-out on the URYXXON® Relax and URYXXON® 500 instruments. The results of the urine parameters blood, urobilinogen, bilirubin, protein, nitrite, ketones, glucose, pH, density and leukocytes are compared with the target values shown in the table as provided in the IFU. The Medi-Test Control solutions are intended to be used by professional users only. Medi-Test control is not for self-testing and not for near-patient testing.

Reagents:
Each pack contains:
• 1 test tube with 15 mL reagent solution Medi-Test Control N
• 1 test tube with 15 mL reagent solution Medi-Test Control P

Safety precautions:
Reagent solutions Medi-Test Control contain Chloromethylisothiazolinone 0.0015 – 0.06 % CAS 26172-55-4. WARNING H317 May cause an allergic skin reaction. P280 Wear protective gloves / eye protection. P302+352 IF ON SKIN: wash with plenty of water. P333+313 If skin irritation or rash occurs: get medical advice / attention. For further information, please ask for safety data sheet *(see www.mn-net.com/MSDS)*.

Storage and Shelf Life:
When not in use, it is recommended that the reagent solutions Medi-Test Control N and P are stored in a dark place at 2 – 8 °C. Do not freeze the solutions under any circumstances.
If correctly stored, the reagent solutions may be used right up until the use-by-date printed on the packaging. After the first use, each reagent solution may be used for up to three months or for dipping the test strip up to 20 times, whichever occurs first.
Precipitations in the reagent solutions have no effect on the measurement result. If the solutions show other contamination, then they must no longer be used. The solutions may be disposed of with plenty of running water via the sewerage of the local wastewater treatment plant.

Assay procedure:
Take the test tubes with the solutions Medi-Test Control P and N out of the refrigerator, and allow them to warm up to room temperature, shake well so that the solutions can mix homogeneously. Avoid frothing. Open the lids of the test tubes. Do not pour the solutions into another vessel. Perform measurements directly in the test tube. Where required, take out a test strip from a test strip container. After taking out a strip, immediately close the container again. Do not touch the test fields with your fingers.
For control of dipping and reaction time use a timer accurate to the second. Dip the test strip with all the test fields into the respective reagent solution for approx. 1 second. After removing the test strip from the solution, briefly pat the edge along one side on an absorbent paper tissue. For instrumental evaluation insert the test strip into the device according to the instructions of the reflection photometers URYXXON® 500 and URYXXON® Relax. The test fields are analyzed, and then the results are printed out.
When visually assessing the reaction colors of the test fields, compare the test fields with the color scale after about 30 – 60 seconds (leukocytes test field after 60 – 120 seconds). The most opportune reading time is after 30 seconds. Any color changes that occur after more than 2 minutes are of no significance.
Any visual assessment of the urine test strips must be made in daylight. Direct sunlight, however, must be avoided.
The urobilinogen test field may display a slightly more orange-red coloring in comparison to the color scale.
When not in use, and after completing the control procedures, replace the lids on the test tubes of the reagent solutions, and store them at 2 – 8 °C.

Performance data:
Precision in repeated measurements (N= 20) and batch to batch precision (N= 3 × 20) were 100 % for all parameters of control solutions N and P.

Notes:
The IFU in additional languages is available on the website *www.mn-net.com*.
Please also note the instructions for the URYXXON® reflection photometers.
Do not ingest the solutions! Avoid any contact with skin or eyes! Store reagent solutions in a safe place inaccessible to children!

Information on reporting obligation if incidents occur:
We wish to point out that all serious incidents which occur in connection with the product must be reported to the manufacturer and the competent authority of the European member state or of the state in which the incident occurred. European vigilance contact points: *https://ec.europa.eu/health/md_sector/contact_en*

Literature:
J. Penders, T. Fiers, J. R. Delanghe, Clinical Chemistry 2002, 48, 2236 – 2241.

Explanation of symbols

CE	Declaration of Conformity
	Please read instructions for use!
	Permitted storage temperature range
	Use by
LOT	Batch identification
REF	Item number
	Manufacturer
	Keep away from sunlight
IVD	*In vitro* diagnostic medical device
CONTROL	Control
CONTROL –	Control, negative
CONTROL +	Control, positive

Reason of revision: Inclusion of the “Protect from sunlight” symbol and GHS warning symbol. Correction of Control P expectation values.

Expected values:
The ranges identified in the table were determined using several different batches of the Medi-Test Combi 10® SGL and the URYXXON® Stick 10, and were ascertained using various different URYXXON® devices. Each laboratory should use the results provided only as a reference and establish own parameters of precision.

Analytes	Medi-Test Combi 10® SGL visually		URYXXON® Stick 10 with URYXXON® 500 / URYXXON® Relax	
	Control N	Control P	Control N	Control P
Blood	Negative	10 – 250 Ery/µL	Negative	10 – 250 Ery/µL
Urobilinogen	Normal	2 – 12 mg/dL[1] (35 – 200 µmol/L)	Normal	2 – 12 mg/dL[1] (35 – 200 µmol/L)
Bilirubin	Negative	1 – 4 mg/dL (1+ – 3+)	Negative	1 – 4 mg/dL (1+ – 3+)
Protein	Negative	30 – 500 mg/dL	Negative	30 – 500 mg/dL
Nitrite	Negative	Positive	Negative	Positive
Ketones	Negative	25 – 300 mg/dL (1+ – 3+) (2.5 – 30 mmol/L)	Negative	25 – 300 mg/dL (1+ – 3+) (2.5 – 30 mmol/L)
Glucose	Negative–Normal	50 – ≥ 1000 mg/dL (2.8 – 55.5 mmol/L)	Negative–Normal	50 – ≥ 500 mg/dL (2.8 – ≥ 27.8 mmol/L)
pH value	5 – 7	7 – 9	5 – 7	7 – 9
Specific gravity (density)	1.000 – 1.060	1.005 – 1.025	1.010 – 1.030	1.005 – 1.025
Leukocytes	Negative	25 – 500 Leu/µL	Negative	25 – 500 Leu/µL

[1] The urobilinogen test field displays an orange-red coloring compared to the color scale.

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