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Urine Comby Control

(en) English

REF 798001

Content

-1x 12 mL Urine Strip & Analyser Control, positive Control
-1x 12 mL Urine Strip & Analyser Control, negative Control

For professional in vitro diagnostic use only.

INTENDED USE

The Urine Comby Control is intended for use in validating the visual and analyser reading of urinalysis with Dialab Urine test strips. The results should be compared to the expected results for Urine Strip 1, 2, 2A, 2MC, 3A, 4, 4SG, 5, 9, 10C, 11, Urine Strip 13 and for Urine Strip 10ME, listed in the tables below (tables 1-3) to ensure the consistent performance of the Urine Strips and in case of use with the corresponding Urine Strip Analyser/Reader. The Urine Comby Control is available in two levels and is ready to use for routine urinalysis.

DIAGNOSTIC SIGNIFICANCE

Please refer to the corresponding section of the instructions for use of the used urine test strips.

TEST PRINCIPLE

The control solutions are measured in the same way, like urine samples. The obtained results are being compared with the specified ranges given by the lot-specific table of the packaging insert, as shown below.

REAGENT COMPOSITION

Level 1: Phosphate buffer, urea, sodium chloride, ProClin®.
Level 2: Protease, sodium nitrite, N(1-Naphthyl) ethylendiamine dihydrochloride, 2,4-dimethylpyrrole-3-carboxy acid, bovine serum albumin, bovine hemoglobin, D-Glucose, sodium chloride, methyl acetoacetate sodium, ProClin®. The product contains constituents of animal (not of human) origin, preservatives and stabilizers.

MATERIAL REQUIRED BUT NOT PROVIDED

- Dialab Urine test strips
- Timer
- Paper towel or comparable material to remove excess of liquid

REAGENT PREPARATION

Urine Comby Control is ready to use.

STORAGE AND STABILITY

Storage:	at 2 – 8 °C
Stability:	stable until the expiration date printed on the bottle label
Stability after opening if stored with the cap on tightly:	at 2 – 8 °C until indicated expiration date at 15 – 30 °C for 30 days

Do not freeze.

WARNINGS AND PRECAUTIONS

- For in vitro diagnostic use only.
- Do not use after the expiration date.
- All materials must be considered potentially hazardous and handled in the same manner as an infectious agent.
- Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents.
  Urine Comby Control contains < 0.1 % ProClin® 300 as a preservative.

Warning

H317	May cause an allergic skin reaction.
P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P272	Contaminated work clothing should not be allowed out of the workplace.
P280	Wear protective gloves / protective clothing / eye protection / face protection.
P302+P352	If on Skin: Wash with plenty of soap and water.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
P362+P364	Take off contaminated clothing and wash it before reuse.
P501	Dispose of contents/container in accordance with local, regional, national and international regulations.

- Discard if there is excessive turbidity or evidence of microbial contamination.
- The used materials should be discarded according to local regulations after testing.
- This product is not intended for use as a standard/calibrator.
- The strip should remain in the closed canister until use.
- To prevent against altered reagent reactivity, protect strips from ambient moisture, light and heat.
- Do not touch the reagent areas of the strip.
- Discard any discoloured strips that may have deteriorated.
- Follow the directions exactly for accurate results.
- In the event of an incident related to the device, report it to the manufacturer and your competent authority as required.

SPECIMEN COLLECTION AND STORAGE

Not applicable.

TEST PROCEDURE

Allow test materials to reach room temperature (15-30 °C) before testing.

1. Invert the diptube with the urine control 3 times to ensure reproducible results, then remove the cap. Completely immerse the reagent areas of the urinalysis reagent strip in the control solution and immediately remove to avoid dissolving of reagents. See *Figure 1*, illustration 1 below.

Note:

- All urine strips:
  While removing the strip from the control solution, run the edge of the strip against the rim of the control solution container to remove excess urine control.
  See *Figure 1*, illustration 2, left side, below.

- All urine strips except Urine Strip 10ME:
  Hold the urine test strip in a horizontal position and bring the edge of the strip into contact with an absorbent material (e.g. a paper towel) to avoid mixing chemicals from adjacent reagent areas and/or soiling hands with urine control. See *Figure 1*, illustration 2, right side, below.

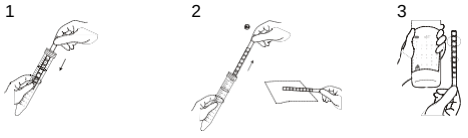
- Do not dip more than 20 urine strips into a single diptube of urine control to avoid inaccurate results.

2. For visual measurement compare the reagent areas to the corresponding color blocks on the color chart at the specified times. Hold the strip close to the color blocks and match carefully. See *Figure 1,* illustration 3 below. Immediately screw the cap on tightly. Results may be read according up to 2 minutes after the specified times shown in the product inserts of the used Dialab urine strip.

Note:

- Results may also be measured using the Urine Strip Analyser / Urine Strip Reader from Dialab in the same way like with urine samples. Refer to the Instruction Manual for details.

Figure 1:



INTERPRETATION OF RESULTS

The expected results of this product are individual for each level of control and each kit lot of Urine Comby Control, dependent on the used method (reading it visually or with instrument) and specific for each strip type. Results should be within the specified range as shown in the tables (1-3) below for the corresponding strip type.

Expected values for the Level 1 control solution were assigned as negative for all parameters, except for Specific Gravity and pH which have a ± 2 color block range. For the Level 2 control solution, expected values were assigned by providing a ± 2 color block range, except Ascorbic Acid which is negative.

Note: The color reactions of Urobilinogen and Bilirubin reagent areas on the urinalysis reagent strips may produce colors that are atypical when visually compared to the color blocks on the color chart.

QUALITY CONTROL AND CALIBRATION

The use of quality control materials is an important part of good laboratory practices (GLP). Quality control materials are an objective method of assessing techniques or practices in use. It is suggested to use quality control materials regularly, especially when opening of a new strip canister, with each measuring session and in any case with suspected malfunction of the used urine strip. Quality control materials should be used in accordance with local, state and/or federal regulations or accreditation requirements.
Urine test-strips are semi-quantitative test systems. Every released lot of Dialab Urine strips has been validated for visual comparison with the colour charts the and for usage with Dialab Strip Analysers / Reader instruments.
Each laboratory should establish corrective action in case of deviations in control recovery.

PERFORMANCE CHARACTERISTICS

Please refer to the corresponding documentation of the used urine test strips and instrument.

TRACEABILITY

The values of Dialab Urine Strips and Urine Comby Control are assigned to predicate devices for urinalysis. The expected values shown in the tables below were obtained from replicate analysis.

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EXPECTED VALUES

For information about the biological reference range of the corresponding parameters please refer to the instruction for use of the used urine strips. Expected values were obtained from replicate analysis. The urine control and urine strip lots can create slight differences in expected results. Different laboratory methods, instruments and reagents can result in variations between laboratories and variations over time. Use the results provided as reference only.

LIMITATIONS

The Urine Comby Control is intended only for the use with urine test strips / analysers from Dialab.
Interpretation of visual results depends on several factors: the variability of color perception, the presence or absence of inhibitory factors, and the lighting conditions when the strip is read. Each color block on the color chart does not correspond to a specific concentration, but it does correspond to a range of analyte concentrations.

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

Please refer to the corresponding section of the used urine strips

USED SYMBOLS

Symbol	Description
	Dispose product, residuals and packaging appropriately

LOT-SPECIFIC VALUES

LOT **Kit: UCDxxxxxxx**	**yyyy-mm-dd**
LOT **Negative Control:**	**xxxxxxxxx(-x)**
LOT **Positive Control:**	**xxxxxxxxx(-x)**

Table 1: Urine Strip 1, 2, 2A, 2MC, 3A, 4, 4SG, 5, 9, 10C, 11

Analyte	Negative Control Visual and Instrument	Positive Control Visual	Positive Control Instrument
LEU	– negative	x – x+ 15 – 500 Leu/µL	± – 3+ 15 – 500 Leu/µL
NIT	– negative	+ positive	+ positive
URO	– – ± 0.2 – 1 mg/dL	1+ – 4+ 2 – 12 mg/dL	1+ – 3+ 2 – 8 mg/dL
PRO	– negative	1+ – 4+ 30 – 2000 mg/dL	1+ – 3+ 30 – 300 mg/dL
pH	5.0 – 7.0	6.5 – 9.0	6.5 – 9.0
BLO	– negative	1+ – 3+ 25 – 200 Ery/µL	1+ – 3+ 25 – 200 Ery/µL
SG	1.015 – 1.030	1.005 – 1.025	1.005 – 1.025
KET	– negative	± – 4+ 5 – 160 mg/dL	± – 3+ 5 – 80 mg/dL
BIL	– negative	1+ – 3+ 1 – 4 mg/dL	1+ – 3+ 1 – 4 mg/dL
GLU	– negative	± – 3+ 100 – 1000 mg/dL	± – 3+ 100 – 1000 mg/dL
ASC	negative	negative	negative
ALB	10 – 30 mg/L	80 – 150 mg/L	80 – 150 mg/L
CRE	10 –100 mg/dL	100 – 300 mg/dL	100 – 300 mg/dL
ALB/CRE Ratio	normal	abnormal	abnormal

Table 2: Urine Strip 10ME

Analyte	Negative Control Visual	Positive Control Visual
BLO	– negative	2+ – 4+ ca. 25 – ca. 250 Ery/µL
BIL	– negative	1+ – 3+ 1 – 6 mg/dL
URO	– 0.2 mg/dL	2+ – 4+ 4 – 12 mg/dL
KET	– negative	1+ – 3+ 10-150 mg/dL
GLU	– negative	2+ – 4+ 100 – 1000 mg/dL
PRO	– negative	1+ – 3+ 30 – 500 mg/dL
NIT	– negative	+ positive
LEU	– negative	1+ – 3+ ca. 10-25 – ca. 500 Leu/µL
pH	5.0 – 7.0	7.0 – 9.0
SG	1.015 – 1.030	1.005 – 1.025

Table 3: Urine Strip 13

Analyte	Negative Control Visual + Instrument	Positive Control Visual	Positive Control Instrument
LEU	– negative	± – 3+ 15 – 500 Leu/µL	± – 3+ 15 – 500 Leu/µL
URO	– – ± 0.2 – 1 mg/dL	1+ – 4+ 2 – 12 mg/dL	1+ – 3+ 2 – 8 mg/dL
ALB	10 – 30 mg/L	80 – 150 mg/L	80 – 150 mg/L
PRO	– negative	1+ – 4+ 30 – 2000 mg/dL	1+ – 3+ 30 – 300 mg/dL
BIL	– negative	1+ – 3+ 1 – 6 mg/dL	1+ – 3+ 1 – 6 mg/dL
GLU	– negative	1+ – 4+ 100 – 1000 mg/dL	1+ – 4+ 100 – 1000 mg/dL
ASC	– negative	– negative	– negative
SG	1.015 – 1.030	1.005 – 1.025	1.005 – 1.025
KET	– negative	± – 4+ 5 – 160 mg/dL	± – 3+ 5 – 80 mg/dL
NIT	– negative	+ positive	+ positive
CRE	10 –100 mg/dL	100 – 300 mg/dL	100 – 300 mg/dL
pH	5.0 – 7.0	6.5 – 9.0	6.5 – 9.0
BLO	– negative	1+ – 3+ 25 – 200 Ery/µL	1+ – 3+ 25 – 200 Ery/µL
PRO/CRE Ratio	normal	abnormal	abnormal

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