LabStrip URINALYSIS Urine Test Strip 12 mALB/CREA

EN IVD CE

REF (Catalogue number)	Name of product	Contents
U12 - 9901-1	LabStrip U12 mALB/CREA	150 reagent strips

Intended purpose:

The **LabStrip U12 mALB/CREA** urine test strip is an in vitro diagnostic medical device for use as a preliminary screening test for diabetes, liver diseases, haemolytic diseases, urogenital and kidney disorders and metabolic abnormalities by the rapid semi-quantitative determination of bilirubin, urobilinogen, ketones, ascorbic acid, glucose, protein, creatinine, blood, pH-value, albumin and leucocytes, as well as qualitative determination of nitrite in human urine and providing albumin-to-creatinine ratio and protein-to-creatinine ratio.

Urinalysis is considered a routine, non-invasive screening method. As per this definition, for this method there are no limitations about the patient groups. Analysis of urine can be performed on all patients irrespective of age, gender, race, medical condition, etc. Also, because of the urinalysis is a non-invasive test, can be repeated at any time

The product is designed for professional, laboratory use and is intended to be used with **LabUMat 2** automated urine chemistry analyzer.

Test Principal [1] – [6]:

Bilirubin (BIL): A red azo compound is obtained in the presence of acid by coupling of bilirubin with a diazonium salt. The presence of bilirubin leads to a color of red-orange peach.

Urobilinogen: The test is based on the coupling of urobilinogen with a stabilized diazonium salt to a red azo compound. The presence of urobilinogen leads to a color change from light to dark pink.

Ketones (KET): The test is based on the reaction of acetone and acetoacetic acid with sodium nitroprusside in alkaline solution to give a violet colored complex (Legal's test).

Ascorbic acid (ASC): The test is based on the discoloration of Tillman's reagent. In the presence of ascorbic acid, the color changes from grey-blue to orange.

Glucose (GLU): The test is based on the glucose oxidase-peroxidasechromogen reaction. The presence of glucose leads to a color change from yellow via lime green to dark teal.

Protein (PRO): The test is based on the „protein error" principle of an indicator. The test is especially sensitive in the presence of albumin. Other proteins are indicated with less sensitivity. The presence of proteins leads to a color change from yellowish to mint green.

Creatinine (CREA): The test is based on the peroxidase-like activity of a copper-creatinine complex. This complex acts as a catalysator for the color reaction, changing the color of the test pad from light green to dark teal.

Blood (BLD): The test is based on the pseudo-peroxidative activity of hemoglobin and myoglobin, which catalyze the oxidation of an indicator by an organic hydroperoxide and a chromogen producing a green color. Intact erythrocytes are reported by punctual colorations on the test pad, whereas hemoglobin and myoglobin are reported by a homogeneous green coloration.

pH: The test paper contains pH indicators, which clearly change color between pH 5 and pH 9 (from orange to green to turquoise).

Nitrite (NIT): The test is based on the principle of the Griess reaction. Any degree of pink-orange coloration should be interpreted as a positive result.

Albumin (mALB): The test is based on the so-called 'protein error of indicators' phenomenon, the indicator being a tetrabromophenol-sulfonephthalein derivative in this case. In an acidic environment, the dye binds to the albumin, causing the color of the test strip to change from light to dark turquoise.

Leucocytes (LEU): The test is based on the esterase activity of granulocytes. This enzyme cleaves heterocyclic carboxylates. If the enzyme is released from the cells, it reacts with a diazonium salt producing a violet dye.

Albumin-to-creatinine ratio (ACR): There is no specific test pad on the test strip for ACR, which is calculated from the result of the Albumin and the Creatinine test pad.

Protein-to-creatinine ration (PCR): There is no specific test pad on the test strip for PCR, which is calculated from the result of the Protein and the Creatinine test pad.

Reagents:

Bilirubin:	Diazonium salt	**3.1 %**
Urobilinogen:	Diazonium salt	**3.6 %**
Ketones:	Sodium nitroprusside	**2.0 %**
Ascorbic acid:	2.6-dichloro-phenol-indophenol	**0.7 %**
Glucose:	Glucose oxidase	**2.1 %**
	Peroxidase	**0.9 %**
	O-Tolidine hydrochloride	**5.0 %**
Protein:	Tetra-bromophenol blue	**0.2 %**
Creatinine:	Copper sulphate	**1.5 %**
	Cumolhydroperoxide	**4.0 %**
	Tetramethylbenzidine	**1.7 %**
Blood:	Isopropylbenzol-hydroperoxide	**21.0 %**
	Tetramethylbenzidine-dihydrochloride	**2.0 %**
pH:	Bromthymol blue	**10.0 %**
	Methyl red	**2.0 %**
Nitrite:	Sulfanilic acid	**1.9 %**
	Tetrahydrobenzol[h]quinolon-3-ol	**1.5 %**
Albumin:	Tetrabromophenol-sulfonephthalein derivative	**1.6 %**
Leucocytes:	Carboxylic acid ester	**0.4 %**
	Diazonium salt	**0.2 %**

Concentrations given are based on reagent composition (w/w) at time of manufacture and may vary within manufacturing tolerances.

Kit Components:

Each kit contains everything needed to perform 150 tests:

- 150 pcs **LabStrip U12 mALB/CREA** test strips,
- 1 pc registration card for registering test strips of **LabUMat 2** automated urine chemistry analyzer,

Other required appliances for urine analysis:

- **LabUMat 2** automated urine chemistry analyzer
- Clean, detergent free and dry container for urine collection

Specimen Collection and Preparation:

- Collect urine in a clean, dry container.
- Do not add preservatives.
- Test the specimen as soon as possible, with the sample well mixed but not centrifuged.
- The use of fresh morning urine is recommended.
- If immediate testing is not possible, the sample should be stored in the refrigerator (+2 to +8 °C) and then brought to room temperature (+15 to +25 °C) before used in the test.
- Non-preserved urine at room temperature may undergo pH changes due to microbial proliferation, which may interfere with protein determination.
- If cleanly voided specimens are not collected from females, positive results for leukocytes may be found du to contamination from outside the urinary tract.
- Skin cleansers containing chlorhexidine may affect positive protein test result if specimen contamination occurs.

Procedure and Notes:

- Use only fresh, well mixed, non-centrifuged urine. First morning urine is recommended. Perform the urine analysis in 4 hours after sample collection! Keep urine away from light.
- Load the test strips into the analyzer immediately after opening the test strip container.
- Do not touch test pads of the reagent strip.
- Do not perform urine analysis at temperatures below +15˚C or above +35˚C
- Use only **LabUMat 2** automated urine chemistry analyzer for **LabStrip U12mALB/CREA** test strip urine analysis.
- A registration card is provided in each **LabStrip U12 mALB/CREA** test strip package for registering test trips with **LabUMat 2** automated urine chemistry analyzer.

Carefully read the instructions for use of **LabUMat 2** automated urine chemistry analyzer.

Results:

The **LabUMat 2** automated urine chemistry analyser measures the colour change of the test pads after 60 seconds incubation time via an optical measurement head. Consult the instrument's user manual for further details.

Storage and Stability:

Keep test strips in tightly closed original tubes in a dry, dark and cool place (between +2 and +25 °C). Load the test strips into the analyzer immediately after opening the test strip container. Consult the instructions for use for test strip loading and removal in the analyzer.

Keep test strips away from moisture, direct sunlight, elevated temperature and chemical fumes. Under proper conditions test strips are stable up to the stated expiry date even after opening. Do not touch the test pads.

Quality control:

Performance of urine test strips should be checked with appropriate control materials, listed in the **LabUMat 2** automated urine chemistry analyzer's instruction for use. Perform quality control measurements according to the internal guidelines of the laboratory and local regulations. The following quality control solutions are recommended: the Dipper (Quantimetrix), the Dropper (Quantimetrix), Dip & Spin (Quantimetrix), Liqua-Trol (Kova International) and Liquichek (BioRad). Consult the instructions for use of the specific control solution for further details.

Limitations of the Procedure [1] – [6]:

Bilirubin: The reaction is unaffected by pH of urine. False low or negative results may be simulated by large amounts of ascorbic acid (up to 100 mg/dl) or nitrite or by longer exposure of the sample to direct light. Increased concentration of urobilinogen can reinforce the sensitivity of the pad. Different urine constituents (e.g. urine indicane) can lead to atypical coloration. For metabolites of drugs see urobilinogen.

Urobilinogen: The reaction is unaffected by pH of urine. Higher concentration of formaldehyde or exposure of the urine to light for a longer period of time may lead to lowered or falsely negative results. Beetroot (excreted pigments) or metabolites of drugs which give a colour at low pH (phenazopyridine, azo dyes, p-aminobenzoic acid or other medicaments which have a red intrinsic coloration in acidic medium) may produce false positive results. Prolonged exposure to light is to be avoided.

Ketones: Phthalein compounds and derivatives of anthraquinone interfere by producing a red coloration in the alkaline range which may mask the coloration of ketones.

Ascorbic acid: No interferences are known on the ascorbic acid test pad.

Glucose: High concentrations of ascorbic acid in urines (greater than 80 mg/dl) with a low glucose concentration (up to 150 mg/dl) may inhibit the reaction and lead to lower or false negative results. Repeat the test 10 hours after stopping the intake of vitamin C. Pay attention to the ascorbic acid pad. In addition, an inhibitory effect is produced by gentisic acid, a pH value of <5 and high specific gravity. False positive reactions can also be produced by a residue of peroxide containing cleansing agents or others.

Protein (albumin): Falsely positive results are possible in high alkaline urine samples (pH >9) and in the presence of high specific gravity, after infusions with polyvinylpyrrolidone (blood substitute) after intake of medicaments containing quinine and also by disinfectant residues containing quaternary ammonium groups in the urine sampling vessel.

Creatinine: Detergents, cleaning agents, disinfectants and preservatives may lead to false values for the creatinine concentration. Different urine contents, especially high concentrations of hemoglobin, riboflavin or bilirubin, can lead to atypical coloration on the test pad.

Blood: Microhaematuria does not affect the colour of urine and is only detectable by microscopic or chemical tests. From a level approx. 25 Ery/µl and above, even at high concentrations of ascorbic acid (up to 80 mg/dl) normally no negative results are observed. Falsely positive reactions can also be produced by a residue of peroxide containing cleansing agents, activities of microbial oxidase due to infections of the urogenital tract or by formalin. For establishing an individual diagnosis, it is therefore indispensable to take into consideration also the clinical manifestations.
The number of erythrocytes which are detected by sediment analysis may be lower than the result of the test strip, because lysed cells are not detected by sediment analysis.

pH: No interferences are known on the pH pad.

Nitrite: Before testing the patient should ingest vegetable-rich meals, reduce fluid intake and discontinue antibiotic and vitamin C therapy 3 days prior to the test. False positive results may occur in stale urine samples, in which nitrite has been formed by contamination of the specimen and in urines containing dyes (derivatives of pyridinium, beetroot). A negative result even in the presence of bacteriuria can have the following reasons: bacteria not containing nitrate reductase, antibiotic treatment, diet with low nitrate content, high diuresis, high content of ascorbic acid or insufficient incubation of the urine in the bladder.

Albumin: Detergents, cleaning agents, disinfectants and preservatives may lead to false values for the albumin concentration. Different urine contents, especially high concentrations of hemoglobin, riboflavin or bilirubin, can lead to atypical coloration on the test pad.

Leukocytes: Strongly coloured compounds (e.g. nitrofurantoin) may disturb the colour of the reaction. High concentrations of glucose, oxalic acid, drugs containing cephalexin, cephalothin or tetracycline can lead to weakened reaction. False-positive reactions may be caused by contamination of vaginal secretion. The number of leucocytes which are detected by sediment analysis may be lower than the result of the strip, because lysed cells are not detected by sediment analysis. Partial cytolysis intensifies the colour response, particularly in the region of the maximum analytical sensitivity. Leucocyte esterase results may be positive in the absence of observable cells if the leucocytes have lysed. False-positive reactions may be caused by formaldehyde (preservative). Protein concentrations above 5 g/l or a high specific gravity may diminish the colour response. Bacteria, trichomonas and erythrocytes however do not react with the test pad.

Notes:

- Diagnostic or therapeutic decisions should not be based on any single result or method.
- Not all cases of interference with every component of any medicine are known. The colour reaction of the pads might change, therefore, another test at the end of any medication with drugs is recommended.
- In rare occasions, the varying test conditions, due to the heterogenity of different urine (for reason of different levels of activators, inhibitors, or different ion concentrations) may cause variation in the intensity and contrast of the colours.

Expected values, measuring ranges, analytical sensitivity:

Parameter	Expected value	Unit	Measuring range	Analytical sensitivity
BIL	neg.	µmol/l	neg., 8.5, 17, 50, 100	≥1 mg/dl (for trace category 0.5-0.7 mg/dl)
		mg/dl	neg., 0.5, 1, 3, 6	
		arb.	neg., (+), +, ++, +++	
UBG	norm.	µmol/l	norm., 35, 70, 140, 200	1.2-1.4 mg/dl
		mg/dl	norm., 2, 4, 8, 12	
		arb.	norm., +, ++, +++, ++++	
KET	neg. - trace	mmol/l	neg., 0.5, 1.5, 5, 15	7-9 mg/dl (for trace category 3-4.5 mg/dl)
		mg/dl	neg., 5, 15, 50,150	
		arb.	neg., (+), +, ++, +++	
ASC	n.a.	g/l	neg., 0.2, 0.4, 1	10-12 mg/dl
		mg/dl	neg., 20, 40, 100	
		arb.	neg., +, ++, +++	
GLU	norm.	mmol/l	norm., 1.7, 2.8, 8, 28, 56	25 mg/dl (for trace category 15 mg/dl)
		mg/dl	norm., 30, 50, 150, 500, 1000	
		arb.	norm., (+), +, ++, +++, ++++	
PRO	neg. - trace	g/l	neg., 0.15, 0.3, 1, 5	27-30 mg/dl (for trace category 15 mg/dl)
		mg/dl	neg., 15, 30, 100, 500	
		arb.	neg., (+), +, ++, +++	
CREA	n.a.	mmol/l	0.9, 4.4, 8.8, 17.7, 26.5	n.a.
		mg/dl	10, 50, 100, 200, 300	
BLD	neg.	Ery/µl	neg., 5-10, 50, 300	5-6 Ery/ µl
		arb.	neg., +, ++, +++	
pH	pH 5 - 8		5, 5.5, 6, 6.5, 7, 7.5, 8, 8.5, 9	n.a.
NIT	neg.	arb.	neg., pos.	0.1 mg/dl
mALB	norm.	mg/l	10, 30, 80, 150, 500	≤30 mg/l
		arb.	norm., +, ++, +++, ++++	
LEU	neg.	Leu/µl	neg., 25, 75, 500	12.5-15 Leu/µl
		arb.	neg., +, ++, +++	
ACR*	norm.	mg/mmol	≤3.4, 3.5-33.8, ≥33.9	n.a.
		mg/g	≤30, 31-299, ≥300	
		arb.	norm., +, ++	
PCR	norm.	mg/mmol	≤56.7, >56.7, ≥113, ≥340	n.a.
		mg/g	≤500, >500, ≥1000, ≥3000	
		arb.	norm., +	

*If the CREA=10 mg/dl and the mALB=10 mg/l, then the sample is too diluted. Repeate the measurement with recollected sample.

Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference ranges.

Performance Characteristics:
Method comparison data of 1279 samples are provided below:

Parameter	Sensitivity [%]	Specificity [%]	Diagnostic accuracy [%]	Extended concordance [%]	NPV* [%]	PPV** [%]
BIL	97.1	97.5	73	95.1	99.5	90.1
UBG	84.1	93.9	92	98.9	96.1	76.7
KET	81.4	95.7	92.9	99.6	95.4	82.4
ASC	n.a.	n.a.	98.1	100	n.a.	n.a.
GLU	95.5	97.5	97.1	98.4	98.9	91
PRO	87.1	93.8	91.6	99.7	93.7	87.4
CREA	n.a.	n.a.	92	98	n.a.	n.a.
BLD	82.1	84.3	83.3	99.8	84.3	82.1
pH	n.a.	n.a.	n.a.	81.6	n.a.	n.a.
NIT	83.9	93.4	92.5	100	98.2	57.8
mALB	93	83	90	93	82	94
LEU	85.2	83.8	84.5	99.8	85.1	83.9
ACR	93	83	90	99	84	92
PCR	56	98	83	94	80	94

*Negative Predictive Value
**Positive Predictive Value

Repeatability
Repeatability was determined by measuring two levels (normal, abnormal) of control Ua solution 20 times. The negative and positive values were correctly identified 100 % of time for all the parameters.

Reproducibility
Reproducibility was determined by measuring two levels (normal, abnormal) of control solution over 20 days. The negative and positive values were correctly identified 100 % of time for all the parameters.

⚠ **Warnings:**
- Keep strips away from heat and direct sunlight.
- Do not reuse test strips.
- Store the test strips in original packages until used. Strips in each vial should not be mixed.
- Diagnoses and therapies cannot be derived from one single test result only, instead they should be based on all available medical diagnoses.
- Inform your 77 Elektronika service representative and your local competent authority about any serious incidents which may occur when using this product.

Biological risk
Handle all specimens and used test strips as if they were contaminated infectious agents. When the assay procedure is completed, dispose of specimens and strips carefully. Follow the relevant local instructions.
- Always follow the general working instruction of the laboratories.
- The test strips do not contain toxic materials

Literature:

[1] **Brunzel, Nancy A.**: Fundamentals of Urine and Body Fluid Analysis-E-Book. Elsevier Health Sciences, 2016, ISBN: 9780323374798
[2] **Kouri, Timo, et al.**: „European urinalysis guidelines." Scandinavian journal of clinical and laboratory investigation 60.sup231 (2000): 1-96.
[3] **Mundt, Lillian A.**: Graff's Textbook of Routine Urinalysis and Body Fluids. LIPPINCOTT WILLIAMS & WILKINS, 2011 ISBN: 978-1582558752
[4] **Roberts, James R.** „Urine dipstick testing: everything you need to know." Emergency Medicine News 29.6 (2007): 24-27.
[5] **Simerville, Jeff A., William C. Maxted, and John J. Pahira.** „Urinalysis: a comprehensive review." American family physician 71.6 (2005): 1153-1162.
[6] **Strasinger, Susan King, and Marjorie Schaub Di Lorenzo.**: Urinalysis and body fluids. FA Davis, 2014.

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Manufacturer:

77 ELEKTRONIKA Kft.
HUNGARY
1116 Budapest, Fehérvári út 98.
Tel: + 36 (1) 2061480
Fax: + 36 (1) 2061481
E-mail: sales@e77.hu
Website: www.e77.hu

Symbols:

IVD In vitro diagnostic medical device

REF Catalogue Number

LOT Lot Number

CE The CE mark identifies that the product complies with the applicable directives of the European Union

Use by

+2°C +25°C Temperature Limitation

Manufacturer

Keep away from sunlight

Consult instructions for use

Caution

Biological Risks

Σ 150 Contents sufficient for 150 tests

Do NOT Reuse

Do not use if package is damaged

EN English language

Not for self-testing

Not for near patient testing

Modification history

Version	Date (dd.mm.yyyy.)	Modifications
2	08.06.2023.	• Updated data for Analytical Sensitivities and Performance Characteristics based on original and additional measurements. • Updated document format.
1	22.03.2022.	First release

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