Anexa tehnica

Analizor automat de urină, Teste pentru analiza generala de urina

Automated Urine Sediment Analyzer, LabUMat 2 & UriSed 3 PRO, LabStrip U12 mALB/CREA test strip, UriSed Cuvette

77 elektronica, Ungaria

Inregistrat la AMDM: DM000570073, DM000570068, DM000570072, DM000570075

Parametri ceruti	Parametri oferiti
Analizor automat de urină,	
1.Sistem complet automat pentru efectuarea examenului de urină – analiză chimică (sumar) și examinarea sedimentului într-o singură unitate integrată (sistem all-in-one).	1. Sistem automat pentru efectuarea examenului de urină – analiză chimică (sumar) și examinarea sedimentului, realizate prin integrarea a două module dedicate, complet automatizate și interconectate.
2.Echipament constituit dintr-o unitate unică de analiză, cu punct unic de aspirare/pipetare pentru efectuarea ambelor determinări.	2. Echipament compus din două unități complementare (analizor chimic și analizor de sediment), cu transfer automat al probelor între module și flux de lucru unificat.
3.Capacitate de încărcare inițială de minimum 50 probe, cu posibilitatea extinderii capacității dacă este necesar.	3. Capacitate de încărcare inițială de 100 probe, cu posibilitate de încărcare continuă și extindere a capacității prin rack-uri suplimentare.
4.Sistem automat de identificare a probelor prin cod de bare, cu posibilitatea citirii interne.	4. Sistem automat de identificare a probelor prin cod de bare, cu cititor integrat.
5.Posibilitatea procesării prioritare a probelor tip STAT	5. Posibilitatea procesării prioritare a probelor tip STAT.
6.Sistem unic de aspirare pentru sumar și sediment, prevăzut cu ac de precizie și funcție automată de spălare între probe pentru prevenirea contaminării încrucișate.	6. Sistem automat de aspirare/pipetare separat optimizat pentru fiecare modul (chimie și sediment), cu funcții de spălare automată pentru prevenirea contaminării încrucișate.
7.Analiza să fie efectuată din urină nativă, fără necesitatea centrifugării sau a colorării suplimentare și fără utilizarea de reactivi adiționali pentru examinarea sedimentului.	7. Analiza sedimentului se realizează din urină nativă, fără centrifugare sau colorare suplimentară, utilizând tehnologie automată de procesare a imaginilor.
8.Posibilitatea analizării și a altor lichide biologice (ex.: LCR, secreții vaginale, lichid peritoneal), în condițiile specificate de producător.	8. Posibilitatea analizării altor lichide biologice (ex. LCR, lichid peritoneal), conform specificațiilor producătorului pentru modulul de sediment.
9.Sistem optic cu minimum 5 lungimi de undă (ex.: 470 nm, 550 nm, 570 nm, 620 nm, 720 nm) pentru creșterea acurateții citirii prin compensarea culorii proprii a urinei și reducerea interferențelor, asigurând calibrare precisă.	9. Sistem optic dedicat fiecărui modul, optimizat pentru tipul de analiză efectuat (reflectometrie pentru chimie și microscopie digitală pentru sediment), asigurând acuratețe ridicată și reducerea interferențelor, calibrat precis.
10.Afișarea în timp real a imaginii benzii reactive și a elementelor figurate din sediment.	10. Afișarea imaginilor pentru sedimentul urinar și posibilitatea vizualizării rezultatelor analizei benzilor reactive.
11.Volum minim necesar pentru analiză: ≤ 2 ml urină, adecvat inclusiv pentru pacienți pediatrici sau cu diureză redusă.	11. Volum minim necesar pentru analiză redus (aprox. 2ml), adecvat inclusiv pentru probe cu volum limitat: 1 ml pentru pacienți pediatrici sau cu diureză redusă.

12.Tehnologie bazată pe procesare digitală a imaginii pentru analiza sedimentului, cu raportarea rezultatelor în diverse unități (ex.: elemente/µL, elemente/LPF etc.). 13.Evaluarea morfologiei eritrocitelor urinare, incluzând indici precum distribuția diametrului (RDW urinar), parametri de variație și histogramă de distribuție, cu posibilitatea orientării asupra originii hematiilor. 14.Posibilitatea redării în timp real a imaginilor sau secvențelor video de detecție pentru sedimentul urinar. 15.Software dedicat furnizat împreună cu echipamentul, bazat pe platformă Windows sau echivalent compatibil. 16.Capacitate de stocare a datelor pentru minimum 100.000 pacienți, incluzând imagini ale sedimentului și ale benzilor reactive, cu posibilitate de export pe suport extern. 17.Modul de control al calității (QC) cu afișare grafică tip Levey-Jennings, calcul automat al mediei, deviației standard și coeficientului de variație, arhivare istoric și posibilitate de imprimare a rapoartelor QC. 18.Se va acorda prioritate echipamentului care prezintă coeficient de variație (CV) cât mai redus pentru testele de reflexie. 19.Pentru analiza sedimentului, concordanța rezultatelor automate cu microscopia manuală pentru elementele figurate trebuie să fie ≥ 85%. 20.Posibilitatea conectării unui cititor extern de coduri de bare și integrare bidirecțională cu sistem informatic de laborator (LIS), prin interfețe LAN, USB, RS-232 sau alte porturi standard. Echipamentul trebuie să permită procesarea selectivă a parametrilor solicitați. 21.Posibilitate de conectare la imprimantă pentru tipărirea rezultatelor și rapoartelor. 22.Interfață de operare intuitivă, cu ecran tip display (touchscreen), compatibilitate cu mouse și tastatură, precum și porturi USB, seriale și de rețea; disponibilitate port video și audio. 23.Design compact, acces facil pentru mentenanță și operațiuni de întreținere efectuate de utilizator. 24.Condiții de funcționare:Temperatură ambientală: 5°C – 40°C, Umiditate relativă: ≤ 85%. 25.Dimensiuni maxime admise: ≤ 650 × 750 × 650 mm.	12. Tehnologie bazată pe procesare digitală a imaginilor pentru analiza sedimentului, cu raportarea rezultatelor în unități standard (elemente/µL, /HPF etc.). 13. Evaluarea morfologică avansată a elementelor figurate (inclusiv eritrocite), pe baza algoritmilor de analiză a imaginii, cu suport pentru interpretare clinică. 14. Posibilitatea stocării și redării imaginilor relevante pentru sedimentul urinar analizat. 15. Software dedicat furnizat împreună cu sistemul, compatibil cu platforme moderne (Windows sau echivalent). 16. Capacitate mare de stocare a datelor (zeci de mii de rezultate), incluzând imagini și rezultate, cu posibilitate de export pe suport extern. 17. Modul de control al calității (QC) integrat, cu reprezentare grafică și funcții statistice (medie, SD, CV), calcul automat al mediei, deviației standard și coeficientului de variație, arhivare istoric și posibilitate de imprimare a rapoartelor QC. 18. Sistem optimizat pentru precizie ridicată și reproductibilitate a rezultatelor. 19. Concordanță ridicată cu microscopia manuală, conform validărilor producătorului, dat fiind ca tot microscopie de facto se efectueaza pentru sediment. 20. Posibilitatea integrării bidirecționale cu LIS prin interfețe standard (LAN, USB, RS-232), inclusiv conectare cititor cod de bare. Echipamentul trebuie să permită procesarea selectivă a parametrilor solicitați. 21. Posibilitate de conectare la imprimantă pentru tipărirea rezultatelor si rapoartelor. 22. Interfață de operare intuitivă, cu display și control facil, compatibilă cu periferice externe. compatibilitate cu mouse și tastatură, precum și porturi USB, seriale și de rețea 23. Design ergonomic, modular, cu acces facil pentru mentenanță și operațiuni de întreținere efectuate de utilizator. 24. Condiții de funcționare standard pentru laborator: Temperatură: aprox. 15–30°C. Umiditate relativă: ≤ 85%. 25. Dimensiuni compacte, specifice fiecărui modul, permițând integrarea eficientă în spațiul de laborator. 600 x 640 x 635 mm, 600x650x635 mm

Teste pentru analiza generala de urina	
1.Limită de detecție pentru eritrocite și leucocite: minimum 5/µL. 2.Utilizarea de benzi reactive dedicate echipamentului, cu minimum 12 parametri/strip, incluzând cel puțin: leucocite, nitriți, proteine, glucoză, corpi cetonici, urobilinogen, bilirubină, hematii, pH, creatinină, calciu urinar, albumină, cu posibilitatea calculării rapoartelor Albumină/Creatinină și Proteine/Creatinină. 3.Posibilitatea determinării parametrilor fizici ai urinei, precum: densitate specifică, osmolaritate, culoare, turbiditate și conductivitate. 4.Parametri minimi pentru analiza sedimentului urinar: - eritrocite - leucocite - celule epiteliale scuamoase - neutrofile segmentate - conglomerate leucocitare - cilindri hialini și granuloși - oxalați - cristale urinare (cristale de acid uric etc.) - bacterii - levuri - mucus - spermatozoizi 5.Sistemul trebuie să permită exprimarea rezultatelor în mod cantitativ și/sau semicantitativ, cu posibilitatea configurării valorilor de referință și a unităților de măsură. 6.Sa fie inclus controlul calitatii zilnic pentru parametrii fizici si sedimentul urinar.	1.Limită de detecție pentru eritrocite și leucocite: 5/µL. 2.Utilizarea de benzi reactive dedicate echipamentului, cu minimum 12 parametri/strip, incluzând : leucocite, nitriți, proteine, glucoză, corpi cetonici, urobilinogen, bilirubină, hematii, pH, creatinină, calciu urinar, albumină, cu posibilitatea calculării rapoartelor Albumină/Creatinină și Proteine/Creatinină. 3.Posibilitatea determinării parametrilor fizici ai urinei, precum: densitate specifică, osmolaritate, culoare, turbiditate și conductivitate. 4.Parametri minimi pentru analiza sedimentului urinar: - eritrocite - leucocite - celule epiteliale scuamoase - neutrofile segmentate - conglomerate leucocitare - cilindri hialini și granuloși - oxalați - cristale urinare (cristale de acid uric etc.) - bacterii - levuri - mucus - spermatozoizi 5.Sistemul permite exprimarea rezultatelor în mod cantitativ și/sau semicantitativ, cu posibilitatea configurării valorilor de referință și a unităților de măsură. 6.este inclus controlul calitatii zilnic pentru parametrii fizici si sedimentul urinar. Quantimetrix

Advantages of PHASE CONTRAST MICROSCOPY by 77 Elektronika

URISED®
TECHNOLOGY

Urinalysis in general

Urinalysis is one of the most common and most important tests for screening urinary tract and kidney diseases. The presence or absence of urinary sediment particles is crucial for the diagnosis of such diseases, even though the manual method, which is the gold standard for urine sediment analysis, is poorly standardized, labor intensive, time consuming and operator dependent. Due to these drawbacks, urine sediment analysis has only been carried out in limited cases during the last few decades.[1,2] The patented UriSed Technology was developed to reduce the shortcomings of manual microscopy through automation.

UriSed Technology

UriSed Technology is the optimized automation of traditional manual microscopy using a special cuvette as the only consumable.
The instruments based on the UriSed Technology offer a reliable, standardized automatic method for the identification of urine sediment particles even from low sample volumes of 2 mL.

Detected particles

- Red Blood Cells
- White Blood Cells
  - WBC Clumps
- Hyaline casts
- Pathological casts
- Squamous Epithelial Cells
- Non-squamous Epithelial Cells
- Bacteria
  - Cocci
  - Rod
- Crystals
  - CaOxm
  - CaOxd
  - Triple phosphate
  - Uric acid
- Yeast
- Mucus
- Spermatozoon
- Amorphous material

[1]Barta Zs, Kránicz T, Bayer G, UriSed Technology - A Standardised Automatic Method of Urine Sediment Analysis, European Infectious Disease, 2011.
[2]Fogazzi GB, The Urinary Sediment, Third Edition, Elsevier, 2009.

Phase contrast microscopy

Phase contrast microscopy is an optical microscopy technique that converts phase shifts in light passing through a transparent specimen to brightness changes in the image. Phase shifts themselves are invisible, but become visible when shown as brightness variations.

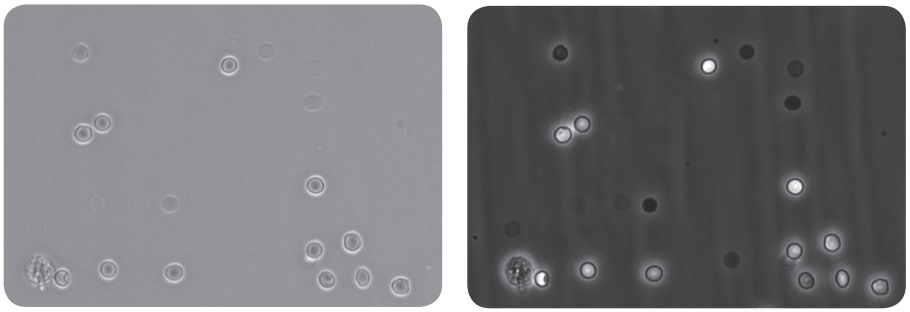
In particular, for urinary sediment examination, phase contrast supplies an optimal identification of particles with a low refractive index (e.g., hyaline casts and RBC devoid of their hemoglobin content, the so-called "ghost RBC") and of cellular morphological details. This last feature is of the highest importance for the differentiation of the renal epithelial cells from transitional epithelial cells. Moreover, it offers the best approach for the evaluation of RBC morphology. Therefore the use of phase contrast microscopy is encouraged also by international guidelines on urinalysis.[3]
The UriSed Technology based UriSed 3 PRO instrument combines both bright-field and phase contrast illumination in one optical system, taking information from both methods of the same viewfield into account.

Particle detection using Phase contrast microscopy

The most spectacular advantage for a user of phase contrast microscopy is that those sediment particles that are mostly transparent become visible! This leads to specific improvement in recognition at several particle types.

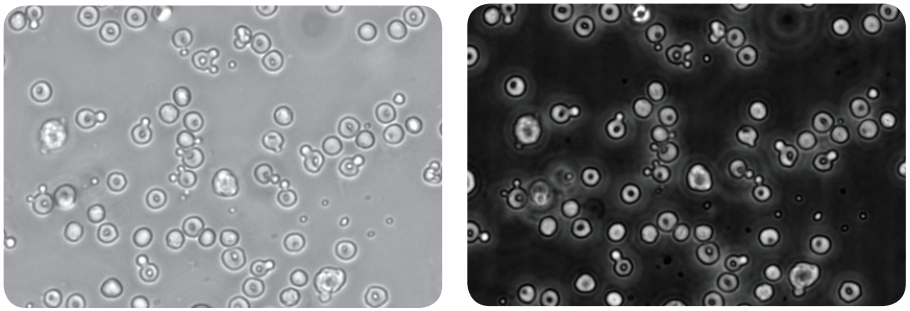
[3]European Urinalysis Guideline, p.23, European Confederation of Laboratory Medicine, 2000

Ghost Red Blood Cells



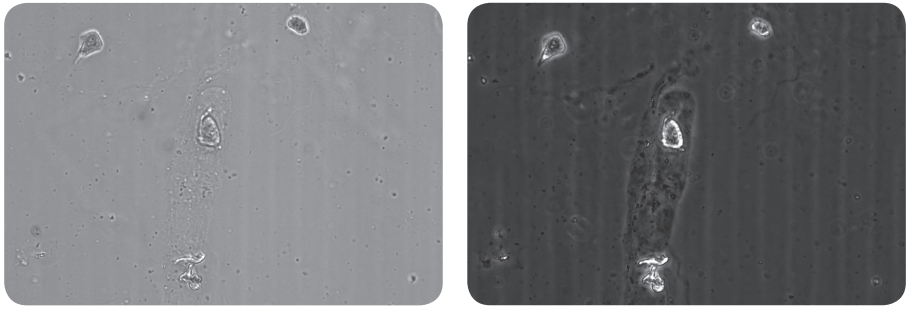
Easier identification of Ghost Red Blood Cells

Acanthocytes



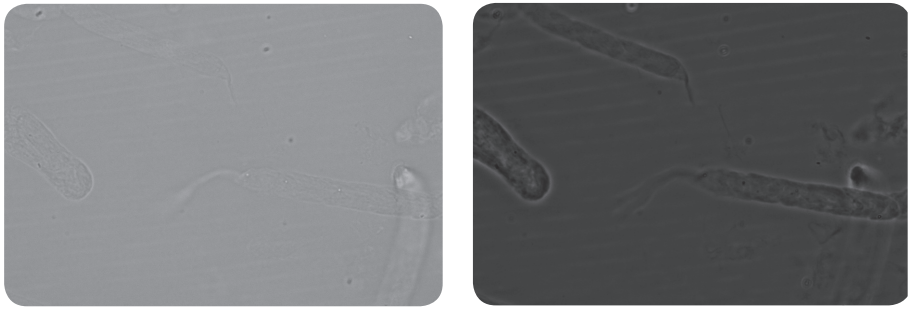
Easier identification of Acanthocytes

Pathological casts



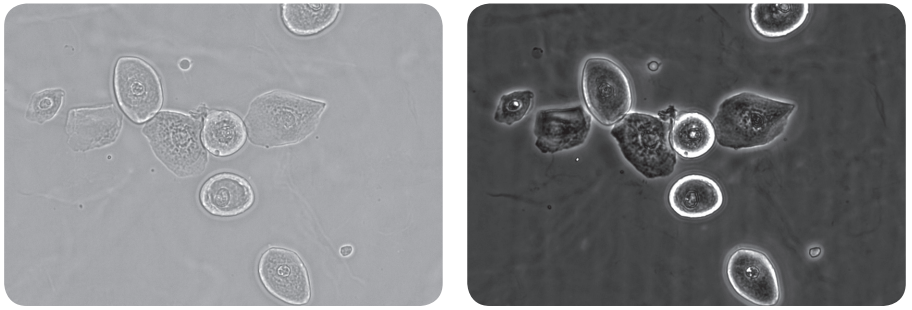
More reliable identification of Pathological Casts

Hyaline casts



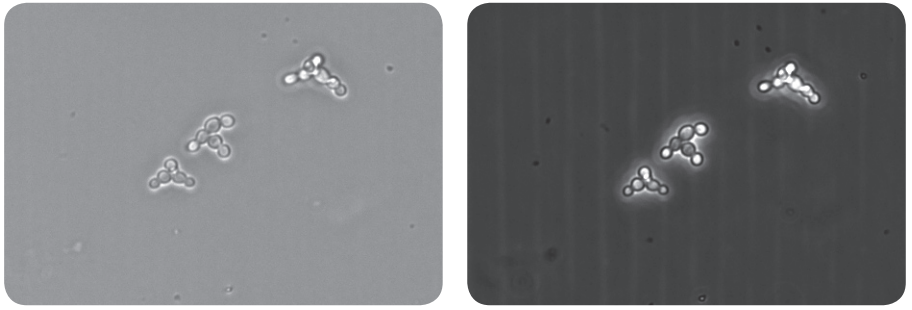
More reliable identification of Hyaline Casts

Squamous & Non-squamous Epithelial Cells



Easier subtype differentiation of Non-squamous Epithelial Cells

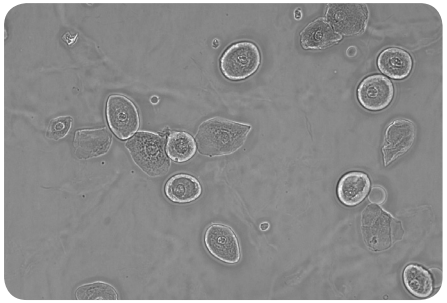
Yeasts

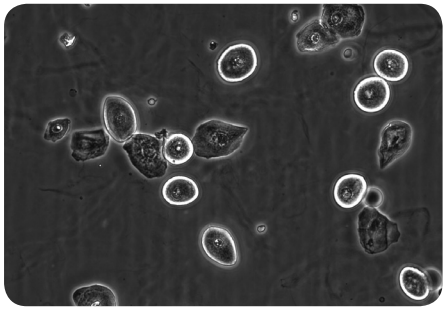


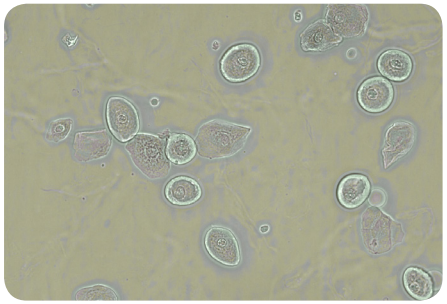
Better differentiation of Yeasts from Red Blood Cells

New PHASE with CONTRAST!

The UriSed 3 PRO instrument utilizes phase-contrast and bright-field microscopy to combine original and innovative technologies whose aim is the progressive improvement of automated urinary sediment examination and the progressive approach to the gold standard method manual microscopy. This instrument performs sample preparation and takes several images of the investigated 2.2 uL sample through its built-in microscope. The zoomable HPF-like images are evaluated by using the Auto Image Evaluation Module (AIEM), which is high-quality image processing software. UriSed 3 PRO takes and saves both a bright-field and a phase-contrast microscopy image from the same viewfield, and generates a composite image of the two to show the features of each image in one view. The evaluation provides a quantitative result for Red Blood Cells and White Blood Cells and semi-quantitative results for all other particle types.







Result Flags

With the aid of the new auto-flag feature, two different RBC subcategories can be identified.
Samples with haematuria are marked when the ratio of the hemolyzed – ghost – RBCs are higher than approximately 30%. This is practical in case of hypotonic urine, because the RBCs swell and release their hemoglobin content to become ghost cells. The auto-flag function also labels the sample if the ratio of acanthocytes – a type of dysmorphic RBC – is higher than 5%, which indicates the possible glomerular origin of the haematuria.

URISED® TECHNOLOGY

77 Elektronika Kft.

The Company

77 Elektronika is a developer, manufacturer of in vitro diagnostic medical devices mainly automated and semi-automated microscopic urine sediment analyzers, urine chemistry analyzers, blood glucose meters, rapid test readers and their consumables under own brand name and as OEM products for market-leading multinational companies in the field of medical diagnostics.

77 Elektronika was established in 1986 and is headquartered in Budapest, Hungary (EU). The company is committed to providing superior products and services to the complete satisfaction of its customers.

DISTRIBUTOR
STAMP

77 Elektronika Kft.

77 Elektronika Kft. Budapest, HUNGARY
E-mail: sales@e77.hu Web: www.e77.hu

URP-9302-3

Automated Urine Sediment Analyzer

UriSed 3 PRO

New PHASE with CONTRAST

- Revolutionary particle visualization and recognition utilizing both bright-field and phase contrast microscopy
- Zoomable HPF-like images
- Dual-view for both bright-field and phase contrast images
- Throughput: up to 130 tests/hour
- Fully automated sample preparation requiring only low sample volume
- Manual microscopy mode: Real-time view of any viewfield of the cuvette to see moving microorganisms as well
- No need for liquid reagents or calibrators
- Automated QC analysis and maintenance procedures
- UriSed 3 PRO and LabUMat 2 together make a Complete Urine Laboratory System
- Streamlined documentation by LIS connectivity

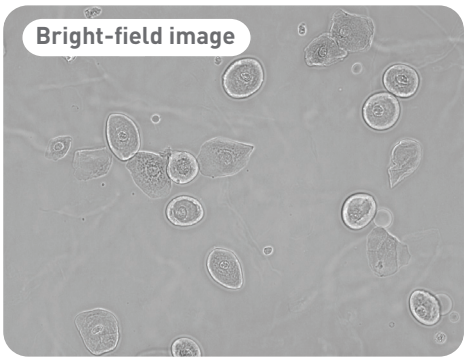
UriSed 3 PRO provides a uniquely advanced visualization and recognition of formed elements in urine sample using a special combination of bright-field and phase contrast microscopy by automating the gold standard method of sediment analysis.
It improves differentiation of hyaline casts, red blood cells, crystals, yeast and overall diagnostic performance in central screening laboratories as well as in specialist laboratories.

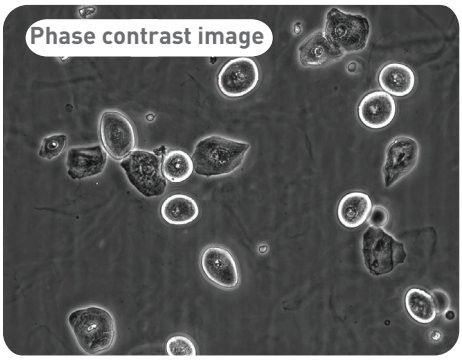
CE For professional Use IVD

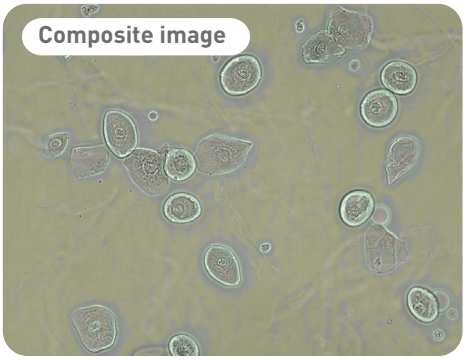
77 Elektronika Kft.

www.tuv.com TÜVRheinland ID:9105013598
- Certified Management System
- DIN EN ISO 14001
- EN ISO 13485
- EN ISO 9001

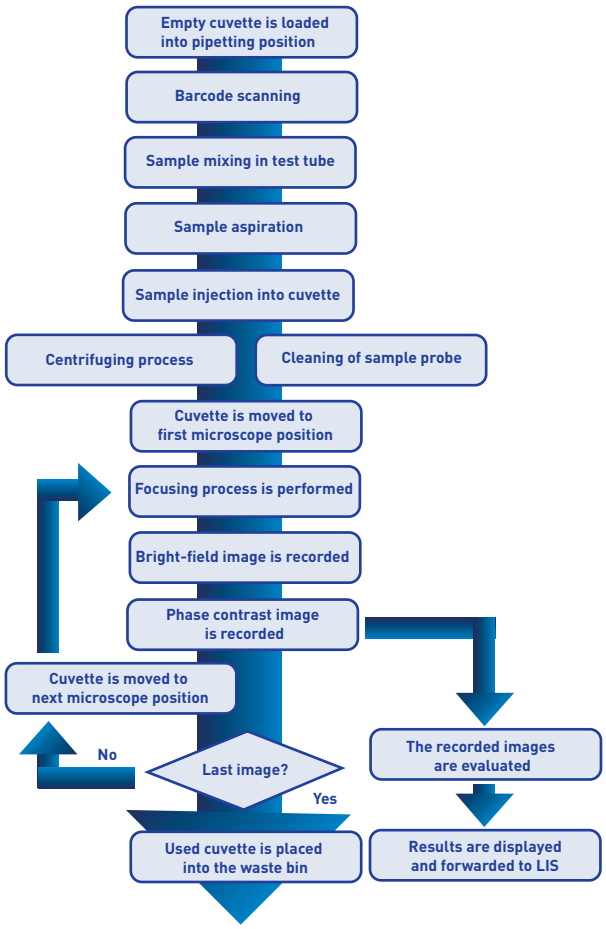
Urine particles with never-seen-before definition and clarity







Patented measurement process



Technical Specifications

Auto-detected particle classes:	Red Blood Cells (RBC); White Blood Cells (WBC); WBC Clumps (WBCc); Hyaline Casts (HYA); Pathological Casts (PAT); Squamous Epithelial Cells (EPI); Non-Squamous Epithelial Cells (NEC); Bacteria Cocci (BACc); Bacteria Rods (BACr); Yeast (YEA); Mucus (MUC); Sperm (SPRM); Crystals (CRY): Calcium-oxalate monohydrate (CaOxm), Calcium-oxalate dihydrate (CaOxd), Uric acid (URI), Triple phosphate (TRI).
Further classes for manual sub-classification are also available!	
Technology:	Cuvette based automated microscopy and image processing
Memory capacity:	10,000 results (including all images)
Throughput:	Up to 130 tests/hour
Magnification:	Zoomable HPF-like images
Displayed images:	Phase contrast, bright-field and composite
Min. sample volume:	2.0 ml (checked by liquid level sensor)
Batch size:	100 test tubes
Barcode reader:	Built-in
Printer:	Optional, external (connected to operating PC)
Interfaces:	USB, LAN, RS232 serial port
LIS connectivity:	LIS2-A2 or HL7
Size:	600 x 640 x 635 mm (W x D x H, without PC)
Weight:	63 kg (without operating PC)
Power (measuring unit):	100-240V AC / 50-60 Hz / max. 200 W
Power (operating PC):	100-127V AC / 47-63 Hz / max. 400 W
	220-240V AC / 47-63 Hz / max. 400 W

The operation of the instrument is based on the patented UriSed Technology. Working without any special liquid reagents, UriSed 3 PRO performs sample preparation, produces whole viewfield microscopic images and evaluates them using the Auto Image Evaluation Module (AIEM), a high-quality image processing software.

Using the phase contrast technology UriSed 3 PRO provides improved performance. It has outstanding visualization and recognition capabilities for every particle type even the ones that conventional bright-field microscopy cannot easily detect (such as casts and ghost red blood cells).

LabUMat 2 & UriSed 3 PRO

Complete Urine Laboratory System

Chemistry and sediment analysis in one system

The efficiency of LabUMat 2 test strip analyzer and UriSed 3 PRO microscopic sediment analyzer – both manufactured by 77 Elektronika – can be maximized by using the two instruments together as one system.
Common operation is enabled with physical and software connections between LabUMat 2 and UriSed 3 PRO. The results of both measurements are stored in a common database and reported as a common report.
Since all necessary measurements which have to be done on urine samples are completed by this integrated system in one process, the combination of LabUMat 2 and UriSed 3 PRO accelerates laboratory throughput and provides the most effective and reliable solution for complete and professional urine analysis.

All you need for complete urine analysis

LabStripU11 Plus GL test strips for LabUMat 2 (closed system)

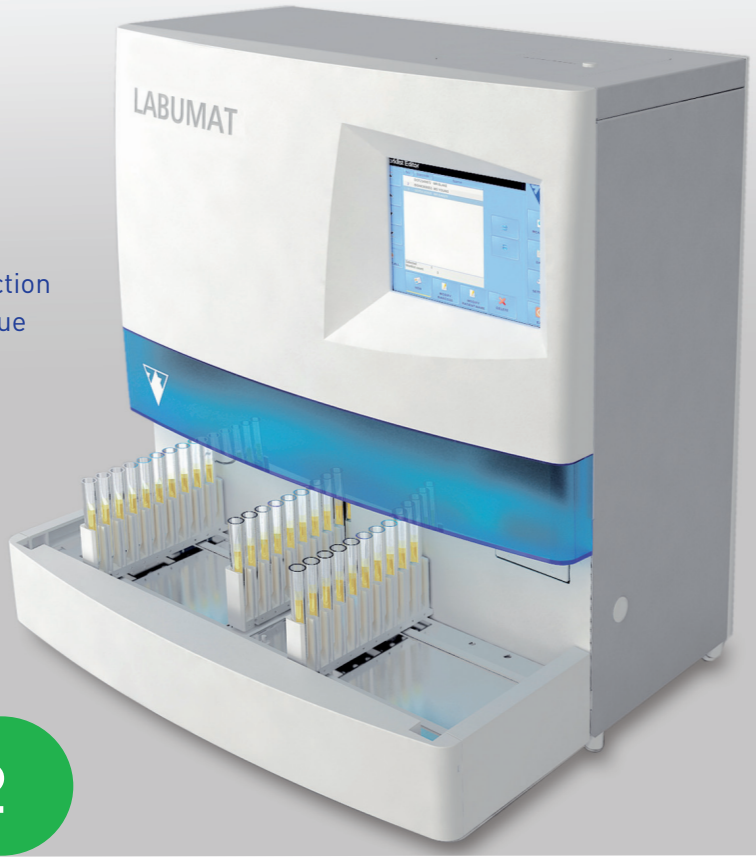
Cuvettes for UriSed 3 PRO (closed system)

Normal distilled water

Standard test tubes

Automated Urine Chemistry Analyzer

- Up to 240 tests/hour throughput
- Spotting method: sample dosage by pipetting unit
- Cost-effective operation without any special liquid reagents
- Low sample volume; liquid level detection
- Advanced, patented detection technique
- Separate PMC module for measuring physical parameters
- User friendly and flexible software; easy operation via color touch screen
- Streamlined documentation by LIS connectivity
- Automated QC analysis and self-check
- Software and language upgrades via USB stick



LabUMat 2

Proficiency and efficiency in urinalysis

The LabUMat 2 is a fully automated urine chemistry analyzer evaluating 10 chemical parameters of LabStrip U11 Plus GL test strips and 3 physical parameters. Besides preserving all its former attractive features, the new version of LabUMat has been significantly improved for an even better performance. Continuing its predecessor's mission, LabUMat 2 is a high quality and reliable instrument meeting the requirements of modern automated laboratories and providing walk-away operation. Easy operation via touch screen, automatic handling of test strips and test tubes – including sample mixing and precise dosing for each test pad by the pipetting unit – advanced detection technique and intelligent data management provide maximum efficiency while making urinalysis simple.

About 77 Elektronika

77 Elektronika Kft. is a major global developer, manufacturer and supplier of in vitro diagnostic medical devices, mainly urine analyzers, rapid test readers, blood glucose meters and their consumables. The products are supplied throughout the world under the 77 Elektronika brand and as OEM products for market-leading multinational companies.

77 Elektronika was established in 1986 and is headquartered in Budapest, Hungary (EU). The company is committed to providing superior products and services to the complete satisfaction of its customers.

Technical features

Methodology:	reflectance photometer, 4 discrete wavelengths
Evaluated parameters:	Bilirubin, Urobilinogen, Ketones, Ascorbic acid, Glucose, Protein, Blood, pH, Nitrite, Leucocytes via LabStrip U11 Plus (GL) urine test strip Specific gravity, Color, Turbidity via PMC (Physical Measurement Cell) module
Max. throughput:	up to 240 tests / hour
Batch size:	100 test tubes
Min. sample volume:	2.0 ml (checked by liquid level sensor)
Memory:	max 10,000 results
Display:	800x600 TFT
Size:	600x650x635 mm (LxDxH)
Weight:	55 kg
Input:	100-250V AC / 50-60 Hz
Power consumption:	max 200 W
Interfaces:	USB, RS232 serial port, PS2, VGA
Printer:	built-in thermal printer
Barcode reader:	built-in barcode reader

77 Elektronika Kft.
Fehérvári út 98. H-1116 Budapest, Hungary
Sales Hotline: +36-1-481-0139
Phone: +36-1-206-1480 Fax: +36-1-206-1481
E-mail: sales@e77.hu Web: www.e77.hu

URP-9303-1

77 Elektronika Kft.

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.

REF U12-9901-1

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

U12-9201EN-2

UriSed Cuvettes

REF

URS-9961HU
URS-9961-1
URS-9971
URS-9972
URS-9974
URS-9961CH-1
URS-9971CH

Instructions for use

Intended use:

UriSed Cuvettes are disposable, single use polycarbonate specimen receptacles used to analyze uncentrifuged, human urine samples with UriSed sediment analyzers. It is intended for professional, laboratory use. It is intended for in vitro diagnostic use.

Test principle:

UriSed Cuvettes are specimen receptacles allowing for microscopic analysis of urine samples.

Materials provided:

600 cuvettes in 12 cuvette holders of 50 cuvettes each

Materials not provided:

- Compatible urine sediment analyzer (UriSed,UriSed2, UriSed 3, UriSed 3 PRO, UriSed mini)
- General laboratory equipment

Using cuvettes:

1 Place the cuvette holder in your analyzer

2 Remove the closing tape of the cuvette holder

Environmental Conditions

Storage temperature	0 – 45°C
Transport temperature	-25°C – 60°C
Transport humidity	20 – 80 %
Operation conditions	According to your analyzer's conditions

⚠ Warnings and cautions

- Do not store cuvettes in direct sunlight
- Do not remove closing tape from the cuvette holder before installing in your analyzer
- Do not remove partially full cuvette holders from your analyzer
- Each cuvette is single use, never perform a test with previously used cuvette
- Since urine is a fluid of human origin, it may be infectious and may constitute a potential biological risk
- Handle used UriSed cuvettes and urine contaminants with care
- Dispose of waste according to accepted laboratory instructions and procedures.
- Contact your distributor to make sure to order cuvettes compatible with your specific analyzer
- Use cuvettes before expiration date

Check your analyzer's instructions for use for details on specimen collection, potential preparatory steps, result calculation, analytical and performance characteristics, interferences, limitations, quality control procedures, specific warnings and cautions.

Incident reporting

Report any serious incidents which may occur when using this product to your 77 Elektronika service representative and your local competent authority.

Symbols:

UDI	Unique Device Identifier
IVD	In vitro diagnostic medical device
REF	Catalogue Number
LOT	Lot Number
CE	The CE mark identifies that the product complie with the applicable directives of the EuropeanUnion
	Use by
0°C +45°C	Temperature Limitation
	Manufacturer
	Keep away from sunlight
	Consult instructions for use
20% 80%	Humidity Limitation
	Caution
	Biological Risks
Σ 600	Contents sufficient for 600 tests
	Do NOT Reuse
	Do not use if package is damaged
GB	English Language
CH	Batch number

Version history

Version	Date	Changes
3	2022.03.25	IVDR compliance update
2	2020.11.25	General update of content
1	2009.02.17	First release

Manufacturer:

77 Elektronika Kft.
98. Fehérvári út, 1116 Budapest
HUNGARY
www.en.e77.hu
sales@e77.hu
Tel: + 36 1 206 - 1480
Fax: + 36 1 206 - 1481

Certificate of Registration

nqa global assurance

This is to certify that the Quality Management System of:

Eastern Business Forms, LLC

530 Old Sulphur Springs Rd.
Greenville SC 29607
United States of America

applicable to:

Manufacture, assembly and distribution of filter paper-based specimen receptacles and kits

has been assessed and approved by
National Quality Assurance, U.S.A., against the provisions of:

ISO 13485:2016

For and on behalf of NQA, USA

ANAB
ANSI National Accreditation Board
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ISO/IEC 17021-1
MANAGEMENT SYSTEMS CERTIFICATION BODY

Certificate Number:	17633
EAC Code:	07
Certified Since:	December 5, 2014
Valid Until:	December 4, 2026
Reissued:	April 27, 2025
Cycle Issued:	December 5, 2023