Literature list – Urinalysis

Customer information

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1   General Urinalysis Publications & Reviews

OA
Kouri T et al. (2024):
The EFLM European Urinalysis Guideline 2023. Clin Chem Lab Med 62(9):1653-1786.

https://pubmed.ncbi.nlm.nih.gov/38554005/

Summary: The EFLM Task and Finish Group Urinalysis has updated the ECLM European Urinalysis Guidelines from the year 2000 on urinalysis and urine bacterial culture, to improve accuracy of these examinations in European clinical laboratories, and to support diagnostic industry to develop new technologies. This guideline provides graded recommendations for the following areas: (I) medical needs and requisition, (II) patient preparation, (III) specimen collection and preservation, (IV) accuracy levels of urinalysis examinations, (V) chemistry, (VI) particles and (VII) bacteriology.

#Urinalysis #Guideline #EFLM

Oyaert M et al. (2022):
Improving clinical performance of urine sediment analysis by implementation of intelligent verification criteria. Clin Chem Lab Med 60(11):1772-1779.

https://pubmed.ncbi.nlm.nih.gov/36069776/

Summary: In this study, urinary diagnostic data, obtained from urinary test strip analysis on the UC-3500 and urinary flow cytometry on the UF-5000 were combined with intelligent verification criteria, aiming to evaluate improvements in diagnostic performance in context of combination of diagnostic data. By this, an increase in specificity from 88.5 to 96.8% and from 88.2 to 94.9% was achieved for RBCs and WBCs, respectively. In addition, the implementation of review rules for RTECs and pathological casts increased the specificity from 66.7 to 74.2% and from 96.2 to 100.0%, respectively. Furthermore, there was an improvement in the diagnostic performance of Atyp.C and crystals. The authors concluded that the implementation of intelligent verification and review rules improved the diagnostic performance of urinary flow cytometry.

#UF5000 #UC3500 #IntelligentReview #WBC #RBC# Xtal # Casts #AtypC #RTEC

OA
Oyaert M and Delanghe JR (2019):
Progress in Automated Urinalysis. Ann Lab Med 39(2):15-22.

https://pubmed.ncbi.nlm.nih.gov/30215225/

Summary: This publication is a comprehensive review of the current status of automated urinalysis, highlighting the potential quantitative reading of urinary test strips using CMOS technology for albuminuria testing and the value of urinary flow cytometry for the differentiation of urinary microorganisms, screening for urinary tract infections and clinical decision support in a variety of nephrological and urological diseases. In addition, progress in automated urinary microscopy and the improved pathogen identification by MALDI-TOF mass spectrometry is reflected and an outlook into future technologies, such as laboratory-on-a-chip approaches, use of microfluids and mobile applications is given.

#AutomatedUrinalysis #AutomatedMicroscopy #uFCM #TestStrip #Review

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2   UN-Series Performance Evaluations

2.1. UF–Series – Automated urine particle analysis

Hoshi M et al. (2024):
Consistency Analysis of the UF-1500 and UF-5000 Automated Urine Particle Analyzers. Clin Lab 70(5).

https://pubmed.ncbi.nlm.nih.gov/38747933/

Summary: This study aimed evaluate the consistency of the analytical performance between the UF-1500 and UF-5000. In total, 554 random urine samples were assessed on both platforms and by manual microscopy. The relative standard deviations for the intra-day and inter-day measurements ranged from 5.9% to 12.6% and 4.9% to 17.2% for samples with low counts and from 1.6% to 9.3% and 2.3% to 16.9% for samples with high counts for RBC, WBC and EC, respectively. The correlation co-efficient for RBCs, WBCs, ECs, SECs, casts, crystals, and bacteria for the UF-1500 were 0.981, 0.993, 0.968, 0.963, 0.821, 0.783, and 0.992, respectively. The authors concluded that the identification of various urine components by both instruments meets laboratory requirements.

#UF1500 #UF5000 #PerformanceComparison #ConsistencyAnalysis

OA

Morita Y et al. (2023):
Evaluation of the fully automated urine particle analyzer UF-1500. J Clin Lab Anal 37(24):e24993.

https://pubmed.ncbi.nlm.nih.gov/38041489/

Summary: This study assessed the performance of the UF-1500 in comparison to the UF-5000 and manual microscopy. In total, 648 residual urine samples were analysed to obtain concordance rates and detection accuracy for the UF-1500. Here, the concordance rates ranged between 75.3%-98.5% for comparison of the UF-1500 and microscopy. The UF-1500 concordance rates within one group agreement were observed to be >90%, for all parameters except for YLCs. The differences within one group agreement between the UF-1500 and manual microscopy were insignificant, in comparison to the UF-5000, with exceptions noted for ECs and YLCs. The sensitivity and specificity of the UF-1500 for RBCs, WBCs, Squa.ECs, and BACT exceeded 80%, while the positive predictive values of ECs and CASTs were below 70%. The authors concluded a performance of the UF-1500, comparable to that of the UF-5000, allowing its clinical application.

#UF1500 #UF5000 #ManualMicroscpopy #PerformanceComparison

Yis OM et al. (2022):
Performance Evaluation of Urine Osmolality Measurement on Sysmex UF-5000 and the Effect of Molecules and Particles in Urine. Clin Lab 69(3).

https://pubmed.ncbi.nlm.nih.gov/36912295/

Summary: This study evaluated the analytical performance of the osmolality measurement on the UF-5000, to examine the effect of different molecules and particles in the urine on the osmolality measurement. Considering the good accessibility of the automated routine urine analyser, UF-5000 can be considered to determine whether urine osmolality is within reference or should be measured by methods based on colligative properties. Thus, referral of patients to a clinic that uses the colligative measurement method may be used more effectively.

#UF5000 #Osmolality #AnalyticalPerformance

OA **Demirel OU et al. (2022)**:
Comparison of Sysmex UF-5000 flow cytometer and Fuchs-Rosenthal chamber urine sediment analysis. Medicine Science 11(1):367-371.

https://www.medicinescience.org/article/2532

Summary: This study evaluated the diagnostic performance of urine sediment analysis of the Sysmex UF-5000 flow cytometer in comparison to manual counting using the Fuchs-Rosenthal chamber. The authors concluded that urinary flow cytometry is a promising area compared to the manual reference method. Urinalysis automation reduces TAT, laboratory workloads and workforce and the need for microscopic review.

#UF5000 #FlowCytometry #AnalyticalPerformance #FuchsRosenthalChamber

OA **Yang SSD et al. (2021)**:
A performance comparison of the fully automated urine particle analyzer UF-5000 with UF-1000i and Gram staining in predicting bacterial growth patterns in women with uncomplicated urinary tract infections. BMC Urol 21:24.

https://pubmed.ncbi.nlm.nih.gov/33579236/

Summary: This study aimed to compare the performance of the new UF-5000, the UF-1000i and Gram staining for determining bacterial patterns in urine samples. Mid-stream urine samples of women with symptoms suggestive of urinary tract infection were collected for gram staining, urine analysis and urine cultures. Bacterial patterns were classified using the UF-1000i, the UF-5000 and Gram staining. The collected data revealed a sensitivity/specificity of the UF-1000i of 81.8/91.1% for gram-negative rods and 23.5/96.9% for cocci/mixed. The sensitivity/specificity of the UF-5000 was 80.0/88.2% for gram negative rods and 70.0/86.5% for gram-positive cocci. The authors conclude that the UF-5000 demonstrated good sensitivity and specificity for Gram-negative bacilli and showed an improved sensitivity for detecting Gram-positive cocci.

#UF5000 #UF1000i #FlowCytometry #AnalyticalPerformance #BacteriaDetection

OA **Yoo DW et al. (2021)**:
Evaluation of conductivity-based osmolality measurement in urine using the Sysmex UF-5000. J Clin Lab Anal 35(1):e23586.

https://pubmed.ncbi.nlm.nih.gov/32969530/

Summary: The aim of this study was the evaluation of the performance of the measurement of urinary osmolality on the UF-5000. Here, the precision of urine osmolality measurement by the UF-5000 was evaluated for 20 days and 4 times a day for 2 concentrations. Additionally, 270 random urine specimens were tested simultaneously using the UF-5000 and the OsmoPro micro-osmometer. The analysis confirmed a linear range for the osmolality measurements. In comparison to the OsmoPro, the median difference was low, but individual difference dispersed largely resulting in a moderate agreement ($\kappa = 0.54$). The authors concluded that the UF-5000 generated an acceptable quantitative analysis of urine osmolality, but in comparison to the freezing point depression method, some measurements were outside the allowable limit.

#UF5000 #Osmolality #Conductivity #OsmoPro #AnalyticalPerformance

Enko D et al. (2020):
Comparison of the diagnostic performance of two automated urine sediment analyzers with manual phase-contrast microscopy. Clin Chem Lab Med 58(2):268-273.

https://www.ncbi.nlm.nih.gov/pubmed/31605578

Summary: This study aimed to compare the diagnostic performance of the UF-5000 and the cobas® u 701 urine sediment analysers with manual phase-contrast microscopy. In total, 195 urine samples were assessed by the two automated platforms and manual microscopy. The agreement of the UF-5000 with manual microscopy was almost perfect ($\kappa > 0.8$) for RBC, WBC, RTECs, hyaline casts, BACT and YLC, substantial ($\kappa = 0.61$-0.80) for SEC and pathological casts, and moderate ($\kappa = 0.41$-0.60) for TEC. The cobas® u 701 showed substantial agreement ($\kappa = 0.61$-0.80) for WBC, moderate agreement ($\kappa = 0.41$-0.60) for hyaline casts, and fair agreement ($\kappa = 0.21$-0.40) for RBC, SEC, NEC, pathologic casts, BACT and YLC. The UF-5000 sensitivities ranged between 98.5% for RBC and 83.3% for pathological casts. The cobas® u 701 showed sensitivities between 83.0% for WBC and 31.6% for YLC. The authors concluded that the analytical performance of the UF-5000 is in strong concordance with manual phase-contrast microscopy and clearly outperforming the Roche cobas® u701 module.

#UF5000 #PerformanceComparison #RocheCobas #PhaseContrastMicroscopy

Kucukgerin C et al. (2019):
Performance of automated urine analyzers using flow cytometric and digital image-based technology in routine urinalysis. Scand J Clin Lab Invest 79(7):468-474.

https://pubmed.ncbi.nlm.nih.gov/31460810/

Summary: This study evaluated the analytical performances of the UF-5000 and the Dirui FUS-20 in comparison to manual microscopy. Thereby, all available urinalysis aspects and sediment results were investigated within one hour after sample collection. Accurate results have been obtained from both analytical systems, the FUS-200 and the UF-5000, as good linearity without carry- over has been shown. The authors concluded that overall, the UF-5000 demonstrated better agreement in classification of WBCs, RBCs, ECs, positively affecting the morphologic recognition and enumeration of cells.

#UF5000 #PerformanceComparison #DiuriFUS200 #ManualMicroscopy

Cho J et al. (2019):
Comparison of five automated urine sediment analyzers with manual microscopy for accurate identification of urine sediment. Clin Chem Lab Med 57(11):1744-1753.

https://www.ncbi.nlm.nih.gov/pubmed/31280239

Summary: This study evaluated the analytical and diagnostic performance of the Sysmex UF-5000, the Roche cobas® u701 module, the URiSCAN PlusScope and the Iris iQ200SPRINT and the SIEMENS UAS800 in comparison to manual microscopy. The authors concluded that each automated urine sediment analyser has distinct features, in addition to the common advantages of reducing the burden of manual processing. Therefore, laboratory physicians are encouraged to understand these features, and to utilize each system in appropriate ways, considering clinical algorithms and laboratory workflow.

#UF5000 #PerformanceComparison #RocheCobas #BeckmanIris #SiemensUAS800 #ManualMicroscopy

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Oyaert M et al. (2019):

Estimated urinary osmolality based on combined urinalysis parameters: a critical evaluation. Clin Chem Lab Med 57(8):1169-1176.

https://pubmed.ncbi.nlm.nih.gov/30753156/

Summary: This study evaluated the analytical performance of the conductivity-based osmolality parameter of the UF-5000, provided algorithmic improvements for the estimation of urinary osmolality and assessed the impact of contrast media on the osmolality measurement. The within-run and between-run imprecision for osmolality and conductivity measured on the Sysmex UF-5000 ranged from 1.1% to 4.9% and 0.7% to 4.8%, respectively. Multiple regression analysis revealed urinary creatinine, conductivity and relative density to be the strongest predictors to estimate urinary osmolality. An excellent correlation between the relative density and % contrast media was demonstrated. The authors concluded that urinary osmolality is an important parameter for assessing specimen dilution in urinalysis. Urinary conductivity, along with relative density and urinary creatinine allows a coarse prediction of urinary osmolality and is insensitive to the osmolal contribution of uncharged particles and contrast media.

#UF5000 #Osmolality #Conductivity #ContrastMedia #AnalyticalPerformance

OA Bakan E et al. (2018):

Evaluation of the analytical performances of Cobas 6500 and Sysmex UN series automated urinalysis systems with manual microscopic particle counting. Biochem Med (Zagreb) 28(2):020712.

https://www.ncbi.nlm.nih.gov/pubmed/30022887

Summary: This study compared the diagnostic performance of the UF-5000 and the Roche cobas® u701 module to manual microscopy. Comparing the quantification of WBCs and RBCs, the UF-5000 obtained the better sensitivities and specificities and showed high agreement with manual microscopy. The authors conclude that the UF-5000 is a reliable tool for urine sediment analysis, but pathological samples should be confirmed by microscopy.

#UF5000 #PerformanceComparison #RocheCobas #ManualMicroscopy

OA Previtali G et al. (2017):

Performance evaluation of the new fully automated urine particle analyser UF-5000 compared to the reference method of the Fuchs-Rosenthal chamber. Clin Chim Acta 472:123-130.

https://www.ncbi.nlm.nih.gov/pubmed/28760666

Summary: In this study, the authors evaluated the analytical performance of the Sysmex UF-5000 for urine sediment samples compared manual counting using the Fuchs-Rosenthal chamber. The evaluation demonstrated sensitivities >0.90 for all particles. The specificity ranged between 0.74 and 0.89 for total cast, EC/NEC/RTEC and RBC, while it was >0.90 for all other parameters. The comparison to Fuchs-Rosenthal chamber reached moderate to high concordance for all parameters. Linearity was 1.00, 1.00 and 0.99 for RBC, WBC and EC, respectively. The within-run imprecision was 25.42%,13.81%,1.36% for RBC; 37.50%,10.16%,1.41% for WBC and 35.25%, 17.85%,6.30% for EC at low, near the cut-off level and high concentrations, respectively. The between-run imprecision was 6.90%,1.60% for RBC, 4.10%,1.90% for WBC and 7.60%,7.30% for EC, using low and high positive quality controls, respectively. The authors concluded a high potential for the UF-5000 to investigate urine sediment particles related to pathological conditions.

#UF5000 #PerformanceComparison #Microscopy #FuchsRosenthalChamber

2.2. UC-Series – Automated urine chemistry analysis

OA

Oyaert M and Delanghe JR (2019):
Semiquantitative, fully automated urine test strip analysis. J Clin Lab Anal 33(5):e22870.

https://pubmed.ncbi.nlm.nih.gov/30803042/

Summary: This study evaluated the analytical and diagnostic performance of the UC-3500 for the presence of glucose, protein, albumin, leukocyte esterase, and haemoglobin peroxidase activity and ordinal scale results in comparison to the analysis of urine sediments using the UF-5000 as well as in comparison to wet clinical chemistry using the Roche cobas® 8000. Especially for detection of glycosuria, proteinuria and albuminuria, a perfect agreement between the reflectance data of the UC-3500 and immunochemistry results has been obtained. This allows the UC-3500 to provide a high-throughput first-level screening method for urinalysis which acts as a reliable sieving system to reduce the workload for further validation methods. Here, the sensitivity and specificity for glucosuria, proteinuria, albuminuria, leucocyturia, and haematuria was 100 and 60%, 94.2 and 88.2%, 81.8 and 89.2%, 81.7 and 92.8%, and 85.1 and 88.6%, respectively. The negative predictive values were 100%, 83.3%, 89.1%, 94.6%, and 96.1%. In total, depending on the parameter, the correlation of the UC-3500 in comparison to the reference methods ranged from 0.915 to 0.967. The authors concluded that the UC-3500 shows a satisfying performance and can reliably rule-out negative urine samples allowing to focus on further characterization of positive samples.

#UC3500 #TestStrip #DiagnosticPerformance #GLU #BLD #LEU #ALB #PRO

Oyaert M et al. (2018):
Quantitative urine test strip reading for leukocyte esterase and hemoglobin peroxidase. Clin Chem Lab Med 56(7):1126-1132.

https://pubmed.ncbi.nlm.nih.gov/29427551/

Summary: This study investigated the diagnostic accuracy of the Sysmex UC-3500 automated urine chemistry analyser that uses CMOS sensor technology for leukocyte esterase and haemoglobin peroxidase analysis. In addition, the influence of urinary dilution, haptoglobin, urinary pH and ascorbic acid on the test results has been assessed. Within- and between-run imprecision ranged from 1.1% to 3.6% and 0.9% to 4.2% for peroxidase and 0.4% to 2.5% and 0.4% to 3.3% for leukocyte esterase. Good agreement was obtained between the UF-5000 for RBCs and peroxidase reflectance (r=0.843) and for WBCs and leukocyte esterase (r=0.821). Specific esterase activity decreased for WBC counts exceeding 100 cells/μL. The authors conclude that CMOS technology allows to obtain high quality test strip results for assessing WBC and RBC in urine. Quantitative peroxidase and leukocyte esterase are complementary with flow cytometry and have an added value in urinalysis.

#UC3500 #TestStrip #DiagnosticPerformance #LEU #BLD #Interferences

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2.3. UD-Series – Automated digital urine microscopy

Hennequin C et al. (2023):
Detection and identification of urinary crystals using an automated urine particle analyzer coupled with a digital particle imaging device. Ann Biol Clin (Paris) 81(1):86-90 [Article in French].

https://pubmed.ncbi.nlm.nih.gov/36762455/

Summary: In this study, the UF-4000 analyser in combination with the UD-10 was assessed for the ability to detect and identify the crystals and the quality of the images provided by the UD-10. The assessment of 76 urine samples by polarised light microscopy and the Uf-4000/UD-10 analysis demonstrated that attentive examination of the UD-10 images is needed to confidently detect crystalluria. The analysis of additional 200 samples revealed sensitivity of 39% and an NPV of 46% for the detection of crystalluria by the UF-4000. Both values increased to 100%, if the analysis of UD-10 images was included. Digital images can therefore serve to screen crystalluria without missing crystals and highlight crystalluria with a PPV of 78%. The authors concluded that the combination of UF-4000 and UD-10 can be used in clinical practice with close examination of the particle images to discriminate positive and negative crystalluria, but microscopy is needed, if crystals are observed on the UD-10 in certain conditions.

#UF4000 #UD10 #Crystalluria #DigitalImaging

3 Nephrology

3.1. Albuminuria and Chronic Kidney Disease (CKD)

NEW

OA

Lambrecht S et al. (2025):
Optimization of screening strategy for chronic kidney disease by urine test strips using the albumin-creatinine read-out. BMC Nephrol 26(1):130.

https://pubmed.ncbi.nlm.nih.gov/40065231/

Summary: Clinical laboratories are vital in diagnosing and monitoring chronic kidney disease (CKD). This study evaluated qualitative and semi-quantitative albumin-to-creatinine ratio (ACR) and protein-to-creatinine ratio (PCR) test strips as screening tools for albuminuria across diverse patient groups. Using the UC-3500 instrument, semi-quantitative ACR and PCR were assessed in two cohorts (n=940 and n=927), comparing them to quantitative measures. Semi-quantitative ACR showed high sensitivity (78.1–89.9%) and specificity (92.1–93.3%) with over 90% agreement to quantitative methods, outperforming qualitative protein and semi-quantitative PCR tests. The findings support urine test strips, particularly ACR, as effective screening tools for CKD in low-risk populations, recommending ACR for reflex testing in urine strip screening protocols.

#UC3500 #TestStrip #Albuminuria #Proteinuria #ACR #PCR #CKDscreening

OA

KDIGO CKD Work Group (2024):
KDIGO 2024 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease. Kidney Int 105(4S):S117-S314.

https://pubmed.ncbi.nlm.nih.gov/38490803/

Summary: The new KDIGO clinical practice guideline for the evaluation and management of chronic kidney diseases replaces the previous version from the year 2012. It provides comprehensive insights and guidance on (I) the burden of CKD, (II) the detection of CKD, (III) the staging of CKD, (IV) the CKD risk assessment, (V) the role of statins, blood pressure control and RAS inhibitors and (VI) the application of SGLT2 inhibitors.

#CKD # KDIGO #ClinicalPractice #Guideline

OA

Francis A et al. (2024):
Chronic kidney disease and the global public health agenda: an international consensus. Nat Rev Nephrol. Online ahead of print.

https://pubmed.ncbi.nlm.nih.gov/38570631/

Summary: In this consensus statement, leading nephrologists and nephrology organisations highlight the need for the inclusion of kidney disease into the current WHO statement on major non-communicable diseases that drive premature mortality in reflection of (I) the lack of awareness for kidney disease, (II) the need for kidney disease detection and prevention programs, (III) epidemiology and burden of kidney disease and (IV) socio-economic differences in kidney disease.

#CKD # PublicHealth #DiseaseBurden #ConsensusStatement #ASN #ERA #ISN

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OA

Nah EH et al. (2021):
Screening of Chronic Kidney Disease in Primary Health: Comparison of the Urine Dipstick Albumin-to-Creatinine Ratio and Dipstick Proteinuria. Annals of Public Health Reports 5(1):152–159.

https://scholars.direct/Articles/public-health/aphr-5-031.pdf

Summary: The aim of this study was to compare test strip ACR with proteinuria for CKD screening in a primary healthcare setting. This cross-sectional study included 88,479 specimens with ACR, and proteinuria was measured on the UC-3500 automated urine test strip analyser. The concordance rates between the dipstick ACR- and proteinuria- or PCR-based CKD risk categories were 88.76% (κ = 0.567) and 92.06% (κ = 0.683), respectively. The data highlight that grouping according to proteinuria leads to an underestimation of CKD risk categories. The authors concluded that ACR-based CKD risk assessment should be performed and recommended the test strip-based CKD screening in primary healthcare settings.

#UC3500 #TestStrip #Albuminuria #Proteinuria #ACR #PCR #CKDscreening

OA

Currin SD et al. (2021):
Diagnostic accuracy of semiquantitative point of care urine albumin to creatinine ratio and urine dipstick analysis in a primary care resource limited setting in South Africa. BMC Nephrol 22(1):103.

https://pubmed.ncbi.nlm.nih.gov/33743616/

Summary: This study evaluated the diagnostic accuracy of the semi-quantitative albumin-creatinine ratio (ACR) measurement on the UC-1000 at the point of care by determining the sensitivity, specificity, positive predictive value, and negative predictive value for the ACR. The prevalence of albuminuria in the study cohort was 11.6% and accompanied by underlying diseases such as diabetes and hypertension. The performance showed of the ACR measurement showed a sensitivity of 0.79, a specificity of 0.84, a positive predictive value of 0.39 and a negative predictive value 0.97. The sensitivity improved, if including additional information, such as underlying diseases and age. The authors conclude that the study demonstrated a good NPV for the test strip-based estimation of the ACR at the point of care, offering the potential for frequent screening of risk group patients and reliable rule-out of albuminuria.

#UC1000 #TestStrip #Albuminuria #ACR #CKDscreening #PrimaryCare

Salinas M et al. (2019):
Laboratory intervention to improve the request of urinary albumin in primary care patients with arterial hypertension and financial implications. Clin Biochem 69:48-15.

https://pubmed.ncbi.nlm.nih.gov/31002773/

Summary: This study summarised an approach to improve the request for urinary albumin assessments in risk group patients, suffering from arterial hypertension. Through the LIS, ACR testing was automatically registered for hypertension patients, if there the last assessment was done in the previous year. ACR measurement was done by test strip on the UC-3500 and by using a quantitative approach. Among 48,075 primary care patients, 3,816 (7.9%) had a confirmed indication for hypertension. In 386 cases, ACR testing was registered automatically. The additional test strip analysis costed 275.80 € but resulted in savings of 1,450.30 € for quantitative albumin assessment in albumin reagent. The authors concluded that laboratory technology can support the screening for CKD among risk groups with improved adherence to guidelines at no additional cost.

#UC3500 #TestStrip #Albuminuria #ACR #Hypertension #CKDscreening #Economics

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Salinas M et al. (2018):

Urinary albumin strip assay as a screening test to replace quantitative technology in certain conditions. Clin Chem Lab Med 57(2):204-209.

https://pubmed.ncbi.nlm.nih.gov/30024851/

Summary: This study aimed to evaluate the diagnostic performances of the Meditape 11A test strip for measuring ACR for differentiating patients who are candidates for subsequent albumin quantification, and to evaluate the economic effects of its implementation. Based on the testing of 9,148 patients, the diagnostic performance at different albumin and creatinine cut-offs was best for ACR values of 10 mg/L and ≥50 mg/dL, respectively. Based on the collected data results, 3,506 quantitative urine albumin and creatinine tests could have been avoided during the study period, corresponding to potential cost savings of 4,226.94 €. The authors concluded that the detection of albumin and ACR by test strip is a suitable screening approach to identify pathological albuminuria. The performance of the test strip and its workflow benefits did not only foster economic savings, but also elucidated the potential for frequent screening among CKD risk groups.

#UC3500 #TestStrip #Albuminuria #ACR #CKDscreening #QuantitativeACR #Economics

Salinas M et al. (2018):

Urinary albumin: a risk marker under-requested in primary care in Spain. Ann Clin Biochem 55(2):281-286.

https://pubmed.ncbi.nlm.nih.gov/28656819/

Summary: This cross-sectional study examined regional differences in albuminuria test requests across Spain, comparing them to guideline recommendations. Data from 2012 to 2014 on test requests by general practitioners were used to calculate a variability index. The study assessed potential underuse in managing diabetes and hypertension by comparing test volumes to disease prevalence. Significant variation was found among regions, with indicators ranging from 46.0 to 125.8, yet no laboratory met the recommended testing thresholds of 78 and 159 tests per 1,000 inhabitants. The findings indicate that urinary albumin testing in Spanish primary care shows substantial regional variability and is insufficient for proper monitoring of diabetes and hypertension.

#Albuminuria #CKDscreening #Diabetes #Hypertension #Spain #GuidelineAdherence

Delanghe JR et al. (2017):

Sensitive albuminuria analysis using dye-binding based test strips. Clin Chim Acta 471:107-112.

https://pubmed.ncbi.nlm.nih.gov/28554541/

Summary: This study assessed the CMOS sensor technology of the UC-3500 for semi-quantitative albuminuria and proteinuria results compared to clinical wet chemistry using the cobas® 8000 immunochemistry analyser for proteinuria and creatinine, and the BNII for albumin measurement. Results showed a strong correlation (r=0.92) between BNII albuminuria and protein test strip reflectance data, and creatinine reflectance correlated well with Jaffe-based urinary creatinine data (r=0.90). Test strip-derived albumin:creatinine ratio also correlated well (r=0.59) with quantitative methods. The study found a detection limit of 5.5 mg/L for albumin, suitable for CKD screening. Authors concluded that the dye-binding albumin test strip with CMOS reflectance on the UC-3500 enables quantitative albuminuria analysis and albumin:creatinine ratio determination.

#UC3500 #TestStrip #Albuminuria #ACR #CMOS #QuantitativeACR #Performance

3.2. Acute Kidney Injury (AKI)

NEW

Oyaert M et al. (2022):
Renal tubular epithelial cells as an easily accessible biomarker for diagnosing AKI post cardiac surgery. Intensive Care Med. Online ahead of print.

https://pubmed.ncbi.nlm.nih.gov/40323452/

Summary: This study assessed urinary particle analysis for diagnosing acute kidney injury (AKI) in adults post-cardiac surgery. Among 239 patients monitored, 73% developed AKI (16.3% stage 1, 50.6% stage 2, 6.3% stage 3), classified by KDIGO criteria. Urinary biomarkers were measured at 4, 12, and 24 hours after ICU admission. Early post-surgery, alpha-1-microglobulin and Nephrocheck® effectively predicted AKI within 48 hours, with Nephrocheck® particularly useful for stage ≥2 AKI. At 12 and 24 hours, renal tubular epithelial cells (RTEC) showed the highest predictive value for AKI, based on serum creatinine and KDIGO criteria, with accuracy extending up to 7 days. Hydration status adjustment did not improve predictions. The study concluded that urinary particle analysis—especially RTEC—supports early AKI diagnosis and clinical decision-making post-surgery.

#UF5000 #RTEC #AKI #CardiacSurgery

3.3. Glomerular diseases

NEW

OA

Lv S et al. (2025):
UF-5000 urinary erythrocyte parameters versus urinary aberrant erythrocytes and acanthocytes for diagnosing IgA glomerular hematuria. Sci Rep 15(1):1157.

https://pubmed.ncbi.nlm.nih.gov/39774763/

Summary: This study assessed the UF-5000 in context of IgA glomerular hematuria. Urine samples from 53 IgA nephropathy cases and 143 controls were analyzed. Two UF-5000 parameters - UF-sRBC% (small red blood cells ratio) and lysed RBCs -showed strong diagnostic performance (AUC = 0.857 and 0.860). Combining these with urine protein dry chemistry improved accuracy (AUC = 0.967; PPV = 91.89%; NPV = 93.10%), outperforming microscopy for aberrant erythrocytes and acanthocytes. A negative correlation existed between erythrocyte size index and aberrant erythrocyte proportion (r = -0.787). Overall, UF-5000 parameters offer a faster, more accurate method for identifying IgA nephropathy, potentially replacing manual microscopy.

#UF5000 #IgANephropathy #lysedRBC #sRBC%

OA

Cho H et al. (2022):
Diagnostic Characteristics of Urinary Red Blood Cell Distribution Incorporated in UF-5000 for Differentiation of Glomerular and Non-Glomerular Hematuria. Ann Lab Med 42(2):160-168.

https://pubmed.ncbi.nlm.nih.gov/34635609/

Summary: This study assessed the UF-5000's urinary RBC distribution (URD) parameter for distinguishing glomerular (GH) from non-glomerular haematuria (NGH). Samples were divided into derivation (N=156) and validation (N=107) cohorts. Several UF-5000 parameters, including URD, were compared between GH and NGH. URD showed significant differences, with AUCs of 0.814 (derivation) and 0.806 (validation). A >20.1% URD cut-off gave high sensitivity (99.0%/89.4%) and moderate specificity (50.9%/63.3%). The study concluded that URD is a fast, objective, and quantitative tool to help differentiate GH from NGH.

#UF5000 #Haematuria #GlomerularHaematuria #URD

Chen Y et al. (2022):
Sysmex UN2000 detection of protein/creatinine ratio and of renal tubular epithelial cells can be used for screening lupus nephritis. BMC Nephrol 23(19.328.

https://pubmed.ncbi.nlm.nih.gov/36199035/

Summary: This study assessed the combined use of the UC-3500 and UF-5000 analyzers to screen for *Lupus nephritis*. Urine samples from 160 SLE patients and 124 with *Lupus nephritis* were analyzed for protein:creatinine ratio (P/C) and renal tubular epithelial cells (RTECs). The UC-3500 showed strong agreement with quantitative P/C methods (κ = 0.858), while UF-5000 moderately agreed with manual RTEC counts (κ = 0.673). RTEC levels were significantly higher in Lupus nephritis patients. A P/C ≥ 2+ alone yielded 97.5% specificity and 96.5% PPV; combining RTEC ≥ 2.8/μL and P/C ≥ 2+ gave similar specificity (97.5%) and 94.0% PPV. Highest sensitivity (96.0%) and NPV (96.2%) occurred when either marker was elevated. The study supports using both devices for *Lupus nephritis* screening.

#UF5000 #UC3500 #Proteinuria #PCR #RTEC #LupusNephritis #SLE

Mizuno G et al. (2021):
Evaluation of red blood cell parameters provided by the UF-5000 urine auto-analyzer in patients with glomerulonephritis. Clin Chem Lab Med 59(9):1547-1553.

https://pubmed.ncbi.nlm.nih.gov/33908221/

Summary: This study evaluated the UF-5000's RBC-related parameters—small RBC (UF-%sRBC) and Lysed-RBC—for distinguishing glomerulonephritis (GN) from non-glomerulonephritis (NGN), compared to labor-intensive microscopy. UF-%sRBC and Lysed-RBC values significantly differed between GN and NGN groups. Cut-offs were set at >56.8% for UF-%sRBC (AUC=0.649; sensitivity 94.1%; specificity 38.1%) and >4.6/μL for Lysed-RBC (AUC=0.708; sensitivity 82.4%; specificity 56.0%). Several parameters, including UF-%sRBC, Lysed-RBCs, UF-P70Fsc, and dRBCs, showed significant differences between GN and NGN, with UF-%sRBC outperforming biochemical markers in sensitivity and cut-off value. The authors concluded that these UF-5000 RBC parameter cut-offs provide sufficient diagnostic accuracy to support glomerulonephritis detection.

#UF5000 #Glomerulonephritis #RBCparameters

Yuan J et al. (2020):
Application of urinary tubular epithelial cells in the renal tubular injury in diabetes mellitus. Chin J Lab Medlin Biochem 55(2):281-286.Chin J Lab Med 12:317-321.

https://pesquisa.bvsalud.org/portal/resource/pt/wpr-871884

Summary: This case-control study evaluated the UF-5000's ability to detect renal tubular epithelial cells (RTEC) for identifying tubular injury in diabetic kidney disease (DKD). Among 452 patients—252 healthy, 113 with type-2 diabetes (T2D) without renal injury, and 87 with T2D and renal injury—urine samples were analyzed by UF-5000 and manual microscopy, showing high agreement (κ = 0.699). Using a 1.7 RTEC/μL cut-off, sensitivity was 79.1%, specificity 81.7%, and AUC 0.861. Median RTEC counts differed significantly among groups: 0.4/μL (healthy), 2.0/μL (T2D), and 2.3/μL (T2D with injury), with positive rates of 2.78%, 56.64%, and 75.86%, respectively. The authors concluded that UF-5000 RTEC detection aids early identification of renal tubular injury in T2D, supporting timely intervention to delay chronic kidney disease progression.

#UF5000 #RTEC #Type2Diabetes #TubularInjury #DKD

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Kim H et al. (2019):
Small Red Blood Cell Fraction on the UF-1000i Urine Analyzer as a Screening Tool to Detect Dysmorphic Red Blood Cells for Diagnosing Glomerulonephritis. Ann Lab Med 39(3):271-277.

https://pubmed.ncbi.nlm.nih.gov/30623619/

Summary: This study assessed the UF-%sRBCs parameter of the UF-1000i for detecting dysmorphic RBCs (%dRBCs) and glomerulonephritis (GN) in 103 patients (47 GN, 56 non-GN). UF-%sRBCs, %dRBCs, urine protein, serum creatinine, and eGFR differed between groups, with UF-%sRBCs and %dRBCs showing the largest differences. ROC analysis showed urine protein had the highest AUC (0.828), followed by %dRBCs (0.771) and UF-%sRBCs (0.745). Optimal cut-offs were >40.5% for UF-%sRBCs and >6.7% for %dRBCs. Both markers distinguished GN from non-GN in patients with isolated haematuria without proteinuria. The authors concluded UF-%sRBCs has similar diagnostic power to %dRBCs by microscopy and may better detect GN in isolated haematuria, offering a useful tool for identifying GN in asymptomatic patients.

#UF1000i #Glomerulonephritis #RBCparameters #DysmorphicRBC

4 Infectious Diseases & Antimicrobial Resistance (AMR)

4.1. Bacterial Infections

NEW

OA

Brenner A et al. (2025):
Performance of UF-5000 in rapidly screening out urinary tract infection, predicting Gram-negative bacteria infection. Microbiol Spectr e0030124.

https://pubmed.ncbi.nlm.nih.gov/40043528/

Summary: This study evaluated machine learning (ML) algorithms to predict positive urine cultures using Sysmex UF-5000 flow cytometry data in suspected bacteriuria cases. Using 1,325 urine samples, CatBoost emerged as the top-performing model, with high sensitivity (94–96%) and moderate accuracy (62–74%) over six months. Predictors included cell counts (bacteria, leukocytes, etc.), age, sex, and sample type. Bacterial and leukocyte counts were most influential. The model showed potential for reducing unnecessary cultures, but its negative predictive value (NPV) declined over time (85% to 67%), requiring re-validation. It also struggled to distinguish clinically relevant uropathogens. Overall, urinary flow cytometry is a promising rapid pre-screening tool, though adding more clinical data could improve accuracy.

Note: the reported performance data represent the performance of the proposed ML model and not the performance of the UF-Series and its parameters!

#UF5000 #UTI #BACT #UTIprediction #MachineLearning

NEW

OA

Trang VAV et al. (2025):
Development of a novel risk score for diagnosing urinary tract infections: Integrating Sysmex UF-5000i urine fluorescence flow cytometry with urinalysis. PLoS One 20(5):e0323664.

https://pubmed.ncbi.nlm.nih.gov/40367086/

Summary: This study developed the UTIRisk score, a rapid diagnostic model for urinary tract infections (UTIs), using urinalysis and flow cytometry data. Among 1,335 UTI cases and 1,282 controls, the score showed strong diagnostic performance (AUC: 0.82 discovery, 0.77 validation), high specificity (96.5%), and positive predictive value (92.6%). It outperformed basic bacterial count thresholds and was especially effective in males and older adults. The UTI risk score offers a reliable alternative to urine culture, with potential impact on diagnostic/antimicrobial stewardship.

Note: the reported performance data represent the performance of the proposed ML model and not the performance of the UF-Series and its parameters!

#UF5000 #UTI #BACT # UTIscore #MachineLearning

OA

Lu W et al. (2024):
Performance of UF-5000 in rapidly screening out urinary tract infection, predicting Gram-negative bacteria infection. Microbiol Spectr e0030124.

https://pubmed.ncbi.nlm.nih.gov/39526790/

Summary: This study assessed the UF-5000 analyzer's ability to exclude bacterial UTIs and detect Gram-negative bacteria in urine. Among 1,522 samples, bacterial counts and analyzer flags were compared to urine cultures. Optimal cut-offs for ruling out UTI were 42.2/μL and 100.2/μL for ≥10^4 and ≥10^5 CFU/mL, respectively. Agreement with culture was fair (Kappa = 0.227). The "Gram Neg?" flag had 94.0% specificity and 87.2% positive predictive value, with the best detection angle at 28°. The UF-5000 is a rapid, reliable tool for ruling-out UTI and detecting Gram negative bacteria.

#UF5000 #UTI #BACT #BACTinfo #GramNegative #RuleOut

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OA **Flores E et al. (2024):**
A step forward in the diagnosis of urinary tract infections: from machine learning to clinical practice. Comput Struct Biotechnol J 24:533-541.

https://pubmed.ncbi.nlm.nih.gov/39220685/

Summary: This study aimed to enhance urinary tract infection (UTI) diagnostics in the Emergency Department (ED) using machine learning (ML) models for real-time prediction. Researchers retrospectively analyzed patient data with positive and negative culture results to develop 'Random Forest' and 'Neural Network' models. These models were validated with 962 cases, achieving an area under the curve (AUC) between 0.81 to 0.88, with the best results coming from their combined use. Implementation of UTI risk assessments led to reduced unnecessary urine cultures and antibiotic prescriptions for low-risk patients while facilitating targeted diagnostics for high-risk cases. Overall, integrating advanced urinalysis technologies with digital health solutions can improve UTI diagnostics, positively impacting laboratory efficiency and antimicrobial stewardship.

#UF5000 #UTI #ClinicalDecisionMaking #ClinicalImpact #CultureRequest
#AntibioticPrescriptions #TreatmentDecision #CliniciansBehaviour

OA **Liu P et al. (2024):**
Enhancing clinical decision-making: Sysmex UF-5000 as a screening tool for bacterial urinary tract infection in children. PLoS One 19(6):e0304286.

https://pubmed.ncbi.nlm.nih.gov/38865329/

Summary: This study investigated the performance of the UF-5000 in context of suspected urinary tract infections in 4,445 paediatric patients by comparison of the BACT and WBC counts of the UF-5000 and data from urine culture. Optimal indicators for positive cultures were BACT counts of 92.2/µL and WBC counts of 40.8/µL, resulting in AUC values of 0.944 and 0.863, respectively. False negative rate was down to 0.9% at a cut-off of 7.8 BACT/µL, reducing unnecessary cultures by 28.1%. The authors concluded that the UF-5000 demonstrated potential value for the screening of paediatric urine cultures for the identification of culture-negative samples and significant growth with the 'BACT Info' flag aiding in early empirical medication.

#UF5000 #UTI #BACT #BACTinfo #RuleOut #Paediatrics

OA **Kaido M et al. (2024):**
The performance of a Fully Automated Urine Particle Analyzer, Sysmex UF-5000, in detecting fastidious bacteria in urine samples. J Microbiol Methods 220:106913.

https://pubmed.ncbi.nlm.nih.gov/38458394/

Summary: In this study, the performance of the UF-5000 for the counting of various types of fastidious bacteria was assessed. The authors concluded that UF-5000 counts fastidious bacteria in urine without the need for culture using measurement principles based on flow cytometry.

#UF5000 #UTI #FastidiousBacteria #RuleOut

OA **Korsten K et al. (2024)**:
Using the Sysmex UF-4000 urine flow cytometer for rapid diagnosis of urinary tract infection in the clinical microbiological laboratory. J Clin Lab Anal 38(5):e25004.

https://pubmed.ncbi.nlm.nih.gov/38454622/

Summary: The aim of this study was to assess the impact of the UF-5000 on UTI-related workflows and to provide guidance on flow cytometry results. The prediction of UTI was assessed by utilization of the BACT, WBC and YLC counts in combination with 'BACT Info' flag. Initially, the UF-4000 results of 970 samples were compared against urine culture results. The identified positivity cut-off of ≥100 bacteria/µL resulted in a sensitivity of 96.2%, specificity of 61.9%, a PPV of 72.7%, and an NPV of 93.9%. The cut-off values were validated on 42,958 midstream urine samples, resulting in a 37% (n = 15,895) culture reduction and uropathogens identification in 69% of the 'UTI?'-flagged samples. The combination of BACT ≥10.000/µL and the 'Gram Negative?' flag resulted in a PPV above 90%. The absence of a 'Gram Positive?' flag or YLC counts resulted in high NPVs of 99% and >99%, respectively, allowing to rule-out the presence of Gram-positive bacteria or yeast. The authors concluded that the UF-4000 allowed the reduction of urine cultures due to the rule-out of UTI and prediction of UTI through the BACT count and the 'Gram Negative?' flag.

#UF4000 #UTI #UrineCulture #BACTinfo #GramNegative #GramPositive #YLC #RuleOut

OA **Angulo-López I et al. (2024)**:
Evaluation of Sysmex UF-5000 flow cytometer flag BACT-info for Gram discrimination in urinary tract infection. Rev Esp Quimioter 37(1):52-57 [Article in Spanish].

https://pubmed.ncbi.nlm.nih.gov/38073260/

Summary: The aim of this study was the evaluation of the ability of the UF-5000 to discriminate the Gram status of detected bacteria. In 449 prospective urine samples the reported 'BACT Info' flag was compared with the outcome of urine culture results. The observed sensitivity for the classification of 'Gram Negative?' and 'Gram Positive?' bacteria was above 95%. The agreement of 'BACT Info' and urine culture was substantial ($\kappa = 0.80$) for the 'Gram Negative?' and moderate ($\kappa = 0.49$) for the 'Gram Positive?' flag. The authors concluded that the reporting of the 'Gram Negative?' flag reduces the response time in the microbiological diagnosis of UTI with potential impact on the reduction and optimisation of empirical treatment.

#UF5000 #UTI #BACTinfo #GramPositive #GramNegative #RuleOut

OA **Del Ben F et al. (2023)**:
A fully interpretable machine learning model for increasing the effectiveness of urine screening. Am J Clin Pathol 60(6):620-632.

https://pubmed.ncbi.nlm.nih.gov/37658807/

Summary: This study aims to assess machine learning (ML) models for the interpretation of urinalysis results to overcome limitation of current diagnostic solutions. In total, 15,312 samples from 10,534 patients with clinical symptoms were analysed on the Sysmex UF-1000*i* and analyser data were applied on decision tree models with or without lookahead strategy. The best model achieved a sensitivity of 94.5% and classified negative samples based on age, bacteria, mucus, and two scattering parameters. The model reduced the workload by an additional 16% compared to the current procedure in the laboratory, with an estimated financial impact of €40,000/y considering 15,000 samples/y. The authors concluded that the proposed ML approach offers an effective and interpretable screening method for urine culture in microbiology, using UF-1000*i*.

#UF1000i #ResultInterpretation #MachineLearning #DecisionTree

El Kettani A et al. (2023):

Evaluation of the Sysmex UF-4000i urine analyzer as a screening test to rule out urinary tract infection and reduce urine cultures. Ann Biol Clin (Paris) 81(2):156-161 [Article in French].

https://pubmed.ncbi.nlm.nih.gov/37144792/

Summary: This study evaluated the performance of the Sysmex UF-4000 for the rule-out UTI-negative urine samples in comparison to urine culture. In total, 502 urine samples were analysed to assess the diagnostic performance. Applying a cut-off of 100 BACT/µL, and/or ≥ 45 WBC/µL showed to be the optimal indicator for positive culture results with a sensitivity, specificity, PPV and NPV of 97,3%, 95%, 87,8% and 98,8% for the BACT count 99,1%, 95,8%, 88,6% and 99,7% for WBC, respectively. The authors concluded that BACT and WBC counts are eligible for rapid screening to exclude UTI by reducing about 70% of urines cultures and then workload.

#UF4000 #UTI #BACT #WBC #DiagnosticPerformance

OA

Wang H et al. (2023):

Accuracy of the Sysmex UF-5000 analyzer for urinary tract infection screening and pathogen classification. PLoS One 18(2):e0281118.

https://pubmed.ncbi.nlm.nih.gov/36724192/

Summary: This study aimed to investigate the screening performance of the UF-5000 for UTI and the BACT Info flag for discrimination of Gram-positive and Gram-negative pathogens. The decision curve showed that urinary bacteria had a higher predictive benefit than WBC with a sensitivity and specificity of the decision tree were 0.69 and 0.95, respectively. The 'Gram Negative?' flag had a PPV of 0.93 in patients with urine bacteria > 1367 /µL. The authors concluded that the urinary bacteria count determined by the UF-5000 had higher screening performance and greater benefit than WBC and that a decision tree could be used to improve the screening performance of routine urinary parameters. In addition, the 'Gram Negative?' flag is a reliable indicator to confirm Gram-negative bacterial infections in UTI patients.

#UF5000 #BACT #BACTinfo #UTI #DiagnosticPerformance

KIM SH et al. (2022):

Clinical Usefulness of BACT Count and BACT-Info Flag of UF-5000 for Screening for Urinary Tract Infection and Prediction of Gram-Negative Bacteria. Clin Lab 68(12).

https://pubmed.ncbi.nlm.nih.gov/36546738/

Summary: In need of a rapid and reliable screening test for (UTI), helping to reduce the turn-around time and to rule out negative results of urine culture, this study assessed the performance of the BACT count and the BACT-Info flag of the UF-5000. A total of 1,063 urine specimens were analysed on the UF-5000 and compared to urine culture results. A BACT count of > 685.3/µL showed the best diagnostic performance with 93.8% sensitivity and 90.2% specificity and a sensitivity 91.5% and a specificity of 90.5%, if combined with the 'BACT Info flag. Here, the sensitivity and specificity of the 'Gram Negative?' flag were 95.5% and 94.8%. The authors recommended the use of a combination of BACT count (685.3/µL) and BACT-Info for UTI assessment, which appeared to be more appropriate for Gram-negative bacteria, and could support the selection of selecting empirical treatment.

#UF5000 #BACT #BACTinfo #DiagnosticPerformance

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OA

Chun TTS et al. (2022):
The diagnostic value of rapid urine test platform UF-5000 for suspected urinary tract infection at the emergency department. Front Cell Infect. Microbiol. 12:936854

https://pubmed.ncbi.nlm.nih.gov/36237433/

Summary: This study evaluated the diagnostic utility of the UF-5000 for the prediction of UTIs at the emergency department in comparison to dipstick and urine culture, including a total of 383 patients. The UF-5000 urinalysis (AUC = 0.821) outperformed the dipstick test (AUC = 0.602) in the predictions of UTI in patients without prior antibiotic treatment. The concordance between UF-5000 and culture for predicting 'Gram Positive?' and 'Gram Negative?' bacteriuria and a negative culture were 44.7% and 96.2%, respectively. The authors concluded that the UF-5000 urinalysis had a significantly better predictive value than the dipstick urine test for predicting UTIs.

#UF5000 #Dipstick #BACT #BACTinfo #UTI #DiagnosticPerformance

OA

Szmulik M et al. (2022):
A novel approach to screening and managing the urinary tract infections suspected sample in the general human population. Front Cell Infect Microbiol 12:936854.

https://pubmed.ncbi.nlm.nih.gov/36093203/

Summary: This study evaluated the performance of laboratory indicators of UTI on digital imaging (Iris iQ®200 ELITE) and fluorescence flow cytometry (UF-5000) urinalysis instruments, as well as by dip stick testing, including a total of 1,131 urine samples. For the prediction of urine culture results for UTI, based on WBC and/or BACT, a good diagnostic performance has been observed with a sensitivity of 100% and a specificity of 83.7%, resulting in a negative predictive value of 100% and a s positive predictive value of 75%. The authors further highlight the capabilities of the UF-Series to rule-out UTIs and to positively improve laboratory workflows in context of UTI.

#UF5000 #UTI #DiagnosticPerformance

OA

Torres-Sangiao E et al. (2022):
Urinary albumin: a risk marker under-requested in primary care in Spain. Ann Clin Biochem 55(2):281-286.

https://pubmed.ncbi.nlm.nih.gov/35625307/

Summary: This study evaluated the combination of different diagnostic technologies including urine flow cytometry, MALDI-TOF mass spectrometry and automated antibiotic susceptibility testing to reduce the time for reporting UTI-positive samples and proposing a suitable antibiotic susceptibility profile. The aim is to allow fast and precise treatment, thereby minimising the risk for antimicrobial resistance. In this context, the UF-5000 was used to select samples, suspected to be positive for UTI, here BACT counts ≥ 150 cells/mL and the 'Gram Negative?' flag were used. After confirmation by MALDI-TOF mass spectrometry, samples positive for *E. coli* were subjected to AST on VITEK 2. The authors conclude that the combination of diagnostic techniques fosters the rapid diagnosis of UTI without the need for long-lasting urine cultures.

#UF5000 #MALDIToF #Vitek2 #UTI #DiagnosticPerformance #RuleOut #RuleIn #Workflow

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Alenkaer LK et al. (2021):

Evaluation of the Sysmex UF-5000 fluorescence flow cytometer as a screening platform for ruling out urinary tract infections in elderly patients presenting at the Emergency Department. Scand J Clin Lab Invest 81(5):379-384.

https://pubmed.ncbi.nlm.nih.gov/34237238/

Summary: This study evaluated the potential of the UF-5000 to rule-out UTI in elderly patients on 1,119 urine samples, including 544 samples from elderly samples in comparison to dipstick test and urine culture. Using a patient group-specific cut-off value of 10^8 CBU/L an NPV of 0.92 has been achieved, allowing to rule-out clinically irrelevant cases, potentially saving up to 36% of ordered urine. A total of 35% false positive samples were mainly caused by contamination or nongrowing bacteria. In comparison, the dipstick showed a sensitivity of 89%, a specificity of 52% and an NPV of 92%. The authors concluded that the quick availability of results from the UF-5000, compared to urine culture, offers the possibility to better guide the prescription of antibiotics.

#UF5000 #Dipstick #UTI #DiagnosticPerformance #RuleOut #ElderlyPatients

OA

Gilboe HM et al. (2021):

Rapid diagnosis and reduced workload for urinary tract infection using flowcytometry combined with direct antibiotic susceptibility testing. PLoS One 16(7):e0254064.

https://pubmed.ncbi.nlm.nih.gov/34228764/

Summary: This study evaluated the potential impact of the UF-5000 on the rapid identification of culture negative and contaminated samples prior to culture plating and on the prediction of positive samples for antibiotic susceptibility testing. Using a cut-off value with bacterial count ≥100.000/mL and WBCs ≥10/µL, urinary flow cytometry predicted 42,1% of samples with non-significant growth and for 52/56 positive samples containing Gram negative bacteria dAST was identical to routine testing. Overall, there was concordance in 555/560 tested antibiotic combinations. The authors concluded that flow cytometry offers allows improvements in UTI diagnostics by reduction of the response times and workloads for negative samples on the day of arrival and by prediction of Gram-negative samples for antibiotic susceptibility testing, allowing a same day report of antibiotic susceptibility profiles.

#UF5000 #UTI #directAST #RapidDiagnostics #DiagnosticPerformance

Oyaert M et al. (2020):

Renal Tubular Epithelial Cells Add Value in the Diagnosis of Upper Urinary Tract Pathology. Clin Chem Lab Med 58(4):597-604.

https://pubmed.ncbi.nlm.nih.gov/31860463/

Summary: This study evaluated the analytical performance characteristics of renal tubular epithelial cells (RTECs) and transitional epithelial cells (TECs) on the Sysmex UF-5000 urine sediment analyser, as well as the diagnostic performance of these parameters to differentiate between lower and upper UTI. In comparison to TECs, increased urinary RTEC levels demonstrated a good potential to serve as a marker for the diagnosis of upper UTI and with an AUC value of 0.932 clearly outperformed α_1-micrglobulin in the discrimination between upper and lower UTI. The authors concluded that the RTEC parameter is a suitable tool to discriminated upper and lower UTI in patients with confirmed UTI, but proper sample handling is required to ensure appropriate results.

#UF5000 #UTI #upperUTI #lowerUTI #RTEC #SampleHandling

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OA

Ippoliti R et al. (2020):

UF-5000 flow cytometer: A new technology to support microbiologists' interpretation of suspected urinary tract infections. MicrobiologyOpen 9(3):e987.

https://pubmed.ncbi.nlm.nih.gov/31908145/

Summary: This case study aimed to describe the adoption of UF-5000 in context of the microbiology diagnostic pathways to investigate suspected urinary tract infections (UTIs). Based on the assessment of 1,295 samples, sensitivity and specificity were equal to 100% and 94%, respectively, with a total of 69 false positives. The AUC value was 0.9691 with PPV and NPV being equal to 72% and 100%, respectively. The authors concluded that the UF-5000 can provide information improve the identification of both contamination and colonization, thus reducing inappropriate antibiotic prescriptions. An implementation of this technology thus allows the supply of sustainable treatments by hospitals, especially in context of the reduction of unnecessary use of antibiotics in false-positive results, obtained by reference methods.

#UF5000 #UTI #DiagnosticPerformance

OA

Allain M et al. (2019):

Performance analysis of the Sysmex UF4000/UD10 for diagnosis of urinary tract infections]. Ann Biol Clin (Paris) 77(6):645-650 [Article in French].

https://pubmed.ncbi.nlm.nih.gov/31859641/

Summary: This study evaluated the performance of the combination of the UF-4000 and the UD-10 in comparison to optical microscopy and urine culture. The discrepancy between the UF-4000 and manual microscopy was 8.5% for WBC, and 16% for RBC, which dropped to 6.9% after implementation of the UD-10. Most of these discrepancies corresponded to quantities close to the clinical threshold. Applying a cut-off of 200 BACT/µL, the 'Gram Negative?' and 'Gram Positive?' flags resulted in 91%/86% and 79%/20% of Gram-significant cultures of Gram-negative bacilli and Gram-positive cocci, respectively. The authors concluded that the combination of UF-4000 and manual microscopy is satisfactory for cellular particles with the UD-10 allowing to correct these discrepancies and to reduce time consuming manual microscopy.

#UF4000 #UD10 #BACT #BACTinfo #DiagnosticPerformance

Herráez O et al. (2018):

Sysmex UF-1000i flow cytometer to screen urinary tract infections: the URISCAM multicentre study. Lett Appl Microbiol 66(3):175-181.

https://pubmed.ncbi.nlm.nih.gov/29223137/

Summary: This study evaluated the feasibility and accuracy of Sysmex UF-1000*i* to screen for UTIs, including a total amount of 2,468 urine samples from six Spanish hospitals. Demographic and clinical data such as age, gender, source and sample type, preserving conditions, cytometer parameters (bacteria, leucocytes and bacteria morphology) as well as urine culture results (gold standard) were recorded. Data mining techniques revealed that age, BACT count and rod morphology were predictive variables of UTI. By using the UF-1000i in combination with a predictive algorithm of three decision rules, identification of 94·9% and 47·4% positive and negative urine samples was possible, respectively, with a negative predictive value of 97% and only 1.17% diagnostic error, mostly due to contamination. The authors concluded that UF-1000*i* together with age can be used to screen for UTIs, allowing a potential culture reduction of 38%.

#UF1000i #BACT #UTI #DiagnosticPerformance

OA **De Rosa R et al. (2018):**
Evaluation of the new Sysmex UF-5000 fluorescence flow cytometry analyser for ruling out bacterial urinary tract infection and for prediction of Gram-negative bacteria in urine cultures. Clin Chim Acta 484:171-178.

https://pubmed.ncbi.nlm.nih.gov/29803898/

Summary: This study investigated the potential of the UF-5000 to rule-out urinary tract infections and its ability to predict the presence of Gram-negative bacteria in urine samples with a request for urine culture in context of a suspected urinary tract infection. With neglectable carry-over and cross-contamination, the UF-5000 demonstrated a high screening performance for urinary tract infections with a high sensitivity of 99.4% and an NPV of 99.7% for bacteria using a cut-off of ≥58/µL. The 'Gram Negative?' flag predicted Gram negative urine cultures with an agreement of 86.6%. The authors concluded that the UF-5000 represents a reliable tool for ruling-out urinary tract infections with high diagnostic accuracy, offering the possibility to detect Gram-negative bacteria in very high agreement with urine culture.

#UF5000 #UTI #BACT #DiagnosticPerformance #UrineCulture #Workflow

OA **Kawamura K et al. (2017):**
Evaluation of automated urine particle analyzer, UF-5000, as a screening tool to identify Gram stainability of urinal pathogens. Jap J Med Technol 66(5):516-523 [Article in Japanese].

https://www.jstage.jst.go.jp/article/jamt/66/5/66_17-9/_article/-char/en

Summary: This study evaluated the performance of UF-5000 (Sysmex) and its ability to identify bacterial Gram stainability ('BACT Info' flag), compared to conventional Gram staining and urine culture. A total of 188 urine samples, suspicious for UTI were assessed. The results, obtained from the UF-5000 were in agreement with Gram staining and culture results in 83.2% and 81.0%, respectively. For Gram-negative bacteria, the UF-5000 revealed a high PPV of 93.3% in comparison to both Gram staining and culture results. The authors concluded that the UF-5000 and the 'BACT Info' flag demonstrated potential value in the screening for UTI pathogens.

#UF5000 #BACT #YLC #UTI #DiagnosticPerformance #RuleOut

Geerts N et al. (2016):
Cut-off values to rule out urinary tract infection should be gender-specific. Clin Chim Acta 452:173–176.

https://pubmed.ncbi.nlm.nih.gov/26616731/

Summary: This study investigated the potential of urine flow cytometry of the UF-5000 to rule-out urinary tract infections and to reduce the load of urine culture samples. Applying cut-off value of >200 bacteria/µL, a sensitivity of 93.0%, a specificity of 63.5% and an NPV of 96.2% has been obtained. As a result, the culturing of 49% of all samples could be avoided. In addition, the data was retrospectively analysed to determine if the introduction of gender-specific cut-off values could improve screening results. The obtained receiver operator curves are indeed significantly different when gender specific cut-offs were used. When an NPV of 95% is considered acceptable the unisex cut-off value of >200bacteria/µL can be used for women (NPV = 94.9%), but the cut-off value for men could be raised to >400bacteria/µL without diminishing the NPV (NPV = 95.0%).

#UF5000 #UTI #CutOff #GenderSpecific #DiagnosticPerformance

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4.2. Fungal Infections

OA

Yanılmaz Ö & İlki AA (2023):
Performance of Sysmex UF-5000 for candiduria screening. New Microbiologica 45(4):292-295.

https://pubmed.ncbi.nlm.nih.gov/36538292/

Summary: This study evaluated the performance of the UF-5000 for the assessment of candiduria to detect or exclude fungal infections by applying the yeast-like cell (YLC) parameter. If compared to *Candida* culture, the use of a cut-off of 5 YLC/µl resulted in an excellent diagnostic performance with 100 % sensitivity, 95 % specificity a negative predictive value of 100 % and a positive predictive value of 66 %. The authors concluded that the performance of the YLC parameter allows the exclusion of candiduria with positive impact on laboratory workflows and antimicrobial stewardship.

#UF5000 #UTI #Funguria #Candiduria #YLC #DiagnosticPerformance

Zhengxin H et al. (2019):
Performance of yeast-like cell counting (YLCC) using the Sysmex UF-1000i for clinical candiduria screening. Eur J Clin Microbiol Infect Dis 38(5):891-894.

https://pubmed.ncbi.nlm.nih.gov/30767096/

Summary: This study aimed to evaluate the performance of the Sysmex UF-1000*i* urine analyser for yeast-like cell counting (YLC) to screen for candiduria prior to urine culture. 5,233 urine samples from 1,813 patients, including 837 males and 976 females were assessed by urine culture and urinary flow cytometry for candiduria. A cut-off value of 0 YLC/µL resulted in 77.04% sensitivity and 93.68% specificity. In a group of 34 hospitalised candiduria patients with serial urinalysis data, 25 were YLC-positive before urine culture. The authors concluded that YLC counting could serve as an auxiliary technique to exclude culture-negative specimens prior to urine culture and positive YLC count results could imply candiduria in certain conditions.

#UF1000i #UTI #Funguria #Candiduria #YLC #DiagnosticPerformance

OA

Zhengxin H et al. (2019):
Candiduria in hospitalized patients: an investigation with the Sysmex UF-1000i urine analyzer. PeerJ 7:e6935.

https://pubmed.ncbi.nlm.nih.gov/31149401/

Summary: This cross-sectional study aimed to assess the performance of the UF-1000*i* in the detection of candiduria. In total, 203 YLC-positive and 127 negative samples assessed by flow cytometry and urine culture. In addition, urinalysis data from 31,648 hospitalized patients were retrospectively investigated. A cut-off value of 84.6 YLC/µL, the sensitivity, specificity, PPV and NPV of the YLC counts to predict candiduria were 61.7%, 84.1%, 88.6% and 66.3%, respectively. The authors concluded that YLC measured by UF-1000*i* is a practical and convenient tool for clinical candiduria screening prior to microbiologic culture.

 # UF1000i #UTI #Funguria #Candiduria #YLC #DiagnosticPerformance

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OA **Song D et al. (2018):**
Selection of unnecessary Urine Culture Specimens Using Sysmex UF-5000 Urine Flow Cytometer. Ann Clin Microbiol21(4):75-79.

https://doi.org/10.5145/ACM.2018.21.4.75

Summary: This study investigated the potential of the UF-5000 to support the reduction of unnecessary urine cultures by ruling-out bacterial and fungal urinary tract infections. Applying urinalysis cut-off values of 50/µl and 100/µl for bacteria and YLC, respectively, 84 out of 126 requested urine cultures were negative and could have been ruled-out by the UF-5000. The authors conclude that the bacteria and yeast-like cell counts delivered by the UF-5000 could be used to predict negative cultures and reduce the load of urine cultures by around 10% without sacrificing positive cultures.

#UF5000 #UTI #Funguria #Candiduria #YLC

4.3. Parasitic Infections

OA **Tjagur S et al. (2020):**
Profile of sexually transmitted infections causing urethritis and a related inflammatory reaction in urine among heterosexual males: A flow-cytometry study. PLoS One 15(12):e0242227.

https://pubmed.ncbi.nlm.nih.gov/33264307/

Summary: This study aimed to evaluate the performance of flow cytometry on first-voided urine in males with infectious urethritis. First-voided urine samples of 306 male patients with confirmed infectious urethritis caused by *Chlamydia trachomatis, Neisseria gonorrhoeae, Mycoplasma genitalium* and *Trichomonas vaginalis* were processed by PCR and on the UF-500i and compared to a specified control group. The most prevalent infection was chlamydia (64.1%), followed by Mycoplasma genitalium (20.9%), gonorrhoea (7.8%) and trichomoniasis (1.6%). Gonorrhoea caused the highest flow-cytometric leucocyte/bacteria count, followed by chlamydia and Mycoplasma genitalium. Trichomonas vaginalis showed nearly absent inflammation in first-voided urine. Using an empiric flow-cytometry diagnostic threshold for urethritis in first-voided urine (leucocytes ≥ 15/µL and bacteria ≥ 20/µL) the total calculated sensitivity was over 90%. The authors concluded that flow cytometric analysis of first-voided urine can be considered as a rapid and objective screening method in case of suspected male infectious urethritis.

#UF500i #Male #STI #Urethritis #PCR #FlowCytometry

4.4. Antimicrobial Resistance

OA **Antimicrobial Resistance Collaborators (2022):**
Global burden of bacterial antimicrobial resistance in 2019: a systematic analysis. Lancet 399(10325):629-655.

https://pubmed.ncbi.nlm.nih.gov/35065702/

Summary: Antimicrobial resistance (AMR) poses a major threat to human health around the world. Previous publications have estimated the effect of AMR on incidence, deaths, hospital length of stay, and health-care costs for specific pathogen–drug combinations in select locations. This review article provides comprehensive insights into the global burden of antimicrobial resistance (AMR).

#AMR #GlobalBurden #Review

5 Urinalysis at the Point-of-Care

5.1. Rapid antibiotic susceptibility testing on the PA-100

OA

Elsisi GH et al. (2024):
Budget impact analysis on the use of Sysmex PA-100 AST system as a point of care for uncomplicated urinary tract infections detection and treatment in Spanish females. J Med Econ 27(1):1434-1443.

https://pubmed.ncbi.nlm.nih.gov/39439232/

Summary: This study evaluated the economic impact of integrating the Sysmex PA-100 for managing uncomplicated urinary tract infections (uUTI) in Spain. A budget impact model analyzed the costs of current uUTI management versus incorporating the Sysmex PA-100, focusing on direct medical and indirect costs over three years. In scenario A, which accounted for costs from antimicrobial resistance (AMR), full implementation of the PA-100 could save EUR 323,657,712 annually and EUR 970,973,137 over three years. Scenario B, assuming no AMR costs, showed annual savings of EUR 4,254,795 and three-year savings of EUR 12,764,385. The adoption of the Sysmex PA-100 demonstrated potential cost savings through timely diagnosis and treatment, reduced complications, and decreased staff time, supporting its implementation for better uUTI management and resource allocation in Spanish healthcare.

#PA100 #Astrego #AST #HealthEconomics

OA

Alonso-Tarrés C et al. (2024):
Bacteriuria and phenotypic antimicrobial susceptibility testing in 45 minutes by point-of-care Sysmex PA-100 System: first clinical evaluation. Eur J Clin Microbiol Infect Dis. Online ahead of print.

https://pubmed.ncbi.nlm.nih.gov/38825624/

Summary: In this study the performance of the PA-100 was compared against routine microbiology data for the detection of uncomplicated UTI and performance of ASTs directly from urine. In total, 278 urine samples from female patients were tested on the PA-100 and with urine culture and disc diffusion AST. Sensitivity and specificity for detection of confirmed bacteriuria within 15 minutes were 84.0% and 99.4%, respectively, for bacterial species, included in the analyser specification, such as *E. coli, K. pneumoniae, P. mirabilis, E. faecalis* and *S. saprophyticus*. Overall categorical agreement for AST results for the antimicrobials tested in the PA-100 (amoxicillin/clavulanic acid, ciprofloxacin, fosfomycin, nitrofurantoin and trimethoprim) ranged from 85.4% for ciprofloxacin to 96.4% for trimethoprim. The PA-100 provided an optimal treatment recommendation in 218/278 cases (78.4%), against 162/278 (58.3%) of clinical decisions. Therefore, the authors concluded that the PA-100 could enable a rapid initiation of the correct treatment of uncomplicated UTI with potential impact on antimicrobial stewardship.

#PA100 #Astrego #AST #ClinicalEffectiveness #DiagnosticAccuracy #Nanofluidics

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OA

Tomlinson E et al. (2024):

Clinical effectiveness of point of care tests for diagnosing urinary tract infection: a systematic review. Clin Microbiol Infect 30(2):197-205.

https://pubmed.ncbi.nlm.nih.gov/37839580/

Summary: Point of care tests (POCTs) have the potential to improve the diagnostic pathway and patient journey for urinary tract infections by providing diagnostic information quickly in a near-patient-setting. This review article aimed to assess the clinical impact, accuracy, and technical characteristics of various point-of-care tests for diagnosing UTI by meta-analyses of randomized controlled trials/non-randomized studies and diagnostic test accuracy studies published since 2000, including rapid tests with result availability in less than 40 minutes (Astrego PA-100 system, Lodestar DX, Uriscreen, UTRiPLEX) and culture tests with result availability in less than 24 hours (Flexicult Human, ID Flexicult, Diaslide, Dipstreak, Chromostreak, Uricult, Uricult Trio, Uricult Plus). The authors concluded that point-of-care tests were easier to use and interpret than standard culture approaches but highlighted that there is currently insufficient evidence to support the use of POCTs in UTI diagnosis.

#PointOfCare #UTI #PA100 #SystematicReview #MetaAnalysis

OA

Hallström E et al. (2023):

Label-free deep learning-based species classification of bacteria imaged by phase-contrast microscopy. PLoS Comput Biol 19(11):e1011181.

https://pubmed.ncbi.nlm.nih.gov/37956197/

Summary: In this proof-of-principle study, phase contrast time-lapse microscopy is combined with deep learning, demonstrating the potential to classify four species of bacteria relevant to human health. The classification is performed on living bacteria without the need for fixation or staining. This allows the determination of bacterial species and their combination with microfluidic devices, enabling parallel determination of susceptibility to antibiotics. This assessment was conducted on convolutional neural networks and vision transformers, where the best model attained a class-average accuracy exceeding 98%. The authors conclude that this approach has the potential to support rapid delivery of AST information, if combined with microfluidic technology.

#PA100 #Astrego #Nanofluidics #RapidAST #AMR #ProofOfConcept

OA

Kandavalli V et al. (2022):

Rapid antibiotic susceptibility testing and species identification for mixed samples. Nat Commun 13(1):6215.

https://pubmed.ncbi.nlm.nih.gov/36266330/

Summary: In this proof-of-principle study, a method to perform phenotypic AST at the single-cell level in a microfluidic chip is introduced, allowing the determination of the susceptibility profile for each species in a mixed sample within 2 hours for four antibiotics and mixed samples with combinations of seven species. The authors conclude this approach to clinically relevant in the light of antimicrobial resistance and its increasing burden.

#PA100 #Astrego #MicroFluidics #RapidAST #AMR #ProofOfConcept

5.2. BTAstat

Ecke TH F et al. (2023):
BTA stat®, NMP22® BladderChek®, UBC® Rapid Test, and CancerCheck® UBC® rapid VISUAL as urinary marker for bladder cancer: Final results of a German multicentre study. Urol Oncol 41(12):484.

https://pubmed.ncbi.nlm.nih.gov/37407421/

Summary: This multicentre study aims to comparing all available rapid tests on a large cohort of bladder cancer patients and healthy controls in one setting. A total of 732 urine samples were analysed by BTA stat®, NMP22® BladderChek®, UBC® Rapid Test, and CancerCheck® UBC® rapid VISUAL. Clinical samples of 464 patients with histologically confirmed urothelial tumours of the urinary bladder, 77 patients with No Evidence of Disease (NED), and from 191 healthy controls were included and sensitivities and specificities were calculated by contingency analyses. All investigated urinary markers showed higher levels in pathological conditions in comparison to tumour-free patients. The calculated diagnostic sensitivies for BTA stat®, NMP22® BladderChek®, UBC® Rapid Test, CancerCheck® UBC® rapid VISUAL, and cytology were 62.4%, 13.4%, 58.2%, 28.6%, 36.2% for low-grade, 83.4%, 49.5%, 84.5%, 63.1%, 71.2% for high-grade non-muscle invasive, and 95.8%, 35.2%, 76.1%, 50.7%, 67.7% for high-grade muscle-invasive bladder cancer. The specificity was 67.9%, 95.5%, 79.4%, 94.4%, and 83.7%, respectively. The area under the curve (AUC) after receiver operating characteristics (ROC) analysis for high-grade non-muscle-invasive tumours was 0.757, 0.725, 0.819, 0.787, and 0.774, respectively. The authors concluded that BTA stat® and UBC® Rapid Test have the potential to be used as a clinical valuable urinary protein biomarker for the detection of high-grade non-muscle-invasive bladder cancer patients and could be included in the management of these tumours.

#UrothelialCarcinoma #BladderCancer #BTAstat #RapidTest

OA

García-Velandria F et al. (2014):
Predicting results of daily-practice cystoscopies. Actas Urol Esp 38(8):538-543.

https://pubmed.ncbi.nlm.nih.gov/24612988/

Summary: The aim of this study is the elaboration of a predictive model of bladder cancer through the BTAstat test in an unselected patient population, submitted to cystoscopy. Among 237 recruited patients, there were 13% and 87% newly diagnosed and surveillance cases were, respectively. Cytology and BTA-test sensitivies were 57.9% and 63.2% with specificities of 84.4% and 82.9%. For the predictive model the BTAstat test, cytology data, time since previous tumour, and treatment with mitomycin or BGC during the last three months were included. The predictive accuracy of the model was 0.85 or 0.79 with or without inclusion of BTAstat, respectively. For the surveillance of bladder cancer, the model achieved in an overall negative predictive value of 95.7%, and 95.0% in low grade tumours. The authors conclude that the predictive model including the BTAstat test could support the reduction of cystoscopies in bladder cancer surveillance among patients with previous low-grade tumours.

#UrothelialCarcinoma #BladderCancer #BTAstat #Cystoscopy

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6   Urothelial carcinoma

NEW

Ren & Qian (2024):
A Model Based on Automated Urinalysis Parameters for Urothelial Carcinoma Risk Stratification in Suspected Patients. Clin Lab 70(10).

https://pubmed.ncbi.nlm.nih.gov/39382911/

Summary: This study aimed to develop and validate a risk stratification model for screening patients with suspected urothelial carcinoma (UC). Researchers enrolled 671 patients and used urinary parameters from the Sysmex UN-9000 analyzer alongside urine cytology from 2019 to 2022. Of these, 191 (28.5%) were diagnosed with UC. The model, named UC-PAAS, includes four key features: urothelial carcinoma presence, protein-to-creatinine ratio (P/C), age, atypical cells (Atyp.C), and small round epithelial cells (SRC). Major criteria are Atyp.C ≥ 0.1/μL and age ≥ 65 (2 points each), while minor criteria are SRC ≥ 2.7/μL and abnormal P/C (1 point each). The model showed good accuracy (AUC = 0.802) and effectively identified high-risk patients for UC, supporting its use as a clinical tool for better patient evaluation and follow-up.

#UF5000 #AtypC #UrothelialCarcinoma #BladderCancer #Surveillance

Wang Y et al. (2024):
Atypical cells in urine sediment: a novel biomarker for early detection of bladder cancer. Clin Chem Lab Med. Online ahead of print.

https://pubmed.ncbi.nlm.nih.gov/39301615/

Summary: This study evaluated the potential of atypical cells (Atyp.C) identified by an automated urine analyzer to predict malignant tumor presence. A total of 3,315 patients were categorized into five groups: primary bladder cancer (BCa), recurrent BCa, post-treatment monitoring, other urological tumors, and controls. Atyp.C values were measured along with other parameters. Results showed that Atyp.C levels in the primary BCa group were significantly higher than in other groups, except for recurrent BCa, and were closely linked to tumor staging. The combination of Atyp.C and bacteria yielded the best diagnostic performance for primary BCa, achieving an AUC of 0.781 in the training cohort and 0.826 in the testing cohort. Thus, Atyp.C may serve as a valuable indicator for the early detection of BCa.

#UF5000 #AtypC #UrothelialCarcinoma #BladderCancer #Surveillance

OA

Zhang T et al. (2024):
The UF-5000 Atyp.C parameter is an independent risk factor for bladder cancer. Sci Rep 14(1):12659.

https://pubmed.ncbi.nlm.nih.gov/38830942/

Summary: This two-centre retrospective case-control study evaluated the association between urinary Atyp.C values and the risk for newly and recurrent bladder cancer. The analysis of 473 urine samples of bladder cancer patients and healthy controls revealed 8.7 times higher levels of Atyp.C counts in the bladder cancer patient population. Atyp.C values were positively correlated with bladder cancer pathological grade (r = 0.360) and invasion (r = 0.367). The authors concluded that elevated Atyp.C values were an independent risk factor for bladder cancer with potential impact on the early diagnosis and long-term surveillance of new and recurrent bladder cancer cases.

#UF5000 #AtypC #UrothelialCarcinoma #BladderCancer #Surveillance

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OA **Shukuya K et al. (2023)**:
Comparison of the clinical performance of the Atyp.C parameter of the UF-5000 fully automated urine particle analyzer with that of microscopic urine sediment analysis. Pract Lab Med 36:e00328.

https://pubmed.ncbi.nlm.nih.gov/37705588/

Summary: In this study, the diagnostic performance of the UF-5000 Atyp.C parameter has been assessed in comparison to urine sediment microscopy for a total of 471 leftover urine samples with 117 and 354 samples being were positive and negative, respectively. By inclusion of histological information, in relation to urothelial carcinoma cells, squamous carcinoma cells and adenocarcinoma cells, the Atyp.C values for Atyp.C-positive and Atyp.C-negative groups were identified as 2.64 ± 0.69 and 0.38 ± 0.16, respectively, with an ideal cut-off of 0.4/μL, resulting in a sensitivity of 79.5% and specificity of 85.1%. The authors concluded that Atyp.C values demonstrated a high predictive performance for Atyp.C-positive specimens identified by urine sediment microscopy and suggest that Atyp.C could be a useful routine screening parameter.

#UF5000 #AtypC #DiagnosticPerformance #UrothelialCarcinoma #Microscopy

Karaburun M et al. (2023):
Investigation of Atypical Cell Parameter in the Surveillance of Patients with NMIBC; Initial Outcomes of a Single Center Prospective Study. J Med Syst 47(1):41.

https://pubmed.ncbi.nlm.nih.gov/36976368/

Summary: In this study, the UF-5000 Atyp.C parameter has been assessed in the follow-up of NMIBC patients in comparison to cytology and cystoscopy. Clinical data from 273 patients undergoing cystoscopy have been collected prospectively and split into groups: (1) patients with no previous diagnosis (41.1%) and (2) patients with a previous diagnosis of NMIBC under follow-up (58.9%). Atyp.C were found significantly higher in cases of malignancy in the first group. In the second group, median 'Atyp.C' values for patients without malignancy, with low-grade and high grade NMIBC recurrence were 0.00, 0.25 and 1.20, respectively. A cut-off of 0.1 atypical cells/μL resulted in 83.33% sensitivity and 53.73% specificity. The authors concluded that the Atyp.C parameter might be used in surveillance of the NMIBC patients, with further studies needed.

#UF5000 #AtypC #UrothelialCarcinoma #BladderCancer #NMIBC #Cystoscopy #Surveillance

OA **Aydin O (2021)**:
Atypical cells parameter in Sysmex UN automated urine analyzer: feedback from the field. Diagn Pathol 16(1):9.

https://pubmed.ncbi.nlm.nih.gov/33482827/

Summary: In this study, the UF-4000 Atyp.C parameter has been assessed in the detection of cellular atypia among the routine patient population by applying a cut-off of 1.0/μL. In total, 50 samples with positive Atyp.C count were included, showing a median atypical cells value of 1.8/μL. For one sample, the cellular atypia could be confirmed by manual microscopy, followed by cystoscopy, revealing high-grade urothelial carcinoma. Other 49 samples were negative for atypical cells in manual microscopy but were crowded with leucocytes and squamous epithelial cells. The author highlighted the capability to detect atypical cells in urine and indicated that vulvovaginal contamination could interfere with the parameter performance.

#UF4000 #AtypC #UrothelialCarcinoma #BladderCancer #Surveillance #Screening

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OA

Ren C et al. (2020):
Investigation of Atyp.C using UF-5000 flow cytometer in patients with a suspected diagnosis of urothelial carcinoma: a single-center study. Diagn Pathol 15(1):77.

https://pubmed.ncbi.nlm.nih.gov/32586345/

Summary: In this study, the predictive power of UF-5000 Atyp.C parameter has been evaluated for patients with a suspected diagnosis of urothelial carcinoma in comparison to urinary cytopathology. Among 163 urine specimens from 128 patients with suspected urothelial carcinoma, urinary cytopathology revealed abnormal findings for 67 specimens (41.1%), including 20 specimens (12.3%) that were diagnosed as atypical urothelial cells, 26 specimens (16.0%), suspicious for malignancy, and 21 specimens (12.9%), confirmed for malignancy. The UF-5000 findings were positive in 59 specimens (36.2%), resulting in an agreement with cytopathology for 73.0% of the investigated cases. The authors conclude that knowing and reporting Atyp.C might be used as an accessory test for patients with suspected urothelial carcinoma, based on its ability to identify high-risk patients who might need closer follow-up or additional medical treatment.

#UF5000 #AtypC #UrothelialCarcinoma #BladderCancer #Cytology #Surveillance

OA

Aydin O (2020):
Atypical cells in Sysmex UN automated urine particle analyzer: a case report and pitfalls for future studies. Turk J Biochem 45(5):617-619.

https://www.degruyter.com/document/doi/10.1515/tjb-2019-0418/html

Summary: In this case report, 73 years old male patient with a recurrent high-grade urothelial carcinoma admitted to our urology outpatient clinic due to haematuria. Besides classical urinalysis findings, the UF-4000 also reported the presence of atypical cells (7.6 Atyp.C/μL). This finding was confirmed by manual microscopy and a subsequent TURBT revealed recurrence of NMIBC. On follow-up, 'Atyp.C' values dropped down to 0.1/μL after 40 days.

#UF4000 #AtypC #UrothelialCarcinoma #BladderCancer #Cystoscopy #Surveillance

OA

Tınay İ et al. (2019):
"Atypical Cell" Parameter in Automated Urine Analysis for the Diagnosis of Bladder Cancer: A Retrospective Pilot Study. Bull Urooncol 18:17-19.

http://cms.galenos.com.tr/Uploads/Article_36890/UOB-19-17-En.pdf

Summary: In this study, the UF-4000 Atyp.C parameter has been evaluated for the detection of bladder cancer by retrospective analysis of 2,365 urine specimens and related information from cystoscopy or surgical treatment for different urological pathologies, especially recent or previous bladder cancer diagnosis. Among 106 patients, 69.8 are follow-up patients with a previous diagnosis and treatment of NMIBC. For patients with low-risk NMIBC (n=27), the sensitivity and specificity were calculated as 75% and 100%. For patients with high-risk NMIBC (n=47), who were previously treated with intravesical BCG, the sensitivity and specificity were calculated as 54.5% and 83.3%. All patients in radical cystectomy group (n=7) with muscle invasive BC had positive urine analyses results for atypical cells, whereas no atypical cells were highlighted in the control group. The authors concluded that the Atyp.C parameter showed acceptable sensitivity and specificity rates and especially highlight its potential value for the low-risk group with regards to decisions on follow-up cystoscopies.

#UF5000 #AtypC #UrothelialCarcinoma #BladderCancer #NMIBC #Cystoscopy #Surveillance

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Muto S et al. (2014):
Isomorphic red blood cells using automated urine flow cytometry is a reliable method in diagnosis of bladder cancer. Int J Clin Oncol 19(5):928-934.

https://pubmed.ncbi.nlm.nih.gov/24105457/

Summary: The aim of this study was to identify patients with gross haematuria who could safely avoid unnecessary radiation and instrumentation in the diagnosis of bladder cancer (BC), by urine flow cytometry. Urine samples from 134 patients with a complaint of haematuria and a positive urine occult blood test or microhaematuria. The specimens were analysed using the UF-1000i to determine RBC morphology. The patients were divided into two groups (BC and non-BC) for statistical analysis. The area under the curve for RBC count using the automated urine flow cytometer was 0.94, representing the highest reference value obtained in this study. Analytical parameters such as sensitivity, specificity, positive predictive value, and negative predictive value of isomorphic RBCs in urine were 100.0, 91.7, 74.3, and 100.0%, respectively. The authors concluded that the detection of urinary isomorphic RBCs by urinary flow cytometry is a reliable method in the diagnosis of bladder cancer with haematuria.

#UF1000i #RBC #Haematuria #UrothelialCarcinoma #BladderCancer

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7 Body Fluid Analysis

Baran E and İlki AA (2023):

Evaluation of Sysmex UF-5000-BF Module for Sterile Body Fluids. An Alternative for Conventional Methods? Clin Lab 69(4).

https://pubmed.ncbi.nlm.nih.gov/37057945/

Summary: This study aims to evaluate the performance of the UF-5000 body fluid mode for white blood cells and bacterial counting in comparison to manual microscopy, gram staining, and culture in a total of 634 body fluid samples. This investigation demonstrated a very strong agreement for CSF samples (r = 0.70) and good agreement for pleural and peritoneal samples (r = 0.63). Sensitivity and specificity were 100% and 64% for pleural samples, 94.1% and 77.4% for ascites samples and 100% and 81,2% for CAPD samples, respectively. Detected BACT and WBC values were significantly higher in culture positive samples. Also, for CSF, pleural and CAPD fluids, the bacteria count showed a sensitivity of 100 % and an NPV of 100 %. Therefore, the authors conclude that flow cytometry approach of the UF-5000 body fluid mode, can be a tool for the rapid detection of culture positive specimens and the direct rule-out of bacteria-negative samples with potential impact on antimicrobial stewardship, especially in combination with MALDI-TOFF mass spectrometry for rapid pathogen identification.

#UF5000 #BodyFluid #CSF #CAPD #Synovial #Pleural #Microscopy #Gram #Culture

OA

Dossou N et al. (2022):

Evaluation of Flow Cytometry for Cell Count and Detection of Bacteria in Biological Fluids. Microbiology Spectrum 10(1):e0183021.

https://pubmed.ncbi.nlm.nih.gov/35196801/

Summary: In the light of diagnostic pathway efficiency for the analysis of body fluids in context of monitoring effusion-causing diseases and the diagnosis of infectious diseases, this study aimed to evaluate the analytical performance (I) of the UF-4000 and the XN-10 as methods for the cytological analysis of different body fluids in comparison to manual counting chambers and manual leukocyte differential counts and (II) of the UF-4000 as a method for the microbiological analysis in comparison with direct Grams staining (DGS) and/or conventional cultures. Three optimal cut-off values have been defined for the prediction of DGS-positivity for peritoneal (465.0 bacteria/µL), synovial (1200.0 bacteria/µL), and cerebrospinal fluids (17.2 bacteria/µL) with maximum sensitivity and highest negative predictive values. In conclusion, bacterial counts, obtained by flow cytometry on the UF-4000 correlate with direct Gram staining and culture results. The authors conclude the body fluid mode of the UF-Series could be used to improve upstream routine microbiological workflows, aiming the improvement and acceleration of the diagnosis of infectious diseases in biological fluids.

#UF4000 #BodyFluid #CSF #CAPD #Synovial #Pleural #Microscopy #Gram #Culture

OA

Siatkowski M et al. (2022):

Performance evaluation of UF-4000 body fluid mode for automated body fluid cell counting. Clin Chim Acta 531:152-156.

https://pubmed.ncbi.nlm.nih.gov/35398022/

Summary: This study evaluated the performance of the UF-4000 body fluid mode in comparison to manual light microscopy for ascitic, cerebrospinal, pleural, synovial and CAPD fluids. The investigation was executed under real operating conditions within a microbiology laboratory setup and revealed an excellent performance for WBC and RBC counting, reaching 100 % sensitivity and 100 % specificity for most fluids. Especially for ascites the body fluid mode showed the potential to rule-out infections in urgent conditions. The authors conclude that the UF-Series body fluid mode has the potential for partial replacement of manual body fluid assessment methods. Manual methods might be still required for some cases with abnormal WBC cell counts and scattergram distributions, but overall, positive workflow impacts have been observed.

#UF4000 #BodyFluid #CSF #CAPD #Synovial #Pleural #Microscopy #Gram #Culture

Seghezzi M et al. (2021):

Performance evaluation of automated cell counts compared with reference methods for body fluid analysis. Diagnosis (Berl) 9(3):369-378.

https://pubmed.ncbi.nlm.nih.gov/34599561/

Summary: This study aimed to evaluate the analytical performance of the UF-5000 body fluid mode in comparison to manual microscopy and the body fluid mode of the XN-1000 for different types of non-CSF body fluids. The authors conclude that the UF-5000 body fluid mode shows a very good performance for differential counts of cells in ascitic, pleural and synovial and is thus a suitable and reliable tool in automated body fluid analysis.

#UF5000 #BodyFluid #XN1000 #XN-BF #CSF #CAPD #Synovial #Pleural #Microscopy

OA

Cho J et al. (2020):

Performance Evaluation of Body Fluid Cellular Analysis Using the Beckman Coulter UniCel DxH 800, Sysmex XN-350, and UF-5000 Automated Cellular Analyzers. Ann Lab Med 40(2):122-130.

https://pubmed.ncbi.nlm.nih.gov/31650728/

Summary: In this study, different types of 542 body fluid specimen were examined using manual counting and three the automated cellular analysers XN-350, UF-5000 and UniCel DxH 800. Additionally, 2,779 BF analysis results were retrospectively reviewed. All three analysers showed good agreement for total nucleated cell (TNC) and red blood cell (RBC) counts, except for the RBC count in CSF samples using the UniCel DxH 800. However, variable degrees of differences were observed during differential cell counting. The authors concluded that conclusion, the three automated analysers showed good analytical performances, but proper reflex and interpretation guidelines are needed to help to utilise the generated data.

#UF4000 #BodyFluid #XN350 #XN-BF #DxH800 #CSF #CAPD #Synovial #Pleural

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OA

Koo M et al. (2019):
Comparison of Red Blood Cell, White Blood Cell and Differential Counts between UF-5000 System and Manual Method. J Lab Med Qual Assur 2019; 41(3): 172-178.

http://www.jlmqa.org/journal/download_pdf.php?doi=10.15263/jlmqa.2019.41.3.172

Summary: This study aimed to validate the analytical and diagnostic performance of the UF-5000 for the analysis of different body fluids. The performance of RBC counts, WBC counts and differentiation of leucocytes was assessed in comparison to light microscopy for ascitic, pleural, and cerebrospinal and other body fluids. Comparing the UF-5000 body fluid mode and manual counting resulted in good correlations for red (r=0.6555) and excellent correlation for white blood cell (r=0.9666) counts. The UF-5000 system also demonstrated excellent performance for differential cell counting (r=0.9028). The authors conclude that the body fluid application on the UF-5000 proved to be an effective and automated alternative to chamber counting in laboratory routine analysis, thereby enhancing laboratory workflow and clinical effectiveness.

#UF5000 #BodyFluid #CSF #CAPD #Synovial #Pleural #Microscopy

Seghezzi M *et al.* (2017):
Preliminary evaluation of UF-5000 Body Fluid Mode for automated cerebrospinal fluid cell counting. Clin Chim Acta. 473:133-138.

https://www.ncbi.nlm.nih.gov/pubmed/28843601

Summary: In this study, the performance of the body fluid mode of the UF-5000 for CSF samples was assessed in comparison to manual microscopy based on 88 CSF samples. For total nucleated cells (TNC-UF) and white blood cells, a LoB, LoD and LoQ of 1×10^6 cells/L, 1.8×10^6 cells/L and 1.9×10^6 cells/L was demonstrated, respectively. For red blood cells the LoB, LoD and LoQ were 2×10^6 cells/L, 3.5×10^6 cells/L and 14×10^6 cells/L, respectively. Whereas there was no carryover detected, the agreement between UF-5000 body fluid mode parameters and manual cell counts was good in all CSF samples. The authors concluded that the UF-5000 a rapid approach for the assessment of CSF samples in clinically relevant concentration ranges, having the potential to partially replace manual microscopy.

#UF5000 #BodyFluidMode #CSF #Microscopy

8   Medico-economics

OA

Herráez Carrera Ó and Jarabon Bueno MDM (2020):
Cost analysis of the automated examination of urine with the Sysmex UN-Series™ in a Spanish population. Pharmacoecon Open (4):605-613.

https://www.ncbi.nlm.nih.gov/pubmed/32086775

Summary: In this study, the potential cost-effectiveness of the Sysmex UN-Series has been assessed in context of operational aspects (e.g. turn-around-time, etc.) and the impact laboratory workloads costs of current urinalysis practice. Retrospective data of more than 90,000 handled urine samples of a 10-year period, including financial data and alternative costs of reference and test scenarios were evaluated. In total, potential average cost savings of 340,000 € per year was identified for the use of the UN-Series. On top, the UN-Series demonstrated the potential to reduce the annual working hours of laboratory personnel to up to 1615 hours. The authors conclude that the implementation of the UN-Series within routine practice in clinical laboratories could minimize costs, provide substantial savings for investment, improve laboratory procedures and could contribute to synergy between clinical analysis and microbiology laboratories.

#UF5000 #UC3500 #UTImanagement #AlbuminuriaScreening #Economics

Ilki AA et al. (2017):
Cost-effectiveness of a new system in ruling out negative urine cultures on the day of administration. Eur J Microbiol Infect Dis 36(7):1119-1123.

https://pubmed.ncbi.nlm.nih.gov/28111725/

Summary: Urine samples account for a significant part of the workload in clinical microbiology laboratories. However, the culture process is time-consuming, and a large proportion is reported as negative. To reduce unnecessary culture procedures and speed up the reporting of negative results, a reliable screening method is needed. For this purpose, urine samples submitted to our clinical microbiology laboratory were simultaneously screened by a flow cytometry method (Sysmex UF-1000i, Japan). During screening, the evaluation of various combinations of leucocytes and bacteria cut-offs demonstrated that cut-offs of 30 and 50/µL, respectively, were the best threshold values to reach a 100% negative predictive value (NPV) with a culture reduction rate of 44.8% in adults and 61.9% in children between the ages of 6 and 17 years. With the culture reduction rates mentioned above, the screening method has provided at least 24% savings in expenditures of the routine clinical microbiology laboratory. Since we did not reach such an NPV with any combinations of screening parameters in children younger than 5 years of age, we recommend cultivation of all urine samples in those patients without a screening step. In conclusion, Sysmex UF-1000i as a screening method could improve the efficiency of the routine microbiology laboratory by providing negative results in a few minutes in children greater than 6 years of age and in adults.

#UF1000i #UTImanagement #Economics

9   Pre-analytics

NEW

Walber GB *et al.* (2025):
Quality indicators for urine sample contamination: can squamous epithelial cells and bacteria count be used to identify properly collected samples? Clin Chem Lab Med 63(5):979-986.

https://pubmed.ncbi.nlm.nih.gov/39745181/

Summary: This study evaluated urinalysis parameters from the Sysmex UF-5000 flow cytometry analyzer to identify mixed cultures and contamination in urine samples. Analyzing 2,527 samples from a Brazilian hospital, cutoff values were established for bacteria and squamous epithelial cells (SEC) to detect contamination and infection. For females, bacteria $\geq193.65/\mu L$ and SEC $\geq21.35/\mu L$ indicated possible contamination or infection, while for males, bacteria $\geq23.55/\mu L$ and SEC $\geq5.05/\mu L$ served similar roles. Logistic regression showed significantly higher odds of mixed cultures with elevated bacteria and SEC counts. The results suggest bacterial presence in male samples often reflects infection, whereas in females, it may indicate infection or contamination. Thus, fluorescent flow cytometry is a valuable quality indicator tool to distinguish contamination and colonization in urine cultures, improving sample assessment accuracy.

#UF5000 #BACT #SquamEC #Contamination

Zhang G *et al.* (2023):
Analysis of factors with low positive predictive value in the diagnosis of urinary tract infection by flow cytometry. World J Urol 41(12):3611-3618.

https://pubmed.ncbi.nlm.nih.gov/37898576/

Summary: This study examined the factor that are associated with low positive predictive value for UTI-positive specimen, which are limiting the clinical application. In total, 5,095 urine specimens were assessed by flow cytometry and urine culture to analyse the diagnostic performance of WBC, BACT, and BACT-info flags and the association of contaminated culture and squamous epithelial cell count and BACT-info flag. The NPVs were 98.9% and 97.9% in males and females, respectively, while PPVs were 86.6% and 77.8%. The PPV of Gram-negative flag was higher than that of Gram-positive flag. There was a statistically significant association between contaminated cultures and squamous epithelial cells count in females, but not in males. The authors conclude contamination is the main reason for a low PPV for UTI diagnosis by flow cytometry and recommend a serial combination of leukocytes and bacteria to maximise the PPV.

#UF5000 #WBC #BACT #BACTinfo #NPV #PPV #lowPPV #SquamEC #Contamination

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OA **Chou YJ** *et al.* **(2023)**:
Albuminuria Is Affected by Urinary Tract Infection: A Comparison between Biochemical Quantitative Method and Automatic Urine Chemistry Analyzer UC-3500. Diagnostics (Basel) 13(21):3366.

https://pubmed.ncbi.nlm.nih.gov/37958262/

Summary: This study assessed the impact of UTIs on albuminuria diagnosis using both the biochemical quantitative method and the test strip method of the UC-3500. Prospectively collected midstream urine from adult female UTI patients before and after one week of cephalexin treatment. The urine samples were subjected to culture, routine urinalysis, and albuminuria diagnosis. Among fifty-four female UTI patients, 24 had transient albuminuria. The quantitative ACR significantly decreased after one week of antibiotic treatment. UC-3500 exhibited a higher false positive rate for diagnosing albuminuria during UTIs (42%) compared to after treatment (19%). Its agreement with the biochemical quantitative method was moderate during UTI (κ = 0.49) and good after treatment (κ = 0.65). Therefore, the authors conclude that UTI should be excluded or treated before its application in albuminuria screening.

#UC3500 #TestStrip #Albuminuria #UTI #PreAnalytics #Interference

Debunne N *et al.* **(2023)**:
Urine transfer devices may impact urinary particle results: a pre-analytical study. Clin Chem Lab Med 61(12):2186-2194.

https://pubmed.ncbi.nlm.nih.gov/37340894/

Summary: In this study, the impact of different urine collection methods and urine transfer devices on the outcome urine test strip and particle analysis has been assessed in comparison to the direct measurement of the native specimen on the respective analysers. In total, 146 selected urine samples were subdivided into three different collection containers and subsequently transferred into its accompanying transfer tube. While there were no significant differences in test strip results, use of the secondary transfer tube showed impact on RTEC, hyaline and pathological cast counts. The authors concluded that urine transfer tubes might impact on the cell count of fragile urinary particles.

#UF5000 #UC3500 #PreAnalytics #Interference

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