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1 General / Review

Oyaert M and Delanghe JR (2019):
https://www.ncbi.nlm.nih.gov/pubmed/30215225

What we see as the essence: 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 microfluidics and mobile applications is given.

#AutomatedUrinalysis #AutomatedMicroscopy #FCM #TestStrip #UTI #LabOnAChip #Microfluidics

2 Performance Evaluation / Comparison

Yang 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

What we see as the essence: This study aims to compare the performance of the new UF-5000 and 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. In conclusions, the UF-5000 demonstrated good sensitivity and specificity for Gram-negative bacilli and demonstrated an improved sensitivity for detecting Gram-positive cocci compared with the UF-1000i.

#UTI #uUTI #UF5000 #UF1000i #GramStaining #BACTinfo
Enko D et al. (2020):

What we see as the essence: Enko and colleagues demonstrate that the analytical performance of the UF-5000 is in strong concordance with manual phase-contrast microscopy and clearly outperforming the Roche cobas® u 701 module. This study included a broad spectrum of urine sediment pathologies, thereby proving the UF-5000 to be a reliable tool for automated urine sediment analysis in daily clinical practice.

#AutomatedUrinalysis #Microscopy #UrineSediment #UF5000 #cobsa701

Kucukgergin C et al. (2019):

What we see as the essence: This study evaluates the analytical performances of the UF-5000 and the Dirui FUS-200, 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. Overall, the UF-5000 demonstrated better agreement in classification of WBCs, RBCs, ECs, positively affecting the morphologic recognition and enumeration of cells.

#AutomatedUrinalysis #UF5000 #FUS-200 #AnalyticalPerformance #UrineMicroscopy

Cho J et al. (2019):
https://www.ncbi.nlm.nih.gov/pubmed/31280239

What we see as the essence: This study evaluated the analytical and diagnostic performance of the Sysmex UF-5000, the Roche cobas® u 701 module, the URISCAN PlusScope and the Iris iQ200SPRINT and the SIEMENS UAS800 in comparison to manual microscopy. Each automated urine sediment analyzer has certain 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.

#AutomatedUrineSedimentAnalyzer #UF5000 #Cobas701 #iQ200SPRINT #UAS800 #PlusScope
Bakan E et al. (2018):


What we see as the essence: This study compared the diagnostic performance of the UF-5000 and the Roche cobas® u 701 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. In conclusion, the UF-5000 is a reliable tool for urine sediment analysis, but pathological samples should be confirmed by microscopy.

#AutomatedUrinalysis #UF5000 #ManualMicroscopy #Urinalysis #cobas701

Previtali G et al. (2017):


What we see as the essence: Previtali and colleagues evaluated the analytical performance of the Sysmex UF-5000 for urine sediment samples compared manual particle counting using the Fuchs-Rosenthal chamber. The study demonstrated high linearity performances for RBCs, WBCs and epithelial cells, as well as high negative predictive values and good sensitivities and specificities for all parameters, especially those of clinical relevance. The authors conclude a high potential of the UF-5000 and its fluorescence flow cytometry technology to investigate urine sediment particles related to pathological conditions of the kidneys and the urinary tract.

#AutomatedUrineAnalysis #FuchsRosenthalChamber #UF5000 #UrineParticles
3 Biochemistry

**Nah 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

*What we see as the essence:* 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. In conclusion, the CKD risk category using test strip proteinuria was underestimated compared to the ACR-based CKD risk category, suggesting a recommendation of the use of test strip ACR for CKD screening in primary healthcare settings.

#PrimaryCare #Urinalysis #UC3500 #CKD #TestStrip #ACR #CKDscreening

**Currin 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 Nephrology 22:103


*What we see as the essence:* 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 of 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. In summary, the study demonstrated a good NPV for ACR at the point of care, offering the potential for frequent screening of risk group patients and reliable rule-out of albuminuria, if screening for CKD.

#PointOfCare #Urinalysis #UC1000 #CKD #Albuminuria #ACR #RiskGroupScreening

What we see as the essence: This study aims to evaluate the diagnostic performances of a test strip for measuring ACR for differentiating patients who are candidates for subsequent albumin quantification, and to evaluate the economic effects of its implementation. In conclusion, the detection of albumin and the albumin:creatinine ratio (ACR) is a suitable screening strip test to identify pathological albuminuria for further confirmation through quantitative methods. The performance of the test strip and its workflow benefits do not only foster economic savings, but also elucidates the potential for frequently screening of risk group patients.

#TestStrip #Urinalysis #UC3500 #CKD #Screening


What we see as the essence: This study evaluated the analytical and diagnostic performance of the UC-3500 for the presence of glucose, protein, albumin, leukocyte esterase, and hemoglobin 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.

#Dipstick #FullyAutomatedUrineAnalyzer #TestStrip #Urinalysis #UrineChemistryAnalysis #UC3500


What we see as the essence: This study investigates diagnostic accuracy of the Sysmex UC-3500 automated urine chemistry analyzer based that uses CMOS sensor technology for leukocyte esterase and hemoglobin peroxidase results. In addition, the influence of urinary dilution, haptoglobin, urinary pH and ascorbic acid on the test results has been assessed. In conclusion, 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, which may form a basis for expert system development.

#HemoglobinPeroxidase #LeukocyteEsterase #UrineSedimentAnalysis #UrineTestStripAnalysis
Delanghe JR et al. (2017):


What we see as the essence: Delanghe and colleagues investigated the potential of the CMOS sensor technology of the UC-3500 for obtaining quantitative albuminuria results in comparison to clinical wet chemistry using the cobas® 8000 immunochemistry analyser. For albumin, this study revealed a limit of detection of 5.5 mg/l, respecting limits for screening for albuminuria in patients at risk of CKD. A strong or good correlation between strip reflectance data and albuminuria creatinine, respectively, potentially allows quantification of albuminuria and ACR by dye-binding test strip.

#Albuminuria #ChronicKidneyDisease #Diabetesmellitus #ReflectanceData #TestStrips
Microbiology & Antimicrobial Resistance (AMR)

**Mancini S et al. (2020):**

https://academic.oup.com/jac/article/75/11/3218/5885055

What we see as the essence: In this study, the preparation of standardized bacterial inocula for Enterobacterales-containing clinical blood cultures and the automated assessment of data of a rapid antimicrobial susceptibility testing (RAST) is reported, aiming to accelerate antibiotic therapy decisions. The UF-4000 was used to enumerate bacteria to adjust the inocula to $10^8$ cfu/mL. Disc diffusion plates were automatically streaked, incubated for 6, 8 and 18 h and imaged automatically. In conclusion, with the standardized and automated RAST method, consistent AST data from blood cultures containing Enterobacterales can be generated after 6–8 h of incubation and subsequently confirmed by standard reading of the same plate after 18 h.

#AST #RapidAntibioticSusceptibilityTesting #UF4000 #AMR

**Oyaert M et al. (2020):**


What we see as the essence: Oyaert and colleagues 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 transitional epithelial cells (TEC), increased urinary levels of renal tubular epithelial cells (RTEC) demonstrated a good potential to serve as a marker for the diagnosis of upper UTI and outperforms $\alpha_1$-microglobulin in the discrimination between upper and lower UTI. However, the diagnostic performance of these parameters is strongly depending on proper sample handling.

#AutomatedUrinarySedimentAnalyser #UF5000 #RTECs #UTI #UpperUTI

**Wagner K et al. (2019):**


What we see as the essence: This study investigated the use of commercially AID AmpC line probe assays for analysis of antibiotic resistance by detection of plasmid-mediated bla_{ampc} $\beta$-lactamase genes in Enterobacterales, which proofed to be an accurate, sensitive and easy-to-use test that can be readily implemented in any diagnostic laboratory. In this context, the UF-5000 has been demonstrated to be a reliable tool to judge samples, sent for molecular testing, for the presence of bacteriuria and to reduce the number of unnecessary molecular testing.

#Microbiology #MolecularTesting #AntibioticResistance #AmpC #UF5000 #PreScreening
**Öğüş E et al. (2019):**


What we see as the essence: This study evaluated the incidence of leukocyte esterase and nitrite positivity, leukocyte and bacterial counts in urine and Gram positive and negative bacterial results interpreted by the UF-5000 for compliance with urine culture results. Incorrect results for the Gram status in comparison to urine culture was obtained for three Gram-positive and three Gram-negative samples. Rates of leukocyte esterase, nitrite positivity, leukocyte and bacterial counts were higher in Gram negative group. In conclusion, especially Gram-negative bacterial interpretation obtained from the UF-5000 be beneficial for rapid typing of bacteria and early treatment in urinary tract infections.

#UF5000 #UTI #UrineCulture #BacterialDiscrimination #GramNegative #Dipstick

**De Rosa R et al. (2018):**


What we see as the essence: De Rosa and colleagues 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 and NPV for the bacteria using a cut-off of ≥58/μl. The “Gran Neg?” flag predicted Gram negative urine cultures with good sensitivity and high specificity. In conclusion, the UF-5000 represents a reliable tool for ruling-out urinary tract infections with high diagnostic accuracy and offers the possibility to detect Gram-negative bacteria in very high agreement with urine culture. Further investigations might reveal the potential for the Gram information for targeted antibiotic.

#Bacteriuria #UTIScreening #FCM #UF5000 #Urinalysis #UrineCulture #GramNegative

**Kim SY et al. (2018):**


What we see as the essence: Kim and colleagues evaluated the performance of the UF-5000 in context of UTI screening, aiming to reduce unnecessary urine culture and improve the determination of antibiotic treatments. The performance to discriminate Gram-negative bacteria was superior to that for Gram-positive bacteria with high sensitivity and specificity in ≥10⁵ CFU/ml monobacterial samples. In conclusion, the UF-5000 demonstrated a potential utility for the rapid screening of negative bacterial cultures, depending on the respective patient population, requiring cut-off optimization.

#UF5000 #BacterialDiscrimination #GramPositive #GramNegative #FCM #UTI #UrineCulture
Duyel Song et al. (2018):


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

What we see as the essence: 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/l for bacteria and YLC, respectively, 84 out of 126 requested urine cultures were negative and could have been ruled-out by the UF-5000. In conclusion, 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 #Screening #UrineCulture #Bacteriuria #Yeast

Juranka J et al. (2018):

The importance of diagnosis gram-negative/gram positive bacteria in urine in the pre-culture screening of urine tract infections in the microbiology laboratory fluorescence flow cytometry on the UF-4000 urine analyser (Sysmex) for early initiation of targeted antibiotic therapy [Poster on ECCMID 2018].

https://www.escmid.org/escmid_publications/escmid_elibrary/material/?mid=62616

What we see as the essence: This study investigated sensitivity and specificity of the UF-4000 for the discrimination between Gram-positive and Gram-negative bacteria in pre-culture screenings for urinary tract infections in a microbiology laboratory using fluorescence flow cytometry. Gram-positive and Gram-negative bacteria have been detected in urine, with sensitivities 78 % and 89 % and specificities of 96 % and 89 %, respectively. In conclusion, UF-4000 demonstrated a high potential in pre-culture screenings of urinary infections in a microbiology laboratory and is of benefit to the patient for its role in early initiation of antibiotic therapy, targeting Gram-positive or Gram-negative bacteria.

#UF4000 # UTI #Screening #UrineCulture #Microbiology #Bacterial Discrimination #GramNegative

Kawamura K et al. (2017):


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

What we see as the essence: Kawamura and colleagues evaluated the performance of the UF-5000 with regards to the provision on information on the Gram status of bacterial cells via the BACT-info flag in comparison to conventional methods including Gram staining and quantitative bacterial culture. In summary, the UF-5000 presented in 83.2 % of UTI cases a Gram information, in line with classical Gram staining. The UF-5000 exhibited a high positive predictive value (93.3%) for both Gram negative staining and culture results. Thus, the UF-5000 using BACT-info shows great promise in screening for UTI pathogens and further improvements of judgement algorithms might make the Gram judgement even more reliable.

#UF5000 #UTI #UrineCulture #Bacterial Discrimination #GramNegative #Dipstick
Geerts N et al. (2016):


What we see as the essence: 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 analyzed 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%).

#CutOffValues #GenderSpecific #UF5000 #UTI #Screening #UrineCulture
5 Bladder Cancer

Aydin O (2021)

Atypical cells parameter in Sysmex UN automated urine analyzer: feedback from the field. Turk J Biochem; Diagnostic Pathology 16:9


What we see as the essence: This study investigates the research parameter “Atypical cells” parameter in context of automated urinalysis to detect cellular atypia as a potential indicator of bladder cancer. In total, 50, mainly female samples with higher than 1 atypical cell/μL result were included in the study with one case of a high-grade urothelial carcinoma. The positive case provided evidence for the capability of the UF-Series to detect atypical cells in urine. The negative cases presented clues that probable vulvovaginal contamination and crowded specimens could be deceptive for this parameter.

#UFseries #AtypicalCells #BladderCancer #Screening

Ren C et al. (2020)


What we see as the essence: This study evaluated the predictive power of the UF-5000 research parameter ‘Atypical Cells’ for patients with a suspected diagnosis of urothelial carcinoma. In total, urinary specimens of 128 patients that were enrolled for urinary cytology analysis were included in this investigation and analysed on the UF-5000, aiming to evaluate its performance in identifying atypical or malignant urothelial cells. The UF-5000 findings were in agreement with cytopathology in 73 % of the investigated cases. Using follow-up histologic diagnosis of urothelial carcinoma with or without urinary tract cytology (UTCy) as a reference standard the sensitivity and specificity were calculated with 59 % and 82.1 %, respectively. This resulted in a positive predictive value of 75.0% and a negative predictive value of 68.8%. In conclusion, the ‘Atypical Cells’ parameter bears the potential of an accessory test for urothelial carcinomas in context of routine urinary diagnostics, that might help to identify high-risk patients that require more specific follow-up and medical treatment.

#UF5000 #AtypicalCells #BladderCancer #Screening
Tinay İ et al. (2020)


What we see as the essence: This study evaluated the application of the UF-5000 and its research parameter ‘Atypical Cell’ in supporting the diagnosis of bladder cancer in a retrospective manner in a heterogenous study population. With an acceptable sensitivity of 75 % and a specificity of 100 %, the UF-5000 demonstrated potential value for diagnostic decisions on follow-up cystoscopy for patients with low-risk non-muscle invasive bladder cancer (NMIBC). For patients with high-risk NMIBC, sensitivity and specificity values are lower, but comparable or even better, if compared to cytology. The authors thus revealed the potential to avoid invasive procedures on patient side and to save costs for unnecessary treatments. To further investigate and validate the presented findings, a prospective study is in preparation.

#UF5000 #AtypicalCells #BladderCancer #Screening

Aydin O et al. (2020)
Atypical cells in Sysmex UN automated urine particle analyzer: a case report and pitfalls for future studies. Turk J Biochem; aop


What we see as the essence: The UF-4000 automatically detected atypical cells in the urine specimen of a 73-year old individual with recurrent high-grade urothelial carcinoma in an outpatient setting, which was confirmed by manual microscopy, demonstrating the potential of the UF-Series to detect malignancies.

#UF4000 #AtypicalCells #BladderCancer #Screening #CaseReport
6 Body fluid

**Cho J et al. (2020):**


**What we see as the essence:** Different types of body fluid specimen were examined using manual counting and three automated 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. In conclusion, the three automated analysers showed good analytical performances and proper reflex and interpretation guidelines can help to utilise the generated data.

#UF5000 # BodyFluidMode #Performance #XN350 #UniCel

**Koo M et al. (2019):**


**What we see as the essence:** Analysis of body fluids provides important information for assessing various medical conditions. This study aims 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. In conclusion, 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 # BodyFluidMode #RBC #WBC #Workflow #AutomatedCellCounting

**Seghezzi M et al. (2017):**


**What we see as the essence:** This study evaluated the body fluid mode of the UF-5000 for analysis of CSF in comparison to microscopy. The UF-5000 showed a high diagnostic accuracy for TNC, WBC and RBC counts, as well as high sensitivities and specificities and confirmed a low limit of detection for the RBCs. In conclusion, the UF-5000 body fluid mode offers rapid and accurate quantification of cells, including bacterial cells in CSF samples in clinically relevant concentration ranges, allowing the replacement of microscopy for CSF samples without abnormal cell counts or scattergrams.

#UF5000 # BodyFluidMode #CSF #AutomatedCellCounting
What we see as the essence: This study aimed to investigate the potential of the Sysmex UN-Series to reduce high financial costs and high and time-consuming laboratory workloads of current urinalysis practice. By investigating more than 90,000 handled urine samples of a 10-year period, including financial data and alternative costs of reference and test scenarios, potential average cost savings of 340,000 € per year was identified for the use of automated urine examination, compared to the current urinalysis practice. On top, the UN-Series has the potential to reduce the annual working hours of laboratory personnel to up to 1615 hours. In conclusion, the implementation of the UN-Series within routine practice in clinical laboratories could minimise costs, provide substantial savings for investment, improve laboratory procedures and could contribute to synergy between clinical analysis and microbiology laboratories.
COVID-19

Please note that more publications with regards to COVID-19 and SARS-CoV-2 infections in context of urinalysis are listed in the dedicated COVID-19 literature list. Here, only Covid-19-related studies including data from the UN-Series are included.

Supraja et al. (2021)

What we see as the essence: Renal involvement in Covid-19 infection is varied and can affect glomeruli, tubules, interstitium and can cause acute kidney injury, a strong predictor of mortality. Routine urinalysis can provide insight into the renal pathology of the patient. Urinary abnormalities in hospitalised Covid-19 patients and their impact on development of AKI and mortality were evaluated in this study, including demographic data and information in comorbidities. Urine abnormalities were seen in 71% of the patients, including proteinuria (58.2 %), haematuria (17.3 %), pyuria (8.2 %) and AKI (28.2 %). In conclusion, a commonly available test like urinalysis can aid in early detection of renal impairment in context of COVID-19 to foster early intervention.

#UNSeries #COVID19 #Urinalysis #Prognosis