

# Literature list – Urinalysis

Customer information



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OA

Open access publications are highlighted by this icon.

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Newly added publications are highlighted by this icon.

## General / Review

OA

### **Oyaert M and Delanghe JR (2019):**

Progress in Automated Urinalysis. Ann Lab Med 39(2):15-22.

<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 microfluids and mobile applications is given.

[#AutomatedUrinalysis](#) [#AutomatedMicroscopy](#) [#FCM](#) [#TestStrip](#) [#UTI](#) [#LabOnAChip](#) [#Microfluidics](#)

## Performance Evaluation / Comparison

### **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 [Online version from 2019].

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

**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):**

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://www.ncbi.nlm.nih.gov/pubmed/31460810>

**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):**

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>

**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](#)

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>

**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](#)

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>

**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](#)

## Biochemistry

OA

### **Oyaert M and Delanghe JR (2019):**

Semiquantitative, fully automated urine test strip analysis. J Clin Lab Anal 33(5):e22870.

<https://www.ncbi.nlm.nih.gov/pubmed/30803042>

**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. Especially the albumin measurement fulfills optimum criteria for trueness allowing a reliable, semiquantitative detection of albumin.

[#Dipstick](#) [#FullyAutomatedUrineAnalyzer](#) [#TestStrip](#) [#Urinalysis](#) [#UrineChemistryAnalysis](#) [#UC3500](#)

### **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://www.ncbi.nlm.nih.gov/pubmed/29427551>

**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):**

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

<https://www.ncbi.nlm.nih.gov/pubmed/28554541>

**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

### **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://www.ncbi.nlm.nih.gov/pubmed/31860463>

**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](#)

OA

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

Evaluation of the AID AmpC line probe assay for molecular detection of AmpC *Enterobacterales*. J Glob Antimicrob Resist 19:8-13.

<https://www.ncbi.nlm.nih.gov/pubmed/31051288>

**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<sub>AmpC</sub>  $\beta$ -lactamase genes in *Enterobacterales*, which proved 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](#)

OA

### **Öğüş E et al. (2019):**

Compatibility of the Results of an Automated Urine Analyzer with Urine Culture. ASMS 3(6):88-92.

<https://www.actascientific.com/ASMS/pdf/ASMS-03-0297.pdf>

**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 leucocyte 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](#)

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://www.ncbi.nlm.nih.gov/pubmed/29803898>

**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  $\geq 58/\mu\text{l}$ . 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](#)

OA

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

Rapid Screening of Urinary Tract Infection and Discrimination of Gram-Positive and Gram-Negative Bacteria by Automated Flow Cytometric Analysis Using Sysmex UF-5000. J Clin Microbiol 56(8):e02004.

<https://www.ncbi.nlm.nih.gov/pubmed/29769277>

**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  $\geq 10^5$  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](#)

OA

**Duyeal Song et al. (2018)**

Selection of Unnecessary Urine Culture Specimens Using Sysmex UF-5000 Urine Flow Cytometer. Ann Clin Microbiol 21(4):75-79.

<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/ $\mu\text{l}$  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](#)



### **Jurankova 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](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](#) [#BacterialDiscrimination](#) [#GramNegative](#)

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](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](#) [#BacterialDiscrimination](#) [#GramNegative](#) [#Dipstick](#)

### **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://www.ncbi.nlm.nih.gov/pubmed/26616731>

**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](#)

## Bladder Cancer

NEW

### 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

OA

<https://diagnosticpathology.biomedcentral.com/track/pdf/10.1186/s13000-020-00993-1>

**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](#)

OA

### Tinay İ *et al.* (2020)

"Atypical Cell" Parameter in Automated Urine Analysis for the Diagnosis of Bladder Cancer: A Retrospective Pilot Study. *Bull Urooncol* 19(1):17-19

[http://cms.galenos.com.tr/Uploads/Article\\_36890/UOB-19-17-En.pdf](http://cms.galenos.com.tr/Uploads/Article_36890/UOB-19-17-En.pdf)

**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

<https://www.degruyter.com/view/journals/tjb/ahead-of-print/article-10.1515-tjb-2019-0418/article-10.1515-tjb-2019-0418.xml>

**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](#)

## Body fluid

### **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>

**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](#)

## Medicoeconomics

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* 10(22) [Online ahead of print].

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

**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.

[#UNSeries](#) [#CostSavings](#) [#Medicoeconomics](#) [#UTI](#)