

Comparative Accuracy of Urine Dipstick Testing vs AutoUA® in the Detection of Urologic and Kidney Disorders

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Abstract

Background: Urine dipstick testing is the most widely used point-of-care method for detecting urinary tract infections, hematuria, and early kidney dysfunction; however, dipstick performance varies across analytes and may be affected by urine concentration. This study compared urine dipstick results with a creatinine-normalized automated urinalysis system, AutoUA® (Sciteck Diagnostics Inc), to assess concordance and potential clinical impact in a community urology practice.

Methods: A prospective comparative accuracy study was performed on 190 patient samples evaluated using both urine dipstick and AutoUA®. Microscopic confirmation for urinary hemoglobin was performed on a subset of samples. Concordance, total error rates, and error patterns were evaluated across analytes relevant to urologic care.

Results: Urine dipstick accuracy varied substantially by analyte. Leukocyte dipstick testing showed a 61.6% total error rate, with 115 urinalyses suggestive of infection missed by urine dipstick compared with AutoUA®. Hemoglobin testing showed 44.7% total discordances, including 46 false positives. Secondary analytes (ie, protein, bilirubin, glucose, ketones, nitrites, and urobilinogen) also demonstrated inconsistent performance by dipstick urinalysis. AutoUA® provided more consistent creatinine-normalized analyte quantification.

Conclusion: When compared with AutoUA®, urine dipstick results deviated considerably across multiple key analytes, raising concern that urine dipsticks are an unreliable tool upon which to rely when making clinical decisions in a urology setting. In contrast, AutoUA® showed more consistent and clinically actionable results for detecting key biomarkers indicative of urinary tract infections, hematuria, and early kidney dysfunction.

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Introduction

Urinalysis remains a cornerstone of diagnostic medicine, providing valuable insights into kidney and urinary tract function as well as systemic metabolic processes.¹ In the field of urinalysis, dipsticks are the most common method employed for point-of-care urinalysis. Dipsticks are a colorimetric strip that provides qualitative or semiquantitative results for several analytes, including leukocytes, nitrites, hemoglobin, and protein.² Despite its convenience, dipstick urinalysis is prone to both analytical and interpretive errors that can lead to misdiagnosis or delayed treatment.³⁻⁶ Studies have demonstrated that dipstick sensitivity for hematuria and leukocytes can vary widely depending on urine concentration (how hydrated someone is), user technique, and reagent stability.^{7,8}

Advancements in automated urinalysis platforms, such as the AutoUA® system (Sciteck Diagnostics Inc), have sought to address these limitations by introducing quantitative, creatinine-normalized measurements that reduce operator dependency and improve the accuracy of results.^{9,10} This study examined the performance of traditional dipstick testing compared with AutoUA® across 8 clinical indicators: bilirubin (for liver dysfunction or biliary obstruction), glucose (for diabetes monitoring and glycemic control), hemoglobin (for hematuria detection), ketones (for diabetic ketoacidosis and metabolic monitoring), leukocytes and nitrites (for urinary tract infection detection), protein (for kidney function assessment and early kidney disease detection), and urobilinogen (for liver disease and hemolytic disorders).

The implications of diagnostic inaccuracy of these parameters are clinically significant. Importantly, missed or delayed diagnosis of lower urinary tract infections can result in progression to more complicated or severe infections, including pyelonephritis and sepsis, if left untreated.^{7,11} False-negative hematuria results may furthermore delay the identification of underlying malignancies or nephropathies, while false-positive hematuria may prompt costly and invasive diagnostic procedures

KEY POINTS

- Urine dipstick analysis exhibited high total error rates, including 61.6% for leukocytes and 44.7% for hemoglobin.
- AutoUA® reduced diagnostic uncertainty with consistent creatinine-normalized results.
- Urine dipstick hemoglobin testing produced 46 excess positives, which may trigger unnecessary workups and follow-up procedures.
- AutoUA® improved identification of early kidney dysfunction through increased sensitivity of total protein at concentrations below 30 mg/dL and quantification of urinary albumin.
- Replacing urine dipstick with AutoUA® may improve diagnostic accuracy and reduce the likelihood of unnecessary evaluations.

ABBREVIATION

CKD, chronic kidney disease

such as cystoscopy.¹²⁻¹⁴ Notably, the rate of dipstick false positives is reported to be as high as 50%, raising serious questions about the test's efficacy.^{12,13} Undetected proteinuria can similarly delay the diagnosis and management of chronic kidney disease (CKD), a condition associated with increased cardiovascular risk and health care burden.^{15,16} According to the National Kidney Foundation, CKD affects approximately 37 million people in the United States, and 90% of people with CKD do not know they have it because of poor detection methods.^{17,18} This comparative analysis provides a quantitative evaluation of dipstick urinalysis error rates and explores the potential clinical and systemic impact of adopting AutoUA® as a diagnostic alternative.

Methods

A total of 190 urine samples were collected from 187 patients in a urology practice setting, with patients ranging from 18 to 90 years of age. The study cohort included samples from 110 male and 80 female patients, reflecting a balanced representation of urologic demographics. Samples were processed according to standard laboratory handling procedures.

Each urine specimen in the study was analyzed using 2 distinct testing methodologies. The first method, traditional dipstick urinalysis, used standard colorimetric reagent strips to detect the presence of leukocytes, hemoglobin, and protein. These results were interpreted using automated readers in an effort to reduce subjectivity. The second method employed the AutoUA® system, which uses a quantitative, creatinine-normalized approach designed to minimize the variability caused by differences in urine concentration. AutoUA® operates through spectrophotometric analysis to generate numerical measurements of key urinary analytes, including hemoglobin, leukocytes, and protein.

Of the total 190 urine samples, 20 were further subjected to confirmatory microscopic analysis specifically for hematuria, serving as a reference for assessing the presence of hemoglobin. The remaining samples were used for direct comparison between traditional dipstick testing and AutoUA®

results across the analytes of interest. Error rates were calculated for each analyte using the AutoUA® results as the comparative gold standard. From these data, false-negative and false-positive results were categorized and quantified. Clinical implications of these errors were assessed based on potential diagnostic consequences and established clinical guidelines, including those from the National Kidney Foundation's 2018 study.¹⁷

Results

The results of the comparative study revealed substantial differences in accuracy between traditional dipstick urinalysis and the AutoUA® system across all analytes tested. The highest overall error rate observed in dipstick testing occurred for leukocyte detection, with dipsticks demonstrating a total error rate of 61.6% (Figure 1). Notably, 60.5% of these discrepancies were false negatives, corresponding

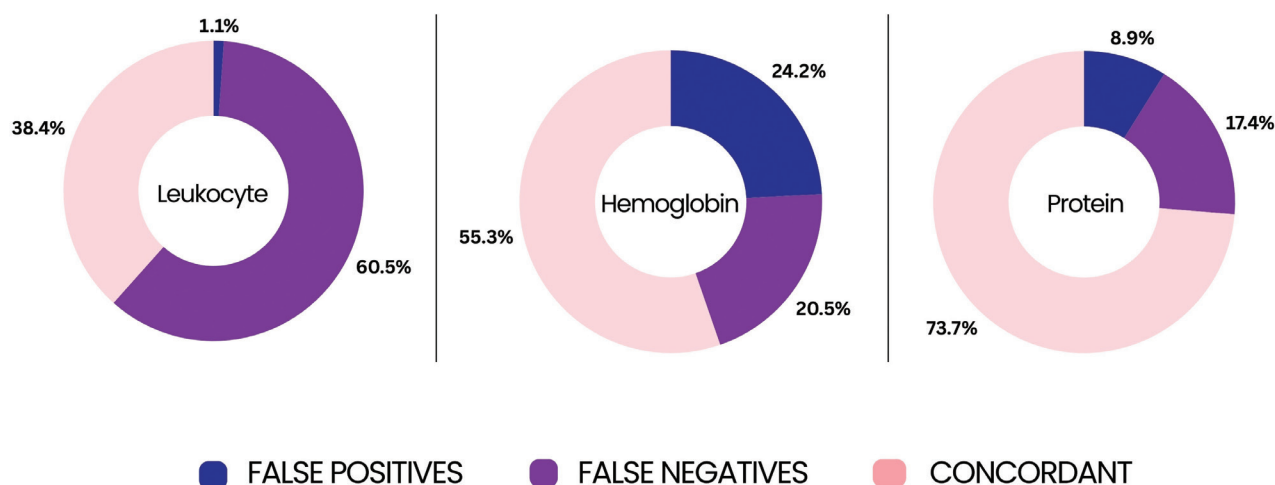


Figure 1. Donut charts show the comparative accuracy of dipstick urinalysis for leukocyte, hemoglobin, and protein detection, illustrating the proportion of concordant, false-positive, and false-negative results for each analyte. Dipstick testing demonstrated the highest overall error rate for leukocyte detection (61.6%), driven largely by false negatives (60.5%), followed by hemoglobin (44.7% total error; 24.2% false positives, 20.5% false negatives) and protein (26.3% total error; 8.9% false positives, 17.4% false negatives). Data highlight the variability and diagnostic limitations of traditional dipstick methods compared with quantitative AutoUA® analysis.

to the presence of inflammation or infection in 115 cases where positive leukocytes were identified by AutoUA®. These findings are consistent with previous studies showing that dipstick leukocyte esterase sensitivity can vary widely, often missing lower-level infections or early inflammation.^{2,19}

In the assessment of hemoglobin for hematuria detection, dipstick testing showed considerable inaccuracy, with a total error rate of 44.7% (Figure 1), including a 24.2% false-positive rate, amounting to 46 cases that could have led to unnecessary diagnostic procedures such as cystoscopy or imaging, as well as a 20.5% false-negative rate, representing 39 missed cases of hematuria. Among the 20 samples that underwent confirmatory microscopy, approximately 90% of AutoUA® results accurately correlated with microscopic findings, whereas approximately 58% of dipstick results were concordant, with a false-positive rate of 32% and a false-negative rate of 26%. These findings mirror prior reports of dipstick hemoglobin sensitivity being influenced by ascorbic acid levels, sample handling, and urinary concentration.^{5,6} Clinically, this bidirectional inaccuracy suggests that many patients may be directed toward unnecessary diagnostic evaluation in hematuria workups while other patients risk delayed diagnosis of underlying malignancy or glomerular disease.¹²

When evaluating the presence of protein in the urine as a marker of kidney dysfunction, dipstick testing produced a total error rate of 26.3%, including a 17.4% false-negative rate corresponding to 33 potential missed cases of proteinuria (Figure 1). These results align with previous evidence indicating that dipstick-based protein detection is affected by urine pH, concentration, and orthostatic variation, leading to underdetection of early kidney disease.^{6,20} In contrast, the AutoUA® system's creatinine-normalized readings correct for urine concentration, yielding more stable and quantitative protein results, even at lower levels.

For the remaining 5 analytes (ie, bilirubin, glucose, ketones, nitrites, and urobilinogen), traditional dipstick urinalysis continued to show both false-negative and false-positive results, though at lower rates than for leukocytes, hemoglobin, and protein. Bilirubin demonstrated a 9.5% false-positive rate and a 1.1%

false-negative rate (see Supplemental Figure S1A), indicating limited reliability in detecting hepatic or biliary abnormalities.^{21,22} Glucose testing yielded no false positives and a 3.7% false-negative rate (see Supplemental Figure S1B), suggesting agreeable accuracy but susceptibility to false negatives in diluted samples and in early hyperglycemia.²³ For ketones, dipstick urinalysis produced a 1.6% false-positive rate and a 4.7% false-negative rate (see Supplemental Figure S1C), which is consistent with literature showing variability as a result of reagent degradation or short fasting periods.²⁴ Nitrite testing demonstrated low error rates, with a 1.6% false-positive rate and a 0.5% false-negative rate (see Supplemental Figure S1D), though its accuracy remains dependent on urine dwell time and bacterial species.¹⁹ Urobilinogen results revealed a 0.5% false-positive rate and a 5.8% false-negative rate (see Supplemental Figure S1E), suggesting potential underdetection of mild elevations linked to liver dysfunction or hemolytic conditions.²¹

Overall, this study demonstrated considerable disparities in urinary dipstick analysis, suggesting that the increased sensitivity and selectivity of AutoUA® could provide timely and critical data with potential clinical implications. The magnitude of these discrepancies, particularly for leukocytes, hemoglobin, and protein, reinforces previously published evidence regarding dipstick variability and supports the clinical value of transitioning to automated, quantitative urinalysis systems.^{3,5}

Discussion

Traditional dipstick urinalysis has long been criticized for its analytical limitations, which compromise accuracy and reproducibility.² One major source of error arises from urine concentration variability, wherein dilute samples can frequently produce false negatives while concentrated specimens can exaggerate positives. Interfering substances such as ascorbic acid, oxidizing agents, vitamin C, and some medications further distort results, particularly for hemoglobin and leukocyte detection.^{25,26}

By contrast, the AutoUA® system was developed to overcome these inherent weaknesses through advanced analytical design. Its creatinine-adjusted approach mathematically normalizes analyte measurements to account for urine concentration, improving accuracy across hydration levels. Because of the liquid-liquid nature of AutoUA®, the system also drastically improves the stoichiometry between the urine and reagent chemistry. This approach provides 2 unique benefits: (1) increasing sensitivity and allowing for earlier detection of clinical analytes and (2) the dilution of many major known interfering substances to increase overall analytical accuracy. AutoUA® also eliminates subjective interpretation by providing quantitative, photometrically derived results, ensuring greater consistency and reproducibility. Moreover, its enhanced spectrophotometric and algorithmic detection methods improve sensitivity and specificity, especially for analytes often missed by dipstick testing.²⁷

The clinical implications of these findings are profound. High dipstick error rates can lead to missed infections, delayed cancer detection, and undiagnosed kidney disease, all of which contribute to poor patient outcomes and higher health care costs.^{7,28,29} The AutoUA® system's precision reduces these diagnostic errors, ensuring earlier detection to support appropriate treatments and improve overall patient care. From an economic perspective, automated testing can also reduce redundant diagnostic testing and unnecessary invasive procedures such as cystoscopies, which carry both financial and psychological burdens.^{12,30}

Recent evidence further highlights the importance of accurate albuminuria quantification. A 2025 analysis demonstrated that precise albumin measurements are strongly predictive of CKD progression and kidney failure risk, serving as a key surrogate end point in clinical trials.³¹ Unlike dipstick urinalysis, AutoUA® specifically measures urinary albumin levels and extrapolates key kidney disease risk factors, such as urine albumin to creatinine ratio and urine protein to creatinine ratio, with its quantitative measurements. This finding reinforces the importance of reliable, quantitative methods, such as AutoUA®, that can

accurately measure factors such as the urinary albumin to creatinine ratio and other risk factors when assessing early kidney dysfunction.

Operationally, AutoUA® offers additional advantages through automation and integration with electronic health record systems, reducing operator dependency and standardizing results. These improvements align with modern trends in laboratory medicine, emphasizing precision diagnostics, workflow efficiency, and data-driven decision-making.^{32,33} Despite these benefits, the limitations of this study, including its small sample size, single-site testing, and limited secondary validation (in the form of microscopic analysis) should be acknowledged. Future multicenter trials with larger and more diverse populations are needed to further confirm these findings and validate the AutoUA® system's performance using independent laboratory standards.

Study Limitations

Although this study included 190 urine samples, only 20 underwent confirmatory microscopic analysis, which served as the secondary source of truth for hematuria detection.

One limitation of this study is the absence of confirmatory testing for additional analytes (eg, leukocyte esterase). Consequently, false-positive and false-negative rates were calculated under the assumption that AutoUA® serves as the reference standard. This assumption is supported by performance data derived from more than 30 clinical laboratories, suggesting an accuracy rate of approximately 85%, which well exceeds the published statistical accuracy of urine dipstick testing, where urine dipstick false-positive rates of 40% to 50% are routinely documented.^{5,20,34} This limited confirmatory subset reduces the study's ability to fully validate hemoglobin-related findings across the entire sample set. In addition, although these results align closely with patterns observed across more than 30 clinical sites using AutoUA®, the data presented here should be considered preliminary.

Further research is needed to perform comprehensive comparisons between AutoUA®, traditional urine dipsticks, and gold-standard confirmatory methods,

including external laboratory microscopy and urine culture. Multicenter studies with larger, more diverse patient populations will be essential to the more rigorous evaluation of diagnostic accuracy and the confirmed generalizability of these findings.

Conclusions

This comparative study reinforces the well-documented limitations of dipstick urinalysis and demonstrates the analytical performance of AutoUA®.^{3,5} By providing accurate, reproducible, and clinically meaningful results, AutoUA® enhances diagnostic confidence while reducing missed diagnoses and unnecessary follow-up procedures. Its integration into clinical practice could improve patient outcomes and health care efficiency by combining diagnostic precision with operational automation. As laboratory medicine advances toward precision diagnostics, automated, creatinine-normalized systems like AutoUA® represent a pivotal step in replacing subjective, colorimetric screening with reliable, quantitative assessment, bridging the gap between convenience and clinical accuracy.^{9,27,33}

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Article Information

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Conflict of Interest Disclosures: J.B. is an employee of Sciteck Diagnostics Inc. J.S. is the chief executive officer of Sciteck Diagnostics Inc, of which he owns all interest, and is associated with proprietary technologies and issued and/or pending patents related to quantitative urinalysis systems, including the AutoUA® platform, which is discussed conceptually in this review. These intellectual property interests are held by or assigned to Sciteck Diagnostics Inc. M.H. is president and chief executive officer of at Anne Arundel Urology. M.L. has no conflicts of interest to disclose.

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Data Availability Statement: The datasets generated and analyzed during the current study are available from the corresponding author upon reasonable request. Additional analytic materials (including code used for error-rate calculations) can also be provided to qualified investigators for research purposes.

Acknowledgments: This study involved the analysis of deidentified urine specimens collected as part of routine clinical care in a community urology practice. In accordance with 45 CFR 46.104(d)(4), the activity qualifies as exempt from institutional review board oversight because no identifiable private information or biospecimens were used. All procedures were conducted in compliance with institutional policy and the ethical principles outlined in the Declaration of Helsinki. Because all data were fully deidentified before analysis and no patient contact occurred, informed consent was not required under applicable federal regulations and institutional policies.

Supplemental Material: Supplemental material is available at *Reviews in Urology* online.