Redefine Urinalysis with AutoUA®

Sciteck® Diagnostics, Inc. is an FDA-registered manufacturer producing all product lines in the United States under cGMP and ISO 13485 standards. AutoUA® represents a fundamental advancement in urinalysis—replacing qualitative, interference-prone dipsticks with fully quantitative, automated chemistry that delivers clinically actionable results.

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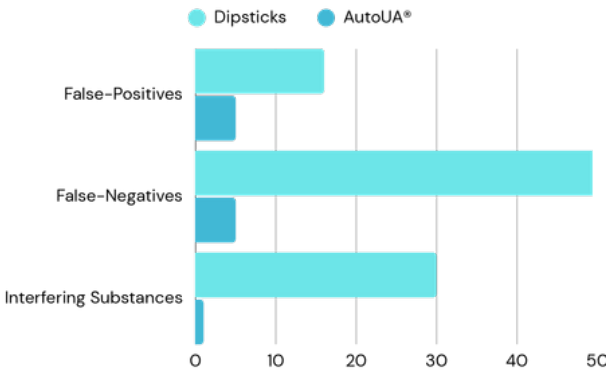
Executive Summary

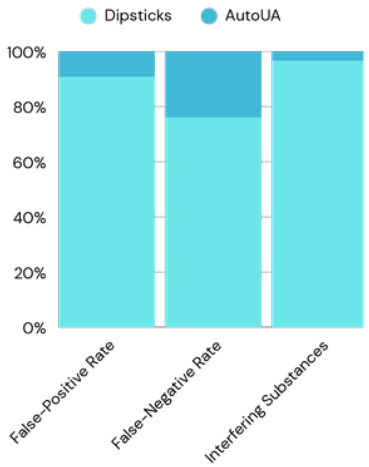
Urinalysis is one of the most frequently ordered laboratory tests worldwide, yet it remains anchored to a 70-year-old screening method that relies on subjective color interpretation and semi-quantitative reporting. Conventional dipstick testing is associated with high false-positive and false-negative rates, significant analytical interference, and limited clinical utility—driving unnecessary follow-up testing, delayed diagnoses, and increased operational burden.

AutoUA® Quantitative Urinalysis establishes a new diagnostic standard. By delivering fully quantitative, concentration-normalized results through automated spectrophotometric chemistry, AutoUA® transforms routine urine testing into a high-confidence clinical tool. Laboratories adopting AutoUA® achieve markedly improved diagnostic accuracy, earlier disease detection, meaningful operational efficiencies, and measurable financial return—while reducing documentation gaps and diagnostic risk.

Key outcomes demonstrated by AutoUA® include:

- Up to 80% improvement in diagnostic accuracy
- Up to 100× greater sensitivity, enabling earlier disease detection
- >97% reduction in analytical interference
- Requires 98% less sample volume reducing the need for recollections
- Significant reductions in staff labor, recollections, and downstream testing
- Seven-figure annual financial impact in mid-volume clinical settings





Regulatory Status:

AutoUA® is FDA 510(k) cleared, categorized as CLIA Moderate complexity, and validated across more than 30 automated analyzers—supporting scalable adoption from physician offices to high-volume diagnostic laboratories.

Traditional Dipstick Urinalysis

Despite its ubiquity, dipstick urinalysis remains fundamentally limited, providing only qualitative to

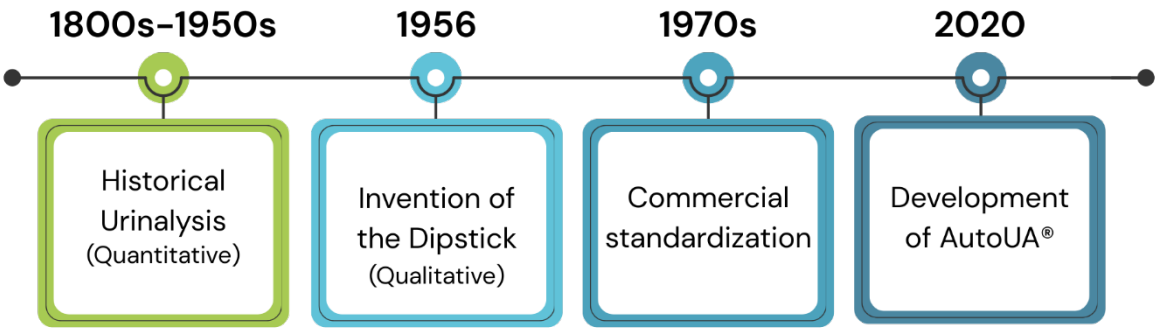
semi-quantitative estimates based on visual or reflectance-based color interpretation, introducing subjectivity and variability at every step of testing.

Published performance comparisons demonstrate that dipstick urinalysis produces approximately 45–50% false-positive results and 15–47% false-negative results when measured against confirmatory quantitative methods.1-4 In addition, more than 30 known interfering substances5 including medications, dietary components, and endogenous metabolites—can compromise dipstick accuracy.

The downstream impact is substantial:

- Unnecessary reflex testing and repeat visits
- Delayed recognition of renal, metabolic, and infectious disease
- Inability to reliably trend results over time
- Increased staff workload and patient dissatisfaction

As healthcare systems transition toward value-based care, these limitations represent not only a clinical concern, but a systemic inefficiency.



AutoUA® Quantitative Urinalysis: A New Standard of Care

Quantitative urinalysis replaces subjective screening with objective measurement. By reporting numeric concentrations rather than categorical color blocks, quantitative testing enables reproducibility, trending, and clinical interpretation aligned with modern laboratory standards.

The Power of Normalization

A critical advancement within quantitative urinalysis is automatic normalization. Urine concentration varies widely based on hydration status, age, and physiology. Normalization—typically to creatinine—corrects for this variability, significantly improving clinical accuracy, particularly in pediatric, geriatric, and dilute urine samples.

AutoUA® is the ONLY FDA-cleared quantitative urinalysis platform for diagnostic use.

AutoUA® is a liquid-reagent, spectrophotometric urinalysis system designed for automated analyzers. Unlike dipsticks, AutoUA® performs true quantitative chemistry, delivering reproducible numeric results with built-in normalization and expanded reportables from every urine sample.

Core capabilities include:

- Fully quantitative analyte measurement
- Automatic urine concentration normalization
- High analytical sensitivity with minimal interference
- Automated workflows compatible with existing laboratory infrastructure

Regulatory status:

- FDA 510(k) cleared
- CLIA Moderate complexity

Test Menu & Analytical Scope

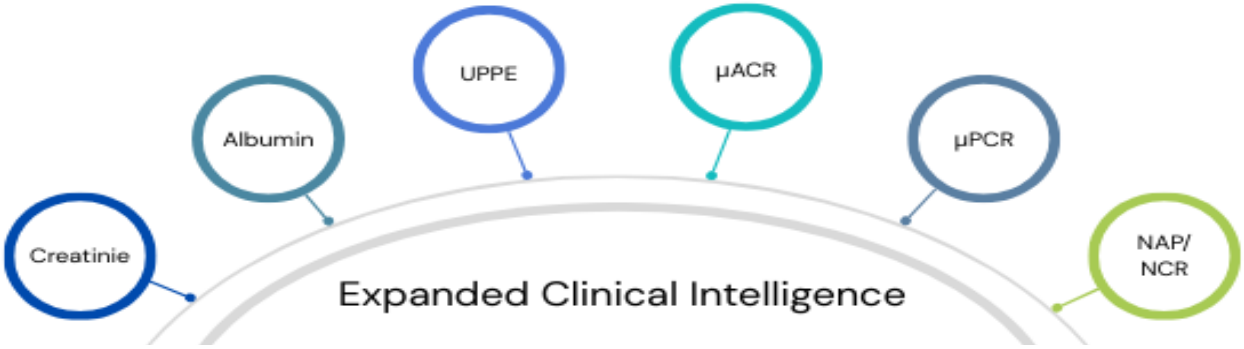
Urology Malpractice: 63–72% of urologists face a malpractice lawsuit in their career, with an annual claim rate of 11% (vs. 7.4% national average).

Most claims stem from diagnostic failure: Misdiagnosis or delayed diagnosis accounts for ~26% of claims; improper treatment for ~28.5%—the exact failure modes associated with screening-only urinalysis.

Defensibility of Dipstick UAs: Semiquantitative, subjective results increase false negatives, inconsistent documentation, and delayed escalation—common allegations in malpractice cases.

Defensibility of AutoUA®: FDA 510(k)-cleared, quantitative, concentration-normalized results reduce missed abnormalities and support earlier, evidence-based clinical decisions. Numeric, reproducible results enable trend monitoring and auditable records—critical given 39–46% plaintiff success at trial.

Risk reduction, not risk elimination: AutoUA® does not prevent lawsuits but reduces exposure in the highest-severity claim categories where median awards range from $335K–$553K.



Clinical Performance and Diagnostic Accuracy

AutoUA® closes critical diagnostic gaps left by dipstick screening. Comparative performance studies demonstrate:

- <5% false-positive and false-negative rates
- Up to 100× greater sensitivity, enabling earlier disease detection
- >97% reduction in analytical interference compared to dipsticks

These improvements translate directly into better clinical outcomes. Numeric, reproducible results support longitudinal trending, audit readiness, and confident decision-making across renal, metabolic, and infectious disease pathways.

Operational example:

In a clinic processing 100 patients per day, replacing dipsticks with AutoUA® eliminates approximately five false-positive hemoglobin results per day, saving an estimated 2.5

staff hours daily previously spent on unnecessary follow-ups—equivalent to 10 hours per week.

Because AutoUA® requires 98% less sample volume and exhibits 97% fewer interfering substances, laboratories experience significantly fewer recollections—approximately 7–8 fewer patients per day in mid-volume settings. This equates to 9–10 staff and appointment hours saved per week, while improving patient experience and access to care.

Financial Impact

As dipstick reimbursement has declined to approximately $2.25 per test, its limited diagnostic value is increasingly misaligned with modern care models. AutoUA® aligns reimbursement with meaningful, defensible diagnostics.

Annual impact example (100 patients/day):

Direct operational savings:

- Labor reduction: $10,631 / year
- Reduced unnecessary testing: $42,525 / year
- Total direct savings: $53,156 / year

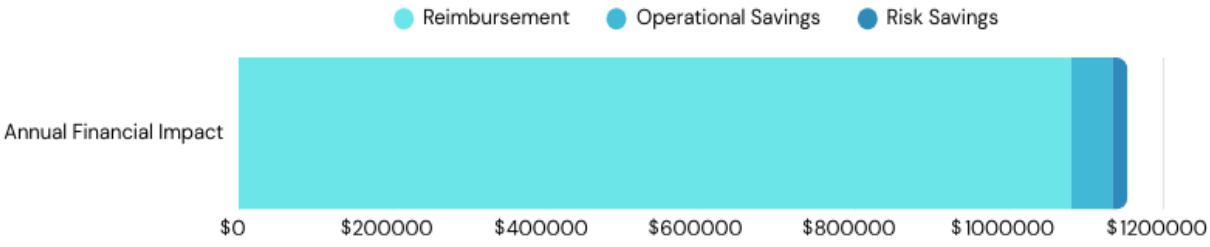
Reimbursement contribution (conservative):

- Net reimbursement per test: $30
- Annual reimbursement: $1,080,000

Soft savings and risk avoidance:

- Reduced callbacks and recollections
- Lower inappropriate antibiotic utilization
- Reduced discrepancy resolution workload
- Estimated value: $10,000–$25,000 / year

Total estimated annual financial impact: ~$1.14 million



Note: CPT and payer policies vary. Reimbursement figures must be validated against current guidance prior to commercial use.

Risk Reduction

Diagnostic failure remains a leading contributor to malpractice exposure in urology (11% annual claim rate), with diagnostic delay or misinterpretation accounting for more than 26% of claims.6-7

Dipstick urinalysis—semi-quantitative and poorly reproducible—often creates documentation gaps that complicate clinical defense. AutoUA® addresses these challenges by providing:

- FDA-cleared quantitative results
- Concentration-normalized values
- Reproducible numeric data suitable for trending and audit
- Comprehensive validation and quality assurance program

While no diagnostic test eliminates legal risk, AutoUA® reduces exposure in high-severity claim categories where documented, quantitative decision-making is critical.

Conclusion: Redefining the Value of Urinalysis

Although urinalysis is among the most commonly ordered diagnostic tests, dipstick-based testing has remained fundamentally unchanged since the mid-20th century,[8] resulting in well-documented limitations in accuracy and clinical reliability. AutoUA® replaces outdated screening with modern quantitative science—delivering real numbers, real confidence, and real impact.

By improving diagnostic accuracy by up to 80%, reducing false results to below 5%, saving dozens of staff hours each week, and generating measurable financial return, AutoUA® redefines what routine urinalysis can—and should—deliver.

AutoUA®: Real numbers. Real confidence. Real impact.

References

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