Comparison of Two Urinalysis Work Cells: Particle Recognition, Flagging Efficiency, and Impact on Reflex Rates

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Abstract

Background: Urinalysis is important in screening for and monitoring nephrological and urological conditions. Urinalysis tests include chemistry and sediment analysis. When performed manually, urinalysis is time-consuming and associated with extensive analytical and clerical errors. Current automated technologies and informatics have greatly reduced the labor intensity of urinalysis and have allowed workflow improvements while optimizing accuracy of results reporting. These instruments, when compared with manual microscopy, achieve acceptable results for major cell types and formed elements. Despite the advantages offered by automated urinalysis, there are multiple testing strategies available from vendors that might not achieve the same performance. There are also concerns that automated urinalysis systems do not perform in the real-world equivalently. These concerns combine to make thorough assessment of new automated urinalysis systems – especially the formed elements flagging and characterization – a necessary element of good laboratory practice. We compared two urinalysis work cells during routine urinalysis and evaluated the differential recognition of abnormal findings.

Methods: Our study involved prospective analysis of specimens submitted for urinalysis at Corewell Health William Beaumont University Hospital, Royal Oak, MI (Sysmex UN-Series) with repeat testing at Henry Ford Hospital, MI, Detroit (Beckman Coulter DxU). The study population was adult emergency and inpatients at Corewell. Abnormal findings from biochemical testing proceeded to sediment testing following each site's usual protocol. Following testing at Corewell Health, specimens were transferred to tubes containing preservative and couriered to Henry Ford for testing the following morning.

Results: In four consecutive days, 272 samples were tested with only RBC, WBC and bacteria yielding sufficient abnormal finding for analysis. Since our goal was to compare reflex rates by each system, we analyzed initial screening results, not final reports. Results were first categorized as normal or abnormal, with limits of RBC ≤3, WBC ≤10, bacteria <1. Overall agreement was RBC 0.864; WBC 0.917; bacteria 0.773. Sysmex had higher rates of abnormal findings compared to DxU: RBC 19.7% v. 12.5%; WBC 18.2% v. 12.5%; bacteria 31.1% v. 13.2%. We calculated the probability that a normal specimen by Sysmex would yield normal by DxU: RBC 0.958; WBC 0.981; bacteria 0.962. Similar calculations for abnormal screens yielded: RBC 0.519; WBC 0.375; bacteria 0.646. In previous work with manual microscopy as predicate, we found DxU yielded 91.70% sensitivity, 94.44% specificity, overall accuracy 93.43%, in gratifying agreement with reports by others.

Conclusions: This real-world study of two urinalysis systems found very high overall agreement between individual specimens but lower agreement for abnormal findings. Falsely abnormal screens lead to follow up by visualizing the captured images or manual microscopy, with added operator time. We found a significant number of positive screens were not confirmed with visualized image reviews increasing the analysis time for those specimens. While the bulk of results did not receive follow-up, a separate assessment of the DxU was consistent with previous reports. Our findings could have been influenced by one or more factors: inherent differences in the testing systems, differences in how the specimens were handled, biased sample collection and differences between testing protocols and staff.

Background

Corewell Health Hospital uses the Sysmex fully automated UN-Series composed of Siemens CLINITEK Novus, Sysmex UD-10, and Sysmex UF-5000. Henry Ford Hospital uses the Beckman Coulter fully automated DxU Iris Workcell composed of the Arkray Aution Max-4030 and DxU 850m Iris. The significant difference between the two systems is the use of fluorescent flow cytometry by Sysmex UF-5000.

Accurate identification of urine formed particles by automated system reduces the frequency of manual microscopic verification and thus reduces labor needs. Clinical studies have shown that the Beckman Coulter automated microscopic system yields positive correlation to manual microscopic identification.

This study used statistical analysis to compare the two fully automated urinalysis systems.

Methods

- Samples were collected at Corewell Health Royal Oak in urine preservative test tubes.
- Inclusion criteria: all specimens submitted for urinalysis from emergency, inpatient and outpatient subjects that could be tested within 2 hours of collection or stored at 4-10˚C until tested.
- Exclusion criteria: patient age less than 21 years, insufficient patient residual urine sample available, pregnant females, specimens collected >8 hours ago or collected <8 hours ago but not stored at 4-10˚C.
- Samples tested were at Corewell Health using Sysmex urinalysis system.
- The Sysmex UN-Series system performed subsequent analysis on samples with positive chemistry results to verify the presence of particles using image capture technology.
- Samples that met qualifications for this study were transported to Henry Ford Hospital in Detroit, MI for subsequent analysis on the Beckman Coulter automated urinalysis system. If necessary, examination on manual microscope could be utilized as a gold standard method of identification.

Results

- A total of 272 samples were analyzed over 4 days, September 23-27, 2024.
- Sysmex had higher rates of abnormal findings compared to DxU: RBC 19.7% v. 12.5%; WBC 18.2% v. 12.5%; bacteria 31.1% v. 13.2%.
- We calculated the probability that a normal specimen by Sysmex would yield normal by DxU: RBC 0.958; WBC 0.981; bacteria 0.962. Similar calculations for abnormal screens yielded: RBC 0.519; WBC 0.375; bacteria 0.646.
- Compared to manual microscopy, we previously found DxU yielded 91.70% sensitivity, 94.44% specificity, overall accuracy 93.43%.
- Normal is defined as: RBC ≤3, WBC ≤10, bacteria <1.
- Abnormal is defined as RBC >3, WBC >10, bacteria ≥1.

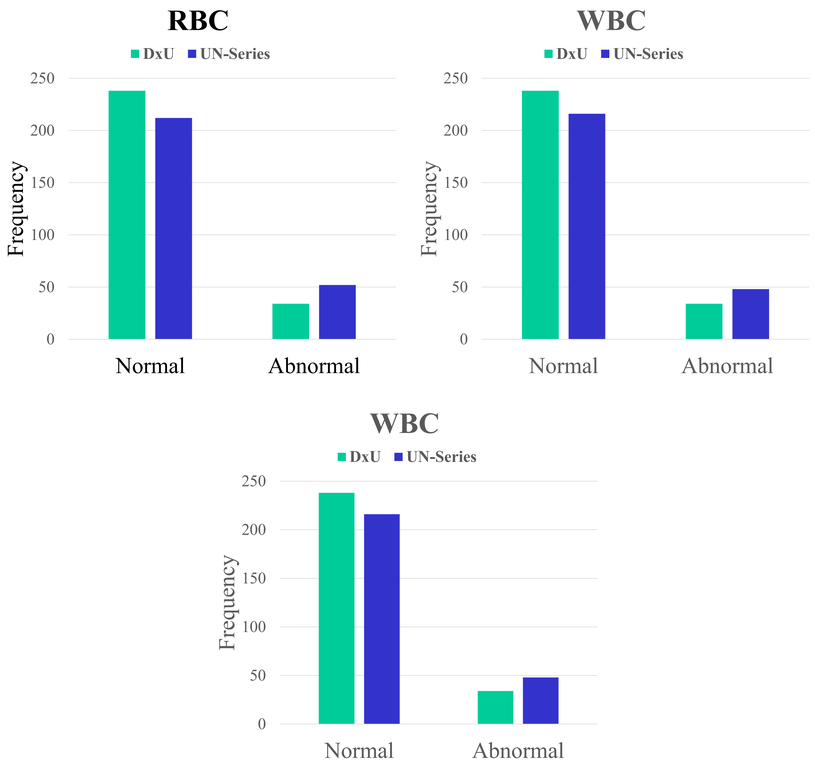

Figure 1. Frequency of Normal and Abnormal Samples by Urinalysis System

Agreement Probabilities

Measures	Agreement
RBC	0.864
WBC	0.917
Bacteria	0.773

Table 1. Proportion of Samples Demonstrating Agreement by Both Systems

Results, continued

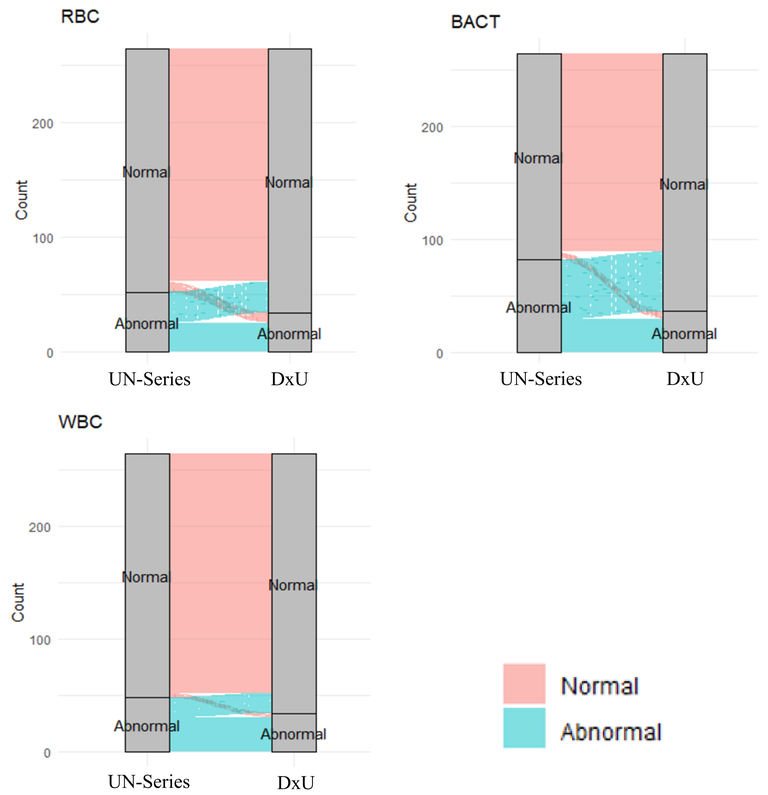

Figure 2. Normal vs. Abnormal Alluvial Plots

Limitations

- Our sample population was limited to patients >21 years of age and these findings may not translate to other ages.
- Manual review protocol differed by testing institution.
- Operator-to-operator differences in classification were possible at both testing sites.
- There was a delay in sample testing between sites due to transport time.
- Sample stability did not allow for gold standard (microscopic) verification after data comparison for all specimens at Henry Ford.

Conclusions

- There was very high overall agreement between individual specimens, with lower agreement for abnormal samples.
- For the same specimen, the probability of Sysmex yielding a normal result was not the same as DxU yielding a normal result, and the probabilities for abnormal results had this same finding.
- Falsely abnormal screens prompted the need for follow up visualization of the captured images or manual microscopy, with added operator time.
- A significant number of positive screens are confirmed with visualized image reviews, increasing the analysis time for those specimens.
- Future studies could expand upon the findings of this study to determine the labor impact associated with manual review time for each system.

References

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2025-14595