Urinalysis provides valuable information, speaking not only to the well-being of the renal and urinary systems, but also to identifying metabolic, hemolytic and other pathological conditions. Total urinalysis comprises of macroscopic (visual observation), chemical (dipstick) and microscopic (urine sediment) analysis. In most, if not all labs, macroscopic analysis is performed at the same time as the chemical analysis. Urine chemistry dipsticks test as many as 12 analytes that include blood (hemoglobin), protein, glucose and other urinary and metabolic biomarkers.

Microscopic analysis is a visual examination — qualitative and quantitative — of cellular and formed particles in the urine. Reflex to microscopy refers to omitting normal specimens and only performing microscopic exams on urine specimens with abnormal dipstick results. This is often common practice when manual microscopy is used to examine urine sediment, as it is one of the most tedious and time-consuming processes in the clinical laboratory. Advances in automated urine microscopy analyzers have significantly improved the workflow efficiencies and diagnostic proficiencies of modern urinalysis. However, despite technical advances, even current users of automated urinalysis systems remain committed to the "old-school" practice of reflexing to microscopy as a continuous effort to improve productivity in the clinical laboratory.

Pathogenic Abnormalities
As more and more clinical and hospital labs adopt efficient and Lean principles as standard operating practice, more focus is placed on waste reduction while improving the quality of patient care. It’s reasonable to assume that excluding normal specimens from microscopic examinations would provide greater cost savings and faster turnaround-times (TAT).

However, this practice may in fact have the opposite effect on laboratory efficiency and diminish patient care as urine samples with normal dipstick results have been later identified as containing pathogenic abnormalities. Such occurrences are by no means isolated events as investigations into the benefits and pitfalls of reflexing to microscopy have shown that omitting microscopy exams results in missed diagnosis, which of course causes repeated specimen collection and additional laboratory testing.

A study authored by Nancy Brunzel and Diane Berry analyzing 709 routine specimens revealed reflexing to microscopy resulted in one in four patient samples being overlooked for pathological conditions. The authors reported the negative predictive value (NPV) for their study using dipstick results and reflexing to microscopy was just 75 percent. Brunzel and Barry highlighted the omission of the presence of blood in normal samples. Their study reported more than 25 percent of patients were misdiagnosed for microhematuria when relying solely on urine dipstick result.

This misdiagnosis is rather concerning as the presence of blood in urine is clinically significant, especially for males. Urine chemistry dipsticks detect for blood by measuring peroxidase activity of red blood cells.
(RBCs). However, this methodology is inherently suspect to interference by various factors that include medications and elevated urine concentrations of protein and ascorbic acid. Hematuria is normally categorized as glomerular, renal or urologic. Routine microscopic analyses can provide better detection as to the quantity and morphology of RBCs which can further assist in identifying the pathogenic source and cause.2,3

Also worth noting from the Brunzel and Berry study was the presence of bacteriuria in normal dipstick specimens. Of the 709 specimens tested via dipstick measurement, 216 were normal; yet, when microscopy was later performed on the normal samples, 25 percent (54) of the specimens were actually positive for pathological components, with bacteriuria (17 percent) as the highest reported abnormality.

A more comprehensive study involving bacteriuria screening involved an evaluation of the Beckman Coulter/IRIS IRCHELl. Performed at Johns Hopkins University and Johns Hopkins Bayview Medical Center, the study by S. Riedel et al, compared reflex testing against total urinalysis as a testing policy for screening urine culture specimens. The authors concluded from their data that reflex testing against total urinalysis yielded low sensitivity and specificity, whereas total urinalysis and, in particular, routine urine microscopy significantly improved the NPV and reduced the omission of false negative specimens.

**The Ultimate Goal**

Today, automated urine sediment analyzers utilizing digital flow morphology (digital imaging) and fluorescence flow cytometry provide clinical and hospital laboratories

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**STATISTICAL ANALYSIS OF AUTOMATED URINE SEDIMENT METHODS**

By Leslie Williams

Comparing a new automated urinalysis method to a traditional manual method often poses unique challenges. Other laboratory analyzers can be easily compared to previous methods because they typically measure values in quantitative units, which facilitates a direct, linear regression method comparison. However, when it comes to validating a new automated urinalysis method, challenges arise that are not often encountered in other diagnostic fields.

Manual urine sediment results are generally presented in qualitative formats — few/moderate/many, or 1+/2+/3+ or even 2-5, 5-10, TNTC — while automated urine sediment analyzers provide precise quantitative results. Interpreting the correlation between qualitative and quantitative methods can be daunting, as there are no “traditional” statistics, such as correlation coefficient, Y-intercept, slope or bias to guide the reviewer. Instead, less-familiar concordance charts (Figure 1) are used, evaluating the correlation on how the new (test) method reports normal/negative or abnormal/positive values compared to the existing (reference) method, rather than as a numeric, value-to-value comparison.

**Figure 1**

<table>
<thead>
<tr>
<th>Test Negative</th>
<th>Test Positive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reference Negative</td>
<td>True Negative (TN)</td>
</tr>
<tr>
<td>Reference Positive</td>
<td>False Negative (FN)</td>
</tr>
<tr>
<td>True Positive (TP)</td>
<td>Positive by both test and reference method</td>
</tr>
<tr>
<td>True Negative (TN)</td>
<td>Negative by both test and reference method</td>
</tr>
<tr>
<td>False Positive (FP)</td>
<td>Positive by test method and normal (negative) by reference method</td>
</tr>
<tr>
<td>False Negative (FN)</td>
<td>Negative by test method and abnormal (positive) by reference method</td>
</tr>
</tbody>
</table>

Concordance chart results can also be used to calculate the sensitivity and specificity of the new method. Sensitivity, or the true positive rate, is simply a calculation of how well the new method will detect abnormal results compared to the existing method. In contrast, specificity (true negative rate) indicates how well the new method will detect normal results compared to the current method. Both values are calculated fractions of the total number of positive and negative results obtained. The ideal sensitivity and specificity values are 100 percent, indicating that the new method will always correctly identify positive and negative results.

**Figure 2**

<table>
<thead>
<tr>
<th>Sensitivity</th>
<th>TP / [TP+FN] x100</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity</td>
<td>TN / [TN+FP] x100</td>
</tr>
</tbody>
</table>

Automating urine sediment analysis brings consistency, accuracy and precision to a commonly-ordered test while eliminating well-known variables. Although traditional correlation statistics cannot be used to compare semi-quantitative and qualitative methods, concordance charts offer an easy way to evaluate the comparison using established normal values. With practice, interpreting these non-traditional statistics can become just as easy as judging linear regression correlations.

Leslie Williams is product manager, Urinalysis, Sysmex America.
the capacity for auto-quantitation and classification of urine microscopy results. In addition, manufacturers have bridged their automated microscopic analyzers with automated urine chemistry analyzers creating fully automated “walk-away” urinalysis workstations.

Software has been developed that drastically improves the data management process. For example, available with the Beckman Coulter/IRIS iRICELL is iWARE, a software program that provides auto-verification of urinalysis results directly from the iRICELL workstation. By combining technologies, it allows users to perform total urinalysis for routine testing as normal specimens would be verified and released and for samples with discordant macroscopic and microscopic results, those samples are withheld from release until manually verified.

The ultimate goal of any hospital or clinical lab is to provide the highest level of care to the patient, and the technology a lab utilizes plays a major role in achieving this objective. As mentioned in the Brunzel and Berry study, 25 percent of reflex samples were present for pathological conditions, indicating the reflex process can be a risk to patient care. After combining their urinalysis system with their Lean Management program, the laboratory reported that they achieved their TAT target of less than 25 minutes 100 percent of the time on macroscopic/chemical results and saw their microscopic TAT improve to the level where automated microscopy is used on all urinalysis samples.

Similar transformations were seen at Providence Alaska Medical Center, Anchorage, AK. Prior to automating urine microscopy, the lab’s target TAT of 45 minutes was met just 73 percent of the time. Since switching their urinalysis microscopy from manual to automated, the lab’s overall TAT target of less than 35 minutes is reached 95 percent of the time.

Automated urinalysis has been around for decades and, with the advent of digital imaging technology, laboratories are realizing a greater impact on laboratory productivity. In addition, fully automated urinalysis has paved the way for easier standardization while being cost effective. This became apparent at the Regional Medical Laboratory in Tulsa, OK. The laboratory team unexpectedly found that by automating urinalysis, they were able to provide better care to the patient while improving their bottom line. As new technology emerges, moving forward, practices used in the past may no longer be relevant as urine automation continues to have broader implications for the patient population. The new advances will lead not only to improved productivity, but will also have a significant impact on diagnosis and disease management.

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References are available at www.advanceweb.com/laboratory.