Evaluation of an automated humidity check for instrument-read urinalysis strips

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The integrity of urine strips is essential in obtaining accurate urinalysis test results. The improper handling of strips, regardless of brand, can lead to false results and possible incorrect diagnosis. If strip bottles are not recapped or tightened completely, the contents can be exposed to humidity, potentially compromising the strip integrity and leading to reagent degradation and false results. A new feature provided with Siemens urinalysis strips used in combination with the Siemens CLINITEK Status+ Analyzer allows for the automatic detection of reagent strips that may have been affected by excess humidity. This study analyzed Siemens' MULTISTIX 10 SG urine reagent strips, Roche Diagnostics' CHEMSTRIP 10 MD, and Diagnostic Test Group's Clarity UROCHECK 10SG to determine product integrity after exposure to room air, a condition that can occur if the strip containers are not closed after use as directed by the manufacturer.

To compare clinical results, each product was tested with approximately 200 test points using test strips from bottles that were both exposed and unexposed to humidity. These were tested with patient samples for the following analytes: occult blood, leukocytes, nitrite, protein, ketone, bilirubin, urobilinogen, specific gravity, pH, and glucose. The study was conducted in routine clinic settings using nurses/medical assistants.

Siemens' CLINITEK Status+ Analyzer was able to detect MULTISTIX 10 SG strips that had been compromised by humidity and prevent potential erroneous results from being reported. Since there is no humidity-detection system implemented, both the Roche and Clarity analyzers reported results for these patient samples, despite the test strips being compromised by humidity. These reported results are likely inaccurate as the analyte results differed between exposed and unexposed test strips for the same patient sample.

Materials and methods

This study compared three manufacturers' urine reagent strips and instruments:

- MULTISTIX 10 SG using a Clinitek Status+ instrument (Siemens Healthcare Diagnostics, Deerfield, IL);
- CHEMSTRIP 10 MD and a Urisys 1100 instrument (Roche Diagnostics, Basel, Switzerland); and
- Clarity UROCHECK strips and a Urocheck 120 instrument. (Diagnostic Test Group, Boca Raton, FL).

The study setting was an outpatient treatment center in an urban area. Nursing personnel and medical assistants completed a majority of the testing with an occasional test conducted by a trained laboratorian, meaning an MT(ASCP). This mix of operators simulated actual testing conditions in the center as stated below. All operators were trained and their competency tested for all three instruments before data gathering occurred.

Two sets of strips were prepared for each manufacturer. In set one, the bottle was opened and left exposed for 40-plus days to room air (22°C to 26°C) and room humidity (26% to 56%) to simulate the exposure the strips could receive by someone not properly closing the strip container (stressed strips). The second set of bottles was left sealed until patient testing was completed (unstressed strips).

Approximately 200 urine samples were tested across all three brands (sample numbers vary slightly because of errors/insufficient volume that occurred during testing). Table 1 at the bottom of this page provides the total number of samples implemented for each manufacturer.
Samples were tested over three months. The samples were tested across all instrument systems in duplicate for each set of strips, stressed and unstressed. These duplicate samples were run consecutively for each combination of strips and instrumentation.

**Results**

The analysis summarized here evaluated the analyte performance agreement between stressed and unstressed strips by examining the first replicate of each set tested. This agreement was then compared to the agreement between the results from the unstressed (control), replicate 1 and replicate 2.

The urinalysis strips manufactured by Siemens (run on a Clinitek Status+ analyzer) are designed to return an error flag rather than a result when the system detects that the strips have been potentially compromised due to excessive exposure to environmental humidity. More than 95% (95% confidence interval: 95.9% to 99.7%) of the stressed Siemens strips returned error flags when tested on the Status+ analyzer, correctly suggesting the strips had been compromised and were no longer suitable for use.

The flagged sample rate for the environmentally stressed Siemens strips was 98.6%. Therefore, all subsequent analysis of stressed performance will include only those strips manufactured by Roche and Clarity, as the Siemens strips did not provide performance data post-stress.

The performance of the unstressed strips (control condition) was the percent agreement (both exact and +/-1 group) between two replicates of unstressed strips for all three manufacturers materials. The authors used a +/-1-block scale, as this is the usual acceptable variance for urine strips.

The results summarized in Tables 2 and 3 demonstrate no significant difference (p>0.05) in replicate agreement among the three vendors strips in an unstressed condition, using either exact or +/-1 block scale. Based on replicate agreement rates for unstressed strips of the other manufacturers, there were only two instances of significantly different percent agreements for the two replicates of unstressed strips. These instances are noted in Tables 2 and 3.

For Clarity and Roche, performance of environmentally stressed strips was assessed by determining the percent agreement between the first replicate of the unstressed strip and the first replicate of the stressed strip. Results are summarized in Tables 4 and 5 for each of the analytes. Those analytes where the percent agreement for the stressed conditions differs significantly from the percent agreement for the control conditions are flagged as “Significant (p<0.05) in the Tables.

Nitrate tests return a binary (positive/negative) result and, therefore, are not a candidate for analysis using the +/-1 group criterion. For nitrite, Roche and Clarity stressed strips had only 11.3% to 14.1% agreement between the nitrate results from replicate 1 of the stressed and replicate 1 of the unstressed conditions as opposed to 96.5% to 98% agreement between the replicates of unstressed condition (control).

For non-binary responses analytes (responses that are numeric), the greatest percentage of disagreement between the unstressed and stressed strips for exact block output was observed with glucose, ketone, leukocyte, and urobilinogen tests on both Clarity and Roche Strips. When the agreement criterion was expanded to +/-1 group, the disagreement was reduced to a large extent for the Roche strips with the exception of leukocyte (79.2% agreement) and protein (91.5% agreement), both agreement rates still being significantly different from the unstressed (control) agreement. For the Clarity strips, the percentage agreement for glucose (57.5%), leukocytes, (27.7%), and urobilinogen (11.3%) remained significantly lower than their respective unstressed conditions.
Based on the data for the Clarity and Roche systems, there were significant differences between stressed and unstressed results because of exposure to room air and humidity. The possibility then exists for an inaccurate diagnosis and treatment based upon the erroneous results generated from the exposed strips. The Siemens system has an automatic warning mechanism that prevents results from being reported when humidity exposure is detected. In this controlled study, approximately 98% of the time, this system would have prevented inaccurate reporting and generated an error message instead of generating a result.

During numerous inspections of laboratories, the authors find it is not uncommon to find urine-strip bottles with the cover ajar or completely removed. This study shows the need for testing entities to strongly enforce the individual manufacturer’s recommendation to keep the strip containers capped when strips are not being removed for analysis. It also would be advantageous in situations where there are multiple operators, which makes it difficult to ascertain compliance, to use a system that would notify the tester of a compromised strip and not allow testing when results might be compromised.

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References

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