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Blot The Difference: Comparing Automated vs Manually Read Urinalysis Results

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Introduction

Urine dipstick testing is widely available to clinical staff at the Point of Care (POC). The multi-analyte results are commonly used as a first-line investigation and may prompt further testing for conditions including urinary tract infections, renal injury, hyperglycaemia, and ketoacidosis. Offered by a variety of manufacturers, the results can be manually eye-read or generated by an automated reader. The analysers aim to aid in the standardising of results and reduce variability in patient care. The test strips utilise absorbent pads containing reagents that cause a colour change when contact is made with the respective analyte. The results are read at analyte-specific time points specified by the manufacturer – the intensity of the colour change is compared and can provide a semiquantitative or qualitative result for the concentration of the analyte detected in the sample. The use of analysers to read the results aid in the standardising of results and can reduce variability in patient care.

Aims

- To compare results obtained via a manual eye-read against an analyser using the same samples performed by the same user.
- To show the possible variability in results when performing a manual eye-read due to user subjectivity.

Methods

A homogenous testing sample was made using distilled water and Chek-Stix positive internal quality control strips. We asked 63 laboratory professionals at UKMedLab23 to perform and report results for this solution first using a manual eye-read, then the analyser (Siemens Clinitek Status Plus) to avoid bias.

The testing strips used were the Siemens Multistix 8SG strips, containing test pads for analytes shown in Figure 4. The Clinitek Status Plus compares the colour change on test pads to a calibration bar, as seen in *Figure 5*.

Manual eye-read results were recorded on a paper slip with a results table, automatic results were printed from the device. The data was collated at the end of the session and analysed in Microsoft excel.



Results



Figure 1: comparison between results reported manually vs analyser read results for qualitative analytes.

Out of all results (n=62) collected, 1.6% of manual eye read results were recorded as "unable to report". There were 0 recorded for the analyser read results.

Discussion

The findings of this study demonstrate the analytical advantages of using an automated method to minimise result imprecision and variability associated with timing inaccuracies and subjective, user-dependent eye-read. 100% concordance of positivity using the automated reader were seen for 7/8 analytes. No analytes showed 100% agreement when eye-read.

According to local guidelines surrounding urinalysis results, a positive result for an analyte



regardless of level of positivity is a trigger for further testing. In this experiment, 16% of results with a positive automated read-out, reported negative by eye-read. While the absolute concentrations of analytes in the testing solution cannot be known, the automated method showed a strong consensus, and highlights the risk of generating false negative results by eye-read, which may delay further patient investigation and diagnosis.

Other factors may impact the quality of manually read results such as record keeping, compliance with the timings each test pad is read at, inconsistencies of the language used when reporting (e.g. '+++' vs 'large') and transcription errors. These factors can be the mitigated with the use of an analyser.

While the use of an automated reader has its own limitations (e.g. risk of inaccurate results if poorly maintained as seen in Figure 5), we recommend that urinalysis users strongly consider the potential benefits to minimise result subjectivity and standardise the format of result output for the benefit of patient care.

Figure 4: the colour change references and their corresponding result value for manual eye-reads

Figure 5: dirty vs clean calibration bar

References

[1] Siemens Multistix® 8SG Kit Insert

[2] POCT Clinitex Status Plus Training Record

[3] NICE QS90 urinary tract infections in adults 2015

[4] NICE NG17 Type 1 diabetes in adults: diagnosis and management

[5] BSPS Urinalysis Flowchart for Uncomplicated UTIs

Acknowledgements

Thank you to Frimley Health NHS Foundation Trust and Berkshire and Pathology Services for providing the time and equipment to conduct this study. Thank you to UKMedLab23 London for hosting.

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