EVALUATION OF ROCHE COBAS 6500 URINE ANALYZER IN A DIAGNOSTIC LABORATORY

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Introduction
Cobas u6500 is a fully automated urine analyzer with 2 modules, Cobas u601 for urine dipstick, and Cobas u701 for urine microscopy. Therefore we aimed to evaluate its performance characteristics for use in a diagnostic laboratory.

Methods
100 and 180 patient samples sent to our laboratory for urine microscopy or dipstick were randomly selected for analysis on Cobas u601 and Cobas u701 respectively, within 1 hour from the initial analysis. The results were correlated with those obtained on IChem Velocity and IQ200 Elite by Iris respectively and the acceptability criteria was 90% concordance for qualitative results and Pearson correlation co-efficient R ≥0.9 for quantitative results.

10 urine samples were run on both Cobas 6500 and Iris and correlated with manual microscopy performed by a single operator to confirm correct identification.

Between-day precision over 10 days was determined using Biorad Liquicheck urinalysis controls for urine red blood cells (uRBC), urine white blood cells (uWBC), glucose, protein, bilirubin, urobilinogen, pH, specific gravity (SG), ketones, nitrites and leucocytes. Statistical analysis was performed using Microsoft Excel.

Results
There was good correlation between Cobas u701 and IQ200 Elite for uRBC (y=0.906x – 1.634, R=0.894) and uWBC (y=0.989x + 0.521, R=0.972), as shown in Charts 1 and 2. Cobas u601 correlated well with IChem Velocity for pH (y=0.983x + 0.087, R=0.986), SG (y = 0.9927x + 0.0099, R = 0.969), glucose, protein, bilirubin, urobilinogen, ketones, nitrites and leucocytes (≥90% concordance).

Urine microscopy results correlation between the automated instruments and manual microscopy was good with ≥90% concordance.

Between-day precision was good with ≥90% concordance for qualitative results and <15% for uRBC and uWBC at concentrations of 201 and 23 per high power field respectively.

Conclusion
The analytical performance met our expectations for a fully automated urine analyzer and we hope to determine its operational characteristics such as turnaround time in future.