Introduction

The Royal College of Pathologists of Australasia Quality Assurance Programs (RCPAQAP) introduced a Body Fluids External Quality Assurance (EQA) program in March 2018 with input from the Australasian Association of Clinical Biochemists (AACB)/RCPAQAP Body Fluids Working Party (BFWP).

This was largely in response to requests from RCPAQAP participants to assist with the validation of their body fluid testing, given most in-vitro diagnostic device (IVDD) providers have no validation claims for these matrices.

Methods

The material is liquid with diluted human plasma as a base and supplemented to mimic a range of body fluids. The samples included in the pilot program had analyte levels consistent with a malignant ascites, a non-infectious pleural effusion and a parapneumonic effusion.

Results and Discussion

The first survey report in the Body Fluids program was issued in May 2018. The BFWP elected to empirically widen the Analytical Performance Specifcations (APSs) by at least twice those of the equivalent analytes in serum-based RCPAQAP Programs, namely General Chemistry, Tumour Markers, and Blood Gases.

The returned results for the surveyed analytes typically fell within the APS. Similar patterns and performance between several analytes in the Body Fluids program were evident; however, there were some analytes/methods where differences were noted.

Creatinine

Method differences were observed between enzymatic and Jaffe (alkaline picrate) methods for creatinine measurement, with participants using Jaffe methods generally returning lower concentrations of creatinine compared to those using enzymatic methods. As shown in Figure 1, this pattern is similar to the General Chemistry program for samples at equivalent creatinine concentrations. The median difference between the two method types (median of Jaffe creatinine participants subtracted from the median of enzymatic creatinine participants) in the General Chemistry program is 8 mmol/L, however, the median difference between the same groups in the Body Fluids program was greater at 35 mmol/L. The sample with lower protein concentration (median 16 mmol/L) also had fewer returned results for creatinine, which may be due to these methods producing negative values in this setting.

The correction factor used in rate-blanked compensated Jaffe methods to allow for non-creatinine chromogens may explain the lower relative values in the Body Fluids matrix, compared to enzymatic methods. The effect of protein may be particularly important as non-creatinine chromogens may explain the lower relative values in the Body Fluids matrix, compared to enzymatic methods. As shown in Figure 1, this pattern is similar to the General Chemistry program for samples at equivalent creatinine concentrations. The median difference between the two method types (median of Jaffe creatinine participants subtracted from the median of enzymatic creatinine participants) in the General Chemistry program is 8 mmol/L, however, the median difference between the same groups in the Body Fluids program was greater at 35 mmol/L. The sample with lower protein concentration (median 16 mmol/L) also had fewer returned results for creatinine, which may be due to these methods producing negative values in this setting.

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Figure 2: The Ortho Clinical Diagnostics VITROS® 4600/5600 Lactate measurements compared to other platforms in the Body Fluids and General Chemistry programs.

Conclusions

Method differences were not immediately evident for most analytes in the Body Fluids program, except in the cases of creatinine and lactate. However, more may be revealed as more survey results are received with different analytic compositions. Further tightening of some APS's may highlight method differences in the future. Finally, it is important that the variable performance of pH is reviewed on an ongoing basis.

While recognizing that a Body Fluids EQA program will not be able to simulate all scenarios in a laboratory setting, the initial results indicate that it should be a useful tool to assist laboratories in validating their methods for analysing various body fluids and ensuring ongoing acceptable performance. It is encouraging that most laboratories and platforms show concordance in analyte recoveries across the program.

Reference


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