Icterus Assessment in an external quality assurance program

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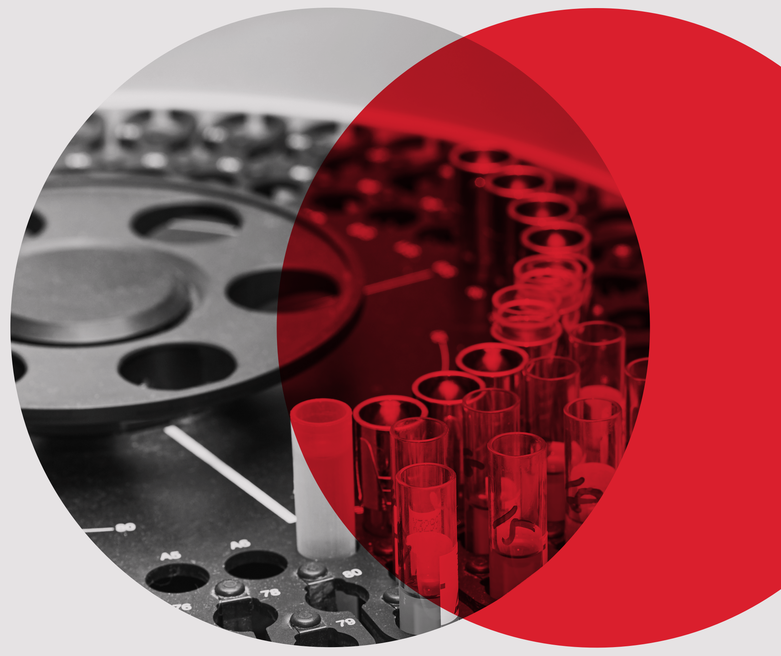

Introduction

The icteric index provided by many automated chemistry analysers is used as an estimate of bilirubin concentration to provide an alert to potential bilirubin interference in a range of chemical pathology assays.

There are known differences between icterus assessment across automated analytical platforms. Reporting units contribute to this variability, where icterus may be expressed semi-quantitatively (e.g. +, ++, +++), mass units (g/L), molar units (µmol/L) or a unitless absolute value (e.g. 1, 2, 3 ...20).

The Royal College of Pathologists Australasia Quality Assurance Programs (RCPAQAP) introduced icterus into the General Serum Chemistry program in 2018. We sought to provide participating laboratories with a means to assess the accuracy and harmonisation of icterus assessment compared to their peer group. Further, the results from this study could potentially be used to design a Serum Indices QAP.

Methods

RCPAQAP General Serum Chemistry program samples with bilirubin target levels ranging from 17 to 101 µmol/L (as measured by a reference Doumas method) were utilised for the study. In 2018 participants who enrolled in this program were given the option to report their icterus results when analysing their survey material. Over 170 participants reported their icterus results quantitatively and over 60 reported qualitatively. We provided for 3 result options, qualitative (+, ++ etc..), semi-quantitative (1, 2, 3 index) and quantitative (µmol/L). The submitted data was analysed using RCPAQAP proprietary software and the Analytical Performance Specifications (APS) were aligned with total bilirubin for the quantitative reports.

Results

We noted variability in icterus reporting both between manufacturers, but also within the same manufacturer as shown in the quantitative results displayed in Figures 1 to 3.

Generally, the quantitative results correlated with the measured total bilirubin concentration (e.g. Level 1 Target of 17 vs Icterus Median of 18, Level 8 Target of 101 vs Icterus Median 115). Icterus differences between platforms also tended to match differences in bilirubin measurements; e.g. Abbott Architect participants showed a similar low bias for icterus and total bilirubin compared to the all lab median/target.

Similarly, platform variation was found for the labs reporting "unitless" values, particularly at higher levels.

The qualitative results however showed a degree of harmonisation with 59 out of 62 labs reporting a "Normal" result for the low (17µmol/L) Level 1 sample and 62 out 64 labs reporting "++" for the high (101 µmol/L) Level 8 sample. Similarly, there were no significant method differences across the other levels (2 – 7) for the qualitative results.

Fig 1. Distribution of results for the low and high concentration in µmol/L

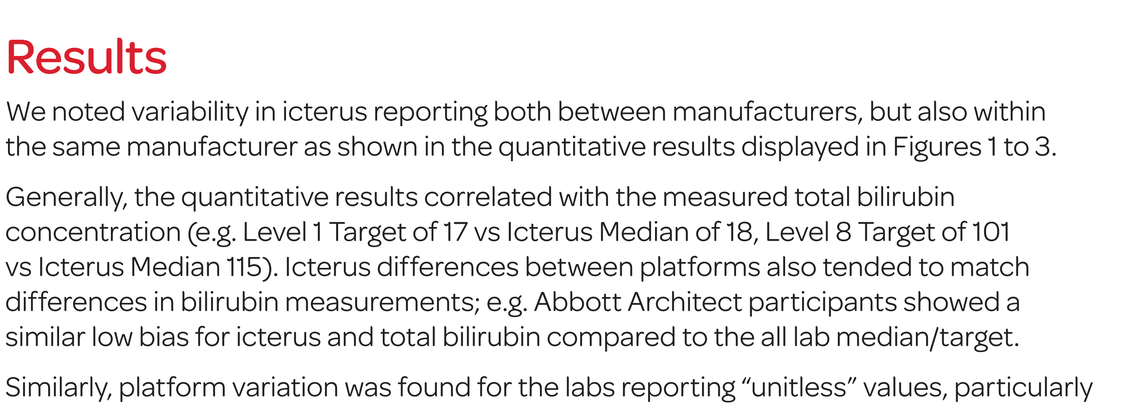

Fig 2. Distribution of results for the high vs low Icterus concentration in µmol/L

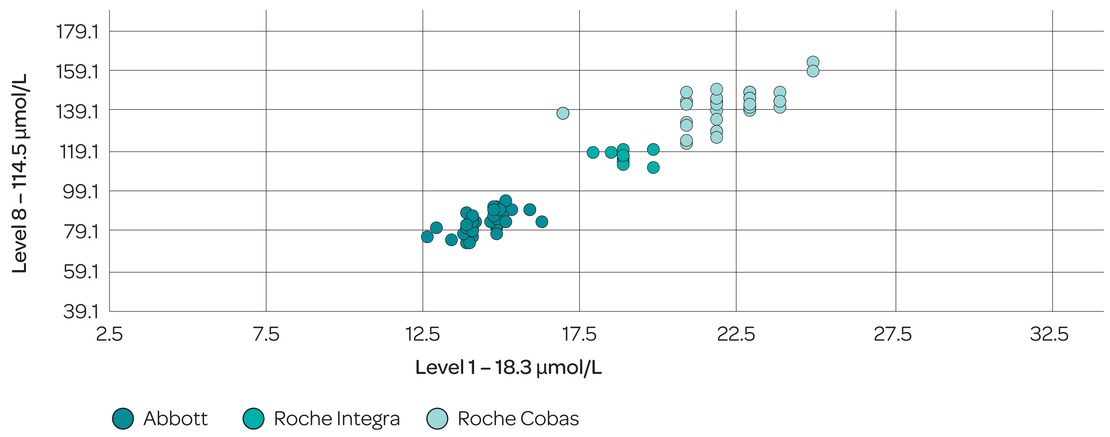

Fig 3. Distribution of results for the low and high Icteric Index

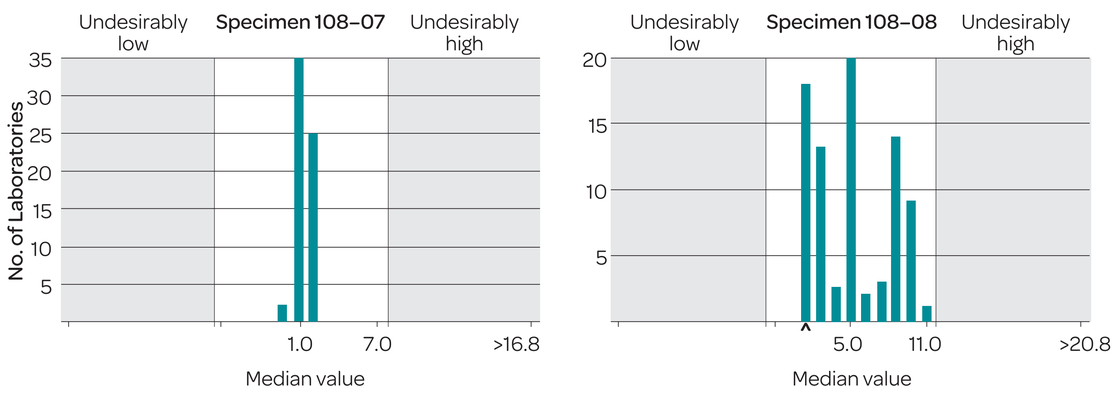

Table 1A. Summary of results for Icterus Qualitative Level 1

Method	Norm	+	++	+++	++++	Abn
ALL	59	3				
Abbott	3					
Beckman	33					
Siemens	22	2				
Roche Cobas	1					
OCD		1				

Table 1B. Summary of results for Icterus Qualitative Level 8

Method	Norm	+	++	+++	++++	Abn
ALL			62	1		1
Abbott			3			
Beckman			35			
Siemens			23	1		
Roche Cobas						1
OCD			1			

Conclusion

This study indicates generally acceptable performance of most methods and confirms the value of an Indices QAP to assist with monitoring and harmonisation of icterus assessment across different platforms.

References

1 Davies G. WEQAS., www.weqas.com/download/2014-scientific-session- eqa-of-serum-indices/ (2014, accessed 26 July 2018).
2. Farrell C. Serum Indices: Managing assay interference. Annals of Clinical Biochemistry 2016 Vol. 53(5) 527-538

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