



Birmingham Quality

# The cost of rejected samples due to pre-analytical factors relating to Serum Indices

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## Introduction

The majority of routine clinical chemistry assays are analytically very good and stable but this is of no relevance to a clinician or patient if there are errors pre-analytically or post-analytically.

Birmingham Quality has been running an EQA service for Serum Indices routinely since 2017. This probes the impact of Haemolysis (H), Icterus (I) and Lipaemia (L) on individual analytes, as well as assessing the quality of the HIL procedures.

## Method

Three specimens from the same pools were distributed in 2017 (Distribution 105), 2018 (Distribution 115) and 2019 (Distribution 127). All were pooled human serum. Specimen A was positive for haemolysis (1.3 g/L), Specimen B was icteric (290 umol/L) and lipaemic (2.8 mmol/L) and Specimen C was lipaemic (2.7 mmol/L). Participants were asked to analyse HIL and sodium as Analyte X on all three specimens, and then return whether they would report the sodium result based on the HIL values.

## Results

Year	n	A	B	C
2017	399	139.4	138.8	138.3
2018	467	138.9	138.7	135.9
2019	500	139.4	139.6	138.3

Table 1. Summary of the ALTM Sodium results in mmol/L for Specimens A, B and C in 2017, 2018 and 2019

Analyte X was sodium in all three distributions. Table 1 summarises the ALTM (All Laboratory Trimmed Mean) Sodium results.

The difference between the Sodium results between all three specimens (A, B and C) is not clinically significant but there are differences in reporting. Figure 1(a) shows the Analyte X Interpretation from Distribution 105 (2017). Overall 95% of participants would report the sodium on the haemolysed sample (A), 80% would report the icteric/lipaemic sample (B) and 80% the lipaemic sample (C). Variations are also observed within manufacturer, and between manufacturers as shown by the Breakdown by Method (%).

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## Sodium

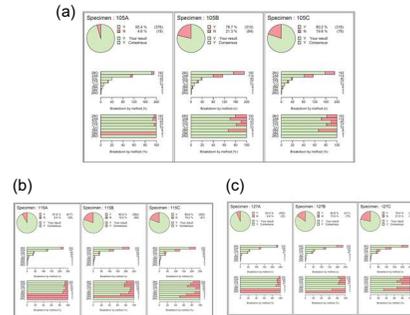


Figure 1. Analyte X Interpretation Page for Sodium (a) Distribution 105 – 2017, (b) Distribution 115 – 2018, (c) Distribution 127 – 2019

It can be seen from review of data across the three years that there has been no significant change in the Serum Indices reported, the Sodium result or the interpretation of whether a result is reported.

## Haemolysis Cut-Off Value Used

Participants are asked what HIL cut-off they use for 'Analyte X'. Figure 2 shows the variation both within and between manufacturers for sodium. This shows there are very wide differences in practice in routine clinical chemistry laboratories.

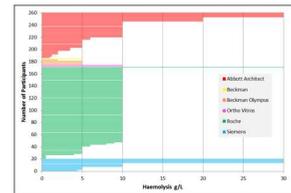


Figure 2. Haemolysis cut-off for Sodium by manufacturer

## Frequency Distribution of Haemolysed Specimens

Data was gathered from a routine laboratory over a one week period for HIL requests. Specimens collected are either from In-Patient or Out-Patients, not General Practice (GP). There were 17,265 HIL requests during a one week period in November 2019, which gave a distribution of Haemolysis results on an Abbott as shown in Figure 3.

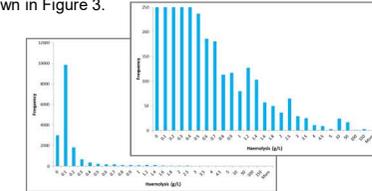


Figure 3. Frequency histogram of Haemolysis values obtained from a Clinical Chemistry laboratory of a large hospital

There is good agreement between different manufacturers for Haemolysis. Figure 4 shows Specimen 127A where the ALTM was 1.3 g/L. From the data shown in Figure 3, 281 specimens (2%) of the weekly workload have an H value of 1.5 - 10 g/L (1.5 g/L chosen as the majority of Abbott users had reported a value less than this, and 10 g/L is the most common cut-off). This could result in 281 repeat requests and patient bleeds per week.

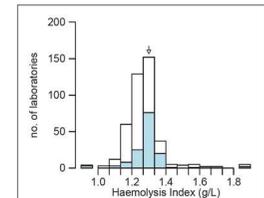


Figure 4. Frequency histogram of Haemolysis Index for Specimen 127A (Abbott user)

10% of Abbott users would not have reported the Sodium result associated with this sample.

## Conclusion

A sodium assay is relatively cheap, but this is far outweighed by the costs to the patient having to have a repeat venesection: potential time off work, delay in diagnosis/management and costs to the health service: phlebotomy service, laboratory processing of sample and clinical time for reporting/interpretation of the result.

Addressing some of the pre-analytical issues within laboratories has the potential to save the health service a significant amount of money as well as reducing the impact on patients.

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