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Pre - analytical variables in haemostasis: Results of the UK National External Quality Assessment Scheme for Blood Coagulation haemolysis supplementary exercise.

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INTRODUCTION

Haemolysis is considered one of the major contributors of non-conformities and sample rejection in coagulation testing (1). It presents as greater or lesser plasma discolouration and in a laboratory is usually subject to a visual check (2). Caused by red blood cell disruption such interference affects both optical and mechanical instrumentation used for sample testing (2). In order to minimise errors associated with haemolysed samples some analysers use an incorporated haemolysis, icterus, lipaemia (HIL) detection system that reports the presence of clinically significant interference for each test (3). However, many automated systems currently in use in hospital laboratories do not have such a system, and therefore a subjective assessment of sample quality by laboratory staff is required.

AIM

To investigate effects of haemolysis on methodology and results in a multicentre exercise, and gather information about laboratory approaches to dealing with haemolysed samples.

METHOD

- In November 2018 UK National External Quality Assessment Scheme for Blood Coagulation(UK NEQAS BC) conducted an exercise.
- The same pooled normal plasma was used to prepare 2 samples S18:19 and S18:20.
- A haemolysate consisting of freeze/thaw red blood cells was added to sample S18:20 in order to create haemolysis at 3g/l haemoglobin concentration.
- The two external quality assessment lyophilised plasma samples (S18:19 non haemolysed and S18:20 haemolysed) were distributed to 800 participants to test for prothrombin time(PT), activated partial thromboplastin time (APTT) and either Clauss fibrinogen or thrombin time (TT).
- Participants also were asked to provide answers to a questionnaire about their laboratory approach to dealing with haemolysed samples including strategies used to deal with different levels of haemolysis.

RESULTS

Sample S18:19 was pooled normal plasma with no added haemolysed red blood cells. Sample S18:20 was pooled normal plasma with haemolysed red blood cells added to create plasma haemoglobin of 3g/l.

Table 1. Summary of received results in the survey

Test	N results	Median ratio S18:19 (range)	Median ratio S18:20 (range)	Median %difference	Correlation between two samples (r)
PT	501	1.05 (0.86 - 1.7)	1.1 (0.85 - 9.23)	4.8	0.94
APTT	503	0.95 (0.76 - 1.47)	0.95 (0.8 - 1.60)	0	0.98
Clauss Fibrinogen	504	2.46 (1.67 - 8.3)	2.56 (1.62 - 8.0)	4.1	0.90
Thrombin time	338	1.05 (0.67 - 1.37)	1.01 (0.71 - 1.42)	-3.8	0.89

There was variability in the number of received results for samples S18:19 and S18:20 which depended on the test registered by participants. Median % difference between two samples was between – 3.8 to 4.8 %. Correlation between results reported on the two samples by individual laboratories was good (r = > 0.89). Results are shown in table 1.

Table 2. Summary of flags reported for analyser groups of 10 or more used for testing in haemostasis

Comments	ACL series (n=229)		Stago series (n=75)		Sysmex series (n=180)	
	S18:19*	S18:20^	S18:19*	S18:20^	S18:19*	S18:20^
No HIL flags reported	115	69	27	22	107	48
Haemolysis	2	44	7	12	2	71
Lipaemia	44	27	3	3	9	11
Icterus	1	14	3	3	-	22
Analyser does not have HIL flags	2	2	-	-	-	-
Not stated	65	73	35	35	62	38

*- no haemolysis, ^ - 3g/ml haemolysis

Apart from haemolysis, reported flags included also lipaemia and icterus (table 2).
Additional sample testing has shown: triglycerides - 1.0 mmol/L in sample S18:19 and 1.1 mmol/L in sample S18:20 and bilirubin - 3.0µmol/L in both samples.

Questionnaire responses
Laboratory approach to haemolysed samples (Fig 1,2,3)

Fig.1 Do haemolysed samples get rejected based on a visual check?

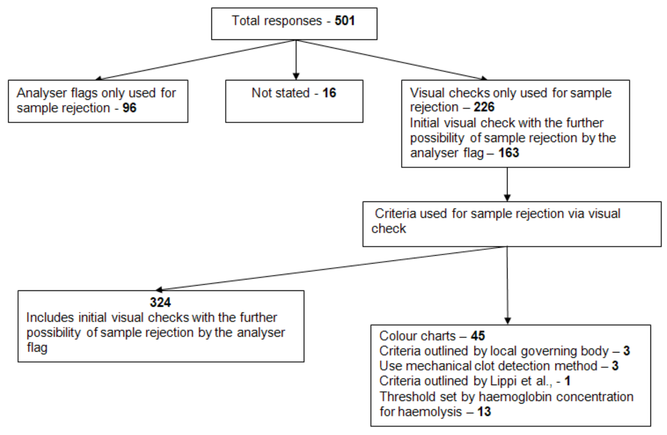


Fig.2 Does the level of haemolysis affect the decision to reject a sample?

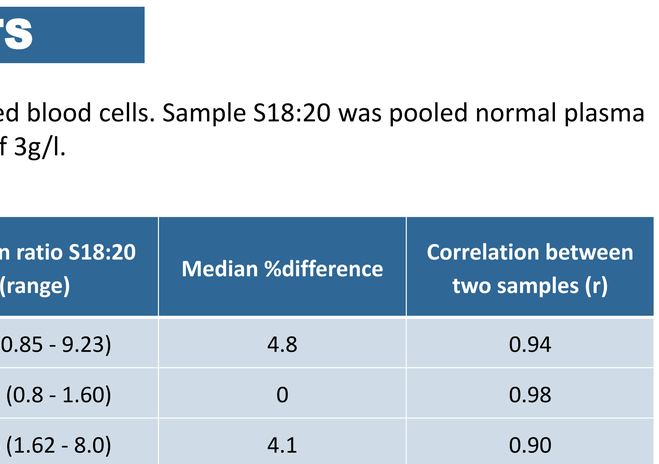
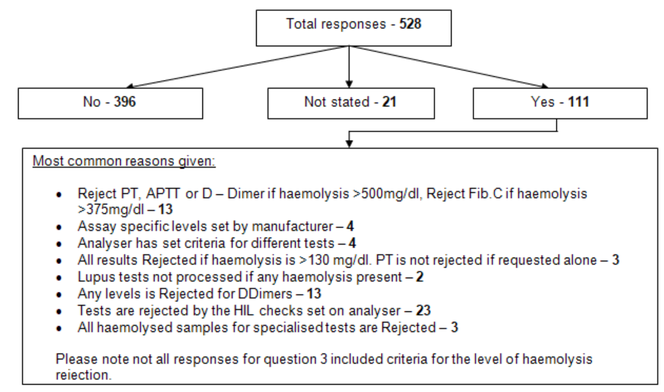


Fig.3 Are different criteria for haemolysed sample used for different tests or assays?



CONCLUSIONS

In this exercise, results for performed tests did not show great variability between two samples. This may be explained by artificial construction of the haemolysed sample in this exercise. Variability of responses for dealing with haemolysed samples reflects a lack of clear guidelines in the pre analytical area of sample processing.

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