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ISTH SSC plasma standard lot #5 – results in a UK National External Quality Assessment Scheme for Blood Coagulation (UK NEQAS BC) exercise.

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INTRODUCTION

The ISTH SSC plasma standard is a secondary coagulation standard developed to aid manufacturers in the labelling of coagulation calibrators. Values are assigned for 24 haemostasis parameters through assessment against relevant WHO International Standards in multi-centre international collaborative studies. However, it is useful to compare results obtained on this plasma with a wide range of reagents and methods in routine laboratory use to confirm that commercial calibrants are accurately labelled.

AIM

UK NEQAS BC has regularly distributed the SSC plasma standard as a blinded sample for assay in proficiency testing exercises. We report here the first comparison of proficiency testing results to the assigned values for the lot #5 of the SSC plasma standard.

METHOD

The plasma was sent as a blinded sample in an exercise distributed in November 2019 to 870 centres, with a request to perform fibrinogen assays, and 385 centres for FVIII, FIX and VWF assays. Results along with method details for each assay were returned. Median results were determined, and compared to the SSC plasma standard assigned values.

CONTACT INFORMATION

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RESULTS

Table 1 shows the median results for all methods for fibrinogen, FVIII, FIX and VWF:Ag assays. Method specific VWF activity assay results are also shown.

Table 1 median results for all methods for fibrinogen, FVIII, FIX and VWF:Ag assays.

Test	Assigned Value	NEQAS BC no.of users	NEQAS BC median value All methods
Clauss fibrinogen	3.19 g/l	836	3.10 g/l
Factor VIII:C	82.0 IU/dL	361	81.0 IU/dL
Factor IX	109.0 IU/dL	319	110 IU/dL
VWF antigen	114 IU/dL	235	117.0 IU/dL
VWF activity (method)			
Aggregometry (VWF:RCo)	82.0 IU/dL	37	82.0 IU/dL
Chemiluminescence (VWF:GPIbR)	95.0 IU/dL	18	97.3 IU/dL
IL VWF:RCo (VWF:GPIbR)	95.0 IU/dL	71	101.0 IU/dL
Siemens (VWF:GPIbM)	80.0 IU/dL	42	83.6 IU/dL
VWF:Collagen binding	102.0 IU/dL	42	102.6 IU/dL

Table 2 shows the results for the most widely used reagent and instrument combinations for fibrinogen assay. Statistically significant differences between results from different manufacturers were observed – for instance reagent G, instrument 6 and reagent E with instrument 4 (3.24g/l vs 3.02g/l, $p<0.001$), and even between reagents from the same manufacturer on the same instrument platform (reagent A 3.20g/l vs reagent B 3.0g/l, $p<0.001$).

Table 2 fibrinogen assay – most widely used methodology

Diagnostic Supplier	Thrombin Reagent	Instrument	n	Median (g/l)
X	A	1	171	3.20
X	B	1	224	3.00
Y	C	2	91	3.00
Y	D	3	70	3.02
Y	E	4	89	3.02
Z	F	5	29	3.20
Z	G	6	59	3.24

Table 3 shows the median results obtained with the most widely employed sources of reference plasma for FVIII and FIX assays. Significant differences were observed between the lowest and highest results in each case ($p<0.001$). Similar results were observed when data were analysed by deficient plasma source – almost every participant in this study employed reference and deficient plasma from the same manufacturer source.

Table 3 . FVIII and FIX assay results

Assay	Reference Plasma	N	Median Factor level (u/dl)	SSC plasma assigned value u/dl
FVIII	A	184	81.4	82.0
FVIII	B	102	88.1	82.0
FVIII	C	52	91.0	82.0
FIX	A	165	107.0	109.0
FIX	B	92	111.6	109.0
FIX	C	45	122.0	109.0

CONCLUSIONS

It is useful to compare values assigned to commercial calibrants against the SSC plasma standard in an exercise with results obtained by a large variety of methods in a proficiency testing exercise. We have demonstrated good agreement of the overall participant median results with the assigned values for fibrinogen, FVIII, FIX, and VWF assays, in particular with the method-specific target values for VWF activity, introduced for the first time with this lot of plasma. However, some method/ reference plasma-related discrepancies in relation to FVIII and FIX require further investigation.