

FXIII ASSAYS

Survey , October 2023

Samples for this exercise were sent to a total of 83 participants of which 71 participants returned results. One sample was distributed in this survey. Sample FXIII 23:05 was from a normal donor with no clinical indication of Factor XIII deficiency. Samples were provided as lyophilised citrated plasma. Participants were asked to perform their routine assays for Factor XIII measurement. Below and overleaf are the overall results for each sample, together with a summary of method-specific medians. Performance against the peer-group median has been calculated for each sample, using % deviation and Z-scores. ISO 13528 suggests a Z-score of >3 should be considered an action flag. An explanation of the scoring systems is given at the end of this report.

FXIII ASSAY RESULTS:

FXIII Assays – Summary:

Table 1. FXIII Clot lysis results, sample FXIII 23:05

FXIII 23:05	n	Median (minutes)	RANGE (minutes)	Interpretation
Clot lysis				
Urea	2	-	>1441, >1440	
Clot lysis				
Urea and Acetic acid	1	-	-	Normal clot detected

Table 2. FXIII assay results, sample FXIII 23:05

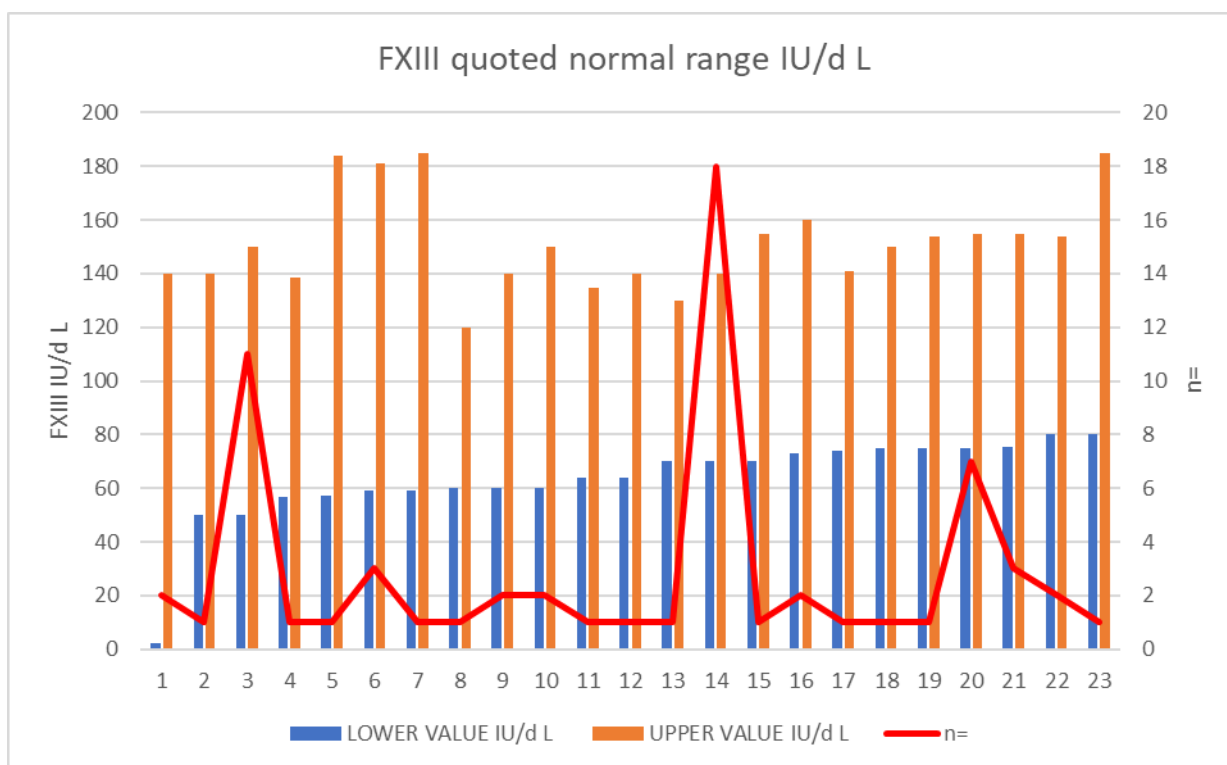
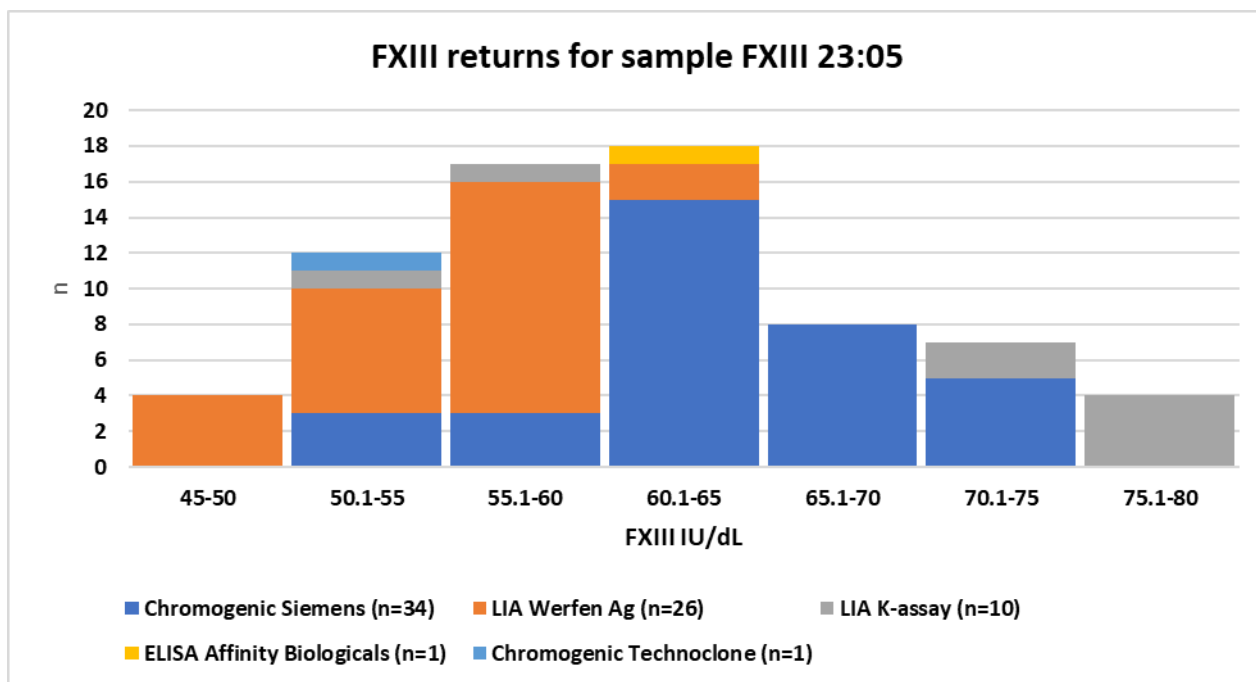
FXIII 23:05	n	Median IU/dL	CV %	RANGE IU/dL	UoM
ELISA : Affinity Biologicals	1	61	-	61	-
Chromogenic : Technoclone	1	52.7	-	52.7	-
LIA : KIMAYA-assay	10	77.5	13.0	54.6-83	3.8
LIA : Werfen Ag	26	56	8.3	46-64.5	1.1
Chromogenic : Siemens	34	64.35	8.6	53.7-76.8	1.2

UoM=Uncertainty of Measurement ($1.25 \times \text{Standard Deviation} / n^{0.5}$)

Interpretations

Centres were asked to provide an interpretation of their FXIII assay results.

Table 3 Interpretation comment	Sample FXIII 23:05 n
Abnormal	32
Borderline	9
Normal	31



Thank you for taking part in this exercise. Any comments or feedback to this exercise would be very welcome.

Professor ID Walker

Director

UK NEQAS (Blood Coagulation)

Appendix: Performance scoring for FXIII assays

The following performance methods have been applied to results in this exercise.

% deviation from the median

The central reference point is the peer group median. Individual results are calculated as a percentage of the peer group median.

Z scores:

The central reference point is the peer group median. The robust mean and SD are calculated by statistical exclusion of outlying results. The z-score is calculated as

$$[\text{result} - \text{mean}] / \text{SD}$$

According to ISO standard 13528, a z-score of $\geq \pm 2$ should be considered a warning flag, and a z-score of $\geq \pm 3$ should be considered an action flag.

z-scores can be unreliable with small numbers of samples ($n < 20$), and this will be noted where relevant on reports.

Fig 1. Z scores and associated performance criteria

Z score	< -3	< -2	-2 to +2	> +2	> +3
Performance	Outwith consensus	Outwith consensus	Within consensus	Outwith consensus	Outwith consensus
Performance flag	Action required	Warning		Warning	Action required

Warning flags in consecutive surveys are also assigned an “action required” flag. Where 2 samples are distributed in a survey, the above criteria apply to either result.

Samples in this exercise passed homogeneity criteria defined in ISO15328. All samples also undergo stability testing for the duration of each survey. Homogeneity and stability tests are subcontracted to the STH NHS Trust Coagulation department.

Sharing results: UK NEQAS (Blood Coagulation) survey reports are posted to named individuals for each registered participant number, or to the secure online data entry system, accessible only by participant number and unique password. Please see our privacy policy, available online at www.neqascoag.org. Results and performance are not shared with any third party with the exception of unresolved performance issues. However, as articulated in the Pathology Quality Assurance Review, participants are encouraged to share their EQA performance data both within and outside of their department.

Report authorised by C Reilly-Stitt, Deputy Manager, 16/12/2023

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