

ADAMTS13 ASSAYS

Summary report Survey 17, October 2023

Samples for this exercise were sent to a total of 42 centres of which 40 centres returned results. Six centres returned more than one activity assay result.

Two aliquots of the same sample were distributed to centres in this survey. Sample AD23:05 was from a patient without a clinical history of TTP. Samples were provided as lyophilised citrated plasma. Participants were asked to perform their routine assays for ADAMTS13 antigen, activity and inhibitor assessment as applicable. Below and overleaf are the overall results for the 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.

ADAMTS 13 ASSAY RESULTS:

Antigen assays

7 centres performed ADAMTS13 antigen assays on these samples, 6 using the Technoclone Technozym assay and 1 centre using In-House assay. 4 centres reported in IU/mL - results were 0.72-0.88 IU/mL for sample AD23:05, 2 centres reported in IU/dL, with results of 78.2-100 IU/dL for sample AD23:05 and 1 centre returning a result of 147% for sample AD23:05.

Activity Assays – Summary:

4 centres returned results using FRET-based assays, 32 centres used the IL/Werfen Acustar CLIA assay and 10 centres used the Technozym ADAMTS13 activity assay. Table 1 shows the results in this exercise.

A variety of reporting methods were noted - %, IU/dL, IU/mL. All results and analysis in the rest of this report will be given in IU/dL.

Note % deviation and z-scores are calculated by peer group data only if group is ≥ 10 .

Table 1. ADAMTS13 activity assay results, sample AD23:05

AD23:05	n	Median IU/dL	CV %	RANGE IU/dL
FRET ELISA assay	4	107.9	-	105-157.8
Technozym ELISA assay *	10	103	-	70-141
Acustar CLIA assay	32	99.85	12.3	80.5-113
All	45	102.7	15.5	70-157.8

Key * = Only 9 numerical values for Technoclone ELISA assay, one centre reported > value.

UoM for Acustar CLIA method AD23:05 2.73IU/dL UoM for Technozym ELISA method AD23:05 8.34IU/dL

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

Antibody assays

In total, 19 centres returned antibody assay (ADAMTS13 inhibitor) results. 15 centres reported results in u/ml, 1 reported results in %, 1 reported a ratio and 2 reported B.U. Table 2 shows all results reported for the sample AD23:05.

Table 2. ADAMTS13 antibody assay results AD 23:05

AD23:05	Reporting units	n	Median result	Cut-off/normal	Range
Bethesda assay	B.U.	2	0.1	<0.5	0-0.1
In house assay (ELISA-based)	%	1	1	0-6	1
Technozym assay§	U/mL	15	2.65	<12 n=14, <15 n=3	1.32-4
Technozym assay	Ratio	1	0.16	>1.26 positive	0.16

Key § = Only 14 numerical values for Technoclone ELISA assay, one centre reported < value.

UoM for Technozym antibody assay AD23:05 0.28U/ml

Interpretations

Centres were asked to provide an interpretation of their ADAMTS13 assay results. Below in table 3 are those comments.

Table 3: Interpretation provided by participants in survey 17	n=
Normal	36
TTP is excluded	1
In normal range	1
ADAMTS-13 activity is normal	1

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 ADAMTS13 assays

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

% deviation from the median

The central reference point is taken as the consensus median. Individual results are calculated as a percentage of this median.

Z scores:

The central reference point is taken as the overall consensus 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 >+/-2 should be considered a warning flag, and a z-score of >+/-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.

Report authorised by C Reilly-Stitt, Deputy Manager, 16/12/23.

A UKAS accredited proficiency testing provider No. 7873.