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1. Scope of Study

The scope of this study was to evaluate if the TECHNOSCREEN® ADAMTS-13 Activity flow through assay would correctly identify samples of < 0.1 IU/mL ADAMTS-13 Activity when compared to results from the TECHNOZYM® ADAMTS-13 Activity ELISA.

The cut off value of 0.1 IU/mL was selected as the critical value.

2. Study Protocol

The sites provided samples for testing with the TECHNOSCREEN® ADAMTS-13 Activity flow through assay from a pool of samples that originated from typical ADAMTS-13 Activity testing requests at the respective study site. These samples included citrated plasma from study participants with Thrombotic Thrombocytopenic Purpura (TTP) as well as other Thrombotic Microangiopathies (TMAs).

3. Study Sites

Both sites were accredited laboratories routinely performing ADAMTS-13 Activity testing using the TECHNOZYM® ADAMTS- 13 Activity ELISA.

4. Samples

Frozen repository as well as fresh citrated samples.

5. Reagent lots used

TECHNOSCREEN® ADAMTS-13 Activity kit lot SA84B00.01 was used by both sites. The ELISA results were determined with the current kit lot of TECHNOZYM ADAMTS-13 Activity in use at each site.

6. Data Analysis

6.1 Calculation of Positive/Negative Predictive values and Sensitivity & Specificity

Data analysis was performed at TECHNOCLONE. Since the TECHNOSCREEN ADAMTS-13 Activity assay is a screening test, the optimal data analysis reflecting its utility calculates the positive and negative predictive values as well as the sensitivity and specificity.

A cut off of 0.1 IU/mL (10%) ADAMTS-13 Activity was selected.

The samples were classified as follows:

		TECHNOSCREEN IU/mL	TECHNOZYM ELISA IU/mL
A	POS / POS	≥0.1	≥0.1
B	POS / NEG	≥0.1	≤0.1
C	NEG / POS	0	≥0.1
D	NEG / NEG	0	≤0.1

An example of classified samples with values:

Sample ID	TECHNOSCREEN IU/ml	ELISA IU/ml	Classified	Class group
1	0	0.02	NEG/NEG	D
2	0.1	0.3	POS/POS	A
3	0.1	0.04	POS/NEG	B
4	0	0.39	NEG/POS	C
5	0.8	0.9	POS/POS	A
6	0.4	0.03	POS/NEG	B

The sum of the numbers of samples for each class was calculated:

Calculations were made as follows:

Positive predicative value = $A / (A+B)$

Negative predicative value = $D / (D+C)$

Sensitivity = $A / (A+C)$

Specificity = $D / (D+B)$

		ELISA				
	0.1IU/mL	POSITIVE	NEGATIVE	Total		
TECHNO SCREEN	POSITIVE	A	B	A+B	PPV	A/(A+B)
	NEGATIVE	C	D	C+D	NPV	D/(C+D)
	Total	A+C	B+D			
		SENSITIVITY				
		SPECIFICITY				
		A/(A+C)				
		D/(B+D)				

Results from the study sites correlated with the package insert claim:

Number of samples analyzed	Positive predictive value	Negative predictive value	Sensitivity	Specificity
170	99%	80%	94%	97%

7. References

1. Joly BS, Coppo P, Veyradier A. Thrombotic thrombocytopenic purpura (Review Series – Clinical Platelet Disorders. Blood 2017;129 (21):2836-2846

The actual data from these studies will be submitted for publication in 2019.