

Performance evaluation of new screening assay for ADAMTS-13 Activity

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INTRODUCTION

Background

The standard laboratory test for ADAMTS-13 Activity is an ELISA, which requires at least 4 h to process. It tends to be performed by specialized laboratories only. Therefore for a physician to receive a patient's ADAMTS-13 activity results can range from 24 h to as much as one week. This delay in reporting could have a negative impact on patient care. With the new TECHNOSCREEN® ADAMTS-13 assay, a rapid and simple assay allows the physician to have an initial result within 1 hour from the blood draw.

MATERIALS AND METHODS

Normal and Thrombocytopenic Purpura (TTP) patient plasma samples were tested in the TECHNOZYM® ADAMTS-13 Activity ELISA and the TECHNOSCREEN® ADAMTS-13 Activity. A cut off value of 0.1 IU/ml was chosen since this reflects the value used by laboratories for classifying a TTP patient. The sample results were classified as either > 0.1IU/mL or <0.1IU/mL in order to calculate the parameters below.

RESULTS

TECHNOSCREEN® ADAMTS-13 Activity Assay

- Based on flow through technology.
- Plasma sample is pre-incubated with ADAMTS-13 specific substrate for 20 minutes at room temperature
- A drop of pre-incubation mixture is added to flow through unit containing a test & control well (see fig 1.& 2)
- In the test well the immobilized antibody (G7) will bind cleaved substrate only
- In the control well the immobilized antibody (anti GST) will bind both cleaved and uncleaved substrate
- Bound substrate is detected using a biotinylated anti GST antibody and Streptavidin-gold conjugate
- The intensity of the red colour in the test well is proportional to the level of ADAMTS-13 Activity in the plasma sample and is compared against a colour standard card, allowing for semi quantitation of activity levels.
- The control well should always be dark red in colour, validating the test result
- Assay is easy to run as all the reagents are added with dropper bottles
- Total assay time is <30 minutes.**

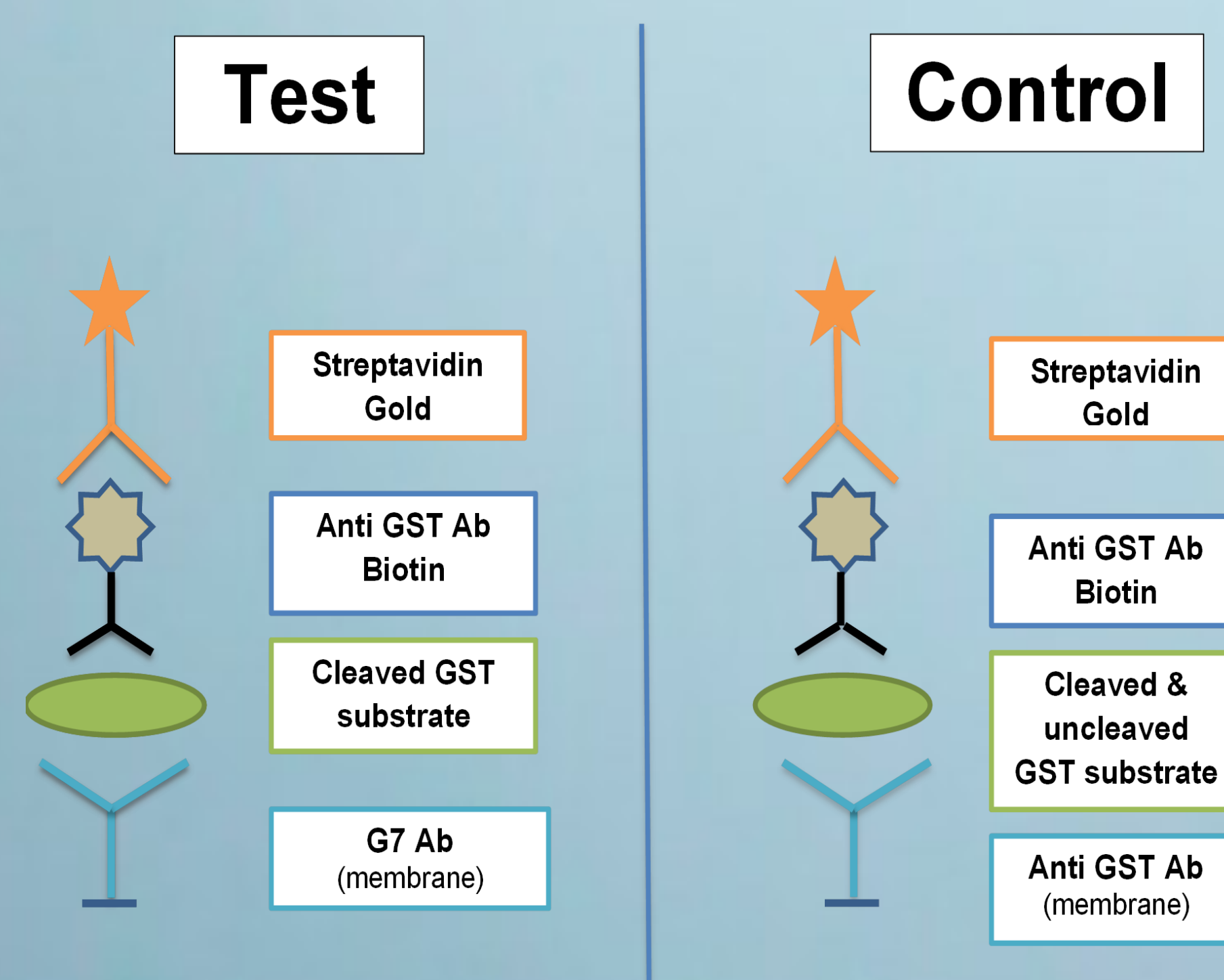


Fig 1. Test Principle of TECHNOSCREEN® ADAMTS-13 Activity

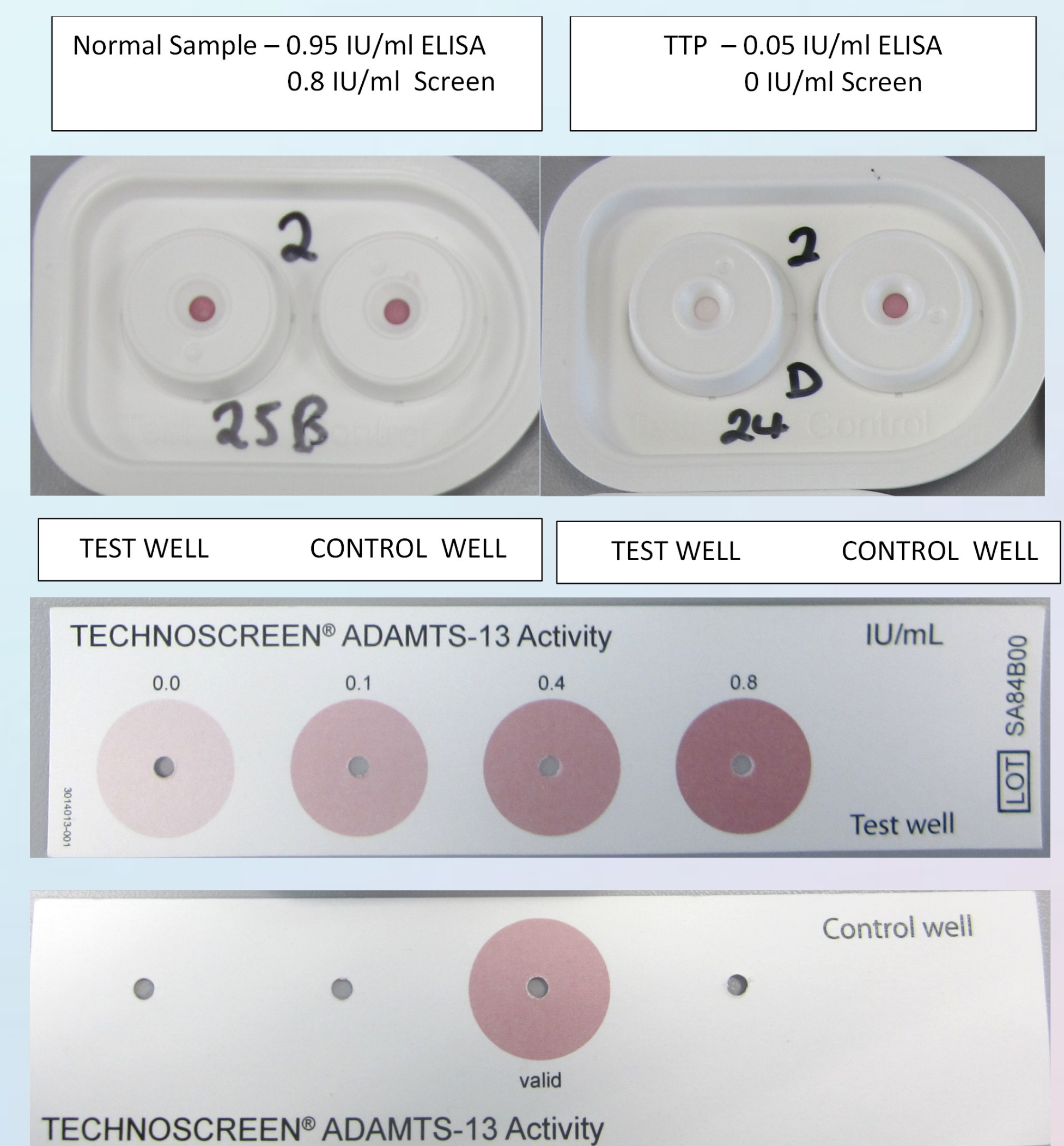


Fig 2. Examples of normal & TTP sample in TECHNOSCREEN® ADAMTS-13 Activity Test

Performance Data

		ELISA	
		POSITIVE (≥0.1 IU/mL)	NEGATIVE (≤0.1 IU/ml)
SCREEN	POSITIVE (≥0.1 IU/mL)	26	3
	NEGATIVE (0 IU/ml)	1	9

Positive Predictive Value	89.7%
Negative Predictive Value	90%
Sensitivity	96.3%
Specificity	75%

CONCLUSIONS

The TECHNOSCREEN ADAMTS-13 Activity is:

- Designed for testing single patient samples
- Versatile as can be performed without specialized laboratory equipment
- Ideal as a cost effective screening tool for TTP