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 TECHNOZYME® 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 1. Test Principle of TECHNOSCREEN® ADAMTS-13 Activity](image)

<table>
<thead>
<tr>
<th>Test</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strepavidin Gold</td>
<td>Strepavidin Gold</td>
</tr>
<tr>
<td>Anti GST Ab Blot</td>
<td>Anti GST Ab Blot</td>
</tr>
<tr>
<td>Cleaved GST substrate</td>
<td>Cleaved &amp; uncleaved GST substrate</td>
</tr>
<tr>
<td>G7 Ab immobilized</td>
<td>Anti GST Ab immobilized</td>
</tr>
</tbody>
</table>

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

![Fig 2. Examples of normal & TTP sample in TECHNOSCREEN® ADAMTS-13 Activity Test](image)

Performance Data

<table>
<thead>
<tr>
<th></th>
<th>ELISA</th>
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<tbody>
<tr>
<td></td>
<td>POSITIVE (≥0.1 IU/mL)</td>
</tr>
<tr>
<td>SCREEN</td>
<td>26</td>
</tr>
<tr>
<td>POSITIVE (≥0.1 IU/mL)</td>
<td>1</td>
</tr>
</tbody>
</table>

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