PT02: R1 (5 x 2 mL) + R2 (1 x 12 mL)
PT05: R1 (10 x 5 mL) + R2 (1 x 60 mL)
Made in France
Revision: 10/10/2018

**THROMBOPLASTIN**

Reagent for determination of Prothrombin time (PT) in human plasma

**QUALITY CONTROL**

**WHO**:

- MNPT: Normal and Pathological Control plasmas

At least once a run, when changing reagent vial or after maintenance of the analyzer, it is advised to use 2 levels of control plasma:
- If the controls results are out the defined range, perform consecutively until correction: repeat of the test with fresh control plasma, calibration with a new vial of reagent, use of a new vial of reference plasma.
- If no solution is found, contact your local supplier or Abliance technical support.

**PROCEDURE**

**Manual method on semi-automated systems**

- Pre-incubate reagent 15 min to reach a temperature of 37 °C and mix gently before use:
  - Plasma: 100 µL
- Incubate for 120 sec at 37 °C
- Working reagent (37 °C): 200 µL
- The automatic countdown timer will start immediately after working reagent addition and stop when the clot is formed.

**Automated method on Thrombolyzer series**

- Refer to the full detailed application specific to the automated system.
- Performances and quality of reagents used must be validated by the customer:
  - Performances and stability data must have been validated on Thrombolyzer Compact X (available on request).
  - With manual procedure and on other automated coagulation analyzer, performances and stability data must be validated by user.
  - Other validated applications or proposal applications are available on request

**CALIBRATION**

**Manual method on semi-automated systems**

- **PT (sec)**: deliver result of patient in second, and reference time found for MNPT.
- **PT (%):** Refer to enclosed calculation board selecting the suitable column according the reference time found for MNPT.

**PERFORMANCES**

The within and between runs studies were performed with normal and abnormal plasma on Thrombolyzer Compact X.

**Within run**

<table>
<thead>
<tr>
<th>S.D. (%)</th>
<th>0.98</th>
<th>0.54</th>
</tr>
</thead>
<tbody>
<tr>
<td>S.D. (%)</td>
<td>1.81</td>
<td>0.99</td>
</tr>
<tr>
<td>C.V. (%)</td>
<td>3.3</td>
<td>1.9</td>
</tr>
</tbody>
</table>

**Between run**

<table>
<thead>
<tr>
<th>S.D. (%)</th>
<th>0.98</th>
<th>0.54</th>
</tr>
</thead>
<tbody>
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<td>3.3</td>
<td>1.9</td>
</tr>
</tbody>
</table>

Comparison with commercially available reagent:

- 167 plasmas: 14% and 110%:
  - r = 0.9958

**REFERENCES**

(4) Quick A. - J. Am. Assoc., (1938), 110. p.1658-1662