Lire attentivement les instructions figurant sur l'étiquetage et/ou la notice d'utilisation des réactifs.

HYPHEN BioMed S.A.S.
155 rue d'Eragny 95000 Neuville-sur-Oise, France • Tél: +33 (0)1.34.40.65.10 • info@hyphen-biomed.com • www.hyphen-biomed.com

New dRVVT assays
Experience the innovation!

Lupus Anticoagulant (LA)
HEMOCLOT™ LA-S
HEMOCLOT™ LA-C

Improved Sensitivity
Better Specificity

From the INNOVATION LEADER in Thrombosis & Hemostasis

More information on HYPHEN BioMed and product catalog is available at:
www.hyphen-biomed.com

Our commitment:
Quality,
Innovation,
Service

Intrinsic Pathway
Extrinsic Pathway

From the INNOVATION LEADER in Thrombosis & Hemostasis

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Lupus Anticoagulant (LA) Assay Panel

HYPHEN BioMed offers Laboratory assays for complete LA profiling:

- In compliance with the SSC/ISTH guidelines
- Improved sensitivity and better specificity than current assays.
- Dedicated LA controls, weak and high positive
- No interference of factor deficiency
- Little impact of Direct Oral Anticoagulants (DOACs) or Vitamin K Antagonists (VKAs)
- No interference of Heparins (LMWH & UFH) up to 1 IU/mL
- Good stability and can be frozen

Reagent

<table>
<thead>
<tr>
<th>Product name</th>
<th>Assay principle</th>
<th>Presentation</th>
<th>Ref. No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>HEMOCLOT™ LA-S (CE-IVD)</td>
<td>Simplified dRVV reagent to screen for the presence of LA. The assay is performed with low phospholipid concentration: LA-S clotting time is expected to be prolonged in the presence of LA</td>
<td>6 x 1 mL</td>
<td>CK090K</td>
</tr>
<tr>
<td>HEMOCLOT™ LA-C (CE-IVD)</td>
<td>dRVV reagent to confirm the presence of LA. The reagent contains a high phospholipid concentration, expected to neutralize LA present in test plasma: clotting time is shortened</td>
<td>6 x 1 mL</td>
<td>CK091K</td>
</tr>
</tbody>
</table>

Associated Controls

<table>
<thead>
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</tr>
</thead>
<tbody>
<tr>
<td>BIOPHEN™ Normal Control Plasma (CE-IVD)</td>
<td>Normal Control Plasma for coagulation assay quality control, which can be used as a negative control for LA clotting assays.</td>
<td>12 x 1 mL</td>
<td>223201</td>
</tr>
<tr>
<td>LA Control Plasma</td>
<td>A set contains 2 levels of lyophilized quality control plasma for LA clotting assays. • C1: LA Control “Weak positive” with indicative normalized ratio of about 1.40 (+0.15). • C2: LA Control “High positive” with indicative normalized ratio of about 2.40 (+0.60).</td>
<td>C1: 6 x 0.5 mL, C2: 6 x 0.5 mL</td>
<td>SC081K</td>
</tr>
<tr>
<td>LA Control Plasma Weak</td>
<td>Weak positive human plasma for the quality control of LA clotting assays.</td>
<td>C1: 6 x 0.5 mL</td>
<td>SC082K</td>
</tr>
<tr>
<td>LA Control Plasma High</td>
<td>High positive human plasma for the quality control of LA clotting assays.</td>
<td>C2: 6 x 0.5 mL</td>
<td>SC083K</td>
</tr>
</tbody>
</table>

dRVVT Assay Principle

**Performance Characteristics**

- **Precision**
  - HEMOCLOT™ LA-S (Ref. 0060K): With-in-run precision N: 30 30 30 CV%: 0.57 1.24
  - Between-run precision N: 30 30 30 CV%: 2.10 4.00 1.38
- **Stability**
  - HEMOCLOT™ LA-S (Ref. 0060K): 48 hrs, 24 hrs, 1 mths
- **Other related products**
  - BIOPHEN™ Normal Control Plasma (Ref. 0060K) 24 hrs* 8 hrs*

**Overview of ISTH recommendation**

1. Perform testing on plasma from healthy donors
2. Two tests using different principles:
   - Dilute Russell’s viper venom time (dRVVT)
   - Stable ATTT (low phospholipid [PL] and silica as activator)
3. Take the cut-off as the value above the 95th percentile of the distribution

**Screening**

1. Perform testing on plasma from healthy donors
2. Two tests using different principles:
   - Dilute Russell’s viper venom time (dRVVT)
   - Stable ATTT (low phospholipid [PL] and silica as activator)
3. Take the cut-off as the value above the 95th percentile of the distribution

**Missed test**

1. Perform testing on plasma from healthy donors
2. Two tests using different principles:
   - Dilute Russell’s viper venom time (dRVVT)
   - Stable ATTT (low phospholipid [PL] and silica as activator)
3. Take the cut-off as the value above the 95th percentile of the distribution

**Confirmatory test**

1. Perform testing on plasma from healthy donors
2. Two tests using different principles:
   - Dilute Russell’s viper venom time (dRVVT)
   - Stable ATTT (low phospholipid [PL] and silica as activator)
3. Take the cut-off as the value above the 95th percentile of the distribution

**Stability**

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<td>CEPHEN® (CE-IVD)</td>
<td>Ready to use liquid APTT reagent with a low sensitivity to LA.</td>
<td>6 x 1 mL</td>
<td>CE011K</td>
</tr>
<tr>
<td>CEPHEN® (CE-IVD)</td>
<td>Ready to use liquid APTT reagent, sensitive to LA.</td>
<td>6 x 5 mL</td>
<td>CE012K</td>
</tr>
<tr>
<td>CEPHEN® (CE-IVD)</td>
<td>Lyophilized normal human control plasma, which can be used for diluting plasma for the diagnosis of LA.</td>
<td>32 x 5 mL</td>
<td>CE013L</td>
</tr>
<tr>
<td>BIOPHEN™ Normal Control Plasma (Ref. 0060K)</td>
<td>an optimised EIA designed for measuring auto-antibodies to E. GpIIb-IIIa of the IgG isoforms of human E. GpIIb-IIIa</td>
<td>6 x 1 mL</td>
<td>BI012K</td>
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