LUPUS DIAGNOSTICS

Clotting Assay

DRVVT

1. **CRYOcheck™ LA CHECK™**

<table>
<thead>
<tr>
<th>Cat. number</th>
<th>Conditioning</th>
<th>Package size</th>
</tr>
</thead>
<tbody>
<tr>
<td>CHK-10</td>
<td>25 x 1.0 mL</td>
<td>300</td>
</tr>
</tbody>
</table>

A dilute Russell’s Viper Venom Time (dRVVT) reagent intended to screen for the presence of lupus anticoagulants (LA) in citrated human plasma.

cryocheck LA Check contains Russell’s viper venom, phospholipids, antiheparin agents, calcium, buffers stabilizers, Sodium azide, and green dye.

2. **CRYOcheck™ LA SURE™**

<table>
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<tr>
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<tbody>
<tr>
<td>SUR-10</td>
<td>25 x 1.0 mL</td>
<td>300</td>
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</table>

A dilute Russell’s Viper Venom Time (drVVT) reagent intended to confirm the presence of lupus anticoagulants (LA) in citrated human plasma.

LA are autoantibodies that are specifically directed against negatively charged phospholipids. They occur in various clinical conditions, especially autoimmune diseases. LA have traditionally been detected using phospholipid sensitive in vitro clotting tests. The drVVT showed improved sensitivity to LA over the APTT partially due to a reduced phospholipid concentration. Russell’s viper venom directly activates factor X, bypassing factor VII of the extrinsic pathway and the contact and antihemophilic factors of the intrinsic pathway.

**Features & benefits**

- Ready to use
- Best lots in store
- Available Performance data report

**Characteristics**

- Stable up to 48 hours when stored at 2...8°C
- If necessary, the plasma can be refrozen once
- Adaptable on hemostasis analyzers (protocols available on request)

**Information**

Recent guidelines and recommendations for laboratory detection of lupus anticoagulants:

The International Society on Haemostasis and Thrombosis (ISTH) and the British Committee for Standards in Haematology (BCSH) have recently updated their lupus anticoagulant (LA) detection guidelines. The Clinical and Laboratory Standards Institute (CLSI) subsequently will publish its first LA guideline. General agreement exists on issues such as sample preparation, the use of dilute Russell viper venom time (dRVVT) in diagnostic repertoires, the use of normalized ratios, calculations to demonstrate phospholipid dependence, calculations to demonstrate inhibition, and interpretive reporting.
3. CRYOCHECK™ LUPUS POSITIVE CONTROL

<table>
<thead>
<tr>
<th>Cat. number</th>
<th>Conditioning</th>
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</thead>
<tbody>
<tr>
<td>CCLP-05</td>
<td>25 x 0.5 mL</td>
</tr>
<tr>
<td>CCLP-10</td>
<td>25 x 1.0 mL</td>
</tr>
</tbody>
</table>

Human source plasma for use as a positive control in assays for lupus anticoagulant.

**CRYOCHECK™** Lupus Positive control contains citrated human plasma collected from donors that have tested positive in accordance with the revised criteria of the SSC Subcommittee for the Standardization of Lupus Anticoagulants.

4. CRYOCHECK™ WEAK LUPUS POSITIVE CONTROL

<table>
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<th>Cat. number</th>
<th>Conditioning</th>
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</thead>
<tbody>
<tr>
<td>CCWLP-05</td>
<td>25 x 0.5 mL</td>
</tr>
<tr>
<td>CCWLP-10</td>
<td>25 x 1.0 mL</td>
</tr>
</tbody>
</table>

Human source plasma for use as a positive control in assays for lupus anticoagulant.

**CRYOCHECK™** Weak Lupus Positive control contains citrated human plasma collected from donors that have tested positive in accordance with the revised criteria of the SSC Subcommittee for the Standardization of Lupus Anticoagulants.

**Use**

A detailed certificate of analysis is provided for each lot.

Calibrated parameters:
- APTT (lupus sensitive)
- APTT (mix 1:1 pool)
- Kaolin Clotting Time
- Ratio DRVVT
- LA Hexagonal phase
- Dilute Thromboplastin Inhibition Assay
- PNP (platelet neutralization)
- Silica Clotting Time
- IgG / IgA / IgM for:
  - Anti-cardiolipin
  - Anti-β-2-glycoprotein 1
  - Anti-Phosphatidylserine

**Lupus Anticoagulants testing**

**Cryoccheck™:** LA Check / LA Sure

- **Plateled-poor plasma**
  - Samples collected into sodium citrate tubes
  - Centrifugation at 1500g for 15 minutes
  - (PPP < 10,000 platelets/µL)

- **LA Screen**
  - **Screen Ratio** = Patient Screen results (sec.) / Screen Normal Range (sec.)

- **LA Confirm**
  - **Confirm Ratio** = Patient Confirm results (sec.) / Confirm Normal Range (sec.)

- **Normalized Ratio**
  - **N.R.** = Screen Ratio / Confirm Ratio

- **LA Confirm** when **N.R. > cut-off** (Mean of Normal Range ± 2SD).
- **Absence of LA** when **N.R. < cut-off** (Mean of Normal Range ± 2SD).

- **Prolonged clotting time:**
  - Inhibitor antibodies (ex: anti FVIII)
  - Heparin > 1IU/mL

- **Normal clotting time:**
  - Factor VIII, IX, XI or XII deficiencies
  - VKA therapy

- **No further testing for LA**
  - **No LA**

- **Mixing studies**
  - 1 volume of patient's plasma
  - 1 volume of Pooled Normal Plasma

- **APTT**
  - Ratio

- **Ratio > 1.2**

- **Ratio < 1.2**