Lyophilized Platelets

REF AG006K-RUO

R1 R2 3 x 5 mL

Platelets for Ristocetin cofactor activity assay (vWF:RCo)
FOR RESEARCH USE ONLY.
DO NOT USE IN DIAGNOSTIC PROCEDURES.

INTENDED USE:
Measurement of platelet aggregation.
This kit should be used for research use only and must not be used for patient diagnosis or treatment.

PRINCIPLE:
When added to a suspension of platelets fixed in a platelet-poor plasma, Ristocetin promotes interaction between von Willebrand factor (vWF) and its platelet receptor, glycoprotein GPIb-IX. The vWF-RCo test measures the biological activity of vWF by agglutination of fixed platelets at a given Ristocetin concentration. Platelet agglutination is thus dependent upon the concentration of vWF in the plasma.

REAGENTS:
- Reagent 1: Formaldehyde-fixed platelets: lyophilized in the presence of stabilizing agent
- Reagent 2: Tris-NaCl buffer (Tris-buffed saline - TBS): for reconstituting the lyophilized platelets (contains BND as a stabilizing agent)

STORAGE CONDITIONS:
Unopened reagents should be stored at 2-6 °C in their original packaging. Under these conditions, they can be used until the expiry date printed on the kit.

WARNING AND PRECAUTIONS:
- Biological products must be handled with all necessary precautions and considered as being potentially infectious.
- Waste should be disposed of in accordance with applicable local regulations.
- The reagents are lyophilized under a vacuum in their vials. To avoid any product loss when opening the vial, gently remove the freeze-drying stopper.
- The usual laboratory health and safety procedures must be followed.

REAGENT PREPARATION AND STABILITY:
- The reagents are lyophilized under a vacuum in their vials. To avoid any product loss when opening the vial, gently remove the freeze-drying stopper.
- Reagent stability after reconstitution, excluding any contamination or evaporation, and stored in the original vial, is of:
  - 56 days at 2-8 °C
  - 7 hours at room temperature (18-25 °C)
- To ensure optimal test results, we recommend testing the specimens and controls in specific working conditions (reagents/instruments/test protocol combination). Record aggregation profile for at least 6 minutes.

STORAGE CONDITIONS:
Unopened reagents should be stored at 2-8 °C in their original packaging. Under these conditions, they can be used until the expiry date printed on the kit.

REAGENTS AND MATERIALS REQUIRED BUT NOT PROVIDED:
Reagents:
- Saline solution (0.9% NaCl)

Materials:
- SD Medical aggregometer (or equivalent), used as per manufacturer's guidelines, with appropriate stirrers and aggregometry cuvettes.
- Sysmex CS-series analyzer and associated consumables.
- Calibrated pipettes.

PROCEDURE:
The reconstituted platelets can be used as a source of platelets for most Ristocetin cofactor activity test procedures.

1. Place a magnetic stirrer in each cuvette
2. Prepare a blank by pipetting 150 µL platelet-poor plasma (PPP) + 150 µL saline solution into a cuvette. Establish the 100% aggregation point with the blank.
3. Pipette 270 µL of platelets into a second cuvette
4. Add 30 µL of a 12 mg/ml ristocetin solution.
5. Add 30 µL of the patient’s plasma, or of calibrator plasma, diluted 1:2, 1:4, 1:8 and 1:16 in saline solution, directly to the mixture.
6. Avoid pipetting the specimen down the walls of the cuvette.

The user is responsible for validating any changes and their impact on all results.

LIMITATIONS:
- To ensure optimum test performance and to meet the specifications, the technical instructions validated by HYPHEN BioMed should be followed carefully. The laboratory is responsible for validating any changes made to these instructions for use.
- Any reagent presenting an unusual appearance or showing signs of contamination must be rejected.
- Any plasma displaying a coagulum or showing signs of contamination must be rejected.
- Any suspicious samples or those showing signs of activation must be rejected.

The results obtained should be used for research use only and must not be used for patient diagnosis or treatment.

PERFORMANCE:

Example of normal and abnormal aggregation (%):

<table>
<thead>
<tr>
<th>Maximum aggregation (%)</th>
<th>Normal</th>
<th>Abnormal</th>
</tr>
</thead>
<tbody>
<tr>
<td>76</td>
<td></td>
<td>13</td>
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</tbody>
</table>

Figure: Example of normal (left) and abnormal (right) aggregation plots with Ristocetin (1.2 mg/mL).

SYMBOLS:
Symbols used and signs listed in the ISO 15223-1 standard, see Symbol definitions document.