FUJI DRI-CHEM CALIBRATOR CP (CRP)

[Intended use]
FUJI DRI-CHEM CALIBRATOR CP (CRP) is the standard solution specially designed for FUJI DRI-CHEM system. This product is used to calibrate C-reactive protein test using FUJI DRI-CHEM SLIDE CRP-S. For in vitro diagnostic use only.

[Components]
[Reagents]
This product is an aqueous solution prepared from pooled human serum. It is added with C-reactive protein purified from human serum and other ingredients.

[Reactive ingredients]
- Human C-reactive protein
  - CP-1: 0.9 mg/dL
  - CP-2: 3.0 mg/dL
  - CP-3: 7.1 mg/dL

[Other ingredients]
- Glucose
- Sodium azide: 0.09 %

[Test object]
Human C-reactive protein

[System applied]
1. Analyzer: FUJI DRI-CHEM ANALYZER
2. Slide: FUJI DRI-CHEM SLIDE CRP-S
3. Diluent: FUJI DRI-CHEM DILUENT DL (CRP)

[Storage and shelf life]
1. Storage condition: Between 2–8 °C (35.6–46.4 °F)
2. Expiry date: printed on the label of the vial and the carton box.

[Warnings and precautions]
1. FUJI DRI-CHEM CALIBRATOR CP (CRP) has been found to be non-reactive for HBs Ag (hepatitis-B virus antigen), anti-HCV (hepatitis-C virus) and anti-HIV (human immunodeficiency virus) antibodies. However, as there is no absolute proof of noninfectiousness, this product should be handled in the same way as patient specimens.
2. Do not remove holders attached to the bottles.
3. When the cap is opened, a liquid membrane produced by surface tension is often observed at the mouth of the bottle. Be sure to remove it before sampling because it may interfere with normal pipetting.
4. For each calibration, do not keep bottles open over five minutes to avoid a concentration of the liquid. And do not use the liquid for calibration more than ten times even within an expiry.
5. After use, please seal it tightly with a bottle label and the cover of the same color immediately to avoid concentration change.
6. If a volume of the liquid is decreased by spillages etc, please refrain from using the liquid for calibration, because it might to be concentrated.
7. Since this product contains 0.09 % of sodium azide as a preservative.
8. The residual liquid is categorized as infectious waste. Make sure to dispose it in accordance with the Waste Disposal Law and other related regulations, which prescribe the proper method of disposal, such as incineration, sterilization or disinfection.
9. This product cannot be applied to other devices not specified by the manufacturer.
10. Please use the check column on the top surface of the box to monitor usage count.

[Procedure]
1. Wear proper gloves, glasses and other protective gear for your safety.
2. This product should be stored between 2-8 °C (35.6-46.4 °F) and warmed up to room temperature before use.
3. Dilute this calibrator 21 times by FUJI DRI-CHEM DILUENT DL (CRP). This can be done automatically in the analyzer equipped with auto dilution function.
4. Select calibration mode on the analyzer and assay this product in the same way as patient specimens.
For further details, consult "INSTRUCTION MANUAL" for FUJI DRI-CHEM ANALYZER.

[Assigned value]

<table>
<thead>
<tr>
<th></th>
<th>CP-1</th>
<th>CP-2</th>
<th>CP-3</th>
</tr>
</thead>
<tbody>
<tr>
<td>CRP</td>
<td>0.9</td>
<td>3.0</td>
<td>7.1</td>
</tr>
</tbody>
</table>

[Contents]
CP-1: 1 x 1 mL
CP-2: 1 x 1 mL
CP-3: 1 x 1 mL

http://www.fujifilm.com/products/medical/

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[Symbols]

- Lot number
- Use by
- Temperature limitation
- Consult instructions for use
- In vitro diagnostic medical devices
- Manufacturer
- Authorized representative in the European Community
- Do not use more than 10 times.
- Do not remove bottle holders.