FUJI DRI-CHEM CONTROL QP-H

[Intended use]
FUJI DRI-CHEM CONTROL QP-H is a control serum specially designed for FUJI DRI-CHEM system. This product is used to confirm performance using slides for plasma and serum. "Mean values and expected ranges" for the tests are provided to evaluate control status.

For in vitro diagnostic use only.

[Components]
[Reagents]
This product is prepared from pooled human serum and provided in a lyophilized form. Enzymes are added for enzyme tests as shown below.

<table>
<thead>
<tr>
<th>Enzyme</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gamma glutamyltransferase</td>
<td>Bovine kidney</td>
</tr>
<tr>
<td>Glutamic oxaloacetic transaminase</td>
<td>Porcine heart</td>
</tr>
<tr>
<td>Glutamic pyruvic transaminase</td>
<td>Porcine heart</td>
</tr>
<tr>
<td>Creatine phosphokinase</td>
<td>Rabbit muscle</td>
</tr>
<tr>
<td>Lactate dehydrogenase</td>
<td>Porcine heart and porcine muscle</td>
</tr>
<tr>
<td>Alkaline phosphatase</td>
<td>Human liver</td>
</tr>
<tr>
<td>Amylase</td>
<td>Porcine pancreas</td>
</tr>
<tr>
<td>Leucine aminopeptidase</td>
<td>Porcine kidney</td>
</tr>
</tbody>
</table>

[Test object]
GLU, BUN, UA, TC, HDL, TG, TP, Ca, ALB, TBIL, IP, GGT, GOT/AST, GPT/ALT, CPK, LDH, ALP, AMYL, LAP and CHE

[System applied]
1. Analyzer : FUJI DRI-CHEM ANALYZER
2. Slide : FUJI DRI-CHEM SLIDE for plasma and serum

[Storage and shelf life]
1. Storage condition : Below -20 °C (-4.0 °F)
2. Expiry date is printed on the carton.

[Warnings and precautions]
1. This product has been found to be non-reactive for HBsAg (hepatitis B surface antigen) by RIA method, and for HCV-Ab (hepatitis-C virus antibody) and HIV-Ab (human immunodeficiency virus antibody) by EIA method. However, as there is no absolute proof of non-infectiousness, this product should be handled with care in the same way as patient specimens.
2. CPK activity could be affected by the temperature of the water added when reconstituting. Results shown in the [Mean values and expected ranges] sheet are obtained when QP-H is reconstituted with distilled water at 25 °C(77 °F). The mean value is about 15% higher at 20 °C(68 °F), and about 12% lower at 30 °C(86 °F).
3. ALP activity rises gradually after reconstitution. It increases about 4% per hour after 30 minutes where the temperature is kept at 25 °C(77 °F).
4. The stability after reconstitution varies with each analyte. Avoid using beyond the time specified in “Stability after reconstitution” as shown below, or when significant change has been observed.
5. TBIL and CPK are known to deteriorate by light. Please be careful when QP-H is transferred to a transparent tube.
6. After use, this product is categorized as an infectious waste. Make sure to dispose of it in accordance with the Waste Disposal Law and other related regulations, which prescribe the proper method of disposal such as incineration, melting, sterilization or disinfection.

[Procedure]
1. Wear proper gloves, glasses and other protective gear for your safety.
2. FUJI DRI-CHEM CONTROL QP-H should be stored below -20 °C (-4.0 °F) and warmed up to room temperature for at least 30 minutes before reconstitution.
3. Remove the metal seal and a rubber stopper from the vial. Add 3 mL of room-temperature distilled water to the vial. Use of a volumetric pipette is recommended for accurate preparation.
4. After adding the distilled water, replace the rubber stopper immediately to avoid concentration.
5. Let stand for 30 minutes with stopper firmly in place, then swirl gently several times so as to mix and dissolve completely. Do not shake.
6. Once reconstituted, this product should be used immediately, and sealed up tightly and stored in a refrigerator between 2–8 °C (35.6–46.4 °F) to keep stable after use.

[Stability after reconstitution]

<table>
<thead>
<tr>
<th>Tests</th>
<th>Temp</th>
<th>Stability</th>
</tr>
</thead>
<tbody>
<tr>
<td>GLU, BUN, UA, TC, HDL, TG, CR, TP, Ca, ALB, TBIL</td>
<td>2–8 °C (35.6–46.4 °F)</td>
<td>12 hrs.</td>
</tr>
<tr>
<td></td>
<td>2–8 °C (35.6–46.4 °F)</td>
<td>8 hrs.</td>
</tr>
<tr>
<td>GGT, GOT/AST, GPT/ALT, LDH, AMYL, LAP, CHE</td>
<td>2–8 °C (35.6–46.4 °F)</td>
<td>6 hrs.</td>
</tr>
<tr>
<td></td>
<td>2–8 °C (35.6–46.4 °F)</td>
<td>4 hrs.</td>
</tr>
<tr>
<td>CPK, ALP</td>
<td>2–8 °C (35.6–46.4 °F)</td>
<td>2 hrs.</td>
</tr>
<tr>
<td></td>
<td>2–8 °C (35.6–46.4 °F)</td>
<td>1 hr.</td>
</tr>
</tbody>
</table>

[Symbols]
Lot number
Use by
Contains sufficient for in vitro tests
Temperature limitation
Consult instructions for use
In vitro diagnostic medical devices
Manufacturer
Authorized representative in the European Community