**Sample requirements**

1. After collecting blood sample immediate measurement is recommended.
2. For plasma, heparin can be used as the anticoagulant. When using heparin, less than 50 units of heparin should be used per 1 mL of whole blood. Do not use EDTA salt, sodium fluoride, citric acid, oxalic acid and monoiodoacetic acid.
3. Avoid using plasma or serum with precipitate such as fibrin.
4. Do not use hemolytic plasma or serum.
5. Samples with glucose content of 30 mg/dL or less should not be used because the measurement reaction requires glucose.
6. When the measured total CPK value exceeds 2000 U/L or CKMB value exceeds 300 U/L, dilute the sample with inactivated serum. In such case, dilution factor must be up to 5 times. Since the data obtained by dilution may deviate more widely than usual, the data should be treated as an estimate. Blood sample which is both over 2000 U/L CPK and under 120 U/L CKMB, or over 10000 U/L CPK cannot be measured correctly even with dilution.

**Procedure**

1. Read in the new QC-card when you switch to a new box of slides.
2. Set slides on FUJI DRI-CHEM ANALYZER.
3. Set a sample tube in the specified sample rack.
4. Input a sequence No. and a sample ID if appropriate.
5. Press the “START” key to initiate testing.

**CAUTION:** Use immediately after opening the individual package.

For further details of operation procedure, consult “INSTRUCTION MANUAL” for FUJI DRI-CHEM ANALYZER.

**Internal quality control**

1. The accuracy and precision of this product can be evaluated with control materials such as pooled human serum. Commercially available control sera may give results which differ between the FUJI DRI-CHEM method and the liquid methods owing to their matrix effect.
2. Concentration levels of the control materials should be adjusted in accordance with clinically significant levels or individual purpose.
3. The control materials should be measured in the same way as patient samples.
5. If results are found outside of the control limits, investigate the cause before submitting reports.

**Reference intervals**

Below 25 U/L (Immuno inhibitory method) (Below 0.418 μkat/L)

As the reference intervals depend on the population of the test, it is required that each laboratory set its own reference intervals.

**Limitation of the examination procedure**

The clinical diagnosis must be made by the doctor in charge based on the measured results in the light of clinical symptoms and other test results.

**Known interfering substances**

No significant effect was observed to the following concentration for each substance.

- CKMM 2000 U/L
- Acorbic acid 5 mg/dL (0.28 mmol/L)
- Bilirubin 20 mg/dL (340 μmol/L)
- LDH 1000 U/L (L→P reaction)

These results are representative;
- Test condition may have some influence on your results.
- Interferences from other substances are not predictable.

**Performance characteristics**

1. **Dynamic range**

<table>
<thead>
<tr>
<th>Concentration range</th>
<th>Accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td>1–300 U/L (0.02–5.01 μkat/L)</td>
<td>Within ± 6 U/L (Within ± 0.10 μkat/L)</td>
</tr>
</tbody>
</table>

2. **Accuracy**

<table>
<thead>
<tr>
<th>Concentration range</th>
<th>Accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td>1–30 U/L (0.02–0.50 μkat/L)</td>
<td>Within ± 6 U/L (Within ± 0.10 μkat/L)</td>
</tr>
<tr>
<td>30–300 U/L (0.50–5.01 μkat/L)</td>
<td>Within ± 20 %</td>
</tr>
</tbody>
</table>

3. **Precision**

<table>
<thead>
<tr>
<th>Concentration range</th>
<th>Precision</th>
</tr>
</thead>
<tbody>
<tr>
<td>1–45 U/L (0.02–0.75 μkat/L)</td>
<td>SD ± 2.7 U/L (SD ± 0.05 μkat/L)</td>
</tr>
<tr>
<td>45–300 U/L (0.75–5.01 μkat/L)</td>
<td>CV ± 6 %</td>
</tr>
</tbody>
</table>

4. **Correlation**

Correlation was evaluated between immunoinhibition method, 37 °C and FUJI DRI-CHEM system. Immunoinhibition method was run on a HITACHI automated analyzer. This examination was carried out at the laboratory of FUJIFILM Corporation.

### Sample Uses

- FUJI HEPARIN/PLAIN TUBE or Blood collection tube specific for the FUJI DRI-CHEM ANALYZER.

### Component Information

- NAD+ (0.10 mg (0.15 mol))
- Glucose-6-phosphate (0.10 mg (0.13 mol))
- Diaphorase 0.24 U
- Glucose-6-phosphate dehydrogenase 2.25 U
- Hexokinase 3.11 U
- Adenosine 5'-diphosphate (ADP) 0.05 mg (0.10 μmol)
- Nitrotetrazolium blue 0.10 mg (0.13 mol)
- Creatine phosphate disodium salt 0.21 mg (0.64 mol)
- CAUTION: Do not use the slide if the individual package is damaged.
Do not touch the center part of the slide.

Warmed up to room temperature before opening the individual packages.

SLIDE CODE

Do not reuse

Lot number

Use by

Contains sufficient for <n> tests

Temperature limitation

Consult instructions for use

In vitro diagnostic medical devices

Manufacturer

Authorized representative in the European Community