Plasma/Serum test for cholinesterase
FUJI DRI-CHEM SLIDE CHE-P

Date of issue: 1/Dec/2014

[Intended use]
Quantitative measurement of cholinesterase activity in plasma or serum.

[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]
The accuracy and precision of this product can be evaluated with FUJI DRI-CHEM CONTROL QP-L and/or QP-H.
1. Select control level in accordance with the expected range.
2. Measure FUJI DRI-CHEM CONTROL QP-L and/or QP-H in the same way as patient samples.
3. When the results obtained are outside the expected range shown in the sheet attached to FUJI DRI-CHEM CONTROL QP-L or QP-H, investigate the cause.
For additional information, consult “Instructions for Use” for FUJI DRI-CHEM CONTROL QP-L or QP-H.

[Reference intervals]
170–420 U/L (3,4 di-hydroxy benzoyl choline UV-Rate method, 37 °C) (2.84–7.01 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.

[Performance characteristics]
1. Dynamic range
   S–500 U/L (0.08–8.35 μkat/L)
2. Accuracy
<table>
<thead>
<tr>
<th>Concentration range</th>
<th>Accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td>5–70 U/L (0.08–1.17 μkat/L)</td>
<td>Within ± 14 U/L (Within ± 0.23 μkat/L)</td>
</tr>
<tr>
<td>70–500 U/L (1.17–8.35 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>5–70 U/L (0.08–1.17 μkat/L)</td>
<td>SD ± 3 U/L (SD ± 0.06 μkat/L)</td>
</tr>
<tr>
<td>70–500 U/L (1.17–8.35 μkat/L)</td>
<td>CV ± 5 %</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>n</th>
<th>Slope</th>
<th>Intercept</th>
<th>Correlation coefficient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum</td>
<td>65</td>
<td>0.982</td>
<td>6.9</td>
</tr>
</tbody>
</table>

[Traceability of calibrators and control materials]
CHE...ReCCS (ChE)
Note: This reference material is applied to the reference method of FUJIFILM Corporation and is not directly applicable to FUJI DRI-CHEM SLIDE.
ReCCS: Reference Material Institute for Clinical Chemistry Standards
[Symbols]

- 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