Plasma/Serum test for glutamic pyruvic transaminase (alanine aminotransferase)

FUJI DRI-CHEM SLIDE GPT/ALT-PIII

[Intended use]
Quantitative measurement of glutamic pyruvic transaminase (alanine aminotransferase) activity in plasma or serum.

[Principle of the measurement]
10 μL of plasma or serum is deposited on a FUJI DRI-CHEM SLIDE GPT/ALT-PIII. The slide is incubated at 37 °C and GPT in the sample catalyses the amino-transfer reaction with the substrate of L-alanine after spreading uniformly in the spreading layer. Pyruvic acid produced by the reaction then reacts with hydrogen peroxide by pyruvate oxidase (POD). Hydrogen peroxide oxidizes diarylimidazole leuco dye by the catalytic reaction of peroxidase (POD) and forms a blue color dye. The increase of absorbance by the generated dye is measured by 650 nm by reflective spectrophotometry and the GPT activity is calculated according to the installed formula.

\[
\text{GPT (EC 2.6.1.2) } = \frac{A_{650} - A_{0}}{C_{\text{sample}}} \times \text{Vol}_{\text{sample}} \times \mu \text{kat/L}
\]

where
- \( A_{650} \): Absorbance at 650 nm
- \( A_{0} \): Absorbance at baseline
- \( C_{\text{sample}} \): Concentration of the sample
- \( \text{Vol}_{\text{sample}} \): Volume of the sample
- \( \mu \text{kat/L} \): Unit

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[Composition of the slide]
1. Multi-layered structure

Sample

<table>
<thead>
<tr>
<th>Transparent support</th>
<th>Reagent layer</th>
<th>Spreading layer</th>
</tr>
</thead>
</table>

2. Ingredients per slide

- L-Alanine: 0.44 mg (4.9 μmol)
- Pyruvic acid: 0.064 mg (0.28 μmol)
- Potassium phosphate: 0.072 mg (0.53 μmol)
- Pyruvate oxidase: 0.54 U
- Peroxidase: 2.4 U
- Diarylimidazole leuco dye: 0.044 mg (0.09 μmol)

[Additional special equipment]
Analyzer: FUJI DRI-CHEM ANALYZER
Other implements: FUJI DRI-CHEM QC CARD (attached)

1. Peroxidase 2.4 U
2. Pyruvate oxidase 0.54 U
3. Potassium phosphate 0.072 mg (0.53 μmol)
4. Phosphate 1.8 mg (0.117 mmol)
5. Diarylimidazole leuco dye 0.044 mg (0.09 μmol)

[Internal quality control]
The accuracy and precision of this product can be evaluated with FUJI DRI-CHEM CONTROL KP-L and/or KP-H.

1. Select control level in accordance with your purpose.
2. Measure FUJI DRI-CHEM CONTROL KP-L and/or KP-H in the same way as patient samples.
3. When the results obtained are outside the expected range given in the sheet attached to FUJI DRI-CHEM CONTROL KP-L or KP-H, investigate the cause.

[Reference intervals]
4–44 U/L (JSCC* standard method, 37 °C) (0.07–0.73 μkat/L)

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

*Japan society of clinical chemistry (JSCC) method does not include pyridoxal phosphate (PALP)

[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
(1) No significant effect was observed to the following concentration for each substance.

- 10 mg/dL (0.57 mmol/L) Ascorbic acid
- 20 mg/dL (0.34 mmol/L) Bilirubin
- 2 mg/dL (0.23 mmol/L) Pyruvic acid
- Total protein: 40–95 g/L

(2) Dobutamine hydrochloride (cardiotonic reagent) and dopamine hydrochloride (cardiotonic reagent) give minus bias.

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>10–30 U/L (0.17–0.50 μkat/L)</td>
<td>Within ± 20 %</td>
</tr>
<tr>
<td>30–100 U/L (0.50–18.70 μkat/L)</td>
<td>Within ± 10 %</td>
</tr>
</tbody>
</table>

2. Accuracy

<table>
<thead>
<tr>
<th>Concentration range</th>
<th>Precision</th>
</tr>
</thead>
<tbody>
<tr>
<td>10–60 U/L (0.17–1.00 μkat/L)</td>
<td>SD ± 3 U/L (SD ± 0.05 μkat/L)</td>
</tr>
<tr>
<td>60–1000 U/L (1.00–16.70 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>56</td>
<td>1.035</td>
<td>-8.1</td>
<td>0.998</td>
</tr>
</tbody>
</table>

[Traceability of calibrators and control materials]
GPT...ReCCS (ERM)
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
[Contents]
Slide : 24
QC card : 1

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

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[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