[Intended use] Quantitative measurement of pancreatic lipase (LIP) activity in plasma or serum. For in vitro diagnostic use only.

[Principle of the measurement] 10 μL of plasma or serum is deposited on a FUJI DRI-CHEM SLIDE LIP-P. The sample is uniformly distributed on the spreading layer and Lipase in the sample catalyzes the hydrolysis of triolein, 2-monoglyceride, the product generated by Lipase is further decomposed by monoglyceride lipase (MGLP) to glycerol. The glycerol generates L-α-glycerophosphate by glycerol kinase (GK) in the presence of ATP and Mg 2+. L-α-glycerophosphate produces hydrogen peroxide by the action of glycerol-3-phosphate oxidase (GPO). Hydrogen peroxide oxidizes diaryl imidazole leuco dye by the action of peroxidase (POD) to produce blue color dye. The increase of absorbance by the generated dye is calculated according to the installed formula.

Triolein + 2H 2O → Lipase. Colipase → 2-Monoglyceride + 2 Oleic acid
2-Monoglyceride + H 2O 2 → MGLP + Glycerol + Oleic acid
Glycerol + ATP → GK. MgCl 2 → L-α-glycerophosphate + ADP
L-α-glycerophosphate + O 2 → GPO → H 2O 2 + Dihydroxyacetone phosphate
Diaryl imidazole leuco dye + H 2O → POD → Blue color dye + 2H 2O

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

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

[Storage and shelf life] 1. Storage: This product must be stored between 2–8 °C (35.6–46.4 °F) before use. CAUTION: Do not use expired slides.

[Warnings and precautions] 1. Only the required number of slides should be taken out of the refrigerator and warmed up to room temperature before opening the individual packages.
2. Do not touch the membrane in the center of the slide.
3. A new slide must be used for each measurement. Do not reuse.
4. Handle all patient samples, control serum and used tips carefully as biohazardous samples. Wear proper gloves, glasses and other protective gear for your safety.
5. Used slides are categorized as infectious waste. Make sure to dispose them 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.
6. Because it is highly sensitive to light, as soon as the slide is taken out of its package, it should be set in the cartridge with the slide weight placed on the top of it.
7. Keep QC card away from magnetic material.
8. Do not use the slide if the individual package is damaged.

[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. When the measured value exceeds the upper limit of the dynamic range, dilute the sample with distilled water. Since the data obtained by dilution may deviate more widely than usual, the data should be treated as estimation. Do not use saline for dilution.
6. When an amperand (A) is applied to the measured value, the sample may be high concentration glycerol sample. Dilute the sample with distilled water and measure it. Since the data obtained by dilution may deviate more widely than usual, the data should be treated as estimation.

[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 serum.
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] 13–42 U/L (0.22–0.70 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.
Ascorbic acid 10 mg/dL (0.57 mmol/L)
Bilirubin 20 mg/dL (340 μmol/L)
Total protein 40–95 g/L
Glycerol 4.6 mg/dL (0.5 mmol/L)

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 20–1000 U/L (0.33–16.70 μkat/L)
2. Accuracy

<table>
<thead>
<tr>
<th>Concentration range</th>
<th>Accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td>20–100 U/L (0.33–1.67 μkat/L)</td>
<td>Within ± 20 U/L (Within ± 0.33 μkat/L)</td>
</tr>
<tr>
<td>100–1000 U/L (1.67–16.70 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>20–100 U/L (0.33–1.67 μkat/L)</td>
<td>SD ± 10 U/L (SD ± 0.17 μkat/L)</td>
</tr>
<tr>
<td>100–1000 U/L (1.67–16.70 μkat/L)</td>
<td>CV ± 10 %</td>
</tr>
</tbody>
</table>

4. Correlation
Correlation was evaluated between DGGR* substrate method and FUJI DRI-CHEM system. DGGR* substrate method was run on a HITACHI automated analyzer. This examination was carried out at the laboratory of FUJIFILM Corporation.

*DGGR: 1,2 -o-Dilauryl-rac-glycero-3-glutaric acid -(6-methyl-resorufin) ester

<table>
<thead>
<tr>
<th>Serum</th>
<th>n</th>
<th>Slope</th>
<th>Intercept</th>
<th>Correlation coefficient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plasma</td>
<td>63</td>
<td>0.974</td>
<td>-3.75</td>
<td>0.995</td>
</tr>
</tbody>
</table>

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[Traceability of calibrators and control materials]
LIP...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/

FUJIFILM Europe GmbH
Heesenstrasse 31, 40549 Düsseldorf, GERMANY
FUJIFILM Corporation
26-30, Nishiazabu 2-Chome, Minato-ku, Tokyo 106-8620, JAPAN

[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