

Plasma/Serum test for lipase

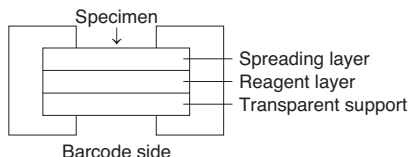
FUJI DRI-CHEM SLIDE LIP-P

[Warnings and precautions]

- Only the required number of slides should be taken out of the refrigerator and warmed up to room temperature before opening the individual packages.
- Do not touch either the center part of the surface or the back of the slide.
- A new slide must be used for each measurement. Do not reuse.
- Handle all patient specimens, control serum and used tips carefully as biohazardous samples. Wear proper gloves, glasses and other protective gear for your safety.
- 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.

[Composition of the slide]

1. Multi-layered structure



2. Ingredients per slide

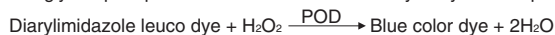
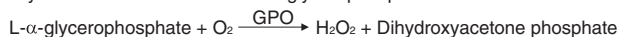
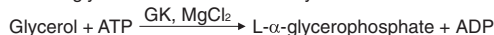
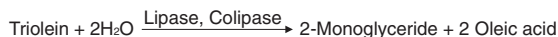
• Monoglyceride lipase (MGLP)	0.69 U
• Glycerol kinase (GK)	0.62 U
• Glycerol-3-phosphate oxidase (GPO)	0.96 U
• Peroxidase (POD)	1.13 U
• Colipase	0.016 mg
• Adenosine triphosphate disodium salt (ATP)	0.23 mg (0.42 μmol)
• Triolein	0.17 mg (0.19 μmol)
• Diarylimidazole leuco dye	0.034 mg (0.066 μmol)
• Magnesium chloride (MgCl ₂)	0.085 mg (0.89 μmol)

[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 specimen is uniformly distributed on the spreading layer and Lipase in the specimen 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 Mg²⁺. L-α-glycerophosphate produces hydrogen peroxide by the action of glycerol-3-phosphate oxidase (GPO). Hydrogen peroxide oxidizes diarylimidazole leuco dye by the action of peroxidase (POD) to produce blue color dye. The increase of absorbance by the generated dye is measured from 3 min to 5 min at 650 nm by reflective spectrophotometry and the Lipase activity is calculated according to the installed formula.



[Additional special equipment]

Analyzer: FUJI DRI-CHEM ANALYZER

Other implements: FUJI DRI-CHEM QC CARD (attached)

- : FUJI DRI-CHEM CLEAN TIPS or FUJI DRI-CHEM AUTO TIPS
- : FUJI HEPARIN/PLAIN TUBE or Blood collection tube specified in the "INSTRUCTION MANUAL" for FUJI DRI-CHEM ANALYZER

[Specimen requirements]

- After collecting the blood specimen, immediate measurement is recommended.
- For plasma, heparin is recommended to use as an 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.
- Avoid using plasma or serum with precipitate such as fibrin.
- Do not use hemolytic plasma or serum.
- 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.
- When an ampersand(&) is affixed 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]

- Read in the new QC-card when you switch to a new box of slides.
- Set slides on FUJI DRI-CHEM ANALYZER.
- Set a sample tube in the specified sample rack.
- Input a sequence No. and a sample ID if appropriate.
- Press the "START" key to initiate testing. For further details of operation procedure, consult "INSTRUCTION MANUAL" for FUJI DRI-CHEM ANALYZER.

[Reference interval]

Plasma or serum: 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. 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** 20–1000 U/L (0.33–16.70 μkat/L)

2. Accuracy

Concentration range	Accuracy
20–100 U/L	Within ± 20 U/L
100–1000 U/L	Within ± 20 %

3. Precision

Concentration range	Precision
20–100 U/L	SD ≤ 10 U/L
100–1000 U/L	CV ≤ 10 %

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

	n	Slope	Intercept	Correlation coefficient
Serum	68	0.979	-3.75	0.995
Plasma	63	0.974	-0.07	0.992

5. Known interfering substances

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

Ascorbic acid	0.57 mmol/L
Bilirubin	340 μmol/L
Total protein	40–95 g/L
Glycerol	0.5 mmol/L

These results are representative;

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

[Internal quality control]

- The accuracy and precision of this product can be evaluated with control materials such as pooled serum.
- Concentration levels of the control materials should be adjusted in accordance with clinically significant levels or individual purpose.
- The control materials should be measured in the same way as patient samples.
- We recommend that control limits be established for assayed analytes so as to enable assessment of the control status.
If results are found outside of the control limits, investigate the cause before submitting reports.

[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

[Storage and shelf life]

- Storage: This product must be stored between 2–8 °C (35.6–46.4 °F) before use.
- Expiry date is printed on the carton.
- Use immediately after opening the individual package.

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



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