FUJIFILM

Use after reading this "Instructions for Use"

IVD

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Plasma/Serum test for leucine aminopeptidase

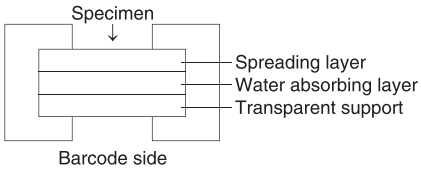
FUJI DRI-CHEM SLIDE LAP-P

[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 either the center part of the surface or the back of the slide.
3. A new slide must be used for each measurement. Do not reuse.
4. Handle all patient specimens, 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.

[Composition of the slide]

1. Multi-layered structure



2. Ingredients per slide

• L-Leucyl-p-nitroanilide hydrochloride 0.23 mg (0.80 µmol)

[Intended use]

Quantitative measurement of leucine aminopeptidase 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 LAP-P. The spotted specimen spreads uniformly on the spreading layer and reacts with the substrate L-leucyl-p-nitroanilide. P-Nitroaniline dye is generated and diffused into the water absorbing layer. The increase of absorbance by the generated dye is measured from 2 min to 4 min at 400 nm by reflective spectrophotometry and the LAP activity is calculated according to the installed formula.

L-Leucyl-p-nitroanilide $\xrightarrow{\text{LAP}}$ L-Leucine + p-Nitroaniline

[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]

1. 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.
2. Avoid using plasma or serum with precipitate such as fibrin.
3. Do not use hemolytic plasma or serum.
4. When the measured value exceeds the upper limit of the dynamic range, dilute the sample with distilled water or saline. 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.
   For further details of operation procedure, consult "INSTRUCTION MANUAL" for FUJI DRI-CHEM ANALYZER.

[Reference interval]

19–69 U/L (L-leucyl-p-nitroanilide method) (0.32–1.15 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.

Three types of LAP are known such as cytoplasmic LAP (C-LAP), microsomal LAP (arylamidase ; AA) and placental LAP (cystyl-aminopeptidase ; CAP). This method is known to detect AA and CAP. The obtained results may be higher compared with the method not detecting CAP.

[Performance characteristics]

1. Dynamic range 10–500 U/L (0.17–8.35 µkat/L)

2. Accuracy

Concentration range	Accuracy
10–20 U/L	Within ± 4 U/L
20–500 U/L	Within ± 20 %

3. Precision

Concentration range	Precision
10–20 U/L	SD ≦ 2 U/L
20–500 U/L	CV ≦ 10 %

4. Correlation

Correlation was evaluated between L-Leucyl-p-nitroanilide method and FUJI DRI-CHEM system. L-Leucyl-p-nitroanilide method was run on a HITACHI automated analyzer. This examination was carried out at the laboratory of FUJIFILM Corporation.

	n	Slope	Intercept	Correlation coefficient
Plasma	50	1.040	-2.2	0.951
Serum	68	0.996	1.5	0.998

5. Known interfering substances

The effects on the measured value were examined by adding substances as shown below to a serum sample obtained from a healthy volunteer or a control serum. No significant effect was observed to the following concentration for each substance.

Ascorbic acid 0.57 mmol/L
Bilirubin 170 µmol/L
Total protein 40–95 g/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 FUJI DRI-CHEM CONTROL QP-L and/or QP-H.

1. Select control level in accordance with your purpose.
2. Measure FUJI DRI-CHEM CONTROL QP-L and/or QP-H in the same way as patient specimens.
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.

[Traceability of calibrators and control materials]

The calibration of this product has already been accomplished in our factory before shipping using internal calibrators which are not commercially available. Calibration data are supplied by a QC card enclosed in this package. Assigned values of the internal calibrators for LAP are traceable to a method with L-leucyl-p-nitroanilide as a substrate.

[Storage and shelf life]

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

[Contents]

: Slide 24
: QC card 1

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

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