FUJIFILM

Use after reading this "Instructions for Use"

IVD

Date of issue: 1/Oct/2008

Plasma/Serum test for amylase

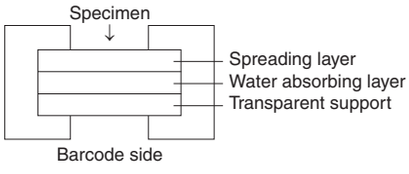
FUJI DRI-CHEM SLIDE AMYL-PIII

[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

- 4,6-ethylidene-4-nitrophenyl-α-D-maltoheptaoside 0.42 mg (0.32 μmol)
- α-Glucosidase 0.8 U

[Intended use]

Quantitative measurement of amylase 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 AMYL-PIII. The specimen is distributed uniformly by the spreading layer and reacts with the substrate (4,6-ethylidene-4-nitrophenyl-α-D-maltoheptaoside : Et-G_7-PNP). The product generated by amylase is further decomposed by α-glucosidase to release p-nitrophenol. The increase of absorbance by the generated dye is measured from 2.5 min to 5 min at 400 nm by reflective spectrophotometry and the amylase activity is calculated according to the installed formula.

$$\text{Et-G}_7\text{-PNP} \xrightarrow{\text{Amylase}} \text{Et-Gm} + \text{Gn-PNP} \quad (m+n=7,\ n=2,3,4)$$

$$\text{Gn-PNP} \xrightarrow{\alpha\text{-Glucosidase}} \text{Gn} + \text{PNP}$$

[Additional special equipment]

Analyzer: FUJI DRI-CHEM ANALYZER
Other implements: FUJI DRI-CHEM QC CARD (attached)
: FUJI CLEAN TIPS or FUJI AUTO TIPS
: FUJI HEPARIN/PLAIN TUBE or Blood collection tube specified in the "INSTRUCTION MANUAL" for FUJI DRI-CHEM ANALYZER

[Specimen requirements]

1. After collecting the blood specimen, immediate measurement is recommended.
2. 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.
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 saline. Since the data obtained by dilution may deviate more widely than usual, the data should be treated as estimation. Do not use distilled water for dilution.

[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 intervals]

Plasma or serum : 37–125U/L (IFCC Consensus Method, 37 °C) (0.62-2.09 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 10–1800 U/L (0.17-30.06 μkat/L)

2. Accuracy

Concentration range	Accuracy
10–50 U/L	Within ± 10 U/L
50–1800 U/L	Within ± 20 %

3. Precision

Concentration range	Precision
10–100 U/L	SD ≦ 6 U/L
100–1800 U/L	CV ≦ 6 %

4. Correlation

Correlation was evaluated between IFCC Consensus Method and FUJI DRI-CHEM system. IFCC Consensus Method was run on a HITACHI automated analyzer. This examination was carried out at the laboratory of FUJIFILM Corporation.

	n	Slope	Intercept	Correlation coefficient
Serum	81	1.010	–1.35	0.998
Plasma	94	1.005	+3.20	0.995

5. Known interfering substances

(1) Maltose gives minus bias.
(2) No significant effect was observed to the following concentration for each substance.

Ascorbic acid	0.57 mmol/L
Bilirubin	255 μmol/L*
Total protein	40–95 g/L
Glucose	16.6 mmol/L

(3) Presence of macroamylase in the sample is known to give minus bias.

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

*At the normal range of amylase activity.

[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 AMYL are traceable to a method with 4,6-ethylidene-4-nitrophenyl-α-D-maltoheptaoside 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

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FPT-800212-FP-1

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AMYL-PIII