FUJIFILM

Use after reading this "Instructions for Use"

IVD

Date of issue: 1/May/2012

Plasma/Serum test for alkaline phosphatase

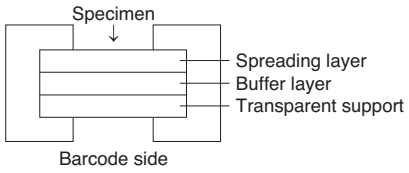
FUJI DRI-CHEM SLIDE ALP-PIII

[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

• p-Nitrophenyl phosphate 0.075 mg (0.18 µmol)

[Intended use]

Quantitative measurement of alkaline phosphatase 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 ALP-PIII. The spotted specimen is incubated at 37 °C and catalyses the hydrolyzing reaction of co-existing p-nitrophenyl phosphate while spreading uniformly in the spreading layer. The p-nitrophenyl dye formed with the start of the reaction is diffused and collected in the buffer layer. Increase in absorption by the generated dye is measured from 2 min to 4 min at 400 nm by reflective spectrophotometry and the ALP activity is calculated according to the installed formula.

p-Nitrophenyl phosphate $\xrightarrow{\text{ALP}}$ p-Nitrophenyl dye + Phosphoric acid

[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. After collecting the blood specimen, 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 specimen containing a high concentration (over 170 µmol/L (10 mg/dL)) of bilirubin is measured, error may occur in a low-concentration region. In such a case, dilute the specimen 5 times with the purified water and reanalyze. If you dilute specimen in the analyzer with auto-dilution function, the measured result is multiplied 5 times automatically.
6. When the measured value exceeds the upper limit of the dynamic range, dilute the sample with distilled water. Do not use saline. Since the data obtained by dilution may deviate more widely than usual, the data should be treated as estimation.
7. When the specimen containing high concentration of ALP5 (small intestine originated isozyme) is measured, the result may give minus bias compared to the JSCC Standard Method which uses the EAE buffer.

[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]

104–338 U/L (JSCC Standard Method*, 37 °C) (1.74–5.64 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.
* JSCC method show 3 times larger value on ALP activity than the IFCC method. The (a, b) conversion function can be used to convert the JSCC based value to the IFCC based value.

[Performance characteristics]

1. Dynamic range 50–3500 U/L (0.84–58.45 µkat/L)

2. Accuracy

Concentration range	Accuracy
50–120 U/L	Within ± 24 U/L
120–3500 U/L	Within ± 20 %

3. Precision

Concentration range	Precision
50–240 U/L	SD ≦ 12 U/L
240–3500 U/L	CV ≦ 5 %

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.

	n	Slope	Intercept	Correlation coefficient
Serum	74	0.994	5.8	0.996

5. Known interfering substances

(1) Theopylline gives minus bias.
(2) Increase of bilirubin gives plus bias.
(3) Lower protein concentration gives plus bias.
(4) 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
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]

ALP...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. The assigned value is traceable to the JSCC Standard Method.
ReCCS: Refference Material Institute for Clinical Chemistry Standards

[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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