[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 sample is incubated at 37 °C and catalyzes 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 at 400 nm by reflective spectrophotometry and the ALP activity is calculated according to the installed formula.

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

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

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Sample ↓
Spreading layer
Buffer layer
Transparent support
Barcode side
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2. Ingredients per slide
- p-Nitrophenyl phosphate 0.075 mg (0.18 μmol)

[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

[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.

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, sterilization or disinfection.
6. Keep QC card away from magnetic material.
7. Do not use the slide if the individual package is damaged.

[Sample requirements]
1. After collecting blood sample immediate measurement is recommended. 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 monooiodoacetic acid.
2. Avoid using plasma or serum with precipitate such as fibrin.
3. Do not use hemolytic plasma or serum.
4. When the sample containing a high concentration (over 10 mg/dL (170 μmol/L)) of bilirubin is measured, error may occur in a low-concentration region. In such a case, dilute the sample 5 times with the purified water and reanalyze. If you dilute sample in the analyzer with auto-dilution function, the measured result is multiplied 5 times automatically.
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.
6. Do not use saline.
7. When the sample 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.

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]
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 samples.
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.
4. For additional information, consult "Instructions for Use" for FUJI DRI-CHEM CONTROL QP-L or QP-H.

[Reference intervals]
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.

32–111 U/L (IFCC standard method) (0.53–1.86 μkat/L)

*The value of IFCC method are calculated by a known correlation equation. In order to convert the ALP measurement value of JSCC to IFCC, it is necessary to input the coefficients of conversion (a=2.95, b=10 for U/L a=2.95, b=0.167 for μkat/L) into FDC. Ref.: Jpn J Clin Chem (vol.33 sup.2 11b)

[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
(1) No significant effect was observed to the following concentration for each substance.
- Ascorbic acid 10 mg/dL (0.57 mmol/L)
- Bilirubin 10 mg/dL (170 μmol/L)
- Total protein 4.0–9.5 g/dL

(2) Theophylline gives minus bias.
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
   - JSCC: 50–3500 U/L (0.84–58.45 μkat/L)
   - IFCC: 14–1183 U/L (0.23–19.76 μkat/L)

2. Accuracy
   - Concentration range
     - JSCC: 50–120 U/L
       - IFCC: 14–37 U/L
     - JSCC: 120–3500 U/L
       - IFCC: 37–1183 U/L

   - Accuracy
     - JSCC: Within ± 24 U/L (Within ± 0.40 μkat/L)
     - JSCC: SD ± 2 U/L (Within ± 0.14 μkat/L)

2. Precision
   - Concentration range
     - JSCC: 50–240 U/L
       - IFCC: 14–78 U/L
     - JSCC: 240–3500 U/L
       - IFCC: 78–1183 U/L

   - Precision
     - JSCC: SD ± 12 U/L (SD ± 0.20 μkat/L)
     - IFCC: SD ± 4 U/L (SD ± 0.07 μkat/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.

<table>
<thead>
<tr>
<th></th>
<th>n</th>
<th>Slope</th>
<th>Intercept</th>
<th>Correlation coefficient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum</td>
<td>74</td>
<td>0.994</td>
<td>5.8</td>
<td>0.996</td>
</tr>
</tbody>
</table>
[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: Reference Material Institute for Clinical Chemistry Standards

[Contents]

Slide : 24
QC card : 1

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

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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