

# Plasma/Serum test for calcium

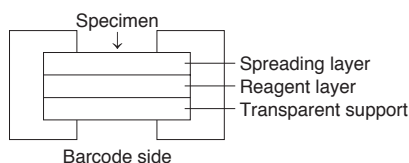
## FUJI DRI-CHEM SLIDE Ca-PIII

### [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.
- A new slide must be used for each measurement. Do not reuse.
- Do not use EDTA salt as an anticoagulant.
- When measured value is displayed as Ca-P >4.00 mmol/L, it is because sample is not deposited or is abnormally high concentration. Confirm the trace of spot and if not spotted, repeat operation of spot.
- 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

- Chlorophosphonazo III 0.058 mg (0.072 μmol)

### [Intended use]

Quantitative measurement of calcium concentration 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 Ca-PIII.

The deposited specimen spreads uniformly in the spreading layer, where bound type calcium is converted to free type calcium by the dissociation agent contained in the layer. The free calcium penetrates into the reagent layer and reacts with chlorophosphonazo III to form a dye.

The slide is incubated at 37 °C for a fixed time in the FUJI DRI-CHEM ANALYZER and the optical reflection density is measured at 625 nm. The optical reflection density is then converted into the calcium concentration using a calibration curve preinstalled in the analyzer.



### [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.
- The amount of heparin should be used less than 50 units per 1 mL of blood. EDTA salt should not be used because of serious interference for calcium determination (calcium concentration ≤ 1.00 mmol/L). Do not use sodium fluoride, citric acid, oxalic acid and monoiodoacetic acid.
- Avoid using plasma or serum with precipitate such as fibrin.
- 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. The saline should not be used because the error may become large.

### [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]

2.10–2.55 mmol/L (8.4–10.2 mg/dL)

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** 1.00–4.00 mmol/L (4.0–16.0 mg/dL)

2. **Accuracy**

Concentration range	Accuracy
1.00–1.75 mmol/L	Within ± 0.25 mmol/L
1.75–4.00 mmol/L	Within ± 15 %

3. **Precision**

Concentration range	Precision
1.00–1.75 mmol/L	SD ≤ 0.09 mmol/L
1.75–4.00 mmol/L	CV ≤ 5 %

#### 4. Correlation

Correlation was evaluated between o-cresolphthalein complexone (CPC) method and FUJI DRI-CHEM system. The CPC 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	75	1.016	-0.05	0.995
Serum	85	0.993	0.02	0.996

#### 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	340 μmol/L
Hemoglobin	3000 mg/L
Total protein	40–95 g/L
Magnesium	1.25 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.

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

Calcium...ReCCS (CA-6)

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.

### [Contents]

: Slide	24
: QC card	1

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

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