**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 sample 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.

\[
\text{Ca}^{2+} + \text{Bound type Ca} \rightarrow \text{Dissociation agent} \rightarrow \text{Ca}^{2+} + \text{Chlorophosphonazo III} \rightarrow \text{Ca-Chlorophosphonazo III}
\]

**Composition of the slide**
1. Multi-layered structure

- Sample
- Spreading layer
- Reagent layer
- Transparent support
- Barcode side

2. Ingredients per slide
- Chlorophosphonazo III 0.058 mg (0.072 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.

**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. Do not use EDTA salt as an anticoagulant.
5. When measured value is displayed as Ca–P&>16 mg/dL (4.00 mmol/L), it is dangerous to classify the trace of spot and if not spotted, repeat operation of spot.
6. Handle all patient samples, control serum and used tips carefully as biohazardous samples. Wear proper gloves, glasses and other protective gear for your safety.
7. Used slides are categorized as infectious waste. Make sure to dispose them safely. Wear proper gloves, glasses and other protective gear for your safety.
8. Keep QC card away from magnetic material.
9. Do not use the slide if the individual package is damaged.

**Sample requirements**
1. After collecting blood sample immediate measurement is recommended.
2. 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 monooiodoacetic acid.
3. Avoid using plasma or serum with precipitate such as fibrin.
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.

**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**
8.4–10.2 mg/dL (2.10–2.55 mmol/L)
As the reference intervals depend on the population of the test, it is required that each laboratory set its own reference intervals.

**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**
No significant effect was observed to the following concentration for each substance.
- Ascorbic acid 10 mg/dL (0.57 mmol/L)
- Bilirubin 20 mg/dL (340 μmol/L)
- Magnesium 3 mg/dL (1.25 mmol/L)
- Hemoglobin 3000 mg/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.

**Performance characteristics**
1. Dynamic range
   
   \[
   4.0–16.0 \text{ mg/dL} (1.00–4.00 \text{ mmol/L})
   \]

2. Accuracy
   
<table>
<thead>
<tr>
<th>Concentration range</th>
<th>Accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.0–7.0 mg/dL (1.00–1.75 mmol/L)</td>
<td>Within ± 0.25 mmol/L</td>
</tr>
<tr>
<td>7.0–16.0 mg/dL (1.75–4.00 mmol/L)</td>
<td>Within ± 15 %</td>
</tr>
</tbody>
</table>

3. Precision
   
<table>
<thead>
<tr>
<th>Concentration range</th>
<th>Precision</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.0–7.0 mg/dL (1.00–1.75 mmol/L)</td>
<td>SD ≤ 0.35 mg/dL (SD ≤ 0.09 mmol/L)</td>
</tr>
<tr>
<td>7.0–16.0 mg/dL (1.75–4.00 mmol/L)</td>
<td>CV ≤ 5 %</td>
</tr>
</tbody>
</table>

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.

**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
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