[Intended use] Quantitative measurement of human CRP (C-reactive protein) concentration in plasma or serum. For in vitro diagnostic use only.

[Principle of the measurement] 10 μL of plasma, serum, or whole blood is diluted 21 fold in advance, on a FUJI DRI-CHEM SLIDE CRP-SIII. The diluted sample, after spreading uniformly in the spreading layer, reacts with amylase (Bacillus sp.)-labeled antibody (Ab-E). Ab-E that did not react with CRP catalyzes the hydrolysis reaction of the substrate, sodium carboxymethyl starch (CMSA). The low molecular weight CMSA generated by the reaction is decomposed to glucose by glucoamylase (GLA), and further, hydrogen peroxide is generated by glucose oxidase (GOD). Hydrogen peroxide oxidizes diarnyliridazole leuc dye by the action of peroxidase (POD) to produce blue color dye. The increase of absorbance by the generated dye is measured at 650 nm by reflectance spectrophotometry and the CRP concentration is calculated according to the installed formula.

CRP + Ab-E ----> Ab-E (active) + CRP:Ab-E (inactive)

CMSA Ab-E ----> Low molecular weight CMSA

Low molecular weight CMSA + H2O2 ----> GLA + Glucose

Glucose + O2 + H2O ----> GOD Glucono lactone + H2O2

Diarnyliridazole leuc dye + H2O2 + POD ----> Blue color dye + 2H2O

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

Sample Spreading layer Reagent layer Transparent support Barcode side

2. Ingredients per slide

- Amylase (Bacillus sp.)-labeled anti-human CRP mouse antibody (monoclonal) 2.1 U
- Sodium carboxymethyl starch 0.055 mg
- Diarnyliridazole leuc dye 0.075 mg (0.15 μmol)
- Glucoamylase 3.0 U
- Glucose oxidase 0.95 U
- Peroxidase 1.9 U

[Additional special equipment] Reagent: FUJI DRI-CHEM CALIBRATOR CP (CRP)
FUJI DRI-CHEM DILUENT DL (CRP)
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 DRI-CHEM DILUENT DL (CRP)
FUJI DRI-CHEM MIXING CUPS or FUJI DRI-CHEM MIXING CUPS S
FUJI DRI-CHEM SLIDE CRP-SIII

[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. When starting to use new lot of CRP test slides, calibration is necessary.
2. Only the required number of slides should be taken out of the refrigerator and stored in the cooled sample rack. Set FUJI DRI-CHEM DILUENT DL (CRP) three-fold.
3. Do not touch the membrane in the center of the slide.
4. A new slide must be used for each measurement. Do not reuse.
5. Handle all patient samples, control serum and used tips carefully as biohazardous samples. Wear protective gloves, glasses and other protective gear for your safety.
6. Used slides are categorized as infectious waste. Make sure to dispose them in the "INSTRUCTION MANUAL" for FUJI DRI-CHEM ANALYZER.
7. Non-specific binding of the antibody in the slide with unknown factor in the sample may cause fluctuation of the data.
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 and EDTA salt can be used as the anticoagulant. When using heparin, less than 40 units should be used per 1 mL of whole blood. When using EDTA salt, less than 10 mg should be used per 1 mL of whole blood. Do not use citric acid, oxalic acid and monooiodoacetic acid. NaF can be used at under 2.5 mg per 1 mL of whole blood.
3. Avoid using plasma or serum with precipitate such as brin.
4. Measure the diluted sample within two hours.
5. When the measured value exceeds the upper limit of the dynamic range, further dilute the X21 diluted sample with FUJI DRI-CHEM DILUENT DL (CRP) three-fold.
6. If results are found outside of the control limits, investigate the cause before submitting reports.

[Reference intervals] As below 0.5 mg/dL, (Below 5 mg/L)

[Performance characteristics] 1. Dynamic range 0.3–7.0 mg/dL (3–70 mg/L)
2. Accuracy Concentration range 0.3–2.0 mg/dL (Within ± 0.4 mg/dL)
Within ± 20 %
3. Precision Concentration range 2.0–7.0 mg/dL (Within ± 2 %)
4. Correlation Correlation was evaluated between latex immunoturbidimetry and FUJI DRI-CHEM system. Latex immunoturbidimetry was run on a HITACHI automated analyzer. This examination was carried out at the laboratory of FUJIFILM Corporation.

[Traceability of calibrators and control materials] C-Reactive protein... IRMM (ERM DA474)

Note: This referencing material is a standard to the reference method of FUJIFILM Corporation and is not directly applicable to FUJI DRI-CHEM SLIDE.

IRMM: Institute for Reference Materials and Measurement
[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