FUJIFILM

Use after reading this "Instructions for Use"

IVD

Date of issue: 1/Apr/2010

Plasma/Serum test for C-reactive protein

FUJI DRI-CHEM SLIDE CRP-SIII

[Warnings and precautions]

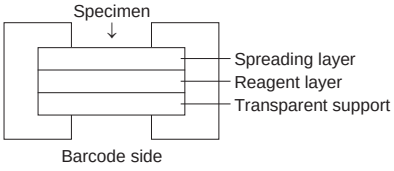
1. Only the required number of slides should be taken out of the refrigerator and warmed up to room temperature before opening the individual packages.
2. Do not touch either the center part of the surface or the back of the slide.
3. A new slide must be used for each measurement. Do not reuse.
4. Handle 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.
6. Nonspecific binding of the antibody in the slide with unknown factor in the specimen may cause fluctuation of the data.

[For the measurement]

1. Calibration is necessary to start using the CRP-SIII slide for the first time.
2. Dilution of the serum or plasma specimen for 21 fold is necessary. Use the diluting solution.
3. As the diluting solution contains 0.02 % sodium azide as a preservative, dilute the residual liquid with plenty of water when disposing.
4. Do not use the diluting solution for any other purpose.
5. When an ampersand (&) is affixed to the measured value, the sample may be an undiluted high glucose or high maltose sample. Measure a high glucose or high maltose sample, after subjecting it to x3 dilution and multiply the measured value by 3.
6. When a yen sign (¥) is affixed to the measured value, the sample has failed to be deposited on the slide for some reason. Repeat the measurement.
7. When a number sign (#) is affixed to the measured value, the calibration has expired or the slide has expired. In the former case, repeat the calibration. In the latter, prepare a new slide.
8. A new slide should be used for each measurement. Do not use a slide on which a specimen has been once spotted.

[Composition of the slide]

1. Multi-layered structure



2. Ingredients per slide

• Amylase (*Bacillus sp.*)-labeled anti-human CRP mouse antibody (monoclonal)	2.1 U
• Sodium carboxymethyl starch	0.55 mg
• Diarylimidazole leuco dye	0.075 mg (0.15 µmol)
• Glucoamylase	3.9 U
• Glucose oxidase	0.95 U
• Peroxidase	1.9 U

[Intended use]

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

[Principle of the measurement]

A serum or a plasma specimen, which is diluted 21 fold in advance, is deposited on a FUJI DRI-CHEM SLIDE CRP-SIII. The deposited specimen, 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 peroxidase oxidizes diarylimidazole leuco dye by the action of peroxidase (POD) to produce blue color dye. The increase of absorbance by the generated dye is measured from 3 min to 5 min at 650 nm by reflective spectrophotometry and the CRP concentration is calculated according to the installed formula.

$$\text{CRP} + \text{Ab-E} \longrightarrow \text{Ab-E (active)} + \text{CRP:Ab-E (inactive)}$$

$$\text{CMSA} \xrightarrow{\text{Ab-E}} \text{Low molecular weight CMSA}$$

$$\text{Low molecular weight CMSA} + H_2O \xrightarrow{\text{GLA}} \text{Glucose}$$

$$\text{Glucose} + O_2 + H_2O \xrightarrow{\text{GOD}} \text{Glucono lactone} + H_2O_2$$

$$\text{Diarylimidazole leuco dye} + H_2O_2 \xrightarrow{\text{POD}} \text{Blue color dye} + 2H_2O$$

[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 CLEAN TIPS or FUJI AUTO TIPS
: FUJI DRI-CHEM MIXING CUPS
: 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 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 monoiodoacetic acid. NaF can be used at under 2.5 mg per 1 mL of whole blood.
3. Avoid using serum or plasma with precipitate such as fibrin.
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. Since the data obtained by dilution may deviate more widely than usual, the data should be treated as estimation.

[Procedure]

(1) Calibration
Calibration is required in the following two cases:
(a) When starting to use CRP-SIII slide for the first time and when the lot number of the slide changes.
Prepare FUJI DRI-CHEM DILUENT DL (CRP) and FUJI DRI-CHEM CALIBRATOR CP (CRP)-1,2,3. Read the FUJI DRI-CHEM QC CARD with card reader and perform calibration following the instructions for the analyzer.
(b) When three months has passed since the previous calibration.
Calibrate using the slide with the same lot number.
Prepare FUJI DRI-CHEM DILUENT DL (CRP) and FUJI DRI-CHEM CALIBRATOR CP (CRP)-1,2,3. Reading the FUJI DRI-CHEM QC CARD is not necessary. Perform calibration following the "INSTRUCTION MANUAL" for the analyzer.
(2) Sample analysis
1. Set slides on FUJI DRI-CHEM ANALYZER.
2. Set a sample tube in the specified sample rack. Set FUJI DRI-CHEM DILUENT DL (CRP) in the specified position. Dilution of the specimen can be done automatically by some of the FUJI DRI-CHEM ANALYZER.
3. Input a sequence No. and a sample ID if appropriate.
4. Press the "START" key to initiate testing.
For further details regarding the operation procedure, consult "INSTRUCTION MANUAL" for FUJI DRI-CHEM ANALYZER.

[Reference interval]

Below 5 mg/L (Below 0.5mg/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 3–70 mg/L (0.3–7.0 mg/dL)

2. Accuracy

Concentration range	Accuracy
3–20 mg/L	Within ± 4 mg/L
20–70 mg/L	Within ± 20 %

3. Precision

Concentration range	Precision
3–20 mg/L	SD ≦ 2 mg/L
20–70 mg/L	CV ≦ 10 %

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.

	n	Slope	Intercept	Correlation coefficient
Serum	60	0.964	0.3	0.998

5. Known interfering substances

(1) 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
Hemoglobin	3000 mg/L
Glucose	22.2 mmol/L
Bilirubin	340 µmol/L
Maltose	11.7 mmol/L
Amylase	600 U/L*
Total protein	40–100 g/L

(2) Samples containing antibody to *Bacillus subtilis* is known to give plus bias.
These results are representative;
• Test condition may have some influence on your results.
• Interferences from other substances are not predictable.
*Near the normal range of CRP concentration.

[Internal quality control]

1. The accuracy and precision of this product can be evaluated with control materials such as pooled human serum. Although the FUJI DRI-CHEM method gives the same results for patient samples as those obtained by other liquid methods, it may give different results for commercially available control sera owing to their matrix effects.
2. Concentration levels of the control materials should be adjusted in accordance with clinically significant levels or individual purpose.
3. The control materials should be measured in the same way as patient samples.
4. We recommend that control limits be established for assayed analytes so as to enable assessment of the control status. For details, consult "Tietz Fundamentals of Clinical Chemistry" 5th edition, Ed. Carl A. Burtis and Edward R. Ashwood, 285-298, 2001; Saunders, ISBN 0-7216-8634-6 or other published references.
5. If results are found outside of the control limits, investigate the cause before submitting reports.

[Traceability of calibrators and control materials]

C-Reactive protein…IRMM (CRM470)
Note: This reference material is applied to the reference method of FUJIFILM Corporation and is not directly applicable to FUJI DRI-CHEM SLIDE.
IRMM: Institute for Reference Materials and Measurement

[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/

EC REP FUJIFILM Europe GmbH
Heesenstr. 31, D-40549 Düsseldorf, GERMANY

FUJIFILM Corporation
26-30, Nishiazabu 2-Chome, Minato-ku, Tokyo, 106-8620, JAPAN

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