This package insert follows the Pharmaceuticals, Medical devices and Other Therapeutic Products Act of Japan.

In Vitro Diagnostics
Marketing Notification No. 13A2X00197218022

** Revised: January 2017 (7th edition)
* Revised: September 2013 (6th edition)

This package insert must be read carefully prior to use.

C-reactive protein assay kit
(Classification No.: 30499000)

QUALIGENT CRP

General Precautions

1. This product is for in vitro diagnostic use, and must not be used for any other purposes.
2. Clinicians should make a comprehensive clinical decision based on assay results in conjunction with clinical symptoms and other examination results.
3. This product should be used only as directed in this package insert. Reliability of results cannot be guaranteed if there are any deviations from the instructions in this package insert.
4. If the reagent accidentally comes in contact with eyes and/or mouth, rinse immediately with ample water as first aid, and consult the doctor if required.
5. Carefully read the operating instructions for each type of automated analyzers prior to using this product. Parameters for each type of analyzers are available, and can be requested from SEKISUI MEDICAL CO., LTD. if required.
6. Perform a quality control test prior to assay to ensure accuracy.

Description (Kit Components) **

Component: Ingredients
CRP Buffer Solution 1:
2-Amino-2-hydroxymethyl-1,3-propanediol buffer
CRP Latex Reagent 2:
Anti-human C-reactive protein mouse monoclonal antibody-coated latex

Intended Use

Measurement of C-reactive protein in serum or plasma

C-reactive protein (CRP) is a protein that is produced as part of the inflammatory response or due to tissue necrosis. It reacts with C-polysaccharide to form a precipitate in the presence of calcium ion. Measurement of CRP is reported to be useful for determining whether or not an inflammatory process is occurring. It is also measured for follow-up and evaluation of the response to treatment.

Assay Principle

1. Assay Principle

In samples, an antigen-antibody reaction occurs between CRP and anti-human C-reactive protein mouse monoclonal antibody-coated latex (anti-CRP antibody-coated latex), resulting in agglutination of the beads. The CRP content is determined by measuring the agglutination as the change of absorbance.

CRP in samples + Anti-CRP antibody-coated latex
⟶ Agglutination by antigen-antibody reaction

2. Features

1) This product has a wide measurement range from low to high concentrations.
2) There is no prozone phenomenon up to high concentration (100 mg/dL).
3) Cells are seldom contaminated.

Procedural Precautions **

1. Properties of Samples and Sampling Methods

1) Samples
Serum and plasma (heparin plasma, EDTA plasma and citrated plasma) may be used.
2) Storage of samples[1)2)]
The isolated serum (plasma) should be tested on the same day.
If samples cannot be measured on the same day, store in a refrigerator for up to 7 days and subsequently freeze at below -20°C.
Bring samples to room temperature (15–30°C) before use.

2. Interfering substances

Assay results are not affected by free bilirubin (up to 50 mg/dL), conjugated bilirubin (up to 50 mg/dL), hemoglobin (up to 1000 mg/dL), or ascorbic acid (100 mg/dL).

3. Others

1) Always use Nanopia CRP Calibrator A for calibration.
2) Precautions for assay range
If the concentration of sample exceeds assay range, dilute the sample with saline and repeat the measurement.

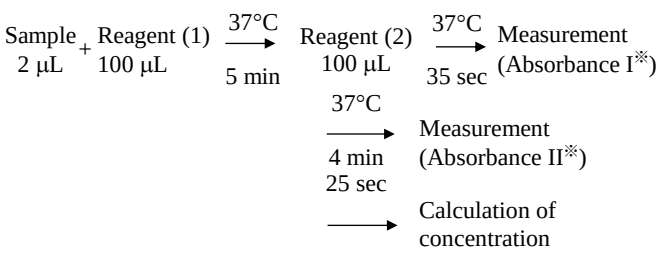
Dosage/Administration (Assay Procedure) * *

1. Preparation of reagents

Reagent (1): CRP Buffer Solution 1 is ready to use.
Reagent (2): CRP Latex Reagent 2 is ready to use.
Before using this product, gently invert the reagent bottles to mix them thoroughly, and check that there are no bubbles.

2. Assay Procedure

This product is compatible with Hitachi 9000 series and LABOSPECT series automated analyzers. Assay procedure is indicated below.



※Absorbance I and II: The difference in absorbance between 800 nm and 570 nm.
Calibration material: Nanopia CRP Calibrator A

(Manufacture's assigned value)
Reagent blank: Purified water or saline

Assessment of Assay Results **

1. **Reference standard range**[3)]
   0.00–0.14 mg/dL
2. There may be reactions or interfering reactions with non-target substances. If assay results appear to be unreliable, repeat the measurement (if necessary, after dilution) or try another analytical methods.

Performance *

1. **Sensitivity**
   1) Reagent blank: change in absorbance being equal to or lower than 0.015
   2) Sensitivity: The change of absorbance is 0.02–0.20 per 1 mg/dL of CRP.
2. **Accuracy:** 90–110% of the expected assay value
3. **Within-run Reproducibility**:
   Coefficient of variation ≤ 5%

(Test methods used for 1. –3. are in-house methods.)

4. **Measurement Range**[7)]: (On a Hitachi 9000 series automated analyzer)
   0.02–42 mg/dL
5. **Correlation**[7)]
   1) Serum N=50 r=0.999 y=1.02x–0.07
   Control method: Approved in vitro diagnostic (Latex turbidimetric assay)
   2) Plasma N=50 r=0.999 y=0.99x+0.03
   Control method: Comparison with the values for plasma samples obtained simultaneously with the serum samples.
6. **Standard Material**
   ERM-DA470/IFCC (IRMM)

Precautions for Use or Handling **

1. Precautions for Handling (to Ensure Safety)

1) All samples used in the test should be handled as a material possibly infected with HIV, HBV, HCV, or other viruses. To prevent infection, use disposable gloves and avoid mouth pipetting during the test.
2) Proclin 300, which possesses skin-irritative potential, is added as an antiseptic agent in the CRP Buffer Solution 1 and CRP Latex Reagent 2. Therefore, if the reagent comes in contact with skin or clothes, rinse immediately with ample water, and consult the doctor if skin irritation develops.

2. Precautions for use

1) This product should be stored as directed, without freezing. Freezing can deteriorate the reagents, which can produce inaccurate results. Therefore, avoid using the reagents which have been previously frozen.
2) Do not use expired reagents. Use of such reagents cannot guarantee the reliability of measurement values.
3) Do not perform the assay under direct sunlight

3. Precautions for Disposal

1) Before disposal, used samples and their containers must be immersed in sodium hypochlorite solution at a concentration of greater than 0.1% for longer than 1 hour or autoclaved at 121ºC for 20 minutes.
2) To prevent infections from spilled samples or solutions containing samples, wipe the spilled area thoroughly with disinfectants such as sodium hypochlorite solution at a concentration of greater than 0.1%.
3) The reagents and treated samples should be discarded as medical waste or industrial waste according to the waste disposal regulations.
4) The reagents should be disposed of in accordance with the Water Pollution Control act or related regulations.

4. Other precautions

1) Do not use the containers for other purposes.
2) Do not take apart the reagent cartridge before use.

Storage and Shelf Life **

1. Storage temperature: 2–10°C
2. Shelf life: 2 years from the date of manufacture
   (The expiration date is printed on the outer package.)

Packaging * *

Name	Package		
QUALIGENT CRP	Set (Cassette for Hitachi 9000 series)	CRP Buffer Solution1 1×15.0 mL CRP Latex Reagent 2 1×15.0 mL	× 2
	L set (Set for Hitachi LABOSPECT series)	CRP Buffer Solution1 1×22 mL CRP Latex Reagent 2 1×22 mL	× 2
	LL set (Set for Hitachi LABOSPECT series)	CRP Buffer Solution 1 1×60 mL CRP Latex Reagent 2 1×60 mL	× 1

References **

1) Medical Practice Editorial Board: Laboratory test guide 2013–2014, 202, Bunkodo, 2013.
2) Comprehensive blood and urine chemical tests and immunological tests (1): Jpn J Clin Med, 57, 197 (1999 extra edition).
3) Kanai M. (supervising editor): Kanai's manual of clinical laboratory medicine. 34th ed. 467, Kanehara Shuppan, 2015.
4) Ujiie S. et al.: J Clin Lab Inst Reag, 26(6), 491, 2003.
5) Onoda C. et al.: J Jpn Soc Clin Labo Autom, 29(5), 612, 2004.
6) Nihonmatsu H. et al.: J Jpn Soc Clin Labo Autom, 30(3), 268, 2005.
7) In house data, SEKISUI MEDICAL CO., LTD.

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Manufacturer **

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