FUJIFILM

CRP-HS II LT

Read this instruction sheet thoroughly before use!

Latex Turbidimetric Immunoassay

For the quantitative determination of C-Reactive Protein (CRP) in Serum or Plasma

CE

462-39493
0318D2

Intended use

CRP-HS II LT is an *in vitro* assay for the quantitative determination of C-reactive protein (CRP) in serum or plasma.

Summary and explanation of the test

C-reactive protein (CRP) was originally discovered by Tillet and Francis in 1930 as a substance in the serum that reacted with the C polysaccharide of pneumococcus. It is a member of the pentraxin family protein which is an annular pentameric disc in shape consisting of 5 units of monomer protein of 224 amino acids. CRP is a plasma protein, an acute phase protein produced by the liver and by adipocytes. Its levels rise dramatically during inflammatory processes due to a stimulating action of IL-6 from macrophages, endothelial cells and T-cells as well as adipocytes.

CRP is used mainly as a marker of inflammation and its levels reflect disease progress or the effectiveness of treatments. The CRP test is used to determine acute inflammation typically from infections, and also to evaluate inflammatory conditions such as rheumatoid arthritis and lupus. Virus infections tend to give a lower CRP level than bacterial infections.[1]

Arterial damage is thought to result from inflammation due to biochemical insults. Recent studies suggest that the elevated basal level of CRP might be a risk factor of cardiovascular disease.2 However, since many factors can cause elevated CRP, it is not a very specific prognostic indicator. A single measurement would be meaningless.

We developed a simple CRP detection reagent the CRP-HS II LT using latex immunoassay method. CRP-HS II LT is applicable to the common automated clinical analyzers.

Principle of the method

When a sample is mixed with Buffer (R1) and Latex Reagent (R2), CRP in the sample combines specifically with the anti-human CRP antibody (goat polyclonal antibody) bound to the latex particles in the Latex Reagent to yield an insoluble aggregate which causes increased turbidity in the solution. The degree of turbidity of solution can be measured optically and is proportional to the concentration of CRP in the patient's sample.

Reagents

Contents and storage conditions

R1:	Buffer	Store at 2–10° C*
R2:	Latex Reagent	Store at 2–10° C* (*Do not freeze)

Ingredients

R1: Buffer	Tris Buffer, pH 7.0 Sodium azide	100 mM 0.09 %
R2: Latex Reagent	Latex sensitized with anti-human CRP Antibody (Goat polyclonal antibody)	adequate dose

Reagent preparation

R1: Use Buffer as supplied.
After opening the bottle, store at 2–10 °C and use within one month.
R2: Use Latex Reagent as supplied.
After opening the bottle, store at 2–10 °C and use within one month.

Specimen collection and preparation

Serum and plasma can be used as specimen.

a) Specimen analysis should be done immediately after collection.
b) Anticoagulants such as heparin, citrate, oxalate, EDTA and sodium fluoride as a glycolytic inhibitor, have no influence on the assay when they are used in their usual amounts.

Performance characteristics

1) **Sensitivity**
   a) When saline is used, the absorbance change is not more than 0.01 (ΔE/min.)
   b) When a control serum of given concentration (CRP 4.0 mg/dL, 37 °C) is assayed, the absorbance change is 0.01–0.12 (ΔE/min).
2) **Accuracy**
   When a sample of known concentration is assayed, the measured value falls within the range of ±10 % of the known concentration.
3) **Reproducibility**
   When a sample is assayed 5 times in a run, CV of the assay value is not more than 10 %.
4) **Minimum detectable level:**
   0.01 mg/dL CRP.

Limitation of the procedure

Measurable range: 0.1–35 mg/dL CRP (In the case of using the standard procedure).

If the CRP value exceeds the upper limit of the measurable range, dilute specimen with saline, repeat the assay and multiply the result by dilution factor. An antigen excess does not occur up to 100 mg/dL.

Correlation

Specimen	Serum
Correlation coefficient	r = 0.9996 (n = 58)
Regression equation	y = 1.0115 x - 0.0809
y	Wako CRP-HS II LT (Latex TIA method)
x	Product of Company A

Interfering substances

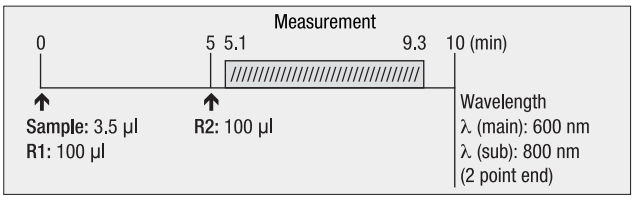
Hemolysis, ascorbic acid and bilirubin do not have significant influences on the assay.

Instruments

The reagent is designed to be used on commercially available automated analyzers. Refer to the operating manual for a description of instrument operation and specifications. A validation on site by the user by way of measurements of adequate controls or patient sera in sufficient number is indispensable.

Standard procedure

Temperature: 37 °C (Hitachi® 917s)



Calibrator
CRP-HS LT Calibrator Set (available separately).
Please refer to the bottom of this page under ordering information.

NOTE: different calibrators for analyzer types!

Application to the various automatic analyzers
Input the parameters according to the instructions of instruments to perform the measurement. Instrument applications are available upon request.

Calibration
The calibration curve is automatically produced in the automated analyzer by plotting absorbance (turbidity) vs. concentration. Use saline or water for blank. Refer to the operator's manual for details on performing calibration. Consult the instrument manufacturer for details.

Standardization

ERM-DA470 provided by Institute for Reference Materials and Measurements (IRMM).

Results

The final results are automatically calculated and printed in concentration. The unit for the concentration is set by the concentration of the calibrator.

In the case of multipoint calibration:

The measuring signal of the test CRP-HS is converted by a non-linear mathematical function into the final concentration. The mathematical model used for the curve fitting and its arithmetic approximation depends on the type of the analyzer used. The validation of the suitability of the used mathematical function lies in the responsibility of the user.

Expected values[3,4]

Serum: 0.3 mg/dL or lower.

Since expected values are affected by age, sex, diet, geographical location and other factors, each laboratory should establish its own expected values for this procedure.

Substances in samples, that may cause non-specific reaction (such as heterophilic antibodies), can give false results. This assay should not be used as the sole determinant for clinical diagnosis.

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Wako

Physical or chemical indications of instability

The presence of precipitates in the reagents or values of control sera outside the manufacturer's acceptable range may be an indication of reagent's instability.

Warnings and precautions

- This product is for in vitro diagnostic use.
- The usage and application of this test is reserved for professional use only. Please refer to respective national and local regulations and legislation.
- Not to be used internally in humans or animals.
- Do not use the reagents in any procedures other than those described herein. Performance cannot be guaranteed if the reagents are used in other procedures or for other purposes.
- Operate the instruments according to operator's manuals under appropriate conditions. Consult the instrument manufacturer for details.
- The results of this assay should be used in conjunction with physician judgment and clinical symptoms.
- Store the reagents under the specified conditions. Do not use reagents past the expiration date stated on each reagent container label.
- Do not use reagents which were frozen in error. Such reagents may give false results.
- After opening the reagents, it is recommended to use them immediately. When the opened reagents are stored, cap the bottles and keep them under the specified conditions.
- Do not use the containers and other materials in the package for any purposes other than those described herein.
- Do not mix different lots of Latex Reagent!
- **Before use of Latex Reagent, homogenize the reagent by slowly turning the bottle upside down.**
- All the devices including reagents and reagent bottles that come in contact with specimens should be considered potentially infectious.
- If the reagents come in contact with the mouth, eyes or skin, wash off immediately with a large amount of water. Consult a physician if necessary.
- The Buffer (R1) contains 0.09 % sodium azide as a stabilizer. Sodium azide may react with copper or lead plumbing to form explosive compounds. Even though the reagent contains minute quantity of sodium azide, drains should be flushed well with a large amount of water, when discarding the reagents.
- The Latex Reagent (R2) contains 3090 mg/L boric acid (540 mg/L as boron).
- When discarding the reagents, dispose of them according to local or national regulations.

CRP-HS II LT (R2) contains components classified as follows according to Regulation (EC) No. 1272/2008: Latex, 5-chloro-2-methyl-2H-isothiazol-3-one [EC No. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC No. 220-239-6] (3:1).

Hazard pictogram

Signal word Danger

Hazard statements

H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H317	May cause an allergic skin reaction.

Precautionary statements

P260	Do not breathe dust.
P281	Use personal protective equipment as required.
P262	Do not get in eyes, on skin, or on clothing.
P303+P361+P353	IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.
P309+P311	If exposed or if you feel unwell: Call a POISON CENTER or doctor/physician.
P304+P341	IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.

Quality control

A quality control program is recommended for all clinical laboratories.

References

1. Whicher, J.: C-reactive protein, in: Clinical Laboratory Diagnostics: use and assessment of clinical laboratory results/ ed. by Lothar Thomas. 1th ed.-Frankfurt/Main, p. 700 - 710 (1998).
2. Clinical Chemistry 55:2 239 - 255 (2009). C-Reactive Protein and Coronary Heart Disease: Predictive Test or Therapeutic Target?
3. Kitasatoigaku: 16, 393 - 401 (1986). (in Japanese)
4. Clinical Chemistry 43:1 52 - 58 (1997). Variability in the measurement of C-reactive protein in healthy subjects: implications for reference intervals and epidemiological applications.

Ordering information

Code No.	Product	Package
462-39493	CRP-HS II LT R1 (Buffer)	R1: 2 x 40 mL
468-39593	CRP-HS II LT R2 (Latex Reagent)	R2: 2 x 40 mL
460-25801	CRP-HS LT Calibrator Set HO (for automated analyzers like Hitachi, AU and Advia Systems)	CAL: 5 conc. x 2 mL
on request	CRP-HS LT Calibrator Set T (for automated analyzers like Architect and Aeroset Systems)	CAL: 7 conc. x 2 mL

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