

Bioway Chemistry Reagent Series

High Sensitivity C-Reactive Protein Reagent Kit

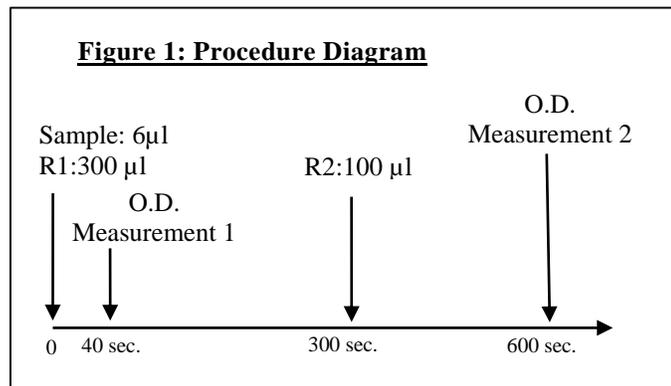
Detection of High Sensitivity CRP in Human Serum on Chemistry Analyzers



Cat. No. R035K11

High Sensitivity CRP Reagent Kit

SUMMARY OF TEST PROCEDURE



*Refer to Figure 1 and the package insert for detail

Table 1: Instrument Parameters*

Calibration method	6 point non-linear	Slope of reaction	increase
Wavelength	Pr:570 nm Se: 800 nm	Sample volume	6 µl
Test method	2 point end	R1 volume	300 µl
Reaction temperature	37°C	R2 volume	100 µl

INTENDED USE

Bioway Chemistry Reagent Series High Sensitivity CRP Reagent Kit (the Kit) is a latex-enhanced immunoturbidimetric assay intended for *in vitro* quantitative detection of C-reactive protein in human serum on automated clinical chemistry analyzers.

SUMMARY AND EXPLANATION

C-reactive protein (CRP) is an acute-phase reactant that reflects low-grade systemic inflammation. In response to an inflammatory stimulus, a rise in CRP level up to 1000 fold may be detected within 6 hours. CRP is sensitive but the increase in CRP is non-specific, thus interpretation of CRP value should be complimented by complete clinical history. CRP measurements may also be performed for early detection of infection in pediatrics and risk assessment of coronary heart disease.

TEST PRINCIPLES

The Kit utilizes latex-enhanced immunoturbidimetry to measure the CRP level in human serum. During the test, CRP in the sample binds with the specific anti-CRP antibody that is coated on latex particles to cause agglutination. The turbidity caused by agglutination is detected optically by chemistry analyzer. The change in absorbance is proportional to the level of CRP in the sample. The actual concentration is obtained by comparing with a calibration curve with known concentrations.

MATERIALS PROVIDED

Reagents:

R1	Glycine buffer solution. Sodium azide < 0.1%
R2	Latex suspension, anti-CRP antibodies, glycine buffer, sodium azide < 0.1%

MATERIALS NEEDED BUT NOT PROVIDED

- Automated chemistry analyzer.
- Hs CRP calibrator set (available for purchase) and control set (commercially available).

INSTRUMENT

The Kit is applicable on most automated chemistry analyzers. Refer to specific instrument application for suggested settings.

STORAGE AND STABILITY

Store the reagents at 2-8°C. Avoid direct sunlight. The Kit is stable through the expiration date when stored properly. R1 and R2 reagents are stable for 1 month at 2-8°C after opening.

PRECAUTIONS

- The Kit is for *in vitro* diagnostic use only. Not for use in humans or animals.
- The instructions must be followed to obtain accurate results.
- Do not use the reagents beyond the expiration date.
- Treat all specimens as infectious. Proper handling and disposal procedures of specimens and test materials should be strictly followed.
- Reagents contain less than 0.1% sodium azide as preservative; avoid contact with skin and eyes, flush with copious amounts of water when disposing.

SPECIMEN COLLECTION AND HANDLING

Follow standard laboratory procedures to collect serum samples. It is recommended to perform test immediately after sample collection. If the test cannot be done immediately, store sample at 2- 8° C for up to 5 days or at -20° C for up to 6 months. Avoid repeated freezing and thawing.

TEST PROCEDURE (see Figure 1)

No pretreatment required for reagents and samples.

Calibration: 6 level calibrator set available for purchase. Recommend using Bioway calibrators for optimal results. Use multi-point non-linear calibration method.

Test procedure: see Figure 1 and Table 1 for instrument parameter setup. Refer to specific instrument application for suggested setting.

- Add 6 µl of sample and 300 µl of R1; mix well and incubate at 37°C.
- Take optical density measurement OD 1 at 40 seconds.
- Add 100 µl of R2, mix well and incubate at 37°C at 300 seconds.
- Take optical density measurement OD 2 at 600 seconds.
- Calculate $\Delta OD = OD 2 - OD 1$

RESULT

The CRP value can be obtained by using the calculated ΔOD to find the corresponding value on a calibration curve prepared with known values.

EXPECTED VALUES

< 3.0 mg/L.

It is recommended for each laboratory to establish its own expected values.

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QUALITY CONTROL

Using commercially available controls with known concentration is recommended before each batch of tests to ensure the test is properly performed and all reagents and the instrument are functional as specified.

LIMITATIONS

1. The Kit is for *in vitro* use on automated chemistry analyzers only.
2. Hemolysis samples may cause inconsistent results.
3. The test result from the Kit should not be used as the only basis for definite diagnosis.

PERFORMANCE CHARACTERISTICS

Linearity: 0 – 350 mg/L ($R \geq 0.990$)

Precision: Within Run: $CV \leq 4\%$;
Run-to-Run: $CV \leq 6\%$

Interference: no interference detected for: ascorbic acid (50 mg/dL), Bilirubin (30 mg/dL), triglycerides (1000 mg/dL), and hemoglobin (500 mg/dL).

Reagent Blank Absorbance: at 570nm wavelength and 10 mm optical diameter, O.D. ≤ 1.20

REFERENCES

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4. Rifai, N. High-sensitivity C-reactive protein: a novel and promising marker of coronary heart disease. Clin Chem 47: 403-11; 2001.
5. Burtis C, Ashwood, ER (ed). Tietz Textbook of clinical Chemistry, 7th ed. Philadelphia, PA; WB Saunders Co; 493; 1999.
6. Wasunna A, et al. C-reactive protein and bacterial infection in preterm infants. Eur J Pediatr 1990; 149: 424-427.

Not Intended for Sale in the United States.

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