C-Reactive Protein Assay Kit (CRP)

Method: Immunoturbidimetric

Cat .No.	Size	Instrument
GB9620M	R1: 3×60 ml R2: 3×20 ml	For Hitachi 7060/7150 & ShimadzuCL7200/8000
GS9621M	R1: 3×60 ml R2: 3×20 ml	For Hitachi 7070 & OlympusAU640/400/600
GB9620M/S	R1:3×20 ml R2:1×20 ml	For Hitachi 7060/7150 & ShimadzuCL7200/8000
Gs9621M/S	R1:3×20 ml R2:1×20 ml	For Hitachi 7070 & OlympusAU640/400/600

INTENDED USE
For the *in vitro* quantitative determination of CRP in serum or plasma samples.

CLINICAL SIGNIFICANCE[1,2]
CRP (C-reactive protein) is an acute phase protein whose concentration is seen to increase as a result of the inflammatory process, most notably in response to pneumococcal (bacterial) infectious, histolytic disease and a variety of disease states. Originally discovered by Tillet et al. in 1930 in patient sera with acute infection, CRP has now come to be used as a marker or general diagnostic indicator of infections and inflammation, in addition to serving as a monitor of patient response to therapy and surgery. Furthermore, regular measurements of CRP in infants can be a useful aid in the early diagnosis of infectious disease.

PRINCIPLE
When an antigen-antibody reaction occurs between CRP in a sample and anti-CRP antiserum, agglutination results. This agglutination is detected as an absorbance change (340 nm), with the magnitude of the change being proportional to the quantity of CRP in the sample. The actual concentration is then determined by interpolation from a calibration curve prepared from calibrators of known concentration.

SPECIMEN COLLECTION
Serum or plasma sample.
CRP remains stable in serum for at least 3 days at 15-25℃, 6 days at 2-8℃ or 6 months at -20℃.

REAGENT COMPOSITION

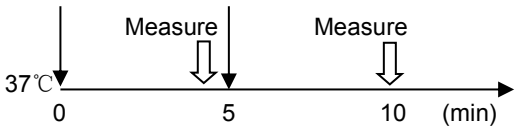
Contents	
Reagent 1 (R1)	
Glycine buffer	50mM
Reagent 2 (R2)	
12% w/v goat anti human CRP anti serum	

STABILITY AND PREPARATION OF REAGENTS
All reagents are ready to use.
Stable up to the expiry date when stored at 2-8℃.

ASSAY PROCEDURE
Test Procedure for Analyzers (HITACHI 917)

Assay Mode: 2 Point End, 16 - 34
Wavelength (main/sub) 340 nm / 700 nm

Sample: 13 µl
R1: 180 µl R2: 60 µl



1. Mix 13 µl sample with 180 µl R1 and incubate at 37℃ for 5 minutes, then read initial absorbance A_1 .
2. Add 60 µl R2 into cuvette, mix and incubate for 5 minutes at 37℃, read final absorbance A_2 .
3. Calculate the absorbance change $\Delta A=A_2-A_1$.

CALIBRATION
Use the calibrator of the assay kit, the calibrator trace to the international reference material ERM-DA474/IFCC, cat NO. GC-CRP9.

CALCULATIONS OF RESULTS
Plot calibrator concentrations against the corresponding ΔA values using graph paper. The concentration of CRP (C-reactive protein) in the sample is obtained by reading of a value from the calibration curve. Do not attempt to extrapolate above or below the range of the calibrators.

QUALITY CONTROL
Using kit GQ-CRP9 as control materials， If the control values fall outside defined limits the following steps should be taken:
1. Check wavelength setting and light source.
2. Ensure that cuvettes are not dirty and that all glassware in use has been cleaned thoroughly.
3. Check water, contaminants, ie. Bacterial growth, may contribute to inaccurate results.
4. Check that assay temperature is accurate.
5. Ensure that reagent pack contents are still within expiry date.

REFERENCE RANGES
Adult: < 0.8 mg/dl.
It is recommended that each laboratory should assign its own normal range as this is dependent upon geographical location.

SPECIFIC PERFORMANCE CHARACTERISTICS

LINEARITY
The method is linear up to 20.5 mg/dL. If sample above this concentration should be diluted with 0.9% NaCl and reassay. Multiply the result by dilution factor.

PRECISION
The CV of the test should be ≤5%.

Intra assay precision		
N=20	Level 1	Level 2
Mean (mg/L)	24.51	49.04
SD	0.25	0.48
CV	1.00%	0.98%

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Inter assay precision		
N=5	Level 1	Level 2
Mean (mg/L)	25.36	50.16
SD	0.44	1.11
CV	1.73%	2.21%

SENSITIVITY

The minimum detectable concentration of CRP with an acceptable level of precision was determined as 0.109 mg/dL.

INTERFERENCE

The following analytes were tested up to the levels indicated and found not to interfere:

Bilirubin: 40 mg/dl
VC: 150 mg/dl
Heparin Sodium 500 mg/dl
Hemoglobin: 100 mg/dl

Chyle blood will cause negative interference to the test.

CORRELATION

This method (Y) was compared with another commercially available method (X) and the following linear regression equation obtained:
Y=1.0028X+0.124, with a correlation coefficient of 0.9995, 70 patient samples were analyzed.

SAFETY PRECAUTIONS AND WARNINGS

1. For *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.
2. Reagent contains Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes or if ingested, seek immediate medical attention.
3. Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of such reagents flush with large volumes of water to prevent azide build up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.
4. Specimens should be treated as potentially infectious (HIV, Hepatitis B virus, Hepatitis C virus, etc.) and handled with appropriate caution.
5. Reagents with different lot numbers should not be interchanged or mixed.

REFERENCES

1. Ng, P.C. et al. Archives of Disease in Childhood (1997), 77(3):221-227
2. Claus et al. Journal of Laboratory and Clinical Medicine (1976), 87(1):120-127

INDEX OF SYMBOLS

	Manufacture
REF	Catalogue Number
LOT	Lot number
	Date of manufacture
	Use by(Expiration date)
IVD	For In-Vitro Diagnostic use only
2℃ 8℃	Stored at 2-8℃
	Attention:See instruction for use
EC REP	Authorized Representative in the European Company

Manufacture：Beijing Strong Biotechnology, Inc.
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