CRP Ultra Wide Range Reagent

CATALOGUE NUMBER: 082 **SIZE:** R1 1 x 30 mL
R2 1 x 20 mL

Note: Changes are highlighted.

INTENDED USE

For the quantitative measurement of C-reactive protein in human serum and lithium heparin or EDTA plasma samples by immunoturbidimetry. Measurement of C-reactive protein is useful in the detection and evaluation of infection, tissue injury and inflammatory disorders.

TEST SUMMARY

CRP (C-reactive protein) is a cytokine-induced, acute phase protein that increases in concentration as result of the inflammatory process, most notably in response to pneumococcal bacterial infections, histolytic disease and a variety of disease states. Originally discovered by Tillet et al in 1930 in patient sera with acute infection, CRP has come to be used as a marker or general diagnostic indicator of infections and inflammation.[1] In healthy persons, serum and plasma levels are usually below 5 mg/L, whereas this threshold is often exceeded within a few hours after an acute inflammatory event, with CRP values reaching 20 to 500 mg/L.[2,3] The assay of CRP is more sensitive than the erythrocyte sedimentation rate (ESR) and the leukocyte count and CRP levels rise and return to reference intervals more rapidly after the disease has subsided.[4]

Increase in CRP values are non-specific and should not be interpreted without a complete clinical assessment.

TEST PRINCIPLE

The CRP Ultra Wide Range Reagent kit is a latex-enhanced turbidimetric *in vitro* immunoassay. CRP in the sample binds to the specific anti-CRP antibody, which has been adsorbed to latex particles and agglutinates. The agglutination is detected as an absorbance change when read on an automated clinical chemistry analyzer (at 570nm). The magnitude of the change is 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 concentrations.

REAGENTS

Composition

Component	Ingredients	Concentration
Reagent 1	Glycine buffer solution	
Reagent 2	Latex particles sensitized with anti-CRP antibodies (rabbit polyclonal)	0.20 w/v %

WARNINGS AND PRECAUTIONS FOR USE

CRP ULTRA WR-R1

IVD

For *in vitro* diagnostic use

℞ ONLY

Warning

Contains: DISODIUM EDTA (CAS No) 6381-92-6

H373 - May cause damage to organs through prolonged or repeated exposure.
P260 - Do not breathe dust/fume/gas/mist/vapors/spray.
P314 - Get medical advice/attention if you feel unwell.
P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

Do not use the reagents beyond the expiration date printed on the label.
Warning: All specimens used in the test should be considered potentially infectious. Universal precautions as they apply to your facility should be used for handling and disposal of materials during and after testing.[5]
CRP Ultra Wide Range Reagents must be used with the CRP Ultra Wide Range Calibrator.
Caution: Reagent 1 and 2 contains < 0.1% sodium azide as an antimicrobial agent. Sodium azide may react with lead and copper plumbing to form potentially explosive metal azide buildup. Flush with copious amounts of water when discarding material.
Powder-free gloves should be worn. Avoid direct skin contact.

See Safety Data Sheet for additional information.

REAGENT PREPARATION, STORAGE AND STABILITY

Reagent 1: Liquid. Mix contents gently prior to use.
Reagent 2: Liquid. Mix contents gently prior to use.

Unopened reagent is stable until the expiration date shown on the label when stored at 2 - 8°C.

REAGENT DETERIORATION

The following may indicate deterioration:
Presence of turbidity or microbial growth.
Inability to recover control values.

DISPOSAL

Reagents must be disposed of in accordance with all Federal, Provincial, State and local regulations.

SPECIMEN

Serum, EDTA plasma, and lithium heparinized plasma are the recommended sample types. Use standard sample collection and preparation methods.

If not analyzed promptly, serum or plasma specimens may be stored at -20°C.

ANALYTICAL SPECIFICITY

Limitations/Interfering Substances

The following do not interfere with the CRP Ultra assay:

Hemoglobin	up to 500 mg/dL
Conjugated bilirubin	up to 30 mg/dL
Unconjugated bilirubin	up to 30 mg/dL
Triglycerides	up to 3000 mg/dL
Intrafat	up to 5%
Rheumatoid factor	up to 560 IU/mL

Samples containing elevated levels of Immunoglobulin M (IgM) or samples from patients with Waldenstrom's Macroglobulinemia may produce unreliable results.

ANALYTICAL PROCEDURE

MATERIALS PROVIDED

CRP Ultra Wide Range Reagents 1 and 2 are required for the measurement of CRP.

Description	Configuration	Catalog Number
CRP Ultra Wide Range Reagent	R1 1 x 30 mL R2 1 x 20 mL	082

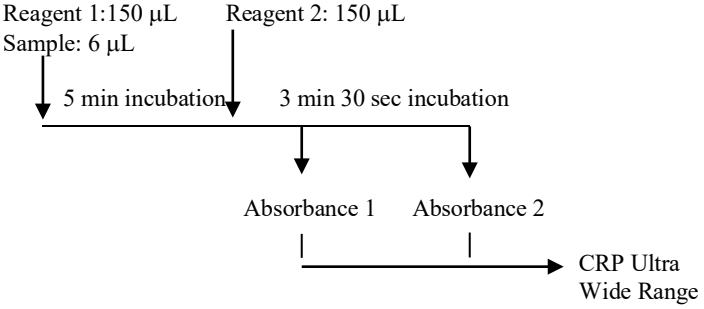
MATERIALS REQUIRED BUT NOT PROVIDED

Description	Configuration	Catalog Number
CRP Ultra Wide Range Calibrator	5 x 2 mL	082B

- Physiological saline to be used as zero calibrator (blank solution)
- Quality Control materials.
- Analyzer capable of running two-reagent chemistries.

ASSAY

Below is a general example of the CRP Ultra Wide Range assay procedure for an automated analyzer. All analyzer applications should be validated.



For assistance with applications on automated analyzers inside the U.S., please contact SEKISUI Diagnostics Technical Services at 800-565-0265.

CALIBRATION

Only the CRP Ultra Wide Range Calibrators should be used to calibrate the CRP Ultra Wide Range assay. The assigned values of the CRP Ultra Wide Range Calibrators are standardized against CRM 470.

Refer to the instrument operator's manual for analyzer specific calibration procedures and for guidance in determining calibration frequency.

Quality Control values should be within the expected ranges.

QUALITY CONTROL

Reliability of test results should be monitored routinely with quality control materials or serum pools that reasonably represent performance with patient specimens. Controls or serum pools should be used to monitor that the reagents are functioning properly and that correct procedures are being followed. An acceptable range for each lot of control material should be established by the laboratory. If control values are not within the expected range, follow normal troubleshooting procedures. If assistance in the U.S. is required, please call SEKISUI Diagnostics Technical Services at 800-565-0265.

Quality control requirements should be established in accordance with local, state and/or federal regulations, or accreditation requirements.

REFERENCE INTERVALS

The normal range of CRP was evaluated in 612 healthy adults (305 men with the age distribution of 20-66 years and 307 women with the age distribution of 19-68 years) using the CRP Ultra Wide Range assay kit. Of the 612 adults, 97% had values <2.5 mg/L and 3% had values from 3.0-4.8 mg/L.

Each laboratory should confirm the reference interval for the patient population it serves.

PERFORMANCE CHARACTERISTICS

RESULTS

Calculation of CRP levels is determined by the automated analyzer, using the prepared calibration curve. To compensate for dilution, multiply the results by the dilution factor to get an accurate result for the pre-diluted sample.

REPORTABLE RANGE

Functional Sensitivity

The functional sensitivity for the CRP Ultra Wide Range reagent was found to be 0.1 mg/L.

The functional sensitivity was determined as the lowest measurable CRP concentration with a CV less than 20%. The functional sensitivity was obtained from 20 replicated measurements of each of the equally spaced serial dilutions of CRP.

Lower Detection Limit

The lower detection limit was found to be 0.05 mg/L. The lower detection limit was assessed using zero standard (saline) and serial dilutions of the lowest CRP Ultra calibrator (10 mg/L). All the samples were assayed in 20 replicates and a mean value and SD were calculated for each sample. The lower detection limit was determined as the CRP concentration of which mean -2SD does not overlap with the mean +2SD of the zero standard (saline).

Specificity

When sera containing known levels of CRP in the assay range were measured, the values obtained for the sera were in the range of the know concentration, plus or minus 10%.

Linearity

The CRP Ultra Wide Range method is linear from 0.05 to 160.0 mg/L.

Specimens above the assay range may be diluted with physiological saline. Multiply the result by the dilution factor to obtain the CRP concentration for the sample.

PRECISION STUDIES

Precision of the CRP Ultra Wide Range Reagent was determined using 3 levels of control material on the Roche Hitachi 917 analyzer.

Within-Run Precision

Control	n	Mean Recovery (mg/L)	Standard Deviation (mg/L)	CV
Level 1	21	0.46	0.03	5.74%
Level 2	21	2.28	0.05	1.99%
Level 3	21	9.81	0.11	1.16%

Total Precision

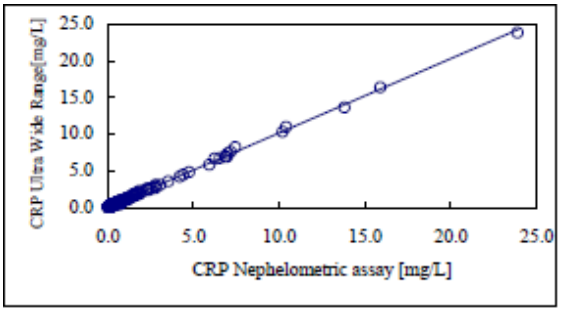
Serum pool/ Control	n	Mean Recovery (mg/L)	Standard Deviation (mg/L)	CV
Level 1	21	0.47	0.03	6.97%
Level 2	21	2.18	0.07	3.34%
Level 3	21	9.76	0.12	1.23%

ACCURACY

Comparative performance studies were conducted using the CRP Ultra Wide Range Reagent on the Roche Hitachi 917 clinical analyzer and a marketed CRP nephelometric assay using 451 male and female serum samples, with concentrations between 0.03 and 23.9 mg/L.

The regression analysis is provided below:

CRP Ultra vs a nephelometric assay(n = 451)	
Slope	1.012
Intercept (units)	0.005
Correlation Coefficient (r)	0.999



Symbols

LOT
Batch Code


Manufactured for


Consult instructions for use

IVD
In vitro diagnostic medical device


Use by date
YYYY-MM-DD or YYYY-MM

REF
Catalog number


Temperature limit


Caution, consult accompanying document


Health Hazard

℞ONLY
Caution: Federal law restricts this device to sale by or on the order of a physician

REFERENCES

1. Tillet WS, Francis T. Serological reactions in pneumonia with a non-protein somatic fraction of pneumococcus. J. Exp. Med. 1930; 52(4): 561-71.
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3. Dixon JS, Bird HA, Sitton NG, Pickup ME, Wright V. C-reactive Protein in the serial assessment of disease activity in rheumatoid arthritis. Scand. J. Rheumatol. 1984; 13(1): 39-44.
4. Kazmierczak M, Sobieska M, Wiktorowicz K, Wysocki H. Changes in acute phase proteins glycosylation profile as a possible prognostic marker if myocardial infarction. Int. J. Cardiol. 1995; 49(3): 201-7.
5. Richardson JH, Barkley WE, Eds. *Biosafety in Microbiological and Biomedical Laboratories.* Washington, DC, US Dept. of Human Health Services, HHS Publication No. (CDC) 84-8395, 1984.

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The Americas
SEKISUI Diagnostics P.E.I. Inc.
70 Watts Avenue
Charlottetown, PE C1E 2B9
Canada
Phone: 800-565-0265
Fax: 902-628-6504
Email: questions@sekisuidiagnostics.com
techservices@sekisuidiagnostics.com

International
SEKISUI Diagnostics (UK) Limited
Liphook Way
Allington, Maidstone
KENT, ME16 0LQ, UK
Email: info@sekisuidiagnostics.com

SEKISUI DIAGNOSTICS

sekisuidiagnostics.com