CORMAY CRP ULTRA 500

DIAGNOSTIC KIT FOR DETERMINATION OF C-REACTIVE PROTEIN CONCENTRATION

Kit name	Kit size	Cat. No
CORMAY CRP ULTRA 500	1 x 1000 ml	6-320

INTRODUCTION

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. CRP 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.

METHOD PRINCIPLE

When an antigen-antibody reaction occurs between CRP in a sample and anti-CRP antibody which has been sensitized to latex particles, agglutination results. This agglutination is detected as an absorbance change (572 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 know concentration.

REAGENTS

Package

1-Reagent	1 x 500 ml
2-Reagent	1 x 500 ml

Reagent preparation and stability

The reagents are ready to use.

The reagents are stable up to the kit expiry date printed on the package when stored at 2-10°C. On board stability of the reagents depends on type of analyser used for analysis. Protect from light and contamination!

Concentrations in the test

suspension of latex particles sensitized with anti-CRP antibodies (rabbit) (pH 7.3)	0.20 w/v%
glycine buffer solution (pH 7.0)	

Warnings and notes

- Product for in vitro diagnostic use only.
- After measurements are taken, reagent bottles should capped and kept at 2-10°C. Care should be taken not to interchange the caps of reagent bottles.
- Reagents with different lot numbers should not be interchanged or mixed.
- The reagents contain sodium azide (< 0.1%) as a preservative. Avoid contact with skin and mucous membranes.

ADDITIONAL EQUIPMENT

- automated clinical chemistry analyzer capable of accommodating two-reagent assays;
- general laboratory equipment;

SPECIMEN

Serum or plasma (Na-EDTA, K-EDTA, Na-Heparin, Li-Heparin, citrate).

If the test cannot be done immediately, the sample should be placed in a tightly sealable container and stored at -20°C. Repeated freezing and thawing should be avoided.

Nevertheless it is recommended to perform the assay with freshly collected samples!

PROCEDURE

wavelength	572 nm
temperature	37°C

These reagents may be used in automatic analysers according to their service manual. Applications for analysers are available on request.

REFERENCE VALUES [3, 4]

serum, plasma	
adults	< 0.5 mg/dl (< 5 mg/l)
children (2 months – 15 years)	0.01 – 0.28 mg/dl (0.1 – 2.8 mg/l)
newborns (0 – 3 weeks)	0.01 – 0.41 mg/dl (0.1 – 4.1 mg/l)

It is recommended for each laboratory to establish its own reference ranges for local population.

QUALITY CONTROL

For internal quality control it is recommended to use the CORMAY IMMUNO-CONTROL I (Cat. No 4-288) with each batch of samples. For the calibration of automatic analysers systems the CORMAY CRP ULTRA CALBRATORS kit (Cat. No 4-276) is recommended. Calibration stability depends on type of analyser used for analysis. The calibration curve should be prepared with change of reagent lot number or as required e.g. quality control findings outside the specified range.

PERFORMANCE CHARACTERISTICS

These metrological characteristics have been obtained using the automatic analysers Biolis 24i Premium and Hitachi 917. Results may vary if a different instrument is used.

- **Sensitivity:** 0.01 mg/dl (0.1 mg/l).
- **Linearity:** up to 32 mg/dl (320 mg/l).
  For higher concentrations dilute the sample with 0.9% NaCl and repeat the assay. Multiply the result by dilution factor.
- **Specificity / Interferences**
  Haemoglobin up to 0.5 g/dl, bilirubin up to 30 mg/dl, triglycerides up to 500 mg/dl and RF up to 500 IU/ml do not interfere with the test.
- **Precision**

Repeatability (run to run) n = 10	Mean [mg/dl]	SD [mg/dl]	CV [%]
level 1	1.87	0.06	3.28
level 2	30.61	0.90	2.94

Reproducibility (day to day) n = 21	Mean [mg/dl]	SD [mg/dl]	CV [%]
level 1	0.047	0.003	6.97
level 2	0.218	0.007	3.34
level 3	0.976	0.012	1.23

- **Method comparison**

A comparison between CRP values determined at Biolis 24i Premium (y) and at Cobas Integra 400 (x) using 38 samples gave following results:

y = 0.9974 x + 0.0887 mg/dl;

R = 0.9982 (R – correlation coefficient)

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

1. Tillet W. S. et al.: Serological reactions in pneumonia with a non-protein somatic fraction of pneumococcus., J. Exp. Med., 52, 561 (1930).
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3. Burtis C.A. Ashwood E.R. Bruns D.E ed. „Tietz Textbook of Clinical Chemistry and Molecular Diagnostics" 4th ed. PA WB Saunders, 2006, p.2263.
4. Schlebusch H, Liappis N, Kalina E, Klein G. High Sensitive CRP and Creatinine: Reference Intervals from Infancyto Childhood. J Lab Med 2002; 26:341-346.

Date of issue: 04. 2013.

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04/13/04/13