hsCRP
For the Quantitative Determination of Human CRP in Serum or Plasma
Cat. No. KAI-160

INTENDED USE
The K-ASSAY® high sensitivity C-reactive protein (hsCRP) assay is for the in vitro quantitative determination of C-reactive protein (CRP) in human serum and plasma on automated clinical chemistry analyzers. Measurement of CRP is of use for the detection and evaluation of inflammatory disorders and associated diseases, infection and tissue injury. For in vitro diagnostic use only.

CLINICAL SIGNIFICANCE
CRP (C-reactive protein, MW = 25,106 Da) 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) 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 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.1

PRINCIPLE OF TEST
The K-ASSAY® hsCRP assay is based on a latex enhanced immunoturbidimetric assay. When an antigen-antibody reaction occurs between CRP in a sample and anti-CRP which has been sensitized to latex particles, agglutination results. This agglutination is detected as an absorbance change (570 nm), with the magnitude of the change being proportional to the quantity of CRP in the sample. The actual concentration is then determined by the interpolation from a calibration curve prepared from calibrators of known concentration.

KIT COMPOSITION
Reagents (Liquid Stable)
R1: Buffer Reagent
Tris(hydroxymethyl)aminomethane (100mM) Sodium Azide (0.09%)
R2: Latex Suspension, pH 6.0
Suspension of latex particles (≤0.5%) coated with goat anti-human CRP
Sodium Azide (0.09%)

PROCEDE
Materials Supplied
Reagent 1 (R-1) Buffer Reagent 1 x 50 mL
Reagent 2 (R-2) Latex Suspension 1 x 10 mL

Materials Required But Not Supplied
Calibrators: K-ASSAY® hsCRP Calibrator, Cat. No. KAI-161C (4 calibrators containing known amounts of human CRP)
Saline, used for diluting serum samples and as a zero calibrator
Controls such as K-ASSAY® hsCRP Controls, Cat. No. K80C-4M

CLINICAL SIGNIFICANCE
Use saline for STD.(1).
Parameters for other automated analyzers are available.

CALIBRATION
We recommend that each laboratory use CRP controls to validate the performance of hsCRP reagents. A set of K-ASSAY® High-Sensitive CRP Controls (Cat. No. K80C-4M) is available separately. The range of acceptable control limits should be established by individual laboratories.

RESULTS
Results are printed out in mg/L. Note: Samples with values greater than 20.0 mg/L should be diluted with saline and rerun. Multiply results by the dilution factor.
A sample with a CRP level exceeding the linearity limit of 20 mg/L should be diluted with 0.9% saline and reassayed incorporating the dilution factor in the calculation of the value.

**PERFORMANCE**

**Precision**

The intra-precision of the **K-ASSAY®** hsCRP Assay was evaluated as follows: in the study, samples containing CRP were tested in duplicate on a Hitachi 917 over 20 days with 2 runs per day.

**Expected Values**

The assay reference interval was determined using serum specimens from 103 apparently healthy adults with ages of 18-62 according to the CLSI C28-A3 guideline. The serum specimens were tested in duplicate by the **K-ASSAY®** hsCRP method. EP Evaluator 8 Software was used to verify the reference interval. The results showed that < 5.0 mg/L CRP was obtained in 95% of the population tested. It is recommended that each laboratory establish a reference interval of normal values for the population it serves.

**REFERENCES**


**INTERFERENCE**

The following substances do not interfere with this assay at the levels tested (less than 10% basis):

- Ascorbic Acid: No interference up to 176 mg/dL
- Bilirubin, Conjugated: No interference up to 40 mg/dL
- Bilirubin, Unconjugated: No interference up to 40 mg/dL
- Hemoglobin: No interference up to 500 mg/dL
- Rheumatoid Factor: No interference up to 400 IU/mL
- Triglycerides: No interference up to 1,000 mg/dL

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