CRP IMMUNOTURBIDIMETRY

C-REACTIVE PROTEIN

Test for the quantitative immunological determination of C-reactive protein in human serum and plasma. Liquid, Dual reagents. Store at 2°C - 8°C. Do not freeze. For in Vitro Diagnostic Use.

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TEST PRINCIPLE

Serum C-reactive protein (CRP) causes agglutination of the latex particles coated with anti-human C-reactive protein. The agglutination of the latex particles is proportional to the CRP concentration and can be measured by turbidimetry.

REAGENT COMPOSITION

Reagent 1:
- Glycine buffer ≤ 0.15 mol/L,
- Sodium azide ≤ 0.99 g/L,
- pH 8.6.

Reagent 2:
- Suspension of latex particles coated with antibody CRP, sodium azide <0.99 g/L.

CRP Calibrator (Standard): C-reactive protein concentration is stated on the vial label. Concentration value is traceable to the Standard Reference Material BCR 470 (Institute for Reference Materials and Measurements, IRMM).

Human serum used in the preparation of the standard has been tested and found to be negative for the presence of antibodies anti-HIV and anti-HCV, as well as for HBs antigen. However, the standard should be handled cautiously as potentially infectious.

REAGENT PREPARATION

The reagent is ready for use.

Working Reagent:
Reagent volumes can be prepared by mixing: 1 mL of Reagent 2 + 4 mL of Reagent 1. Gently mix the Reagent 2 vial before pipetting.

CRP Calibrator (Standard): Reconstitute with 1.00 mL of distilled water. Stable for 3 days at 2-8°C. After reconstitution; freezed samples are stable at least 1 month.

REAGENT STABILITY AND STORAGE

Store at 2-8°C.
Reagents are stable until the expiry date shown on the label when stored tightly closed and if contaminations are prevented during their use.

Indications of deterioration:
Reagents: absorbance of the blank over 0.900 at 540 nm.
Calibrator: Presence of moisture.

SAMPLES

Serum collected by standard procedures.
C-reactive protein in serum is stable for 7 days at 2-8°C.

TEST PROCEDURE

1. Bring the Working Reagent and the instrument to 37°C.
2. Pipette into a cuvette (Notes 1, 2):

| Working Reagent | 1.0 mL |
| Standard (S) or Sample | 7 μL |

3. Mix and insert cuvette into the instrument. Start stopwatch.
4. Record the absorbance at 540 nm after 10 seconds (A₁) and after 2 minutes (A₂).

**CALCULATIONS**
The C-reactive protein concentration in the sample is calculated using the following general formula:

\[
\frac{A₂ - A₁}{A₂ - A₁} \times C \text{ Standard} = C \text{ Sample}
\]

**EXPECTED VALUES**
Serum Adults: Up to 5 mg/L. (0.5 mg/dl)
*It is recommended that each laboratory establish its own reference range.

**QUALITY CONTROL**
It is recommended to use the Rheumatoid Control Serum level I (Ref No:RCN01) and II (Ref No:RCN05) to verify the performance of the measurement procedure. Quality control is recommended every morning. Calibration is not recommended if QC control values are acceptable. Reagent should be calibrated after lot changes.

Calibrator:
We recommend: ARCHEM Calibrator (Standard) Ref.No. TA101S.

*Calibration Stability: It is strongly depend on application to auto analyzers and auto analyzers specification. Calibration stability is 30 days in general.

*Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if controls do not recover within the acceptable tolerances.

**METROLOGICAL CHARACTERISTICS**
Detection limit: 1 mg/L CRP
Linearity limit: 150 mg/L (15 mg/dL) CRP. For higher values dilute sample 1/5 with distilled water and repeat measurement. Linearity may considerably vary depending on the instrument used.

**Repeatability (within run):**
Mean concentration CV n
7.4 mg/L 4.6 % 25
19.0 mg/L 3.7 % 25

**Sensitivity**: 4.3 mA L/mg

**Trueness**: Results obtained with this reagent did not show systematic differences when compared with reference reagents. Details of the comparison experiments are available on request.

**Zone effect**: falsely low values are obtained when CRP is present in the sample at a concentration higher than 250 mg/L.

**Interferences**: Hemoglobin (10 g/L), bilirubin (20 mg/dL), lipemia (triglycerides 10 g/L) and rheumatoid factors (200 IU/mL) do not interfere. Other drugs and substances may interfere. These metrological characteristics have been obtained using an analyzer. Results may vary if a different instrument or a manual procedure are used.

**DIAGNOSTIC CHARACTERISTICS**
C-Reactive Protein (CRP), which is synthesized in the liver, is one of the the most sensitive acute phase reactants after tissue damage or inflammation. CRP activates the classical complement pathway as a response to the inflammatory reaction.

CRP levels in plasma can rise dramatically after myocardial infarction, stress, trauma, infection, inflammation, surgery or neoplastic proliferation. The increase occurs within 24 to 48 hours and the level may be 2000 times normal. An elevation can be expected in virtually all diseases involving tissue damages so the finding is nonspecific.

Clinical diagnosis should not be made on the findings of a single test result, but should integrate both clinical and laboratory data.

**NOTES**
1. If working reagent will be used; shake the Reagent 2 vial gently before pouring its contents into the Reagent 1 bottle. It is advisable to wash the Reagent 2 vial with a small volume of the prepared mixture in order to completely rinse the vial and avoid any losses.

2. These reagents may be used in several automatic analyzers. Instructions for many of them are available on request.

3. The linearity limit depends on the sample to reagent ratio. It will be higher by decreasing the sample volume, although the sensitivity of the test will be proportionally decreased.
Special adaptations for automatic analyzers can supply on request.

Ready, bar-coded pack system supplied for biochemistry auto analyzers.

REFERENCES


SYMBOLS

- IVD: Only for in vitro diagnostic use
- LOT: Lot of manufacturing
- R1: Reagent 1
- R2: Reagent 2
- CONC: Concentration
- INGRED: Reagent Ingredients
- REF: Reference Number (Catalog Number)
- SN: Serial Number
- EXPIRED: Expiration date
- INTERVAL: Storage temperature interval
- DIRECTIONS: Read the directions
- BIOHazard: Biological risk

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