

Reagent kit for immuno-turbidimetric determination of C-reactive protein in human serum.

Principle

Measurement of antigen/antibody reaction by the endpoint method.

Reference values

Serum: 0-1 mg/dl (0-10 mg/l)

It is recommended that each laboratory should assign its own normal range.

Reagents

1. Reagent 1 (R1)

buffer
sodium-azide (0,50 g/l)

2. Reagent 2 (R2)

antisera
sodium-azide (0,50 g/l)

Precaution

Discard cloudy reagent. Avoid contamination by using clean laboratory material (pipettes, plastic vials for analyzers,...). The reagents contain 0.1% sodium azide. To avoid the possible build-up of azide compounds, flush waste-pipes with water after the disposal of undiluted reagent.

Sample

Use fresh serum. The serum can be stored at 2-8 °C for 48 hours. If stored for a longer period, the sample should be frozen.

Procedure

The reagents are ready for use.

Assay conditions

Wavelength: 340 nm
Temperature: 37 °C
Cuvette: 1 cm light path
Read against: sample blank
Method: endpoint (increasing)

Pipette into cuvette

	Blank	Standard	Sample
1. reagent (R1)	240 µl	240 µl	240 µl
Standard	18 µl or	18 µl	
Sample	18 µl		18 µl

Mix, wait 1 minute then add:

2. reagent (R2)		60 µl	60 µl
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Mix and after 7 minutes incubation read the absorbance against the sample blank.

Calibration:

5 level (at the least 3) standard set is necessary for calibration.

S1: Distilled water or physiological salt solution

S2-S6: 5 level standard set

New calibration is recommended:

- after reagent lot change,
- as required following quality control procedures.

Calculation

Based on the calibration curve.

Quality control

A quality control program is recommended for all clinical laboratories. The analysis of control material in both the normal and abnormal ranges with each assay is recommended for monitoring the performance of the procedure. Each laboratory should establish corrective measures to be taken if values fall outside the limits.

PERFORMANCES DATA

The following data were obtained using the Olympus AU600 and (37°C).

Linearity

The test is linear up to 20 mg/dl (200 mg/l).

Sensitivity

It is recommended that each laboratory establishes its own range of sensitivity as this is limited by the sensitivity of the spectrophotometer used.

The estimated value of limit of detection (LOD) is 0,06 mg/l.

Precision

Sample	Reproducibility		
	Average concentration (mg/l)	SD	CV%
sample I	4,56	0,33	7,20
sample II	6,62	0,24	3,62
sample III	7,20	0,51	7,08

Sample	Repeatability		
	Average concentration (mg/l)	SD	CV%
sample I.	3,82	0,28	7,44
sample II.	30,70	0,71	2,33

Correlation

Comparative studies were done to compare our reagent with another commercial C-Reactive protein reagent. The results from these studies are detailed below.

Correlation coefficient: $r=0,9905$

Linear regression: $y (g/l) = 0,903x + 1,366$

(x= other commercial reagent, y= own reagent).

Specificity

Bilirubin 20 mg/dl, triglycerides 2500 mg/dl, haemoglobin 250 mg/dl don't interfere with the assay up to the given levels.

NOTE

Do not use reagents after the expiry date stated on each reagent container label. Do not use products, test solutions and reagents described above for any purpose other than described herein.

For in vitro diagnostic use only.

The following symbols are used on labels

 For in vitro diagnostic use

 Use by (last day of the month)

 Temperature limitation

 Batch Code

 Code

Bibliography

1. Manack, J.R. and Richards, CB., J. Immunol. **20**, 1019 (1971)
2. Ritchie, RF., J. Lab. Clin., Med. **70**, 512 (1967)
3. Pepys MB. et al., Ann. NY Acad. Sci. **389**, 459 (1982)