TURBITEST AA LINE

CRP hs

Latex immunoturbidimetric method for the quantitative determination of C-reactive protein (CRP)

SUMMARY

In 1930, Tillet and Francis found a substance in the serum of patients with pneumococcal infections with the ability to bind the polysaccharide-C of the cell wall of Streptococcus pneumoniae. Years later, this substance was characterized as a non-specific protein related to inflammatory processes and/or acute infectious and consequently was called C-reactive protein (CRP).

Due to the quickness and magnitude of its response, the CRP is recognized as one of the most sensitive markers of acute phase. After myocardial infarction, stress, trauma, infection, inflammation, surgery or neoplastic proliferation, the CRP level may increase within 24 to 48 hours of the episode to 2000-fold over baseline. However, the increase in CRP is non-specific and cannot be interpreted without knowledge of the complete medical history and previous values of the patient.

Determining CRP is clinically useful in screening for infectious and inflammatory diseases; to monitor the activity of inflammatory diseases such as rheumatoid arthritis; for detection of intercurrent infections in systemic lupus erythematosus, leukemia or after surgery; for detecting transplant rejection and for the management of sepsis and neonatal meningitis.

Recent evidence has clearly shown that CRP increases within the reference range is associated with future cardiovascular events in subjects with and without established cardiovascular disease.

Individuals with a baseline CRP in the highest quartile have 2 to 4 times more risk of future myocardial infarction, ischemic stroke, peripheral vascular disease or sudden cardiac death than those individuals with a level of CRP in the lowest quartile.

Comparing with traditional and new markers of coronary artery disease, CRP was shown to be the strongest predictor of future coronary events and when combined with total cholesterol, HDL-cholesterol, LDL-cholesterol it significantly improves its predictive value.

In order to assess the risk of cardiovascular disease in apparently healthy individuals, methods with higher sensitivity than the traditional methods for determining CRP are required.

PRINCIPLE

CRP present in the sample is able to agglutinate latex particles coated with anti-CRP antibodies. The turbidity caused by the agglutination of the latex particles is proportional to the concentration of CRP in the sample and can be measured spectrophotometrically.

PROVIDED REAGENTS

A. Reagent A: glycine buffer solution.
B. Reagent B: suspension of latex particles coated with anti-CRP antibodies.

NON-PROVIDED REAGENTS

- Saline solution.
- PCR Calibrador en serie Turbitest AA from Wiener lab.

INSTRUCTIONS FOR USE

Provided Reagents: ready to use.
The Reagents should be homogenized by gentle inversion several times before use.

WARNING

The reagents are for diagnostic use "in vitro".
All patient samples should be handled as if capable of transmitting infection.
Use the reagents keeping the usual work precautions in the clinical chemistry laboratory.
All reagents and samples should be discarded according to local regulations.

STABILITY AND STORAGE INSTRUCTIONS

Provided Reagents: stable in refrigerator (2-10ºC) until the expiration date shown on the box. Do not freeze.

SAMPLE

Serum or plasma
a) Collection: obtain the sample in the usual manner.
b) Additives: if the sample used is plasma, the use of heparin as anticoagulant is recommended.
c) Known interfering substances: do not use hemolyzed, lipemic or contaminated samples.
Samples with precipitates should be centrifuged prior to testing.
No interference is observed by bilirubin up to 25 mg/dL (250 mg/l), triglycerides up to 3000 mg/dl, hemoglobin up to 1000 mg/dl and rheumatoid factor up to 500 IU/ml.
Refer to the literature of Young for the effects of drugs on the present method.
d) Stability and storage instructions: samples can be stored for 2 months in refrigerator (2-10ºC) or for 3 years frozen (-20ºC). Avoid repeated freezing and thawing.

REQUIRED MATERIAL (non-provided)

Automatic analyzer capable of measuring absorbance at 570 nm.

REACTION CONDITIONS

General parameters for automatic analyzers:

Test	CRP hs
Reaction type	Two-point
Primary wavelength	570 nm
Temperature	37ºC
Sample volume	5 µl
Sample dilution	1/4
Reagent A volume	150 µl
Reagent B volume	150 µl
Incubation time Reagent A + Sample	300”
Reading time - ΔT	180”
Calibration	6 points
PCR Calibrador en serie	1, 3, 4, 5, 6 y 7
Measuring range	0.2 - 100 mg/l*

* The lower limit of the measuring range (quantification limit) will depend on the analyzer used.
Sample and reagent volumes can be varied proportionally without altering calculation factors.

Request the applications for the analyzers marketed by Wiener lab.
Applications not provided by Wiener lab. must be validated.

CALIBRATION

The method has been standardized against the European Reference Material ERM-DA470 (BCR-470) - IRMM (Institute for Reference Materials and Measurements).
To calibrate the application for **CRP hs Turbitest AA**, calibrators 1, 3, 4, 5, 6 from PCR Calibrador en serie Turbitest AA must be used.

QUALITY CONTROL METHOD

Control Inmunológico nivel 1, **Control Inmunológico nivel 2** or **PCR Control N Turbitest AA**.
Controls are processed in the same way as the samples.

REFERENCE VALUES

0 - 5 mg/l
It is generally recommended that each laboratory establish its own reference intervals within its patient population.
It is advisable to perform two or more periodic determinations to follow the development of the disease.

PROCEDURE LIMITATIONS

See Known Interfering Substances under SAMPLE.
It is recommended to perform a complete recalibration when changing reagent lot or when quality control so determines.
In the course of inflammatory processes CRP levels can reach 1000 to 2000 times higher than the normal level. It is recommended to dilute samples 1: 5 or 1:10 in saline solution in case of obtaining high results or suspected severe inflammatory processes.
To preserve the integrity of the reagents all kinds of contaminations should be avoided only using perfectly clean and dry micropipettes for measurement.
Elevated CRP levels are non-specific and cannot be interpreted without a complete patient history.
In assessing CRP as a risk factor for cardiovascular disease values obtained should always be compared to previous values.

PERFORMANCE

a) Inaccuracy: tested using EP5A protocol from CLSI processing controls and samples of different CRP concentrations.

Samples	Mean (mg/l)	SD_{wr} (mg/l)	CV_{wr} (%)	SD_T (mg/l)	CV_T (%)
Control Inmunológico nivel 1	14.3	0.2	1.3	0.3	2.0
Control Inmunológico nivel 2	31.5	0.2	0.6	0.5	1.6
PCR Control N	5.88	0.05	0.9	0.13	2.2
Sample 1	0.63	0.03	4.8	0.03	5.5
Sample 2	18.1	0.1	0.6	0.3	1.9
Sample 3	83.4	0.5	0.6	2.1	2.5

SD_{wr}: intra-run standard deviation
SD_T: total standard deviation
CV_{wr} intra-run coefficient of variation
CV_T: total coefficient of variation

b) Detection limit: is the minimum analyte amount capable of being detected as a non-zero sample and corresponds to the concentration 0.1 mg/L CRP.
c) Measuring range: corresponds to the exactly quantifiable interval of values and ranges from 0.3 mg/l to the last calibration point (approximately 100 mg/l CRP).
d) Prozone effect: no prozone effect is evidenced up to 1000 mg/l CRP.

Performance data were obtained using CT60i analyzer from Wiener lab, therefore these values may vary when a different analyzer or manual technique is used.

WIENER LAB PROVIDES

60 ml: - 1 x 30 ml Reagent A
- 1 x 30 ml Reagent B
(Cat. Nº 1009230)

60 ml: - 1 x 30 ml Reagent A
- 1 x 30 ml Reagent B
(Cat. Nº 1009379)

60 ml: - 1 x 30 ml Reagent A
- 1 x 30 ml Reagent B
(Cat. Nº 1683263)

120 ml: - 1 x 60 ml Reagent A
- 1 x 60 ml Reagent B
(Cat. Nº 1009677)

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SYMBOLS

The following symbols are used in the packaging for Wiener lab. diagnostic reagents kits.

CE	This product fulfills the requirements of the European Directive 98/79 EC for "in vitro" diagnostic medical devices
EC REP	Authorized representative in the European Community
IVD	"In vitro" diagnostic medical device
Σ	Contains sufficient for <n> tests
	Use by
	Temperature limitation (store at)
	Do not freeze
	Biological risks
⟶	Volume after reconstitution
Cont.	Contents
LOT	Batch code
	Manufactured by:
	Harmful
	Corrosive / Caustic
	Irritant
	Consult instructions for use
Calibr.	Calibrator
CONTROL +	Control
CONTROL +	Positive Control
CONTROL −	Negative Control
REF	Catalog number

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