

VITASSAY

CRP

-Turbidimetric Assay-

Rapid test for the quantitative detection of C reactive protein in human serum samples.

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For professional *in vitro* diagnostic use only. Professional trained in turbidimetric techniques.

INTENDED USE

Vitassay CRP–Turbidimetric Assay- is a Turbidimetric assay for the quantitative detection of C reactive protein in human serum samples.

Simple, non-invasive, and highly sensitivity assay for the measurement of CRP in serum samples which is a suitable marker of inflammation process. This product is optimized for several automated analyzer. Test results should be **exclusively be used to evaluate CRP in serum samples.**

INTRODUCTION

C reactive protein is considered to be an acute phase protein, an early indicator of infectious or inflammatory conditions due to its involvement in the innate immune system.

CRP determination is useful to detect acute infections and monitoring of inflammatory processes. Under normal conditions, CRP is found in low concentration (less than 5 mg/L), in those situations CRP increases up to 500 mg/L after 6 hours and peak after 48 hours.

Not only it is a more sensitive determination, since the increase of CRP occurs rapidly, it can be used as a indicator before leukocyte count or erythrocyte sedimentation rate can be. Moreover, they decrease faster to baseline values after healing.

PRINCIPLE

Vitassay CRP Turbidimetric Assay- is a quantitative turbidimetric assay for the detection of C reactive protein in human serum samples.

Vitassay CRP Turbidimetric Assay is based on antigen-antibody agglutination reactions between the antigen contained in the sample and the antibodies anti-antigen coated on polystyrene latex particles.

Such agglutination is measured as an increase in absorbance proportional to the quantity of antigen contained in the sample.

The use of an external control is used to verify that the test is working properly.

PRECAUTIONS

- For professional *in vitro* use only.
- A trained person in Turbidimetric technique and autoanalyzer use is required.
- Do not use after expiration date.
- Do not use the test if its primary containers are damaged.
- Specimens should be considered as potentially hazardous and handle in the same manner as an infectious agent. Avoid contamination errors, follow proper work procedure.

- The reagents after use should be discarded in a proper biohazard container after testing.
- Reagents contain preservatives. Avoid any contact with the skin or mucous membrane. Consult safety data sheet, available on request.
- Components provided in the kit are approved for use with the **Vitassay CRP-Turbidimetric Assay-**. Do not use any other commercial component.
- Follow Good Laboratory Practices, wear protective clothing, use disposal gloves, goggles, and mask. Do not use any other commercial kit component.
- If measure range is exceeding, use the sample diluent to dilute the sample and repeat the assay again.
- Read and follow up the instructions for use provided in the kit.
- Prepare and adjust the analyzer before starting measurements.

STORAGE AND STABILITY

Store as packaged in the original primary container, the reagents should be preserved at refrigerated temperature (2-8°C/35.6-46.4°F), the sample diluent could be preserved refrigerated or at room temperature (2-30°C/35.6-86°F).

The product is stable until the expiration date printed on the label, if they have been preserved under the recommended conditions.

Do not freeze and keep away from the sunlight.

MATERIALS

MATERIAL PROVIDED	MATERIAL REQUIRED BUT NOT PROVIDED
<ul style="list-style-type: none"> ▪ Reagent R1 (Enhancer buffer) ▪ Reagent R2 (Latex particles) ▪ Calibrator 0 ▪ Calibrator 1 ▪ Calibrator 2 ▪ Control 1 ▪ Instruction for use. ▪ Certificate of analysis 	<ul style="list-style-type: none"> ▪ Specimen collection container. ▪ Disposable gloves and laboratory equipment. ▪ Extraction needle for sample collection.

SPECIMEN COLLECTION

Collect sufficient quantity of human blood. Blood samples should be collected in clean and dry containers.

In order to get the serum, blood samples must be centrifugated. These samples can be directly analyzed or stored in the refrigerator (2-8°C/35.6-46.4°F) for 7 days prior to testing.

PROCEDURE

Reagent R1 y Reagent R2 are ready to use.

Calibration curve

For calibration only use CRP Calibrator: Cal0, Cal1 and Cal2. Contain CRP at different concentrations indicated on the label of each of the vials.

	Reference	Calibrator 1	Calibrator 2
Conc.	0 µg/mL	20 µg/mL	150 µg/mL
Vol.	300µL	300µL	300µL

Reagents are ready to use. The frequency in the realization of the calibration curve must be established by the end user in the function of the criteria established for the clinical laboratory.

Note: See section quality control.

Analytical procedure

Measure range: 0-20 µg/mL of C reactive protein.

Procedure	Steps	
R1 addition	200 µL	0 s
Sample addition	2 µL	10 s
R2 addition	50µL	300 s
Blank measure	570 nm	310 s
Mainly measure	570 nm	610 s

*Dat obtained by Biolis 24i analyser (Tokio Boeki).

INTERPRETATION OF RESULTS

Positive results: higher or equal than the Cut-off fixed by the clinical laboratory.

Recommended cut-off values: 10.0 µg of CRP/mL of serum for diagnostics .

Positive results determine the abnormal level of CRP in serum samples.

Cut-off value of **Vitassay CRP -Turbidimetric Assay**:

CRP values equal or lowers than 10.0 µg of CRP/mL of serum are considered normal and not an indicative of inflammation. Values above this value are indicative of the onset of an inflammatory reaction or infection.

QUALITY CONTROL

Vitassay CRP -Turbidimetric Assay C1 Control is ready to use.

CRP Control 1: is liquid control at a certain concentration of CRP. Concentration is indicated on the label of the vial.

The use of control is recommended to verify test precision.

If the obtain results are out of the tolerance range, the equipment, the reagents or the technique must be reviewed. If the problems persists, stop using the reagents and contact your distributor.

LIMITATIONS

- **Vitassay CRP -Turbidimetric Assay** should be only used in human serum samples.
- The quality of **Vitassay CRP-Turbidimetric Assay** depends on the quality of the sample; Proper serum specimens must be obtained.
- Values up to 10 µg/mL should be reviewed by the specialist.

EXPECTED VALUES

Our reference rangue is established as:

- Concentration values lower than 10.0 µg of CRP/mL indicate mild infections and inflammations.
- Concentration values between 10.0 to 40.0 µg of CRP/mL are considered as medium risk, indicate moderate and more severe inflammations.
- Concentration values higher than 40.0 µg of CRP/mL are considered as high risk.

PERFORMANCE CHARACTERISTICS

Analytical sensitivity:

Quantification limit: 1.00 µg/mL of C reactive protein.

Prozone:

Lower concentrations of 640 µg /mL of serum do not show prozone effect and no false negative results have been observed. Studies using higher concentrations have not been carried out.

Within-Run Precision

	Low (20.0 µg/mL)	High (150.0 µg/mL)
N	20	20
Media (µg/mL)	16.6	151.7
SD (µg/mL)	1.8	9.0
CV (%)	11.0	6.0

*Data obtained by the analyzer Biolis 24i (Tokio Boeki)

Cross reactivity:

No cross reactivity was detected against:

Paracetamol	None	Urea	None
Human transferrin	None	Bilirubin	None
Human hemoglobin	None		

Interferences:












No interference were founded against:

Bovine serum albumin	None	Octanoic acid	None
Ascorbic acid	None	Butyric acid	None
Sucrose	None		

REFERENCES

1. Clyne B, Olshaker JS. The C-reactive protein. J Emerg Med. 1999;17(6):1019-25.
2. Gotschlich EC. C-Reactive Protein: A Historical Overview. Annals of the New York Academy of Sciences. 1989;557(1):9-18.
3. Kindmark CO. The concentration of c-reactive protein in sera from healthy individuals. Scand J Clin Lab Invest. 1972;29(4):407-11.

SYMBOLS FOR IVD COMPONENTS AND REAGENTS

	in vitro diagnostic device		Keep dry
	Consult instructions for use		Temperature limitation
	Use by		Manufacturer
	Batch code		Contains sufficient for <n> test
	Sample diluent		Catalogue number
	Keep out of the sunlight		

ADAPTED EQUIPMENT

- Biolis 24i/Biolis 50i (Tokio Boeki)
- BS200 (Mindray)
- Chemwell-T (Awareness)



