VITASSAY

High Sens-CRP
-Turbidimetric Assay-

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

IUE-7115006 Ed00 May 2022

CE IVD EN

Vitassay

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

INTENDED USE

Vitassay High Sens-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 High sensitivity 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. One of the most common causes of cardiovascular diseases are inflammatory conditions, thus CRP can appreciate cardiovascular risk when analysed by sensitive assays, that are able to measure extremely low concentrations of CRP, called high sensitivity CRP.

Cardiovascular disease are the main cause of death in developed countries, for that reason, the detection of biomarkers as high sensitivity C reactive protein is of utmost importance.

PRINCIPLE

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

Vitassay High Sens-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 High Sens-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 (2-8ºC/35.6-46.4ºF), the sample diluent could be preserved refrigerated or at room temperature (2-30ºC/35.6-86ºF).

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
▪ Reagent R1 (Enhancer buffer) ▪ Reagent R2 (Latex particles) ▪ Calibrator 0 ▪ Calibrator 1 ▪ Calibrator 2 ▪ Control 1 ▪ Instruction for use. ▪ Certificate of analysis	▪ 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 (2-8ºC/35.6-46.4ºF) for 7 days prior to testing.

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PROCEDURE

Reagent R1 y Reagent R2 are ready to use.

Calibration curve

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

	Reference	Calibrator 1	Calibrator 2
Conc.	0 µg/mL	5 µg/mL	20 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: 5.0 µg of CRP/mL of serum for diagnostics.

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

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

CRP values equal or lowers than 3.0 µg of CRP/mL of serum are considered normal and not an indicative of inflammation. Values between 3.0-5.0 µg of CRP/mL are considered medium risk of inflammation and values higher than 5.0 µg of CRP/mL of serum are indicative of a severe inflammation.

QUALITY CONTROL

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

High Sens-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 distribuitor.

LIMITATIONS

- **Vitassay High Sens-CRP -Turbidimetric Assay** should be only used in human serum samples.
- The quality of **Vitassay High Sens-CRP-Turbidimetric Assay** depends on the quality of the sample; Proper serum specimens must be obtained.
- Values up to 3 µg/mL should be reviewed by the specialist.

EXPECTED VALUES

Our reference rangue is established as:

- Concentration values lower than 3.0 µg of CRP/mL are considered as a low cardiovascular risk.
- Concentration values between 3.0 to 5.0 µg of CRP/mL are considered as medium risk.
- Concentration values higher than 5.0 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 (5.0 µg/mL)	High (20.0 µg/mL)
N	**20**	**20**
Media (µg/mL)	**3.6**	**17.5**
SD (µg/mL)	**0.4**	**1.3**
CV (%)	**11.0**	**8.0**

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

Cross reactivity:

No cross reactivity was detected against:

Paracetamol	*None*	*Urea*	*None*
Human transferrin	*None*	*Billirubin*	*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

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

ADAPTED EQUIPMENT

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

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