HS-CRP-CHECK-1

High sensitive Quantitative determination of C-Reactive Protein in whole blood, plasma or serum samples

- FOR EASY READER® OR EASY READER+® USE ONLY -

Ref. HS34091-3L (20 tests) & Ref. HS34091-3L-10T

- PATENTED TEST -

I- PRINCIPLE

C-reactive protein (CRP) is a non-specific, acute-phase reactant used to diagnose bacterial infectious disease and inflammatory disorders, such as acute rheumatic fever and rheumatoid arthritis (1).

Published studies (2,3) suggest that cardiovascular disease (CVD) and peripheral vascular disease (PVD) are inflammatory processes due to myocardial necrosis and can result in low levels of inflammatory markers such as C-reactive protein. Therefore the determination of CRP level can be helpful to predict a healthy person's risk of cardiovascular disease, heart attacks and strokes. The level of CRP correlates with peak levels of the MB isoenzyme of creatine kinase, but CRP peaks occur 1 to 3 days later. Failure of CRP to normalise may indicate ongoing damage to the heart tissue. Levels are not elevated in patients with angina.

The measurement of CRP does not indicate where is occurring the inflammation which may come from cells in the fatty deposits in arterial walls reflecting the process of atherosclerosis. The American Heart Association (AHA) and Centers for Disease control (CDC) have defined risk groups as follows (4):

Low risk: less than 1.0 (µg/mL or mg/L).
Average risk: 1.0 – 3.0 (µg/mL or mg/L).
High risk: Above 3.0 (µg/mL or mg/L).

Studies conducted, in the United States and Europe, on subjects which did not have CVD at entry but may have had other risk factors (eg, hypercholesterolemia, hypertension, diabetes, tobacco use) have identified CRP as a strong, independent risk factor for CVD (5). CRP is classically measured using latex agglutination and nephelometric or turbidimetric methods. HS-CRP-CHECK-1 is a rapid quantitative screening test for the detection of CRP in serum, plasma or whole blood samples.

The method relies on competitive binding of gold conjugate anti-CRP monoclonal antibodies with free CRP present in the sample and membrane coated CRP.

Depending on CRP concentration in the sample, different lines will appear on the test, allowing the quantitative measurement of CRP in serum, plasma or whole blood samples, when used in combination with the EASY READER® or EASY READER+® rapid test readers.

II-HS-CRP-CHECK-1 KIT COMPONENTS

Each kit contains everything needed to perform 10 or 20 tests.

1- HS-CRP-CHECK-1 test devices:	10	20
2- Plastic tubes containing 2 mL diluent:	10	20
3- Instruction leaflet:	1	1

4- Controls (Optional):

Positive control (ref. V340HS) and Negative control (ref. V341HS): a freeze-dried preparation of a non-infectious compound in diluted human serum, tested and found negative for anti-HIV, anti-HCV and HBs antigen, containing 0.05 % sodium azide is optionally available as a positive and negative control (1x 0.50 mL). The concentration range is indicated on the vial label.

III- MATERIAL REQUIRED BUT NOT PROVIDED

1- Automatic precision pipette for sampling (25 µL for serum/plasma samples or 50 µL for whole blood samples).
2- Timer.

IV- STORAGE AND STABILITY

1- All HS-CRP-CHECK-1 kit components, including optional control before reconstitution with distilled water, should be stored at any temperature between +4°C and +30°C in the sealed pouch.
2- **Do not freeze the test kit**.
3- The HS-CRP-CHECK-1 kit is stable until the expiry date stated on the package label.

V- PRECAUTIONS

1- This test is designed for *in vitro* diagnostic use and professional use only.
2- Read carefully the instructions before using this test.
3- Handle all specimens as if they contained infectious agents. When the assay procedure is completed, dispose of specimens carefully after autoclaving them for at least one hour. Alternatively, they can be treated with 0.5% to 1% solution of sodium hypochlorite for one hour before disposal.
4- Wear protective clothing such as laboratory coats and disposable gloves while assaying samples.
5- Do not eat, drink or smoke in the area where specimens and kit reagents are handled.
6- Avoid any contact between hands and eyes or nose during specimen collection and testing.
7- Do not use beyond the expiry date which appears on the package label.
8- Do not use a test from a damaged protective wrapper.

VI- SPECIMEN COLLECTION AND PREPARATION

1- HS-CRP-CHECK-1 rapid test is performed on human serum, plasma or whole blood.
2- The specimen should be collected under the standard laboratory conditions (aseptically in such a way as to avoid haemolysis).
2- If anticoagulant is needed, only citrate, EDTA or heparin should be used.
4- Each specimen should be treated as if potentially infectious.
5- Whole blood samples should be tested immediately (< 4 hours). Finger prick samples should be assayed just after collection.
6- If the test is to be run within 48 hours after collection the specimen should be stored in the refrigerator (+2°C to +8°C). If testing is delayed more than 48 hours, the specimen should be frozen. The frozen specimen must be completely thawed, thoroughly mixed and brought to room temperature prior to testing. Avoid repeated freezing and thawing.
7- In case of cloudiness, high viscosity or presence of particulate matter into the serum specimen, it should be diluted with equal volume (V/V) of diluting buffer (not provided but available upon request) before testing.

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VII. ASSAY PROCEDURE

IMPORTANT: Switch the reader on and allow it to warm up for at least 30 minutes before performing any measurements.

A) Preparation

a) Controls (no dilution required)

1- Add 0.5 mL of distilled or tap water to the vial using a lab pipette and wait for 15 minutes after freeze-dried dissolving.

2- The expected concentration (**in µg/mL or mg/L**) is indicated on the vial label. The concentrations levels can change slightly depending on lot number.

3- **The reconstituted vial should be kept between +2°C and +8°C and should be used within 7 days after reconstitution.**

b) Samples (dilution required)

1- Label one plastic tube containing the diluent with patient's name.
2- Unscrew the tube.
3- Using a precision pipette, add 25 µL of serum/plasma sample into the tube containing the diluent. If whole blood is to be used, add 50 µL of sample into the tube.
4- Screw back again the tube.
5- Mix well by inverting upside-down the tube several times.

B) Testing

Follow the instructions below or refer to the picture n°1.

– Allow samples and HS-CRP-CHECK-1 test devices to come to room temperature prior to testing.
– Remove the reaction device from its protective wrapper by tearing along the split.
– Label device with the patient's name or control number.

a) **Controls:**

1- Using a precision pipette, dispense **150 µL of reconstituted control** into the sample well of the cassette (▷).

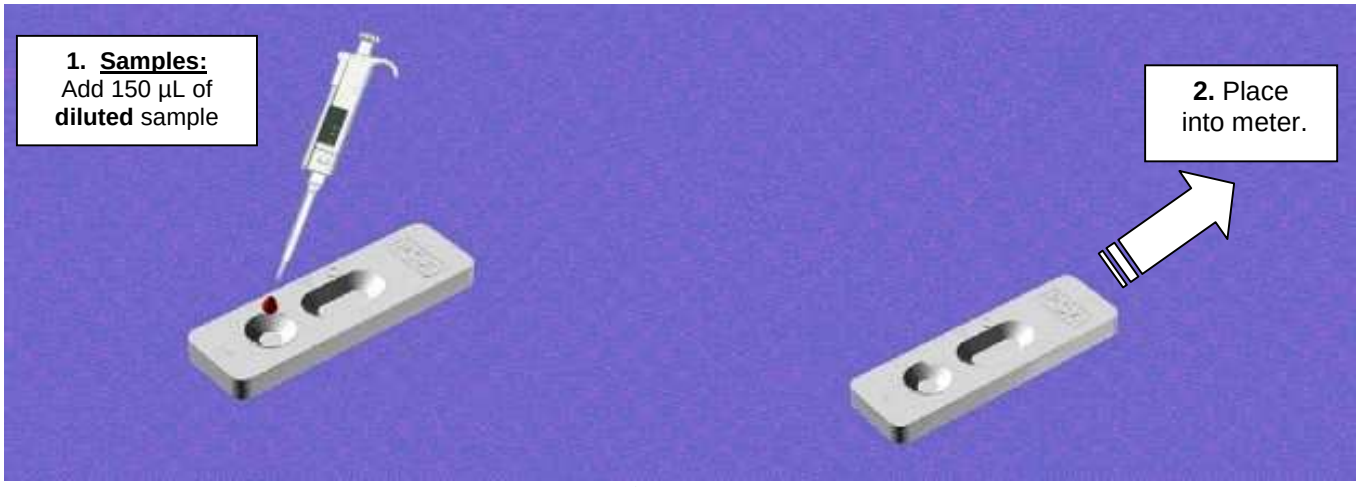
2- Read the result **(in µg/mL or mg/L**) after 10 minutes, either using the immediate or countdown reading mode (See MD-361018 Part V. Assay procedure).

b) **Samples:**

1- Using a precision pipette, add **150µL of diluted sample (preparation described in VII. b**) into the **sample well (▷)** of the cassette.

2- Read the result (**in µg/mL or mg/L**) after 10 minutes, either using the immediate or countdown reading mode (See corresponding leaflet).

For general instructions describing how to use the EASY READER® or EASY READER+® meters, refer to the corresponding leaflet.



Picture n°1

VIII- PERFORMANCES CHARACTERISTICS

a) Linearity

The measuring range is 0.1 to 400 µg/mL or mg/L and results will be given as per the table hereunder.

CRP concentration (µg/mL or mg/L)	Reader results (µg/mL or mg/L)
0 – 0.1	"< 0.1mg/L"
0.1 - 400	Quantitative results
400 and over	"> 400 mg/L"

The linear measuring range is 0.1 – 400 mg/L. In case the CRP concentration of the sample is over 400 mg/L, a second measurement with a diluted sample should be performed if the exact sample CRP concentration is needed.

b) Accuracy

A study has been performed using a range of standards prepared by dilution of international W.H.O. standard Nr 85-506 in a serum depleted in CRP and covering a range of 0 to 400 mg/L.

Optical densities expressed as a function of CRP concentrations are described by following curve:

$$Y = \frac{498.85\ x}{(52.75+x)} \quad (r = 0.99).$$

c) Sensitivity

The HS-CRP-CHECK-1 is allowing to detect CRP concentration of 0.1 mg/L, according to WHO 1st CRP International Standard Nr 85-506.

d) Precision

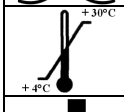
A panel of 57 human sera pre-assayed on ROCHE COBAS® analyser has been evaluated using the HS-CRP-CHECK-1 quantitative rapid device. Results are measured with the Easy Reader photometer. A correlation of 99% has been established between VEDALAB rapid test and ROCHE reagent using HS-CRP-CHECK-1.

IX- LIMITATIONS

1- As HS-CRP tests are measuring a marker of inflammation, it is important that any person having the tests be healthy in order for the tests to be of any value in predicting the risk of coronary disease or heart attack.
2- Since the HS-CRP and CRP tests identify the same molecule, people with chronic inflammation such as those with arthritis should not have HS-CRP levels measured. Their CRP levels will be very high due to the arthritis and will not give the information of a potential CVD. As well testing should not be performed for at least two weeks following the resolution of a known acute inflammation or infection.
3- Although several high-sensitivity CRP assays are currently available for assessing CVD risk, some variation between assays has been observed (6). It is optimal to confirm results obtained with the rapid test using another assay (nephelometry, EIA…).
4- As it is the case with any diagnostic procedure, the physician should evaluate the data obtained using this kit in the light of the other clinical information available.
5- Use only fresh whole blood samples (< 4 hours) when test is performed with blood samples. Finger prick samples should be assayed just after collection.
6- This format of test is to be used only with VEDALAB rapid test readers (EASY READER® or EASY READER+®).
7- If the reading time (10 minutes) is not strictly respected, wrong results will be obtained.
8- This format of test should not be used for visual reading.
9- As it is true for any diagnostic method or for any measurements through analysers, there is a variability of the obtained result. Therefore, a confidence range of +/- 25% should be considered for the final value and for the clinical significance of the result.
10-Do not use the reader for measurements before at least 30 minutes warm-up after having switched on.

X- BIBLIOGRAPHY

1-Van Lente F, "The Diagnostic Utility of C-Reactive Protein", Hum Pathol, 1982 13(12) : 1061-3.
2- Ridker, P.M.. Clinical application of C-reactive protein for cardiovascular disease detection and prevention. Circulation. 2003, 107 : 363-369.
3- Ridker, P.M., Buring, J.E., Cool, N.R., Rifai, N. C-reactive protein, the metabolic syndrome, and risk of incident cardiovascular events. Circulation. 2003, 107 : 391-397.
4- Pearson, T., Mensah, G., Alexander, R et al. Markers of inflammation and cardiovascular disease : Application to clinical and public health practice. Circulation. 2003, 107 : 499-511.
5-Morrow, D.A., Ridker, P.M. High-sensitivity C-reactive protein (hs-CRP) : A novel risk marker in cardiovascular disease. Prev. Cardiol. 1999, 1:13-16,41.
6- Roberts, W.L., Sedrick, R., Moulton, L., Spencer, A., Rifai, N. Evaluation of four automated high-sensitivity C-reactive protein methods : Implications for clinical and epidemiological applications. Clin. Chem. 2000, 46(4) : 461-468.

	Read the instructions before use		For *in vitro* diagnostic use
	Temperature limitations		Do not reuse
	Manufacturer		

 Manufactured by VEDALAB - France