WARRANTY

This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose. In the event of performance changes or product malfunction, please contact manufacturer.

BIBLIOGRAPHY

1. Zhao heping, xiao qunfeng. Quantitative determination of c-reactive protein. Journal of practical medicine, 2006, 13(21):3908.
2. Yang zhenxiu. Detection of c-reactive protein. Shanghai journal of medical examinations, 1999, 14(5):261-263.

SYMBOL KEYS

Temperature Limitation	Consult Instructions for use	Date of Manufacture	Do not reuse
Manufacturer	IVD *In vitro* Diagnostic Medical Device	This side up	Use by
Σ Contains sufficient for <n> tests	REF Catalogue Number	LOT Batch Number / Lot Number	DEVICE Device

Manufactured by:

Zephyr Biomedicals

A Division of Tulip Diagnostics (P) Ltd.

M 46-47, Phase III B, Verna Industrial Estate, Verna, Goa - 403 722, INDIA.

Regd. Office: Gitanjali, Tulip Block, Dr. Antonio Do Rego Bagh, Alto Santacruz, Bambolim Complex P.O., Goa - 403 202, INDIA.

0123/VER-02

FIAcheck™

CRP

Fluorescence Immunoassay for Quantitative determination of CRP in Human Serum, Plasma or Whole blood

DEVICE

FOR IN VITRO DIAGNOSTIC USE ONLY

Store at 4°C to 30°C

INTENDED USE

FIAcheck™ CRP Fluorescence Immunoassay is intended for the in-vitro quantitative measurement of CRP in human serum, plasma or whole blood.

INTRODUCTION

C-reactive protein (CRP) is an acute phase protein synthesized in the liver. Its rate of synthesis increases within hours of acute injury or the onset of inflammation and may reach as high as 20 times the normal levels. A rapid fall of CRP indicates recovery. The degree of elevation of CRP level directly reflects the mass or activity of inflamed tissue. And its ability to fall to normal levels on resolution of the condition renders quantified CRP values to be a good indicator to allow rapid selection of appropriate anti-inflammatory therapy in several rheumatic diseases, which are, clinically difficult to assess.

Apart from indicating inflammatory disorders, CRP levels helps in differential diagnosis, in the management of neonatal septicemia and meningitis where standard microbiological investigations are difficult. CRP levels rise invariably after major surgery, but fall to normal within 7-10 days. Absence of this fall is indicative of septic or inflammatory postoperative complications. Serum CRP concentration provides useful information in patients with myocardial infarction there being an excellent correlation between peak levels of CRP and creatine phosphokinase.

PRINCIPLE OF THE TEST

FIAcheck™ CRP is based on principle of agglutination of antibodies/anti-sera with respective antigen in immuno-chromatographic format using fluorophores as signal generators. The **FIAcheck™ CRP** test device is coated with immobilized CRP mouse monoclonal antibody 1 on the test line, sheep anti chicken IgY in control line and a mixture of CRP mouse monoclonal antibody 2 and Chicken IgY labeled with fluorescent microspheres on the binding pad.

CRP in sample binds to the CRP mouse monoclonal antibody 2 labeled with fluorescent microspheres in the binding pad.

The fluorescent labeled Ag-Ab complex moves forward due to capillary action and is captured by the immobilized CRP mouse monoclonal antibody 1 forming a double antibody sandwich and produces the test line. Chicken IgY labelled with fluorescent microspheres binds with sheep anti chicken IgY to produce the control line. When the **FIAcheck™** test device is inserted in the **FIAcheck™** analyzer, it scans both the test line and control line. The ratio of the two fluorescence values is used to calculate the concentration of the analyte present in the sample.

MATERIALS AND COMPONENTS

Materials provided with the test kits:

- **FIAcheck™ CRP** test device in a sealed pouch with desiccant.
- QR Code card for calibration.
- Sample Diluent. Ready to use.
- Empty vials for sample dilution.

Materials required but not provided

- Precision pipettes: 5µl, 100-1000µl
- Disposable pipette tips
- Disposable Gloves
- **FIAcheck™** Analyzer (Time Resolved Fluorescence Immunoassay Analyzer)
- Digital Thermometer
- Stopwatch

STORAGE AND STABILITY

1. **FIAcheck™ CRP** kit is stable at 4°C to 30°C upto expiry date printed on the label. DO NOT FREEZE.
2. **FIAcheck™** Test device should be used within 30 minutes once the foil pouch is opened.
3. If the colour of the desiccant has changed from blue to pink or colourless at the time of opening the pouch, kindly discard the device and use another device.
4. Once opened, the sample diluent can be stored between 4°C to 30°C for remaining duration of shelf life.

SAMPLE COLLECTION

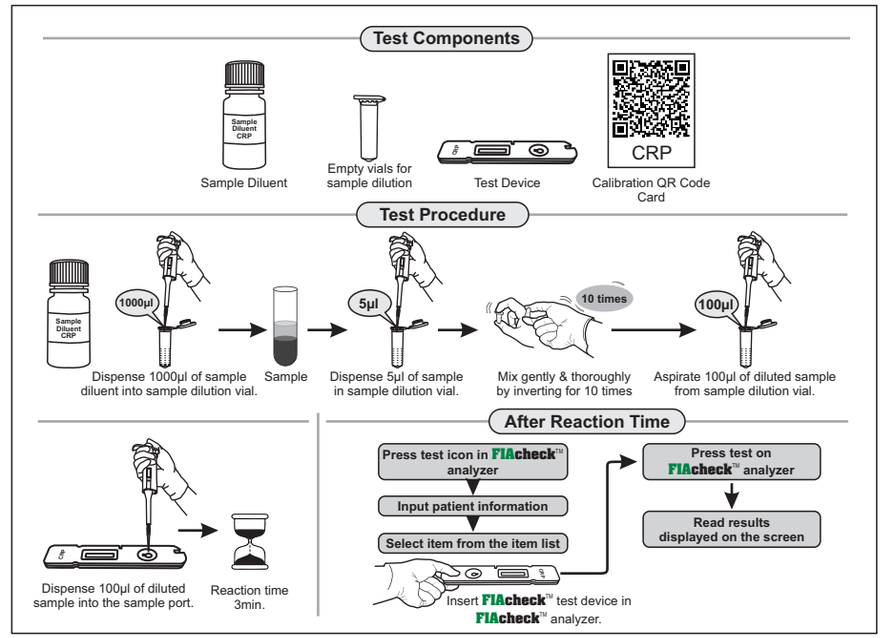
1. Only human Serum/Plasma/Whole blood sample should be used. Other bodily fluids and samples may not give accurate result.
2. Plasma can be anti-coagulated with Heparin and Sodium citrate or Tri sodium citrate under aseptic conditions.
3. Whole blood can be anti-coagulated with EDTA under aseptic conditions.
4. The test should be performed within 4 hours after the sample collection at room temperature.
5. Avoid grossly hemolytic, lipemic or turbid serum/plasma samples. Do not use clotted or hemolysed whole blood samples.
6. Preferably use fresh samples. Serum/plasma samples can be stored for 3 days at 2°C to 8°C, and if more than 3 days, they should be stored at -20°C. Whole blood samples should be used immediately and should not be frozen.
7. The sample should be recovered to room temperature (18°C to 30°C) before testing. Avoid repeated freezing and thawing of samples as it can affect the test values.
8. Samples containing precipitate or particulate matter should be clarified by centrifugation prior to use.
9. Samples should be free from particulate matter and microbial contamination.

PRECAUTIONS

1. Only for In vitro diagnostic use.
2. Bring all reagents and samples to room temperature before use.
3. After the test device is removed from the sealed pouch, it should be used immediately or within 30 minutes of opening the pouch.
4. Do not reuse the tested **FIAcheck**™ device. Do not use sample dilution vial for more than one sample.
5. Do not use damaged **FIAcheck**™ test device or pouch.
6. All samples should be considered potentially infectious and discarded appropriately as per Standard Bio-Safety guidelines.
7. Do not use kit after the expiry date.
8. Do not mix components of one kit with another.
9. Always use new tip for each sample and reagent.
10. Scan QR code card specific to the lot you are using.
11. Ambient temperature of testing environment directly impacts the accuracy of results. Ideal working temperature is 18°C to 30°C.
12. It is highly recommended to mix the sample diluent and sample mixture thoroughly by gently inverting the vial 10 times. (Refer pictorial presentation.)
13. It is not recommended to use the sample diluent and sample mixture beyond specified time.
14. The **FIAcheck**™ test device should be read immediately after the specified reaction time. Delay in reading might affect the accuracy of results.
15. The **FIAcheck**™ test device should be used only in conjunction with **FIAcheck**™ analyzer for accurate and reliable results.

TEST PROCEDURE

1. To calibrate the **FIAcheck**™ **CRP** kit, scan the QR code card provided with the kit.
2. Dispense **1000** µl of sample diluent into the empty sample dilution vial.
3. Add **5**µl of the test sample into this sample diluent & mix by rinsing the tip 3 times.
4. Close the lid of the sample dilution vial, label with sample identity and mix the content of the vial by gently inverting it for 10 times. (See pictorial representation).
5. Remove **FIAcheck**™ **CRP** test device from sealed pouch and place it horizontally on a clean table, label the device with sample identity.
6. Dispense 100 µl of the above mixture at the sample port in the **FIAcheck**™ **CRP** test device.
7. Incubate at room temperature (18°C to 30°C) for **3 minutes**.
8. After 3 minutes, insert the test device immediately into the **FIAcheck**™ analyzer and read results.



Expected Range
Cut-Off value: 10 µg/mL
CRP concentration is determined using samples obtained from 200 apparently healthy individuals.
It is recommended that each laboratory establish its own reference range for the population it serves.

PERFORMANCE CHARACTERISTICS

1. Measuring Range: 0.5-200µg/mL.
2. Lower Detection Limit: ≤0.5µg/mL.
3. Upper Detection Limit: ≥200µg/mL.
4. Accuracy: Based on comparison experiments, the relative standard deviation of ≤15%, and the correlation coefficient of r≥0.990 was observed.
5. Within-Run Precision: ≤15%.
6. Between-Run Precision: ≤15%.
7. Hook Test: No hook effect with high concentration sample. Hook test was conducted with reference material exceeding the upper limit of measuring range, and the detection result was greater than the upper limit of detection.
8. In an internal Study, **FIAcheck**™ **CRP** was evaluated against commercially available licensed kit with 100 random clinical samples and **FIAcheck**™ **CRP** has demonstrated 100% clinical correlation with the commercially available licensed kit.

CRP Levels	No. of samples	FIAcheck™ CRP	Reference method
Normal	80	80	80
Low	8	8	8
High	12	12	12

9. In an external Study, **FIAcheck**™ **CRP** has been evaluated by a NABL accredited lab against their reference method. In this evaluation **FIAcheck**™ **CRP** has demonstrated 100% correlation with the reference method.
*Data file: Zephyr Biomedicals (A Division of Tulip Diagnostics (P) Ltd).

LIMITATIONS OF THE ASSAY

1. As with all diagnostic tests, a definite clinical diagnosis should not be based on the results of a single test but should only be made by the physician after all clinical and laboratory findings have been evaluated.
2. This kit is only for human serum, plasma and whole blood.