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. Yang Zhenhua, Pan Baizhong, Xu. Predictors of Chinese Medical Association inspection documents: guidelines for the application of markers of myocardial injury. Chinese Journal of laboratory medicine, 2002, 25 (3): 85.
2. Jin Caining, Xu Guobin, Zhu Lihua, et al. Determination of the biological characteristics of human cardiac TnI and its application in clinical diagnosis. Journal of clinical test, 2002, 20 (2): 18.
3. Department of medical administration, ministry of health. National operational procedures for clinical examination. Southeast university press, 1991.

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.

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0323/VER-01

FIAcheck™

cTnI

Fluorescence Immunoassay for Quantitative detection of Cardiac Troponin I (cTnI) in Human Serum/Plasma

DEVICE

FOR IN VITRO DIAGNOSTIC USE ONLY

Store at 4°C to 30°C

INTENDED USE

FIAcheck™ cTnI Fluorescence Immunoassay is intended for the in-vitro quantitative measurement of Cardiac Troponi I (cTnI) in human serum/plasma.

INTRODUCTION

Cardiac troponins are currently the most sensitive and specific biochemical markers of myocardial necrosis. There are three types of troponin in heart muscle fibers. Those are troponin C, troponin I, and troponin T. Together they contribute to make cardiac muscle fibres contract. The clinical measurement of serum Tn I has become an important tool in the diagnosis of acute myocardial infarction.

Serum Tn I is a more reliable than creatine kinase as a prognostic marker in people with ischemic chest pain. National and international scientific organizations have suggested the use of troponins, Tn I and Tn T, when implementing new diagnostic strategies in patients with acute coronary syndrome.

PRINCIPLE OF THE TEST

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

cTnI in sample binds to the cTnI 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 cTnI 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™ cTnI** 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: 100-1000µl
- Disposable pipette tips
- Disposable Gloves
- **FIAcheck™** Analyzer (Time Resolved Fluorescence Immunoassay Analyzer)
- Digital Thermometer
- Stopwatch

STORAGE AND STABILITY

1. **FIAcheck™ cTnI** 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

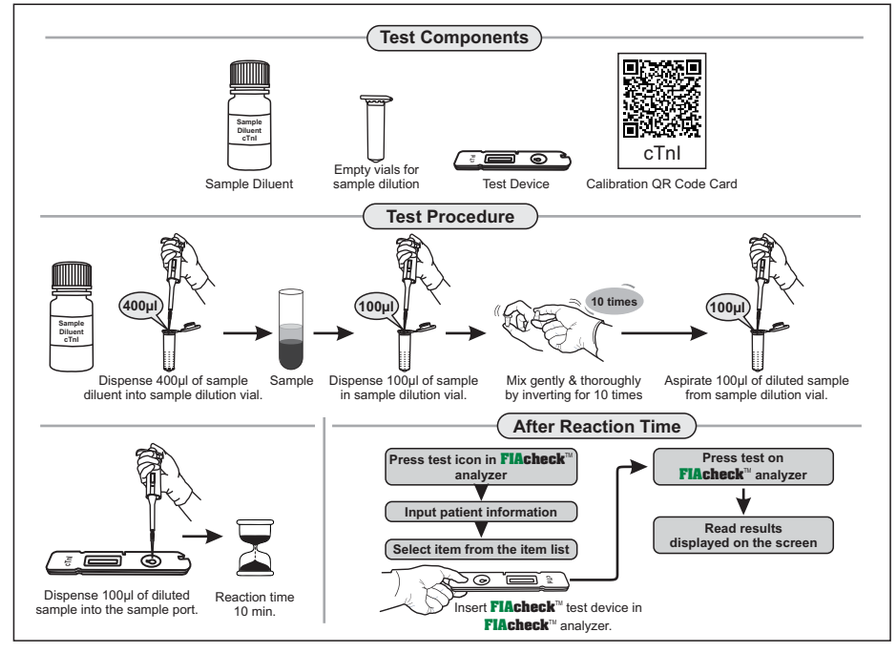
1. Only human Serum/Plasma sample should be used. Other bodily fluids and samples may not give accurate result.
2. Plasma can be anti-coagulated with Heparin and Sodium citrate or Tri sodium citrate under aseptic conditions.
3. The test should be performed within 4 hours after the sample collection at room temperature.
4. Avoid grossly hemolytic, lipemic or turbid samples.
5. Preferably use fresh samples. However, 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.
6. 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.
7. Samples containing precipitate or particulate matter should be clarified by centrifugation prior to use.
8. 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**™ **cTnI** kit, scan the QR code card provided with the kit.
2. Dispense **400** µl of sample diluent into the empty sample dilution vial.
3. Add **100**µl of the test sample into the 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**™ **cTnI** 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**™ **cTnI** test device.
7. Incubate at room temperature (18°C to 30°C) for **10 minutes**.
8. After 10 minutes, insert the test device immediately into the **FIAcheck**™ analyzer and read results.



Expected Range

Cut-Off Value: 0.3ng/mL.

The cut-off value for cTnI was determined by testing samples from 160 apparently healthy individuals. The 99th percentile of the concentration for cTnI is 0.3ng/mL. (The probability that value of a normal person below 0.3ng/mL is 99%.)
It is recommended that each laboratory establish its own reference range for the population it serves.

PERFORMANCE CHARACTERISTICS

1. Measuring Range: 0.1-40ng/mL.
2. Lower Detection Limit: ≤0.05ng/mL.
3. Upper Detection Limit: ≥40ng/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**™ **cTnI** was evaluated against commercially available licensed kit with 100 random clinical samples and **FIAcheck**™ **cTnI** has demonstrated 100% clinical correlation with the commercially available licensed kit.

cTnI Levels	No. of samples	FIAcheck™ cTnI	EIA cTnI
Normal	80	80	80
Low	8	8	8
High	12	12	12

9. In an external Study, **FIAcheck**™ **cTnI** has been evaluated by a NABL accredited lab against their reference method. In this evaluation **FIAcheck**™ **cTnI** 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 and plasma.