Cardiac Troponin I Test Kit (FIA) Package Insert

REF VID09-03-011	English

INTENDED USE

***VivaDiag*™ Cardiac Troponin I Test Kit (FIA)** is a fluorescence immunoassay (FIA) for the quantitative determination of Cardiac troponin I in human whole blood, serum or plasma. Cardiac troponin I (cTnI) has high myocardial specificity and sensitivity, so cardiac troponin I has become the most ideal marker of myocardial infarction. [1]

For *in vitro* diagnostic use only.

For professional use only.

INTRODUCTION

Troponin is composed of troponin I, T and C Sanya base. They interacted with tropomyosin to regulate actin and myosin interaction by regulating Ca2+ activity on the ATP protein enzyme. After myocardial injury, the cardiac troponin complex was released into the blood. After 4-6 hours, it began to increase in the blood. The elevated cardiac troponin I could remain in the blood for a long time (6 ~ 10 days), which provided a longer detection period. [2]

cTnI is used to assist in the diagnosis of myocardial infarction (MI) and to assist in the evaluation of patients with acute coronary syndrome (ACS) and prognosis related to all-cause death and major cardiac adverse events such as myocardial infarction, cardiovascular recanalization, and cardiogenic death Condition. [3]

PRINCIPLE

***VivaDiag*™ Cardiac Troponin I Test Kit (FIA)** is based on fluorescence immunoassay technology. ***VivaDiag*™ Cardiac Troponin I Test Kit (FIA)** uses a sandwich immunodetection method, such that the fluorescence-labeled detector antibody binds to the target protein (cTnI) in blood specimen. In the sample well of the device there is a membrane coated with cTnI-specific monoclonal antibodies. A diluted sample is applied to the test device. The cTnI will be bound by the cTnI antibody which conjugated by the fluorescence to form fluorescence complex. When the fluorescence complex flows through the membrane, it will be captured by the cTnI antibody. Signal intensity of fluorescence reflects amount of the cTnI captured and is detected by ***VivaDiag*™ POCT Multifunction Meter** to show the cTnI concentration in specimen.

COMPONENT

***VivaDiag*™ Cardiac Troponin I Test Kit (FIA)** contains the '**Test Device** (packaged in pouch with desiccant)', '**Code Chip**', '**Buffer Tube** (prefilled with buffer)', '**75 µL Pipette**' and '**Package Insert**'.

- **Test Device**: It is composed of glass fiber, nitrocellulose membrane, plastic backer, absorbent paper and plastic cassette.
- **Code Chip**: Calibration information.
- **75 µL Pipette**: Collect sample and mixed solution.
- **Buffer Tube**: Sample diluent.
- **Package Insert**: Instruction for use.

MATERIALS SUPPLIED

Each ***VivaDiag*™ Cardiac Troponin I Test Kit (FIA)** contains:

· Test Device	25
· Code Chip	1
· Buffer Tube	25
· 75 µL Pipette	50
· Package Insert	1

MATERIALS REQUIRED BUT NOT SUPPLIED

- ***VivaDiag*™ POCT Multifunction Meter**

REF VIM220H-00-011

- Timer
- ***VivaDiag*™ Cardiac Troponin I Control Solution (FIA)**

REF VIC09-03-011

STORAGE AND STABILITY

- Store the test kit in a cool, dry place between 2 ~ 30°C. Keep away from light. Exposure to temperature and/or humidity outside the specified conditions may cause inaccurate results.
- Do not freeze.
- Do not open the pouch until ready to perform the assay.
- Once the pouch is opened, the test device should be used in 1 hour.
- All expiration dates are printed in Year-Month-Day format. Example: 2024-06-18 indicates June 18, 2024.

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use only.
- For professional use only. Testing should be applied by well-trained healthcare professionals, and conducted in central laboratories, GP offices, clinics, pharmacy and medical examination centers etc.
- Please follow the **Package Insert** when testing.
- The **Test Device** should remain sealed in its original pouch until just before use. Do not use the **Test Device**, if pouch is damaged or has already been opened.
- Do not reuse the **Test Device** and do not use your test kits beyond the expiration date. Biological materials used beyond their expiry date can become unstable and fail.
- It is recommended to use an anticoagulant blood collection tube (EDTA, heparin or citrate). Other anticoagulants have not been evaluated in ***VivaDiag*™ Cardiac Troponin I Test Kit (FIA)** and thus should not be used.
- Use the test kits at temperatures between 18 ~ 25°C.
- Use the test kits between 10 ~ 90% humidity.
- Do not use the **Test Device** in extremely temperature. If the **Test Device** has been stored refrigerated, bring to the ambient temperature (18 ~ 25°C) prior to testing and avoid moisture absorption.
- Keep the test kit away from direct sunlight.
- All parts of kit are considered biohazardous and can potentially transmit infectious diseases from blood borne pathogens, even after you have performed cleaning and disinfection. Follow proper precautions and all local regulations when disposing of the used test kits and other accessories.
- Do not interchange the test components between different lots or use the test components after the expiration date, either of which might yield incorrect test result(s).
- Please contact your local distributor to solve problems timely if you have any questions or need help.
- ***VivaDiag*™ Cardiac Troponin I Test Kit (FIA)** will provide accurate and reliable results subject to the below conditions:

a) ***VivaDiag*™ Cardiac Troponin I Test Kit (FIA)** should be used combined with ***VivaDiag*™ POCT Multifunction Meter**.

b) Whole blood or plasma samples should be collected with a suitable anticoagulant blood collection tube (EDTA, heparin or citrate is recommended).

SAMPLE COLLECTION AND PROCESSING

The sample type for ***VivaDiag*™ Cardiac Troponin I Test Kit (FIA)** is human whole blood/serum/plasma.

- For serum sample, collect the blood in a coagulation-promoting tube. Remove the serum from the clot as soon as possible to avoid hemolysis.
- For whole blood or plasma sample, collect the blood with a suitable anticoagulant blood collection tube (EDTA, heparin or citrate is recommended).
- The serum/plasma can be stored at 2 ~ 8°C for 7 days, or frozen at -10°C ~ -30°C for 6 months; the whole blood can be stored at 2 ~ 8°C for 2 days, and avoid frozen.
- Once the serum/plasma sample was frozen, it should be thawed only once. As a repeated freeze-thaw cycle may affect the test result, do not refreeze previously frozen samples.

PREPARE FOR TEST

- Turn on the **Meter** for at least 5 minutes before testing.
- If the test kit has been stored in a refrigerator, place it on a clean and flat surface at 18 ~ 25°C for at least 30 minutes before testing.
- Check the contents of ***VivaDiag*™ Cardiac Troponin I Test Kit (FIA)**: '**Test Device** (packaged in pouch with desiccant)', '**Code Chip**', '**Buffer Tube** (prefilled with buffer)', '**75 µL Pipette**' and '**Package Insert**'.
- Check the label information of the **Code Chip** to make sure that the **Code Chip** matches the **Test Device**.

TEST PROCEDURE

Input Information

1. Insert the **Code Chip** into the **Meter**.
2. The **Meter** will read the information automatically.
3. The **Meter** makes a beep when the information is read successfully.
4. The **Meter** displays the lot number and item name. Remove the **Code Chip**.

Note: *Please refer to the* ***User's Manual*** *of* ***VivaDiag*™ *POCT Multifunction Meter*** *for more operating instructions.*

Run Test (Standard Test Model)

1. Take the **Test Device** out of the foil pouch and place it on a clean, dust-free and flat surface.
2. Draw 75 µL human whole blood/serum/plasma to the **Buffer Tube** by the **75 µL Pipette**.
3. Gently invert and mix the solution well. Avoid bubbles. Use the mixed solution within one hour.
4. Apply 75 µL mixed solution from the **Buffer Tube** by a new **75 µL Pipette** to the sample well of the **Test Device**. Avoid bubbles.
5. Insert the **Test Device** into the slot of ***VivaDiag*™ POCT Multifunction Meter**. Ensure proper orientation of the **Test Device** before pushing it into the holder.
6. The **Meter** will automatically display the result after 15 minutes countdown.

Run Test (Quick Test Model)

1. Take the **Test Device** out of the foil pouch and place it on a clean, dust-free and flat surface.
2. Draw 75 µL human whole blood/serum/plasma to the **Buffer Tube** by the **75 µL Pipette**.
3. Gently invert and mix the solution well. Avoid bubbles. Use the mixed solution within one hour.
4. Apply 75 µL mixed solution from the **Buffer Tube** by a new **75 µL Pipette** to the sample well of the **Test Device**. Avoid bubbles.
5. Place the sample-loaded **Test Device** on a clean, dust-free and flat surface and reaction for 15 minutes.
6. Insert the **Test Device** into the slot of ***VivaDiag*™ POCT Multifunction Meter**. Ensure proper orientation of the **Test Device** before pushing it into the holder.
7. The **Meter** will automatically display the result.

INTERPRETATION OF TEST RESULT

The **Meter** calculates the cTnI test result automatically and displays "cTnI" concentration on the screen.

Reference Interval:

cTnI: ≤0.300 ng/mL (300 ng/L)

Parameter	Result	Suggestion
cTnI	0 ~ 0.300 ng/mL (0 ~ 300 ng/L)	Normal conditions
	>0.300 ng/mL (>300 ng/L)	Indicates the risk of myocardial infarction

Unit Conversion:

ng/mL * 1000 = ng/L

Note: *Each laboratory should establish a reference interval that is representative of the population to be evaluated. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.*

QUALITY CONTROL

- Users should follow government guidelines and/or accreditation requirements for quality control.
- Quality control tests are a part of the good testing practice to confirm the expected results and validity of the assay and should be performed at regular intervals.
- Quality control tests should be performed immediately after opening a new test lot to ensure the test performance is not altered.
- Quality control tests should also be performed if the result and the symptoms are not consistent or if there are doubts about their accuracy.
- Control materials are not provided with ***VivaDiag*™ Cardiac Troponin I Test Kit (FIA)**. For more information regarding obtaining the control materials, contact with your local distributor for assistance.

Note: *Please refer to the* ***Package Insert*** *of* ***VivaDiag*™ *Cardiac Troponin I Control Solution (FIA)*** *for detailed information.*

LIMITATIONS OF THE PROCEDURE

- The performance of this product has been established for human whole blood/serum/plasma only. Other specimen types have not been evaluated.
- The test may yield false negative result. The non-responsiveness of the antigen to the antibodies is most common where the epitope is masked by some unknown components, so as not to be detected or captured by the antibodies. The instability or degradation of the antigen with time and/or temperature may cause the false negative as it makes antigen unrecognizable by the antibodies.
- There is a possibility that substances and/or factors may interfere with the test and cause false results. Technical or procedural errors can also contribute to erroneous results.
- The false positive results may be caused by the cross-reactions and/or other non-specific adhesion of certain sample components to the capture/detector antibodies.
- Test results must always be evaluated with other data available to the physician. Any clinical diagnosis based on the test result must be supported by a comprehensive judgment of the concerned physician including clinical symptoms and other relevant test results. The test result cannot be used for diagnosis. If the result is not matched the clinical evaluation,

please do more testing.

PERFORMANCE CHARACTERISTICS

· **Measuring Range and Detection Capability**

Measuring Range: 0.100~ 50.000 ng/mL (100 ~ 50000 ng/L)
Limit of Blank (LoB): 0.06 ng/mL (60 ng/L)
Limit of Detection (LoD): 0.08 ng/mL (80 ng/L)

· **Precision**

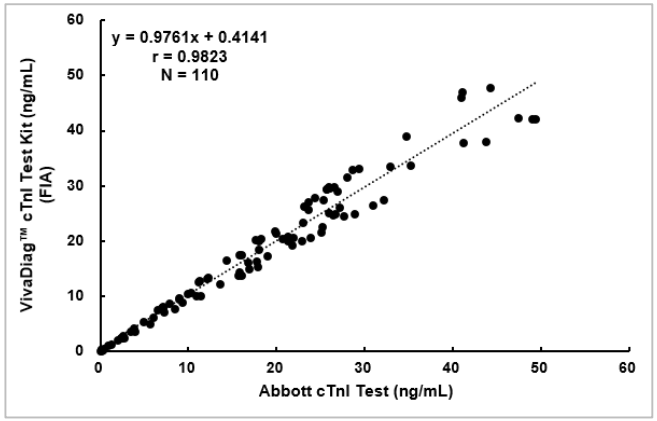
Repeatability: On the one meter, the specified 3 levels of samples were tested for one day, measured 20 times a day.
Reproducibility: In three laboratories, on the 3 meters, the specified 3 levels of samples were tested for 5 days by 3 operators, measured 5 times a day.

Sample	cTnI (ng/mL)	Repeatability		Reproducibility	
		SD	CV (%)	SD	CV (%)
1	0.5	0.05	10.14	0.04	7.54
2	5	0.43	8.89	0.51	10.08
3	35	2.27	6.35	3.12	8.91

· **Accuracy**

A comparison study using 110 human serum samples, demonstrated good correlation with a commercially available kit. Comparison between ***VivaDiag*™ Cardiac Troponin I Test Kit (FIA)** and ***Abbott* cTnI Test** is summarized in the following table and figure:

Method	Number of Specimens	Intercept	Slope	Correlation Coefficient
Ordinary Linear Regression	110	0.4141	0.9761	0.9823



· **Specificity**

The following substances do not interfere with the test results at the indicated concentrations:

Interfering Substance	Concentration
Bilirubin	5 mg/L
Triglyceride	50 mg/L
Hemoglobin	10 g/L
Rheumatoid Factors	200 IU/mL

LITERATURE REFERENCES

[1] Bates Morrow DA, Cannon CP, Jesse RL, et a1. National academy of clinical biochemistry laboratory medicine practice guidelines: clinical characteristics and utilization of biochemical markers in acute coronary syndromes [J]. Clin Chem, 2007, 53(4): 552—574.

[2] Maynard SJ, Menown IB, Adgey AA. Troponin T and troponin I as cardiac markers in ischaemic heart disease [J]. Heart, 2000, 83(4): 371-373.

[3] Apple FS, Collinson PO, IFCC Task Force on Clinical Applications of Cardiac Biomarkers. Analytical charac· teristics of high—sensitivity cardiac troponin assays [J]. Clin Chem, 2012, 58(1): 54-61.

INDEX OF SYMBOLS

	Consult instructions for use or consult electronic instructions for use
	Use-by date
	Contains sufficient for <n> tests
IVD	In vitro diagnostic medical device
LOT	Batch code
REF	Catalogue number
	Manufacturer
	Temperature limit
	Do not re-use
EC REP	Authorized representative in the European Community/European Union

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