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Cardiac

AFIAS Troponin T

INTENDED USE

AFIAS Troponin T is a fluorescence Immunoassay (FIA) for the quantitative determination of cardiac Troponin T (Tn-T) level in human whole blood/serum/plasma. It is useful as an aid in management and monitoring of acute myocardial infarction (AMI).

For *in vitro* diagnostic use only.

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 fibers contract. Troponin T especially binds to tropomyosin and helps binding to actin protein during muscle contraction. Studies have shown elevated levels of troponin T after myocardial infarction and significantly associated with the cardiovascular death and incidence of heart failure. National and international scientific organizations have suggested the use of troponins, Troponin T and Troponin I, when implementing new diagnostic strategies in patients with acute coronary syndrome.

PRINCIPLE

The test uses a sandwich immunodetection method; the detector antibodies in buffer bind to antigens in the sample, forming antigen-antibody complexes, and migrate onto nitrocellulose matrix to be captured by the other immobilized-antibodies on the test strip.

More antigens in sample will form more antigen-antibody complexes which lead to stronger fluorescence signal by detector antibodies, which is processed by the instrument for AFIAS tests to show Troponin T concentration in the sample.

COMPONENTS

AFIAS Troponin T consists of 'cartridges'.

- Each sealed aluminum pouch contains two cartridges.
- Each cartridge packaged in an aluminum pouch has three components including a cartridge part, detector part and diluent part.
- The cartridge part contains the membrane called a test strip which has streptavidin at the test line, and chicken IgY at the control line.
- The detector tube part has 2 granules containing the anti-Troponin T fluorescence conjugate, anti-Troponin T biotin conjugate, anti-chicken IgY-fluorescence conjugate, bovine serum albumin, bromophenol blue, and sodium azide in Tris buffer.
- The diluent part contains tween 20, and sodium szide in MES buffer.

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use only.
- Follow instructions and procedures described in this 'Instructions for use'.
- Use only fresh samples and avoid direct sunlight.
- Lot numbers of all the test components (cartridge and ID chip) must match each other.
- 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).
- Do not reuse cartridges, c-tips, or tips. A cartridge should be used for testing one sample only.
- The cartridge should remain sealed in its original pouch until just before use. Do not use a cartridge, if the pouch is damaged or has already been opened.
- Frozen sample should be thawed only once. For shipping, samples must be packed in accordance with local regulations. Sample with severe hemolysis and/or hyperlipidemia must not be used.
- If test components and/or sample are stored in refrigerator, then allow cartridge and sample to be at room temperature for approximately 30 minutes before use.
- The instrument for AFIAS tests may generate slight vibration during use.
- Used cartridges, c-tips and pipette tips should be handled carefully and disposed by an appropriate method in accordance with relevant local regulations.
- The cartridge contains sodium azide (NaN_3), and they may cause certain health issues like convulsions, low blood pressure and heart rate, loss of consciousness, lung injury and respiratory failure. Avoid contact with skin, eyes, and clothing. In case of contact, rinse immediately with running water.
- No Biotin interference was observed in **AFIAS Troponin T** when biotin concentration in the sample was below 2 ng/mL. If a patient has been taking biotin at dosage of more than 0.03 mg a day, it is recommended to test again 24 hours after discontinuation of biotin intake.
- **AFIAS Troponin T** will provide accurate and reliable results subject to the below conditions.
  - **AFIAS Troponin T** should be used only in conjunction with the instrument for AFIAS tests.
  - Have to use recommended anticoagulant.

Recommended anticoagulant
K_3EDTA, K_2EDTA ,Lithium Heparin, Sodium Heparin

[C-tip]

- Wear disposable gloves and protective equipment for safety.
- Do not reuse the c-tips as they are disposable.
- Check the surface for damage or contamination.
- Touch the surface of the sample with c-tip.
- Careful when collecting sample to prevent air bubbles from forming in the c-tip.
- Careful not to get blood on the surface of the c-tip
- Wipe the surface of the c-tip with tissue.
- Sample collection tool and sample container are infectious and therefore must be handled carefully and discarded by an appropriate method in accordance with relevant local regulations.
- Whole blood should be immediately tested after collection.

LIMITATIONS OF THE TEST SYSTEM

- The test may yield false positive result(s) due to the cross-reactions and/or non-specific adhesion of certain sample components to the capture/detector antibodies.
- The test may yield false negative result(s) due to the non-responsiveness of the antigen to the antibodies which is the most common if the epitope is masked by some unknown components, so therefore not being able to be detected or captured by the antibodies. The instability or degradation of the antigen with time and/or temperature may also cause false negative result as it makes the antigen unrecognizable by the antibodies.
- Other factors may interfere with the test and cause erroneous results, such as technical/procedural errors, degradation of the test components/reagents or presence of interfering substances in the test samples.
- Any clinical diagnosis based on the test result must be supported by a comprehensive judgment of the concerned physician in conjunction with clinical symptoms and other relevant test results.

STORAGE AND STABILITY

Component	Storage condition		
	Storage Temperature	Shelf life	Note
Cartridge	2 - 30 °C	20 months	Unopened
	2 - 30 °C	1 months	Resealed

- Return an unused cartridge to the spare cartridge zipper bag containing the desiccant pack. Reseal along entire edge of zip-seal.

MATERIALS SUPPLIED

REF SMFP-95

Components of **AFIAS Troponin T**

- Cartridge Box Contains
  - Cartridge 24
  - Pipette tip (zipper bag) 24
  - Spare cartridge zipper bag 1
  - ID chip 1
  - Instruction for use 1

MATERIALS REQUIRED BUT SUPPLIED ON DEMAND

Following items can be purchased separately from **AFIAS Troponin T.**

Please contact our sales division for more information.

- **AFIAS-1** REF FPRR019
- **AFIAS-6** REF FPRR020
- **AFIAS-3** REF FPRR040
- **AFIAS-10** REF FPRR038
- **Boditech Troponin T Control** REF CFPO-306
- **Boditech Troponin T Calibrator** REF CFPO-307
- **C-tip** (Zipper bag, 30 μL) REF CFPO-199

SAMPLE COLLECTION AND PROCESSING

The sample type for **AFIAS Troponin T** is human whole blood/serum/plasma.

- It is recommended to test the sample within 24 hours after collection.
- The samples (serum, plasma) should be separated from the clot by centrifugation within 3 hours after the collection of whole blood.
- The samples (whole blood, serum, plasma) may be stored for 24 hours at 2-8 °C prior to being tested. If testing will be delayed more than 24 hours, samples should be frozen at -20 °C or below.
- The samples (serum, plasma) stored frozen at -20 °C for 12 months showed no performance difference.
- After thawing, gently shake the sample to mix.
- However, the whole blood sample should not be kept in a freezer in any case.
- As a repeated freeze-thaw cycle may affect the test result, do not refreeze previously frozen samples.
- Collection of whole blood sample using C-tip

1) Hold the C-tip horizontally and touch the surface of the blood with the tip of the C-tip.
2) Capillary action will automatically draw the blood sample to C-tip and stop.
3) Wipe off any excess blood around the tip.
4) Double-check if whole blood is filled accurately in the C-tip and AFIAS reader is ready for a test on the 'C-tip mode'.

TEST SETUP

- Check the components of the **AFIAS Troponin T** as described below: Cartridges, pipette tips, C-tips(30 μL), ID chip, spare cartridge zipper bag and instruction for use.
- If the sealed cartridge has been stored in a refrigerator, place them on a clean and flat surface at room temperature for at least 30 minutes before testing.
- Turn on the instrument for AFIAS tests.
- Empty the tip box.
- Insert the ID chip into the "ID chip port".

※ **Please refer to the instrument for AFIAS tests operation manual for complete information and operating instructions.**

TEST PROCEDURE

▶ **AFIAS-1, AFIAS-3, AFIAS-6**

General mode

1) Insert a cartridge into the cartridge holder.
2) Insert a tip into the tip hole of the cartridge.
3) Select the 'General mode' in the instrument for AFIAS tests.
4) Take 100 μL of the sample (whole blood/plasma/serum/control) using a pipette and dispense it into the sample well of the cartridge.
5) Tap the 'Start' button on the screen.
6) The test result will be displayed on the screen after 12 minutes.

C-tip mode

1) Insert a cartridge into the cartridge holder.

2) Take 30 µL of whole blood using a C-tip.
3) Insert the whole blood-filled C-tip into the tip hole of the cartridge.
4) Select the 'C-tip mode' in the instrument for AFIAS tests.
5) Tap the 'Start' button on the screen.
6) The test result will be displayed on the screen after 12 minutes.

▶ **AFIAS-10**

Normal mode

1) Insert a cartridge into the cartridge holder.
2) Insert a tip into the tip hole of the cartridge.
3) Tap the 'Load' button of the bay that holds the cartridge with the tip to read the barcode of the cartridge and please confirm the item name written on the cartridge.
4) Insert the sample tube into the tube rack.
5) Insert the tube rack into the loading part of the sampling station.
6) Tap the 'Start' button on the screen.
7) The test result will be displayed on the screen after 12 minutes.

Emergency mode – General tip

1) The test procedure is same with the 'Normal mode 1) – 3)'.
2) Convert the 'Emergency mode' in AFIAS-10.
3) Select the tip type (general tip) on the screen.
4) Select the sample type (whole blood/plasma/serum) on the screen.
5) Take 100 µL of the sample using a pipette and dispense it into the sample well of the cartridge.
6) Tap the 'Start' button on the screen.
7) The test result will be displayed on the screen after 12 minutes.

Emergency mode – C-tip

1) Insert a cartridge into the cartridge holder.
2) Take 30 µL of whole blood using a C-tip.
3) Insert the C-tip with sample into the tip hole of the cartridge.
4) Tap the 'Load' button of the bay that holds the cartridge with a tip to read the barcode of the cartridge and please confirm the item name written on the cartridge.
5) Convert the 'Emergency mode' in AFIAS-10.
6) Select the tip type (C-tip) on the screen.
7) Tap the 'Start' button on the screen.
8) The test result will be displayed on the screen after 12 minutes.

INTERPRETATION OF TEST RESULT

- The instrument for AFIAS tests calculate the test result automatically and displays Troponin T concentration of the test sample in terms of pg/mL.
- Working range : **AFIAS Troponin T** is 10 – 20,000 pg/mL.
- Expected Values
  - In the studies performed with the AFIAS Troponin T assay involving 125 healthy volunteers in Korea, the upper reference limit (99th percentile) for Troponin T was 17 pg/mL. The lowest concentration with a CV less than or equal to 10% with the AFIAS Troponin T assay was 16 pg/mL.
  - Due to the release kinetics of Troponin T, a result below the reference value within the first hours of the onset of symptoms does not rule out myocardial infarction with certainty. If myocardial infarction is still suspected, repeat the test at appropriate intervals.
  - According to the WHO(World Health Organization) criteria for the definition of AMI from the 1970's, the cutoff (clinical discriminator) value for troponin T is 0.1 µg/L (ng/mL) or 100 ng/L (pg/mL) as determined from ROC analysis.
  - Laboratories should establish their own diagnostic cut-off concentration based on the clinical practice at their perspective institutions.

QUALITY CONTROL

- The 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.
- The control tests should be performed immediately after opening a new test lot to ensure the test performance is not altered.
- The quality control tests should also be performed whenever there is any question concerning the validity of the test results.
- Control materials are provided on demand with **AFIAS Troponin T**. For more information regarding obtaining the control materials, contact Boditech Med Inc.'s Sales Division for assistance.
  (Please refer to the instruction for use of control material.)

PERFORMANCE CHARACTERISTICS

- **Analytical sensitivity**
  - Limit of Blank (LoB) 6.25 pg/mL
  - Limit of Detection (LoD) 10.00 pg/mL
  - Limit of Quantification (LoQ) 16.00 pg/mL

- **Analytical Specificity**
  - **Cross-reactivity**
    Biomolecules such as below the ones in the table were added to the test sample(s) at concentrations much higher than their normal physiological levels in the blood. **AFIAS Troponin T** test results did not show any significant cross-reactivity with these biomolecules.

Cross reactants	Conc.
CK-MB	60 ng/mL
NT-proBNP	1,000 ng/mL
Myoglobin	1,000 ng/mL
D-Dimer	1,000 ng/mL

  - **Interference**
    Interferents listed in the following table were added to the test sample at the concentration mentioned below. **AFIAS Troponin T** test results did not show any significant interference with these materials.

interference materials	Conc.
D-glucose	55 mmol/L
L-Ascorbic acid	170 µmol/L
Bilirubin	342 µmol/L
Hemoglobin	2 g/L
Cholesterol	13 mmol/L
Triglyceride	37 mmol/L
Heparin	3000 U/L
EDTA	3.4 µmol/L

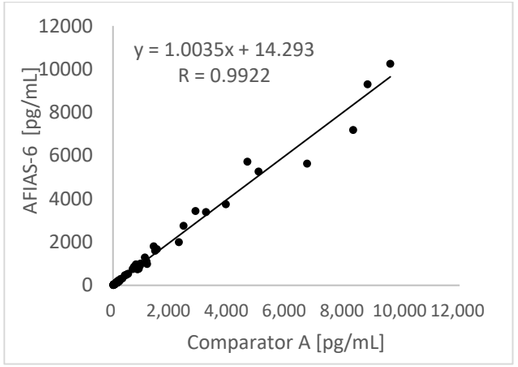
- **Precision**
  - Between Lot
    One person tested three different lots of **AFIAS Troponin T**, ten times at each concentration of the control standard.
  - Between person
    Three different persons tested one lot of **AFIAS Troponin T**; ten times at each concentration of the control standard.
  - Between day
    One person tested one lot **AFIAS Troponin T** during five days; ten times at each concentration of the control standard.
  - Between site
    One person tested one **AFIAS Troponin T** at three different sites; ten times at each concentration of the control standard.

Conc.	Between lot		Between person	
[pg/mL]	AVG	CV (%)	AVG	CV (%)
100	99.86	6.0	99.78	5.5
600	601.02	6.7	597.56	5.7
5000	5000.3	6.4	4957.69	5.5
Conc.	Between day		Between site	
[pg/mL]	AVG	CV (%)	AVG	CV (%)
100	99.41	5.4	101.52	4.9
600	588.73	5.5	610.97	5.9
5000	4969.02	6.3	4859.20	6.1

- **Accuracy**
  The accuracy was confirmed by testing 3 different lots, ten times at each concentration of the control standard.

Conc. [pg/mL]	Lot 1	Lot 2	Lot 3
100	96.81	97.36	98.90
600	605.02	574.52	606.44
5000	4966.16	4968.27	5062.51
Conc. [pg/mL]	Mean	CV (%)	Recovery (%)
100	97.69	5.2	98
600	595.33	6.9	99
5000	4998.98	5.9	100

- **Comparability**
  Troponin T concentration of 100 clinical samples were quantified independently with **AFIAS Troponin T (AFIAS-6)** and **comparator A** as per prescribed test procedures. Test results were compared, and their comparability was investigated with linear regression and correlation coefficient (R). The regression equation and correlation coefficient are as follows.



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Note: Please refer to the table below to identify various symbols.

Σ	Sufficient for <n> tests
	Read instruction for use
	Use by Date
LOT	Batch code
REF	Catalog number
	Caution
	Manufacturer
EC REP	Authorized representative of the European Community
IVD	In vitro diagnostic medical device
	Temperature limit
	Do not reuse
CE	This product fulfills the requirements of the Directive 98/79/EC on in vitro diagnostic medical devices

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