






### Raw Material

Raw Material	Function	Concentration
Test strip		
cTnT mAb	Determination of cTnT Antigenin human blood sample	<0.7 ug
GAR	Antibody for QC line	<0.4 ug
cTnT mAb-fluorescence conjugate	Fluorescent antibody for detection of cTnT human blood samples	<2.1 ug
Rabbit IgG-fluorescence conjugate	React with the QC line GAR to make it fluorescent after detection	<1.2 ug
Diluents:		
KH <sub>2</sub> PO <sub>4</sub>	Play a buffer function, balance the PH in the sample	<0.08 mg
Na <sub>2</sub> HPO <sub>4</sub>	Play a buffer function, balance the PH in the sample	<0.15 mg
TRIS	Play a buffer function, balance the PH in the sample	<0.21 mg
HCl	Play a buffer function, balance the PH in the sample	<0.16 mg
NaCl	Balance the ionic strengthin the reaction system	<8.78 mg
Proclin300	Preservative	<0.03%

Accessories	Function	General products picture
Test Device (including device and desiccant)	The quantitative determination of cTnT	
Buffer Solution	Dilute the sample	
Pipette 1	Draw the blood sample	
Pipette 2	Draw the mixed solution	
Code Chip	Calculate the test results	
Package Insert	Instruction for use	/

## SAFETY DATA SHEET

### 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY UNDERTAKING

<b>Trade name</b>	VivaDiag™ Cardiac Troponin T Test Kit (FIA)
<b>Chemical description/Application</b>	The VivaDiag™ Cardiac Troponin T Test Kit (FIA) includes diluents and test strips that work with the VivaDiag™ POCT Multifunction Meter to measure the cTnT concentration in blood sample. In Vitro diagnostic use only.
<b>Supplier</b>	VivaChek Biotech (Hangzhou) Co., Ltd., Level 2, Block 2, 146 East Chaofeng Rd., Yuhang Economy Development Zone, Hangzhou, 311100, Zhejiang, PRC. Phone: 86-571-8918-2700 Fax: 86-571-8918-2733

### 2. HAZARDS IDENTIFICATION

The product may be harmful to health if the user swallow them, and may pollute the environment if not be disposed as the medical rubbish after used.

### 3. COMPOSITION /INFORMATION ON INGREDIENTS

The cTnT Test Strips is stored in a sealed aluminum foil bag with desiccant, and the diluent is stored in a centrifugal tube. Each test kit contains the following chemicals.

	CAS number	Concentration
Test strip:		
cTnT mAb	Not applicable	<0.7 ug
GAR	Not applicable	<0.4 ug
cTnT mAb-fluorescence conjugate	Not applicable	<2.1 ug
Rabbit IgG-fluorescence conjugate	Not applicable	<1.2 ug
Diluents:		
KH <sub>2</sub> PO <sub>4</sub>	7778-77-0	<0.08 mg
Na <sub>2</sub> HPO <sub>4</sub>	7558-79-4	<0.15 mg
TRIS	77-86-1	<0.21 mg
HCl	2647-01-0	<0.16 mg

NaCl	7647-14-5	<8.78 mg
Proclin300	97-59-6	<0.03%

All above components contained in the product are below accepted limited, and no harm to health of user and environment has been found.

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#### 4. FIRST-AID MEASURES

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<b>Inhalation</b>	Not applicable
<b>Skin</b>	Wash with water
<b>Eyes</b>	Immediately flush eyes with plenty of water for at least 15 minutes. Assure adequate flushing by separating the eyelids with fingers. Get medical attention immediately.
<b>Ingestion</b>	Get medical attention immediately.

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#### 5. FIRE FIGHTING MEASURES

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Not applicable.

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#### 6. ACCIDENTAL RELEASE MEASURES

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<b>Personal precaution</b>	Not applicable.
<b>Environmental precautions</b>	Dispose the strips as medical rubbish.
<b>Methods for cleaning up</b>	Dispose the strips as medical rubbish.

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#### 7. HANDLING AND STORAGE

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<b>Handling</b>	Add blood sample into diluents, then apply mixed solution on the strips to work with Device to test the cTnT.
<b>Storage</b>	Store test strip in a cool, dry place at room temperature, 2-30 °C. Store them away from heat and direct sunlight.

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#### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

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<b>Exposure limits</b>	Wear gloves
<b>Engineering controls</b>	Not applicable



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**Personal protection**

<b>Hand</b>	Not applicable
<b>Eye</b>	Not applicable
<b>Respiratory</b>	Not applicable

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**9. PHYSICAL-CHEMICAL PROPERTIES**

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<b>Appearance</b>	The test kit contains a test strip that is a plastic card with a sample hole and reaction window, and the clear diluents.
<b>Color</b>	The plastic card is white, the diluents is clear and colorless.
<b>Odour</b>	No special odour
<b>Boiling point(°C)</b>	Not applicable
<b>Melting Point(°C)</b>	Not applicable
<b>Flash point(°C)</b>	Not applicable
<b>Autoignition temperature(°C)</b>	Not applicable
<b>Density(kg/m<sup>3</sup>)</b>	Not applicable
<b>Viscosity</b>	Not applicable
<b>pH value</b>	Not applicable
<b>Solubility in water</b>	Not dissolve

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**10. STABILITY AND REACTIVITY**

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<b>Stability</b>	Stable
<b>Hazardous decomposition products</b>	Not applicable

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**11. TOXICOLOGICAL INFORMATION**

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None.

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**12. ECOLOGICAL INFORMATION**

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Not applicable.

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### 13. DISPOSAL CONSIDERATIONS

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**Disposal methods**                      Dispose as medical rubbish after being used.

**Waste category**                      Medical rubbish.

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### 14. TRANSPORT INFORMATION

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This substance is ordinary goods and no other dangerous properties.

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### 15. REGULATORY INFORMATION

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Not classified as hazardous according to EEC criteria.

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### 16. OTHER INFORMATION

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The information contained in this document is believed to be correct as of data shown.