






Raw Materia

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 ₂ PO ₄	Play a buffer function, balance the PH in the sample	<0.08 mg
Na ₂ HPO ₄	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	 <p>The image shows a vertical, white plastic test device. At the top, there is a QR code and the brand name 'VivaDiag'. Below the QR code is a rectangular window with a yellow arrow pointing upwards. Further down, there is a circular window and a small 'ID:' label. At the bottom, there is a circular opening with a grey ring around it.</p>
Buffer Solution	Dilute the sample	 <p>The image shows a clear plastic bottle with a white cap, containing a clear liquid. The bottle has a small white label on the side.</p>
Pipette 1	Draw the blood sample	 <p>The image shows a single-use pipette with a blue body and a white tip. It is shown against a dark blue background.</p>
Pipette 2	Draw the mixed solution	 <p>The image shows a single-use pipette with a blue body and a white tip, identical to Pipette 1. It is shown against a dark blue background.</p>
Code Chip	Calculate the test results	 <p>The image shows a small, white, rectangular chip with a black base and several vertical black lines on the bottom edge.</p>
Package Insert	Instruction for use	/

SAFETY DATA SHEET

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

Trade name	VivaDiag™ Cardiac Troponin T Test Kit (FIA)
Chemical description/Application	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.
Supplier	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 ₂ PO ₄	7778-77-0	<0.08 mg
Na ₂ HPO ₄	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.

4. FIRST-AID MEASURES

Inhalation	Not applicable
Skin	Wash with water
Eyes	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.
Ingestion	Get medical attention immediately.

5. FIRE FIGHTING MEASURES

Not applicable.

6. ACCIDENTAL RELEASE MEASURES

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

7. HANDLING AND STORAGE

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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure limits	Wear gloves
Engineering controls	Not applicable

Personal protection

Hand	Not applicable
Eye	Not applicable
Respiratory	Not applicable

9. PHYSICAL-CHEMICAL PROPERTIES

Appearance	The test kit contains a test strip that is a plastic card with a sample hole and reaction window, and the clear diluents.
Color	The plastic card is white, the diluents is clear and colorless.
Odour	No special odour
Boiling point(°C)	Not applicable
Melting Point(°C)	Not applicable
Flash point(°C)	Not applicable
Autoignition temperature(°C)	Not applicable
Density(kg/m³)	Not applicable
Viscosity	Not applicable
pH value	Not applicable
Solubility in water	Not dissolve

10. STABILITY AND REACTIVITY

Stability	Stable
Hazardous decomposition products	Not applicable

11. TOXICOLOGICAL INFORMATION

None.

12. ECOLOGICAL INFORMATION

Not applicable.

13. DISPOSAL CONSIDERATIONS

Disposal methods Dispose as medical rubbish after being used.

Waste category Medical rubbish.

14. TRANSPORT INFORMATION

This substance is ordinary goods and no other dangerous properties.

15. REGULATORY INFORMATION

Not classified as hazardous according to EEC criteria.

16. OTHER INFORMATION

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