

cTnI Rapid Test Kit

Instruction for use

【Product Name】 cTnI Rapid Test Kit

【REF】 A10034001B, A10034001C, A10034001D, A10034001E

【Specification】 1 test/kit, 5 tests/kit, 10 tests/kit, 25 tests/kit

【Intended Use】

The cTnI Rapid Test Kit is a colloidal gold immunochromatography intended for the qualitative detection of Cardiac troponin I (cTnI) in human whole blood, serum or plasma. It is mainly used for auxiliary diagnosis of myocardial infarction.

【Summary】

Troponin I is composed of 205 amino acids with a relative molecular weight of 24kd. It is a protein rich in α -helix. It forms complex with cTnT and cTnc, which have their own structure and function. After myocardial injury, cardiac myocytes burst, and troponin I released into the blood circulation system, which increased significantly in 4-8 hours, peaked in 12-16 hours after myocardial injury, and remained high in 5-9 days. Troponin I is the most ideal biomarker of myocardial infarction, because of its high specificity and sensitivity.

【Test Principle】

The test is a sandwich immunoassay. If there are cTnI in the sample, it will be combined with colloidal gold labeled anti-cTnI monoclonal antibody, form a complex. Under the action of chromatography, the complex flows on the nitrocellulose membrane. Then, the complex will combine to another anti-cTnI monoclonal antibody (T line) coated on the nitrocellulose membrane. The control line (C line) must appear in the control area of the rod for the result to be valid. A line will appear in the test line area, indicating a positive result.

【Main components】

Materials Provided:

Specification Material	1 test/kit	5 tests/kit	10 tests/kit	25 tests/kit
Test Cassette	1	5	10	25
Whole Blood Buffer	1	1	1	1
Disposable Pipettes	1	5	10	25
Instruction for Use	1	1	1	1

Materials Optioned:

1. Alcohol pad
2. Safety lancet

Materials Required but Not Provided:

- 1.Timer
- 2.Vortex mixer
- 3.Tube rack for specimens
- 4.Any necessary personal protective equipment

【Storage Conditions and Validity】

- 1.This product should be stored in a dark and dry place at 2~30°C.The validity period of the kit is 24 months.
- 2.After unpacking the aluminum foil bag of the test card, It should be used in the specified environment (Temperature 2-35°C, Humidity 40%-90%) within 1 hour.
- 3.Please see label for the information about the date of manufacture and shelf life.

【Samples Collection Handling】

1. This kit is used to detect human serum/plasma/whole blood samples. The plasma and whole blood samples are recommended to use EDTA, heparin or sodium citrate for anticoagulation. Other body fluids and samples may not get accurate results.

2. After the blood samples are collected, if they cannot be tested in time, the serum/plasma should be stored at 2-8°C for 7 days.The sample can be stored for 30 days under -15°C. The whole blood samples should not be frozen and can be stored for 3 days at 2-8°C.

【Test Method】

- 1.Read the instructions for use completely before testing
- 2.Before use, take out the reagents and specimens, places the reagent on a flat table and balance them to room temperature (18-25°C).
- 3.The operators take the test card out of the packaging bag and place it on the platform table.
- 4.Add the specimens

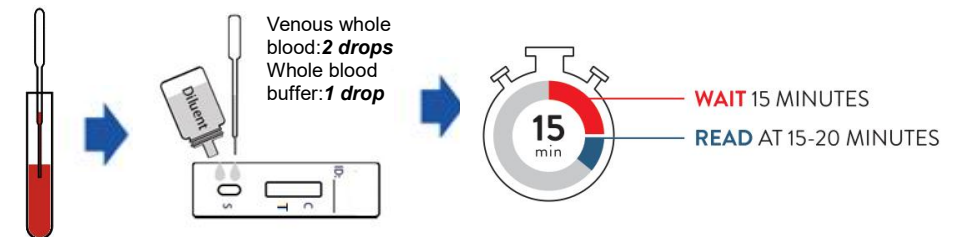
For serum or plasma samples

- Collect and process blood samples according to standard operating procedures to obtain serum/plasma samples.
- The operator uses a disposable pipette to absorb 2 drops (60 μ L) of the Serum or Plasma sample,add it to the sample well.After finish adding sample,the operators start timing and keep it react for 15 minutes.



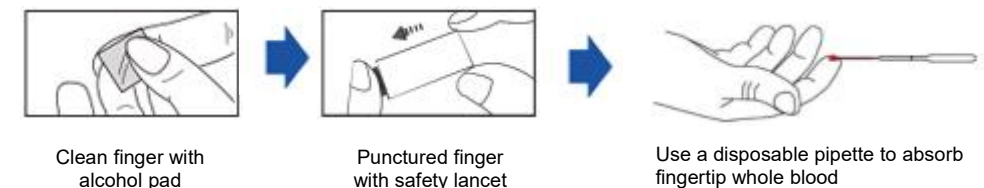
For venous whole blood samples

- Collect and process blood samples according to standard operating procedures to obtain Venous whole blood samples.
- The operator uses a disposable pipette to absorb 2 drops (60 μ L) of the Venous whole blood sample,add it to the sample well. Immediately add 1 drop of whole blood buffer to the sample well.After finish adding sample,the operators start timing and keep it react for 15 minutes.



For fingertip whole blood samples

- Clean the puncture site with the alcohol pad
- After the alcohol is dried, the fingertips are punctured with safety lancet to form blood droplets
- The operator uses a disposable pipette to absorb 2 drops (60 μ L) of the fingertip whole blood sample,add it to the sample well. Immediately add 1 drop of whole blood buffer to the sample well. After finish adding sample, the operators start timing and keep it react for 15 minutes.



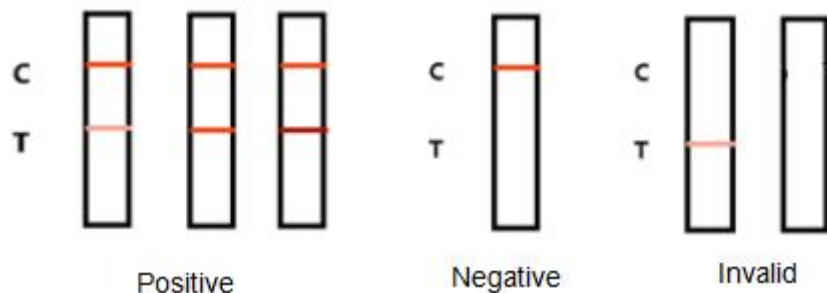


【Interpretation of Test Results】

Positive(+): There is coloration on line C, and a colored line appeared T line.

Negative(-): There is coloration on line C only showing as following picture.

Invalid: There is no coloration on line C, as shown in the following pictures. The test is invalid or an error in operation occurred. Repeat the assay with a new cartridge.



【Reporting of Results】

Positive test:

If any Positive, there is currently a suspicion of question of myocardial infarction, etc. contact your doctor or local health department immediately. Perform another test or to confirm the result.

Negative test:

Negative test results do not preclude infection and should not be used as the sole basis for treatment or other patient management decisions. It is recommended that these results be confirmed by other testing methods, if necessary, for patient management Control.

Invalid:

If the control line C is not visible, the result is invalid. An invalid result may have been caused by the incorrect execution of the test. Please perform a new test with a new sample and a new test cassette. If the result is invalid again, you should consult a doctor or a test center.

【Limitation of The Test】

1. This test has been developed for testing human whole blood, serum and plasma specimen.
2. The results of cTnI Rapid Test Kit should be evaluated with all clinical and laboratory data available. If cTnI test results do not agree with the clinical evaluation, additional tests should be performed.
3. The false positive results may come from cross-reactions with some similar antibodies in blood; and similar epitopes from non-specific components in blood capturing colloidal gold labeled antibodies.
4. Other factors may interfere with Anbio cTnI Rapid Test Kit and may cause erroneous results. These include technical or operation errors, as well as additional substances in blood specimens.

【Performance Characteristics】

1. The clinical performance of cTnI Rapid Test Kit was evaluated in comparison to cTnI test using clinical specimens. The results are shown in the following tables.

For serum samples

cTnI Rapid Test Kit	Commercial cTnI test		
	Positive	Negative	Total
Positive	52(a)	2(b)	54(a+b)

Negative	1(c)	100(d)	101(c+d)
Total	53(a+c)	102(b+d)	155(a+b+c+d)
Coincidence rate and 95% confidence interval			
	Coincidence	95% Confidence Interval	
Clinical sensitivity	98.11%	89.93%~99.95%	
Clinical specificity	98.04%	93.10%~99.76%	
Total coincidence rate	98.06%	94.45%~99.60%	

For plasma samples

cTnI Rapid Test Kit	Commercial cTnI test		
	Positive	Negative	Total
Positive	52(a)	1(b)	53(a+b)
Negative	1(c)	101(d)	102(c+d)
Total	53(a+c)	102(b+d)	155(a+b+c+d)
Coincidence rate and 95% confidence interval			
	Coincidence	95% Confidence Interval	
Clinical sensitivity	98.11%	89.93%~99.95%	
Clinical specificity	99.02%	94.66%~99.98%	
Total coincidence rate	98.71%	95.42%~99.84%	

For whole blood samples

cTnI Rapid Test Kit	Commercial cTnI test		
	Positive	Negative	Total
Positive	51(a)	1(b)	52(a+b)
Negative	2(c)	101(d)	103(c+d)
Total	53(a+c)	102(b+d)	155(a+b+c+d)
Coincidence rate and 95% confidence interval			
	Coincidence	95% Confidence Interval	
Clinical sensitivity	96.23%	87.02%~99.54%	
Clinical specificity	99.02%	94.66%~99.98%	
Total coincidence rate	98.06%	94.45%~99.60%	

2. **Limitation of Detection (LoD)**

The LoD of cTnI Rapid Test Kit is 0.3 ng/mL.













3. **Interfering substances:** The Concentrations of triglycerides 40mmol/L, hemoglobin 2g/L, rheumatoid factor 1000IU/mL, bilirubin 350µmol/L and HAMA 600ng/mL have no effect on the test results.

【Precautions】

1. After opening the package, the kit should be ready for use as soon as possible and avoid placing it in a high temperature (over 30°C) and high humidity environment for a long time.
2. All samples (whole blood, serum and plasma) and test cards after use should be considered potentially dangerous and should be treated as infectious materials, and the waste should be disposed of in accordance with the regulations of the hospital or environmental protection department.
3. The test strips with any color lines before the test should not be used and the reagents with damaged packaging bags or invalid seals should not be used.
4. The kit is for in vitro diagnostic use only. The kit is for single-use, please do not use the product after it expires.


【Index of Symbols】

IVD	In vitro diagnostic medical device		Do not re-use
EC REP	Authorized representative in the European Community/ European Union		Consult instructions for use or consult electronic instructions for use

	Caution		Manufacturer
	Temperature limit		Batch code
	Use-by date		Keep dry
	Keep away from sunlight		Catalog number
	Date of manufacture		Contains sufficient for <n> tests
	The product meets the basic requirements of European in vitro diagnostic medical devices directive 98/79/EC		Do not use if package is damaged and consult instructions for use

【Basic Information】

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