06991335001V8.0

TROPT Sensitive

cobas®

Troponin T Sensitive

REF 11621947196 ∑ 5

REF 11621904193 ∑ 10

SYSTEM **cobas h** 232

English

Intended use

Qualitative immunological test for the specific detection of cardiac troponin T in heparinised or EDTA venous blood.

Summary

Cardiac troponin T is a muscle structural protein which is released in the event of cell damage (necrosis) to the myocardium. The TROPT Sensitive test is designed for qualitative determination of cardiac troponin T in the blood as an aid for risk stratification of patients with unstable angina pectoris and for diagnosis of myocardial infarction (ST-segment elevation myocardial infarction (STEMI) and Non-ST-segment elevation myocardial infarction (NSTEMI)) among patients suffering from thoracic pain or who are suspected of experiencing myocardial infarction or acute coronary syndrome in accordance with the redefinition of myocardial infarction by the ESC (European Society of Cardiology) and the ACC (American College of Cardiology)[1] as well as the guidelines laid down by the ACC and the AHA (American Heart Association)[2].

A negative troponin T result does not rule out myocardial infarction as the release of troponin T from the damaged myocardial cells into the circulating blood occurs with time delays which vary from person to person.

The release kinetics of troponin T after an infarction should therefore be taken into account when interpreting the test results. Troponin T can first be detected in the blood after a time period of 2 to more than 10 hours after the onset of symptoms. This means that a negative troponin T result does not rule out myocardial infarction. Typical or atypical symptoms and a negative Trop T result call for further diagnostic measures to be applied, including more troponin T tests. Due to its release kinetics, troponin T can be detected for up to 14 days after onset of cardiac infarction.[3]

Test principle

The test contains two monoclonal antibodies specific for cardiac troponin T (cTnT): one gold-labelled, the other biotinylated. Both antibodies form a sandwich complex with any cTnT present in the blood sample. Erythrocytes are removed from the sample, and the plasma passes through the detection zone, in which the cTnT sandwich complexes gather along a line, appearing as a red streak. Excess gold-labelled antibodies gather along the control line, signalling visually that the test was valid.

Reagents

One test contains:

Biotinylated mouse monoclonal anti-troponin T antibodies 0.23 µg

Gold-labelled mouse monoclonal anti-troponin T antibodies 0.11 µg

Buffer and non-reactive components 2.3 mg

Precautions and warnings

For in vitro diagnostic use.
Exercise the normal precautions required for handling all laboratory reagents.
Disposal of all waste material should be in accordance with local guidelines.
Safety data sheet available for professional user on request.

Storage and stability

Until the printed expiration date at 2-8 °C.

At room temperature (15-25 °C), the unopened pouch is stable for up to 4 weeks but not beyond the expiration date.

The test can be used immediately after removal from the refrigerator.

The test must be used within 15 minutes once the pouch has been opened.

Sample stability: 8 hours at room temperature. Do not refrigerate or freeze sample.

Specimen collection and preparation

Use **heparinised** or **EDTA** venous **whole blood** only.

Do not use other anticoagulants, capillary blood, serum or plasma, blood collection tubes containing citrate, sodium fluoride or other additives.

For specimen collection and preparation only use suitable tubes or collection containers.

The following heparin blood collection tubes have been tested: Sarstedt Monovette, Becton Dickinson Vacutainer, Becton Dickinson Vacutainer PST II, Greiner Vacuette, Terumo Venosafe. In the case of Sarstedt Monovettes, only tubes without separating gel are suitable.

No data is available for blood collection tubes supplied by other manufacturers. An influence on the test result in individual cases cannot be ruled out.

Sample volume: 150 µL

Materials provided

- REF 11621947196, TROPT Sensitive, 5 tests,
  Roche CARDIAC Pipettes, 5 disposable syringes
  5 documentation labels / 5 cover strips / 1 test processing label
- REF 11621904193, TROPT Sensitive, 10 tests,
  10 documentation labels / 10 cover strips / 1 test processing label

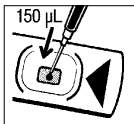
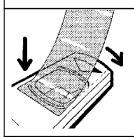
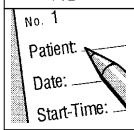
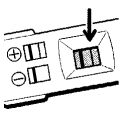
Materials required (but not provided)

- REF 11622889190, Roche CARDIAC Pipettes, 20 disposable syringes (150 µL)
- REF 11937553193, Roche CARDIAC Control Troponin T (2 x 1 ml)
- General laboratory equipment

For Germany only:

- REF 05915864190, Roche CARDIAC Control Troponin T (2 x 1 ml)

Testing procedure

	1. Pipette the total volume of 150 µL onto the application area marked with a red triangle.
	2. As an anti-infection precaution, cover the application area with a numbered cover strip provided. Gently peel off the label and attach it to the strip as shown.
	3. Enter patient information, date and start time (in minutes) on the appropriate numbered documentation label to ensure correct matching of test strip and patient.
	4. Read the result in the window within 15–20 minutes of transferring the sample, and record it on the documentation label. The label may be removed and attached to the patient's medical record.

WARNING
Before use, visually check if the packaging of the Cardiac pipettes and/or the pipettes are intact. If the needle falls off or gets stuck during use, do not try to re-cap it. Stop using the pipette immediately and dispose of it in a sturdy sharps container (in accordance with applicable local regulations and directives and your facility's guidelines).

Quality control

For quality control, use Roche CARDIAC Control Troponin T.

The results must correspond with the expected values in the control solution method sheet.

The control intervals and limits should be adapted to each laboratory's individual requirements. Values obtained should fall within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the defined limits.

Follow the applicable government regulations and local guidelines for quality control.

Limitations - interference

The assay is unaffected by icterus (bilirubin ≤ 20 mg/dL), hemolysis (Hb ≤ 200 mg/dL), lipemia (triglycerides ≤ 500 mg/dL), haematocrit values in the range of 14-55 %, and biotin ≤ 100 ng/mL.

TROPT Sensitive

cobas®

Troponin T Sensitive

Samples should not be taken from patients receiving therapy with high biotin doses (i.e. > 5 mg/day) until at least 8 hours following the last biotin administration.

High concentrations of lipoic acid (e. g. in pharmaceuticals or as food additive) can lead to lower measurement values.

Skeletal muscle-troponin T in a concentration up to 500 ng/mL does not interfere with the test result.

There is no high-dose hook effect at analyte concentrations up to 200 ng/mL.

At very high concentrations of troponin T the control line may fail to appear. In this case, the test must be carried out using another method, like the Elecsys Troponin T test.

Patient samples may contain heterophilic antibodies which could react in immunoassays to give falsely elevated or decreased results. Reasons for the presence of heterophilic antibodies might be for example elevated levels of rheumatoid factors or the treatment of patients with monoclonal mouse antibodies for therapeutic or diagnostic purposes.

The Roche CARDIAC TROPT Sensitive test contains ingredients that minimise interference from heterophilic antibodies. However, complete elimination of interference from all samples cannot be guaranteed.

Interferences caused by pharmaceuticals at therapeutic concentrations are not known.

For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

Measuring range

 ⊖ No detection line, only control line = negative

 ⊕ Visible detection line and control line = positive

Information on reading results

- **The absence of the control line indicates that the result must not be used. Repeat the test using a new test strip.**
- The control line serves only to ensure that the test strip is working properly. The intensity of the control line should not be compared with the detection line. The detection line is usually much lighter in colour. **Even a very faint detection line indicates a positive test result, regardless of the colour intensity and thickness of the control line.**
- The reaction normally takes 15 minutes. The detection line may appear after only a few minutes if high concentrations are present, however.
- The maximum amount of time you may take between applying the sample and reading the result is 20 minutes. A detection line appearing later than **20 minutes** following application may indicate a false positive result. If in doubt, repeat the test.
- The detection line may appear in varying intensity and at different times within the reaction period, depending on the troponin T concentration in the sample. **The result is positive even if the detection line is very faint.**
- To observe the result, hold the test so as to prevent shadows being cast on the result window. Bright diffuse light is best. If the colour seen in the result window turns reddish-brown, the result can no longer be properly read. If this occurs, repeat the test.

Expected values

A **positive result** means that the concentration of troponin T in the sample is above the test's threshold value of 0.1 ng/mL. This is evidence of cell damage to the myocardium.

A **negative result**: Due to the release kinetics of troponin T, a negative result does not rule out a cardiac infarction or myocardial cell damage with certainty. If suspicion of an infarction persists, the test should be repeated at suitable time intervals in keeping with the guidelines from the professional cardiology societies. A negative Trop T result must not be used as the sole diagnostic criterion.

Test interpretation in patients with chest pain and suspected myocardial infarction:[a)]

Typical symptoms or ECG clearly positive	**no cTnT**	Emergency hospital admission with physician in attendance
Atypical symptoms ECG inconclusive	**cTnT positive**	Emergency hospital admission with physician in attendance
between 0.03 ng/mL and 0.1 ng/mL	**cTnT negative**	Repeat ECG and TnT after 6 hours. If ECG normal, TnT negative and symptoms atypical: further outpatient investigation

a) Recommendation by the German expert committee for inclusion and evaluation of TROPT Rapid Test in the Doctors' Fees Tariff, dated 10 January 1996.

Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference ranges.

References

1 Myocardial infarction redefined – a consensus document of the Joint European Society of Cardiology/American College of Cardiology Committee for the redefinition of myocardial infarction. EUR Heart I 2000;21:1502-1513.

2 ACC/AHA Guidelines for the Management of Patients with Unstable Angina and Non-ST-Segment Elevation Myocardial Infarction: Executive Summary and Recommendations. Circulation 2000;102:1193-1209.

3 Hamm CW. Leitlinien: Akutes Koronarsyndrom (ACS), Teil 1: ACS ohne persistierende ST-Hebung. Z Kardiol 2004;93:72-90.

For further information, please refer to the appropriate operator's manual for the analyzer concerned, and the Method Sheets of all necessary components.

A point (period/stop) is always used in this Method Sheet as the decimal separator to mark the border between the integral and the fractional parts of a decimal numeral. Separators for thousands are not used.

Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard:

CONTENT	Contents of kit
SYSTEM	Analyzers/Instruments on which reagents can be used
REAGENT	Reagent
CALIBRATOR	Calibrator
→	Volume after reconstitution or mixing
GTIN	Global Trade Item Number

CE

Roche Diagnostics GmbH, Sandhofer Strasse 116, D-68305 Mannheim
www.roche.com

Roche