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Roche CARDIAC T Quantitative

cobas®

Troponin T Quantitative

REF 04877772190 | Σ 10 | SYSTEM **cobas h** 232

English

Intended use

Quantitative immunological test for the specific detection of cardiac troponin T in heparinised venous blood for use with the **cobas h** 232 instrument.

Summary

The Roche CARDIAC T Quantitative test serves as an aid in the diagnosis of patients with suspected myocardial cell damage, for example in case of acute coronary syndromes (detection and ruling out of acute myocardial infarction (AMI) and subacute myocardial infarction, determination of infarction size, risk stratification of AMI patients). Troponin T levels may also be elevated as a consequence of inflammatory diseases of the myocardium (myocarditis) as well as mechanical, chemical and electrical damage to the myocardium (contusion, PTCA, heart operation, heart transplantation, prosthetic heart valve, biopsy, cardiotoxic substances, defibrillation, catheter ablation). A troponin T result of less than 50 ng/L 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 cannot be detected in the blood before a time period of 2 to more than 10 hours following the infarction. This means that a troponin T result of less than 50 ng/L does not rule out myocardial infarction. Both typical and atypical symptoms in connection with a troponin T result of less than 50 ng/L call for the application of further diagnostic measures, including repeated troponin T tests. Due to its release kinetics, troponin T can be detected for up to 14 days after onset of cardiac infarction.[1,2,3,4,5,6,7,8]

Test principle

The Roche CARDIAC T Quantitative test contains two monoclonal antibodies specific to cardiac troponin T (cTnT): one gold-labelled, the other biotinylated. The antibodies form a sandwich complex with the cTnT in the blood. Following removal of erythrocytes from the sample, plasma passes through the detection zone in which the gold-labelled cTnT sandwich complexes accumulate and the positive signal is displayed as a reddish line (the signal line). Excess gold-labelled antibodies accumulate along the control line, signalling that the test was valid. The intensity of the signal line increases in proportion to the troponin T concentration.

The optical system of the instrument detects the two lines and measures the intensity of the signal line. The integrated software converts the signal intensity to a quantitative result and shows it in the display.

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.

Up to 1 week at room temperature (15-25 °C).

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** venous **whole blood** only.

Do not use other anticoagulants, capillary blood, serum or plasma, blood collection tubes containing EDTA, 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 04877772190, Roche CARDIAC T Quantitative test
- 1 code chip

Materials required (but not provided)

- REF 11622889190, Roche CARDIAC Pipettes, 20 disposable syringes (150 µL)
- REF 04890515190, Roche CARDIAC Control Troponin T (2 x 1 mL)
- REF 04880668190, Roche CARDIAC IQC
- REF 04901126190, **cobas h** 232 instrument
- REF 04901142190, **cobas h** 232 instrument with scanner

General laboratory equipment

Calibration

The Roche CARDIAC T Quantitative test is calibrated against the Elecsys Troponin T hs test using serum.

The instrument automatically reads in the lot-specific calibration data from the code chip, eliminating the need for calibration by the user.

Lot code

Every kit contains a lot-specific code chip. The instrument display prompts the user to insert the chip. To ensure that the code chip and test strip lot match, compare the lot number in the display with the number on the code chip. The code chip provides the instrument with all required lot-specific information. An error message is displayed if the wrong code chip is inserted for a test strip lot.

Quality control

For quality control, use Roche CARDIAC Control Troponin T.

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.

Calculation

The instrument automatically calculates the concentration of each sample.

The reaction time for the Roche CARDIAC T Quantitative test to display a quantitative result is 12 minutes. In addition, approximately 2 minutes are required for sample detection.

Limitations - interference

The assay is unaffected by icterus (bilirubin ≤ 20 mg/dL), hemolysis (Hb ≤ 200 mg/dL), lipemia (triglycerides ≤ 440 mg/dL), haematocrit values in the range of 30-50 %, and biotin ≤ 200 ng/mL.

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.

No interference was observed from rheumatoid factors up to a concentration of 300 IU/mL.

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

Skeletal muscle troponin T up to 500000 ng/L leads to a maximum increase of + 10 %; at 1000000 ng/L the increase may be up to 30 %.

There is no high-dose hook effect at analyte concentrations up to 200000 ng/L.

At very high concentrations of troponin T the control line may fail to appear, and the instrument may display an error message. In this case, the test

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must be carried out using another method, like the Elecsys Troponin T hs 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 T Quantitative 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

50-100 ng/L (semi-quantitative)

100-2000 ng/L (quantitative)

Expected values

Troponin T concentration	Result displayed	Comment
below 50 ng/L	Trop T < 50 ng/L	Acute myocardial infarction not likely, but still possible; in context of clinical assessment repeat the test (e.g. after 3-6 h) to detect rising Troponin T levels.
between 50 ng/L and 100 ng/L	Trop T 50-100 ng/L	Acute myocardial infarction possible, repeat the test to detect rising Troponin T levels in context of clinical assessment according to guidelines; search for differential diagnosis and other causes of Troponin T elevation.
between 100 ng/L and 2000 ng/L	for example, Trop T 900 ng/L	Acute myocardial infarction likely; consider differential diagnosis for other causes of Troponin T elevation.
above 2000 ng/L	Trop T > 2000 ng/L	Acute myocardial infarction very likely; consider differential diagnosis for other causes of Troponin T elevation.

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

Interpretation of results

A typical pattern of rise and fall together with an elevation of the troponin T concentration above the test's detection limit of 50 ng/L is regarded as an acute MI[9], if one additional out of several criteria for evidence of myocardial ischemia as given in the Universal Definition of Myocardial Infarction is fulfilled.[10]

Result < 50 ng/L: Due to the release kinetics of troponin T, even a result of less than 50 ng/L does not rule out 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 troponin T result must not be used as the sole diagnostic criterion.

Specific performance data

Representative performance data on the instruments are given below. Results obtained in individual laboratories may differ.[11]

Precision

Repeatability was measured with 3 lots of Roche CARDIAC T Quantitative tests and heparinised human blood. The majority of the variation coefficients were below 9 % over the entire measurement range.

Intermediate precision was measured with the Roche CARDIAC ControlTroponin T quality control in 5 different hospitals. The majority of the variation coefficients were below 11 %.

Method comparison

A comparison of 3 lots of the Roche CARDIAC T Quantitative test with the Elecsys Troponin T test in a clinical patient population showed slopes between 0.80 and 1.20 in the majority of the method comparisons with a correlation coefficient of ≥ 0.9.

References

1 Alpert JS, Thygesen K. Myocardial infarction redefined – A consensus document of The Joint European Society of Cardiology/American College of Cardiology Commitee for the Redefinition of Myocardial Infarction. Eur Heart J 2000;21:1502-1513.

2 Braunwald E, et al. ACC/AHA Guidelines for the Management of Patients WithUnstable Angina and Non-ST-Segment Elevation Myocardial Infarction: Executive Summary and Recommendations. Circulation 2000;102:1193-1209.

3 Katus HA, Remppis A, Neumann FJ, et al. Diagnostic efficiency of Troponin T measurements in acute myocardial infarction. Circulation 1991;83:902–912.

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6 Ohman EM, Armstrong PW, Christenson RH, et al. for the GUSTO-IIa Investigators. Cardiac troponin T levels for risk stratification in acute myocardial ischemia. New Engl J Med 1996;335:1333-1341.

7 Stubbs P, Collinson P, Moseley D, et al. Prognostic significance of admission troponin T concentrations in patients with myocardial infarction. Circulation 1996;94:1291-1297.

8 Wu AHB, Apple FS, Gibler WB, et al. National Academy of Clinical Biochemistry Standards of Laboratory Practice: Recommendations for the Use of Cardiac Markers in Coronary Artery Diseases. Clin Chem 1999;45:7,1104-1121.

9 Giannitsis E, Katus HA. Current recommendations for interpretation of the highly sensitive troponin T assay for diagnostic, therapeutic and prognostic purposes in patients with a non-ST-segment-elevation acute coronary syndrome. European Cardiology 2010;5:44-47.

10 Thygesen K, Alpert JS, White HD, on behalf of the Joint ESC/ACCF/AHA/WHF Task Force for the Redefinition of Myocardial Infarction. Universal definition of myocardial infarction. Eur Heart J 2007;28:2525-2538.

11 Bertsch T, Chapelle JP, et. al. Multicentre analytical evaluation of a new point-of-care system for the determination of cardiac and thromboembolic markers. Clin Lab 2010;56:37-49.

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 (for USA: see https://usdiagnostics.roche.com for definition of symbols used):

SYSTEM	Analyzers/Instruments on which reagents can be used
GTIN	Global Trade Item Number

06341454001V6.0

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