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Roche CARDIAC D-Dimer

cobas®

REF	Σ	SYSTEM
04877802190	10	**cobas h** 232
04877802191	10	

English

Intended use

The Roche CARDIAC D-Dimer is an in vitro diagnostic quantitative immunological test for the detection of d-dimer in heparinized venous blood for use with the **cobas h** 232 instrument.

The Roche CARDIAC D-Dimer test serves as an aid in diagnosis when deep venous thrombosis and pulmonary embolism is suspected. A negative d-dimer result is an indication that these diseases can be ruled out with high probability.

The Roche CARDIAC D-Dimer test is intended for near-patient testing.

Not for self-testing.

Summary

D-dimer is a degradation product of crosslinked fibrin. The d-dimer concentration is a measure of the fibrinolytic activity of plasmin in the vascular system. Elevated concentrations of d-dimer indicate increased coagulatory and fibrinolytic activity. With a normal d-dimer value, acute deep vein thrombosis and pulmonary embolisms may be ruled out with very high reliability.[1,2,3,4,5,6,7,8,9,10,11,12,13,14]

The Roche CARDIAC D-Dimer test is intended to be used in professional non-critical care and critical care environments such as general practitioner's offices, hospital wards, and intensive care units.

Test principle

The test contains two monoclonal antibodies against fibrin degradation products which contain the d-dimer structure element. One of the antibodies is gold-labelled, the other biotinylated. The antibodies form a sandwich complex with the d-dimer in the blood. Following removal of erythrocytes from the sample, plasma passes through the detection zone in which the gold-labelled d-dimer 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 d-dimer concentration.

The optical system of the instrument detects the 2 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-d-dimer antibodies ≥ 1.0 µg

Gold-labelled mouse monoclonal anti-d-dimer antibodies ≥ 1.0 µg

Buffer and non-reactive components ≥ 2.8 mg

Precautions and warnings

For in vitro diagnostic use for health care professionals. Exercise the normal precautions required for handling all laboratory reagents.

Infectious or microbial waste:
Warning: handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

Environmental hazards:
Apply all relevant local disposal regulations to determine the safe disposal.

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 **heparinized** 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.

The following heparin blood collection tubes have been tested: Sarstedt Monovette, Becton Dickinson Vacutainer, Becton Dickinson Vacutainer PST II, Greiner Vacuette. 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 04877802190, REF 04877802191 Roche CARDIAC D-Dimer test
- 1 code chip

Materials required (but not provided)

- REF 11622889190, Roche CARDIAC Pipettes, 20 disposable syringes, 150 µL (or other suitable pipettes with pipetting volume of 150 µL)
- REF 04890523190, Roche CARDIAC Control D-Dimer (2 x 1 mL)
- REF 04880668190, Roche CARDIAC IQC
- REF 04901126xxx, **cobas h** 232 instrument
- REF 04901142xxx, **cobas h** 232 instrument with scanner
- General laboratory equipment

Calibration

The Roche CARDIAC D-Dimer test is calibrated against the Tina-quant D-Dimer test using citrate plasma.

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 D-Dimer.

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 D-Dimer test to display a quantitative result is 8 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 ≤ 470 mg/dL), haematocrit values in the range of 26-56 %, and biotin ≤ 30 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.

Very high d-dimer concentrations (approx. > 50 µg/mL) can lead to lowered values (hook effect). However, this effect does not result in false normal values. Alternatively, the control line may fail to appear and the instrument may display an error message. In this case, determination must be carried out using another method, like the Tina-quant D-Dimer test from Roche.

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High concentrations of d-fragments as may appear under thrombolytic therapy, such as Reteplase, can lead to lower measurement values.

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 D-Dimer test contains ingredients that minimize 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.

Interferences caused by pharmaceuticals at therapeutic concentrations are not known.

No interferences of the following special cardiac drugs have been observed up to the specified concentrations:
Amlodipine (0.075 mg/L), Evolocumab (300 mg/L), Atorvastatin (0.15 mg/L), Canagliflozin (300 mg/L), Carvedilol (50 mg/L), Clopidogrel (75 mg/L), Dabigatran (525 mg/L), Digoxin (0.5 mg/L), Epinephrine (Adrenaline) (0.5 mg/L), Insulin (1.6 mg/L), Isosorbide mononitrate (2.21 mg/L), Lidocaine (100 mg/L), Liraglutide (0.168 mg/L), Lisinopril (40 mg/L), Methylprednisolone (80 mg/L), Metoprolol (150 mg/L), Phenprocoumon (Marcumar) (15 mg/L), Propafenone (900 mg/L), Rivaroxaban (8 mg/L), Sacubitril (194.4 mg/L), Spironolactone (400 mg/L), Tolbutamide (300 mg/L), Torasemide (200 mg/L), Valsartan (205.6 mg/L), Verapamil (240 mg/L).

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

Measuring range

0.15-4 µg/mL.

1 µg/mL corresponds to 1 µg FEU/mL.

Expected values

The normal range for the Roche CARDIAC D-Dimer test includes values up to 0.5 µg/mL. Values above 0.5 µg/mL are to be considered as pathologically elevated.

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

Specific performance data

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

Precision

Repeatability was measured with 3 lots of Roche CARDIAC D-Dimer tests and heparinised human blood. The majority of the variation coefficients was below 11 %. Intermediate precision was measured with the Roche CARDIAC Control D-Dimer quality control in 5 different hospitals. The majority of the variation coefficients was below 10 % (level 1) and below 17 % (level 2).

Method comparison

A comparison using 3 different lots of the Roche CARDIAC D-Dimer test with the Tina-quant D-Dimer test in a clinical patient population showed slopes between 0.94 and 1.03 in the majority of the method comparisons. The majority of the correlations in these method comparisons were ≥ 0.93.

References

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9 van der Graaf F, van den Borne H, van der Kolk M, et al. Exclusion of deep venous thrombosis with D-dimer testing--comparison of 13 D-dimer methods in 99 outpatients suspected of deep venous thrombosis using venography as reference standard. Thromb Haemost. 2000;83(2):191-198.

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11 NICE guideline. Venous thromboembolic diseases: diagnosis, management and thrombophilia testing. Published: 26 March 2020. www.nice.org.uk/guidance/ng158.

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14 Toll DB, Oudega R, Vergouwe Y, et al. A new diagnostic rule for deep vein thrombosis: safety and efficiency in clinically relevant subgroups. Fam Pract. 2008;25(1):3-8.

For further information, please refer to the appropriate Operators 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.

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

The Summary of Safety & Performance Report can be found here: https://ec.europa.eu/tools/eudamed

Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard (for USA: see dialog.roche.com for definition of symbols used):

	Device for near-patient testing
	Device not for self-testing
CONTENT	Contents of kit
SYSTEM	Analyzers/Instruments on which reagents can be used
GTIN	Global Trade Item Number
UDI	Unique Device Identifier
PZN	Pharmazentralnummer (for Germany only)

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