05051053001V2.0

D-Dimer Gen.2 Control I/II

cobas®

REF **05050936** 190

2 x 1 mL D-Dimer Gen.2 Control I

2 x 1 mL D-Dimer Gen.2 Control II

English

System information

For use on Roche/Hitachi MODULAR and **cobas c** analyzers the control code is 242 for Control I and 243 for Control II.

For use on COBAS INTEGRA analyzers the system ID is 07 6995 9 for Control I and 07 6996 7 for Control II.

Intended use

D-Dimer Gen.2 Control I/II is for use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the enclosed value sheets.

Summary

D-Dimer Gen.2 Control I/II contains 2 liquid ready-for-use controls based on human serum matrix. The adjusted concentrations of the control components are in the low concentration range for Control I and the elevated concentration range for Control II.

Some methods specified in the relevant value sheet may not be available in all countries.

Reagents – working solutions

Reactive components:

Human serum matrix with chemical additives and material of biological origin as specified. The origin of the biological additive is as follows:

Analyte	Origin
D-Dimer containing fragments	human

Non-reactive components:
Preservatives

The concentrations of the control components are lot-specific. The exact target values are given in the electronically available or enclosed value sheets.

The values are also encoded in the enclosed control barcode sheets for Roche/Hitachi MODULAR and COBAS INTEGRA analyzers.

For the **cobas c** analyzers (except for the **cobas c** 111 analyzer) the values are encoded in electronic files sent via the **cobas** link to the analyzers.

The D-Dimer concentrations are given in µg FEU[a)]/mL. They refer to the quantity of fibrinogen used to prepare the original D-Dimer reference standard.[1,2]

a) Fibrinogen Equivalent Unit

Target values and ranges

The target values were determined using the method stated in the electronically available or enclosed value sheets. Determinations for Roche methods were performed under strictly standardized conditions on Roche analyzers using Roche system reagents and the Roche master calibrator. The target value specified is the mean of all values obtained. The corresponding control range is calculated as the target value ± 3 standard deviations (the standard deviation being the value obtained from several target value determinations). Results should be within the defined ranges. Each laboratory should establish corrective measures to be taken if values fall outside the range.

A clinically insignificant difference may be seen between the value(s) listed on the value sheet and the value(s) obtained from the instrument readable data. This is caused by:

- the rounding of value(s) during conversion from the unit in the instrument readable data to the unit that is being used.
- the calculation of the ranges by the analyzer using the percentage values for the ranges encoded in the barcodes.

The traceability of the target value is given in the respective Method Sheets for the system reagents to be used in combination with the recommended calibrator.

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.

All human material should be considered potentially infectious. All products derived from human blood are prepared exclusively from the blood of donors tested individually and shown to be free from HBsAg and antibodies to HCV and HIV.
The testing methods applied were FDA-approved or cleared in compliance with the European Directive 98/79/EC, Annex II, List A.
However, as no testing method can rule out the potential risk of infection with absolute certainty, the material should be handled with the same level of care as a patient specimen. In the event of exposure, the directives of the responsible health authorities should be followed.[3,4]

Handling

The product is ready-for-use. Mix carefully before use. Avoid the formation of foam.

The enclosed barcoded labels are intended exclusively for the Roche/Hitachi MODULAR analyzers and **cobas c** systems to identify the control. Attach the barcoded labels to the tubes carrying the sample cups containing the control material.

Storage and stability

Store at 2-8 °C.

Criterion for the stability data stated by Roche:
Recovery within ± 10 % of initial value.

Stability:

Unopened:	up to the stated expiration date at 2-8 °C
After opening:	1 day at 15-25 °C or 3 months at 2-8 °C provided that dispensing of the control occurs without microbial contamination, e.g. by pouring out.

Store controls tightly capped when not in use.

Materials provided

- See “Reagents – working solutions” section
- Barcoded labels

Materials required (but not provided)

- Roche system reagents and clinical chemistry analyzers
- General laboratory equipment

Assay

Dispense the required volume into a sample cup and analyze in the same way as patient samples.

The controls should be run daily in parallel with patient samples and after every calibration. Control intervals must be adapted to individual laboratory’s requirements.

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

References

1 Adema E, Gebert U. Pooled patient samples as reference material for D-Dimer. Thromb Res 1995;80(1):85-88.

2 Amiral J, Plassart V, Minard F. Measurement and clinical relevance of D-dimer by ELISA. In: fibrinogen and its derivatives. Müller-Berghaus G, Scheefers-Berchel U, Selmayr E and Henschen A, eds. 285-290 experta Medica, Amsterdam 1986.

3 Occupational Safety and Health Standards: bloodborne pathogens. (29 CFR Part 1910.1030). Fed. Register.

4 Directive 2000/54/EC of the European Parliament and Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work.

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.

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Symbols

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

CONTENT	Contents of kit
→	Volume after reconstitution or mixing

FOR US CUSTOMERS ONLY: LIMITED WARRANTY

Roche Diagnostics warrants that this product will meet the specifications stated in the labeling when used in accordance with such labeling and will be free from defects in material and workmanship until the expiration date printed on the label. THIS LIMITED WARRANTY IS IN LIEU OF ANY OTHER WARRANTY, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR PARTICULAR PURPOSE. IN NO EVENT SHALL ROCHE DIAGNOSTICS BE LIABLE FOR INCIDENTAL, INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES.

Significant additions or changes are indicated by a change bar in the margin.

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