05051037001V2.0

D-Dimer Gen.2 Calibrator Set

cobas®

REF **05050901** 190 6 x 0.5 mL Calibrator

English

System information

For use on Roche/Hitachi analyzers and **cobas c** analyzers the calibrator codes are 764–769.

For use on COBAS INTEGRA analyzers the system ID is 07 6994 0.

Intended use

D-Dimer Gen.2 Calibrator Set is for use in the calibration of quantitative Roche methods on Roche clinical chemistry analyzers as specified in the enclosed value sheets.

Summary

D-Dimer Gen.2 Calibrator Set consists of 6 liquid ready-for-use calibrators based on a human serum matrix.

The concentrations of the calibrator components have been adjusted to ensure optimal calibration of the appropriate Roche methods on clinical chemistry analyzers.

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

Reagents – working solutions

Reactive components:

1 Human serum matrix (zero calibrator).

2-6 Human D-Dimer fragments in a human serum matrix.

Non-reactive components:

Preservatives

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

The values are also encoded in the enclosed calibrator barcode sheets for Roche/Hitachi MODULAR, COBAS INTEGRA and **cobas c** 111 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.

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

a) Fibrinogen Equivalent Unit

Calibrator values

The calibrator values were determined using the method stated in the electronically available or enclosed value sheets. Determinations were performed under strictly standardized conditions on Roche analyzers using Roche system reagents and the Roche master calibrator.

The calibrator values were obtained via 5-fold determinations performed in different laboratories, in several separate runs. The calibrator value specified is the mean of all values obtained.

Traceability information is given in the relevant Method Sheets for the system reagents.

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 calibrator bottles are ready for use. Mix carefully before use. Avoid the formation of foam.

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

Storage and stability

Store at 2-8 °C.

Criterion for the stability data stated by Roche:

Recovery within ± 10 % of the 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 calibrator occurs without microbial contamination, e.g. by pouring out.

Store calibrator 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

Use D-Dimer Gen.2 Calibrator Set as specified in the relevant Method Sheet for the system reagents.

Note: on Roche/Hitachi instruments standard 1 is the zero standard and standard 6 is the highest D-Dimer calibrator.

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.

Symbols

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

CONTENT	Contents of kit
CALIBRATOR	Calibrator
→	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.

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