DIAGON
Kutatások és megoldások

INSTRUCTIONS FOR USE

Dia-CAL Ddi

Calibrator for Latex D-dimer tests

Cat. No: 96006 **6 x 1 ml**
6 x 3 ml Dia-CAl Ddi Diluent

PRODUCT NAME
Dia-CAL Ddi

INTENDED USE
(Only for in vitro diagnostic purposes)
The D-dimer calibrator is a human plasma-based lyophilizate; along with its diluent it is suitable for the calibration of Diagon Dia D-Dimer test.

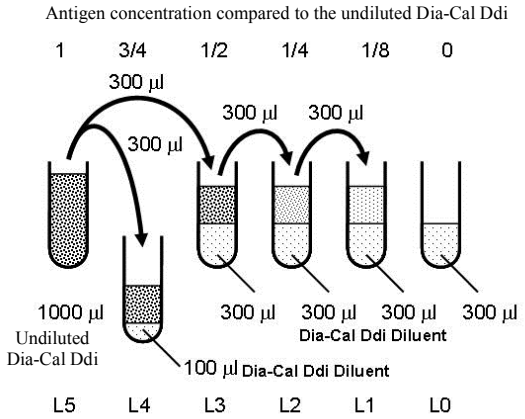
SUMMARY AND BACKGROUND
During the coagulation of plasma the soluble fibrinogen is converted to fibrin by the action of thrombin. Fibrin fibers created as a result of polymerisation process are cross-linked by factor XIIIa. The enzymatic cleavage of cross-linked fibrin results in the release of D-dimer, a characteristic product.
D-dimer levels are increased in conditions with thrombosis and microthrombi (e.g disseminated intravascular coagulation, DIC). D-dimer test is primarily used for the exclusion of deep vein thrombosis of the lower extremity and pulmonary embolism.

PRINCIPLE
D-dimer levels are determined with turbidimetry, based on the antigen – antibody interaction between D-dimer antibodies bound to polystriol beads and D-dimer antigen molecules. Calibration is required for the determination of D-dimer concentration.

COMPONENTS
Lyophilised Dia-CAL Ddi calibrator contains D-dimer antigen derived from human plasma with enzymatic digestion, salts and plasma proteins.
The Diluent is an aqueous solution containing salt, plasma protein and sodium azid (<0.01%) as preservative.

CAUTIONS AND WARNINGS
- Dia-CAL Ddi calibrator is to be used exclusively by a properly trained laboratory professional.
- Calculation with inappropriate data and the inadequate use of data presented in the Annex may lead to false results.
- The Dia-CAL Ddi should be treated with caution due to its ingredients; regulation on handling of hazardous materials should be followed.
- The calibrator should be considered as potentially infectious as it may get in contact with laboratory samples and other materials; precautionary measures should be taken.
- Caution is required to prevent microbiological contamination of the calibrator as this may possibly lead to false results during measurements.
- According to current knowledge the product does not contain particles possibly traversing from animals to human.
- Reagents that are used for the measurements or remaining thereafter and disposable plastic tools are hazardous waste. The handling of hazardous waste is determined by the applicable law and regulation.
- Do not use the calibrator after the expiry date indicated on the label of the product.

PREPARATION
Dia-CAL Ddi calibrator should be dissolved in 1 mL (1000 µL) distilled water. **The Diluent must not be used for dissolution of the lyophilized calibrator!** For the appropriate dissolution keep the reagent at room temperature for at least 30 minutes. Before use gently mix the reagent several times (5 – 10-fold) horizontally, but do not shake it. Wait until the reagent heats up to the working temperature.
Dilution series required for the calibration should be prepared by the dilution buffer (Diluent) of the same lot number.
In case of manual dilution follow steps presented on Figure below.



After each diluting step the calibrator should be homogenized by mixing. For each dilution step a new pipet tip is to be used in order to prevent carry-over phenomenon.
Calibration points compared to the undiluted calibrator are as follows during manual and automated measurements:

L5	L4	L3	L2	L1	L0
1	3/4	1/2	1/4	1/8	0

For concentrations for the actual lot number see the attached document.

CALIBRATION

When obtaining the calibration curve one should use the calibrator and the individual elements of Dilution Series and follow instructions described in the User Manual of the measuring device and the Application procedure of the latex agglutination D-dimer test to be calibrated, respectively.

STORAGE AND SHELF LIFE

The unopened Dia-CAL Ddi reagent in intact packaging is stable until the expiry date when stored at 2 - 8°C. After opening the stability of the reagent kept in the original vial is presented in the Table below.

T [°C]	20-25	15-19	2-8
Time [hour]	8	24	48

The reagent should not be frozen.

STANDARD VALUES / RESULTS

Calibrator values are traceable to fibrinogen cleaved by the plasmin (FEU). The value is determined by the calculation of the average concentration measured in clinically characterized samples when the cut-off value of deep vein thrombosis of the lower extremities was 0.5 µg FEU/mL.

Target values for the individual calibrator may change with lot numbers. Check lot-specific values presented in the attached document.

For further information refer to the homepage of Diagon (www.diagon.com/hu/termektamogatas).

LIMITS OF USE

The calibrator value is valid when Diagon Dia D-Dimer reagent is used. The use of Diagon devices (Coag Line) is recommended. The validation of calibrator is a must when other reagents are used.

PERFORMANCE CHARACTERISTICS

Reliability tests performed with undiluted Dia-CAL Ddi calibrator on an automated coagulometer provided the following results:

	Intraassay repeatability (10 sequential measurements)	Interassay reproducibility (on 5 sequential days)
Mean [µg FEU/ml]	5.5	5.5
CV [%]	4%	4%

INSTRUMENTS AND MATERIALS NEEDED FOR OPERATION

- Distilled water
- Optical analyzer for the measurements. The use of Diagon devices (Coag Line) is recommended.
- 1 ml pipet
- General laboratory consumables for the production of manual calibration series.

REFERENCES

1. Stenman UH. Standardization of immunoassays. In: Price CP, Newman DJ, editors. Principles and practice of immunoassay. New York: Stockton Press; 1997.p.243-68.

2. CLSI. Quantitative D-dimer for the Exclusion of Venous Thromboembolic Disease; Approved Guideline. CLSI Document H59-A. Wayne, PA: Clinical and Laboratory Standards Institute; 2011.

3. ISO Guide 35 - Reference materials – General and statistical principles for certification.

4. Wells, P.S., Anderson, D.R., Rodger, M., et al. Evaluation of D-dimer in the diagnosis of suspected deep-vein thrombosis N. Engl. J. Med. 2003; 349(13):1227-1235

5. Biosafety in Microbiological and Biomedical Laboratories. U.S. Department of Health and Human Services, Washington 1993 (HHS Publication No. [CDC] 93-8395)

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SYMBOLS			
	Manufacturer		Expiry date
LOT	Batch code	REF	Catalogue number
	Do not use if the package is damaged.		Fragile, handle with care
	Keep dry		Temperature limits
	Biological hazard		Refer to the instructions for use
	Warning	IVD	*In vitro* diagnostics
	Content is sufficient for <*n*> tests		This side up
CE	CE sign		