

DIA-CAL

CALIBRATOR PLASMA FOR COAGULATION TESTS



Cat. No.: 95012

12 x 1 ml

PRODUCT NAME

Dia-CAL calibrator plasma for coagulation tests.

INTENDED USE

(For In Vitro Diagnostic Use Only)

Dia-CAL calibrator plasma is intended to calibrate of the following coagulation tests:

- prothrombin time (PT),
- fibrinogen (FIB),
- antithrombin III (AT).

SUMMARY AND EXPLANATIONS

Dia-CAL calibrator is dedicated for calibration of coagulation tests. There are test specific calibrator target values in the lot specific value sheet for the given reagents. The target values relate to values of healthy adult population or 2nd international standards.

ACTIVE INGREDIENTS

Dia-CAL calibrator is derived from human, anticoagulated, freeze-dried, pooled human plasma from healthy donors with preservative.

PRECAUTIONS

- Person installing the Dia-CAL calibrator must be a trained laboratory professional!
- By calculating with inappropriate data or using the supplied data improperly, erroneous results may occur!
- Dia-CAL calibrator, due to its ingredients should be handled with care by observing the precautions recommended for biohazards material!
- Calibrator coming into contact with specimens and other materials should be handled as if capable of transmitting infection and should be disposed of with proper precautions!
- Avoid microbial contamination of the calibrator otherwise erroneous results may occur!
- Each donor unit used in the preparation of this calibrator tested with HBsAg, anti-HIV 1-2, anti-HCV, anti-TP screening tests and found to be non-reactive.
- All calibrator, waste and utilized disposable laboratory equipment should be considered as hazardous waste! Their handling and disposal should be done according to the valid hazardous material processing regulation.
- Do not use the calibrator beyond the expiration date printed on the label!

PREPARATION

Dia-CAL calibrator is dissolved with 1ml distilled water. Allow them to stand at room temperature (20-25°C) for at least 30 minutes. The gently horizontal mixing is recommended during the reconstitution. Swirl the vial gently and horizontal again before use, but do not shake!

TEST PROCEDURE

Prepare dilution series from Dia-CAL calibrator. Follow as described in the instruction for use of correspondence tests to measure the required parameter. Write the target value in the serial number specific value sheet of the calibrator into the appropriate menu, following the manual of the concerned instrument.

STORAGE AND STABILITY

Dia-CAL calibrator in intact vial is stable until the expiration date given on the vial, when stored at 2-8°C. Stability after opening in the original vial is shown in below table:

| T (°C) | 20-25 | ≤ -20 |
|--------|---------|---------|
| Time | 4 hours | 30 days |

The reconstituted calibrator can be frozen and thawed back only once. Thawed calibrator should be used within two hours, when stored at 20-25°C.

EXPECTED RESULTS

The test specific calibrator target values for each of the parameters may vary from lot to lot. Check the lot specific target values in the value sheet in the box. Normal and pathological controls are recommended for verification of calibration curve.

LIMITATIONS

The calibration curve is valid for the actual lot of the used reagent. New calibration is necessary, if the lot of reagent and/or the measurement circumstances are changed.

In case of unexpected control values, new calibration is needed.
















MATERIALS REQUIRED BUT NOT PROVIDED

- For calibrating of PT test:
 - Dia-PT; Cat. No.: 81100, 81050, 81025, 81020
 - Dia-PT LIQUID; Cat. No.: 82096, 82048, 82024, 82012
 - Dia-PT R; Cat. No.: 83100, 83050; 83025
- For calibrating of FIB test:
 - Dia-FIB; Cat. No.: 61060, 61024
- For dilution of PT, FIB calibration: Dia-IMIDAZOL; Cat. No.: 21180
- For calibrating of AT test:
 - Dia-AT III (FIIa); Cat. No.: 33012
- Different levels of control for quality control:
 - Dia-CONT I-II; Cat. No.: 91020, 91010
- Optical or mechanical coagulation analyser for measuring, Diagon analysers (Coag Line) are recommended.



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| SYMBOLS | | | |
|---|-----------------------------------|---|---|
|  | Manufacturer |  | Use-by date |
|  | Batch code |  | Catalogue number |
|  | Do not use if package is damaged |  | Fragile, handle with care |
|  | Keep dry |  | Temperature limit |
|  | Biological risks |  | Consult instruction for use |
|  | Caution |  | <i>In vitro</i> diagnostic medical device |
|  | Contains sufficient for <n> tests |  | This side up |
|  | CE mark | | |