

Dia-CONT I-II

CONTROL PLASMAS FOR COAGULATION TESTS



Cat. No.: 91020 2 x 10 x 1 ml
Cat. No.: 91010 2 x 5 x 1 ml

- Do not use the control beyond the expiration date printed on the label!

PRODUCT NAME

Dia-CONT I-II control plasmas for coagulation tests.

INTENDED USE

(For In Vitro Diagnostic Use Only)

Dia-CONT I-II two levels control plasmas are intended to control of the following coagulation tests:

- prothrombin time (PT),
- activated partial thromboplastin time (APTT),
- fibrinogen (FIB),
- thrombin time (TT) only for control I,
- antithrombin III (AT).

SUMMARY AND EXPLANATIONS

Dia-CONT I-II controls are dedicated for internal quality control of coagulation measuring system. There are instrument, test and lot specific control ranges in the issued sheet for the given reagents.

ACTIVE INGREDIENTS

Dia-CONT I-II controls are derived from human, anticoagulated, freeze-dried, pooled human plasma from healthy donors with preservative. Dia-CONT I-II controls represent two different measuring range.

PRECAUTIONS

- Person installing the Dia-CONT I-II controls must be a trained laboratory professional!
- By calculating with inappropriate data or using the supplied data improperly, erroneous results may occur!
- Dia-CONT I-II controls, due to its ingredients should be handled with care by observing the precautions recommended for biohazards material!
- Control 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 control otherwise erroneous results may occur!
- Each donor unit used in the preparation of this control tested with HBsAg, anti-HIV 1-2, anti-HCV, anti-TP screening tests and found to be non-reactive.
- All controls, 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.

PREPARATION

Dia-CONT I-II controls are 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

Dia-CONT I-II controls are to be used as that of patients' plasmas as investigated with coagulation tests.

STORAGE AND STABILITY

Dia-CONT I-II controls 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 control can be frozen and thawed back only once. Thawed control should be used within two hours, when stored at 20-25°C.

EXPECTED RESULTS

The instrument and test specific control ranges for each of the parameters may vary from lot to lot. Compare the measured value with the declared one on the issued sheet. The obtained results:

- have to be inside of the reference range declared, but the get the exact mean is not obligatory,
- should be considered as a guidance, but every laboratory should determine its own control ranges.

LIMITATIONS
















To check the accuracy of the reported result join and perform external quality assurance program in regular intervals.

In case of unexpected control values check all components of the test system are functioning correctly.

MATERIALS REQUIRED BUT NOT PROVIDED

- For controlling 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
- For controlling of APTT test:
 - Dia-PTT; Cat. No.: 71048, 71030, 71024
 - Dia-PTT LIQUID; Cat. No.: 72096, 72048, 72024, 72012
 - Dia-CaCl₂; Cat. No.: 41192, 41048
- For controlling of FIB test:
 - Dia-FIB; Cat. No.: 61060, 61024
 - Dia-IMIDAZOL; Cat. No.: 21180
- For controlling of TT test:
 - Dia-TT; Cat. No.: 51036
- For controlling of AT test:
 - Dia-AT III (FIIa); Cat. No.: 33012
- 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 | | |