

D-DIMER CONTROL



REF 1478-1186

Packaging: 2 x 1 mL + 2 x 1 mL

INTENDED USE

Material for internal quality control of assays for cross-linked derivatives of fibrin decomposition that contain D-Dimer, in human plasma using Medicon reagent with Diatron Pictus® P700 and P500 analyzers. For in vitro diagnostic use only by trained laboratory professionals.

COMPOSITION

Human plasma based lyophilized formulation containing known quantities of D-Dimer and preservatives.

WARNINGS – PRECAUTIONS

- For in vitro use only
- Biological materials of human origin contained in this product were tested for Anti-HCV, HbsAg and Anti-HIV 1 and 2 using FDA approved methods and were found to be non-reactive. As there is no known test method that can offer complete assurance that products derived from human blood will not transmit infectious agents this product should be handled as a potentially infectious material.
- Any serious incident that may occur in relation to this device must be reported by the user to the manufacturer and the competent authority of the country in which the user and/or the patient is established!

PREPARATION

Remove the rubber stopper very carefully. As the material is packed under vacuum, sudden air influx may force material out of the vial. Reconstitute by adding exactly 1ml of cold (2°-8°C) deionized or distilled water.

Place the rubber stopper back on the vial, swirl gently 2-3 times and let it stand for 10 minutes. Mix gently to obtain a homogeneous mixture. Ideally use a hematology tubes mixer for 20 minutes. Avoid foaming. Use 30 minutes after water addition.

Replace cap immediately after use and store at 2-8°C. Unsuitable storage, handling, or errors during the analytical procedure may give erroneous results.

MATERIALS REQUIRED BUT NOT PROVIDED WITH THE KIT

- D-DIMER assay reagent.
- Automated biochemistry analyzer.
- Usual laboratory equipment.

STORAGE - STABILITY

The contents of vials are stable at 2 – 8°C until the expiry date stated on the label. Once reconstituted, contents remain stable for 1 month when stored tightly capped at 2 – 8°C after each use.

TEST PROCEDURE

Refer to the appropriate User's Guide and the accompanying Instrument Setting Sheet for analyzer-specific assay instructions for calibration.

If any trends or sudden shifts in values are detected, review all operating parameters. Control recovery should lie within the acceptable intervals.

Results outside the specified values even after recalibration could be due to reagent/calibrator/control deterioration, unsuitable storage conditions, instrument malfunction, or error during test procedure.

Every laboratory should establish its own corrective measures in case control recovery lies outside acceptable intervals.

Make sure the LOT on the vial is the same as on the value sheet accompanying the material.

WASTE DISPOSAL

Dispose of all waste materials in accordance with local guidelines for material of biological origin. Safety data sheet is available for professional use on request.

ASSIGNED VALUES – Lot specific

Please refer to the value sheet for the specific lot available at <https://medicondoc.com>.

SYMBOLS



Manufacturer



In vitro diagnostic medical device



Temperature Limit



Catalogue Number



Caution



Biological Risks