

sebia

**CALIBRATEURS CDT
MINICAP (2 niveaux)**

**CDT MINICAP
CALIBRATORS (2 levels)**

Ref. 4761

IVD

CE

R_xonly

2019/12

CDT MINICAP CALIBRATORS (2 levels)

IMPORTANT : The CDT Controls / Calibrators Diluent, SEBIA (1 vial, 5 mL), is necessary for the reconstitution of the calibrators.

Intended use

The CDT MINICAP CALIBRATORS (2 levels) are designed for the calibration of the quantification method of the CDT-IFCC fraction (calibrated disialotransferrin) with the SEBIA MINICAP CDT-IFCC capillary electrophoresis procedure performed with the MINICAP and MINICAP FLEX-PIERCING automated instruments.

They allow to obtain consistent results with the recommendations of the IFCC working group for standardization of CDT measurement (1, 2).

They should be used as human sera.

WARNING : *The calibrators are specific for the MINICAP CDT-IFCC procedure.*

For *In Vitro* Diagnostic Use.

IFCC : International Federation of Clinical Chemistry and Laboratory Medicine.

Composition

The CDT MINICAP Calibrators 1 and 2 are obtained from pools of human sera. The calibrators are in a stabilized lyophilized form.

The CDT MINICAP Calibrator 1 presents a normal CDT-IFCC level, the CDT MINICAP Calibrator 2 presents an elevated CDT-IFCC level.

CDT calibrators values are traceable to the international IFCC reference procedure (which corresponds to the highest order in the hierarchy of metrological traceability).

The CDT Controls / Calibrators Diluent, necessary for the reconstitution of the calibrators, is ready to use. It contains : additives, nonhazardous at concentrations used, necessary for optimum performance.

Storage and stability

- Before reconstitution, store the lyophilized calibrators between - 18 °C and - 30 °C. They are stable until the expiration date indicated on the vial labels.

WARNING : *Do not store lyophilized calibrators refrigerated (2 - 8 °C).*

- The CDT Controls / Calibrators diluent can be stored frozen (between - 30 and - 18 °C), refrigerated (2 to 8 °C) or at room temperature (15 to 30 °C).

It is recommended to take the diluent vial out of the kit upon receipt and to store it at a constant temperature refrigerated (2 to 8 °C) or at room temperature (15 to 30 °C).

The product is stable until the expiration date indicated on the vial label.

The diluent must be free of precipitate. Discard the diluent if changes are noted with its appearance, e.g., becomes cloudy due to microbial contamination.

Mix the diluent prior to use.

- After reconstitution, store the calibrators at 2 - 8 °C in a closed microtube and use them within the day (for 18 hours maximum). After use, they must be stored without any delay between - 18 °C and - 30 °C due to the risk of microbial contamination and denaturation. They are stable for 12 months maximum between - 18 °C and - 30 °C.

- After storage between - 18 °C and - 30 °C and before use, thaw the reconstituted calibrators at 2 - 8 °C for at least 30 minutes before the analysis. Homogenize calibrators before use. Store the thawed calibrators at 2 - 8 °C and use them within the day (for 18 hours maximum). Do not freeze and thaw the reconstituted calibrators more than once (due to the reconstitution volume of each calibrator, one vial allows the preparation of 2 reagent cups, each cup allows to perform 3 successive analysis sequences).

NOTE : *During transportation, the lyophilized calibrators can be kept refrigerated (between 2 to 8 °C maximum) for 1 month without any adverse effects on performance.*

Procedure

Reconstitute each lyophilized calibrator vial with 0.2 mL of CDT Controls / Calibrators Diluent. Allow to stand for 30 minutes at 2 - 8 °C and mix gently (avoid formation of foam).

NOTE : The precision of the reconstitution volume to be maintained is ± 1.0 %.

Apply the whole amount of each reconstituted calibrator in a microtube and cut the cap of the microtube when analyzing the calibrators on MINICAP and MINICAP FLEX-PIERCING instruments.

IMPORTANT : To take the whole amount of the reconstituted calibrator, use a pipette with a sufficiently thin tip than cannot become lodged in the opening of the vial.

NOTE : When a reconstituted calibrator becomes cloudy or a precipitate is observed, vortex the tube for 1 minute. If the turbidity or the precipitate persists, discard the calibrator.

See the instructions for use of the MINICAP CDT kit, MINICAP CDT-IFCC procedure.

IMPORTANT : For optimal use of each calibrator, it is necessary to use the bar code labels intended to identify the hemolysing tube used as holder for microtube which contains the analyzed calibrator (cut the cap of the microtube before using it).

WARNING :

- Please check that the LOT NUMBERS of the calibrators (indicated on each vial) are identical as the ones currently used with the instrument. If not, perform 3 successive calibrations with the new lots. The lots of calibrator vials must never be separated.
- No test method can provide an absolute assurance of the absence of HIV, hepatitis B and C or other infectious agents. Therefore, handle the CDT MINICAP Calibrators 1 and 2 as a hazardous biological material. These lots of sera were found negative on assays approved by FDA or EU equivalent regulatory agency :
 - against hepatitis B surface antigen,
 - for antibody to HCV,
 - for antibody to HIV1 and HIV2.

CDT-IFCC PERCENTAGES

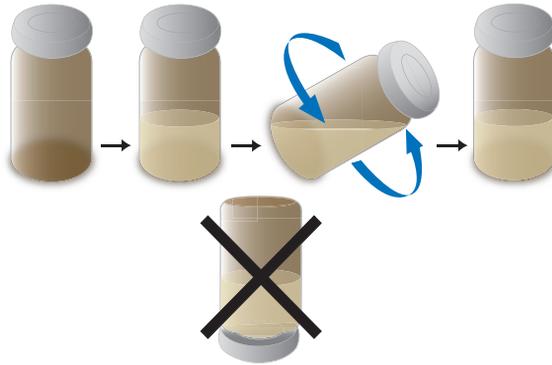
Assigned CDT-IFCC values have been established with the IFCC reference method and according to the recommendations of the IFCC working group for standardization of CDT measurement.

The CDT percentage is indicated in IFCC unit (calibrated % of disialotransferrin).

NOTES :

- *The CDT-IFCC percentages are indicated in the package insert provided with the calibrator vials.*
- *The values and / or the electrophoretic patterns are applicable whatever the reagent lot or the concerned instrument.*
- *The different transferrin isoforms appear on the pattern in the following order : disialotransferrin, trisialotransferrin and tetrasialotransferrin associated to pentasialotransferrin (from time to time, the asialotransferrin fraction from the Calibrator 2 may be detected by the software before the disialotransferrin fraction, without any adverse effect on calibration).*

CALIBRATORS RECONSTITUTION



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