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MINICAP CDT

Ref. 2208

Ref. 2228*

Technique MINICAP CDT-IFCC

MINICAP CDT-IFCC procedure

IVD

CE

2019/12

INTENDED USE

The MINICAP CDT kit is designed for the separation and quantification of the disialotransferrin fraction ("CDT-IFCC") in human serum by capillary electrophoresis in alkaline buffer (pH 8.8) with the MINICAP and MINICAP FLEX-PIERCING instruments. CDT (carbohydrate deficient transferrin) is used as a biomarker of chronic moderate to heavy alcohol consumption.

For *In Vitro* Diagnostic Use.

NOTE : The term CDT-IFCC is used to indicate disialotransferrin which according to the first recommendation of the IFCC working group (WG-CDT) "should be the primary target molecule for CDT measurement and the single analyte on which CDT standardization is based" (1).

(1) Toward standardization of carbohydrate-deficient transferrin (CDT) measurements: I. Analyte definition and proposal of a candidate reference method. Jan-Olof Jeppsson, Torsten Arndt, François Schellenberg, Jos P.M. Wielders, Raymond F. Anton, John B. Whitfield and Anders Helander.

PRINCIPLE OF THE TEST

NOTE : In this instruction sheet, the name "MINICAP" is used for automated MINICAP and MINICAP FLEX-PIERCING instruments.

CDT (Carbohydrate Deficient Transferrin) quantification of transferrin isoforms in serum by electrophoresis is a technique used in clinical laboratories for screening samples from patients for chronic alcohol abuse. Transferrin isoforms separate into 5 major fractions according to their sialylation level : asialotransferrin (non sialylated), disialotransferrin, trisialotransferrin, tetrasialotransferrin and pentasialotransferrin. The low-sialylated isoforms (disialotransferrin associated with asialotransferrin in some cases) are biochemical markers of chronic alcohol abuse.

Capillary electrophoresis is a technique of electrokinetic separation carried out in a tube of internal diameter lower than 100 µm filled with a buffer composed of electrolytes. In many aspects, the methodology can be considered as an intermediary type of technique between classical zone electrophoresis and liquid chromatography.
The MINICAP instrument uses the principle of capillary electrophoresis in free solution. With this technique, charged molecules are separated by their electrophoretic mobility in an alkaline buffer with a specific pH. Separation also occurs according to the electrolyte pH and electroosmotic flow. The MINICAP instrument has 2 silica capillaries functioning in parallel allowing 2 simultaneous analyses for CDT quantification. A sample dilution with a specific sample diluent is prepared and injected by aspiration at the anodic end of the capillary. A high voltage protein separation is then performed and direct detection of the proteins is made at an absorbance of 200 nm at the cathodic end of the capillary. The capillaries are immediately washed with a Wash Solution and prepared for the next analysis with buffer.
By using alkaline buffer, transferrin isoforms are detected in the following order : asialotransferrin, disialotransferrin, trisialotransferrin, tetrasialotransferrin and pentasialotransferrin.

After calibration of the analysis system with specific calibrators, the direct detection provides automatically the calibrated percentage of disialotransferrin (= CDT-IFCC) calculated from the total amount of detected transferrin.
The MINICAP CDT-IFCC procedure complies with the recommendations of the IFCC working group for standardization of CDT measurement.

REAGENTS AND MATERIALS SUPPLIED IN THE MINICAP CDT KITS

WARNING : See the safety data sheets.

ITEMS	PN 2208	PN 2228*
Buffer (ready to use)	2 vials, 250 mL each	6 vials, 250 mL each
Sample diluent (ready to use)	1 vial, 80 mL	3 vials, 80 mL each
Wash solution (stock solution)	1 vial, 25 mL	3 vials, 25 mL each
CDT wash solution (ready to use)	1 vial, 80 mL	3 vials, 80 mL each
Reagent cups	1 pack of 125	3 packs of 125 each
Filters	3 filters	3 filters
Bins for used cups	4 bins	12 bins
"Sample diluent" bar code labels	5 sheets of 4 labels	15 sheets of 4 labels
"CDT wash solution" bar code labels	5 sheets of 4 labels	15 sheets of 4 labels

** MINICAP CDT MAXI-KIT*

FOR OPTIMAL MANAGEMENT OF TRACEABILITY : All reagents from the same kit must be used together.

TO OBTAIN THE EXPECTED PERFORMANCES : The package insert instructions must be observed.

WARNING : Do not use marketed deionized water, such as water for ironing for example (risk of important capillaries damage). Use only water with ultrapure quality, such as injection grade water.

1. BUFFER

Preparation

The buffer is ready to use. It contains : buffer solution pH 8.8 ± 0.5 ; additives, nonhazardous at concentrations used, necessary for optimum performance.

Use

Buffer for analysis of transferrin isoforms by capillary electrophoresis.

Storage, stability and signs of deterioration

Store the buffer at room temperature (15 to 30 °C) or refrigerated (2 to 8 °C). It is stable until the expiration date indicated on the kit package or buffer vial labels. Avoid storage close to a window or to a heat source.

NOTE : When the buffer is stored between 2 to 8 °C, it is recommended to allow it to come to room temperature prior to use.

DO NOT FREEZE.

Once the buffer vial has been opened and positioned on the MINICAP instrument, it is stable for a maximum of 2 months (accumulated). If the buffer vial is planned to be used for more than 2 months, it must be removed from the instrument after each use and stored at room temperature (15 to 30 °C) or refrigerated (between 2 and 8 °C), it is then stable until the expiration date indicated on the buffer vial label.

Discard buffer if it changes its appearance, e.g., becomes cloudy due to microbial contamination.

2. SAMPLE DILUENT

Preparation

The sample diluent is ready to use. It contains additives, nonhazardous at concentrations used, necessary for optimum performance and effective separation of transferrin isoforms.

Use

For automatic serum samples dilution.

Storage, stability and signs of deterioration

Store the sample diluent at room temperature (15 to 30 °C). It is stable until the expiration date indicated on the kit package or sample diluent vial label.

NOTE : Sample diluent may become cloudy or precipitate at room temperature. Heat to 37 °C to redissolve. Stir it gently prior to use.

DO NOT FREEZE.

Discard sample diluent if it changes appearance, e.g., becomes cloudy due to microbial contamination.

3. WASH SOLUTION

Preparation

The vial of the stock wash solution should be diluted up to 250 mL with distilled or deionized water.

After dilution, the wash solution contains an alkaline solution pH ≈ 12.

Use

For washing the capillaries after transferrin isoforms electrophoresis.

IMPORTANT : Before filling the wash solution container, it is recommended to wash the opening of the container, the connector and the tube with plenty of distilled or deionized water to avoid salts deposit.

Storage, stability and signs of deterioration

Store the stock and working wash solutions in closed containers at room temperature (15 to 30 °C) or refrigerated (2 to 8 °C). The stock wash solution is stable until the expiration date indicated on the kit or wash solution vial label.

Working wash solution is stable for 3 months.

Discard working wash solution if it changes its appearance, e.g., becomes cloudy due to microbial contamination.

4. CAPILLARYS / MINICAP CDT WASH SOLUTION

Preparation

The CAPILLARYS / MINICAP CDT wash solution vial is ready to use. It contains additives, nonhazardous at concentrations used, necessary for optimum performance.

Use

For the DAILY sample probe and capillaries cleaning in automated system MINICAP, SEBIA, for capillary electrophoresis, **to use at the end of each working session and necessarily before using another MINICAP analysis technique.**

See the instruction manual of MINICAP, SEBIA.

- Apply in a microtube 1 mL of CAPILLARYS / MINICAP CDT wash solution.
- Cut the cap of the microtube.
- Place the microtube, located on a new hemolysing tube used as a support (identified with one bar code label specific to the CDT wash solution) at the end of a series of samples, on the rotating sampler of MINICAP.
- Position a new reagent cup on the automated loading system for cups of MINICAP (a message will be displayed if the reagent cup is missing).
- Slide the rotating sampler into the MINICAP instrument.
- Close the doors of the MINICAP instrument, the cleaning sequence starts automatically.

IMPORTANT : For optimal use of the CDT wash solution with the MINICAP instrument, it is necessary to use one bar code label intended to identify the hemolysing tube holding the microtube which contains the solution (cut the cap of the microtube before using it).

Storage, stability and signs of deterioration

Store the wash solution at room temperature (15 to 30 °C) in closed container to prevent evaporation.

It is stable until the expiration date indicated on the kit package or buffer vial labels. DO NOT FREEZE.

NOTE : The wash solution may become cloudy or precipitate at room temperature. Heat to 37 °C to redissolve. Stir it gently prior to use.

Discard the wash solution if it changes its appearance, e.g., becomes cloudy due to microbial contamination.

5. REAGENT CUPS

Use

Single use cups for the preparation of biological samples to analyze with the automated instrument. To be placed on the automated loading system for cups of MINICAP. One reagent cup is intended for the analysis of 2 samples.

WARNING : After use, reagent cups with biological samples have to be handled with care. When the analysis is completed, reagent cups must be discarded with biological waste products and they must NEVER be reused.

Storage

Before use, store the reagent cups in their sealed package in a clean and dry place and at a temperature comprised between 2 and 30 °C.

6. FILTERS

Use

Disposable filters for filtration of analysis buffer, working wash solution and distilled water (used for capillaries rinsing).

IMPORTANT : When kit replacement, change systematically all the filters. Wear clean gloves for handling and installation of filters.

Screw one filter at the connector situated at the extremity of each tube that plunges in the vials of buffer, wash solution and distilled or deionized water. When setting filters on MINICAP instrument, rinse the connectors and the tubes with distilled or deionized water.
The filter intended for analysis buffer must be used for filtration of both buffer vials ; the two other filters are intended for filtration of working wash solution and for distilled or deionized water (for capillary rinsing).

Storage

Before use, store the filters in their sealed package in a dry place at room temperature (15 to 30 °C) or refrigerated (2 to 8 °C).

7. BINS FOR USED CUPS

Use

Bins intended for automated collection of used reagent cups in MINICAP. To place in MINICAP at the location intended for this purpose.

WARNING : Bins containing used reagent cups with biological samples have to be handled with care.

8. SAMPLE DILUENT BAR CODE LABELS

Use

Labels to identify the tube containing the sample diluent ("CDT SAMPLE DILUENT").

9. CDT WASH SOLUTION BAR CODE LABELS

Use

Labels to identify the tube containing the CDT wash solution ("CDT WASH SOLUTION").

REAGENTS REQUIRED BUT NOT SUPPLIED WITH THE KIT

WARNING : See the safety data sheets.

1. CDT MINICAP CALIBRATORS (2 LEVELS)

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

Composition

The CDT MINICAP CALIBRATORS (2 levels) (SEBIA, PN 4761) 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.
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.

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 automated instrument. They allow to obtain consistent results with the recommendations of the IFCC working group for standardization of CDT measurement.

The recommendations to calibrate are the following :

- Perform 3 successive series of analyses with both calibrators within the same working day followed by 1 series of analyses with the Normal CDT Control and the High CDT Control, before the analysis of samples :
  - for the first use of the "CDT" analysis program with the MINICAP instrument,
  - after having changed the lot number of calibrators.
- In routine, perform 1 series of analyses with both calibrators within the same working day followed by 1 series of analyses with the Normal CDT Control and the High CDT Control, before the analysis of samples :
  - in case of analyses of CDT controls giving CDT-IFCC value outside the expected values (and after having confirmed this deviation by a second series of analyses with the same CDT Control),
  - once a year.

Use

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).
- Both calibrators must imperatively be analyzed within the same working day for an effective calibration, the run order of both calibrators is indifferent.

- Reconstitute each lyophilized CDT MINICAP Calibrator 1 and 2 vial with the volume of CDT Controls / Calibrators Diluent indicated in the instructions for use of the CDT MINICAP CALIBRATORS (2 levels). Allow to stand for 30 minutes at 2 – 8 °C and mix gently (avoid formation of foam).
  Each reconstituted calibrator should be used as a human serum.
  NOTE : The precision of the reconstitution volume to be maintained is ± 1.0 %.
- Apply the total amount of each reconstituted calibrator in a microtube.
- Cut the cap of the microtube.
- For each calibrator, identify a new hemolysing tube that will be used as a holder, with a bar code label of the calibrator.
- The analysis of each calibrator must be performed according to the same procedure as described below.
- For each calibrator, place the microtube, located on the hemolysing tube used as a support tube, in position No. 28 on a MINICAP rotating sampler ("Control" position).
- Pour 1 mL of CAPILLARYS / MINICAP CDT sample diluent in a hemolysing tube (identified with the sample diluent bar code label) without introducing air bubbles and place it in position No. 27 on the rotating sampler ("Diluent / Solution" position) (A message will be displayed if the tube or the sample diluent is missing).
  IMPORTANT : Ensure the absence of foam in the tube of sample diluent before placing it on the rotating sampler.
- **Do not place any sample tube in positions No. 1 to 26 of the rotating sampler.**
- Slide the rotating sampler into the MINICAP instrument.
- Close the doors of the instrument, the analysis starts automatically.
- Enter or check in the window called "CDT Calibrator level…" which appears on the screen, the parameters of the analyzed calibrator, indicated in the instructions for use of the CDT MINICAP CALIBRATORS (2 levels) : CDT-IFCC %, lot number and expiration date.
  NOTE : The CDT percentage is indicated in IFCC unit (calibrated % of disialotransferrin).
- Select in this window the number of analyses of the calibrator to perform, according to the cases described above, and validate.
- The results are then automatically considered by the software for the data analysis.
- Remove the tube with calibrator from position No. 28 as soon as the window appears indicating to remove the tube.
- When the analysis of the first calibrator is completed, perform the analysis of the second calibrator according to the same procedure.

WARNING : After having closed the doors of the instrument, to start the analysis of the second calibrator :
- wait until the instrument has checked the absence of tube in position No. 1,
- click on the flashing button to open the "Information messages" window indicating the absence of tube in position No. 1,
- close the "Information messages" window,
- start the analysis using the "Click to run the control in position 28" button.

- After the analyses of both calibrators, perform 1 series of analyses with the Normal CDT Control and the High CDT Control on both capillaries to validate the calibration of the instrument. The values obtained must fall within the range provided with each lot of CDT Control.
- When obtained values comply with specifications, the instrument can then be used for analyses. If not, confirm the deviation with a second series of analyses with the same CDT Control.
- Calibrate again the instrument when the obtained values do not still fall within the range provided with the lot of CDT Control.

- **In routine**, analyze only once each calibrator according to the protocol previously described.
- Perform 1 series of analyses with the Normal CDT Control and the High CDT Control on both capillaries to validate the calibration of the instrument. The values obtained must fall within the range provided with each lot of CDT Control.
- When obtained values comply with specifications, the instrument can then be used for analyses. If not, confirm the deviation with a second series of analyses with the same CDT Control.
- Calibrate again the instrument with only one series of analyses of both calibrators when the obtained values do not still fall within the range provided with the lot of CDT Control.

Storage, stability and signs of deterioration

See the CDT MINICAP CALIBRATORS (2 levels) instructions for use.

WARNING : 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 as a hazardous biological material.
These 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.

2. NORMAL CDT CONTROL

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

Composition

The Normal CDT Control, SEBIA, PN 4795, is obtained from a pool of normal human sera.
The Normal CDT Control is in a stabilized lyophilized form.
The CDT Controls / Calibrators Diluent, necessary for the reconstitution of the Normal CDT Control, is ready to use. It contains : additives, nonhazardous at concentrations used, necessary for optimum performance.

Intended use

The Normal CDT Control is designed for :
- the normalization of capillaries for the first use or after a prolonged stoppage (over 1 week) of the MINICAP instrument, or after having changed and activated capillaries,
- the quality control performed after capillary calibration and,
- the quality control performed among a series of samples,

for the quantification of human transferrin isoforms with the MINICAP CDT-IFCC electrophoresis procedure.

- Reconstitute each Normal CDT Control lyophilized vial with the volume of CDT Controls / Calibrators Diluent indicated in the instructions for use of the Normal CDT Control. Allow to stand for 30 minutes and mix gently (avoid formation of foam).

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

  The reconstituted Normal CDT Control should be used as a normal human serum.

Normalization of capillaries and quality control performed after capillary calibration :
- Use a microtube containing the reconstituted Normal CDT Control.
- Cut the cap of the microtube.
- Identify a new hemolysing tube with a bar code label of the Normal CDT Control.
- Place the microtube, located on the hemolysing tube used as a support tube, in position No. 28 on a MINICAP rotating sampler ("Control" position).
- Pour 1 mL of CAPILLARYS / MINICAP CDT sample diluent in a hemolysing tube (identified with the sample diluent bar code label) without introducing air bubbles and place it in position No. 27 on the rotating sampler ("Diluent / Solution" position) (A message will be displayed if the tube or the sample diluent is missing).

  IMPORTANT : Ensure the absence of foam in the tube of sample diluent before placing it on the rotating sampler.
- Slide the rotating sampler into the MINICAP instrument.
- Close the doors of the instrument, the analysis starts automatically.
- In the window which appears on the screen, select the number of analyses of the Normal CDT Control to perform and validate.

NOTE : Only one analysis of the Normal CDT Control permits the normalization of the 2 capillaries of the MINICAP instrument.

The results are then automatically considered by the software for the data analysis.
The values obtained must fall within the range provided with each lot of control.

Quality control performed in a series of samples :
- Use a microtube containing the reconstituted Normal CDT Control.
- Cut the cap of the microtube.
- Identify a new hemolysing tube with a bar code label of the Normal CDT Control.
- Place the microtube, located on the hemolysing tube used as a support tube, on the rotating sampler among a series of samples to analyze.
- Start the analysis by sliding the rotating sampler into the instrument.

The values obtained must fall within the range provided with each lot of control.

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

Storage, stability and signs of deterioration

See the Normal CDT Control instructions for use.

WARNING : No test method can provide an absolute assurance of the absence of HIV, hepatitis B and C or other infectious agents. Therefore, handle the Normal CDT Control as a hazardous biological material.
This control serum was 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.

3. HIGH CDT CONTROL

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

Composition

The High CDT Control, SEBIA, PN 4772, is obtained from a pool of human sera with an elevated CDT fraction.
The High CDT Control is in a stabilized lyophilized form.
The CDT Controls / Calibrators Diluent, necessary for the reconstitution of the High CDT Control, is ready to use. It contains : additives, nonhazardous at concentrations used, necessary for optimum performance.

Intended use

The High CDT Control is designed for :
- the quality control performed after capillary calibration of the MINICAP instrument and,
- the quality control performed among a series of samples,

for the quantification of human transferrin isoforms with the MINICAP CDT-IFCC electrophoresis procedure.

- Reconstitute the High CDT Control lyophilized vial with the volume of CDT Controls / Calibrators Diluent indicated in the instructions for use of the High CDT Control. Allow to stand for 30 minutes and mix gently (avoid formation of foam).

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

  The reconstituted High CDT Control should be used as a human serum.

Quality control performed after capillary calibration :
- Use a microtube containing the reconstituted High CDT Control.
- Cut the cap of the microtube.
- Identify a new hemolysing tube with a bar code label of the High CDT Control.
- Place the microtube, located on the hemolysing tube used as a support tube, in position No. 28 on a MINICAP rotating sampler ("Control" position).
- Pour 1 mL of CAPILLARYS / MINICAP CDT sample diluent in a hemolysing tube (identified with the sample diluent bar code label) without introducing air bubbles and place it in position No. 27 on the rotating sampler ("Diluent / Solution" position) (A message will be displayed if the tube or the sample diluent is missing).

IMPORTANT : Ensure the absence of foam in the tube of sample diluent before placing it on the rotating sampler.
- Slide the rotating sampler into the MINICAP instrument.
- Close the doors of the instrument, the analysis starts automatically.
- In the window which appears on the screen, select the number of analyses of the High CDT Control to perform and validate.

The results are then automatically considered by the software for the data analysis.
The values obtained must fall within the range provided with each lot of control.

Quality control performed in a series of samples :
- Use a microtube containing the reconstituted High CDT Control.
- Cut the cap of the microtube.
- Identify a new hemolysing tube with a bar code label of the High CDT Control.
- Place the microtube, located on the hemolysing tube used as a support tube, on the rotating sampler among a series of samples to analyze.
- Start the analysis by sliding the rotating sampler into the instrument.

The values obtained must fall within the range provided with each lot of control.

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

Storage, stability and signs of deterioration

See the High CDT Control instructions for use.

WARNING : No test method can provide an absolute assurance of the absence of HIV, hepatitis B and C or other infectious agents. Therefore, handle the High CDT Control as a hazardous biological material.
This control serum was 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.

4. DISTILLED OR DEIONIZED WATER

Use

For rinsing capillaries in automated system MINICAP, SEBIA, for capillary electrophoresis.
It is recommended to use filtered distilled or deionized water (on a filter with a porosity ≤ 0.45 µm) and with a conductivity lower than 3 µS/cm, which corresponds to a resistivity higher than 0.33 MΩ.cm.
To prevent microbial proliferation, change the water every day.
For optimal operation, add CLEAN PROTECT (SEBIA, PN 2059, 1 vial of 5 mL) in distilled or deionized water (see the instructions for use of CLEAN PROTECT) or use directly the ready to use CAPIprotect* solution (SEBIA, PN 2061 : 2 containers of 5 L of distilled water with CLEAN PROTECT).

IMPORTANT : Before filling the rinse container, it is recommended to wash it with plenty of distilled or deionized water.

** NOTE : The CAPIprotect solution can also be used to dilute the stock wash solution. Then, in that case, the diluted wash solution may show a transient more or less marked yellow colour without any adverse effects on its performance.*

5. CAPICLEAN (FOR MINICAP) OR MINICAP FLEX-PIERCING CAPICLEAN (FOR MINICAP FLEX-PIERCING)

Composition

The vial of CAPICLEAN concentrated solution (CAPICLEAN, SEBIA, PN 2058, 1 vial, 25 mL or MINICAP FLEX-PIERCING CAPICLEAN, SEBIA, PN 2251, 1 vial, 25 mL) contains : proteolytic enzymes, surfactants and additives nonhazardous at concentrations used, necessary for optimum performances.

Use

For the sample probe cleaning in automated instrument MINICAP or MINICAP FLEX-PIERCING, SEBIA, for capillary electrophoresis, during the CAPICLEAN cleaning sequence.

IMPORTANT : Launch a CAPICLEAN cleaning sequence at least once a week and at maximum once a day, or after every 500 analyses when performed within less than one week.

See the instruction sheets of CAPICLEAN or MINICAP FLEX-PIERCING CAPICLEAN, SEBIA.

IMPORTANT : For optimal use of the CAPICLEAN solution with the MINICAP and MINICAP FLEX-PIERCING instruments, it is necessary to use one bar code label intended to identify the tube which contains the diluted CAPICLEAN solution.

Storage, stability and signs of deterioration

Store CAPICLEAN refrigerated (2 – 8 °C). It is stable until the expiration date indicated on the vial label. DO NOT FREEZE.
Precipitate or combined particles in suspension (floccules) may be observed in the CAPICLEAN vial without any adverse effects on its utilization.
Do not dissolve this precipitate or these particles. It is recommended to collect only the supernatant.
For later use, store the tube containing the diluted solution at 2 – 8 °C. It must be used within the day.

6. SODIUM HYPOCHLORITE SOLUTION (for sample probe cleaning)

Preparation

Prepare a sodium hypochlorite solution (2 % to 3 % chloride) by diluting 250 mL 9.6 % chloride concentrated solution to 1 liter with cold distilled or deionized water.

Use

For the sample probe cleaning in automated instrument MINICAP or MINICAP FLEX-PIERCING, SEBIA, for capillary electrophoresis (weekly maintenance in order to eliminate adsorbed proteins from the probe).

See the SEBIA MINICAP or MINICAP FLEX-PIERCING instruction manual.

- For MINICAP, apply in a hemolysis tube 2 mL of diluted chlorinated solution previously prepared.
- For MINICAP FLEX-PIERCING, apply in a 100 mm tube 2 mL of diluted chlorinated solution previously prepared.
- Place the tube (identified with one bar code label specific to the sodium hypochlorite solution) on the rotating sampler of MINICAP or MINICAP FLEX-PIERCING.
- Check that new reagent cups are placed on the automated loading system for cups of MINICAP / MINICAP FLEX-PIERCING (a message will be displayed if the reagent cup is missing).
- Slide the rotating sampler into the MINICAP / MINICAP FLEX-PIERCING instrument.
- Close the doors of the MINICAP / MINICAP FLEX-PIERCING instrument, the cleaning sequence starts automatically.

IMPORTANT : For optimal use of the sodium hypochlorite solution with the MINICAP and MINICAP FLEX-PIERCING instruments, it is necessary to use one bar code label intended to identify the tube which contains the solution.

Storage, stability and signs of deterioration

Store the working chlorinated solution at room temperature (15 to 30 °C) in a closed container, it is stable for 3 months. Avoid storage in sunlight, close to heat and ignition source, and to acids and ammonia.

7. CAPILLARYS / MINICAP WASH SOLUTION

Preparation

Each vial of the stock CAPILLARYS / MINICAP Wash solution (SEBIA, PN 2052, 2 vials, 75 mL) should be diluted up to 750 mL with distilled or deionized water.
For MINICAP, it is convenient to dilute only 25 mL of the stock solution to 250 mL with distilled or deionized water.
After dilution, the wash solution contains an alkaline solution pH ≈ 12.

Use

For washing the MINICAP capillaries.

IMPORTANT : Before filling the wash solution container, it is recommended to wash the opening of the container, the connector and the tube with plenty of distilled or deionized water to avoid salts deposit.

Storage, stability and signs of deterioration

Store the stock and working wash solutions in closed containers at room temperature (15 to 30 °C) or refrigerated (2 to 8 °C). The stock wash solution is stable until the expiration date indicated on the kit or wash solution vial label.
Working wash solution is stable for 3 months.
Discard working wash solution if it changes its appearance, e.g., becomes cloudy due to microbial contamination.

8. CAPILLARYS / MINICAP CDT SAMPLES TREATMENT SOLUTION (Not FDA cleared for US market)

Preparation

The vial of CAPILLARYS / MINICAP CDT samples treatment solution (SEBIA, PN 2054, 50 mL) is ready to use. It contains additives, nonhazardous at concentrations used, necessary for optimum performance.

Use

For the treatment, if necessary, of serum samples with interferences corresponding to the presented profiles, see "Electrophoretic patterns" showing some examples of samples with interferences.
The samples treatment solution has a precipitating action on some immunoglobulins that may disturb the electrophoretic pattern.

NOTE : The samples treatment solution is especially effective when the following interferences are visualized :

- *appearance of one or many thin additional fractions on the pattern or of a wide fraction before disialotransferrin,*
- *shift of the electrophoretic pattern which invalidates the CDT quantification.*

See paragraph "Sample preparation" for using the treatment solution.

Storage, stability and signs of deterioration

Store the samples treatment solution refrigerated (2 – 8 °C). It is stable until the expiration date indicated on the box or vial labels. DO NOT FREEZE. Discard samples treatment solution if it changes its appearance, e.g., becomes cloudy due to microbial contamination.

NOTES :

The assays that were performed for the validation of reagents demonstrated that, for the different solutions and using an adapted equipment for the reconstitution volume, a variation of ± 5 % on the final volume has no adverse effect on the analysis.
The distilled or deionized water used to reconstitute solutions, must be free of bacterial proliferation and mold (use a filter ≤ 0.45 µm) and have a conductivity lower than 3 µS/cm, which corresponds to a resistivity higher than 0.33 MΩ.cm.

EQUIPMENT AND ACCESSORIES REQUIRED

1. MINICAP instrument for capillary electrophoresis : MINICAP SEBIA, PN 1230 or MINICAP FLEX-PIERCING SEBIA, PN 1232.
2. Rotating sampler supplied with MINICAP.
3. Container Kit supplied with MINICAP : Rinse (to fill with distilled or deionized water) and waste container.
4. MINICAP Reagent cups / 125 (3), SEBIA, PN 2281.
5. Lids for bins for used reagent cups, SEBIA (12 units), PN 2286 : lids to close the bins containing used cups.
6. Hemolysing tubes (with 8 to 16 mm diameter and 50 to 100 mm length).

For samples treatment, if necessary :

- 1.5 mL microtube.
- Hemolysing tube (75 mm high and 13 mm in diameter).
- Centrifuge (600 / 1700 g).

SAMPLES FOR ANALYSIS

Sample collection and storage

Fresh serum samples are recommended for analysis. Sera must be collected following established procedures used in the clinical laboratory testing. Samples can be stored refrigerated for up to 10 days between 2 and 8 °C.
Samples should not be stored for more than 48 hours (including duration of the transport) at room temperature (15 to 30 °C).

NOTE : Optimally, it is recommended to transport and to store the samples at 2 – 8 °C.

For longer storage, samples should be frozen at - 18 / - 30 °C within 8 hours of collection. Frozen sera are stable for 12 months.
Sample storage can lead protein degradation in particular C3 complement. Due to the C3 degradation, an additional fraction, C3d, may be observed on the transferrin isoforms electrophoretic pattern. This fraction appears after the pentasialotransferrin (more anodic) and does not interfere with any electrophoretically separated transferrin isoforms. The C3d fraction may increase during storage.

Sample preparation

- Use undiluted serum samples.
- Upon storage at 2 to 8 °C or after freezing, some sera (particularly those containing cryoglobulin or cryogel) may become viscous or develop turbidity. At room temperature, such samples can be directly analyzed.
- It is advised to observe the serum appearance before analysis (e.g., signs of hemolysis, cryoglobulins or turbidity).

Preparation of serum samples with interferences (See "Electrophoretic patterns" showing some examples of samples with interferences) :

- Place 200 µL of serum to treat in a microtube.
- Add 50 µL of CAPILLARYS / MINICAP CDT samples treatment solution.
- Vortex for 5 seconds.
- Centrifuge the microtube for 10 minutes at 600 g.
- Collect the supernatant and place it into a new microtube to perform the analysis.
- Cut the cap of this microtube.
- Place the microtube containing the supernatant of the treated sample on a new hemolysing tube (used as a holder) and then on the MINICAP rotating sampler.
- Perform the analysis as with a non-treated sample.

Samples to avoid

- Do not use hemolyzed serum samples. Hemolysis causes a distortion in the transferrin isoforms electrophoretic pattern and invalidates CDT quantification.
- Avoid aged, improperly stored serum samples.
- Avoid plasma samples. Fibrinogen migrates before the asialotransferrin isoform and causes distortion of the electrophoretic pattern. When the fibrinogen fraction is too large, it may interfere with the transferrin isoforms analysis and prevents CDT quantification.
- Do not analyze samples that contain EDTA or citrate. These distort the electrophoretic pattern and invalidate CDT quantification.

NOTE : Collection tubes and centrifugation parameters for biological samples are described in the available documentation on pre-analytical phase for bio-medical analysis (data provided by the tube manufacturers, guides and recommendations on biological sample collection…). Without any indication in the instructions for use on the type of tube to use or on the centrifugation, please refer to this documentation and for the dimensions of tube to use, refer to the SEBIA document "Characteristics of tubes to use according to the instrument". The pre-analytical phase must be performed according to the state of art, the different recommendations, including those provided by the tube manufacturers, and applicable regulations.

PROCEDURE

The MINICAP system is a multiparameter instrument for serum proteins analysis on parallel capillaries. The transferrin isoforms assay uses 2 capillaries to run the samples.
The sequence of automated steps is as follows :

- bar code reading of sample tubes (for up to 26 tubes), sample diluent tube and rotating sampler,
- sample dilution from primary tubes into reagent cups,
- capillary washing,
- injection of diluted samples,
- protein separation and direct detection of the separated proteins on capillaries.

The manual steps include :

- set up the uncapped sample tubes in rotating sampler in positions No. 1 to 26,
- set up the sample diluent tube in rotating sampler in position No. 27,
- set up the rotating sampler in the MINICAP instrument,
- remove the sample tubes after analysis,
- remove and close the bins for used cups.

PLEASE CAREFULLY READ THE MINICAP OR MINICAP FLEX-PIERCING INSTRUCTION MANUALS.

I. PREPARATION OF ELECTROPHORETIC ANALYSIS

1. Switch on MINICAP instrument and computer.
2. In order to start the instrument, position at least one new reagent cup on the automated loading system for cups of MINICAP (a message will be displayed if a reagent cup is missing).
3. Set up the software, the instrument automatically starts.
4. The MINICAP CDT kit is intended to run with "CDT" analysis program from the MINICAP instrument. To select "CDT" analysis program and place the MINICAP CDT buffer vial in position "B2" in the instrument, please read carefully the MINICAP instruction manual and follow the instructions displayed on the screen.

   IMPORTANT : Always associate and identify the quick coupling cap, the pipe and the filter according to the buffer. If this procedure is not perfectly respected, a contamination of the migration buffer with the previous buffer may lead to migration artefacts, which would disturb the current analysis.
5. Position new reagent cups on the automated loading system for cups of MINICAP (a message will be displayed if the reagent cups are missing).
6. Position a new bin for used cups in MINICAP at the location intended for this purpose.
7. Check the fill level of the reagent vials, add reagent if necessary and empty the waste container. In the window "Check reagent levels", update the software by moving the cursor buttons.
8. The rotating sampler contains 28 positions for sample tubes :
   - Position up to 26 uncapped sample tubes on the rotating sampler (positions No. 1 to 26), the bar code of each tube must be visible in the openings of the rotating sampler.
   - Pour CAPILLARYS / MINICAP CDT sample diluent in a hemolysing tube, identified with the sample diluent bar code label, without introducing air bubbles : 0.5 mL for the analysis of 1 or 2 samples or 1 mL for the analysis of 8 samples. Place this tube in position No. 27 on the rotating sampler ("Diluent / Solution" position).

   IMPORTANT : Ensure the absence of foam in the tube of sample diluent before placing it on the rotating sampler.

   IMPORTANT : If a tube is missing into positions No. 1 to 26 (sample tubes) and into position No. 27 (sample diluent tube), the analysis cannot start and a message will be displayed.
9. Slide the rotating sampler into the MINICAP instrument.
10. Close the doors of the MINICAP instrument, the analysis starts automatically.
11. After the analysis, remove the rotating sampler with analyzed sample tubes.
12. If necessary, take off carefully the bin containing used reagent cups, close it tightly with the corresponding lid and discard it.

    WARNING : Bins containing used reagent cups with biological samples have to be handled with care.

DILUTION - MIGRATION - DESCRIPTION OF THE AUTOMATED STEPS

1. Bar codes are read on sample tubes and on rotating sampler.
2. Samples are diluted in sample diluent and the sample probe is rinsed after each sample.
3. Capillaries are washed.
4. Diluted samples are injected into capillaries.
5. Migration is carried out under constant voltage for about 8 minutes and the temperature is controlled by Peltier effect.
6. Transferrin isoforms are detected directly by scanning at 200 nm and an electrophoretic profile appears on the screen of the system.

NOTE : These automated steps are described for the two first analyzed sample tubes. The electrophoretic patterns appear after about 18 minutes from the start of the analysis. For the following sample tubes, the two first steps (bar code reading and sample dilution) are performed during the analysis of the 2 previous samples.

II. RESULT ANALYSIS

At the end of the analysis, relative quantification of individual transferrin isoforms is performed automatically and the profiles can be analyzed ; the system calculates the percentage of each fraction which appears in the following order : pentasialotransferrin associated with tetrasialotransferrin, trisialotransferrin, disialotransferrin and asialotransferrin.
On the electrophoretic pattern, the curves of transferrin isoform except asialotransferrin are calculated and redrawn by fitting with adjustment (or fitted) and are superimposed with the native profile. Pentasialotransferrin and tetrasialotransferrin are individually integrated and each transferrin fraction is identified by a specific color.
After calibration of the analysis system with specific calibrators, the direct detection provides automatically the calibrated percentage of disialotransferrin (CDT-IFCC %) calculated from the total amount of detected transferrin.

The identification of normal serum samples and of serum samples with elevated CDT-IFCC level is automatically performed and the profiles can be distinguished in the mosaic of patterns and the curve review window by a blue color for normal samples or a orange color for samples with elevated CDT-IFCC level :
- Normal samples, with CDT-IFCC percentage lower than 1.7 % or equal, are indicated in blue color.
- Samples with CDT-IFCC percentage higher than 1.7 % are indicated in orange color.

Electrophoretic patterns with abnormality (such as an additional fraction or deletion of a normal fraction among transferrin fractions) are indicated in pink color with "Atypical profile" indication.

The following table presents the warning and message signals that are displayed and the procedures to follow according to the analyzed sample :

<table>
<tr><th>Warning signal
Analyzed sample</th><th> 
Analysis not in conformity and not considered</th><th> 
Shift* of the pattern (or CDT value > 3 % in the absence of 0-sialotranferrin fraction)</th><th> 
Insufficient optical density for 4-sialotransferrin fraction</th><th>"Atypical profile" (presence of an additional fraction or deletion of a normal fraction)</th><th> 
CDT-IFCC value outside the expected values for controls analyzed with the Quality Control (QC) mode</th></tr>
<tr><td rowspan="2">Calibrators identified with bar code labels</td><td>2-sialotransferrin % value not complying to specifications.</td><td>/</td><td>/</td><td>/</td><td rowspan="2">/</td></tr>
<tr><td colspan="4">Warning message : "analysis of the calibrator not in conformity". Analyze the controls to check that results may be reported on failing capillaries.</td></tr>
<tr><td rowspan="2">Controls identified with bar code labels</td><td>/</td><td>No CDT / CDT-IFCC value displayed in case of shifted pattern without any fraction identification.</td><td>/</td><td>/</td><td rowspan="2">With the Quality Control mode :
- "+" or "-" identification according to the obtained CDT-IFCC value compared to the expected values,
- warning message : "analysis of the control not in conformity",
- confirmation or not of the deviation after a 2nd analysis of the control sample,
- if the deviation is confirmed, repeat the calibration.</td></tr>
<tr><td>/</td><td colspan="3">Warning message : "analysis of the control not in conformity":
1. repeat the analysis using the same vial,
2. repeat the analysis with a new vial,
3. call SEBIA Technical Service if the failure is confirmed.</td></tr>
<tr><td>Serum sample from patient</td><td>No CDT / CDT-IFCC value displayed.</td><td>No CDT / CDT-IFCC value displayed in case of shifted pattern without any fraction identification : repeat the analysis for confirmation.
In case of shifted pattern, when the fractions are identified and the order of peaks is observed, the CDT / CDT-IFCC value can be reported.</td><td>Warning message "too low OD" (< 0.05) for a sample that is not abnormal, repeat the analysis : if the result is confirmed the CDT / CDT-IFCC value can be reported (please note the background).</td><td>"atypical profile": suspect the presence of an interferent factor or a variant.</td><td>/</td></tr>
</table>

** A message "migration centering out of range" may be displayed on the pattern according to the amplitude of the shift.*

III. END OF ANALYSIS SEQUENCE

At the end of each analysis sequence, the operator must initiate the "shut down" procedure of the MINICAP instrument in order to store capillaries in optimal conditions.

IMPORTANT : Check that new reagent cups are placed on the automated loading system for cups of MINICAP (a message will be displayed if the reagent cup is missing).

IV. FILLING OF REAGENT CONTAINERS

The MINICAP automated instrument has a reagent automatic control.

IMPORTANT : Please refer to the instructions for replacement of reagent containers respecting color code for vials and connectors.

A message will be displayed when it is necessary to perform one of the following tasks :

- place a new buffer vial and / or,
- fill the container with working wash solution and / or,
- fill the container with filtered distilled or deionized water for rinsing capillaries and / or,
- empty the waste container.

WARNING : Do not use marketed deionized water, such as water for ironing for example (risk of important capillaries damage). Use only water with ultrapure quality, such as injection grade water.

IMPORTANT : Before filling the rinse container, it is recommended to wash it with plenty of distilled or deionized water.

PLEASE CAREFULLY READ THE MINICAP OR MINICAP FLEX-PIERCING INSTRUCTION MANUALS.

QUALITY CONTROL

Analyze the Normal CDT Control, SEBIA, PN 4795, and the High CDT Control, SEBIA, PN 4772, after each capillary calibration of the MINICAP instrument.

Additionally, it is advised to include the Normal CDT Control, the High CDT Control or the Intermediate CDT Control, SEBIA, PN 4773, with each sequence of analysis.

RESULTS

Values

Direct detection at 200 nm in capillaries yields relative concentrations (percentages) of individual transferrin isoforms, and especially the calibrated percentage of disialotransferrin (CDT-IFCC).

- The upper limit of the reference interval (according to the IFCC working group) is 1.7 %.
  => CDT-IFCC ≤ 1.7 % : normal result.

- The proposed cut-off value is 2.0 % for forensic use (this value is based upon the upper reference limit plus the expended uncertainty of the measurement).
  => CDT-IFCC > 2.0 % : For clinical purposes, values above 2 % are consistent with alcohol abuse or excessive alcohol consumption (according to the IFCC working group).

- CDT-IFCC > 1.7 % and ≤ 2.0 % : inconclusive result (electrophoretic pattern with "NC" labeling). In this interval, the results do not permit to conclude.

Interpretation

The CDT-IFCC values > 2.0 % are considered positive and due to chronic alcohol abuse.

WARNING : The graduation of the horizontal axis does not allow, in any case, the identification of a fraction which has not been automatically identified by the software.

Interference and Limitations

The factors listed below may interfere with the CDT assay and may disturb or prevent the CDT quantification. It is recommended to examine each pattern visually for distortions, additional fraction and any conceptual departure from the appearance of normal (nonalcoholic) or CDT elevated (alcohol abuse) patterns (see ELECTROPHORETIC PATTERNS, Fig. No. 1 and 2). When interfering pattern abnormalities are present, the CDT value eventually displayed must not be considered.

- CDG syndrome (Congenital Disorders of Glycosylation),
- Genetic variants of transferrin,
- Some monoclonal components or high polyclonal background,
- Fibrinogen and hemolyzed samples,
- Anticoagulants (citrate, EDTA),
- Aged and improperly stored samples,
- Liver injuries (serious, end stage disease).

See also SAMPLES FOR ANALYSIS.

The CDT-IFCC cannot be quantified with the MINICAP CDT-IFCC procedure in serum samples with genetic variants of transferrin isoforms. In this case, only the CDT value is displayed in the review window, but not the CDT-IFCC value. The CDT quantification is obtained by calculation, the "CDT (*)" labeling is then displayed on the screen and the comment "CDT calculated" is added nearby the "CDT (*)" labeling when printing the ticket result. For a CDT percentage closed to the threshold value, it is recommended to analyze the patient clinical data.

Hepatic disorders may interfere with the CDT quantification.

A block containing disialotransferrin and trisialotransferrin may be observed when analyzing serum sample from patient with liver injuries, cirrhosis due to chronic alcohol abuse for example (see "ELECTROPHORETIC PATTERNS"). In this case, a decrease of transferrin is then generally observed linked to an increase of trisialotransferrin.

IMPORTANT : It is also necessary to analyze the patient clinical data, as complementary results.

Due to the variability of interfering factors, it is possible that the samples treatment solution may not be efficient with this CDT quantification method. When disialotransferrin is higher than 3 % and asialotransferrin is absent, a yellow warning signal is displayed on the screen. This signal may indicate a potential interference on disialotransferrin. It is then recommended to examine carefully the electrophoretic pattern and if necessary, to treat the sample with the CAPILLARYS / MINICAP CDT samples treatment solution. The analysis of the sample by serum protein electrophoresis may be used to verify that no monoclonal protein migrates in beta zone.

NOTES : When analyzing a sample treated with the CAPILLARYS / MINICAP CDT samples treatment solution, a decrease of the optical density may be observed without affecting the result of the analysis. Shifted electrophoretic patterns will remain interpretable only when 0-sialo and 5-sialo fractions are comprised in the acquisition window of the software for data treatment.

When encountering a CDT variant, it is important to check the following points :
- Has the sample been stored at room temperature (15 to 30 °C) (if yes, how long) ?
- Is the C3 concentration elevated ?
- What is the Transferrin concentration ?

With an increased C3 concentration, and a sample stored for several days at room temperature (15 to 30 °C), the degraded C3 (C3d) is increased and may reach an optical density (OD) similar to the tetrasialotransferrin (4-sialo) fraction OD.
With a low transferrin concentration (due to hepatic problem), the tetrasialotransferrin peak (4-sialo) can be significantly decreased.
These parameters, when combined, may lead to a "variant like" profile. When such a situation arises, it is advised to renew the analysis on a fresh serum sample or a serum sample stored at 2 - 8 °C or frozen.

Troubleshooting

Call SEBIA Technical Service of the supplier when the test fails to perform while the instruction for the preparation and storage of materials, and for the procedure were carefully followed.
Kit reagent Safety Data Sheets and information on cleaning and waste disposal, labeling and safety rules applied by SEBIA, packaging for the transportation of biological samples, and instruments cleaning are available on the SEBIA's extranet website : www.sebia.com.

PERFORMANCE DATA

Precision

The precision of the MINICAP CDT-IFCC procedure was evaluated in a study based on the Clinical and Laboratory Standards Institute (CLSI - USA) EP5-A2 guideline "Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline – Second Edition".
The means and coefficients of variation (CV %) were calculated for CDT-IFCC percentage (%) for each sample, using statistical tools recommended by CLSI.

Reproducibility within the same capillary from the same instrument

10 different serum samples were run using the MINICAP CDT-IFCC procedure.
In this study, each serum sample was analyzed on the same capillary from the same instrument and with 3 lots of kit, including 12 runs over 6 working days (at 2 different times of the day). Within each run, samples were analyzed in duplicate.
CV ranges were obtained for each sample by conducting this study on both capillaries from 3 different instruments.
The following table summarizes the repeatability and the total reproducibility CV (%) ranges for the CDT-IFCC percentages.

Sample No.	Mean (CDT-IFCC %)	Repeatability						Total reproducibility					
		Instrument No. 1		Instrument No. 2		Instrument No. 3		Instrument No. 1		Instrument No. 2		Instrument No. 3	
		CV min (%)	CV max (%)	CV min (%)	CV max (%)	CV min (%)	CV max (%)	CV min (%)	CV max (%)	CV min (%)	CV max (%)	CV min (%)	CV max (%)
1	1.3	3.5	3.6	2.2	2.3	3.1	3.5	4.3	4.3	3.8	4.3	4.0	4.0
2	1.4	3.2	3.5	1.5	3.7	2.0	3.8	3.5	3.5	1.5	3.9	3.1	4.1
3	1.6	2.7	4.5	2.6	2.8	3.1	3.3	3.2	5.0	3.1	3.1	3.4	3.8
4	2.0	1.8	2.3	1.8	2.7	1.8	2.7	2.9	3.1	3.2	3.8	2.9	3.8
5	3.0	2.7	3.7	1.7	2.0	2.0	2.7	3.3	4.1	2.5	2.9	3.3	4.1
6	3.6	1.3	1.7	1.0	1.3	1.8	2.7	2.6	3.1	1.6	2.2	2.9	3.8
7	4.4	0.9	1.4	1.4	1.5	1.5	1.7	1.6	1.6	1.5	1.7	1.9	2.8
8	6.0	1.0	1.1	0.8	1.1	0.9	1.2	1.5	1.8	1.0	1.4	1.4	2.4
9	10.7	0.8	0.8	0.8	1.5	1.0	1.4	1.2	1.6	1.3	1.6	2.2	2.4
10	18.3	0.8	0.9	0.6	0.7	0.7	1.1	1.0	2.1	0.9	1.5	1.9	3.1
CV (%) ranges		0.8	4.5	0.6	3.7	0.7	3.8	1.0	5.0	0.9	4.3	1.4	4.1

Reproducibility between capillaries from the same instrument

10 different serum samples were run using the MINICAP CDT-IFCC procedure.
In this study, each serum sample was analyzed on both capillaries from the same instrument and with 1 lot of kit, including 8 runs over 4 working days (at 2 different times of the day). Within each run, samples were analyzed in duplicate.
CV ranges were obtained for each sample by conducting this study with 3 lots of kit on 3 different instruments.
The following table summarizes the repeatability and the total reproducibility CV (%) ranges for the CDT-IFCC percentages.

Sample No.	Mean (CDT-IFCC %)	Repeatability						Total reproducibility					
		Instrument No. 1		Instrument No. 2		Instrument No. 3		Instrument No. 1		Instrument No. 2		Instrument No. 3	
		CV min (%)	CV max (%)	CV min (%)	CV max (%)	CV min (%)	CV max (%)	CV min (%)	CV max (%)	CV min (%)	CV max (%)	CV min (%)	CV max (%)
1	1.3	2.7	4.9	1.9	2.7	3.3	3.4	3.3	5.0	3.3	4.3	3.4	4.2
2	1.4	0.0	4.7	2.5	3.5	2.4	3.4	2.5	4.7	3.3	4.6	3.5	4.7
3	1.6	2.7	4.8	2.3	3.1	3.1	3.4	5.2	6.1	3.3	3.5	3.5	3.5
4	2.0	1.8	2.2	1.8	2.6	1.8	2.9	2.2	2.4	2.5	3.2	1.8	4.2
5	3.0	2.4	3.8	1.2	2.7	1.8	2.7	2.7	5.1	1.7	3.8	3.0	3.4
6	3.6	1.0	1.9	0.0	1.5	1.0	2.8	1.7	6.2	1.4	2.5	3.1	3.7
7	4.4	1.0	1.4	1.1	1.7	1.3	1.9	2.2	3.5	1.3	2.2	1.8	3.3
8	6.0	0.9	1.3	0.6	1.1	0.6	1.3	1.3	1.9	1.0	1.3	1.3	2.3
9	10.7	0.7	1.0	1.0	1.5	0.8	1.5	0.9	2.3	1.3	1.7	1.7	1.9
10	18.3	0.6	1.0	0.4	0.9	0.8	1.1	1.4	1.8	0.8	1.1	1.1	2.3
CV (%) ranges		0.0	4.9	0.0	3.5	0.6	3.4	0.9	6.2	0.8	4.6	1.1	4.7

Reproducibility between lots and between instruments

10 different serum samples were run using the MINICAP CDT-IFCC procedure.
In this study, each serum sample was analyzed at 2 different times of the day on both capillaries from 3 different instruments and with 3 lots of kit. Within each run, samples were analyzed in duplicate.
The analysis of obtained results allows to demonstrate the reproducibility :

- between lots : from data obtained with 3 lots of kit on the same instrument, including 24 runs over 12 working days. CV ranges were obtained for each sample by conducting this study on 3 different instruments.
- between instruments : from data obtained with 3 instruments and 1 lot of kit, including 24 runs over 12 working days. CV ranges were obtained for each sample by conducting this study on 3 different lots.
- between lots and between instruments : from combined data obtained with the 3 instruments and the 3 lots of kit, including 72 runs over 36 working days.

The following table summarizes the repeatability and the total reproducibility CV (%) ranges for the CDT-IFCC percentages.

Sample No.	Mean (CDT-IFCC %)	Between-lot reproducibility				Between-instrument reproducibility				Between-lot and between-instrument reproducibility			
		Repeatability		Total reproducibility		Repeatability		Total reproducibility		Repeatability		Total reproducibility	
		CV min (%)	CV max (%)	CV min (%)	CV max (%)	CV min (%)	CV max (%)	CV min (%)	CV max (%)	CV (%)		CV (%)	
1	1.3	2.2	3.6	3.7	4.4	2.7	3.6	3.3	3.9	3.1		4.0	
2	1.4	2.9	3.4	3.5	3.9	2.7	3.6	3.3	4.3	3.1		3.6	
3	1.6	2.7	3.8	3.2	5.4	3.0	3.6	3.8	4.1	3.3		4.1	
4	2.0	2.1	2.3	2.8	3.7	1.9	2.5	2.2	3.1	2.2		3.3	
5	3.0	1.9	3.2	2.7	3.7	1.9	2.9	2.8	3.5	2.5		3.3	
6	3.6	1.1	2.3	2.0	3.9	1.1	1.9	2.3	4.2	1.7		3.2	
7	4.4	1.2	1.6	1.7	2.6	1.3	1.6	2.1	2.7	1.4		2.5	
8	6.0	0.9	1.1	1.2	2.0	0.8	1.2	1.2	1.9	1.0		1.6	
9	10.7	0.8	1.2	1.5	2.3	1.0	1.2	1.8	2.1	1.1		2.1	
10	18.3	0.7	0.9	1.2	2.5	0.8	0.9	1.3	2.4	0.8		2.1	
CV (%) ranges		0.7	3.8	1.2	5.4	0.8	3.6	1.2	4.3	0.8	3.3	1.6	4.1

Linearity

The linearity study of the MINICAP CDT-IFCC procedure was evaluated in a study based on the Clinical Laboratory Standards Institute (CLSI - USA) EP6-A guideline "Evaluation of the Linearity of Quantitative Measurement Procedures : A statistical Approach ; Approved Guideline".
The results for CDT-IFCC percentages (%) were analyzed using statistical tools recommended by CLSI.

2 different serum samples, including a serum sample with normal CDT-IFCC level (1.1 % CDT-IFCC) and a sample with elevated CDT-IFCC level (17.4 % CDT-IFCC) were mixed within different proportions and the mixtures were electrophoresed with the MINICAP CDT-IFCC procedure. For each mixture, samples were analyzed in triplicate.
The tests were determined to be linear within the entire ranges studied for CDT-IFCC percentage between 1.1 and 17.4 % of CDT-IFCC.

Accuracy – Internal correlation

The internal concordance study of the MINICAP CDT-IFCC procedure was evaluated in a study based on the Clinical and Laboratory Standards Institute (CLSI - USA) EP09-A2 guideline "Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline – Second Edition (Interim Revision)".
The results for CDT-IFCC percentages (%) were analyzed using statistical tools recommended by CLSI.

NOTE : The results presented below have been obtained from 1 internal accuracy study. The analyzed serum samples were provided by 4 laboratories in France, the Netherlands and USA.

The levels of CDT-IFCC were measured in 130 serum samples, including samples with normal and elevated CDT-IFCC level, by electrophoretic separations obtained with the MINICAP CDT-IFCC procedure and a reference HPLC system for CDT quantification.
The measured values of CDT-IFCC percentages from both procedures were analyzed by a linear regression statistical procedure.
The results of linear regression analysis are tabulated below (y = MINICAP CDT-IFCC), the sensibility and specificity of the MINICAP CDT-IFCC procedure compared to the reference procedure have been calculated using the recommended method (Wendling, 1986).

	Correlation coefficient	y-Intercept	Slope	Range of CDT-IFCC % MINICAP CDT-IFCC	Sensibility (%)	Specificity (%)
CDT-IFCC (%)	0.997	-0.006	0.999	0.9 – 18.1	97.0	96.2

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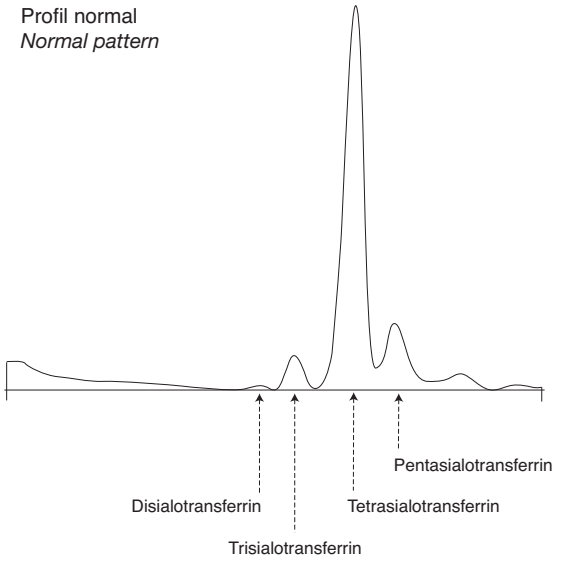
SCHÉMAS / FIGURES

ABBILDUNGEN - FIGUREN - FIGURE - FIGURAS - BILDER - EIKONEΣ - SLIKE - PAVEIKSLAI - RYSUNKI - FIGURI - ÁBRÁK - ŞEKİLLER - OBRÁZKY - ФИГУРИ - FIGURER - 插图 - РИСУНКИ - 図 - CIPARI - JOONISED

PROFILS ÉLECTROPHORÉTIQUES - ELECTROPHORETIC PATTERNS

1



FR : PROFILS ÉLECTROPHORÉTIQUES	*Profil normal*
GB : ELECTROPHORETIC PATTERNS	*Normal pattern*
DE : ELEKTROPHORESEMUSTER	*Normales Muster*
NL : ELEKTROFORETISCHE PATRONEN	*Normaal patroon*
IT : PROFILI ELETTROFORETICI	*Profilo normale*
ES : PERFILES ELECTROFORÉTICOS	*Perfil normal*
PT : PADRÕES ELETROFORÉTICOS	*Padrão normal*
SV : ELEKTROFORETISKA MÖNSTER	*Normalt mönster*
GR : ΗΛΕΚΤΡΟΦΟΡΗΤΙΚΑ ΠΡΟΤΥΠΑ	*Φυσιολογικό αποτύπωμα*
HR : ELEKTROFORETSKI OBRASCI	*Normalan profil*
LT : ELEKTROFOREZĖS ŠABLONAI	*Normalus šablonas*
PL : OBRAZY ELEKTROFORETYCZNE	*Obraz prawidłowy*
RO : TIPARE ELECTROFORETICE	*Tipar normal*
CS : ELEKTROFORETSKÍ ŠABLONI	*Normalní šablon*
HU : ELEKTROFORETIKUS MINTÁZATOK	*Normál mintázat*
TR : ELEKTROFORETİK PATERNLER	*Normal patern*
CZ : ELEKTROFORETICKÉ TYPY	*Normální typ*
BG : ЕЛЕКТРОФОРЕТИЧНИ МОДЕЛИ	*Нормален модел*
NO : ELEKTROFORETISKE MØNSTRE	*Vanlig mønster*
DK : ELEKTROFORETISKE MØNSTRE	*Normalt mønster*
CN : 电泳图谱	*正常图谱*
RU : ЭЛЕКТРОФОРЕТИЧЕСКИЕ ПРОФИЛИ	*Нормальный профиль*
JP : 電気泳動パターン	*正常パターン*
LV : ELEKTROFORĒTISKIE SPEKTRI	*Normāls spektrs*
SK : ELEKTROFORÉZNE VZORY	*Normálny vzor*
EE : ELEKTROFOREETILISED MUSTRID	*Normaalne muster*

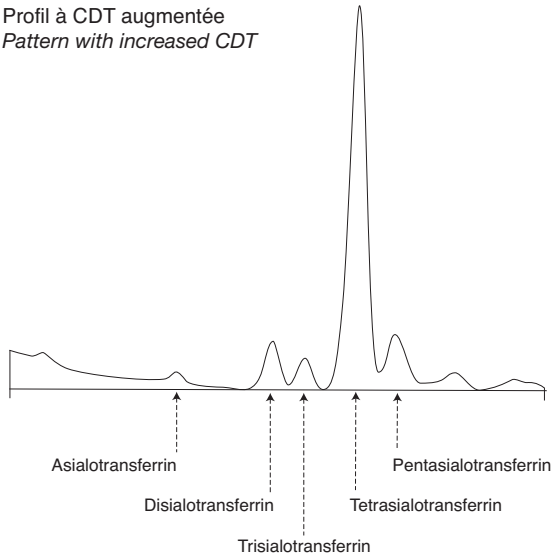
SCHÉMAS / FIGURES

ABBILDUNGEN - FIGUREN - FIGURE - FIGURAS - BILDER - ΕΙΚΟΝΕΣ - SLIKE - PAVEIKSLAI - RYSUNKI - FIGURI - ÁBRÁK - ŞEKİLLER - OBRÁZKY - ФИГУРИ - FIGURER - 插图 - РИСУНКИ - 図 - CIPARI - JOONISED

PROFILS ÉLECTROPHORÉTIQUES - ELECTROPHORETIC PATTERNS

2

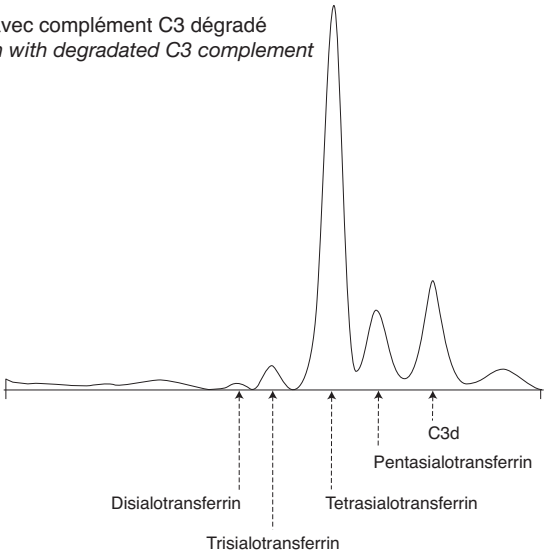
Profil à CDT augmentée
Pattern with increased CDT



FR : Profil à CDT augmentée
GB : Pattern with increased CDT
DE : Muster mit erhöhtem CDT
NL : Patroon met verhoogde CDT waarde
IT : Profilo con CDT aumentata
ES : Perfil con CDT aumentada
PT : Padrão com CDT aumentada
SV : Mönster med ökat CDT
GR : Πρότυπο με αυξημένο επίπεδο CDT
HR : Profil s povišenom vrijednošću CDT
LT : Šablonas esant padidėjusiam CDT lygiui
PL : Obraz z podwyższonym stężeniem CDT
RO : Tipar cu CDT crescut
CS : Šablon sa povećanim CDT
HU : Emelkedett CDT-szintes mintázat
TR : Yüksek CDT içeren patern
CZ : Typ se zvýšeným CDT
BG : Модел с повишен CDT
NO : Mønster med økt CDT
DK : Mønster med øget CDT
CN : CDT升高图谱
RU : Профиль с повышенным уровнем CDT
JP : CDTが高値のパターン
LV : Spektrs ar paaugstinātu CDT līmeni
SK : Vzor so zvýšenou hladinou CDT
EE : Muster suurenenud CDT-ga

3

Profil avec complément C3 dégradé
Pattern with degradated C3 complement



FR : Profil avec complément C3 dégradé
GB : Pattern with degraded C3 complement
DE : Muster mit degradiertem C3-Komplement
NL : Patroon met afgebroken C3 complement
IT : Profilo con complemento C3 degradato
ES : Perfil con complemento C3 degradado
PT : Padrão com complemento C3 degradado
SV : Mönster med nedbrutet C3 komplement
GR : Πρότυπο με αποσυντεθειμένο συμπλήρωμα C3
HR : Profil s degradacijom komplementa C3
LT : Šablonas esant suskilusio C3 komplemento
PL : Obraz z rozłożonym dopełniaczem C3
RO : Tipar cu complement degradat C3
CS : Šablon sa degradiranim C3 komplementom
HU : Degradálódott C3 komplementes mintázat
TR : İndirgenmiş C3 komplemanı içeren patern
CZ : Typ s degradovanou složkou C3
BG : Модел с разграден C3 комплемент
NO : Mønster med degradert C3-komplement
DK : Mønster med nedbrudt C3-komplement
CN : C3 补体降解图谱
RU : Профиль с подвергнувшимся разложению C3 компонентом комплемента
JP : 劣化したC3補体でのパターン
LV : Spektrs ar noārdītu C3 komplementu
SK : Vzor s degradovaným komplementom C3
EE : Muster lagunenud C3 komplemendiga

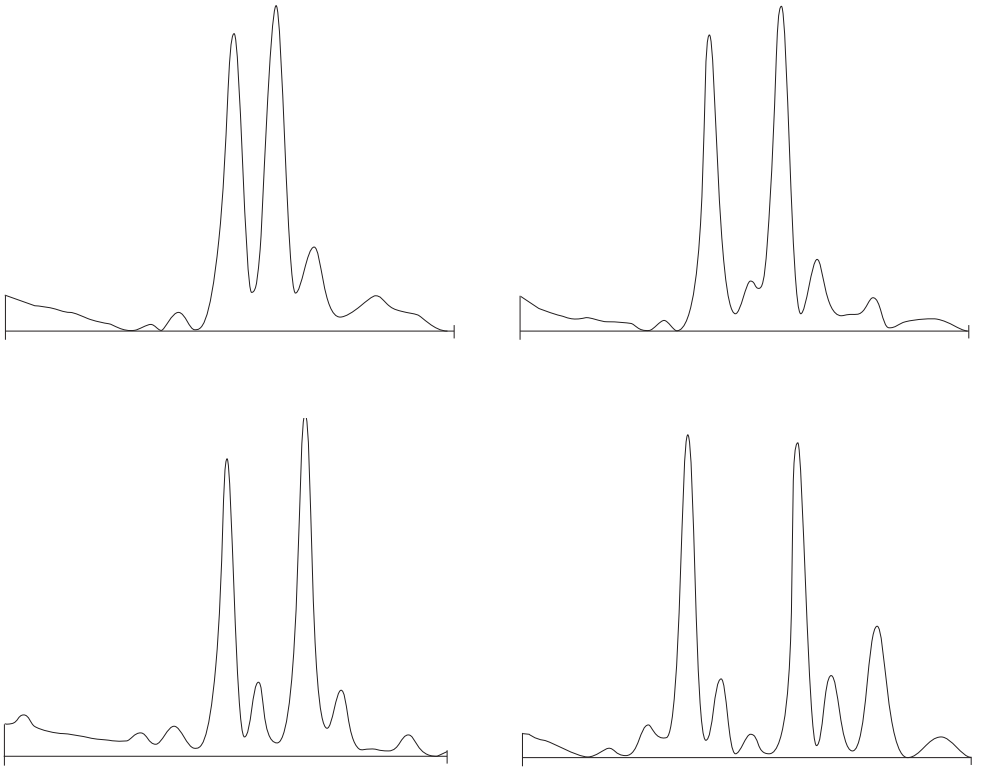
SCHÉMAS / FIGURES

ABBILDUNGEN - FIGUREN - FIGURE - FIGURAS - BILDER - ΕΙΚΟΝΕΣ - SLIKE - PAVEIKSLAI - RYSUNKI - FIGURI - ÁBRÁK - ŞEKİLLER - OBRÁZKY - ФИГУРИ - FIGURER - 插图 - РИСУНКИ - 図 - CIPARI - JOONISED

PROFILS ÉLECTROPHORÉTIQUES - ELECTROPHORETIC PATTERNS

4

Variants de la CDT - CDT variants



FR : Variants de la CDT
GB : CDT variants
DE : CDT-Varianten
NL : CDT varianten
IT : Varianti della CDT
ES : Variantes de la CDT
PT : Variantes de CDT
SV : CDT varianter
GR : Παραλλαγές CDT
HR : Varijante CDT-a
LT : CDT variantai
PL : Odmiany CDT
RO : Variante CDT
CS : CDT varijante
HU : CDT-variánsok
TR : CDT varyantları
CZ : Varianty CDT
BG : CDT варианти
NO : CDT-varianter
DK : CDT-varianter
CN : CDT变体
RU : Вариации CDT
JP : CDT変異体
LV : CDT varianti
SK : Varianty CDT
EE : CDT variandid

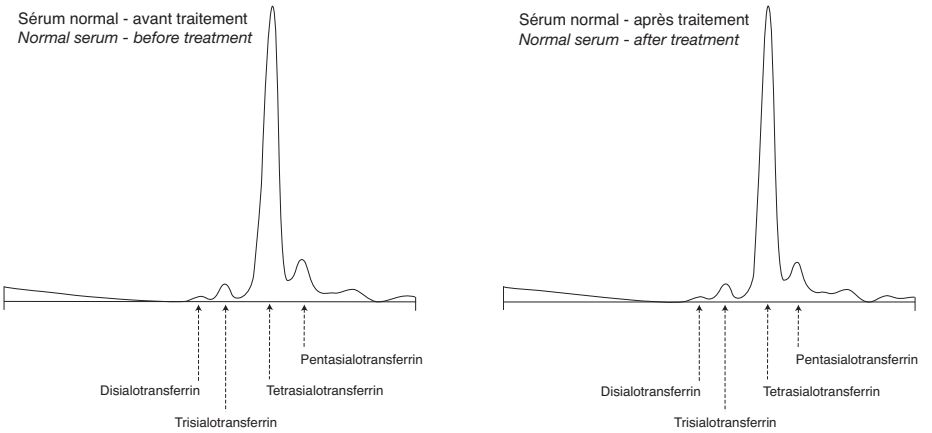
SCHÉMAS / FIGURES

ABBILDUNGEN - FIGUREN - FIGURE - FIGURAS - BILDER - ΕΙΚΟΝΕΣ - SLIKE - PAVEIKSLAI - RYSUNKI - FIGURI - ÁBRÁK - ŞEKİLLER - OBRÁZKY - ФИГУРИ - FIGURER - 插图 - РИСУНКИ - 図 - CIPARI - JOONISED

PROFILS ÉLECTROPHORÉTIQUES - ELECTROPHORETIC PATTERNS

5

Solution de traitement des échantillons (exemples)
Samples treatment solution (examples)



FR :	*Solution de traitement des échantillons (exemples)*	*Sérum normal - avant traitement*	*Sérum normal - après traitement*
GB :	*Samples treatment solution (examples)*	*Normal serum - before treatment*	*Normal serum - after treatment*
DE :	*Probenbehandlungslösung (Beispiele)*	*Normales Serum - vor der Behandlung*	*Normales Serum - nach der Behandlung*
NL :	*Oplossing voor de behandeling van monsters (voorbeelden)*	*Normaal serum - vóór behandeling*	*Normaal serum - na behandeling*
IT :	*Soluzione di trattamento dei campioni (esempi)*	*Siero normale - prima del trattamento*	*Siero normale - dopo il trattamento*
ES :	*Solución de tratamiento de muestras (ejemplos)*	*Suero normal - antes del tratamiento*	*Suero normal - después del tratamiento*
PT :	*Solução de tratamento de amostras (exemplos)*	*Soro normal - antes do tratamento*	*Soro normal - depois do tratamento*
SV :	*Lösning för provbehandling (exempel)*	*Normalt serum - innan behandling*	*Normalt serum - efter behandling*
GR :	*Διάλυμα επεξεργασίας δειγμάτων (παραδείγματα)*	*Φυσιολογικός ορός - πριν από την επεξεργασία*	*Φυσιολογικός ορός - μετά την επεξεργασία*
HR :	*Uzorci otopine za obradu uzoraka (primjeri)*	*Normalan serum - prije obrade*	*Normalan serum - poslije obrade*
LT :	*Mėginių apdorojimo tirpalas (pavyzdžiai)*	*Normalus serumas - prieš apdorojant*	*Normalus serumas - apdorojus*
PL :	*Roztwór do obróbki próbek (przykłady)*	*Surowica prawidłowa - przed obróbką*	*Surowica prawidłowa - po obróbce*
RO :	*Probe soluţie de tratament (exemple)*	*Ser normal - înainte de tratament*	*Ser normal - după tratament*
CS :	*Rastvor za tretiranje uzoraka (primeri)*	*Normalan serum - pre tretiranja*	*Normalan serum - posle tretiranja*
HU :	*Mintakezelő oldat (példák)*	*Normál szérum - kezelés előtt*	*Normál szérum - kezelés után*
TR :	*Numune işleme solüsyonu (örnekler)*	*Normal serum - işlemden önce*	*Normal serum - işlemden sonra*
CZ :	*Roztok na úpravu vzorků (příklady)*	*Normální sérum - před léčbou*	*Normální sérum - po léčbě*
BG :	*Разтвор за третиране на проби (примери)*	*Нормален серум - преди третиране*	*Нормален серум - след третиране*
NO :	*Behandlingsløsning for prøver (eksempler)*	*Normal serum - før behandling*	*Normal serum - etter behandling*
DK :	*Prøvebehandlingsopløsning (eksempler)*	*Normalt serum - før behandling*	*Normalt serum - efter behandling*
CN :	*样品处理液（示例）*	*正常血清-处理前*	*正常血清-处理后*
RU :	*Образцы раствора для обработки (примеры)*	*Нормальная сыворотка - до обработки*	*Нормальная сыворотка - после обработки*
JP :	***サンプル**処理液（例）*	*正常血清 - 処理前*	*正常血清 - 処理後*
LV :	*Paraugu apstrādes šķīdums (piemēri)*	*Normāls serums, pirms apstrādes*	*Normāls serums, pēc apstrādes*
SK :	*Roztok na spracovanie vzoriek (príklady)*	*Normálne sérum - pred spracovaním*	*Normálne sérum - po spracovaní*
EE :	*Proovide töötlemislahus (näited)*	*Normaalne seerum - enne töötlemist*	*Normaalne seerum - pärast töötlemist*

SCHÉMAS / FIGURES

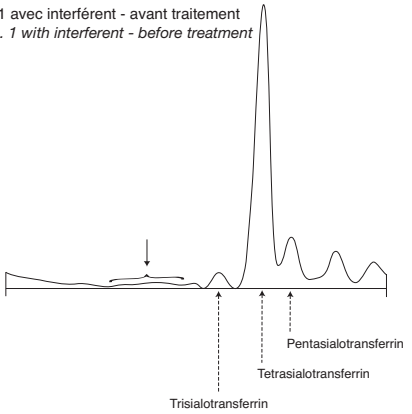
ABBILDUNGEN - FIGUREN - FIGURE - FIGURAS - BILDER - ΕΙΚΟΝΕΣ - SLIKE - PAVEIKSLAI - RYSUNKI - FIGURI - ÁBRÁK - ŞEKİLLER - OBRÁZKY - ФИГУРИ - FIGURER - 插图 - РИСУНКИ - 図 - CIPARI - JOONISED

PROFILS ÉLECTROPHORÉTIQUES - ELECTROPHORETIC PATTERNS

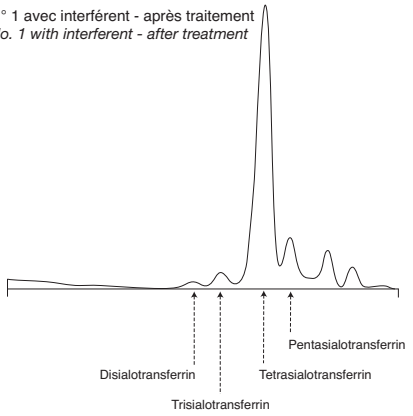
6

Solution de traitement des échantillons (exemples)
Samples treatment solution (examples)

Sérum N° 1 avec interférent - avant traitement
Normal No. 1 with interferent - before treatment



Sérum N° 1 avec interférent - après traitement
Serum No. 1 with interferent - after treatment



FR : Sérum N° 1 avec interférent - avant traitement
GB : Serum No. 1 with interferent - before treatment
DE : Serum Nr. 1 mit Störstoff - vor der Behandlung
NL : Serum nr. 1 met interferent - vóór behandeling
IT : Siero N. 1 con interferente - prima del trattamento
ES : Suero N° 1 con interferente - antes del tratamiento
PT : Soro n.º 1 com interferente - antes do tratamento
SV : Serum nr. 1 med interferens - innan behandling
GR : Ορός υπ' αριθ. 1 με στοιχείο παρεμβολής - πριν από την επεξεργασία
HR : Serum br. 1 s interferentom - prije obrade
LT : 1 serumas su trukdžiu - prieš apdorojant
PL : Surowica nr 1 z czynnikiem zakłócającym - przed obróbką
RO : Ser nr. 1 cu interferent - înainte de tratament
CS : Serum br. 1 sa interferentom - pre tretmana
HU : 1. sz. szérum zavaró hatású anyaggal - kezelés előtt
TR : Etkileşen içeren Serum No. 1 - işlemden önce
CZ : Sérum č. 1 s rušivou frakcí - před léčbou
BG : Серум № 1 с интерферент - преди третиране
NO : Serum nr 1 med interferens - før behandling
DK : Serum nr. 1 med interferent - før behandling
CN : 含干扰物质的1号血清-处理前
RU : Сыворотка № 1 с мешающим компонентом - до обработки
JP : 干渉のある血清No. 1 - 処理前
LV : Serums Nr. 1 ar traucējošo komponentu, pirms apstrādes
SK : Sérum č. 1 s rušivým faktorom - pred spracovaním
EE : Seerum nr 1 interferendiga - enne töötlemist

Sérum N° 1 avec interférent - après traitement
Serum No. 1 with interferent - after treatment
Serum Nr. 1 mit Störstoff - nach der Behandlung
Serum nr. 1 met interferent - na behandeling
Siero N. 1 con interferente - dopo il trattamento
Suero N° 1 con interferente - después del tratamiento
Soro n.º 1 com interferente - depois do tratamento
Serum nr. 1 med interferens - efter behandling
Ορός υπ' αριθ. 1 με στοιχείο παρεμβολής - μετά την επεξεργασία
Serum br. 1 s interferentom - poslije obrade
1 serumas su trukdžiu - apdorojus
Surowica nr 1 z czynnikiem zakłócającym - po obróbce
Ser nr. 1 cu interferent - după tratament
Serum br. 1 sa interferentom - posle tretmana
1. sz. szérum zavaró hatású anyaggal - kezelés után
Etkileşen içeren Serum No. 1 - işlemden sonra
Sérum č. 1 s rušivou frakcí - po léčbě
Серум № 1 с интерферент - след третиране
Serum nr 1 med interferens - etter behandling
Serum nr. 1 med interferent - efter behandling
含干扰物质的1号血清-处理后
Сыворотка № 1 с мешающим компонентом - после обработки
干渉のある血清No. 1 - 処理後
Serums Nr. 1 ar traucējošo komponentu, pēc apstrādes
Sérum č. 1 s rušivým faktorom - po spracovaní
Seerum nr 1 interferendiga - pärast töötlemist

SCHÉMAS / FIGURES

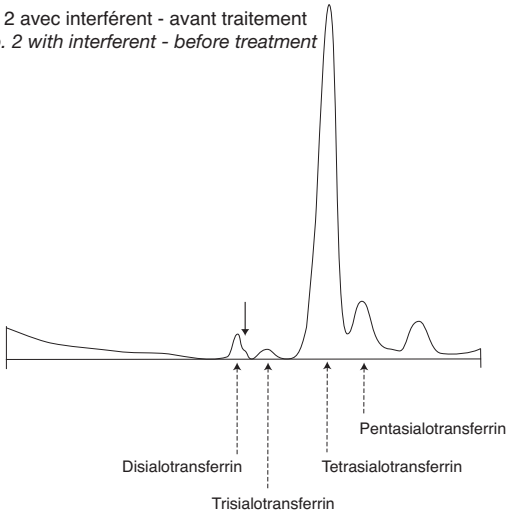
ABBILDUNGEN - FIGUREN - FIGURE - FIGURAS - BILDER - ΕΙΚΟΝΕΣ - SLIKE - PAVEIKSLAI - RYSUNKI - FIGURI - ÁBRÁK - ŞEKİLLER - OBRÁZKY - ФИГУРИ - FIGURER - 插图 - РИСУНКИ - 図 - CIPARI - JOONISED

PROFILS ÉLECTROPHORÉTIQUES - ELECTROPHORETIC PATTERNS

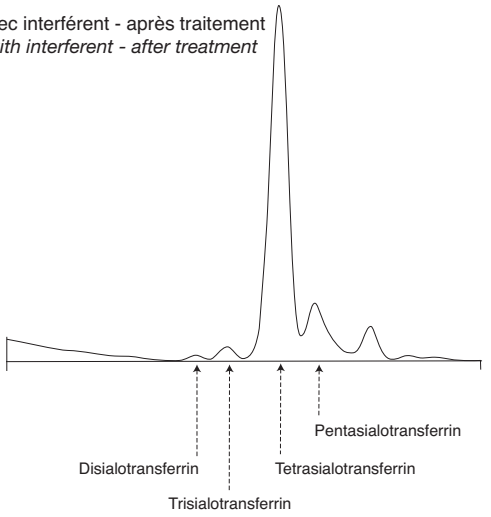
7

Solution de traitement des échantillons (exemples)
Samples treatment solution (examples)

Sérum N° 2 avec interférent - avant traitement
Serum No. 2 with interferent - before treatment



Sérum N° 2 avec interférent - après traitement
Serum No. 2 with interferent - after treatment



SCHÉMAS / FIGURES

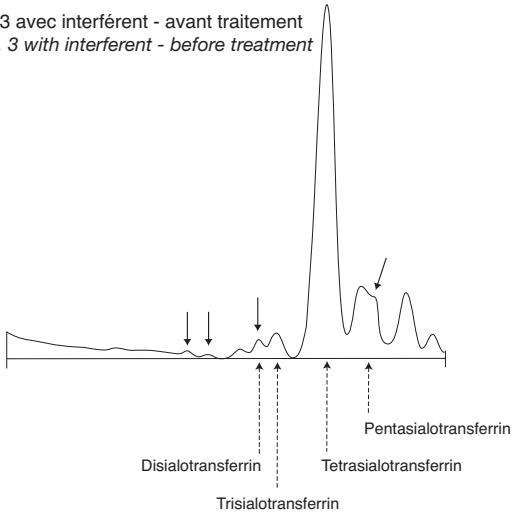
ABBILDUNGEN - FIGUREN - FIGURE - FIGURAS - BILDER - ΕΙΚΟΝΕΣ - SLIKE - PAVEIKSLAI - RYSUNKI - FIGURI - ÁBRÁK - ŞEKİLLER - OBRÁZKY - ФИГУРИ - FIGURER - 插图 - РИСУНКИ - 図 - CIPARI - JOONISED

PROFILS ÉLECTROPHORÉTIQUES - ELECTROPHORETIC PATTERNS

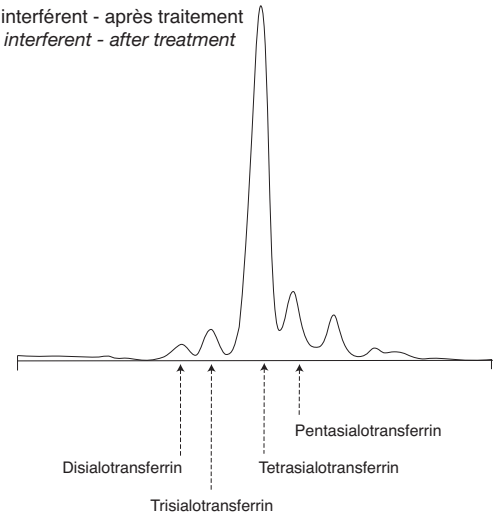
8

Solution de traitement des échantillons (exemples)
Samples treatment solution (examples)

Sérum N° 3 avec interférent - avant traitement
Serum No. 3 with interferent - before treatment



Sérum N° 3 avec interférent - après traitement
Serum No. 3 with interferent - after treatment



SCHÉMAS / FIGURES

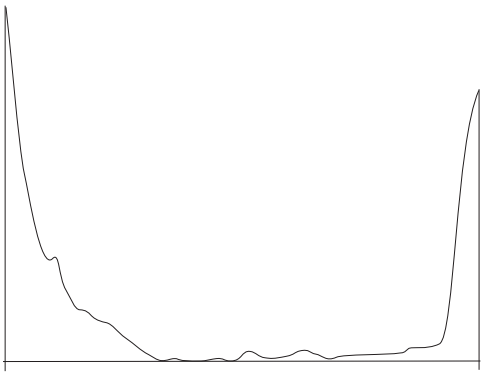
ABBILDUNGEN - FIGUREN - FIGURE - FIGURAS - BILDER - ΕΙΚΟΝΕΣ - SLIKE - PAVEIKSLAI - RYSUNKI - FIGURI - ÁBRÁK - ŞEKİLLER - OBRÁZKY - ФИГУРИ - FIGURER - 插图 - РИСУНКИ - 図 - CIPARI - JOONISED

PROFILS ÉLECTROPHORÉTIQUES - ELECTROPHORETIC PATTERNS

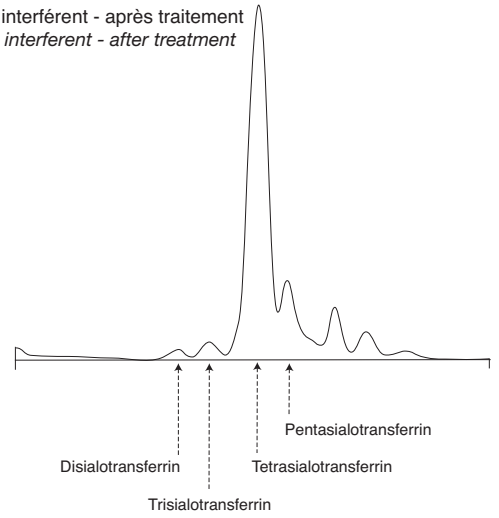
9

Solution de traitement des échantillons (exemples)
Samples treatment solution (examples)

Sérum N° 4 avec interférent - avant traitement
Serum No. 4 with interferent - before treatment



Sérum N° 4 avec interférent - après traitement
Serum No. 4 with interferent - after treatment

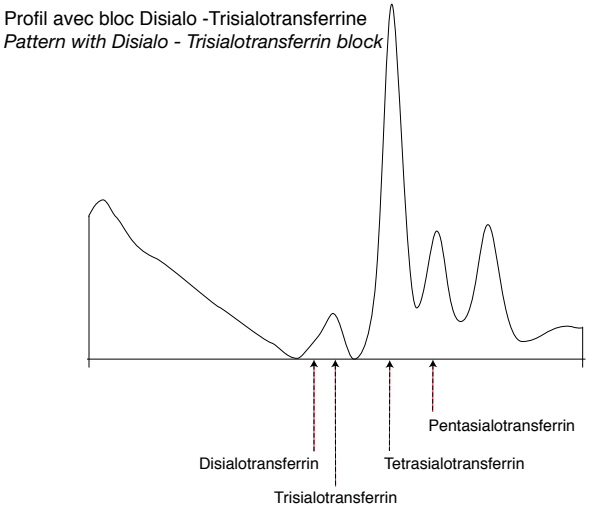


SCHÉMAS / FIGURES

ABBILDUNGEN - FIGUREN - FIGURE - FIGURAS - BILDER - ΕΙΚΟΝΕΣ - SLIKE - PAVEIKSLAI - RYSUNKI - FIGURI - ÁBRÁK - ŞEKİLLER - OBRÁZKY - ФИГУРИ - FIGURER - 插图 - РИСУНКИ - 図 - CIPARI - JOONISED

PROFILS ÉLECTROPHORÉTIQUES - ELECTROPHORETIC PATTERNS

10



FR : Profil avec bloc Disialo -Trisialotransferrine
GB : Pattern with Disialo - Trisialotransferrin block
DE : Muster mit Disialo - Trisialotransferrin-Block
NL : Patroon met disialo-trisialotransferrineblok
IT : Profilo con blocco disialo-trisialotransferrina
ES : Perfil con bloque Disialo -Trisialotransferrina
PT : Padrão com disialo - Bloco de trisialotransferrina
SV : Mönster med Disialo - Trisialotransferrin block
GR : Πρότυπο με μπλοκ δισιαλο - τρισιαλοτρανσφερίνης
HR : Profil s disijalo-trisijalotransferinskim blokom
LT : Šablonas su disialotransferino-trisialotransferino bloku
PL : Obraz z blokiem disialo-trisialotransferyna
RO : Tipar cu bloc disialo - trisialotransferină
CS : Šablon sa Disialo - Trisialotransferin blokom
HU : Diszialo-/triszialotranszferrin blokkos mintázat
TR : Disialo içeren pattern - Trisialotransferrin bloku
CZ : Typ s blokem disialo-trisialotransferinu
BG : Модел с блок дисиало-трисиалотрансферин
NO : Mønster med Disialo - Trisialotransferrin-blok
DK : Mønster med Disialo - Trisialotransferrin-blok
CN : 二-三唾液酸转铁蛋白阻断的图谱
RU : Профиль с блоком десиалированного трисиалотрансферрина
JP : Disialoでのパターン - トリシアロトランスフェリンブロック
LV : Spektrs ar Disialo-trisialotransferīna bloku
SK : Vzor s disialo-trisialotransferínovým blokom
EE : Muster disialo-trisialotransferriini plokiga

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