sebia

CAPILLARYS PROTEIN(E) 6

Ref. 2003

Ref. 2023*

IVD

CE

2016/10

INTENDED USE

The CAPILLARYS PROTEIN(E) 6 kit is designed for the separation of human serum and urine proteins in alkaline buffer (pH 9.9) by capillary electrophoresis with the CAPILLARYS System.
Normal serum proteins separate into six major fractions.
Urine proteins separate into five zones, after the preparation of urine samples with the CAPILLARYS / MINICAP URINE kit (See the instruction sheets of the CAPILLARYS / MINICAP URINE kit, SEBIA, PN 2013).
The CAPILLARYS performs all sequences automatically to obtain a protein profile for qualitative or quantitative analysis. The proteins, separated in silica capillaries, are directly detected at an absorbance of 200 nm. The electrophoregrams can be interpreted visually to screen for any pattern abnormalities. Direct detection provides accurate relative quantification of individual protein fractions.

For *In Vitro* Diagnostic Use.

NOTE : In this instruction sheet, the name "CAPILLARYS" is used for automated CAPILLARYS, CAPILLARYS 2 and CAPILLARYS 2 FLEX-PIERCING instruments.

PRINCIPLE OF THE TEST[1-11]

Protein electrophoresis is a well established technique routinely used in clinical laboratories for screening samples for protein abnormalities [1,2,3,10].
The CAPILLARYS has been developed to provide complete automation of this testing with fast separation and good resolution. In many respects, the methodology can be considered as an intermediary type of technique between classical zone electrophoresis and liquid chromatography [1,3,8,11].
The CAPILLARYS System 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 CAPILLARYS System has 8 capillaries functioning in parallel allowing 8 simultaneous analyses. A sample dilution with buffer 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 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.
Proteins are detected in the following order : gamma globulins, beta-2 globulins, beta-1 globulins, alpha-2 globulins, alpha-1 globulins and albumin with each zone containing one or more proteins.

REAGENTS AND MATERIALS SUPPLIED IN THE CAPILLARYS PROTEIN(E) 6 KITS

WARNING : See the safety data sheets.

ITEMS	PN. 2003	PN. 2023*
Buffer (ready to use)	2 vials, 700 mL each	8 vials, 700 mL each
Wash solution (stock solution)	1 vial, 75 mL	4 vials, 75 mL each
Dilution segments	1 pack of 90	4 packs of 90
Filters	3 filters	12 filters

** CAPILLARYS PROTEIN(E) 6 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 9.9 ± 0.5 ; additives, nonhazardous at concentrations used, necessary for optimum performance.

Use
Buffer for protein analysis in 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 analysis buffer is stored between 2 to 8 °C, it is recommended to allow reagent to come to room temperature prior to use.
DO NOT FREEZE.
Once the buffer vial has been opened and positioned on the CAPILLARYS 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. WASH SOLUTION

Preparation
The vial of the stock wash solution should be diluted up to 750 mL with distilled or deionized water.
After dilution, the wash solution contains an alkaline solution pH ≈ 12.

Use
For washing the capillaries after protein electrophoretic separation.
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.

3. DILUTION SEGMENTS

Use
Single use segments for sample dilution on the automated instrument.
WARNING : Dilution segments with biological samples have to be handled with care.

4. 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 plunging in vials of buffer, wash solution and distilled or deionized water. When setting filters on CAPILLARYS system, rinse the connectors and the tubes with distilled or deionized water.

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).

REAGENTS REQUIRED BUT NOT SUPPLIED

WARNING : See the safety data sheets.

1. DISTILLED OR DEIONIZED WATER

Use
For capillaries rinsing in automated system CAPILLARYS, 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.

2. CAPICLEAN

Composition
The vial of CAPICLEAN concentrated solution (SEBIA, PN 2058, 25 mL) contains : proteolytic enzymes, surfactants and additives nonhazardous at concentrations used, necessary for optimum performances.

Use
For sample probe cleaning in automated system CAPILLARYS, SEBIA, for capillary electrophoresis, during the CAPICLEAN cleaning sequence.
IMPORTANT :
- When less than 500 samples are analyzed within a week, launch a CAPICLEAN cleaning sequence at least once a week.
- When less than 500 samples are analyzed within a day but more than 500 samples are analyzed within a week, launch a CAPICLEAN cleaning sequence after every 500 analyses.
- When more than 500 samples are analyzed within a day, launch a CAPICLEAN cleaning sequence once a day.

See the instruction sheets of CAPICLEAN, SEBIA.

IMPORTANT : Do not re-use the dilution segment after sample probe cleaning.

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.

3. 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 the CAPILLARYS System (weekly maintenance in order to eliminate adsorbed proteins from the probe).

See the instruction sheets of CAPILLARYS, SEBIA.

- Use the sample rack designed for the maintenance (No. 100).
- Place a tube containing 2 mL diluted chlorinated solution previously prepared, in position No. 1 on this sample rack.
- Slide the sample rack No. 100 for maintenance in the CAPILLARYS System.
- In the "MAINTENANCE" window which appears on the screen, select "Launch the probe cleaning (chlorinated sodium hypochlorite solution)" and validate.

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.

4. 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.
After dilution, the wash solution contains an alkaline solution pH ≈ 12.

Use

For washing the capillaries of CAPILLARYS. This additional reagent is necessary when the number of tests by serie is below 40.
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.

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. CAPILLARYS System SEBIA : CAPILLARYS PN 1220, CAPILLARYS 2 PN 1222 or CAPILLARYS 2 FLEX-PIERCING PN 1227.
2. Sample racks supplied with CAPILLARYS.
3. Container Kit supplied with CAPILLARYS : Rinse (to fill with distilled or deionized water), wash solution and waste container.

SAMPLES FOR ANALYSIS

ANALYSIS OF SERUM SAMPLES

Sample collection and storage

Fresh serum samples are recommended for analysis. Sera must be collected following established procedures used in clinical laboratory testing.
Samples can be stored up to 10 days between 2 and 8 °C.
For longer storage, samples should be frozen at - 18 / - 30 °C within 8 hours of collection.
Frozen sera are stable for 2 months.
Proteins of the samples stored at 2 to 8 °C or between 15 and 30 °C, degrade, particularly the C3 complement for which the degradation kinetics is very rapid at 15 - 30 °C and is clearly visible beyond 3 days.
A serum stored between 2 and 8 °C or between 15 and 30 °C has a beta-2 fraction that gradually decreases and may appear distorted (with small additional fractions appearing on the gamma side and / or beta-1 following the deterioration of C3 complement) and an alpha-2 fraction whose shape can be slightly changed.
Beyond 10 days between 2 and 8 °C or 3 days between 15 and 30 °C, the beta-1 fraction deforms by expanding, and the beta-2 fraction strongly decreases.
Depending to the samples, during their storage beyond 10 days at 2 to 8 °C or 3 days at 15 and 30 °C, the automated integration of fractions by the software for data processing may potentially be disturbed.
NOTE : Each laboratory must ensure that the samples are transported in optimal conditions for their integrity [1].

[1] ISO 15189 : Medical laboratories - Requirements for quality and competence.

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 (15 to 30 °C), these samples can be directly analyzed. Samples containing a polymerized immunoglobulin may be used without any treatment.
It is advised to observe the serum aspect before analysis (cases of hemolysis, cryoglobulins or turbidity).

Samples to avoid

- Avoid hemolysed serum samples. Hemolysis induces a double alpha-2 zone.
- Avoid aged, improperly stored serum samples, beta-2 fraction would be decreased.
- Avoid plasma samples. Fibrinogen migrates in beta-2 position (shoulder on beta-2 or superimposed with the beta-2 zone with possibly an increase of this fraction). When it is present in some samples (plasma, serum not totally defibrinated or patient with anticoagulant treatment), fibrinogen may interfere on the analysis and makes interpretation inaccurate (suspicion of monoclonal band or beta-2 fraction increase). When analysing an aged plasma sample (not recommended), the C3 complement which is labile over the time is partially degraded, the beta-2 zone then corresponds essentially to fibrinogen.

ANALYSIS OF URINE SAMPLES

See the instruction sheets of the CAPILLARYS / MINICAP URINE kit, SEBIA, PN 2013.

NOTE : Collection tubes 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, 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 CAPILLARYS system is a multiparameter instrument for serum proteins analysis on 8 parallel capillaries in the following sequence :
- Bar code reading of sample tubes (for up to 8 tubes) and samples-racks ;
- Sample dilution from primary tubes into dilution segments ;
- Capillary washing ;
- Injection of diluted samples ;
- Protein analysis and direct detection on capillaries.

The manual steps include :
- Placement of sample tubes in sample-racks ;
- Placement of racks on the CAPILLARYS instrument ;
- Removal of sample-racks after analysis.

PLEASE CAREFULLY READ THE CAPILLARYS INSTRUCTION MANUAL.

I. PREPARATION OF ELECTROPHORETIC ANALYSIS

1. Switch on CAPILLARYS instrument and computer.
2. Set up the software, enter and the instrument automatically starts.
3. The CAPILLARYS PROTEIN(E) 6 kit is intended to run with "PROTEIN(E) 6" analysis program from the CAPILLARYS instrument. To select "PROTEIN(E) 6" analysis program and place the CAPILLARYS PROTEIN(E) 6 buffer vial in the instrument, please read carefully the CAPILLARYS instruction manual.
4. The sample rack contains 8 positions for sample tubes. Position 8 sample tubes on each sample rack ; the bar code of each tube must be visible in the openings of the sample rack.
   IMPORTANT: If the number of tubes to analyze is lower than 8, complete the sample rack with tubes containing distilled or deionized water.
5. Position a new dilution segment on each sample rack. The sample rack will be ejected if the segment is missing.
6. Slide the complete sample carrier(s) into the CAPILLARYS system through the opening in the middle of the instrument. Up to 13 sample racks can be introduced successively and continously into the system. It is advised to use the sample rack No 0 intended for control serum.
7. Remove analyzed sample racks from the plate on the left side of the instrument.
8. Take off carefully used dilution segments from the sample rack and discard them.
   WARNING : Dilution segments with biological samples have to be handled with care.

DILUTION - MIGRATION - DESCRIPTION OF THE AUTOMATED STEPS

1. Bar codes are read on both sample tubes and on samples racks.
2. Samples are diluted in buffer 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, controlled by Peltier effect for about 4 minutes.
6. Proteins are detected directly by scanning at 200 nm and an electrophoretic profile appears on the screen of the system.

NOTE : These steps are described for the first introduced sample rack. The electrophoretic patterns appear after 10 minutes. For the following sample rack, the two first steps (bar code reading and sample dilution) are made during analysis of the previous sample rack.

II. RESULT ANALYSIS

At the end of the analysis, relative quantification of individual zones is made automatically and profiles can be analyzed. With the total protein concentration, the system will calculate each fraction concentration.
The electrophoregrams are interpreted visually for pattern abnormalities.
Electrophoretic profiles are visualized by default using the re-drawn mode : then, the alpha-1 fraction is closer to albumin.
Optionally, the standard mode allows to visualize the initial pattern obtained with raw data.
PLEASE CAREFULLY READ THE CAPILLARYS INSTRUCTION MANUAL.

III. END OF ANALYSIS SEQUENCE

At the end of each analysis sequence, the operator must start the stand by or shut down procedure of the CAPILLARYS system in order to store capillaries in optimal conditions.

IV. FILLING OF REAGENT CONTAINERS

The CAPILLARYS system 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 CAPILLARYS INSTRUCTION MANUAL.

QUALITY CONTROL

It is advised to include a control serum with each sequence of analysis.

** US customers : Follow federal, state and local guidelines for quality control.*

RESULTS

Values

Direct detection at 200 nm in capillaries yields relative concentrations (percentages) of individual protein zones.
Reference values (mean ± 2 SD) for individual major electrophoretic serum protein zones in the CAPILLARYS system have been established from a healthy population of 246 adults with normal triglycerides levels (men and women):

	CAPILLARYS PROTEIN(E) 6
Albumin	55.8 - 66.1 %
Alpha-1 globulins	2.9 - 4.9 %
Alpha-2 globulins	7.1 - 11.8 %
Beta globulins	8.4 - 13.1 %
Beta-1 globulins	*4.7 - 7.2 %*
Beta-2 globulins	*3.2 - 6.5 %*
Gamma globulins	11.1 - 18.8 %

It is recommended each laboratory establish its own reference values.

NOTE : Reference values have been established using the standard parameters of the PHORESIS software (smoothing 2 and automatic drift).

Interpretation

The C4 complement migrates between beta-1 and beta-2 zones ; CRP migrates in beta-2 position, see ELECTROPHORETIC PATTERNS.
A relative increase of the beta-2 zone compared to the beta-1 zone, without any clinical context of inflammatory disease, must be a warning signal for necessary complementary analyses.
In case of doubt concerning the interpretation of the pattern and / or the positioning of minima (particularly during the analysis of an external control), it is necessary to overlay the obtained pattern with that of the Normal Control Serum (SEBIA, PN 4785).
A monoclonal component may be suspected in the serum sample when a single protein electrophoretic pattern is delayed or distorted or in the case of impossibility for the software (PHORESIS version ≥ 8.63) to redraw the albumin / alpha-1 zone. The following warning message is then displayed on the electrophoretic pattern "Warning: Migration time out of range" with a red warning signal. This red warning signal is also displayed on the curves mosaic and in the result table for the sample concerned. To confirm the presence of a monoclonal component in such sample, it is necessary to treat the sample with beta-mercaptoethanol and to repeat the analysis on the sample after reducing treatment. In this case (i) prepare 1 % beta-mercaptoethanol (BME, or 2-mercaptoethanol, 2 ME) in Fluidil (SEBIA, PN 4587, 1 vial 5 mL), (ii) the CAPILLARYS system ready waiting for rack, add 100 µL of this reducing solution to 300 µL neat serum, (iii) vortex and wait for 15 minutes maximum, then follow the standard procedure.
IMPORTANT : After reducing treatment with beta-mercaptoethanol, the sample must be analyzed without any delay ; no introduced sample rack must be waiting for analysis in the CAPILLARYS system.
When many electrophoretic patterns show the same warning signal, call SEBIA Technical Service.
An identification is recommended to characterize monoclonal or oligoclonal components:
- by immunotyping with SEBIA CAPILLARYS IMMUNOTYPING kit or,
- by immunofixation with SEBIA HYDRAGEL IF kits.

As an aid in interpretation of serum protein electrophoregrams, see BIBLIOGRAPHY.
Alpha-2 zone :
- In some samples and according to the haptoglobin phenotype, alpha-2 zone can be split, see ELECTROPHORETIC PATTERNS.

Interference and Limitations

See SAMPLES FOR ANALYSIS.
Lipoproteins / triglycerides or biliary pigments (with a characteristic yellow – green color of the serum) at high concentration in the sample may lead to the visual impression of a bisalbuminemia on the electrophoretic pattern.
The CAPILLARYS PROTEIN(E) 6 technique has the option to select an additional washing program (Sample Probe Wash). This additional washing program activates an additional wash cycle between all samples that are run within a specific rack or an entire run of samples.
In rare cases, if a patient sample (following a high concentration monoclonal sample) presents with discordant results, SEBIA suggests that the sample should be repeated either by reversing the sample order, repeating the sample in a different position, or the activation of the additional special washing program for the sample probe (NOTE : The activation of the Sample Probe Wash program will decrease the throughput by half for all samples. See the CAPILLARYS Operations Manual for specific instruction for activation of the Sample Wash program).
Due to the resolution and sensitivity limits of zone electrophoresis, it is possible that some monoclonal components may not be detected with this method.
A monoclonal component may be not detected (i.e., polymerized immunoglobulin spread or hidden in the polyclonal background). Conversely, a slight distortion of the electrophoretic pattern may indicate the presence of a monoclonal immunoglobulin. In all cases, the clinical context must be analyzed and if a gammopathy is suspected, it is then recommended to perform an immunotyping analysis on the sample. If an uncertainty persists, confirm the result by an immunofixation technique on agarose gel.

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

Results obtained using the CAPILLARYS PROTEIN(E) 6 procedure indicate a very good reproducibility for quantitative analysis with a mean CV % of about 2.0 % for each protein fraction.
Results presented below have been obtained using the standard parameters of the CAPILLARYS software (smoothing 2 and automatic drift).

Reproducibility within run

Five (5) different serum samples were run in 8 capillaries using the CAPILLARYS PROTEIN(E) 6 procedure with 2 lots of analysis buffer. The mean, SD and CV (n = 8) were calculated for each sample, each zone and each lot. The table shows the values for the 5 tested samples for each protein fraction and with the 2 lots of buffer.

FRACTION	ALBUMIN	ALPHA-1	ALPHA-2	BETA-1	BETA-2	GAMMA
Serum A : lot no. 1 / lot no. 2						
MEAN (%)	60.8 / 60.6	3.8 / 3.7	8.8 / 8.5	6.1 / 6.3	4.7 / 4.8	15.8 / 16.1
SD	0.3 / 0.4	0.1 / 0.1	0.2 / 0.2	0.1 / 0.1	0.1 / 0.2	0.1 / 0.2
CV (%)	0.5 / 0.6	2.6 / 1.9	2.8 / 1.8	1.8 / 2.2	2.6 / 3.4	0.9 / 1.2
Serum B : lot no. 1 / lot no. 2						
MEAN (%)	61.8 / 61.9	4.5 / 4.4	10.7 / 10.4	5.9 / 6.1	4.3 / 4.4	12.9 / 12.9
SD	0.3 / 0.5	0.1 / 0.05	0.1 / 0.1	0.1 / 0.1	0.2 / 0.2	0.1 / 0.2
CV (%)	0.4 / 0.8	2.5 / 1.1	1.0 / 1.3	1.4 / 2.3	3.7 / 4.0	1.2 / 1.6
Serum C : lot no. 1 / lot no. 2						
MEAN (%)	60.6 / 60.9	4.4 / 4.4	10.6 / 10.3	5.9 / 6.0	4.4 / 4.4	14.2 / 14.0
SD	0.5 / 0.3	0.1 / 0.1	0.1 / 0.1	0.1 / 0.1	0.2 / 0.1	0.1 / 0.2
CV (%)	0.8 / 0.5	3.0 / 3.0	1.3 / 1.3	1.5 / 1.8	3.6 / 2.9	0.9 / 1.3
Serum D : lot no. 1 / lot no. 2						
MEAN (%)	62.6 / 62.5	4.1 / 4.1	9.0 / 8.8	6.3 / 6.6	4.3 / 4.3	13.6 / 13.7
SD	0.5 / 0.5	0.1 / 0.1	0.2 / 0.3	0.1 / 0.2	0.1 / 0.1	0.2 / 0.2
CV (%)	0.8 / 0.9	2.1 / 3.5	2.1 / 2.9	1.6 / 2.7	2.8 / 2.4	1.6 / 1.4
Serum E : lot no. 1 / lot no. 2						
MEAN (%)	47.6 / 47.0	5.2 / 5.2	7.5 / 7.3	5.5 / 5.7	5.4 / 5.5	28.8 / 29.3
SD	0.5 / 0.6	0.2 / 0.2	0.2 / 0.2	0.1 / 0.1	0.2 / 0.2	0.5 / 0.3
CV (%)	1.0 / 1.3	4.1 / 3.1	2.7 / 2.9	1.7 / 2.3	3.7 / 2.8	1.7 / 1.2
SD MAX	1.2	0.4	0.7	0.7	0.5	0.5
CV (%) MAX	2.0	7.0	7.0	7.0	7.0	4.0

NOTE : Maximal values for standard deviation and coefficient of variation (SD MAX and CV (%) MAX) have been determined by additional reproducibility analyses of control sera performed on a series of instruments. They are independent from values indicated in the above result table.

Reproducibility between run

Eight (8) different serum samples were run 10 times in 8 capillaries using the CAPILLARYS PROTEIN(E) 6 procedure with 3 lots of analysis buffer. The mean, SD and CV (n = 10) were calculated for each sample, each zone and each lot. The table shows the limit values for the 8 tested samples and the 3 lots of buffer and a mean CV calculated from the CV's for each fraction (n = 24).

FRACTION	MEAN (%)	SD	CV (%)	MEAN CV (%)
Albumin	46.5 - 64.6	0.1 - 0.7	0.2 - 1.2	0.6
Alpha-1	3.0 - 5.3	0.04 - 0.2	1.1 - 4.0	2.6
Alpha-2	7.5 - 11.1	0.1 - 0.3	0.6 - 3.0	1.7
Beta-1	4.6 - 7.0	0.1 - 0.3	1.0 - 5.0	2.2
Beta-2	3.7 - 6.6	0.1 - 0.2	1.1 - 3.8	2.2
Gamma	9.4 - 29.4	0.1 - 0.3	0.6 - 2.1	1.0

Reproducibility between lots

Eight (8) different serum samples were run 10 times in 8 capillaries using the CAPILLARYS PROTEIN(E) 6 procedure with 3 lots of analysis buffer. The mean, SD and CV (n = 30) were calculated for each sample, each zone and each lot. The table shows the limit values for the 8 samples tested with the 3 lots of buffer and a mean CV calculated from the CV's for each fraction (n = 3).

FRACTION	MEAN (%)	SD	CV (%)	MEAN CV (%)
Albumin	46.7 - 64.4	0.3 - 0.6	0.4 - 1.1	0.7
Alpha-1	3.0 - 5.2	0.1 - 0.2	2.2 - 3.9	3.2
Alpha-2	7.7 - 10.8	0.1 - 0.3	1.2 - 3.3	2.2
Beta-1	4.6 - 6.7	0.1 - 0.4	1.8 - 5.5	2.9
Beta-2	3.9 - 6.6	0.1	1.7 - 3.4	2.5
Gamma	9.5 - 29.2	0.1 - 0.3	0.7 - 1.6	1.2

Accuracy

Pathological and normal serum samples (n = 135) were run using the CAPILLARYS PROTEIN(E) 6 procedure and a another commercially available agarose gel system. The correlation parameters calculated for individual zones from the pooled data for CAPILLARYS PROTEIN(E) 6 vs. the comparative gel systems (y = CAPILLARYS PROTEIN(E) 6) were :

Fraction	Correlation coefficient	y-intercept	Slope	Range of % values CAPILLARYS PROTEIN(E) 6
Albumin	0.973	-4.539	0.972	32.2 - 74.3
Alpha-1	0.975	1.189	1.519	2.9 - 13.9
Alpha-2	0.947	0.073	1.028	7.1 - 20.1
Beta-1	0.850	-0.903	0.932	4.0 - 18.8
Beta-2	0.969	0.478	1.189	1.2 - 27.4
Gamma	0.969	3.724	0.959	0.7 - 49.8

Sensitivity

Serial dilutions of one serum sample with a monoclonal protein 0.429 g/dL was electrophoresed using the CAPILLARYS PROTEIN(E) 6 procedure. The highest dilution with a discernible monoclonal band corresponded to 1 : 16, or a concentration of 27 mg/dL of the monoclonal protein.

NOTE : According to the position of the monoclonal component and polyclonal background in the gamma zone, the detection limit may vary.

Linearity

An albumin solution with 5.2 g/dL and a gammaglobulin solution with 3.1 g/dL (protein concentrations determined using nephelometry at 280 nm) were mixed within different proportions from 10 to 10 (100 % albumin solution + 0 % gammaglobulin solution, 90 % + 10 %, etc..., 0 % albumin solution + 100 % gammaglobulin solution) and the mixtures were electrophoresed with CAPILLARYS PROTEIN(E) 6 procedure.

The results demonstrated that the obtained percentage of each fraction is perfectly correlated with the theoretical percentage of each fraction within the mixture and that any variation may be detected with linearity using the CAPILLARYS PROTEIN(E) 6 procedure.

The CAPILLARYS PROTEIN(E) 6 procedure was determined to be linear for albumin and gammaglobulins fractions within the entire concentration range studied (between 0.0 and 5.2 g/dL of albumin and 3.1 g/dL of gammaglobulins).

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SCHÉMAS / FIGURES

PROFILS ÉLECTROPHORÉTIQUES - ELECTROPHORETIC PATTERNS

Figure 1

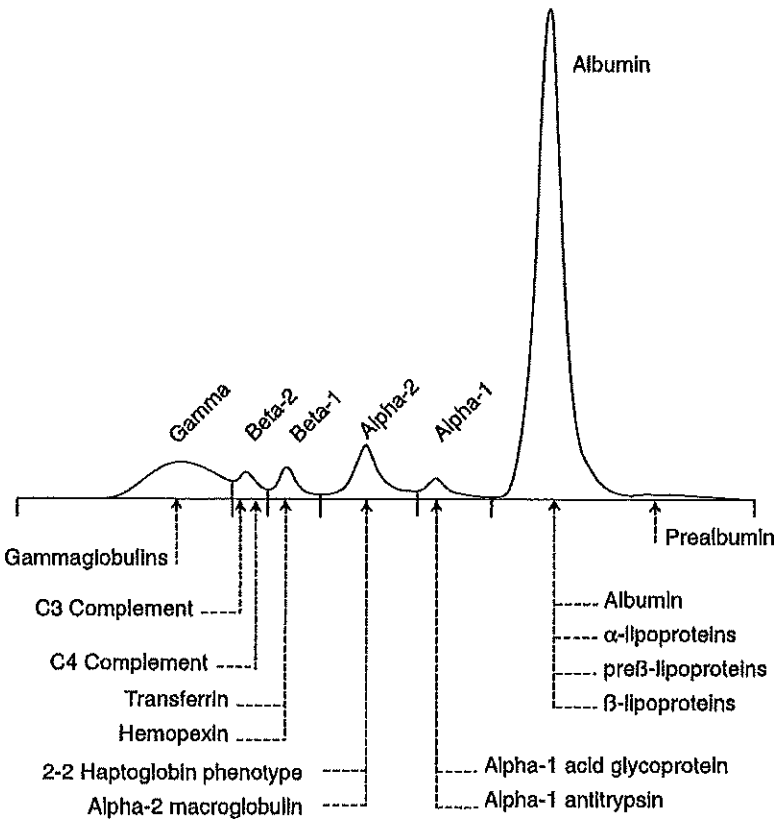
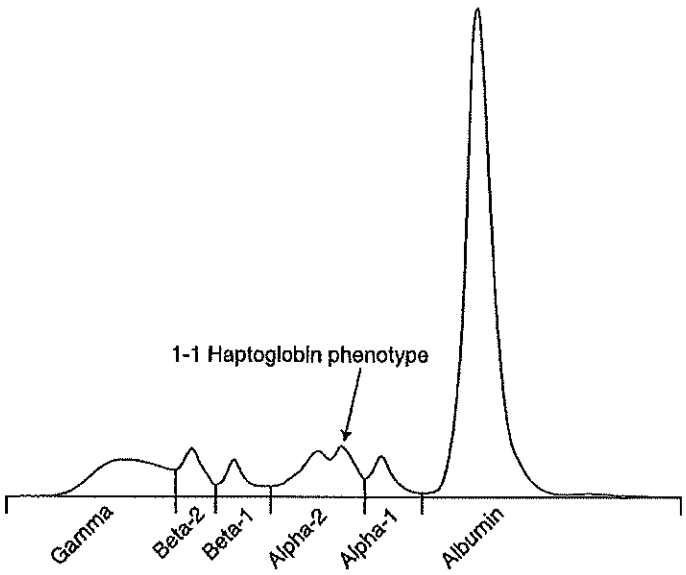


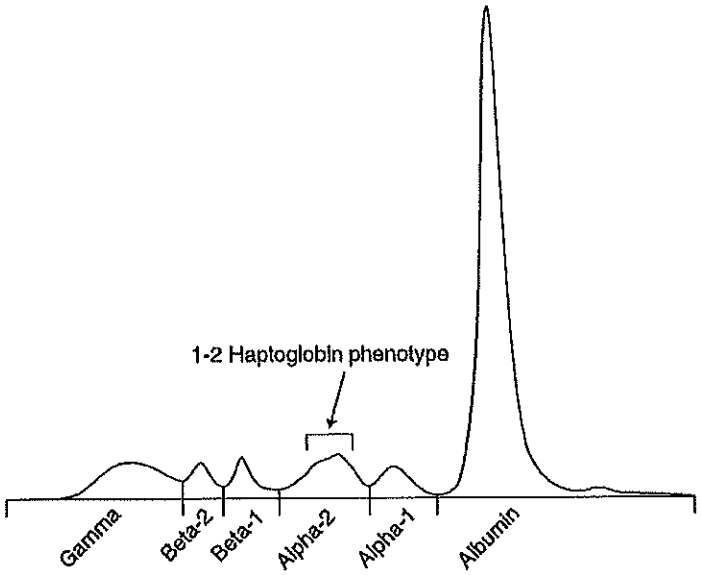
Figure 2



SCHÉMAS / FIGURES

PROFILS ÉLECTROPHORÉTIQUES - ELECTROPHORETIC PATTERNS

Figure 3



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