

sebia

CAPILLARYS PROTEIN(E) 6

Ref. 2003

IVD

CE

2008/12

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 URINE kit (See the instruction sheets of the CAPILLARYS URINE kit, SEBIA, PN 2012).

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.

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 KIT

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

FOR OPTIMAL RESULTS :

All reagents from the same kit must be always used together and according to the package insert instructions.

PLEASE READ THE PACKAGE INSERT CAREFULLY.

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 : alkaline buffer pH 9.9 ; 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.

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.

WARNING : The wash solution contains sodium hydroxide. Corrosive solution. Causes severe burns. Keep out of reach of children. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. Take off immediately all contaminated clothing. Wear suitable clothes and eye/face protection.

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 or refrigerated. 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 three 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. Used filters must be rinsed before discard. 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 or refrigerated.

REAGENTS REQUIRED BUT NOT SUPPLIED

1. DISTILLED OR DEIONIZED WATER

Use

For capillaries rinsing in automated system CAPILLARYS, SEBIA, for capillary electrophoresis.

It is recommended to filter distilled or deionized water on 0.45 µm filter before use.

To prevent microbial proliferation, change the water every day. In case of longer storage, add 3.5 µL/dL of ProClin 300.

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.

WARNING : *The CAPICLEAN solution may cause irritation or burns to skin, eyes and mucous membranes.*

Use

For weekly capillaries and sample probe cleaning in automated system CAPILLARYS, SEBIA, for capillary electrophoresis.

See the instruction sheets of CAPICLEAN, SEBIA.

IMPORTANT : Do not re-use the dilution segment after capillaries and 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.

CAPICLEAN must be free of precipitate. Discard CAPICLEAN if it changes its appearance, e.g., becomes cloudy due to microbial contamination.

3. SODIUM HYPOCHLORITE SOLUTION (for sample probe cleaning)

Preparation

Prepare a 9° chlorinated sodium hypochlorite solution (2 % to 3 % chloride) by diluting 250 mL 36° chlorinated concentrated solution (9.6 % chloride) 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 or CDT wash solution)" and validate.

Storage, stability and signs of deterioration

Store the working chlorinated solution at room temperature in a closed container, it is stable for 1 year. Avoid storage in sunlight, close to heat and ignition source, and to acids and ammonia.

4. CAPILLARYS WASH SOLUTION

Preparation

Each vial of the stock CAPILLARYS Wash Solution (SEBIA, PN 2052, 2 vials, 75 mL) should be diluted up to 750 mL with distilled or deionized water.

WARNING: *The wash solution contains sodium hydroxide. Corrosive solution. Causes severe burns. Keep out of reach of children. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. Take off immediately all contaminated clothing. Wear suitable clothes and eye/face protection.*

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 or refrigerated.

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.

EQUIPMENT AND ACCESSORIES REQUIRED

1. CAPILLARYS System SEBIA, PN 1220 or PN 1222.
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 within 8 hours of collection. Frozen sera are stable for one month.

Protein degradation, and in particular complement degradation, is very sample dependent for sera stored between 2 to 8 °C. With degradation, the beta-2 fraction progressively decreases and may appear distorted with small fractions appearing in the gamma zone and / or in beta-1 fraction. Alpha-2 may also appear slightly distorted.

After 10-day refrigerated storage (2 to 8 °C), the beta-1 fraction may appear increased with no beta-2 fraction present.

NOTE : *During their transportation, the samples can be kept at room temperature for up to 5 days. It is highly recommended to transport them at 2 - 8 °C.*

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, 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

- Do not use 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 URINE kit, SEBIA, PN 2012.

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. A message will be displayed 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 continuously 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 dilution needle 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.

RESULTS

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.

Values

Direct detection at 200 nm in capillaries yields relative concentrations (percentages) of individual protein zones.

Normal values (mean \pm 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-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 normal values.

NOTE : Normal values have been established using the standard parameters of the CAPILLARYS 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.

A monoclonal component may be suspected in the serum sample when the following warning signal appears on the screen " Warning: Migration centering is out of range " or when the protein electrophoretic pattern is delayed or distorted.

To confirm the presence of a monoclonal component in the serum 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 Fluidi (SEBIA, PN 4587, 1 vial 5 mL), (ii) the CAPILLARYS system ready waiting for rack, add 100 μ L of this reducing solution to 300 μ L 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.

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 routine procedure or the activation of the additional washing program in which the samples will be repeated in the same sequential order. (NOTE: The system analysis will decrease by half with the activation of the Sample Probe Wash program. 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). If the clinical context let suspect a gammopathy, when a distortion appears on the electrophoretic pattern, even very slight (observed with smoothing 0), it is then recommended to perform an immunotyping analysis on the sample, after reducing treatment. 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 informations on waste products elimination are available from the Technical Service of the supplier.

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
<i>Serum A : lot no. 1 / lot no. 2</i>						
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
<i>Serum B : lot no. 1 / lot no. 2</i>						
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
<i>Serum C : lot no. 1 / lot no. 2</i>						
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
<i>Serum D : lot no. 1 / lot no. 2</i>						
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
<i>Serum E : lot no. 1 / lot no. 2</i>						
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

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	1.199	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

The CAPILLARYS PROTEIN(E) 6 test was determined to be linear to at least 5.2 g/dL albumin and 3.1 g/dL gammaglobulins.

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SCHÉMAS / FIGURES

PROFILS ÉLECTROPHORÉTIQUES - ELECTROPHORETIC PATTERNS

Figure 1

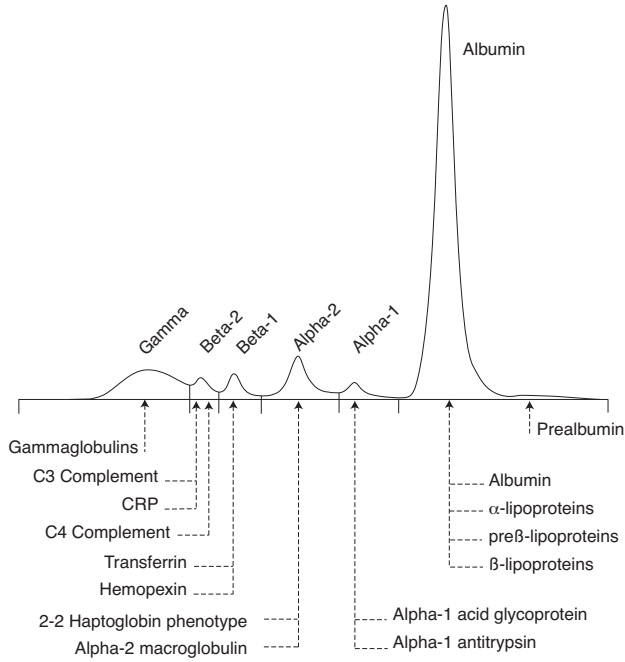
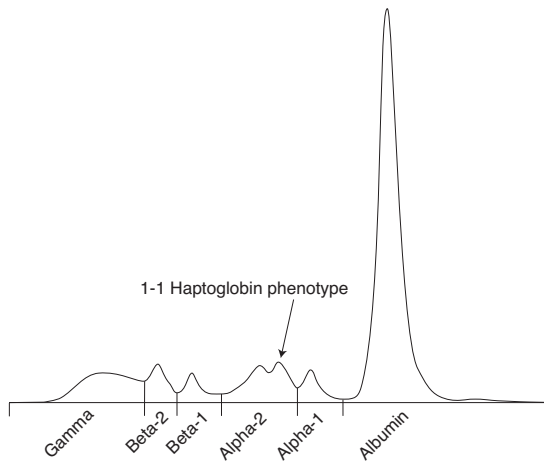


Figure 2



SCHÉMAS / FIGURES

PROFILS ÉLECTROPHORÉTIQUES - ELECTROPHORETIC PATTERNS

Figure 3

