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MINICAP PROTEIN(E) 6

Ref. 2203

Ref. 2223*

Người đại diện hợp pháp của cơ sở
Tổng Giám Đốc

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INTENDED USE

The MINICAP PROTEIN(E) 6 kit is designed for the separation of human serum proteins in alkaline buffer (pH 9.9) by capillary electrophoresis with the MINICAP system.
Normal serum proteins separate into six major fractions.
The MINICAP 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 "MINICAP" is used for automated MINICAP and MINICAP 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 MINICAP 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 MINICAP 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 in tubes with internal diameter of 100 μm. Separation also occurs according to the electrolyte pH and electroosmotic flow.
The MINICAP System has 2 capillaries functioning in parallel allowing 2 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 MINICAP PROTEIN(E) 6 KITS

WARNING : See the safety data sheets.

ITEMS	PN 2203	PN 2223*
Buffer (ready to use)	2 vials, 250 mL each	6 vials, 250 mL each
Wash solution (stock solution)	1 vial, 25 mL	3 vials, 25 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

** MINICAP 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 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. 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 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. 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.

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 MINICAP 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).

5. 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.

REAGENTS REQUIRED BUT NOT SUPPLIED

WARNING : See the safety data sheets.

1. DISTILLED OR DEIONIZED WATER

Use
For capillaries rinsing 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.*

2. 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.

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 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 system.
- Close the doors of the MINICAP / MINICAP FLEX-PIERCING system, 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.

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.
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.

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 System, SEBIA, PN 1230, MINICAP FLEX-PIERCING System, SEBIA, PN 1232.
2. Rotating samplers 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.

SAMPLES FOR ANALYSIS

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.

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 MINICAP system is a multiparameter instrument for serum proteins analysis on 2 parallel capillaries in the following sequence :

- Bar code reading of sample tubes (for up to 28 tubes) and rotating sampler ;
- Sample dilution from primary tubes into reagent cups ;
- Capillary washing ;
- Injection of diluted samples ;
- Protein analysis and direct detection in the capillaries.

The manual steps are :

- Set up the sample tubes in rotating sampler ;
- 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 INSTRUCTION MANUAL.

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 PROTEIN(E) 6 kit is intended to run with "PROTEIN(E) 6" analysis program from the MINICAP instrument. To select "PROTEIN(E) 6" analysis program and place the MINICAP PROTEIN(E) 6 buffer vial in the instrument, please read carefully the MINICAP instruction manual.
5. The rotating sampler contains 28 positions for sample tubes. Position up to 28 sample tubes on the rotating sampler by starting into position No. 1 ; the bar code of each tube must be visible in the openings of the rotating sampler.
   IMPORTANT : If the first sample tube to analyze is not into position No. 1, the analysis can not start (a message will be displayed if a sample tube is missing into position No. 1).
   NOTE : When using a control serum, it is necessary to use the specific bar code label.
6. Position new reagent cups on the automated loading system for cups of MINICAP (a message will be displayed if the reagent cups are missing).
7. **Position a new bin for used cups in MINICAP at the location intended for this purpose.**
8. Slide the rotating sampler into the MINICAP system.
9. Close the doors of the MINICAP System, the analysis starts automatically.
10. After the analysis, remove the rotating sampler with analyzed sample tubes.
11. 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 both sample tubes and on rotating sampler.
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 two first analyzed sample tubes. The electrophoretic patterns appear after 10 minutes. For the following sample tubes, the two first steps (bar code reading and sample dilution) are made during analysis of the 2 previous samples.

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 MINICAP 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 MINICAP system in order to store capillaries in optimal conditions.

IMPORTANT : 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).

IV. FILLING OF REAGENT CONTAINERS

The MINICAP 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 MINICAP INSTRUCTION MANUAL.

QUALITY CONTROL

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

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 have been established from a healthy population of 246 adults with normal triglycerides levels (men and women) :

	MINICAP 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) add 100 µL of this reducing solution to 300 µL neat serum, (iii) vortex and wait for 15 minutes, then follow the standard procedure.

IMPORTANT : After reducing treatment with beta-mercaptoethanol, the sample must be analyzed without any delay ; no introduced sample tube must be waiting for analysis in the MINICAP 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 MINICAP 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.
In the case of suspected contamination between two samples (very rare), due to the presence of some monoclonal components (in high concentration for example), it is recommended to repeat the test on those investigated samples (contaminating and potentially contaminated) by reversing their analysis order.
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 MINICAP PROTEIN(E) 6 procedure indicate a very good reproducibility for quantitative analysis with a mean CV % of about 2.1 % for each protein fraction.
Results presented below have been obtained using the standard parameters of the MINICAP software (smoothing 2 and automatic drift).

Reproducibility within sequence and between runs

Four (4) different serum samples were run on 2 MINICAP systems using the MINICAP PROTEIN(E) 6 procedure and the same lot of analysis buffer. Each sample was run 5 times on the 2 capillaries of each system. The mean, SD and CV (n = 10) were calculated for each sample, each zone and each system.
The table shows the values for the 4 tested samples for each protein fraction calculated with the 2 MINICAP systems.

Fraction	Albumin	Alpha 1	Alpha 2	Beta 1	Beta 2	Gamma
Serum A : system No. 1 - system No. 2						
MEAN (%)	59.2 - 58.6	5.0 - 5.2	8.6 - 8.6	4.9 - 5.1	4.5 - 4.5	17.8 - 18.0
SD	0.53 - 0.74	0.14 - 0.16	0.28 - 0.16	0.21 - 0.15	0.11 - 0.13	0.29 - 0.30
CV (%)	0.9 - 1.3	2.8 - 3.0	3.2 - 1.9	4.3 - 3.0	2.5 - 2.9	1.6 - 1.7
Serum B : system No. 1 - system No. 2						
MEAN (%)	60.7 - 59.7	3.5 - 3.6	8.9 - 9.2	6.7 - 7.1	5.2 - 5.0	15.0 - 15.5
SD	0.55 - 0.45	0.09 - 0.10	0.23 - 0.15	0.18 - 0.11	0.17 - 0.15	0.20 - 0.24
CV (%)	0.9 - 0.8	2.7 - 2.7	2.5 - 1.6	2.7 - 1.5	3.3 - 3.0	1.3 - 1.6
Serum C : system No. 1 - system No. 2						
MEAN (%)	55.4 - 54.1	3.6 - 3.7	10.1 - 10.5	5.7 - 5.8	3.8 - 3.9	21.3 - 22.1
SD	0.73 - 0.49	0.14 - 0.14	0.27 - 0.16	0.13 - 0.05	0.11 - 0.13	0.45 - 0.25
CV (%)	1.3 - 0.9	3.8 - 3.8	2.7 - 1.5	2.3 - 0.9	2.8 - 3.3	2.1 - 1.1
Serum F : system No. 1 - system No. 2						
MEAN (%)	60.9 - 60.9	4.7 - 4.2	9.0 - 9.6	6.3 - 6.2	4.5 - 4.5	14.6 - 14.7
SD	0.38 - 0.46	0.10 - 0.10	0.21 - 0.18	0.18 - 0.13	0.14 - 0.12	0.20 - 0.20
CV (%)	0.6 - 0.7	2.2 - 2.5	2.3 - 1.9	2.9 - 2.1	3.0 - 2.7	1.4 - 1.4
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 runs

Five (5) different serum samples were run 10 times using the MINICAP PROTEIN(E) 6 procedure on 3 MINICAP systems and with the same lot of analysis buffer. The mean, SD and CV (n = 10) were calculated for each sample, each zone and each system.
The table shows the limit values for the 5 tested samples on the 3 systems and a mean CV calculated from the CV's for each fraction (n = 15).

FRACTION	MEAN (%)	SD	CV (%)	MEAN CV (%)
Albumin	52.4 - 61.1	0.21 - 0.60	0.4 - 1.0	0.7 %
Alpha 1	3.4 - 4.9	0.06 - 0.28	1.8 - 6.6	3.1 %
Alpha 2	9.1 - 12.5	0.09 - 0.29	0.8 - 3.0	1.4 %
Beta 1	5.4 - 6.7	0.05 - 0.17	1.0 - 2.7	1.9 %
Beta 2	3.5 - 6.8	0.04 - 0.16	1.3 - 3.7	2.4 %
Gamma	14.1 - 18.5	0.06 - 0.44	0.4 - 2.4	1.4 %

Reproducibility between systems

Five (5) different serum samples were run 10 times using the MINICAP PROTEIN(E) 6 procedure on 3 MINICAP systems and with the same lot of analysis buffer. The mean, SD and CV (n = 30) were calculated for each sample, each zone on the 3 systems.
The table shows the limit values for the 5 tested samples on the 3 systems and a mean CV calculated from the CV's for each fraction (n = 5).

FRACTION	MEAN (%)	SD	CV (%)	MEAN CV (%)
Albumin	52.6 - 60.5	0.39 - 1.00	0.7 - 1.7	1.2 %
Alpha 1	3.5 - 4.8	0.13 - 0.31	2.9 - 7.0	4.4 %
Alpha 2	9.5 - 12.2	0.12 - 0.36	1.0 - 3.8	2.7 %
Beta 1	5.4 - 6.5	0.10 - 0.31	1.8 - 4.9	3.1 %
Beta 2	3.7 - 6.8	0.13 - 0.21	1.9 - 5.6	3.7 %
Gamma	14.2 - 18.2	0.15 - 0.45	1.0 - 3.0	2.0 %

Accuracy

Pathological and normal serum samples (n = 60) were run using the MINICAP PROTEIN(E) 6 procedure and another commercially available capillary electrophoresis system. The correlation parameters calculated for individual zones from the pooled data for MINICAP PROTEIN(E) 6 vs. the comparative capillary electrophoresis system (y = MINICAP PROTEIN(E) 6) were :

Fraction	Correlation coefficient	y-intercept	Slope	Range of % values MINICAP PROTEIN(E) 6
Albumin	0.996	0.046	0.985	37.4 - 74.0
Alpha 1	0.987	0.032	1.012	3.1 - 13.0
Alpha 2	0.993	0.347	1.024	7.8 - 23.5
Beta 1	0.944	0.686	0.911	3.1 - 10.2
Beta 2	0.986	-0.232	1.035	1.9 - 14.4
Gamma	0.999	0.222	0.986	3.5 - 34.7

Sensitivity

Serial dilutions of one serum sample with a monoclonal protein 0.103 g/dL was electrophoresed using the MINICAP PROTEIN(E) 6 procedure. The highest dilution with a discernible monoclonal band corresponded to 1 : 4, or a concentration of 26 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 MINICAP 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 MINICAP PROTEIN(E) 6 procedure.
The MINICAP 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

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PROFILS ÉLECTROPHORÉTIQUES - ELECTROPHORETIC PATTERNS

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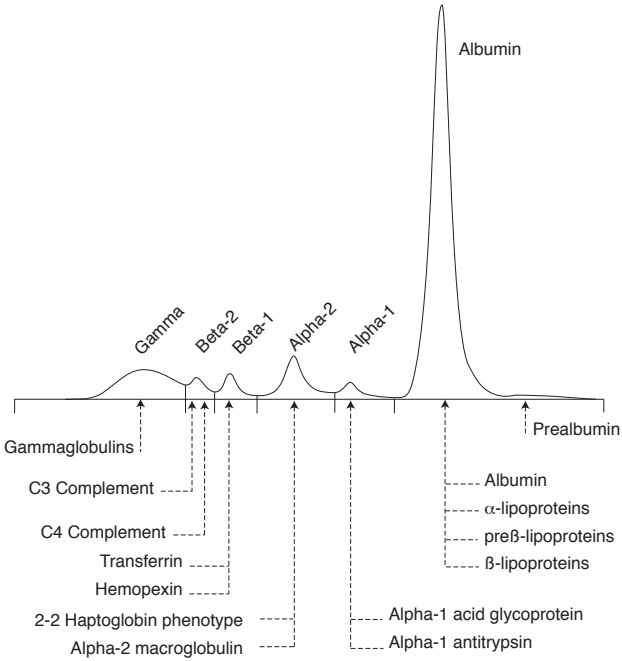

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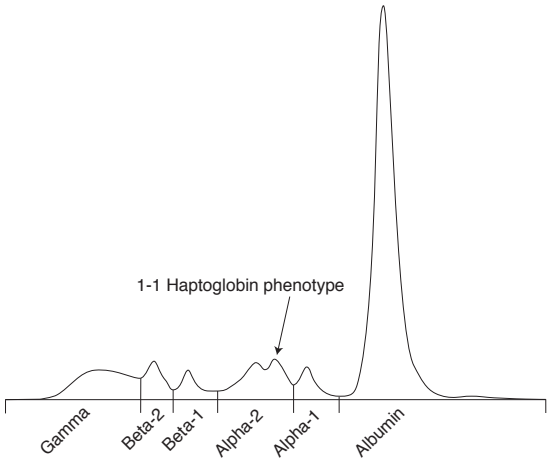

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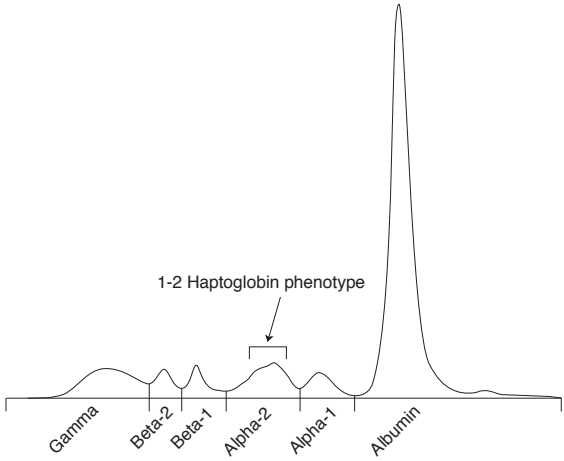
3



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