CAPILLARYS HR
Ref. 2004
The CAPILLARYS HR kit is designed for the multi-fractionation of human serum proteins in alkaline buffer (pH 9.9) with the CAPILLARYS System. Normal serum proteins separate into 8 major fractions. 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 4 individual major protein fractions: albumin, alpha-1 acid glycoprotein (orosomucoid), alpha-1 antitrypsin and haptoglobin.

CAPILLARYS HR procedure allows an excellent resolution and high sensitivity particularly in the gamma-zone.

**INTENDED USE**

For **In Vitro Diagnostic Use.**

**PRINCIPLE OF THE TEST**

Protein electrophoresis is a well established technique routinely used in clinical laboratories for screening samples for protein abnormalities. 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.

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.

With basic pH buffer, serum proteins are detected in the following order: gamma globulins, beta-2 globulins, beta-1 globulins, alpha-2 macroglobulin, haptoglobin, alpha-1 antitrypsin, alpha-1 acid glycoprotein and albumin. The fraction identification and interpretation is made by comparing the electrophoregrams of the clinical sample and a reference normal serum.

**REAGENTS AND MATERIALS SUPPLIED IN THE CAPILLARYS HR KIT**

<table>
<thead>
<tr>
<th>ITEMS</th>
<th>PN. 2004</th>
</tr>
</thead>
<tbody>
<tr>
<td>Buffer (ready to use)</td>
<td>2 vials, 700 mL each</td>
</tr>
<tr>
<td>Wash solution (stock solution)</td>
<td>1 vial, 70 mL</td>
</tr>
<tr>
<td>Dilution segments</td>
<td>1 pack of 70</td>
</tr>
<tr>
<td>Filters</td>
<td>3 filters</td>
</tr>
</tbody>
</table>

**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.**

**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). Before being opened, the buffer 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 CAPILLARYS Wash Solution should be diluted up to 700 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.

**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

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.

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 2051, 12 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, 70 mL each) should be diluted up to 700 mL with distilled or deionized water.


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

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

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 2 days between 2 and 8 °C, without any detectable C3 complement degradation. After 2-day refrigerated storage (2 to 8 °C), C3 complement degradation may progressively affect beta-1 and beta-2 fractions and the end of the gamma zone; the other protein fractions remain unchanged for 10-day storage between 2 and 8 °C.

For longer storage, samples should be frozen within 8 hours of collection. Frozen sera are stable for one month.

NOTE: Samples should not be stored at room temperature!

Protein degradation, and in particular complement degradation, is very sample dependent for sera stored between 2 to 8 °C.

After 2-day refrigerated storage (2 to 8 °C), the beta-2 fraction may appear distorted (shoulder on beta-1 side) and a small fraction may appear in the gamma zone, which hides potential increased CRP (See ELECTROPHORETIC PATTERNS).

After 8-day refrigerated storage (2 to 8 °C), the beta-2 fraction progressively decreases and may appear distorted with small fractions appearing in the gamma zone (which hides potential increased CRP) and/or in beta-1 fraction (See ELECTROPHORETIC PATTERNS).

When samples are stored for more than 8 days, beta-1 fraction broadens (with a new fraction on the alpha-2 macroglobulin side). A fraction in gamma zone on the CRP position can still be observed and beta-2 fraction tends to disappear totally (See ELECTROPHORETIC PATTERNS).

After – 20 °C storage, alpha-2 macroglobulin becomes distorted and decreases.

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 samples. Hemolysis induces a hemoglobin/haptoglobin complex and haptoglobin migrates towards alpha-2 macroglobulin fraction. This phenomenon may be observed on slightly hemolysed samples and the quantitative analysis of haptoglobin may be affected.
• Avoid aged, improperly stored serum samples, beta-1 and beta-2 fractions would be highly modified.
• Avoid plasma samples. Fibrinogen migrates just before beta-2 zone (on CRP position). When present in samples (plasma, serum not totally defibrinized or patient with anticoagulant treatment), fibrinogen may interfere on the analysis and makes interpretation inaccurate (suspicion of CRP fraction increase).

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 sample-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;
• Setting up the instrument for operation;
• 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 HR kit is intended to run with "HR" analysis program from the CAPILLARYS instrument. To select "HR" analysis program and place the CAPILLARYS HR buffer vial in the instrument, please read carrefully 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 sample 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 7 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 12 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.

SHUT DOWN

1. Start the shut down sequence.
2. Replace the CAPILLARYS HR buffer vial by a container with filtered distilled or deionized water.
3. Enter ; then, the shut down sequence will start automatically.

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 the concentration of the 4 following major proteins: albumin, orosomucoid, alpha-1 antitrypsin, and haptoglobin.
The electrophorograms are interpreted visually for pattern abnormalities.

NOTE: The accuracy of the 4 major proteins concentrations is directly linked to the accuracy of the total proteins concentration.

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.

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 normal sample serum into each run of samples.

Values
Direct detection at 200 nm in capillaries yields relative concentrations (percentages) of individual protein zones. The concentration is calculated for each protein from the relative concentrations and the total proteins concentration.
Normal values for the 4 major electrophoretic serum proteins in the CAPILLARYS system have been established from a population of 111 adults with normal values obtained by nephelometric determinations.

<table>
<thead>
<tr>
<th>Protein</th>
<th>Normal Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Albumin</td>
<td>34.12 - 49.94 g/L</td>
</tr>
<tr>
<td>Alpha-1 acid glycoprotein (Orosomucoid)</td>
<td>0.19 - 0.73 g/L</td>
</tr>
<tr>
<td>Alpha-1 antitrypsin</td>
<td>0.86 - 2.25 g/L</td>
</tr>
<tr>
<td>Haptoglobin</td>
<td>1.12 - 3.79 g/L</td>
</tr>
</tbody>
</table>

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 0 and automatic drift with triangulation).

Indicated values for haptoglobin are doubled but they are perfectly in agreement with values obtained by immunochemistry.

Interpretation
An inflammatory syndrome is characterized by the increase of one or more inflammatory proteins (orosomucoid and haptoglobin) with sometimes a CRP peak in the anodic gamma zone.
Any other electrophoretic pattern modification, such as an additional thin peak in beta-1, beta-2 and gamma zones indicates also a disorder.
As an aid in interpretation of serum protein electrophoregrams, see BIBLIOGRAPHY.
**Alpha zones**:
- Haptoglobin position on the electrophoretic pattern varies according to its phenotype (between alpha-1 antitrypsin and alpha-2 macroglobulin fractions).
- For very low haptoglobin concentrations (hemolytic syndrome for example), the corresponding fraction might not be correctly identified in CAPILLARYS HR procedure. Then, manual identification will be necessary.
- Manual identification will also be necessary for samples with very low orosomucoid concentration and/or with orosomucoid fraction close to alpha-1 antitrypsin.

**Beta zones**:
- C4 complement migrates between beta-1 and beta-2 fractions; CRP migrates before beta-2 fraction and its detection limit is about 3 mg/dL in fresh serum samples (See ELECTROPHORETIC PATTERNS).
- Hemopexin may give a shoulder on the beta-1 zone (alpha-2 macroglobulin side) (See ELECTROPHORETIC PATTERNS).
- Beta lipoproteins may give one small fraction between alpha-2 macroglobulin and beta-1 zone (See ELECTROPHORETIC PATTERNS).
- If hemopexin and beta lipoproteins are highly increased, they will be detected as extra individual fractions in CAPILLARYS HR procedure.

**Interference and Limitations**
See SAMPLES FOR ANALYSIS. Due to the resolution and sensitivity limits of zone electrophoresis, it is possible that some monoclonal components may not be detected with this method.

**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 HR procedure indicate a very good reproducibility for quantitative analysis with a mean CV % of about 2.6 % for Albumin, Alpha-1 acid glycoprotein, Alpha-1 antitrypsin and Haptoglobin protein fraction.

Results presented below have been obtained using the standard parameters of the CAPILLARYS software (smoothing 0 and automatic drift with triangulation).

**Reproducibility within run**
Five (5) different serum samples (with Normal Control Serum and Hypergamma Control Serum, SEBIA) were run in 8 capillaries using the CAPILLARYS HR 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 the 4 major protein fractions and with the 2 lots of buffer.

<table>
<thead>
<tr>
<th>FRACTION</th>
<th>ALBUMIN</th>
<th>ALPHA-1 ACID GLYCOPROTEIN</th>
<th>ALPHA-1 ANTITRYPSIN</th>
<th>HAPTOGLOBIN</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Serum A : lot no. 1 / lot no. 2</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MEAN (%)</td>
<td>58.6 / 58.3</td>
<td>1.3 / 1.3</td>
<td>2.4 / 2.4</td>
<td>5.4 / 5.6</td>
</tr>
<tr>
<td>SD</td>
<td>1.05 / 0.99</td>
<td>0.09 / 0.05</td>
<td>0.21 / 0.23</td>
<td>0.07 / 0.09</td>
</tr>
<tr>
<td>CV (%)</td>
<td>1.8 / 1.7</td>
<td>6.8 / 3.6</td>
<td>8.9 / 9.4</td>
<td>1.3 / 1.6</td>
</tr>
<tr>
<td><strong>Serum B : lot no. 1 / lot no. 2</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MEAN (%)</td>
<td>50.7 / 50.1</td>
<td>2.2 / 2.1</td>
<td>4.3 / 4.3</td>
<td>10.3 / 10.4</td>
</tr>
<tr>
<td>SD</td>
<td>0.95 / 0.79</td>
<td>0.05 / 0.05</td>
<td>0.16 / 0.14</td>
<td>0.18 / 0.19</td>
</tr>
<tr>
<td>CV (%)</td>
<td>1.9 / 1.6</td>
<td>2.2 / 2.3</td>
<td>3.7 / 3.2</td>
<td>1.8 / 1.9</td>
</tr>
<tr>
<td><strong>Serum C : lot no. 1 / lot no. 2</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MEAN (%)</td>
<td>62.8 / 62.5</td>
<td>0.4 / 0.5</td>
<td>2.5 / 2.4</td>
<td>2.6 / 2.8</td>
</tr>
<tr>
<td>SD</td>
<td>0.92 / 0.60</td>
<td>0.03 / 0.00</td>
<td>0.07 / 0.06</td>
<td>0.10 / 0.05</td>
</tr>
<tr>
<td>CV (%)</td>
<td>1.5 / 1.0</td>
<td>8.0 / 0.0</td>
<td>2.9 / 2.5</td>
<td>3.8 / 1.8</td>
</tr>
<tr>
<td><strong>Normal Control Serum : lot no. 1 / lot no. 2</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MEAN (%)</td>
<td>62.2 / 63.7</td>
<td>0.8 / 0.7</td>
<td>2.6 / 2.7</td>
<td>4.1 / 3.9</td>
</tr>
<tr>
<td>SD</td>
<td>0.78 / 0.43</td>
<td>0.03 / 0.00</td>
<td>0.09 / 0.07</td>
<td>0.07 / 0.07</td>
</tr>
<tr>
<td>CV (%)</td>
<td>1.3 / 0.7</td>
<td>4.2 / 0.0</td>
<td>3.2 / 2.6</td>
<td>1.7 / 1.7</td>
</tr>
<tr>
<td><strong>Hypergamma Control Serum : lot no. 1 / lot no. 2</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MEAN (%)</td>
<td>44.6 / 44.1</td>
<td>1.9 / 1.9</td>
<td>2.7 / 2.8</td>
<td>3.6 / 3.8</td>
</tr>
<tr>
<td>SD</td>
<td>0.56 / 0.58</td>
<td>0.04 / 0.03</td>
<td>0.12 / 0.05</td>
<td>0.09 / 0.10</td>
</tr>
<tr>
<td>CV (%)</td>
<td>1.3 / 1.3</td>
<td>2.2 / 1.8</td>
<td>4.5 / 1.8</td>
<td>2.4 / 2.6</td>
</tr>
</tbody>
</table>
Reproducibility between run

Eight (8) different serum samples were run 10 times in 8 capillaries using the CAPILLARYS HR 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 the 4 major protein fractions (n = 24).

<table>
<thead>
<tr>
<th>FRACTION</th>
<th>MEAN (%)</th>
<th>SD</th>
<th>CV (%)</th>
<th>MEAN CV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Albumin</td>
<td>44.5 - 66.7</td>
<td>0.12 - 1.38</td>
<td>0.2 - 2.2</td>
<td>0.8</td>
</tr>
<tr>
<td>Alpha-1 acid glycoprotein</td>
<td>0.4 - 1.3</td>
<td>0.00 - 0.06</td>
<td>0.0 - 7.6</td>
<td>3.9</td>
</tr>
<tr>
<td>Alpha-1 Antitrypsin</td>
<td>2.3 - 3.2</td>
<td>0.04 - 0.10</td>
<td>1.4 - 3.9</td>
<td>2.5</td>
</tr>
<tr>
<td>Haptoglobin</td>
<td>2.7 - 7.6</td>
<td>0.05 - 0.16</td>
<td>0.9 - 4.5</td>
<td>2.2</td>
</tr>
</tbody>
</table>

Reproducibility between lots

Eight (8) different serum samples were run 10 times in 8 capillaries using the CAPILLARYS HR 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 the 4 major protein fractions (n = 3).

<table>
<thead>
<tr>
<th>FRACTION</th>
<th>MEAN (%)</th>
<th>SD</th>
<th>CV (%)</th>
<th>MEAN CV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Albumin</td>
<td>45.0 - 66.2</td>
<td>0.39 - 1.25</td>
<td>0.6 - 2.0</td>
<td>1.3</td>
</tr>
<tr>
<td>Alpha-1 acid glycoprotein</td>
<td>0.4 - 1.7</td>
<td>0.00 - 0.06</td>
<td>0.0 - 8.8</td>
<td>5.0</td>
</tr>
<tr>
<td>Alpha-1 Antitrypsin</td>
<td>2.3 - 3.2</td>
<td>0.06 - 0.11</td>
<td>1.8 - 4.6</td>
<td>3.1</td>
</tr>
<tr>
<td>Haptoglobin</td>
<td>2.8 - 7.5</td>
<td>0.10 - 0.15</td>
<td>1.8 - 4.0</td>
<td>3.2</td>
</tr>
</tbody>
</table>

Accuracy

Pathological and normal serum samples (n = 135) were run using the CAPILLARYS HR procedure and commercially available nephelometric techniques for albumin, alpha-1 acid glycoprotein, alpha-1 antitrypsin and haptoglobin quantification. The correlation parameters calculated for individual zones from the pooled data for CAPILLARYS HR vs. the comparative nephelometric system (y = CAPILLARYS HR) were:

<table>
<thead>
<tr>
<th>Fraction</th>
<th>Correlation coefficient</th>
<th>y-intercept</th>
<th>Slope</th>
<th>Range of concentration values (g/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Albumin</td>
<td>0.942</td>
<td>5.862</td>
<td>0.813</td>
<td>17.86 - 49.43</td>
</tr>
<tr>
<td>Alpha-1 acid glycoprotein</td>
<td>0.949</td>
<td>-0.109</td>
<td>0.834</td>
<td>0.14 - 2.96</td>
</tr>
<tr>
<td>Alpha-1 Antitrypsin</td>
<td>0.879</td>
<td>0.109</td>
<td>1.117</td>
<td>0.40 - 5.31</td>
</tr>
<tr>
<td>Haptoglobin</td>
<td>0.969</td>
<td>0.743</td>
<td>1.614</td>
<td>0.32 - 9.87</td>
</tr>
</tbody>
</table>

Sensitivity

Serial dilutions of one serum sample with two monoclonal proteins 0.09 and 0.486 g/dL were electrophoresed using the CAPILLARYS HR procedure. The highest dilutions with a discernible monoclonal band corresponded to 1 : 16 and 1 : 32, respectively, corresponding to a concentration of about 6 to 15 mg/dL of each 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 HR test was determined to be linear to at least 5.2 g/dL albumin and 3.1 g/dL gammaglobulins.

BIBLIOGRAPHY


Figure 1

Profil normal
*Normal pattern*

Figure 2

Profil inflammatoire
*Inflammatory pattern*
Profil avec complément C3 dégradé

Pattern with degraded C3 complement