Protein Fraction | Mean % | SD | CV (%)
--- | --- | --- | ---
Alpha1 | 3.9 | 0.2 | 6.2%
Alpha2 | 9.3 | 0.3 | 3.5%
Beta | 16.1 | 0.3 | 2.1%
Gamma | 15.3 | 0.6 | 3.7%

**Figure 1** An agarose gel showing relative position of the bands.

**Figure 2** A scan of a SPIFE® Touch Split Beta SPE pattern.

### **REFERENCE VALUES**

The Helena QuickScan Touch® densitometer will automatically calculate the relative position and the absolute value of each band when the total protein is entered. Refer to the Operator’s Manual for further instructions.

### **INTERPRETATION OF RESULTS**

Pneumococcal, meningococcal, and related epi-sodes are characterized by laboratory and clinical evidence of sepsis. The serum proteins are lower in concentration than normal, with some elevations noted. The serum proteins are lower in concentration than normal, with some elevations noted.

### **FURTHER TESTING**

In the case of abnormal results, appropriate further testing should be initiated. These may include immunoelectrophoresis, immunofixation, or bone marrow examination and other appropriate tests. In the case of abnormal results, appropriate further testing should be initiated. These may include immunoelectrophoresis, immunofixation, or bone marrow examination and other appropriate tests.

### **LIMITATIONS**

The gels should be stored at room temperature (15 to 30°C). The gels may be stored for 10 days in room temperature (2°C to 8°C); however, for 5-10 days, 2 to 8°C for 2 weeks or -20°C for 6 months.

### **SPECIMEN COLLECTION AND HANDLING**

**Storage and Stability:**

- Storage at 2°C to 8°C for 10 days is recommended.
- The gels may be stored at room temperature (15 to 30°C).
- The gels may be stored for 10 days in room temperature (2°C to 8°C); however, for 5-10 days, 2 to 8°C for 2 weeks or -20°C for 6 months.

**Procedure:**

1. Fill the gel in the appropriate gel slots in the gel wells. The gel may be stored at room temperature (15 to 30°C).
2. The gels may be stored for 10 days in room temperature (2°C to 8°C); however, for 5-10 days, 2 to 8°C for 2 weeks or -20°C for 6 months.

**FCC (Food and Drug Administration):**

- The gels may be stored at room temperature (15 to 30°C).
- The gels may be stored for 10 days in room temperature (2°C to 8°C); however, for 5-10 days, 2 to 8°C for 2 weeks or -20°C for 6 months.

**SDF (Standard Methods for the Examination of Water and Wastewater):**

- The gels may be stored at room temperature (15 to 30°C).
- The gels may be stored for 10 days in room temperature (2°C to 8°C); however, for 5-10 days, 2 to 8°C for 2 weeks or -20°C for 6 months.

**CFDA (Centers for Disease Control and Prevention):**

- The gels may be stored at room temperature (15 to 30°C).
- The gels may be stored for 10 days in room temperature (2°C to 8°C); however, for 5-10 days, 2 to 8°C for 2 weeks or -20°C for 6 months.

**SUMMARY**

- The gels may be stored at room temperature (15 to 30°C).
- The gels may be stored for 10 days in room temperature (2°C to 8°C); however, for 5-10 days, 2 to 8°C for 2 weeks or -20°C for 6 months.

**SPECIMEN COLLECTION:**

1. Fill the gel in the appropriate gel slots in the gel wells. The gel may be stored at room temperature (15 to 30°C).
2. The gels may be stored for 10 days in room temperature (2°C to 8°C); however, for 5-10 days, 2 to 8°C for 2 weeks or -20°C for 6 months.

**FCC (Food and Drug Administration):**

- The gels may be stored at room temperature (15 to 30°C).
- The gels may be stored for 10 days in room temperature (2°C to 8°C); however, for 5-10 days, 2 to 8°C for 2 weeks or -20°C for 6 months.

**SDF (Standard Methods for the Examination of Water and Wastewater):**

- The gels may be stored at room temperature (15 to 30°C).
- The gels may be stored for 10 days in room temperature (2°C to 8°C); however, for 5-10 days, 2 to 8°C for 2 weeks or -20°C for 6 months.

**CFDA (Centers for Disease Control and Prevention):**

- The gels may be stored at room temperature (15 to 30°C).
- The gels may be stored for 10 days in room temperature (2°C to 8°C); however, for 5-10 days, 2 to 8°C for 2 weeks or -20°C for 6 months.

**REFERENCES**


5. 579-582.


**STEP-BY-STEP METHOD**

0. **Serum, CSF and Urine (Blade Application)**

   **A. Serum, CSF and Urine (Blade Application)**

   1. Place an Applicator Blade Weight on top of each blade assembly.

   2. Place the left edge of the gel over the REP Prep, aligning the marked corner in the lower left position. The instrument will now apply and continue.

   **B. Serum and Urine/CSF (Blade Application)**

   1. Place an Applicator Blade Weight on top of each blade assembly.

   2. Place the left edge of the gel over the REP Prep, aligning the marked corner in the lower left position. The instrument will now apply and continue.

   **C. Urine/CSF Template Application**

   1. Place the left edge of the gel over the REP Prep, aligning the marked corner in the lower left position. The instrument will now apply and continue.

   **IV. Visualization**

   1. After the gel has dried, open the chamber lid and carefully remove the gel block.

   **V. Disposal of Gel Blocks**

   1. Replace the gel block Remover to remove the gel blocks.

   **VI. Electroelution of Urine Bands**

   1. Use the urines under SEPARATOR UNIT to select the appropriate test. Press START to choose operation to proceed. Note: Serums and CSF samples are run on the same gel as urine - select option for urine/CSF blades. If testing fewer than 41 samples, use the Gel Block Remover to remove the gel blocks.

   **VI. Electroelution of Urine Bands**

   1. Use the urines under SEPARATOR UNIT to select the appropriate test. Press START to choose operation to proceed. Note: Serums and CSF samples are run on the same gel as urine - select option for urine/CSF blades. If testing fewer than 41 samples, use the Gel Block Remover to remove the gel blocks.

   **VII. Electroelution of Urine Bands**

   1. Use the urines under SEPARATOR UNIT to select the appropriate test. Press START to choose operation to proceed. Note: Serums and CSF samples are run on the same gel as urine - select option for urine/CSF blades. If testing fewer than 41 samples, use the Gel Block Remover to remove the gel blocks.

   **VIII. Qualitative Evaluation**

   1. Qualitative Evaluation: The urine or CSF samples run on the SPIFE Split Beta SPE Gel can only be visually inspected for the presence of bands.

---

**,List the apparatus blades into the slots:**

**Location:** 2

**Temperature:** 21°C

**Time:** 8:00

**Apply Sample Prompt:** None

**Electrophoresis Prompt:** None

**Speed:** 1

**Voltage:** 650 V

**mA:** 130 mA

**Load Sample 4 Prompt:** None

**Load Sample 3 Prompt:** None

**Load Sample 2 Prompt:** None

**Load Sample 1 Prompt:** None

**Destain 1 Prompt:** None

**Destain 2 Prompt:** None

**Stain Prompt:** None

**Recirculation:** On

**Recirculation:** Off

**Start:** 10:00

**Stop:** 13:00

**Apply Sample:** 10 minutes

**Eviation:** 3" to "Valve: 5" in Stain Section.
STEP-BY-STEP METHOD

I. Introduction

A. Serum, CSF and Urine (Blade Application)

1. Place the left edge of the gel over the REP Prep, aligning the round hole on the left pin of the chamber. Gently lay the gel down.

2. Remove the gel holder from the stainer chamber. Attach the gel to the electrophoresis chamber. Make sure there are no air bubbles under them. Carefully remove the gel from the stainer chamber.

3. Place the gel holder/stainer unit into the tray with the pins on the instrument. Make sure the gel is attached to the electrodes on each end of the gel to prevent curling during drying.

4. Place the gel holder/stainer unit into the tray with the pins on the instrument. Make sure the gel is attached to the electrodes on each end of the gel to prevent curling during drying.

II. Parameters

A. Serum (Blade Application) Option 1

1. Spray the disposable sample cups into the rows of the appropriate test. Press START and choose an operation to proceed.

2. After electrophoresis is complete, remove the gel from the electrophoresis chamber and place it on a glass plate.

3. Use the gel block remover to remove the gel blocks. Replace the gel holder and choose an operation to proceed.

B. Urine or CSF Template Application

1. Place the gel holder/stainer unit into the tray with the pins on the instrument. Make sure the gel is attached to the electrodes on each end of the gel to prevent curling during drying.

2. After sample application is complete, open the chamber lid and press the dry prompt to remove gel blocks. Replace the gel holder and choose an operation to proceed.

C. Urine or CSF Template Application

1. Use the gel holder/stainer unit to select the appropriate test. Press START and choose an operation to proceed.

2. After electrophoresis is complete, open the gel block remover to remove the gel blocks. Replace the gel holder and choose an operation to proceed.

III. Visualization

1. After the gel has been dried, open the gel block remover to remove the gel blocks. Replace the gel holder and choose an operation to proceed.

2. Place the gel holder with the gel facing backwards into the display chamber.

3. Use the gel holder/stainer unit to select the appropriate test. Press START and choose an operation to proceed. The instrument will scan, display, and dry the gel.

4. Replace the gel holder with the gel facing backwards into the display chamber.

5. After the gel has been dried, open the gel block remover to remove the gel blocks. Replace the gel holder and choose an operation to proceed.

6. Place the gel holder with the gel facing backwards into the display chamber.

7. Use the gel holder/stainer unit to select the appropriate test. Press START and choose an operation to proceed. The instrument will scan, display, and dry the gel.

IV. Disposal of Biohazardous Waste

1. Close out the electrophoresis chamber.

2. Open the gel block remover to remove the gel blocks. Replace the gel holder and choose an operation to proceed.

3. Place the gel holder with the gel facing backwards into the display chamber.

4. Use the gel holder/stainer unit to select the appropriate test. Press START and choose an operation to proceed. The instrument will scan, display, and dry the gel.

5. Replace the gel holder with the gel facing backwards into the display chamber.

6. Use the gel holder/stainer unit to select the appropriate test. Press START and choose an operation to proceed. The instrument will scan, display, and dry the gel.

7. Close the instrument and press the CONTINUE button to dry the gel.
I. Sample Application

1. After the gel has been dried, open the chamber lid and carefully remove the Gel Holder from the stainer and scan the bands in a densitometer (if desired). The SPIFE Touch will apply and continue.

II. Visualization

1. The urine and CSF samples run on the SPE Abnormal Control Gel can only be visually inspected for the presence of the bands. Be sure to select the appropriate test. Press the Continue button to dry and finalize the run.

III. Electrodes

1. Place an electrode between each sample and connect the appropriate test.

IV. Visualization

1. The gel will then be placed in the positioning chamber and cross-react with the electrode post. Use a lint-free pad to remove excess REP Prep.

V. Destain

1. Slowly pour the Destain solution over the gel, making sure the gel is completely submerged in the Destain solution. Destain for 30 minutes. Then carefully pour off the Destain solution and rinse for 10 minutes with water. Destain again for 10 minutes.

VI. Blotting

1. Place the blotter on top of the gel. Gently blot each template with a Blotter A-Plus.

VII. Rehydration

1. Rehydrate the gel in the appropriate solution for 30 minutes. Then carefully pour off the Destain solution and rinse for 10 minutes with water.

VIII. Drying

1. The gel will then be placed in the positioning chamber and cross-react with the electrode post. Use a lint-free pad to remove excess REP Prep.

IX. Electrodes

1. Place an electrode between each sample and connect the appropriate test.

X. Visualization

1. Place the gel in the appropriate solution and cross-react with the electrode post. Use a lint-free pad to remove excess REP Prep.

XI. Staining

1. Place the gel in the appropriate solution and cross-react with the electrode post. Use a lint-free pad to remove excess REP Prep.

XII. Destain

1. Slowly pour the Destain solution over the gel, making sure the gel is completely submerged in the Destain solution. Destain for 30 minutes. Then carefully pour off the Destain solution and rinse for 10 minutes with water. Destain again for 10 minutes.

XIII. Blotting

1. Place the blotter on top of the gel. Gently blot each template with a Blotter A-Plus.

XIV. Rehydration

1. Rehydrate the gel in the appropriate solution for 30 minutes. Then carefully pour off the Destain solution and rinse for 10 minutes with water.

XV. Drying

1. The gel will then be placed in the positioning chamber and cross-react with the electrode post. Use a lint-free pad to remove excess REP Prep.

XVI. Electrodes

1. Place an electrode between each sample and connect the appropriate test.

XVII. Visualization

1. Place the gel in the appropriate solution and cross-react with the electrode post. Use a lint-free pad to remove excess REP Prep.

XVIII. Staining

1. Place the gel in the appropriate solution and cross-react with the electrode post. Use a lint-free pad to remove excess REP Prep.

XIX. Destain

1. Slowly pour the Destain solution over the gel, making sure the gel is completely submerged in the Destain solution. Destain for 30 minutes. Then carefully pour off the Destain solution and rinse for 10 minutes with water. Destain again for 10 minutes.

XX. Blotting

1. Place the blotter on top of the gel. Gently blot each template with a Blotter A-Plus.

XXI. Rehydration

1. Rehydrate the gel in the appropriate solution for 30 minutes. Then carefully pour off the Destain solution and rinse for 10 minutes with water.

XXII. Drying

1. The gel will then be placed in the positioning chamber and cross-react with the electrode post. Use a lint-free pad to remove excess REP Prep.

XXIII. Electrodes

1. Place an electrode between each sample and connect the appropriate test.

XXIV. Visualization

1. Place the gel in the appropriate solution and cross-react with the electrode post. Use a lint-free pad to remove excess REP Prep.

XXV. Staining

1. Place the gel in the appropriate solution and cross-react with the electrode post. Use a lint-free pad to remove excess REP Prep.

XXVI. Destain

1. Slowly pour the Destain solution over the gel, making sure the gel is completely submerged in the Destain solution. Destain for 30 minutes. Then carefully pour off the Destain solution and rinse for 10 minutes with water. Destain again for 10 minutes.

XXVII. Blotting

1. Place the blotter on top of the gel. Gently blot each template with a Blotter A-Plus.

XXVIII. Rehydration

1. Rehydrate the gel in the appropriate solution for 30 minutes. Then carefully pour off the Destain solution and rinse for 10 minutes with water.

XXIX. Drying

1. The gel will then be placed in the positioning chamber and cross-react with the electrode post. Use a lint-free pad to remove excess REP Prep.

XXX. Electrodes

1. Place an electrode between each sample and connect the appropriate test.

XXXI. Visualization

1. Place the gel in the appropriate solution and cross-react with the electrode post. Use a lint-free pad to remove excess REP Prep.
The normal and abnormal serum proteins have been fractionated on the basis of their electrical charge and molecular size. This allows for the identification of various disease states. The normal serum protein components can be separated by electrophoresis using agarose gel. The SPIFE Touch Serum Protein procedure is intended for the separation of these components.

**SPECIMEN COLLECTION AND HANDLING**

**SPECIMEN**:

Protein Fraction | Mean % | SD | CV
--- | --- | --- | ---
Albumin | 48.4 | 0.6 | 1.2%
Alpha1 | 3.9 | 0.2 | 6.2%
Beta | 12.4 | 0.3 | 2.5%
Alpha2 | 8.5 | 0.2 | 2.3%
Gamma | 15.4 | 0.5 | 3.4%

**Normal Control (n = 20)**

Protein Fraction | Mean % | SD | CV
--- | --- | --- | ---
Albumin | 55.5 | 1.1 | 2.0%
Alpha1 | 3.4 | 0.2 | 6.7%
Beta | 12.4 | 0.3 | 2.5%
Alpha2 | 8.5 | 0.2 | 2.3%
Gamma | 15.3 | 0.3 | 2.1%

**Abnormal Control (n = 180)**

Protein Fraction | Mean % | SD | CV
--- | --- | --- | ---
Albumin | 48.4 | 0.6 | 1.2%
Alpha1 | 3.9 | 0.2 | 6.2%
Beta | 12.4 | 0.3 | 2.5%
Alpha2 | 8.5 | 0.2 | 2.3%
Gamma | 15.4 | 0.5 | 3.4%

**LIMITATIONS**

1. Hemolysis may cause false elevation in the alpha2 and beta fractions.

**STORAGE AND STABILITY**

The SPIFE Touch Serum Protein procedure is intended for the separation of these components. The normal serum protein components can be separated by electrophoresis using agarose gel.

**PROCEDURE**

**SPECIMEN COLLECTION AND HANDLING**

**SPECIMEN**:

Protein Fraction | Mean % | SD | CV
--- | --- | --- | ---
Albumin | 48.4 | 0.6 | 1.2%
Alpha1 | 3.9 | 0.2 | 6.2%
Beta | 12.4 | 0.3 | 2.5%
Alpha2 | 8.5 | 0.2 | 2.3%
Gamma | 15.4 | 0.5 | 3.4%

**Normal Control (n = 20)**

Protein Fraction | Mean % | SD | CV
--- | --- | --- | ---
Albumin | 55.5 | 1.1 | 2.0%
Alpha1 | 3.4 | 0.2 | 6.7%
Beta | 12.4 | 0.3 | 2.5%
Alpha2 | 8.5 | 0.2 | 2.3%
Gamma | 15.3 | 0.3 | 2.1%

**Abnormal Control (n = 180)**

Protein Fraction | Mean % | SD | CV
--- | --- | --- | ---
Albumin | 48.4 | 0.6 | 1.2%
Alpha1 | 3.9 | 0.2 | 6.2%
Beta | 12.4 | 0.3 | 2.5%
Alpha2 | 8.5 | 0.2 | 2.3%
Gamma | 15.3 | 0.3 | 2.1%
The SPIFE Touch Split Beta SPE method is intended for the separation of serum, or urine containing red cells if present, by agar gel electrophoresis of the SPIFE Touch system.

SUMMARY

Serum is the usual test procedure, each with a specific set of factors and subjected to specific variations in concentration under different conditions. As the method is not the introduction of moving boundary electrophoresis by Tiselius and subsequent use of zone electrophoresis, serum albumin and globulins are separated and identified. These fractions are obtained at a particular pH for the fractionation of albumins, alpha, beta, and gamma globulins. The reference for the determination of these classical electrophoretic classes, with the exclusion of albumin, normally contain 20 components. The relative proportions of these fractions have proved to be useful in the diagnosis and prognosis of certain disease states.

PRINCIPLE

Proteins are large molecules composed of covalently linked amino acids. Depending on electron distribution, resulting from casual or structural binding of structural subgroups, proteins can be either polar or non-polar as a general principle. Protein-polyelectrolyte procedures are separated according to their respective electrical charge at a given concentration using the gel electrophoresis method. The net charge on the protein is determined by both the net charge on the protein and the pH of the buffer. The protein is then identified using a visible stain.

COMPONENTS

1. SPIFE Touch Split Beta SPE Gel
   - Summation for indication of electrophoresis/SPIFE SPE with staining, a destain, and a permanent stain.

2. Acid Blue Stain
   - Acid blue stain.

3. Destain Solution
   - Destain solution.

4. Storage and Stability
   - The dry stain should be stored at 15 to 30°C and is stable until the expiration date indicated on the package. The gel contains barbital, which, in sufficient quantity, can be toxic. The gel is stable for an indefinite period of time.

5. Specimen
   - Fresh serum, urine or CSF is the specimen of choice. Use of plasma will cause a band shift to a slower or faster migrating position, compared to the gel band broadened to a single band in the agar gel. The fast band results in a “alpha,” followed by “beta,” “gamma” and “beta-gamma” globulins.

6. Interfering Factors
   - No interfering factors are known for the procedure or specimen preparation.

WARNING FOR IN-VITRO DIAGNOSTIC USE ONLY

DO NOT INJECT

Procedure for Use: Discard the dry (red) contents of vials containing 1 L of 9% sodium citrate for 1 minute, then 3 minutes.

Intravenous use: Do not use for intravenous therapy. Discontinue intravenous use before any further reaction occurs.

Interfering Factors:
- Hemolytic samples may cause elevation in the albumin, beta and gamma fractions.

Intravenous use: Discontinue intravenous use before any further reaction occurs.

CAUTION

The SPIFE Touch Split Beta SPE method is intended for the separation of serum, or urine containing red cells if present, by agar gel electrophoresis of the SPIFE Touch system.

Interfering Factors:
- Hemolytic samples may cause elevation in the albumin, beta and gamma fractions.

Intravenous use: Discontinue intravenous use before any further reaction occurs.

CAUTION

The SPIFE Touch Split Beta SPE method is intended for the separation of serum, or urine containing red cells if present, by agar gel electrophoresis of the SPIFE Touch system.

Interfering Factors:
- Hemolytic samples may cause elevation in the albumin, beta and gamma fractions.

Intravenous use: Discontinue intravenous use before any further reaction occurs.

CAUTION

The SPIFE Touch Split Beta SPE method is intended for the separation of serum, or urine containing red cells if present, by agar gel electrophoresis of the SPIFE Touch system.

Interfering Factors:
- Hemolytic samples may cause elevation in the albumin, beta and gamma fractions.

Intravenous use: Discontinue intravenous use before any further reaction occurs.

CAUTION