

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY**

A. 510(k) Number:

k070486

B. Purpose for Submission:

New device

C. Measurand:

Urine Proteins

D. Type of Test:

Qualitative Capillary Electrophoresis

E. Applicant:

SEBIA, INC.

F. Proprietary and Established Names:

CAPILLARYS URINE (PN 2012)

G. Regulatory Information:

1. Regulation section:

21 CFR § 866.5150 Bence Jones proteins immunological systems

2. Classification:

Class II

3. Product codes:

JKM – Immunochemical, Bence Jones Protein

4. Panel:

Immunology 82

H. Intended Use:

1. Intended use:

The CAPILLARYS URINE kit is designed for the preparation of urine samples before separation of human urine proteins in alkaline buffer (pH 9.9) with the CAPILLARYS System.

The CAPILLARYS performs automatically all sequences to obtain a urinary protein profile for qualitative analysis. The proteins, separated in silica capillaries, are directly detected at an absorbance of 200 nm. The electrophoregrams can be interpreted visually to detect any pattern abnormalities (monoclonal components, particularly Bence Jones proteins and other urinary proteins).

For *In Vitro* Diagnostic Use.

2. Indication(s) for use:

Same as Intended use.

3. Special conditions for use statement(s):

For prescription only.

4. Special instrument requirements:

SEBIA CAPILLARYS System

I. Device Description:

The CAPILLARYS URINE kit (PN 2012) is designed for the preparation of urine samples before separation of human urine proteins in alkaline buffer (pH 9.9) with the

CAPILLARYS System.

The kit contains 2 vials (480 mL each) of Dialysis buffer (stock solution). Each vial should be diluted twice (v/v) with distilled or deionized water. After dilution, it contains alkaline buffer pH 9.9, additives, non-hazardous at concentrations used, necessary for optimum performance.

Other reagents required but not supplied: CAPILLARYS PROTEIN(E) 6 kit (SEBIA PN 2003; k022227), distilled or deionized water, CAPICLEAN (SEBIA PN 2051), Sodium Hypochlorite solution (for sample probe cleaning), CAPILLARYS wash solution (SEBIA PN 2052), Normal Control Serum (SEBIA PN 4785; k040925), CAPILLARYS dialysis system (SEBIA PN 9200): 24 tubes of 20 mL with PES membrane 10,000 MWCO (10 KDa).

J. Substantial Equivalence Information:

1. Predicate device name(s):
SEBIA HYDRAGEL 7 & 15 HR agarose gel, Acid violet
2. Predicate K number(s):
k982450 (Hydragel 7 HR), Amido black
k983375 (Hydragel 15 HR), Amido black
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Electrophoretic separation/fractionation of urine proteins	Qualitative visual detection of protein abnormalities	Same

Differences		
Item	Device	Predicate
Intended Use	The CAPILLARYS URINE kit is designed for the preparation of urine samples before separation of human urine proteins in alkaline buffer (pH 9.9) with the CAPILLARYS System. The CAPILLARYS performs automatically all sequences to obtain a urinary protein profile for qualitative analysis. The proteins, separated in silica capillaries, are directly detected at an absorbance of 200 nm. The electrophoregrams	The HYDRAGEL 7 HR and HYDRAGEL 15 HR are designed for multi-fractionation of proteins from human sera or other biological fluids, such as urine and cerebrospinal fluid (CSF), by electrophoresis on alkaline buffered (pH 8.6) agarose gels. The kits are used in conjunction with semi-automated HYDRASYS instrument. The electrophoretic separations are evaluated

Differences		
Item	Device	Predicate
	can be interpreted visually to detect any pattern abnormalities (monoclonal components, particularly Bence Jones proteins and other urinary proteins).	visually for protein pattern abnormalities. Densitometry can provide semi-quantitative, relative values.
Technology	Capillary electrophoretic protein migration	Agarose gel electrophoretic migration
Methodology	Capillary electrophoresis	Gel electrophoresis
Equipment	Capillary System	Hydrasys System
Sample matrix	Urine	Human serum, and other biological fluids such as Urine, and CSF

K. Standard/Guidance Document Referenced (if applicable):

None provided.

L. Test Principle:

Protein electrophoresis is a well established technique routinely used in clinical laboratories to screen 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. The sample is prepared before the analysis by dialysis and concentration with buffer and then 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.

Urinary proteins are separated at alkaline buffer into five different zones and detected in the following order: gamma zone, beta zone, alpha-2 zone, alpha-1 zone and albumin with each zone containing one or more proteins.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Within run precision: two different pathological urine samples (one urine sample containing five protein fractions and one sample with a Bence Jones protein) and on one normal urine sample. Each sample was prepared with dialysis buffer from

two different lots, then applied in all wells of dilution segments and analyzed using CAPILLARYS URINE procedure with the same analysis buffer. The three samples were performed on eight capillaries within the same run. All repeats gave concordant qualitative results within-run and within the two dialysis buffer lots.

The within-run testing was also performed on two pathological urines (Sample B had a protein in the beta zone and Sample C had a Bence Jones protein in the gamma zone) on two dialysis buffer lots and performed twice.

Results of the protein fractionation analysis of sample B (Total Protein = 83 mg/dL) on the two dialysis buffer lots were as follows: The mean values of the Albumin fractions were 66.1% (CV 4.0%) and 69.9% (CV 4.7%) and the Beta zone fractions 1.8% (CV 6.1%) and 2.1% (CV 6.5%) respectively. (TP results were from a different quantitative method).

The protein fractionation analysis of sample C (TP = 112 mg/dL) on the two dialysis buffer lots were as follows: The mean values of the Albumin fractions were 2.7% (CV 11.0%) and 3.7% (CV 6.8%); and Bence Jones fractions 21.3% (CV 11.7%) and 25.7% (CV 5.9%) respectively.

Between-run precision: six different pathological urine samples containing one to seven protein fractions and on two normal samples prepared each with dialysis buffer from three different lots. These samples were analyzed 10 times using CAPILLARYS URINE procedure for each dialysis buffer lot and with the same analysis buffer. All repeats gave concordant qualitative results between runs and lot-to-lot.

The between-run testing was also performed on five pathological urines containing albumin and one - two Bence Jones proteins prepared on three dialysis buffer lots and performed ten times. The % CV of protein fractionation of these samples with Total Proteins range of 40, 227, 237, 368, and 2327 mg/dL on the three dialysis buffer lots were as follows: lot #1: Albumin fraction % CV were from 3.0 – 8.7, and Gamma or Bence Jones protein fraction % CV were from 3.7 – 10.3; lot # 2: Albumin fraction % CV were from 1.9 – 15.4, and Gamma or Bence Jones protein fraction % CV were from 2.6 – 6.9; lot # 3: Albumin fraction % CV were from 3.7 – 12.2, and Gamma or Bence Jones protein fraction % CV were from 4.5 – 10.4.

b. *Linearity/assay reportable range:*

Not applicable.

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

Not applicable

d. *Detection limit:*

The detection limit was determined by testing serial two-fold dilutions prepared from one pathological urine sample containing a Bence Jones protein (at concentration about 0.34 g/L). It was diluted in normal urine and analyzed using the CAPILLARYS URINE procedure. The minimal detection limit of

the monoclonal component was about 2.0 mg/dL.

e. Analytical specificity:

There was no need to test drugs and salts interferences because these are eliminated during dialysis. However, hemoglobin is commonly known to co-migrate with transferrin if not removed by dialysis. Hemoglobin interference study was not evaluated for this assay. The Limitation section of the package insert states: “Hemoglobin is commonly known to co-migrate with transferrin when it is in the urine sample. It is advised to observe the urine sample features after the first centrifugation (5 000 rpm for 10 minutes) (e.g., signs of red blood cells and/ or hemolysis in the urine sample)”.

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

A total of 100 urine samples (65 were 24-hour collection samples and 35 random samples) were performed on CAPILLARYS SYSTEM and HYDRAGEL System. Eighty-one (81) were pathological urine samples and 19 were normal urine samples. The total protein concentrations ranged from 0.07 – 10.83 g/L. There was 100% qualitative agreement between the two methods.

The monoclonal proteins were qualitatively identified in the beta or gamma regions of the protein electrophoresis scans.

b. Matrix comparison:

Not applicable.

3. Clinical studies:

a. Clinical Sensitivity:

Not given.

b. Clinical specificity:

Not given.

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable.

4. Clinical cut-off:

Same as Expected values/Reference range.

5. Expected values/Reference range:

Absence of urine Bence Jones proteins.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.