

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE**

A. 510(k) Number:

k070757

B. Purpose for Submission:

New device

C. Measurand:

Total protein in urine

D. Type of Test:

Colorimetric assay

E. Applicant:

Pointe Scientific Inc

F. Proprietary and Established Names:

Microprotein reagent

Microprotein standard

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
JGP - Lowry (colorimetric), Total Protein	Class II, exempt meets limitations of exemptions	21 CFR 862.1635 Total Protein Test System 21CFR862.9 (c)(5)	75 Clinical Chemistry(CH)
Product Code	Classification	Regulation Section	Panel
JIX- Calibrator, Primary	Class II	21 CFR 862.1150 Calibrator	75 Clinical Chemistry(CH)

H. Intended Use:

1. Intended use(s):

See Indications for use below.

2. Indication(s) for use:

The Microprotein reagent set is intended to be used in a diagnostic laboratory setting by qualified laboratory technologists for the quantitative determination of Total Protein in human urine. It is for In Vitro diagnostic use only. The Microprotein Standard is intended to be used to calibrate the Microprotein assay. Increased amounts of protein in urine is used as an early indicator of renal damage in diabetes.

3. Special conditions for use statement(s):

For prescription use only

4. Special instrument requirements:

Assay performance was demonstrated on the Roche Hitachi 917 chemistry analyzer.

I. Device Description:

The Microprotein reagent set is supplied as a liquid, two reagent kit. Microprotein reagent contains buffer, Pyrogallol Red 0.067 mmol/L, Ammonium Molybdate 0.153 mmol/L, stabilizer, surfactants, and preservative. The second liquid, microprotein standard contains Albumin 50 mg/dL in saline. The reagent is supplied in 2 X 120 mL and standard in 1X 15 mL bottles.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Wako Autokit Micro TP

2. Predicate 510(k) number(s):

k920531

3. Comparison with predicate:

Characteristics	Microprotein Reagent Set (Proposed Device)	Wako, Autokit Micro TP Reagent (Predicate Device)
Intended Use	For the quantitative determination of total protein in urine.	Autokit Micro TP is a kit for measuring the total protein in the urine.
Reagent	Reagent: Pyrogallol Red 0.067 mmol/L, Ammonium Molybdate 0.153 mmol/L, Sodium Oxalate 3.433 mmol/L, Buffers, Surfactants and Preservatives. Standard: Bovine Albumin in a Saline solution, 50.0 mg/dl. Sodium Azide 0.1%.	Reagent: Glycine buffer solution 0.1 mol/L, Pyrogallol Red 0.067 mmol/L, Ammonium Molybdate 0.026 mmol/L, Surfactant. Standard: Total Protein 100 mg/dl (Human Serum Albumin)
Format	The product consists of 2 x 120 mL of a stable liquid reagent and 1 x 15 mL of aqueous (saline) based standard, 50 mg/dL.	Reagent is provided in 2x 230 ml of a stable liquid reagent and 1x5 ml 100 mg/dl standard
Stability	<ul style="list-style-type: none"> ● Reagent is stable until expiration date indicated on vial label when stored tightly capped at 2-8°C. ● Shelf life is 18 months when stored tightly capped at 2-8°C. ● Standard is stable until expiration date indicated on vial label when stored tightly capped at 2-8°C. 	<ul style="list-style-type: none"> ● Reagent is stable until expiration date indicated on vial label when stored tightly capped at 2-25°C. ● Shelf life not listed on insert. ● Standard is stable until expiration date indicated

	<ul style="list-style-type: none"> Shelf life is 24 months when stored tightly capped at 2-8°C. 	on vial label when stored tightly capped at 2-10°C. <ul style="list-style-type: none"> Shelf life information not listed on insert
Linearity / Assay range	2.0 – 250 mg/dL	up to 400 mg/dL
Low Limit of Detection	2.0 mg/dL	Not listed in insert.
Traceability of Calibration	The value assigned to the Microprotein standard is traceable to NIST Total Protein Standard Reference Material, SRM (Standard Reference Material) 927c. The Pointe Scientific, Inc. QA laboratory calibrates the Microprotein assay with a NIST traceable (SRM 927c) material and performs a minimum of two assay runs on the Microprotein standard generating a minimum of 14 data points. A mean is then determined and the % deviation should be less than or equal to 2.0 % of the target mean of 50.0 mg/dL.	Protein standard value verified using the kjeldahl method.

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

CLSI EP7-A: Evaluation CLSI EP7-A: Interference Testing in Clinical Chemistry; Approved Guideline.

L. Test Principle:

Microprotein Reagent is a quantitative colorimetric assay. Pyrogallol Red is mixed with Sodium Molybdate to form a complex at low pH. When this complex is combined with protein in the sample, it forms a blue-purple color complex. The increase in absorbance at 600 nm is measured and is directly proportional to the protein content in the sample.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

The precision was evaluated using 3 levels of VeriChem Linearity materials on the Hitachi 917 chemistry analyzer. Within-day precision was evaluated by running the two specimens in replicates of 20 on the same day. Run-to-run precision was evaluated by assaying the same control material in replicates of five over a three day period. The results are tabulated below.

Within-day Precision

Description	Control 1 (Low)	Control 2 (Mid)	Control 2 (High)
No. of data points	40	40	40
Mean (mg/dL)	8.7	121.8	240.3
SD (mmol/L)	0.7	2.1	1.7
CV (%)			

Run-to-Run Precision

Description	Control 1 (Low)	Control 2 (Mid)	Control 3 (High)
No. of data points	20	20	20
Mean (mmol/L)	10.2	127.0	242.5
SD (mmol/L)	0.9	1.6	2.4
CV (%)	8.6	1.2	1.0

b. Linearity/assay reportable range:

To determine the linearity range, the sponsor prepared 11 microprotein solutions through serial dilution of a 250 mg/dL stock standard. The samples ranged in concentration from 1.23 to 259.43 mg/dL. All eleven levels were run in duplicate on the Hitachi 917 analyzer. Based on the acceptance criteria of allowable systematic error of 10%, the reagent showed the assay is linear within the entire test range. Up to this level, the linear regression analysis demonstrated a linear regression equation, $Y=1.058X+0.12$. The assay range claimed by the sponsor is 2.0 to 250 mg/dL.

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

The value assigned to the Microprotein standard is traceable to NIST Total Protein Standard Reference Material, SRM927c. The Pointe Scientific, Inc. QA laboratory calibrates the Microprotein assay with a NIST traceable (SRM 927c) material and performs a minimum of two assay runs on the Microprotein standard generating a minimum of 14 data points. The value as assigned based on the mean value determined and to be acceptable, the deviation should be $\leq 2.0\%$ of the target mean of 50.0 mg/dL.

Reagent is stable until expiration date (shelf life is 18 months) indicated on vial label when stored tightly capped at 2-8°C. Standard is stable until expiration date (shelf life is 24 months) indicated on vial label when stored tightly capped at 2-8°C.

d. Detection limit:

To demonstrate the lower limit of detection, the lowest level (10 mg/dL) of Verichem Linearity set traceable to NIST Total Protein Standard Reference Material, SRM927c and a saline sample (0 mg/dL) were tested in five replicates using a Hitachi 917 analyzer. The sponsor defined the limit of blank sample as mean $\pm 2SD$, which was demonstrated to be 1.9322 mg/dL. Based on these results, the sponsor claimed lowest detection limit of the assay is 2.0 mg/dL.

e. *Analytical specificity:*

For evaluation of the interference, the sponsor used two levels of microprotein approximately, 10 and 130 mg/dL. Based on the sponsor-defined interference limit of $\pm 5\%$ of control, results indicated that there was no interference up to the concentrations of bilirubin up to 20.0 mg/dL and Ascorbic acid up to 3 mg/dL. However, hemoglobin being a protein, addition of hemoglobin increased the urine protein values. The sponsor recommends in the labeling that urine samples containing blood should not be tested. The pH variation (1.8 – 12.3) was found to have no effect on the total protein determination. The effects of specific gravity variation were not evaluated. The sponsor recommends not using urine specimens with added preservatives since some added preservatives such as HCL and Benzoic acid have been shown to interfere in the protein assay, giving low results. The sponsor states some drugs may interfere. A literature reference was provided. (Reference: Fujita, Y., Mori, I., Kitano, S., Bunseki Kagaku 32: E379-386, 1983).

f. *Assay cut-off:*

Not Applicable.

2. Comparison studies:

a. *Method comparison with predicate device:*

Performance of the Microprotein Reagent was compared with performance of the predicate device, Wako Autokit Micro TP (Wako Chemicals, USA, Inc.). The study was performed on Hitachi-917 chemistry analyzer using 45 human urine samples (range: 2.5 - 213.3 mg/dL) along with controls and linearity material. Results yielded a correlation coefficient of 0.9997 and a regression equation of $y=1.000x+0.83$.

b. *Matrix comparison:*

Microprotein Reagent is to be used with urine only.

3. Clinical studies:

a. *Clinical Sensitivity:*

Not Applicable.

b. *Clinical specificity:*

Not Applicable.

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

4. Clinical cut-off:

Not Applicable.

5. Expected values/Reference range*:

The expected values of microprotein are based on literature. However, the sponsor recommends in the labeling that each laboratory should confirm the validity of the interval ranges listed for the population it serves.

24-Hour Urinary Protein: 28 - 141 mg/day

Random Urine: <10 mg/dL

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.