510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE

A. 510(k) Number:
k042243

B. Purpose for Submission:
New Device

C. Analyte:
Albumin

D. Type of Test:
Quantitative

E. Applicant:
Diagnostic Chemicals Limited

F. Proprietary and Established Names:
Microalbumin Multi-Calibrator Set

G. Regulatory Information:

1. Regulation section:
   21 CFR 862.1150 Calibrator
2. Classification:
   II
3. Product Code:
   JIX
4. Panel:
   75

H. Intended Use:

1. Intended use(s):
   For IN VITRO diagnostic use as a calibrator for the DCL Microalbumin Assay for quantitation of albumin in human urine.

2. Indication(s) for use:
   For IN VITRO diagnostic use as a calibrator for the DCL Microalbumin Assay for quantitation of albumin in human urine.

3. Special condition for use statement(s):
   For Prescription Use Only

4. Special instrument Requirements:
   N/A

I. Device Description:

The Microalbumin Multi-Calibrator set contains 6 levels of 1 mL of liquid solutions corresponding to the following values: 1, 5, 10, 50, 100 and 300 mg/L. The human donor unit used to produce this control was tested by FDA accepted methods and found free of Hepatitis B Surface Antigen (HBsAG), antibody to Hepatitis C (HCV) and antibody to HIV.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Kamiya Biomedical Company Microalbumin Calibrator Set
2. Predicate K number(s):
   K991166
3. Comparison with predicate:

Similarities		
Item	**Device**	**Predicate**
Intended Use	For IN VITRO diagnostic use as a calibrator for the DCL Microalbumin Assay for quantitation of albumin in human urine.	The K-Assay microalbumin Calibrator Set is used for the calibration of the K-Assay Microalbumin immunoturbimetric assay for quantitating albumin in urine specimens.
Sample	Urine	Urine
Matrix	Liquid	Liquid

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

ICH Biocompatibility Guidance

L. Test Principle:

Not Applicable

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
   a. *Precision/Reproducibility:*
      Not Applicable
   b. *Linearity/assay reportable range:*
      Not Applicable
   c. *Traceability (controls, calibrators, or method):*
      Scripps Lab (Cat # A0213) Human Serum

      Stability

Once opened, the calibrators are stable for 30 days when stored at 2-8 °C. An accelerated study was conducted on the Microalbumin Calibrator set to support the shelf life of 12 months. An on-going real time study is being conducted and the Microalbumin Calibrator set is checked at its half life and at 13 months.

Value Assignment
An inhouse standard is used to prepare a calibration curve by diluting it to the desired concentrations. The values of the calibrator concentrations are assigned from multiple readings using DCL Microalbumin reagent on a Hitachi 717 or equivalent analyzer. The acceptable CV % for each sample is 3 percent. The recovery rate of each concentration of the diluted primary standard is 1.00 +/- 0.03. The calibrator lots are validated using the internal standard, serum with a known value, and the previous lot of calibrators. The new lot is acceptable if the sample results fall within 100 +/- 5% of their known values.

d. Detection limit:
N/A

e. Analytical specificity:
N/A

f. Assay cut-off:
N/A

2. Comparison studies:
   a. Method comparison with predicate device:
   N/A
   b. Matrix comparison:
   N/A

3. Clinical studies:
   a. Clinical sensitivity:
   N/A
   b. Clinical specificity:
   N/A
   c. Other clinical supportive data (when a and b are not applicable):
   N/A

4. Clinical cut-off:
   N/A

5. Expected values/Reference range:
   The concentrations of the calibrators in the Microalbumin Multi-Calibrator Set have lot specific values that range from 0 to 300 mg/L.

N. Conclusion:

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