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

**A. 510(k) Number:**

k111952

**B. Purpose for Submission:**

New Device

**C. Measurand:**

Calibrators for Folic Acid.

**D. Type of Test:**

Not Applicable.

**E. Applicant:**

Beckman Coulter, Inc.

**F. Proprietary and Established Names:**

Access Folate Calibrators.

**G. Regulatory Information:**

| Product Code | Classification | Regulation Section | Panel |
|---|---|---|---|
| JIT | Class II | 21 CFR § 862.1150, Calibrator | Clinical Chemistry (75) |

**H. Intended Use:**

1. Intended use(s):

   Please see intended use below.

2. Indication(s) for use:
   The Access Folate Calibrators are intended to calibrate the Access Folate assay for the quantitative determination of folic acid levels in human serum, plasma (heparin) and red blood cells using the Access Immunoassay Systems.

3. Special conditions for use statement(s):

   For prescription Use.

4. Special instrument requirements:

   To be used on the Access Immunoassay Systems.

## I. Device Description:

The Access Folate Calibrators are a six level calibrator set intended to calibrate the Access Folate assay for the quantitative determination of folic acid levels in human serum, plasma (heparin) and red blood cells using the Access Immunoassay System. The calibrator set provides calibrators at six levels – zero and approximately 1.2, 3.1, 6.2, 12.4 and 24.8 ng/mL (2.8, 7.0, 14.0, 28.1, and 56.2 nmol/L). The calibrators are contained in 4.0 mL vials. The calibrator vials are intended for storage at -20°C or colder.

Calibration cards are provided with each calibrator kit. Calibration cards contain bar codes that are encrypted with the individual calibrator concentrations for each calibrator level.

Folate Calibrator S0 is intended for use with Access Folate assay to dilute patient samples containing analyte concentrations greater than the analyte specific S5 calibrator. The Access Folate Calibrators are a buffered matrix with human serum albumin (HSA) surfactant, < 0.1% sodium azide, and 0.25% ProClin 300.

## J. Substantial Equivalence Information:

1. Predicate device name(s):

   Access Folate Calibrators

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

   k060774

3. Comparison with predicate:

| Attribute | Access Folate Calibrator (Candidate Device) | Access Folate Calibrator (Predicate - k060774) |
|---|---|---|
| Indication for use / Intended for Use | The Access Folate Calibrators are intended to calibrate the Access Folate assay for the quantitative determination of folic acid levels in human serum, plasma (heparin) and red blood cells using the Access Immunoassay Systems. | Same |
| Test System (Instrumentation / technology) | Access Immunoassay Systems | Same |
| Calibrators Antigen | Folate (pteroylmonoglutamic acid) in buffered matrix | Same |
| Calibrator Range | 0 – 25 ng/mL | 0 – 20 ng/mL |

| | | |
|---|---|---|
| Storage Temperature after opening | 2 - 10°C | Same |
| Shelf life | 6 months | 12 months |

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

ISO 14971:2007 Medical Devices - Application of risk management to medical devices.

WHO International Standard Vitamin B12 and Serum Folate; 03/178

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

Traceability
The Access Folate Calibrator (A98033) is traceable to the USP Folic Acid Reference Standard. The reference standard is rehydrated and used to prepare six predetermined concentrations which are then compared to the WHO International Standard 03/178.

Calibrator Value Assignment
For each calibrator level, multiple replicates of the reference calibrators and multiple replicates of the commercial calibrators are analyzed on multiple Access 2 analyzers. These values are then used to determine the commercial calibrator values.
A reference curve is then established using multiple Access Analyzers with a 95% confidence interval (CI).

Stability
Real time stability study protocols and acceptance criteria were described and found to be acceptable.

The claimed calibrators' stability is 7 months at -20ºC for unopened vials and at 2-10ºC 90 days when thawed.

*d. Detection limit:*

Not applicable.

*e. Analytical specificity:*

Not applicable.

*f. Assay cut-off:*

Not applicable.

2. Comparison studies:

*a. Method comparison with predicate device:*

Not applicable.

*b. Matrix comparison:*

Not applicable.

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):*

Not applicable.

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

| Level | Expected Values |
|---|---|
| Calibrator Level S0 | 0 ng/mL<br>0 nmol/L |
| Calibrator Level S1 | 1.2 ng/mL<br>2.8 nmol/L |
| Calibrator Level S2 | 3.1 ng/mL<br>7.0 nmol/L |
| Calibrator Level S3 | 6.2 ng/mL<br>14.0 nmol/L |
| Calibrator Level S4 | 12.4 ng/mL<br>28.1 nmol/L |
| Calibrator Level S5 | 24.8 ng/mL<br>56.2 nmol/L |
| Calibrator Range | 0 – 25 ng/mL |

**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.