

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

A. 510(k) Number: k042551

B. Purpose For Submission:

Premarket Notification (510(k)) of intention to manufacture and market the Wako Chemicals USA, Inc. Multi-Chem Calibrator A.

C. Analyte: Calcium, FE, UIBC, Inorganic Phosphorus, Magnesium

D. Type of Test: Not Applicable

E. Applicant: Wako Chemicals USA, Inc.

F. Proprietary and Established Names: Multi-Chem Calibrator A

G. Regulatory Information:

1. Regulation section: §862.1150, Calibrator, Multi-Analyte Mixture
2. Classification: Class II
3. Product Code: JIX
4. Panel: 75 (Chemistry)

H. Intended use(s):

1. Intended use(s)

The Multi-Chem Calibrator A is designed to be used with Wako's assays to determine the points of reference that are used in the determination of Calcium, FE, UIBC, Inorganic Phosphorus, and Magnesium in human serum.

2. Indication(s) for use:

The Multi-Chem Calibrator A is designed to be used with Wako's assays to determine the points of reference that are used in the determination of Calcium, FE, UIBC, Inorganic Phosphorus, and Magnesium in human serum.

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

4. Special instrument Requirements: Not Applicable

I. Device Description:

The Multi-Chem Calibrator A is liquid and ready to use. It consists of 4 x 5 mL bottles of aqueous solution containing Calcium, FE, UIBC, Inorganic Phosphorus, and Magnesium. This solution is stable until the date printed on the label when stored as directed. Calibrator traceability was stated as certified by the Japan Calibration Service System (JCSS).

J. Substantial Equivalence Information:

1. Predicate device name(s): Wako's Calcium, Fe, UIBC, Inorganic Phosphorus and Magnesium Standards.
2. Predicate K number(s): k872051, k984119, k871764, k871762
3. Comparison with Predicate:

	Multi-Chem Calibrator A	Calcium	Fe	UIBC	Inorganic Phosphorus	Magnesium
<u>Format</u>	Liquid	Liquid	Liquid	Liquid	Liquid	Liquid
<u>Constituents</u>	Ammonium iron (II) Sulfate 0.0017% Calcium Carbonate 2.5 mmol/L Magnesium Chloride 2.1 mmol/L Potassium Dihydrogen Phosphate 3.2 mmol/L Sodium Benzoate 0.1% Aqueous Solution	Calcium Carbonate 2.5 mmol/L	Iron Sulfate 0.0017%	Iron Sulfate 0.0017%	Potassium Phosphate 3.2 mmol/L	Magnesium 2.1 mmol/L
<u>Storage</u>	2-10° C	2-10° C	2-10° C	2-10° C	2-10° C	2-10° C
<u>510(K) #</u>	k042551	k872051	k984119	k984119	k871764	K871762

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

Calibrator traceability was stated as certified by the Japan Calibration Service System (JCSS).

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):*

The Waco Multi-Chem Calibrator is traceable to the following referenced standards:

Primary Standard

Item	Primary Standard or Method
Ca:	Calcium Standard Solution (Ca 1000)
Fe:	Iron Standard Solution (Fe 1000)
Phos:	Phosphate Ion Standard Solution (PO ₄ ³⁻ 1000)
Mg:	Magnesium Standard Solution (Mg 1000)

Multi Chem Calibrator A

Item	Assigned Value	Method
Ca:	10 mg/dL	Assayed by 0-cresolphthalein complexone method
Fe:	200 µg/dL	Assayed by bathophenanthroline direct method
Phos:	10 mg/dL	Assayed by molybdate direct method
Mg:	5 mg/dL	Assayed by enzymatic method

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:*

The Multi-Chem Calibrator A is designed to be used with Wako's assays to determine the points of reference that are used in the determination of Calcium, FE, UIBC, Inorganic Phosphorus, and Magnesium in human serum.

The safety and effectiveness of the Multi-Chem Calibrator A is demonstrated by its substantial equivalence to Wako's Calcium, Fe, UIBC, Inorganic Phosphorus and Magnesium Standards. The calibration materials are used to calibrate instruments to determine the points of reference. The following are results of the comparison studies against the predicates:

Calcium (Calcium-HR2 reagent)

	n	80
	Correlation coefficient	0.9997
	Slope	1.0065
	Intercept	-0.0187

Fe (L-type Fe reagent)

	n	70
	Correlation coefficient	0.9998
	Slope	0.9931
	Intercept	-0.0304

UIBC (L-type UIBC reagent)

	n	60
	Correlation coefficient	0.9990
	Slope	1.0021
	Intercept	-0.6674

Phosphorus (phosphorus-HR2 reagent)

	n	80
	Correlation coefficient	0.9997
	Slope	1.0043
	Intercept	0.0059

Phosphorus (phosphorus-HA reagent)

	n	80
	Correlation coefficient	0.9998
	Slope	1.0068
	Intercept	-0.0124

Magnesium (phosphorus-HR2 reagent)

	n	80
	Correlation coefficient	0.9993
	Slope	0.9717
	Intercept	-0.0159

3. Clinical studies:a. *Clinical sensitivity:*

Clinical studies are not typically submitted for this device type.

b. *Clinical specificity:*

Clinical studies are not typically submitted for this device type.

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

Not applicable

4. Clinical cut-off: Not applicable5. Expected values/Reference range:**Multi Chem Calibrator A**

Item	Assigned Value	Method
Ca:	10 mg/dL	Assayed by 0-cresolphthalein complexone method
Fe:	200 µg/dL	Assayed by bathophenanthroline direct method
Phos:	10 mg/dL	Assayed by molybdate direct method
Mg:	5 mg/dL	Assayed by enzymatic method

N. Conclusion:

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