

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

A. 510(k) Number:

k040226

B. Analyte:

Prealbumin

C. Type of Test:

Calibrators and quality control material for quantitative Prealbumin immunoturbidometric assay

D. Applicant:

Wako Chemicals, USA, Inc.

E. Proprietary and Established Names:

Prealbumin Calibrator Set

Prealbumin Control Set

F. Regulatory Information:

1. Regulation section:
21 CFR § 862.1150, Calibrator
862.1660, Quality control material (assayed and unassayed)
2. Classification:
Class II, Class I
3. Product Code:
JIT, Calibrator, secondary
JJX, Single (specified) analyte controls (assayed and unassayed)
4. Panel:
Clinical Chemistry (75)

G. Intended Use:

1. Intended Use:

The Wako Prealbumin Calibrator Set is intended to be used in the Wako Prealbumin test system to establish points of reference that are to be used in determination of values in the measurement of prealbumin in human serum or plasma.

The Wako Prealbumin Control Set is intended to be used in the Wako Prealbumin Test System to estimate test precision and detect systematic analytical deviations that may arise from reagent or analytical instrument variation.

2. Indication(s) for use:
See intended use.
3. Special condition for use statement(s):
The assay to be calibrated is for prescription use only
4. Special instrument Requirements:
Not applicable

H. Device Description:

The Wako Prealbumin Calibrator set consists of 5 levels of calibration material. The calibrators are provided ready-to-use. The prealbumin control set consists of 2 ready-to-use levels of quality control material.

I. Substantial Equivalence Information:

1. Predicate device name(s):
Wako Lipase Calibrator
Wako Complement Control
2. Predicate k number(s):
k001002
k960874
3. Comparison with predicate:

Calibrator Set:

Similarities		
Item	Device	Predicate
Intended use	Calibration for prealbumin testing	Calibration for Lipase testing
Differences		
Item	Device	Predicate
Levels	5 levels	Single level
Form provided	Liquid	lyophilized

Control Set:

Similarities		
Item	Device	Predicate
Intended use	Quality control for prealbumin assay	Quality control for complement activity
Matrix	Human serum	Human serum
Levels	2 levels	2 levels
Differences		
Item	Device	Predicate
Form provided	Liquid	lyophilized

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

None referenced

K. Test Principle:

Not applicable. This review concerns calibrators and controls for a Class I exempt device.

L. 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 Wako prealbumin calibrators are prepared gravimetrically by adding human prealbumin to a human serum matrix to the following targeted values: 5, 10, 20, 40, and 60 mg/dL prealbumin. The calibrators are traceable to an internal primary standard which is traceable to the CRM470 standard. Values are verified by multiple replicate testing on a Hitachi 917s analyzer.

The Wako prealbumin controls are prepared gravimetrically by adding human prealbumin to a human serum matrix to the following targeted ranges: 10-20 mg/dL prealbumin and 35-45 mg/dL prealbumin. The controls are traceable to an internal primary standard which is traceable to the CRM470 standard. Values are verified by replicate testing (n=21) on a Hitachi 917s analyzer.

Real time, open vial stability studies are described and support the manufacturer's stability claim.

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:
Not applicable.

M. Conclusion:

I recommend that the Wako Prealbumin Calibrator Set and the Wako Prealbumin Control Set are substantially equivalent to the legally marketed predicate devices.