

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY**

A. 510(k) Number:

k062379

B. Purpose for Submission:

New device

C. Measurand:

Assayed control for prealbumin and ceruloplasmin assays.

D. Type of Test:

Not applicable.

E. Applicant:

Roche Diagnostics Corp.

F. Proprietary and Established Names:

Prealbumin/Ceruloplasmin Control Set (Precinorm/Precipath PC)

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
JJY	Class I	21 CFR 862.1660	Chemistry (75)

H. Intended Use:

1. Intended use(s):

Prealbumin/Ceruloplasmin Control Set (Precinorm/Precipath PC) is used for quality control by monitoring accuracy and precision for the quantitative methods as specified in the enclosed value sheet.

2. Indication(s) for use:

Prealbumin/Ceruloplasmin Control Set (Precinorm/Precipath PC) is used for quality control by monitoring accuracy and precision for the quantitative methods as specified in the enclosed value sheet.

3. Special conditions for use statement(s):

Prescription use

4. Special instrument requirements:

COBAS INTEGRA and Roche/Hitachi family of analyzers.

I. Device Description:

The Prealbumin/Ceruloplasmin Control Set (Precinorm/Precipath PC) is a lyophilized control based on human serum. The adjusted concentrations of the control components are usually in the normal range or at the normal/pathological threshold. Each Precinorm/Precipath PC Control Set contains 3 bottles of controls (a 1.0 ml fill volume per bottle) at Levels I, and II. Individual donors units were tested by FDA approved methods for HBsAg, HCV and HIV and found to be nonreactive.

J. Substantial Equivalence Information:

Predicate	K040280 Precinorm PUC
Describe the item being compared	
Prealbumin/Ceruloplasmin Control Set (Precinorm/Precipath PC) is used for quality control by monitoring accuracy and precision for the quantitative methods as specified in the enclosed value sheet.	

Similarities		
Item	New Device	Predicate
Intended Use	Prealbumin/Ceruloplasmin Control Set (Precinorm/Precipath PC) is used for quality control by monitoring accuracy and precision for the quantitative methods as specified in the enclosed value sheet	Precinorm PUC (Proteins in Urine/CSF) is for use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the enclosed value sheet

Differences		
Item	New Device	Predicate
Matrix	Human serum based	Buffered aqueous solution
Format	Lyophilized	Liquid, ready to use
Handling	Reconstitute with exactly 1.0 mL of distilled water and allow to stand closed for 30 minutes to reconstitute, and then mix gently.	Ready to use.

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

GUIDANCE			
Document Title	Office	Division	Web Page
Points to Consider Guidance Document on Assayed and Unassayed Quality Control Material; Draft	OIVD		http://www.fda.gov/cdrh/ode/99.html

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):*
The Precinorm/Precipath Control Set products are assayed and traceable to the Institute for Reference Methods and Materials (IRMM). Values are assigned at three internal laboratories using the COBAS Integra and Roche Hitachi c systems. Each laboratory runs at least three independent series of analyses on each instrument for each analyte. Each sample is tested in singleton. The target value is then calculated as the median of the determined values. The following tables list lot-specific target values and ranges.

Precinorm PC	Target value Roche/Hitachi systems	Target Value COBAS INTEGRA systems
Ceruloplasmin	21.7-35.5 mg/dL	21.3-34.5 mg/dL
Prealbumin	16.9-27.7 mg/dL	16.6-26.8 mg/dL

Precipath	Target value Roche/Hitachi systems	Target Value COBAS INTEGRA systems
Ceruloplasmin	49.0-80.2 mg/dL	51.7-84.1
Prealbumin	39.6-64.8 mg/dL	40.6-66.4

The unopened products are stable for 18 months when stored at 2 to 8 °C. The following table lists the reconstituted products stability:

Temperature	Stability
15 - 25°C	up to 8 hours
2 - 8°C	2 days
-15 to -25°C	2 weeks, freeze only once

Protocols and acceptance criteria for stability testing were described and found to be acceptable.

- 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

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.