

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

A. 510(k) Number:

k081533

B. Purpose for Submission:

New device

C. Measurand:

Plasmaproteins - Ceruloplasmin, Kappa light chains, Lambda light chains, Transferrin, Alpha 1-Acid Glycoprotein, Alpha 1-Antitrypsin, Haptoglobin, Immunoglobulin A, Immunoglobulin G and Immunoglobulin M

D. Type of Test:

Calibrator, Multi-Analyte

E. Applicant:

SENTINEL CH. SPA

F. Proprietary and Established Names:

Sentinel Plasmaproteins Cal 3x

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
JIX -Calibrator	Class II	862.1150	75, Chemistry

H. Intended Use:

1. Intended use(s):

Sentinel Plasmaproteins Cal 3x must only be used for the calibration of plasmaprotein tests with the immunoturbidimetric methods.

2. Indication(s) for use:

Clinical Chemistry – The Sentinel Plasaproteins Cal 3x is a device intended for medical purposes for use in Ceruloplasmin, Kappa light chains, Lambda light chains, Transferrin, Alpha 1-Acid Glycoprotein, Alpha 1-Antitrypsin, Haptoglobin, Immunoglobulin A, Immunoglobulin G and Immunoglobulin M assays, to establish points of reference that are used in the determination of values in the measurement of Ceruloplasmin, Kappa light chains, Lambda light chains, Transferrin, Alpha 1-Acid Glycoprotein, Alpha 1-Antitrypsin, Haptoglobin, Immunoglobulin A, Immunoglobulin G and Immunoglobulin M in human serum and plasma.

3. Special conditions for use statement(s):

For Prescription Use Only

4. Special instrument requirements:

Automated, semi-automated and manual clinical chemistry systems using immunoturbidimetric methods.

I. Device Description:

The Sentinel Plasmaprotein Cal 3x is a liquid, ready-to-use calibrator prepared from plasmatic plasmaproteins in human-based serum. It consists of 4 x 1 mL bottles of aqueous material containing Ceruloplasmin, Kappa light chains, Lambda light chains, Transferrin, Alpha 1-Acid Glycoprotein, Alpha 1-Antitrypsin, Haptoglobin, Immunoglobulin A, Immunoglobulin G and Immunoglobulin M in human serum matrix.

Human source material was tested and found negative for HIV 1 and 2, HBV and HCV using FDA approved methods.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Calibrator for Automated Systems (C.f.a.s.) Proteins, Roche Diagnostics Corp.
Plasmaproteins Cal 3x, SENTINEL CH. SPA

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

k011226 and k051457 respectively

3. Comparison with predicate:

Similarities/Differences			
Item	Roche k011226	Plasmaprotein Cal 3x k051457	Device
Intended use	Must be used only for the calibration of plasmaprotein tests with immunoturbidimetric methods.	Same	Same
Storage	2-8° C	Same	Same
Standardization	ERM-DA 470 (CRM-470)	Same	Same
Matrix	Liquid- ready-to-use	Same	Same
Constituents	Ceruloplasmin, C-Reactive Protein, Immunoglobulin A, Immunoglobulin G and Immunoglobulin M, Transferrin, Haptoglobin, Alpha 1-Antitrypsin, C3c, C4, Prealbumin and Ferritin	Ceruloplasmin, Kappa light chains and Lambda light chains	Ceruloplasmin, Kappa light chains, Lambda light chains, Transferrin, Alpha 1-Acid Glycoprotein, Alpha 1-Antitrypsin, Haptoglobin, Immunoglobulin A, Immunoglobulin G and Immunoglobulin M

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

Guidance for Industry – Abbreviated 510(k) Submissions for In Vitro Calibrators, dated February 22, 1999

The New Paradigm, Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications. Dated March 20, 1998

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 calibrator is traceable to CRM 470 (Certified Reference Material) renamed ERM-DA 470 (European Reference Material).

Stability:

Real time stability studies have been conducted. Protocols and acceptance criteria were described and found to be acceptable. The manufacturer claims the following:

Un-open calibrator has an expiration date of 24 months when stored at 2-8° C.

Open calibrator has an expiration date of 6 weeks when stored at 2-8° C.

Value Assignment:

The value assigned to each plasmaprotein is specific for each lot and is determined by calculating the mean of the results obtained in multiple determinations for multiple instruments.

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.