

**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.