

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

A. 510(k) Number:

k040245

B. Analyte:

Prealbumin, Anti-streptolysin O (ASLO), and Ceruloplasmin

C. Type of Test:

Calibrator, Multi-Analyte Mixture

D. Applicant:

Roche Diagnostics

E. Proprietary and Established Names:

Calibrator for Automated Systems Prealbumin-ASLO-Ceruloplasmin (C.f.a.s. PAC)

F. Regulatory Information:

1. Regulation section:
21 CFR 862.1150
2. Classification:
Class II
3. Product Code:
JIX
4. Panel:
Chemistry (75)

G. Intended Use:

1. Intended use(s):
“The C.f.a.s. PAC is intended for use in the calibration of quantitative Roche methods on Roche clinical chemistry analyzers as specified in the enclosed value sheet.”
2. Special condition for use statement(s):
None noted.
3. Special instrument Requirements:
Roche/Hitachi analyzers, Roche/Hitachi MODULAR analyzers, and COBRAS INTEGRA analyzers.

H. Device Description:

The C.f.a.s PAC is a lyophilized product consisting of human serum with biological materials added as required to obtain desired component levels. Values for constituent analytes are provided in the product labeling.

I. Substantial Equivalence Information:

1. Predicate device name(s):
Calibrator for Automated Systems Lipids
2. Predicate K number(s):
k011658
3. Comparison with predicate:
Both products have the same intended use, are single level products used on the Roche clinical chemistry analyzers, are lyophilized, based on a human serum matrix, are handled the same way. They measure different analytes and the predicate is stable slightly longer after reconstitution.

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

See traceability below.

K. Test Principle:

Not applicable.

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):*
Traceability: The sponsor maintains a set of master calibrators for each assay that are traceable to various 'gold' standards. In this case, prealbumin and ceruloplasmin values are traceable to European Communities' CRM 470. ASLO is traceable to an internal reference standard.

Value Assignment: Seven external laboratories run five independent series that includes full calibration with a new master calibrator and uses needing assignment as sample vials. Following outlier detection, the median is assigned as the target value.

Stability: Real-time stability testing (2-8°C for 20 months) and accelerated stability testing (storage at 35°C for 3 weeks) demonstrated that lyophilized C.f.a.s. is stable throughout the testing period. Claimed stability is 18 months. Testing of reconstituted samples indicates that the product is stable 8 hours at 15 to 25°C, 2 days at 2 to 8°C, and 2 weeks at -25 to -15°C. In all studies, the acceptance criterion was recovery of 90-110% of the reference value.

- 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:

Representative target values

Analyte	Target Value Hitachi Systems	Target Value COBRAS Integra
Prealbumin	34.0 mg/dL	35.2 mg/dL
ASLO	163 IU/mL	164 IU/mL
Ceruloplasmin	39.7 mg/dL	41.2 mg/dL

M. Conclusion:

I recommend that the Calibrator for Automated Systems Prealbumin-ASLO-Ceruloplasmin (C.f.a.s. PAC) be found substantially equivalent to the predicate.