

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

**A. 510(k) Number:**

K040264

**B. Analyte:**

Albumin, Total Protein, Urine/CSF (U/CSF) Protein

**C. Type of Test:**

Calibrator, Multi-Analyte Mixture

**D. Applicant:**

Roche Diagnostics

**E. Proprietary and Established Names:**

Calibrator for Automated Systems Proteins in Urine/CSF (C.f.a.s. PUC)

**F. Regulatory Information:**

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

**G. Intended Use:**

1. Indication(s) for use:  
“C.f.a.s. (Calibrator for automated systems) PUC (Proteins in Urine/CSF) is 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 systems (for albumin and U/CSF protein) and Cobas Integra (for total U/CSF protein)

**H. Device Description:**

C.f.a.s. PUC is a liquid single-level calibrator consisting of a buffered aqueous matrix with added calibrator components to ensure optimal concentration. Albumin is detected immunoturbidimetrically, while total protein and U/CSF protein are detected turbidimetrically.

**I. Substantial Equivalence Information:**

1. Predicate device name(s):  
Calibrator for Automated Systems (C.f.a.s.) Proteins
2. Predicate K number(s):  
K011226
3. Comparison with predicate:  
Both devices are liquid, single-level calibrators. They have the same intended use and stability. They contain different analytes, and the predicate is based on stabilized human serum while the C.f.a.s. PUC is based on a buffered aqueous solution containing both human and ovine serum components.

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

See L.1.c 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 with albumin levels traceable to European Communities' CRM 470, and total protein and U/CSF protein levels traceable to a NIST primary bovine serum albumin standard.

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

Stability: Both real-time stability studies (C.f.a.s. PUC stored at 2-8°C for 18 months) and an accelerated stability study (C.f.a.s. PUC stored at 35°C for 14 days) support a claim that unopened C.f.a.s. PUC is stable for 18 months. Open-vial stability studies support a claim that C.f.a.s. PUC is stable up to 4 weeks at 4°C. In all studies the acceptance criteria was a mean recovery of 90-110% of the reference (i.e. Day 0) material that was stored at -80°C.

- 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:

#### Values of One Representative Lot

Analyte	Calibration Value (mg/L)	
	HITACHI Systems	COBAS Integra
Albumin	441	N/A
Total Protein	N/A	2080
U/CSF Protein	2080	N/A

#### M. Conclusion:

I recommend that the Calibrator for Automated Systems Proteins in Urine/CSF (C.f.a.s. PUC) be found substantially equivalent to the predicate.