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

A. 510(k) Number:
k040280

B. Analyte:
Multi-analyte Controls assayed and unassayed (proteins in urine/csf)

C. Type of Test:
Not Applicable

D. Applicant:
ROCHE DIAGNOSTICS CORP.

E. Proprietary and Established Names:
Precinorm proteins in urine/csf and Precipath proteins in urine/csf controls

F. Regulatory Information:

1. Regulation section:
   21CFR §862.1660 -Quality control material (assayed and unassayed).
2. Classification:
   Class 1
3. Product Code:
   JJY
4. Panel:
   Chemistry (75)

G. Intended Use:

1. Indication(s) for use:
   The Precinorm PUC (Proteins in Urine/CSF) is for the use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the enclosed value sheet.

   The Precipath PUC (Proteins in Urine/CSF) is for the use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the enclosed value sheet.

2. Special condition for use statement(s):
   Prescription use

3. Special instrument Requirements:
   For use on the Roche Hitachi and Cobas family of analyzers.

H. Device Description:

The Precinorm PUC and Precipath PUC controls consist of a buffered aqueous solution with biological materials added as required to obtain desired component levies in either the normal or pathological range. Values for constituent analytes are provided in product labeling.

I. Substantial Equivalence Information:

1. Predicate device name(s):
   Precinorm protein precipath protein controls

2. Predicate K number(s):
   k981401
3. Comparison with predicate:

Similarities		
Item	**Device**	**Predicate**
Stability	Same	Unopened: 2-8 ^{o}C until expiration date Opened: stable for 4 weeks at 2-8 ^{o}C
Format	Same	Liquid ready-for use
Range	Same	Adjusted to represent normal and pathological ranges
Differences		
Item	**Device**	**Predicate**
Intended Use	For QC monitoring of specified quantitative methods	For QC monitoring of quantitative methods on both manual techniques and for assay on automated clinical analyzers
Matrix	Buffered aqueous solution	Stabilized human serum
Analytes	Albumin Creatinine Total Protein Urine/CSF Protein	Alph1-acid glycoprotein Albumin Alpha1-anittrypsin Antistreptolysin O C3c C4 Ceruloplasmin C-Reactive Protein Ferritin Haptoglobin IgA IgG IgM

		Prealbumin Total Protein Transferrin

J. Standard/Guidance Document Referenced (if applicable):
None Referenced

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):*
    The value assignment takes place in seven external laboratories. Each laboratory runs 5 independent series. An independent series includes full calibration using a new calibrator vial and sample vial. After outlier deletion the median is used as setpoint. Controls which have to be assigned are used as samples. The master calibrator is used for calibration.

    Along with value assignment, two additional samples are used for trend control. Both are processed control materials using the same or comparable matrix as the assigned control. If one of the trend controls is out of the defined ranges, a check of the reference standardization is initiated.
    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:*
    N/A
    b. *Matrix comparison:*
    Not Applicable
3. Clinical studies:
    a. *Clinical sensitivity:*
    Not Applicable
    b. *Clinical specificity:*
    Not Applicable
4. Clinical cut-off:

Not Applicable

5. Expected values/Reference range:
   Not Applicable

M. Conclusion:

The information and data provided by ROCHE DIAGNOSTICS CORP. supports a Substantial Equivalence (SE) determination of Precinorm proteins in urine/csf and Precipath proteins in urine/csf controls to other multi-analyte controls, all kinds (assayed and unassayed) regulated under 21 CFR §862.1660 - Quality control material (assayed and unassayed).