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

A. 510(k) Number:

k102016

B. Purpose for Submission:

New device

C. Measurand:

Multiple constituents listed in the package insert

D. Type of Test:

Multi-analyte control materials

E. Applicant:

Roche Diagnostics

F. Proprietary and Established Names:

PreciControl ClinChem Multi 1 and 2

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
JJY	Class 1, reserved	21 CFR 862.1660	(75) Chemistry

H. Intended Use:

1. Intended use(s):

   See indications for use below.

2. Indication(s) for use:

PreciControl ClinChem Multi 1 and 2 are for use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the value sheets.

3. Special conditions for use statement(s):

For prescription use only

4. Special instrument requirements:

The assays were run on modular P, cobas c 510 and Integra analyzers

I. Device Description:

The PreciControl ClinChem Multi 1 and 2 consist of lyophilized human sera with constituents added as required to obtain desired component levels. Concentrations of the components in the controls have been adjusted to represent normal and pathological levels. The concentrations of the components in the controls are lot-specific.

All products derived from human blood are prepared exclusively from the blood of donors tested individually and shown to be free from HBsAg and antibodies to HCV and HIV. The testing methods applied were FDA-approved

J. Substantial Equivalence Information:

1. Predicate device name:

Precinorm U plus and Precipath U plus controls

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

k042389

3. Comparison with predicate:

Similarities

Characteristic	**PreciControl ClinChem Multi 1 and 2 controls**	**Precinorm U plus and Precipath U plus controls (K042389)**
Intended Use	Same	For use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the value sheets.

Format	Same	Precinorm U plus and Precipath U plus are lyophilized controls based on human serum. The adjusted concentrations and activities of the control components are usually in the normal and pathological ranges.
Stability	• Same • Same *Exceptions stated for total bilirubin, direct bilirubin, UIBC, and ALT	• Unopened: Stable at 2-8°C until expiration date. • Stability of components after reconstitution*: at 15–25 °C 12 hours at 2–8 °C 5 days at (-15)–(-25) °C 4 weeks (when frozen once) *Exceptions stated for total bilirubin, direct bilirubin and Bicarbonate
Traceability	Same	Traceability of the target values is given in the respective instructions for use of the system reagents.
Value Assignment	Same	Traceable through Master lot to standard or reference method

Differences : The PreciControl ClinChem Multi 1 and 2 controls(candidate device) and Precinorm U plus and Precipath U plus controls(predicate) differ only in the constituent analytes.

The following table gives a list of the constituent analytes included in each test system

PreciControl ClinChem Multi 1 and 2 controls	**Precinorm U plus and Precipath U plus controls (k042389)**

Same	Alanine aminotransferase, Albumin, Alkaline phosphatase, Amylase, Amylase pancreatic, Aspartate aminotransferase, Bilirubin direct, Bilirubin total, Calcium, Chloride, Cholesterol, Cholinesterase, Creatine kinase, Creatinine, Glucose, gamma Glutamyltransferase, Iron, Lactate, Lactate dehydrogenase, Lipase, Lithium, Magnesium, Phosphate, Potassium, Sodium, Total protein, Triglycerides, Unsaturated iron -binding capacity, Urea, Uric acid
Not included	Acid phosphatase, Aldolase, Bicarbonate, Copper, Digoxin, Glutamate dehydrogenase, alpha Hydroxybutyrate dehydrogenase, Leucine aminopeptidase, Phospholipids, Thyroxine, T-uptake
alpha 1 Acid glycoprotein, Antistreptolysin O, alpha 1 Antitrypsin, Apolipoprotein A1, Apolipoprotein B, C Reactive protein, Ceruloplasmin, Complement C3c, Complement C4, Creatine kinase MB, HDL-Cholesterol, Haptoglobin, Immunoglobulin A, Immunoglobulin G, Immunoglobulin M, LDL-Cholesterol, Prealbumin, Transferrin, Ferritin	Not included

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

Guidance for Industry and FDA Staff - Assayed and Unassayed Quality Control Material

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):

Value Assignment:

The value assignments for each lot of control are performed using three analyzers (modular P, cobas c 501 and integra) from each analyzer family Integra/c111 and Hitachi/cobas. Full calibration using a master calibrator and at least three separate runs were performed on each analyzer. Each run used one or more replicates of the control as sample for each assay being assigned. The mean of all the runs was calculated for each assay and was used as the assigned control target value. The corresponding control range is calculated as the target value ± 3 standard deviations (with the standard deviation being the value obtained from several target value determinations).

The concentrations and activities of the components are lot-specific. The exact target values are given in the value sheets provided with the finished device or electronically at the sponsor's website.

Traceability:

Roche Diagnostics maintains a set of Roche master calibrators for each assay that have values assigned that are traceable to the various standards, or in-house developed standards.
Traceability of the target values is given in the respective instructions for use of the system reagents.

Stability:

The shelf-life was 25 months at 2-8 ^{o}C (closed vial) and 16 hours at 25 ^{o}C, 6 days at 4 ^{o}C and 29 days at -20 ^{o}C (open vial/accelerated stability) were demonstrated through the following studies by the sponsor to support the stability claims stated in the labeling.

Closed Vial Stability (Real-time/Shelf-life stability)

PCCC1 and PCCC2 are stored at 2-8°C for 25 months. After 25 months, three replicates of test lot material are analyzed and the average value of % analyte recovery was compared to the reference material (stored at -80 °C and fresh reconstituted). Percent recovery was also measured with at least two intermittent time periods, prior to 25 months. The data supports the shelf life claim 24 months at normal storage conditions of 2-8 °C.

Opened Vial Stability

Data support that samples stored at 2-8 °C for 25 months then keptfor 5 days at 35°C and reconstituted according to the package insert directions and stored (at 15 – 25 °C for 16 hours; at 2-8°C for 6 days and at (-15) – (-25)°C for 29 days) were stable. Three replicates of test lot materials are analyzed and the average values for % analyte recovery was compared to the reference material (fresh reconstituted PCCC1 and PCCC2). These data respectively support the package insert claim of stability of the product at 15–25 °C 12 hours, at 2–8 °C 5 days and at (-15)–(-25) °C 28 days (when frozen once)

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:

Specific values for each lot are stated in the labeling

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.