

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

A. 510(k) Number:

k053153

B. Purpose for Submission:

New device

C. Measurand:

Calibrator for Albumin, Alkaline Phosphatase, ALT (GPT), Amylase Pancreatic, Amylase Total, Acid Phosphatase (non-prostatic, Prostatic and Total), AST (GOT), Bile Acids, Bicarbonate, Bilirubin Direct, Bilirubin Total, Calcium, Cholesterol, Chloride, Cholinesterase, CK Total, Copper, Creatinine, D-3-Hydroxybutyrate, Gamma-GT, Glutamate Dehydrogenase (GLDH), Glucose, Alpha Hydroxybutyrate Dehydrogenase (α -HBDH), Iron, Lactate, Leucine Aminopeptidase (LAP), LD (LDH), Lipase, Lithium, Magnesium, Osmolality, Phosphate Inorganic, Potassium, Protein Total, Sodium, TIBC, Triglycerides, Uric Acid (Urate), Urea and Zinc

D. Type of Test:

Calibrator, Multi-Analyte Mixture

E. Applicant:

Randox Laboratories

F. Proprietary and Established Names:

Randox Calibration Serum

G. Regulatory Information:

1. Regulation section:

21 CFR §862.1150, Calibrator

2. Classification:

Class II

3. Product code:

JIX

4. Panel:

75, Chemistry

H. Intended Use:

1. Intended use(s):

See indications for use

2. Indication(s) for use:

This is an in vitro diagnostic product intended for use as a calibration serum in clinical chemistry assays. Randox calibration sera contain 42 analytes and are based on lyophilized human serum. The concentrations and activities are suitable for calibration of clinical chemistry assays both manually and on a wide range of automatic analyzers. Constituent concentrations are available at 2 levels.

3. Special conditions for use statement(s):

For Prescription Use Only

4. Special instrument requirements:

Not applicable

I. Device Description:

The Randox Calibration Serum is a two level lyophilized calibrator prepared with human serum. The product consists of 20x5 mL bottles for each calibrator level. The concentrations are suitable for calibration of multiple chemistry assays on a wide range of automatic analyzers.

All human source material was tested and found negative by FDA approved methods for , HBsAG, HCV and HIV-1/2.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Calibrator for Automated Systems, Roche Diagnostics Corp.

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

k990460

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended use	For calibration of chemistry tests	For calibration of chemistry tests
Matrix	Lyophilized, Human serum	Lyophilized, Human serum

Differences		
Item	Device	Predicate
Reconstituted Stability	8 hours at +25°C, 7days at +4°C and 1 month at -20°C	15-25°C 8 hours, 2 days at 2-8°C and 2 weeks at -15-(-25) °C

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

None referenced

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):*

The calibrator is prepared by adding prepared stock solutions to the base material to give concentrations within approved ranges. Value assignment is done by two methods. The first involves distributing each batch serum to approximately 3000 laboratories worldwide which use reference methods. The consensus mean target values are verified against a master lot of calibrator which has values that are traceable to reference methods or reference materials. The second is done in-house by taking duplicate samples from each of 5 vials of test calibrator, master lot of calibrator, and 2 lots of released QC material, reconstituting them, and testing them for each analyte. The mean analyte values are calculated using the master lot of calibrator and target values are assigned. Acceptance criterion each control must be within $\pm 5\%$ from the previous control. The calibration values for each instrument have been determined in at least 10 independent laboratories.

Stability:

Shelf-life stability was established by taking a set of stored calibrators (2-8 °C and -80 °C) and reconstituting and assaying them at 6, 12, 18, 24, 30, 36, 42 and 48 months. The sponsor's acceptance criteria were that a percentage change should be within $\pm 5\%$ for all analytes except Bicarbonate, ALP and Total/Prostatic Acid Phosphatase (10%), AST and ALT (7%). Closed vial stability is 3 years stored at 2-8 °C.

Open vial stability was established by running reconstituted calibrators at the following temperature and time periods; +25°C 8 hours, +4°C 4 days, +4°C 7 days, -20°C 1 month. Results of the open vials are compared to freshly reconstituted calibrator. Depending on the analyte, the sponsor's acceptance criteria were that values must be within 3% -20%. Open vial is 8 hours at 25°C, 7 days at 4°C and 1 month at -20 °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:

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.