

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

A. 510(k) Number:

k130337

B. Purpose for Submission:

New device

C. Measurand:

Multi-analyte control materials: 1-25 hydroxy-Vitamin D [1-25 (OH)² Vitamin D], 25 hydroxy-Vitamin D (25-OH-vitamin D), anti-Thyroglobulin (anti-TG), anti-Thyroid Peroxidase (anti-TPO), C-peptide of Proinsulin (C-peptide), Insulin Like Growth Factor (IGF-1), Parathyroid hormone (PTH), Procalcitonin, and Insulin

D. Type of Test:

Not applicable

E. Applicant:

Randox Laboratories Limited

F. Proprietary and Established Names:

Randox Immunoassay Speciality Control (I) Levels 1, 2 and 3

G. Regulatory Information:

1. Regulation section:

21 CFR 862.1660, Quality control material (assayed and unassayed)

2. Classification:

Class I, reserved

3. Product code:

JJY

4. Panel:

Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

The Randox Immunoassay Speciality Control (I) Levels 1, 2 and 3 are intended for in vitro diagnostic use as assayed quality control material to monitor the precision of laboratory testing procedures for 1-25 Dihydroxy Vitamin D (1-25 (OH)² Vitamin D), 25 Hydroxy Vitamin D (25-OH Vitamin D), anti-Thyroglobulin (anti-TG), anti-Thyroid Peroxidase (anti-TPO), C-Peptide, Insulin Like Growth Factor (IGF-1), Parathyroid Hormone (PTH), Procalcitonin and Insulin.

2. Indication(s) for use:

Same as intended use.

3. Special conditions for use statement(s):

For in vitro diagnostic use

For prescription use only

4. Special instrument requirements:

Values are listed in the labeling for several analyzers. Values were assigned on these analyzers. Representative analyzer specific values are shown in below.

I. Device Description:

Randox Immunoassay Speciality Control (I) is manufactured at three levels, Level 1, Level 2 and Level 3, for each analyte. Individual analyte values listed in the package insert are specific for the instrument system utilized.

Each control is prepared from human serum with added constituents of human origin, chemicals, stabilizers and preservatives. They are supplied in lyophilized form in 5x2ml vials and require reconstitution with 2ml of distilled water.

The individual analyte concentrations in each of the three levels have been chosen to span a range that includes the chemically significant or medical decision levels.

Human source material from which this product has been derived has been tested at the donor level for the Human Immunodeficiency Virus (HIV-1 & HIV-2) antibody, Hepatitis B surface antigen (HbsAg) and the Hepatitis C virus (HCV) antibody and were found to be non-reactive based on FDA approved methods.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Biorad Liquichek™ Speciality Immunoassay Control LTA Levels 1, 2 and 3

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

k043108

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	The Randox Immunoassay Speciality Control (I), Levels 1, 2 & 3 are intended for in vitro diagnostic use as assayed quality control material to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.	For use as a quality control serum to monitor the precision of laboratory testing procedures listed in the package insert
Matrix	Human Serum	same

Differences		
Size	2 ml	5 ml
Format	Lyophilized	Liquid
Storage (Unopened)	2 to 8°C Until expiration date	-20 to -70°C Until expiration date
Analytes:		
1-25 (OH) ₂ Vitamin D	Present	Not present
25-OH Vitamin D	Present	Present
anti-TG	Present	Present
anti-TPO	Present	Present
C-peptide	Present	Present
IGF-1	Present	Present
PTH	Present	Intact PTH
Procalcitonin	Present	Not present
Insulin	Present	Not present
Osteocalcin	Not present	Present
Open Vial Stability	Store refrigerated +2 to 8°C Insulin, Anti-TPO 1-25 (OH) ² Vitamin D and 25 OH Vitamin D are stable for 5	Once the product is thawed and opened, all analytes will be stable for 30days when stored tightly capped at 2-8°C with the exception of PTH which will be

Differences		
	<p>days at +2°C to +8°C if kept capped in original container and free from contamination. Anti-TG is stable for 3 days at +2°C to +8°C.</p> <p>C-Peptide, IGF-1 and Procalcitonin are stable for 1 day at +2°C to +8°C.</p> <p>The Immunoassay Speciality Control (I) is stable for 4 weeks frozen once at -20°C.</p> <p>Parathyroid hormone (PTH) should be tested within 4 hours of reconstitution when stored at +2°C to +8°C, or within 2 weeks when stored below -20°C.</p>	<p>stable for 23 days.</p> <p>PTH, Anti-TG and Anti TPO will be stable for 30 days when stored in tightly capped aliquot vials at -20°C to -70°C.</p>
Shipping Temperature	+2 to 8°C	-20 to -70°C

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

None were 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):

Traceability:

The analytes contained in the Randox Speciality Immunoassay Control (I) Levels 1, 2 and 3 were obtained from commercially available sources. Not traceable to WHO

standards.

Value Assignment:

Each batch of Immunoassay Speciality (I) Control is submitted to a number of external laboratories and values were assigned from a consensus of results obtained. Each batch has lot-specific target values for each analyte. A range of $\pm 25\%$ is provided for individual analytes and each analyzer method. The sponsor recommends that the range provided should only be considered as a reference and that each laboratory establishes its own ranges.

Table 1: Immunoassay Speciality (I) Control values

Analyte	Analyzer	Units	Level 1	Level 2	Level 3
1-25 OH Vitamin D	IDS RIA	pmol/l	34.2	121.0	203.0
25 OH Vitamin D	Roche Elecsys	nmol/l	N/A	96.8	116.0
	Roche Cobas E411	nmol/l	60.5	N/A	108.0
	Diasorin Liaison	nmol/l	46.9	76.7	108.0
	IDS ELISA	nmol/l	63.5	107	N/A
	Abbott Architect	nmol/l	N/A	65.3	83.7
	Ortho Vitros ECi/ECiQ/3600/5600	nmol/l	58.4	87.4	105.6
Anti TG	Siemens Immulite 2000/2500	IU/ml	33.1	127	230.0
	Abbott Architect	IU/ml	28.0	72.6	100.0
	Abbott AXSYM	IU/ml	53.2	185.0	315.0
	Roche Cobas E411	IU/ml	175.0	633.0	801.0
	Roche Elecsys	IU/ml	157.0	622.0	761.0
	Roche Cobas 6000/8000	IU/ml	164.0	551.0	704.0
	Roche Modular E170	IU/ml	N/A	N/A	705.0
Anti TPO	Siemens Advia Centaur	IU/ml	135.0	624.0	N/A
	Roche Modular E170	IU/ml	13.1	103.0	188.0
	Abbott Architect	IU/ml	31.2	101.0	160.0
	Abbott AXSYM	IU/ml	N/A	N/A	116.0
	Siemens Immulite 1000	IU/ml	33.6	N/A	N/A
	Siemens Immulite 2000/2500	IU/ml	33.2	113.0	170.0
	Roche Cobas E411	IU/ml	15.3	105.0	201.0
	Roche Cobas 6000/8000	IU/ml	N/A	102.0	189.0
	Roche Elecsys	IU/ml	14.7	101.0	203.0
Beckman DxI 600/800	IU/ml	26.2	85.5	142.0	

Analyte	Analyzer	Units	Level 1	Level 2	Level 3
	Siemens Advia Centaur	IU/ml	182.0	365.0	476.0
C-Peptide	Tosoh A II 600	ng/ml	1.71	N/A	N/A
	Siemens Advia Centaur	ng/ml	1.19	2.60	4.35
	Roche Cobas 6000/8000	ng/ml	1.58	3.02	5.31
	Roche Elecsys	ng/ml	1.54	N/A	N/A
	Siemens Immulite 1000	ng/ml	1.02	2.35	4.71
	Abbott Architect	ng/ml	1.17	N/A	N/A
	Siemens Immulite 2000/2500	ng/ml	1.06	2.35	4.71
	Roche Modular E170	ng/ml	1.50	2.90	5.10
	Roche Cobas E411	ng/ml	1.52	2.93	5.28
IGF 1	Siemens Immulite 2000/2500	ng/ml	44.0	287.0	587.0
	Siemens Immulite 1000	ng/ml	53.3	345.0	769.0
Insulin	Abbott Architect	mU/l	N/A	8.31	N/A
	Siemens Advia Centaur	mU/l	6.08	10.3	28.0
	Roche Cobas 6000/8000	mU/l	N/A	9.12	N/A
	Roche Elecsys	mU/l	N/A	8.38	29.7
	Roche Cobas E411	mU/l	5.45	9.66	27.0
Parathyroid Hormone (PTH)	Abbott Architect	pg/ml	23.6	304.0	997.0
	Siemens Immulite 1000	pg/ml	25.8	384.0	1102.0
	Siemens Immulite 2000/2500	pg/ml	30.4	350.0	1130.0
	Roche Elecsys	pg/ml	21.2	185.0	591.0
	Roche Cobas 6000/8000	pg/ml	17.8	172.0	547.0
	Roche Modular E170	pg/ml	N/A	N/A	532.0
	Siemens Advia Centaur	pg/ml	27.4	293.0	1016.0
Procalcitonin	bioMerieux Vidas	ng/ml	1.33	2.47	18.9
	Brahms Kryptor	ng/ml	N/A	0.690	7.76
	Brahms VIDAS PCT	ng/ml	N/A	2.41	N/A
	Siemens Advia Centaur	ng/ml	2.31	3.23	19.5

(NA refers to Not Applicable)

Stability Studies:

Shelf-life and open-vial stability protocols and acceptance criteria were reviewed and found to be acceptable.

Shelf-life stability studies: Accelerated stability was used to predict the shelf life of control materials. The Immunoassay Speciality Controls (I) were stored at +37°C for a period of two weeks. The shelf life of these products was set at 2 years from the date of manufacture, based on the performance of the accelerated stability testing. The real time stability of the controls was monitored to verify and validate the predicted or desirable shelf life. Current Real Time studies support a 2 year shelf life.

Open-vial stability studies: The Immunoassay Speciality (I) Controls were reconstituted as instructed on the product insert sheet and stored at +2 to +8°C until testing at different time points. The studies support a reconstituted stability claim of 5 days at +2°C to +8°C for Insulin, Anti-TPO and 1,25 (OH) Vitamin D, 3 days at +2°C to +8°C for Anti-TG, and 1 day at +2°C to +8°C for C-Peptide, IGF-1, and Procalcitonin. Parathyroid hormone (PTH) should be tested within 4 hours of reconstitution when stored at +2°C to +8°C.

Frozen stability studies were designed to establish the stability of each analyte in frozen serum. Samples were reconstituted and stored at -18 to -24°C for 28 days. The current studies support a frozen stability claim of 4 weeks when stored frozen at -20°C. Parathyroid hormone (PTH) should be tested within 2 weeks when stored below -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:

Target and range values for representative analyzers are provided in the labeling for each specific lot.

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.