

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

A. 510(k) Number:

k111650

B. Purpose for Submission:

New Device

C. Measurand:

Quality Control materials for CTX-I and 25 Hydroxy Vitamin D

D. Type of Test:

Quality Control Material

E. Applicant:

Immunodiagnostic Systems Ltd.

F. Proprietary and Established Names:

IDS-iSYS CTX-I (Crosslaps®) Calibration Verifiers, IDS-iSYS 25 Hydroxy Vitamin D Calibration Verifiers, and IDS-iSyS CTX-I (Crosslaps®) Control Set with model(s):IS-3035, IS-2735, and IS-3030

G. Regulatory Information:

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

H. Intended Use:

1. Intended use(s):

See indications for use.

2. Indication(s) for use:

IDS-iSYS CTX- I (Crosslaps) Control Set

The IDS-iSYS CTX-I (CrossLaps) Control Set is intended for medical purposes for use in the IDS-iSYS CTX-I (Crosslaps) Assay on the IDS-iSYS Multi-Discipline Automated Analyser to monitor the accuracy and quality of the IDS-iSYS CTX-I (Crosslaps) Assay.

IDS-iSYS CTX-I (Crosslaps) Calibrator Verifiers

The IDS-iSYS CTX-I (CrossLaps) Calibrator Verifier is a device intended for medical purposes for use in the quantitative verification of calibration and assay range of the IDS-iSYS CTX-I (CrossLaps®) Assay when performed on the IDS-iSYS Multi-Discipline Automated Analyzer.

IDS-iSYS 25 Hydroxy Vitamin D Calibrator Verifiers

The IDS-iSYS 25-Hydroxy Vitamin D Calibration Verifiers are intended for use in the quantitative verification of calibration and assay range of the IDS-iSYS 25 Hydroxy Vitamin D Assay when performed on the IDS-iSYS Multi-Discipline Automated Analyzer.

3. Special conditions for use statement(s):

For prescription use

4. Special instrument requirements:

IDS iSYS Multi-Discipline analyzer (models IS-3035, IS-2735, IS-3030)

I. Device Description:

The IDS-iSYS CTX-I (CrossLaps®) Control Set is a single analyte, liquid, bovine serum albumin based product containing CTX-I and <0.1% w/w sodium azide as a preservative. The packaging consists of three control levels (two vials per level containing 2.5 mL per vial).

The IDS-iSYS CTX-I (CrossLaps®) Calibration Verifiers are a single analyte, liquid, bovine serum albumin based product containing CTX-I and <0.1% w/w sodium azide as a preservative. The packaging consists of four verifier levels (two vials per level, 2.5 mL for level 0, 1 mL for levels 1-3).

IDS-iSYS 25 Hydroxy Vitamin D Calibrator Verifiers are a single analyte, liquid equine serum/buffer based product containing 25-OH D and <0.1% w/w sodium azide as a preservative. The packaging consists of four verifier levels (two vials per level

containing 2.5 mL per vial).

J. Substantial Equivalence Information:

1. Predicate device name(s):

Elecsys PreciControl Bone

Elecsys b Crosslaps® calcheck

IDS-iSYS 25-Hydroxy Vitamin D Control Set

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

k051543

k000042

k091849

3. Comparison with predicate:

Similarities and Differences

Characteristic	Candidate device:	Predicate device:
	IDS-iSYS CTX-I (Crosslaps) Control Set (k111650)	Elecsys PreciControl Bone (k051543)
Intended Use	Same	Elecsys PreciControl Bone is used for quality control of specified assays.
Levels	Same	3 Levels
Matrix	Liquid, Phosphate bovine serum albumin	Lyophilized, based on equine serum
Stability and Storage	2-8°C – unopened until expiration date After opening: stable for 28 days at 4°C On board the IDS-iSYS – 3 hours	2-8°C – unopened until expiration date Reconstituted/thawed: @ 20-25°C – 8 hours, @ 2-8°C – 5 days, @ -20°C (4 freeze thaw cycles possible) – 1 month
Analyte concentrations	CTX-I: Low control: 0.2 ng/mL.	β -CTX (synthetic): approximately 0.315, 0.75 and 3.0 ng/mL

	<p>Medium control: 0.8 ng/mL.</p> <p>High control: 2 ng/mL.</p>	<p>PTH (synthetic):</p> <p>approximately 60, 205 and 850 pg/mL</p> <p>Osteocalcin (synthetic):</p> <p>approximately 20, 100 and 205 ng/mL</p>
Analyzer System	IDS-iSYS Multi-Discipline Automated Analyzer	Elecsys immunoassay analyzers

Characteristic	Candidate device: IDS-iSYS CTX-I (Crosslaps) Calibrator Verifiers (k111650)	Predicate device: Elecsys b Crosslaps® calcheck (k000042)
Intended Use	Same	For use in the verification of the calibration and assay range.
Levels	Levels 0, 1, 2,3	Levels 1,2,3
Matrix	Liquid, phosphate bovine serum albumin	Crosslaps free human serum
Stability and Storage	<p>2-8°C – unopened until expiration date</p> <p>On board stability: Single use-use then discard</p>	<p>Store unopened at 2-8°C.</p> <p>Unopened stability at 2-8°C – until expiration date</p> <p>Stability reconstituted: 4 hours at 20-25°C.</p>
Analyte concentrations	<p>CTX-I:</p> <p>0.0 ng/mL, 0.6 ng/mL, 3.0 ng/mL, 5.0 ng/mL</p>	<p>β –CTX (synthetic)</p> <p>0.5 ng/mL, 1.8 ng/mL, 3.8 ng/mL</p>
Analyzer System	IDS-iSYS Multi-Discipline Automated Analyzer	Elecsys 1010 or 2010 immunoassay system

Characteristic	Candidate device: IDS-iSYS 25 Hydroxy Vitamin	Predicate device: IDS-iSYS 25-Hydroxy
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	D Calibrator Verifiers (k111650)	Vitamin D Control Set (k091849)
Intended Use	Same	The IDS-iSYS 25-Hydroxy Vitamin D Control Set is intended for use as assayed quality control samples to monitor the accuracy and precision of the IDS-iSYS25-Hydroxy Vitamin D Assay.
Levels	Levels 0,1,2,3	Levels 1, 2, 3
Matrix	Liquid, buffered equine serum	Buffered horse serum
Stability and Storage	2-8°C – unopened until expiration date On board stability: Single use-use then discard	2-8°C – unopened until expiration date On board the IDS-iSYS – 2.5 hours
Analyte concentrations	25-Hydroxy Vitamin D: 0 ng/mL, 10 ng/mL, 70 ng/mL, and 120 ng/mL	25-Hydroxy Vitamin D: 6.6ng/mL, 33.0ng/mL, and 72.5ng/mL
Analyzer System	Same	IDS-iSYS Multi-Discipline Automated Analyzer

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

CEN 13640, Stability Testing of In Vitro Diagnostic Reagents.

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):*

IDS-iSYS CTX-I (Crosslaps) Control Set

Traceability and Value Assignment:

Each control level is tested on three IDS-iSYS analyzers with a minimum of three runs for each cartridge batch tested in triplicate. Control solutions are prepared gravimetrically from an intermediate stock solution and concentrations are confirmed by spectrophotometric analysis. In the value assignment process, controls were calibrated using a master calibrator to generate a master curve. The assigned target value of each control level is defined as the mean of all the runs for the CTX-I assay and analyzer. The following are the expected values for each level of control: 0.2 ng/mL, 0.8 ng/mL, and 2 ng/mL.

Stability:

Closed vial:

For the real time closed vial testing, three lots of controls were stored at 4°C using cartridges with lids pierced by the IDS-iSYS then stored at 4°C. Each control material was tested in triplicate in 3 month intervals for up to a minimum of 15 months. Each control vial tested was compared back to reference control material stored at -20°C. Percent recoveries were within the sponsor's acceptance criteria of 10% of the reference material concentration and supports the sponsor's stability claim of 6 months when stored at 4°C.

Open Vial:

Open vial (in-use) stability of controls were performed at 4°C and tested against unopened vials of control material stored at 4°C. Controls were tested in duplicate at the timepoints stated in the stability protocol. Percent recoveries of each material were within the sponsor's acceptance criteria of 10% of the reference material concentration. Data supports the open vial stability claim of 28 days when stored at 4°C.

On-board stability studies were performed using two batches of controls using two IDS-iSYS instruments on the same day. Controls were tested at time 0, 3 hours, and 4.5 hours and compared to a reference material run at time 0. The on board stability data supports the sponsor's claimed on-board stability of 3 hours.

IDS-iSYS CTX-I (Crosslaps) Calibrator Verifiers

Traceability and Value Assignment:

Four levels of calibrator verifiers were used to validate the calibration on the IDS-iSYS and validate the range of the analytical measurement. Each lot-specific value assignment was tested in three runs on at least three different IDS-iSYS analyzers in triplicate. The assigned target value of each calibrator verifier was defined as the mean of all the runs for each calibrator verifier. The following are the expected values for each calibrator verifier: 0.0 ng/mL, 0.6 ng/mL, 3.0 ng/mL, 5.0 ng/mL.

Stability:

For the real time closed vial testing, three lots of calibrators were stored at 4°C using cartridges with lids pierced by the IDS-iSYS then stored at 4°C. Each calibrator material was tested in triplicate in 3 month intervals for up to a minimum of 15 months. Each calibrator vial tested was compared back to reference control material stored at -20°C. Percent recoveries were within 10% of the reference material concentration and supports the sponsor's stability claim of 6 months when stored at 4°C.

The sponsor states that the IDS-iSYS CTX-I (Crosslaps) Calibrator Verifiers will be defined as "single use and then discard."

IDS-iSYS 25 Hydroxy Vitamin D Calibrator Verifiers

Traceability and Value Assignment:

Four levels of calibrator verifiers were used to validate the calibration on the IDS-iSYS and validate the range of the analytical measurement. Master calibrators are prepared gravimetrically from stock solution and each concentration is traceable to spectrophotometric analysis. Each lot-specific value assignment was tested in three runs on at least three different IDS-iSYS analyzers in triplicate. The assigned target value of each calibrator verifier was defined as the mean of all the runs for each calibrator verifier. The following are the expected values for each calibrator verifier: 0, 10, 70, and 120 ng/mL.

Stability:

For real time closed vial testing, multiple sets of calibrators were stored at 4°C. Each calibrator was tested in quadruplicate using four separate 25 Hydroxy Vitamin D assays and the concentrations were compared back to reference material stored at -20°C. Percent recoveries were within the

sponsor's acceptance criteria of 10% of the reference material and support the sponsor's stability claim of 6 months.

The sponsor states that the IDS-iSYS Hydroxy Vitamin D Calibrator Verifiers will be defined as "single use and then discard."

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):

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.