

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

A. 510(k) Number:

k143324

B. Purpose for Submission:

New device

C. Measurand:

Calibration Verification Material (CVM) for the IDS-iSYS CTX-I (CrossLaps®) Assay

D. Type of Test:

Not applicable

E. Applicant:

Immunodiagnostic Systems Ltd.

F. Proprietary and Established Names:

IDS-iSYS CTX-I (Crosslaps®) Calibration Verifiers

G. Regulatory Information:

1. Regulation section:

21 CFR 862.1660, Quality Control Material (Assayed)

2. Classification:

Class I, Reserved

3. Product code:

JJX

4. Panel:

Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

See indications for use statement below.

2. Indication(s) for use:

The IDS-iSYS CTX-I (CrossLaps®) Calibration Verifiers is a device intended for the verification of calibration of the IDS-iSYS CTX-I (CrossLaps®) Assay when performed on the IDS-iSYS Multi-Discipline Automated Analyzer.

3. Special conditions for use statement(s):

For Prescription use only

4. Special instrument requirements:

IDS-iSYS Multi-Discipline Analyzer

I. Device Description:

The IDS-iSYS CTX-I (CrossLaps®) Calibration Verifiers consists of one set of four vials, 2.5 mL each in liquid form. Cal.Ver.0 0 contains heat inactivated horse serum matrix with <0.1% (w/w) sodium azide as a preservative. Cal.Ver.1, Cal.Ver.2, and Cal.Ver.3 contain heat inactivated horse serum matrix with <0.1% (w/w) sodium azide as a preservative and human CTX-I (CrossLaps®).

CTX-1 Target Range Levels

| Cal. Ver. Level | Target Range (ng/mL) |
|-----------------|----------------------|
| Cal. Ver. 0 | Undetectable |
| Cal. Ver. 1 | 0.12-0.16 |
| Cal. Ver. 2 | 2.4 - 3.2 |
| Cal. Ver. 3 | 5.6 - 6.6 |

The package insert has the following warning:

CAUTION: The Calibration Verifiers contain material of human origin. The material has been tested by FDA-approved assays or equivalent for the presence of antibody to Human Immunodeficiency Virus (HIV I and II), Hepatitis B surface antigen, antibody to Hepatitis C, and found negative.

J. Substantial Equivalence Information:

1. Predicate device name(s):
IDS-iSYS CTX-I (CrossLaps®) Calibration Verifiers
2. Predicate 510(k) number(s):
k111650
3. Comparison with predicate:

| Similarities | | |
|---------------------|---|--|
| Item | Candidate Device IDS-iSYS CTX-I (CrossLaps®) Calibration Verifiers (Catalog # IS- 3035A) | Predicate Device IDS-iSYS CTX-I (CrossLaps®) Calibration Verifiers (Catalog # IS-3035) |
| Indications for Use | The calibration verifier is intended for use for verifying the calibration of the assay. | Same |
| Analyte | CTX-I | Same |
| Form | Liquid, ready to use | Same |
| Levels | 4 | Same |
| Values | Cal. Ver. 0: Undetectable Cal. Ver. 1: 0.12-0.16 ng/mL Cal. Ver. 2: 2.4 – 3.2 ng/mL Cal. Ver. 3: 5.6 – 6.6 ng/mL | Cal. Ver. 0: 0.0 ng/mL Cal. Ver. 1: 0.6 ng/mL Cal. Ver. 2: 3.0 ng/mL Cal. Ver. 3: 5.0 ng/mL |
| Analyzer System | IDS-iSYS Multi-Discipline Automated Analyzer | Same |

| Differences | | |
|--------------------|--|---|
| Item | Candidate Device IDS-iSYS CTX-I (CrossLaps®) Calibration Verifiers (Catalog # IS- 3035A) | Predicate Device IDS-iSYS CTX-I (CrossLaps®) Calibration Verifiers (Catalog # IS-3035) |
| Stability | 2-8°C – unopened until expiration date On board stability: 3 hours, single use only. | 2-8°C – unopened until expiration date On board stability: Single use-use then discard |
| Matrix | Horse serum containing CTX-I and sodium azide as preservative (<0.1%). 1 vial each of levels 0-3 (2.5 mL). | Liquid, phosphate bovine serum albumin |

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

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

Format for Traditional and Abbreviated 510(k)s - Guidance for Industry and FDA Staff

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 and Value Assignment:

Value assignment for IDS-iSYS CTX-I Calibration Verifiers was performed on the IDS-iSYS Multi-Discipline Automated Analyzer using assigned reference calibrators. The reference calibrators are traceable to in-house reference standards (CTX-I in horse serum). The lot-specific assigned target value of each calibrator verifier was calculated using the mean of all runs (3 replicates x 3 analyzers x 5 runs). The assigned target value of each calibrator verifier was defined as the mean of all the runs for each calibrator verifier. The Guideline Range of each calibrator verifier level was defined as the target mean \pm 2SD. The lot-specific target values are provided in the IDS-iSYS CTX-I Calibration Verifiers Certificate of Analysis. The following target mean values and ranges for each calibrator verifier are intended to be used as a guide only. Values may vary from lot to lot.

| CVM | Target Mean (ng/mL) | Standard Deviation (SD) | Target Range (ng/mL) |
|-------------|---------------------|-------------------------|----------------------|
| Cal. Ver. 0 | 0 (Undetectable) | NA | NA |
| Cal. Ver. 1 | 0.14 | 0.009 | 0.12 – 0.16 |
| Cal. Ver. 2 | 2.8 | 0.168 | 2.4 – 3.2 |
| Cal. Ver. 3 | 6.1 | 0.366 | 5.6 – 6.6 |

Stability:

An accelerated stability study was performed to support closed-vial shelf life claim. The stability study protocols and acceptance criteria were reviewed and found to be adequate. All acceptance criteria were met and support a shelf life stability claim of 12 months when stored at 2-8°C. Real time stability study protocols and acceptance criteria were reviewed and found acceptable. A real time stability study to support the shelf life stability claim is ongoing.

On board stability studies were performed to validate the on board stability claims for the IDS-iSYS CTX-I Calibration Verifiers. All acceptance criteria were met and support a stability claim of 3 hours when stored on board the IDS-iSYS Multi-Discipline Automated Analyzer at 23°C±3°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.