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

A. 510(k) Number:

k111938

B. Purpose for Submission:

New device

C. Measurand:

Quality control materials for insulin-like growth factor binding protein-3 (IGFBP-3) and human growth hormone (hGH).

D. Type of Test:

Quality control materials

E. Applicant:

Immunodiagnostic Systems Limited

F. Proprietary and Established Names:

IDS-iSYS IGFBP-3 Calibration Verifiers

IDS-iSYS IGFBP-3 Control Set

IDS-iSYS hGH Calibration Verifiers

G. Regulatory Information:

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

H. Intended Use:

1. Intended use(s):

    Refer to indication for use below.

2. Indication(s) for use:

The IDS-iSYS IGFBP-3 controls set is a quality control material device intended for medical purposes for use in the IDS-iSYS IGFBP-3 assay on the IDS-iSYS multi discipline automated analyzer to monitor the accuracy and quality of the IDS-iSYS IGFBP-3 assay.

The IDS-iSYS IGFBP-3 calibration verifier is a device intended for medical purposes for use in the quantitative verification of calibration of the IDS-iSYS IGFBP-3 assay when performed on the IDS-iSYS multi-disciplined automated analyzer.

The IDS-iSYS hGH calibration verifier is a device intended for medical purposes for use in the quantitative verification of calibration of the IDS-iSYS hGH assay when performed on the IDS-iSYS multi-disciplined automated analyzer.

3. Special conditions for use statement(s):

None

4. Special instrument requirements:

IDS-iSYS automated analyzer platform

I. Device Description:

The IDS-iSYS IGFBP-3 calibration verifier is lyophilized bovine serum albumin in a buffer with sodium azide as a preservative.

The IDS-iSYS IGFBP-3 control set is a lyophilized phosphate BSA matrix containing IGFBP-3 and sodium azide as a preservative.

The IDS-iSYS hGH calibration verifier is ready to use bovine serum albumin in a buffer with sodium azide as a preservative.

IDS-iSYS IGFP-3 Calibration Verifiers

Level	Target Value (ng/mL)	Target Range (ng/mL)
0	<LOQ	<LOQ
1	512.5	400 – 600
2	5125	4000 – 6000
3	8400	6500 - 9500

IDS-iSYS IGFP-3 Control Set

Level	Target Value (ng/mL)	Target Range (ng/mL)
1	2050	1250 – 2850
2	4100	3000 - 5200
3	6150	5000 - 7300

IDS-iSYS hGH Calibration Verifiers.

Level	Target Value (ng/mL)	Target Range (ng/mL)
1	10	8 – 12
2	50	45 - 55
3	90	81 - 99

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Elecsys hGH CalCheck 5

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

   k103221

3. Comparison with predicate:

Characteristic	IDS-iSYS IGFBP-3 Control Set (New Device)	IDS-iSYS IGFBP-3 Calibration Verifiers (New Device)	IDS-iSYS hGH Calibration Verifiers (New Device)	Elecsys hGH CalSet (Predicate Device) k103221
Intended use/ Indications for use	Same	Same	Same	Assayed quality control material for use in calibration verification and assay verification.
Unopened Stability	Same	Same	Same	Store at 2-8ºC until expiration date
Analyte	IGFBP-3	IGFBP-3	hGH	hGH
Levels	3	4	3	5
Matrix	Bovine serum albumin	Buffered protein	Bovine serum albumin	Human serum matrix
Format	Lyophilized	Lyophilized	Ready to use liquid form	Lyophilized
Reconstituted Stability	Not applicable	On the analyzer: up to 2.5 hours	On the analyzer: up to 2.5 hours	On the analyzer: up to 5 hours

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 <u>Analytical performance:</u>

a. Precision/Reproducibility:

Not applicable

b. Linearity/Assay Reportable Range:

Not applicable

c. Traceability, Stability, Expected Values (controls, calibrators, or methods):

<u>Traceability</u>

The IDS-iSYS IGFBP-3 control set is traceable to the NISBC 93/560 international standard.
The IDS-iSYS IGFBP-3 calibration verifier is traceable to the NISBC 93/560 international standard.
The IDS-iSYS hGH calibration verifier is traceable to the NISBC 98/574 international standard.

<u>Value Assignment:</u>

IDS-iSYS IGFBP-3 control set concentrations are value assigned on three different iSYS analyzers, with a minimum of three runs for a total of at least 15 runs. The controls are quantitated with the associated lot-specific calibrators, and are analyzed with all batches of cartridges on the market.
Results of the controls must be ±1 SD of each other (to show no bias between batches of cartridges). Once assay kits are assembled, a kit will be brought to the quality control department for a final validation check, and the final assigned ranges for each control are designated as the assigned value ±3SD.

IDS-iSYS IGFBP-3 Calibration Verifiers

Four levels of calibrator verifiers were used to validate the calibration of 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 respectively: 512.5 ng/mL, 5125 ng/mL, and 8400 ng/mL.

IDS-iSYS hGH Calibration Verifiers

Three levels of calibrator verifiers were used to validate the calibration of 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: 10ng/mL, 50ng/mL, and 90ng/mL.

Stability:

IDS-iSYS IGFBP-3 Control Set real time stability studies are performed on the control material at 3 month intervals for a minimum of 15 months.
An accelerated stability study was performed to simulate a shelf life of 6 months at normal storage conditions of 2-8ºC. Stability data supports this package insert claim and percent recoveries met the stated acceptance criteria of 90-110% of concentration based on unstressed material.

IDS-iSYS IGFBP-3 Calibration Verifiers stability testing was performed on the IDS-iSYS automated analyzer.
- Shelf-life stability
  The accelerated stability testing supports an initial shelf-life claim of 6 months at 2-8ºC. Real time testing at 2-8ºC is on-going.

- Stability after reconstitution :
- Real time testing was performed and supports the following claims:
  Reconstituted IDS-iSYS IGFBP-3 calibration verifiers are stable for up to 2.5 hours on the board the IDS-iSYS. The IDS-iSYS IGFBP-3 calibration verifiers are not stored on board the analyzer.

IDS-iSYS hGH Calibration Verifiers stability testing was performed on the IDS-iSYS automated analyzer.
- Shelf-life stability
  The accelerated stability testing supports an initial shelf-life claim of 6 months at 2-8ºC. Real time testing at 2-8ºC is on-going.

  - In use stability:
    Real time testing was performed and supports the following claims:

The IDS-iSYS hGH calibration verifiers are stable for up to 2.5 hours on the board the IDS-iSYS. The IDS-iSYS hGH calibration verifiers are not stored on board the analyzer.

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 Labelling:

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.