

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

A. 510(k) Number:

k110412

B. Purpose for Submission:

New device

C. Measurand:

Quality control material for IGF-I control set

D. Type of Test:

Quality control material

E. Applicant:

Immunodiagnostic Systems Ltd.

F. Proprietary and Established Names:

IDS-iSYS IGF-I Controls Set

G. Regulatory Information:

1. Regulation section:

21 CFR 862.1660, Quality Control Material

2. Classification:

Class I, reserved

3. Product code:

JJX – Single (Specified) Analyte Controls

4. Panel:

Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

See indications for use below

2. Indication(s) for use:

The IDS-iSYS IGF-I Controls Set is a quality control material device intended for medical purposes for use in the IDS-iSYS Insulin like Growth Factor-I (IGF-I) Assay on the IDS-iSYS Multi-Discipline Automated Analyser to monitor the accuracy and quality of the IDS-iSYS IGF-I Assay.

For prescription use only

4. Special instrument requirements:

IDS-iSYS Multi-Discipline Automated Analyzer

I. Device Description:

The IDS-iSYS IGF-I Controls Set is an *in vitro* diagnostic device that contains lyophilized bovine serum albumin in buffer matrix with IGF-I (human recombinant) and a sodium azide preservative (<0.1% reconstituted). The set contains 3 each of 3 levels of control, each requiring reconstitution with 1.0 mL distilled/deionized water. Target control values are specified as 30 ng/mL, 250 ng/mL and 900 ng/mL.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Bio-Rad Liquichek Tumor Marker Control Levels 1, 2 and 3

2. Predicate K number(s):

k071675

3. Comparison with predicate:

Similarities		
Item	Candidate Device	Predicate
Indications for Use	Same	Liquichek Tumor Marker control is intended as an assayed quality control material to monitor the precision of laboratory testing

Similarities		
Item	Candidate Device	Predicate
		procedures for the analytes listed in the package insert (IGF-I).
Preservative	Same	Contains preservative
Levels	Same	Three

Differences		
Item	Candidate Device	Predicate
Analyte Concentration	Insulin (ng/mL): Level 1 = 30 Level 2 = 250 Level 3 = 900	Insulin (ng/mL): Level 1 = 68.7 Level 2 = 269 Level 3 = 530
Stability	Unopened: • Store at 2-8°C until expiration date Reconstituted: • on the analyzer: up to 3 hours • at -20 °C: 7 weeks	Frozen: • Store unopened at -20 to -80°C until expiration date Thawed: • Store unopened at 2-8°C: 35 days • Opened and recapped at 2-8°C: 15 days
Analyzer System	IDS-iSYS Multi-Discipline Automated Analyzer	Siemens Immulite 2000/2500
Format	Lyophilized	Liquid
Matrix	Bovine serum albumin	Human and bovine serum

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

Stability Testing of In Vitro Diagnostic Reagents (CEN 13640)

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

The IGF-I control material is traceable to the WHO International Standard for Insulin-like Growth Factor-I, (human recombinant); NIBSC code: 02/254.

The recombinant human IGF-I is dissolved in a BSA buffer to obtain a stock solution, which is then added to the calibrator buffer to obtain the target control concentrations. Control concentrations are then value assigned on three different 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. The lot-specific calibrators have been value assigned with a 33 run master curve establishment protocol using the full reference calibrator (calibrated against the WHO standard) and the WHO standard. Results of the controls must be ± 1 SD of the calculated average, or the results must be at ± 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 ± 3 SD.

Stability

Real time stability studies are performed on the control material at 3 month intervals for a minimum of 15 months, and data supports the expiration date claim of stability at 2-8 °C for 12 months. Stability data meets the stated acceptance criteria of 90-110% recovery of concentration based on unstressed material.

An accelerated stability study was performed to simulate a shelf life of 12 months at normal storage conditions of 2-8 °C. Stability data supports this package insert claim and percent recoveries meet the stated acceptance criteria of 90-110% of concentration based on unstressed material.

Reconstituted control material is stable frozen at -20 °C for 7 weeks. Stability data supports this package insert claim and percent recoveries meet the stated acceptance criteria of 90-110% of concentration based on unstressed material.

Reconstituted control material is stable sitting on the analyzers for 3 hours. Stability data supports this package insert claim and percent recoveries meet the stated acceptance criteria of 90-110% of concentration based on unstressed material.

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:

The control ranges are provided in the labeling and are designated as the assigned value $\pm 3SD$.

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.