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

A. 510(k) Number:

k111996

B. Purpose for Submission:

New device

C. Measurand:

Quality Control Material for the ELITech clinical Systems ISE Na, K, Cl, Total CO_2 on ELITech Clinical Systems Selectra analyzers equipped with ISE module

D. Type of Test:

Not Applicable

E. Applicant:

ELITechGroup

F. Proprietary and Established Names:

ELITech Clinical Systems ISE Control I
ELITech Clinical Systems ISE Control II

G. Regulatory Information:

1. Regulation section:

   21 CFR §862.1660, Quality Control Material

2. Classification:

   Class I, reserved

3. Product code:

   JJY – Multi-Analyte Controls

4. Panel:

Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

   See indications for use below.

2. Indications(s) for use:

   ELITech Clinical Systems ISE CONTROL I and CONTROL II are control sera for in vitro diagnostic use in quality control of ELITech Clinical Systems ISE Na, K, Cl, Total CO_2, on ELITech Clinical Systems Selectra analyzers equipped with ISE Module.

3. Special conditions for use statement(s):

   For prescription use only

4. Special instrument requirements:

   The ELITech Clinical Systems ISE CONTROL I and CONTROL II are to be used with ELITech Clinical System Selectra analyzers.

I. Device Description:

ISE Control I and ISE Control II are two level quality control products consisting of lyophilized human serum with added constituents of purified biochemical chemicals, therapeutic drugs, preservatives and stabilizers containing constituent at desired levels.

ISE Control I and ISE Control II are prepared exclusively from the blood of donors tested individually and found to be negative for HbsAg and to antibodies to HCV and HIV according to FDA-approved methods.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Biorad-lypochek Assayed Chemistry Control Level 1 and Level 2

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

   k040273

3. Comparison with predicate:

Reagent Similarities and Differences		
	Candidate Device ELITech Clinical Systems ISE Control I and II (k111996)	Predicate Device Biorad Lypochek Assayed Chemistry Control Level 1 and 2 (k040273)
Intended/Indications for Use	The ISE Control I and ISE Control II are control sera of in vitro diagnostic use in quality control of clinical Systems ISE Na, K, Cl, Total Co2	Same
Specimen Matrix	Lyophilized Human serum	Same
Levels	Two Levels	Same
Handling	Carefully open the vial avoiding the loss of lyophilizate, and pipette in exactly 5 mL of distilled/deionized water. Carefully close the vial and dissolve the contents completely by occasional gentle swirling within 30 minutes avoiding the formation of foam.	Using a volumetric pipet, reconstitute each vial with 5.0 mL of distilled or deionized water. Replace the stopper and allow the control to stand for 20 minutes, swirling occasionally.
Stability	Prior to reconstitution: when stored at 2-8°C and protected from light, the controls are stable until the expiration date stated on the label. After reconstitution: Between 2-8°C for 7 days Between -20 to -10 °C for 28 days when frozen once Note: Store control sera tightly capped and protected from light after reconstitution	When stored unopened the product is stable until the expiration date at 2-8°C. Once the control is reconstituted, all analytes are stable for 7 days when stored tightly capped at 2-8°C and 30 days at -10 to -20°C. Once thawed, do not refreeze

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

- Stability Testing of In Vitro Diagnostic Reagents - (CEN-13640)
- Standardization of Sodium and Potassium Ion Selective Electrode Systems to the Flame Photometric Reference Method (NCCLS-C29-A2)
- Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions; Approved Guideline-Third Addition(CLSI C24-A3)

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:
   Assigned values are traceable to a reference material or a reference method and provided in the table below.

Components	Test Methods of ELITech Clinical Systems reagents available in the USA	Traceability
Sodium	ISE Indirect potentiometry	NIST SRM 919b
Potassium	ISE Indirect potentiometry	NIST SRM 918b
Chloride	ISE Indirect potentiometry	NIST SRM 918b/919b
Total CO_2	ISE Indirect potentiometry	NIST SRM 924a

   Stability:
   Unlabeled vials are purchased from a contract manufacturer and ELITech labels and kits the vial using their labeling. Real-time and accelerated stability studies for open and closed-vials were performed and all lots met the acceptance criteria. The shelf life is 36 months prior to reconstitution when stored at 2-8°C and 7 days after reconstitution when stored at 2-8°C or 28 days when stored between -20 to -10°C when frozen once.

   Value Assignment
   The target values and ranges were determined and defined by ELITech on ELITech Clinical Systems Selectra analyzers equipped with ISE module using ELITech Clinical Systems ISE Na, K, Cl and Total CO2 reagents and ISE calibrators. Calibration was performed with ELITech Clinical System ISE Calibrators which is traceable to reference material. The assignment protocol was performed on two different analyzers with 48 measurements in total (2 analyzers, 2 lots, 3 vials and 4 measurements per vial). The results for ISE Control I are as follows:

Analyte	Confidence Range	Expected Range
Chloride	10%	92.2-112.6 mEQ /L
Potassium	10%	3.33-4.07 mEQ /L
Sodium	10%	128.0-156.5 mEQ /L
Total CO_2	20%	24.8-37.2 mEQ /L

The results for ISE Control II are as follows:

Analyte	Confidence Range	Expected Range
Chloride	10%	81.6-99.7 mEQ /L
Potassium	10%	5.43-6.64 mEQ/L
Sodium	10%	114.6-140.0 mEQ /L
Total CO_2	20%	17.1-25.7 mEQ /L

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 expected values are provided in the value sheet available in each kit box. The assigned values were defined by ELITech on ELITech Clinical Systems Selectra analyzers equipped with ISE module using ELITech Clinical Systems ISE Na, K, Cl, and Total CO_2 reagents and ISE calibrators.

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.