

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

A. 510(k) Number:

k052193

B. Purpose for Submission:

New device

C. Measurand:

Calibrator for sodium, potassium, and chloride

D. Type of Test:

Calibrator

E. Applicant:

Roche Diagnostics

F. Proprietary and Established Names:

ISE Compensator

G. Regulatory Information:

1. Regulation section:

21 CFR Section 862.1150, Calibrator

2. Classification:

Class II

3. Product code:

JIX, Calibrator, Multi-analyte mixture

4. Panel:

Chemistry (75)

H. Intended Use:

1. Intended use(s):

ISE Compensator is for use in the calibration of Ion Selective Electrodes on Roche/Hitachi analyzers.

2. Indication(s) for use:

ISE Compensator is for use in the calibration of Ion Selective Electrodes on Roche/Hitachi analyzers.

3. Special conditions for use statement(s):

For prescription use

4. Special instrument requirements:

For use only with Roche/Hitachi analyzers with Ion Selective Electrodes

I. Device Description:

The ISE Compensator is a ready-to-use calibrator. It is composed of a buffered human serum matrix with defined concentrations of sodium, potassium, and chloride, and added stabilizers. It is supplied in 10, 1 mL sized bottles.

The human serum used in the preparation of the ISE Compensator has been screened by FDA approved methods and found to be negative for HBsAg and antibodies to HCV and HIV.

J. Substantial Equivalence Information:

1. Predicate device name(s):

I.S.E. Calibrator/Conditioner

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

k870379

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended use	Same	For use in the calibration of sodium, potassium, and chloride on the Hitachi systems with Ion Selective electrodes
Matrix	same	Human serum with K+, Na+, and Cl-

Differences		
Item	Device	Predicate
Format	liquid	Lyophilized
Stability	Store unopened at 2-8°C until expiration date. Once opened, stable for 2 weeks at 2-8°C.	Store unopened at 2-8°C until expiration date. Once reconstituted, stable for 5 days at 2-8°C, or 5 days at -20°C.

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

Not Applicable

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: ISE Compensator is traceable to the reference material NIST-SRM909b. The reference method is flame photometry for the sodium and potassium analytes and coulometry for the chloride analyte. The value assignment process takes place using multiple external laboratories and using different Hitachi analyzers with ion selective electrodes. The final value assigned to each analyte is lot specific and is found on the Value Sheet that is provided with the product.

Stability: The shelf-life and open-vial stability of ISE Compensator when stored at 2-8°C have been demonstrated using real time stability data and predetermined acceptance criteria.

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 substantial equivalence decision.