

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

**A. 510(k) Number:**

k093498

**B. Purpose for Submission:**

New device

**C. Measurand:**

Calibration verification materials for the LIAISON® N-TACT® PTH Assay

**D. Type of Test:**

Quality control materials

**E. Applicant:**

DiaSorin Inc.

**F. Proprietary and Established Names:**

LIAISON® N-TACT® PTH Calibration Verifiers

**G. Regulatory Information:**

Product Code	Classification	Regulation Section	Panel
JJX	Class I, reserved	862.1660	Chemistry 75

**H. Intended Use:**

1. Intended use(s):

Refer to indications for use below

2. Indication(s) for use:

The DiaSorin LIAISON® N-TACT® Calibration Verifiers are assayed quality control materials intended for use in the quantitative verification of calibration and reportable range of the LIAISON® N-TACT® PTH Assay when performed on the LIAISON Analyzer.

3. Special conditions for use statement(s):

For Prescription Use

4. Special instrument requirements:

DiaSorin LIAISON® Analyzer. Included in cleared assays: k033426, k081685, k082050.

**I. Device Description:**

The DiaSorin LIAISON® N-TACT® PTH calibration Verifiers consist of four levels (20, 150, 350 and 1500 pg/mL). Each vial contains lyophilized pooled human plasma with preservatives, stabilizer and spiked with PTH.

All human source materials were tested and found to be non-reactive for HIV 1/2, HBsAg, and HCV by FDA- approved methods.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):

LIAISON® N-TACT® PTH Control Set

2. Predicate 510(k) number(s)

k033426

3. Comparison with Predicate

Similarities		
Item	Candidate Device	Predicate Device
Intended Use	Assayed quality control samples for use in the quantitative verification of calibration and reportable range of the LIAISON® N-TACT® PTH Assay	Same
Analyte	Parathyroid Hormone	Same
Matrix	Pooled human plasma with stabilizers and Proclin® 300	Same

Format	Lyophilized	Same
Product Storage	2- 8°C before reconstitution -20°C after reconstitution	Same
Volume	2.0 mL after reconstitution	Same
Required Reagent	LIAISON® N-TACT® PTH Assay	Same

Differences		
Item	Candidate Device	Predicate Device
Levels	Four	Two

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

CLSI EP5-A2 Evaluation of Precision Performance of Quantitative Measurement Methods

CLSI EP15-A2, User Verification of Performance for Precision and Trueness

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

**L. Test Principle:**

Not applicable

**M. Performance Characteristics (if/when applicable):**

1. Analytical performance:

*a. Precision/Reproducibility:*

A twenty day reproducibility/precision study was performed. One lot of LIAISON® N-TACT® PTH Controls (KC 1 and KC 2) and one lot of Calibration Verifiers A-D were tested in two replicates per day, for 20 operating days on two LIAISON® analyzers for a total of 80 replicate results per sample. One kit lot of LIAISON® N-TACT® PTH Assay was used throughout the study. The CLSI document EP5-A2, Evaluation of Precision Performance of Quantitative Measurement Methods, was consulted for this study design.

A five day reproducibility/precision study was conducted to verify the results of the twenty day study. The CLSI document EP15-A2, User Verification of Performance for Precision and Trueness, was consulted in the preparation of the testing protocol. This study included one lot of LIAISON® N-TACT® PTH Assay and LIAISON® N-TACT® PTH Control Set, and 3 lots of LIAISON® N-TACT® PTH Calibration

Verifiers. Testing was performed on three LIAISON® analyzers; one lot of calibration verifiers per LIAISON® analyzer. The calibration verifier samples were analyzed daily in quadruplicate, the assay controls were analyzed daily in duplicate for five days. The results of the five day precision study were provided and found to be sufficient.

Reproducibility/Precision Results – 20 day

Sample ID	N	Mean conc. pg/mL	within run		between run (day)		between instrument		overall	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
KC 1	80	47.1	1.29	2.8	2.87	6.1	0.29	0.6	3.15	6.7
KC 2	80	491.1	4.61	0.9	17.06	3.5	3.73	0.8	17.85	3.6
cal ver A	80	17.4	0.77	4.5	1.42	8.3	0.29	1.7	1.86	10.7
cal ver B	80	137.0	2.26	1.7	6.79	5.0	1.43	1.0	7.17	5.2
cal ver C	80	310.8	5.25	1.7	15.27	4.9	1.93	0.6	15.94	5.1
cal ver D	80	1303.5	22.96	1.8	85.36	6.6	1.84	0.1	92.50	7.1

b. *Linearity/assay reportable range:*

Not applicable

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

Traceability

The LIAISON® N-TACT® PTH Calibration Verifier concentrations are referenced to standard in-house materials containing a pure preparation of synthetic human PTH. The Calibration Verifiers are composed of the reference material added to a human plasma-based matrix.

Value-Assignment

A minimum of 10 vials of each level of calibration verifier are used in the final range assignment. The LIAISON® N-TACT® PTH Calibration Verifiers are tested on multiple LIAISON® Analyzers, using multiple LIAISON® N-TACT® PTH assay kit lots, on multiple assay runs. A range of two standard deviations is assigned for each level of calibration verifier.

Stability

Stability characteristics of the LIAISON® N-TACT® PTH Calibration Verifiers were determined using real time stability, open vial, and freeze thaw stability studies. An unopened shelf-life of 3 months is expected at the recommended storage temperature of 2-8°C. Open vial and freeze thaw studies determined that LIAISON® N-TACT®

PTH Calibration Verifiers are stable through 1 freeze/thaw cycle at -20°C and for at least 8 hours at room temperature (18° to 22°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:

The expected mean and ranges are provided in the labeling. The sponsor recommends in

the labeling that each laboratory should determine the ranges based on their own test system and tolerance limits.

**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.