DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

DIASORIN INC.
CAROL DEPOUW
REGULATORY AFFAIRS SPECIALIST
1951 NORTHWESTERN AVENUE
STILLWATER MN 55082-1482

June 22, 2015

Re: K150879
Trade/Device Name: LIAISON® 1-84 PTH Assay
LIAISON® 1-84 PTH Control Set
LIAISON® 1-84 PTH Calibration Verifiers
Regulation Number: 21 CFR 862.1545
Regulation Name: Parathyroid hormone test system
Regulatory Class: II
Product Code: CEW, JJX
Dated: March 31, 2015
Received: April 1, 2015

Dear Carol Depouw:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the

electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Katherine Serrano -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150879

Device Name
LIAISON® 1-84 PTH Assay
LIAISON® 1-84 PTH Control Set
LIAISON® 1-84 PTH Calibration Verifiers

Indications for Use *(Describe)*
The DiaSorin LIAISON® 1-84 PTH assay is an in vitro chemiluminescent immunoassay (CLIA) intended for the quantitative determination of parathyroid hormone (1-84) in human serum and EDTA plasma. Measurements of parathyroid hormone levels are used in the differential diagnosis of hypercalcemia and hypocalcemia resulting from disorders of calcium metabolism.
The test has to be performed on the LIAISON® Analyzer.

The DiaSorin LIAISON® 1-84 PTH Control Set is intended for in vitro diagnostic use as assayed quality control samples to monitor the accuracy and precision of the LIAISON® 1-84 PTH Assay.

The DiaSorin LIAISON® 1-84 PTH Calibration Verifiers are assayed quality control materials intended for in vitro diagnostic use in the quantitative verification of calibration and reportable range of the LIAISON® 1-84 PTH Assay.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

LIAISON® 1-84 PTH Assay
LIAISON® 1-84 PTH Control Set
LIAISON® 1-84 PTH Calibration Verifiers

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

1. 510(k) Number: K150879

2. Applicant: Carol A. DePouw
DiaSorin Inc.
1951 Northwestern Avenue, P.O. Box 285**,** Stillwater, MN 55082-0285
Office Number: 651-351-5850; Fax Number: 651-351-5669
Email: carol.depouw@diasorin.com

3. Date: March 26, 2015

4. Proprietary and Established Names:

LIAISON® 1-84 PTH Assay
LIAISON® 1-84 PTH Control Set
LIAISON® 1-84 PTH Calibration Verifiers

5. Regulatory Information:

LIAISON® 1-84 PTH Assay

Regulation Section: 21 CFR 862.1545
Classification: Class II
Product Code: CEW
Panel: Clinical Chemistry (75)

LIAISON® 1-84 PTH Control Set
LIAISON® 1-84 PTH Calibration Verifiers

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

6. Predicate Devices:

The predicate device used to demonstrate substantial equivalence to the LIAISON® 1-84 PTH Assay is the Scantibodies Laboratory, Inc. Whole PTH™ (1-84) Specific immunoradiometric (IRMA) assay previously cleared under (K001411).

The predicate device used to demonstrate substantial equivalence to the LIAISON® 1-84 PTH Control Set is the LIAISON® N-TACT® PTH Control Set previously cleared under k033426.

The predicate device used to demonstrate substantial equivalence to the LIAISON® 1-84 PTH Calibration Verifiers is the LIAISON® N-TACT® PTH Calibration Verifiers previously cleared under k093498.

7. Device Description:

The LIAISON® 1-84 PTH Assay is a modified two-step, two-site sandwich assay that uses two polyclonal antibodies for capture and detection of the 1-84 PTH molecule. Results are determined by a 2 point calibration conversion of the master curve to a working curve. The light signal is measured by a photomultiplier as relative light units (RLU) and is proportional to the concentration of 1-84 PTH present in the calibrators, controls or samples.

LIAISON® 1-84 PTH Control set contains;

- 2 levels controls containing human plasma spiked with 1-84 PTH, and preservatives; 4 vials each level; lyophilized

The target concentration for control level 1 is 30 pg/mL.
The target concentration for control Level 2 is 260 pg/mL.

The range of concentrations of each control is reported on the certificate of analysis provided with each LIAISON® 1-84 PTH Control set.

LIAISON® 1-84 PTH Calibration Verifier set contains:

- 4 levels containing human plasma spiked with 1-84 PTH, with preservative, 1 vial each level, lyophilized.

The target concentration for cal verifier A is 10 pg/mL.
The target concentration for cal verifier B is 80 pg/mL.
The target concentration for cal verifier C is 400 pg/mL.
The target concentration for cal verifier D is 1450 pg/mL.

The range of concentrations of each calibration verifier is reported on the certificate of analysis provided with each LIAISON® 1-84 PTH Calibration Verifier set.

8. Intended Use:

The DiaSorin LIAISON® 1-84 PTH Assay is an *in vitro* chemiluminescent immunoassay (CLIA) intended for the quantitative determination of parathyroid hormone (1-84) in human serum and EDTA plasma. Measurements of parathyroid hormone levels are used in the differential diagnosis of hypercalcemia and hypocalcemia resulting from disorders of calcium metabolism.
The test has to be performed on the LIAISON® Analyzer.

The DiaSorin LIAISON® 1-84 PTH Control Set is intended for *in vitro* diagnostic use as assayed quality control samples to monitor the accuracy and precision of the LIAISON® 1-84 PTH Assay.

The DiaSorin LIAISON® 1-84 PTH Calibration Verifiers are assayed quality control materials intended for *in vitro* diagnostic use in the quantitative verification of calibration and reportable range of the LIAISON® 1-84 PTH Assay.

9. Indication(s) for Use:

Same as Intended Use

10. Substantial Equivalence Information:

A comparison of the similarities and differences between the LIAISON® 1-84 PTH Assay and the predicate Scantibodies Laboratory, Inc. Whole PTH™ (1-84) Specific (IRMA) assay are provided in the following table:

Assay Similarities and Differences		
Characteristic	**Candidate Device LIAISON® 1-84 PTH Assay**	**Predicate Device Whole PTH™ (1-84) Specific Scantibodies Laboratory Inc. (k001411)**
Intended Use	intended for the quantitative determination of parathyroid hormone (1-84)	intended for the *in vitro* quantitative determination of human whole parathyroid hormone (PTH)
Measured Analyte	Parathyroid Hormone (whole molecule)	Parathyroid Hormone (whole molecule)
Assay Type	Chemiluminescent Immunoassay	Immunoradiometric (IRMA) assay
Antibody	Goat polyclonal	Goat polyclonal
Sample Matrix	EDTA Plasma and Serum	EDTA plasma
Sample size	150µL	200µL
Sample Handling/Processing	Automated	Manual
Calibrators	2 levels Included with kit	7 levels included with kit
Calibration Interval	Two-point calibration curve stable for 7 weeks	7 calibrator levels tested with every assay
Measuring range	4 - 1800 pg/mL	0 - 2300 pg/mL
Reference range	EDTA Plasma: 5.72 – 45.4 pg/mL Serum: 5.68 – 47.8 pg/mL	EDTA Plasma: 5 - 39 pg/mL

Control Similarities and Differences		
Characteristic	**Candidate Device LIAISON® 1-84 PTH Control Set**	**Predicate Device LIAISON® N-TACT® PTH Control Set (k033426)**
Intended Use	intended for use as assayed quality control samples to monitor the accuracy and precision of the LIAISON® 1-84 PTH	intended for use as assayed quality control samples to monitor the accuracy and precision of the LIAISON® N-TACT® PTH
Storage	Store at 2-8°C until ready to use	Same
Levels	2 levels: lyophilized Level 1 (approx 30 pg/mL) Level 2 (approx 260 pg/mL)	2 levels: lyophilized Level 1 (approx 60 pg/mL) Level 2 (approx 560 pg/mL

Calibration Verifiers Similarities and Differences		
Characteristic	**Candidate Device LIAISON® 1-84 PTH Calibration Verifiers**	**Predicate Device LIAISON® N-TACT® PTH Calibration Verifiers (k093498)**
Intended Use	assayed quality control materials intended for the quantitative verification of calibration and reportable range of the LIAISON® 1-84 PTH Assay	assayed quality control materials intended for the quantitative verification of calibration and reportable range of the LIAISON® N-TACT® PTH
Storage	2 to 8°C	Same
Levels	4 levels; lyophilized Cal Ver A (approx 10 pg/mL) Cal Ver B (approx 80 pg/mL) Cal Ver C (approx 400 pg/mL) Cal Ver D (approx 1450 pg/mL)	4 levels; lyophilized Cal Ver A (approx 20 pg/mL) Cal Ver B (approx 150 pg/mL) Cal Ver C (approx 350 pg/mL) Cal Ver D (approx 1500 pg/mL)
Volume	2.0 mLs	Same

11. Standard/guidance Document Reference:

- CLSI Guideline EP5-A2, Evaluation of Precision Performance of Quantitative Measurement Methods;
- CLSI Guideline EP6-A, Evaluation of Linearity of Quantitative Analytical Methods;
- CLSI Guideline EP7-A2, Interference Testing in Clinical Chemistry;
- CLSI Guideline EP9-A3, Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline;
- CLSI Guideline EP17-A2, Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures;
- CLSI Guideline C28-A3, Defining, Establishing and Verifying Reference Intervals in the Clinical Laboratory.

12. Performance Characters:

Method Comparison

A method comparison study was performed following CLSI EP9-A3, mean of the duplicate results for the Scantibodies Laboratory Inc. Whole PTH™ (1-84) Specific and

singlicate results for the LIAISON® 1-84 PTH Assay were plotted. Passing & Bablok linear regression analyses were performed and gave the following results:

Passing & Bablok Fit					
n	Slope	95% Confidence Interval	Intercept pg/mL	95% Confidence Interval	Correlation coefficient (R)
193	0.9810	0.9497 to 1.0204	-2.23	-5.29 to -0.61	0.9812

Sample Matrix Comparison

One Hundred Eighty-eight (188) matched patient sets of EDTA plasma and serum samples were tested to determine if these sample types provide equivalent results on the LIAISON® 1-84 PTH Assay.

The following Passing & Bablok regression analyses results were obtained:

EDTA plasma vs.	**Slope**	**95% CI**	**Intercept pg/mL**	**95% CI**	**R^2**
Serum	1.0481	1.03 – 1.08	0.14	-0.48 - 0.69	0.9981

Reference Range

It is recommended that each laboratory establish its own range of expected values.

To assess the expected reference range for the LIAISON® 1-84 PTH Assay, a study was performed with 125 EDTA plasma samples (91 females and 34 males) and 124 serum samples (90 females and 34 males) collected from apparently healthy adults; 21 – 70 years of age, from mixed ethnic backgrounds (32.0% dark-skinned, 67.2% light-skinned and 0.8% unknown) with normal 25 OH Vitamin D, TSH, Total Calcium, Phosphorus, Magnesium, Creatinine and Alkaline Phosphatase levels from the northern and southern regions of the U.S. Based on the parametric method with 95% Reference Limit, the following values were established following CLSI guideline C28-A3.

Population United States	N	Median PTH (pg/mL)	Observed Range 2.5^{th} to 97.5^{th} Percentile
EDTA Plasma	125	25.0	5.72 – 45.4 pg/mL
Serum	124	25.2	5.68 – 47.8 pg/mL

Precision

Precision testing was performed following CLSI Guideline EP5-A2, Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline – Second Edition. A coded panel comprised of 7 frozen EDTA plasma samples spanning the assay range was prepared by DiaSorin Inc. One lot of LIAISON® 1-84 PTH controls (2 levels) were also tested in the study. The precision panel samples and kit controls were tested on two lots of LIAISON® 1-84 PTH in two replicates per run, 2 runs per day for 20 operating days on 1 LIAISON® Analyzer for a total of 160 replicate results per sample.

The 20 day results are summarized for the combined reagent lot numbers as sample mean PTH concentration in pg/mL, standard deviations and coefficient of variation (%CV) for between lot and Total across lots.

Combined lot precision

Sample ID	n	Mean PTH (pg/mL)	Between-Lot		Total (Across Lots)	
			SD	%CV	SD	%CV
Kit Control 1	160	30.2	1.02	3.4%	1.52	5.0%
Kit Control 2	160	305.6	9.86	3.2%	14.08	4.6%
EDTA PTH-S1	160	11.8	0.37	3.2%	1.23	10.4%
EDTA PTH-S2	160	18.7	0.78	4.1%	1.45	7.7%
EDTA PTH-S3	160	35.2	0.87	2.5%	2.03	5.8%
EDTA S4-PTH	160	176.5	5.67	3.2%	6.69	3.8%
EDTA S5-PTH	160	399.6	12.56	3.1%	18.20	4.6%
EDTA S6-PTH	160	1124.7	37.89	3.4%	50.62	4.5%
EDTA S7-PTH	160	1743.9	47.97	2.8%	101.00	5.8%

The calibration verifiers were tested on one LIAISON® Analyzer with one lot of LIAISON® 1-84 PTH Assay in two replicates per run, 2 runs per day for 20 operating days for a total of 80 replicate results per calibration verifier.
The mean, standard deviation, and coefficient of variation (%CV) of the results were computed for each of the tested calibration verifier levels.

Calibration Verifiers 20 day precision

Sample ID	n	Mean (pg/mL)	Intra-Run		Run-to-Run		Day-to-Day		TOTAL (Within-lot)	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
Cal Verifier A	80	13.0	0.83	6.4%	0.61	4.7%	0.30	2.3%	1.07	8.2%
Cal Verifier B	80	87.2	3.58	4.1%	2.81	3.2%	0.00	0.0%	4.52	5.2%
Cal Verifier C	80	376	12.53	3.3%	12.46	3.3%	9.95	2.6%	20.28	5.4%
Cal Verifier D	80	1487	56.71	3.8%	6.25	0.4%	62.43	4.2%	84.58	5.7%

Linearity

One sample pool of each type; serum and EDTA plasma were diluted and analyzed by the LIAISON® 1-84 PTH Assay following CLSI EP6-A. The results were analyzed by a regression of Observed PTH Concentration versus Expected PTH Concentration.

The resulting equations for each sample type are:
Serum: Observed 1-84 PTH = 0.9992x – 0.0835; R^2 = 0.9976
EDTA plasma: Observed 1-84 PTH = 0.9679x – 3.328; R^2 = 0.9971

High Dose Hook Effect

Testing was conducted to determine if the LIAISON® 1-84 PTH Assay is susceptible to artificially low results in the presence of very high levels of PTH (Hook Effect). Three serum and 3 EDTA plasma samples were spiked with 1-84 PTH to equal several concentrations above the assay measuring range of 1800 pg/mL. The spiked samples were measured in triplicate.

No high dose hook effect was observed for 1-84 PTH concentrations measured up to 60,000 pg/mL.

Recovery Study

Five (5) high concentration EDTA plasma samples and 5 low concentration samples EDTA plasma samples were analyzed neat on the LIAISON® 1-84 PTH Assay. Recovery samples were then prepared by mixing defined ratios of the high and low samples and tested in replicates of 5. The observed values were compared to the expected values to determine the % recovery.

Sample	Defined pg/mL	Expected pg/mL	Observed pg/mL	% Recovery
High Sample 1 (HS1)	534			
2 HS1 : 1 LS1		364	344	94%
1 HS1 : 1 LS1		277	262	95%
1 HS1 : 2 LS1		189	178	94%
Low Sample 1 (LS1)	18.9			
High Sample 2 (HS2)	1088			
2 HS2 : 1 LS2		734	713	97%
1 HS2 : 1 LS2		551	514	93%
1 HS2 : 2 LS2		368	331	90%
Low Sample 2 (LS2)	13.8			
High Sample 3 (HS3)	457			
2 HS3 : 1 LS3		311	300	97%
1 HS3 : 1 LS3		235	224	95%
1 HS3 : 2 LS3		159	153	96%
Low Sample 3 (LS3)	12.7			
High Sample 4 (HS4)	45.2			
2 HS4 : 1 LS4		32.2	31.3	97%
1 HS4 : 1 LS4		25.5	24.8	97%
1 HS4 : 2 LS4		18.8	18.6	99%
Low Sample 4 (LS4)	5.74			
High Sample 5 (HS5)	1546			
2 HS5 : 1 LS5		1045	990	95%
1 HS5 : 1 LS5		787	733	93%
1 HS5 : 2 LS5		529	501	95%
Low Sample 5 (LS5)	28.2			
		Mean Recovery		95%

Sample Equivalence:

One hundred Eighty-eight matched patient sets of EDTA plasma and serum with results spanning the assay range of the LIAISON® 1-84 PTH Assay were tested to determine sample equivalence.

Comparison of serum to EDTA plasma yielded the following equation:

Serum = 1.0481x + 0.1438; R^2 = 0.9981.

Analytical Specificity
Cross-Reactivity Studies

Controlled studies of potentially cross-reacting substances were performed on the LIAISON® 1-84 PTH Assay. LIAISON® 1-84 PTH Specimen Diluent was spiked with the following human PTH fragments and structurally similar proteins at the concentrations listed below. Testing was based on CLSI EP-7A2.

Cross-Reactant	Spiked concentration	% Cross Reactivity
7 – 84 PTH	200,000 pg/mL	0.00105%
1 – 34 PTH	200,000 pg/mL	0.00005%
13 – 34 PTH	200,000 pg/mL	0.00020%
39 – 68 PTH	200,000 pg/mL	0.00090%
44 – 68 PTH	200,000 pg/mL	0.00055%
39 – 84 PTH	200,000 pg/mL	0.00050%
53 – 84 PTH	200,000 pg/mL	0.00015%
Calcitonin	200,000 pg/mL	0.00008%
Osteocalcin	200,000 pg/mL	0.00005%
C-Telopeptide (β-crosslaps)	200,000 pg/mL	0.00001%

Interference Studies

Controlled studies of potentially interfering endogenous substances performed in EDTA plasma at two PTH levels (40 and 70 pg/mL) showed no interference in the LIAISON® 1-84 PTH Assay at the highest spiked concentration for each substance listed below.

Drug/Substance	Concentration at which no significant interference (≥ ±10%) was observed
Hemoglobin	500 mg/dL
Bilirubin (conjugated)	40 mg/dL
Bilirubin (unconjugated)	20 mg/dL
Triglycerides	3,000 mg/dL
Cholesterol	500 mg/dL
Albumin	12 g/dL
HAMA	4,088 ng/mL
Rheumatoid Factor	5,380 IU/mL

Controlled studies of potentially interfering exogenous substances performed in EDTA plasma at two PTH levels (40 and70 pg/mL) showed no interference in the LIAISON® 1-84 PTH Assay at the highest spiked concentration for each substance listed below.

Drug/Substance	**Concentration at which no significant interference (≥ ±10%) was observed**
Acetaminophen	20 mg/dL
Acetylsalicylic Acid	65 mg/dL
Salicylic Acid	60 mg/dL
Ibuprofen	50 mg/dL
Alendronate	8 mg/dL
Etidronate	105 mg/dL
Pamidronate	18 mg/dL
Risedronate	6 mg/dL
Vitamin D2	240 ng/mL
Vitamin D3	240 ng/mL
Calcitriol	1 ng/mL
Alfacalcidol	2.5 µg/mL
Biotin	1 µg/mL
Calcium Acetate	40 mg/dL
Calcium Citrate	40 mg/dL
Magnesium Chloride	40 mg/dL
Aluminum Sulfate	40 mg/dL
Lanthanum Chloride	40 mg/dL

Limit of Blank, Limit of Detection and Limit of Quantitation

The Limit of Blank, Limit of Detection and Limit of Quantitation were determined according to CLSI EP17-A2: Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline June 2012- Second Edition.

The following limits for serum and EDTA plasma were determined with the LIAISON® 1-84 PTH Assay:

LoB	LoD	LoQ
≤ 0.5 pg/mL	1.7 pg/mL	4.0 pg/mL

Stability

Product	Storage Conditions		Claimed stability
Reagent Integral	Open vial	on system	28 days
Reagent Integral	Open vial	2-8°C	28 days
Calibrators	Open vial - Reconstituted	on system/RT	2 hours
	Open vial - Reconstituted and Frozen	-20°C	8 weeks
Calibration curve	N/A	N/A	7 days
Controls	Open vial - Reconstituted	on system/RT	2 hours
	Open vial - Reconstituted and Frozen	-20°C	8 weeks
Calibration Verifiers	Open vial - Reconstituted	on system/RT	2 hours
	Open vial - Reconstituted and Frozen	-20°C	2 weeks

Traceability

The LIAISON® 1-84 PTH Calibrators, Controls and Calibration Verifiers concentrations are referenced to an in-house standard preparation containing synthetic human PTH (1-84).

Value Assignment

Calibrators

A minimum of 5 vials of each level of calibrator are tested on a minimum of 3 LIAISON® Analyzers, using 2 different approved LIAISON®1-84 PTH Assay kit lots, in a minimum of 5 assay runs with 6 replicates per vial resulting in a minimum of 30 individual replicate results per calibrator level for final value assignment.

Controls

A minimum of 10 vials of each level of control are tested on a minimum of 3 LIAISON® Analyzers, using 2 different approved LIAISON® 1-84 PTH Assay kit lots, in a minimum of 5 assay runs over 10 days with four replicates per vial resulting in a minimum of 40 individual replicate results per control used for final value range assignment.
The mean, standard deviation (sd) and % CV for each level of kit control is calculated and a ± 2SD range is established.

Calibration Verifiers

A minimum of 12 vials of each level of calibration verifier are tested on a minimum of 4 LIAISON® Analyzers, using 2 different approved LIAISON® 1-84 PTH Assay kit lots, in a minimum of 6 assay runs with four replicates per vial resulting in a minimum of 48 individual replicate results used per calibration verifier for final value range assignment.
The mean, standard deviation (sd) and % CV for each level of calibration verifier is calculated and a ± 2SD range is established.

13. Conclusion:

The LIAISON® 1-84 PTH Assay**,** LIAISON® 1-84 PTH Control Set and the LIAISON® 1-84 PTH Calibration Verifiers are substantially equivalent in principle and performance to the Scantibodies Laboratory, Inc. Whole PTH™ (1-84) Specific immunoradiometric (IRMA) assay, the LIAISON® N-TACT® PTH Control Set and the LIAISON® N-TACT® PTH Calibration Verifiers, respectively.