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SeaLite Sciences, Inc.

510(k) SUMMARY

As described in 21 C.F.R. § 807.92, the following is a summary of the safety and effectiveness of the SeaLite Sciences, Inc. AquaLite® Intact PTH.

I. GENERAL INFORMATION

Trade or proprietary name - SeaLite Sciences, Inc. AquaLite® Intact PTH

Common or usual name - Bioluminescent immunoassay (BIA)

Classification name - FDA has classified parathyroid hormone test systems intended for the measurement of PTH in the diagnosis of disorders of calcium metabolism as Class II devices. 21 C.F.R. §862.1545.

Submitter's Name and Address:	Cathryn N. Cambria Director, Regulatory Affairs and Quality Assurance SeaLite Sciences, Inc. 3000 Northwoods Parkway Suite 200 Norcross, GA 30071 (800) 874-4471, x227
Submission Date:	February 7, 1997
Legally Market Device to Which Claim Substantial Equivalence:	Nichols Institute Intact PTH assay

II. INDICATIONS FOR USE

The AquaLite® Intact PTH Bioluminescent Immunoassay (BIA) Kit (or the AquaLite® Intact PTH assay) is intended to be used in clinical laboratories for the quantitative determination of human intact parathyroid hormone in serum [redacted] Intact PTH

measurements are used in the diagnosis of disorders of calcium metabolism and the parathyroid gland. The AquaLite® Intact PTH assay is for *in vitro* diagnostic use.

III. DEVICE DESCRIPTION

The AquaLite® Intact PTH Bioluminescent Immunoassay Kit uses a goat polyclonal anti-PTH antibody that is pre-coated onto polystyrene tubes (solid phase). Serum samples, appropriate calibrators, and controls, are pipetted (100μL) into the pre-coated tubes. A second goat polyclonal anti-PTH antibody covalently linked to AquaLite® (150μL) is then added to the tubes. Intact PTH in the sample simultaneously combines with anti-PTH antibody on the solid phase and conjugate antibody to form an immune complex or "sandwich" bound to the solid phase. Complex formation is complete after a 120-minute incubation period at room temperature (18° to 25°C) on a standard orbital shaker. The tubes are then washed to remove unbound conjugate.

The washed tubes are placed in a luminometer that is capable of reading a triggered, flash-type reaction in 12 x 75 mm tubes. Injection of the calcium trigger buffer causes AquaLite® to oxide its self-contained luciferin molecule, producing a flash of light which is measured by the luminometer. The intensity of the light emitted from antibody bound to the tubes is directly proportional to the concentration of intact PTH in the sample. To calculate results, the luminometer uses a cubic spline curve fit applied to a logit-log transformation of the light intensity (in relative light units, RLU) of the intact PTH calibrators versus intact PTH concentration (in pg/mL).

Note: Samples that generate signals greater than the signal from the highest calibrator are off-scale. These samples must be diluted and re-assayed. Remember to multiply the results from diluted samples by the dilution factor used.

IV. SUMMARY OF STUDIES AND TECHNOLOGICAL CHARACTERISTICS

Studies on SeaLite Sciences, Inc. AquaLite® Intact PTH were conducted at SeaLite Sciences. The results are summarized below:

Performance Characteristics

1. **Sensitivity**

The sensitivity or detection limit of the AquaLite® Intact PTH is 0.7 pg/mL. Sensitivity is determined by adding the mean signal of twenty (20) replicates of the zero level calibrator plus two (2) standard deviations above this mean. The PTH concentration (pg/mL) associated with this calculated signal is defined as the sensitivity of the assay.

2. **Specificity**

The AquaLite® Intact PTH captures antibody coated onto the solid phase, and the conjugate antibody recognizes distinct segments of intact (1-84) PTH. A complex bound to the solid phase is formed only with the intact PTH molecule. Cross reactivity of the Aqualite® Intact PTH assay with PTH fragments was determined by spiking a sample containing intact PTH (17 pg/mL) with PTH fragments.

PTH Fragment	Concentration (pg/mL)	% Inhibition
1-34	400	50
39-84	100,000	0
53-84	100,000	0
39-68	100,000	0
44-68	100,000	0

3. **High Dose Hook Effect**

No high dose hook effect occurs prior to 100,000 pg/mL intact PTH.

4. **Precision**

(a) **Intra-assay precision.** Two serum commercial controls containing PTH at the following concentrations were assayed to determine intra-assay precision. (Total N = 20 per concentration level.)

PTH Level (pg/ml)	% CV
26.10	6.95%
173.71	5.45%

(b) **Inter-assay precision.** Two serum controls containing prolactin at the following concentrations were assayed in 20 assays. A new standard curve was generated for each assay (n=2x20=40).

PTH Level (pg/ml)	% CV
51.7	8.9%
332.3	8.3%

5. **Method Comparison**

The AquaLite® Intact PTH was used to assay PTH in patient samples (N=57) that were previously assayed by a commercially available chemiluminometric kit for PTH. Correlation by linear regression analysis gave a slope of 0.964 with a y- intercept of 10.017. The correlation coefficient was 0.95.

6. Linearity and Nonparallelism

Three human serum samples containing the levels of endogenous PTH shown below were diluted as indicated using Calibrator A (0 pg/mL) and assayed in duplicate using AquaLite® Intact PTH. All concentrations are in pg/mL.

Sample ID	Dilution Factor	PTH Found (pg/mL)	PTH Expected (pg/mL)	Recovery (%)
A	Undiluted	37.4	----	----
	1:2	19.9	18.7	106
	1:4	9.7	9.4	103
	1:8	5.0	4.7	106
B	Undiluted	85.7	----	----
	1:2	46.4	42.9	108
	1:4	22.9	21.4	107
	1:8	10.6	10.7	99
C	Undiluted	709.0	----	----
	1:2	354.0	354.0	100
	1:4	182.0	177.0	103
	1:8	92.6	88.6	105

7. **Recovery**

PTH serum samples were mixed in 2:1, 1:1 and 1:2 ratios and assayed in duplicate. All values are in pg/mL.

Sample	Dilution	PTH Observed	PTH Expected	% Recovered
A	UndilutedA	4.0	----	----
	2A:1B	24.9	28.0	89
	1A:1B	37.5	40.2	93
	1A:2B	48.2	52.0	93
B	Undiluted B	76.4	----	----
C	Undiluted C	15.0	----	
	2C:1D	52.0	58.0	90
	1C:1D	71.0	79.0	90
	1C:2D	92.0	100	92
D	Undiluted D	143.0	----	----

V. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

Use Universal Precautions. No known test method can offer complete assurance that products derived from human serum are pathogen-free; therefore, handle all materials of human origin as though they were potentially infectious.

Sodium azide is used as a preservative. This preservative may react with metallic plumbing to from explosive metal azides. Flush with large volumes of water when disposing of materials containing sodium azide.

As an *in vitro* diagnostic test, there are not direct adverse effects on the health of a patient from the use of this product. However, failure of the device to perform as indicated, the contamination of reagents, the use of reagents past the labeled expiration dates, the use of improper specimens, or human error during the performance of the test may lead to erroneous results and possible improper patient management.

VI. CONCLUSIONS DRAWN FROM STUDIES

The data from the studies conducted demonstrated that the performance of SeaLite Sciences, Inc. AquaLite® Intact PTH is similar and substantially equivalent to that of other commercially available assays for intact PTH.