

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

A. 510(k) Number:

k051888

B. Purpose for Submission:

New device

C. Measurand:

Intact parathyroid hormone

D. Type of Test:

Quantitative

E. Applicant:

Scantibodies Laboratory, Inc.

F. Proprietary and Established Names:

Total Intact PTH Immunoradiometric Assay (Coated Tube Version)

G. Regulatory Information:

1. Regulation section:

21 CFR 862.1545 – Parathyroid hormone test system

2. Classification:

Class II

3. Product code:

CEW

4. Panel:

Chemistry (75)

H. Intended Use:

1. Intended use(s):

This kit has been designed for the quantitative determination of total immunoreactive intact PTH (Total Intact PTH) in blood samples. The Total Intact PTH level is the sum of PTH (1-84) and N-truncated PTH fragments.

2. Indication(s) for use:

The Scantibodies Laboratory, Inc. Total Intact Parathyroid Hormone (PTH) test system is a device intended to measure the levels of parathyroid hormone in serum and plasma. Measurements of parathyroid hormone levels are used in the differential diagnosis of hypercalcemia (abnormally high levels of calcium in the blood) and hypocalcemia (abnormally low levels of calcium in the blood) resulting from disorders of calcium metabolism.

3. Special conditions for use statement(s):

This device is for prescription use.

4. Special instrument requirements:

This is a manual assay and doesn't require use of an automated analyzer.

I. Device Description:

The Total Intact PTH Coated Tube Kit is supplied with the following:

- 7 vials of PTH calibrators (lyophilized human serum)
- 2 vials of PTH controls (lyophilized human serum)
- 2 packages of 50 tubes (polyclonal goat anti-PTH)
- 2 vials of PTH tracer (polyclonal goat anti-PTH labeled with ¹²⁵I)
- 1 bottle of wash concentrate

J. Substantial Equivalence Information:

1. Predicate device name(s):

Total Intact PTH Immunoradiometric Assay (Coated Bead Version)

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

k004038

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	Assay used to detect human PTH in blood samples	Same
Assay Principle	IRMA	Same

Differences		
Item	Device	Predicate
Specimen	EDTA plasma or serum	EDTA plasma
Solid Phase	Antibody coated tubes	Antibody coated beads
Analytical Sensitivity	~1.0 pg/mL	~1.23 pg/mL
Normal Range	10-57 pg/mL	14-66 pg/mL

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

CLSI guideline C28-A

L. Test Principle:

Scantibodies Total Intact PTH Coated Tube Kit is an immunoradiometric assay (IRMA) utilizing two polyclonal antibodies, one that tends to bind in the N terminal region of 1-84 PTH (radioactive labeled antibody) and the other that tends to bind in the C terminal region of 1-84 PTH (capture antibody). Total intact PTH in patient samples is bound to the tubes and label antibody, followed by incubation and wash steps. The concentration of total intact PTH is directly proportional to the radioactivity bound to the tubes after separation. The concentration of PTH in unknown patient samples and controls is determined by interpolation using a calibration curve.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Interassay precision was evaluated by performing 20 different assays on three EDTA plasma samples, across three kit lots.

Interassay Precision			
Kit Batch	Mean Value (pg/mL)	Std. Dev. (pg/mL)	%CV
E1	39.31	1.62	4.13
	204.16	9.62	4.71
	419.79	14.12	3.36
E2	37.17	3.28	8.82
	209.66	7.17	3.42
	424.54	25.21	5.94
E3	39.52	1.77	4.47
	200.71	9.23	4.60
	416.15	11.07	2.66

Intra-assay precision was evaluated by performing 20 replicate determinations on three EDTA plasma samples in the same assay, across three kit lots.

Intra-assay Precision			
Kit Batch	Mean Value (pg/mL)	Std. Dev. (pg/mL)	%CV
E1	40.98	1.04	2.54
	211.49	3.56	1.69
	437.56	5.32	1.22
E2	36.56	1.65	4.51
	208.33	6.50	3.12
	408.40	15.73	3.85
E3	39.08	1.05	2.69
	199.39	2.47	1.24
	411.90	5.68	1.38

b. Linearity/assay reportable range:

The assay reportable range is 1 to 2300 pg/mL.

Accuracy, Recovery

Different serum samples with approximately 40 to 424 pg/mL of PTH were spiked with two amounts of PTH. In addition, one plasma sample with approximately 1118 pg/mL of PTH was spiked with two concentrations of PTH. The % recovery was determined following assay of the spiked samples. The % recoveries found ranged from 90.5 to 109.7.

Accuracy, Dilution

Different serum samples with high concentrations of PTH (431.20 to 2458 pg/mL) were diluted in a sample with low concentrations of PTH. The % recovery was determined following assay of the spiked samples. The %

recoveries found ranged from 77.2 to 108.1.

High Dose Hook Response

The high dose hook response of the assay was determined as 20,000 pg/mL of synthetic PTH (1-84) and PTH (7-84). Samples greater than the highest standard (approximately 2300 pg/mL) and up to 20,000 pg/mL PTH will read CPM values greater than that of the highest standard.

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

The calibrators and controls consist of human serum, which has been prepared from human donors. The human serum was tested by FDA approved immunoassays and found to be non-reactive for Hepatitis B Surface Antigen (HBsAg), Anti HIV I/II and Anti HCV.

The value assignment and stability of the standards and controls were addressed in the predicate device (K004038) and remains the same.

d. Detection limit:

The detection limit of this assay was determined by assaying the zero calibrator 20 times in the same assay. The detection limit is approximately 1.0 pg/mL at two standard deviations above the geometric mean of the PTH zero calibrator.

e. Analytical specificity:

The assay does not show any cross-reactivity to the following PTH fragments at 100,000 pg/mL: 1-34, 39-68, 53-84, 44-68, and 39-84.

The following substances were added to a 42.71 pg/mL PTH sample and evaluated for interference: triglycerides up to 250 mg/dL, hemoglobin up to 15 mg/dL, and bilirubin up to 15 mg/dL. The recoveries ranged from 94% to 100%, demonstrating no interference up to these levels.

f. Assay cut-off:

See "Detection limit" above.

2. Comparison studies:

a. Method comparison with predicate device:

A method comparison was performed by measuring 243 plasma samples from males and females on both the subject device and a commercially available

predicate PTH kit. PTH concentrations ranged from 8 -2024 pg/mL. The results yielded the following correlation: $y = 1.05x - 2.20$, $r = 1.00$.

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 normal range was determined following the CLSI guideline C28-A using 252 samples from apparently healthy individuals. The package insert states that the values found may differ from other published data and recommends that each laboratory establish its own range.

Patient Classification	Total Intact PTH (pg/mL)
Normal	10-57
Hyperparathyroidism	>57

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.