510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE

A. 510(k) Number:
k031534

B. Analyte:
Parathyroid Hormone

C. Type of Test:
Quantitative

D. Applicant:
SCANTIBODIES Laboratory, Inc.

E. Proprietary and Established Names:
Cyclase Activating PTH (CAP) IRMA Assay

F. Regulatory Information:
1. Regulation section:
   21 CFR 862.1545
2. Classification:
   Class II
3. Product Code:
   CEW
4. Panel:
   75 (clinical chemistry and clinical toxicology

G. Intended Use:
1. Indication(s) for use:
   The Cyclase Activating PTH (CAP) IRMA Assay has been designed for the quantitative determination of Cyclase activating parathyroid hormone (PTH) without cross-reaction to PTH (7-84) fragment in serum and plasma samples. The 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.
2. Special condition for use statement(s):
   NA
3. Special instrument Requirements:
   Gamma counter calibrated to detect ^{125}I

H. Device Description:
The in vitro diagnostic reagent kit contains sufficient reagents for 100 single determinations. The reagents consist of the following: 7 vials of lyophilized human serum calibrator materials, 2 vials of lyophilized human serum control materials, 2 bottles of 125I tracer (goat anti-PTH), 100 polystyrene beads coated with goat anti-PTH (39-84) and one bottle of 30 mL of phosphate buffered saline wash concentration.

I. Substantial Equivalence Information:

1. Predicate device name(s):
   Scantibodies Laboratory Inc. Whole PTH (1-84) Specific Immunoradiometric Assay
2. Predicate K number(s):
   k001411
3. Comparison with predicate:

Item	Device	Predicate
Intended use	For the quantitative determination of cyclase activating parathyroid hormone (PTH) without cross-reaction to PTH (7-84) fragment in EDTA plasma and serum samples	For the quantitative determination of human whole parathyroid hormone PTH (1-84) without cross-reaction to PTH (7-84) fragment in EDTA plasma samples
Principle of the method	Immunoradiometric (IRMA) with coated bead technology	Same
Measuring range	1.0 – 2300 pg/mL	Same
QC and calibrator materials	2 lyophilized QC materials and 7 lyophilized calibrators provided with assay kit	Same
Sample type	EDTA plasma and serum	EDTA plasma
Labeled polyclonal PTH antibodies directed against	PTH (1-12) and C-terminal PTH	N-terminal and C-terminal PTH

J. Standard/Guidance Document Referenced (if applicable):
   NCCLS C28-A guideline
K. Test Principle:
   Immunoradiometric (IRMA) using coated bead technology
L. Performance Characteristics (if/when applicable):

1. Analytical performance:
   a. *Precision/Reproducibility:*
   The inter-assay imprecision was evaluated by assaying two samples in duplicate for 20 days, using 3 kits in 20 separate assays. The inter-assay imprecision as measured by %CV for sample means 16.55, 20.15, 26.96, 218.3, 219.0 and 302.1 pg/mL were 4.15, 4.69, 4.0, 3.44, 3.71 and 2.21 %CV, respectively.
   The intra-assay imprecision was evaluated by performing 20 replicates on two samples, using 3 kits. The intra-assay imprecision as measured by %CVs for sample means 25.64, 24.55, 25.88, 269.88, 264.07, and 304.54 pg/mL were 4.49, 2.36, 3.47, 2.52, 2.19,2.34 %CV, respectively.

    b. *Linearity/assay reportable range:*
Three samples with high PTH values, 290.28, 551.44 and 670.58 pg/mL were diluted 1:2, 1:4 and 1:8 with low PTH samples. The resulting recovery values ranged from 87.8% to 96.7%.

    c. *Traceability (controls, calibrators, or method):*

    d. *Detection limit:*
The detection limit of the assay is defined as the lowest measurable value distinguishable from zero. The sensitivity was determined by assaying the zero calibrator 20 times in the same assay. The detection limit is approximately 1.0 pg/mL at 2 standard deviations above the PTH zero calibrator utilizing tracer less than 1 week from manufacturing.

    e. *Analytical specificity:*
Synthetic PTH peptide (7-84) was serially diluted with the zero calibrator and assayed. The measured PTH concentration was undetectable for PTH (7-84) concentrations of 2500, 5000, 10,000, and 20,000 pg/mL.
Samples containing 100 and 200 mg/dL triglyceride, 7.5 and 15 mg/dL hemoglobin and 3.75, 7.5 and 15 mg/dL of bilirubin did not exhibit any effect on the assay as defined by recovery ranging from 96.2% to 108.6%.

    f. *Assay cut-off:*
NA

2. <u>Comparison studies:</u>

    a. *Method comparison with predicate device:*
A study analyzing 250 plasma samples, ranging in concentration from 7.2 – 1088 pg/mL, with this device (Y) and the predicate device (X) was performed. A linear regression equation of $Y = 0.946X + 2.46$ pg/mL, $r = 0.996$ was obtained.

    b. *Matrix comparison:*
A study using 120 paired serum and plasma samples was performed. The resulting regression equation was Y (serum) $= 0.94X$ (plasma) $+ 1.57$ pg/mL, $r = 0.971$.

3. <u>Clinical studies:</u>

    a. *Clinical sensitivity:*
NA

    b. *Clinical specificity:*
NA

    c. *Other clinical supportive data (when a and b are not applicable):*
NA

4. <u>Clinical cut-off:</u>
NA

5. <u>Expected values/Reference range:</u>
   Serum and plasma samples from 120 subjects were assayed (N=240)
   following the NCCLS C28-A guideline. The 95% reference interval for serum
   and plasma is 11-52 pg/mL.

M. Conclusion:

Based upon the information provided for the file, I recommend a determination of
substantial equivalence for Cyclase Activating PTH (CAP) IRMA Assay to the predicate
device regulated by 21CFR 862.1545.