

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

A. 510(k) Number:

k050748

B. Purpose for Submission:

Notification of intent to manufacture and market the device: ACTH Immunoradiometric (IRMA) Assay Kit

C. Measurand:

Quantitative determination of human Adrenocorticotrophic hormone (ACTH)

D. Type of Test:

Immunoradiometric

E. Applicant:

Scantibodies Laboratory, Inc

F. Proprietary and Established Names:

Proprietary name & Established name: ACTH Immunoradiometric (IRMA) Assay

G. Regulatory Information:

1. Regulation section:

21 CFR 862.1025 – ACTH Radioimmunoassay

2. Classification:

Class II

3. Product code:

CKG

4. Panel:

75, Chemistry

H. Intended Use:

1. Intended use(s):

See indications for use below

2. Indication(s) for use:

The Scantibodies Laboratory, Inc. Adrenocorticotrophic Hormone (ACTH) test system is a device intended to measure Adrenocorticotrophic hormone in plasma. ACTH measurements are used in the differential diagnosis and treatment of certain disorders of the adrenal glands, such as Cushing's syndrome, adrenocortical insufficiency, and the ectopic ACTH syndrome.

3. Special conditions for use statement(s):

For professional use only

4. Special instrument requirements:

A gamma counter calibrated to detect I¹²⁵ is required.

I. Device Description:

The Scantibodies ACTH kit is supplied with the following: ACTH Standards – seven vials containing lyophilized human serum with synthetic ACTH peptide. ACTH Controls – two vials containing human lyophilized serum containing ACTH. ACTH Antibody coated tubes, two packages of polystyrene tubes coated with goat anti-ACTH (1-16), and ACTH I¹²⁵ antibody – two bottles of I¹²⁵ – anti ACTH (24-39).

The human serum in this kit has been prepared from human donors and it has been tested by FDA approved immunoassays and found to be non-reactive for Hepatitis B surface antigen, Anti-HIV I/II and anti HCV.

This test kit contains radioactive materials.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Nichols Institute Intact ACTH IRMA assay

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

k926396

3. Comparison with predicate:

Comparison of device to predicate		
Item	Device	Predicate
Intended Use	Quantitative determination of human ACTH	Same
Specimen	human Plasma	Same
Assay Format	IRMA	Same
Result Read Time	1 minute	Same
Analytical Sensitivity	~1 pg/mL	1 pg/mL
Normal Range	5 - 77 pg/ml	9 - 52 pg/ml
Solid Phase	ACTH Antibody Coated Tubes	ACTH Antibody Coated Beads

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

CLSI guideline C28-A

L. Test Principle:

Immunoradiometric

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Intra assay coefficient of variation was evaluated by performing 20 replicate determinations on 3 EDTA-plasma pools in the same assay.

ACTH				
Precision, Intra assay				
Kit Batch	Sample	Mean value (pg/mL)	Std. Dev. (pg/mL)	%CV
E1	1	30.76	2.39	7.76
E1	2	616.39	5.61	0.91
E1	3	1417.72	27.38	1.93
E2	1	37.38	2.99	8.00
E2	2	671.50	14.44	2.15
E2	3	1484.68	29.22	1.97
E3	1	29.11	2.33	8.00
E3	2	614.87	21.83	3.55
E3	3	1425.17	30.74	2.16

Intra assay coefficient of variation was evaluated by performing 20 replicate determinations on 4 EDTA-plasma pools.

ACTH				
Precision, Intra assay				
Kit Batch	Sample	Mean value (pg/mL)	Std. Dev. (pg/mL)	%CV
E1	1	31.11	3.67	11.78
E1	2	234.84	15.59	6.64
E1	3	643.17	27.24	4.24
E1	4	1425.39	38.52	2.70
E2	1	31.14	4.77	15.31
E2	2	232.89	9.84	4.23
E2	3	641.81	33.08	5.15
E2	4	1436.86	48.79	3.40
E3	1	31.33	3.94	12.59
E3	2	230.68	10.93	4.74
E3	3	641.64	34.33	5.35
E3	4	1438.2	54.27	3.77

b. Linearity/assay reportable range:

The high dose hook response was determined as 25,000 pg/mL of ACTH. Samples greater than the highest standard (approximately 1800 pg/ml) and up to 25,000 pg/mL will read CPM values greater than the highest standard.

Different samples with concentrations of ACTH were spiked with three amounts of ACTH in the first study. In the second study, different samples with high concentrations of ACTH were diluted in a sera with zero calibrator. The following percent recoveries were determined:

ACTH IRMA					
Accuracy, Recovery					
Sample	Sample value (pg/mL)	Added ACTH (pg/mL)	Measured value (pg/mL)	Expected value (pg/mL)	Recovery %
1	35.81	40.0	95.77	75.81	126
		80.0	142.27	115.81	123
		120.0	182.98	155.81	117
2	670.16	40.0	719.58	710.16	101
		80.0	756.57	750.16	101
		120.0	784.27	790.16	90
3	1434.1	40.0	1470.3	1474.1	99.7
		80.0	1469.4	1514.1	97
		120.0	1494.6	1554.1	96
ACTH					
Accuracy, Dilution					
Sample	Dilution	Measured value (pg/mL)	Expected value (pg/mL)	Recovery %	
1	Neat	336.60	-	-	
	1 to 2	170.20	168.3	101.1	
	1 to 4	91.67	84.15	108.1	
	1 to 8	45.43	42.08	108.0	
2	Neat	1050.40	-	-	
	1 to 2	471.75	525.2	89.8	
	1 to 4	234.30	262.6	89.2	
	1 to 8	131.71	131.3	100.3	
3	Neat	1327.10	-	-	
	1 to 2	658.17	663.55	99.2	
	1 to 4	333.98	331.78	100.7	
	1 to 8	180.99	165.89	109.1	
	1 to 16	101.13	82.94	121.9	

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

The standard values were assigned by testing using a commercially available ACTH IRMA assay. Five assays are run by multiple analysts on different days. The mean values are calculated and assigned to the standards. Subsequent lots of standard are assigned by testing using a previously approved lot of standards.

The control range values were assigned by running the control as unknown in five assays and assigning the range as +/- 20% of the mean for both Control 1 and Control 2.

d. *Detection limit:*

The detection limit is defined as the lowest measurable value distinguishable from zero. This sensitivity was determined by assaying the zero calibrator 20 times in the same assay. The detection limit is approximately ≤ 1.0 pg/mL. 1.0 pg/mL was used as a conservative estimate of sensitivity where data generated supported a sensitivity of a lower value.

e. *Analytical specificity:*

The specificity of Scantibodies ACTH assay was determined from testing the cross-reactivity with other synthetic peptides. Assay standard zero was spiked with doses of these peptides up to 100,000 pg/mL. ACTH measurement was zero for all samples spiked with ACTH (18-30), ACTH (1-10), ACTH (1-24), α -MSH, β -MSH, and β -Endorphin.

Samples containing up to 250 mg/dL of triglyceride, 15 mg/dL hemoglobin, and 15 mg/dL bilirubin do not exhibit any effect on the assay.

Grossly hemolyzed and lipemic samples, samples from patients receiving radioisotopes and/or contamination of the sample or assay tube with ^{125}I or radioisotopes are known to cause interference.

f. *Assay cut-off:*

Not applicable

2. Comparison studies:

a. *Method comparison with predicate device:*

Correlation testing was performed by assaying normal EDTA plasma samples and EDTA plasma samples spiked with ACTH on three different lots of Scantibodies ACTH Kits. The same samples were also tested using the Nichols ACTH Kit. Correlation data was generated on normal samples, spiked samples and normal and spiked samples combined. The regression equation obtained from the comparison of the Scantibodies Assay kit to the Nichols Diagnostics Assay kit (predicate device) is: $n=161$ $y=1.0645x + 3.7579$ $r^2=0.9698$.

b. *Matrix comparison:*

EDTA plasma is the only sample type indicated.

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:

EDTA-plasma from 120 apparently healthy, fasting patients was drawn between the hours of 8am and 12pm. Plasma ACTH levels were measured with the Scantibodies ACTH assay. Consistent with CLSI guideline (C28-A), the normal range of ACTH in this group was between 5 to 77 pg/mL. The central 95% reference interval calculation was utilized to obtain normal range. In the product labeling, the applicant recommends that each laboratory establish its own range of normal values.

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.