K120009

510(k) Summary (Summary of Safety and Effectiveness)

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

SEP 11 2012

1. Applicant Name

John Rizos, Regulatory Affairs Project Manager
Regulatory Affairs
Abbott Laboratories Diagnostics Division
Dept 9V6, AP5N-2
100 Abbott Park Road
Abbott Park, IL 60064
Telephone Number: (847) 935-1813
Fax Number: (847) 937-4836
Date Summary prepared: September 7, 2012

2. Device Name

ARCHITECT 2nd Generation Testosterone
ARCHITECT 2nd Generation Testosterone Calibrators
ARCHITECT 2nd Generation Testosterone Controls

Reagents
Classification Name: Testosterone test system
Trade Name: ARCHITECT 2nd Generation Testosterone
Common Name: Testosterone
Governing Regulation: 862.1680
Device Classification: Class I, reserved
Classification Panel: Clinical Chemistry
Product Code: CDZ

Calibrators
Classification Name: Calibrator
Trade Name: ARCHITECT 2nd Generation Testosterone Calibrators
Common Name: Calibrator
Governing Regulation: 862.1150
Device Classification: Class II
Classification Panel: Clinical Chemistry
Product Code: JIT

Controls
Classification Name: Quality Control Material (assayed and unassayed)
Trade Name: ARCHITECT 2nd Generation Testosterone Controls
Common Name: Control
Governing Regulation: 862.1660
Device Classification: Class I , reserved
Classification Panel: Clinical Chemistry
Product Code: JJX

3. Predicate Device

Roche Elecsys Testosterone II assay (k093421)

4. Intended Use of Device

The ARCHITECT 2nd Generation Testosterone assay is a chemiluminescent microparticle immunoassay (CMIA) for the quantitative determination of testosterone in human serum and plasma. Measurements of testosterone are used in the diagnosis and treatment of disorders involving the male sex hormones (androgens), including primary and secondary hypogonadism, delayed or precocious puberty, impotence in males and, in females, hirsutism (excessive hair) and virilization (masculinization) due to tumors, polycystic ovaries, and adrenogenital syndromes.

The ARCHITECT 2nd Generation Testosterone Calibrators are for the calibration of the ARCHITECT *i* System when used for the quantitative determination of testosterone in human serum and plasma.

The ARCHITECT 2nd Generation Testosterone Controls are for the verification of the accuracy and precision of the ARCHITECT *i* System when used for the quantitative determination of testosterone in human serum and plasma.

5. Description of Device

ARCHITECT 2nd Generation Testosterone Reagents

The ARCHITECT 2nd Generation Testosterone Reagent Kit consists of 100 (1 x 100) or 400 (4 x 100) tests. Each kit contains 1 or 4 bottle(s) each of Microparticles, Conjugate, Assay Specific Diluent, and Specimen Diluent.

- Microparticles – 1 or 4 Bottle(s) (6.6 mL) Anti-Testosterone (sheep, monoclonal) coated microparticles in BIS Tris buffer with protein (bovine) stabilizer. Minimum concentration: 0.1% solids. Preservative: ProClin 300.

- Conjugate –1 or 4 Bottle(s) (6.9 mL) Testosterone acridinium-labeled conjugate in BIS Tris buffer with surfactant stabilizer. Minimum concentration: 6.5 nmol/L. Preservative: ProClin 300.

- Assay Specific Diluent – 1 or 4 Bottle(s) (25.0 mL) Testosterone Assay Diluent containing phosphate and glycine in citrate buffer. Preservative: ProClin 300.

- Specimen Diluent – 1 or 4 Bottle(s) (12.2 mL) Testosterone Specimen Diluent containing PBS buffer. Preservative: ProClin 300.

ARCHITECT 2nd Generation Testosterone Calibrators

Each ARCHITECT 2nd Generation Testosterone Calibrator Kit contains 6 Bottles (4.0 mL each) of ARCHITECT 2nd Generation Testosterone Calibrators A-F. Calibrator A contains PBS buffer. Calibrators B through F contain testosterone in PBS buffer. All calibrators contain a protein (bovine) stabilizer. Preservative: ProClin 300.

The calibrators are manufactured at the following concentrations:

Calibrator	Concentration		
	nmol/L	ng/dL	ng/mL
Cal A	0.00	0.00	0.00
Cal B	0.10	2.88	0.03
Cal C	0.20	5.77	0.06
Cal D	1.60	46.14	0.46
Cal E	12.50	360.50	3.60
Cal F	30.00	865.20	8.64

ARCHITECT 2nd Generation Testosterone Controls

Each ARCHITECT 2nd Generation Testosterone Control Kit contains 3 Bottles (8.0 mL each) of ARCHITECT 2nd Generation Testosterone Controls. The Low, Medium, and High Controls contain testosterone in PBS buffer with a protein (bovine) stabilizer. Preservative: ProClin 300.

The controls are at the following concentrations:

Control	Target Concentration / Range					
	nmol/L		ng/dL		ng/mL	
Control L	0.31	0.16 - 0.46	8.94	4.61 - 13.27	0.09	0.05 - 0.13
Control M	2.42	1.52 - 3.32	69.79	43.62 - 95.96	0.70	0.44 - 0.96
Control H	7.58	4.74 - 10.42	218.61	136.63 - 300.59	2.18	1.37 - 2.99

6. Comparison of Technological Characteristics

The ARCHITECT 2nd Generation Testosterone assay utilizes chemiluminescent microparticle immunoassay (CMIA) technology for the quantitative determination of testosterone in human serum and plasma. The Roche Elecsys Testosterone II assay utilizes electrochemiluminescence immunoassay technology ("ECLIA") and is intended for use on Elecsys and cobas e immunoassay analyzers.

Reagent Kit Similarities and Differences		
Characteristics	**Submission Device ARCHITECT 2nd Generation Testosterone**	**Predicate Device Roche Elecsys Testosterone II (k093421)**
Intended Use and Indications for Use	Immunoassay for the *in vitro* quantitative determination of testosterone in human serum and plasma. Measurements of testosterone are used in the diagnosis and treatment of disorders involving the male sex hormones (androgens), including primary and secondary hypogonadism, delayed or precocious puberty, impotence in males and, in females, hirsutism (excessive hair) and virilization (masculinization) due to tumors, polycystic ovaries, and adrenogenital syndromes.	Same

Reagent Kit Similarities and Differences		
Characteristics	**Submission Device ARCHITECT 2nd Generation Testosterone**	**Predicate Device Roche Elecsys Testosterone II (k093421)**
Platform	ARCHITECT *i* System (immunoassay analyzer)	Elecsys and cobas e immunoassay analyzers
Methodology	Chemiluminescence (CMIA)	Electrochemiluminescence (ECLIA)
Specimen type	Serum and plasma	Serum and plasma
Expected Values	• Males (21-49) : 47.01 - 980.56 ng/dL • Males (≥ 50 years of age): 127.18-1020.36 ng/dL • Females (21-49): 7.21-79.31 ng/dL • Females (≥ 50 years of age): 8.65-36.92 ng/dL	• Males (20-49): 249 - 836 ng/dL • Males (≥ 50): 193 - 740 ng/dL • Females (20-49): 8.40 - 48.1 ng/dL • Females (≥ 50): 2.90 - 40.8 ng/dL In addition, a reference range study using pediatric population (95 males and 100 females) under 18 years old, who were in good endocrinological health was performed.
Measuring Interval	Measuring interval is defined as the range of values in ng/dL (nmol/L) which meets the acceptable performance for both imprecision and bias across all available assay file dilutions. The range was 4.33 ng/dL (0.15 nmol/L) (Limit of Quantitation - LoQ) to 1500.00 ng/dL (52.01 nmol/L).	Measuring Range: 2.50 - 1500 ng/dL or 0.087 - 52.0 nmol/L (defined by the limit of detection and the maximum of the master curve). Values below the limit of detection are reported as < 2.50 ng/dL or < 0.087 nmol/L. Values above the measuring range are reported as > 1500 ng/dL or > 52.0 nmol/L
LoB LoD	LoB: 1.73 ng/dL (0.06 nmol/L)	LoB: 1.20 ng/dL or 0.42 nmol/L

Reagent Kit Similarities and Differences		
Characteristics	**Submission Device ARCHITECT 2nd Generation Testosterone**	**Predicate Device Roche Elecsys Testosterone II (k093421)**
LoQ	LoD: 2.67 ng/dL (0.10 nmol/L) LoQ: 4.33 ng/dL (0.15 nmol/L)	LoD: 2.50 ng/dL or 0.087 nmol/L LoQ: 12.0 ng/dL or 0.416 nmol/L
Components:		
1	Microparticles: 1 or 4 Bottle(s) (6.6 mL) Anti-Testosterone (sheep, monoclonal) coated microparticles in BIS Tris buffer with protein (bovine) stabilizer. Minimum concentration: 0.1% solids. Preservative: ProClin 300.	M: Streptavidin-coated microparticles (transparent cap), 1 bottle, 6.5mL: Streptavidin-coated microparticles 0.72 mg/mL, preservative.
2	Conjugate: 1 or 4 Bottle(s) (6.9 mL) Testosterone acridinium-labeled conjugate in BIS Tris buffer with surfactant stabilizer. Minimum concentration: 6.5 nmol/L. Preservative: ProClin 300.	R1: Anti-testosterone-Ab~biotin (gray cap), 1 bottle, 10mL: Biotinylated monoclonal anti-testosterone antibody (sheep) 40 ng/mL; releasing reagent 2-bromoestradiol; MES buffer 50 mmol/L, pH 6.0; preservative.
3	Assay Specific Diluent: 1 or 4 Bottle(s) (25.0 mL) Testosterone Assay Diluent containing phosphate and glycine in citrate buffer. Preservative: ProClin 300.	R2: Testosterone-peptide ~Ru(bpy)$_3^{2+}$ (black cap), 1 bottle, 9 mL: Testosterone derivative, labeled with ruthenium complex 1.5 ng/mL; MES buffer 50 mmol/L, pH 6.0; preservative.
4	Specimen Diluent: 1 or 4 Bottle(s) (12.2 mL) Testosterone Specimen Diluent containing PBS buffer. Preservative: ProClin 300.	NA

<table>
<tr><th colspan="3">Calibrators: Similarities and Differences:</th></tr>
<tr><th>Characteristics</th><th>Submission Device
ARCHITECT 2nd Generation Testosterone</th><th>Predicate Device
Roche Elecsys Testosterone II (k093421)</th></tr>
<tr><td>Intended use</td><td>The ARCHITECT 2nd Generation Testosterone Calibrators are for the calibration of the ARCHITECT i System when used for the quantitative determination of testosterone in human serum and plasma.</td><td>The Elecsys Testosterone CalSetII is intended for the calibration of the quantitative testosterone assay on the Elecsys immunoassay analyzer systems.</td></tr>
<tr><td>Levels</td><td>6 levels
<table><tr><th></th><th>nmol/L</th><th>ng/dL</th><th>ng/mL</th></tr><tr><td>A</td><td>0.00</td><td>0.00</td><td>0.00</td></tr><tr><td>B</td><td>0.10</td><td>2.88</td><td>0.03</td></tr><tr><td>C</td><td>0.20</td><td>5.77</td><td>0.06</td></tr><tr><td>D</td><td>1.60</td><td>46.14</td><td>0.46</td></tr><tr><td>E</td><td>12.50</td><td>360.50</td><td>3.60</td></tr><tr><td>F</td><td>30.00</td><td>865.20</td><td>8.64</td></tr></table></td><td>The calibration curve is instrument-specifically generated by 2-point calibration and a master curve provided via the reagent barcode. Testosterone II CalSet II -2 levels.</td></tr>
<tr><td>Components</td><td>6 Bottles (4.0 mL each) of ARCHITECT 2nd Generation Testosterone Calibrators A-F. Calibrator A contains PBS buffer. Calibrators B through F contain testosterone in PBS buffer. All calibrators contain a protein (bovine) stabilizer. Preservative: ProClin 300.</td><td>Lyophilized human serum with 2 testosterone concentration levels</td></tr>
<tr><td>Standardization/ Traceability</td><td>Abbott manufactures internal reference standards for ARCHITECT 2nd Generation Testosterone using Testosterone Reference Standard (USP). Testosterone calibrators are manufactured gravimetrically and tested against these internal reference standards.</td><td>This method has been standardized via ID-GC/MS (Isotope Dilution-Gas Chromatography/Mass Spectrometry).</td></tr>
</table>

<table>
<tr><th colspan="3">Controls: Similarities and Differences:</th></tr>
<tr><th>Characteristics</th><th>Submission Device
ARCHITECT 2nd Generation Testosterone</th><th>Predicate Device
Roche Elecsys Testosterone II (k093421)</th></tr>
<tr><td>Intended use</td><td>The ARCHITECT 2nd Generation Testosterone Controls are for the verification of the accuracy and precision of the ARCHITECT i System when used for the quantitative determination of testosterone in human serum and plasma.</td><td>The Elecsys PreciControl Universal 1 and 2, are used for monitoring the accuracy and precision of Elecsys immunoassays.</td></tr>
<tr><td>Matrix and Components</td><td>3 Bottles (8.0 mL each) of ARCHITECT 2nd Generation Testosterone Controls. Low, Medium, and High Controls contain testosterone in PBS buffer with a protein (bovine) stabilizer. Preservative: ProClin 300.</td><td>Lyophilized control serum based on human serum</td></tr>
<tr><td>Levels</td><td>3 levels: Low. Medium, and High
Targets:
<table>
<tr><th></th><th>nmol/L</th><th>ng/dL</th><th>ng/mL</th></tr>
<tr><td>L</td><td>0.31</td><td>8.94</td><td>0.09</td></tr>
<tr><td>M</td><td>2.42</td><td>69.79</td><td>0.70</td></tr>
<tr><td>H</td><td>7.58</td><td>218.61</td><td>2.18</td></tr>
</table></td><td>2 levels (multi-constituent, concentration variable on lot-to-lot basis)</td></tr>
</table>

7. Summary of Nonclinical Performance

SPECIFIC PERFORMANCE CHARACTERISTICS

Precision

The ARCHITECT 2nd Generation Testosterone assay is designed to have a within-laboratory (total) imprecision of ≤ 10% CV for samples with testosterone concentrations ≥ 14.4 ng/dL to 1009 ng/dL.

Within-Laboratory Precision

A study was performed based on guidance from the National Committee for Clinical Laboratory Standards (NCCLS) document EP5-A2. Testing was conducted using two instruments, two ARCHITECT 2nd Generation Testosterone Reagent Kit lots, and one lot each of ARCHITECT 2nd Generation Testosterone Calibrators and Controls. Three levels of controls and 1 human serum panel were assayed with a minimum of 2 replicates at 2 separate times per day for 20 different days. The data are summarized in the following table.

Sample	Instrument	Reagent Lot	n	Mean ng/dL	Within Run		Within - Laboratory (Total)	
					SD	%CV	SD	%CV
Control Level 1	1	1	80	9.88	0.456	4.6	0.477	4.8
		2	80	9.24	0.358	3.9	0.472	5.1
	2	1	80	9.56	0.390	4.1	0.439	4.6
		2	80	9.02	0.459	5.1	0.468	5.2
Control Level 2	1	1	80	76.07	2.339	3.1	2.734	3.6
		2	80	72.07	2.277	3.2	2.361	3.3
	2	1	80	74.24	2.492	3.4	2.661	3.6
		2	80	72.86	1.769	2.4	2.684	3.7
Control Level 3	1	1	80	228.38	4.811	2.1	5.993	2.6
		2	80	226.67	4.643	2.0	6.008	2.7
	2	1	80	227.22	5.732	2.5	7.496	3.3
		2	80	229.95	5.504	2.4	6.391	2.8
Panel	1	1	80	62.35	2.287	3.7	2.379	3.8
		2	80	60.72	1.285	2.1	1.796	3.0
	2	1	80	61.30	1.888	3.1	2.184	3.6
		2	80	61.53	1.558	2.5	2.028	3.3

Sensitivity

Limit of Quantitation

The ARCHITECT 2nd Generation Testosterone assay is designed to have a Limit of Quantitation (LoQ) of ≤ 4.33 ng/dL. The LoQ is defined as the lowest analyte concentration that meets an inter-assay imprecision of < 20%. The LoQ study design was based on guidance from NCCLS document EP17-A. The observed LoQ for the ARCHITECT 2nd Generation Testosterone assay was 4.33 ng/dL with an inter-assay CV of 15.6%.

Limit of Blank and Limit of Detection

In the same study, the Limit of Blank (LoB) and Limit of Detection (LoD) were determined. The LoB was 1.73 ng/dL and the LoD was 2.67 ng/dL.

Measuring Interval (Reportable Range)

Measuring interval is defined as the range of values in ng/dL which meets the acceptable performance for both imprecision and bias across all available assay file dilutions. The range was 4.33 ng/dL (Limit of Quantitation) to 1500.00 ng/dL.

Linearity

A study was performed based on guidance from the NCCLS document EP6-A. Using an absolute deviation from linearity of 3.605 ng/dL for samples with concentrations of ≤ 14.4 ng/dL, and 10% for samples with concentrations > 14.4 ng/dL, a linear range of 3.82 – 1862.27 ng/dL was demonstrated for the ARCHITECT 2nd Generation Testosterone assay which supports the Measuring Interval (Reportable Range) of 4.33 ng/dL to 1500 ng/dL.

Interference

Potentially Interfering Endogenous Substances

Potential interference in the ARCHITECT 2nd Generation Testosterone assay from bilirubin, hemoglobin, total protein, triglycerides, biotin, and Sex Hormone Binding Globulin (SHBG) was evaluated to be < 10%. Interference was demonstrated by a study based on guidance from the CLSI protocol EP7-A2. The data are summarized in the following table.

Potentially Interfering Endogenous Substance	Interferent Concentration	% Interference Testosterone Concentration	
		201.9 ng/dL	700.8 ng/dL
Bilirubin (unconjugated)	20 mg/dL	-0.2	1.9
Bilirubin (conjugated)	20 mg/dL	-2.0	4.4
Hemoglobin	500 mg/dL	2.5	2.2
Total Protein	12 g/dL	-4.6	-7.0
Triglycerides	2000 mg/dL	-6.5	-1.1
Biotin	30 ng/mL	-2.1	-0.8
SHBG	200 nmol/L	-5.3	-9.1

Potentially Interfering Drugs and Other Compounds

A study was performed based on guidance from the CLSI document EP7-A2. Potentially interfering drugs and other compounds were evaluated to determine whether testosterone concentrations were affected when using the ARCHITECT 2nd Generation Testosterone assay. The data are summarized in the following table. NOTE: Test compound concentration is in ng/mL unless noted otherwise.

Test Compound (Drugs)	Test Compound Conc. ng/mL	Testosterone Concentration			
		201.9 ng/dL		700.8 ng/dL	
		Conc.Diff.	% Cross-Reactivity	Conc.Diff.	% Cross-Reactivity
Danazol	1,000	724.19	0.7	606.24	0.6
Dexamethasone	2,000	1.12	0.0	-0.58	0.0
Ethisterone	1,000	**	NA	**	NA
Mestranol (17a-Ethynylestradiol 3 methyl ether)	1,000	-3.75	0.0	2.31	0.0
D(-) Norgestrel	20	-16.83	-0.8	-12.69	-0.6
	1000	1072.19	1.1	783.66	0.8
19-nortestosterone (Nandrolone)	30 nmol/L	**	NA	**	NA
Prednisolone	1,000	2.64	0.0	5.44	0.0
Prednisone	1,000	1.92	0.0	-9.59	0.0
Spironolactone	500	0.43	0.0	-4.21	0.0
Testosterone Propionate	100	2843.19	28.4	883.00	8.8
5a-Androstane-3b,17b-diol	1,000	477.51	0.5	348.41	0.3
Androstenediol	1,000	-3.11	0.0	-7.94	0.0
Androstenedione	100	177.29	1.8	121.47	1.2
Cortisol	1,000	0.85	0.0	15.36	0.0
Cortisone	2,000	1.06	0.0	10.11	0.0
DHEA	1,000	-13.07	0.0	-9.34	0.0
DHEAS	50,000	96.65	0.0	99.94	0.0
Dihydrotestosterone	500	352.85	0.7	223.05	0.4
Epitestosterone	100 nmol/L	2.71	0.1	12.32	0.4
Estradiol (17b-Estradiol)	1,000	8.67	0.0	-5.50	0.0

Test Compound (Drugs)	Test Compound Conc. ng/mL	Testosterone Concentration			
		201.9 ng/dL		700.8 ng/dL	
		Conc.Diff.	% Cross-Reactivity	Conc.Diff.	% Cross-Reactivity
Estrone	1,000	-8.90	0.0	-9.09	0.0
Ethynodiol diacetate	50	-5.44	-0.1	-2.19	0.0
17a-Ethynyl estradiol	1000	-11.79	0.0	3.23	0.0
11b-Hydroxytestosterone	100	**	NA	**	NA
11-Ketotestosterone	1,000	**	NA	**	NA
Progesterone	1,000	-1.75	0.0	18.65	0.0

** These compounds tested above the measuring interval and the % Cross-reactivity could not be calculated.

Tube Type Matrix Comparison

A study was performed to evaluate the types of blood collection tubes that can be used with the ARCHITECT 2nd Generation Testosterone assay. The tube types were evaluated using the Passing-Bablok regression method to compare each evaluation tube type (N =54) to the control tube type (serum plastic). The data are summarized in the following table.

Evaluation Tube Type	Control Tube (serum plastic) Range (ng/dL)	Evaluation Tube Range (ng/dL)	r [a]	Intercept (ng/dL)	Slope
Serum, glass	14.61-1430.75	14.42-1469.01	1.000	-0.38	1.01
Serum separator, plastic		14.23-1477.86	0.999	-0.42	0.99
Serum separator II Advance		14.32-1419.41	0.999	-0.07	0.98
Dipotassium EDTA		13.41-1526.41	0.997	-0.96	1.02

[a] r = Correlation Coefficient

EXPECTED VALUES

The expected ranges for the ARCHITECT 2nd Generation Testosterone assay were obtained from testing a minimum of 120 samples from apparently healthy individuals in the following categories: normal males, 21-49 years of age with an intact reproductive system, and normal females 21-49 years of age. Additional samples were tested from apparently healthy males and females (≥ 50 years of age). The data are summarized in the following table.

Category Apparently Healthy	n	Age Range (years)	Testosterone ng/dL				
			Median	Min.	Max.	5th percentile	95th percentile
Males (21-49 years of age)	129	21-49	494.03	47.01	980.56	240.24	870.68
Males (≥ 50 years of age)	71	50-77	442.41	127.18	1020.36	220.91	715.81
Females (21-49 years of age)	129	21-49	24.80	7.21	79.31	13.84	53.35
Females (≥ 50 years of age)	52	50-82	23.50	8.65	36.92	12.40	35.76

Method Comparison

The ARCHITECT 2nd Generation Testosterone assay is designed to have a slope of 1.0 ± 0.2 and a correlation coefficient (r) of ≥ 0.95 for samples with testosterone concentrations ranging from 4.33 ng/dL (LoQ) to 1500.00 ng/dL when compared to Liquid Chromatography - Tandem Mass Spectrometry (LCMS). A method comparison study was performed based on guidance from the CLSI document EP9-A2-IR using the Passing-Bablok regression method to compare the ARCHITECT 2nd Generation Testosterone assay to the LCMS testosterone method. The data are summarized in the following tables.

ARCHITECT 2nd Generation Testosterone vs. LCMS
(n = 138)

Concentration Range ng/dL		Correlation Coefficient (r)	Intercept ng/dL	95% CI[a]	Slope	95% CI[a]
ARCHITECT	LCMS					
13.74-1429.61	6.0-1330.00	0.994	-3.70	(-5.00, -1.66)	1.00	(0.98, 1.03)

[a] CI = Confidence Interval

ARCHITECT 2nd Generation Testosterone vs. LCMS
Female Specimens (n = 73)

Concentration Range ng/dL		Correlation Coefficient (r)	Intercept ng/dL	95% CI[a]	Slope	95% CI[a]
ARCHITECT	LCMS					
13.74-349.97	6.0-346.5	0.985	2.77	(0.53, 4.45)	0.82	(0.77, 0.88)

[a] CI = Confidence Interval

ARCHITECT 2nd Generation Testosterone vs. LCMS
Male Specimens (n = 65)

Concentration Range ng/dL		Correlation Coefficient (r)	Intercept ng/dL	95% CI[a]	Slope	95% CI[a]
ARCHITECT	LCMS					
86.93-1429.61	115.0-1330.0	0.990	-48.63	(-62.25, -32.25)	1.10	(1.07, 1.13)

[a] CI = Confidence Interval

8. Conclusion

The data presented in this premarket notification demonstrates that the ARCHITECT 2nd Generation Testosterone assay performs substantially equivalent to the predicate device, the Roche Elecsys Testosterone II assay (k093421). Accuracy was demonstrated by comparison to a Liquid Chromatography – Tandem Mass Spectrometry (LCMS) reference method. The data presented in the premarket notification provide reasonable assurance that the ARCHITECT 2nd Generation Testosterone assay is safe and effective for the stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

Abbott Laboratories
Abbott Laboratories Diagnostics Division
c/o John Rizos
Dept 9V6, AP5N-2
100 Abbott Park Road
Abbott Park, IL 60064

SEP 11 2012

Re: k120009
Trade Name: ARCHITECT 2nd Generation Testosterone
ARCHITECT 2nd Generation Testosterone Calibrators
ARCHITECT 2nd Generation Testosterone Controls
Regulation Number: 21 CFR §862.1680
Regulation Name: Testosterone Test System
Regulatory Class: Class I, reserved
Product Codes: CDZ, JIT, JJX
Dated: July 27, 2012
Received: July 30, 2012

Dear Mr. Rizos:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k120009
Device Name: ARCHITECT 2nd Generation Testosterone
ARCHITECT 2nd Generation Testosterone Calibrators
ARCHITECT 2nd Generation Testosterone Controls

Indications for Use:

The ARCHITECT 2nd Generation Testosterone assay is a chemiluminescent microparticle immunoassay (CMIA) for the quantitative determination of testosterone in human serum and plasma. Measurements of testosterone are used in the diagnosis and treatment of disorders involving the male sex hormones (androgens), including primary and secondary hypogonadism, delayed or precocious puberty, impotence in males and, in females, hirsutism (excessive hair) and virilization (masculinization) due to tumors, polycystic ovaries, and adrenogenital syndromes.

The ARCHITECT 2nd Generation Testosterone Calibrators are for the calibration of the ARCHITECT *i* System when used for the quantitative determination of testosterone in human serum and plasma.

The ARCHITECT 2nd Generation Testosterone Controls are for the verification of the accuracy and precision of the ARCHITECT *i* System when used for the quantitative determination of testosterone in human serum and plasma.

Prescription Use _X_ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Yung Chan

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) k120009