K121314

MAY 17 2012

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.

1. Applicant Name

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2. Device Name

Reagents
Classification Name: Vitamin B12 test system
Trade Name: ARCHITECT B12
Common Name: B12
Governing Regulation: 862.1810
Device Classification: Class II
Classification Panel: Clinical Chemistry
Product Code: CDD

Calibrators
Classification Name: Calibrator
Trade Name: ARCHITECT B12 Calibrators (A-F)
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 B12 Controls (Low, Medium, and High)
Common Name: Control
Governing Regulation: 862.1660
Device Classification: Class I
Classification Panel: Clinical Chemistry
Product Code: JJX

3. Predicate Device

Abbott ARCHITECT B12 (k110579).

4. Intended Use of Device

The ARCHITECT B12 assay is a chemiluminescent microparticle Intrinsic Factor assay for the quantitative determination of vitamin B12 in human serum and plasma on the ARCHITECT *i* System.

5. Description of Device

The ARCHITECT B12 assay is a two-step assay with an automated sample pretreatment, for determining the presence of B12 in human serum and plasma using chemiluminescent microparticle immunoassay (CMIA) technology with flexible assay protocols, referred to as Chemiflex.

ARCHITECT B12 Reagent Kit

The ARCHITECT B12 Reagent Kit consists of 100 (1 x 100) or 500 (1 x 500) tests. Each kit contains 1 bottle each of the following reagents:

- ARCHITECT B12 Microparticles - 1 bottle (6.6 mL per 100-test bottle/27.0 mL per 500-test bottle) intrinsic factor (porcine) coated microparticles in borate buffer with protein (bovine) stabilizers. Minimum Concentration: 0.1% solids. Preservative: antimicrobial agents.
- ARCHITECT B12 Conjugate - 1 Bottle (5.9 mL per 100-test bottle/26.3 mL per 500-test bottle) B12 acridinium-labeled conjugate in MES buffer. Minimum concentration: 0.7 ng/mL. Preservative: ProClin 300.
- ARCHITECT B12 Assay Diluent - 1 Bottle (10.0 mL per 100-test bottle/51.0 mL per 500-test bottle) B12 Assay Diluent containing borate buffer with EDTA. Preservative: antimicrobial agents.
- ARCHITECT B12 Pre-Treatment Reagent 1 - 1 Bottle (27.0 mL per 100-test bottle/50.4 mL per 500-test bottle) B12 Pre-Treatment Reagent 1 containing 1.0 N sodium hydroxide with 0.005% potassium cyanide.
- ARCHITECT B12 Pre-Treatment Reagent 2 - 1 Bottle (5.5 mL per 100-test bottle/25.9 mL per 500-test bottle) B12 Pre-Treatment Reagent 2 containing alpha monothioglycerol and EDTA.

- ARCHITECT B12 Pre-Treatment Reagent 3 - 1 Bottle (5.5 mL per 100-test bottle/25.9 mL per 500-test bottle) B12 Pre-Treatment Reagent 3 containing cobinamide dicyanide in borate buffer with protein (avian) stabilizers. Preservative: sodium azide.

ARCHITECT B12 Calibrator Kit

Each ARCHITECT B12 Calibrator Kit contains 6 Bottles (4 mL each) of ARCHITECT B12 Calibrators (1 bottle each of Calibrators A – F). Preservative: sodium azide. Calibrator A contains borate buffer with protein stabilizer (human albumin). Calibrators B – F contain gravimetrically prepared cyanocobalamin in borate buffer with protein stabilizer (human albumin). Calibrators have the following approximate concentrations: 0, 110, 250, 500, 1000, and 2000 pg/mL.

ARCHITECT B12 Control Kit

Each ARCHITECT B12 Control Kit contains 3 bottles (8 mL each) of ARCHITECT B12 Controls (1 bottle of low control, 1 bottle of medium control, and 1 bottle of high control). Preservative: sodium azide. The Low and High Controls (Control L and Control H) contain cyanocobalamin in borate buffer with protein stabilizer (human albumin). The Medium Control (Control M) contains cyanocobalamin in human serum. Controls have the following approximate concentrations: Low Control, 251 pg/mL; Medium Control, 454 pg/mL; and High Control, 915 pg/mL.

6. Comparison of Technological Characteristics

The ARCHITECT B12 assay utilizes chemiluminescent microparticle immunoassay (CMIA) technology for the quantitative determination of vitamin B12 in human serum and plasma. The Abbott ARCHITECT B12 (LN7K61) assay (k110579) utilizes CMIA technology for the quantitative determination of vitamin B12 in human serum.

Reagents:		
Characteristics	**Submission Device ARCHITECT B12 (Plasma Claim)**	**Predicate Device ARCHITECT B12 (k110579)**
Intended Use and Indications for Use	The ARCHITECT B12 assay is a chemiluminescent microparticle Intrinsic Factor assay for the quantitative determination of vitamin B12 in human serum **and plasma** on the ARCHITECT *i* System. Measurements obtained by this device are used in the diagnosis and treatment of anemias of gastrointestinal malabsorption.	The ARCHITECT B12 assay is a chemiluminescent microparticle Intrinsic Factor assay for the quantitative determination of vitamin B12 in human serum on the ARCHITECT *i* System. Measurements obtained by this device are used in the diagnosis and treatment of anemias of gastrointestinal malabsorption.
Platform	Same as predicate.	ARCHITECT *i* System (immunoassay analyzer)
Methodology	Same as predicate.	Chemiluminescence
Specimen type	Serum and Plasma (lithium heparin)	Serum
Calibration Range	Same as predicate.	0–2,000 pg/mL
Expected Values	Same as predicate.	Normal range: US: 195-886 pg/mL
Measuring Interval	Same as predicate.	146-2000 pg/mL

Calibrators:		
Characteristics	**Submission Device ARCHITECT B12 (Plasma Claim)**	**Predicate Device ARCHITECT B12 (k093401)**
Intended use and Indications for Use - Calibrators	The ARCHITECT B12 Calibrators are used to calibrate the ARCHITECT *i* System when the system is used for the quantitative determination of vitamin B12 in human serum **and plasma** using the ARCHITECT B12 Reagent Kit.	The ARCHITECT B12 Calibrators are used to calibrate the ARCHITECT *i* System when the system is used for the quantitative determination of vitamin B12 in human serum using the ARCHITECT B12 Reagent Kit.
Calibrator Levels	Same as predicate.	6 levels A: 0 pg/mL, B: 110 pg/mL C: 250 pg/mL D: 500 pg/mL E: 1,000 pg/mL F: 2,000 pg/mL
Standardization/ Traceability	Same as predicate.	Abbott manufactures B12 internal standards gravimetrically using cyancobalamin (USP Reference Standard). The B12 calibrators are manufactured and tested against these internal standards.

Controls:		
Characteristics	**Submission Device ARCHITECT B12 (Plasma Claim)**	**Predicate Device ARCHITECT B12 (k093401)**
Intended use and Indications for Use - Controls	The ARCHITECT B12 Controls are used for the estimation of test precision and the detection of systematic analytical deviations of the ARCHITECT *i* System when used for the quantitative determination of vitamin B12 in human serum **and plasma** when using the ARCHITECT B12 Reagent Kit.	The ARCHITECT B12 Controls are used for the estimation of test precision and the detection of systematic analytical deviations of the ARCHITECT *i* System when used for the quantitative determination of vitamin B12 in human serum when using the ARCHITECT B12 Reagent Kit.
Control Matrix and Components	Same as predicate.	Control L and H contain cyanocobalamin in borate buffer with protein stabilizers (human albumin). Preservative: sodium azide Control M contains cyanocobalamin in human serum. Preservative: sodium azide
Control Levels	Same as predicate.	3 levels Targets: Low: 251 pg/mL Medium: 454 pg/mL High: 915 pg/mL

7. Summary of Nonclinical Performance

a. Precision

A 20-day precision study was conducted to evaluate the precision performance of the ARCHITECT B12 assay using plasma panels. This study was based on guidance from the Clinical and Laboratory Standards Institute (CLSI) document EP5-A2. Low, Medium, and High lithium heparin plasma panels were tested. Testing was performed using 2 lots of reagents, and 1 lot each of calibrators and controls on 2 ARCHITECT *i* 2000_{SR} instruments. The 3 plasma panel levels were each tested in replicates of 3, twice daily (a minimum of 2 hours apart), on each of 20 days, using 2 reagent lots on 2 ARCHITECT *i* 2000_{SR} instruments.

The calibration curve generated for each reagent lot was stored on each instrument for the duration of the study.

The data demonstrated acceptable total (within-laboratory) imprecision of $\leq$ 10% CV using lithium heparin plasma panels on the ARCHITECT B12 assay.

Both the serum (cleared in k110579) and plasma demonstrated acceptable total imprecision of $\leq$ 10% CV at all levels tested.

The results are summarized in the following table.

ARCHITECT B12

Within-Laboratory Precision (20-Day) Summary (by Instrument, Lot, and Level)[a]

						Within Run		Between Run		Between Day		Within-Laboratory (Total)[b]	
Instrument	Lot	Level	N	Unit	Mean	SD	%CV	SD	%CV	SD	%CV	SD	%CV
1	Lot 1	Low Panel	119	pg/mL	182	9.8	5.4	3.6	2.0	6.2	3.4	12.2	6.7
2		Low Panel	118	pg/mL	173	8.6	4.9	3.0	1.8	5.9	3.4	10.9	6.3
1		Medium Panel	119	pg/mL	966	26.2	2.7	14.3	1.5	5.5	0.6	30.4	3.1
2		Medium Panel	120	pg/mL	987	27.1	2.7	10.2	1.0	10.4	1.0	30.7	3.1
1		High Panel	119	pg/mL	1698	53.1	3.1	22.1	1.3	24.3	1.4	62.5	3.7
2		High Panel	120	pg/mL	1734	47.3	2.7	19.8	1.1	13.4	0.8	53.0	3.1
1	Lot 2	Low Panel	119	pg/mL	180	10.4	5.8	0.0	0.0	3.0	1.7	10.9	6.0
2		Low Panel	120	pg/mL	165	8.8	5.3	5.5	3.3	4.6	2.8	11.4	6.9
1		Medium Panel	119	pg/mL	975	40.7	4.2	11.7	1.2	5.9	0.6	42.8	4.4
2		Medium Panel	118	pg/mL	979	28.3	2.9	0.0	0.0	10.2	1.0	30.1	3.1
1		High Panel	118	pg/mL	1912	107.5	5.6	31.0	1.6	28.6	1.5	115.4	6.0
2		High Panel	118	pg/mL	1693	55.1	3.3	6.7	0.4	8.0	0.5	56.1	3.3

[a]Study Design includes factors of RUN and DAY.

[b]Within-Laboratory (Total) SD and %CV contains WITHIN RUN, BETWEEN RUN, and BETWEEN DAY variance components.

b. Tube Type

A study was performed based on guidance from the Clinical and Laboratory Standards Institute (CLSI) document EP7-A2.

Plastic serum and lithium heparin plasma separator tubes were used to collect blood from 63 unique donors. Each of the 63 pairs of samples was tested in the same manner, in replicates of at least two using the ARCHITECT B12 assay on one ARCHITECT *i* 2000_{SR} instrument using 1 lot each of ARCHITECT B12 Reagent Kit, Calibrators, and Controls. The lithium heparin plasma separator blood collection tube was evaluated by comparing the concentrations of specimens collected in that tube type (evaluation tube type) against the concentrations of specimens from the same donors collected in plastic serum tubes (control).

The distribution of % differences across all 63 donors was tested for normality using the Shapiro-Wilk test and a significance level of 0.0100. The data were not normal (p-value=0.0055), so the median and the non-parametric two-sided 95% confidence limits around the median were calculated. The lower and upper confidence limits were 2.2% and 4.7%, respectively. Since the limits fell entirely within the +/-10.0% criteria, the null hypothesis was rejected, demonstrating that the difference between tube types was within the maximum allowable difference of 10.0%.

	% Difference[a]				
Evaluation Tube Type	**No. of Donors**	**Shapiro-Wilk p-Value**	**Mean/ Median[b]**	**SD[c]**	**95% CI**
Lithium heparin plasma separator	63	0.0055	3.3	NA	(2.2, 4.7)

The Passing-Bablok regression was performed on samples by regressing the mean concentration values of the lithium heparin tube type versus the mean concentration of the serum tube type.

In addition, individual replicates from the lithium heparin plasma separator tube were analyzed separately (First Replicates, Second Replicates and Third Replicates). The First, Second, and Third Replicate groups were regressed separately against the mean of the serum plastic control tube values using Passing-Bablok Regression. The summary is provided below.

Evaluation Tube Type	N	Control Tube (serum plastic) Range (pg/mL)	Evaluation Tube Range (pg/mL)	r	Intercept (pg/mL)	Slope
Lithium heparin plasma separator First replicate	63	173 - 1866	215 - 1971	0.998	11.13	1.02
Lithium heparin plasma separator Second replicate	63	173 – 1866	185 – 1979	0.997	5.42	1.01
Lithium heparin plasma separator Third replicate	60	173 – 1866	212 – 1959	0.997	-0.14	1.02

The data support the use of lithium heparin plasma separator blood collection tube type with the ARCHITECT B12 assay.

8. Conclusion

The data presented for the use of lithium heparin plasma as a sample type in the pre-market notification demonstrates that the ARCHITECT B12 assay performs substantially equivalent to the predicate device, the Abbott ARCHITECT B12 assay (k110579).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

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Abbott Diagnostic Division
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Dept. 09V6 AP5 North
Abbott Park, IL 60064

MAY 17 2012

Re: k121314
Trade Name: Architect B12 Reagent Kit, Architect B12 Calibrators, Architect B12 Controls
Regulation Number: 21 CFR §862.1810
Regulation Name: Vitamin B12 test system
Regulatory Class: Class II
Product Codes: CDD, JIT, JJX
Dated: April 30, 2012
Received: May 2, 2012

Dear Ms. Abano:

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

k 121314

Indications for Use

510(k) Number (if known):

Device Name: ARCHITECT B12 Reagent Kit
ARCHITECT B12 Calibrators
ARCHITECT B12 Controls

Indications for Use

The ARCHITECT B12 assay is a chemiluminescent microparticle Intrinsic Factor assay for the quantitative determination of vitamin B12 in human serum and plasma on the ARCHITECT *i* System. Measurements obtained by this device are used in the diagnosis and treatment of anemias of gastrointestinal malabsorption.

The ARCHITECT B12 Calibrators are used to calibrate the ARCHITECT *i* System when the system is used for the quantitative determination of vitamin B12 in human serum and plasma using the ARCHITECT B12 Reagent Kit.

The ARCHITECT B12 Controls are used for the estimation of test precision and the detection of systematic analytical deviations of the ARCHITECT *i* System when used for the quantitative determination of vitamin B12 in human serum and plasma when using the ARCHITECT B12 Reagent Kit.

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

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k121314