DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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October 23, 2017

ABBOTT LABORATORIES
LINDA SOHN
REGULATORY AFFAIRS SENIOR SPECIALIST
DEPT. 9AA, BLDG AP8
100 ABBOTT PARK ROAD
ABBOTT PARK, IL 60064

Re: K170317
Trade/Device Name: Alinity i Total β-hCG Reagent Kit
Alinity i System
Regulation Number: 21 CFR 862.1155
Regulation Name: Human chorionic gonadotropin (HCG) test system
Regulatory Class: II
Product Code: DHA, JJE
Dated: September 19, 2017
Received: September 20, 2017

Dear Linda Sohn:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the

electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). 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 Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kellie B. Kelm -S

for Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
k170317

Device Name
Alinity i Total β-hCG Reagent Kit
Alinity i System

Indications for Use *(Describe)*
Alinity i Total β-hCG Reagent Kit

The Alinity i Total β-hCG assay is a chemiluminescent microparticle immunoassay (CMIA) used for the quantitative and qualitative determination of beta-human chorionic gonadotropin (β-hCG) in human serum and plasma for the early detection of pregnancy on the Alinity i analyzer.

Alinity i System

The Alinity i System is a fully automated immunoassay analyzer allowing random and continuous access, as well as priority and automated retest processing using chemiluminescent microparticle immunoassay (CMIA) technology. CMIA technology is used to determine the presence of antigens, antibodies, and analyte in samples.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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k170317

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.

I. Applicant Name

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Dept. 09AA, AP8-1
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Date Summary Prepared: January 31, 2017.

Date Summary Revised: October 23, 2017.

II. Device Name

Alinity i Total β-hCG Reagent Kit
Alinity i System

Alinity i Total β-hCG Reagent Kit

Device Classification: Class II
Classification Name: Human chorionic gonadotropin (HCG) test system
Governing Regulation: 862.1155
Product Code: DHA

Alinity i System

Device Classification: Class I
Classification Name: Discrete photometric chemistry analyzer for clinical use
Governing Regulation: 21 CFR 862.2160
Product Code: JJE

III. Predicate Device

Reagents

ARCHITECT Total β-hCG (k983424)

Instrument

ARCHITECT i System (k983212)

IV. Description of Device

A. Reagents

Kit Contents

Volumes (mL) listed in the table below indicate the volume per cartridge:

REF	**07P5120**	**07P5130**
Tests per cartridge	100	600
Number of cartridges per kit	2	2
Tests per kit	200	1200
Microparticles	6.6 mL	32.1 mL
Conjugate	4.2 mL	9.0 mL

- **Microparticles:** Anti-β-hCG (mouse, monoclonal) coated microparticles in TRIS buffer with protein (bovine) stabilizers. Minimum concentration: 0.06% solids. Preservatives: antimicrobial agents.
- **Conjugate:** Anti-β-hCG (mouse, monoclonal) acridinium-labeled conjugate in MES buffer with protein (bovine) stabilizers. Minimum concentration: 2.9 µg/mL. Preservative: antimicrobial agent.

B. Calibrators

Contents

Cal A through Cal F prepared in human serum. Preservative: Sodium azide.

		Total β-hCG Concentration	
Calibrator	**Quantity**	**(mIU/mL)**	**(IU/L)**
A	1 x 3.0 mL	0	0
B	1 x 3.0 mL	10	10
C	1 x 3.0 mL	250	250
D	1 x 3.0 mL	1000	1000
E	1 x 3.0 mL	7500	7500
F	1 x 3.0 mL	15,000	15,000

Standardization Statement

The calibrators are manufactured gravimetrically and referenced to the World Health Organization (WHO) 4th International Reference Standard 75/589 for β-hCG at each concentration level.

C. Controls

Contents

The controls recommended for use with the Alinity i Total β-hCG assay were cleared under k983424 with the name ARCHITECT Total β-hCG Controls. The Total β-hCG assay on the Alinity i System uses the same ARCHITECT Total β-hCG Controls with no change to formulation or container. Therefore, Abbott is not seeking a new clearance for the Alinity i Total β-hCG Controls in this submission because only the branding has changed.

Control L, Control M, and Control H contain hCG prepared in human serum. Preservative: Sodium azide.

The following target concentration ranges may be used for individual replicate control specifications on the Alinity i analyzer:

Control	**Quantity**	**Total β-hCG Concentration (mIU/mL) (IU/L)**	**Range (mIU/mL) (IU/L)**
Control L	1 x 8.0 mL	25	16 – 34
Control M	1 x 8.0 mL	750	488 – 1013
Control H	1 x 8.0 mL	5000	3250 – 6750

D. Alinity i System

The Alinity i System (also known as the Alinity i analyzer) uses chemiluminescent microparticle immunoassay (CMIA) detection technology to measure the concentration of analytes in samples. The modular design of the Alinity family of analyzers allows multiple processing modules, which perform all sample processing activities, to be physically joined to form a single workstation or system. The selection of processing module(s) determines the configuration of the system.

Each Alinity analyzer, regardless of type, consists of a System Control Module (SCM), Reagent and Sample Manager (RSM), and processing module.

E. Principles of the Procedure

The Alinity i Total β-hCG assay is a two-step immunoassay for the quantitative and qualitative determination of β-hCG in human serum and plasma using chemiluminescent microparticle immunoassay (CMIA) technology.

The Alinity i analyzer processes Total β-hCG test orders as follows:

1. Sample and anti-β-hCG coated paramagnetic microparticles are combined and incubated.
2. The β-hCG present in the sample binds to the anti-β-hCG coated microparticles.
3. The mixture is washed.
4. Anti- β-hCG acridinium-labeled conjugate is added to create a reaction mixture and incubated.
5. Following a wash cycle, Pre-Trigger and Trigger Solutions are added.
6. The resulting chemiluminescent reaction is measured as relative light units (RLUs). There is a direct relationship between the amount of β-hCG in the sample and the RLUs detected by the system optics.

V. Intended Use of the Device

The Alinity i Total β-hCG assay is a chemiluminescent microparticle immunoassay (CMIA) used for the quantitative and qualitative determination of beta-human chorionic gonadotropin (β-hCG) in human serum and plasma for the early detection of pregnancy on the Alinity i analyzer.

The Alinity i System is a fully automated immunoassay analyzer allowing random and continuous access, as well as priority and automated retest processing using chemiluminescent microparticle immunoassay (CMIA) technology. CMIA technology is used to determine the presence of antigens, antibodies, and analytes in samples.

VI. Comparison of Technological Characteristics

The Alinity i Total β-hCG assay (candidate assay) utilizes a chemiluminescent microparticle immunoassay (CMIA) methodology for the quantitative and qualitative determination of Total β-hCG and is intended for use on the Alinity i analyzer.

The Alinity i System is a fully automated immunoassay analyzer allowing random and continuous access, as well as priority and automated retest processing using chemiluminescent microparticle immunoassay (CMIA) technology. CMIA technology is used to determine the presence of antigens, antibodies, and analytes in samples.

The similarities and differences between the candidate assay and the predicate assay and the candidate instrument and the predicate instrument are presented in Tables 1 through 4 starting on page 8.

Comparison of Candidate Alinity i Total β-hCG to Predicate ARCHITECT Total β-hCG

Table 1: Reagent Similarities

Characteristics	Candidate Assay Alinity i Total β-hCG	Predicate Assay (k983424) ARCHITECT Total β-hCG
Technical Characteristics		
Methodology	Chemiluminescent Microparticle Immunoassay (CMIA)	Same
Intended Use/ Indications for Use	The Alinity i Total β-hCG assay is a chemiluminescent microparticle immunoassay (CMIA) used for the quantitative and qualitative determination of beta-human chorionic gonadotropin (β-hCG) in human serum and plasma for the early detection of pregnancy on the Alinity i analyzer.	The ARCHITECT Total β‑hCG assay is a Chemiluminescent Microparticle Immunoassay (CMIA) for the quantitative and qualitative determination of beta human chorionic gonadotropin (β‑hCG) in human serum and plasma for the early detection of pregnancy.
Specific Analyte Detected	Total β‑hCG	Same
Formulation	Microparticles – Anti-β-hCG (mouse, monoclonal) coated microparticles in TRIS buffer with protein (bovine) stabilizers. Minimum concentration: 0.06% solids. Preservatives: antimicrobial agents. Conjugate – Anti-β-hCG (mouse, monoclonal) acridinium-labeled conjugate in MES buffer with protein (bovine) stabilizers. Minimum concentration: 2.9 µg/mL. Preservative: antimicrobial agent.	Same
Assay Protocol	2-step	Same

Table 1: Reagent Similarities

Characteristics	Candidate Assay Alinity i Total β-hCG	Predicate Assay (k983424) ARCHITECT Total β-hCG
Calibration Curve Type	6-point 4 Parameter Logistic Curve fit data reduction method (4PLC, Y-weighted)	Same
Specimen Type	Serum and plasma	Same
Performance Characteristics		
Within-Laboratory Precision (20-Day)	The within-laboratory (total) imprecision (within-run, between-run, and between-day) was ≤ 10 %CV for the Low, Medium, and High Controls (target range from 25 - 5000 mIU/mL).	Same
Linearity	This assay is linear across the measuring interval of 2.42 to 15,000 mIU/mL (2.42 to 15,000 IU/L).	The assay range is 1.2 to 15,000 mIU/mL.
Measuring Interval	The measuring interval is 2.42 to 15,000.00 mIU/mL (2.42 to 15,000.00 IU/L). **Note:** The measuring interval is defined as the range of values in mIU/mL (IU/L) which meets the limits of acceptable performance for bias, imprecision, and linearity. The inputs to the measuring interval include precision, linearity, and the quantitation limit.	The ARCHITECT Total β-hCG assay was designed to have an analytical sensitivity of ≤ 1.2 mIU/mL, with an Assay Range of 1.2 mIU/mL to 15,000 mIU/mL.
Detection Limit: Limit of Detection (LoD) and Limit of Quantitation (LoQ)	• The highest observed LoD value was 0.67 mIU/mL (IU/L). • The highest observed LoQ value at 25% TEa was 2.42 mIU/mL (IU/L).	The analytical sensitivity is ≤ 1.2 mIU/mL. **Note:** The LoQ was not measured for ARCHITECT.

Table 1: Reagent Similarities

Characteristics	Candidate Assay Alinity i Total β-hCG	Predicate Assay (k983424) ARCHITECT Total β-hCG
Analytical Specificity (Cross Reactivity, FSH, LH, TSH, hCG alpha subunit)	The cross reactivity was calculated as a difference in the measured concentration of β-hCG and was shown to be within or equal to ±10% for each cross reactant.	Same
Potentially Interfering Substances (Bilirubin, Hemoglobin, Triglycerides, and Total Protein)	Potential interference from bilirubin, hemoglobin, total protein, and triglycerides showed a difference in measured concentration of β-hCG within or equal to ±10% at the levels indicated below: • Bilirubin ≤ 20 mg/dL • Hemoglobin ≤ 500 mg/dL • Total Protein ≤ 12 g/dL • Triglycerides ≤ 3000 mg/dL	Same
Within-Assay Sample Carryover	Carryover from a sample containing 1,000,000 mIU/mL β-hCG to an adjacent 0 mIU/mL β-hCG sample was less than 7.5 mIU/mL β-hCG.	Same

Table 1: Reagent Similarities

Characteristics	Candidate Assay Alinity i Total β-hCG	Predicate Assay (k983424) ARCHITECT Total β-hCG
Tube Types	<u>Serum</u> • Serum • Serum Separator <u>Plasma</u> • Dipotassium EDTA • Tripotassium EDTA • Lithium heparin • Lithium heparin plasma separator • Sodium heparin	<u>Human Serum</u> • Serum • Serum Separator <u>Plasma</u> • Lithium Heparin • Sodium Heparin • Potassium EDTA
Use of Calibrators	Yes	Same
Use of Controls	Yes	Same

Table 2: Reagent Differences

Characteristics	Candidate Assay Alinity i Total β-hCG	Predicate Assay (k983424) ARCHITECT Total β-hCG
Container and Closure Materials		
Container	Polypropylene (PP) Black colorant	High Density Polyethylene (HDPE) • Natural (microparticles) • Black colorant (conjugate only)
Closure Material (contact only)	Sealed integrated black polyolefin elastomer septum and moved the product contact from the cap to the septum.	F217 cap liner, Polyethylene Foam between Low-Density Polyethylene liners, within PP cap; white polyolefin elastomer septum (customer-placed upon first use)

Comparison of the Candidate Alinity i System to the Predicate ARCHITECT *i* System

Table 3: Instrument Similarities

Category	Candidate Device Alinity i System	Predicate Device ARCHITECT *i* System (k983212)
Intended Use/Indication for Use	The Alinity i System is a fully automated, random/continuous access, immunoassay analyzer, which utilizes chemiluminescent microparticle immunoassay (CMIA) detection technology for both large and small molecular weight analytes.	Same
Detection Technology	Chemiluminescent microparticle immunoassay (CMIA)	Same
Sample Handling	Robotic sample handler (RSH) transport system that has random and continuous access to samples. Autoretest Capability Priority and batch sample loading	Same Same
Reagent Handling	The on-board storage area cooler and the septum cap provide evaporation control. Continuous Reagent Access.	Same
User Interface	Continuous access to Trigger and Pre-Trigger and reconstituted Wash Buffer solutions are stored on-board.	Same

Table 4: Instrument Differences

Characteristics	Candidate Device Alinity i System	Predicate Device ARCHITECT *i* System (k983212)
Dedicated Pretreatment Lane	Includes dedicated pretreatment lane	N/A
Dedicated Wash Station	Dedicated wash cups for sample pipettor and reagent pipettors	Sample pipettor and reagent pipettors do not have dedicated wash cups

VII. Summary of Nonclinical Performance

Within-Laboratory Precision (20-Day)

Precision was performed based on guidance from the Clinical and Laboratory Standards Institute (CLSI) document EP05-A2.

A summary of results is presented below:

			Within-Run (Repeatability)		Within-Laboratory (Total)[a]	
Panel Member	**n**	**Mean mIU/mL (IU/L)**	**SD**	**%CV**	**SD (Range[b])**	**%CV (Range[b])**
1	398	25.35	0.844	3.3	1.293 (1.154-1.416)	5.1 (4.6-5.5)
2	399	765.76	11.099	1.4	14.809 (11.542-17.734)	1.9 (1.5-2.3)
3	399	4971.95	73.079	1.5	110.173 (85.849-131.611)	2.2 (1.7-2.7)
B	400	5.33	0.269	5.0	0.408 (0.357 – 0.463)	7.6 (7.1 – 8.2)
C	400	165.16	3.680	2.2	4.583 (4.386 – 5.639)	2.9 (2.7 – 3.3)
D	399	9421.08	194.693	2.1	265.152 (2.14698 – 339.368)	2.8 (2.2 – 3.5)
E	400	13069.37	314.717	2.4	412.842 (372.088 - 484.306)	3.2 (2.8 – 3.6)

[a] Includes within-run, between-run, and between-day variability.

[b] Minimum and maximum SD or %CV for each reagent lot and instrument combination.

The precision of the Alinity i Total β-hCG assay was considered acceptable if the within laboratory (total) imprecision (within run, between run, and between day) was ≤ 10 %CV for the Low, Medium, and High Controls (target range from 25 to 5000 mIU/mL).

Nine samples were assayed in replicates of at least 22 on 2 runs in a single day on 2 instruments and reagent lots. The number of replicates within negative and positive concentrations are shown in the table below.

Mean Concentration (mIU/mL) (IU/L)	**n**	**Negative ≤ 5 mIU/mL (IU/L)**	**> 5 and < 25 mIU/mL (IU/L)[a]**	**Positive ≥ 25 mIU/mL (IU/L)**
0.01	176	176	0	0
3.15	176	176	0	0
4.06	176	176	0	0
6.57	176	0	176	0
8.47	176	0	176	0
21.10	176	0	176	0
24.00	176	0	139	37
28.41	176	0	0	176
29.94	176	0	0	176
*2.32[b]	401	401	0	0
*5.33[b]	400	106	294	0
*25.35[b]	398	0	173	225

[a] Status not determined. Redraw is recommended after 48 hours to determine status.

[b] These samples are from the 20-day precision study.

The Alinity i Total β-hCG assay demonstrated acceptable precision.

Linearity

Linearity was evaluated based on guidance from the Clinical and Laboratory Standards Institute (CLSI) document EP06-A.

The assay was linear across the range of 2.42 to 15,000 mIU/mL.

Limits of Blank, Detection, and Quantitation (LoB, LoD, and LoQ)

The LoB, LoD, and LoQ study was performed based on guidance from the Clinical and Laboratory Standards Institute (CLSI) document EP17-A2.

Across the instruments and reagents lots, the LoB ranged from 0.00 to 0.20 mIU/mL, the LoD ranged from 0.16 to 0.67 mIU/mL, and the LoQ ranged from 1.10 to 2.42 mIU/mL.

The LoB represents the 95th percentile from $n \geq 60$ replicates of zero-analyte samples.

The LoD represents the lowest concentration at which the analyte can be detected with 95% probability based on $n \geq 60$ replicates of low-analyte level samples.

The LoQ was determined from $n \geq 60$ replicates of low-analyte level samples and is defined as the lowest concentration at which a maximum TEa (Total Error allowable) of 25% was met.

Measuring Interval

The measuring interval of the Alinity i Total β-hCG assay is 2.42 to 15,000.00 mIU/mL (2.42 to 15,000.00 IU/L).

Specificity (Cross-Reactivity)

Potential interference was evaluated based on guidance from the Clinical Laboratory and Standards Institute (CLSI) document EP07-A2. The cross-reactivity was calculated as a percent interference for samples with a β-hCG concentration > 25 mIU/mL (> 25 IU/L) and was shown to be less than 10% for each cross-reactant.

The Alinity i Total β-hCG assay is not susceptible to interference from the cross-reactants when evaluated at the levels presented in the table below:

Cross-Reactant	Cross-Reactant Level
TSH	≤ 100 µIU/mL
LH	≤ 500 mIU/mL
FSH	≤ 500 mIU/mL
hCG alpha subunit	≤ 500 mIU/mL

Potentially Interfering Substances – Bilirubin, Hemoglobin, Triglycerides, and Total Protein

Potential interference was evaluated based on guidance from the Clinical Laboratory and Standards Institute (CLSI) document EP07-A2. Interference effects were assessed by comparing test samples containing potentially-interfering endogenous substances to reference samples. The percent interference for Total β-hCG samples was shown to be less than or equal to 10% for each potentially interfering endogenous substance.

The Alinity i Total β-hCG assay is not susceptible to interference effects from the following interferents at the interferent levels listed in the table below:

Interferent	Interferent Level
Conjugated Bilirubin	≤ 20 mg/dL
Unconjugated Bilirubin	≤ 20 mg/dL
Hemoglobin	≤ 500 mg/dL
Triglycerides	≤ 3000 mg/dL
Total Protein	≤ 12 g/dL

Potentially Interfering Exogenous Substances – Drugs

Potential interference was evaluated based on guidance from the Clinical Laboratory and Standards Institute (CLSI) document EP07-A2. The percent interference for Total β-hCG samples was shown to be less than or equal to 10% for each potentially interfering exogenous substance.

The Alinity i Total β-hCG assay is not susceptible to interference effects from the following interferents at the interferent levels listed in the table below:

Interferent	Target Interferent Level
Acetaminophen	≤ 20 mg/dL
Acetylcysteine	≤ 167 mg/dL
Acetylsalicylic Acid	≤ 66 mg/dL
Ampicillin	≤ 53 mg/L
Ascorbic Acid	≤ 6 mg/dL
Atropine	≤ 20 mg/dL
Ca-Dobesilate	≤ 200 mg/L
Caffeine	≤ 20 mg/dL
Cyclosporine	≤ 5 mg/L
Cefoxitin	≤ 660 mg/L
Doxcycline	≤ 30 mg/L
Ethanol	≤ 1%
EDTA	≤ 80 mg/dL
Ibuprofen	≤ 50 mg/dL
Levodopa	≤ 20 mg/L
Methyldopa	≤ 15 mg/L
Metronidazole	≤ 120 mg/L
Phenylbutazone	≤ 400 mg/L
Rheumatoid Factor (RF)	≤ 194 IU/L
Rifampicin	≤ 64 mg/L
Sodium Heparin	≤ 3000 U/L
Sodium Salicylic Acid	≤ 70 mg/dL
Theophylline	≤ 40 mg/L
Gentisic Acid	≤ 20 mg/dL

Method Comparison

Quantitative

A study was performed using serum specimens based on guidance from CLSI EP09-A3 using the Weighted Deming regression method.

The data summary below presents that data with all outliers included.

	Sample Type	Units	N	Correlation Coefficient	Intercept	Slope	Concentration Range
Alinity i Total β-hCG vs ARCHITECT Total β-hCG	Serum	mIU/mL (IU/L)	210	1.00	0.12	1.01	2.40 – 14,866.03

Qualitative

A total of 381 Alinity i Total β-hCG qualitative results were analyzed for concordance with the ARCHITECT Total β-hCG assay. Samples below the lower limit of the measuring interval were included in the analysis.

	ARCHITECT Total β-hCG mIU/mL (IU/L)		
Alinity i Total ß-hCG mIU/mL (IU/L)	Positive ≥ 25.00	> 5.00 - < 25.00 [a]	Negative ≤ 5.00
Positive ≥ 25.00	201	0	0
> 5.00 - < 25.00[a]	1	44	3
Negative ≤ 5.00	0	0	132

[a] Status not determined. Redraw is recommended after 48 hours to determine status.

Concentration Values of Discordant Specimens	
Alinity i Total ß-hCG mIU/mL (IU/L)	ARCHITECT Total β-hCG mIU/mL (IU/L)
24.42	26.41
5.25	4.58
5.06	4.62
5.16	4.80

The method comparison data for the investigational method, Alinity i Total β-hCG and the comparator method, ARCHITECT Total β-hCG was acceptable.

Within-Assay Sample Carryover

The difference between the protected sample and the unprotected sample was 0.22 mIU/mL. The Alinity i Total β-hCG assay is not susceptible to within-assay sample carryover.

Tube Type Equivalency (Matrix Comparison)

The study used 43 unique positive pregnant donor's serum specimens to supplement the concentration of 45 unique female non-pregnant whole blood specimens to achieve concentrations across the measuring interval. The whole blood, after supplementing, was aliquoted into 7 tube types. The samples were processed according to the blood collection tube manufacturer's instructions and evaluated for β-hCG compared to the serum control.

The following blood collection tube types are acceptable for use with the Alinity i Total β-hCG assay:

Evaluation Tube Types
Serum (separator tube)
Dipotassium EDTA
Tripotassium EDTA
Lithium heparin
Lithium heparin (separator tube)
Sodium heparin

Expected Values Non-Pregnant (Reference Range)

Because hCG is normally synthesized and secreted by cells of the placenta or its precursor, levels of the hormone in normal, non-pregnant individuals are low to undetectable. Concentrations of β-hCG measured in the sera of non-pregnant individuals, as reported in the literature, are < 5 mIU/mL. The concentration of β-hCG in maternal serum rises rapidly during early pregnancy. β-hCG levels between 5 mIU/mL and 25 mIU/mL may be indicative of early pregnancy. Values for β-hCG generally peak during the first trimester and decline slowly throughout the remainder of the pregnancy.

Human serum specimens were collected from non-pregnant, pre-menopausal, peri-menopausal, and post-menopausal females and were evaluated using the Alinity i Total β-hCG assay. The results are summarized in the following table.

Age (years)	n	Menopausal Status	Reference Interval (mIU/mL) (2.5 - 97.5 percentile)
18 – 41	128	pre-menopausal	< 2.42
42 – 55	140	peri-menopausal	< 2.42 – 4.87
> 55	137	post-menopausal*	< 2.42 – 7.60

* Post-menopausal is defined as female subjects who had not had a menstrual period for 12 months or more.

Isoform Recognition

Seven β-hCG isoforms were evaluated by comparing test and reference samples of pooled normal human female serum (β-hCG concentrations less than 1.2 mIU/mL). Test samples were supplemented with stock solutions of each isoform. Reference samples were unsupplemented.

The results are presented in the table below:

Isoform	WHO Code	Isoform Concentration (nmol/mL)	% Recovery
Chorionic Gonadatrophin, intact, Human	99/688	0.0001128	103.5
Chorionic Gonadatrophin, beta subunit, Human	99/650	0.0011	86.3
Chorionic Gonadatrophin, nicked, Human	99/642	0.0001326	95.0
Chorionic Gonadatrophin, nicked beta subunit, Human	99/692	0.002244	85.8
Chorionic Gonadatrophin, beta subunit, Human (purified)	75/551	0.0011256	93.7
Chorionic Gonadatrophin, beta core fragment, Human	99/708	0.00225	N/A*

Isoform	WHO Code	Isoform Concentration (nmol/mL)	% Recovery
Chorionic Gonadatrophin, alpha subunit, Human (purified)	99/720	0.0001428	N/A*

* The beta core fragment and alpha subunit are not detectable by the assay as the Test Mean is less than the Limit of Quantitation of the assay.

Verification of Auto-Dilution

A total of 25 samples were created by supplementing β-hCG stock solution into normal male serum. An aliquot of each sample was tested using the 1:15 automated dilution protocol on both the Alinity i analyzer and the ARCHITECT instrument.

The performance of the Alinity i Total β-hCG automated dilution protocol was considered acceptable if, the difference in mean concentration was within +/- 10% when comparing the auto diluted samples on the Alinity i system to auto diluted samples on the ARCHITECT system.

The mean % difference was 0.3%.

VIII. Summary of Clinical Performance

The section does not apply.

IX. Conclusion Drawn from Nonclinical Laboratory Studies

The results presented in this 510(k) premarket notification demonstrate that the candidate assay (Alinity i Total β-hCG, List No. 07P51) performance is substantially equivalent to the predicate assay (ARCHITECT Total β-hCG, k983424) and that the candidate instrument (Alinity i System) is substantially equivalent to the predicate instrument (ARCHITECT *i* System, k983212).

The similarities and differences between the candidate assay and predicate assay and the candidate instrument and predicate instrument are presented in the tables starting on page 5-8. The results presented in this 510(k) provide reasonable assurance that the

candidate Alinity i Total β-hCG assay and the candidate Alinity i System are safe and effective for the stated intended use. Any differences between the candidate assay and the predicate assay and the candidate instrument and the predicate instrument shown in the tables do not affect the safety and effectiveness of the candidate assay and instrument.