DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 20, 2015

SIEMENS HEALTHCARE DIAGNOSTICS,INC.
PHILIP LIU
SENIOR MANAGER, REGULATORY AFFAIRS AND COMPLIANCE
511 BENEDICT AVENUE
TARRYTOWN NY 10591

Re: K151792
Trade/Device Name: Trinidad IM Thyroid Stimulating Hormone (TSH) assay, Trinidad Immunoassay (IM) system, Trinidad IM TSH Calibrators
Regulation Number: 21 CFR 862.1690
Regulation Name: Thyroid stimulating hormone test system
Regulatory Class: II
Product Code: JLW, JJE, JIT
Dated: October 15, 2015
Received: October 16, 2015

Dear Philip Liu:

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,

Katherine Serrano -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k151792

Device Name
Trinidad Immunoassay (IM) system
Trinidad IM Thyroid Stimulating Hormone (TSH) assay
Trinidad IM TSH Calibrators

Indications for Use *(Describe)*
The Trinidad Immunoassay (IM) system is an automated, immunoassay analyzer designed to perform in vitro diagnostic tests on clinical specimens. The Trinidad IM system's assay applications utilize chemiluminescent technology for clinical use.

The Trinidad IM Thyroid Stimulating Hormone (TSH) assay is for in vitro diagnostic use in the quantitative determination of thyroid-stimulating hormone (TSH, thyrotropin) in human serum and plasma (EDTA and lithium heparin) using the Trinidad IM system. Measurements of thyroid stimulating hormone produced by the anterior pituitary are used in the diagnosis of thyroid or pituitary disorders.

The Trinidad IM TSH Calibrators are for in vitro diagnostic use in calibrating the Trinidad IM system TSH assay.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary of Safety and Effectiveness for the

Trinidad Immunoassay (IM) System
Trinidad IM Thyroid Stimulating Hormone Assay

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

A. 510(k) Number: k151792

B. Date of Preparation: November 18, 2015

C. Proprietary and Established Names:

Trinidad IM Thyroid Stimulating Hormone (TSH) Assay
Trinidad IM TSH Calibrators
Trinidad Immunoassay (IM) System

D. Applicant:

Siemens Healthcare Diagnostics Inc.,
511 Benedict Ave, Tarrytown, NY 10591
Philip Liu, Senior Manager, Regulatory Affairs and Compliance
Office: (914) 524-2443
Fax: (914) 524-3579

E. Regulatory Information:

System
1. Regulation section: 21 CFR § 862.2160
2. Classification: Class I
3. Product Code: JJE, Photometric Analyzer for Clinical Use
4. Panel: Clinical Chemistry

Assay
1. Regulation section: 21 CFR § 862.1690
2. Classification: Class II
3. Product Code: JLW, Thyroid stimulating hormone test system
4. Panel: Clinical Chemistry

Calibrator
1. Regulation section: 21 CFR § 862.1150
2. Classification: Class II
3. Product Code: JIT – Calibrator, Secondary
4. Panel: Clinical Chemistry

F. Predicate Devices:

ADVIA® Centaur XP system cleared under 510(k) k041133.

ADVIA® Centaur Thyroid Stimulating Hormone (TSH3 Ultra) Assay and Calibrators cleared under k150403.

G. Device Description:

Trinidad Immunoassay (IM) System:

The Siemens Healthcare Diagnostics Trinidad Immunoassay (IM) system is a floor model, fully automated, microprocessor-controlled, integrated instrument system that utilizes chemiluminescent technology and uses pre-packaged reagent packs to measure a variety of analytes in human body fluids. It is controlled through a combination of custom and off-the-shelf software

The Trinidad IM system performs the following functions:

- Aspirates and dispenses samples
- Performs dilutions
- Adds reagents
- Incubates reaction vessels
- Separates solid and liquid wastes
- Measures photon emissions
- Performs data reduction
- Collects and maintains patient demographics and results

Trinidad IM TSH assay:

The Trinidad IM TSH assay reagent kit comes in two configurations (100 or 500 test kit) and each kit contains the following:

500 Test Kit:

- 5 ReadyPack primary reagent packs containing Trinidad IM TSH Lite Reagent, Solid Phase, and Ancillary Reagent
- 2 vials of lyophilized Trinidad IM TSH low calibrator
- 2 vials of lyophilized Trinidad IM TSH high calibrator

100 Test Kit:

- 1 ReadyPack primary reagent packs containing Trinidad IM TSH Lite Reagent, Solid Phase, and Ancillary Reagent
- 1 vial of lyophilized Trinidad IM TSH low calibrator
- 1 vial of lyophilized Trinidad IM TSH high calibrator

The ReadyPack consists of the following:

- Lite Reagent 6.0 mL/ reagent pack:
  The Lite Reagent contains bovine serum albumin (BSA) conjugated to murine monoclonal anti-TSH (~0.3 µg/mL) antibody labeled with acridinium ester, buffer, stabilizers (murine, bovine, caprine proteins), surfactant, and preservatives.
- Solid Phase Reagent 21.0 mL/ reagent pack:
  The Solid Phase reagent contains anti-fluorescein murine monoclonal antibody covalently linked to paramagnetic particles (~85 µg/mL), buffer, stabilizers (bovine, caprine proteins), surfactant, and preservatives.
- Ancillary Reagent 6.0 mL/ reagent pack:
  The Ancillary reagent contains FITC conjugated to murine monoclonal anti-TSH antibody (~3 µg/mL), buffer, stabilizers (murine, bovine, caprine proteins), surfactant, and preservatives.

The TSH Calibrator consists of the following:

- After reconstitution, low and high levels of thyroid stimulating hormone (TSH) in HEPES buffered equine serum with sodium azide (< 0.1%) and preservatives. The low and high calibrators are targeted at ~ 0.032 and 97.5 µIU/mL, respectively.

H. Intended Use / Indications for Use:

The Trinidad Immunoassay (IM) system is an automated, immunoassay analyzer designed to perform in vitro diagnostic tests on clinical specimens. The Trinidad IM system's assay applications utilize chemiluminescent technology for clinical use.

The Trinidad IM Thyroid Stimulating Hormone (TSH) assay is for *in vitro* diagnostic use in the quantitative determination of thyroid-stimulating hormone (TSH, thyrotropin) in human serum and plasma (EDTA and lithium heparin) using the Trinidad IM system. Measurements of thyroid stimulating hormone produced by the anterior pituitary are used in the diagnosis of thyroid or pituitary disorders.

The Trinidad IM TSH Calibrators are for *in vitr*o diagnostic use in calibrating the Trinidad IM system TSH assay.

I. Substantial Equivalence Information:

Both the Trinidad IM TSH assay (New Device) on the Trinidad IM system and the ADVIA Centaur TSH3 Ultra assay on the ADVIA Centaur (Predicate Device cleared under k150403) employ the same prepackaged reagents for use on automated test systems. The Intended Use / Indications for Use, Assay Principle and reagent formulations are the same. The major differences between the New and Predicate Devices are the reagent packaging and the instrument. A comparison of the important similarities and differences of these assays, calibrators, and systems are shown in the following tables:

System:

Similarities and Differences:

Feature	Predicate Device: ADVIA Centaur XP	New Device: Trinidad IM
Intended Use	Automated, immunoassay analyzer designed to perform in vitro diagnostic tests on clinical specimens.	Same
Principles of Assay Operation	Chemiluminescence using magnetic-particle solid phase and chemiluminescent label	Same
Type of System	Random Access and Batch	Same
Throughput Rate	120 to 240 tests/hr.	250 to 450 tests/hr.
Time to First Result	18 min., 30 min., 60 min. depending upon assay protocol	10 min., 14 min., 28 min., 55 min depending upon assay protocol

Feature	Predicate Device: ADVIA Centaur XP	New Device: Trinidad IM
Optical System	PMT used in photon counting mode	Same
Temp control	Ambient temp 18-30C	Same
Test Processing	Sample scheduling optimized for throughput; continuous operation	Same
	7.5 minute incubation, single step	"Fast 1-pass" assays: 8 minute incubation
	20 minute incubation, single step	“Routine 1-pass” assays: 12 minute incubation
	7.5 minute - 20 minute incubation, two step	NA
	20 minute - 20 minute incubation, two Step	“2-pass” assay: 12 minute - 12 minute incubations or 12 minute - 20 minute incubations
	Reactions are controlled at 37°C	Same
Sample Handling		
Sample Container	Sample cups or primary tubes may be used	Same
Sample Type	Serum, plasma, urine, whole blood hemolysate, amniotic	Same
	Disposable Sample Pipette Tips	Same
Dispense System	Automated pipetting of samples using precision syringe	Same
Sample Probe	Air pressure fluid sensing and disposable tip sensing; clog detection mechanism to alert operator to clogged sample probe	Same
Sample Volume	10 to 200 µl	10 to 100 µl
Sample Rack	5 tube racks hold sample tubes. The Sample Input, In-Process and Output Queue holds up to 180 samples; tube size selected on sample tube rack using an encoded barcode with the additional capability of multiple size tubes on the same rack.	Samples identified delivered by Trinidad Direct load
Dilutions	Allowed on a per-assay basis; capability of dilution of samples requiring pretreatment	Same
Reagent Handling		
Assay Reagent Tray	Refrigerated with 30 positions; Reagent Pack contains both Solid Phase and Tracer Reagent in separate wells	Rotating refrigerated tray with 42 positions; Reagent Pack contains both Solid Phase and Tracer Reagent in separate wells
Ancillary Reagent Tray	Refrigerated compartment with 25 positions for ancillary packs	Rotating refrigerated compartment with 42 positions
Reagent Storage	4°C to 8°C	4°C to 8°C

Feature	Predicate Device: ADVIA Centaur XP	New Device: Trinidad IM
Reagents	Primary Reagent Pack contains both Solid Phase and Tracer Reagent in separate wells; solid phase is Chemiluminescent labeled (Acridinium Ester)	Same (identical reagent formulation)
	Ancillary Reagent Pack – contains components of the primary reagent and/or sample diluents	Modifications in container shape
System Bulk Fluids	Wash 1, Acid and Base	Modifications in container size and shape
Dispense system	Automated pipetting using precision syringe	Same
Mixing	Reagents mixed via rocking platform	Reagent mixing is via rotation and not rocking
Reagent Probes	Reagent preheating; no level sense; probe sent to bottom of container; fluid monitoring during aspiration	No reagent preheating; fluid monitoring on aspiration and dispense using liquid pressure sensing
Calibration		
	6 to 10 point stored calibration for each reagent	Same
	2 point user run calibration	Same
	Calibrators checked with barcode	Same
	Calibrator lot numbers stored and displayed	Same
Controls	Capability to dilute controls	Same
General Specifications		
Power Requirements	<2000 watts	~3000 watts
Dimensions	42 in D x 58 in L x 60 in H	880 mm D x 1350mm L x1500 mm H
Weight	~550 kg	< 750 kg
Computers/OS		
CPU	Primary PC - Sun Sparc Station	Intel processor with Windows 7 operating system
Display/Monitor	19” display (optional Touch screen)	24” touch screen
Software		
GUI Application	User interface is unique to ADVIA Centaur systems	Universal Instrument Workstation common to new Siemens IVD systems
On-Line Help	Separate for System application and ADVIA QC	Not available at this time
QC	ADVIA QC V3.2x application provides stored control results, Levy-Jennings plotting, and statistics	Similar
LIS Interfaces	LIS ASTM standards 1394/1381, and LIS HL7 standards	Not available at this time
LAS Interfaces	Siemens URAP LAS Interface	Utilize pick and place sampling rather than point in space

Feature	Predicate Device: ADVIA Centaur XP	New Device: Trinidad IM
Real-Time Solutions (RTS) support	Interface to RTS via LabCom protocol and RTS via i2i protocol	Not available at this time
External printers	Parallel port and USB interfaced printers	Not available at this time

Assay:

Similarities and Differences:

Item	Predicate Device: ADVIA Centaur TSH3 Ultra Assay	New Device: Trinidad IM TSH Assay
Intended Use	For in vitro diagnostic use in the quantitative determination of thyroid-stimulating hormone (TSH, thyrotropin) in serum, heparinized plasma, and EDTA plasma	Same
Indications for Use	Measurements of thyroid stimulating hormone produced by the anterior pituitary are used in the diagnosis of thyroid or pituitary disorders.	Same
Sample type	Serum and Plasma	Same
Measurement	Quantitative	Same
Assay Principle	Sandwich immunoassay	Same
Technology	Chemiluminescence	Same
Detection Antibody	Monoclonal murine anti-TSH antibody BSA conjugate labeled with acridinium ester (AE)	Same
Capture Antibody	Anti-fluorescein labeled (FITC) monoclonal murine anti-TSH antibody covalently bound to paramagnetic particles (PMP)	Same
Assay Range	0.008 – 150 uIU/mL	Same
Calibration	2 Point	Same
Calibrators	ADVIA Centaur TSH Calibrators	Trinidad TSH Calibrators (identical formulation)
Number of calibrators	Two (2) levels	Same
Use of Controls	Yes (recommended)	Same
Standardization / Traceability	Standardized to internal standards and is traceable to the World Health Organization (WHO) 3rd International standard for human TSH (IRP 81/565)	Same
Calibrators packaging	Provided with reagent kit	Same
Expected Values	Infants: 0.87 - 6.15 µIU/mL Children:0.67 - 4.16 µIU/mL Adolescent: 0.48- 4.17 µIU/mL Adult: 0.55 – 4.78 µIU/mL	Same

Calibrators:

Similarities and Differences:

Item	Predicate Device: ADVIA Centaur TSH3 Ultra Assay	New Device: Trinidad IM TSH Assay
Intended Use/Indication for use	For *in vitro* diagnostic use in calibrating TSH assay	Same
Antigen used in calibrators	Thyroid stimulating hormone	Same
Number of levels	2	Same
Matrix	Lyophilized buffered equine serum	Same
Storage temperature	2-8°C	Same
Standardization / Traceability	Standardized to internal standards and is traceable to the World Health Organization (WHO) 3rd International standard for human TSH (IRP 81/565)	Same
Packaging	Provided with reagent kit	Same

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

- CLSI Guideline EP05-A3: Evaluation of Precision Performance of Qualitative Measurement Methods
- CLSI Guideline EP17-A2: Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures
- CLSI Guideline EP28-A3: Defining, Establishing, And Verifying Reference Intervals In The Clinical Laboratory; Approved Guideline- Third Edition
- CLSI Guideline EP7-A2: Interference Testing in Clinical Chemistry; Approved Guideline

L. Test Principle

The Trinidad IM TSH assay is a third-generation assay that employs anti-FITC monoclonal antibody covalently bound to paramagnetic particles, an FITC-labeled anti-TSH capture monoclonal antibody, and a tracer consisting of a proprietary acridinium ester and an anti-TSH monoclonal antibody conjugated to bovine serum albumin (BSA) for chemiluminescent detection. A direct relationship exists between the amount of TSH present in the patient sample and the amount of relative light units (RLUs) detected by the system.

M. Performance Characteristics

Substantial equivalence of the Trinidad IM TSH assay on the Trinidad IM system was demonstrated by testing several performance characteristics including detection limits (LoB, LoD, and LoQ), imprecision, linearity, interfering substances and method comparison.

a. Detection Limits

The limit of blank (LoB), limit of detection (LoD), and the limit of quantitation (LoQ) of the Trinidad IM TSH assay were determined as described in CLSI Document EP17-A2. The Trinidad IM TSH assay had a LoB of 0.001 µIU/mL, a LoD of 0.005 µIU/mL, and a LoQ of 0.008 µIU/mL.

The LoB is defined as the concentration of TSH that corresponds to the 95th percentile of the distribution of the TSH zero standard; the TSH zero standard was assayed 10 times in each of at least 10 runs using 1 lot of reagent on 2 systems over a period of at least 5 days (n = 200).

The LoD is defined as the lowest concentration of TSH that can be detected with 95% probability. The LoD was determined by using low level TSH serum samples that were assayed in duplicate in each of at least 20 runs using 1 lot of reagents on 2 systems over a period of at least 10 days (n=80).

The LoQ, or functional sensitivity, is the lowest concentration of TSH at which the total imprecision for the assay does not exceed 20%, and was determined by assaying multiple patient samples with low TSH values in duplicate in each of 10 runs on 2 systems over a period of 10 days.

b. Linearity

The Trinidad IM TSH analytical linearity was evaluated by testing a linearity pool that was prepared using a high TSH serum sample mixed with an equine serum pool to prepare nine (9) equally spaced pools, ranging in TSH levels from 0.0001 to 151 µIU/mL. The weighted linear regression of the Observed (y) vs. Expected (x) values for this pool is:

$$y = 0.957x + 0.0000, R = 1.000$$

The Trinidad IM TSH assay is linear from 0.0001 to 150 µIU/mL.

c. Precision

Precision estimates were computed according to CLSI Document EP05-A2, Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline. Repeatability and within lab imprecision were evaluated by testing four commercial control, six serum samples and six plasma samples. Each sample was assayed in 2 replicates per run, 2 runs per day for 20 days for a total of 80 replicates. Testing was done using two reagent lots on two systems.

A representative lot is summarized below:

			Repeatability		Within-Lab	
Specimen Type	N	Mean (µIU/mL)	SD (µIU/mL)	CV (%)	SD (µIU/mL)	CV (%)
Control 1	80	0.034	0.00	2.36	0.00	4.45
Control 2	80	0.40	0.01	1.96	0.02	4.20
Control 3	80	5.26	0.09	1.74	0.23	4.44
Control 4	80	32.8	0.60	1.82	1.62	4.95
Plasma Pool 1	80	3.38	0.08	2.34	0.15	4.51
Plasma Pool 2	80	37.9	1.26	3.32	2.25	5.95
Plasma Pool 3	80	144	3.68	2.56	7.67	5.34
Plasma Pool 4	80	0.72	0.01	1.45	0.03	4.00
Plasma Pool 5	80	4.99	0.11	2.12	0.21	4.19
Plasma Pool 6	80	79.9	1.79	2.24	3.86	4.82
Serum Pool 1	80	1.11	0.02	1.46	0.04	3.67
Serum Pool 2	80	5.83	0.09	1.47	0.24	4.15
Serum Pool 3	80	11.4	0.21	1.86	0.42	3.71
Serum Pool 4	80	34.7	0.63	1.80	1.25	3.59
Serum Pool 5	80	59.9	1.06	1.76	2.27	3.78
Serum Pool 6	80	132	2.66	2.01	6.23	4.72

d. Interfering Substances

Interfering substances were tested as described in CLSI Document EP7-A2 using the Trinidad IM TSH assay. There was no indication of interference (≤ 10% effect) up to the interferent levels claimed. Results showed less than 5% change at the interferent levels tested.

Serum specimens that are . . .	Demonstrate ≤ 5% change in results up to . . .
hemolyzed	500 mg/dL of hemoglobin
lipemic	1000 mg/dL of triglycerides
icteric	40 mg/dL of conjugated bilirubin
icteric	40 mg/dL of unconjugated bilirubin

e. Heterophile Interference

HAMA Type 1 and Type 2 interference studies were provided with the ADVIA Centaur TSH3 Ultra assay cleared in 510(k) k150403; no interference was observed. The Trinidad IM TSH reagents are the same reagents as the Predicate ADVIA Centaur TSH3 Ultra reagents. The packaging is identical and the only difference is the labeling. Therefore, the performance of the Trinidad IM TSH reagents are the same as the ADVIA Centaur TSH3 Ultra reagents in regards to Heterophile interference.

f. Cross-reactivity

Cross reactivity was evaluated in the Trinidad IM TSH with hCG, FSH, and LH by adding these hormones to human samples containing TSH. Cross reactivity was non-detectable at the levels tested for hCG (200,000 µIU/mL), FSH (1500 µIU/mL) and LH (600 µIU/mL).

g. High Dose Hook Effect

The potential for the high dose hook effect in the Trinidad IM TSH assay was evaluated by testing serial dilutions of a very high TSH sample. No high dose hook effect was observed in samples with TSH levels as high as 3,000 µIU/mL.

h. Method Comparison

A method comparison study with the Trinidad IM TSH assay was done versus the Predicate ADVIA Centaur TSH3 Ultra assay. The Trinidad IM assay shows good correlation (R value) in sample results compared to and the Predicate. Based on the weighted Deming regression results, the Trinidad IM TSH assay is equivalent to the Predicate.

X-axis	Y-axis	Slope	Intercept	R*	Sample Range
ADVIA Centaur TSH3 Ultra	Trinidad IM TSH	1.07	- 0.003	0.994	0.008 – 148.8 µIU/mL

*From Least squares linear regression

i. Serum Plasma Matrix Equivalency

Lithium heparin and EDTA plasma samples were compared to serum in the Trinidad IM TSH assay. The weighted Deming analyses of the lithium heparin and EDTA plasma samples versus serum demonstrate that these matrices are equivalent using the Trinidad IM TSH assay.

X-axis	Y-axis	Slope	Intercept	R	Sample Range
Serum	Lithium Heparin Plasma	1.01	- 0.001	1.00	0.014 – 134.5 µIU/mL
Serum	EDTA Plasma	1.00	- 0.000	1.00	0.014 – 134.5 µIU/mL

j. Expected Values

The Expected Values for the ADVIA Centaur TSH3 Ultra assay (cleared under 510(k) k150403) were verified on the Trinidad IM TSH assay by testing infant (1 – 23 months), children (2 – 12 years), adolescent (13 – 20 years) and adult (≥ 21 years) populations. The number of individuals tested and used in the analysis and the Expected Values are as follows:

Age Range	N	Expected Values
Infants (01 – 23 months)	46	0.87 - 6.15 µIU/mL
Children (02 – 12 years)	136	0.67 - 4.16 µIU/mL
Adolescents (13 – 20 years)	160	0.48- 4.17 µIU/mL
Adults (≥ 21 years)	155	0.55 – 4.78 µIU/mL

k. Stability

The Trinidad IM TSH reagents are the same reagents as the Predicate ADVIA Centaur TSH3 Ultra reagents cleared in 510(k) k150403. The packaging is identical and the only difference is the labeling. Therefore, the shelf-life stability of the Trinidad IM TSH

reagents is identical to those of the ADVIA Centaur TSH3 Ultra reagents. The shelf-life stability of the reagents was provided in 510(k) k150403 as 12 months at 2 – 8°C.

N. Conclusions

Comparative testing of the Trinidad IM TSH assay on the Trinidad IM system is substantially equivalent in principle and performance to the Predicate Device ADVIA Centaur TSH3 Ultra assay on the ADVIA Centaur system cleared under 510(k) k150403.