June 20, 2025

Siemens Healthcare Diagnostics, Inc.
Mey Vasquez
Regulatory Affairs Professional
511 Benedict Avenue
Tarrytown, New York 10591

Re: K242981
Trade/Device Name: Atellica IM Thyroglobulin (Tg)
Regulation Number: 21 CFR 866.6010
Regulation Name: Tumor-Associated Antigen Immunological Test System
Regulatory Class: Class II
Product Code: MSW
Dated: May 21, 2025
Received: May 22, 2025

Dear Mey Vasquez:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ying Mao -S

Ying Mao, Ph.D.
Branch Chief
Division of Immunology and Hematology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242981

Device Name
Atellica IM Thyroglobulin (Tg)

Indications for Use *(Describe)*
The Atellica IM Thyroglobulin (Tg) assay is for in vitro diagnostic use in the quantitative measurement of thyroglobulin in human serum and plasma (EDTA and lithium heparin) using the Atellica IM Analyzer.

Thyroglobulin measurements are used as an aid in monitoring differentiated thyroid cancer patients who have undergone thyroidectomy with or without radioiodine ablation.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary of Safety and Effectiveness

Introduction: According to the requirements of SMDA 1990 and 21 CFR 807.92, the following information provides sufficient details to understand the basis for determination of substantial equivalence.

The assigned 510(k) Number: ___K242981 _____

1. Date Prepared

June 12, 2025

2. Applicant Information

Siemens Healthcare Diagnostics Inc.
511 Benedict Avenue,
Tarrytown, NY 10591 USA

Contact: Mey Vasquez
Regulatory Affairs Professional
E-mail : mey.vasquez@siemens-healthineers.com

3. Regulatory Information

Assay

Trade Name	Atellica IM Thyroglobulin (Tg)
Device	Thyroglobulin Test System
Definition	Thyroglobulin test system is an in vitro diagnostic device intended to measure Thyroglobulin in human serum and plasma. The test is intended to be used as an aid in monitoring differentiated thyroid cancer patients who have undergone thyroidectomy with or without radioiodine ablation.
FDA Classification	Class II
Review Panel	Clinical Chemistry
Product Code	MSW

Regulation Number	21 CFR 866.6010

4. PREDICATE DEVICE

Name of Device: Access Thyroglobulin

510(k): K241423

5. DEVICE DESCRIPTION

The following devices are included in the Atellica® IM Thyroglobulin (Tg):

Material Description
Tg ReadyPack® primary reagent pack **Lite Reagent** 7.5 mL/reagent pack Mouse monoclonal anti-human Tg antibody labeled with acridinium ester (~1.13 µg/mL); bovine serum albumin (BSA); mouse IgG; buffer; stabilizers; preservatives **Solid Phase** 15.0 mL/reagent pack Streptavidin-coated paramagnetic microparticles preformed with biotinylated mouse monoclonal antihuman Tg antibody (~267 µg/mL); BSA; mouse IgG; buffer; stabilizers; preservatives **Ancillary Well Reagent** 6.0 mL/reagent pack BSA; bovine gamma globulin; buffer; preservatives
Tg CAL 2.0 mL/vial After reconstitution, human thyroglobulin; BSA; buffer; stabilizers; preservatives

The following devices are sold separately:

Material Description
Atellica IM Tg MCM:

MCM 1:
1.0 mL/vial After reconstitution, bovine serum albumin (BSA); buffer; stabilizers; preservatives
Atellica IM Tg MCM:
MCM 2–5: 1.0 mL/vial After reconstitution, various levels of human thyroglobulin; BSA; buffer; stabilizers; preservatives

6. INTENDED USE/ INDICATIONS FOR USE

The Atellica® IM Thyroglobulin (Tg) assay is for *in vitro* diagnostic use in the quantitative measurement of thyroglobulin in human serum and plasma (EDTA and lithium heparin) using the Atellica® IM Analyzer.

Thyroglobulin measurements are used as an aid in monitoring differentiated thyroid cancer patients who have undergone thyroidectomy with or without radioiodine ablation.

7. Special Conditions for Use Statement

For Prescription Use

8. COMPARISION OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

	Candidate Device	Predicate
Item	**Atellica IM Tg assay**	**Beckman Coulter Access Thyroglobulin (K241423)**
Intended Use	The Atellica® IM Thyroglobulin (Tg) assay is for *in vitro* diagnostic use in the quantitative measurement of thyroglobulin in human serum and plasma (EDTA and lithium heparin) using the Atellica® IM Analyzer. Thyroglobulin measurements are used as an aid in monitoring	Access Thyroglobulin assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of thyroglobulin levels in human serum and plasma using the Access Immunoassay Systems. This device is

	Candidate Device	Predicate
Item	**Atellica IM Tg assay**	**Beckman Coulter Access Thyroglobulin (K241423)**
	differentiated thyroid cancer patients who have undergone thyroidectomy with or without radioiodine ablation.	intended to aid in monitoring for the presence of persistent or recurrent/metastatic disease in patients who have differentiated thyroid cancer (DTC) and have had thyroid surgery (with or without ablative therapy), and who lack serum thyroglobulin antibodies.
Indications for Use	Same as Intended Use (Candidate)	Same (for Predicate)
Similarities		
LoB	0.039 ng/mL (0.059 pmol/L)	≤ 0.03 ng/mL
LoD	0.044 ng/mL (0.067 pmol/L)	≤ 0.05 ng/mL
LoQ	0.050 ng/mL (0.076 pmol/L)	≤ 0.1 ng/mL
Measurement	Quantitative	Same
Technology	Chemiluminescent	Same
Operating Principle	Fully automated Sandwich immunoassay	Same
Sample type	Serum, EDTA plasma, lithium heparin plasma	Human Serum and Plasma
Standardization	The assay standardization is traceable to the Community Bureau of Reference (BCR) Certified Reference Material (CRM) 457.	Community Bureau of Reference (BCR) Certified Reference Material (CRM) 457

	Candidate Device	Predicate
Item	**Atellica IM Tg assay**	**Beckman Coulter Access Thyroglobulin (K241423)**
	Assigned values for calibrators are traceable to this standardization.	
Clinical Cut-Off	0.2 ng/mL	Not applicable
Intended Use Population(s)	Thyroid cancer patients who have undergone thyroidectomy with or without radioiodine ablation.	Patients who have differentiated thyroid cancer (DTC) and have had thyroid surgery (with or without ablative therapy), and who lack serum thyroglobulin antibodies.
Differences		
Calibration	2 levels	6 levels
Assay Range	0.050–150 ng/mL (0.076–227 pmol/L)	0.1 - 500 ng/mL
Hook Effect	No hook effect up to 80,000 ng/mL (121,200 pmol/L).	No hook effect up to at least 40,000 ng/mL.
Sample Volume	100 µL	40 µL
Detection Antibody	Mouse monoclonal anti-human Tg antibody labeled with acridinium ester.	Mouse monoclonal anti-thyroglobulin-alkaline phosphatase (bovine) conjugate in a TRIS buffer with protein (bovine, murine).
Capture Antibody	Biotinylated mouse monoclonal anti-human Tg antibody that is bound to streptavidin-coated paramagnetic latex particles.	Mouse monoclonal anti-thyroglobulin antibodies coupled to biotin in a HEPES buffer with protein (bovine and mouse).

9. PERFORMANCE CHARACTERISTICS DATA

9.1. Detection Capability

The limit of blank (LoB), limit of detection (LoD), and the limit of quantitation (LoQ) were determined as described in CLSI protocol EP17-A2.

The Atellica IM Tg assay has a LoB of 0.039 ng/mL (0.059 pmol/L), a LoD of 0.044 ng/mL (0.067 pmol/L), and a LoQ of 0.050 ng/mL (0.076 pmol/L).

9.2. Precision

Precision was determined in accordance with CLSI Document EP05-A3.

Samples were assayed in replicates of 2 with 2 runs per day using a 20-day protocol. The following results are representative of the performance of the assay:

			Repeatability		Within-Laboratory Precision	
Sample	**N[a]**	**Mean ng/mL (pmol/L)**	**SD[b] ng/mL (pmol/L)**	**CV[c] (%)**	**SD ng/mL (pmol/L)**	**CV (%)**
Serum A	80	0.078 (0.118)	0.005 (0.008)	6.4	0.007 (0.011)	9.0
Serum B	80	0.153 (0.232)	0.003 (0.005)	2.0	0.005 (0.008)	3.3
Serum C	80	1.79 (2.71)	0.032 (0.048)	1.8	0.042 (0.064)	2.3
Serum D	80	6.12 (9.27)	0.082 (0.124)	1.3	0.145 (0.220)	2.4
Serum E	80	25.1 (38.0)	0.575 (0.871)	2.3	0.793 (1.20)	3.2
Serum F	80	78.9 (120)	0.976 (1.48)	1.2	2.12 (3.21)	2.7
Serum G	80	136 (206)	2.59 (3.92)	1.9	3.95 (5.98)	2.9
Control 1	80	3.83 (5.80)	0.097 (0.147)	2.5	0.151 (0.229)	3.9
Control 2	80	42.7 (64.7)	1.24 (1.88)	2.9	1.71 (2.59)	4.0
Control 3	80	121 (183)	2.91 (4.41)	2.4	4.38 (6.64)	3.6

[a] Number of measurements.

[b] Standard deviation.

[c] Coefficient of variation.

9.3. Reproducibility

Reproducibility was determined using the Atellica IM Analyzer in accordance with CLSI document EP05-A3. Testing was performed using 3 sites and 1 reagent lot. Samples were assayed in replicates of 3 with 2 runs per day using a 5-day protocol (Number of measurements per sample = 90). The following results are representative of the performance of the assay:

Sample	Mean ng/mL (pmol/L)	Repeatability		Between-Run		Between-Day		Between-Site		Reproducibility	
		SD[a] ng/mL (pmol/L)	CV[b] (%)	SD ng/mL (pmol/L)	CV (%)	SD ng/mL (pmol/L)	CV (%)	SD ng/mL (pmol/L)	CV (%)	SD ng/mL (pmol/L)	CV (%)
Serum A	0.155 (0.235)	0.005 (0.008)	3.2	0.000 (0.000)	0.0	0.000 (0.000)	0.0	0.003 (0.005)	1.9	0.006 (0.009)	3.9
Serum B	1.83 (2.77)	0.031 (0.047)	1.7	0.015 (0.023)	0.8	0.008 (0.012)	0.4	0.101 (0.153)	5.5	0.107 (0.162)	5.8
Serum C	25.7 (38.9)	0.321 (0.486)	1.2	0.100 (0.152)	0.4	0.098 (0.148)	0.4	0.359 (0.544)	1.4	0.501 (0.759)	1.9
Serum D	74.5 (113)	1.12 (1.70)	1.5	0.000 (0.000)	0.0	0.243 (0.368)	0.3	1.91 (2.89)	2.6	2.23 (3.38)	3.0
Serum E	119 (180)	1.76 (2.67)	1.5	0.716 (1.08)	0.6	0.845 (1.28)	0.7	4.53 (6.86)	3.8	4.99 (7.56)	4.2
Control 1	4.35 (6.59)	0.070 (0.106)	1.6	0.049 (0.074)	1.1	0.053 (0.080)	1.2	0.065 (0.098)	1.5	0.120 (0.182)	2.8
Control 2	43.6 (66.1)	0.812 (1.23)	1.9	0.499 (0.756)	1.1	0.000 (0.000)	0.0	1.29 (1.95)	3.0	1.60 (2.42)	3.7
Control 3	128 (194)	2.53 (3.83)	2.0	1.69 (2.56)	1.3	0.000 (0.000)	0.0	6.38 (9.67)	5.0	7.07 (10.7)	5.5

9.4. Linearity

Linearity testing was performed using the Atellica IM Analyzer in accordance with CLSI Document EP06-ed2. The assay is linear for the measuring interval of 0.050–150 ng/mL (0.076–227 pmol/L).

9.5. Specimen Equivalence

Specimen equivalency was tested in accordance with the governing standard CLSI Document EP09c-ed3. Specimen matrix studies were conducted to compare serum to the

following specimen types and collection devices: dipotassium EDTA plasma, lithium heparin

plasma, serum gel barrier tube, lithium heparin plasma gel-barrier tube. Each matrix comparison study included a minimum of 84 paired samples across the assay measuring interval. Results of these studies confirm that the performance of the assay is equivalent across the supported specimen types and collection devices.

9.6. Interferences

Hemolysis, Icterus, Lipemia (HIL)

Interference testing was performed using the Atellica IM Analyzer in accordance with CLSI document EP07-ed3. Interference as defined by bias greater than 10% was not observed for the following substances when tested at analyte concentrations of 0.144–0.224 ng/mL (0.218–0.339 pmol/L) and 21.9–26.9 ng/mL (33.2–40.8 pmol/L).

Substance	Substance Test Concentration
Hemoglobin	1000 mg/dL
Bilirubin, conjugated	60 mg/dL
Bilirubin, unconjugated	60 mg/dL
Lipemia (Intralipid)	1900 mg/dL
Lipemia (triglycerides)	1500 mg/dL

Other Substances

Interference testing was performed using the Atellica IM Analyzer in accordance with CLSI document EP07-ed3.19 Interference as defined by bias greater than 10% was not observed for the following substances when tested at analyte concentrations of 0.125–0.235 ng/mL (0.189–0.356 pmol/L) and 21.6–27.8 ng/mL (32.7–42.1 pmol/L).

Substance	Substance Test Concentration	Substance	Substance Test Concentration
Acetaminophen	20 mg/dL	Itraconazole	3 mg/dL
Acetylsalicylic Acid (Aspirin)	65 mg/dL	K3 EDTA	5.4 mg/mL
AFP	881.24 ng/mL	Lenvatinib Mesylate	2.62 mg/dL
Amiodarone	8.92 µmol/L	Levodopa	0.75 mg/dL
Ampicillin	33.0 mg/dL	Methyldopa	2.25 mg/dL
Ascorbic Acid	2590 mg/dL	Metronidazole	12.3 mg/dL
Biotin	3510 ng/mL	Octreotide Acetate (Sandostatin)	5.2 ng/mL

Substance	Substance Test Concentration	Substance	Substance Test Concentration
Cabozantinib-S-Malate	15.3 mg/dL	Perchlorate	200 µg/mL
Carbimazole	2.4 µg/mL	Phenylbutazone	32.1 mg/dL
Cefoxitin	92.7 mg/dL	Prednisolone	8.31 µmol/L
Cyclosporine	0.075 mg/dL	Propranolol	7.71 µmol/L
Doxycycline	4.5 mg/dL	Propylthiouracil	7.2 µg/mL
Fluocortolone	270 ng/mL	Rifampicin	7.5 mg/dL
Fluorescein	6 µg/mL	Rheumatoid Factor (RF)	550 IU/mL
FSH	40 mIU/mL	Silwet L720	0.03 mg/mL
Hydrocortisone	984 ng/mL	TBG (thyroxine binding globulin)	210 µg/mL
Ibuprofen	50 mg/dL	Theophylline	6 mg/dL
Imatinib (TKI)	13.4 µg/mL	Thiamazole (Methimazole)	300 ng/mL
Immunoglobulin G (IgG)	2 g/dL	Total Protein	30 mg/mL
Immunoglobulin M (IgM)	0.3 g/dL	Total Protein	120 mg/mL
Iodide	38 mg/dL	VEGF	2835 pg/mL

9.7. Cross-Reactivity

Cross-reactivity was determined using the Atellica IM Analyzer in accordance with CLSI document EP07-ed3. Cross-reactivity of samples spiked with various substances does not exceed 1.0% at analyte concentrations of 0.185–0.261 ng/mL (0.280–0.395 pmol/L) and 23.9–27.5 ng/mL (36.2–41.6 pmol/L).

Substance	Substance Test Concentration
T3	100 ng/mL
T4	10 µg/mL
TSH	235 mIU/mL
Galectin-3	1 µg/mL
Diiodothyronine (T2)	55 µg/mL

9.8. Reagent Stability

The on-board stability of the Atellica IM Tg reagents was determined to be 28 days on AIM with a calibration interval of 50 days.

The Atellica IM Tg calibrators when reconstituted were determined to be stable at 2-8ºC and ≤ -20ºC for 45 days and 60 days (thaw only once), respectively.

9.9. Sample Stability

- After centrifugation, specimens in the primary collection device are stable for up to 3 days at 2-8° C. Samples in the primary collection device include serum stored on the clot, plasma stored on packed red cells, and samples processed and stored in gel-barrier blood collection tubes.
- Separated serum samples are stable for up to 4 days at room temperature, and for up to 7 days at 2-8° C.
- Separated plasma samples are stable for up to 3 days at room temperature, and for up to 4 days at 2-8° C.
- Separated samples are stable at ≤ -20° C for up to 12 months and at ≤ -70° C for up to 24 months. Avoid more than 4 freeze-thaw cycles. Do not store in a frost-free freezer. Thoroughly mix thawed samples and centrifuge them before using.

9.10. High Dose Hook Effect

High Tg concentrations can cause a paradoxical decrease in the RLUs (high-dose hook effect). In this assay, no hook effect was observed up to 80,000 ng/mL (121,200 pmol/L).

9.11. Expected Values

Reference intervals were established on the Atellica IM Analyzer in accordance with CLSI Document EP28-A3c. A total 321 apparently healthy patient serum samples which consisted of 164 healthy adult females and 157 healthy adult males were obtained.

Reference intervals were determined by calculating the 2.5th and 97.5th percentiles of the distribution of values.

Group	N[a]	Reference Interval
Apparently healthy adults (≥ 22 years)	321	2.44-74.9 ng/mL (3.70-113 pmol/L)
Apparently healthy adult females	164	2.58-78.3 ng/mL (3.91-119 pmol/L)
Apparently healthy adult males	157	2.37-70.1 ng/mL (3.59-106 pmol/L)

Serum samples from 136 post-thyroidectomy adults were tested. Pregnant subjects and samples with detectable levels of anti-Tg were excluded from the study. The reference interval was determined by calculating the 95th percentile of the distribution of values.

Group	N[a]	Reference Interval
Post-thyroidectomy adults (≥ 22 years)	136	< 1.27 ng/mL (1.92 pmol/L)

[a] Number of samples tested.

As with all in vitro diagnostic assays, each laboratory should determine its own reference interval for the diagnostic evaluation of patient results. Consider these values as guidance only.

9.12. Clinical Performance

A prospective, multi-center study was conducted using the Atellica IM Analyzer to assess the clinical performance of the Atellica IM Tg assay. A total of 291 serum samples were collected from 189 subjects diagnosed with differentiated thyroid cancer, 6 or more weeks following thyroidectomy or radioiodine ablation.
Sensitivity and specificity were calculated by comparing the Atellica IM Tg assay result to structural disease (SD). The assay result was considered positive if the Tg concentration was ≥ 0.2 ng/mL and negative if the Tg concentration was < 0.2 ng/mL. SD was established and classified as either positive or negative by cross-sectional or functional imaging results. The following table shows the concordance of Tg results to SD, at a cut-off value of 0.2 ng/mL.

	Structural Disease		
Atellica IM Tg Assay Result	**Positive**	**Negative**	**Total**
≥ 0.2 ng/mL	54	110	164
< 0.2 ng/mL	1	126	127
Total	55	236	291

Clinical sensitivity and specificity were determined in accordance with CLSI Document EP12-A2. Estimates of sensitivity, specificity, positive predictive value (PPV), and negative predicative value (NPV), along with two-sided 95% confidence intervals are presented in the table below.

Parameter	**N[a]**	**Estimate[b]**	**95% CI[b]**
Sensitivity	55	98.2%	(94.6%, 100.0%)

Parameter	N[a]	Estimate[b]	95% CI[b]
Specificity	236	53.4%	(47.8%, 58.0%)
PPV	164	10.0%	(8.7%, 11.2%)
NPV	127	99.8%	(99.5%, 100.0%)

[a] Number of samples tested.
[b] The estimates and 95% confidence intervals were bootstrapped at 10,000 or more iterations.

10. CONCLUSION

Comparative testing of the Atellica IM Thyroglobulin (Tg) assay is substantially equivalent in principle and performance to the Predicate Device, the Beckman Coulter Access Thyroglobulin assay cleared under 510(k) K241423.