December 4, 2025

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

Re: K250816
Trade/Device Name: ADVIA Centaur Anti-Thyroglobulin II (aTgII)
Regulation Number: 21 CFR 866.5870
Regulation Name: Thyroid Autoantibody Immunological Test System
Regulatory Class: Class II
Product Code: JNL
Dated: October 31, 2025
Received: November 3, 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)*
k250816

Device Name
ADVIA Centaur Anti-Thyroglobulin II (aTgII)

Indications for Use *(Describe)*
The ADVIA Centaur Anti-Thyroglobulin II (aTgII) assay is for in vitro diagnostic use in the quantitative measurement of autoantibodies against thyroglobulin in human serum and plasma (EDTA, lithium heparin, sodium heparin) using the ADVIA Centaur XP system.
Anti-thyroglobulin (aTg) measurements are used, in conjunction with clinical assessment, as an aid in the diagnosis of autoimmune thyroiditis and Graves' disease.

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.

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This 510(k) Summary is being submitted in accordance with the requirements of 21 CFR 807.92 and the Safe Medical Device Act of 1990.

The assigned 510(k) Number is: **k250816**

1. Date Prepared

December 03, 2025

2. Applicant Information

Contact: Mey Vasquez
Regulatory Affairs Professional

Address: Siemens Healthcare Diagnostics Inc.
511 Benedict Avenue
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Email mey.vasquez@siemens-healthineers.com

3. Regulatory Information

Table 1. Regulatory Information for ADVIA Centaur Anti-Thyroglobulin II (aTgII) Assay

Trade Name	ADVIA Centaur® Anti-Thyroglobulin II (aTgII)
Common Name	System, Test, Thyroid Autoantibody
Classification Name	Thyroid autoantibody immunological test system
FDA Classification	Class II
Review Panel	Immunology
Product Code	JNL
Regulation Number	866.5870

4. Predicate Device Information

Name of Device Name: Beckman Coulter Access Thyroglobulin Antibody II (TgAbII) assay

510(k) Number: K112933

5. Intended Use / Indications for Use

The ADVIA Centaur Anti-Thyroglobulin II (aTgII) assay is for in vitro diagnostic use in the quantitative measurement of autoantibodies against thyroglobulin in human serum and plasma (EDTA, lithium heparin, sodium heparin) using the ADVIA Centaur XP system.

Anti-thyroglobulin (aTg) measurements are used, in conjunction with clinical assessment, as an aid in the diagnosis of autoimmune thyroiditis and Graves' disease.

6. Device Description

Component	Volume	Ingredients
ADVIA Centaur aTgII Primary Reagent ReadyPack (included in assay kit)		
ADVIA Centaur aTgII Lite Reagent	10.0 mL/pack	Human thyroglobulin labeled with acridinium ester (~1.2 µg/mL); buffered saline; bovine gamma globulin;

Component	Volume	Ingredients
		bovine serum albumin (BSA); sodium azide (< 0.1%); preservative
ADVIA Centaur aTgII Solid Phase Reagent	20.0 mL/pack	Biotinylated human thyroglobulin bound to streptavidin-coated paramagnetic particles (~0.6 mg/mL); buffered saline; bovine gamma globulin; BSA; sodium azide (< 0.1%); preservative
ADVIA Centaur aTgII Ancillary Reagent ReadyPack (included in assay kit)		
ADVIA Centaur aTgII Ancillary Reagent	17.5 mL/pack	Goat serum; mouse serum; sodium azide (< 0.1%); preservative
ADVIA Centaur aTgII Calibrator (included in assay kit)		
ADVIA Centaur aTgII Low and High Calibrators	1.0 mL/vial Lyophilized	After reconstitution, low or high levels of monoclonal mouse anti-human thyroglobulin; goat serum; mouse serum; sodium azide (< 0.1%); preservative

7. Comparison of Technological Characteristics with the Predicate Device

	Candidate Device	Predicate
Item	**ADVIA Centaur Anti-Thyroglobulin II (aTgII) Assay**	**Beckman Coulter Access Thyroglobulin Antibody II (TgAbII) assay (K112933)**
Intended Use	The ADVIA Centaur Anti-Thyroglobulin II (aTgII) assay is for in vitro diagnostic use in the quantitative measurement of autoantibodies against thyroglobulin in human serum and plasma (EDTA, lithium heparin, sodium heparin) using the ADVIA Centaur XP system. Anti-thyroglobulin (aTg) measurements are used, in conjunction with clinical assessment, as an aid in the diagnosis of autoimmune thyroiditis and Graves' disease.	The Access Thyroglobulin antibody II assay is a paramagnetic chemiluminescent immunoassay for the quantitative determination of thyroglobulin antibody levels in human serum and plasma using the Access Immunoassay Systems. The measurement of thyroid autoantibodies may aid in the diagnosis of Hashimoto's disease, nontoxic goiter, and Graves' disease.
Measurement	Quantitative	Same
Assay Range	1.1 – 1000 IU/mL	0.9 – 2500 IU/mL
Autoimmune Cut-Off Values	≤4.5 IU/mL	≤4.0 IU/mL
Operating Principle	1-Step Sandwich immunoassay	2-Step Sandwich immunoassay
Technology	Chemiluminescence	Same
Sample type	Plasma and Serum	Same
Sample Volume	25 µL	10 µL
Standardization	The assay standardization is traceable to the World Health Organization (WHO) International Reference	NIBSC Anti-Thyroglobulin Serum, Human First

	Candidate Device	Predicate
Item	**ADVIA Centaur Anti-Thyroglobulin II (aTgII) Assay**	**Beckman Coulter Access Thyroglobulin Antibody II (TgAbII) assay (K112933)**
	Preparation for Anti-Thyroglobulin Serum, Human (NIBSC 65/093). Assigned values for calibrators and controls are traceable to this standardization.	International Reference Preoaration, WHO Coded 65/93.
Calibration	2 levels	6 level
Calibrators	ADVIA Centaur aTgII Calibrators	Access Thyroglobulin Antibody II Calibrators
Detection Antibody	Human thyroglobulin conjugated to Acridium Ester in the Lite Reagent	Human thyroglobulin-alkaline phosphatase (bovine) conjugate in a TRIS buffer with protein (bovine)
Capture Antibody	Biotinylated human thyroglobulin bound to streptavidin-coated paramagnetic particles pre-formed in Solid Phase Reagent	Paramagnetic particles coated with streptavidin and coupled to biotinylated human thyroglobulin, suspended in a TRIS buffer with protein (bovine)
Precision (Within-Lab)	Repeatability was evaluated across concentrations ranging from 2.1 to 872.0 IU/mL. The highest variability was observed at the lowest concentration (13.5% at 2.1 IU/mL). The lowest variability at 1.8% was observed at 496.0 IU/mL). The performance around the assay cut off was observed to be 3.6% at 4.1 IU/mL.	Imprecision was tested for concentrations from approximately 27.0 to 721.0 IU/mL. The within run imprecision ranged from 4.0% CV to 5.8% CV. Between-run assay imprecision ranged from 2.7% CV to 5.1% CV. Total imprecision ranged from 4.8% CV to 7.0% CV. For low dose imprecision was tested for concentrations from approximately 1.7 to 10.5 IU/mL. The SD for these samples ranged from 0.3 to 0.8 SD.
Precision (Repeatability)	Precision was evaluated across concentrations ranging from 2.1 to 872.0 IU/mL. The highest variability was observed at the lowest concentration (14.6% at 2.1 IU/mL). The lowest variability was observed at a sample near the assay cut off (4.2% at 4.1 IU/mL).	
Interferences	The following interferents and concentrations were tested: Hemoglobin (1000 mg/dL) Bilirubin (Conjugated) (60 mg/dL) Bilirubin (Unconjugated) (60 mg/dL)	The following interferents and concentrations were tested: Acetaminophen (20 mg/dL) Acetylsalicylic Acid (65 mg/dL) Bilirubin (40 mg/dL) Hemoglobin (500 mg/dL)

	Candidate Device	Predicate
Item	**ADVIA Centaur Anti-Thyroglobulin II (aTgII) Assay**	**Beckman Coulter Access Thyroglobulin Antibody II (TgAbII) assay (K112933)**
	RF (Rheumatoid Factor) (750 IU/mL) Low Protein (3.00 g/dL) High Protein (12.00 g/dL) IgG (6 g/dL) Lipemia (Intralipid) (3500 mg/dL) Biotin 3500 ng/mL (0.35 mg/dL) Aspirin (65.2 mg/dL) Acetaminophen (20 mg/dL) Ibuprofen (50 mg/dL) T3 Antibodies (0.55 mg/mL) T4 Antibodies (1.01 mg/mL) Iodide (3.00 mM (38 mg/dL) L-Thyroxine (T4) 10,000 ng/mL (1 mg/dL) Methimazole 1.00 µg/mL (0.1 mg/dL) Insulin (18 mIU/L)	Heparin (Sodium) (8000 U/dL) Total protein (human serum albumin) (6 g/dL) Ibuprofen (50 mg/dL) Multi-vitamin (1:20) Triglycerides (intralipid) (500 mg/dL)

8. Performance Characteristics: ADVIA Centaur aTgII assay

8.1 Expected Values

A reference interval for apparently healthy adults was established non-parametrically using the ADVIA Centaur XP system in accordance with CLSI Document EP28-A3c. Samples were collected prospectively from male and female subjects 27–69 years of age, with normal TSH levels, no personal or family history of thyroid disease, and absence of non-thyroid autoimmune disease.

Group	N[a]	Median IU/mL	Reference Interval IU/mL
Adults (≥ 22 years)	123	< 1.1	< 1.2

[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.

8.2 Clinical Performance

The evaluation of the ADVIA Centaur aTgII assay in the detection of autoimmune thyroiditis (AITD) was performed using the ADVIA Centaur XP system in accordance with CLSI Document EP12-A2.

8.2.1 Results by Specimen Classification

A total of 373 samples were collected from patients presenting to endocrinologists with signs and symptoms of AITD. This population included patients with previously diagnosed Graves' disease and autoimmune thyroiditis who were treatment-naïve or had been on treatment ≤ 6 months, and female patients who were pregnant or postpartum. Definitive diagnosis of AITD or non-autoimmune thyroid disease (NAITD) was made by the endocrinologist according to American Thyroid Association criteria.

Additionally, 302 samples were collected from subjects with other thyroid conditions, disease states, or pregnancy, which may be expected to have elevated thyroid antibodies.
For each clinical subgroup, the percent positivity was calculated using an assay cut-off of 4.5 IU/mL.

Positivity Rates in AITD and Differential Diagnosis Controls

Group	N[a]	ADVIA Centaur aTgII Assay		Comparative Assay	
		Number Positive	% Positive	Number Positive	% Positive
AITD:					
Graves' disease	105	29	27.6	33	31.4
Autoimmune thyroiditis	111	45	40.5	41	36.9
Differential diagnosis controls:					
Multinodular goiter	62	4	6.5	4	6.5
NAITD	95	18	18.9	13	13.7
Silent painless thyroiditis	20	7	35.0	5	25.0
Subacute thyroiditis	10	1	10.0	1	10.0
Thyroid cancer	20	1	5.0	1	5.0
Hepatitis C virus (HCV)	20	0	0.0	0	0.0
Hepatitis B virus (HBV)	20	10	50.0	8	40.0
Human immunodeficiency virus (HIV)	20	0	0.0	0	0.0
Diabetes type 1	10	1	10.0	1	10.0
Sjogren’s syndrome	10	1	10.0	1	10.0
Primary biliary cholangitis	10	3	30.0	3	30.0
Systemic sclerosis	10	2	20.0	2	20.0
Pernicious anemia	10	2	20.0	2	20.0
Rheumatoid arthritis	10	0	0.0	0	0.0
Systemic lupus erythematosus (SLE)	10	1	10.0	1	10.0
Addison's disease	10	0	0.0	0	0.0
Miscarriage	20	13	65.0	13	65.0
Trimester 1	31	0	0.0	0	0.0
Trimester 2	30	0	0.0	1	3.3
Trimester 3	31	0	0.0	0	0.0

a Number of samples tested.

Clinical Sensitivity and Specificity

Clinical sensitivity and specificity were determined in accordance with CLSI Document EP12-A2. The results were calculated by comparing the ADVIA Centaur aTgII assay result to the clinical diagnosis. A total of 373 samples were collected from patients presenting to endocrinologists with signs and symptoms of AITD. Definitive diagnosis of AITD or NAITD was made by the endocrinologist according to American Thyroid Association criteria. Estimates of sensitivity for subjects with Graves' disease, autoimmune thyroiditis, and both combined, along with specificity for NAITD subjects are presented in the table below.

	Clinical Diagnosis	Estimate	95% Confidence Interval
Sensitivity	Graves' disease	27.6% (29/105)	20.0–36.9%
	Autoimmune thyroiditis	40.5% (45/111)	31.9–49.8%
	Combined Graves' disease and autoimmune thyroiditis	34.3% (74/216)	28.3–40.8%
Specificity	NAITD	86.0% (135/157)	79.7–90.6%

Additionally, 302 samples were collected from subjects without a definitive diagnosis of AITD or NAITD, but with other thyroid conditions, disease states, or pregnancy, which may be expected to have elevated thyroid antibodies. These samples were added to 157 samples from subjects diagnostically confirmed negative for AITD. The estimate of specificity for this combined sample group is presented in the table below.

		N[a]
ADVIA Centaur aTgII Assay	**≥ 4.5 IU/mL**	64
	< 4.5 IU/mL	395
	Total	459
Specificity: 86.1% (395/459) [95% Confidence Interval: 82.6–88.9%]		

[a] Number of samples tested.

8.2.2 Percent Agreement

The percent agreement between the ADVIA Centaur aTgII assay and a commercially available aTg assay was evaluated in accordance with CLSI Document EP12-A2 using 730 samples collected prospectively and retrospectively. Results outside of the assay's measuring interval were excluded from the analysis. The percent agreement estimates are presented in the table below.

		Comparative Assay		
		Positive	**Negative**	**Total**
ADVIA Centaur aTgII Assay	**≥ 4.5 IU/mL**	117	15	132

		Comparative Assay		
		Positive	Negative	Total
	< 4.5 IU/mL	4	176	180
	Total	121	191	312
PPA: 96.7% (117/121) [95% Confidence Interval: 91.8%–98.7%] NPA: 92.2% (176/191) [95% Confidence Interval: 87.5%–95.2%]				

Agreement of the assays may vary depending on the study design, comparative assay, and population tested.

8.3 Detection Limit

Detection capability was determined in accordance with CLSI Document EP17-A2. Results obtained at individual laboratories may vary from the data presented.

Detection Capability	Result
Limit of Blank (LoB)	0.6 IU/mL
Limit of Detection (LoD)	1.0 IU/mL
Limit of Quantitation (LoQ)	1.1 IU/mL

The LoB corresponds to the highest measurement result likely to be observed for a blank sample with a probability of 95%.
The LoD corresponds to the lowest analyte concentration that can be detected with a probability of 95%.
The LoQ corresponds to the lowest analyte concentration at which the within laboratory CV is ≤ 20%.

8.4 Precision

Precision was determined using the ADVIA Centaur XP system 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 IU/mL	SD[b] IU/mL	CV[c] (%)	SD IU/mL	CV (%)
Serum A	80	2.1	0.28	13.5	0.30	14.6
Serum B	80	4.1	0.15	3.6	0.17	4.1
Serum C	80	6.7	0.39	5.9	0.49	7.3
Serum D	80	13.0	0.77	6.0	1.00	7.7
Serum E	80	18.3	0.73	4.0	1.03	5.6

Sample	N[a]	Mean IU/mL	Repeatability SD[b] IU/mL	Repeatability CV[c] (%)	Within-Laboratory Precision SD IU/mL	Within-Laboratory Precision CV (%)
Serum F	80	50.4	1.56	3.1	2.43	4.8
Serum G	80	496.0	8.88	1.8	20.7	4.2
Serum H	80	872.0	27.9	3.2	49.3	5.7
Control 1	80	48.1	1.28	2.7	1.41	2.9
Control 2	80	448.8	11.82	2.6	14.49	3.2

a Number of measurements.
b Standard deviation.
c Coefficient of variation.

8.5 Reproducibility

Reproducibility was determined using the ADVIA Centaur XP system in accordance with CLSI document EP05-A3. Testing was performed using 3 instruments and 3 reagent lots. Samples were assayed in replicates of 5 with 2 runs per day using a 5-day protocol (Number of measurements per sample = 225). The following results are representative of the performance of the assay:

Sample	Mean IU/mL	Repeatability SD[a] IU/mL	Repeatability CV[b] (%)	Between Day SD IU/mL	Between Day CV (%)	Between Lot SD IU/mL	Between Lot CV (%)	Between Instrument SD IU/mL	Between Instrument CV (%)	Reproducibility SD IU/mL	Reproducibility CV (%)
Serum A	2.1	0.20	9.5	0.19	8.9	0.05	2.2	0.15	7.1	0.32	15.0
Serum B	2.3	0.22	9.5	0.23	9.8	0.10	4.2	0.20	8.4	0.39	16.6
Serum C	5.1	0.27	5.3	0.43	8.4	0.34	6.7	0.00	0.0	0.61	12.0
Serum D	15.3	0.55	3.6	0.68	4.4	1.09	7.1	0.54	3.5	1.50	9.8
Serum E	43.3	1.59	3.7	1.84	4.2	1.54	3.6	0.00	0.0	2.88	6.7
Serum F	424.1	12.58	3.0	17.62	4.2	21.20	5.0	10.63	2.5	32.11	7.6
Serum G	707.6	22.68	3.2	27.85	3.9	24.00	3.4	15.12	2.1	45.77	6.5
Control 1	45.8	1.35	2.9	0.84	1.8	1.79	3.9	0.32	0.7	2.41	5.3
Control 2	433.3	14.44	3.3	9.46	2.2	9.10	2.1	7.83	1.8	21.02	4.9

a Standard deviation.
b Coefficient of variation.

8.6 Specimen Equivalence

Specimen equivalency was determined with the weighted Deming regression model using the ADVIA Centaur XP system in accordance with CLSI Document EP09c-A3.
Agreement of the specimen types may vary depending on the study design and population tested.

Tube (y) vs. Serum (x)	Regression Equation	Sample Interval	N[a]	r[b]
Plasma, dipotassium EDTA	y = 0.98x + 0.2 IU/mL	1.0–934.2 IU/mL	42	0.999
Plasma, lithium heparin	y = 0.98x + 0.0 IU/mL	1.0–934.2 IU/mL	42	0.998
Plasma, sodium heparin	y = 0.97x + 0.1 IU/mL	1.0–934.2 IU/mL	42	0.997
Serum, gel-barrier	y = 0.98x + 0.1 IU/mL	1.0–934.2 IU/mL	42	0.999

a Number of samples tested.
b Correlation coefficient.

8.7 Interferences

8.7.1 *Hemolysis, Icterus, Lipemia (HIL)*

Interference testing was performed using the ADVIA Centaur XP system 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 4.6–5.5 IU/mL, 43.9–48.8 IU/mL, and 406.6–450.6 IU/mL.

Substance	Substance Test Concentration
Hemoglobin	1000 mg/dL
Bilirubin, conjugated	60.0 mg/dL
Bilirubin, unconjugated	60.0 mg/dL
Lipemia (Intralipid)	3500 mg/dL

8.7.2 Other Substances

Interference testing was performed using the ADVIA Centaur XP system in accordance with CLSI Document EP07-ed3 and EP37-ed1. Interference as defined by bias greater than 10% was not observed for the following substances when tested at analyte concentrations of 4.3–6.0 IU/mL, 35.5–60.1 IU/mL, and 357.8–506.8 IU/mL.

Substance	Substance Test Concentration
Acetaminophen	20.0 mg/dL
Acetylsalicylic Acid (Aspirin)	65.2 mg/dL
Biotin	3500 ng/mL (0.35 mg/dL)
Human Immunoglobulin G (IgG)	6.00 g/dL
Ibuprofen	50.0 mg/dL
Insulin	18.0 mIU/L
Iodide	3.00 mM (38 mg/dL)
L-Thyroxine (T4)	10,000 ng/mL (1 mg/dL)
Methimazole	1.00 µg/mL (0.1 mg/dL)
Protein (low)	3.00 g/dL
Protein (high)	12.0 g/dL
Rheumatoid Factor (RF)	750 IU/mL

8.8 Cross-Reactivity

Cross-reactivity was determined using the ADVIA Centaur XP system in accordance with CLSI Document EP07-ed3. Cross-reactivity of samples spiked with various substances does not exceed 5.3–5.4 IU/mL, 41.5–45.0 IU/mL, and 407.4–431.0 IU/mL.

Substance	Substance Test Concentration
T3 antibodies	0.55 mg/mL (55 mg/dL)
T4 antibodies	1.01 mg/mL (101 mg/dL)

8.9 Linearity

Linearity testing was performed in accordance with CLSI Document EP06 ED2:2020. The ADVIA Centaur aTgII assay is linear for the measuring interval of 1.1–1000 IU/mL.

8.10 High Dose Hook Effect

High anti-Tg concentrations can cause a paradoxical decrease in the RLUs (high-dose hook effect). In this assay, no hook effect was observed up to 50,000 IU/mL.

9. Reagent Stability

- The shelf-life stability of the ADVIA Centaur aTgII reagents (ReadyPack and calibrator) and ADVIA Centaur aTgII ancillary reagent was determined to be 24 months.
- The on-board stability of the ADVIA Centaur aTgII reagents (ReadyPack and calibrator) was determined to be 28 days on the ADVIA Centaur XP system with a calibration interval of 28 days.
- The on-board stability of the ADVIA Centaur aTgII calibrators on the ADVIA Centaur XP system was determined to be 8 hours.
- The on-board stability of the ADVIA Centaur aTgII ancillary reagent on the ADVIA Centaur XP system was determined to be 28 days.
- The ADVIA Centaur aTgII calibrators when reconstituted were determined to be stable at 2-8ºC and room temperature for 60 days and 8 hours, respectively.

9.1 Sample Stability

- Serum and plasma (EDTA, lithium heparin, and sodium heparin) are the recommended sample types for this assay.

  Sample stability studies were conducted using SST, K2 EDTA Plasma, and Lithium Heparin tube types.
- Separated samples are stable for up to 8 hours at room temperature, and for up to 7 days at 2–8°C.
- Separated samples are stable at ≤ -20°C for up to 6 months. Avoid more than 2 freeze thaw cycles.

10. Conclusions

Based on the results of comparative testing, ADVIA Centaur Anti-Thyroglobulin II (aTgII) assay is substantially equivalent in principle and performance to the currently marketed predicate device, the Beckman Coulter Access Thyroglobulin Antibody II (TgAbII) assay cleared under 510(k) K112933.