September 30, 2023

Roche Diagnostics
Phil Williams
Regulatory Affairs Program Manager
9115 Hague Road
Indianapolis, Indiana 46250

Re: K221890
Trade/Device Name: Elecsys Tg II
Regulation Number: 21 CFR 866.6010
Regulation Name: Tumor-Associated Antigen Immunological Test System
Regulatory Class: Class II
Product Code: MSW
Dated: April 21, 2023
Received: April 21, 2023

Dear Phil Williams:

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. 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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221890

Device Name
Elecsys Tg II

Indications for Use *(Describe)*

Immunoassay for the in vitro quantitative determination of thyroglobulin in human serum and plasma. Determination of Tg is used as an 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).
The electrochemiluminescence immunoassay "ECLIA" is intended for use on cobas e immunoassay analyzers.

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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K221890

510(k) Summary

Submitter Name	Roche Diagnostics
Address	9115 Hague Road Indianapolis, IN 46250
Contact	Phil Williams Email: phil.williams@roche.com
Date Prepared	May 19, 2023
Device Trade Name	Elecsys Tg II (08906556160)
Common Name	Tumor-associated antigen immunological test system
Classification Name	System, Test, Thyroglobulin
Regulation Number	866.6010
Product Codes, Regulation Numbers	MSW
Legally Marketed Predicate Devices	k002905 Access® Thyroglobulin Reagents on the Access® Immunoassay MSW

1. DEVICE DESCRIPTION SUMMARY

The Tg II immunoassay makes use of a two-step, double antigen sandwich principle using a biotinylated monoclonal Tg-specific antibody and monoclonal Tg-specific antibodies labeled with a ruthenium complex. The Tg II immunoassay is intended for the in vitro quantitative determination of thyroglobulin in human serum and plasma. Determination of Tg is used 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). It is intended for use on the **cobas e** immunoassay analyzers. Results are determined via a calibration curve which is instrument-specifically generated by 2-point calibration and a master curve provided via the reagent barcode or e-barcode.

2. INTENDED USE/INDICATIONS FOR USE

Immunoassay for the in vitro quantitative determination of thyroglobulin in human serum and plasma. Determination of Tg is used as an 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).

The electrochemiluminescence immunoassay "ECLIA" is intended for use on **cobas e** immunoassay analyzers.

3. INDICATIONS FOR USE COMPARISON

The Elecsys Tg II is substantially equivalent to the Access® Thyroglobulin Reagents on the Access® Immunoassay Systems. Both test systems are for the quantitative determination of thyroglobulin levels in human serum and plasma and used as an aid in the monitoring for the presence of local and metastatic thyroid tissue in patients who have thyroid cancer and have had thyroid surgery.

4. TECHNOLOGICAL COMPARISON

Item	Predicate (Beckman Access, k002905)	Candidate Device (Elecsys Tg II)
Test Principle	The Access Thyroglobulin assay is a simultaneous one-step immunoenzymatic ("sandwich") assay. A sample is added to a reaction vessel, along with a biotinylated mixture of four monoclonal Tg antibodies, streptavidin coated paramagnetic particles, and monoclonal anti-Tg antibody alkaline phosphatase conjugate. The biotinylated antibodies and the serum or plasma thyroglobulin binds to the solid phase, while the conjugate antibody reacts with a different antigenic site on the thyroglobulin molecule. After incubation in a reaction vessel, materials bound to the solid phase are held in a magnetic field while unbound materials are washed away. Then, the chemiluminescent substrate Lumi-Phos* 530 is added to the vessel and light generated by the reaction is measured with a luminometer. The light production is directly proportional to the concentration of thyroglobulin in the sample. The amount of analyte in the sample is determined from a stored, multi-point calibration curve.	Sandwich principle. Total duration of assay: 18 minutes. ▪ 1st incubation: Tg from 35 µL of sample, a biotinylated monoclonal Tg-specific antibody and monoclonal Tg-specific antibodies labeled with a ruthenium complex [a)] react to form a sandwich complex. ▪ 2nd incubation: After addition of streptavidin-coated microparticles, the complex becomes bound to the solid phase via interaction of biotin and streptavidin. ▪The reaction mixture is aspirated into the measuring cell where the microparticles are magnetically captured onto the surface of the electrode. Unbound substances are then removed with ProCell/ProCell M. Application of a voltage to the electrode then induces chemiluminescent emission which is measured by a photomultiplier. ▪Results are determined via a calibration curve which is instrument-specifically generated by 2 point calibration and a master curve provided via the reagent barcode or e barcode a) Tris(2,2'-bipyridyl)ruthenium(II)-complex (Ru(bpy))
Instrument	Access® Immunoassay Systems	**cobas e** immunoassay analyzers

Item	Predicate (Beckman Access, k002905)	Candidate Device (Elecsys Tg II)
Reagent Composition	R1: Access Thyroglobulin Reagent Test Packs: Cat# 33860. 100 determinations, 50 tests/pack R1a: Dynabeads Paramagnetic particles coated with streptavidin, suspended in a Tris-buffered saline, surfactant, bovine serum albumin (BSA) <0.1%sodium azide 0.1% ProClin** 300. R1b: Mouse monoclonal anti-thyroglobulin-alkaline phosphatase (bovine) conjugate in a Tris buffer, with protein (bovine), <0.1%sodium azide 0.1% ProClin** 300. R1c: Mouse monoclonal anti-thyroglobulin antibodies coupled to biotin in a HEPES buffer with protein (bovine and mouse), < 0.1% sodium azide, and 0.05% ProClin 300	The reagent rackpack: • M Streptavidin-coated microparticles (transparent cap), 1 bottle, 6.5 mL: Streptavidin-coated microparticles 0.72 mg/mL; preservative. • R1 Anti-Tg-Ab~biotin (gray cap), 1 bottle, 9 mL: Biotinylated monoclonal anti-Tg antibody (mouse) 1 mg/L; Bis-Tris buffer 50 mmol/L, pH 6.3; preservative. • R2 Anti-Tg-Ab~Ru(bpy) (black cap), 1 bottle, 9 mL: Monoclonal anti-Tg antibodies (mouse) labeled with ruthenium complex 3.1 mg/L; Bis-Tris buffer 50 mmol/L, pH 6.3; preservative.
Sample Type/Matrix	Serum and (heparinized) plasma	Serum, Li-Heparin, K_2-EDTA, and K_3-EDTA
Calibrator	Access Thyroglobulin Calibrators	Tg II CalSet
Calibration Interval	Calibration is required every 56 days or whenever new lot numbers of reagents are placed into use	Renewed calibration is recommended as follows: ▪ after 1 month (28 days) when using the same reagent lot ▪ after 7 days (when using the same reagent kit on the analyzer) ▪ as required: e.g. quality control findings outside the defined limits
Controls	Commercial control materials	PreciControl Universal, PreciControl TS, or other suitable control material
Traceability/ Standardization	Calibrators are traceable to the European Community Bureau of Reference (BCR) CRM 457 thyroglobulin standard	Standardized against CRM (Certified Reference Material) 457, of the BCR (Community Bureau of Reference) of the European Union.
Reagent Stability	Stable until the expiration date stated on the label when stored at 2 to 10°C.	up to the stated expiration date (unopened at 2-8 °C) 84 days (12 weeks) after opening, stored at 2-8 °C
Reagent On-Board Stability	After initial use, the pack is stable at 2 to 10°C for 28 days.	28 days (4 weeks)
Measuring Range	0.1 – 500 ng/mL	0.1 ng/mL – 500 ng/mL

Item	Predicate (Beckman Access, k002905)	Candidate Device (Elecsys Tg II)
Lower Limits of Measurement	The lowest detectable level of Tg distinguishable from zero (Access Thyroglobulin Calibrator S0) with 95% confidence is 0.1 ng/mL. This value is determined by processing a complete six-point calibration curve, controls and ten replicates of the zero calibrator in multiple assays. The analytical sensitivity value is calculated from the curve at the point that is two standard deviations from the fitted zero calibrator signal.	Limit of Blank = 0.02 ng/mL Limit of Detection = 0.04 ng/mL Limit of Quantitation = 0.1 ng/mL

5. CLINICAL AND ANALYTICAL STUDIES SUMMARY & CONCLUSIONS

A reference range study was performed with 244 apparently healthy male subjects between 22 and 79 years of age and 219 apparently healthy female subjects between 22 and 77 years of age. Reference intervals (2.5th and 97.5th percentiles) together with medians are presented in the following table:

	N	2.5th percentile	Median=50th percentile	97.5th percentile
Males	244	3.3 ng/mL	15.1 ng/mL	63.2 ng/mL
Females	219	3.9 ng/mL	18.3 ng/mL	104 ng/mL
Males and Females	463	3.6 ng/mL	16.6 ng/mL	77.3 ng/mL

Study for the expected values obtained from a total of 127 subjects with differentiated thyroid cancer (100 female; 27 male) with no evidence of disease for 4 or more years following total/near total thyroidectomy was conducted. The percentage of measurements below the LoQ of 0.1 ng/ml was 80.3%. The 95th percentile was 0.786 ng/mL (95% of patients had results ≤0.786 ng/mL).

A prospective, multi-center study was conducted on the **cobas e** 411 analyzer to assess the clinical performance of Elecsys Tg II. Samples were collected from 9 sites across the U.S. 530 samples were available for analysis.

Serum samples were collected from subjects in the longitudinal cohort within 4 - 12 weeks following total or near total thyroidectomy but before radioiodine ablation (if planned). Thyroglobulin levels were measured at 4 additional time points (approximately 6 months, 12 months, 18 months, and 24 months post-surgery/radioiodine ablation), 5 planned longitudinal visits per patient.

Samples from the cross-sectional cohort (structural disease positive) were used to increase the number of observations from patients with structural disease in the longitudinal cohort due to the

low prevalence of structural disease in the longitudinal cohort. Subjects from the cross-sectional cohort had only 1 single visit.

The longitudinal and the cross-sectional cohorts were combined to increase the prevalence to determine a more precise estimate for sensitivity and NPV (negative predictive value). NPV and PPV (positive predictive value) estimates were adjusted based on the real-world prevalence of structural disease observed in the longitudinal cohort (4.99 % = 23/461).

Structural disease was defined as evidence of disease on ultrasound, cross sectional or functional imaging, or biopsy proven disease as determined by the investigator.

The combined data of 530 samples are presented in the table below:

	Tg Concentration	**SD[a)]+**	**SD-**	
Elecsys Tg II	≥0.2 ng/mL	91	204	295
	<0.2 ng/mL	1	234	235
	Total	92	438	530

a) SD = structural disease

Sensitivity and specificity for the combined data were calculated for Elecsys Tg II assay result < 0.2 ng/mL as a negative result and Elecsys Tg II assay result ≥ 0.2 ng/mL as a positive result. Estimates of sensitivity and specificity along with two-sided 95% confidence intervals are presented in the table below. Prevalence of structural disease (SD+) in the longitudinal part of the clinical study was 4.99% (23/461). NPV and PPV were calculated for the prevalence of 4.99% along with two-sided 95% confidence intervals and results of the calculations are presented in the table below.

Clinical Performance Measures	**Estimate**	**95% CI**
Sensitivity	98.91% (91/92)	(94.10%; 99.81%)
Specificity	53.42% (234/438)	(48.74%; 58.05%)
Prevalence	4.99% (23/461)	(3.35%; 7.37%)
Negative Predictive Value (NPV)	99.89%	(99.42%; 99.98%)
Positive Predictive Value (PPV)	10.03%	(9.16%; 11.03%)

The pre-defined suppressed Tg concentrations according to the ATA Response Classification categories: Excellent Response, Indeterminate Response and Biochemical Incomplete Response are presented in the table below:

▪	Excellent Response = Tg < 0.2 ng/mL
▪	Indeterminate Response = Tg ≥ 0.2 ng/mL AND Tg < 1.0 ng/mL
▪	Biochemical Incomplete Response = Tg ≥ 1.0 ng/mL

The results from the clinical study demonstrated that at Tg concentrations ≥ 1.0 ng/mL (corresponding to ATA "Biochemical Incomplete Response"), the probability of structural disease was much higher than the probability of structural disease for Tg concentrations <0.2 ng/mL (corresponding to ATA "Excellent Response").

Within-laboratory precision of the Elecsys Tg II assay was evaluated using Elecsys reagents, samples, and controls in accordance with the CLSI document EP05-A3: 2 runs per day in duplicate each for 21 days (n = 84). The following results were obtained:

Sample	N	Mean	Repeatability (Within Run)		Between-Run		Between-Day		Within-Laboratory	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
HS 1[b)]	84	0.129	0.010	7.56	0.000	0.000	0.007	5.49	0.012	9.34
HS 2	84	0.145	0.009	5.86	0.000	0.000	0.009	6.50	0.013	8.75
HS 3	84	0.228	0.009	4.00	0.004	1.81	0.008	3.59	0.013	5.67
HS 4	84	1.67	0.045	2.67	0.015	0.908	0.025	1.50	0.053	3.20
HS 5	84	38.7	0.503	1.30	0.000	0.000	0.460	1.19	0.682	1.76
HS 6	84	235	4.52	1.92	0.000	0.000	2.90	1.23	5.37	2.28
HSP[c)] 7	84	459	7.76	1.69	5.00	1.09	4.39	0.958	10.2	2.23
PCU[d)]_1	84	24.1	0.267	1.11	0.038	0.156	0.308	1.28	0.409	1.70
PCU_2	84	84.4	0.865	1.02	0.509	0.603	1.03	1.22	1.44	1.71
PC TS[e)]	84	1.05	0.016	1.55	0.000	0.000	0.019	1.79	0.025	2.37

b) HS = Human Serum
c) HSP = Human Serum Pool
d) PCU = PreciControl Universal
d) PC TS = PreciControl TS

Site-to-site reproducibility study was conducted on 3 **cobas e** 411 analyzers at 3 sites using 3 lots of reagents (2 reagent lots per site). The following samples and controls were tested in 5 replicates per run, in a single run per day, for 5 days according to the CLSI document EP05-A3 (n=150). The overall reproducibility (imprecision) data are summarized in the following table:

			Repeatability		Between-Day		Between-Lot		Between-Lab		Total	
Sample	**N**	**Mean**	**SD**	**CV [%]**	**SD**	**CV [%]**	**SD**	**CV [%]**	**SD**	**CV [%]**	**SD**	**CV [%]**
HS_01	148	0.217	0.016	7.56	0.014	6.66	0.014	6.49	0.014	6.45	0.030	13.6
HS_02	148	0.315	0.021	6.62	0.022	7.14	0.012	3.77	0.022	6.88	0.039	12.5
HS_03	146	2.00	0.076	3.79	0.090	4.52	0.012	0.622	0.067	3.34	0.136	6.81
HS_04	148	39.7	1.26	3.17	2.02	5.08	0.541	1.36	1.53	3.86	2.88	7.26
HP_05	149	261	11.0	4.20	12.1	4.64	8.02	3.07	13.4	5.15	22.6	8.67
HSP_06	148	407	14.0	3.43	17.8	4.37	10.6	2.61	20.4	5.01	32.2	7.92
HSP_07	149	464	17.6	3.79	19.3	4.16	0.000	0.000	18.5	3.98	32.0	6.89
PCU_1	149	24.2	1.16	4.80	1.79	7.43	0.892	3.70	1.26	5.20	2.63	10.9
PCU_2	148	93.0	4.31	4.63	4.62	4.97	3.32	3.57	3.10	3.34	7.78	8.36
PC TS	149	1.08	0.034	3.15	0.045	4.23	0.033	3.08	0.017	1.57	0.068	6.30

The Limit of Blank (LoB) was determined according to CLSI EP17-A2. Five analyte-free samples including native human serum samples and serum pools were measured in two replicates per run, six runs distributed over 4 days using three reagent lots on one analyzer. The LoB of the Elecsys Tg II assay is set to 0.02 ng/mL.

The Limit of Detection (LoD) was determined according to CLSI EP17-A2. Five native samples with low-analyte concentration were measured in two replicates per run, six runs distributed over 4 days, using three reagent lots on one analyzer. The LoD of the Elecsys Tg II assay is set to 0.04 ng/mL.

The Limit of Quantitation (LoQ) was determined according to CLSI EP17-A2. Seven low-level human serum samples (HS) were measured in five replicates with one run per day over 5 days using three reagent lots on one analyzer. The acceptance criteria were %CV of within-laboratory precision ≤ 20% and %bias within ±15%. The LoQ of the Elecsys Tg II assay is set to 0.1 ng/mL.

The linearity study for Elecsys Tg II assay was conducted on the **cobas e** 411 analyzer with 3 lots of reagent using two native, unmodified human serum samples (low, high) mixed in different proportions. A weighted linear regression was performed in accordance with the CLSI document EP06-Ed2. All deviations from linearity met the specification of ±10% for values ≥0.3 ng/mL and within ±0.03 ng/mL for values <0.3 ng/mL. Results of the regression analysis are presented in the table below.

The extended measuring interval is 500 – 5,000 ng/mL for manually or automatically 1:10 diluted samples. Samples with Tg concentrations above the analytical measuring range can be diluted with Diluent MultiAssay. The recommended dilution is 1:10 (either automatically by the analyzers or manually). The concentration of the diluted sample must be ≥ 40 ng/mL. After

manual dilution, multiply the result by the dilution factor of 10. After dilution by the analyzers, the software automatically takes the dilution into account when calculating the sample concentration.

Three matrix comparison studies were conducted: Li-heparin plasma vs serum, K2-EDTA plasma vs serum, and K3-EDTA plasma vs serum. Each matrix comparison study included 65 pairs that cover the analytical measuring interval. Matrix comparison studies showed that performance of Elecsys Tg II assay with these matrices are similar.

The high-dose hook effect was assessed in three replicates. Three human serum samples (single donors) were spiked with analyte (human Tg) to achieve high Thyroglobulin concentrations. For each sample, a dilution series was performed. The hook concentration reported corresponds to the highest analyte concentration that generates a signal ≥ 10% above the upper limit of the measuring range. There was no hook effect up to ≥ 120000 ng/mL Tg.

The effect on quantitation of Tg in the presence of biotin was tested with native human serum samples. The interfering pool was diluted into the dilution pool in 10% increments. The recovery for each sample was calculated by comparison to the control (unspiked) sample. The biotin interference claim is set to 1200 ng/mL in labeling.

The effect of the following endogenous substances and pharmaceutical compounds on assay performance was tested. Interferences were tested up to the listed concentrations of the interferent and non-significant interferences were observed. Non-significant interferences were defined as %interferences within ± 10 %.

Compound	**Concentration tested**
Bilirubin	≤ 1128 µmol/L or ≤ 66 mg/dL
Hemoglobin	≤ 0.373 mmol/L or ≤ 600 mg/dL
Intralipid	≤ 2000 mg/dL
Biotin	≤ 4912 nmol/L or ≤ 1200 ng/mL
IgG	≤ 2 g/dL
Albumin	7 g/dL

Pharmaceuticals interferences were tested by spiking serum samples. Interference testing was performed on 17 commonly used pharmaceuticals. No significant interference with the assay was found. The following special drugs were tested with concentrations shown in the table below.

Drug	Concentration (mg/L)
Iodide	0.2
Carbimazole	30
Thiamazole	80
Propylthiouracil	300
Perchlorate	2000
Propranolol	240
Amiodarone	200
Prednisolone	100
Hydrocortisone	200
Fluocortolone	100
Octreotide	0.3
L-T3	0.5
D-T3	0.5
L-T4	5
D-T4	5
Cabozantinib-S-Malate	4.14
Lenvatinib Mesylate	0.15

Drug interferences are measured based on recommendations given in CLSI guidelines EP07-A3 and EP37-Ed1 and other published literature.

The effect of the presence of human anti-mouse antibodies (HAMA) on the Elecsys Tg II assay was assessed on the **cobas e** 411 with four replicates. A serum pool with an endogenous analyte concentration (approximately 7 ng/mL) having a high-HAMA concentration and the corresponding serum pool without HAMA were tested. The recovery of the serum pool containing HAMA compared to the serum pool without HAMA was calculated. There was no significant HAMA interference at 805 µg/L HAMA.

The following cross-reactivities were investigated with thyroglobulin concentrations of approximately 5 and 50 ng/mL:

Cross-reactant	Concentration tested	Cross-reactivity %
TSH	1000 mIU/L	Within ±0.36%
TBG	200000 ng/mL	Within ±0.0001%

The effect on quantitation of analyte in the presence of anticoagulants with Elecsys Tg II was determined by comparing values obtained from human serum samples and sample pools drawn into Serum, Li-Heparin, K2-EDTA, and K3-EDTA plasma tubes. Sixty five (65) serum/plasma pairs were tested in singleton with one reagent lot. Matrix comparison studies showed that performance of Elecsys Tg II assay with these matrices are similar.

The shelf-life stability of the Elecsys Tg II was conducted. The reagent packs were stored at 2–8ºC and the real-time stability was evaluated at baseline and testing timepoints up to 17 months. The data support a shelf-life of the Elecsys Tg II up to 15 months at 2–8ºC.
Reagent stability after first opening for the Elecsys Tg II assay was tested on one **cobas e** 411 analyzer. Elecsys Tg II reagent kits can be used after first opening for up to 84 days (12 weeks) when stored at 2-8°C.

On-board reagent stability for the Elecsys Tg II assay was tested on one **cobas e** 411 analyzer. Elecsys Tg II reagent kits can be stored on-board the analyzers for up to 28 days (4 weeks).

Lot calibration frequency for the Elecsys Tg II assay was tested on one **cobas e** 411 analyzer. Calibrations of an Elecsys Tg II reagent is recommended after 28 days (1 month) when using the same reagent lot.

Reagent on-board calibration frequency for Elecsys Tg II assay was tested on one cobas e 411 analyzer. Elecsys Tg II reagent kits can be stored on board of the analyzers for up to 7 days without a new calibration.

The sample stability of serum, Li-Heparin plasma, K2-EDTA and K3-EDTA plasma was evaluated for each sample matrix using Elecsys Tg II assay on one cobas e 411 analyzer. All samples can be stored for 14 days at 2−8°C, 14 days at 15−25°C, and 24 months at -20 (± 5)°C.