510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K241423

B Applicant

Beckman Coulter, Inc

C Proprietary and Established Names

Access Thyroglobulin

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
MSW	Class II	21 CFR 866.6010 - Tumor-Associated Antigen Immunological Test System	IM - Immunology

II Submission/Device Overview:

A Purpose for Submission:

Addition of plasma sample type to the previously cleared Access Thyroglobulin

B Measurand:

Thyroglobulin

C Type of Test:

Quantitative, Chemiluminescent Immunoassay

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
www.fda.gov

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

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 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.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only
For In Vitro Diagnostic Use Only

The Instructions for Use of the device contains the following warning statement:

"The presence of serum autoantibodies to thyroglobulin (TgAb) can interfere with assays for thyroglobulin (Tg). Therefore, sera which contain TgAb, even at very low levels, should not be tested for Tg.

The concentration of thyroglobulin in a given specimen determined with assays from different manufacturers can vary due to differences in assay methods and reagent specificity. The results reported by the laboratory to the physician must include the identity of the Tg assay used. Values obtained with different assay methods cannot be used interchangeably. If, in the course of monitoring a patient, the assay method used for determining Tg levels serially is changed, additional sequential testing should be carried out to confirm baseline values."

D Special Instrument Requirements:

Access Immunoassay Systems (Access Immunoassay System and Access 2 Immunoassay System)

IV Device/System Characteristics:

A Device Description:

Access Thyroglobulin assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of thyroglobulin levels in human serum and plasma (heparinized) using the Access Immunoassay Systems.

Materials included in the Access Thyroglobulin assay

Reagent Pack (2 packs, 50 tests/pack) contains:

- R1a (3.25 mL): Dynabeads paramagnetic particles coated with streptavidin and coupled to biotinylated mouse monoclonal antithyroglobulin antibodies in TRIS buffer with protein (bovine) and preservatives
- R1b (3.10 mL): Mouse monoclonal anti-thyroglobulin-alkaline phosphatase (bovine) conjugate in a TRIS buffer with protein (bovine, murine) and preservatives
- R1c (3.10 mL): HEPES buffer with protein (bovine, murine) and preservatives

Materials needed but not supplied

- Access Thyroglobulin Calibrators: Six levels – 0, 1.0, 10, 100, 250, and 500 ng/mL
- Quality control materials: commercial control material
- Access Thyroglobulin Sample Diluent
- Access Substrate
- Access Wash Buffer II / Unicel DxI Wash Buffer II

B Principle of Operation:

The Access Thyroglobulin assay is a simultaneous one-step immunoenzymatic ("sandwich") assay. A sample is added to a reaction vessel with four biotinylated anti-thyroglobulin antibodies coated on streptavidin paramagnetic particles, and monoclonal anti-thyroglobulin antibody alkaline phosphatase conjugate. The thyroglobulin in the sample binds to the biotinylated antibodies on 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 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.

V Substantial Equivalence Information:

A Predicate Device Name(s):

Access Thyroglobulin

B Predicate 510(k) Number(s):

K220972

C Comparison with Predicate(s):

Device & Predicate Device(s):	K241423	K220972
Device Trade Name	Access Thyroglobulin	Access Thyroglobulin
General Device Characteristic Similarities		
Intended Use/ Indications for Use	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 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.	Access Thyroglobulin assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of thyroglobulin levels in human serum using the Access Immunoassay Systems. This device is 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.
Technology	Chemiluminescent immunoassay	Same
Analyte	Thyroglobulin	Same
Antibodies	Mouse monoclonal antibodies	Same
Method	Automated	Same
Assay Architecture	Biotinylated mouse monoclonal anti-thyroglobulin antibodies pre-coupled to paramagnetic particles coated with streptavidin.	Same
Sample Volume	40 µL	Same
Assay Throughput	~42 minutes	Same
Measuring Range	0.1 – 500 ng/mL	Same
General Device Characteristic Differences		
Sample Matrix	Serum and Plasma	Serum

VI Standards/Guidance Documents Referenced:

The following Clinical and Laboratory Standards Institute (CLSI) guideline was used:

- CLSI EP35, Assessment of Equivalence or Suitability of Specimen Types for Medical Measurement Procedures – Third Edition

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

   Refer to K220972

2. Linearity:

   Refer to K220972

3. Analytical Specificity/Interference:

   Refer to K220972

4. Assay Reportable Range:

   Refer to K220972. The assay reportable range for the Access Thyroglobulin is the same as the claimed analytical measuring interval (AMI): 0.1–500 ng/mL.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

   Refer to K220972

6. Detection Limit:

   Refer to K220972

7. Assay Cut-Off:

   Not applicable

B Comparison Studies:

1. Method Comparison with Predicate Device:

   Refer to K220972

2. Matrix Comparison:

   A study was performed to demonstrate that lithium heparin and sodium heparin plasma matrices yield comparable values as serum for the same patient with the Access Thyroglobulin assay. The study included 45 matched native samples with thyroglobulin concentration covering the measuring range of the assay. Samples were tested in replicates of three for each sample pair using one reagent lot of the Access Thyroglobulin assay on one Access 2 Immunoassay System. Passing-Bablok regression analyses were performed by comparing the results of plasma samples to the results of corresponding serum samples. Representative results of single replicate are summarized in the table below:

Plasma/Serum	N	Range (ng/mL)	Slope (95% CI)	Intercept (95% CI)	Correlation Coefficient (r)
Li-heparin plasma vs Serum	45	0.227 to 494.070	1.000 (0.983; 1.015)	0.163 (-0.212; 0.712)	0.999
Na-heparin plasma vs Serum	45	0.227 to 494.070	1.021 (1.010; 1.039)	0.147 (-0.246; 0.952)	0.999

C Clinical Studies:

1. Clinical Sensitivity:

   Refer to K002905

2. Clinical Specificity:

   Refer to K002905

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

   Not applicable

D Clinical Cut-Off:

Refer to K002905

E Expected Values/Reference Range:

Refer to K220972

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.