



TRAb

TSH Receptor Antibodies

A fully automated assay for detection of antibodies to the TSH receptor.

Designed with a 3rd generation antibody and has liquid, ready to use calibrators, and controls.

ROLE OF TRAb^{1,2}

- The TRAb assay is to be used as an aid in the differential diagnosis of Graves' disease
- Graves' disease is an autoimmune form of hyperthyroidism caused by autoantibodies to the thyroid-stimulating hormone (TSH, also known as thyrotropin) receptor site on the thyroid cells
- Elevations of these thyrotropin receptor antibodies demonstrated high clinical sensitivity and specificity for Graves' disease when used as an aid in the differential diagnosis and etiology of hyperthyroidism

DISEASE BURDEN³

- 2%-3% of the general population are affected by Graves' Disease
- Most common cause of hyperthyroidism at 60%-80%
- Peak incidence of occurrence is between 40-60 years of age
- Females are affected more than males by a ratio of 5-10 to 1

For *In Vitro* Diagnostics Use

INTENDED USE^{1,2}

The TRAb assay is a chemiluminescent microparticle immunoassay (CMIA) used for the quantitative determination of thyroid stimulating hormone receptor antibodies (TRAb) in human serum on the Alinity i system and the ARCHITECT i system. The TRAb assay is to be used as an aid in the differential diagnosis of Grave's disease.



KEY BENEFITS

- Liquid, ready to use calibrators, and controls
- Biotin interference free assay design
- Both automatic and manual dilution options

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TRAb KEY ASSAY CHARACTERISTICS

	ARCHITECT ^{2,4-6}	ALINITY ^{i1,7-9}
Methodology	Quantitative one-step chemiluminescent microparticle immunoassay (CMIA)	
Time to Result	29 minutes	
Throughput	Up to 100 tests/hour on i1000SR	Up to 200 tests/hour
Measuring Interval	Analytical Measuring Interval: 1.26–50.00 IU/L Extended Measuring Interval: 50.00–500.00 IU/L	
Specimen Volume	100 µL for first test 50 µL for each additional test	
Specimen Type	Human serum	
Sensitivity	Limit of Blank: 0.48 IU/L Limit of Detection: 0.70 IU/L Limit of Quantitation: 1.26 IU/L	Limit of Blank: 0.38 IU/L Limit of Detection: 0.70 IU/L Limit of Quantitation: 1.26 IU/L
Reagent Storage	Opened/Unopened: 2 to 8°C – until expiration Onboard: System Temperature – 7 days maximum storage time	
Calibrators and Controls	Calibrators: Cal A (0.00 IU/L) – F (50.00 IU/L) Controls: Low – 3.00 IU/L, Medium – 10.00 IU/L, High – 30.00 IU/L	
Precision	Within Laboratory: 0.9–5.8% (1.97–45.08 IU/L)	Within Laboratory: 1.2–9.4% (1.91–46.00 IU/L)
Control Frequency	Once every 24 hours, each day of use	

PRODUCT COMPONENTS^{1,2,4-9}

SYSTEM	PRODUCT DESCRIPTION	SIZE AND QUANTITY	LIST NUMBER
ARCHITECT i1000SR/i2000SR	TRAb Reagent Kit	100 tests	09P0825
	TRAb Reagent Kit	500 tests	09P0835
	TRAb Calibrators	4.0 mL, 6 bottles, 6 levels each	09P0801
	TRAb Controls	8.0 mL, 3 bottles, 3 levels each	09P0810
Alinity i	TRAb Reagent Kit	2 x 100 tests	04V1822
	TRAb Reagent Kit	2 x 500 tests	04V1832
	TRAb Calibrators	3.0 mL, 6 bottles, 6 levels each	04V1801
	TRAb Controls	8.0 mL, 3 bottles, 3 levels each	04V1810

REFERENCES

- Abbott Alinity i TRAb Reagent Instructions for Use.
- Abbott ARCHITECT TRAb Reagent Instructions for Use.
- National Organization for Rare Disorders (NORD). <https://rarediseases.org/rare-diseases/graves-disease/>. Accessed May 18, 2021.
- ARCHITECT Systems Operations Manual. 96211-118.
- Abbott ARCHITECT TRAb Calibrator Instructions for Use.
- Abbott ARCHITECT TRAb Control Instructions for Use.
- Alinity ci-series Operations Manual. 80000071-106.
- Abbott Alinity i Calibrator Instructions for Use.
- Abbott Alinity i Control Instructions for Use.