TSH Receptor Autoantibody (TRAb)

ELISA

THYROID

ASSAY CHARACTERISTICS

Semi-Quantitative:	Reported as U/L, or % Inhibition Index
Calibration:	4 Calibrators, 1 – 40 U/L NIBSC 08/204
Controls (Included):	1 Positive, 1 Negative

TOTAL RUNNING TIME

1 Hour and 50 Minutes

SPECIMEN MATRIX

Human Serum

REFERENCE RANGE

≤ 1.0 U/L: Negative

> 1.0 U/L: Positive

PRECISION

Intra-Assay Dose (% Inhib)	% CV	Inter-Assay Dose (% Inhib)	% CV
1.96	7.2	1.99	8.5
4.93	3.1	4.56	3.3

PATIENT GROUP	NUMBER OF PATIENTS POSITIVE FOR TRAB	%
Graves' Disease	70/82	85%
Autoimmune Hypothyroidism	0/18	0%
Systemic Lupus Erythematosus	0/8	0%
Rheumatoid Arthritis	0/10	0%
Healthy Blood Donors	0/104	0%

CLINICAL SENSITIVITY & SPECIFICITY

Sensitivity:	85%
Specificity:	100%

ORDERING INFORMATION

KR7110 — 96 Well Kit

The KRONUS TSH Receptor Autoantibody (TRAb) ELISA Assay Kit is for the semi-quantitative determination of TSH receptor autoantibodies in human serum, and is useful as an aid in the differential diagnosis of Graves' Disease in conjunction with other clinical and laboratory findings.

There is convincing evidence that autoantibodies to TSH receptor (TRAb) are responsible for Graves' hyperthyroidism. These antibodies are detectable in approximately 90% of untreated Graves' patients when measured by receptor assays. The presence of TRAb indicates that the patient's thyrotoxicosis is of autoimmune etiology rather than due to toxic nodular goiter. Because the form of treatment for Graves' disease may differ from the treatment of other forms of thyrotoxicosis, an initial TRAb measurement is clearly of value.

KRONUS' TRAb ELISA Assay Kit measures TRAb based on the inhibition of a human monoclonal thyroid antibody M22 (directly coupled to peroxidase) to the TSHR coated ELISA plate wells.

The measurement of TRAb by receptor assay provides a rapid, sensitive and inexpensive diagnostic marker for Graves' disease.

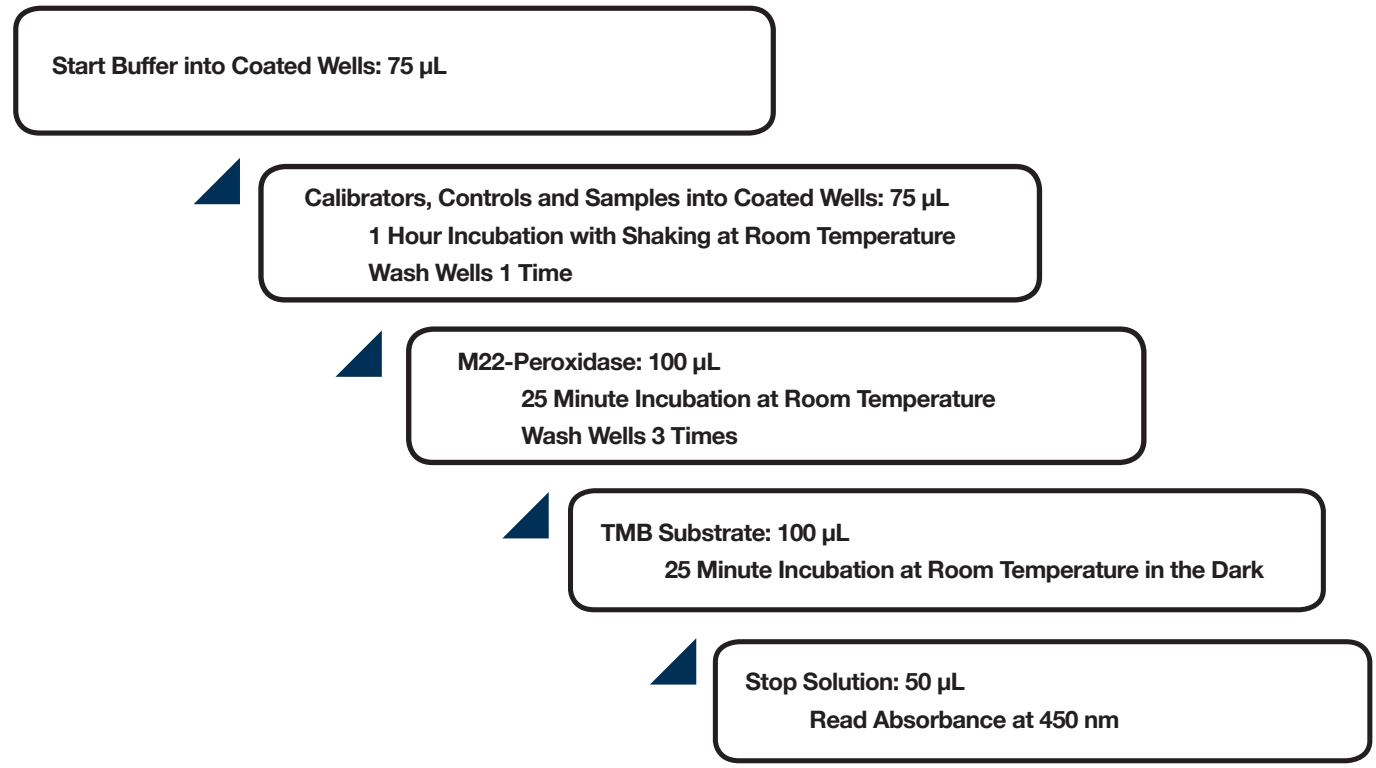
For In Vitro Diagnostic Use

KRONUS

800.4.KRONUS (800.457.6687) | 208.377.4800 | www.kronus.com | kronus@kronus.com

ASSAY PROCEDURE

Sample Volume: 75 µL per Well



REFERENCES

1. Adams DD, Purves HD. Abnormal responses in the assay for thyrotrophin. Proc Univ Otago Med Sch. 1956 Apr;34:11-12.
2. Smith BR, Hall R. Measurement of thyrotropin receptor antibodies. Methods Enzymol. 1981;74(100):405–420.
3. Manley SW, Bourke JR, Hawker RW. The thyrotrophin receptor in guinea-pig thyroid homogenate: interaction with the long-acting thyroid stimulator. J Endocrinol. 1974 Jun;61: 437.
4. Smith BR, Hall R. Thyroid-stimulating immunoglobulins in Graves' disease. Lancet. 1974 Aug;2(7878):427-430.
5. Mehdi SQ, Nussey SS. A radio-ligand receptor assay for the long-acting thyroid stimulator. Biochem J. 1975 Jan;145(1):105-111.
6. Burman KD, Pandian R. Clinical utility of assays for TSH receptor antibodies. Endocrinologist. 1998 Jul;8(4):284-290.
7. Wilson R, McKillop JH, Pearson DW, Cuthbert GF, Thomson JA. Relapse of Graves' disease after medical therapy: predictive value of thyroidal technetium-99m uptake and serum thyroid stimulating hormone receptor antibody levels. J Nucl Med. 1985 Sep;26(9):1024–1028.
8. Wilson R, McKillop JH, Henderson N, Pearson DW, Thomson JA. The ability of the serum thyrotrophin receptor antibody (TRAb) index and HLA status to predict long-term remission of thyrotoxicosis following medical therapy for Graves' disease. Clin Endocrinol. 1986 Aug;25(2):151-156.
9. Tamaki H, Amino N, Watanabe Y, Aozasa M, Hayashi H, Tachi J, Miyai K. Radioreceptor assay of anti-TSH receptor antibody activity: comparison of assays using unextracted serum and immunoglobulin fractions, and standardization of expression of activities. J Clin Lab Immunol. 1986 May;20(1):1-6.
10. Creagh F, Teece M, Williams S, Didcote S, Perkins W, Hashim F, Smith BR. An analysis of thyrotrophin receptor binding and thyroid stimulating activities in a series of Graves' sera. Clin Endocrinol. 1985 Oct;23(4):395-404.

KRONUS …Your Source for Sensitive Autoimmune Diagnostics