

ASSAY SERVICE**THYROID STIMULATING AUTOANTIBODY BIOASSAY****BioassayRSR™ TSAb****General information**

Description:	Bioassay for the determination of TSHR stimulating autoantibodies (TSAb) in serum.
Disease reference:	Graves' disease
Advantages:	Sensitive and specific bioassay
Literature:	Y Ochi et al, Thyroid 2000 10:653-657 Sensitive thyroid-stimulating antibody assay in whole serum containing five percent polyethylene glycol using porcine thyroid cells B Rees Smith et al, Thyroid 2007 17:923-938 TSH receptor antibodies B Rees Smith et al, Horm Metab Res 2009 41:448-455 TSH receptor – Autoantibody interactions

Sample requirement See also [Request form for TSAb](#)

Assay service code:	AS/TSA
Test samples:	Serum from clotted blood, lipaemic or haemolysed samples are not suitable. Plasma should not be used.
Sample volume:	500µL per patient sample
Test results:	2 - 4 weeks from sample receipt.

This assay service is intended for research use only. Result obtained to be used by professional persons only. The data quoted is for guidance only.

Address samples to:

Assay Service Department, FIRS Laboratories, RSR Ltd
Parc Ty Glas, Llanishen, Cardiff, CF14 5DU United Kingdom

Tel: +44 (0) 29 2076 5550
E-mail: firs-assay@firs-rsr.co.uk

RSR Limited**Diagnostics for Autoimmunity**

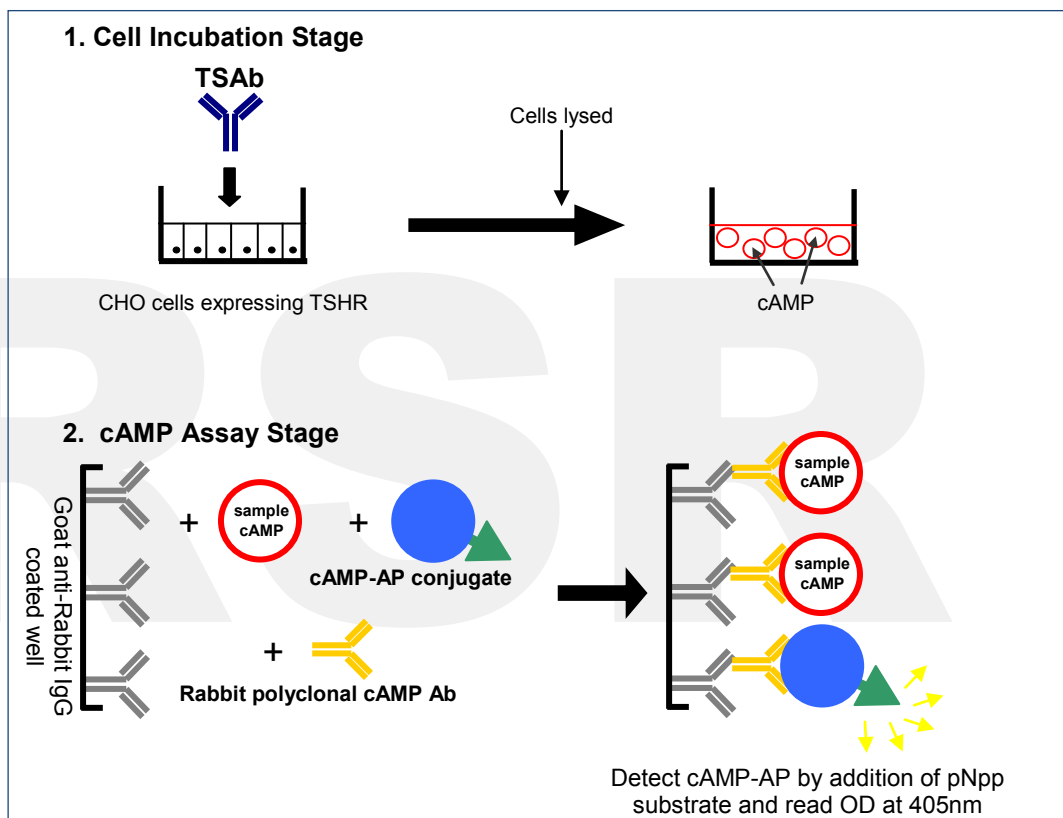
Parc Ty Glas, Llanishen, Cardiff, CF14 5DU United Kingdom
<http://www.rsrltd.com> E-mail: info@rsrltd.com

Tel: +44 (0) 29 2068 9299
Fax: +44 (0) 29 2075 7770

Technical information

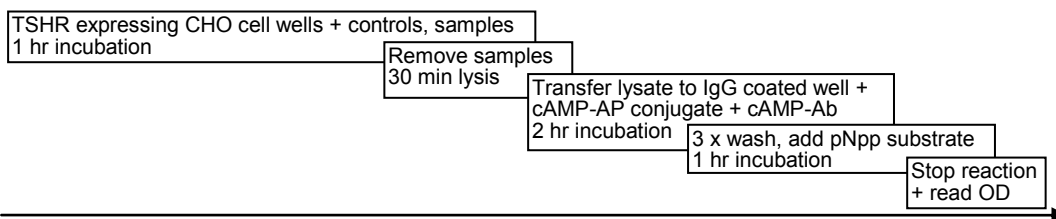
Assay method: Bioassay

Assay principle:



Sample cAMP, cAMP-AP (AP = alkaline phosphatase) conjugate and rabbit polyclonal cAMP antibody are added to goat anti-rabbit IgG coated wells where they compete for binding. Sample cAMP is detected by decreased colour development after addition of substrate.

Assay procedure:



1. Test serum samples and controls diluted 1 in 10 in buffer and added to TSHR expressing CHO cells. 1 hr incubation at 37°C.
2. Samples removed from cell wells then cells lysed for 30 min.
3. Lysates transferred to goat anti-rabbit IgG coated wells with addition of cAMP-AP conjugate and rabbit polyclonal cAMP-Ab. 2 hr incubation.
4. Wash, add pNpp substrate. 1 hr incubation.
5. Stop reaction and read OD at 405nm.
6. Read cAMP levels off the standard curve.
7. Calculate % stimulation using the formula: -

$$\% \text{ stimulation} = \frac{\text{test serum cAMP (pmol/mL)}}{\text{pool of healthy blood donor sera cAMP (pmol/mL)}} \times 100$$

This assay service is intended for research use only. Result obtained to be used by professional persons only. The data quoted is for guidance only.

Address samples to:

Assay Service Department, FIRS Laboratories, RSR Ltd
Parc Ty Glas, Llanishen, Cardiff, CF14 5DU United Kingdom

Tel: +44 (0) 29 2076 5550
E-mail: firs-assay@firs-rsr.co.uk

RSR Limited

Diagnostics for Autoimmunity

Parc Ty Glas, Llanishen, Cardiff, CF14 5DU United Kingdom
http://www.rsrltd.com E-mail: info@rsrltd.com

Tel: +44 (0) 29 2068 9299
Fax: +44 (0) 29 2075 7770

©RSR Limited All Rights Reserved

16/02/2026 AS/TSA Rev 2

Page 2 of 4

Assay performance

- Sensitivity:** 89% for Graves' disease (n = 44 treated and untreated patients positive for TRAb by ElisaRSR™ TRAb 3rd Generation and/or RiaRSR™ TRAb CT).
- Specificity:** 100% relative to healthy blood donors (n = 40).
- Detection range:** 0.2 – 50 IU/L (units: NIBSC 08/204: www.nibsc.ac.uk)
- Lower detection limit:** 124% stimulation (mean +3 standard deviations in assay of negative control; n = 36)
- Reference cut-off:** No detectable stimulating activity: <150% stimulation
Positive for stimulating activity: ≥150% stimulation
- Cross reactivity:** Using 150% stimulation cut-off, 0/13 Addison's disease patients, 0/20 rheumatoid arthritis patients and 0/19 type 1 diabetes mellitus patients were positive for TSAb activity
- Interference:** Serum TSH levels >10 mU/L (normal range approx. 0.4 – 4 mU/L) result in stimulation of cAMP production.
Serum hCG levels >90,000 mU/mL result in stimulation of cAMP production (normal levels for males and non pregnant females 0–5 mU/mL, in pregnant females levels can reach >200,000 mU/mL).
Serum LH concentrations up to 6,000 mU/mL (normal range approx. 5 -25 mU/mL) and serum FSH concentrations up to 10,000 mU/mL (normal range approx. 1.5 – 135 mU/mL) do not cause stimulation of cAMP production.
Bilirubin (20 mg/dL), haemoglobin (500 mg/dL) and lipid (3,000 mg/dL) do not interfere with the BioassayRSR™ TSAb assay.
Plasma samples are not suitable for use in the BioassayRSR™ TSAb assay.

Inter assay precision:

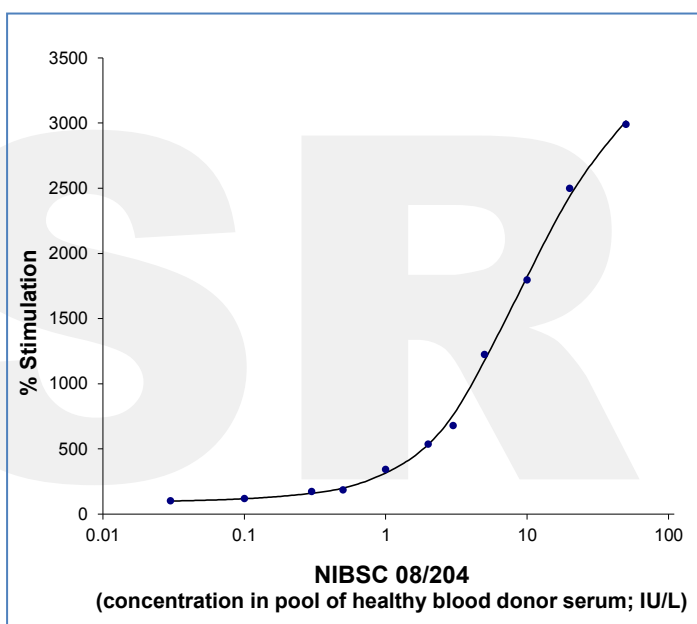
Sample (n=20)	% stimulation	CV (%)
A	326	15.5
B	871	17.7
C	1185	17.6

Intra assay precision:

Sample (n=25)	% stimulation	CV (%)
1	330	11.7
2	523	11.8
3	920	17.1

NIBSC 08/204 curve:

Dilution profile of the international standard for Thyroid Stimulating Antibody NIBSC 08/204 shows a wide dose-response range, similar to current TRAb assays based on inhibition of M22™ binding to the TSH receptor. 0.2 IU/L gives approximately 150%.



This assay service is intended for research use only. Result obtained to be used by professional persons only. The data quoted is for guidance only.

Address samples to:

Assay Service Department, FIRS Laboratories, RSR Ltd
Parc Ty Glas, Llanishen, Cardiff, CF14 5DU United Kingdom

Tel: +44 (0) 29 2076 5550
E-mail: firs-assay@firs-rsr.co.uk

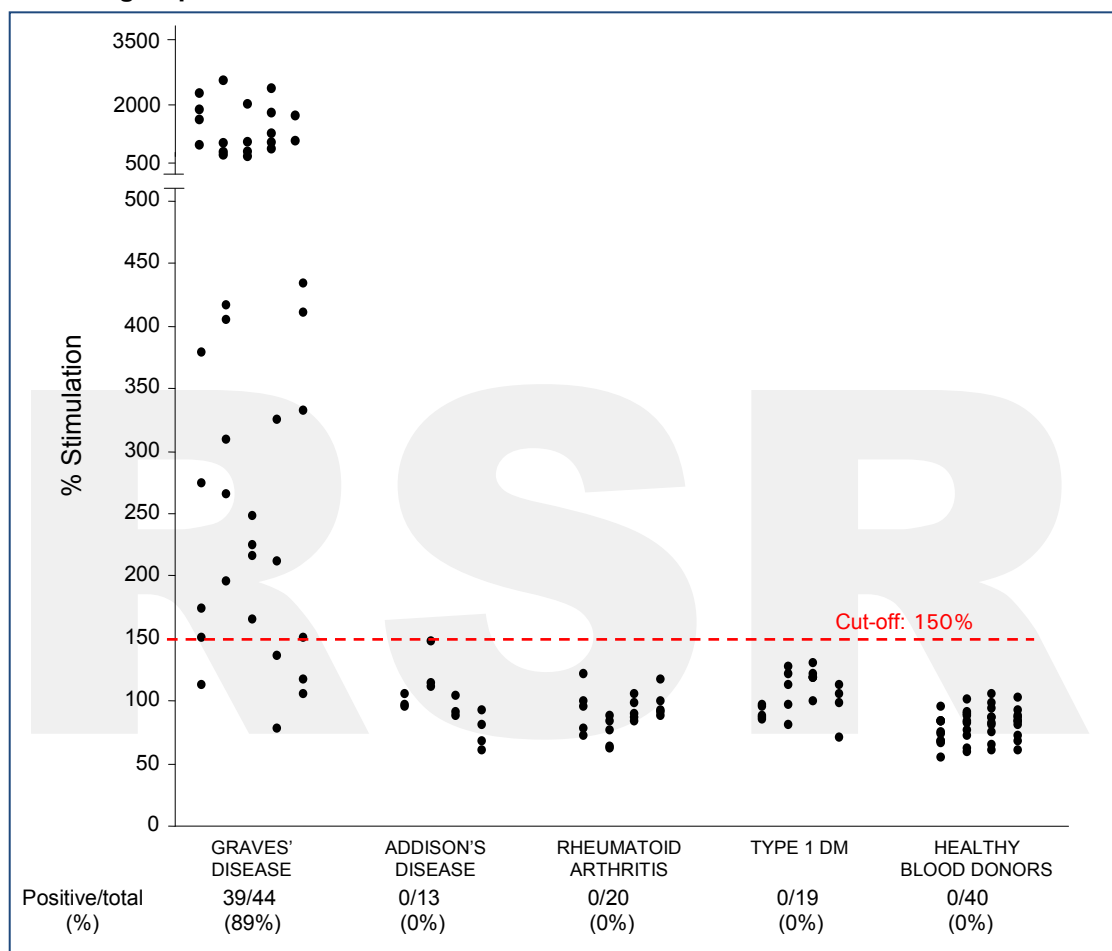
RSR Limited

Diagnostics for Autoimmunity

Parc Ty Glas, Llanishen, Cardiff, CF14 5DU United Kingdom
<http://www.rsrltd.com> E-mail: info@rsrltd.com

Tel: +44 (0) 29 2068 9299
Fax: +44 (0) 29 2075 7770

Measurements in different groups:



Samples from Graves' disease patients (n = 44), healthy blood donors (n = 40), Addison's disease patients (n = 13), rheumatoid arthritis patients (n = 20) and type 1 diabetes mellitus patients (n = 19) were tested for TSAb using BioassayRSR™ TSAb.

RESULTS:

39/44 (89%) patients positive for TRAb tested by ElisaRSR™ TRAb 3rd Generation and/or RiaRSR™ TRAb CT were positive for TSAb.

All 40 (100%) healthy controls were identified as being negative for TSAb.

None of the Addison's disease patients (n = 13, positive for 21-OH Ab by RiaRSR™ 21-OH Ab), rheumatoid arthritis patients (n = 20, positive for rheumatoid factor) or the type 1 diabetes mellitus patients (n = 19, positive for GADAb by ElisaRSR™ GADAb) were positive for TSAb.

Other information

Significance: Thyroid stimulating autoantibodies are the cause of hyperthyroidism in Graves' disease.

This assay service is intended for research use only. Result obtained to be used by professional persons only. The data quoted is for guidance only.

Address samples to:

Assay Service Department, FIRS Laboratories, RSR Ltd
Parc Ty Glas, Llanishen, Cardiff, CF14 5DU United Kingdom

Tel: +44 (0) 29 2076 5550
E-mail: firs-assay@firs-rsr.co.uk

RSR Limited

Diagnostics for Autoimmunity

Parc Ty Glas, Llanishen, Cardiff, CF14 5DU United Kingdom
http://www.rsrltd.com E-mail: info@rsrltd.com

Tel: +44 (0) 29 2068 9299
Fax: +44 (0) 29 2075 7770

©RSR Limited All Rights Reserved

16/02/2026 AS/TSA Rev 2

Page 4 of 4