

# AUTO-IMMUNITY PART 1

Ordering information	Description	Article code	Kitsize
	DIAsource Auto-Immunity RIA assays (Part 1)		
	Anti-AChR (Anti-AcetylCholine Receptor)	KIPIB21021	100 tests
	AIA (Anti-Insulin Antibodies)	KIP0091	100 tests
	dsDNA-Ab (anti-ds DNA antibodies)	KIPIB19011	100 tests
	Tg-Ab* (Thyroglobulin AutoAntibodies)	RVR-CI-100	100 tests
	TPO-Ab* (Anti-Thyropoxidase AutoAntibodies)	RVR-CO-100	100 tests
	TSH-R Ab* (TSH Receptors Autoantibodies)	RVR-CT-100	100 tests
DIAsource Auto-Immunity ELISA assays (Part 1)			
TSH-R Ab – 3rd generation (TSH Receptors Autoantibodies)	KAPD4834	96 tests	

\*Not distributed in Belgium, Luxemburg and Germany

### MAIN FEATURES:

- Good analytical performances
- Excellent clinical specificity and sensitivity
- Highly sensitive assays



For more information: visit [www.diasource-diagnostics.com](http://www.diasource-diagnostics.com)

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Distributed by:

Anti-AcetylCholine Receptor  
 Anti-Insulin Antibodies  
 Thyroglobulin AutoAntibodies  
 Anti-Thyropoxidase AutoAntibodies

## ACETYLCHOLINE RECEPTOR (AChR)

Myasthenia gravis (MG) is a skeletal muscle disorder characterized by muscular weakness. In such cases, muscular weakness is due to anti-acetylcholine receptor (AChR) antibodies. Anti-AChR antibodies are present in approximately 90% of patients with MG. The results of thirty-eight MG-positive and fifteen samples negative for MG were used to study clinical sensitivity and specificity. The equivocal results were considered as positive.

	MG +	Equivocal	MG-	Total
DIAsource Positive	37	0	0	37
DIAsource Equivocal	2	0	0	2
DIAsource Negative	0	2	12	12
	39	2	12	53

Positive agreement = 95.1% (39/41) with 95% CI: 83.5% to 99.4%;

Negative agreement = 100% (12/12) with 95% CI: 73.5% to 100%.

## ANTI INSULIN ANTIBODIES (AIA)

The presence of circulating anti-insulin antibodies (AIA) in diabetics treated with insulin has been recognized as early as 1955. The highly purified insulin preparations, recently available, are less immunogenic than some of the previously used, less pure, preparations. Bovine insulin is more immunogenic than the porcine hormone. Also, it has recently been recognized that AIA may develop, in patients treated with human insulin. The determination of circulating anti-insulin antibodies is of clinical importance for the following reasons:

- The presence of free anti-insulin antibodies in plasma interferes with the determination of insulin by immunoassays.
- At very high titers, the anti-insulin antibodies may induce a state of insulin resistance.
- Anti-insulin antibodies may influence the quality of the glycemic control, in diabetic patients, by prolonging the half-life of insulin.

## THYROGLOBULIN AUTOANTIBODIES (TgAb) / ANTI-THYROPEROXIDASE AUTOANTIBODIES (TPO-Ab)

Thyroid autoimmunity is more frequently registered in women. Antibody prevalence in women increases with age, rising from approximately 10% at the age of 18-24 up to 30% at the age of 55-65 for TgAb and from 15% at the age of 18-24 up to 24% at the age of 55-65 for TMAb.

## TSH RECEPTORS AUTOANTIBODIES (TSH-R Ab)

Hyperthyroidism in Graves' disease is due to auto-antibodies directed against the thyrotropin (TSH) receptor and measurement of these auto-antibodies is valuable in the diagnosis and management of the Graves' disease.

### DIASOURCE TSH-R AB CLINICAL PERFORMANCES:

Clinical Specificity: 139 samples from healthy blood donors were assayed in the 3rd generation TRAb ELISA kit. All 139 (100 %) were found to be negative for TSHR autoantibodies.

Clinical Sensitivity: 108 samples from patients with Graves' disease (treated and untreated patients) were assayed 103 (95%) were identified as being positive for TSHR autoantibodies.

Detection Limit: The kit negative control was assayed 50 times and the mean and standard deviation calculated. The lower detection limit at 2 standard deviations was 0.08 U/L.

### dsDNA-Ab RIA

The presence of antibodies to double-stranded DNA (dsDNA, native DNA) in serum is highly characteristic for patients with SLE. It is important to quantitate the amount of antibody to dsDNA in order to differentiate between SLE and closely related auto-immune diseases. Antibodies to dsDNA show a good correlation to the disease activity.

## ASSAY CHARACTERISTICS

Anti-AChR Anti-Acetyl Choline Receptor	AIA Anti-Insulin Antibodies	dsDNA-Ab RIA	Tg-Ab Thyroglobulin AutoAntibodies	TPO-Ab Anti- Thyroperoxidase AutoAntibodies	TSH-R Ab TSH Receptors Autoantibodies	
Clinical Use						
Myasthenia gravis	Follow-up of Insulin Therapy Insulin Resistance status	Systemic lupus erythematosus (SLE or Lupus)	Thyroid autoimmunity	Thyroid autoimmunity	Hyperthyroidism in Graves' disease	
Method						
RIA	RIA	RIA	*RIA	*RIA	*RIA	ELISA
Incubation Time (min)						
120+ 30 + 15 + 15	120 + 15 + 15	60 + 15	90	90	150	120 + 25 + 20 + 30
Sample Type						
Serum, Plasma	Serum, Plasma	Serum	Serum	Serum	Serum	Serum
Sample Size						
20 µL	100 µL	25 µl	20 µL	20 µL	50 µL	75 µL
Standard Range						
0,2 - 8,0 nmol/L	-	3 - 80 IU/ml	20-2000 IU/mL	20-3000 IU/mL	5-405 U/L	0,4-30 U/L
Detection Limit						
0,01 nmol/L	0,043 ng/mL	2.5 IU/ml	0,082 ng/mL	0,044 µg/mL	0,8 U/L	0,08 U/L
Reference Intervals						
Serum: 0,029 nmol/L	< 8,2 %	Apparently healthy subjects show the following values: < 7 IU/mL	< 30 IU/mL Negative	< 60 IU/mL Negative	< 9 U/mL Negative	< 0,4 U/L Negative
Plasma: 0,023 nmol/L			Between 30 - 70 IU/mL Borderline	Between 60 - 80 IU/mL Borderline	Between 9 - 14 U/mL Borderline	> 0,4 U/L Positive
			> 70 IU/mL Positive	> 80 IU/mL Positive	> 14 U/mL Positive	
Controls						
2 levels	3 levels	2 levels	2 levels	2 levels	2 levels	2 levels
Shelf Life						
7 weeks	8 weeks	10 weeks	8 weeks	8 weeks	7 weeks	48 weeks

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