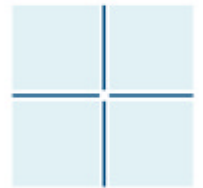
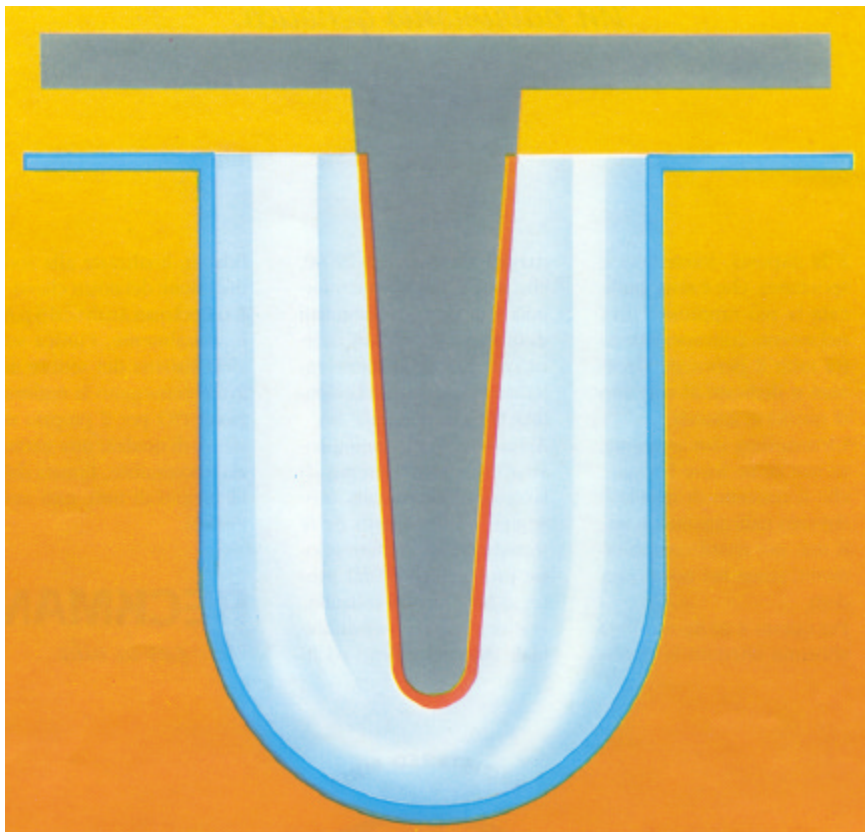
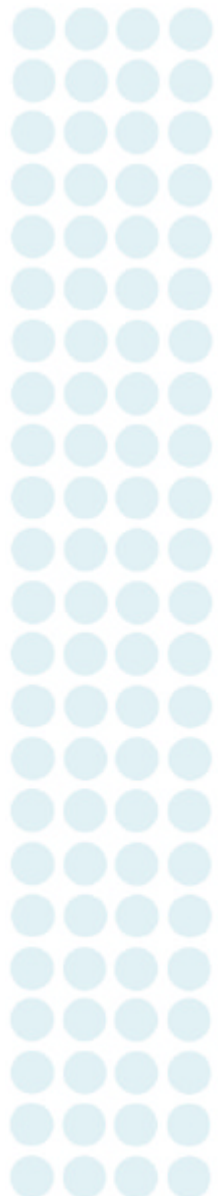


MELISA™ TAB

MICROPIN ENZYME-LINKED
IMMUNOSORBENT ASSAYS FOR
THYROID ANTIBODIES



CAMBRIDGE
— LIFE —
SCIENCES

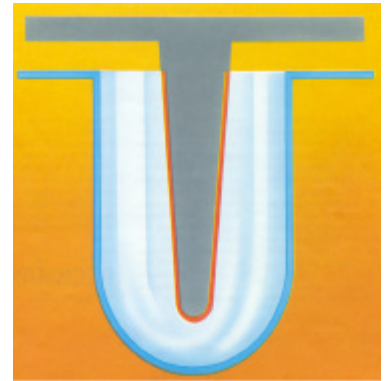


MELISA™

(Micropin Enzyme-Linked Immunosorbent Assay)

In contrast with conventional ELISA technology in which the immunological reaction takes place on the surface of microwells, MELISA™ uses a transferable solid phase system - micropins.

All reaction steps are performed in separate microwells. The immunological reactions and the enzyme substrate reaction occur on the surface of the MELISA™ pins. Thus, incubations are simultaneous and, as a result, there is no possibility of assay 'drift'.



The technology offers the following advantages:

- short incubation times
- simultaneous incubations - no assay drift
- simple washing - no extra equipment required
- colour-coded reagents
- liquid ready-to-use reagents
- long shelf-life

Major Benefits

● **Reliable and Precise**

Stringent quality controlled manufacturing ensures that the performance and the integrity of the kit is maintained throughout a long shelf-life. The MELISA™ micropin technology ensures that each individual sample is treated in the same way, reducing assay drift. This gives consistent reproducibility and precision for better monitoring. Results can be used with confidence.

● **Specific and Sensitive**

Employs high quality purified antigen to ensure a high degree of specificity and provide confidence in diagnosis. This, coupled with high sensitivity and low minimum detectable concentrations, make these assays ideal and vital for patient monitoring.

● **Rapid and Easy to Use**

Assays are rapid with short incubation times saving valuable time. Simple instructions coupled with colour-coded and ready-to-use reagents make this an ideal assay.

● **Safe and Effective**

Non-isotopic detection makes it safe from the inherent hazards associated with handling radioisotopes. Availability of a range of assays makes it effective and suitable for volume screening and patient monitoring.

MELISA™ - Thyroid Antibody (TAB) Determination

● Weight loss, proptosis, enlarged thyroid - is this autoimmune thyroid disease?

In thyroid diseases, such as Hashimoto's thyroiditis and Graves' disease, the most common underlying factor is an autoimmune response to components of the thyroid gland. Women show an increased prevalence to such conditions, as do patients who have a previous history of autoimmunity.

Graves' disease patients show clinical symptoms of weight loss, anxiety, proptosis and tremor. These are distinct from the lethargy and dry skin/hair symptoms shown by patients suffering from Hashimoto's disease, although in both conditions an enlarged thyroid gland is seen. Early detection can reverse the symptoms.

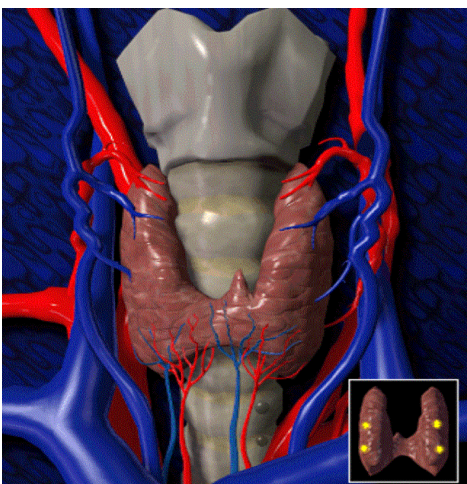
Of all the autoimmune conditions, Graves' disease and Hashimoto's thyroiditis are perhaps the easiest to treat, provided that they are detected at an early stage. This requires sensitive detection of antibodies to thyroglobulin (Tg) and to thyroid peroxidase (TPO), together with the ability to monitor the antibody response to drugs, radiotherapy or surgery. TPO has been identified as the specific antigenic determinant of the thyroid microsomal antigen. Both Tg and TPO thyroid components play key roles in the biosynthesis of thyroid hormones.

● Why are the MELISA™ TAB assays so effective?

Current assays for the detection of thyroid antibodies, including partial haemagglutination and radioimmunoassay, have a number of drawbacks. Although agglutination methods are simple and rapid to perform they suffer from low sensitivity, poor specificity and frequently require subjective reading of the results. In addition, as results are given as a titre, accurate quantitation is not possible. Radioimmunoassay methods obviously suffer from inherent hazards associated with handling radioisotopes.

MELISA™ TAB, based on the sandwich ELISA principle, offers significant advantages over traditional agglutination and radioimmunoassays:

- a range of assays for quantification of anti-Tg and anti-TPO antibodies
- calibrated to international reference standards
- no cross-reaction with other auto-antibodies
- combination kits for the simultaneous detection of anti-Tg and anti-TPO



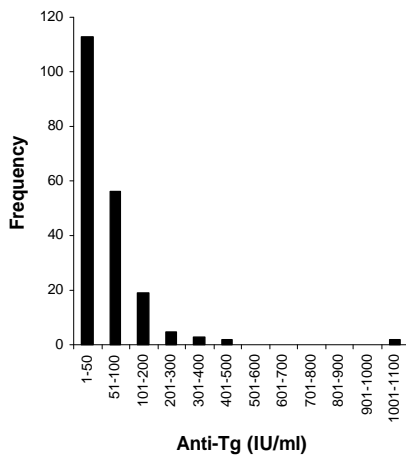
The assay system employs ready-to-use, colour-coded reagents resulting in less 'hands on' time. In addition, the TPO employed is a human recombinant antigen raised in Chinese hamster ovary cells. The Tg is an affinity-purified antigen derived from human thyroid. Results can, therefore, be reported with confidence.

Technical Information

Anti-Tg (Code: M2196)

Reference Range

Normal range < 164.3 IU/mL
 Borderline 164.3 - 217.6 IU/mL
 Positive > 217.6 IU/mL



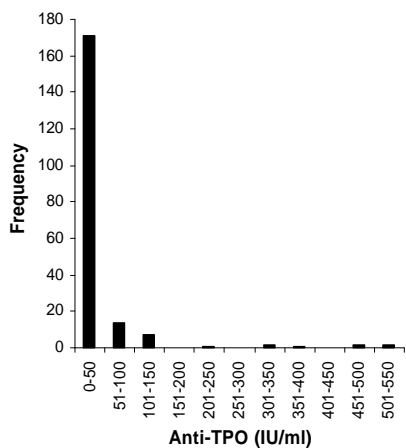
Precision

Intra-assay (n=20)	
Mean (IU/mL)	CV %
101.0	6.0
699.5	6.1
Inter-assay (n=10)	
Mean (IU/mL)	CV %
113.3	8.6
667.4	11.9

Anti-TPO (Code: M2396)

Reference Range

Normal range < 72.5 IU/mL
 Borderline 172.5 - 97.6 IU/mL
 Positive > 97.6 IU/mL



Precision

Intra-assay (n=20)	
Mean (IU/mL)	CV %
32.0	8.0
239.9	9.0
Inter-assay (n=10)	
Mean (IU/mL)	CV %
38.7	8.6
225.8	6.5

Product Range

Description Code

MELISA™ TAB anti-Tg	M2196
MELISA™ TAB anti-TPO	M2396
MELISA™ TAB Combination anti-Tg/TPO	M2496

Test Procedure

↓ ↓
100 µL standard

U Dilute sample
1/200

Add pins
↓ ↓ incubate for
10 minutes

Wash Pins

100 µL conjugate
Add pins
↓ ↓ incubate for
10 minutes

Wash Pins

200 µL substrate
Add pins
↓ ↓ incubate for
10 minutes
Remove Pins

Add 100 µL
stop solution
↓ ↓ Measure at
absorbance
450nm