

# Thyroperoxidase Ab (TPOAb)

General Chemistry

**Immunodiagnosics**

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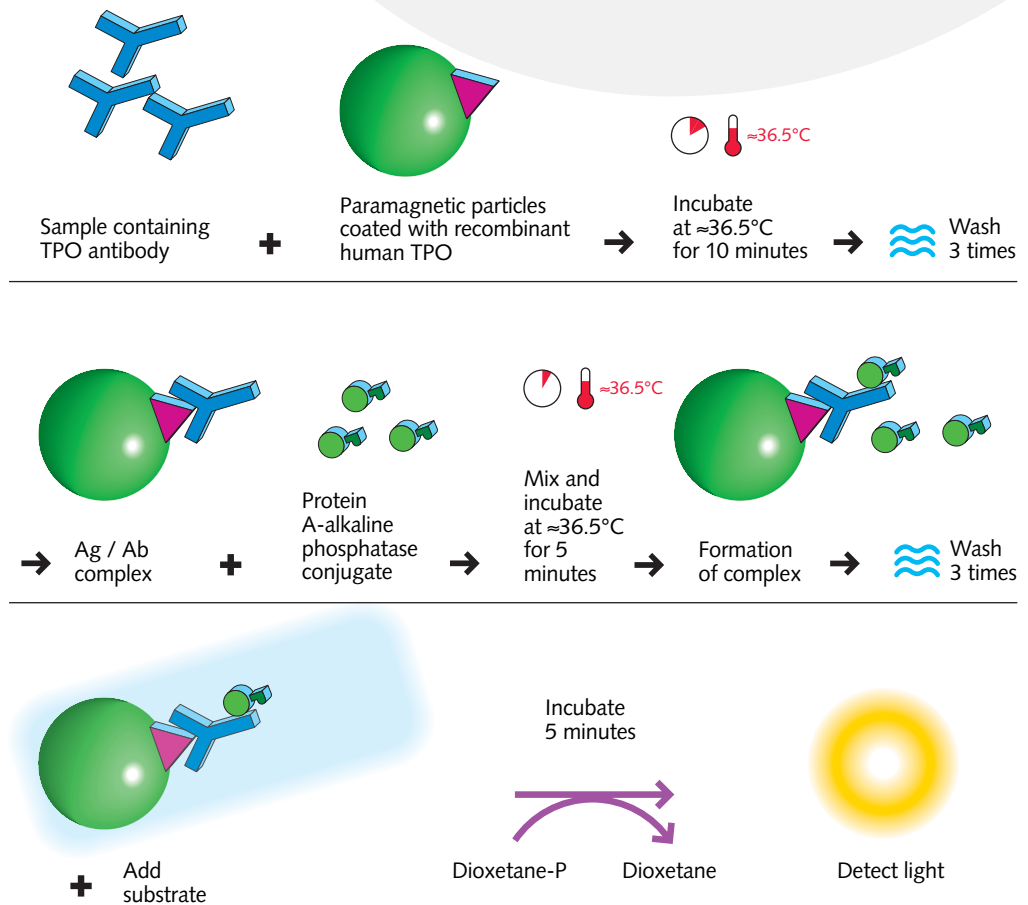
Primary Care



## Thyroid

- Quantitative method aids in the diagnosis of autoimmune thyroid disease in human serum or plasma
- Utilizes recombinant human TPO to eliminate contamination from other thyroid antigens
- Standardized to WHO 66/387 international standard
- Reference interval established following NACB guidelines
- Small sample size (10  $\mu$ L)
- Broad dynamic range: 0.25 – 1000 IU/mL

2-step sandwich technique



Signal produced is proportional to the thyropoxidase antibody concentration in the sample.



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# TPOAb

## Methods Comparison: Agreement

A total of 320 routine, clinical samples were evaluated with the DPC Immulite 2000\* Anti-TPO Ab assay and then tested on the Access® TPOAb assay.

		Immulite 2000 Anti-TPO Antibody				
		Pos	Neg	Total		95% Confidence Interval
Access TPOAb Assay	Pos	96	15	111	Positive % Agreement = 99.0%	94.4 – 100%
	Neg	1	208	209	Negative % Agreement = 93.3%	89.1 – 96.2%
	Total	97	223	320	% Agreement = 95.0%	

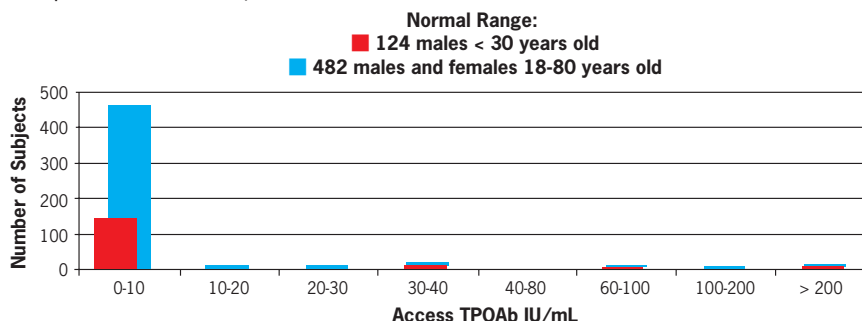
Discrepant analysis was performed using the Nichols Advantage\* Anti-TPO Antibody assay. Fourteen of the sixteen discrepant samples were resolved in favor of the Access TPOAb assay, demonstrating its ability to deliver highly accurate results.

## Expected Values

Guideline 33, "Reference Intervals for Thyroid Antibody Tests," from the National Academy of Clinical Biochemistry (NACB), was followed to establish the expected value for the Access TPOAb assay.

Researchers obtained sera samples from 166 males in the U.S. < 30 years of age. Screening criteria included serum TSH levels between 0.5 and 2.0 mIU/L as well as absence of goiter, personal or family history of thyroid disease, and absence of non-thyroid autoimmune disease. After screening, 124 samples were tested generating a 95% non-parametric upper reference limit below 9 IU/mL.

Additionally, 679 normal samples were collected from males and females in the U.S. ranging in age from 18–80 years old, with the same screening criteria. After screening, 492 samples were tested; 93% of these samples fell below 9 IU/mL.



## Characteristics

Sample Type/Size	Serum or plasma (EDTA and Lithium Heparin), 10 µL
Time to First Result	Approximately 30 minutes
Analytical Sensitivity	0.25 IU/mL
Calibrator Levels	Approximately 0, 5, 20, 75, 300, 1000 IU/mL
Reference Range	< 9 IU/mL
Open Pack Stability	56 days
Calibration Stability	56 days
Precision	< 12% at concentrations ≥ 0.6 IU/mL

## Ordering Information

Access® TPOAb - 2 packs of 50 tests/pack	A12985
Access® TPOAb calibrators 6 vials, 2.0 mL/vial	A18227
Access® Sample Diluent A - 1 vial of 4.0 mL	81908

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