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Diagnostic Products Corporation
IMMULITE Anti-TPO Ab
November 8, 1996

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510 (k) Summary
Safety and Effectiveness

This summary of safety and effectiveness information has been prepared in accordance with the requirements of SMDA 1990 and 21 CFR Part 807.92.

Name: **Address:**	Diagnostic Products Corporation 5700 West 96th Street Los Angeles, California 90045-5597
Telephone Number: **Facsimile Number:**	(213) 776-0180 (213) 776-0204
Contact Person:	Edward M. Levine, Ph.D. Director of Clinical Affairs
Date of Preparation:	November 8, 1996
Device Name: **Trade:**	IMMULITE® Anti-TPO Ab Reagent system for the determination of TPO Antibodies in serum and EDTA plasma.
Catalog Number:	LKTOZ (50 tests), LKTO1 (100 tests), LKTO5 (500 tests)
Classification:	Class II device, 82-JZO (21CFR 866.5870)
Manufacturer:	EURO/DPC Ltd. (Manufacturing under a Quality System- ISO 9002/EN29002/BS 5750)
Sole U.S. Importer:	Diagnostic Products Corporation 5700 West 96th Street Los Angeles, California 90045-5597
Establishment Registration Number:	EURO/DPC: Not Applicable DPC: 2017183
Substantially Equivalent Predicate Device:	ORGenTec anti-TPO PIN Immuno Assay (K950090) Manufactured by ORGenTec, and distributed in the USA by ALPCO, Windham, NH
Description of Device:	IMMULITE Anti-TPO Ab is a clinical device for use with the IMMULITE Automated Immunoassay Analyzer.

Intended Use of the Device:

IMMULITE Anti-TPO Ab is a solid-phase, enzyme chemiluminescent immunoassay for use with the IMMULITE Automated Analyzer and designed for the quantitative measurement of antibodies against thyroid peroxidase (TPO) in serum and EDTA plasma. It is intended strictly for *in vitro* diagnostic use as an aid in the clinical diagnosis of thyroid diseases.

Performance Equivalence:

Diagnostic Products Corporation (DPC) asserts that the IMMULITE Anti-TPO Ab produces substantially equivalent results to other commercially marketed Anti-TPO assays, such as the ORGenTec anti-TPO PIN Immuno Assay. Each product is intended strictly for *in vitro* diagnostic use to aid in the clinical diagnosis of thyroid diseases.

Technological Comparison to Predicate:

IMMULITE Anti-TPO Ab is a solid-phase, chemiluminescent enzyme immunoassay. The solid-phase, a polystyrene bead enclosed within an IMMULITE Test Unit, is coated with highly purified TPO.

The prediluted patient sample and a buffer matrix are simultaneously introduced into the Test Unit, and incubated for 30 minutes at 37° C with intermittent agitation. During this time anti-TPO antibodies in the sample bind to the TPO-coated bead. The serum/buffer mixture is then removed by a centrifugal wash.

An alkaline phosphatase-labeled anti-human-IgG antibody is introduced, and the Test Unit is incubated for another 30-minute cycle. The unbound enzyme conjugate is removed by a centrifugal wash. Substrate is then added, and the Test Unit is incubated for a further 10 minutes.

The chemiluminescent substrate, a phosphate ester of adamantyl dioxetane, undergoes hydrolysis in the presence of alkaline phosphatase to yield an unstable intermediate. The continuous production of this intermediate results in the sustained emission of light, thus improving precision by providing a window for multiple readings. The bound enzyme conjugate-and thus also the photon output, as measured by the luminometer- is proportional to the concentration of anti-TPO antibodies in the sample.

Technological Comparison to Predicate (continued):

The ORGenTec anti-TPO PIN Immuno Assay is an indirect solid phase enzyme immunometric assay (ELISA) based on coated micropins corresponding to a microplate format. Designed for the quantitative measurement of IgG class autoantibodies directed against human thyroid peroxidase, called microsomal antigen. The Pin assay employs a unique antigen coated micropin technology. Coated PinStrips act as the transferable solid phase. Seven pre-scored breaking lines allow strips to be used in a 2, 4, 6, 8, or 10 row strip assay, while a complete plate provides for 96 determinations. The assay takes place in three reaction phases:

Phase 1: Standards, controls and patient samples are pipetted into the wells of the first microplate. Micropins, coated with highly purified antigen, are immersed into the samples allowing any antibody present to bind to the pin surface. After a 10 minute incubation, the pins are removed, non-reactive components are washed away by dipping the pins into wash buffer.

Phase 2: The pins are then immersed into a second microplate containing enzyme conjugate, which recognizes the autoantibodies bound to the immobilized antigens. Any conjugate not specifically bound, is washed away after a 10 minute incubation.

Phase 3: The pins are then immersed into the wells of a third microplate containing chromogenic substrate solution of OPD which changes from colorless to yellow during a 5 minute incubation. Color development is stopped by dispensing 3M sulfuric acid. The amount of color is directly proportional to the concentration of IgG present in the original sample. Optical density is read with a microplate reader at 490 nm. Bichromatic measurement is recommended with a 650 nm reference.

Method Comparison:

The IMMULITE Anti-TPO Ab procedure was compared to the ORGenTec anti-TPO PIN Immuno Assay on 94 patient samples yielding an agreement of 97.8% and a relative sensitivity and specificity of 100% and 95.6%, respectively.

Conclusion:

The data presented in this summary of safety and effectiveness is the data that the Food and Drug Administration used in granting DPC substantial equivalence for IMMULITE Anti-TPO Ab.

Edward M. Levine

11/8/96

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Date