

Diagnostic Products Corporation
5700 West 96th Street
Los Angeles, CA 90045-5597
Tel: (213) 776-0180
Fax: (213) 776-0204

K962936

APR 24 1997

**510(k) Summary
Safety and Effectiveness**



This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR Part 807.92.

Name: Diagnostic Products Corporation
Address: 5700 West 96th Street
Los Angeles, California 90045-5597

Telephone Number: (213) 776-0180
Facsimile Number: (213) 776-0280

Contact Person: Edward M. Levine, Ph.D.
Manager of Clinical Affairs

Date of Preparation: July 25, 1996

Device Name:
Proprietary Name: IMMULITE® Toxoplasma Quantitative IgG
Catalog Number: LKTXQ1 (100 tests); LKTXQ5 (500 tests)
Common: Reagent system for the determination of *Toxoplasma gondii* IgG antibodies in human serum.

Classification: Class II device (866.3780)

Manufacturer: Diagnostic Products Corporation
5700 West 96th Street
Los Angeles, California 90045-5597

Establishment Registration #: DPC's Registration # is 2017183

Substantially Equivalent Predicate Device: bioMérieux Vitek VIDAS® Toxo IgG
Abbott Laboratories IMx® Toxo IgG

Description of Device: IMMULITE Toxoplasma Quantitative IgG is a clinical device for use with the IMMULITE Automated Immunoassay Analyzer.

Intended Use of the Device: IMMULITE Toxoplasma Quantitative IgG is designed for the *quantitative* detection of IgG antibodies to *Toxoplasma gondii* in human serum and is intended strictly for *in vitro* diagnostic use as an aid in the determination of serological status to *Toxoplasma gondii*.

Summary and Explanation of the Device:

IMMULITE® Toxoplasma Quantitative IgG is a solid-phase, two-step, chemiluminescent enzyme immunoassay. The solid phase, a polystyrene bead enclosed within an IMMULITE® Test Unit, is coated with a partially purified *Toxoplasma gondii* antigen, strain RH.

Prediluted patient sample (1-in-21 dilution) and a protein-based buffer are simultaneously introduced into the Test Unit, and incubated for approximately 30 minutes at 37°C with intermittent



Summary and Explanation of the Device (continued):

agitation. During this time, toxoplasma IgG in the sample binds to the toxoplasma antigen-coated bead. Unbound serum 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 an additional 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 complex - and thus the photon output, as measured by the luminometer - is directly related to the quantity of toxoplasma IgG in the sample. A quantitative result in IU/mL is then obtained by comparing the patient result to a stored Master Curve, and which is adjusted to the response of each analyzer.

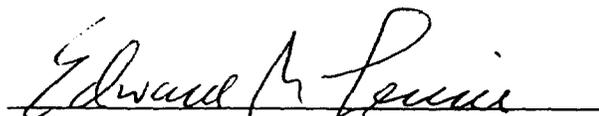
Summary of Studies:

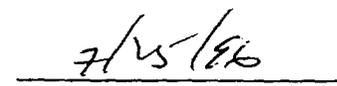
The clinical performance of the IMMULITE Toxoplasma IgG procedure was compared to the VIDAS® and IMx® Toxoplasma IgG assays, using a total of 199 serum specimens. A summary of the results is shown in the table below.

	IMMULITE vs. VIDAS®	IMMULITE vs. IMx®
Agreement	99.0%	96.4%
Sensitivity	96.3%	90.2%
Specificity	100.0%	98.6%
n=	199	194

Conclusion:

The conclusions drawn from the clinical and nonclinical studies demonstrate that the device is safe, effective, and performs as well as, or better, than the current legally marketed devices.


Edward M. Levine, Ph.D.
Manager of Clinical Affairs


Date