Diagnostic Products Corporation
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K950670

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DPC®

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
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Telephone Number:	(213) 776-0180
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Contact Person:	Edward M. Levine, Ph.D.
Date of Preparation:	March 28, 1996
Device Name:	
Trade:	IMMULITE Herpes I & II IgG
Catalog Number:	LKHSZ (50 tests); LKHS2 (200 tests)
Common:	Reagent system for the determination of Herpes I & II IgG antibodies in human serum.
Classification:	Class III device (866.3305)
Manufacturer:	EURO/DPC, a wholly-owned subsidiary of Diagnostic Products Corporation. (Manufacturing under a Quality System - ISO 9001/EN29001/BS 5750/part 1)
Establishment Registration #:	EURO/DPC: Not Applicable DPC: 2017183
Substantially Equivalent Predicate Device:	BioWhittaker HSV ELISA II IgG (K822883)
Description of Device:	IMMULITE Herpes I & II IgG is a clinical device for use with the IMMULITE Automated Immunoassay Analyzer
Intended Use of the Device:	IMMULITE Herpes I & II IgG is designed for the qualitative detection of IgG antibodies to herpes simplex virus (HSV) type I & II in human serum. It is intended strictly for *in vitro* diagnostic use as an aid in the determination of serological status to HSV I & II.

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Summary and Explanation of the Test:

Herpes simplex virus (HSV) is an ancient and ubiquitous virus, known to cause acute and recurrent infections in humans. The virus enters the mucous membranes (ocular, genital, or oral) and replicates locally and may enter the sensory root ganglion, resulting in latent, recurrent infections. Infection of neonates during passage through the birth canal may result in neurological damage and death.

In the 1960s it was recognized that HSV consisted of two distinct types, HSV-I and HSV-II. HSV-I is considered to be primarily associated with ocular and oral infection, while HSV-II is considered to be a genital infection. However, HSV types I and II share several common antigens, and the use of specific monoclonal antibodies or restriction endonuclease mapping is required to type individual strains.

Infections with HSV type I or type II can differ in their clinical manifestations and severity. The immune response of the host can play an important role in controlling the severity of primary or reactivated infections. Those at highest risk for severe infections are neonates, who are infected during delivery, and immunocompromised patients.

While isolation of the virus in tissue culture is recommended for the diagnosis of active infections, serological testing can provide valuable information in the management of at-risk populations, such as pregnant women.

Summary and Explanation of the Device:

IMMULITE® Herpes I & II 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 HSV I and II viral antigen.

- Prediluted patient sample (1-in-21 dilution: 1 part in a total of 21 parts) and a protein-based buffer are simultaneously introduced into the Test Unit, and incubated for approximately 30 minutes at 37°C with intermittent agitation. During this time, Herpes I and II IgG in the sample binds to the HSV I and II 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 a further 10 minutes.

The chemiluminescent substrate, PPD (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 a sustained emission of light, thus improving precision by providing a window for multiple readings. The bound complex - and thus also the photon output, as measured by the luminometer - is related to the presence of HSV I and II IgG in the sample. A qualitative result is then obtained by comparing the patient result to an established Cutoff.

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Performance Equivalence - Technology Comparison:

Diagnostic Products Corporation (DPC) asserts that **IMMULITE® Herpes I & II IgG** is substantially equivalent to the **HSV ELISA II IgG** kit marketed by BioWhittaker Inc.*(Walkersville, MD)*.

Each product is designed for the detection of IgG antibodies to HSV I & II virus in human serum. Each product is intended strictly for *in vitro* diagnostic use as an aid in the determination of serological status to HSV I & II.

IMMULITE® Herpes I & II IgG is a chemiluminescent enzyme immunoassay and the HSV ELISA II IgG test is an enzyme-linked immunosorbent assay (ELISA). The technology in DPC's IMMULITE® Herpes I & II IgG is identical to technology used in previously cleared and commercially marketed IMMULITE® products.

In the BioWhittaker HSV ELISA II IgG assay, partially purified herpes antigen is attached to the surface of microplate wells. Diluted patient serum is added to the wells, and the herpes specific antibody, if present, binds to the antigen. All unbound antibody is washed away and enzyme-conjugated anti-human IgG is added. The enzyme conjugate binds to the antibody-antigen complex. Excess enzyme conjugate is washed away and substrate is added. Bound enzyme conjugate begins a hydrolytic reaction. After a specified time, the enzyme reaction is stopped. The intensity of the color generated is proportional to the amount of herpes IgG specific antibody in the sample. The results are read by a spectrophotometer, producing an indirect measurement of the herpes IgG specific antibody in the serum.

Performance Equivalence - Method Comparison:

The clinical performance of the IMMULITE Herpes I & II IgG assay was studied at Diagnostic Products Corporation (DPC) using a CMV/HSV proficiency panel obtained from the United States Centers for Disease Control and Prevention (CDC).

The in-house (DPC) retrospective study was conducted by assaying the CDC serum panel with the IMMULITE Herpes I & II IgG assay and sending the results to the CDC for unmasking. The results are presented as a means to convey further information on the performance of this assay with a masked, characterized serum panel. This does not imply an endorsement of the assay by the CDC.

The panel consisted of 72% positive and 28% negative samples. IMMULITE Herpes I & II IgG demonstrated 97% total agreement with the CDC results. Of the results obtained by IMMULITE, there was 99% agreement with the positive specimens and 93% agreement with the negative results.

Studies on the clinical performance of the IMMULITE Herpes I & II IgG assay and the BioWhittaker HSV ELISA II IgG assay were also conducted nonconcurrently at two independent sites. A summary of the results is shown in the table below.

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Performance Equivalence - Method Comparison ***(continued)*****:**

	IMMULITE vs. BioWhittaker (Site 1)	IMMULITE vs. BioWhittaker (Site 2)
Agreement	99.0%	96.0%
Relative Sensitivity	100.0%	96.2%
Relative Specificity	96.6%	94.9%
n =	200	202

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

4/3/96

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

Date