K950672

JUN 17 1996

Attachment 9

# 510 (k) Summary

# Safety and Effectiveness

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# 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<br>Los Angeles, California 90045 |
| **Telephone Number:** | (213) 776-0180 |
| **Contact Person:** | Kenneth B. Asarch, Pharm.D., Ph.D. |
| **Date of Preparation:** | February 10, 1995 |
| **Device Name:** | |
| **Trade:** | IMMULITE® CMV IgG |
| **Catalog Number:** | LKCVZ (50 tests); LKCV2 (200 tests) |
| **Common:** | Reagent system for the determination of cytomegalovirus IgG antibodies in human serum. |
| **Classification:** | Class II device (866.3175) |
| **Manufacturer:** | Diagnostic Products Corporation<br>5700 West 96th Street<br>Los Angeles, California 90045 |
| **Establishment Registration #:** | DPC's Registration # is 2017183 |
| **Substantially Equivalent Predicate Device:** | BioWhittaker CYTOMEGELISA II IgG<br>Abbott Laboratories' IMx® CMV IgG |
| **Description of Device:** | IMMULITE CMV IgG is a clinical device for use with the IMMULITE Automated Immunoassay Analyzer. |
| **Intended Use of the Device:** | IMMULITE CMV IgG is designed for the qualitative detection of IgG antibodies to cytomegalovirus (CMV) in human serum. It is intended strictly for *in vitro* diagnostic use as an aid in the determination of serological status to CMV |

## Summary and Explanation of the Test:

Cytomegalovirus (CMV), a member of the Herpesvirus group is found throughout the world. Humans of all ages are susceptible and infection is spread through sexual contact, direct exposure to infected body fluids, blood transfusions and organ transplants. Infection can be severe in patients with congenital or acquired cellular immune defects, including cancer patients, organ recipients and AIDS patients. The majority of infections are asymptomatic, however, CMV infections can be severe in neonates and immunocompromised individuals.

CMV is the most common congenital infection, infecting between 0.5 and 2.5 percent of newborn infants. Five percent of these will develop classic cyromegalic inclusion disease with jaundice, pneumonia and central nervous system disorder. Infected infants may be asymptomatic at birth, but can develop neurological problems later in life.

Between 40 and 100 percent of people have detectable antibody, with the prevalance highest in developing countries. Serological screening of blood used for transfusion cna limit the transmission of infection. In addition, transplantation of organs from donors seronegative for CMV antibodies appears to limit the incidence of acute infection in the recipient.

## Summary and Explanation of the Device:

**IMMULITE® CMV 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 CMV antigen.

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 agitation. During this time, CMV IgG in the sample binds to the CMV 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 reading. The bound complex - and thus the photon output, as measured by the luminometer - is directly related to the presence of CMV IgG in the sample. A qualitative result is then obtained by comparing the patient result to a stored Master Cutoff.

## Performance Equivalence - Technology Comparison:

Diagnostic Products Corporation (DPC) asserts that **IMMULITE® CMV IgG** is substantially equivalent to the **CYTOMEGELISA II IgG** kit marketed by BioWhittaker Inc. *(Walkersville, MD)*, and the **IMx® CMV IgG** kit marketed by Abbott Laboratories *(Abbott Park, IL)*.

Each product is designed for the detection of IgG antibodies to cytomegalovirus (CMV) in human serum. Each product is intended strictly for *in vitro* diagnostic use as an aid in the determination of serological status to CMV.

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

**IMMULITE® CMV IgG** is a chemiluminescent enzyme immunoassay, **CYTOMEGELISA II IgG** is an enzyme-linked immunosorbent assay (ELISA), and **IMx CMV IgG** is a microparticle enzyme immunoassay (MEIA). The technology in DPC's IMMULITE CMV IgG is identical to technology used in previously cleared and commercially marketed IMMULITE® products.

In the **CYTOMEGELISA II IgG** assay, purified CMV antigen is attached to the surface of microplate wells. Diluted patient serum is added to the wells, and the CMV IgG specific antibody, if present, binds to the antigen. All unbound antibody is washed away and enyzme-conjugated anti-human IgG is added. The enzyme conjugate binds to the antibody-antigen complex. Excess 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 CMV IgG specific antibody in the sample. The results are read by a spectrophotometer, producing an indirect measurement of the CMV IgG specific antibody in the serum.

In the **IMx CMV IgG** assay, the patient sample and diluent buffer are added to predilution well of a reaction cell. CMV coated microparticles and the diluted sample are added to an incubation well. The CMV antibody binds to the CMV coated microparticles, forming an antigen-antibody complex. Diluent buffer is added to the reaction mixture and an aliquot of the antigen-antibody complex is transferred to the glass fiber matrix. The microparticles bind irreversibly to the glass fiber matrix. The matrix is washed to remove unbound materials. The anti-human IgG/alkaline phosphatase conjugate is dispensed onto the matrix and binds to the antigen-antibody complex. Finally, the matrix is washed to remove unbound materials, the substrate, 4-Methylumbelliferyl Phosphate, is added to the matrix, and the fluorescent product is measured by the optical assembly.

**Performance Equivalence - Method Comparison:**

The clinical performance of the IMMULITE CMV IgG procedure was compared to a CMV proficiency panel obtained from the United States Centers for Disease Control and Prevention (CDC), the CYTOMEGELISA II IgG assay, and the IMx CMV IgG assay. A summary of the results is shown in the table below.

| | IMMULITE vs. CDC | IMMULITE vs. CYTOMEGELISA II IgG | IMMULITE vs. IMx CMV IgG |
|---|---|---|---|
| Agreement | 100.0% | 98.5% | 99.5% |
| Sensitivity | 100.0% | 97.9% | 100.0% |
| Specificity | 100.0% | 100.0% | 98.7% |
| n = | 100 | 202 | 200 |

**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.

Kenneth B Asarch — 2/10/95

***Kenneth B. Asarch, Pharm.D., Ph.D.***
***Director of Regulatory Affairs***

***Date***