K963084

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510(k) Summary for OPUS Anti CMV Expanded Intended Use

1. Manufacturer Name, Address, phone number, contact name and date of preparation:

Manufacturer Behring Diagnostics Inc.,
151 University Avenue
Westwood, MA 02090
617-320-3153
Contact name: Kathleen Dray-Lyons

date of preparation: October 2, 1996

2. Device Name/Classification:

OPUS Anti-CMV *Cytomegalovirus* serological reagents

Classification number: Class II (866-3175)

3. Identification of the legally marketed device to which the submitter claims equivalence.

Abbott CMV Total AB EIA

4. Proposed Device Description:

OPUS Anti CMV is a qualitative fluorogenic enzyme-linked immunosorbent assay (ELISA), based on liquid phase binding of CMV antibodies to enzyme labeled recombinant CMV antigen. Each test module contains a solid phase recombinant protein A/G immobilized onto glass fiber. A recombinant CMV antigen/alkaline phosphatase conjugate solution and a wash/substrate solution (4-methylumbelliferyl phosphate) are sealed in separate well within the test module.

5. Proposed Device Intended Use:

OPUS® Anti CMV is a qualitative fluorogenic enzyme-linked immunosorbent assay (ELISA) used in the detection of total antibody to cytomegalovirus in human serum or heparin plasma to determine serological evidence of previous CMV infection. The OPUS Anti CMV assay is also intended for use to screen blood and/plasma donors to determine serological evidence of previous CMV infection. OPUS Anti CMV is intended for use with the OPUS analyzers.

6. Medical device to which equivalence is claimed and comparison information:

The OPUS Anti CMV assay is substantially equivalent in intended use to the Abbott CMV Total AB EIA test system. Both products are *in vitro* diagnostic test systems intended for use as a qualitative measurement of Cytomegalovirus (CMV) in the blood/plasma donor population. The Abbott CMV Total AB EIA, like the proposed product, employs an enzyme-labeled conjugate for the qualitative detection of total antibody to CMV in human serum. Both are based on a two level calibrator system.

The OPUS Anti-CMV differs from the Abbott CMV Total AB EIA in that the OPUS CMV contains Omnibind™ A/G to bind human immunoglobulins whereas the Abbott CMV contains anti-human immunoglobulins. Additionally, the OPUS CMV uses a recombinant CMV antigen in its conjugate preparation whereas Abbott uses native CMV coated onto a bead.

7. Proposed Device Performance characteristics:

Precision:

Precision of the OPUS Anti-CMV test system was evaluated on the OPUS Immunoassay System. Assay precision was determined by the evaluation of reactive and nonreactive calibrator signals (assay value/cutoff) and individual clinical specimen signals.

Intra-assay precision %CV's ranged from 5.8-20%.

Inter-assay precision %/CV's ranged from 8.9-21.4%.

Interfering Substances:

Levels of the following do not appear to interfere with the OPUS Anti CMV assay:

	Up to:
total protein	11.5 g/dL
triglycerides	780 mg/dL
cholesterol	450 mg/dL
hemoglobin	1000 mg/dL
immunoglobulins	16000 mg/dL
bilirubin	25.4 mg/dL
Rheumatoid factor	567 IU/mL
ANA	1:640
Epstein-Barr	3.33 (signal/cutoff)
herpes simplex I/II	I=3.64/II=2.17 (signal/cutoff)
Herpes-Zoster	2.31(signal/cutoff)
HBsAG	118 (signal/cutoff)
Elevated IgM	1550 (signal/cutoff)
Anti-HIV Positive	(western blot confirmed)
Anti-HCV postive	>4.505 signal over range
Anti-HAV positive	26.000 (signal/cutoff)

Accuracy by Correlation:

Results of comparative studies using the OPUS Anti CMV assay and the Abbott CMV test in both preselected and blood donor populations ranged from a relative sensitivity of 96.6-97.7% and a relative specificity of 100% respectively.

Expected Values:

Based on the studies performed in blood and plasma donor centers using the OPUS Anti CMV assay, the expected CMV antibody positive frequency for the population tested is 27.4% in Massachusetts, 14.4% in Florida and 30.6% in Illinois.