K960434

I. SUMMARY OF SAFETY AND EFFECTIVENESS

OCT 17 1996

DEVICE NAME: INCSTAR CMV IgM Capture ELISA Kit

CLASSIFICATION: Cytomegalovirus serological reagents
21 CFR 866.3175
Class II (Performance Standards)

APPLICANT: INCSTAR Corporation
1990 Industrial Boulevard
Stillwater, Minnesota 55082-0285

INTENDED USE:

The INCSTAR CMV IgM Capture ELISA Kit contains instructions and materials for the qualitative and/or semi-quantitative detection of IgM antibodies to cytomegalovirus in human serum by reverse capture enzyme-linked immunosorbent assay (ELISA) technique. When performed according to instructions, the CMV IgM Capture ELISA test can be used as an aid in the diagnosis of current or recent active CMV infection. The evaluation of paired CMV IgM sera can also aid in determining the stage of active CMV infection.

DEVICE DESCRIPTION:

The INCSTAR CMV IgM Capture ELISA test kit utilizes the enzyme-linked immunosorbent assay (ELISA) based on the antibody capture technique. Diluted patient serum is incubated with mouse monoclonal antibody against human IgM (μ chain specific) bound to the solid surface of a microtiter well. Patient IgM is "captured" by the surface bound antibody. The presence of patient anti-CMV IgM antibodies are then "detected" and bound by CMV antigen which is linked to an anti-CMV monoclonal antibody conjugated to horseradish peroxidase. Bound horseradish peroxidase is reacted with chromogen, resulting in color development. The absorbance of the solution, measured at 450 nm, is directly proportional to the concentration of IgM to CMV antigen present in the reaction solution.

I. SUMMARY OF SAFETY AND EFFECTIVENESS (continued)

SAFETY AND EFFECTIVENESS:

The INCSTAR CMV IgM Capture ELISA Kit is substantially equivalent (SE) to the BioWhittaker CMV CAP-M ELISA test, 510(k) No K896295, which has been cleared by the FDA and is currently in U.S. commercial distribution.

In clinical performance studies, 529 serum samples represented by 474 individuals were tested using the INCSTAR CMV IgM Capture ELISA Kit and results were compared to those results generated from the BioWhittaker CMV CAP-M ELISA Test. The samples utilized represent a mixed population of healthy donors, immunocompromised hosts, transplant patients, congenital CMV babies, and patients having various other illnesses. Upon completion of assay correlation, the results (using 95% confidence intervals) demonstrated a relative sensitivity of 88% to 97% and a relative specificity of 92% to 97%. In addition, the assay displayed an overall agreement of 92% to 96%.

Further resolution of discrepant results by a commercial CMV IgM ELISA method [Gull CMV IgM ELISA (510(K) No. K903807)] demonstrated that of the 21 samples positive by the INCSTAR CMV IgM Capture ELISA assay but negative by the reference ELISA assay, 17 samples contained sufficient quantities for resolution and 10 were found to be positive by the resolving ELISA method. Of the 10 samples negative by the INCSTAR CMV IgM Capture ELISA assay but positive by the reference ELISA assay, 9 samples contained sufficient quantities for resolution and 8 were found to be negative by the resolving ELISA method.

Prevalency, cross-reactivity, interference, linearity and precision studies have been conducted and are summarized in the INCSTAR CMV IgM Capture Kit package insert.