K955360

I. SUMMARY OF SAFETY AND EFFECTIVENESS

DEVICE NAME: INCSTAR CMV IgG "fast" ELISA Kit

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

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

INTENDED USE:

The INCSTAR CMV IgG "fast" ELISA Kit contains instructions and materials for the qualitative and/or semi-quantitative detection of IgG antibodies to cytomegalovirus in human serum by indirect enzyme-linked immunosorbent assay (ELISA) technique. When performed according to instructions, the CMV IgG "fast" ELISA test is of value in the determination of immunological response to infection with CMV. The evaluation of paired sera, acute and convalescent, by demonstrating seroconversion or a significant rise in antibody can aid in the diagnosis of primary infection, reactivated infection, or reinfection with cytomegalovirus.

DEVICE DESCRIPTION:

The INCSTAR CMV IgG "fast" ELISA test kit utilizes the enzyme-linked immunosorbant assay (ELISA) technique for the detection of cytomegalovirus IgG antibodies. Polystyrene microtiter wells are coated with purified CMV antigen. Diluted patient serum is incubated with purified CMV antigen bound to the solid surface of a microtiter well. The CMV antibodies that are present in the patient's serum will be captured by the solid phase. After washing, these complexes bind with horseradish peroxidase labeled antihuman IgG which react with the addition of chromogen (tetramethylbenzidine), resulting in color development. The absorbance of the solution, measured at 450 nm, is directly proportional to the concentration of IgG antibodies to CMV antigen present in the reaction solution.

I. SUMMARY OF SAFETY AND EFFECTIVENESS (continued)

SAFETY AND EFFECTIVENESS:

The INCSTAR CMV IgG "fast" ELISA Kit is substantially equivalent (SE) to the GULL CMV IgG ELISA test, 510(k) No. K915892, which has been cleared by the FDA and is currently in U.S. commercial distribution.

In clinical performance studies, 308 serum samples represented by 296 individuals were tested using the INCSTAR CMV IgG "fast" ELISA Kit and results were compared to those results generated from the GULL CMV IgG ELISA Test. The samples utilized represent a mixed population of healthy donors, immunocompromised hosts, transplant patients, and patients with other various illnesses. Upon completion of assay correlation, the results (using 95% confidence intervals) demonstrated a relative sensitivity of 99% to 100% and a relative specificity of 95% to 100%. In addition, the assay displayed an overall agreement of 90% to 100%.

Further resolution of discrepant results by a commercial CMV IgG ELISA demonstrated that of the 2 samples positive by the INCSTAR CMV IgG "fast" assay but negative by the Gull ELISA kit, 1 was positive by the resolving ELISA assay.

Prevalence, cross-reactivity, interference, linearity and precision studies have been conducted and are summarized in the INCSTAR CMV IgG "fast" ELISA Kit package insert.