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I. SUMMARY OF SAFETY AND EFFECTIVENESS

DEVICE NAME: INCSTAR Toxoplasma IgM Capture ELISA Kit

CLASSIFICATION: *Toxoplasma gondii* Serological Reagents
21 CFR 866.3780
Class II (Performance Standards)

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

INTENDED USE:

The INCSTAR Toxoplasma IgM Capture ELISA kit contains instructions and materials for the qualitative detection of IgM antibodies to *Toxoplasma gondii* in human serum by reverse capture enzyme-linked immunosorbent assay (ELISA) technique. When performed according to instructions, the Toxoplasma IgM Capture ELISA test can be used as an aid in the diagnosis of current or recent active *Toxoplasma gondii* infection. This product is not FDA cleared for use in testing (i.e., screening) blood or plasma donors.

DEVICE DESCRIPTION:

The INCSTAR Toxoplasma IgM Capture ELISA Kit utilizes the enzyme-linked immunosorbent assay (ELISA) based on the antibody capture technique. Diluted patient serum is incubated with monoclonal mouse antibody against human IgM (μ chain specific) bound to the solid surface of the microtiter well. Patient IgM is "captured" by the surface bound antibody. The presence of patient anti-*Toxoplasma* IgM antibodies are then "detected" and bound by *Toxoplasma* antigen which is linked to an anti-*Toxoplasma* 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 / 630 nm, is directly proportional to the concentration of IgM to *Toxoplasma* antigen present in the reaction solution.

I. SUMMARY OF SAFETY AND EFFECTIVENESS (continued)

SAFETY AND EFFECTIVENESS:

The INCSTAR Toxoplasma IgM Capture ELISA Kit is substantially equivalent (SE) to the BioWhittaker TOXOCAP-M ELISA test which has been cleared by the FDA and is currently in U.S. commercial distribution.

In clinical performance studies, 406 serum samples represented by 375 individuals were tested with the INCSTAR Toxoplasma IgM Capture ELISA kit and results were compared to those results generated from the BioWhittaker TOXOCAP-M ELISA kit. The samples utilized represent a mixed population of healthy donors, transplant patients, immunocompromised hosts, pregnant women, *Toxoplasma* proven individuals, and patients having various other illnesses. Upon completion of assay correlation, the results (using 95% confidence intervals) demonstrated relative sensitivity of 91% to 99% and relative specificity of 99% to 100%. In addition, the assay displayed an overall agreement of 97% to 100%.

Correlation, prevalency, cross-reactivity, interference, IgM specificity and precision studies have been conducted and are summarized in the INCSTAR Toxoplasma IgM Capture Kit package insert.