

K954576

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ATTACHMENT A

[510(k)] Summary Of Safety And Effectiveness Information Supporting A

Substantially Equivalent Determination

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The following information as presented in the [510(k)] notification for the AxSYM Toxo IgM assay constitutes data supporting a substantially equivalent determination:

[510(k)] Summary of Device Performance

The AxSYM Toxo IgM assay is a Microparticle Enzyme Immunoassay (MEIA) for the qualitative measurement of IgM antibodies to *Toxoplasma gondii* in human serum and plasma (EDTA, heparin, or sodium citrate) to aid in the diagnosis of primary infection. The AxSYM Toxo IgM assay is not for use with cord blood or neonatal specimens. This product is not FDA cleared for use in testing blood or plasma donors.

The predicate device for determination of substantial equivalence is the bioMerieux VIDAS Toxo-M. The VIDAS Toxo IgM (TXM) assay is intended for use with a VIDAS (Vitek ImmunoDiagnostic Assay System) instrument as an automated enzyme-linked fluorescent immunoassay (ELFA) for the qualitative detection of anti-*Toxoplasma gondii* IgM antibodies in human serum, as an aid in the diagnosis of toxoplasmosis. It is not intended for use in testing (screening) blood or plasma donors.

In two U.S. sites and one European site, the AxSYM Toxo IgM assay was compared to the VIDAS Toxo IgM assay using 1,400 samples from pregnant women, non-pregnant individuals and individuals positive for IgM antibodies to *T. gondii*. Discordant results were resolved by testing with Platelia Toxo IgM (Sanofi) and Abbott IMx Toxo IgM Antibody assay, both of which are legally marketed devices in the United States. Based on this study, the AxSYM Toxo IgM assay showed relative sensitivity of 96.3%, relative specificity of 99.8% and relative agreement of 99.3%. Specimens giving equivocal results were not included in the calculation of relative agreement, relative sensitivity, or relative specificity. Percent CV's on positive panel members and positive control was 6.0% to 10.1%.

In conclusion, the AxSYM Toxo IgM Assay is substantially equivalent to the VIDAS Toxo IgM assay for the detection of IgM antibodies to *T. gondii* in human serum and plasma (EDTA, heparin, or sodium citrate) specimens.

[510(k)] Summary Of Technological Comparison

The AxSYM Toxo IgM Antibody assay and the bioMerieux VIDAS Toxo IgM are substantially equivalent in that:

- A. Both are in vitro immunologic test methods.
- B. Both are intended for use in the detection of IgM antibody to *T. gondii* in human serum.
- C. Both are based on information of immune complexes between *T. gondii* antigens and antibody.
- D. Both use a polystyrene solid phase.
- E. Both are qualitative assays.
- F. Both use automated immunoassay analyzers.
- G. Both use 4 methylumbelliferyl phosphate (MUP) as the enzyme substrate.

The AxSYM Toxo IgM Antibody assay and the VIDAS Toxo IgM assay differ in that:

- A. The solid phase in the AxSYM Toxo IgM assay contains polystyrene microparticles coated with *Toxoplasma gondii* antigen. The VIDAS Toxo IgM assay is coated with goat anti- μ chain antibodies inside of the SPR (solid phase receptacle).
- B. The conjugate in the AxSYM Toxo IgM assay contains goat anti-human IgM antibody conjugated to alkaline phosphatase. The conjugate in the VIDAS Toxo IgM assay contains an immune complex of *T. gondii* antigen and anti-P30 mouse monoclonal antibody conjugated to alkaline phosphatase.
- C. Serum and plasma (EDTA, heparin, sodium citrate) specimens may be tested in the AxSYM Toxo IgM assay. The use of plasma specimens has not been validated in the VIDAS Toxo IgM Assay.
- D. The AxSYM Toxo IgM assay utilizes a rheumatoid neutralization buffer to remove rheumatoid factor interference antibodies. The VIDAS Toxo IgM assay does not utilize a buffer for rheumatoid factor interference antibodies.

Comparison Of Methods

<u>Assay Characteristic</u>	<u>AxSYM Toxo IgM Assay</u>	<u>VIDAS Toxo IgM Assay</u>
Assay Type	Qualitative	Qualitative
Antibody Measured	Specific IgM	Specific IgM
Assay Principle	MEIA	EIA (ELFA)
Solid Phase	polystyrene microparticle	polystyrene solid phase receptacle
Solid Phase Coating	Toxoplasma antigen, RH strain derived from HeLa cell culture	goat anti- μ chain antibodies
Conjugate	goat anti-human IgM antibodies conjugated to alkaline phosphatase	mouse anti-P30 monoclonal antibody conjugated to alkaline phosphatase
Specimen	Human serum and plasma (EDTA, heparin, citrate)	Human serum
Automation	performed on an automated instrument	performed on an automated instrument
Relative Specificity	99.8% (European & U.S.)	93.0% - 94.3% (U.S.) 99.4% - 99.6% (European)
Relative Sensitivity	96.3% (European & U.S.)	87.9% - 99.5% (U.S.) 97.7% - 100.0% (European)