ATTACHMENT A

[510(k)] Summary of Safety and Effectiveness Information Supporting A Substantially Equivalent Determination

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

[510(k)]Summary of Device Performance

The AxSYM Toxo IgG Antibody assay is a Microparticle Enzyme Immunoassay (MEIA) for the quantitative measurement of IgG antibodies to *Toxoplasma gondii* in human serum or plasma (EDTA, heparin or sodium citrate) to aid in the determination of immune status. 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 IgG assay.

The VIDAS Toxo IgG (TXG) assay is intended for use with a VIDAS (Vitek ImmunoDiagnostic Assay System) instrument as a semi-quantitative automated enzyme-linked fluorescent immunoassay (ELFA). It is intended for use in determination of *Toxoplasma gondii* immunological experience from a single serum sample, or as an aid in the diagnosis of *T. gondii* recent infection or reactivation through evaluation of paired sera for a significant increase in *T. gondii*-specific IgG. 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 IgG Antibody assay was compared to the VIDAS Toxo IgG Antibody assay using 1400 specimens from pregnant women and random low risk individuals. Discordant results were resolved by testing with IMx Toxo IgG Antibody assay and Platelia Toxo IgG, both of which are legally marketed devices. Discordant results were also resolved by the Sabin-Feldman dye test, a reference laboratory method for the determination of antibody to *Toxoplasma gondii* in human serum. This method was first developed in 1948 and is still considered the most sensitive and specific method for the detection of IgG antibodies to toxoplasma. Based on this study, the AxSYM Toxo IgG showed relative sensitivity of 99.66%, relative specificity of 99.10% and relative agreement of 99.34%. 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 were 7.6% to 12 7%.

In conclusion, the AxSYM Toxo IgG antibody assay is substantially equivalent to the bioMerieux VIDAS Toxo IgG antibody assay for the detection of IgG antibodies to toxoplasmosis in human serum and plasma (EDTA, heparin, or sodium citrate) samples.

[510(k)] Summary Of Technological Comparison

The AxSYM Toxo IgG Antibody Assay and the VIDAS Toxo IgG Antibody assay are substantially equivalent in that:

A. Both are in vitro immunologic test methods.
B. Both are intended for use in the detection of IgG antibody to *Toxoplasmosis gondii* in human serum.
C. Both are based on the formation of immune complexes between *Toxoplasmosis gondii* antigens and antibody.
D. Both are quantitative assays.
E. Both use automated immunoassay analyzers.
F. Both use a polystyrene solid phase.
G. Both use an anti-human IgG antibody conjugated to alkaline phosphatase.
H. Both use 4-Methylumbelliferyl Phosphate (MUP) as the enzyme substrate.

The AxSYM Toxo IgG Antibody Assay and VIDAS Toxo IgG Antibody assay differ in that:

1. The solid phase in the AxSYM Toxo IgG assay is polystyrene microparticles coated with *Toxoplasmosis gondii* antigen (RH strain derived from HeLa cell cultures). The solid phase for the VIDAS Toxo IgG assay consists of *Toxoplasmosis gondii* antigen coated to the inside of the SPR (solid phase receptacle).
2. The conjugate in the AxSYM Toxo IgG assay uses goat anti-human IgG antibody. The conjugate in the VIDAS Toxo IgG assay uses mouse monoclonal anti-human IgG antibody.
3. Plasma (EDTA, heparin, sodium citrate) specimens may be tested in the AxSYM Toxo IgG assay. The use of plasma specimens has not been validated in the VIDAS Toxo IgG assay.

Comparison of Methods

Assay Characteristics	AxSYM Toxo IgG	VIDAS Toxo IgG
Assay Type	Quantitative	Quantitative
Antibody Measured	Specific IgG	Specific IgG
Assay Principle	MEIA	EIA(ELFA)
Solid Phase	polystyrene microparticles	polystyrene solid phase receptacle
Solid Phase Coating	Toxo antigen, RH strain derived from HeLa cell cultures	Toxo antigen, RH strain
Conjugate	goat anti-human IgG conjugated to alkaline phosphatase	mouse monoclonal anti-human IgG conjugated to alkaline phosphatase
Specimen	Human serum and plasma (EDTA, heparin, sodium citrate)	Human serum
Automation	Performed on an automated instrument	Performed on an automated instrument
Relative Specificity	99.1% (European & U S)	97.8% (European study) 97.9% (U.S. study)
Relative Sensitivity (final interpretation)	99.6% (European & U S)	98.4% (European study) 96.0% (U.S. study)