ATTACHMENT A

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

K953943

SEP 20 1996

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

[510(K)] Summary Of Device Performance

The AxSYM CMV IgG assay is a Microparticle Enzyme Immunoassay (MEIA) for the semi-quantitative measurement of IgG antibodies to cytomegalovirus in serum and plasma (EDTA, heparin or sodium citrate) as an indication of past or current infection with cytomegalovirus. This product is not FDA cleared for use in testing blood or plasma donors.

The predicate device used for determination of substantial equivalence is the Vidas CMV IgG Assay, a semi-quantitative automated enzyme-linked fluorescent immunoassay (ELFA). It is intended for use in determination of CMV immunological experience from a single serum sample, or as an aid in the diagnosis of current CMV infection through evaluation of paired sera for a significant increase in CMV-specific IgG. It is not intended for use in testing (screening) blood or plasma donors.

Twelve hundred (1200) patient specimens were evaluated for the presence of IgG antibody to cytomegalovirus at 2 U.S. laboratories and 1 European laboratory using the AxSYM CMV IgG Antibody assay. In addition, each specimen was tested using a legally marketed EIA (ELFA). Of the 1200 specimens evaluated, 3 were equivocal by EIA (ELFA). Specimens giving equivocal results using EIA (ELFA) were not included in the calculation of relative agreement, relative specificity or relative sensitivity. Three specimens yielded discordant results between EIA (ELFA) and AxSYM. The relative agreement was 99.8% (1194/1197). The relative sensitivity was 99.5% (589/592) and the relative specificity was 100% (605/605). Further evaluation of the 3 discordant specimens was performed using 2 additional legally marketed assays. Of the 3 specimens positive by EIA (ELFA) and negative by AxSYM, all 3 were negative after resolution.

In conclusion, the AxSYM CMV IgG assay is substantially equivalent to the Vidas CMV IgG assay for the detection of IgG antibodies to cytomegalovirus in human serum specimens.

[510(K)] Summary Of Technological Comparison

The AxSYM CMV IgG Antibody Assay and the Vidas CMV IgG Assay are Substantially Equivalent in that:

1. Both are in vitro immunologic test methods.
2. Both are intended for use in the detection of IgG antibody to cytomegalovirus in human serum.
3. Both are based on the formation of immune complexes between cytomegalovirus antigens and antibody.
4. Both use antigen coated solid phases.
5. Both use a solid phase coated with cytomegalovirus strain AD 169.
6. Both are semi-quantitative assays.
7. Both conjugates are conjugated to alkaline phosphatase.
8. Both assays are automated.

The AxSYM CMV IgG Antibody Assay and Vidas CMV IgG Assay Differ in that:

1. The AxSYM CMV IgG Antibody assay is an automated microparticle enzyme immunoassay performed with the AxSYM random and continuously accessed automated immunoassay analyzer. The Vidas CMV IgG assay is an automated enzyme-linked fluorescent immunoassay performed with a Vidas (Vitek ImmunoDiadnostic Assay System) instrument.
2. The solid phase used in the AxSYM CMV IgG Antibody assay is a polystyrene microparticle. The solid phase used in the Vidas CMV IgG assay is a Solid Phase Receptacle (SPR).
3. The conjugate in the AxSYM CMV IgG Antibody assay uses goat anti-human IgG antibody conjugated to alkaline phosphatase. The conjugate in the Vidas CMV IgG assay consists of mouse monoclonal anti-human IgG antibody conjugated to alkaline phosphatase.
4. Plasma (EDTA, sodium citrate, and heparin) specimens may be tested in the AxSYM CMV IgG Antibody assay. The use of plasma specimens has not been validated for use in the Vidas CMV IgG assay.

Comparison of Methods

Assay Characteristics	AxSYM CMV IgG	Vidas CMV IgG
Assay Type	Semi-quantitative	Semi-quantitative
Antibody Measured	Specific IgG	Specific IgG
Assay Principle	MEIA	EIA (ELFA)
Solid Phase	polystyrene microparticles	solid phase receptacle
Solid Phase Coating	cytomegalovirus antigen strain AD169	cytomegalovirus antigen strain AD169
Conjugate	goat anti-human IgG conjugated to alkaline phosphatase	mouse monoclonal anti-human IgG conjugated to alkaline phosphatase
Specimen	Human serum and plasma (EDTA, sodium citrate, heparin)	Human serum
Automation	Performed on automated instrument	Performed on automated instrument
Relative Sensitivity	99.5%	100%
Relative Specificity	100%	98.1%