

**ATTACHMENT A**

**[510(k)] Summary of Safety and Effectiveness Information Supporting a  
Substantially Equivalent Determination and Certification of Search for  
Adverse Safety and Effectiveness**

K954318

**MAY 14 1996**

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

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

**[510(k)] Summary of Device Performance**

The AxSYM Rubella IgM Antibody assay is a Microparticle Enzyme Immunoassay (MEIA) for the qualitative measurement of IgM antibodies to rubella virus in human serum and plasma (EDTA, heparin or sodium citrate) to aid in the diagnosis of primary or acute infection. The AxSYM Rubella IgM assay is not for use with cord blood or neonatal specimens.

The predicate device for determination of substantial equivalence is Abbott's legally marketed IMx Rubella IgM Antibody assay; a Microparticle Enzyme Immunoassay (MEIA) for the qualitative measurement of IgM antibodies to rubella virus in human serum or plasma (EDTA, heparin or sodium citrate) to aid in the diagnosis of primary infection. The IMx Rubella IgM assay is not for use with cord blood or neonate specimens.

In three clinical sites, the AxSYM Rubella IgM Antibody assay was compared to the Abbott IMx Rubella IgM Antibody assay using 1300 samples from pregnant women, non-pregnant individuals and individuals positive for IgM antibodies to rubella. The AxSYM Rubella IgM Antibody assay was shown to have a relative sensitivity of 95.7%, relative specificity of 99.4% and a relative agreement of 99.1%. Percent CV's on positive panel members and positive controls was 6.9% to 12.6%.

Further evaluation of 11 discordant specimens was performed using two additional legally marketed assays (Abbott Rubazyme M EIA and BioWhittaker RUBASTAT M). Of the seven specimens positive by AxSYM and negative by EIA, two were found to be positive, four were found to be negative and one was found to be equivocal for IgM antibody. Of the four specimens negative by AxSYM and positive by EIA, one was found to be negative and three were found to be equivocal for IgM antibody. Specimens giving equivocal results using AxSYM and/or EIA were not included in the calculation of relative agreement, relative sensitivity and relative specificity.

In conclusion, the AxSYM Rubella IgM Antibody assay is substantially equivalent to the Abbott IMx Rubella IgM Antibody assay for the detection of IgM antibodies to rubella virus in human serum and plasma (EDTA, heparin or sodium citrate) specimens to aid in the diagnosis of primary or acute infection.

**[510(k)] Summary Of Technological Comparison**

**The AxSYM Rubella IgM Antibody Assay and the IMx Rubella IgM Antibody assay are Substantially Equivalent in that:**

1. Both are in vitro immunologic test methods.
2. Both are intended for use in the detection of IgM antibody to rubella virus in human serum or plasma (EDTA, heparin or sodium citrate).
3. Both are based on the formation of immune complexes between rubella virus antigens and antibody.
4. Both use a polystyrene microparticle solid phase.
5. Both are qualitative assays.
6. Both use a solid phase coated with antigen from rubella virus strain HPV-77.
7. Both use antigen produced in Vero cell culture.
8. Both use goat anti-human IgM antibody conjugated to alkaline phosphatase.
9. Both use MUP as the enzyme substrate.
10. Both use an automated instrument.

**The AxSYM Rubella IgM Antibody Assay and the IMx Rubella IgM Antibody assay Differ in that:**

1. The AxSYM Rubella IgM Antibody assay is an automated microparticle enzyme immunoassay performed with the AxSYM, a random and continuously accessed automated immunoassay analyzer. The IMx Rubella IgM Antibody assay is an automated microparticle enzyme immunoassay performed with the IMx automated immunoassay analyzer.
2. The IMx Rubella IgM Antibody assay requires that all positive samples be treated (RF neutralized) with human IgG microparticles and retested due to the potential for RF interference. The AxSYM Rubella IgM Antibody assay pretreats all samples with an RF neutralization buffer and does not require additional treatment and testing of positive samples.

**Comparison of Methods**

<u>Assay Characteristics</u>	<u>AxSYM Rubella IgM</u>	<u>IMx Rubella IgM</u>
<b>Assay Type</b>	Qualitative	Qualitative
<b>Antibody Measured</b>	Specific IgM	Specific IgM
<b>Assay Principle</b>	MEIA	MEIA
<b>Solid Phase</b>	Polystyrene microparticles	Polystyrene microparticles
<b>Solid Phase Coating</b>	Rubella virus antigen strain HPV-77 grown in Vero cells	Rubella virus antigen strain HPV-77 grown in Vero cells
<b>Conjugate</b>	Goat anti-human IgM conjugated to alkaline phosphatase	Goat anti-human IgM conjugated to alkaline phosphatase
<b>Specimen</b>	Human serum and plasma (EDTA, heparin or sodium citrate)	Human serum and plasma (EDTA, heparin or sodium citrate)
<b>Automation</b>	Performed on automated instrument	Performed on automated instrument
<b>Relative Sensitivity</b>	95.7%	95.4%
<b>Relative Specificity</b>	99.4%	99.4%

**Certification of search for adverse safety and effectiveness**

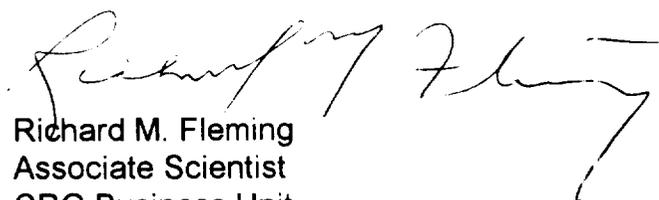
The undersigned certifies to the best of his knowledge and belief that reasonable search of all information known or otherwise presently available to Abbott Laboratories has been conducted. The scope of the search was as follows:

Accuracy/Clinical Utility/Reproducibility/Safety of Rubella Immunoassays  
Biohazard of Rubella Antigen  
Adverse Effects and Safety of Sodium Azide

The searches were performed by Abbott Laboratories Information Services Department for the undersigned individual on March 2, 1995.

Dialog® Information Service was used for database searches. A list of databases is included on the following page in this section.

Conclusion: No adverse safety and effectiveness data was found in the search provided the product is used as intended for *in vitro* diagnostic use.



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Databases Searched:

Database File Name

5: BIOSIS PREVIEWS® 1969-1995/Feb W2  
72: EMBASE 1985-1995/ISS 06  
73: EMBASE 1974-1995/ISS 05  
144: PASCAL 1973-1994/Aug  
154: MEDLINE (R) 1985-1995/Apr W2  
155: MEDLINE® 1966-1995/Apr W2  
156: TOXLINE(R) 1965-1995/Jan  
336: REG TOX EFF CHEM SUB 1994/Oct  
434: SCISEARCH(R) 1974-1995/Jan W5