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VII. SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act of 1990.

DATE OF SUMMARY PREPARATION: June 26, 1996

MANUFACTURER:

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NAME OF DEVICE: Copalis™ CMV Total Antibody Assay

COMMON NAME: Immunoassay for the detection of total antibody to CMV

PREDICATE DEVICE: Becton Dickinson and Co.
CMVscan Test

DEVICE DESCRIPTION:

Intended Use: The Copalis™ CMV Total Antibody Assay uses Coupled Particle Light Scattering (Copalis™) technology in a microparticle agglutination-based immunoassay for the qualitative and semi-quantitative detection of total antibodies (IgG and IgM) to cytomegalovirus (CMV) in human serum using the Copalis™ One Immunoassay System. The presence of antibodies is indicative of current or prior infection with the suspected organism. The results of this assay on a single serum specimen are used to indicate presence of antibody to CMV. When evaluating properly paired sera, the results of this assay are used to demonstrate seroconversion or a significant increase in antibody level as evidence of recent infection. Both specimens should be tested simultaneously (see Interpretation of Results). This assay has not been FDA cleared or approved for the screening of blood or plasma donors.

Kit Description: Coupled Particle Light Scattering (Copalis) technology provides a rapid method for the measurement of antibodies to specific viral or bacterial pathogens.

The Copalis CMV Total Antibody Assay is based on the principle of antibody-dependent particle aggregation as detected by measurement of changes in light scattering. Latex particles coated with inactivated CMV antigens aggregate in the presence of antibodies to CMV. After 10 minutes of agitation, the level of aggregation is determined by measurement of the number of reacted and unreacted particles as they flow past a detector. The number of reacted particles is related to the level of CMV antibodies present in the test specimen. Without prior infection, antibody levels are absent or low. After infection, antibody levels rise and usually remain stable (but declining in titer) for years. Reactivity is assessed by the level of aggregation relative to a cutoff value. The Copalis CMV Assay detects the presence of both IgM and IgG antibodies. Two levels of controls are used to monitor proficiency.

PERFORMANCE DATA:

Clinical Comparison: Six hundred eighty-nine (689) patient sera samples representing the mid-Atlantic and Gulf Coast regions of the U.S. were tested at 2 clinical laboratories and at Sienna Biotech Inc. In the study, the Copalis CMV Total Antibody Assay was compared to the Becton Dickinson and Co. CMVscan Test. Combined site relative sensitivity and specificity were 97.6% and 97.8%,respectively; combined site relative agreement was 97.7%.

Reproducibility: Reproducibility studies were performed at the 3 sites using one lot of TORC tests. Assay reproducibility was determined by testing four (4) samples across a range of reactivity. Five (5) runs of six (6) replicates of each sample were tested over three days. Results are presented below by clinical trial site:

	Site #1			Site #2			Site #3		
Level	Mean (CTR)	Within Assay %CV	Between Assay %CV	Mean (CTR)	Within Assay %CV	Between Assay %CV	Mean (CTR)	Within Assay %CV	Between Assay %CV
RP1	100	2.2	0.0	100	2.0	0.6	101	1.6	0.4
RP2	114	2.8	0.0	124	3.0	1.5	128	4.5	1.0
RP3	133	3.5	0.0	157	4.4	0.8	161	5.1	3.9
RP4	174	5.3	1.7	210	6.3	2.0	222	8.8	3.2

During the clinical trials, the Low Positive Control which is near the assay cutoff was assayed with each tray. Results are summarized below:

Low Positive Control Total Precision

Site	Mean (CTR)	S.D.	%CV	Min	Max
#1	120	5.3	4.4	113	136
#2	119	4.9	4.1	111	134
#3	125	5.0	4.0	114	140

Reproducibility of the conversion coefficient was also evaluated at the 3 trial sites. Thirty sets of a simulated acute and convalescent pair were analyzed over several days at each site. Reproducibility was expressed as the percent of those sets which met the conversion coefficient criterion for significant rise in antibody level. Of the 30 sets per site, 30, 19 and 29 sets met the criterion of $\geq$ 50%, representing 100%, 63% and 97% agreement for sites 1, 2 and 3, respectively.

CDC CMV Serum Panel: The following information is from a serum panel obtained from the CDC and tested by Sienna Biotech, Inc. The results are presented as a means to convey further information of the performance of this assay with a masked, characterized serum panel. This does not imply an endorsement of the assay by the CDC.

The panel consists of 66% positive and 34% negative samples. The Copalis CMV Total Antibody Assay demonstrated 100% total agreement with the CDC results.

Interfering Substances: Testing was conducted at Sienna Biotech, Inc. to demonstrate that rheumatoid factor (RF) and antinuclear antibodies (ANA) do not interfere with the performance of the assay. In addition, patient samples containing antibodies to HSV, EBV, VZV, and rubella were tested. None of these factors or antibodies interfered with the Copalis CMV assay results.