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SUMMARY OF SAFETY AND EFFECTIVENESS

SUBMITTED BY:

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NAME OF DEVICES:

Trade Name:	Copalis TORC Total Antibody Assay
Common Names/Descriptions:	Immunoassay for the Detection of Total Antibodies to *Toxoplasma gondii*, Rubella and Cytomegalovirus
Classification Names:	*Toxoplasma gondii* serological reagents; Rubella virus serological reagents; Cytomegalovirus serological reagents

PREDICATE DEVICES:

Abbott IMx Toxo IgG 2.0, Rubella IgG 2.0, CMV IgG

DEVICE DESCRIPTION:

INTENDED USE: The Copalis™ TORC Total Antibody Assay uses Coupled Particle Light Scattering (Copalis™) technology in a microparticle agglutination-based immunoassay for the qualitative detection of total antibodies (IgG and IgM) to *Toxoplasma gondii*, rubella and 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 determine the patient's immune status for rubella and to determine the patient's immunological experience for *Toxoplasma gondii* and CMV. When evaluating properly paired sera, the results of this assay are used to demonstrate seroconversion 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 protozoal pathogens.

The Copalis TORC Total Antibody Assay is based on the principle of antibody-dependent particle aggregation as detected by measurement of changes in light scattering. Due to the unique measuring system, a sample can be tested for antibodies to *Toxoplasma gondii*, rubella and CMV using a single reagent and obtain results for the individual antibodies. Sized latex microparticles coated with inactivated *Toxoplasma gondii*, rubella and CMV antigens aggregate in the presence of antibodies to these infectious agents. After 10 minutes of agitation, the levels of aggregation are determined by discrimination of particle sizes and measurement of the number of reacted and unreacted particles as they flow past a detector. Reactivity is assessed by the level of aggregation per particle size relative to a cutoff value. The Copalis TORC Total Antibody Assay detects the presence of both IgM and IgG antibodies. Two levels of controls are used to monitor proficiency.

PERFORMANCE DATA:

Clinical Sample Testing: Clinical sample testing was conducted at Sienna Biotech laboratory to evaluate the performance of the Copalis TORC Total Antibody Assay (TORC) compared to the corresponding Abbott IMx assays.

A total of 250 serum samples were tested. In initial testing, relative sensitivity of the *Toxoplasma gondii* antibody component of the assay was 91.4%; relative specificity was 98.6%. Relative sensitivity of the rubella antibody component of the assay was 98.7%; relative specificity was 100%. Relative sensitivity of the CMV antibody component of the assay was 94.4%; relative specificity was 100%.

Physician Office Laboratory (POL) Proficiency Study:

A study was conducted at 3 POL sites to evaluate the proficiency and reproducibility of different operators with the Copalis TORC Total Antibody Assay (TORC). The 3 sites represented POLs ranging from small to large group practices; 4 operators participated in the study, representing high school to 4-year educational levels.

A 14-member blinded proficiency panel was tested by each operator in each of three runs. Proficiency among operators was determined by comparison of Copalis TORC assay results for each panel member with the "expected" results as established by in-house testing on a comparator assay. The study showed 100% agreement between Copalis results from all operators and expected results.

Reproducibility was determined based on the 7 samples run in duplicate within each run. Within-run and total percent coefficient of variation (%CV) were calculated among operators for each sample. See the following table for a summary of %CV ranges.

SUMMARY OF SAFETY AND EFFECTIVENESS (cont.)

Physician Office Laboratory Reproducibility;
Total Precision - All Sites, All Operators

SAMPLE	RANGE	TOXO	RUBELLA	CMV
#1	CTR	131	190	215
	WITHIN-RUN %CV	5.9	6.0	11.9
	TOTAL %CV	7.7	8.2	13.9
#2	CTR	151	189	100
	WITHIN-RUN %CV	6.7	7.9	2.4
	TOTAL %CV	9.0	7.6	2.4
#3	CTR	134	188	127
	WITHIN-RUN %CV	6.6	9.5	6.5
	TOTAL %CV	8.0	8.3	6.0
#4	CTR	101	201	223
	WITHIN-RUN %CV	1.5	6.0	6.3
	TOTAL %CV	2.3	7.4	13.2
#5	CTR	101	150	101
	WITHIN-RUN %CV	1.7	5.2	2.1
	TOTAL %CV	2.3	5.4	2.8
#6	CTR	100	133	250
	WITHIN-RUN %CV	1.6	4.1	8.2
	TOTAL %CV	2.4	6.7	15.8
#7	CTR	101	141	140
	WITHIN-RUN %CV	1.0	3.6	2.2
	TOTAL %CV	2.5	7.0	7.5