

510(k) SUMMARY

K961053

Applicant: Quest International, Inc. SEP - 4 1996
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Registration No. FDA form 2891 was submitted on April 1, 1995.

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Manufacturing Site: Same as above

Device: SeraQuest™ Rubella IgG

Device Name: Rubella serological reagents (21CFR § 866.3510)

Device Classification: Class III (premarket approval)

Description:

The SeraQuest™ Rubella IgG test is a solid-phase enzyme immunoassay (EIA), which is performed in microwells, at room temperature, in three thirty minute incubations. It has been developed to detect IgG antibodies which are directed against rubella virus, in human serum.

The Calibrators in the SeraQuest Rubella IgG test set have been assigned Index values based on an in-house standard, and International Unit values (IU / ml) which are traceable to the WHO International Reference Preparation of Anti-rubella Serum. Test results may be reported as Index values, or as IU / ml.

Principle:

Diluted samples are incubated in rubella antigen-coated wells. Rubella antibodies (if present) are immobilized in the wells. Residual sample is eliminated by washing and draining, and conjugate (enzyme-labeled antibodies to human IgG) is added and incubated. If IgG antibodies to rubella are present, the conjugate will be immobilized in the wells. Residual conjugate is eliminated by washing and draining, and the enzyme substrate is added and incubated. In the presence of the enzyme, the substrate is converted to a yellow end-product which is read photometrically.

Intended Use:

For the qualitative and quantitative detection of human IgG antibodies to Rubella in human serum by enzyme immunoassay, to aid in the determination of infection with rubella virus. When used as a qualitative test, SeraQuest Rubella IgG aids in the assessment of the patient's immunological response to rubella. For manual use, or for use with the HyPrep System Plus.

Predicate device:

The SeraQuest™ Rubella IgG test is substantially equivalent in intended use and performance, to the Rubella IgG Clin-ELISA™ kit, INCSTAR Corporation, Stillwater Minnesota.

Summary of technological characteristics:

<u>Characteristic</u>	<u>SeraQuest™ Rubella IgG</u>	<u>INCSTAR Rubella IgG Clin-ELISA™</u>
Description:	Enzyme Immunoassay	Enzyme Immunoassay
Intended Use:	The detection of IgG antibodies against Rubella in human serum.	The detection of IgG antibodies against Rubella in human serum.
Solid Phase:	Plastic Microwell	Plastic Microwell
Antigen Strain:	HPV 77	Not Stated in Package Insert
Number of Incubation Periods:	Three	Three
Sample Dilution:	1:50	1:50
Sample Incubation Duration:	30 minutes	30 minutes
Incubation Temperature:	Room temperature	Room temperature
Ezyme-labeled Conjugate:		
Antibody	Goat anti-human IgG	Goat or Sheep anti-human IgG
Enzyme	Alkaline phosphatase	Alkaline phosphatase
Conjugate Volume:	100 µl	200 µl

Conjugate Incubation Duration:	30 minutes	30 minutes
Substrate:	p-Nitrophenyl phosphate	p-Nitrophenyl phosphate
Substrate Volume:	100 µl	200 µl
Substrate Incubation Duration:	30 minutes	45 minutes
Stop Reagent:	0.5 M Trisodium phosphate	3 N Sodium Hydroxide
Stop Reagent Volume:	100 µl	50 µl
Readout:	Spectrophotometric 405 nm	Spectrophotometric 405 nm

Summary of Clinical Testing:

Two hundred and sixty sera from normal blood donors were assayed for the presence of Rubella IgG antibodies, using the SeraQuest™ Rubella IgG test and the INCSTAR Rubella IgG Clin-ELISA™ test. Two hundred and four specimens were positive and forty-one specimens were negative in both tests. Seven specimens were negative in the SeraQuest Rubella IgG test, which were weakly positive in the INCSTAR Rubella IgG Clin-ELISA™ test; and 8 specimens gave equivocal results in the SeraQuest test, which were also weakly positive in the INCSTAR test. The latter test does not have an equivocal interpretation. Excluding the equivocal results, the overall agreement between the two tests was 97.2 % (95% Confidence Interval = 95.2 to 99.3). These results are shown below in Table 1.

TABLE 1.

RESULTS OF SeraQuest™ RUBELLA IgG ASSAYS, AND INCSTAR RUBELLA IgG Clin-ELISA ASSAYS, OF 260 SERUM SPECIMENS.

INCSTAR RUBELLA IgG	SeraQuest RUBELLA IgG			95 % CI*
	Positive	Equivocal	Negative	
Positive	204	8	7	Relative sensitivity√ 94.3 to 99.1
Negative	0	0	41	Relative specificity√ 95.4 to 100
				Overall agreement√ 95.2 to 99.3

Excluding equivocal results.
 Calculated by the normal method .