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510(k) SUMMARY

Applicant: Quest International, Inc.
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Registration No. 1061839

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Manufacturing Site: Same as above

Device: SeraQuest™ HSV IgG

Device Name: Herpes Simplex Virus serological reagents (21CFR § 866.3305)

Device Classification: Class III (premarket approval)

Description:

The SeraQuest™ HSV 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 type 1 or type 2 herpes simplex virus (HSV), in human serum.

The Calibrators in the SeraQuest HSV IgG test set have been assigned Index values based on an in-house standard. Test results are normalized and reported as Index values.

Principle:

Diluted samples are incubated in wells coated with Type 1 and Type 2 herpes simplex virus. HSV 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 HSV 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 semi-quantitative detection of human IgG antibodies to herpes simplex virus (type 1 or type 2) in human serum by enzyme immunoassay, to aid in the assessment of the patient's immunological response to herpes simplex virus. For manual use, or for use with the HyPrep System Plus. These reagents have not received FDA clearance for use in testing blood or plasma donors.

Predicate device:

The SeraQuest™ HSV IgG test is substantially equivalent in intended use and performance, to the HSV-1 and HSV-2 Clin-ELISA™ kits, INCSTAR Corporation, Stillwater Minnesota.

Summary of technological characteristics:

<u>Characteristic</u>	<u>SeraQuest™ HSV IgG</u>	<u>INCSTAR Herpes Type 1 and Type 2 Clin-ELISA™</u>
Description:	Enzyme Immunoassay	Enzyme Immunoassay
Intended Use:	Detection of IgG antibodies against type 1 HSV and type 2 HSV, in human serum.	Detection of IgG antibodies against type 1 HSV or type 2 HSV, in human serum.
Solid Phase:	Plastic Microwell	Plastic Microwell
Antigen Strain:	Type 1: MacIntyre Type 2: MS	Type 1: MacIntyre Type 2: MS
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 (gamma chain specific)	Goat or Sheep anti-human IgG (gamma chain specific)
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 μ l	200 μ l
Substrate Incubation Duration:	30 minutes	45 minutes
Stop Reagent:	0.5 M Trisodium phosphate	3 N Sodium Hydroxide
Stop Reagent Volume:	100 μ l	50 μ l
Readout:	Spectrophotometric 405 nm	Spectrophotometric 405 nm

Summary of Test Results Obtained with the Centers for Disease Control and Prevention HSV / CMV evaluation panel

The following information was obtained with the Centers for Disease Control and Prevention (CDC) serum panel for HSV / CMV serology assays, which was tested in-house by the SeraQuest™ HSV IgG test. The results are presented here as a means to convey further information on the performance of this assay with a masked, characterized serum panel. This does not imply an endorsement by the CDC.

The panel consists of 72 % positive and 28 % negative samples. The SeraQuest HSV IgG Test demonstrated 95 % total agreement with the CDC results. Of the results obtained by SeraQuest, there was 93 % agreement with the positive specimens, and 100 % agreement with the negative specimens.

Comparison testing with the Predicate Device

Two hundred and seven serum specimens, which were randomly obtained in South Florida were assayed by the SeraQuest HSV IgG test and a predicate device which utilizes antigen wells coated with non-specific type 1, or type 2 HSV antigens. The results of these assays are shown below in Table 1.

TABLE 1.

RESULTS OF SeraQuest™ HSV IgG ASSAYS (USING THE REVISED CUT-OFF VALUES AS PER C.D.C.), AND ANOTHER COMMERCIALY AVAILABLE HSV IgG ASSAY, OF 207 SERUM SPECIMENS. THE TEST SPECIMENS, WHICH INCLUDED 40 FROM WOMEN OF CHILD BEARING AGE (18 TO 45 YEARS), WERE COLLECTED IN SOUTH FLORIDA, AND TESTED AT QUEST INTERNATIONAL, INC., MIAMI, FL.

SeraQuest HSV IgG

INCSTAR
HERPES IgG
TYPE 1

	Positive	Equivocal	Negative	95 % CI*	
Positive	158 {36}	0	0	Relative sensitivity√	99.5 to 100
Negative	11 {2}	8	30 {2}	Relative specificity√	59.6 to 86.7
				Overall agreement√	91.3 to 97.6

INCSTAR
HERPES IgG
TYPE 2

	Positive	Equivocal	Negative	95 % CI*	
Positive	153 {35}	0	0	Relative sensitivity√	99.5 to 100
Negative	16 {3}	8	30 {2}	Relative specificity√	51.5 to 79.0
				Overall agreement√	88.2 to 95.7

INCSTAR
HERPES IgG
TYPE 1 & TYPE 2

	Positive	Equivocal	Negative	95 % CI*	
Positive	158 {36}	0	0	Relative sensitivity√	99.5 to 100
Negative	11 {2}	8	30 {2}	Relative specificity√	59.6 to 86.7
				Overall agreement√	91.3 to 97.6

√ Excluding equivocal results.

Calculated by the normal method.

Number of female donors of childbearing age.