510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION MEMORANDUM
ASSAY AND INSTRUMENT COMBINATION TEMPLATE

A. 510(k) Number:

K181514

B. Purpose for Submission:

Clearance of New Device. The assay was cleared under K152353 for SeraQuest HSV Type 2 Specific IgG assay conducted by manual method. In this submission the sponsor intends to conduct the same assay with the ChemWell Automated Analyzer.

C. Measurand:

Herpes Simplex Virus-2 (HSV-2) type specific IgG antibodies to glycoprotein G (gG) 2 antigen

D. Type of Test:

Enzyme linked immunosorbent assay (ELISA)

E. Applicant:

Quest International, Inc.

F. Proprietary and Established Names:

SeraQuest HSV Type 2 Specific IgG assay

G. Regulatory Information:

1. Regulation section:

   21 CFR§866.3305. Herpes simplex virus serological assays

2. Classification:

   Class II

3. Product code:

   MYF (Enzyme Linked Immunosorbent Assay, Herpes Simplex Virus, HSV-2)

4. Panel:

   Microbiology

H. Intended Use:

1. Intended use(s):

   The SeraQuest HSV Type 2 Specific IgG assay is an enzyme-linked immunosorbent assay (ELISA) intended for the qualitative detection of human IgG antibodies to type 2 herpes simplex virus (HSV) in human serum. The test is indicated for sexually active individuals and expectant mothers as an aid in the presumptive diagnosis of HSV-2 infection. The predictive value of a positive or negative result depends on the prevalence of HSV-2 infection in the population and the pre-test likelihood of HSV-2 infection.

   The test is not FDA cleared for screening blood or plasma donors. The performance of this assay has not been established for immunocompromised patients, pediatric patients or matrices other than human serum.

2. Indication(s) for use:

   Same as Intended Use

3. Special conditions for use statement(s):

   For prescription use only

4. Special instrument requirements:

   ChemWell Automated Analyzer

I. Device Description:

The SeraQuest HSV Type 2 Specific IgG test is a solid-phase enzyme-linked immunoassay (ELISA), which is performed in microwells, at room temperature, and in three thirty minute incubations. The test detects IgG antibodies which are directed against HSV-2 antigen,in human serum. The calibrators in the SeraQuest HSV Type 2 Specific IgG test set have been assigned index values based on an in-house standard. Test results are reported as index values. The following table shows the interpretation of results:

Table 1: Interpretation of results

Index	Result	Interpretation
≤ 0.9	Negative	No HSV-2 IgG antibodies detected. Patient is presumed not to have had a previous HSV-2 infection
$0.9 < X < 1.0$	Equivocal	Obtain an additional sample for re-testing
≥ 1.0	Positive	IgG antibody to HSV-2 detected

Notes:

1. A single positive result only indicates previous immunologic exposure; the level of antibody response may not be used to determine active infection or disease stage.

2. When equivocal results are obtained, another specimen should be obtained ten to fourteen days later, and tested in parallel with the initial specimen. If the second specimen is also equivocal, the patient is negative for primary or recent infection, and equivocal for antibody status. If the second sample is positive, the patient can be considered to have previous experience with HSV-2 infection.

3. Values obtained with different manufacturer's assay methods may not be used interchangeably. The magnitude of the reported IgG index value cannot be correlated to an endpoint titer. The magnitude of results above the cut-off is not an indicator of total antibody present.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   SeraQuest HSV Type 2 Specific IgG assay performed by manual method

2. Predicate 510(k) number(s):

   K152353

3. Comparison with predicate:

   A comparison of the device test procedure and the predicate device test procedure appears below:

Similarities		
Item	SeraQuest HSV Type 2 Specific IgG assay performed by ChemWell Automated Analyzer	SeraQuest HSV Type 2 Specific IgG assay performed by manual method (Predicate)
Intended Use	The SeraQuest HSV Type 2 Specific IgG assay is an enzyme-linked immunosorbent assay (ELISA) intended for the qualitative detection of human IgG antibodies to type 2 herpes simplex virus (HSV) in human serum. The test is	The SeraQuest HSV Type 2 Specific IgG assay is an enzyme-linked immunosorbent assay (ELISA) intended for the qualitative detection of human IgG antibodies to type 2 herpes simplex virus (HSV) in human serum. The test is

Similarities		
Item	SeraQuest HSV Type 2 Specific IgG assay performed by ChemWell Automated Analyzer	SeraQuest HSV Type 2 Specific IgG assay performed by manual method (Predicate)
	indicated for sexually active individuals and expectant mothers as an aid in the presumptive diagnosis of HSV-2 infection. The predictive value of a positive or negative result depends on the prevalence of HSV-2 infection in the population and the pre-test likelihood of HSV-2 infection. The test is not FDA cleared for screening blood or plasma donors. The performance of this assay has not been established for immunocompromised patients, pediatric patients or matrices other than human serum.	indicated for sexually active individuals and expectant mothers as an aid in the presumptive diagnosis of HSV-2 infection. The predictive value of a positive or negative result depends on the prevalence of HSV-2 infection in the population and the pre-test likelihood of HSV-2 infection. The test is not FDA cleared for screening blood or plasma donors. The performance of this assay has not been established for immunocompromised patients, pediatric patients or matrices other than human serum.
Sample Matrix	Human Serum	Human Serum
Solid Phase	Polystyrene Microwells	Polystyrene Microwells
Antigen	Purified HSV gG 2	Purified HSV gG 2
Incubation Periods	Three 30 minute	Three 30 minute
Sample Dilution	1:51	1:51
Sample Volume	100 µl	100 µl
Sample Incubation Duration	30 minutes	30 minutes
Incubation Temperature	Room temperature	Room temperature
Washing Steps	Two	Two
Cycles per Washing Step	Four	Four
Enzyme-Labeled Conjugate	Alkaline Phosphatase Conjugated Goat Anti-Human IgG	Alkaline Phosphatase Conjugated Goat Anti-Human IgG
Conjugate Volume	100 µl	100 µl
Conjugate	30 minutes	30 minutes

Similarities		
Item	SeraQuest HSV Type 2 Specific IgG assay performed by ChemWell Automated Analyzer	SeraQuest HSV Type 2 Specific IgG assay performed by manual method (Predicate)
Incubation		
Enzyme Substrate	p-nitrophenyl phosphate	p-nitrophenyl phosphate
Substrate Volume	100 µl	100 µl
Substrate Incubation	30 minutes	30 minutes
Stop Reagent	0.5 M Trisodium Phosphate	0.5 M Trisodium Phosphate
Stop Reagent Volume	100 µl	100 µl
Drying Step	None	None
Readout	Spectrophotometric 405 nm	Spectrophotometric 405 nm
Controls	Positive and negative controls included with kit	Positive and negative controls included with kit

Differences		
Item	SeraQuest HSV Type 2 Specific IgG assay performed by ChemWell Automated Analyzer	SeraQuest HSV Type 2 Specific IgG assay performed by manual method (Predicate)
Testing Procedure	Uses the ChemWell Automated Analyzer	Is conducted manually

K. Standard/Guidance Document Referenced (if applicable):

Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Herpes Simplex Virus Types 1 and 2 Serological Assays (issued August 9, 2011).

L. Test Principle:

Diluted patient samples are incubated in antigen-coated wells. HSV Type 2 antibodies, if present in the patient sample, are immobilized in the wells by binding to the antigen. 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-2 are present, the conjugate will be immobilized in the wells. Residual conjugate is eliminated by washing and draining, and the substrate is added and incubated. In the presence of the conjugate, the substrate is converted to a yellow end-product which is read photometrically.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility: A within laboratory precision study with a panel of samples was conducted with the SeraQuest HSV Type 2 Specific IgG assay by both the manual method and the ChemWell Automated Analyzer. The panel consists of samples in the following categories: true negative, high negative, low positive, and moderate positive. Precision evaluation of within-run, between-run, between-day, and within lab precision was determined over the duration of 12 days, with 2 runs per day, and 2 replicates of each sample per run and 1 replicate per control per run. Data analysis includes calculation of the mean, standard deviation and %CV for each panel, as summarized in tables 2 and 3.

Table 2: The precision results for SeraQuest HSV Type 2 Specific IgG assay by the manual method

Sample Description	N	Mean Value	Within-Run		Between-Run		Between-Day		Within Lab	
			SD	%CV	SD	%CV	SD	CV%	SD	CV%
Negative Control	24	0.18	-	-	0.03	15.75%	0.03	13.84%	0.04	20.96%
Positive Control	24	2.66	-	-	0.11	3.98%	0.04	1.55%	0.11	4.27%
True Negative	48	0.19	0.03	13.48%	0.03	13.48%	0.01	3.32%	0.04	19.35%
High Negative	48	0.76	0.03	4.24%	0.04	5.02%	0.02	2.76%	0.05	6.54%
Low Positive	48	1.56	0.04	2.61%	0.04	2.61%	0.06	3.83%	0.08	5.32%
Moderate Positive	48	2.86	0.06	1.95%	0.09	3.23%	0.09	3.11%	0.14	4.89%

Table 3: The precision results for SeraQuest HSV Type 2 Specific IgG assay by the ChemWell Automated Analyzer

Sample Description	N	Mean Value	Within Run		Between-Run		Between-Day		Within Lab	
			SD	%CV	SD	CV%	SD	CV%	SD	CV%
Negative Control	24	0.13	-	-	0.05	35.34%	0.01	6.74%	0.05	35.97%
Positive Control	24	2.52	-	-	0.11	4.36%	0.01	0.35%	0.11	4.37%
True Negative	48	0.13	0.04	31.61%	0.01	11.17%	0.02	12.38%	0.05	35.74%
High Negative	48	0.75	0.05	7.20%	0.05	6.09%	0.02	3.31%	0.07	9.99%
Low Positve	48	1.59	0.07	4.54%	0.09	5.37%	0.05	3.35%	0.12	7.79%
Moderate Positive	48	2.68	0.08	3.14%	0.10	3.57%	0.07	2.78%	0.15	5.51%

b. Linearity/assay reportable range:

Not Applicable

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

No changes were made from the clearance of K152353

d. Detection limit:

No changes were made from the clearance of K152353

e. Analytical specificity:

No changes were made from the clearance of K152353

f. Assay cut-off:

No changes were made from the clearance of K152353

2. Comparison studies:

a. Method comparison with predicate device: The percent agreement was evaluated by testing a total of 226 samples with the SeraQuest HSV Type 2 Specific IgG assay by the manual method and the ChemWell Automated Analyzer. Samples were obtained from remnants of patient samples and purchased from vendors. Additional samples were prepared by spiking negative samples with positive samples or dilution with diluent reagent to span the range of the assay measuring interval.

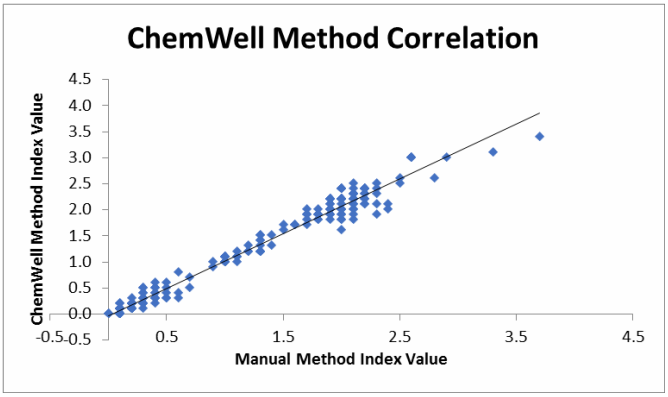
The concordance analysis for the manual and the ChemWell Automated Analyzer are summarized in Table 4.

Table 4: Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA) between the SeraQuest HSV Type 2 Specific IgG assay by the manual method and the ChemWell Automated Analyzer

SeraQuest HSV Type 2 Specific IgG assay		**Manual Method**			
		Positive	**Equivocal**	**Negative**	**Total**
ChemWell Automated Method	**Positive**	125	0	1	126
	Equivocal	0	0	0	0
	Negative	0	0	100	100
	Total	125	0	101	226

	Absolute	**Relative**	**Two-sided 95% CI**
Positive Percent Agreement (PPA)	125/125	100%	97.02% to 100%
Negative Percent Agreement (NPA)	100/101	99.01%	94.60% to 99.83%

Figure 1: Linear Regression - All Points



Parameter	Slope	Intercept	R^2	Range	n
HSV-2	1.0526	0.0364	0.9770	0 – 3.7	226

b. Matrix comparison:

Not applicable

3. Clinical studies:

a. Clinical Sensitivity:

No changes were made from the clearance of K152353

b. Clinical specificity:

No changes were made from the clearance of K152353

c. Other clinical supportive data (when a. and b. are not applicable):
No changes were made from the clearance of K152353

4. Clinical cut-off**:**

Not applicable

5. Expected values/Reference range:

No changes were made from the clearance of K152353

N. Instrument Name:

ChemWell Automated Analyzer

O. System Descriptions:

1. Modes of Operation:

   Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?

   Yes __X____ or No _____

   Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?

   Yes _____ or No ___X_____

2. Software:

   FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

   Yes ___X____ or No _____

3. Specimen Identification:

   No changes were made from the clearance of K152353

4. Specimen Sampling and Handling:

   The ChemWell Automated Analyzer method is designed to be equivalent to the manual test method. All reagents, controls, calibrators, and critical procedural steps of the test are identical. The end user should select, the HSV Type 2 IgG assay and the patients on the user interface of the ChemWell automated analyzer and load all reagents and samples according to on-screen instructions. After reviewing all reagents have been loaded correctly, the user should press 'Start' to begin the automation of HSV Type 2 IgG assay.

   The ChemWell Automatic Analyzer conducts a 1:51 dilution for each control and sample to the plate followed by 30 minutes incubation. Each strip will be automatically washed using the wash buffer. Conjugate will be added followed by 30 minutes incubation and a wash cycle. Substrate will be added followed by 30 minutes incubation, the addition of Stop Reagent, and read at 405nm.

5. Calibration:

   No changes were made from the clearance of K152353

6. Quality Control:

No changes were made from the clearance of K152353

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:

Not applicable

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

R. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.