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NOV 3 0 2006

Establishment Registration No. 9617857

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Summary Date November 29, 2006

Propriety Name Spectral West Nile Virus IgM STATus™ Test

Generic Name Rapid 1 WNV IgM Test

Classification West Nile Virus Serological Reagents
21 CFR § 866.3940
Class II

Predicate Device Focus West Nile Virus IgM Capture ELISA (K031952)

Device Description

A Simple and Rapid Immunoassay for the Qualitative Detection of West Nile Virus IgM Antibodies in Human Serum or Plasma

Intended Use

The Spectral West Nile virus IgM STATus™ test is a rapid immunochromatographic lateral flow assay that utilizes recombinant West Nile virus (WNV) antigen (E protein) for the qualitative detection of IgM antibodies to WNV in human serum or plasma (sodium heparin or sodium citrate). This test is for the presumptive laboratory diagnosis of West Nile virus infection in patients having signs and symptoms of meningoencephalitis. Positive results must be confirmed by the PRNT (Plaque Neutralization Reduction Test), or by using the current CDC guidelines for diagnosis of this disease. The Spectral test is not intended for point of care testing, home use or in screening blood donor samples.

Test Principle:
The Spectral WNV IgM STATus™ test (henceforth referred to as the Spectral device) employs solid-phase immunochromatographic assay technology to qualitatively detect the presence of WNV IgM antibodies in serum or plasma. When the specimen to be tested is dispensed into the sample well of the Spectral device, anti-WNV IgM in the sample will bind to the recombinant WNV antigen (envelop glycoprotein (E) of West Nile virus, NY99 strain) to form a tertiary complex with gold-labeled monoclonal murine antibody against flavivirus family glycoprotein E. This tertiary complex will migrate through reaction strip and be captured by goat anti-human IgM antibodies at the Test area. Excess, unreacted gold complex detector is captured by immobilized anti-mouse IgG antibodies at the Control area.

A visible pinkish-purple horizontal band will appear in the Test area within 15 minutes following the addition of a sample if the level of the WNV IgM antibodies in the human serum sample is above the cut-off level. A pinkish-purple band in the Control area indicates that the test is working properly and such a band must always appear, irrespective of the WNV IgM levels, in order for the test to be valid.

Result Interpretation: Spectral WNV IgM STATus™ device

Test band	**Control band**	**WNV IgM STATus Result**
Band absent	Band present	**Negative**
Band present	Band present	**Positive***
Band present	Band absent	**Invalid Test****
Band absent	Band absent	**Invalid Test****

* Consider West Nile Virus infection: WNV IgM levels are at or above the cut-off level.
** Invalid test. Test must be repeated with a new Spectral WNV IgM STATus™ device.

Expected Results:
Serum specimens from a total of 346 presumably healthy individuals (n=67) or non-WNV ailments (n=279) including 61 febrile patients were tested with the Spectral WNV IgM STATus™ test (henceforth referred to as the Spectral device) in a general population from endemic regions of USA and Canada. The samples were about equally distributed between male (47.1%) and female (52.9%) populations. Positive results were observed and determined to be positive due to heterophile antibodies interferences.

Prevalence of WNV IgM and Efficacy of Spectral Device in Endemic Population

Age (Years)	Negative	Positive	% Positive
0 to 9	0	0	0.0% (0/0)
10 to 19	8	0	0.0% (0/8)
20 to 29	39	1	2.5% (1/40)
30 to 39	56	1	1.7% (1/57)
40 to 49	53	1	1.8% (1/54)
50 to 59	56	0	0.0% (0/55)
60 to 69	49	1	2.0% (1/50)
70 to 79	39	1	2.5% (1/40)
80+	41	0	0.0% (0/41)
Overall	**341**	**5**	**1.4% (5/346)**

Performance Characteristics:

Reproducibility:

Reproducibility studies were performed using 15 patient serum samples at 3 study sites over a three day period. Each day a new lot was used and a different operator was employed. The 15 member reproducibility panel consisted of 6 clinical specimens with a mean index value 25% above the cutoff, 6 clinical specimens with a mean index value 15% below the cutoff, and 3 clinical specimens with a mean index value 6 times the cutoff level of a commercially available WNV IgM Capture ELISA device (comparator device). All sites and operators produced the expected result for all panel members on every day of testing.

Method Comparison

Study sites 1-3: Negative agreement of Spectral device with comparator in non-flavivirus IgM samples:

Studies were performed at three sites on clinical serum specimens collected prospectively from patients with a variety of non-flavivirus ailments (rash, febrile, bronchitis, diarrhea, drug, neuropathy, acute coronary syndrome etc) and from endemic normal populations either at emergency departments of hospitals or at in-house collection. Site 1 represents an endemic region at the South-Western State of America; sites 2 and 3 represent endemic regions of South Eastern Provinces of Canada. These specimens were tested at individual sites concomitantly with the Spectral and a commercially available comparator device. The results are tabulated as "Pos" (positive), or "Neg" (negative). Indeterminate results produced by the comparator device are listed as equivocal ("Eqv")

Study Site 1: Negative agreement of Spectral device with comparator in non-flavivirus IgM samples (n=160).

		Comparator device			
		Pos	Eqv	Neg	Total
Spectral Device	Pos	0	0	1**	1
	Neg	0	2*	157	159*
	Total	0	2	158	160

Negative agreement with the comparator device = 157/158* 99.4% 96.5-99.9% (95% CI)

*Note: Two specimens that produced equivocal results with the comparator device were determined to have interference from crossreacting antibodies.

**One Spectral false positive result was observed and determined to be due to interference from crossreacting antibodies

Study Site 2: Negative agreement of Spectral device with comparator in non-flavivirus IgM samples (n=114).

		Comparator device			
		Pos	Eqv	Neg	Total
Spectral Device	Pos	0	0	2*	2
	Neg	0	-	112	112
	Total	0	0	114	114

Negative agreement with the comparator device = 112/114 98.2% 93.8-99.8% (95% CI)

*Two Spectral false positive results were observed and determined to be due to interference from crossreacting antibodies

Study Site 3: Negative agreement of Spectral device with comparator in non-flavivirus IgM samples (n=72).

		Comparator device			
		Pos	Eqv	Neg	Total
Spectral Device	Pos	1*	0	1	2**
	Neg	0	0	70	70
	Total	1	0	71	72

Negative agreement with the comparator device = 70/71 98.6% 92.4-99.9% (95% CI)

*False positive due to cross reacting antibodies, as the sample remained positive with both devices when antigen was removed.

**Two Spectral false positive results were observed and determined to be due to interference from crossreacting antibodies.

All Sites (1-3): Negative agreement of Spectral device with comparator in non-flavivirus IgM samples **(n= 346)**

		Comparator device			
		Pos	Eqv	Neg	Total
Spectral Device	Pos	1*	0	4	5***
	Neg	0	2**	339	341*
	Total	1	2	343	346
Negative agreement with the comparator device = (95% CI)		339/343	98.8%	97.1-99.7%	

*False positive due to cross reacting antibodies (e.g. RF & heterophiles), as the sample remained positive with both devices when antigen was removed.

**Two specimens that produced equivocal results with the comparator device were determined to have interference from crossreacting antibodies.

***Five Spectral false positive results were observed and determined to be due to interference from crossreacting antibodies

Study Site 4: A provincial health laboratory located at South Eastern Province of Canada assessed the performance of the Spectral device with randomized retrospective patient serum specimens (n=90) that were sent to the laboratory with suspected WNV infection based on clinical signs and symptoms. This batch of samples constituted 40 WNV PRNT confirmed and 50 CDC WNV IgM ELISA negative specimens. All specimens were randomized and tested blinded with the Spectral device.

Results Study Site 4: Spectral WNV IgM STATus™ test reactivity with WNV PRNT Positive/CDC WNV IgM ELISA positive and CDC WNV IgM ELISA negative specimens

Specimen Characterized by Reference Assays	**Spectral WNV IgM STATus™ Results**				
	Pos	**Neg**	**Total**	**Pos or Neg Agreement**	**95%CI**
Serological sensitivity (CDC WNV IgM and IgG ELISA Positive and WNV PRNT Positive), n=40	38	2	40	95%	83.1%-99.4%
Negative Agreement with presumptive CDC WNV IgM ELISA Negative, n=50	2	48	50	96%	86.3%-99.5%

Study Site 5:

Spectral device reactivity was assessed at a public health laboratory located in a prairie Province at Central Canada using a banked panel of clinical serum specimens that were drawn from patients (n=79) with clinical symptomlogy consistent with the West Nile virus infection. These samples also included symptomatic acutely infected patients (PRNT confirmed, n= 24) exhibiting either febrile illness or neuro-invasive disease such as meningoencephalitis (n=5) and, others specimens from asymptomatic patients (n=25) that were sent to the

laboratory to detect previous West Nile virus exposures. All these samples were then randomized, blinded and tested with the Spectral device.

Results Study Site 5: Spectral WNV IgM STATus™ test reactivity with WNV PRNT Positive/CDC WNV IgM Elisa positive and CDC WNV IgM Elisa negative specimens

Specimen Characterized by Reference Assays	Spectral WNV IgM STATus™ Results				
	Pos	Neg	Total	Pos or Neg Agreement	95%CI
Serological sensitivity for acute PRNT Pos, CDC WNV IgM & IgG Elisa Pos (n=24)	24	0	24	100%	88.3%-100%
Serological sensitivity for late PRNT Pos, CDC WNV IgM & IgG Elisa Pos (n=25)	20	5	25	80%	59.3%-93.2%
Negative agreement with presumptive CDC WNV IgM Elisa Neg (n=30)	1	29	30	97%	82.8%-99.9%

Interfering Substances

The following constituents of human blood were tested to ensure that they did not interfere with the performance of the Spectral device. The concentration of the serum proteins or lipids shown in Table below were added to positive and negative serum specimens and tested with the Spectral device. No interference up to the concentrations listed below was observed.

Potential Interferents and Concentrations

Potential Interfering material	Concentration
Human serum albumin	16 g/dL
Bilirubin (unconj.)	60 mg/dL
Hemoglobin	25 g/dL
Triglycerides	1.3 g/dL
Human IgM	300 mg/dL

IgM Specificity:

The IgM specificity of the Spectral WNV IgM test was assessed in 14 paired positive samples by treating with 5mM dithiothreitol (DTT) solution for one hr at room temperature (22-24°C). All 14 treated samples produced negative results following the treatment with DTT and their respective untreated paired samples remained positive, indicating the presence of IgM class antibodies in the positive samples (9).

Cross Reactivity:
Cross- reactivity studies with sera that were sero-positive to other potentially cross-reactive pathogens were conducted at a Public Health Laboratory in the North Eastern USA (site 1). Three out of seven Dengue post infection samples were tested at Public Health Laboratory at Mid-West Canada (site 3); 29 out of 33 RF positive sera and 23 out of 28 ANA positive sera were tested in-house (site 2). Cross reactivity with Eastern Equine Encephalitis specimens was studied at a CDC laboratory at Mid-West USA (site 4). Results of these studies are tabulated below.

Results: Cross Reactivity Results

Potentially Cross-Reactive Agents	**Spectral WNV IgM STATus™ test Results**				
	Site	**Number of Samples**	**Negative**	**Positive**	**% Cross-Reactive Samples**
Herpes Simplex Virus 1 and/or 2	1	10	9	1	10%
Cytomegalovirus Polyvalent Test, all reactive	1	5	5	0	0%
Syphilis (trep Reactive)	1	10	10	0	0%
Epstein Barr Virus, IgG and IgM reactive	1	5	5	0	0%
ANA (anti-nuclear antibody)	1,2	28	17	11	39%
Rheumatoid Factor	1,2	33	23	10	30%
HIV(human immunodeficiency virus)	1	5	4	1	20%
Japanese Encephalitis Virus (vaccine recipients) IgM/IgG reactive,(CDC)	1	5	5	0	0%
Saint Louis Encephalitis Virus. SLE IgM (4/5) and IgG (5/5) reactive, CDC	1	5	5	0	0%
Dengue Virus (5 recent and 2 post infection)- DEN IgM & IgG	1,3	10	9	1	10%

reactive, CDC					
Hepatitis B Virus (HbsAg)	1	5	5	0	0%
Hepatitis C Virus (HCAb)	1	5	5	0	0%
California Encephalitis PRNT reactive as JC or LAX	1	6	6	0	0%
Legionella, Polyvalent Test, all reactive	1	5	5	0	0%
Yellow Fever (vaccine recipients)	1	5	4	1	20%
E. coli infection (culture confirmed)	2	4	4	0	0%
Eastern Equine Encephalitis	4	2	2	0	0%

Summary

The existing WNV IgM tests marketed in North America are all ELISA based tests (e.g. Focus Diagnostics West Nile Virus IgM Capture ELISA, InBios' West Nile Detect™ IgM Capture ELISA, Panbio WNV IgM capture ELISA, etc). These assays are multi-step procedures that require instrumentation to read the tests, need subsequent calculation for the interpretation of the test results and take more than 4 hours to complete. Spectral WNV IgM STATus™ test, described here is a rapid format test that produces the results visibly in 15 minutes and is shown to be substantially equivalent to the commercially available device. Data presented above describes the assay performance characteristics and, safety and effectiveness of the Spectral rapid format device.

Conclusion:

The *Spectral WNV IgM STATus™ test* is a safe and effective device for the qualitative determination of WNV IgM antibodies in human serum and plasma as proven through performance characteristics and methods comparison with the predicate device and confirmed through the testing of both normal and clinical samples.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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NOV 3 0 2006

Re: k052519
Trade/Device Name: Spectral West Nile Virus IgM STATus™ Test
Regulation Number: 21 CFR 866.3940
Regulation Name: West Nile Virus Serological Reagents
Regulatory Class: Class II
Product Code: NOP
Dated: November 10, 2006
Received: November 14, 2006

Dear Dr. Shaikh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

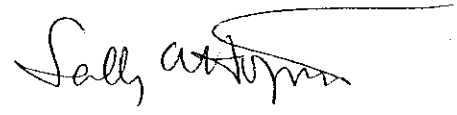
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240)276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K052519

Device Name: Spectral WNV IgM STATus™ test

Indications for Use:

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Prescription Use ___X____ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K052519