24th June 2003

Document Mail Center, ODE, (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

FDA/CDRH/ODE/DMC
2003 JUL -3 A 11:13

Re: Request for Evaluation of Automatic Class III Designation

Dear Sir / Madam,

PANBIO wishes to request an Evaluation of Automatic Class III Designation in accordance with section 513(f)(2) of the CFR, for the following device:

Device Name: West Nile Virus IgM Capture ELISA
Device 510k: K031703
Current Classification: Automatic Class III (no predicate device available)

PANBIO wishes to communicate via email. We understand that this mode of communication is not completely secure, however, acknowledge that the Food and Drug Administration will try to ensure confidentiality.

Yours Sincerely,

Carl Stubbings
Senior Vice President for

Kate Wersin
Regulatory Affairs Officer

PANBIO Limited
116 Lutwyche Road, Windsor
Brisbane, Queensland, 4030, Australia
Enc.

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REQUEST FOR EVALUATION OF AUTOMATIC CLASS III DESIGNATION

In accordance with section 513(f)(2) of the Act

Device 510(k) – K031703
Device Name: West Nile Virus IgM Capture ELISA

Request for Evaluation of Automatic Class III Designation

PANBIO wishes to request an evaluation of automatic class III designation for the West Nile Virus IgM Capture ELISA.

This is a new device with a class III designation under the statute. There is no predicate device to which substantial equivalence may be claimed. The 510(k) submission was received at the FDA Document Mail Center on 2nd June 2003, and allocated the 510(k) reference number, K031703.

In consideration of the data presented in the 510(k) submission, K031703, submitted 2nd June 2003, and the listed benefits and risks of the device outlined in this document, PANBIO wishes to request a classification downgrade to class II with special controls as yet to be determined.

The potential benefits of the device when used as intended are as follows:

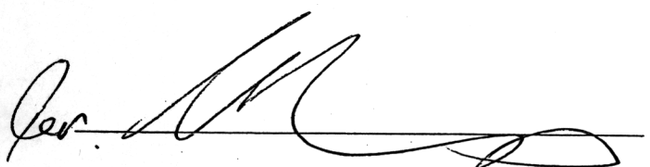
1. There is no current marketed device available in the United States for the detection of IgM antibodies to West Nile virus.
2. The spread of West Nile virus is considered a public health risk in the United States.
3. This device can be used to assist in the differential diagnosis of patients presenting with symptoms of encephalitis.

PANBIO considers the West Nile Virus IgM Capture ELISA to be a low-risk device when used as intended due to the following:

1. This device is used for the presumptive detection of IgM antibodies to West Nile virus in serum of patients presenting with symptoms of encephalitis. It is recommended in the instructions for use that any positive results should be confirmed by PRNT or, alternatively, consult the current CDC guidelines for diagnosis.
2. This device requires end-users to be competent, trained staff located at clinical laboratories.
3. This device is non-sterile and does not require sterile conditions for operation.
4. The antigen is a purified, whole-virus preparation from strain # NY99 that has been rendered non-infectious by formalin treatment.
5. The human control serum is tested by FDA approved methods and certified for the absence of antibody to HIV 1 and 2, Hepatitis C, as well as Hepatitis B surface antigen.
6. Refer to section 2.0 "Performance Characteristics" of the 510(k) Submission K031730 for further information on points 4 and 5 above.

This device is not exempt from a premarket review under section 510(k). Design controls are applicable for this device.

The "Summary of Safety and Effectiveness" for this device is detailed in the following pages.



Helen Jennings, VP, Quality and Regulatory Affairs
PANBIO Limited
24th June, 2003

1.10 10(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is:

Applicant Information:

Submission Date:	30th May, 2003
Name:	PANBIO Limited
Address:	116 Lutwyche Road, Windsor Queensland 4030 Australia
Contact Person:	Helen Jennings
Phone Number:	+61-(0)7-3357-1177
Fax Number:	+61-(0)7-3357-1222

Device Information:

Trade Name:	West Nile Virus IgM Capture ELISA
Common Name:	West Nile Virus IgM Capture EIA Test
Classification Name:	None allocated.

Equivalent Device:
No marketed EIA device is currently available for West Nile virus IgM detection. The West Nile Virus IgM Capture ELISA is similar in intended use to the Epstein-Barr Virus IgM ELISA in that both assays use the ELISA methodology and detect IgM antibodies in patient serum. A description of the Epstein-Barr Virus IgM ELISA methodology is found in the package insert in section 1.6.

Device Description:
The West Nile Virus IgM Capture ELISA is an Enzyme Linked Immunosorbent Assay for the qualitative detection of IgM antibodies to West Nile virus in patients with symptoms of encephalitis.

Intended Use:
The West Nile Virus IgM Capture ELISA is for the qualitative detection of IgM antibodies to West Nile virus in serum as an aid in the clinical laboratory diagnosis of West Nile virus infection in patients with clinical symptoms consistent with encephalitis. The PANBIO West Nile Virus IgM Capture ELISA should be used in conjunction with other West Nile virus serology.

Principle of Procedure:
Serum antibodies of the IgM class, when present, combine with anti-human IgM antibodies attached to the polystyrene surface of the microwell test strips (assay plate). Antigen reconstitution buffer is added to the antigen vial containing lyophilised West Nile virus antigen. An equal volume of the HRP conjugated monoclonal antibody (Mab) is added to the reconstituted antigen, which allows the formation of antigen-Mab complexes. Residual serum is removed from the assay plate by washing, and complexed antigen-Mab is added to the assay plate. After incubation, the microwells are washed and a colourless substrate system, tetramethylbenzidine/hydrogen peroxide (TMB/H_2O_2) is added. The substrate is hydrolysed by the enzyme and the chromogen changes to a blue colour. After stopping the

reaction with acid, the TMB becomes yellow. Colour development is indicative of the presence of West Nile virus antibodies in the test sample.

PERFORMANCE CHARACTERISTICS

Study Site 1:

This study consisted of 335 retrospective sera of various ages and genders tested by Louisiana Department of Health and Hospitals. The sera includes samples from the following groups: 100 samples characterized as positive for West Nile virus by PRNT, 200 randomly selected normal specimens from routine laboratory testing which do not have a flavivirus related illness, 25 samples confirmed positive for Saint Louis encephalitis by PRNT, 9 samples characterized positive for California encephalitis by IFA and 1 sample confirmed positive for Eastern Equine encephalitis by PRNT. These samples were tested on the PANBIO West Nile Virus IgM Capture ELISA assay and the results were compared to the clinical and serological characterization of the samples to determine performance of the assay. The data is summarized in Tables 1 and 2.

TABLE 1

Louisiana Department of Health and Hospitals, LA
Specimen Analysis and the
PANBIO West Nile Virus IgM Capture ELISA

	PANBIO ELISA			
Clinical Characterisation	**Positive**	**Negative**	**Equivocal**	**Total**
West Nile virus Positive (PRNT confirmed)	99	0	1 [a]	100
Endemic Normal Specimens (randomly selected) [b]	19	177	4 [a]	200
Total	118	177	5	300

[a] *These specimens were repeated in duplicate and remained equivocal on the PANBIO ELISA.*

[b] *Uncharacterised, randomly selected normal specimens from routine laboratory testing from 2002-2003. Not known to have a flavivirus related illness.*

			95% Confidence Interval
West Nile virus Positive Specimens			
Serological Sensitivity	= 99/100	99.0%	94.5 – 100.0%
Endemic Normal Specimens			
Clinical specificity	= 177/200	88.5%	84.1 – 92.9%

TABLE 2

Cross-reactivity Analysis of the PANBIO West Nile Virus IgM Capture ELISA

Disease (characterization)	Total Specimens	PANBIO ELISA P or E Result [c]
Saint Louis encephalitis Positive, West Nile virus Negative (PRNT confirmed)	25	4/25
California encephalitis Positive (IgG IFA, Negative remaining arboviral panel [d])	9	0/9
Eastern Equine encephalitis Positive (IgG/IgM IFA, PRNT confirmed)	1	0/1
Total	**35**	**4/35**

[c] *P = Positive, E = Equivocal. Equivocal specimens were repeated in duplicate and remained equivocal on the PANBIO ELISA.*

[d] *Subclinical IgG positive for California encephalitis and negative for remaining IgG/IgM arboviral panel (Western & Eastern Equine encephalitis viruses, California and Flavivirus group (SLE & WN viruses))*

Results indicate that four characterized positive SLE specimens (4/25) were positive on the PANBIO West Nile virus IgM Capture ELISA. All other characterized positive SLE, CE and EEE specimens were negative on the PANBIO West Nile Virus IgM Capture ELISA.

Study Site 2:

This study consisted of 348 retrospective sera of various ages and genders tested by ARUP Laboratories. The sera includes samples form the following groups: 29 samples with symptoms of encephalitis characterized positive for West Nile virus (WNV) by PRNT and/or CDC MAC EIA for WNV, 22 samples characterized as positive for WNV by PRNT and CDC MAC EIA for WNV, 16 samples characterized as positive for WNV by CDC MAC EIA for WNV, 3 samples characterized as negative by CDC MAC EIA for WNV, 144 samples characterized as IgM positive for WNV by IFA slides (ASR), 145 samples characterized IgM negative for WNV by IFA slides (ASR), 15 samples characterized as IgM positive for Dengue by IgM Capture EIA (ASR) and 1 sample characterized as positive for Jamestown Canyon virus by PRNT. These samples were tested by the PANBIO West Nile Virus IgM Capture ELISA and the results were compared to the clinical and serological characterization of the samples to determine the performance of the assay. The data is summarized in Tables 3, 4 and 5.

TABLE 3

ARUP Laboratories

Patients Presenting with Clinical Symptoms of Encephalitis (and Positive to PRNT and/or CDC MAC EIA) and the PANBIO West Nile Virus IgM Capture ELISA

		PANBIO ELISA			
Symptoms of Encephalitis (with PRNT and/or CDC MAC EIA)	**Result**	**Positive**	**Negative**	**Equivocal**	**Total**
Total	P	26	2	1 [a]	29

[a] *This specimen was repeated in duplicate and remained equivocal on the PANBIO ELISA.*

			95% Confidence Interval
Encephalitic symptoms (and PRNT and/or CDC MAC EIA)			
Serological Sensitivity	= 26/29	89.7%	72.7 – 97.8%

TABLE 4

ARUP Laboratories

Specimen Characterisation and the
PANBIO West Nile Virus IgM Capture ELISA

Clinical Characterisation	Result	PANBIO ELISA Positive	Negative	Equivocal	Total
West Nile virus positive (Confirmed by CDC MAC EIA / PRNT)	P	19	2	1 [a]	22
West Nile virus positive (Presumptive by CDC MAC EIA)	P	15	1	0	16
West Nile virus negative (Presumptive by CDC MAC EIA)	N (P/N [b])	0 (0)	3 (2)	0 (0)	3 (2)
West Nile Virus positive (Presumptive by PANBIO IgM IFA ASR slides)	P	141	3	0	144
West Nile Virus negative (Presumptive by PANBIO IgM IFA ASR slides)	N	9	135	1 [a]	145
Total		184	144	2	330

[a] *These specimens were repeated in duplicate and remained equivocal on the PANBIO ELISA.*
[b] *Specimens with a presumptive CDC MAC EIA of "P/N" were uninterpretable and were therefore excluded from the calculations.*

			95% Confidence Interval
West Nile virus (Confirmed)			
Serological Sensitivity	= 19/22	86.4%	65.1 – 97.1%
West Nile virus (Presumptive)			
Serological Sensitivity	= 15/16	93.8%	69.8 – 99.8%
Serological Specificity	= 3/3	100.0%	29.2 – 100.0%
Serological Agreement	= 18/19	94.7%	74.0 – 99.9%
West Nile virus IFA (Presumptive)			
Serological Sensitivity	= 141/144	97.9%	94.0- 99.6%
Serological Specificity	= 135/145	93.1%	87.7 – 96.6%
Serological Agreement	= 276/289	95.5%	92.4 – 97.6%

TABLE 5

ARUP Laboratories

Cross-reactivity Analysis of the
PANBIO West Nile Virus IgM Capture ELISA

Disease (characterization)	Total Specimens	PANBIO ELISA P or E Result[c]
Dengue virus Positive (EIA IgM Capture, Focus Technologies)	15	4/15
Jamestown Canyon virus Positive (PRNT confirmed)	1	0/1
Total	**16**	**4/16**

[c] *P = Positive, E = Equivocal. Equivocal specimens were repeated in duplicate and remained equivocal on the PANBIO ELISA.*

Results indicate that four characterized positive Dengue specimens (4/15) were positive on the PANBIO West Nile Virus IgM Capture ELISA. All other characterized positive Dengue specimens and the Jamestown Canyon virus specimen were negative on the PANBIO West Nile Virus IgM Capture ELISA.

Study Site 3:

This study consisted of 324 retrospective sera of various ages and genders tested by the Children's Hospital, Columbus. The sera included samples from 77 patients with symptoms of encephalitis and West Nile virus (WNV) antibodies confirmed by PRNT and/or CDC MAC EIA for WNV, 199 samples with no symptoms of encephalitis, 52 samples characterized as WNV positive by PRNT, 32 samples characterized as IgM positive for WNV by the CDC MAC EIA for WNV, and 26 samples characterized as positive for LaCrosse virus by IgG IFA. These samples were tested on the PANBIO West Nile Virus IgM Capture ELISA and the results were compared to the clinical and serological characterization of the samples to determine the performance of the assay. The data is summarized in Tables 6,7 and 8.

TABLE 6

Children's Hospital, Columbus, OH

Patients Presenting with Clinical Symptoms of Encephalitis (and Positive to PRNT and/or CDC MAC EIA) and the PANBIO West Nile Virus IgM Capture ELISA

		PANBIO ELISA			
Clinical Category	**Result**	**Positive**	**Negative**	**Equivocal**	**Total**
Symptoms of Encephalitis (with PRNT and/or CDC MAC EIA)	P	77	0	0	77
Endemic Normal specimens (without symptoms of encephalitis)	N	10	187	2 [a]	199
Total		87	187	2	276

[a] *These specimens were repeated in duplicate and remained equivocal on the PANBIO ELISA.*

			95% Confidence Interval
Encephalitic symptoms (and PRNT and/or CDC MAC EIA)			
Clinical Sensitivity	= 77/77	100.0%	95.3 – 100.0%
Endemic Normal specimens (without symptoms of encephalitis)			
Clinical Specificity	= 187/199	94.0%	89.7 – 96.8%
Relative Agreement	**= 264/276**	**95.7%**	**92.5 – 97.7%**

TABLE 7

Children's Hospital, Columbus, OH

Specimen Characterisation and the PANBIO West Nile Virus IgM Capture ELISA

		PANBIO ELISA			
Clinical Characterisation	**Result**	**Positive**	**Negative**	**Equivocal**	**Total**
West Nile virus (Confirmed) by PRNT	P	52	0	0	52
West Nile virus (Presumptive) by CDC MAC EIA	P	32	0	0	32
Total		84	0	0	84

			95% Confidence Interval
West Nile virus (Confirmed)			
Serological Sensitivity	= 52/52	100.0%	93.2 – 100.0%
West Nile virus (Presumptive)			
Serological Sensitivity	= 32/32	100.0%	89.1 – 100.0%

TABLE 8

Children's Hospital, Columbus, OH

Cross-reactivity Analysis of the PANBIO West Nile Virus IgM Capture ELISA

Disease (characterization)	**Total Specimens**	**PANBIO ELISA P or E Result [b]**
La Crosse virus Positive (IFA IgG, Focus Technologies) [c]	26	1/26

[b] *P = Positive, E = Equivocal. Equivocal specimens were repeated in duplicate and remained equivocal on the PANBIO ELISA.*

[c] *Nine of 26 specimens were confirmed positive for La Crosse encephalitis by identification of a four-fold rise in IgG antibody titre in the convalescent sample.*

Results indicate that one characterized positive La Crosse encephalitis specimen (1/26) was positive on the PANBIO West Nile Virus IgM Capture ELISA.

REPRODUCIBILITY

Study Sites 3, 4 & 5:

The reproducibility of the PANBIO West Nile Virus IgM Capture ELISA kit was determined by testing 8 sera 3 times each on 3 different assays at one Australian study site and two study sites in the USA. Study Site 3 was the Children's Hospital in Columbus, Ohio and Study Site 4 was Labcorp/Viromed and Study Site 5 is PANBIO Limited (Australia). Within-run, between day, between site and total precision were estimated by Analysis of Variance (ANOVA Type II). The results are presented in Table 9 below.

TABLE 9

Children's Hospital, Columbus, OH, Labcorp / Viromed, PANBIO Limited

PANBIO West Nile Virus IgM Capture ELISA

Precision Measures – ANOVA Type II (Using Cut-Off Ratio*)

			Within		Between Day		Between Site		Total	
Sample	n	*Mean	*S.D	CV	*S.D	CV	*S.D	CV	*S.D	CV
Cut-off	27	1.00	0.04	4.3%	0.00	0.0%	0.00	0.0%	0.04	3.9%
#1	27	3.76	0.19	5.0%	0.09	2.4%	0.28	7.5%	0.31	8.2%
#2	27	3.79	0.18	4.7%	0.00	0.0%	0.26	7.0%	0.28	7.4%
#3	27	3.65	0.17	4.6%	0.06	1.8%	0.28	7.7%	0.29	8.0%
#4	27	0.93	0.05	5.0%	0.03	3.0%	0.00	0.3%	0.05	5.6%
#5	27	1.41	0.10	6.9%	0.00	0.0%	0.08	5.3%	0.11	8.0%
#6	27	2.26	0.13	5.6%	0.00	0.0%	0.19	8.6%	0.21	9.1%
#7	27	0.83	0.05	5.7%	0.00	0.0%	0.02	2.0%	0.05	5.8%
#8	27	1.03	0.06	5.4%	0.02	2.1%	0.04	4.3%	0.07	6.7%

Site 3: Three days of triplicates
Site 4: Three days of triplicates
Site 5: Three days of triplicates

All values are calculated from Ratios (Cut-off using O.D)
SD = Standard Deviation; CV = Coefficient of Variation (%)

Note: Standard Deviation results have been rounded to two decimal places for tabulation purposes.

*Cut-off Ratio is calculated as the Absorbance of the Sample divided by the Mean Absorbance of the Cut-off.

POTENTIAL CROSS-REACTIVITY

Study Site 5:

This study consisted of a panel of 133 specimens from patients with confirmed diseases other than West Nile virus (WNV). The purpose of this study is to establish the analytical specificity of the PANBIO West Nile Virus IgM Capture ELISA through the analysis of specimens from patients with diseases that have the potential for cross-reactivity. Each of the specimens included in the study was characterized with respect to disease state prior to the analysis of the specimens with the PANBIO West Nile Virus IgM Capture ELISA. Table 10 below provides a summary of specimens in the disease panel presented in Table 11 (next page):

TABLE 10
Cross-reactivity Analysis of the
PANBIO West Nile Virus IgM Capture ELISA

Disease (IgM Antibodies)	Total Specimens	CDC MAC ELISA P or U Result [a]	PANBIO ELISA P or E Result [b]
La Crosse encephalitis	10	1/10	1/10
Saint Louis encephalitis	10	9/10	2/10
Rheumatoid Factor	10	3/10	0/10
Anti-Nuclear Antibody	10	0/10	0/10
Hepatitis A	11	1/11	1/11
Epstein-Barr virus	15	1/15	1/15
Dengue virus	16	14/16	4/16
Cytomegalovirus	9	0/9	0/9
Varicella zoster	10	0/10	0/10
Ross River Virus	26	2/26	3/26
Enterovirus	6	0/6	2/6
Total	**133**	**31/133**	**14/133**

Results indicate that nine specimens (14/133) were positive on the PANBIO West Nile Virus IgM Capture ELISA against presumptive negative specimens to West Nile virus. Thirty-one specimens (31/133) were positive on the CDC MAC ELISA reference method.

[a] CDC MAC ELISA positive (P) or uninterpretable (U) result
[b] PANBIO ELISA positive (P) or equivocal (E) result.

POTENTIAL CROSS-REACTIVITY

Study Site 5:

This study consisted of a panel of 133 specimens from patients with confirmed diseases other than West Nile virus (WNV). The purpose of this study is to establish the analytical specificity of the PANBIO West Nile Virus IgM Capture ELISA through the analysis of specimens from patients with diseases that have the potential for cross-reactivity. Each of the specimens included in the study was characterized with respect to disease state prior to the analysis of the specimens with the PANBIO West Nile Virus IgM Capture ELISA. Table 10 below provides a summary of specimens in the disease panel presented in Table 11 (next page):

TABLE 10
Cross-reactivity Analysis of the
PANBIO West Nile Virus IgM Capture ELISA

Disease (IgM Antibodies)	Total Specimens	CDC MAC ELISA P or U Result [a]	PANBIO ELISA P or E Result [b]
La Crosse encephalitis	10	1/10	1/10
Saint Louis encephalitis	10	9/10	2/10
Rheumatoid Factor	10	3/10	0/10
Anti-Nuclear Antibody	10	0/10	0/10
Hepatitis A	11	1/11	1/11
Epstein-Barr virus	15	1/15	1/15
Dengue virus	16	14/16	4/16
Cytomegalovirus	9	0/9	0/9
Varicella zoster	10	0/10	0/10
Ross River Virus	26	2/26	3/26
Enterovirus	6	0/6	2/6
Total	**133**	**31/133**	**14/133**

Results indicate that nine specimens (14/133) were positive on the PANBIO West Nile Virus IgM Capture ELISA against presumptive negative specimens to West Nile virus. Thirty-one specimens (31/133) were positive on the CDC MAC ELISA reference method.

[a] CDC MAC ELISA positive (P) or uninterpretable (U) result
[b] PANBIO ELISA positive (P) or equivocal (E) result.

TABLE 11
Cross-reactivity Analysis of the PANBIO West Nile Virus IgM Capture ELISA

Sample	IgM Antibody Type	CDC MAC ELISA Result Lot EB100.091 (Expiry 05Apr03)	PANBIO EIA Result E-WNV01M #03077 (2004/02)	
		Result	PANBIO Index	Result
1	La Crosse IgM	P	0.79	N
2	La Crosse IgM	N	0.54	N
3	La Crosse IgM	N	0.65	N
4	La Crosse IgM	N	0.68	N
5	La Crosse IgM	N	0.43	N
6	La Crosse IgM	N	0.51	N
7	La Crosse IgM	N	1.11	P
8	La Crosse IgM	N	0.46	N
9	La Crosse IgM	N	0.48	N
10	La Crosse IgM	N	0.72	N
11	SLE IgM	P	0.59	N
12	SLE IgM	P	1.35	P
13	SLE IgM	P	0.42	N
14	SLE IgM	P	0.89	N
15	SLE IgM	P	0.52	N
16	SLE IgM	P	0.58	N
17	SLE IgM	P	1.00	E
18	SLE IgM	P	0.80	N
19	SLE IgM	P	0.69	N
20	SLE IgM	N	0.48	N
21	RF	N	0.22	N
22	RF	Uninterpretable	0.50	N
23	RF	N	0.35	N
24	RF	N	0.42	N
25	RF	N	0.43	N
26	RF	Uninterpretable	0.34	N
27	RF	N	0.30	N
28	RF	Uninterpretable	0.55	N
29	RF	N	0.34	N
30	RF	N	0.30	N

INTERPRETATION

ELISA	Positive = P	Equivocal	Negative = N
PANBIO Index	> 1.1	0.9 – 1.1	< 0.9

Sample	IgM Antibody Type	CDC MAC ELISA Result Lot EB100.091 (Expiry 05Apr03)	PANBIO EIA Result E-WNV01M #03077 (2004/02)	
		Result	PANBIO Index	Result
67	Dengue IgM	P	0.59	N
68	Dengue IgM	P	1.80	P
69	Dengue IgM	P	0.62	N
70	Dengue IgM	P	0.54	N
71	Dengue IgM	P	0.50	N
72	Dengue IgM	P	0.49	N
73	Dengue IgM	N	1.38	P
74	Dengue IgM	P	0.55	N
75	Dengue IgM	P	0.53	N
76	Dengue IgM	P	0.55	N
77	Dengue IgM	P	0.69	N
78	Dengue IgM	P	1.12	P
79	Dengue IgM	N	0.59	N
80	Dengue IgM	P	0.98	E
81	Dengue IgM	P	0.57	N
82	Dengue IgM	P	0.51	N
83	CMV IgM	N	0.46	N
84	CMV IgM	N	0.52	N
85	CMV IgM	N	0.29	N
86	CMV IgM	N	0.31	N
87	CMV IgM	N	0.51	N
88	CMV IgM	N	0.43	N
89	CMV IgM	N	0.76	N
90	CMV IgM	N	0.52	N
91	CMV IgM	N	0.60	N
92	VZV IgM	N	0.45	N
93	VZV IgM	N	0.43	N
94	VZV IgM	N	0.72	N
95	VZV IgM	N	0.37	N
96	VZV IgM	N	0.25	N
97	VZV IgM	N	0.64	N
98	VZV IgM	N	0.50	N
99	VZV IgM	N	0.70	N
100	VZV IgM	N	0.33	N
101	VZV IgM	N	0.65	N

TABLE 11 - continued

Sample	IgM Antibody Type	CDC MAC ELISA Result Lot EB100.091 (Expiry 05Apr03)	PANBIO EIA Result E-WNV01M #03077 (2004/02)	
		Result	PANBIO Index	Result
102	RRV IgM	N	0.44	N
103	RRV IgM	N	0.96	E
104	RRV IgM	N	0.46	N
105	RRV IgM	N	0.34	N
106	RRV IgM	N	0.39	N
107	RRV IgM	N	0.32	N
108	RRV IgM	N	0.42	N
109	RRV IgM	N	0.36	N
110	RRV IgM	N	0.40	N
111	RRV IgM	N	0.39	N
112	RRV IgM	N	0.24	N
113	RRV IgM	N	2.54	P
114	RRV IgM	N	0.27	N
115	RRV IgM	N	0.26	N
116	RRV IgM	N	0.44	N
117	RRV IgM	N	0.38	N
118	RRV IgM	P	1.08	E
119	RRV IgM	N	0.27	N
120	RRV IgM	N	0.29	N
121	RRV IgM	N	0.26	N
122	RRV IgM	P	0.27	N
123	RRV IgM	N	0.24	N
124	RRV IgM	N	0.38	N
125	RRV IgM	N	0.60	N
126	RRV IgM	N	0.40	N
127	RRV IgM	N	0.37	N
128	EV IgM	N	0.46	N
129	EV IgM	N	2.04	P
130	EV IgM	N	0.75	N
131	EV IgM	N	0.66	N
132	EV IgM	N	0.48	N
133	EV IgM	N	0.99	E