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1.9 510(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: **K041068**

Applicant Information:

Submission Date:	21st April, 2004
Date Modified:	15th October, 2004
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Device Information:

Trade Name:	West Nile Virus IgG Indirect ELISA
Common Name:	West Nile Virus IgG Indirect EIA Test
Classification Name:	West Nile virus, serological reagents (21 CFR 866.3940).

Equivalent Device:

No marketed EIA device was available at the time that performance studies were conducted. Equivalence shall be demonstrated through gold standard test reference methods. The West Nile Virus IgG Indirect ELISA is a new device that falls under the FDA's classification name "West Nile virus, serological reagents" (21 CFR 866.3940).

Device Description:

The PANBIO West Nile Virus IgG Indirect ELISA is for the qualitative detection of IgG antibodies to West Nile virus in serum. In conjunction with the PANBIO West Nile Virus IgM Capture ELISA, this test is intended as an aid in the presumptive laboratory diagnosis of West Nile virus infection in patients with clinical symptoms consistent with encephalitis / meningitis.

Intended Use:

The PANBIO West Nile Virus IgG Indirect ELISA is for the qualitative presumptive detection of IgG antibodies to West Nile virus in serum. In conjunction with the PANBIO West Nile Virus IgM Capture ELISA, this test is intended as an aid in the clinical laboratory diagnosis of West Nile virus infection in patients with clinical symptoms consistent with encephalitis / meningitis. Positive results must be confirmed by Plaque Reduction Neutralization Test (PRNT), or by using the current Centers for Disease Control and Prevention (CDC) guidelines for diagnosis of this disease.

Assay performance characteristics have not been established for testing cord blood, neonate, prenatal screening, general population screening without symptoms of meningioencephalitis or automated instruments. The user is responsible for establishing these assay performance characteristics.

Principle of Procedure:

Serum antibodies combine with purified and inactivated WNV antigen coated on the polystyrene surface of the microwell test strips (assay plate). Residual serum is removed from the assay plate by washing. HRP-conjugated anti-human IgG monoclonal antibody (Mab) is added to the assay plate. After incubation, the microwells are washed and a colorless substrate system, tetramethylbenzidine/hydrogen peroxide (TMB/H_2O_2), is added. The substrate is hydrolyzed by the HRP, if present, and the chromogen changes to a blue color. After stopping the reaction with acid, the TMB becomes yellow. Color development is indicative of the presence of WNV antibodies in the test sample.

PERFORMANCE CHARACTERISTICS

Study Site 1:

Three hundred (300) retrospective sera from individuals of various ages and both genders were tested at a state health laboratory in Louisiana, USA. The sera include samples from the following groups: 100 samples characterised as positive for WN virus by PRNT and 200 randomly selected normal specimens from routine laboratory testing not known to have a flavivirus related illness. These samples were masked and tested on the PANBIO West Nile Virus IgG Indirect ELISA and the results were compared to the clinical and serological characterisation of the samples to determine performance of the assay. The data is summarised in Table 1.

Table 1 – Study Site 1
PANBIO West Nile Virus IgG Indirect ELISA Reactivity with Endemic Normal and WNV PRNT Confirmed Specimens

Specimen Characterisation	PANBIO IgG ELISA Results			
	Pos	Eqv [a]	Neg	Total
Endemic normal specimens (randomly selected) [b]	18 [d]	1	181	200
West Nile virus Positive [c] (PRNT confirmed)	79	0	21 [e]	100
Total	97	1	202	**300**

[a] *Retesting of equivocals was not conducted as samples were unavailable.*
[b] *Randomly selected normal specimens from routine laboratory testing from 2002-2003. Not known to have a flavivirus related illness. Further tested by WNV IgG IFA.*
[c] *West Nile virus PRNT positive. Collected in 2002. Further tested by WNV IgG IFA.*
[d] *Nine of the 18 endemic specimens that were positive by PANBIO ELISA were also positive by IgG IFA. Refer to note below.*
[e] *Ten of the 21 PRNT confirmed positive specimens that were negative by PANBIO ELISA were negative by IgG IFA and positive by PANBIO WNV IgM Capture ELISA.*

			95% Confidence Interval
Endemic normal specimens			
Negative presumptive agreement	= 181/200	90.5%	85.6 – 94.2%
Adjusted specificity [f]	= 191/201	95.0%	91.0 – 97.6%
West Nile virus positive specimens			
Serological sensitivity (PRNT)	= 79/100	79.0%	69.7 – 86.5%
Adjusted sensitivity [f]	= 88/99	88.9%	81.0 – 94.3%

[f] *Adjusted specificity and sensitivity calculations have been presented to reflect the presumptive redefinition of the specimens identified in [d] and [e] above.*
Adjusted specificity: (9 endemic / IgG IFA positive specimens excluded and 10 PRNT positive / IgM ELISA positive / IgG IFA negative specimens included).
Adjusted sensitivity: (9 endemic / IgG IFA positive specimens included and 10 PRNT positive / IgM ELISA positive / IgG IFA negative specimens excluded).

Study Site 2:
Three hundred and twenty-five (325) retrospective sera from individuals of various ages and both genders were tested at a private reference laboratory in Utah, USA. The serum panel was comprised of 166 samples that were characterized positive and 159 samples that were characterized negative for WNV by IFA slides (ASR). Thirty-four of these samples were from patients with clinical symptoms consistent with encephalitis / meningitis, of which 32 were characterized positive and 2 were characterized negative for WNV by IFA. The samples were not masked and were tested by the PANBIO West Nile Virus IgG Indirect ELISA. Assay performance was determined by comparing PANBIO West Nile Virus IgG Indirect ELISA results with the clinical and serological characterization of the samples. The data is summarised in Table 2 and Table 3.

Table 2 – Study Site 2
PANBIO West Nile Virus IgG Indirect ELISA Reactivity with Encephalitis / Meningitis Patients

Specimen Characterization	PANBIO IgG ELISA Results			
	Pos	Eqv [a]	Neg	Total
Encephalitis/ meningitis patients (IgG IFA positive)	26	2	4	32
Encephalitis/meningitis patients (IgG IFA negative)	0	0	2	2
Total	26	2	6	34

[a] *Retesting of equivocals was not conducted as cut-off was modified following clinical trials.*

			95% Confidence Interval
Encephalitic symptoms (IgG IFA positive)			
Positive Presumptive Agreement	= 26/32	81.3%	63.6 – 92.8%
WNV (presumptive by (IgG IFA negative))			
Negative Presumptive Agreement	=2/2	100.0%	15.8 – 100.0%

Table 3 – Study Site 2
PANBIO West Nile Virus IgG Indirect ELISA Reactivity with WNV IFA Characterized Specimens

Specimen Characterization	PANBIO IgG ELISA Results			
	Pos	Eqv [a]	Neg	Total
WNV positive (IgG IFA positive)	146	5	15	166
WNV negative (IgG IFA negative)	15	4	140	159
Total	161	9	155	325

[a] *Retesting of equivocals was not conducted as cut-off was modified following clinical trials.*

			95% Confidence Interval
WNV IFA positive (presumptive)			
Positive Presumptive Agreement	= 286/325	88.0%	84.5 – 91.5%
Negative Presumptive Agreement	= 140/159	88.1%	83.0 – 93.1%

Study Site 3:

Two-hundred and eighty-four (284) retrospective sera collected in 2002 from individuals of various ages and both genders were tested at a hospital laboratory in Ohio, USA. The sera included specimens from 89 patients with symptoms of encephalitis / meningitis (51 samples were confirmed positive for WN virus by PRNT and positive for IFA, and 38 samples were positive by IFA), and 195 randomly selected normal specimens from routine laboratory testing, negative for WN virus by IFA. These samples were masked and tested on the PANBIO West Nile Virus IgG Indirect ELISA and the results were compared to the clinical and serological characterisation of the samples to determine the performance of the assay. The data is summarised in Table 4.

Table 4 – Study Site 3
PANBIO West Nile Virus IgG Indirect ELISA Reactivity with Endemic Normal and Encephalitis / Meningitis Patients

Specimen Characterization	PANBIO IgG ELISA Results			
	Pos	Eqv [a]	Neg	Total
Endemic normal specimens (randomly selected / IgG IFA negative) [b]	10	5	180	195
Encephalitis/meningitis patients (PRNT positive & IgG IFA positive) [c]	41	1	9	51
Encephalitis/meningitis patients (IgG IFA positive) [c]	29	2	7	38
Total	80	8	196	284

[a] *Retesting of equivocals was not conducted as cut-off was modified following clinical trials.*
[b] *Endemic randomly selected specimens not known to have an arbovirus infection. All specimens (n=195) further tested negative by PANBIO WNV IgG IFA ASR.*
[c] *Encephalitis/meningitis patients. Specimens collected in 2002. Fifty-one samples were tested by WNV PRNT. All specimens (n=89) further tested positive by PANBIO WNV IgG IFA ASR.*

			95% Confidence Interval
Endemic normal specimens			
Negative Presumptive Agreement	= 180/195	92.3%	87.6 – 95.6%
Encephalitis/meningitis patients			
Clinical sensitivity (PRNT)	= 41/51	80.4%	66.9 – 90.2%
Positive Presumptive Agreement	= 29/38	76.3%	59.8 – 88.6%

REPRODUCIBILITY

The reproducibility of the PANBIO West Nile Virus IgG Indirect ELISA 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. Within-run, between day, between site and total precision were estimated by Analysis of Variance (ANOVA) Type II. The results are presented in Table 5 below.

Table 5 – Reproducibility Data
PANBIO West Nile Virus IgG Indirect ELISA
Precision Measures – ANOVA Type II (Using Cut-Off Ratio*)

Sample	n	*Mean	Within		Between Day		Between Site		Total	
			*SD	CV	*SD	CV	*SD	CV	*SD	CV
Reactive	27	5.83	0.25	4.3%	0.00	0.0%	0.00	0.0%	0.24	4.2%
Negative	27	0.19	0.02	8.8%	0.00	0.0%	0.08	45.5%	0.07	38.8%
#1	27	2.24	0.16	7.0%	0.12	5.1%	1.08	48.3%	0.92	41.0%
#2	27	2.94	0.20	6.9%	0.16	5.5%	0.13	4.3%	0.26	9.0%
#3	27	4.07	0.32	7.9%	0.00	0.0%	0.52	12.8%	0.53	13.1%
#4	27	1.48	0.11	7.7%	0.11	7.6%	0.08	5.6%	0.16	11.0%
#5	27	1.53	0.06	4.2%	0.06	3.9%	0.18	11.9%	0.17	11.2%
#6	27	1.23	0.09	7.4%	0.03	2.3%	0.16	13.3%	0.17	13.5%
#7	27	0.82	0.05	6.2%	0.02	1.9%	0.13	16.0%	0.12	14.8%
#8	27	0.84	0.07	7.9%	0.00	0.0%	0.12	14.7%	0.12	14.4%

All values are calculated from Ratios *
SD = Standard Deviation; CV = Coefficient of Variation (%)

Notes:
- *Standard deviation results have been rounded to two decimal places for tabulation purposes.*
- *The cut-off ratio * is calculated by dividing the sample absorbance by the cut-off value. The cut-off value is calculated by multiplying the average absorbance of the triplicates of the calibrator by the calibration factor. The calibrator cannot be calculated as a true cut-off ratio and therefore has been excluded from this analysis.*

CROSS REACTIVITY

This study consisted of a panel of 314 specimens from patients with confirmed diseases other than WNV. The purpose of this study was to establish the analytical specificity of the PANBIO West Nile Virus IgG Indirect 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 characterised with respect to disease state prior to analysis of the specimens with the PANBIO West Nile Virus IgG Indirect ELISA. Table 6 below provides a summary of specimens in the disease panel outlined in Table 7.

Table 6 – Summary of Cross-reactivity Analysis
PANBIO West Nile Virus IgG Indirect ELISA

Disease State	Total Specimens[a]	PANBIO IgG ELISA Results		
		Pos	Eqv	Pos and Eqv
Dengue virus	15	14	0	14/15
St. Louis encephalitis	35	25	3	28/35
Japanese encephalitis	3	3	0	3/3
La Crosse encephalitis	26	2	0	2/26
California encephalitis	11	0	1	1/11
Eastern Equine encephalitis	1	0	0	0/1
Varicella-Zoster virus	15	0	0	0/15
Cytomegalovirus	48	7	0	7/48
Epstein-Barr virus	40	7	0	7/40
Enterovirus	15	1	0	1/15
Ross River virus	39	10	1	11/39[b]
Barmah Forest virus	36	10	3	13/36[c]
Rheumatoid Factor	15	4	0	4/15
Anti-Nuclear Antibody	15	2	0	2/15

[a] *Sample testing was conducted at PANBIO (Site 5) except as follows:*
Site 1: Testing on 25 Saint Louis encephalitis, 9 California encephalitis and 1 Eastern Equine encephalitis specimens was conducted at a state health laboratory in Louisiana, USA.
Site 2: Testing on 5 Dengue virus, 10 Saint Louis encephalitis and 2 California encephalitis specimens was conducted at a private reference laboratory in Utah, USA.
Site 3: Testing on 26 La Crosse encephalitis specimens was conducted at a hospital laboratory in Ohio, USA.
Site 6: Testing on 25 Epstein-Barr virus and 33 Cytomegalovirus specimens was conducted at a private research laboratory in Maryland, USA.

[b] *11 of 11 samples that were reactive on PANBIO West Nile virus IgG Indirect ELISA were confirmed flavivirus positive by Western blot.*

[c] *9 of 13 samples that were reactive on PANBIO West Nile virus IgG Indirect ELISA were confirmed flavivirus positive by Western blot.*

Table 7 – Results of Cross-reactivity Analysis
PANBIO West Nile Virus IgG Indirect ELISA

Sample	Site *	IgG Antibody Type	PANBIO E-WNV01G ELISA Result	
			Units	Result
1	2	Dengue virus	25.6	P
2	2	Dengue virus	100.3	P
3	2	Dengue virus	5.1	N
4	2	Dengue virus	102.3	P
5	2	Dengue virus	82.7	P
6	5	Dengue virus	96.1	P
7	5	Dengue virus	103.6	P
8	5	Dengue virus	105.7	P
9	5	Dengue virus	114.7	P
10	5	Dengue virus	126.7	P
11	5	Dengue virus	102.5	P
12	5	Dengue virus	123.5	P
13	5	Dengue virus	116.6	P
14	5	Dengue virus	112.3	P
15	5	Dengue virus	118.6	P
16	1	Saint Louis encephalitis	15.6	E
17	1	Saint Louis encephalitis	21.4	P
18	1	Saint Louis encephalitis	4.2	N
19	1	Saint Louis encephalitis	8.7	N
20	1	Saint Louis encephalitis	18.2	P
21	1	Saint Louis encephalitis	28.9	P
22	1	Saint Louis encephalitis	35.9	P
23	1	Saint Louis encephalitis	40.5	P
24	1	Saint Louis encephalitis	1.2	N
25	1	Saint Louis encephalitis	28.2	P
26	1	Saint Louis encephalitis	7.8	N
27	1	Saint Louis encephalitis	27.0	P
28	1	Saint Louis encephalitis	47.8	P
29	1	Saint Louis encephalitis	43.0	P
30	1	Saint Louis encephalitis	57.2	P
31	1	Saint Louis encephalitis	47.9	P
32	1	Saint Louis encephalitis	29.4	P
33	1	Saint Louis encephalitis	31.0	P
34	1	Saint Louis encephalitis	16.5	P
35	1	Saint Louis encephalitis	43.1	P
36	1	Saint Louis encephalitis	68.5	P
37	1	Saint Louis encephalitis	59.5	P
38	1	Saint Louis encephalitis	10.0	N

Table 7 – Results of Cross-reactivity Analysis – Continued

Sample	Site *	IgG Antibody Type	PANBIO E-WNV01G ELISA Result	
			Units	Result
39	1	Saint Louis encephalitis	13.4	N
40	1	Saint Louis encephalitis	54.6	P
41	2	Saint Louis encephalitis	15.4	E
42	2	Saint Louis encephalitis	15.7	E
43	2	Saint Louis encephalitis	41.6	P
44	2	Saint Louis encephalitis	6.0	N
45	2	Saint Louis encephalitis	73.6	P
46	2	Saint Louis encephalitis	32.6	P
47	2	Saint Louis encephalitis	79.1	P
48	2	Saint Louis encephalitis	62.8	P
49	2	Saint Louis encephalitis	32.8	P
50	2	Saint Louis encephalitis	25.3	P
51	5	Japanese encephalitis	66.0	P
52	5	Japanese encephalitis	41.6	P
53	5	Japanese encephalitis	103.9	P
54	3	La Crosse encephalitis	2.1	N
55	3	La Crosse encephalitis	1.8	N
56	3	La Crosse encephalitis	3.6	N
57	3	La Crosse encephalitis	2.1	N
58	3	La Crosse encephalitis	16.5	P
59	3	La Crosse encephalitis	4.4	N
60	3	La Crosse encephalitis	5.8	N
61	3	La Crosse encephalitis	2.5	N
62	3	La Crosse encephalitis	1.9	N
63	3	La Crosse encephalitis	3.2	N
64	3	La Crosse encephalitis	2.2	N
65	3	La Crosse encephalitis	2.2	N
66	3	La Crosse encephalitis	2.8	N
67	3	La Crosse encephalitis	2.2	N
68	3	La Crosse encephalitis	1.3	N
69	3	La Crosse encephalitis	3	N
70	3	La Crosse encephalitis	5.5	N
71	3	La Crosse encephalitis	6.4	N
72	3	La Crosse encephalitis	3.6	N
73	3	La Crosse encephalitis	3.6	N
74	3	La Crosse encephalitis	13.2	N
75	3	La Crosse encephalitis	1.7	N
76	3	La Crosse encephalitis	5.4	N

Table 7 – Results of Cross-reactivity Analysis – Continued

Sample	Site *	IgG Antibody Type	PANBIO E-WNV01G ELISA Result	
			Units	Result
77	3	La Crosse encephalitis	2.5	N
78	3	La Crosse encephalitis	6	N
79	3	La Crosse encephalitis	16.8	P
80	1	California encephalitis	6.1	N
81	1	California encephalitis	11.5	N
82	1	California encephalitis	14.1	E
83	1	California encephalitis	1.5	N
84	1	California encephalitis	5.4	N
85	1	California encephalitis	8.5	N
86	1	California encephalitis	6.2	N
87	1	California encephalitis	4	N
88	1	California encephalitis	4.7	N
89	2	California encephalitis	13.2	N
90	2	California encephalitis	4.4	N
91	1	Eastern Equine enceph.	3.6	N
92	5	Varicella-Zoster virus	3.7	N
93	5	Varicella-Zoster virus	2.4	N
94	5	Varicella-Zoster virus	5.7	N
95	5	Varicella-Zoster virus	5.3	N
96	5	Varicella-Zoster virus	3.8	N
97	5	Varicella-Zoster virus	7.7	N
98	5	Varicella-Zoster virus	2.6	N
99	5	Varicella-Zoster virus	3.8	N
100	5	Varicella-Zoster virus	10.0	N
101	5	Varicella-Zoster virus	1.2	N
102	5	Varicella-Zoster virus	2.2	N
103	5	Varicella-Zoster virus	2.5	N
104	5	Varicella-Zoster virus	6.7	N
105	5	Varicella-Zoster virus	2.6	N
106	5	Varicella-Zoster virus	3.9	N
107	5	Cytomegalovirus	4.6	N
108	5	Cytomegalovirus	1.5	N
109	5	Cytomegalovirus	1.9	N
110	5	Cytomegalovirus	1.8	N
111	5	Cytomegalovirus	16.7	P
112	5	Cytomegalovirus	4.4	N
113	5	Cytomegalovirus	1.9	N
114	5	Cytomegalovirus	44.5	P

Table 7 – Results of Cross-reactivity Analysis – Continued

Sample	Site *	IgG Antibody Type	PANBIO E-WNV01G ELISA Result	
			Units	Result
115	5	Cytomegalovirus	69.4	P
116	5	Cytomegalovirus	5.2	N
117	5	Cytomegalovirus	3.8	N
118	5	Cytomegalovirus	46.9	P
119	5	Cytomegalovirus	16.2	P
120	5	Cytomegalovirus	3.3	N
121	5	Cytomegalovirus	31.0	P
122	6	Cytomegalovirus	11.9	N
123	6	Cytomegalovirus	0.5	N
124	6	Cytomegalovirus	0.3	N
125	6	Cytomegalovirus	3.7	N
126	6	Cytomegalovirus	1.3	N
127	6	Cytomegalovirus	0.6	N
128	6	Cytomegalovirus	2.9	N
129	6	Cytomegalovirus	1.1	N
130	6	Cytomegalovirus	2.1	N
131	6	Cytomegalovirus	4.4	N
132	6	Cytomegalovirus	4.1	N
133	6	Cytomegalovirus	1.4	N
134	6	Cytomegalovirus	0.4	N
135	6	Cytomegalovirus	7.8	N
136	6	Cytomegalovirus	4.9	N
137	6	Cytomegalovirus	11.6	N
138	6	Cytomegalovirus	20.4	P
139	6	Cytomegalovirus	7.5	N
140	6	Cytomegalovirus	0.8	N
141	6	Cytomegalovirus	2.2	N
142	6	Cytomegalovirus	12.1	N
143	6	Cytomegalovirus	4.4	N
144	6	Cytomegalovirus	9.8	N
145	6	Cytomegalovirus	1.3	N
146	6	Cytomegalovirus	0.5	N
147	6	Cytomegalovirus	2.8	N
148	6	Cytomegalovirus	1.3	N
149	6	Cytomegalovirus	1.7	N
150	6	Cytomegalovirus	0.4	N
151	6	Cytomegalovirus	5.5	N
152	6	Cytomegalovirus	3.4	N

Table 7 – Results of Cross-reactivity Analysis – Continued

Sample	Site *	IgG Antibody Type	PANBIO E-WNV01G ELISA Result	
			Units	Result
153	6	Cytomegalovirus	0.6	N
154	6	Cytomegalovirus	6.2	N
155	5	Epstein-Barr virus	3.3	N
156	5	Epstein-Barr virus	2.0	N
157	5	Epstein-Barr virus	3.8	N
158	5	Epstein-Barr virus	2.4	N
159	5	Epstein-Barr virus	18.0	P
160	5	Epstein-Barr virus	5.5	N
161	5	Epstein-Barr virus	1.9	N
162	5	Epstein-Barr virus	19.9	P
163	5	Epstein-Barr virus	2.3	N
164	5	Epstein-Barr virus	6.7	N
165	5	Epstein-Barr virus	3.4	N
166	5	Epstein-Barr virus	17.9	P
167	5	Epstein-Barr virus	6.6	N
168	5	Epstein-Barr virus	134.2	P
169	5	Epstein-Barr virus	3.2	N
170	6	Epstein-Barr virus	10.2	N
171	6	Epstein-Barr virus	4.6	N
172	6	Epstein-Barr virus	5.8	N
173	6	Epstein-Barr virus	5.8	N
174	6	Epstein-Barr virus	17.4	P
175	6	Epstein-Barr virus	7.4	N
176	6	Epstein-Barr virus	5.1	N
177	6	Epstein-Barr virus	5.5	N
178	6	Epstein-Barr virus	29.0	P
179	6	Epstein-Barr virus	6.5	N
180	6	Epstein-Barr virus	5.6	N
181	6	Epstein-Barr virus	3.4	N
182	6	Epstein-Barr virus	4.0	N
183	6	Epstein-Barr virus	1.9	N
184	6	Epstein-Barr virus	50.0	P
185	6	Epstein-Barr virus	2.8	N
186	6	Epstein-Barr virus	12.3	N
187	6	Epstein-Barr virus	6.0	N
188	6	Epstein-Barr virus	8.9	N
189	6	Epstein-Barr virus	2.0	N
190	6	Epstein-Barr virus	3.3	N

Table 7 – Results of Cross-reactivity Analysis – Continued

Sample	Site *	IgG Antibody Type	PANBIO E-WNV01G ELISA Result	
			Units	Result
191	6	Epstein-Barr virus	12.3	N
192	6	Epstein-Barr virus	13.9	N
193	6	Epstein-Barr virus	4.8	N
194	6	Epstein-Barr virus	6.0	N
195	5	Enterovirus	2.6	N
196	5	Enterovirus	7.0	N
197	5	Enterovirus	1.3	N
198	5	Enterovirus	4.7	N
199	5	Enterovirus	1.7	N
200	5	Enterovirus	6.1	N
201	5	Enterovirus	2.9	N
202	5	Enterovirus	1.8	N
203	5	Enterovirus	2.6	N
204	5	Enterovirus	1.2	N
205	5	Enterovirus	1.6	N
206	5	Enterovirus	3.5	N
207	5	Enterovirus	17.7	P
208	5	Enterovirus	2.8	N
209	5	Enterovirus	8.5	N
210	5	Ross River virus	95.8	P[a]
211	5	Ross River virus	12.5	N
212	5	Ross River virus	22.6	P[a]
213	5	Ross River virus	4.3	N
214	5	Ross River virus	8.6	N
215	5	Ross River virus	3.2	N
216	5	Ross River virus	6.2	N
217	5	Ross River virus	5.8	N
218	5	Ross River virus	30.4	P[a]
219	5	Ross River virus	7.3	N
220	5	Ross River virus	3.0	N
221	5	Ross River virus	4.4	N
222	5	Ross River virus	17.9	P[a]
223	5	Ross River virus	12.7	N
224	5	Ross River virus	4.9	N
225	5	Ross River virus	19.7	P[a]
226	5	Ross River virus	5.6	N
227	5	Ross River virus	5.0	N
228	5	Ross River virus	7.1	N

Table 7 – Results of Cross-reactivity Analysis – Continued

Sample	Site *	IgG Antibody Type	PANBIO E-WNV01G ELISA Result	
			Units	Result
229	5	Ross River virus	38.9	P[a]
230	5	Ross River virus	12.3	N
231	5	Ross River virus	6.5	N
232	5	Ross River virus	15.8	E[a]
233	5	Ross River virus	9.3	N
234	5	Ross River virus	16.3	P[a]
235	5	Ross River virus	12.6	N
236	5	Ross River virus	6.1	N
237	5	Ross River virus	4.8	N
238	5	Ross River virus	5.4	N
239	5	Ross River virus	8.1	N
240	5	Ross River virus	7.1	N
241	5	Ross River virus	16.1	P[a]
242	5	Ross River virus	8.1	N
243	5	Ross River virus	7.9	N
244	5	Ross River virus	6.8	N
245	5	Ross River virus	60.8	P[a]
246	5	Ross River virus	10.1	N
247	5	Ross River virus	6.9	N
248	5	Ross River virus	17.5	P[a]
249	5	Barmah forest virus	5.9	N
250	5	Barmah forest virus	8.1	N
251	5	Barmah forest virus	15.7	E[a]
252	5	Barmah forest virus	9.7	N
253	5	Barmah forest virus	11.6	N
254	5	Barmah forest virus	5.8	N
255	5	Barmah forest virus	4.6	N
256	5	Barmah forest virus	4.9	N
257	5	Barmah forest virus	7.5	N
258	5	Barmah forest virus	2.5	N
259	5	Barmah forest virus	12.5	N
260	5	Barmah forest virus	34.9	P[a]
261	5	Barmah forest virus	8.0	N
262	5	Barmah forest virus	98.0	P[a]
263	5	Barmah forest virus	9.3	N
264	5	Barmah forest virus	10.9	N
265	5	Barmah forest virus	10.6	N
266	5	Barmah forest virus	8.8	N

Table 7 – Results of Cross-reactivity Analysis – Continued

Sample	Site *	IgG Antibody Type	PANBIO E-WNV01G ELISA Result	
			Units	Result
267	5	Barmah forest virus	55.2	P[a]
268	5	Barmah forest virus	6.4	N
269	5	Barmah forest virus	8.8	N
270	5	Barmah forest virus	8.8	N
271	5	Barmah forest virus	52.4	P[a]
272	5	Barmah forest virus	10.4	N
273	5	Barmah forest virus	19.5	P[a]
274	5	Barmah forest virus	6.2	N
275	5	Barmah forest virus	9.0	N
276	5	Barmah forest virus	5.5	N
277	5	Barmah forest virus	26.0	P
278	5	Barmah forest virus	27.6	P[a]
279	5	Barmah forest virus	14.2	E
280	5	Barmah forest virus	34.3	P
281	5	Barmah forest virus	6.2	N
282	5	Barmah forest virus	79.1	P[a]
283	5	Barmah forest virus	49.7	P
284	5	Barmah forest virus	14.4	E[a]
285	5	Rheumatoid Factor	16.3	P
286	5	Rheumatoid Factor	2.5	N
287	5	Rheumatoid Factor	6.4	N
288	5	Rheumatoid Factor	5.0	N
289	5	Rheumatoid Factor	21.3	P
290	5	Rheumatoid Factor	1.4	N
291	5	Rheumatoid Factor	3.6	N
292	5	Rheumatoid Factor	3.9	N
293	5	Rheumatoid Factor	7.1	N
294	5	Rheumatoid Factor	4.6	N
295	5	Rheumatoid Factor	45.2	P
296	5	Rheumatoid Factor	7.5	N
297	5	Rheumatoid Factor	36.5	P
298	5	Rheumatoid Factor	4.5	N
299	5	Rheumatoid Factor	4.5	N
300	5	Anti-Nuclear Antibody	2.88	N
301	5	Anti-Nuclear Antibody	1.94	N
302	5	Anti-Nuclear Antibody	1.28	N
303	5	Anti-Nuclear Antibody	7.04	N
304	5	Anti-Nuclear Antibody	4.07	N

Table 7 – Results of Cross-reactivity Analysis – Continued

Sample	Site *	IgG Antibody Type	PANBIO E-WNV01G ELISA Result	
			Units	Result
305	5	Anti-Nuclear Antibody	5.63	N
306	5	Anti-Nuclear Antibody	13.33	N
307	5	Anti-Nuclear Antibody	8.2	N
308	5	Anti-Nuclear Antibody	48.9	P
309	5	Anti-Nuclear Antibody	2.6	N
310	5	Anti-Nuclear Antibody	7.2	N
311	5	Anti-Nuclear Antibody	3.5	N
312	5	Anti-Nuclear Antibody	6.1	N
313	5	Anti-Nuclear Antibody	50.0	P
314	5	Anti-Nuclear Antibody	2.1	N

[a] *Flavivirus reactivity in these samples has been confirmed by Western blot analysis.*

INTERPRETATION

ELISA	Positive = P	Equivocal = E	Negative = N
PANBIO Units	> 16	14 – 16	< 14

* *Refer to summary table for explanation of sites.*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 2 0 2004

Ms. Jillianne Keller
Regulatory Affairs Officer
PANBIO Limited.
116 Lutwyche Road, Windsor
Brisbane, Queensland 4030
Australia

Re: k041068
Trade/Device Name: West Nile Virus IgG Indirect ELISA
Regulation Number: 21 CFR 866.3940
Regulation Name: West Nile Virus Serological Reagents
Regulatory Class: Class II
Product Code: NOP
Dated: September 17, 2004
Received: September 20, 2004

Dear Ms. Keller:

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 (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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

Indications for Use

20 October, 2004

510(k) Number (if known): K041068

Device Name: West Nile Virus IgG Indirect ELISA

Indications For Use:

The PANBIO West Nile Virus IgG Indirect ELISA is for the qualitative presumptive detection of IgG antibodies to West Nile virus in serum. In conjunction with the PANBIO West Nile Virus IgM Capture ELISA, this test is intended as an aid in the clinical laboratory diagnosis of West Nile virus infection in patients with clinical symptoms consistent with encephalitis / meningitis. Positive results must be confirmed by plaque reduction neutralization test (PRNT), or by using the current Centers for Disease Control and Prevention (CDC) guidelines for diagnosis of this disease.

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 Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K041068