JUN 1 3 2002

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: K020717

Applicant Information:

Date Prepared:	07th June, 2002
Name:	PANBIO Limited
Address:	116 Lutwyche Road Windsor 4030 Australia
Contact Person:	Helen Jennings
Phone Number.	61-(0)7-3357-1177
Fax Number.	61-(0)7-3357-1222

Device Information:

Trade Name:	EBV-VCA IgM ELISA Kit
Common Name.	EBV-VCA IgM EIA Test
Classification Name;	EBV-VCA IgM Serological Reagent

Equivalent Device:
DiaSorin Incstar EBV-VCA IgM ELISA

Device Description:
The EBV-VCA IgM ELISA Kit is an enzyme-linked immunosorbent assay (ELISA) for the detection of IgM antibodies to EBV-VCA antigen in human serum.

Intended Use:
The Epstein-Barr Viral Capsid Antigen (VCA) IgM ELISA Test is for the qualitative detection of IgM antibodies to EBV VCA in serum as an aid in the clinical laboratory diagnosis of EBV infection in patients with clinical symptoms consistent with infectious mononucleosis (IM). The PANBIO EBV VCA IgM ELISA should be used in conjunction with other EBV serology.

Principle of Procedure:
Serum containing antibodies to VCA antigen, when present, combine with EBV-VCA antigen, which is immunopurified utilising a monoclonal specific for gp125 and attached to the polystyrene surface of the microwells. Residual serum is removed by washing and peroxidase conjugated anti-human IgM is added. 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. Color development is indicative of the presence of EBV-VCA IgM antibodies in the test sample.

PERFORMANCE CHARACTERISTICS

Study Site 2:

156 frozen retrospective sera of various ages and genders were submitted to a state health lab in Maryland USA for EBV testing. The sera include samples from the following groups: 28 seronegative samples, 26 samples from patients with acute Infectious Mononucleosis, and 102 samples from patients with past exposure to EBV. These sera were tested on the PANBIO EBV-VCA IgM kit and EBV ELISA assays from an alternate manufacturer to determine the EBV status of the sera. The PANBIO EBV VCA IgM results were compared to the EBV status of the sera to determine the sensitivity, specificity, and agreement of the assay relative to the EBV serological status. The data is summarized in the Table 1.

TABLE 1
EBV VCA IgM Serological Sensitivity and Specificity of PANBIO ELISA versus EBV Status

	PANBIO ELISA			
EBV Status	**Positive**	**Equivocal***	**Negative**	**Total**
Seronegative VCA IgG (-) VCA IgM (-) EBNA IgG (-)	0	0	28	28
Acute VCA IgM (+) EBNA IgG (-)	26	0	0	26
Past Infection VCA IgG (+) VCA IgM (-) EBNA IgG (+)	5	5	92	102
Total	31	5	120	156

			95% Confidence Interval
Serological Sensitivity (Acute)	= 26/26	= 100 %	86.8 – 100 %
Serological Sensitivity (Past)	= 92/102	= 90.2 %	82.7 – 95.2 %
Serological Specificity (Negative)	= 28/28	= 100%	87.7 – 100 %
Serological Agreement	= 146/156	= 93.6 %	88.5 – 96.9 %

*Retesting of equivocal samples was not conducted, as the samples were unavailable.

Note: "Serological" sensitivity and specificity refers to the comparison of the PANBIO assay results to other assays normally used to diagnose EBV associated IM. There was not an attempt to correlate the assay's results with disease presence or absence. No judgement can be made on the comparison's accuracy to predict disease. Since the above studies were performed on a pre-selected, retrospective, population, no calculations for the assay's positive and negative predictive value may be done or inferred.

Study Site 3:

352 prospective sera of various ages and genders were submitted to a private pathology laboratory in Queensland Australia for EBV testing. The sera include samples from the following groups: 48 seronegative samples, 42 samples from patients with acute Infectious Mononucleosis, and 262 samples from patients with past exposure to EBV. These sera were tested on the PANBIO EBV-VCA IgM kit and EBV ELISA assays from an alternate manufacturer to determine the EBV status of the sera. The PANBIO VCA IgM results were compared to the EBV status of the sera to determine the sensitivity, specificity, and agreement of the assay relative to the EBV serological status. The data is summarized in Table 2.

TABLE 2
EBV-VCA IgM Serological Sensitivity and Specificity of PANBIO ELISA versus EBV Status

	PANBIO ELISA			
EBV Status	**Positive**	**Equivocal***	**Negative**	**Total**
Seronegative VCA IgG (-) VCA IgM (-) EBNA IgG (-)	5	1	42	48
Acute VCA IgM (+) EBNA IgG (-)	36	1	5	42
Past Infection VCA IgG (+) VCA IgM (-) EBNA IgG (+)	5	0	257	262
Total	46	2	304	352

			95% Confidence Interval
Serological Sensitivity (Acute)	= 36/42	= 85.7%	71.5 – 94.6%
Serological Specificity (Past)	= 257/262	= 98.1%	95.6 – 99.4%
Serological Specificity (Negative)	= 42/48	= 87.5%	74.7 – 95.3%
Serological Agreement	= 335/352	= 95.2%	92.4 – 97.2%

*These equivocal samples were not tested on an alternative method due to insufficient sample. Collection of a further sample was not possible.

REPRODUCIBILITY

The reproducibility of the PANBIO EBV-VCA IgM ELISA kit was determined by testing 8 sera 3 times each on three different days at three Australian study sites. Two sites were private pathology laboratories and the third site was PANBIO. Within-run, between day, between site and total precision were estimated by analysis of variance (ANOVA Type II) and are presented in table 3 below.

TABLE 3
REPRODUCIBILITY DATA
PANBIO EBV-VCA IgM Study Site 1, 2 & 3
Precision Measures (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**
Positive	27	2.38	0.17	6.9%	0.09	3.9%	0.01	0.4%	0.18	7.7%
Cut-off	27	1.00	0.05	5.2%	0.00	0.0%	0.00	0.0%	0.05	4.8%
Negative	27	0.10	0.02	15.5%	0.02	15.5%	0.01	9.4%	0.02	21.6%
#1	27	2.97	0.19	6.3%	0.23	7.8%	0.13	4.2%	0.29	9.7%
#2	27	3.20	0.19	5.9%	0.19	6.0%	0.06	1.9%	0.25	7.9%
#3	27	1.20	0.13	10.5%	0.13	10.9%	0.00	0.0%	0.16	13.6%
#4	27	1.28	0.06	5.0%	0.05	3.9%	0.06	4.8%	0.09	7.2%
#5	27	0.65	0.12	18.3%	0.05	8.1%	0.01	1.5%	0.13	19.5%
#6	27	0.95	0.08	8.8%	0.06	6.3%	0.00	0.0%	0.10	10.1%
#7	27	3.45	0.24	7.1%	0.32	9.1%	0.00	0.0%	0.35	10.2%
#8	27	1.37	0.27	19.8%	0.31	22.8%	0.10	7.4%	0.38	28.1%

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

POTENTIAL CROSS-REACTIVITY

Study Site 5:

A panel of 50 specimens from patients with confirmed diseases other than Epstein Barr Virus was tested to establish the analytical specificity of the EBV-VCA IgM ELISA Test. The specimens were 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 diagnosis prior to analysis with the EBV-VCA IgM ELISA Test. Table 4 lists a summary of the results.

TABLE 4

PANBIO EBV-VCA IgM CROSS-REACTIVITY SPECIMEN PANEL

Disease Type	Number of Specimens	Positive Result
Cytomegalovirus	9	(0/9)
Varicella zoster	10	(0/10)
Herpes simplex virus 1 & 2	8	(0/8)
Anti-Nuclear Antigen	14	(0/14)
Rheumatoid Factor	9	(0/9)
Total	**50**	**(0/50)**

Results indicate that no specimens (0/50) were positive when analysed with the EBV-VCA IgM ELISA Kit. Refer to 'Study Document – Site 5' for raw data and section 2.3.4.1 for the summary table.

The true negative result of 100% for the above disease panel is consistent with good analytical specificity for the EBV-VCA IgM ELISA Test.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 13 2002

Ms. Helen Jennings
Quality and Regulatory Affairs Manager
PANBIO Limited
116 Lutwyche Road
Windsor, Brisbane
Queensland, 4030
Australia

Re: k020717
Trade/Device Name: EBV Viral Capsid Antigen IgM ELISA Test
Regulation Number: 21 CFR 866.3235
Regulation Name: Epstein - Barr virus Serological Reagents
Regulatory Class: Class I
Product Code: GNP
Dated: May 9, 2002
Received: May 15, 2002

Dear Ms. Jennings:

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 the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 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 advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K020717

Device Name: EBV-VCA IgM ELISA

Indications For Use: The Epstein-Barr Viral Capsid Antigen (VCA) IgM ELISA Test is for the qualitative detection of IgM antibodies to EBV VCA in serum as an aid in the clinical laboratory diagnosis of EBV infection in patients with clinical symptoms consistent with infectious mononucleosis (IM). The PANBIO EBV VCA IgM ELISA should be used in conjunction with other EBV serology.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Woody Dubois

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K020717

PRESCRIPTION USE X

(Optional Format 3-10-98)