K980596

JUL 22 1998

Summary of Safety and Effectiveness Information
VCA IgM ELISA Test Kit

I. Trinity Biotech US
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Telephone: 716-483-3851
Date of preparation: Feb 11,1998

II. Description of Device

The Wampole Epstein-Barr Virus Viral Capsid Antigen (VCA) IgM kit is an Enzyme-Linked Immunosorbent Assays (ELISA) for the qualitative determination of IgM antibodies in human serum to VCA antigen. The Wampole anti-VCA IgM assay may be used in conjunction with other Epstein-Barr serologies (VCA IgG, EBNA-1 IgG, EA-D IgG, EBNA-1 IgM and heterophile) as an aid in the diagnosis of infectious mononucleosis.

For In Vitro Diagnostic Use Only.

The VCA IgM ELISA test is an enzyme linked immunosorbent assay to detect IgM antibodies to Epstein-Barr Viral Capsid antigen. Afinity purified gp125 VCA antigen is attached to a solid phase microtiter well. Diluted test sera is added to each well. If the antibodies are present that recognize the antigen, they will bind to the antigen in the well. After incubation the wells are washed to remove unbound antibody. An enzyme labeled anti-human IgM is added to each well. If antibody is present it will bind to the antibody attached to the antigen on the well. After incubation the wells are washed to remove unbound conjugate. A substrate solution is added to each well. If enzyme is present the substrate will undergo a color change. After an incubation period the reaction is stopped and the color intensity is measured photometrically, producing an indirect measurement of specific antibody in the patient specimen.

III. Predicate Device

The VCA IgM ELISA test is substantially equivalent to EBV serology. Equivalence is demonstrated by the following comparative results:

Performance Characteristics

1. Sensitivity and Specificity Based on Serum Characterization

One hundred and sixty six selected serum were tested at a clinical lab. The serum from the study were characterized as seronegative (no serological evidence of past or present EBV infection), acute (VCA IgM and heterophile antibody present, EBNA IgG absent), or seropositive (presence of VCA IgG antibodies and EBNA IgG, no evidence of VCA IgM or heterophile antibody, indicative of past infection). The sensitivity, specificity and agreement of the assay was determined based on this characterization. It was assumed that the VCA IgM response should be negative for seronegative, and convalescent serum, and positive for acute serum. The results are summarized in Table 1.

Table 1

		Acute VCA IgM+ EBNA IgG - Heterophile +	Seropositive VCA IgG+ EBNA IgG+ VCA IgM- Heterophile -	Seronegative VCA IgG- EBNA IgG - VCA IgM - Heterophile -
Wampole VCA IgM	Positive	37	1	1
	Equivocal	1	0	0
	Negative	1	98	27
	Total	39	99	28

Relative Sensitivity (Acute) = 37/38 = 97.4% 95% Confidence Interval = 92.2%-100%
Relative Specificity (Seronegative) = 27/28 = 96.4% 95% Confidence Interval = 89.4%-100%
Relative Specificity (Seropositive) = 98/99 = 99.0% 95% Confidence Interval = 97.0%-100%
Relative Agreement = 162/165 = 98.2% 95% Confidence Interval = 96.1%-100%

Equivocal results were not included in the calculations.
Equivocal results were not retested. They were reported as equivocal.
The 95% confidence intervals were calculated using the normal method.

2. Precision.

The Wampole VCA IgM EIA was evaluated for precision by testing six sera ten times each on three different days at two different sites. The results are summarized in the table below.

Inter Site Precision Data

Inter Site Precision (n=60)

Serum#	X	S.D.	C.V.
1	1.55	0.230	14.87%
2	1.55	0.172	11.11%
3	4.61	0.491	10.67%
4	3.09	0.389	12.59%
5	0.35	0.215	62.22%
6	0.04	0.039	94.67%
HPC*	3.23	0.480	14.90%
CAL**	2.00	0.110	5.49%
NC*	0.01	0.016	192.25%

X = Mean ISR Value
S.D. = Standard Deviation
C.V. = Coefficient of Variation

* HPC and NC n=6
** Cal n = 18

3. Cross-Reactivity. Sera containing IgM antibody detectable by ELISA to Herpes Simplex Virus I & II, Cytomegalovirus, and Varicella Zoster Virus were assayed. Sera containing rhuematoid factor (RF) were also assayed. The data summarized in Table 3 indicates that antibodies to Herpes Viruses and sera containing RF do not cross-react with the VCA IgM EIA kit.

Specificity	VCA IgM		Alternate Assay	
RF +	0.04	-	1.87	+
RF +	0.03	-	1.82	+
RF +	0.01	-	1.73	+
RF +	0.01	-	1.80	+
RF +	0.02	-	1.85	+
VZV M +	0.33	-	3.28	+
VZV M +	0.10	-	5.46	+
VZV M +	0.04	-	4.98	+
VZV M +	0.08	-	2.34	+
VZV M +	0.03	-	2.18	+
HSV 1 M +	0.02	-	2.53	+
HSV 1 M +	0.02	-	1.65	+
HSV 1 M +	0.01	-	1.34	+
HSV 1 M +	0.01	-	1.32	+
HSV 2 M +	0.06	-	1.76	+
HSV 2 M +	0.05	-	1.60	+
HSV 2 M +	0.03	-	2.09	+
HSV 2 M +	0.04	-	1.96	+
CMV M +	0.07	-	1.23	+
CMV M +	0.04	-	1.92	+
CMV M +	0.04	-	3.83	+
CMV M +	0.06	-	1.32	+

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 22 1998

CLARK LABORATORIES, INC.
c/o William L. Boteler, Jr.
IMMUNO PROBE, INC.
1306 Bailes Lane, Suite F
Frederick, MD 21701

Re: K980596
Trade Name: VCA IgM ELISA
Regulatory Class: II
Product Code: LSE
Dated: April 22, 1998
Received: April 30, 1998

Dear Mr. Boteler:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/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: K980596

Device Name: VCA IgM ELISA

Indications For Use: The Viral Capsid Antigen (VCA) IgM kit is an Enzyme-Linked Immunosorbent Assay (ELISA) for the qualitative determination of IgM antibodies in human serum to VCA antigen. The Clark anti-VCA IgM assay may be used in conjunction with other Epstein-Barr serologies (EA-D IgG, VCA IgG, EBNA-1 IgG, EBNA-1 IgM and heterophile) as an aid in the diagnosis of infectious mononucleosis in the adult population.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The Counter Use____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K980596