SEP 22 1998

K974226

510(k) Summary

Contact	Bryan Kiehl
Address	GenBio 15222-A Avenue of Science San Diego, CA 92128
Telephone	(619) 592-9300 ext 309
FAX	(619) 592-9400
Email	Bryan@GenBio.com
Date:	17 September, 1998

DEVICE NAME	IMMUNODOT MONO G TEST
Common, usual, or classification name	Mononucleosis Test
Classification Number (if known)	

Identification of the legally marketed device substantial equivalence is claimed:
ImmunoDOT Infectious Mononucleosis Test, GenBio, San Diego, CA

Description of the new device:
The product is an ELISA test method detecting viral capsid antigen Epstein-Barr nuclear antigen, cytomegalovirus and toxoplasma IgG antibodies.

Intended Use of New Device:
The Mono G Test is a qualitative enzyme immunoassay (EIA) that detects IgG antibodies to Epstein-Barr virus capsid antigen (EBV-VCA), Epstein-Barr early nuclear antigen (EBV-EBNA), cytomegalovirus (CMV), and toxoplasma (toxo). When used in conjunction with Mono-M Test it is an aid in the serodiagnosis of infectious (EBV) mononucleosis and presumptive serodiagnosis of CMV or toxoplasma mononucleosis-like syndrome.

This assay has not been FDA cleared or approved for the screening of blood or plasma donors. Performance with this device has not been established for either prenatal screening or newborn testing. **Performance for this assay has not been established in a non-clinical laboratory environment (e.g., point of care testing).**

Similarities and/or differences

ITEM	PREDICATE DEVICE	NEW DEVICE
Methodology	ELISA	ELISA
Specimen Type	Serum	Serum
Test Objective	Mononucleosis Serology	Mononucleosis Serology
Product type, e.g., calibrator, control, kit	Kit	Kit
Intended Use	Mononucleosis Serodiagnosis	Mononucleosis Serodiagnosis
Other	EBV, CMV and toxoplasma infections. IgG and IgM are detected within one assay.	EBV, CMV and toxoplasma infections. IgG and IgM are detected separately but reported together.

Relative Performance

A prospective study was performed to assess assay performance. Site A information based on profile comparison is presented in Table 1. Site B information is shown in Table 2 and the combined data can be seen in Table 3.

Table 1: Site A EBV Performance

	Reference Results		
ImmunoDOT	Negative	Current	Past/Recent
Negative	33	0	1
Current	2	23	1
Past/Recent	0	1	112
Indeterminate	0	6	7

Table 2: Site B EBV Performance

ImmunoDOT	Reference Results		
	Negative	Current	Past/Recent
Negative	9	0	0
Current	1	10	1
Past/Recent	0	0	92
Indeterminate	2	0	1

Table 3: EBV Performance Summary

ImmunoDOT	Reference Results		
	Negative	Current	Past/Recent
Negative	42	0	1
Current	3	33	2
Past/Recent	0	1	204
Indeterminate	2	6	8

There was no toxoplasma IM cases identified during the prospective trial period. Two CMV mononucleosis cases at Site A and three CMV mononucleosis cases at Site B were observed. Three of the five sera from presumptive CMV mononucleosis cases were positive according to reference results. These CMV results are included in Table 4 as ImmunoDOT current positives and summarize overall ImmunoDOT performance.

Table 4: Overall Performance Summary

ImmunoDOT	Reference Results		
	Negative	Current	Past/Recent
Negative	42	0	1
Current	5	36	2
Past/Recent	0	1	199
Indeterminate	2	6	8

Using the above information, assay performance characteristics are shown in Table 5. Indeterminate results are not used for the calculations.

Table 5: Performance Characteristics

	Sensitivity	Sensitivity Range	Specificity	Specificity Range
EBV Infectious Mononucleosis	98.8% (238/241)	96-99.7%	93% (42/45)	93-99%
Mononucleosis Syndrome	98.7% (236/239)	96-99.7%	89% (42/47)	77-96%

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The intensity of the dot is directly related to precision. The darkest dots are most reliable while weaker reactions are proportionately less reliable. Site A and Site B laboratories were supplied masked specimens containing mixtures of the various analytes. Therefore, not all analytes tested the same number of replicates. Testing was conducted in triplicate each day. Tests were performed on six different days. The results are shown below. The results (Tables 12 and 13) show adequate qualitative discrimination for each analyte.

Table 6: ImmunoDOT Mono M Precision Results

Antibody Level	Level 1 Heterophil	Level 2 Heterophil	VCA IgM	CMV IgM
Moderate	100% (36/36)	100% (36/36)	100% (36/36)	100% (72/72)
Low	100% (108/108)	100% (108/108)	100% (72/72)	100% (144/144)

Table 7: ImmunoDOT Mono G Precision Results

Antibody Level	VCA IgG	EBNA IgG	CMV IgG	Toxoplasma IgG
Moderate	100% (144/144)	100% (36/36)	100% (144/144)	100% (72/72)
Low	100% (72/72)	100% (144/144)	100% (72/72)	85% (122/144)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 22 1998

Bryan L. Kiehl, Ph.D.
Vice President
GenBio
15222 Avenue of Science, Suite A
San Diego, California 92128

Re: K974226/S2
Trade Name: ImmunoDOT Mono-G
Regulatory Class: I
Product Code: LSE
Dated: July 7, 1998
Received: July 8, 1998

Dear Dr. Kiehl:

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 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). 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 requirements, 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.

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 (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

Indications for Use

510(k) Number (if known):

Device Name: ImmunoDOT Mono–G

Indications for Use:

The Mono G Test is a qualitative enzyme immunoassay (EIA) that detects IgG antibodies to Epstein-Barr virus capsid antigen (EBV-VCA), Epstein-Barr early nuclear antigen (EBV-EBNA), cytomegalovirus (CMV), and toxoplasma (toxo). When used in conjunction with Mono-M Test it is an aid in the serodiagnosis of infectious (EBV) mononucleosis and presumptive serodiagnosis of CMV or toxoplasma mononucleosis-like syndrome.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Woody Dubois
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K974226