510(k) Summary
Adenovirus Antigen Detection ELISA Test Kit K972406

DEC 24 1997

I. Trinity Biotech plc.
Three Rocks Road
Sandyford Industrial Estate
Dublin 18, Ireland
Contact person: Sinead Flynn
Telephone: 011-353-1-295-5111
Date of preparation: June 23, 1997

II. Description of Device

The Adenovirus Antigen Detection ELISA Test System is an Enzyme-Linked Immunosorbent Assay (ELISA) for the qualitative determination of Adenovirus antigen in human fecal samples as an aid in the diagnosis of acute non-bacterial gastro-enteritis. Performance for this assay has not been established on children over the age of five and immunocompromised patients. The antibody utilized in this assay is a group specific antigen and cannot differentiate between types of adenovirus. Performance of this assay has not been established for specimens other than human feces. **For in vitro diagnostic use only.**

The Adenovirus Antigen Detection ELISA test is an enzyme linked immunosorbent assay to detect adenovirus antigen in fecal samples. Purified monoclonal antibody specific to adenovirus is attached to a solid phase microtiter well. Diluted fecal sample is added to each well. If the adenovirus antigen is present, it will bind to the monoclonal antibody in the well. After incubation the wells are washed to remove unbound antigen. An enzyme labeled anti-adenovirus polyclonal antibody is added to each well. If antigen is present the conjugate antibody will bind to the antigen attached to the antibody 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 Adenovirus Antigen Detection ELISA test is substantially equivalent to cell culture of adenovirus from fecal samples. Equivalence is demonstrated by the following comparative results:

Performance Characteristics

1. Relative sensitivity and specificity. One hundred and twenty retrospective frozen fecal specimens sent to a University Virus Reference Laboratory in Ireland for routine testing were tested with the Trinity Adenovirus Antigen detection ELISA and by cell culture isolation. 90% of the specimens were from adults. The samples were approximately 50% solid, and 50% liquid. The data in Table 1 illustrates good sensitivity and specificity of the Adenovirus Antigen Detection ELISA relative to cell culture isolation.

Table 1
Adenovirus Antigen Detection ELISA Sensitivity & Specificity
Relative to Cell Culture Study 1

		Wampole Adenovirus Antigen Detection ELISA			
		+	**E**	**-**	**Total**
Cell Culture	+	75	2	0	77
	-	2	0	41	43
	Total	77	2	41	120

Equivocals are not included in the following calculations:

Sensitivity = 75/75 = 100.0% 95% Confidence Interval = 96.0-100.0%*
Specificity = 41/43 = 95.4% 95% Confidence Interval = 88.9-100.0%
Agreement = 116/118 = 98.3% 95% confidence Interval = 95.9-100.0%

The 95% confidence intervals were calculated using the regular method.
* The 95% confidence interval was calculated assuming one false negative.

Note: The positive cultures were identified by cytopathic effect (CPE) and confirmed by electron microscopy (EM) using a standard negative staining technique, which is considered presumptive for adenovirus types 40 and 41 when using fecal samples.

Four hundred eighty one sera were tested on the Adenovirus Antigen Detection ELISA and an alternate commercially available adenovirus EIA at a large public health lab in the UK. 57% of the samples were from patients less than 5 years old and 43 % were from patients greater than five years old. All were retrospective frozen fecal specimens with half being solid and half liquid. After retesting discrepants, the remaining descrepants were tested by EM. The data in Table 2 illustrates good sensitivity and specificity of the Adenovirus Antigen Detection ELISA relative to an alternate commercially available EIA.

Table 2
Adenovirus Antigen Detection ELISA Sensitivity & Specificity
Relative to an Alternate adenovirus EIA Study 2

		Wampole Adenovirus Antigen Detection ELISA			
		+	**E**	**-**	**Total**
Alternate ELISA	+	141	8	19	168
	-	11	6	296	313
	Total	152	14	315	481

Equivocals are not included in the following calculations:

Sensitivity = 141/160 = 88.13%	95% Confidence Interval = 83.01 - 93.24%
Specificity = 296/307 = 96.42%	95% Confidence Interval = 94.30 - 98.54%
Agreement = 437/467 = 93.58%	95% confidence Interval = 91.31 -95.85%

The 95% confidence intervals were calculated using the normal method.

After retesting discordant samples on the Wampole Adenovirus Antigen Detection ELISA, 15 samples remained discordant and were tested by Electron Microscopy (EM). Eight of the 15 discordants were false negatives and two were false positives versus EM.

Please be advised that 'relative' refers to the comparison of this assay's results to that of a similar assay. There was not an attempt to correlate the assay's results with disease presence or absence. No judgment can be made on the comparison assay's accuracy to predict disease.

2. Limit of Detection. Plaque assays were carried out in HEK-293 cells on fecal clinical samples containing Adenovirus 40 and Adenovirus 41. The number of plaque forming units per milliliter (PFU/mL) was established for each specimen which was serially diluted and assayed on the Adenovirus Antigen Detection ELISA. The limit of detection was found to be 125 PFU for Adenovirus 40 and 39 PFU for Adenovirus 41.

Limits of Detection: Enteric Adenoviruses					
Adenovirus 40: 2 X 10^4 PFU/mL			Adenovirus 41: 2.5 X 10^3 PFU/mL		
Dilution	**OD**	**PFU/100ul**	**Dilution**	**OD**	**PFU/100ul**
Neat	0.521	2 X 10^3	**Neat**	0.259	2.5 X 10^2
1/8	0.385	0.25 X 10^3	**1/8**	0.161	0.312 X 10^2
1/16	0.201*	0.125 X 10^3	**1/16**	0.271	0.156 X 10^2
1/32	0.165	0.062 X 10^3	**1/32**	0.201	0.078 X 10^2
1/64	0.063	0.031 X 10^3	**1/64**	0.183*	0.039 X 10^2
1/128	0.061	0.015 X 10^3	**1/128**	0.126	0.019 X 10^2
1/256	0.053	0.007 X 10^3	**1/256**	0.092	0.009 X 10^2
1/512	0.121	0.003 X 10^3	**1/512**	0.063	0.004 X 10^2
1/1024	0.041	0.001 X 10^3	**1/1024**	0.065	0.002 X 10^2
1/2048	-		**1/2048**	0.052	0.001 X 10^2

*Limit of Detection

3. Precision. Six samples containing Type 2 adenovirus from cell culture and the positive and negative controls were each run in triplicate on three consecutive days at three different sites. The results are shown below in Table 3.

Table 3
Adenovirus Antigen Detection ELISA Inter Assay Precision Between Sites

	Inter-Assay (n=27)			
#	X	SD	CV	n
1.	1.558	0.091	5.87%	27
2.	1.275	0.051	4.01%	27
3.	0.501	0.018	3.65%	27
4.	0.435	0.016	3.78%	27
5.	0.295	0.012	4.12%	27
6.	0.054	0.005	9.22%	27
PC	1.211	0.051	4.23%	27
NC	0.050	0.003	6.11%	27

A total of 216 determinations were made at the three sites. In all 216 determinations there was not a case a positive result for a negative sample or a negative result for a positive sample.

X = Mean O.D.
SD = standard deviation
CV = coefficient of variation = SD/X x 100

The methods in NCCLS EP5 were utilized for precision parameters.

4. Cross-Reactivity.

The following common intestinal pathogens and other organisms occasionally found in feces were tested on the Wampole Adenovirus Antigen detection kit. Specimens from the bacteria panel contained 3 X 10^8 particles per mL. The Chlamydia trachomatis L2 strain contained 1 X 10^6 inclusion forming units per ml. With the exception of Norwalk virus and Hepatitis A virus, all the viruses included in the panel were cell culture isolates which were passaged at least once. The titers of the viruses were unknown. The Norwalk virus was obtained from a vomitus sample shown to be positive by immune electron microscopy. The Hepatitis A sample was obtained from a hepatitis A specific immunoglobulin assay kit. The organisms were spiked with Type 2 adenovirus from cell culture harvests (titer unknown).

Bacteria Panel

	Organism alone	Organism and Adenovirus
Haemophilus influenza	0.025	0.605
Actinobacter spp.	0.022	0.595
Bacillus spp.	0.017	0.554
Shigella sunnei	0.021	0.489
Neisseria meningitiidis	0.032	0.582
Pseudomonas aeruginosa	0.043	0.519
Candida albicans	0.022	0.441
Campylobacter spp.	0.029	0.489
Clostridium welchii	0.041	0.475
Escherichia coli	0.023	0.534
Aeromonas spp.	0.022	0.548
Salmonella spp.	0.037	0.526
Gardinella spp.	0.031	0.628
Klebsiella pneumoniae	0.026	0.497
Staphylococcus aureus (Cowan)	0.028	0.483
Streptococcus pneumoniae	0.035	0.440
Streptococcus group G	0.029	0.486
Streptococcus group F	0.034	0.573
Streptococcus group A	0.035	0.495
Chlamydia trachomatis L2 strain	0.026	0.562

4. Cross-Reactivity. (Cont'd.)

Viral Panel

Varicella Zoster virus	0.022	0.655
Herpes Simplex type 1	0.026	0.770
Herpes Simplex type 2	0.027	0.653
Cytomegalovirus	0.018	0.762
Epstein-Barr virus	0.038	0.837
Rhinovirus	0.021	0.827
Poliovirus 1	0.022	0.655
Poliovirus 2	0.025	0.689
Poliovirus 3	0.035	0.741
Coxsackievirus B5	0.032	0.602
Coxsackievirus B4	0.028	0.676
Echovirus 7	0.042	0.592
Echovirus 20	0.035	0.681
RS virus	0.023	0.786
Parainfluenza virus 1	0.029	0.666
Parainfluenza virus 2	0.023	0.833
Parainfluenza virus 3	0.032	0.846
Influenza A virus	0.026	0.553
Influenza B virus	0.022	0.694
Hepatitis A virus	0.033	0.764
Rotavirus	0.022	0.712
Norwalk virus	0.031	0.654

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 22 1997

William L. Boteler, Jr.
President
Immuno Probe, Inc.
1306F Bailes Lane
Frederick, Maryland 21701

Re: K972406
Trade Name: Adenovirus Antigen Detection ELISA Test System
Regulatory Class: I
Product Code: GOD
Dated: October 3, 1997
Received: October 6, 1997

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 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.

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

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 22 1997

William L. Boteler, Jr.
President
Immuno Probe, Inc.
1306F Bailes Lane
Frederick, Maryland 21701

Re: K972406
Trade Name: Adenovirus Antigen Detection ELISA Test System
Regulatory Class: I
Product Code: GOD
Dated: October 3, 1997
Received: October 6, 1997

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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: K972406

Device Name: Adenovirus Antigen Detection ELISA

Indications For Use: The Adenovirus Antigen Detection ELISA Test System is an Enzyme-Linked Immunosorbent Assay (ELISA) for the qualitative determination of Adenovirus antigen in human fecal samples as an aid in the diagnosis of acute non-bacterial gastro-enteritis. Performance for this assay has not been established on children over the age of five and immunocompromised patients. The antibody utilized in this assay is a group specific antigen and cannot differentiate between types of adenovirus. Performance of this assay has not been established for specimens other than human feces.

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)

Sally T. Delapaul for J. Tucchinst

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number_____