



NOV 30 1998

K982898

510(k) Notification
ANCA IFA
IMMCO Diagnostics, Inc.

510(k) Summary

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.

Submitter: IMMCO Diagnostics, Inc.

Address: 60 Pineview Drive
Amherst, NY 14228

Phone: (716) 691-0091

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Contact: Kevin Lawson

Date of Summary: 8/13/98

The assigned 510(k) number is: K982898

Name of Device: ImmuGlo™ Anti-Neutrophil Cytoplasmic Antibody (ANCA) Test System

Common Name: ANCA IFA

Classification Name: 866.5660 Multiple autoantibodies immunological test system

Equivalent Device:

- Anti-neutrophil Cytoplasmic Antibody (ANCA) Test System from Scimedx Corporation
- NOVA Lite™ ANCA System by INOVA Diagnostics

Intended Use:

This assay is an indirect immunofluorescence antibody test for the detection and semi-quantitation of anti-neutrophil cytoplasmic antibodies (ANCA) in human serum.



Technological Characteristics:

Technological characteristics of this device compared with the 2 equivalent devices listed above is summarized in the following table:

	IMMCO	SciMedx	INOVA
Indirect Immunofluorescence Assay	Y	Y	Y
Detection of Autoantibodies in Sera	ANCA	ANCA	ANCA
Screening for Ab's and/or Determination of Ab Titers	Y	Y	Y
Screening Dilution	1:20	1:20	1:20
Similar Methodology	Y	Y	Y
Substrate Used	human PMN cells	human PMN cells	human PMN cells
Fluorescein-Labeled Conjugate, Anti-human IgG	Y	Y	Y
Evans Blue Counterstain	in wash (optional)	in conjugate	in conjugate
Positive Control Sera	cANCA and pANCA	cANCA	cANCA and pANCA
Negative Control Serum	Y	Y	Y
Buffered Diluent	Y	Y	Y
Phosphate Buffered Saline	Y	Y	Y
Mounting Medium	Y	Y	Y
Storage of Substrate Slides	2°-8°C	2°-8°C	2°-8°C

Clinical Test Data to Demonstrate Substantial Equivalence:

Substantial equivalence between the IMMCO and Scimedx assays is demonstrated in the table below.

		IMMCO		
		Positive	Negative	Total
SciMedx	Positive	49	0	49
	Negative	7	73	80
	Total	56	73	129

Relative Specificity: 91%
 Relative Sensitivity: 100%
 Relative Agreement: 95%

Conclusions:

This test is substantially equivalent to that of Scimedx. The seven discrepant samples observed by indirect immunofluorescent method in the table above were tested by ELISA for antibodies to myeloperoxidase (MPO) or proteinase 3 (PR3) antigens, the two major antigens associated with ANCA. Of the seven samples positive on IMMCO's IFA system and negative on the Scimedx IFA system, all but one tested positive by ELISA, suggesting thereby, the true positivity of these samples. This discrepancy can therefore be accounted for by the greater sensitivity of the ImmGlo™ Anti-Neutrophil Cytoplasmic Antibody (ANCA) Test System.



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Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Kevin J. Lawson
Chief Information Officer
IMMCO DIAGNOSTICS
60 Pineview Drive
Amherst, NY 14228

Re: K982898

Trade Name: ImmuGlo™ Anti-Neutrophil Cytoplasmic Antibody
(ANCA) Test System
Regulatory Class: II
Product Code: MOB
Dated: November 13, 1998
Received: November 16, 1998

Dear Mr. Lawson:

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.

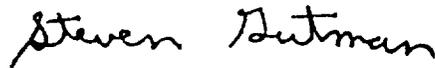
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

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

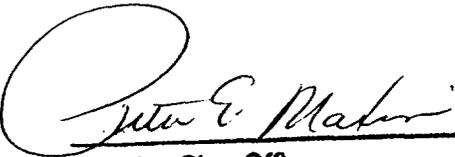
Enclosure

INDICATIONS FOR USE STATEMENT

510(K) Number: K982898

Device Name: ImmuGlo™ Anti-Neutrophil Cytoplasmic Antibody (ANCA) Test System

Indications For Use: An indirect immunofluorescence antibody test for the detection and semi-quantitation of anti-neutrophil cytoplasmic antibodies (ANCA) in human serum to aid in the diagnosis of patients with necrotizing vasculitides.



(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K982898

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use _____
(Optional Format 1-2-96)