



MATERIAL SAFETY DATA SHEET

DCN MSDSA060L

Title SCIMEDX ANCA IFA TEST SYSTEM

Rev Initial Issue

Authors Jeanne K. Derbyshire, Katrina Merikas,
Patricia Sager

Effective 6/28/04

1.0 COMPANY IDENTIFICATION

Manufacturer Scimedx Corporation
 100 Ford Road
 Denville, NJ 07834
 Web www.scimedx.com

Emergency Phone Tel 973-625-8822
 Monday – Friday, 8:00 AM – 5:00 PM EST

2.0 PRODUCT IDENTIFICATION

Product Code AO60L, A120L

Product Type Diagnostic test kit

Description Immunofluorescence Antibody Test is an indirect method for the detection of specific circulating antibodies in human serum.
 The technique utilizes a fluorochrome conjugate and a known antibody serum as a positive reference, which are applied to tissue and cellular substrates. Reactions are visualized using a fluorescent microscope system.

Intended Use The SCIMEDX Corporation immunofluorescence assay (IFA) is for the in vitro diagnostic detection of anti-neutrophil cytoplasmic antibodies in human serum using ethanol fixed human neutrophils as substrate. The test is intended as an aid in the diagnosis of Wegener’s granulomatosis, Idiopathic Crescentic Glomerulonephritis, Microscopic Polyarteritis, Pulmonary Renal Syndrome.

CATALOG NO.	KIT	COMPONENTS
A060L	ANCA IFA immunofluorescence assay for the detection of anti-neutrophil cytoplasmic antibodies in human serum	Slides, ANCA (ethanol fixed)
A120L		C-ANCA positive control
		ANCA negative control
		ANCA mounting medium
		PBS buffer



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		FITC Antihuman IgG Conjugate with Evans Blue
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3.0 COMPOSITION, INFORMATION ON REAGENTS

The components of this kit may contain one or more hazardous chemicals. The hazardous ingredients listed are only those as required by 29 CFR 1910.1200.

This product is for in vitro diagnostic use only. Only staff trained and specially advised in methods of in vitro diagnostics shall perform the kit. Although this product is not considered particularly toxic, or dangerous in conditions of normal safety, refer to sections four and five for maximum safety.

COMPONENTS CONTRIBUTING TO HAZARD

NONE

COMPONENTS PRESENTING A HAZARD BUT UNDER THE HAZARD THRESHOLD

POSITIVE CONTROL

Ready for use containing human serum (diluted), 0.095% Sodium Azide (preservative)

NEGATIVE CONTROL

Ready for use containing human serum (diluted), 0.095% Sodium Azide (preservative)

CONJUGATE

Goat antihuman FITC containing Evans Blue, 0.95% Sodium Azide (preservative)

BUFFER

PBS buffer



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MOUNTING MEDIUM

Containing Glycerol

4.0 HAZARDS IDENTIFICATION

- Antigens Tissue antigens are inactivated and do not pose a hazard. Legionella and FTA antigens are inactivated but may be considered potentially infectious and should be handled accordingly.
- Antibody All human serum has been tested for Hepatitis B surface antigen, Hepatitis C antibody and HIV 1/2 (AIDS) antibody by FDA-approved methods and found to be negative. However, no known test methods can provide complete assurance that human serum will not transmit these or other infectious agents. The controls and equipment being exposed to human serum should be considered potentially infectious, therefore handled, and disposed of with proper biohazard precautions. May be harmful if inhaled, ingested or absorbed by skin.
- Evans Blue Evans Blue is possibly a carcinogen. May be harmful if inhaled, ingested or absorbed by skin.
- Sodium Azide Avoid contact with components that contain Sodium Azide, which is highly toxic and harmful if inhaled, ingested or absorbed by skin. Sodium Azide can also react with lead and copper plumbing.

5.0 FIRST AID MEASURES

- Eyes Flush with copious amounts of water for at least 15 minutes. Assure adequate flushing by separating eyelids with fingers. Call a physician.
- Skin Wash thoroughly with soap and water. Remove contaminated clothing and shoes.



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Ingestion Avoid ingestion of hazardous chemicals (obviously!). However, recognize that you can **accidentally** ingest toxic materials by eating/handling food in areas where toxic substances are used. Having a chemical on your hands and then eating or smoking are common ways that chemicals are accidentally ingested.

Be sure that all containers are properly labeled. **NEVER STORE CHEMICALS OF ANY SORT IN FOOD CONTAINERS.** Do not store food and chemicals in the same refrigerator.

Always have your poison control center phone number handy with your other emergency information. Always clean up chemical spills.

Inhalation Remove to fresh air. If breathing becomes difficult, call a physician.

6.0 FIRE-FIGHTING MEASURES

Condition Use extinguishing media appropriate for surrounding fire. No fire or explosion hazards. Packaging material will burn in a fire. No special equipment or procedure is required.

7.0 ACCIDENTAL RELEASE MEASURES

Ventilation No special ventilation is necessary, however, a biosafety cabinet, as recommended in the CDC/NIH manual, may be necessary.

8.0 HANDLING AND STORAGE

Handling Do not eat, drink, smoke or apply cosmetics in laboratory areas. Do not pipette reagents or samples by mouth. Avoid splashing and forming aerosols. Use reagents according to the product insert. Avoid extreme temperatures during transport.

Storage Store all components as directed in the package insert.

9.0 EXPOSURE CONTROLS, PERSONNEL PROTECTION

Wear appropriate personal protective equipment when working with components or samples, including laboratory coats, disposable gloves and eye protection. Avoid hand and mouth contact. Wash hands as soon as possible after handling components or samples.

10.0 PHYSICAL & CHEMICAL PROPERTIES

Physical data is not available

11.0 STABILITY AND REACTIVITY

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The components are stable at the temperatures indicated in the package insert.

12.0 TOXICOLOGICAL INFORMATION

Not available

13.0 ECOLOGICAL INFORMATION

Not available

14.0 DISPOSAL CONSIDERATIONS

Dispose of according to local and national laws

15.0 TRANSPORT INFORMATION

Proper shipping label In vitro diagnostic

Hazard class and number None

16.0 REGULATORY INFORMATION

Health hazards present in concentrations found in this kit are minimal provided the product is used according to work instructions and used by persons with proper technical skills.

17.0 OTHER INFORMATION

The information contained in this Material Safety Data Sheet is believed to be accurate but it is the responsibility of the user to determine the applicability of the data to the formulation of necessary safety precautions. Scimedx Corporation shall not be held responsible for any damage resulting from the use of the above product or the information contained in this Material Safety Data Sheet. Since conditions and manner of use are outside our control, Scimedx can assume no liability in connection with any use of this information.