



MATERIAL SAFETY DATA SHEET

DCN MSDS5048L

Title THYROID ANTIBODY TEST SYSTEM

Rev Initial Issue

Author Jeanne K. Derbyshire

Effective 11/11/04

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 AND COMPANY IDENTIFICATION

Product Code 5048L

Product Type Diagnostic test kit

Description (IFA) 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 Thyroid Antibody Test System is a qualitative and quantitative immunofluorescence test for the diagnosis of autoimmune thyroid diseases, particularly in patients with subclinical autoimmune thyroiditis.

| CATALOG NO. | KIT | COMPONENTS |
|-----------------------|------------------------------|---|
| 5048L, 5096L, 50408LA | THYROID ANTIBODY TEST SYSTEM | M. Thyroid Well Slide |
| | | Positive Control Microsomal/Thyroglobulin |
| | | Negative Control |
| | | FITC Conjugate with Evans Blue |
| | | FITC Mounting Medium |
| | | PBS (IFA & DFA) |



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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

READY FOR USE STOP SOLUTION CONTAINING SODIUM HYDROXIDE

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

Ready for use containing anti-human immunoglobulins conjugated to horseradish peroxidase

BUFFER

PBS buffer



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4.0 HAZARDS IDENTIFICATION

- | | |
|--------------|--|
| Antigens | Tissue antigens are inactivated and do not pose a hazard 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. |
| Human serum | 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. |
| 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.

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

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



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Physical data is not available

11.0 STABILITY AND REACTIVITY

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

12.0 TOXICOLOGICAL INFORMATION

| | | |
|-------------------|-----------------|--|
| Route of Exposure | Skin contact | May cause skin irritation |
| | Skin absorption | May be harmful if absorbed through the skin |
| | Eye Contact | May cause eye irritation |
| | Inhalation | Material may be irritating to mucous membranes and upper respiratory tract. May be harmful if inhaled. |
| | Ingestion | May be harmful if swallowed. |

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.



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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.