1.0 COMPANY IDENTIFICATION

MANUFACTURER Scimedx Corporation
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Monday – Friday, 8:00 AM – 5:00 PM EST

2.0 PRODUCT AND COMPANY IDENTIFICATION

Product Code 5548L

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 Islet Cell Antibody is a qualitative and quantitative immufluorescence test for Islet Cell antibodies associated with endocrine disorders, more specifically with insulin dependent diabetes.

CATALOG NO.	KIT	COMPONENTS
5548L 5596L	ISLET CELL ANTIBODY TEST SYSTEM	Antigen slide, monkey pancreas
		Islet cell positive control
		Universal negative
		FITC mounting medium
		PBS buffer
		Conjugate (primate) with Evans Blue

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

BUFFER
PBS buffer

MOUNTING MEDIUM
Containing Glycerol

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.
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.
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 & CHEMCAL PROPERTIES

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

Not available

13.0 ECOLOGICAL INFORMATION

When the components of this test are properly disposed of (see section 14.0) it poses no ecological threat.

14.0 DISPOSAL CONSIDERATIONS

Disposal should be done in accordance with existing disposal practices employed for infectious waste at your institution. Observe all local, national and international 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.