

**MATERIAL SAFETY DATA SHEET**

DCN MSDS GBM396

Title GBM TEST SYSTEM

Rev Initial Issue

Authors Jeanne K. Derbyshire

Effective 6/28/04

1.0 COMPANY IDENTIFICATION

Manufacturer Scimedx Corporation
100 Ford Road
Denville, NJ 07834
Web www.scimedx.com
Tel 973-625-8822
Monday – Friday, 8:00 AM – 5:00 PM EST

Emergency Phone Contact American Association of Poison Control Centers
USA 1-800-222-1222

2.0 PRODUCT IDENTIFICATION

PRODUCT CODE GBM396

PRODUCT TYPE ENZYME-LINKED IMMUNOSORBENT ASSAY DIAGNOSTIC TEST KIT

DESCRIPTION (EIA) enzyme-linked immunosorbent assay is a rapid test where an antibody or antigen is linked to an enzyme as a means of detecting a match between the antibody and antigen.

INTENDED USE The SCIMEDX Corporation Scanlisa enzyme immunoassay (EIA) kit is for the *in vitro* diagnostic detection of anti-Glomerular Basement Membrane (GBM) IgG antibodies in human serum as an aid in the diagnosis of autoimmune renal disorders such as Goodpasture's syndrome.

CATALOG NO.	KIT	COMPONENTS
GBM396	GBM TEST SYSTEM	ELISA Plate
		Positive Control
		Negative Control
		Calibrator(s)
		Conjugate, Alkaline Phosphatase
		Diluent, Green
		Wash Buffer
		pNPP Substrate Solution
		Stop Solution

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3.0 COMPOSITION, INFORMATION ON COMPONENTS

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.

COMPONENTS CONTRIBUTING TO HAZARD**SUBSTRATE**

Ready for use pNPP (p-Nitrophenyl Phosphate) substrate

STOP SOLUTION

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) and Proclin (preservative)

NEGATIVE CONTROL

Ready for use containing human serum (diluted) and Proclin (preservative)

CALIBRATORS (COLOR INCREASING WITH CONCENTRATION)

Ready for use containing human serum (diluted) and Proclin (preservative).

BUFFERS

Wash buffer containing 0.095% Sodium Azide (preservative)

Sample diluent containing Proclin (preservative)

CONJUGATE

Alkaline Phosphatase

ELISA PLATE



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ELISA PLATE

Ready for use well strips with breakaway microwells. See intended use paragraph.

4.0 HAZARD IDENTIFICATION

- HUMAN SERUM** The human serum components used in the preparation of the Controls and Calibrator in this kit have been tested by an FDA approved method for the presence of antibodies to human immunodeficiency virus 1 & 2 (HIV 1&2), hepatitis C (HCV) as well as hepatitis B surface antigen and found negative. Because no test method can offer complete assurance that HIV, HCV, hepatitis B virus, or other infectious agents are absent, specimens and human based reagents should be handled as if capable of transmitting infectious disease and disposed of with proper biohazard precautions. May be harmful if inhaled, ingested or absorbed by skin.
- PROCLIN 300** Components that contain Proclin 300, 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.
- STOP SOLUTION** Stop Solution should be handled carefully as it can cause burns or irritation to the skin and eyes. If contact occurs, flush immediately with water.

Corrosive, may causes burns. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. Immediately take off all contaminated clothing. Wear suitable protective clothing, gloves and eye/face protection.
- SUBSTRATE** pNPP (p-Nitrophenyl phosphate) in high concentrations.

May cause Cancer and is possible mutagen. Avoid all contact. Harmful if swallowed, inhaled, or absorbed through the skin.

5.0 FIRST AID MEASURES

The following general first aid measures apply to all components of the kit.

- EYES** Immediately flush thoroughly with copious amounts of water for at least 15 minutes and notify medical personnel.



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SKIN In case of contact, immediately flush eyes or skin with copious amounts of water for at least 15 minutes while removing contaminated clothing and shoes. Discard contaminated clothing and shoes. If swallowed, wash out mouth with water provided person is conscious.

INGESTION If swallowed, wash out mouth with water and notify medical personnel. Remove and wash contaminated clothing and shoes.

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 Immediately remove to fresh air and notify medical personnel. If not breathing, give artificial respiration. If breathing becomes difficult, call a physician and/or give oxygen.

BIOLOGICAL HAZARD The reagents used to prepare this product were derived from human blood or other tissues, and were found negative for HIV and hepatitis C virus antibodies and hepatitis B surface antigen when tested.

HEALTH HAZARD DATA Risk of virus contamination. No known test method can offer total assurance that products derived from human tissues will not transmit hepatitis or AIDS.

Emergency first aid procedures: Wash with a disinfectant such as dilute bleach.

6.0 FIRE-FIGHTING MEASURES

The following general measures apply to all components of the kit.

EXTINGUISHING Use dry chemical foam or carbon dioxide. Water may not be effective.
MEDIA:



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SPECIFIC HAZARDS For DMSO (dimethylsulfoxide) vapors may flow along surfaces to distant ignition sources and flash back. Closed containers exposed to heat may explode.
For sulfuric acid, contact with most metals causes formation of flammable and explosive hydrogen gas.

SPECIFIC METHODS OF FIRE FIGHTING In the event of a fire, wear full protective clothing and NIOSH approved self-contained breathing apparatus with full face piece operated in the pressure demand or other positive pressure mode

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.

PERSONAL PRECAUTIONS Ventilate area of leak or spill. Wear appropriate personal protective equipment as specified in Section 9. Isolate hazard area. Keep unnecessary and unprotected personnel from entering.

METHODS OF CLEANING UP Contain liquid when possible. Use non-sparking tools and equipment. Absorb with paper towels. Ventilate area and wash spill site after material pickup is complete.

8.0 HANDLING AND STORAGE

HANDLING Avoid contact with skin, eyes or clothing. Use adequate ventilation or minimize exposures to mists or aerosols. Wash thoroughly after handling. DO NOT permit contact with acids and other incompatible substances.

Do not eat, drink, smoke or apply cosmetics in laboratory areas. Do not pipette reagents or samples by mouth. 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, PERSONAL 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.



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Occupational Exposure Limits: There are no established exposure limits for this product.

Personal Protective Equipment

Eye and Face Protection: Wear safety glasses with side shield, or full face shield if eye contact is likely. The choice of protection should be based on the job activity and potential for exposure to eyes and face.

Respiratory protection: When handling bulk quantities or for long durations where aerosolization of material is likely, wear a NIOSH – air purifying respirator.

Skin and body protection: Wear gloves, lab coat, or other protective over-garment if skin contact is likely. The choice of skin protection should be based on the job activity and potential for exposure to the skin.

Hygiene measures: Wash hands immediately after handling materials (especially before eating, drinking or smoking). Decontaminate or discard protective equipment after each use.

Remove personal protective equipment when leaving work area.

10.0 PHYSICAL & CHEMICAL PROPERTIES

Physical and chemical properties and not applicable

11.0 STABILITY AND REACTIVITY

The kit should only be used as instructed in the package insert. See package insert for further information of kit stability.

12.0 TOXICOLOGICAL INFORMATION

Components in this kit are not supplied at concentrations or quantities thought to have toxicological effect and if used in accordance with its intended use.

13.0 ECOLOGICAL INFORMATION

Not available

14.0 DISPOSAL CONSIDERATIONS

Dispose of according to federal, state and local requirements.



15.0 TRANSPORT INFORMATION

PROPER SHIPPING LABEL *In vitro diagnostic test kit*

HAZARD CLASS AND NUMBER None

16.0 REGULATORY INFORMATION

Labeling according to EU guidelines:

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

Recommended use: This product is an *in vitro diagnostic* testing kit and should only be used according to its package insert instructions.

Other: 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.