THE EFFECTIVE DATE OF THIS PUBLICATION IS AUGUST 17, 2001

• Information that appears in the MSA User’s Guide but does not appear on the test report is designated as Note.

• Watch the Biomedical Diagnostics website for test changes or descriptions of new information as it becomes available.

• Mammastatin Serum Assay (MSA) data published in the MSA User’s Guide is also located on the Biomedical Diagnostics website.
LABORATORY SERVICES

MSA USER’S GUIDE

INTRODUCTION TO BIOMEDICAL DIAGNOSTICS, LLC
LABORATORY SERVICES

DESCRIPTION

Biomedical Diagnostics, LLC was created in November 1998 and is a wholly owned subsidiary of Genesis Bioventures, Inc. (GBIW.OB). Corporate headquarters and laboratory facilities are located in Ann Arbor, Michigan. The company’s mission is to provide innovative, high-quality, easy-to-use cancer screening products and services worldwide. The company will accomplish this mission through the highest of ethical and professional standards and through unwavering attention to its shareholders, customers, employees and suppliers.

The company’s first technology is the Mammastatin Serum Assay (MSA), which measures the level of the protein Mammastatin in blood serum. Low levels of Mammastatin have been measured in women with breast cancer or with a close family history of breast cancer and may indicate high risk of developing the disease. Higher levels are seen in women with no breast cancer history and may indicate lower risk of developing the disease.

The focus of Biomedical Diagnostics Laboratory Services is to provide quality, expedient, reliable and accurate test results that supplement the testing available in local communities. Clients include academic medical centers, community hospitals, independent hospital groups, reference laboratories and physician offices.

BIOMEDICAL DIAGNOSTICS, LLC QUALITY POLICY

Biomedical Diagnostics, LLC is committed to the development of products and delivery of services of the highest quality consistent with contractual and regulatory requirements and with customer expectations.

Biomedical Diagnostics Laboratory Services is committed to achieving these goals by:

- Recognizing that quality is everyone’s responsibility
- Ensuring that all staff receive necessary training
- Providing a good working environment
- Fostering a quality ethos at all levels of the organization
- Using quality measurements to improve the quality process
- Using procedures that meet regulatory and other relevant standards
- Being committed to continuous improvements in the quality of products and services produced to meet customer expectations
- Never becoming complacent with our current achievement.

ACCREDITATION/LICENSURE

The Laboratory Services Division of Biomedical Diagnostics, LLC maintains a current CLIA number with the U.S. Department of Health and Human Services Health Care Financing Administration. For additional information or a copy of our certificate, please see our Website at www.bio-diagnostics.com.
MEDICARE COVERAGE OF LABORATORY TESTING

The patient is responsible for the charges associated with the MSA test technology performed by Biomedical Diagnostics Laboratory Services. Biomedical Diagnostics Laboratory Services is not a participating Medicare or Medicaid provider and does not bill either of these programs for the costs associated with this test. Some private insurance companies may reimburse the patient for the cost associated with the test.

CONTACT INFORMATION

E-Mail address:  info@bio-diagnostics.com

Call Center:  1-888-652-4246

BIOMEDICAL DIAGNOSTICS LABORATORY SERVICES WEB SITE

www.bio-diagnostics.com

You can find new information from Biomedical Diagnostics Laboratory Services on our website as well as the most current version of the MSA User’s Guide. MSA User’s Guide changes are available on the website at least 30 days prior to the effective date of change.

Also, see our website for additional information, including accreditation/licensure certificates, test request forms and new updates.

HOLIDAY COVERAGE

Biomedical Diagnostics Laboratory Services recognizes the following as official holidays:

- New Year’s Day, January 1
- Memorial Day, Last Monday in May
- Independence Day, July 4
- Labor Day, First Monday in September
- Thanksgiving, Fourth Thursday in November
- Chrissas, December 25

Holidays occurring on a weekend are observed on Friday or Monday.
MAMMASTATIN SERUM ASSAY (MSA) TEST

Information about the MSA test can be found on our website at www.bio-diagnostics.com. Frequently Asked Questions on both the Home page and in the Physician’s Information section provide additional background information as well as detailed technology information. General Instructions for Specimen Collection and Shipment, including MSA Specimen requirements, specimen containers, labeling, transport, specimen rejection plus reference intervals, interpretive data, and notes can be found in this User’s Guide.

MSA TEST ORDER FORMS

Instructions and order forms are available on our Web site at www.bio-diagnostics.com.

RESULT REPORTING

Final written reports of the results are generated at the completion of the assay. If requested, preliminary results will be reported by phone to the physician or requesting lab. Phone notification should be requested in writing on the original MSA Test Order Form. Information must include the name of the person or lab to contact, and the telephone number.

GENERAL INSTRUCTIONS FOR SPECIMEN COLLECTION AND SHIPMENT

General Instructions for the Physician’s Office

1. Complete an MSA Test Order Form for each patient as outlined here.
2. Be sure to record the following:
   a. Patient name, birth date, sex and race
   b. Collection time and date
   c. Number of tubes drawn
   d. Patient medical history information
3. Fill in the physician’s patient I.D. number or the lab reference number in order for the patient’s number to appear on the MSA Final Report.
4. Indicate how results should be reported, by mail, fax or e-mail.
5. Be sure the referring physician signs the MSA Test Order form. The test CANNOT be performed without the signature of the referring physician. Refer to MSA User’s Guide section MSA SPECIMEN REJECTION for other criteria that may cause rejection or test cancellation.
6. Keep a photocopy of the form for your records.
7. Write patient’s first and last name legibly and spelled correctly, on the specimen container.
8. Send samples overnight delivery to:

   Biomedical Diagnostics, LLC
   Attn: Laboratory Services
   5692 Plymouth Road, Suite B
   Ann Arbor, MI 48105

Basic Concepts for Collection

1. Patient should have fasted for at least four (4) hours before blood draw.
2. Decontaminate the skin surface. Use 70-95% alcohol (ALC) to prepare the site. Allow a contact time of two minutes to maximize the antiseptic effect. Collect a sufficient quantity of material. (Minimum of 10ml of blood) Refer to MSA User’s Guide section MSA SPECIMEN REQUIREMENTS.
3. Use appropriate collection devices: sterile, leak proof specimen containers and syringes. Refer to User’s Guide section MSA SPECIMEN CONTAINERS.
4. Whenever possible, collect specimens before administration of antibiotics, antivirals or biopsy.
5. Properly label the specimen and complete the MSA Test Order Form. Refer to User’s Guide section MSA SPECIMEN LABELING.
6. Minimize transport time. Maintain an
appropriate environment between collection of specimens and delivery to Biomedical Diagnostics Laboratory Services. Specimen should be shipped to laboratory within 24 hours. Refer to MSA User’s Guide section MSA SPECIMEN TRANSPORT.

**MSA SPECIMEN REQUIREMENTS**

**General Specimen Requirements**

To produce valid results for MSA tests, specimen integrity is crucial and must be maintained. All specimens sent for testing must be collected and shipped in the following manner:

**Serum Sample**

1. Obtain venous blood by clean venipuncture. Do not use needles smaller than 23 gauge.
2. Fill red top tubes with a minimum of 10mL of blood.
3. Allow tube to stand for a minimum of 30 minutes at room temperature to allow clotting to occur.
4. Centrifuge the specimen at 2-8°C at 830 x g for 5 minutes (or at a speed and time required to consistently separate the clot and red blood cells from serum). **Hemolyzed specimens will be rejected.** Refer to User’s Guide section MSA SPECIMEN REJECTION.
5. Immediately remove only the top two-thirds of the serum from the sample using a plastic transfer pipette (use of glass transfer pipettes may result in activation and/or clotting of the serum). Place the serum in a properly labeled plastic vial and clearly mark the vial contents as serum. **Glass vials will be rejected.** Refer to MSA User’s Guide section MSA SPECIMEN REJECTION.
6. Quick-freeze the serum samples using a dry ice and methanol bath or a -60°C to -70°C freezer. Each assay requested must be submitted in a separate plastic vial.
7. Ship samples in a Styrofoam container with five pounds of block dry ice.
8. All requests for MSA tests must include a completed MSA Test Order Form with a brief patient history and other pertinent clinical information. **Note:** Specimens collected in blue-top tubes, green top tubes, red/gray top-tubes, and lavender top tubes will be rejected for MSA tests. Refer to User’s Guide section MSA SPECIMEN REJECTION.

9. Consultation is available for any questions concerning the MSA test. Contact Biomedical Diagnostics Laboratory Services at info@biodiagnostics.com

**Blood Sample**

1. Obtain venous blood by clean venipuncture. Do not use needles smaller than 23 gauge.
2. Fill red top tubes with a minimum of 10mL of blood.
3. Allow tube to stand for a minimum of 30 minutes at room temperature to allow clotting to occur, then refrigerate and ship within 24 hours.
4. Ship samples in Styrofoam container with gel packs.
5. All requests for MSA tests must include a completed MSA Test Order form with a brief patient history, packing list and other pertinent clinical information. **Note:** Specimens collected in blue-top tubes, green top tubes, red/gray top-tubes, and lavender top tubes will be rejected for MSA tests. Refer to User’s Guide section MSA SPECIMEN REJECTION.

**Minimum Acceptable Volumes**

The minimum acceptable test volume is 10mL of blood or 2ml of serum. This volume is defined as the amount sufficient to perform one test, with no repeat or confirmatory testing. If an insufficient volume is received for testing, an attempt will be made to locate any additional sample that was collected at the same time. In this case, there may be delays and the test request may be referred to the Laboratory Director for issuance of a Specimen Rejection report.
MSA USER’S GUIDE

MSA SPECIMEN CONTAINERS

Biomedical Diagnostics Laboratory Services requests that clients use the following guidelines to ensure safe handling procedures, non-compromised specimens, and fast and accurate test results.

Standardized Serum Transfer Tubes

Biomedical Diagnostics Laboratory Services requires use of the standardized serum transfer tube for specimen submission. The benefits of the standardized transfer tube are numerous including faster turnaround time (frozen samples can be thawed in less than an hour) and reduced handling and errors.

Notes:

1. The tube has graduated markings up to 4 mL, with a capacity of 5 mL. To reach capacity, fill the tube to the ring at the base of the threaded top.
2. When submitting frozen specimens, it is critical to leave an air space at the top of the tube to allow for expansion and to prevent leakage. For this reason, liquid should never exceed 5 mL.
3. The tube’s threaded cap provides a leak-proof seal when screwed on properly. It is not a push-on cap.

Containers that may be accepted, but must be avoided:

1. Glass tubes for non-frozen specimens.
2. Syringes (where required) that are plastic and have a Luer Lock fitting which secures the cap. The syringe should be enclosed in two plastic bags and placed in a small cardboard box or plastic jar with a screw cap to protect the plunger from accidental pushing. Needle must be removed.

Containers that will NOT be accepted:

1. Glass tubes for frozen specimens
2. Tubes from an automatic aliquoting system with a “pop top” type of cap. The caps may come off during air transport and do not comply with DOT regulations.
3. Leaking specimens that are not placed in a secured secondary container or that are leaking in such a way as to compromise testing.
4. Syringes with needles attached.
5. Transfer tubes secured with Parafilm.
6. Specimens received in expired transport containers or media.

MSA SPECIMEN LABELING

To assure positive identification and optimum integrity of patient specimens from the time of collection until testing is completed and results reported, the client must label all specimens submitted to Biomedical Diagnostics Laboratory Services for testing with the patient’s first and last name, correctly spelled, and/or a unique identifying number (i.e., medical record number). Samples should be labeled with the date and time of collection and the collector’s initials.

Clients will be notified of inappropriately labeled specimens, and the specimen will be returned to the client upon request.

MSA SPECIMEN TRANSPORT

It is critical that all specimens are transported as quickly as possible. Prompt processing minimizes loss in signal and ensures a more accurate appraisal of the specimen.

To ensure optimum testing conditions for a specimen that is sent to Biomedical Diagnostics Laboratory Services, the shipper must determine two things.

1. The infectious nature of the specimen to be sent, using the definitions below.
2. The temperature at which the specimen must be maintained during transit, using instructions in section MSA SPECIMEN REQUIREMENTS.

Definitions of “Diagnostic” and “Infectious” Specimens

Diagnostic Specimens: Any human or animal material, including, but not limited to, excreta, secreta, blood and its components, tissue and tissue fluids, being shipped for purposes of diagnosis, but excluding live, infected animals. Diagnostic specimens not known or thought likely to be infectious are excluded from following procedures for shipping Infectious Substances.

Infectious Substances: Specimens known to contain, or thought likely to contain, pathogens. These specimens are capable of spreading disease when an individual is exposed to them. Transport authority requires the shipping laboratory to identify specimens as to their shipping description. Specimens not identified as infectious by this definition should be shipped as “Diagnostic Specimens.” Additional specimens may meet the criteria for Infectious Substances.

Transport of Diagnostic Specimens

Specimens that are not identified as infectious will be shipped as “Diagnostic Specimens.” Specimen volume must not exceed 500 mL per individual primary container. Specimens must be kept from contact with each other, and the number of specimens in a container (plastic bag) must have sufficient absorbent material to absorb the entire contents of the container.

All specimens must be in leak-resistant primary containers, and must be placed in leak-resistant secondary containers (plastic bags). Couriers are not allowed to pick up specimens that are leaking or are not in secondary containers.
When Shipping Specimen

1. Fill in the shipper and consignee information on the Air Waybill, including the name and phone number of the person sending the shipment.
2. Follow shipper requirements and any other controlling regulations for packaging blood for shipment.

Note: Shipments sent via Federal Express or Airborne, including frozen or refrigerated samples, should only be shipped Monday through Thursday. Do not ship on Friday. Samples are accepted Monday through Friday only. Samples must be shipped for overnight delivery.

3. A description of the contents of the shipment must be listed. This description will include “Medical Specimens” (diagnostics) and “Dry Ice” (if applicable). The weight of the dry ice should be listed in kilograms.
4. Send samples in a Styrofoam shipper with ice pack or dry ice along with a packing list and the completed MSA Test Order Form for each sample. The packing list should include the total numbers of samples sent.
5. Send samples overnight delivery to:
   Biomedical Diagnostics, LLC
   Attn: Laboratory Services
   5692 Plymouth Road, Suite B
   Ann Arbor, MI 48105

MSA SPECIMEN REJECTION

Specimens to which the following conditions apply will be rejected and returned to the originating site.

1. Specimen is submitted without an MSA Test Order Form.
2. Specimen is not labeled with the patient name.
3. The patient name (or other identifying information) on the specimen and order form do not correspond.
4. The specimen is labeled appropriately but the MSA Test Order Form is not complete.
5. The specimen is irreparably broken or damaged.
6. Specimen is submitted from an unauthorized source.
7. The referring physician has not signed the MSA Test Order Form.

All specimens must be collected, labeled, transported and processed according to procedure. Selecting the container type, volume and special handling requirements needed for analysis before the specimen is collected is essential. If the criteria for these processes are not met, the specimen may be rejected or the test may be canceled. The following represent some reasons for specimen rejection or test cancellation.

1. Inappropriate specimen type or difficulty in obtaining the specimen (e.g. hemolysis, lipemic specimens)
2. Insufficient volume for analysis
3. Improperly labeled specimen
4. Inappropriate specimen container
5. Improper specimen transport
6. Specimen that has leaked in transit
7. Specimen that has been sent in expired transport media
8. Incomplete or incorrect test order form
9. Test request without a specimen
10. Specimen without a test order form
11. Glass vials were used for serum containment
12. Specimens collected in blue-top, green-top, red/gray-top, or lavender-top tubes.

QUESTIONS

Main E-Mail address: info@bio-diagnostics.com