Policies—Meriter Laboratories

Animal Specimens

Meriter Laboratories (ML) accepts animal specimens for pathology, histology, and laboratory testing. Please indicate the animal species on the ML requisition.

Billing Services

Client—As per your agreement with ML, you will receive an itemized invoice/statement which will indicate the date of service, patient name, CPT code, test name, and test charge on a weekly or monthly basis.

Patient—If you elect to have ML bill your patients, please include the following necessary billing information on the requisition:

- Current patient address (street, city, state, zip code)
- Diagnosis (ICD-10 Code)
- Insurance company
- Insurance policy number
- Patient's name
- Responsible party
- Telephone number

Please advise your patients that they or their insurance company will receive a bill for laboratory services from ML. VISA®, Discover®, and MasterCard® are acceptable forms of payment. Payment may be made online at www.meriter.com.

Patient Authorizations and Signatures on File—If a physician or facility requests ML to bill services to insurance (Medicare, Medicaid, commercial insurance, etc.), it is the responsibility of the requestor to obtain all necessary patient authorizations for ML to submit claims and for the referring facility to release records for audits as necessary. All authorizations should be obtained and maintained by the referring facility in accordance with State and Federal regulations pertaining to record release and confidentiality as well as regulations pertaining to claim submission for the patient's insurer, Medicare, and/or Medicaid Rules. In order to submit claims and receive payment it is necessary for ML to disclose the procedure performed via CPT code, the patient's diagnosis via ICD-9 code, and pertinent patient demographics.

Cancellation of Tests

Cancellations received prior to test setup will be honored at no charge. Requests received following test setup cannot be honored. A report will be issued automatically. Testing that could not be cancelled will be billed to the facility since non medically-necessary charges cannot be passed to the patient.

Confidentiality of Results

ML is committed to maintaining confidentiality of patient information. To ensure Health Insurance Portability and Accountability Act of 1996 (HIPAA) compliance with appropriate release of patient results, ML requires one of the following identifiers for telephone inquiries:

- ML accession ID number for specimen
- Client account number from ML along with patient name
- Client accession ID number interfaced to ML
- Identification by individual that he or she is, in fact, "referring physician" identified on requisition form by ML client

Consultation Services

Meriter Laboratories has staff available to discuss appropriate testing, test ordering and test interpretation. The Client Service Department is available at 608-471-6529 or 800-236-0465. Client Services Representatives can assist you with test choices and ordering. In addition, the board-certified pathologists of Wisconsin Pathologists, SV are available to provide consultation regarding the ordering of appropriate tests and the medical significance of laboratory data.

General Information

For the convenience of our clients and their patients, ML provides specimen collection service in the Outpatient Department of our laboratory at 202 South Park Street at 2Center located in Meriter Hospital. Appointments are recommended, but ML will accommodate walk-in patients.

2Center Draw Station is open:

- Monday through Friday: 7:00 a.m. to 5 p.m.
- Saturday: 7:00 a.m. to 10:00 a.m.

Infectious Material

The Centers for Disease Control (CDC) in its regulations of July 21, 1980, has listed organisms/diseases for which special packaging and labeling must be applied. Required special containers and packaging instructions can be obtained from us by using the "Request for Supplies" form.

Shipping regulations require that infectious substances affecting humans be shipped in a special manner. See "Infectious Material." A copy of the regulations can be requested from the International Air Transport Association (IATA); they may be contacted by phone at 514-390-6770 or faxed at 514-874-2660.

Informed Consent Certification

Submission of an order for any tests contained in this catalog constitutes the certification to ML by the ordering physician that:

1. The ordering physician has obtained the "Informed Consent" of the subject patient as required by any applicable state or federal laws with respect to each test ordered.
2. The ordering physician has obtained from the subject patient authorization permitting ML to report the results of each test ordered directly to the ordering physician.

Medicaid Limited Coverage Plans

Medicaid has developed many limited coverage plans for beneficiaries. Examples of these plans are Family Planning, Emergency Services only, End-Stage Renal Coverage, and Well Woman Program. Each of these plans only covers a very limited number of services. It is the ordering physician/facilities responsibility to identify when a patient has 1 of these plans, and to notify the patient if the services being ordered (including laboratory services sent to ML) will be covered by their plan. If the tests being ordered or subsequent additional test requests will not be covered the patient must be notified that they will be financially responsible prior to services being rendered. If the patient has not been notified, then ML reserves the right to invoice the ordering facility for the services. For more information on Medicaid Limited Coverage Plans and patient notification requirements, please see the Wisconsin Medicaid web site.

Medical Necessity, National Coverage Determinations (NCD), and Advanced Beneficiary Notice (ABN)

ML complies with federal and state regulations pertaining to Medicare and Medicaid claims submission. Each state has the right to develop local policies; ML follows the policies for the State of Wisconsin.

Medicare will only pay for tests that are considered medically necessary. This includes most diagnostic tests and a few screening tests. Medicare performs post payment audits for medical necessity reviewing the test order, results as well as the ordering physician/facility's records. If a test is determined to be not medically necessary Medicare may

recoup any payments made for that test. To reduce Medicare paying for not medically necessary tests, Medicare has developed and published policies that define the diagnoses and frequencies for tests identified as having significant historical data on questionable medical necessity.

Medicare policies current as of March, 2012 pertaining to medical necessity for tests performed by ML are listed in "Medicare Policies for Medical Necessity on Laboratory Tests" in "Medicare Policies" in "Special Instructions." ML will issue memos announcing significant updates to these policies. We encourage clients to read Medicare announcements and to check the Medicare web site for all revisions.

National Coverage Determinations (NCDs) are coverage guidelines for clinical laboratory tests determined in cooperation between government health care officials and health care providers. NCDs standardize the coverage for laboratory tests at the national level.

When not medically necessary testing or testing not covered in the NCDs is requested, it is the responsibility of the physician/ facility to obtain an Advanced Beneficiary Notice (ABN). The ABN is an acknowledgment from the patient that they were notified that Medicare does not cover the test, and why it is not covered. The patient's signature is an acceptance of financial responsibility for the test. If an appropriate ABN is not obtained, ML reserves the right to hold the facility submitting the specimen financially responsible for that testing.

The Centers for Medicare and Medicaid (CMS) mandated a standard ABN. It is the providers responsibility to use the most current form. For information on the ABN please contact ML's Billing Department at 608-417-3870 .

Patient Identification Accuracy

ML must adhere to proper identification of patient specimens for good patient care, for quality and safety reasons, and to meet the regulatory requirements of the College of American Pathologists (CAP) and The Joint Commission (TJC). To be compliant, it is important that each specimen be properly labeled with the same demographics that appear on the paperwork or electronic order. If a discrepancy is identified upon specimen arrival at ML, we will contact you to make you aware of the discrepancy and **cancel the test order**.

Radioactive Specimens

Specimens from patients receiving radioactive tracers or material should be labeled as such. Specimens are not routinely tested at ML for background radioactivity. This radioactivity may invalidate the results of radioimmunoassays.

Reference Ranges

Laboratory certification agencies and laboratory vendors recommend periodic verifications of normal ranges for the local population. ML conducted a 10-month study to verify our reference ranges. Specimens were collected from 180 healthy volunteers who were referred by (but not limited to) local clinics, research clients, and employers. Test data was reviewed and graphed using multiple statistical packages, and then compared to multiple published references to determine the new normal ranges.

A key feature of these new ranges is expanded, more defined normals for specific ages of the population, particularly for pediatric and geriatric populations. The pediatric and geriatric normals were developed after an extensive review of scientific and medical literature.

Reference values are influenced by the patient's age and sex, and are based on our regional population and published literature. Adult reference ranges are listed for procedures in this manual as applicable. Reference ranges specific to the patient's age, sex, and species are printed with each test report. Age-dependent reference ranges are calculated using the subject's date of birth and the date the specimen is collected.

When the patient's age and sex are provided on the requisition, results falling outside the reference range are designated with an "H" for abnormally high or an "L" for abnormally low. The letter "C" will precede the "L" or "H" for all

critical values.

Failure to provide the sex and date of birth of the patient may result in incorrect reference ranges. If the sex is not provided, reference values will be reported as a female. If the date of birth is not provided, the reference range will be reported as a 40- year-old.

Reflex Testing

Reflex testing occurs when initial test results are positive or outside normal parameters and indicate that a second related test is medically appropriate. These tests are identified in the Meriter Laboratories manual with the criteria for when additional reflex testing will be performed. All reflex tests are listed independently with their corresponding fees and CPT codes. In many cases, the components of reflex tests are offered individually as well as together. Clients should familiarize themselves with the tests offerings and make a decision whether to order a reflex test or an individual component.

Reportable Disease

ML complies with all Wisconsin state requirements for reportable disease reporting. Wisconsin Information is transmitted electronically to the Public Health Department. If you need further information, please do not hesitate to call ML Client Services at 608-417-6529 or 800-236-0465.

Result Reporting

Telephoned, Faxed, or Printed Results: When requested, ML will telephone or fax results to our clients. Results may also be transmitted by ML to a fax in your facility. Transmission occurs 24 hours a day, 7 days a week. Results considered critical are promptly communicated by telephone to the requesting physician or clinic. In the event of an unexpected computer downtime, the client will be notified if their scheduled fax or print times are interrupted, and if turnaround time is impacted.

Mailed or Courier-Delivered Reports: Reports being delivered by the US Postal Service are taken to the post office on the final day of testing. Reports delivered by the ML courier are normally delivered the next business day.

Service Priorities and Turnaround Time

ML is committed to providing timely results to all clinicians and laboratories. ML defines turnaround time as the interval between receipt of the specimen and the availability of the result. This catalog lists the days on which the test is set up as a guide to expected turnaround times. Repeated tests take additional time.

If a considerable delay in reporting test results occurs, ML will do the following:

- Notify the hospital inpatient units that are ordering STAT testing of the delay, cause, and expected resolution if known.
- Place a notification on MyMeriter.
- Notify the NAC, ER and a member of Lab Leadership

STAT: In some cases, the test result may be needed more urgently than routine testing provides. Where possible, such a test may be ordered STAT by checking the appropriate box on the requisition or if placing an electronic order, select the STAT priority and placing a STAT label on the specimen bag. A phone call to the Client Services Department is advisable to establish whether a test is available on a STAT basis. A frozen section on tissue is considered a STAT. The Department of Pathology should be notified by the requesting client by telephone when this is to be scheduled. STAT tests are given a priority, and the results of STAT testing are telephoned if requested or critical. STAT results will be automatically faxed or printed to clients with auto-print or auto-fax capabilities. The telephone number (with extension or secondary location) for receiving the results should be indicated on the requisition for all clients that do not have automatic prints or faxes. A printed copy of the results will be sent in the usual manner with other routine results.

Specimen Volume

The "Specimen Required" section of each test includes 2 volumes - the preferred volume and the minimum volume. The preferred volume has been established to optimize testing and allows the laboratory to quickly process specimen containers, present the containers to the instruments, perform the test, and repeat the test, if necessary. Many of our testing processes are fully automated; and as a result, this volume allows hands-free testing and our quickest turnaround time (TAT). Since patient values are frequently abnormal, repeat testing, dilutions, or other specimen manipulations often are required to obtain a reliable, reportable result. Our preferred specimen requirements allow expeditious testing and reporting.

When the venipuncture is difficult or the patient is at risk of complications from blood loss (eg, pediatric or intensive care patients), smaller volumes may be necessary. The specimen minimum volume is the amount required to perform an assay once, including instrument and container dead space.

When patient conditions do not mandate reduced collection volumes, we ask that our clients submit the preferred volume to facilitate rapid, cost-effective, reliable test results. Submitting less than the preferred volume may negatively impact the quality of care by slowing TAT, increasing the hands-on personnel time (and therefore cost) required to perform the test. ML makes every possible effort to successfully test your patient's specimen. If you have concerns about submitting a specimen for testing, please call ML Client Services Department at 608-417-6529 or 800-236-0465. Our staff will discuss the test and the specimen you have available. While in some cases specimens are obviously inadequate for the desired test, in other cases, testing can be performed using alternative techniques.

Standing or Add-On Orders

To place a standing order or add-on order for laboratory testing, call ML Client Services Department at 608-417-6529 or 800-236-0465. Be prepared to supply the following information:

- Facility name-ward
- Date and time testing is to be performed
- Fax number if results are to be faxed
- Frequency of testing
- ICD-10 code
- Patient's full name
- Patient's insurance if ML is to bill insurance
- Phone number if results are to be called
- Physician's full name
- Test(s) name

ML asks that all standing orders be reviewed and renewed every 6 months. The Clinical Laboratory Improvement Amendment (CLIA '88) requires ML to obtain a written order for each laboratory test performed.

Supplies

Supplies may be requested by completing ML's "Supply Requisition) in "Requisitions, Consent Forms, and Billing Information" in "Special Instructions" or contacting the Client Services Department at 608-417-6529 or 800-236-0465. Supplies will generally be filled within 48 hours. Please allow
3 working days for delivery by courier. If supplies must be sent by UPS or U.S. mail, please allow 1 week for delivery.

The supplies provided by ML are solely to be used for the collection and preparation of specimens which are being sent to our laboratory for testing. Federal regulations prohibit using supplies provided by our company for any other use. Placing orders for and receiving supplies is an acknowledgment of understanding and agreeing to these conditions.

Tests Referred to Another Laboratory

As a convenience to our clients, ML can process specimens for testing not performed at our laboratory. We charge a handling fee for this service. As these tests become available in our laboratory, the price will be updated according to our cost to perform the test. Clients will be notified of all tests added to our listings by a technical update memo. When a test is not performed in-house, ML will decide to which laboratory the specimen(s) will be referred. This decision takes into account test accuracy, turnaround time, and laboratory charges. ML does not ordinarily accept orders for tests to be redirected to a particular laboratory. If a client has a particular request for a test that cannot be done at our usual reference laboratory, ML will consult with the requesting physician or clinic and jointly choose a reference laboratory.

Note: Other Laboratories also follow guidelines for billing only medically necessary testing. The client may be held responsible for testing when supporting information does not meet Medicare guidelines and an Advance Beneficiary Notice is not on file. For detailed information see "Medical Necessity, National Coverage Determinations (NCD) and Advanced Beneficiary Notice (ABN)" in this section.

Note: Not all laboratories will bill Medicaid for testing they perform. The patient is responsible for these costs only when they have been notified, in advance, that the laboratory will not bill. It is the ordering facility's responsibility to notify the patient of this expense. Laboratories that have been identified as unwilling to bill Medicaid include Prodesse, Specialty Laboratories Inc., and the University of Utah.

Unacceptable Specimens

Some specimens cannot be analyzed because of improper collection or degradation in transit. Other specimens may have prolonged turnaround times because of lack of necessary ancillary specimens or the patient information.

Criteria for Specimen Rejection: In order to assure the accuracy of results from our laboratory, we insist on proper collection, labeling and handling of specimens. The failure to carry out these procedures as recommended may result in jeopardizing the integrity of the testing process or our ability to perform the tests(s) requested.

Clerical Errors: When there is an error in labeling or specimen identification is inadequate, ML strongly encourages the specimen to be recollected. If the recollection is not possible due to lack of stability or unable to duplicate specimens, such as timed specimens and tissues, testing will be performed and results held until verbal authorization has been received. The final identity needed verification after receipt in the laboratory. Clerical errors such as wrong date of birth or gender may result in an incorrect reference range being reported. Recording the wrong collection times or volumes may result in inaccurate calculations that may affect test results.

Technical Processing Issues: Specimens are sometimes unacceptable due to issues such as:

- Clots in EDTA or citrate specimens
- Hemolysis
- Lipemia
- Quantity not sufficient
- Wrong specimen type submitted
- Inaccurate timing of urine collections
- Radioactive interference

In such cases, the laboratory will contact the client to request a repeat specimen (if possible), or to explain the limitations on testing. In most cases, the test will be cancelled.