

St. Marys Laboratory Services

Licenses and Accreditation

College of American Pathologists	17842 01 01
Medicare Provider Number	110 12 700
National Provider Identifier Number (NPI)	1184621211
Federal Tax ID#	390806393
CLIA Identification Number	52D0393669

Location

St. Mary's Hospital 700 South Park Street
Madison, WI 53715-0450

608-258-6917

1-800-236-6917

608-258-6900 (After 6:00PM)

608-259-5865 (FAX) (All SLS orders, ABN information)

608-258-6268 (FAX) (Any non-order related information)

Client Services

Messenger Service

Our messenger service picks up specimens and delivers results Monday through Friday for SLS clients. Routine Saturday pickup is available on a limited basis. Although our laboratory is open, the messenger service is not available on the following holidays: New Year's Day, Memorial Day, Independence Day, Labor Day, Thanksgiving and Christmas.

Supplies/Requisition Forms

The majority of supplies required for collection and transport of samples which will be tested at SLS are provided to clients without charge. A supply ordering form is provided to assist in filling your order promptly. If supplies other than those on the order form are required, please call the office staff to help facilitate your request. Please allow one week (5 business days) for the preparation and delivery of these supplies and requisition forms.

Test Turnaround Time

This manual lists the days on which each test is set up and the time you can expect results available after each run. Preliminary test results are available for most of the tests which require several days to complete. Results will be phoned to you or the physician directly if you indicate a phone number and name of a contact on the order requisition. If you request a result to be called after your usual office or laboratory hours, please provide the phone number where the physician can be reached on evenings or weekends.

Quality Assurance and Repeat Assays

An extensive quality control program and follow-up on all suspected erroneous results are an integral part of the quality of service we provide. We will repeat, at no charge, any test where our initial results are incompatible with the physician's clinical findings. Specimens are held for seven days after being tested. Any request received during that time will be done on the original specimen provided the component in question is stable and the necessary volume is available. If not, a repeat will be done on a newly submitted sample.

Outpatient Specimen Collection

A client may prefer to have a patient's specimen collected at our laboratory directly. Arrangements for this service can be scheduled by calling our office between the hours of 8AM and 4:30 PM. Please instruct patients to come to the laboratory directly; patient registration is not necessary, however there is a fee for collection which is listed in your fee schedule.

Consultations

Associated Pathologists, SC, are available for test result interpretation or consultation. In addition, we have a fully qualified staff of experienced technical personnel who are available to provide assistance. If you desire these types of services, please use the resource listing found on Page 2 of this manual to reach the appropriate person. Our Technical Representative can also be used to arrange any special consultation services for you.

Customer Assistance

Technical representatives are available to work with you in your laboratory as needed. We can offer assistance in resolving technical problems, evaluating equipment needs, delivery or billing problems or daily quality control issues. Appropriate assistance can be arranged by calling our Customer Services Assistants at 608-258-6917.

Keeping Informed

St. Marys Laboratory Services periodically publishes bulletins about changing aspects of clinical laboratory testing, new procedure availability, changes in specimen requirements and significant interpretative changes. These are presented in a format which you can maintain for ready reference.

Networking with St. Marys Staff

The laboratory staff of St. Marys Laboratory Services would be happy to have you visit our facilities at any time. Such visits provide the opportunity to exchange information on testing, equipment, methodologies and policies, as well as seeing first hand the quality of service we provide. It also provides an opportunity for us to learn more about your facility and expectations.

Unlisted Tests

With very few exceptions, our laboratories working in conjunction with each other can provide the full range of services to meet the needs of your patients and physicians -- your laboratory as the primary laboratory service, SLS as the secondary reference lab and other SLS contracted reference laboratories as the tertiary service for both of our facilities. Occasionally SLS uses services of other reference laboratories for very specific tests; in those cases specimens you refer to us will be sent there. We only refer specimens to accredited reference laboratories meeting our specifications.

When requesting tests which will be referred on to a tertiary reference lab, please use the Clinical Laboratory Referral Test requisition provided. If a test is not listed, please print the appropriate test name and test code on the requisition when available. The name of the laboratory performing the test will be included with the report. Charges for tests which we refer to another laboratory for you will appear on your SLS monthly invoice and will include a nominal fee (\$5.00) to cover our cost to process the referral.

Billing and Crediting Policies

Fee Schedule and Billing

Our fee schedule is published separately on an annual cycle and is available through the office. A contract billing summary and detail invoice (see sample), issued the first week of every month, covers those test procedures requested during the previous calendar month. All payments are due forty five (45) days from the date of the related invoice and are independent of any reimbursement received by the client from patients or third party payors. Questions regarding clarification on any invoice should be directed to the office staff.

Medicare Coverage for Lab Testing

- Consistent with federal regulations, charges for tests you have referred on Medicare or Medicaid patients will be billed directly to the carrier by St. Marys Hospital Medical Center. **Appropriate Medicare/Medicaid numbers and ICD-9 codes must be included at the time the test is ordered.**
- Each individual component of any panel must be medically necessary to qualify for Reimbursement. Medicare will not pay for non FDA-approved tests or for screening tests.
- If there is reason to believe that Medicare will not pay for a test, the patient should be informed of that fact. The patient should then sign an Advance Beneficiary Notice (ABN), to indicate that he or she is responsible for the test if Medicare denies payment.
- If no ABN was received with the specimen before processing or there was inadequate documentation and payment was denied by the fiscal intermediary, SLS will bill the client for the services that were provided.
- The client accepts financial responsibility for any test ordered where insufficient diagnosis information has been given and/or are considered not medically necessary according to Medicare and Medicaid.
- In the event a client discovers that the patient is actually a Medicare patient after a test was submitted and completed, the client will be allowed a 45 day grace period after the receipt of the invoice to provide appropriate Medicare information for SLS to bill Medicare appropriately. The client account will be credited for the initial charge. The client will be responsible to pay SLS for any test for which information received exceeds the 45 day grace period.
- If these lab orders are being done in conjunction with an inpatient hospital stay at the time of order or planned within the next 72 hours, billing must be included in the DRG billing done at the hospital where the patient is/or will be.

Medicaid Billing

If the patient's primary insurance coverage for laboratory services is Medicaid, SLS will invoice Medicaid directly. The client is not responsible for payment of covered services under Medicaid when it is the primary insurance.

Specimen Information

Ordering Information

An order requisition must accompany each specimen or group of specimens. St. Marys Laboratory Services provides four types of order requisition, one for clinical laboratory, one for surgical pathology, one for microbiology, and one for frequently ordered tests that are sent to another reference laboratory. Order requisitions are pre-printed with client name and account number for your convenience. For accuracy in testing, reporting and billing, please print clearly or type all patient information requested. Minimum patient information required for accurate result interpretation includes the patient's full "legal" name (First and Last), date of birth and sex, as reference ranges are age and sex dependent. If a clinic record or patient identification number is necessary for proper distribution of reports in your office, please include it in the patient number or lab number area on the order requisition. Your number will be transferred to the patient's report and will appear on the result copy headers of the report. The originator's copy is provided as a record for you to verify orders and monthly invoices.

St. Marys Laboratory Services participates in the Medicare/Medicaid programs and accepts assignment for patients covered by these programs in accordance with current regulations. When referring tests on patients covered by one of these programs, additional patient information is required to process the bill directly: Patient's address, Medicare or Medicaid number, ICD-9 Code(s), and supplemental insurance information. **This information must be supplied at the time the test is ordered.** SLS relies on the ordering physician to notify and educate Medicare patients when the tests they are ordering are not covered by Medicare as being medically necessary. The ordering facility is required to obtain a government approved Advanced Beneficiary Notice (ABN), indicating the patient is aware of his/her responsibility to pay for non covered service. One copy of the signed ABN should be sent with the specimen, one given to the patient and one maintained at the ordering facility.

A miscellaneous area for ordering tests which do not appear on the requisition is provided for additional tests, specimen or patient information.

Examples of requisitions are on the following pages.

Multiple Tests

When multiple tests requiring different processing are requested on the same patient, please identify the specimen type on the transport tube. Be as specific as you can be, especially since many different types of plasmas are now tested, i.e.: EDTA plasma (for cardiac marker), citrate plasma (for coagulation) and heparinized plasma for CKMB. If a single sample tube needs multiple tests done on it, please do not freeze unless you first aliquot to separate tubes.

Reference Ranges

As methodology or instrumentation changes in our laboratory, our reference ranges also may change. The ranges listed in this manual reflect adult values for current methodology unless indicated. Age specific reference ranges for neonates, pediatrics and adolescents are included in addendum #5. It is important to refer to the reference range printed on the patient's result copy as this will always reflect the correct normal value for the methodology currently in use, the age, and sex of the patient.

Reporting

Most frequently ordered tests are reported within 24 hours following receipt of the specimen at St. Marys. Those which require a longer processing time will be reported as soon as they are completed. This manual lists the days on which each test is set up as a guide to the expected turnaround time.

St. Marys Laboratory Services' computerized reporting system includes a chart-ready report form with reference ranges for the age and sex of the patient. Abnormal results are identified with an "H", "L", or "P" following the patient value indicating a result higher or lower than the expected reference range, or that the value is a "panic or life threatening" value. A panic laboratory value is a value at such variance with normal that it represents a pathophysiologic state which is life-threatening and requires immediate and appropriate medical action. Our laboratory staff communicates each and every panic value immediately to the client, ordering physician or his/her nurse. If you receive such a call, please forward the information to the physician immediately. See the following table of Panic Laboratory Values as reference for results which will be called.

If you need results before your next scheduled printing or delivery, we will be happy to fax your results. Please supply the fax numbers. **If results are needed after your usual hours, please provide a phone number where the physician can be reached.**

Preliminary results will be reported for tests which require a lengthy time to process, such as cultures; positive culture results will be phoned.

Patient Result Report Sample

Physician Summary

**St♥ Mary's
Laboratory
Services**

Nov 26, 2006 1413

SectionLab (1)

Page: 1

700 S Park Street
Madison, WI
53715-0450
608-258-6917
800-236-6917

Pat Name: DOE, JANE

Unit #/Acct #: 000000117/A9633100001

Loc: CON

Attending Dr-Svc: SMITH, JOHN - LAB

Admitting Dr: XSLs,ST MARYS HEALTHWORKS

In: 11/26/06 1410

Spec: Blood

Out: 11/26/06 1412

Coll Time: 11/26/06 0800 Ordering Phys: SMITH, JOHN Techs:

VKMCDER TCHAGLU

[A9633100001/15795]

CBC NO DIFFERENTIAL

Result Name	Result	Reference Range
WBC:	11.5 H	5.0-11.0
Hgb:	15.0	14.0-18.0
Hct:	40.6	40-54
MCV:	98	80-100
RDW:	14.2	11.5-14.5
Plt:	350	150-450
Accn Comment:	134683b26	

End of Report - 11/26/06 1413

DOE, JANE

BD: 01/05/56

St. Marys Hospital Medical Center

LABORATORY CRITICAL “PANIC” VALUES

Chemistry	Low	High
Alcohol		≥ 300 mg/dL
Ammonia		≥ 80 umol/L
Bicarbonate, arterial	≤ 10 mmol/L	≥ 40 mmol/L
Bilirubin, neonatal (≤ 1 month)		≥ 18 mg/dL
Blood Gases		
pCO ₂ , arterial	≤ 20 mmHg	≥ 70 mmHg
pH, arterial or venous	≤ 7.2	
pO ₂		
arterial	≤ 49 mmHg	
Cath venous/capillary (IICU)	≤ 10 mmHg	
venous/capillary	≤ 40 mm Hg	
Cord Blood	Not necessary to call panic values	
Calcium	≤ 6.0 mg/dL	≥ 13.0 mg/dL
Carbon Monoxide		≥ 12%
Creatinine		≥ 7.0 mg/dL
Glucose	≤ 40 mg/dL	≥ 500 mg/dL
Glucose (newborn)	≤ 30 mg/dL	≥ 300 mg/dL
Iron (overdose)		≥ 300 ug/dL
Lactic Acid		≥ 3.0 mmol/L
Magnesium	≤ 1.0 mg/dL	≥ 7.0 mg/dL
Methemoglobin		≥ 2%
Phosphorus	≤ 1.0 mg/dL	≥ 8.0 mg/dL
Potassium	≤ 2.5 mmol/L	≥ 6.5 mmol/L
Potassium (newborn)	≤ 2.5 mmol/L	≥ 8.0 mmol/L
Sodium	≤ 120 mmol/L	≥ 160 mmol/L

LABORATORY CRITICAL “PANIC” VALUES

Drug Levels	Low	High
Acetaminophen		≥ 150 ug/mL
Carbamazepine		≥ 15.0 ug/mL
Digoxin		≥ 3.0 ng/mL (≥ 6 hrs after dose)
Dilantin (Phenytoin)		≥ 30.0 ug/mL
Gentamicin/Tobramycin		Trough ≥ 4 ug/mL Trough ≥ 3 ug/mL-IICU Peak ≥ 12 ug/mL
Lithium		≥ 1.5 mmol/L
Phenobarbital		≥ 50.0 ug/mL
Salicylate		≥ 30 mg/dL
Theophylline		> 20.0 ug/mL
Valproate (Valproic Acid)		≥ 150ug/mL
Vancomycin		Trough ≥ 30.0 ug/mL Peak ≥ 60.0 ug/mL

Hematology	Low	High
Fibrinogen	≤ 100 mg/dL	
WBC (newborn to 16 years)	< 1,000/uL	
Hematocrit	≤ 21.0%	≥ 57.0%
Hematocrit (newborn)		≥ 72%
Hemoglobin	≤ 7.0 g/dL	≥ 19.0 g/dL
Hemoglobin (newborn)		≥ 24.0 g/dL
Platelets	≤ 30,000	≥ 1,000,000
Platelets (newborn & peds)	≤ 20,000	
INR		≥ 6
Reducing substance in children		Positive
Urine Ketones		≥ 2+ in the presence of positive glucose
Smear Malaria		Positive Smear

Microbiology

Positive Blood Culture
Positive CSF (lumbar puncture) Gram Stain or Culture

Blood Bank

Clinically significant antibody found in Hemolytic Disease of Newborn work-up.

Specimen Identification

Proper identification of samples is the responsibility of the client. Each specimen should be clearly and legibly labeled with the following information: A typed label is preferred.

Patient's First and Last (Legal) Name
Date of Birth
Client Name
Tests Ordered
Collection Date and Time
Specimen type (serum or plasma)

Unacceptable Specimens

Some specimens cannot be analyzed because of improper collection, identification or storage. Our laboratory does not accept or test unlabeled or mislabeled specimens for venous blood, stool, or urine. You will be notified of any specimen problem on receipt. Notification of any corrective action taken will be documented for you on the report.

Following is a checklist you should confirm before referring any specimen:

Patient/Specimen Identified Properly

Correct Specimen Type
Adequate Specimen Volume
Appropriate Transportation Medium or Container
Specimen labeled is attached and correct
Lack of Hemolysis
All Requested Patient Information is Included
Medicare Information, if Applicable
ICD-9 Diagnosis Code(s) is Included

Collection and Storage

To ensure the most accurate and reliable results, it is imperative that all specimens are properly collected, separated and stored at the proper temperature prior to pickup. Specimen requirements and volumes required are included with each procedure, with special handling instructions appearing in bold print. **Refrigerate** all specimens until pickup unless otherwise indicated.

Frozen Specimens

Frozen specimens will be transported on dry ice. If multiple tests are ordered and one or more are required to be frozen, please aliquot the specimen in the appropriate quantity for each test **before** freezing.

Fasting Specimens

Certain tests are most accurate if performed when the patient has been fasting. Instruction to the patient should include avoiding intake of all food and beverages except water for 12 hours prior to the time the specimen will be collected.

Vacutainers

The type of specimen and collection code appear with the specimen requirement for each test as indicated below: (When multiple tests are drawn, please draw in the same order listed.)

<u>Color of Vacutainer Top (BD)</u>	<u>Color of Vacutainer Top (Greiner)</u>	<u>Specimen Type</u>
Red	-	Serum
Lt Blue	Lt Blue	Citrated Plasma
Gold Serum Separator (SST)	Red/Yellow	Serum (clot activator)
Dark Green	Green	Lithium Heparinized Plasma
Green Plasma Separator (PST)	Green/Yellow	Lithium Heparinized Plasma
Lavender	Lavender	Whole Blood or EDTA Plasma
Pink	Pink	Whole Blood

Serum

Red Top: Allow the blood to clot at room temperature for 15-20 minutes. Centrifuge and transfer the cell-free serum to an appropriately labeled transfer tube within 10 minutes. Refrigerate until pickup.

Red/Yellow gel tube or Gold Top Serum Separator: Allow the blood to clot at room temperature for 15-20 minutes. Centrifuge with the stopper intact for ten minutes **only once**. Serum in SST tubes does not need to be transferred if the barrier forms properly and the specimen will be tested within 24 hours. If the specimen will be held for more than one day, such as a weekend, please separate serum into a transfer tube. If the barrier is not complete and cells are exposed to the serum, pour serum into a clean centrifuge tube, cap, re-centrifuge and transfer serum to a transfer tube for delivery. Refrigerate transfer tubes and spun SST tubes until pickup.

Plasma

The ratio of blood to anticoagulant is critical therefore, tubes must be filled completely. Mix gently, but thoroughly, immediately after collection. Centrifuge all tubes with stopper on immediately after collection. Separate cell-free plasma into an appropriately labeled transfer tube; refrigerate until pickup.

Lithium Heparinized Plasma: Centrifuge for ten minutes; separate cell-free plasma into an appropriately labeled transfer tube. Refrigerate until pickup.

Green/yellow gel tube or PST Lithium Heparinized Plasma: Centrifuge for ten minutes; plasma in PST tubes does not need to be transferred if the barrier forms properly and the specimen will be tested within 24 hours. If a specimen will not be delivered and tested within 24 hours, please separate cell-free plasma into a transfer tube. If the barrier is not complete and cells are exposed to the plasma, pour plasma into a clean centrifuge tube, cap, re-centrifuge and transfer plasma into a transfer tube for delivery. Refrigerate transfer tubes and spun PST tubes until pickup.

Citrated Plasma: Centrifuge immediately at 2500-3000 RPM for 10 minutes. Remove only the top two thirds of plasma volume. Separate cell-free plasma immediately and place in an appropriately labeled transfer tube. Place on ice or refrigerate until pickup. Freeze the plasma if it will be stored longer than 12 hours before pickup.

Note: Anticoagulant: Blood ration must be adjusted for hematocrits > 55%.

Whole Blood

Mix gently, but thoroughly, immediately after collection. Refrigerate if specimen will be held longer than 4 hours before pickup.

Blood Bank Specimens

Use pink top vacutainers only. Refrigerate with cells intact until pickup. Do not refrigerate if order is a Direct Coombs test. All specimens with blood bank orders should be delivered within 48 hours.

Hematology Specimens

Most hematology tests are performed on an EDTA tube and should be analyzed within 36 hours after collection. If you know the sample will not be delivered within 12 hours, refrigerate immediately. If a differential is required, two slides should be made before the sample is refrigerated. Please label slides **in pencil** with patient's name. A Sedimentation Rate must be analyzed within 24 hours of collection. Specimens being tested for a Reticulocyte Count should be refrigerated immediately and analyzed within 72 hours.

Microbiology Specimens

Collection and handling instructions are included with specific test information. For viral specimen collection and handling guidelines, refer to Addendum in addition to individual test requirements.

Surgical Pathology Specimens

Immerse specimen completely in 10% phosphate buffered formalin in a container which can be completely sealed. Label should include patient's full name, type and number of specimens, tests desired, date and client. Pertinent history and information about the specimen, including the body site from which it was obtained, should be included on the requisition. All surgical pathology specimens must be submitted with a formaldehyde caution label available through SLS. All containers must be placed in a zip-top or leak-proof bag.

24 Hour Urine Collection

Instruct the patient to empty their bladder when they get up in the morning. Start the 24 hour collection period from that time. Using the proper preservative, collect all the urine passed in the next 24 hours. If no preservative is used, refrigerate during collection. The final collection should be when the bladder is emptied the same time the following morning. Measure and record the full 24 hour volume on the order requisition. If sending an aliquot, a minimum of 20 mL of well mixed urine should be submitted for testing unless a specified amount is indicated.

Special Handling

BLOOD AND BODY FLUID SPECIMEN DELIVERY PRECAUTIONS

1. General Precautions

Extraordinary care must be taken to avoid accidental wounds from sharp instruments contaminated with potentially infectious material and to avoid contact of an open skin lesion with material from these patients.

2. Handling

Disposable gloves should be worn when handling blood specimens, blood soiled items, body fluids, excretions and secretions as well as surfaces, material and objects exposed to them. Hands should be washed after removal of disposable gloves.

3. Centrifugation

All specimen tubes should be spun with the cork in position in a sealed container to guard against aerosol formation each time the specimen is spun. Transfer of specimens should be done with dispopipettes - no mouth pipetting.

4. Specimen Handling

After proper collection and processing, each specimen should be put in a zip lock transport bag with the requisition folded and put in the outside pocket of the bag with patient's name facing out.

5. Transportation

All couriers must comply with Federal Regulations which specify how specimens must be packaged for transport. Couriers may not transport improperly packaged specimens. Couriers will refuse to transport specimens which are not correctly packaged at time of pickup.

- A. Personnel other than SLS Messenger (cab, physician, client employee, volunteer)
Transportation via Cab.
 - 1. Place specimen in a plastic container with a leak proof cap.
 - 2. Place plastic container in a zip top plastic bag with a biohazard label. (If needed, place ice inside the bag also, taking care not to overfill it.) Ensure that bag is securely closed.
 - 3. Place bagged specimen in a rigid container, such as a Styrofoam box or plastic specimen container ("cottage cheese" type) and seal
 - 4. If desired, place inside a brown paper bag for ease of carrying. The outer most container (brown bag or rigid container if paper bag not used must have a label identifying the contents:
 - a. If a biological specimen, use biohazard symbol.
 - b. If a pathology specimen in formalin, use formaldehyde warning label.

- B. US Mail (primarily tissue specimens) The US Postal Service requires the following packaging:
1. Place specimen in a plastic pre-filled formalin container with a leak proof cap. Note warning label and handle with care.
 2. Label specimen container with patient name and type/site of tissue. Wrap container in sufficient absorbent material to completely absorb the contents in case of leakage.
 3. Place wrapped plastic container in a zip top plastic bag. Ensure that bag is securely closed. Paperwork should be placed in the outer pocket of the bag.
 4. Place bagged specimen in a Styrofoam box and seal with tape.
 5. Place Styrofoam box inside addressed cardboard mailing sleeve. The outside mailing box must be labeled with a formaldehyde warning.
- C. Overnight courier (primarily flow cytometry specimens)
1. Fresh tissue specimens must be shipped by overnight courier.
 2. Place fresh tissue specimens in a plastic container with a leak proof cap. The container must contain tissue culture media (RPMI 1640 or similar media), in order to retain the specimen integrity. Media is available upon request. Make sure that the volume of media is at least twice the volume of the tissue. Place container in a zip top plastic bag.
 3. If specimen is whole blood or bone marrow place the container in a zip top plastic bag. Ensure that the bag is securely closed.
 4. Place the bagged specimen and enough absorbent material to absorb the liquid in the container. Place paper work in a mailing cylinder or box, and seal it with tape.
 5. Place the overnight courier label and a biohazard label on the outermost container.
 6. Call the flow cytometry lab (608-258-6309) and inform them the specimen will arrive the next day. This will ensure that the specimen is processed as soon as it arrives.
 7. *** During excessively cold weather conditions, please contact the flow cytometry lab for further instructions. ***

Confidentiality

Any and all resident records, charts or reports produced by SLS are and remain the property of SLS. Any and all resident records, charts or reports produced by client are and remain the property of client. If either party has access to such resident records, it must handle such records in accordance with applicable law and regulations relating to patient confidentiality. The parties agree to execute any documents and take any action required by the Health Insurance Portability and Accountability Act of 1996 with respect to the reports, records and supporting documentation prepared in connect with this Agreement.

Certification and Compliance

SLS is and shall remain at all times compliance with all applicable laws and regulations in connection with its provisions of laboratory services and billing for services. SLS is and shall remain at all times during the term of this Agreement licensed to provide all types of clinical laboratory testing by the State of Wisconsin, the United States Department of Health and Social Services, Medicare and Wisconsin Medical Assistance. If SLS CLIA certification is suspended or revoked, Client will receive written notification of such and have the option of termination of their agreement immediately.