AVERA SACRED HEART HOSPITAL
YANKTON, SOUTH DAKOTA

Policy:
Specimen Collection

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Mission Statement:

Our locally owned and operated Avera LabNet Service Centers located in Aberdeen, Mitchell, Sioux Falls and Yankton offer comprehensive laboratory outreach services to physicians, hospitals, clinics, nursing homes and other providers requiring laboratory services in our five state region.

Our Service Centers are equipped with state-of-the-art methodologies and equipment to provide testing in all major clinical specialties. Test offerings are further enhanced through direct, quality relationships with nationally recognized laboratories specializing in esoteric laboratory testing.

Integrated, personalized, and caring services are the outstanding features of our Avera Laboratory Network. We acknowledge the importance of providing integrated services in our five state region but our services continue to emphasize our belief that each of our customers and the patients they serve, have needs that are unique and require individually structured services. Therefore, we strive at all times to personally customize our services to meet the needs of the customers we serve.

Professional Staff:

Avera Sacred Heart Hospital Laboratory is quality driven by board certified pathologists. Collectively our pathologists represent over 50+ years of experience in all specialties of clinical pathology, cytology, and anatomic pathology. Our pathologists serve as active clinical consultants and are available 24 hours a day for consultation on concerns related to appropriate test utilization, test result interpretive assistance or any concerns that may occur in the course of patient management.

In addition, our laboratory takes pride in our dedicated 24+ clinical laboratory professionals which include directors, managers, consultants, technical staff and customer support staff whose combined education, experience and expertise assure quality through all pre-analytical, analytical, and post-analytical phases of laboratory and customer support services.
General Information

Client Services:

*Avera LabNet’s* Client Service Representatives and Account Representatives take pride in serving our customers needs in a caring and effective manner.

Our Client Service Departments specialize in handling all client needs relating to:

- Specimen requirements
- Test result inquiries
- Test availability assistance
- Client communication needs
- Specialized reporting requirements
- Courier and supply assistance
- Testing change assistance
- Billing inquiries

We take pride in our Extended Client Service Coverage which is available 7 days a week, 24 hours a day to handle all our customers immediate assistance requests relating to direct testing information, specimen requirements and result inquiries.

Logistics:

*Avera LabNet* Service Centers provide regional courier services at no charge to our service areas in Iowa, Minnesota, Nebraska, North Dakota and South Dakota. Postal service and specialized contracted courier service may be utilized in areas outside of our direct service region.

Supplies:

Supplies required to assure proper specimen collection, preparation, ordering and transportation to Avera Laboratory Network (ALN) Service Centers are supplied at no charge. Supplies are provided only for those tests referred to ALN.

Supplies may be obtained by filling out a “Supply Requisition Form” to your ALN Service Center’s Client Service Department. Supplies that may be ordered at no charge include, but are not limited to:

- Specimen transport bags, containers and pour-over tubes
- Specialty collection kits and tubes
- Vacutainer tubes for testing being sent to ALN
- Vacutainer needles and holders for sites that do not operate a CLIA licensed laboratory
- Centrifuges for sites that do not operate a CLIA licensed laboratory
- Requisitions and information forms
- Computer hardware/printers as needed to utilize secure online test requisitioning and result reporting if criteria is met
Consultation Services:

Experienced consultants are available for administrative and/or technical consultative services. Services offered are structured to meet the individual client's needs at the frequency defined by the individual client and may include, but may not be limited to:

- Review and recommendation on laboratory policies/procedures
- Review and recommendation on quality processes and process improvement strategies
- Performance of instrument validations and/or review of preventive maintenance programs
- Continuing education
- Review and recommendation on regulatory guidelines and accreditation standards
- Assistance in general laboratory management accountabilities in the areas of purchasing, capital equipment, and personnel

Consultation services are charged for on an hourly fee for service basis and require a signed agreement outlining client-requested services and frequency guidelines.
Policy Information
Billing and Compliance:

Billing Overview:

*Avera LabNet* Service Centers are established to perform various types of billing services. It is the responsibility of requesting facility to designate the appropriate type of billing required for the services rendered and to provide correct and complete billing information based on the type of billing to be performed. In the event, that the method of billing is not marked on the requisition or if incomplete billing information is provided, the client will be billed for the services requested.

Client Billing:

Itemized monthly statements will be issued. Terms of payment are net 30 days. If an invoice is in question, please contact your Service Center’s Client Service Department who may direct you to our appropriate Business Office personnel for assistance.

Clinic/Physician: *Avera LabNet* Service Centers are required to bill all tests performed on-site on Medicare and Medicaid patients. All other patient types may at the direction of the client be billed to their account.

Hospitals: Hospital clients are required to request Client Billing for all of their inpatient and outpatient laboratory services.

Medicare/ Medicaid Billing:

*Avera LabNet* Service Centers will bill Medicare and Medicaid programs directly in accordance with all appropriate regulations. It is the responsibility of the submitting client to determine appropriate primary and secondary coverage specifics as required by federal law. All required test requisition information must be supplied at the time the test request is received. Required information includes but may not be limited to:

- Patient’s specific demographic information (full legal name, sex, DOB)
- Patient’s complete address
- Medicare (or Medicaid) number(s)
- Diagnosis information (ICD-9 Codes)
- Requesting physician’s complete name (or last name, first initial)
- Physician UPIN identification number if not previously on file at providing laboratory

In the event that incomplete information is given at the time of the test request, test processing, resulting and reporting may be held until the client has been contacted for the complete information required by federally funded programs.
General Information

Patient Billing:

*Avera LabNet Service Centers will bill a clinic’s or physician’s patient directly if complete billing information is provided on the test requisition at the time the specimen is submitted.* If you request that we bill the patient directly, please advise the patient to expect a bill from our laboratory. Required information includes:

- Patient’s specific demographic information (full legal name, sex, DOB)
- Patient’s complete address
- Patient’s current phone number, including area code
- Guarantor’s complete information (full name, address, phone number, relationship to patient)
- Requesting physician’s complete name (or last name, first initial)

Third Party Billing:

*Avera LabNet Service Centers will bill third party payers directly upon request.* Complete billing information must be provided on the test requisition at the time that the specimen is submitted. Required information includes:

- Patient specific demographic information (full legal name, sex, DOB)
- Patient’s complete address
- Policy holder’s/Guarantor’s complete information (full name, address, phone number, relationship to patient)
- Insurance company complete information (name, address, policy and group number)
- Diagnosis information (ICD-9 Codes)

Compliance and Medical Necessity:

*Avera LabNet Service Centers have adopted and implemented comprehensive Compliance Programs that enforce internal controls that promote adherence to applicable federal and state law and the program requirements of federal, state and private health plans.* Through these formal programs, we are showing our commitment to the compliance process. We also remind all clients that they too are responsible by law to enforce and abide by rules and regulations relating to compliance regulations.
Medical Necessity and Diagnosis Codes:

- The Medicare program will only pay for tests that meet Medicare coverage criteria and are reasonable and necessary to treat or diagnose an individual patient.
- Organ or disease related panels would only be paid in whole when all components are medically necessary.
- Medicare generally does not cover routine screening tests unless covered under approved screening program criteria.
- It is the responsibility of the laboratory and the ordering physician or other authorized individual to ensure that claims being submitted for payment to federally funded programs occur only when services are covered, reasonable and necessary. Non-covered services must be identified as non-covered services through appropriate mechanisms.
- It is the responsibility of the treating physician, authorized person on the physician’s staff or other authorized individual to order tests by law, to maintain in the patient record all required documentation to support the medical necessity of the service the laboratory has provided and billed to a federal or private health care program.
- It is the responsibility of the treating physician, authorized person on the physician’s staff or other authorized individual to order tests by law, to provide at the time of the test request, all specific diagnostic information documenting the medical necessity of the tests requested. ICD-9 coding is the preferred format of providing diagnosis information. In the event that written diagnosis information is given, it must be in such format as to allow for direct conversion to an approved ICD-9 code. Inappropriate diagnostic information includes the use of abbreviations or truncated terminology. In the event, that written diagnosis information cannot be coded, the appropriate individual will be contacted for diagnosis clarification.
Use of Advanced Beneficiary Notices or Waiver of Liability:

An ABN need only be obtained for laboratory testing that Medicare may deny as “not reasonable and necessary” upon submission of the claim. This includes testing for which Medicare has a Local Medical Review Policy (LMRP) that defines when the testing is determined by policy to be medically necessary.

When testing ordered is to be referred to a laboratory provider that will not see the patient or have the opportunity to obtain the ABN, the responsibility of obtaining the ABN form in correct format is the responsibility of the referring entity. The completed ABN form must be submitted at the same time that the test is requested and the specimen is sent into the laboratory for testing.

Criteria for an appropriately obtained and documented ABN includes:

- The ABN must be in writing, using approved notice language.
- The laboratory providing services must retain a copy of the ABN. Blanket waivers are not acceptable.
- The ABN must be signed and dated by the beneficiary (or a person acting on the beneficiary’s behalf) prior to the service being provided.
- The ABN must cite the specific service (testing) for which payment is likely to be denied.
- The ABN must cite the physician’s specific reason(s) for believing Medicare payment will be denied. (The notice is not an acceptable waiver if it is no more than a statement to the effect that there is a possibility that Medicare may not pay for the service.)

Panel Utilization:

- Physician’s and other authorized individuals are encouraged, whenever possible, to order individual tests specific to their patient’s clinical needs. Panel ordering is not encouraged.
- Only AMA approved organ and disease specific panels will be offered.
- Physicians and authorized individuals are reminded that the Office of the Inspector General (OIG) takes the position that an individual who knowingly causes a false claim to be submitted may be subject to sanctions or remedies available under federal law.
General Information

Screening Tests:

An ABN should be obtained for payable screening tests if the service may be denied due to frequency limitations.

Routine screening services are services not covered by Medicare and do not require an ABN. ICD-9 code V82.9 (special screening of other conditions, unspecified condition) should be used to bill routine, non-covered screening tests performed in the absence of a specific sign, symptom, or complaint.

Non-covered Services:

An ABN is not needed for non-covered services under Medicare due to “statutory exclusion”. As a courtesy, please inform your patient that the services are not covered by Medicare. The following service does not require an ABN as it is specifically excluded from the limitation of liability provision: Routine physician checkups (including lab tests furnished as part of the routine physical examination).

CPT Coding:

CPT coding references published by Avera LabNet are provided only as guidance to assist you in billing. The CPT codes listed reflect our interpretation of CPT coding requirements only and are subject to change any time. Avera LabNet assumes no responsibility for billing errors due to reliance on the CPT codes we publish. It is your responsibility to verify the accuracy of the codes provided and to assign values to each code based on the guidelines for your facility.

For further reference on CPT coding, please consult the CPT Coding Manual published by the American Medical Association, and if you have any questions regarding the use of the code, please contact your local Medicare carrier.
Test Requesting (overview):

Test requests may only be made by authorized individuals and may only be in written or system-driven electronic format. Test requisitions preprinted with customer identification information will be provided at no charge to expedite written test requests.

Each specimen referred to our Service Centers must be accompanied by a completed test requisition form (written or electronically generated) that contains all required patient demographic, billing information, compliance information, and test order information. It is the responsibility of the requesting provider to complete all required information. In the event that incomplete required information is supplied, specimen testing and reporting may be held until the customer has been contacted for the information.

For ancillary departments of Avera Sacred Heart Hospital, refer to the Order Entry Module to complete this task.

Telephone or verbal test requests will be accepted but do require that written authorization protocol be followed.
Obtaining Orders:

Verbal Phone Orders “Read Back” Policy:
When orders are given over the phone, the orders will be repeated back by the person from the laboratory to the person giving the orders, which will include patient’s name and orders. This “read back” will be documented in the comments area with the initials of the person reading the orders and the initials of the person receiving the order. A written order must follow.

Lab Orders that Need Clarification:
Every attempt will be made to accurately place a written or verbal order in Meditech. If clarification or further interpretation is needed, the unit, doctor or submitting client will be contacted for the information needed. The name of the person contacted to clarify the order will be documented in Meditech.

Inpatients
• Inpatients assigned to a bed location will have orders placed into the computer by the physician or nursing staff. These orders create computer-generated labels, which the laboratory staff takes with them to draw the specimen.

Outpatients:
• Outpatients with a hospital location (ex. ED, SDS, etc.), will have orders placed into the computer by the physician or nursing staff. These orders create computer-generated labels, which the laboratory staff takes with them to draw the specimen.
• Outpatients that come to the laboratory to be drawn will have one of the following forms of orders:
  • a written order from their physician (patient may have this with them or a faxed order in lab)
  • an electronic order in “hold que” placed by the physician or the physician’s nurse.
  • Any verbal orders will be verified by “read-back” of the results by the person receiving the orders. (See “Read Back” policy above) Any order taken over the phone must be followed up with a written order.

Outreach:
• Outreach orders will be made available to the laboratory on a requisition that has been provided to the outreach client by the laboratory. This requisition will accompany the specimen to the laboratory.
• Most outreach facilities that have access to electronic ordering.
• If an outreach client requires a test to be added on to a specimen that is already at the laboratory, the laboratory will fax an “Add Test” request form to the outreach client who will sign and fax it back to the laboratory.

Test Add-ons:
The Client Service Departments can arrange to do additional testing on specimens previously submitted for testing providing the following conditions apply:
• Sufficient volume is available
• Original specimen type is acceptable for additional testing requested
• Specimen stability guidelines have not been exceeded
• Additional testing requested does not require documentation that is not available and is required by federally funded programs (i.e. covered by Local Medical Review Policy)
• “Add Test” form has been received. Laboratory will fax this form to ordering client.
General Information

Result Reporting:

Verbal Phone Results “Read Back” Policy:
When results are given over the phone verbally, the results will be asked to be repeated back to the person from the laboratory, which will include patient’s name and the results. This “read back” will be documented in the comments area with the name of the person receiving the result and the name of the person reading the results.

Inpatients:
• Inpatients assigned to a bed location will have results reported as soon as they are verified. Critical results are called to the nursing station for the bed location and the nurse will follow-up with the physician who ordered the test. (See “Read Back” policy above)
• Inpatients assigned to a temporary location will have results reported as soon as they are verified to both the temporary location and their bed location. Critical results will be called to the temporary location. (See “Read Back” policy above)
• Inpatients with a discharge status in the Meditech system, will have the result report printed in medical records and in the attending physician’s fax number or printer. Results that meet our critical criteria are also called to the physician’s office. (See “Read Back” policy above)

Outpatients:
• Outpatients with a hospital location (ex. ED, SDS, etc.), will have the results printed at their location upon verification of the test result.
• Outpatients that have been discharge in the Meditech system will have the result report printed in medical records and at the attending physician’s fax number or printer. In the event that there is not a physician listed besides the ED physician, the results will be forwarded to the ED department for patient follow-up. Results that meet our critical criteria are also called to the physician’s office. (See “Read Back” policy above)

Out Reach:
• Outreach testing will have results printed/faxed to the client’s location automatically after verification on a schedule of 2-4 times per day.
• Critical results will be called ASAP. If the outreach client is closed the result will be called using the critical call list provided on the hospital Share Point page.
• Clients may request our laboratory to forward test results to another healthcare provider. Avera Sacred Heart requires a contact person, the business name and address, a telephone number and a secured fax number to send results to. This is necessary to have on file for HIPPA compliance.
General Information

Test Turn-Around-Time (TAT) Guidelines:

Reporting TAT’s vary in the type of reporting chosen to specifically meet the individual needs of the customer. Mailed or hand-delivered reports may slightly increase the result TAT as compared to electronic or direct reporting mechanisms. The individual test listing section of the on-line test dictionary will give general guidelines as to when the analytical procedure is performed and then reporting will occur shortly thereafter. If testing results are needed and have not been final reported to the ordering customer, results may be obtained by calling your Service Center’s Client Service Department.

Reporting of results should occur within the following time frames, from received to verified in lab. If the results cannot be reported within this time, the appropriate floor/unit should be notified of the delay and estimated result time:

- STATS... ≤ 35 minutes
- ASAP... ≤ 60 minutes
- Routine... ≤ 60 minutes
- Routine reference testing... same day
- Testing that requires > 6 hours to perform or specimens that are sent to reference labs, do not fall under these restrictions.

Blood Products and Components at Avera Sacred Heart Hospital

ASHH has a contractual agreement with the Life Serve in Des Moines, IA. Life Serve provides an inventory of blood products at ASHH to supply 95% of the transfusion needs at ASHH. Life Serve is available to process and deliver blood products 24/7, 365 days a year.

Avera Sacred Heart Hospital Laboratory keeps the following products on site:

Leukoreduced Packed Red Cells  Fresh Frozen Plasma
- O positive  type O
- O negative  type A
- A positive  type AB
- A negative
- B (neg or pos)

Platelets  Cryoprecipitate

Special request blood products require additional time to test or modify the blood product. Blood products considered special requests would include, but not limited to phenotyping, CMV negative, irradiated, single donor platelets, etc. If the blood product is currently in Life Serve’s regional inventory, the product can be available at ASHH in less than 24 hrs. If the product needs to be harvested from a donor or shipped from another blood bank’s special reserve, the process may take up to 72 hrs before it is available at ASHH.
**Critical Value Reporting:**

When critical values are obtained during the testing process, Client Service or Technical personnel will call results to the appropriate care provider. The Critical Call List, found on Share Point, is useful. If the patient has been dismissed, the result will be called to the physician or designee. In the event that critical values are obtained during hours or days when a client facility is not open or the physician cannot be reached, the result will be called to the pathologist on call and a phone call will be placed to the client facility during the next available business day.

Critical values are also “flagged” on the test report, so in the event that reports are directly transmitted to facilities via faxes, printers, or electronic systems, it is the responsibility of the receiving facility to closely review the reports being received for critical values.

**Test Cancellations:**

*Avera LabNet Service Centers will accept requests for test cancellation received from the originating client prior to the testing being completed. The client will not be charged for the testing cancelled. The specific information relating to the test cancellation will be documented appropriately. Requests for test cancellation received after testing is completed cannot be honored; the test will be reported and the client will be charged appropriately.*

Verbal orders for laboratory tests are permitted by *Avera LabNet Service Centers only if the ordering physician or authorized individual agrees to complete written authorization for the test request within an acceptable time frame.*
Specialized Reporting Requests:

To serve our customers individualized needs specialized reporting requests will be honored. It is the responsibility of the customer to clearly document on each test request complete instructions for the specialized reporting requested such as “call results to” or “copy results to”. Instructions must clearly identify the reporting specifics required and must include complete:

- Name of facility, physician, or authorized individual to receive the report
- Fax or phone number; or
- Address, if results are to be mailed

Confidentiality of Results:

Avera LabNet Service Centers strive to maintain the confidentiality of all patient information. To ensure the appropriate release of patient results in response to a telephone inquiry, one of the following may be required:

- Specimen identification number
- Client identification number
- Name the person placing the verbal request and the phone number the results may be called to

Direct result transmission to a client’s facility via fax, printer, or electronic system is considered to be a confidential transmission. Clients are requested to enforce appropriate confidentiality requirements on the receiving end.

Professional Courtesy Testing:

Federal and state regulations prohibit offering, “professional courtesy testing”; therefore, we cannot honor requests for this service.

Referral of Testing to Other Laboratories:

Testing that is not completed within our Avera LabNet Service Centers is referred out to approved reputable, licensed reference laboratories. These laboratories are carefully selected on the quality and service that they provide. If a client requests that testing be sent out to another laboratory when the testing is either performed on site or is routinely sent to our approved reference laboratory, our Service Center will charge an additional processing to cover special handling to the facility requesting the special referral.
Release of Patient Information:

Testing results will only be released to authorized individuals. Patient results will automatically be reported to the ordering physician or authorized individual via the reporting mechanism established with the originating client facility. If patient results need to be reported to a secondary referring physician and/or facility, a written order must be received indicating where results are to be reported. The primary ordering physician and/or facility will not release patient results to a secondary referring physician or facility without prior authorization.

Results will only be released to a patient when a written order to release information is on file from the ordering physician or authorized individual. Patients may also request release of their testing results by completing the appropriate “Medical Release Statement”.

Repeat Testing:

Repeat testing determinations are performed routinely as part of Avera LabNet’s Service Centers ongoing quality assurance programs. This type of repeat testing is performed prior to the testing results being verified and reported.

If there are any questions relating to the validity of a result with respect to clinical findings, Avera LabNet Service Centers will be happy to repeat the assay at no additional charge. Please contact your Service Center’s Client Service Department and request that testing be repeated. You may also be asked to provide documentation as to why you wish to have the testing repeated.
The accuracy of any laboratory test result is dependent upon the integrity of the specimen on which it is performed. This section gives guidelines to follow for collecting and transporting blood and body fluids. Specific test requirements are found in the Alphabetical Test Listing in the ALN Service Guide or the Quick reference guide following this manual. Please feel free to call your Avera LabNet service center with any questions.

**Fasting Specimens:**

An overnight (12-16 hour) fast is required for most fasting specimens. Patient should not eat or drink anything except water. If individual tests require specific fasting requirements, the requirements will be outlined in the Collection Notes Section of the individual test listing.

**Serum or Plasma:**

Draw blood into tube appropriate for the test(s) required. The amount of blood should be 2.5 times the volume of serum/plasma required for testing. Allow the tube to fill properly. Tubes with anticoagulant need to be inverted 8-10 times to avoid clot formation. Do not shake. Centrifuge the specimen and separate the serum/plasma as soon as possible ( < 1 hour from time of collection) into a plastic transport tube, being careful not to transfer any cells. Samples for potassium measurement should not be centrifuged more than once because results will be falsely increased. Carefully tighten transport cap. On the transport tube clearly identify the specimen as serum or plasma (and anticoagulant when used). Rare testing may require different timing from collection to sample separation. Special requirements will be clearly identified in the individual test listings under Collection Notes.

**Platelet-Poor Plasma:** Refer to Coagulation Special Instructions Section

**Whole Blood:**

Draw blood using correct anticoagulant tube appropriate for the test(s) required. Allow the tube to fill completely and invert 8-10 times to facilitate mixing with anticoagulant and avoid clot formation. Submit original collection tube, completely labeled, for testing.

**CSF:**

Transfer CSF to leak proof plastic vial for transport. Conventional CSF screw cap collection tubes generally leak and are not recommended. If multiple specimens are being submitted for different types of testing, be sure to label specimen transport tubes with the original specimen container number (tube #1, tube #2, etc.). Use tube 1 for chemistry, tube 2 for microbiology, tube 3 for hematology, and tube 4 for other testing. **Specimen transport of CSF within the physical plant at Avera Sacred Heart Hospital will be accepted as long these specimen tubes are transported in an upright position.**
Specimen Collection and Handling Guidelines

Venipuncture Collection Guidelines:

- It is the policy of Avera Sacred Heart Laboratory to protect employees from exposure to blood borne pathogens through Universal Precautions and compliance with the OSHA Blood borne Pathogen Standard Section 1910.1030 (Safety Management Manual: Universal Precautions).
- Assemble all supplies necessary for the venipuncture
- Properly identify the patient (See Patient Identification/Verification, this section)
- Apply tourniquet around arm, 3-4 inches above the preselected venipuncture site. (See special instructions for drawing lactic acids following this section on page 22)
- Cleanse site with alcohol or approved site preparation solution (certain procedures will require that alcohol not be used in cleansing the site)
- Allow cleansed area to air dry to prevent burning sensation or hemolysis of specimen
- Grasp patient’s arm firmly, placing thumb 1-2 inches below the chosen site to draw the skin tight (this technique will also assist in anchoring the vein for access)
- Perform venipuncture with needle bevel side up.
- Collect specimen(s) utilizing a vacuum tube system or syringe method. (See: Drawing Order For Vacuum Tube Collection System, this section) Utilize safety features of blood collecting devices.
- When using vacuum tube system for collecting the specimens, assure that all tubes containing anticoagulant are filled to required volumes (exhaustion of vacuum) and are mixed 8-10 times by gentle inversion immediately after collection. DO NOT SHAKE specimens
- If the collection of citrated specimen is performed in a manner that includes tubing with dead space, be sure to use two citrate collection tubes. One to take up the dead space and result in a partial fill and a second tube to collect a full and properly anticoagulated specimen.
- Release tourniquet as soon as possible after venous access is successful.
- Remove needle from site, apply direct pressure with cotton ball or gauze.
- Ensure hemostasis is complete before patient is bandaged. This requires pressure to the puncture to be released and a visual observation of a duration that ensures the detection of subcutaneous bleeding.
- Band-Aids may be applied to patients 3 years and older.
- After safety features have been activated with the vacuum tube collection set, discard without disassembly.
- After safety features have been activated for a needle attached to a syringe, remove and discard the needle and replace it with a safety-transfer device to fill the tubes.
- Label all specimens according to protocol prior to leaving the drawing area
- Blood letting devices are to be stored and disposed of in a manner that conforms to the Infection Control Manual; Standard Precautions. (Public Folders; Section VIII)
- Tourniquets will be discarded after use. Tourniquets may be used repeatedly for the same patient if kept by the bedside until dismissal.

Adverse reactions from blood collection can occur and personnel collecting blood specimens must know what can occur and how best to manage the reactions. The following policy addresses some adverse reactions and what should be done to address these reactions. This policy also addresses the issue of patient blood volumes and how to manage blood collections and not compromise a patient’s health. Occurrences warranting documentation should be placed in the Risk Management module in Meditech.

- **Hematoma**: Blood can leak out of a vein and under the skin during venipuncture. This can cause discomfort and pain and can complicate further collections from that site. As soon as a hematoma is noted, remove the needle and tourniquet and apply pressure at the site for a minimum of 3 minutes. Check the site and if the hematoma has stopped forming, put on a bandage or gauze with tape and inform the patient of the hematoma. The bandage should remain in place for a minimum of a half hour.

- **Arterial puncture**: If the blood pulses into the collection system or fills collection tubes rapidly and is bright red, an artery has been punctured. If no hematoma is forming and the patient is not under any noted duress, continue the collection without the tourniquet. Apply pressure for a minimum of 5 minutes. Check the site before applying a bandage to ensure the artery has sealed and notify the patient that the site needs to have a bandage on it for an hour and not to use the arm for lifting anything over 5 pounds for the day. Let the patient know there may be more discomfort at the site than if the draw was a venipuncture draw.
**Specimen Collection and Handling Guidelines**

- **Pain:** Since nerves are very close to veins and arteries, there is some risk a nerve may be pierced by a needle during blood collection. The patient will complain that he/she feels an electric shock going up his/her arm. Immediately remove the needle from the patient’s arm and put pressure on the site. Ask the patient if the sensation has stopped. If so, try to redraw at another site if the patient is willing. Explain to the patient that a nerve was touched by the needle and that was what he/she felt. Ask them to let us know if they have any more numbness, weakness, or shocking sensations at the first site. See Nerve Damage.

- **Nerve Damage:** If a nerve has been pierced or cut, the patient will feel pain or numbness or a shocking sensation as discussed in #3 Pain. If the patient continues to have these symptoms, ask for one of our ED (Emergency Department) physicians to meet with the patient and ask the staff there to examine the patient for nerve damage. The patient may need to be seen by his or her doctor to follow-up. Comfort the patient and let them know we cannot feel for nerves and this is a rare outcome of venipuncture.

- **Re-Bleed:** Patients with some liver disease, vascular diseases, clotting disorders, or medications may complicate normal clotting after a blood collection. Hot temperatures outside may cause a site to re-bleed because the veins dilate to cool the body. Always check the site after holding it and keeping the patient sitting and their arm slightly bent. If the bleeding has not stopped, continue to apply pressure. If bleeding still continues, ask a CLS (Clinical Laboratory Scientist) or pathologist to look at the site and ask the patient if they have any bleeding issues. The patient may need to be taken to ED to evaluate the bleeding. He/she may need to see his/her own doctor to evaluate the bleeding. Normally if the site is held at least 5 minutes, the bandage is kept in place for one hour and the patient does not lift objects over 5 pounds for that same period, the site should seal and not re-bleed. The patient may have more bruising than usually because of the causes mentioned and this should be explained to the patient.

- **Allergy:** Some patients may have itching or burning at the collection site. Rashes or hives may form near the site. Avera is latex free to ensure our equipment does not have any latex, which has been a common allergy among some patients. If the symptoms or signs are severe or the patient is having difficulty breathing, stop the collection immediately and get the patient to ED. If the patient passes out or stops breathing call a Response Team Alert and get emergency care to the patient. CPR should be started immediately in anaphylactic shock. If the reaction is mild, have the patient see his or her physician immediately or take him or her to ED or contact the nursing house supervisor for an exam.

- **Phlebitis:** Phlebitis is inflammation of a vein. Thrombophlebitis is due to one or more blood clots in a vein that cause inflammation. Thrombophlebitis usually occurs in leg veins, but it may occur in an arm. The thrombus in the vein causes pain and irritation and may block blood flow in the veins. Phlebitis can occur in both the surface (superficial) or deep veins.

  - **Superficial phlebitis:** Will affect veins on the skin surface. The condition is rarely serious and, with proper care, usually resolves rapidly. There is usually a slow onset of a tender red area along the superficial veins on the skin. A long, thin red area may be seen as the inflammation follows a superficial vein.
    1. This area may feel hard, warm, and tender. The skin around the vein may be itchy and swollen.
    2. The area may begin to throb or burn.
    3. A low-grade fever may occur.
    4. Sometimes phlebitis may occur where a peripheral intravenous line was started. The surrounding area may be sore and tender along the vein.
    5. If an infection is present, symptoms may include redness, fever, pain, swelling, or breakdown of the skin.
    6. Sometimes people with superficial phlebitis also get deep vein thrombophlebitis, so a medical evaluation is necessary.
    7. Avoid these areas for blood collection and have the patient seek medical care if the symptoms persist.

- **Deep Vein Thrombosis:** Will affect the larger blood vessels deep in the legs. Large blood clots can form, which may break off and travel to the lungs. This is a serious condition called pulmonary embolism and must be treated immediately by a doctor.
Specimen Collection and Handling Guidelines

- **Vasovagal reaction:** Is a reflex of the involuntary nervous system that causes the heart to slow down (bradycardia) and that, at the same time, affects the nerves to the blood vessels in the legs permitting those vessels to dilate (widen). As a result the heart puts out less blood, the blood pressure drops, and what blood is circulating tends to go into the legs rather than to the head. The brain is deprived of oxygen and a fainting episode occurs. The vasovagal reaction is also called a vasovagal attack. Stop collection immediately and help control the patient to prevent injury. If the patient is moving to the floor, activate the alarm for help and gently help the patient to the floor. Call ED or the Administrative House Supervisor or designee to help evaluate the patient. If the patient does not revive quickly or has any other adverse reactions, call a Response Team Alert and get emergency care to the patient.

- **Anxiety/fear:** Patients, especially children under the age of 12 or mentally disabled persons, may show anxiety and/or fear when they present for blood collection. Take the time to explain to the patient exactly what will happen at the patient's level of understanding. Ask care givers to assist with calming the patient. Then seek out help to hold the arm still during collection and make sure you let the patient know each step you are doing and what he/she will be feeling. Use a focus point for the patient to look at while you draw like a caregiver, a stuffed animal, some stickers, or something else in the room away from the site of collection. Remain calm and comforting and put yourself in the patient's position to help guide you in the collection. If the patient refuses, notify medical staff immediately and wait for their direction before trying to draw the patient. Seek out caregiver/family member for help if possible.

In summary, appropriate actions include:

A. Checking that the tourniquet is providing sufficient venous engorgement
B. Removing collection system and starting again at a different site
C. Obtaining support from a more experienced practitioner.
D. Ask for help if you are unsure and keep the patient's safety foremost in your decision making.

Precautions

- If after 2 unsuccessful attempts at the venipuncture, request another laboratory staff member to assess the success probability and attempt if confident of a successful blood draw. A third attempt may be tried if no other staff is available. If at that time there is no success, notify the physician of the situation.
- In general, blood should not be drawn for laboratory testing during blood infusion. If testing must be done, blood should be drawn from the arm opposite where the blood is being administered.
- Never draw on the side of a mastectomy or from the feet unless you have a doctor's order.
- If patients ask for the test results of previous work, direct the question to the patient's physician. Laboratory personnel are not allowed to give out this type of information.
- Beware of the combative patient, ask for help.
- If the patient refuses to have blood drawn, DO NOT ATTEMPT TO DRAW IT. In a voluntary hospital this could result in assault and battery charges. Inform the nurse in charge and document on report or cancellation memo in computer. A new requisition will be required from the nursing service personnel if the patient changes his/her mind.

Drawing order for Vacuum Tube Collection System

- Culture tubes or culture vials
- Sodium-citrate tubes (light blue tops)
- Serum tubes with or without clot activator, with or without gel separator (SST)(red, gold, speckled tops)
- Heparin tubes with or without gel (green)
- EDTA tubes (lavender)
- Sodium fluoride (gray)

The same order of draw should be followed when transferring blood specimens from a syringe to multiple blood collection tubes (NCCLS)
Vacuum Tube System Reminders

- Use vacuum tubes that are within their expiration date and that have been stored per their manufacturer’s instructions.
- Tubes with powdered anticoagulants should be tapped near the stopper to dislodge any anticoagulant that may be between the stopper and the tube wall.
- All tubes with liquid anticoagulants should be filled to the exhaustion of the vacuum to ensure proper ratio of anticoagulant to blood.

Blood Drawn from Lines:
Blood drawn from lines may be used for laboratory testing, except for coagulation testing. The first 5 mL of blood withdrawn from a line should be discarded prior to placing blood for testing into tubes. For coagulation testing the blood must be drawn from a venipuncture.

- “Under certain circumstances, blood specimens for coagulation testing may be drawn from a vascular access device (VAD) using a blood collection system or a syringe. When obtaining a blood specimen from a VAD, the components of the blood collection system should be checked to ensure compatibility to avoid air leaks which may cause hemolysis and incorrect draw volumes. Collection of the blood through lines previously flushed with heparin should be avoided, if possible. If the blood must be drawn though a VAD, possible heparin contamination and specimen dilution should be considered. In this case the line should be flushed with 5 mL of saline and the first 5 mL of blood or six dead space volumes of the VAD discarded. If blood is obtained from a normal saline lock (a capped off intravenous port), two dead space volumes of the catheter and extension set should be discarded.” (CLSI-H21)

Blood Drawn from Arms with Intravenous Fluids
When an intravenous fluid (including transfused blood products) is being administered in a patient’s arm, blood should not be drawn from that arm if at all possible. Test results from this blood may be erroneous and thus misleading to the physician. If the opposite arm is not available, you may draw from below the IV site. In this case have the nurse turn off the IV for 2 minutes before drawing the blood sample.

Satisfactory specimens may be drawn above the IV site only if other alternatives are not possible. The following procedure should be followed.

- Ask the responsible caregiver for the intravenous infusion to turn off the IV for at least five minutes before venipuncture. Care should be taken to ensure that the flow has been completely discontinued.
- Perform the venipuncture.
- Document that the venipuncture was performed above an infusion site and that the infusion was temporarily stopped.

Pediatric Collection Guide: Since pediatric patients are at a higher risk for blood loss due to blood collection, the next section details how much can be removed from a patient and when.

Always work with medical staff if there is any question about how much blood should be taken. All laboratory tests have a minimum volume needed for the tests ordered. If there is a risk of too much blood being removed in one draw, let the medical staff know immediately before collection so any order adjustments can be done if possible. Use these guides to know how much blood can safely be taken from the patient.

Always work with doctors and nursing staff who are directly caring for our patients if there are any adverse reactions or risk of over phlebotomizing a patient. This guide does not encompass all possible reactions and use caution if there are any unusual outcomes or reactions during blood collection or after.
<table>
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<tr>
<th>Body Wt (Kg)</th>
<th>Body Wt (lbs)</th>
<th>Total blood volume (mL)</th>
<th>Maximum allowable volume (mL) in one blood draw (= 2.5% of total blood volume)</th>
<th>Total volume (clinical + research) maximum volume (mL) drawn in a 30-day period</th>
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<th>Minimum Hgb required at time of blood draw if subject has respiratory/CV compromise</th>
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Vacuum Tube System Reminders

- Use vacuum tubes that are within their expiration date and that have been stored per their manufacturer’s instructions.
- Tubes with powdered anticoagulants should be tapped near the stopper to dislodge any anticoagulant that may be between the stopper and the tube wall.
- All tubes with liquid anticoagulants should be filled to the exhaustion of the vacuum to ensure proper ratio of anticoagulant to blood.

Capillary Collection Guidelines

- When it is necessary to use capillary blood for a test procedure, all reports should contain the phrase “heelstick” or “fingerstick” in the comments section.
- A single skin puncture using a tenderfoot (for heelstick) and tenderlett (for fingerstick) is sufficient for the collection of about 0.1 ml of blood in about 90% of patients.
- The typical amount of serum or plasma available from this volume blood is about 30 to 40 ul, assuming a hematocrit of 50%.
- Following skin puncture, apply pressure until bleeding has stopped. Band-Aids may be applied to all heelsticks and also to fingersticks of patients 3 years and older.
- Figure 1. Heel of neonate showing preferred site for skin puncture. (After Siumenfeid et al: Lancet h230. 1979)

Lactic Acid Specimen Collection

Venous specimen: Plasma: Gray top (Na-Fluoride/K-Oxalate)
Minimum collection volume: Fill tube ½ full (2.0 ml in 4.0 ml 13x75mm tube.)
Collection tubes should be immediately packed on ice and transported to the lab.
Do not use dry ice or the Blue Cryo freezer pack
Separate plasma for the red cells within 15 minutes of collection

Note
- The lactate level increases rapidly with physical exercise. The time required for return to normal lactate values depends on the physical fitness of the subject. Thirty minutes at rest is usually sufficient for this purpose.
- Avoid the use of a tourniquet. Blood samples should be drawn from a stasis-free vein. If a tourniquet is necessary, the band should not be applied for more than 30 seconds. Do not release the tourniquet while the sample is being collected.
- The patient should not clinch their fist prior to or during the collection.
- Arterial specimen is acceptable but the reference range is not the same. See procedure for comment to be added for correct reference Arterial reference range.

Patient Identification / Verification

- When obtaining a specimen from a patient with wristband identification, compare name and account number on their wristband with name and account number with the order in hand.
- All in-patients and outpatients will be identified with wristband identification. Ask the patient to verbally verify his/her identity and date of birth, whenever possible, at the time of specimen collection.
- Exceptions (patients without wristband identification):
  - Employee drug screen clients (identify with a photo ID or employer representative)
  - Paternity test clients (identify with a photo ID)
  - Health screen clients.
  - Patients with recurrent account (identify by asking patient name and birth date)
**Specimen Labeling Guidelines**

Label all primary specimens collection tubes with:

- Patient's name and one other identifier at the time of collection. Submitted slides must be labeled with two identifiers. Examples of other acceptable identifiers include but are not limited to: date of birth, hospital number, or requisition number. Label tubes from the patient's wrist band.
- Collection date/time
- Phlebotomist name or initials.
- Sample type should be indicated on the tube.
- Proper identification of the patient and subsequent samples must begin when the specimen is collected. The identifying link; two patient identifiers and sample type, must be maintained pre-analytically, analytically, and post-analytically.
  - Do not label empty collection tubes. Affix labels after sample has been introduced to the tube.
- Over-labeling: In such case it is necessary to place a label over the existing label, the initials of the person over-labeling the specimen should be placed on the new label.
- Transport specimen to lab following the guidelines outlined in the Infection Control Policy Manual; Section X- Handling Specimen in Transport to Lab, Accidents and Spills. For use of the pneumatic tube system in transporting specimens, see Section VIII-37 of the Infection Control Policy Manual.

**Sample aliquots:**

- In such case that additional testing is requested, an aliquot specimen may be used if analyte integrity has been maintained and the aliquot sample has been labeled with two identifiers and sample type.

**Blood Bank Specimen Labeling Requirements for In-House**

Mandatory blood bank specimen labeling requirements are required. EDTA specimen may be labeled with a barcode label. Overwrite the DOB on the label/tube. The following information must be included on the label:

- patient's full name and date of birth
- date and time specimen was collected
- initials of person that drew the blood
- hospital account number

If there is no blood type documented in the patient history at ASHH, a second person must verify the identity of the patient with the sample tube. This second person will take the tube to the bedside and compare the identifying information on the tube to the identifying information on the patient's wristband. This second person also needs to initial the tube of blood.

**Required Labeling for Blood Bank Testing for Out-Reach**

**Tests for which Blood Bank labeling requirements apply:**

- ABO & Rh Type
- Antibody Titer
- Antibody Identification
- Antibody Screen
- Direct Antiglobulin Testing (DAT)
- OB Panels
- Type & Screen
- Type & Crossmatch

**Specimen Labeling Requirements:**

- The following information is determined to be **MANDATORY** to allow a positive patient identification for all blood bank specimens and must be present on the sample tube and requisitions:
  - Patient Full name (Last Name, First Name, & MI if known)
  - Patient Date of Birth
  - Unique identifier or facility permanent identification number (refer to specifics listed below)
  - Date/Time Specimen Collected
  - Phlebotomist initials

**Special Hand Labeling Requirement for Transfusion-Related Testing:**

- Blood bank specimens drawn for the possibility of transfusion of blood products must be **labeled completely before leaving the side of the patient by the person drawing the sample.**
- Specimens labeled with only a computer generated specimen label **must have date of birth labeled on tube.** (specimen will be discarded if not properly labeled, and patient will need to be redrawn and labeled
appropriately for testing.

**Other REQUIRED information** must be present either on the requisition or electronic order or sample tube (not mandatory on the tube).
- Initials of person collecting specimen may be used or name of person collecting the specimen
- Patient gender
- Test(s) to be performed
- Ordering provider
- Complete patient billing and coding information if Yankton is requested to bill for testing

**Unique Patient Identification Number/ Date of Birth:**
For Yankton outreach blood bank testing, the facility assigns a number that is considered the unique patient identification number. This unique patient identification number must be present on both the specimen tube submitted for testing and on the requisition. The patient’s date of birth allows a complete blood bank patient historical verification on previous testing that has been performed on this patient within the Yankton system. This historical verification assists with identifying potential specimen collection and testing errors.

**Special Note:** All labeling on the specimen tube(s) must be identical to the requisition/test request. If not identical, testing will not be performed until the client is contacted and discrepancy resolved. Specimen labeling or requisition discrepancies that do not allow positive patient identification and discrepancy is not straightforward omission or clerical/transcription error will require that the specimen be discarded and testing will not be performed. Examples of obvious omission/clerical errors include: inversing letter in names – Nielsen/Neilsen; common suffix misspelling – Nielsen/Nielson; date of birth or ID number 1 digit variance; shortened/nickname – Barbara/Barb or Thomas/Tom

**Trauma Lab Protocol**
The ED physician or ED nurse will direct the Communications operator to activate the trauma team and level of activation (i.e. Trauma Team RED or Trauma Team YELLOW). The operator will audio page overhead (i.e. “Trauma Team Red”) three times with ETA if applicable. Lab personnel will respond by going to the Emergency Department.

**Lab Tech:**
- Timely completion of lab testing and communicates abnormal labs directly to trauma nurse.
- Coordinates Blood Bank for O Negative units, type and crossmatch process and type specific blood. Temperature validated coolers are available to transport uncrossmatched units ED for trauma red codes.
- Lab draws as needed if blood is not obtained during IV access.
- See page 66 for tests included in trauma lab panel.

**Samples collected for other labs**
Procedure for tests not done at our facility and results not received by our facility:
- When drawing patients that come in with kits or orders for tests to be done at another lab:
  - Order VP
  - Process fee CHG.PROCESS
  - Misc test (on order line put the test name and where it is going) If drawing for a possible transplant match, no charges are to be made
LABORATORY TESTING AND REPORTING OF NEWBORN SCREENS

Designated Laboratory
In order to conduct effective, timely follow-up for newborns affected by any of the disorders, the South Dakota Department of Health uses a centralized system to coordinate analyzing, reporting, and follow-up of newborn metabolic screens. As of June 1, 2007, the University of Iowa Hygienic Laboratory (UHL) in Ankeny, Iowa, is the laboratory authorized to conduct newborn screening services for the State of South Dakota. All newborn screening specimens for infants born in South Dakota must be submitted to UHL. The UHL newborn screening laboratory operates every day including nights, weekends and holidays, 365 days/year. UHL is responsible for testing, record keeping, quality control of laboratory testing, and the notification of test results.

Notification of Newborn Screening Test Results
All providers are to ascertain the results of newborn screening on any infant in their care. Do not presume that a newborn screening test was obtained, or that the results of the newborn screen were normal. Laboratory reports will be sent to the submitter of the specimen. These results are to be used as a record for the child’s medical chart.

Normal Test Results
Normal results in hard copy format will be sent to the submitter by USPS to be placed in the child’s medical record.

Unacceptable Specimens-Poor Quality-Recollct
The UHL NBS Laboratory may consider a specimen to be of poor quality due to any of the following reasons: insufficient quality, layering, blood applied to both sides of the filter paper, blood not allowed to dry, contamination, serum separation, received more than 14 days after collection, etc. Since a poor quality specimen may compromise the results, submitters are notified immediately (within 24 hours) by fax notification by UHL. UHL will identify these specimens by a “PQ” for Poor Quality. This notification indicates the need for a recollected specimen as soon as possible. Invalid specimens, those with missing information, specimens collected after transfusion, and specimens collected from infants prior to 24 hours of age are tracked each workday and the submitting health care provider (and SDNMSP) will be notified by fax to collect another specimen as soon as possible.

Repeat Testing
As part of the contract with the designated newborn screening laboratory, follow-up staff are required to notify the submitter, physician and the SDNMSP of any specimen needing a repeat specimen collected on filter paper: early collection, unsatisfactory specimen, transfused specimen, and some abnormal or inconclusive results requiring only a repeat filter paper specimen testing. The SDNMSP also communicates with the infant’s physician to assure they have received notification of abnormal results and will monitor for repeat testing results.

Abnormal Test Results (Presumptive Positive)
As part of the contract with the designated newborn screening laboratory, follow-staff are required to notify the submitter, physician and SDNMSP of any abnormal screening result. Some of these will fall in a “borderline” range requiring only a repeat filter paper specimen at that point in time. Others will require a different type of specimen to be tested by a different methodology.

Confirmatory Testing
Confirmation testing information and instructions will be included with the notification process of presumptive positive results. Pay particular attention to the testing that is needed and the correct specimen type.

UHL Laboratory Web Site
University of Iowa Hygienic Laboratory (UHL) in Ankeny, Iowa
www.shl.uiowa.edu-State Hygienic Laboratory

HEELSTICK BLOOD COLLECTION FOR NEWBORN SCREENING

- Check that the expiration date of the specimen card has not passed. Avoid touching the filter paper before or after blood collection. These instructions are based on the CLSI standard NBS10-A6. Blood Collection on Filter Paper for Newborn Screening Programs, Approved Standard-Sixth Edition.
- Warm the infant’s foot to help increase blood flow. Wipe infant’s heel with 70% isopropyl alcohol and allow heel to air dry.
• The puncture should be made within the shaded area as illustrated in the figure on the preceding pages of this manual. Any puncture device used should be selected so that the puncture does not exceed 2mm in depth. A retractable incision device may provide improved blood flow by making a standard incision 1.0 mm deep by 2.5 mm long.
• Wipe away the first drop of blood with sterile gauze. Wait for formation of a large blood droplet and gently touch the filter paper card to the blood drop. Do not touch the filter paper to the heel.
• Fill each printed circle with a SINGLE application of blood. Do not layer successive drops of blood on the target spot. All circles should be completely filled.
• Allow blood specimen to air dry at room temperature in a horizontal position for at least three hours.
• Avoid practices which could compromise specimen quality and delay testing.
• DO NOT squeeze tissue to obtain blood.
• DO NOT use devices that contain EDTA or heparin.
• DO NOT apply blood to both sides of the filter paper
• DO NOT apply layers of blood to filter paper.
• DO NOT expose card to heat, moisture, or direct sunlight
• DO NOT stack wet specimens
• DO NOT hold specimens for batch shipping.
• Any additional information is available by phone at 515-725-1630 or online at www.shl.uiowa.edu.

Paternity Testing

Use kits provided by the investigating agency: Lab Corp, Identity Genetics, Inc., and Orchid Cellmark-Dayton 
Follow all instructions included in the kit
• Client information
• Collection of samples
• Client authorization form, including provided affidavits, court orders etc.
• Sealing and providing all requested chain of custody documentation
• Ship by service included in kit
If payment is enclosed with the kit for the collection, use UNKNOWN as client when putting into the computer. Otherwise list the investigating agency as the client.
CCCOLP is entered for the test code.

Urine drug screen for outpatient request:

Example: Parent requesting drug test for child
• Pay before testing done: cash or check, $55.00
• See On Site Drug Testing Manual in drawing room. Kits are in lower cabinet below forms
• Give customer the top copy with result sticker in place. If positive you do not need to send for confirmation.
• In computer: client is unknown, charge CCCOL and CCCOL5

Procedures for drug testing for employers on their employees can be found in the Information Manual for Urine and Alcohol Collection located in the drawing room.

Non-medical blood alcohol upon individual request

• Collect fee of $70.00 cash or check. Use lab receipt book located in drawer by the pneumatic tube system. Include requester’s address and phone number.
• Use state alcohol collection kit and collect sample according to blood alcohol procedures. Fill out form as shown in appendix.
• Keep yellow copies of the receipt and state request forms.
• Send to state with ASHH lab courier.
• Results: State will send ASHH lab the results, we will send them to the individual requesting testing.
**Specimen Collection and Handling Guidelines**

**Specimen Storage and Transport Guidelines**

Individual test listing will specify correct specimen storage and transport temperatures required.

Specimens should be refrigerated until courier pick up or mailing unless otherwise specified in the test listing. Specimens requiring refrigeration during transport should be sent with chilled “cool packs”.

Certain tests will list temperature requirement as “Frozen (< -20C); Refrigerate LIMITED TIME ONLY - See Notes”. This type of storage requirement will allow for storage and transport of specimen at refrigerated temperature ONLY if transport/storage of specimen will not exceed a certain time frame. If there is any possibility that time frame from specimen collection to time prepared specimen is received by the Service Center for testing will exceed time limits, please freeze specimen. Contact your Service Center with any questions relating to frozen specimen integrity.

Specimens which require freezing should be frozen ASAP in a PLASTIC TRANSPORT TUBE [unless Collection Note Section includes different instructions], allowing room for expansion during freezing. Transport with frozen cool packs in an insulated container may be adequate provided the specimen will be delivered to the Service Center within 4 hours. Otherwise, dry ice should be used in transport.

Send a separate specimen for each test requiring a frozen sample. This will prevent compromising the specimen by thawing and refreezing of the sample if testing is performed on different days or at different locations.

All specimens must be placed in a sealed leak proof biohazard transport bag prior to transporting with courier.

**General Criteria for Unacceptable Specimens**

Specimens may be rejected for many reasons including the following:

- Hemolysis
- Lipemia
- Insufficient quantity
- Improper preservative
- Unlabeled specimen
- Mislabeled specimen
- Improper specimen collection

Individual test listings will outline certain biological criteria that will determine a sample to not be suitable for testing. You will be notified of specimen rejection ASAP. No specimen will be discarded due to rejection until the ordering physician or client has been notified. If recollection of the specimen is impossible or would compromise patient care, it may be possible in some cases to provide a result WITH THE FULL UNDERSTANDING OF THE PHYSICIAN that, the validity of the results may be questionable.

- Use “QSS” canned comment in Meditech to document request by clinician to test substandard specimen.

**Unlabeled/ Mislabeled Specimens**

Avera Sacred Heart Laboratory will make every attempt to correctly identify specimens. However, when we find an improperly labeled specimen, we will follow these flow charts to determine if the specimen should be recollected.
Specimen Redraw Protocol

Specimen rejection protocol: Substandard specimen received for testing. Identify all samples collected and evaluate if additional orders would be affected.

1. Able to recollect specimen immediately.
   a. Unreceive initial sample(s) and add “QRCI” specimen comment to the requisition.
      • Desktops
      • Specimen
      • Enter/Edit Req (right)
      • Enter specimen #
      • Specimens button (top of page)
      • Choose Sample line
      • Received field: change “N”
      • Col Cat field: Ensure that SH is in front of the time.
      • Comment field: (F5, enter “QRCI”) describe the sample condition, who collected and what time of initial collection. May also describe the collection process (i.e. IV Start). Curser will move to each required bracket with F12.
      QRCI comment: Make sure @ signs stay at front of lines when adding to the comment.
      This sample was recollected because the first sample was [ ].
      @Initial sample was collected at [ ] by [ ]
      @Collection technique on first sample:
      Noted by [f usern] at [f now] on [f today].
      @Add RC marker
   b. How to Add “RC” Marker
      o Specimen edits
      o Enter/Edit Markers
      o Enter specimen #, add RC marker, F12
   c. Print Label and recollect specimen. Mark through the Bar Code so that testing on the new sample is initiated manually with the specimen ID number.

2. Unable to recollect specimen within a reasonable time frame. (>10 minutes will elapse)
   a. Call appropriate nursing unit to inform patient’s nurse that the specimen is substandard for testing--
      Recollection of sample is indicated.
      • Avera Sacred Heart Hospital draws: Follow directions above with the addition of the QCALL comment.
      QCALL comment
      Recollection status called to and read back by [ ].
      Noted by [f usern] at [f now] on [f today].
      • Outreach site to recollect sample.
      o Add QRCOUT comment. Curser will move to each required bracket with F12.
      QRCOUT COMMENT:
      Sample submitted is substandard for testing.
      Sample Description: [ ]
      Recollection notice called to [ ]:
      Noted by [f usern] at [f now] on [f today].

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New specimen to be attained at a later time. Please resubmit with new orders.

- “RC” marker as explained above.
- Cancel the test(s).

b. Clinician may choose testing to be performed on the initial sample submitted.
   
   - **Add Specimen comment QSSTD. Curser will move to each required bracket with F12.**
     
     **QSSTD COMMENT:**
     
     **Sample Description:** [ ]
     
     **Clinician has requested testing be performed on substandard specimen.**
     
     **Some or all tests may not be analytically valid.**
     
     **Lab was directed to perform testing by:** [ ]
     
     **Noted by [f user] at [f now] on [f today].**
     
     **@Add SS marker**
     
   - **How to Add SS marker.**
     
     - Specimen edits
     - Enter/Edit Markers
     - Enter specimen #, add SS marker, F12

3. **Marker Report**

   a. **Review marker reports (RC and SS)**
      
      - Laboratory
      - Management Reports
      - Specimen Marker Report
      - Marker Report enter 3
      - Enter appropriate dates
      - Markers-enter RC and SS
      - LIS Site-enter SHH, Action “I”
      - Sp Status-delete CAN

   b. **Evaluate collection issues**

   c. **Provide feedback and training to phlebotomy staff.**
Does specimen label and requisition contain conflicting information (related to name, e.g.)?

- **NO**
  - Continue patient

- **Yes**
  - Call doctor or nurse and describe conflicting information. Ask if tests can be performed despite the problem.
    - **NO**
      - Reject specimen *
    - **YES**
      - Ask doctor or nurse to make new requisition and send to lab ASAP. For outpatients tell them to Fax new requisition to lab ASAP.
        - Continue

Append comments to all orders as follows:

---Conflicting information.
--New requisition to be sent by doctor or nurse.
--Your initials, date, and time

* Cancel
Unsatisfactory Specimen Flowchart
Delta Check Failures

Specimen results do not compare reasonably with Results previously run on this patient?

Yes

Is there a logical reason for the poor comparison? (e.g. transfusion, surgery, drug therapy, other therapies?)

Yes

Continue specimen processing

No

Is specimen difficult to recollect? (usually blood sample, urine, & culture specimens are not considered difficult to recollect)

Yes

Notify supervisor or senior tech to immediately troubleshoot or resolve. Document on report reason for rejection. Date, time, and tech the report.

No

Have specimen recollected ASAP*

*Edit specimen collection time and add comment. If specimen is to be recollected outside the hospital cancel and reorder.
Unlabeled/Mislabeled Specimen Flowchart

Is specimen received unlabeled or mislabeled? (at minimum it must include first and last name)

Yes

Is specimen difficult to recollect? (usually blood sample, urine, & blood culture specimens are not considered difficult to recollect)

No

Continue Processing

Yes

Call doctor, explain the problem. Does doctor still want testing done? (OK to contact responsible person to resolve mislabeled specimen)

No

Reject Specimen*

Yes

Reject Specimen*

No

Reject Specimen*

*Cancel Charges

Append comments to all orders as follows:
--Specimen received unlabeled or mislabeled
--OK to run per doctor or nurse (first and last name)
--Your tech initials, date, & time
Specimen Collection and Handling Guidelines

Specimen collection and storage on a gel barrier heparin tube can decrease the concentration of certain drugs in the specimen. Depending on the specimen volume and the storage time, the decreases may be clinically significant. We do not recommend the use of a heparin separator gel tubes for collection of therapeutic drug testing for assays that will not be tested promptly.

Peak, Trough and Random Levels: Reference ranges for certain therapeutic drugs are based on the time the specimens are drawn according to time guidelines around the time of the drug dose/infusion (Peak and Trough Levels). If a drug level is offered as a “Peak or Trough” level, it is recommended to follow the specimen timed drawing guidelines listed under the Collection Notes for the individual test. If the ordering physician does not specify which level to draw, contact the physician to confirm which level is clinically indicated. Random levels are recommended to only be used in cases of suspected toxicity or if the drug level required does not list specific peak and trough drawing guidelines.

Urinalysis and urine cultures

Ordering Guidelines:
- Order written as: UA or urinalysis – means UA (dipstick) without microscopic.
- Order written as: UA w/microscopic – means UA (dipstick) with microscopic
- Order written as: UA w/microscopic reflex to culture – means UA (dipstick) with microscopic + reflex to urine culture if any of the following criteria are met:
  - \( \geq 5 \) WBC
  - moderate to many bacteria with few or less epi’s
  - nitrite positive
  - leukocyte dipstick moderate to large

The last option prevents unnecessary culture expenses for the patient. The urine will only be cultured if any of those four criteria are met.

The moderate to many bacteria with few or less epi’s prevents us from culturing urines that may be contaminated which would be indicated by more epi’s.
Specimen Collection and Handling Guidelines

Urine Collection:

**FEMALE**

1. Wash and dry your hands.
2. Open urine collection container, placing the cap upside down so the inner surface does not touch the surface of the sink.
3. Open two packages of pre-moistened towelettes.
4. Sit on toilet.
5. With one hand, spread the outer folds of the urinary opening and keep separated until you have finished obtaining the specimen.
6. With the other hand, wipe the urinary opening from front to back with the towelette. Use the towelette only once and repeat with the second one.
7. Pass a small amount of urine into the toilet.
8. Continue to pass urine and fill the collection container about 1/2 full.
9. Place lid on the container tightly.
10. Notify nurse that the specimen has been collected.

**MALE**

1. Wash and dry your hands.
2. Open urine collection container, placing the cap upside down so the inner surface does not touch the surface of the sink.
3. Open two packages of pre-moistened towelettes.
4. After retracting foreskin, cleanse glans with towelette.
5. Void forcibly, allowing initial stream of urine to escape.
6. Continue to pass urine and fill the collection container about 1/2 full.
7. Place lid on the container tightly.
8. Wash and dry your hands.
9. Notify nurse that the specimen has been collected

**Urine Specimen Stability for Urinalysis:**

- Specimens are best if examined immediately after collection. If the specimen cannot be examined immediately, it should be refrigerated for preservation. Allow urine specimen to return to room temperature before testing. If possible, all specimens should have the analysis completed within 2 hours of voiding. Deterioration of cellular elements and casts may begin after 2 hours. If over 4 hours has elapsed since collection, the specimen is not satisfactory for analysis and a fresh specimen should be requested.
- If an unacceptable specimen is received, note the reason for rejection in the computer and request a new, acceptable specimen from the patient. **Important:** Some urine specimens may have been collected during a critical procedure or by means of an invasive procedure, therefore, it is important to never dispose of an unacceptable specimen until the caregiver has been notified.
- The urine preservative tube is good for 72 hours at room temperature.

**Urine Specimen Stability for Cultures**

- The sample must be refrigerated if it cannot be processed within one hour of collection. Bacterial counts of refrigerated urine remain constant for as long as 24 hours. Therefore, any urine older than 24 hours must be recollected, unless the urine culture preservative tube is used and then the urine is good for 48 hours at room temperature.
24 - Hour Urine Collection Instructions:

- Most 24-hour urine specimens can be collected in a clean, non-metal container without preservatives if the specimen is refrigerated during the collection and transport to the laboratory. The laboratory provides 24-hour collection containers with specimen labels to record times.

- When the specimen is received by your laboratory:
  - Pool the entire collection into one container or completely mix the collection together.
  - Mix the specimen 15–30 times by inversion of the sealed container.
  - Measure the total volume. Read volume from the graduations provided on the container.
  - Record both the collection time and the total volume.

- If a single test is requested, refer to the test directory to determine the required submission volume, the method of preservation, and acceptable transportation conditions. For the safety of our customers, preservative will be added to the specimen at our Avera lab location.

- If multiple tests are requested, send adequate specimen. Mix urine well and remove the required aliquot(s) into standard transport tubes, 4 ml should be sufficient, unless otherwise specified.

- Reference lab testing: Store an aliquot of the 24° urine specimen in our specimen storage rack.

- Label each aliquot with the following information:
  - Patient name
  - Patient identification number
  - Collection time and date
  - Total volume and collection duration
  - Specify preservative or no preservative pH value
  - Name of requested test

Provide each patient with collection instructions. For convenience, you may copy “Patient 24-Hour Urine Collection Instructions” in appendix.

Also a “Urine Chemistry Quick Reference Guide for Common Urine Chemistries Requiring pH Adjustments” is available in the Specimen Collection Reference Guide. These pH adjustments will be made by the ALN laboratory.
Coagulation Special Instructions:

Testing to evaluate the hemostatic mechanism is extremely sensitive to methods of sample collection and processing. Test results are a direct reflection of sample integrity. Specimens should be processed, and sent according to acceptable protocol.

**Platelet-Poor Plasma Preparation - Double centrifugation Method**

1. **General Specimen Drawing Instructions:**
   a. Vacuum tubes must be filled to completion to ensure the proper 9:1 ratio of blood to anticoagulant is achieved.
   b. When drawing specimen avoid contaminating sample with tissue thromboplastin or heparin as they may alter testing results:
      - Venipuncture must be clean, with no trauma
      - Hemolyzed specimens are not acceptable
      - See page 21 for information concerning draws through an indwelling catheter.
      - If the collection of citrated specimen is performed in a manner that includes tubing with dead space, be sure to use two citrate collection tubes. One to take up the dead space and result in a partial fill and a second tube to collect a full and properly anticoagulated specimen.
   c. Draw appropriate number of tubes to provide required volume of plasma for testing [required specimen volumes listed in “Alphabetical Test Listing”].
   d. Invert collection tubes gently 5-6 times to mix blood with anticoagulant. DO NOT SHAKE tubes. Process specimens immediately.

2. Centrifuge for 10-15 minutes at 3000 RPM.

3. With a plastic transfer pipette carefully remove plasma, place in a plastic tube and centrifuge again [10-15 minutes at 3000 RPM]. **Platelet-poor plasma must have a final platelet count of <10,000. Please validate centrifugation and time guidelines to your facility’s equipment by completing a platelet count on a plasma specimen prepared with these guidelines. If platelet count is >10,000, adjust times, centrifuge rpm, or complete a third centrifugation step prior to submitting specimen for testing.**

4. With a plastic transfer pipette, transfer plasma to plastic transport tube being careful to avoid aspirating the buffy coat.

5. Each individual coagulation test ordered should be prepared and submitted as an individual specimen. DO NOT submit multiple test specimens in one tube. Coagulation Consultation Study testing also requires submission of “normal control specimens” - Refer to the following section on Coagulation Consultation Special Collection Instructions.


7. Freeze immediately.

8. Specimen must remain frozen and be received within 24 hours. Specimens not received in the frozen state will be rejected for testing.

AVERA LABNET SIOUX FALLS SERVICE CENTER: COAGULATION
SPECIAL COLLECTION INSTRUCTIONS: MIXING STUDIES AND OTHER COAGULATION CONSULTATION STUDIES

1. Mixing studies are sent to McKennan. Ordered in Meditech as MIX (ALN test code 424) Instructions on specimen handling can be found in the ALN catalogue.
2. Patient must avoid warfarin (Coumadin) therapy for 2 weeks and heparin therapy for 2 days prior to collection of specimens for testing.
3. Follow all “Platelet-Poor Plasma” collection and preparation instructions previously outlined.
4. 2-4 5mL 3.2% Sodium Citrate tubes should be drawn from the patient depending the required number of individual plasma specimens for testing (5-8 1 mL aliquots frozen platelet-poor plasma specimens). Number of required 1.0 mL aliquots is outlined in the “Alphabetical Test Listing” for the specific type of Coagulation Consult ordered.

AmniSure ROM (Rupture Of [fetal] Membrane) Test

The AmniSure ROM (Rupture Of [fetal] Membrane) Test is a rapid, non-instrumented, qualitative immunochromatographic test for the in vitro detection of amniotic fluid in vaginal secretions of pregnant women. AmniSure detects PAMG-1 protein marker of the amniotic fluid in vaginal secretions.

Storage and Stability
- Store the kit in a dry place at room temperature or under refrigeration at 4 to 20°C (40 to 68°F). DO NOT FREEZE.
- When stored in the foil pouch at the recommended temperature, the test is stable until the “Use By” date on the foil pouch.
- AmniSure® test should be used within six (6) hours after removing from foil pouch.

Specimen Collection
- Open AmniSURE foil pouch and remove the plastic vial containing solvent solution. Take the solvent vial by its cap and shake well to make sure all liquid in the vial dropped on the bottom. Open the solvent vial and put it in a vertical position.
- Remove the sterile swab from its pack following instructions on the pack. The Dacron tip should not touch anything, prior to its insertion into vagina. Hold the swab in the middle of the stick and, while patient is lying flat on her back, carefully insert the Dacron tip of the swab into the vagina no more than 2-3 inches (5-7) cm deep. Withdraw the swab from the vagina after 1 minute.
- Place the Dacron tip into the vial and rinse the swab in the solvent by rotating for one minute.
- Remove and dispose of the swab.
- Place patient name on the vial and send the vial and the foil pouch containing the test strip to the lab immediately.

A false positive result may occur in the case of bleeding in a woman with a pathological pregnancy. It is not recommended to conduct the test when there is a discharge of blood. In this case, another sample without considerable discharge of blood should be taken and tested. The result may turn out false negative when the sample is taken 12 or more hours after a presumed fetal membrane rupture has occurred. If there is suspicion for such scenario, it is recommended to use other clinically available means of testing for ROM.
Specimen Collection and Handling Guidelines

**Fetal Fibronectin Collection, Guidelines:**

Proper specimen collection and handling is essential in providing high quality Fetal Fibronectin testing results. All individuals responsible for the collection of these specimens are requested to follow all precautions, warnings and instructions listed in the package insert of the specialized specimen collection kit. Send sample to Avera McKennan, Sioux Falls. If sample is ready to transport, and it is more than 2 hours before our courier goes to Sioux Falls, call a cab to have it taken to McKennan. Please alert McKennan that one is coming and order it Stat.

**GENERAL SPECIMEN COLLECTION PRECAUTIONS AND WARNINGS:**

1. Specimens for Fetal Fibronectin testing should be collected prior to collection of culture specimens.
2. Specimens should be obtained prior to digital cervical examination or vaginal probe ultrasound examination as manipulation of the cervix may cause the release of Fetal Fibronectin.
3. Specimens should not be collected if the patient has had sexual intercourse within 24 hours prior to the sampling time because semen and/or sperm present in the sample may increase the possibility of the test giving a false positive result.
4. Specimens will not be tested if the specimen transport tubes have leaked in transit.
5. Care must be taken not to contaminate the swab or cervicovaginal secretions with lubricants, soaps, or disinfectants [i.e. K-Y Jelly lubricant, Betadine disinfectant, Monistat cream, hexachlorophene]. These substances may interfere with absorption of the specimen by the Dacron collection swab or with the antibody-antigen reaction of the test analysis.
6. Fetal Fibronectin tests are not intended for use in the management of patients with moderate or gross vaginal bleeding. The presence of vaginal bleeding judged by the caregiver to be moderate or gross in amount may contribute to difficulty in interpreting the analytical result.
7. Rupture of membranes should be ruled out prior to specimen collection since Fetal Fibronectin is found in both amniotic fluid and the fetal membranes.
8. Specimens should not be obtained from patients with suspected or known placental abruption, placental previa, or patients with cancers of the reproductive tract.
9. There is insufficient information characterizing the association of Fetal Fibronectin expression to delivery in asymptomatic women with HIV/AIDS.
10. Collected specimens should always be stored and transported in temperatures < 25°C. Refrigerated (2-8°C) temperatures are preferred.
11. Use only one Specimen Collection Device per patient sample and DO NOT use collection kits past their expiration date.

**FETAL FIBRONECTIN GENERAL COLLECTION INSTRUCTIONS:**

1. Always use special collection kits specific for Fetal Fibronectin testing and follow Specimen Collection Kit specific instructions.
2. **Collection from Symptomatic Women:** During sterile speculum exam, prior to any examination or manipulation of the cervix or vaginal tract, lightly rotate the collection kit swab across the posterior fornix of the vagina for approximately 10 seconds to absorb cervicovaginal secretions. Subsequent attempts to saturate the swab may invalidate the test.
3. **Collection from Asymptomatic Women:** During sterile speculum exam, prior to any examination or manipulation of the cervix or vaginal tract, lightly rotate the collection kit swab across either the posterior fornix of the vagina or the ectocervical region of the external cervical for approximately 10 seconds to absorb cervicovaginal secretions. Subsequent attempts to saturate the swab may invalidate the test.
4. Remove swab and immerse Dacron tip in buffer. Break the shaft [at the score] even with the top of the transport tube.
5. Align the shaft with the hole inside the tube cap and push down tightly over the shaft, sealing the tube. WARNING – the shaft must be aligned to avoid leakage of the specimen.
6. Specimens must be stored at refrigerated temperatures and have testing completed within 3 days of collection. Do not collect specimens after routine courier pickups on Fridays or prior to extended holiday weekend.

FETAL FIBRONECTIN INDETERMINATE TEST RESULTS – CAUSES AND ACTIONS:
On rare occasions, the testing of a fetal fibronectin specimen will result in an “indeterminate or Invalid” reading on the instrument used for testing. In this instance, the method is unable to determine if the specimen is positive or negative for fetal fibronectin.

Possible reasons for “invalid/indeterminate” results include the following:
1. Atypically high concentration of fibronectin due to a presence of amniotic fluid. (The assay is intended to be used on women with intact fetal membranes.)
2. Interfering substances (may include soaps and lubricants) are present in the specimen.
3. Sample matrix abnormality.

Summary of actions taken when “invalid/indeterminate” results occur:
- Result will be reported as indeterminate and will be called to you by our Service Center.
- Specimen will be referred out for further testing that will result in a positive or negative determination. This result will be reported and called to you as soon as available.
- If the quantity of the remaining specimen is not sufficient for the referred testing, you will be contacted and requested to collect another specimen. If requested to collect another specimen, you must wait 24 hours after the original collection (or since the most recent digital exam) to recollect or the test results will be inaccurate.
BreathTek Kits are found in the outreach supply area

See full test information in the product insert in the kit.

Patient Preparation
1. Remind the patient that Pranactin-Citric contains phenylalanine (one of the protein components of Aspartame). Phenylketonurics restrict dietary phenylalanine.
2. The patient should have fasted at least 1 hour before administering the BreathTek UBT.
3. The patient should not have taken antibiotics, proton pump inhibitors (PPIs), or bismuth preparations within 2 weeks prior to administering the BreathTek UBT. If PPIs are used within 2 weeks of BreathTek UBT testing, false negative test results may occur, and the test should be repeated 2 weeks after discontinuation of PPI treatment. A positive result for a patient on PPI could be considered positive and be acted upon.
4. The effect of histamine 2-receptor antagonists (H2RAs) may reduce urease activity on urea breath tests. H2RAs may be discontinued for 24-48 hours before the BreathTek UBT.
5. Use of antacids does not appear to affect the accuracy of the BreathTek UBT.
6. For administration by a healthcare professional only. Do not provide this kit to the patient for self-administration.
7. If repeat testing is needed, BreathTek UBT can be administered again on the following day.

Procedure for Collecting Breath Samples Using BreathTek UBT Kit, for Analysis by Infrared Spectrophotometer

Materials
Each sealed single-patient BreathTek UBT Kit contains:
1. One (1) “How To” guide with One (1) patient p-UHR card
2. Test instructions
3. One (1) pouch of Pranactin-Citric powder (3 g)
4. A set of four (4) self-adhesive bar-code stickers. All bar-codes should bear the same number.
5. Two (2) breath collection bags, one (1) blue bag for the BASELINE sample and one (1) pink bag for the POST-DOSE sample.
6. One (1) sample transport bag
7. One (1) plastic straw
8. One (1) plastic drinking cup

Materials needed but not provided
8. A timer capable of timing an interval up to 15 minutes

Step-By-Step Procedure
Time intervals listed in the following step-by-step procedure are critical.
1. Verify that the patient has been prepared for the test as specified in the section above: Patient Preparation.
2. Open the BreathTek UBT Kit, which should contain all the materials listed Materials. Label each breath collection bag to maintain patient identification using the bar-code labels provided, or according to your laboratory or office procedure.
3. Collect the BASELINE breath sample according to the following procedure:
   a. Pick up the blue breath collection bag.
   b. Remove the pull-off cap from the mouthpiece of the breath collection bag.
   c. Instruct the patient to: (1) breathe normally; (2) take a deep breath then pause momentarily;
      (3) exhale into the mouthpiece of the bag.
   d. Replace the cap firmly until it clicks on the mouthpiece of the bag.
4. Prepare the Pranactin-Citric solution no more than 60 minutes before administering it to the
patient. Urea slowly decomposes in water.

a. Pick up the Pranactin-Citric pouch. Tap the upright packet of Pranactin-Citric to settle the contents in the bottom half.
b. Tear off the top of the packet and carefully empty the contents into the drinking cup provided, making sure to transfer all of the contents by tapping on the bottom of the pouch.
c. Add drinking water to the fill line indicated on the outside of the cup by a raised plastic ridge.
d. Close the lid securely by pressing down until you hear a click and swirl the mixture for up to 2 minutes to dissolve the packet contents; typically, only 1 minute is required for complete dissolution. The resulting drug solution should be clear with no particulate matter. If particulate matter is present after thorough mixing, the drug solution should not be used.

5. Instruct the patient, including pediatric patients aged 3-17 regardless of age and body weight, to drink all of the drug solution with the straw provided, without stopping. Advise the patient NOT to 'rinse' the inside of his/her mouth with the drug solution before swallowing.

a. Discard the straw after the patient has finished drinking the drug solution.
b. Not using the straw may result in inaccurate results.

6. Set the timer for 15 minutes. The patient should sit quietly and should not eat, drink or smoke during the 15 minute interval. Breath sample may be collected no later than 30 minutes POST-DOSE.

7. After 15 minutes have elapsed, pick up the pink breath collection bag. Collect the POST-DOSE breath sample according to the procedure described in Steps 3. b through 3 d.

8. Store the specimens at 15°-30°C (59°-86°F) until analysis is performed.

9. Perform breath sample analysis within 7 days of breath sample collection. If desired, use the plastic sample transport bag for transport of the breath samples.

When shipping breath sample bags from pediatric patients to a laboratory for analysis, complete the pediatric UHR card by entering collection date, patient ID, gender, age, height and weight. Place the completed card inside the sample transport bag along with the collected breath samples and the laboratory's test requisition form.

Complete instructions are found in each kit.
Specimen Collection and Handling Guidelines

**Pre-Glucose Tolerance Test Carbohydrate Diet:**

For certain types of Glucose Tolerance Tests, a carbohydrate-enriched diet is required for 3 days prior to Glucose Tolerance Test collection. At a minimum, a 150-gram carbohydrate diet is required. The amount of carbohydrates consumed during this time frame may always be more than the minimum required amount.

Remind the patient that no food or liquid, except water, should be consumed after 10:00 pm, prior to the morning of the test.

**Example 300-Gram Carbohydrate Diet:**

<table>
<thead>
<tr>
<th>Breakfast</th>
<th>Lunch</th>
<th>Dinner</th>
<th>Snacks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fruit (1 banana, 1 orange, 1/2 grapefruit or 1/2 c. juice)</td>
<td>Meat, cheese or egg (amount desired)</td>
<td>Potato (1 medium)</td>
<td>Are permitted in any quantity or type</td>
</tr>
<tr>
<td>Cereal (1/2 cup)</td>
<td>Bread (2 slices) - or - Spaghetti, macaroni, rice (1 cup cooked) - or - Noodles (1 cup cooked)</td>
<td>Vegetable (at least 1/2 cup)</td>
<td></td>
</tr>
<tr>
<td>Bread (1 slice)</td>
<td>Dessert (fruit, cake, pie or cookies)</td>
<td>Bread (1 slice)</td>
<td></td>
</tr>
<tr>
<td>Milk (1/2 cup)</td>
<td>Milk (1 cup)</td>
<td>Meat (as desired)</td>
<td></td>
</tr>
<tr>
<td>Sugar (2 teaspoonfuls)</td>
<td></td>
<td>Milk (1 cup)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Dessert (tapioca or rice pudding, fruit)</td>
<td></td>
</tr>
</tbody>
</table>

**Fecal Specimen for Occult Blood**

The Hemoccult test requires only a small fecal specimen. The specimen is applied to the quaiac paper of the Hemoccult slide as a **THIN SMEAR** using the applicator stick provided. To increase the probability of detecting occult blood, separate samples should be taken from two different sections of each fecal specimen.

**Preparing the Test**

- Use collection hat or obtain sample from commode or bedpan. Using applicator provided, collect small fecal sample.
- Apply a thin smear covering Box A.
- Reuse applicator to obtain second sample from a different part of stool. Apply a thin smear covering Box B.
- Close cover flap. Dispose of applicator in waste container.
- Label slide with patient information and send to laboratory.
Principle:
Lactose intolerance results when the lactose enzyme, produced in the small intestine, is lacking or inadequate to process lactose (milk sugar) in the body. Unprocessed lactose goes to the colon, where bacteria break down the sugar. The gases produced by this fermentation can create discomfort, gas, cramps, bloating, and diarrhea. ARUP laboratories provide the test kit for this breath test assay. Send specimens directly to Genova Laboratories for testing.

Material Required:
Lactose Intolerance Breath test kit: (on outreach shelves, obtain from ARUP laboratory) Toothbrush (obtain from Nursing unit, place in kit when received) 8 ounces drinking water

Procedure:
Patient Preparations: Provide patient with the Patient instructions and Dietary Recommendations. (Copy included with this procedure).

Testing procedure is outlined in the instructions provided with the test kit.

Meditech order: Other test (OD)

ARUP order: Register Patient in the 2000 system
Order: Misc Ambient Test: Breath Lactose Intolerance Test
Cost: $156.00
CPT: 91065

Requisition: Genova Diagnostics form provided in the test kit. Complete form and send kit directly to Genova Diagnostics for testing.

Results:
Report and billing will come back thru ARUP.
Turn around time expected within 14 calendar days or less from the date samples are received.

Reference:
Lactose Intolerance Breath Test:
Lactose intolerance results when the lactase enzyme, produced in the small intestine, is lacking or inadequate to process lactose (milk sugar) in the body. Unprocessed lactose goes to the colon, where bacteria break down the sugar. The gases produced by this fermentation can create discomfort, gas, cramps, bloating, and diarrhea. Your doctor has ordered a breathe test to evaluate the function of the lactase enzyme in your digestive system.

**Patient instructions:**

2 days before the test:
- Stop eating high-fiber and lactose-containing foods for a full 36 hours before specimen collection. This usually means starting with the dinner meal 2 nights before doing the test. See the list of allowed/non-allowed foods.
- Stop taking any fiber supplements, such as Metamucil or Fibercon.
- Avoid aspirin during this time.

The evening before the test:
- Eat a light dinner: Refer to the allowed foods list, concentrating on the A list.
- Stop eating and drinking anything other than water at least 12 hours before the specimen collection.

The day of testing at Avera Sacred Heart Hospital Laboratory:
- Do not drink anything for the first hour of collection. After the first hour you may drink water only. Continue fasting until you complete the entire test.
- Do not smoke, use toothpaste, nap, or exercise vigorously for at least 30 minutes before or during the test.
- Remain at the Hospital laboratory until all samples have been collected.
Specimen Collection and Handling Guidelines

Dietary Recommendations for Lactose Intolerance testing:

Allowed Foods
A List: no restriction, unless otherwise directed by your physician.

- All meat and poultry
- Shellfish
- Fish
- Eggs
- Aged cheeses (parmesan, romano and asiago)
- Bean sprouts, alfalfa sprouts, celery, cucumber, endive, Boston lettuce, iceberg lettuce, leaf lettuce, green peppers, red peppers, yellow peppers, chili peppers, radishes.
- Fruit and vegetable juices
- Sherbet (make sure does not include cream)
- Margarine (no butter)
- Salad and cooking oil
- Alcohol beverages
- Coffee, tea, soda
- Condiments (ketchup, mustard, pickle relish, soy sauce)

B list: allowed foods, but to be eaten sparingly

- White bread and white crackers (soda or saltine), or other products made from white flour other than pasta.
- Highly refined cereals (corn flakes, puffed rice, cheerios, rice krispies, cream of wheat)
- White or instant rice
- Tofu
- Rice or soy milk
- Popcorn (no butter, but oil or margarine okay)
- Avocado, mushrooms, olives, onion, parsley, asparagus, beets, cabbage, cauliflower, cilantro, yellow squash
- Cantaloupe, honeydew melon, pineapple, grapefruit, grapes, melons, shinned peaches, plums, or apricots, skinned tomatoes, grapes, watermelon
- Fruit jellies
- Sugar

Foods to Avoid; Starting with the dinner meal 2 nights before the collection date

- All bean and legumes (baked beans, kidney beans, split peas, dried lima, garbanzos, pinto beans, black beans, lentils
- Soybeans and all soy products, other than tofu, soy milk, miso and soy sauce
- Whole wheat and other whole-grain of high-fiber cereal products, including rye, oats, buckwheat and stone-ground cornmeal. (Bread, pastas, pizzas, pancakes and muffins made with these whole-grain flours)
- Corn and products made from cornmeal, other than corn flakes
- Basmati rice, wild or brown rice (unpolished)
- Pasta products
- Green peas, lima beans, broccoli, yams, white and sweet potatoes, green beans, pole beans, broad beans, dark green leafy vegetables (spinach, beet greens, kale, collards, swiss chard, and turnip greens), Brussels sprouts, carrots, artichoke (whole or hearts), winter squash (butternut, acorn spaghetti), zucchini, okra, eggplant seaweed
- Dried fruits (figs, apricots, dates, raisins, prunes), raspberries, blackberries, strawberries, cherries, bananas, coconut, kiwi, oranges, tangerines, apples, pears
- Nuts and seeds
- Dairy products, except for aged cheeses (see list A)
Microbiological procedures used are those recommended by the American Society for Microbiology, American Society of Clinical Pathologists, College of American Pathologists, and National Committee for Clinical Laboratory Standards.

For the collection and evaluation of microbiology specimens, it is necessary to understand that any given body site develops its own "usual/normal" flora. When collecting cultures from sites, special care must be taken to bypass contaminating flora. Examples of such sites are skin, upper respiratory tract, intestinal tract, female genital area, and open draining wounds. Submit aspirated material whenever possible.

**Culture Collection Basics:**

- Collect the specimen at optimal times and prior to antimicrobial therapy, if possible.
- Collect sufficient quantity.
- Use proper collection containers and transport media. Always assure that transport containers are leak proof.
- If required, prepare site to assure uncontaminated collection. Submit aspirated material whenever possible.
- Indicate source and collection time information on the requisition and/or specimen.
- Minimize transport time. The survival of bacteria in a transport medium depends on many factors. These include the types of bacteria, duration on transport medium. BBL Culture Swab devices maintain viability of many microorganisms for 24-48 hours. For fastidious bacteria, such as Neisseria gonorrohoeae and Streptococcus pneumoniae, swab specimens should be plated directly onto culture medium or transported immediately to the laboratory and cultured within 24 hours.

**Reflex Testing General Guidelines:**

Certain microbiology procedures require reflex testing to be completed to provide appropriate information to the ordering physician to allow for result interpretation and therapy intervention decisions to be made.

Reflex Testing Guidelines are identified under each test in the "Alphabetical Test Listing". Reflex testing completed will be individually billed.

Examples of reflex testing on potential pathogenic cultures include, but may not be limited to:

- Bacterial Identification(s)
- Susceptibility Testing(s)
- Monoclonal Testing(s)

It is the responsibility of the ordering physician to specifically order "reflex testing is not to be completed" if at the time of the test request reflex testing is not clinically indicated.

If reflex testing is not required due to culture results or if the physician has specifically requested, testing will not be completed or billed.
Microbiology Routine Culture Collection Guidelines:

Acid-Fast Bacilli Culture and/or Smear:

Acceptable Specimen Guidelines:

- **Pulmonary specimens:**
  1. Spontaneously produced sputum - specimen of choice; collect approximately 5-10 mL of a first morning expectorated specimen; collect in sterile container
    - To raise sputum, patient must be instructed to take a deep breath, hold it momentarily, and then cough deeply and vigorously
  2. Induced sputum - should be collected by appropriate personnel following facility procedures; collect in sterile container
  3. Bronchoscopy, bronchial washings, lavages, brushings, etc. - should be collected by appropriate personnel following facility procedures; collect approximately 5-10 mL if possible; collect in sterile container
  4. Transtracheal aspiration or laryngeal swabbing - should be collected by appropriate personnel following facility procedures; collect in sterile container

Note: A series of three specimens collected on three separate days is recommended.

(Acid-Fast Acceptable Specimens)

- **Gastric specimen:** Gastric lavage may be used to collect specimens from patients who have swallowed their sputum during the night; specimen should be collected before patient arises in the morning; in sterile collection container collect 20-25 mL of gastric contents; series of three specimens collected on three separate days is recommended

- **Urine specimen:** Specimen should be collected as outlined in Urine Culture; early morning specimen is preferred; collect 50 mL of urine and submit in sterile collection container; series of three specimens collected on three separate days is recommended

- **Cerebrospinal fluid specimen:** Specimen volume for testing is critical to assure isolation of the AFB; 10 mL of CSF is recommended; collect in sterile container

- **Fecal specimen:** Feces are not routinely cultured for AFB unless being ordered on an HIV positive patient suspected of having Mycobacterium avium infection; collect approximately 50 grams of stool specimen in a clean, leak proof container

- **Blood specimen:** Call Service Center Microbiology Department for specific collection instructions and appropriate collection tubes

- **Tissue, Pus, Exudate specimen:**
  1. Pus or Exudate: may collect utilizing culture swab system; specimen may also be collected on small pieces of sterile bandage material place in sterile leak proof container
  2. Tissue biopsy: send in sterile leak proof container with a small amount of sterile saline added to prevent drying

- **Other body fluids specimens:** Specimens such as pleural, pericardial, and joint fluid may be tested; collect in sterile container such as a syringe; cap syringe appropriately - do not submit with needle attached

General AFB Collection Reminders:

1. Collect in a sterile, leak proof container. [Exception - fecal specimen, see previous section]
2. A series of three specimens collected on three separate days is recommended for urine, gastric, and sputum specimens.
3. Transport specimen within 24 hours.
4. If specimen will not be transported immediately, refrigerate specimen.
5. Ship whole blood at ambient temperature.
Specimen Collection and Handling Guidelines: Microbiology

Anaerobe Culture:
- Refer to "Alphabetical Test Listing" for acceptable and unacceptable specimen collection sites
- Anaerobic bacteria are fastidious in nature, therefore special precautions and techniques should be used in the collection and transport of specimens.
- Contamination with normal site flora must be minimized during specimen collection.

Acceptable Anaerobe Culture Sources/ Sites:
1. Any closed abscess not of bowel origin [Aspiration by needle and syringe; surgically obtained tissue]
2. Urine [Suprapubic needle aspiration of the bladder]
3. Pulmonary [Percutaneous transtracheal aspiration of lower respiratory secretions – protected bronchial brush catheter is of questionable utility due to possible anaerobic contamination]
4. Female Genital Tract [Peritoneal fluid by culdocentesis; Endometrium via protected catheter]
5. Soft tissue, bone and joint [Percutaneous needle aspiration – after prior surface decontamination, preferably an uninvolved surface; surgically obtained tissue]
6. Sinus tract and deep wound [Aspiration by needle or plastic intravenous type catheter threaded into infected site – after prior surface decontamination]
7. Blood and other normally sterile body fluids other than urine [Anaerobic bottle for blood; syringe or anaerobic transport tube for other fluids]

Unacceptable Anaerobe Culture Sources/ Sites:
1. Abscesses of bowel origin including appendiceal and perirectal abscesses
2. Feces, rectal swabs and colostomy discharge [when clinically indicated, these types of specimens may be used for the diagnosis of botulism and for intestinal disease caused by Clostridium difficile and Clostridium perfringens]
3. Gastric specimens
4. Superficial skin lesions, skin ulcers and pilonidal sinus
5. Abdominal wounds contaminated with feces [eg. open fistulas] and exudative wounds not properly collected [must exclude skin contamination]
6. Surgical drain sites
7. Voided or catheterized urine and Foley catheter tips
8. Vaginal or cervical specimens including lochia
9. Prostatic or seminal fluid
10. Throat and nasopharyngeal swabs and oral secretions
11. Sputum and bronchoscopic specimens
12. Gingival swabs
Anaerobe Collection Guidelines:

Needle or Catheter Aspiration Collection:
1. Aspirated material is preferred.
2. Aspirate material with a long needle or intravenous-type catheter into a sterile syringe. Remove needle or catheter, tightly cap syringe, and submit for testing. DO NOT transport syringe with needle attached.
3. Soft tissue infections may be cultured by injection of 1-2 mL sterile saline into the infected site and then aspirate saline/tissue fluid with syringe system.
4. Portion of aspirated material may also be transferred to anaerobic swab collection system and handled as outlined under “Swab Collection”.
5. Aspiration Method Reference:

<table>
<thead>
<tr>
<th>Source</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lower Respiratory Secretions</td>
<td>Percutaneous trans-tracheal aspiration</td>
</tr>
<tr>
<td>Closed Abscess or Body Fluid</td>
<td>Aspiration by needle and syringe. Swab method may also be used if material is scanty in amount</td>
</tr>
<tr>
<td>Urine</td>
<td>Suprapubic aspiration</td>
</tr>
<tr>
<td>Sinus tract, uterine cavity,</td>
<td>Decontaminate site with Betadine; Syringe aspiration using plastic intravenous type catheter threaded into infected site</td>
</tr>
<tr>
<td>deep wound, etc.</td>
<td></td>
</tr>
<tr>
<td>Endometrial Technique</td>
<td>Through a speculum, a catheter is introduced into the cervical os and a swab extended through the catheter into the endometrial cavity</td>
</tr>
<tr>
<td>Pelvic Inflammatory Disease</td>
<td>Swab vagina with betadine and aspirate through posterior vaginal wall (culdocentesis)</td>
</tr>
</tbody>
</table>

Swab Collection:
1. Only use approved anaerobe culturette swabs. Swabs can be obtained by contacting your Service Center. Swabs should only be used to collect scanty material. Aspiration specimens are preferred when amount of specimen allows for aspiration.
2. Collect as much specimen as possible so that culturette tip is completely saturated. Place swab immediately into culturette container. Follow all culturette collection instructions on package.

Specimen General Reminders:
- Label specimen and transport as soon as possible
- When transport delay is unavoidable, specimen should be held at room temperature
- Specimen collected for anaerobic culture are also suitable for aerobic, AFB, and fungal cultures. Make sure that quantity of specimen collected is adequate for all testing requested
Specimen Collection and Handling Guidelines: Microbiology

Blood Culture:
Ship filled blood culture bottles at ambient temperature.

REAGENTS
1. Aerobic bottle-BacT/ALERT SA (30mls of media in each bottle) Blue flip-top and label color.
2. Anaerobic bottle-BacT/ALERT SN (40mls of media in each bottle) Purple flip-top and label color.
3. Pediatric draws-BacT/ALERT PF (20mls of media in each bottle) Supports pediatric draws. Yellow flip-top and label color.
4. ChloraPrep One-Step Frepp Applicators (on children less than 2 months of age, do not use ChloraPrep, use Iodophor PVP pad, or iodine pad)
5. Blood drawing apparatus, disposable gloves, appropriate biohazard waste containers for materials potentially contaminated with infectious agents.

Follow all "exposure control" guidelines required by your facility [i.e. gloves, lab coat, proper sharps disposal, etc.]

PROCEDURE FOR COLLECTION
Specimen collection is extremely important in obtaining blood cultures. Proper skin disinfection is essential to reduce the incidence of contamination. Universal Precautions must be followed.

1. Inspect the bottle surface, the media and the sensor on the bottom of the bottle. Ensure that the broth is clear and the sensor is intact and is a blu-green color. Do not use the bottle if the sensor is yellow.
2. Blood culture bottles must be at room temperature before being inoculated. Remove the plastic flip-top from the blood culture bottle(s). The septum is not sterile and must be disinfected with 70% isopropanol or iodine. Allow to dry for 1 minute before inoculation.
3. Following palpation, the venipuncture site should be cleansed. Scrub the venipuncture site with ChloraPrep for 30 seconds. Allow the site to air dry before the blood culture is drawn. This will allow maximum effectiveness of the disinfectant. Do not touch the prepared venipuncture site. (Very important: Do not use ChloraPrep on children less than 2 months of age because of the potential for excessive skin irritation and increased drug absorption. On these children use Iodophor PVP prep pad, iodine pad. Apply iodine and let dry)
4. Sample may be collected by needle and syringe or by direct draw with blood collection set.
   Needle and syringe
   a. Draw appropriate amount.
   b. Directly inoculate the bottles, using the syringe markings as a guide for correct volume.
   Direct draw with blood collection set
   a. Use the BacT/Alert blood collection adapter cap and insert.
   b. Connect the adapter cap to the luer connector of the butterfly collection set.
   c. Perform venipuncture. When the needle is in the vein, secure it with tape or hold it in place.
   d. Place adapter cap on the aerobic BacT/Alert culture bottle septum and press down to penetrate and obtain blood flow. Hold the adapter cap down on the bottle.
   e. Using the fill indicator lines on the label, obtain the specified amount of blood. Move the adapter cap from the aerobic bottle to the anaerobic bottle and continue to fill.
   f. If additional blood is required for other tests, place the adapter insert into the adapter cap and snap into place. This makes the cap compatible with vacuum collection tubes. After blood collection is complete, remove the adapter cap from the culture bottle and then remove the needle from the patient's vein.

Obtain patient sample volume as indicated:
Specimen Volumes: (there are no designated minimum volumes)
Adult Up to 10 ml blood or normally sterile body fluid (SBF) (optimum 10ml for each bottle)
Pediatric Up to 4 ml blood (up to 4 years old)

If only enough blood has been drawn to fill one bottle, inoculate an aerobic bottle. Do not over fill bottles, as this may cause false positive readings. To avoid contamination of the blood culture sample, inoculate blood culture bottles first. Then fill additional blood collection tubes.
Specimen Collection and Handling Guidelines: Microbiology

Chlamydia Culture:
- Acceptable specimen sources: Cervical, urethral, rectal, or eye swab. Also acceptable for newborns: nasopharyngeal aspirate/washing/swab.
- Use a sterile swab from a culturette collection swab. After collection, insert the swab into the culturette holder.
- Transport at ambient temperature immediately to the lab, if the specimen cannot be sent to the lab immediately place in universal transport media (UTM) immediately. Transport media and specimen at 2-8°C.

Chlamydia by Amplified detection:
- Endocervical or urethral swabs collected using the Aptima GenProbe Collection Kit, these may be obtained by contacting the Client Service Department. Take special care to follow instructions on kit packaging to collect specimen.
- Urine- Patient should not void 1 hr. prior to specimen collection. Patient must collect the first 20-30 mls of urine in a plastic, preservative-free collection cup.
- Urine specimen must be transferred to Aptima GenProbe Urine Specimen Collection Kit within 24 hours of collection. Aptima GenProbe Urine Specimen Collection Kits may be obtained by contacting the Client Service Department. Ship at ambient temperature.

Eye Culture:
- Acceptable specimen sources: conjunctiva, cornea, eyelid margin, aqueous or vitreous. Specify “right” or “left” eye.
- Use a sterile swab from a culturette collection swab. After collection, insert the swab into the culturette holder.
- Ship at ambient temperature within 24 hours of collection.

Ear Culture:
- Acceptable specimen sources: fluid obtained by tympanocentesis, scrapings from external ear.
- Transport aspirated material or material collected by needle and syringe in a sterile tube. Send scrapings in a sterile screw cap tube.
- If eardrum has ruptured and fluid is draining, cleanse the external ear canal and use a small swab to collect material. After collection insert the swab into the culturette holder.
- Ship at ambient temperature within 24 hours.

Fungus Culture:
- Specimens from a sterile body (fluids – min 5ml, tissues, etc.) in a sterile leakproof container – ambient.
- Specimens from a non-sterile site (respiratory, GI tract, etc.) in a sterile leakproof container – refrigerated.
Specimen Collection and Handling Guidelines: Microbiology

Genital Culture:
- Collect vaginal, cervical or urethral specimen using a swab from a culturette collection swab.
- After collection, insert the swab into culturette holder.
- Identify collection site on test requisition.
- Ship at ambient temperature within 24 hours.
For GC culture only, submit inoculated a Modified Thayer-Martin plate or swab at room temperature.

Miscellaneous Culture (Wound, Body Fluid, Aspirates, etc.):
- Acceptable specimen sources: deep wounds, abscesses, aspirates, CSF and other body fluids or sites.
- Collect specimen using the swab from a culturette collection swab, by aspiration (depending on specimen source) or by placing collected fluid specimen in a sterile leak proof container.
- Swab Specimen: After collection, insert the swab into culturette holder.
- Ship specimen at ambient temperature preferably within 24 hours.

Neisseria Gonorrhea by Amplified detection:
- Endocervical or urethral swabs collected using the Aptima GenProbe Collection Kit, these may be obtained by contacting the Client Service Department. Take special care to follow instructions on kit packaging to collect specimen.
- Urine- Patient should not void 1 hr. prior to specimen collection. Patient must collect the first 20-30 mls of urine in a plastic, preservative-free collection cup.
- Urine specimen must be transferred to Aptima GenProbe Urine Specimen Collection Kit within 24 hours of collection. Aptima GenProbe Urine Specimen Collection Kits may be obtained by contacting the Client Service Department. Ship at ambient temperature.
  Check outdate on Aptima Gen-Probe Collection Kit before use.

Sputum Culture:
- Patient should gargle and rinse mouth with water prior to collection.
- Collect 5-10 ml early morning sputum in a sterile, leak proof container. Specimen collected using deep cough technique is preferred.
- Specimen submitted for testing should not appear to be only "clear saliva". Specimen must contain "thick, purulent like" material.
- Transport specimen as soon as possible at 2-8ºC.

Stool Culture:
- Specimen of choice: fresh stool collected as soon after onset of symptoms as possible (3-5 days).
- Collect 1-2 grams fresh stool in a clean, dry container. Do not let urine or water from the toilet touch the specimen. Place specimen in Modified Cary Blair transport media. Transport at room temperature within 96 hours.
- Send fresh specimens to lab within 2 hours.
- Only one culture per 24 hours is recommended.

Throat/ Nose Culture:
- Rub posterior of the tonsils, soft palate and back wall of the lower pharynx or swab nares with a sterile collection swab.
- After collection, insert the swab into a culturette holder.
- Ship specimen at ambient temperature within 24 hours.
Specimen Collection and Handling Guidelines: Microbiology

**Urine Culture:**
- Preferred specimens include: first morning specimen collected as a clean-catch midstream specimen or catheterized specimen. All non-catheterized specimens must be collected as clean-catch midstream specimens.
- Patient instruction on correct procedure to follow for obtaining a midstream collection is very important. Example collection instructions on next page may be copied and used for patient education as needed.
- Transport as soon as possible. Refrigerate immediately following collection and send the same day. Or transfer an aliquot to a urine culture transport kit and transport within 24-48 hours.
- Ship refrigerated 24 hours or urine transport media ambient 48 hours.

**Vaginal Pathogens DNA Direct Probe**
- Collect vaginal fluid with the BD Affirm VP111 Collection Kit
- Specimen collected with this kit is stable for 3 days room temp or refrigerated.
- Collection kit is available at Client Services.
- Tests for Candida species, Gardnerella vaginalis, and Trichomonas vaginalis

**Vaginal Work-up**
- Collect 2 swabs from vaginal drainage, send to lab immediately.
- Tests include wet mounts for fungal elements, sniff test, clue cells, motile elements, white blood cells.

**Wound Culture**
- Use a sterile swab from a culturette collection swab. After collection, insert the swab into the culturette holder.
- Ship at ambient temperature.
- Indicate culture source on requisition.
Specimen Collection and Handling Guidelines: Parasitology

Pin Worm Cellophane Tape Collection General Instructions:
- Specimens are best obtained a few hours after the patient has retired, or the first thing in the morning before a bowel movement or bath. If the patient is a child still in diapers, the specimen should be collected between 10:00 p.m. and midnight [child should have not just defecated prior to collection].
- To assure recovery of parasitic elements that may be passed intermittently and in fluctuating numbers, it is recommended to collect three specimens on different days [multiple specimens should not be collected on the same day]. The number of specimens to be tested must be defined by the ordering physician.
- Supply the patient with the appropriate amount of wooden tongue depressors, glass slides, and clear cellophane tape to collect the required number of specimens.
- General instructions for collection should include:
  1. Attach cellophane tape to the wooden tongue depressor with the sticky side out. Approximately 2-3 inches of sticky surface should be sufficient.
  2. Hold the tongue depressor in one hand. With the other hand, separate the patient’s buttocks.
  3. Firmly press the tape collection area to all the skin directly around the anus.
  4. Remind the person collecting the specimen that the eggs are not visible to the naked eye.
  5. Remove the tape from the tongue depressor avoiding contact with the sticky tape area as much as possible.
  6. Spread the tape, sticky side down, on the microscope slide provided. Smooth the tape down with a cotton ball or tissue.
  7. Remind the person collecting the specimen, to wash their hands, including under the nails, after collecting the specimen.
  8. If multiple specimens are being collected, specimens may be kept until the last specimen is collected and then all returned to the laboratory at the same time.
  9. Instruct the person collecting the specimen to label each slide collected with the patient’s full name and date of collection.
Patient Ova & Parasite Collection Instructions:

IMPORTANT:
Please Read All Instructions Before Specimen Collection Is Completed

You have been given a collection kit, which will help you conveniently collect a stool specimen for testing that your physician has ordered. All directions must be closely followed to assure the best possible specimen for testing. The kit you have been given may include multiple containers. Please be sure that you have put some of your specimen in all the tubes. If you are instructed to collect multiple specimens on different days, you will be given the appropriate number of collection kits for the days required.

CAUTION:

- Solutions in the collection containers are poisonous. DO NOT DRINK. Keep them out of the reach of children.
- Antidote If Swallowed: Dilute by drinking 2-4 glasses of water. Immediately contact an emergency facility, poison information center or a physician to receive medical attention. Save the collection container; label information will be helpful for determining appropriate medical treatment.
- If any liquid from the collection containers gets on your skin or in your eyes, flush with plenty of water. If irritation develops, consult your physician.

Collection Instructions:

1. The stool should be passed into a clean, DRY container. Use a bedpan or place a large plastic bag into a wastebasket to catch the specimen. A clean margarine tub, clean wide-mouthed jar or clean milk carton with the top cut off can also be used.
2. Do not urinate in the container. The stool specimen must not come into contact with urine or toilet water. Do not pass the specimen directly into the collection kit containers.
3. After the stool is collected, open the kit container. Using the collection spoon built into the lid of the container place small scoopfuls of the stool from areas which appear bloody, slimy or watery into the container. If the stool is formed [hard], please try to sample small amounts from each end and the middle. Continue to add specimen level reaches the "fill to here" line or indicator. DO NOT contaminate the outside of the collection container with the stool sample.
4. Mix the stool sample with the liquid in the container with the spoon. Twist the cap tightly closed and shake the container vigorously until the content is well mixed.
5. Repeat steps 3 and 4 until all kit containers have been filled with stool specimen. After all containers have been filled, the remaining stool specimen may be discarded.
6. Double check all caps to be sure they are tightly closed.
7. Fill in all information required on each container. Be sure to check the box on the container which describes the consistency of the specimen you collected. [Formed = distinct shape and hard; Soft = distinct shape but soft; Loose = no distinct shape, thick sludge-like; Watery = very loose, liquid-like]
8. Wash hands thoroughly after collection is complete.
9. Store collected specimens at room temperature and return them to the laboratory as soon as all required specimens have been collected.
Virology Collection Guidelines & Special Instructions:

Viral specimens should be collected early in the illness. Certain types of viral agents associated with different types of clinical syndromes are more easily isolated out of different types of specimens. The "Practical Medical Virology: Guide to Specimen Collection" chart included in this section is provided to help guide you and your ordering physician to proper specimen collections. This guide will also outline appropriate tests your physician may order [culture vs. direct staining techniques/DFA] to identify viral agents.

Transport CSF, nasopharyngeal washing aspirate, urine, stool, or tracheal aspirate in sterile, leak-proof container at 2-8ºC. Eye swab, nasopharyngeal swab, throat swab, or tissue in universal transport media (UTM) at 2-8ºC, 5ml whole blood or bone marrow (lavender EDTA) at 2-8ºC. Viral Transport Media (UTM) may be obtained by contacting your Avera LabNet Service Center. In situations where no viral transport medium is available, the laboratory will accept specimens on moist swabs or in clean containers if they are kept cool. Because many viruses are labile, it is always best to collect the specimen just prior to transport to the Service Center.

NOTE: Culture site is required on request form for processing. Indicate the specific viruses or clinical syndromes testing is to be completed for. Transport specimens within 24 hours of collection.

Suitable Collection Sites for Viral Culture:

1. Oral-pharyngeal swabs (deep throat, not nasopharyngeal swabs)
2. Throat washings
3. Nasopharyngeal aspirates
4. Stool or rectal swabs
5. Spinal or other body fluids
6. Urine
7. Vesicular fluid
8. Eye exudate
9. Biopsy or autopsy tissue
10. EDTA anticoagulated whole blood
11. Sputum
12. Skin or mucous membrane lesions

Unacceptable Specimens for Viral Culture:

The following specimens will be rejected:
1. Swabs that have dried
2. Specimens in non-viral transport medium.
3. Calcium alginate swabs.
4. Wood swabs.
Site Specific General Guidelines:

Oral-pharyngeal Specimens:
- Deep throat swabs are collected by vigorously rubbing the tonsils and posterior nasal passages with a sterile swab.
- The swab is then placed in the Universal Transport Medium.
- Throat washing may be collected and placed in the Universal Transport Medium.
- Nasopharynx specimens may be obtained by inserting a flexible N-P wire collection swab into the posterior nasopharynx or by aspiration of the secretions with a one-ounce bulb. **Note:** Nasal aspirates yield better results due to the increase of cell volume collected.

Nasopharyngeal aspirates:
- Collect nasopharyngeal aspirates with a suction catheter into a sterile container.
- A nasopharyngeal wash may be collected by placing 5 ml of sterile saline delivered into one nostril and aspirated to collect the wash. Repeat with the other nostril.
- Send the specimen in a sterile container at 2-8°C.
- If both culture and DFA are ordered, split specimen and handle as outlined.

Stool or Rectal Specimens:
- Collect 2-5 grams of stool in a clean container.
- A rectal swab is acceptable only if unable to collect a stool for viral culture. To collect, insert a moistened swab 2-3 cm into the anal orifice and rotate.
- Place specimen in sterile leak proof container. **DO NOT** freeze.

Urine:
- A voided urine should be collected in a sterile container.
- Send urine in the sterile container at 2-8°C.

Spinal Fluid or Other Body Fluids:
- Body fluids should be collected in appropriate sterile tubes.
- As soon as possible send specimen to the Service Center.
- If spinal fluid is to be submitted, collect at least 1 mL of CSF; 2-3 mL is preferred.
Specimen Collection and Handling Guidelines: Virology

**Vesicular Fluid and Lesions:**
- Collect the specimen within 3 days of the eruption.
- Carefully wash the surface of vesicle with 70% ethanol.
- Aspirate the vesicle fluid with a tuberculin syringe.
- Place the aspirated fluid in universal transport medium.
- A vesicle may be opened up with a sterile blade and then the lesion rubbed with a swab. Place the swab in universal transport medium at 2-8°C.
- Swabs from vesicles may be placed in universal transport medium already containing vesicle fluid.

**Eye Exudates:**
- Eye exudates from the palpebral conjunctivae are collected on a sterile swab.
- Place the swab in universal transport medium at 2-8°C.

**Sputum:**
- Collect a deep cough sputum specimen in a sterile container.
- Place specimen in universal transport medium at 2-8°C.

**Skin or Mucous Lesions:**
- Vesicles or pox should be ruptured and the base of the underlying ulcer scraped with a sterile swab to obtain both cells and vesicle fluid.
- Place the swab in universal transport medium at 2-8°C.

**Biopsy of Autopsy Tissue:**
- If possible, collect tissue specimen aseptically.
- Place specimen in universal transport medium at 2-8°C. **Do not place tissue in formalin.**

**Blood - Buffy Coat:**
- 5 ml of blood collected in EDTA vacutainer tube.
- This specimen must reach the lab within 24 hour from collection and the laboratory should be called prior to transport of specimen.
- 1 ml of blood is suitable for pediatric specimens.
Ebola Virus

A minimum volume of 4mL whole blood preserved with EDTA, clot activator, sodium polyanethol sulfonate (SPS), or citrate in plastic collection tubes can be submitted for EVD testing. Do not submit specimens to CDC in glass containers. Do not submit specimens preserved in heparin tubes. Specimens should be stored at 4°C or frozen. Specimens other than blood may be submitted upon consult with the CDC by calling the Emergency Operations Center at 770-488-7100.

Packaging and Shipping Clinical Specimens to CDC

Specimens collected for EVD testing should be packaged and shipped without attempting to open collection tubes or aliquot specimens. Specimens for shipment should be packaged following the basic triple packaging system which consists of a primary receptacle (a sealable specimen bag) wrapped with absorbent material, secondary receptacle (watertight, leak-proof), and an outer shipping package.

The following steps outline the submission process to CDC.

• NO specimens will be accepted without prior consultation. For consultation call the EOC at 770-488-7100.
• Email tracking number to EOCEVENT246@CDC.GOV.
• Do not ship for weekend delivery unless instructed by CDC.
• Ship to:
  Centers for Disease Control and Prevention
  ATTN STAT LAB: VSPB, UNIT #70
  1600 Clifton Road NE
  Atlanta, GA 30333
  Phone 770-488-7100
• Include the following information: your name, the patient’s name, test(s) requested, date of collection, laboratory or accession number, and the type of specimen being shipped.
• Include the CDC Infectious Disease (CDC Form 50.34) and Viral Special Pathogens Branch [PDF - 2 pages] specimen submission forms.
• On the outside of the box, specify how the specimen should be stored: refrigerated or frozen.
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<th>Test</th>
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### Specimen Collection and Handling Guidelines: Virology

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### Abbreviation Key:

- **BAL**: bronchoalveolar lavage
- **CMV**: cytomegalovirus
- **CSF**: cerebrospinal fluid
- **Culture**: viral culture
- **DFA**: immunofluorescent assays
- **EBV**: Epstein-Barr virus
- **EEE**: eastern equine encephalitis
- **EM**: electron microscopy
- **HIV**: human immunodeficiency virus
- **HSV**: herpes simplex virus
- **Lg**: lung tissue
- **NPA**: nasopharyngeal aspirate
- **NS**: nasal swab
- **NW**: nasal wash
- **Rapid Culture**: Rapid CMV Culture
- **RSV**: respiratory syncytial virus
- **TS**: throat swab
- **VZV**: varicella-zoster virus
- **WEE**: western equine encephalitis
1. **Routine surgical pathology specimens from the operating room and emergency department.**
   a. Policy Statement from Sacred Heart Hospital Medical Staff By-Laws Rules and Regulations indicating that:
      "All tissues removed in the OR shall be sent to the hospital pathologist who shall make such examination as he/she
      may consider necessary to arrive at tissue diagnosis. The authenticated report shall be made a part of the patients’
      medical record." See Histology section on Share Point for more information on all Histology procedures.
   b. The circulating nurse must label all specimens before being removed from the operating room.
   c. Fasten label to the side of the container. The label shall contain the name of the patient, the patient birth date, and
      the nature of the specimen.
   d. All specimens are to be placed in 10% formalin unless otherwise indicated. 10% formalin is obtained from the
      Anatomic Pathology laboratory.
   e. All specimens will be brought to the laboratory by operating room or designated personnel, and the specimens
      shall be accompanied by an appropriately completed requisition.
   f. Amputated extremities or amputation revisions are to be labeled appropriately, as above, and be accompanied with
      a surgical requisition form and a “Permission for Release of Severed Body Part” form signed by the patient.
   g. Stones for gross description and/or chemical analysis shall be placed in a dry container and be submitted to the
      Pathology laboratory.
   h. When a fresh specimen is desired, place it in a dry sterile container, properly labeled, and deliver to the Anatomic
      Pathology laboratory ASAP and notify the histologist.

2. **Frozen Sections**
   a. Frozen sections shall be scheduled the day before the surgery in so far as possible by indicating it on
      the operating schedule circulated to the laboratory or by a phone call to the pathologist or histology
      department.
   b. The specimen is placed in a dry sterile container, which is properly labeled, as above, and taken to the laboratory
      accompanied by a requisition which contains the patient's name, date of birth, and the nature of the specimen. It
      should indicate a frozen section is to be done along with the extension the surgeon can be reached by the
      pathologist for provisional diagnosis.
   c. Frozen section examination of each block of tissue to be examined takes about 15 minutes to prepare and
      examine.
   d. When the pathologist completes the frozen section examination, he will speak to the surgeon via phone extension
      provided on the surgical requisition to provide a provisional diagnosis.

3. **Cytopathology**
   a. Bronchial washings and brushings
      - Collect the material in bronchial washing bottles.
      - Label properly including identification of the specimen.
      - The operating room personnel will deliver the specimen(s) to the Anatomic Pathology laboratory.
   b. Sputum Specimens
      - Collect sputum in special containers partially filled with fixative obtained from the laboratory.
Induced sputum provides the most satisfactory specimens for cytological examination inasmuch as the object is to examine material from the lower respiratory tract.

- The container shall be properly labeled on the side.
- Each specimen shall be accompanied by the appropriate requisition; the same as used for surgical pathology specimens.
- The specimen shall be brought to the Anatomic Pathology laboratory by designated personnel.

c. Gyn Pap smears
- The attending physician or surgeon prepares the specimen immediately.
- The ThinPrep Pap test fixative is used and supplies are obtained from the laboratory.
- The container is properly labeled on the side with the patient’s full name and date of birth and brought to the laboratory with an appropriate Physicians Laboratory cytology requisition.

4. Body Fluid:
- Body fluids include pleural effusions, ascitic fluid, peritoneal washings, urine, and cerebrospinal fluid.
- They are collected in sterile containers.
- The specimens are properly labeled with the full patient name and date of birth.
- The specimens are brought to the Anatomic Pathology laboratory by designated personnel and accompanied by a properly completed requisition.
- Since cytological specimens quickly deteriorate, prompt fixation is indicated. If that is not possible, the specimens shall be refrigerated. This is particularly important when specimens are brought to the laboratory at night or on weekends when the regular Histology technicians are not on duty.

4. Surgical pathology specimens obtained from units other than the operating room suite shall be placed in 10% formalin containers and submitted to the Anatomic Pathology laboratory, accompanied by a completed surgical pathology requisition. These specimens shall be properly labeled.

5. Specimen identification and requisition
a. The computer-generated requisition must accompany pathology samples to the laboratory. The following information must be included on the requisition:
   - Patients Name
   - Age  Sex
   - Room Number
   - Hospital Identification Number
   - Surgeon or Physician’s Name
b. Surgical Pathology Requisitions (form L-15), shall contain the following information:
   - Brief history; pertinent clinical data.
   - Pro-Operative diagnosis
   - Operative findings
   - Tissues submitted
   - Surgeon’s or Physician’s signature
Appendix

SACRED HEART HEALTH SERVICES
REFERENCE LABORATORY PANELS

ARTHRITIS PANEL ART
CPT 80072
uric acid ESR ANA RA

BASIC METABOLIC PANEL BMP
CPT 80048
carbon dioxide chloride potassium sodium glucose creatinine BUN calcium

COMPREHENSIVE METABOLIC PANEL CMP
CPT 80053
albumin total bilirubin calcium chloride creatinine glucose alkaline phosphatase potassium total protein sodium CO2 aspartate amino transferase (AST/SGOT) BUN alanine amino transferase (ALT/GPT)

DIC PANEL DICP
PT/INR aPTT Fibrinogen D-Dimer Platelet

ELECTROLYTE PANEL LYTEs
CPT 80051
carbon dioxide chloride potassium sodium

GENERAL HEALTH PANEL
CPT 80050
CBC comprehensive metabolic panel TSH

HEPATIC FUNCTION PANEL LFP
CPT 80076
albumin total bilirubin direct bilirubin alkaline phosphatase total protein alanine amino transferase (ALT/SGPT) aspartate amino transferase (AST/SGOT)

HEPATITIS PANEL, ACUTE HEPAP
CPT 80074
HBsAg HBCAb (IgG&IgM) HAAb (IgG&IgM) HCAb

IRON AND IBC PANEL FEIBC
Iron TIBC FE Sat%

DR GUTNIK ELEVATED HEPATIC PANEL LFT-GNTK
PT TIBC ANA AMA A1A FERRITIN CERULOPLASMIN AFP TM SMAB IGG AB/RFL EBV IGG and IGM CMV IGG and IGM HAV IGM and Total HCV Hep BsAg Hep B Core total Hep B surface AB

LIPID PANEL LI PID
CPT 80061
Cholesterol Triglycerides HDL LDL(calculated) Chol/HDL Ratio

LIPID PANEL REFLEX TO LDL LI PIDRX
CPT 80061
Cholesterol Triglycerides HDL LDL (calculated) LDL-Direct when Trig is >400 mg/dL Chol/HDL Ratio
METABOLIC STONE WORKUP (DR HATHAWAY)
UOX UCIT U24CA U24CREAT U24PHOS U24NA U24URIC URPH ICA NA K CL BUN CREATGFR PTH

NEEDLE STICK EXPOSURE (lab orders are generated by the ED department)
Source: HBSAG HCVPCR Exposure HIV
Exposed: HBsAb HCVRX HIV

OBSTETRIC PANEL OBP CPT 80055
CBC HBsAg rubella Ab syphilis antibody screen ABO-Rh

RENAL FUNCTION PANEL RFP CPT 80069
Sodium potassium chloride carbon dioxide albumin calcium glucose
Phosphorous BUN creatinine

TRAUMA LABS
Draw: Blue, Red, Green, Lavender and Pink Band Patient with BB ID band

CBCD CMP AMY ETOH PT/PTT and HCG SERUM (Females only)
UA Urine DRGS
Blood Bank:
Trauma Yellow: TS
Trauma Red: TC

TSH REFLEX TSHRX
TSH FT4 when TSH is abnormal
24-HOUR URINE COLLECTION INSTRUCTIONS:

The accurately timed urine collection, which you are about to make, is an important part of your examination. Decisions important to your health may depend on it. The test that has been ordered on you is valid ONLY if the collection includes ALL the urine that you pass in a 24-hour period. If for any reason some of the urine passed during the collection time is NOT put into the container for collection, the test will NOT be accurate and a new collection should be scheduled. Please contact your laboratory immediately if you will need to begin a new collection and will require a new container.

You are being supplied with one container that is capped. Additional collection containers can be attained from Avera SHH Lab (605) 668-8169.

KEEP THE COLLECTION CONTAINER CLOSED AND IN A COOL PLACE, PREFERABLY REFRIGERATED.

Patient Name: ________________________________    Date/Time collection started:___________
Test Name: __________________________________    Date/Time collection ended:___________

INSTRUCTIONS:

1. Start the 24-hour collection period at 7:00 a.m. or when you get up in the morning. Empty your bladder at this time and DISCARD this urine (void in the toilet).
2. Collect all urine that you pass for the next 24-hours, until 7:00 a.m. or the specific time you began the collection.
3. At exactly 7:00 a.m., or the specific time you began the urine collection, again empty your bladder and place this collected specimen in the container. This is the LAST specimen that should be added to the container.
4. Should you have a bowel movement during the 24-hour period, try to pass your urine prior to the bowel movement to avoid loss of the urine that may be passed at this time. Do not allow any of the feces passed to contaminate the urine being collected. If feces does contaminate the urine specimen, the collection must be restarted.
5. As soon as collection is complete, return the specimen to the laboratory department along with the lab order that you were given. BLOOD MAY NEED TO BE DRAWN WHEN THE URINE IS DROPPED OFF.
Acct#______________________________

(For ASHH lab use only) Check the appropriate box

Additional Test Request ☐
Verbal Order Verification ☐
Fax Results Order ☐

Patient Name: ________________________________________________

Date of Birth: ________________ SS #: __________________________

Collection Date: __________________________________________________________________________

Ordering Physician: ________________________________________________

Caller: __________________________________________________________________________________

Date of call: ______________________________________________________________________________

Test(s) Requested: ____________________________ Diagnosis: ________________________________

Fax Request:
Fax Results to: Name: __________________________ Fax number: ______________________________

Mislabeled Specimen/Requisition Authorization ☐

Testing requested to be performed under (name): ____________________________________________

Requisition labeled as __________________________ Client ______________________________

Specimen labeled as: __________________________ Client contact: __________________________

Specimen date: ____________________________ ASL Rep: ________________________________

Comments: _____________________________________________________________________________

Client please sign and return by fax to 1-605-668-8168.

Signature __________________________ Date __________________________

Sacred Heart Hospital 605-668-8169 or 1-866-256-2744

Federal Regulations state: The laboratory must perform tests only at the written or electronic request of an authorized person. Oral requests for laboratory tests are permitted only if the laboratory subsequently obtains written authorization.