6. Specimen Documentation and Transportation

A. Fundamentals of Documentation

1. All health care facilities must have methods of documenting patient information.
2. The medical record is the definitive legal document of the patient’s care.
3. Documentation is critical for the following reasons.
   a. Document quality of care
   b. Plan coordination of patient care
   c. Required for accrediting and licensing organizations
   d. Ensures quality monitoring
   e. Useful for peer review
   f. Legal protection
   g. Research in teaching institutions
4. General documentation guidelines
   a. Accurately record facts, not opinions or assumptions.
   b. Complete documentation of routine observations as well as problems; this is very important in phlebotomy.
   c. Written in an objective manner.
   d. Document as soon as possible.
   e. If handwritten, use blue or black ink, NEVER use pencil.
   f. Errors must never be erased – place a single line through the error, make the correction and initial the correction
   g. Correction of electronic errors must be performed by authorized employee(s) and follow facility protocol.

B. Laboratory Communication Network

1. Purpose of clinical laboratory work can be broken down into three phases
   a. Pre-analytical phase Involves all processes including: ordering the test, acquisition of appropriate specimen for test ordered and processing the samples.
   b. Analytical phase Accurate testing of the specimens.
c. **Post-analytical phase** Timely reporting of results to the doctor.

2. Number of people and steps involved in the communication cycle varies with the size and type of institution and type of lab within the institution.
   a. With each additional step or person, more potential sources of error are created.
   b. It is the responsibility of the lab to be involved and concerned with **all** parts of the cycle, not just running the tests.

3. In developing the communication cycle, the lab must address pre-analytical variables that the phlebotomist may encounter such as:
   a. patient variables
   b. specimen transportation and handling variables
   c. specimen processing and storage variables
   d. specimen variables

C. Intra-laboratory Communication Network: covers all aspects of laboratory procedures

1. **Policy and procedure manuals** cover topics such as *Specimen Collection, Administrative, Safety, Infection Control, and Quality Control* guidelines for the institution.
   a. Well written manual removes the need to remake decisions, are usually written in consultation with lab employees, must comply with the institutional policies and must be approved by the lab director.
   b. Procedure manuals provide information relevant to a given situation, event, problem, or protocol to be followed and must be available to employees.
   c. Each laboratory department will have additional manuals specific to the testing done in that department, including testing procedures, critical values, instrument and maintenance manuals

2. **Specimen Collection Manual** is required by accredited clinical labs and must be available to all individuals involved in blood collection. Instructions must include:
   a. Patient preparation (if any)
   b. Type of container and sample volume required
   c. Timing of collection
   d. Type and amount of anticoagulant and/or preservative
   e. Special handling or transport requirements
   f. Labeling requirements
g. Additional clinical data when indicated

h. For an in-patient setting the Specimen Collection Manual should also address special or unusual circumstances such as:
   1) Inability to draw sample
   2) Patient unavailable
   3) Patient refuses to have blood drawn
   4) Combative patient

3. Employees must be made aware of the expectations of the employer. These can be found in the *Administrative procedures* which provide important information, such as:
   a. Job description, evaluations and discipline
   b. Time off, attendance and punctuality, scheduling, holiday work schedule, over-time
   c. Employee accidents
   d. In-service and continuing education requirements
   e. Vaccination policies
   f. Telephone etiquette
   g. Translation procedures
   h. Sexual harassment
   i. Dress code
   j. Quality improvement plan
   k. Maintaining confidentiality and privacy of patient information (HIPAA)

4. *Safety manuals* should be distributed to all managers, available in each department, and must be made known to all personnel. It should include information on:
   a. Fire safety
   b. Internal and external disaster plan
   c. Radiation safety
   d. Exposure control plan
   e. Hazard communication manual, including Material Safety Data Sheets

5. *Infection control policy manual* will address issues concerning employee exposure to potentially infectious materials and will include:
a. Procedures for handling specimens, including shipment of specimens to and from the laboratory
b. Precautions to follow when handling patient specimens
c. Isolation procedures
d. Biohazard disposal policy
e. Decontamination procedures
f. Hand washing or sanitizing procedures
g. Accidental needle stick injury or mucous membrane exposures
h. Post exposure procedures

6. Every laboratory department will have a Quality Control (QC) Procedure manual specific to that department, but all will have the following common elements:
   a. QC records including information about potential hazards
   b. Maintaining appropriate supplies
   c. Monitoring of reagents and equipment
   d. Proper use, storage, handling and disposal of supplies
   e. Stability of reagents and expiration dates
   f. Measuring precision and accuracy
   g. Documentation of routine, preventive maintenance on instrumentation, as well as repairs

7. The Joint Commission periodically inspects hospitals and requires annual review and documentation of each employee for each of the following:
   a. Fire safety
   b. Electrical safety
   c. Physical safety
   d. Internal and external disaster plans
   e. Radiation safety
   f. Biologic hazards
   g. Hazard communication policies
   h. Infection control policies
8. Laboratories are periodically inspected by entities such as:
   a. The College of American Pathologist (CAP) – accredits hospital labs and independent labs
   b. Clinical Laboratory Improvement Act (CLIA)
      1) Regulations apply to any site that test human specimens regardless of size of lab or complexity of testing performed.
      2) Inspects labs that perform CLIA moderate and highly complex testing
      3) Monitors labs performing CLIA waived testing
   c. COLA (formerly Commission on Office Laboratory Accreditation)
      1) Has deemed status for CLIA
      2) Accredits physician office labs

9. Continuing Education (CE)
   a. With the increasing complexity of laboratory medicine services, it is essential for phlebotomists to attend in-service education sessions
   b. CLIA requires proof of CE
   c. Read journals, attend conventions and workshops offered at other institutions, or give a CE presentation yourself
   d. Many online opportunities through professional associations including self study modules, teleconferences or webinars

10. Staff meetings are a method to improve intra-laboratory communication
    a. Use to discuss problems, new policies/procedures and planning
    b. A written agenda should be developed and posted in advance
    c. Minutes of the meeting should be taken and distributed to all, especially those unable to attend.
    d. Can use conference calling for institutions with multiple off-site locations

11. Other modes of Intra-laboratory communications
    a. Bulletin boards, posters, checklists and clipboards are non-computerized methods of distributing current information.
    b. One individual should be responsible for periodically removing old, posting new.
    c. E-mail has become a frequently utilized form of communication.
d. Certain notices, such as non-discrimination policy, must be posted

D. Extra laboratory Communications Network

1. Communication with other health care professionals outside the lab is enhanced in a variety of ways
   a. Information bulletin board, laboratory manual or intra-net web site of lab services available should be on every patient unit, both in- and out-patient
   b. Should contain:
      1) Directory of lab departments
      2) Key staff members
      3) Location of lab
      4) Phone numbers
      5) Menu of lab test with normal values and turnaround times
      6) Specimen required
   c. Methods used for collection, identification, storage, preservation and transporting of specimens should be included
   d. Should be reviewed and updated on a regularly scheduled basis

2. Other opportunities for communication with other health care professionals include:
   a. Task force meetings
   b. Committees for patient safety or quality improvement
   c. Periodic reports
   d. Online tips, including a list of Frequently Asked Questions (FAQ), newsletters, email
   e. Volunteer opportunities

3. The telephone is the most frequently used method of two-way communication
   a. Operation of different features
      1) Phlebotomist must learn how to use special features with specific phones used
      2) Includes forwarding a call to the correct department or putting a call on hold
   b. Answering the phone
1) Give your department’s name AND your name, followed by “May I help you” if appropriate.

2) Prior to ending the conversation, make sure you have answered all questions; ask if there are additional questions.

3) Say “thank you” if appropriate

c. Conversational techniques and manners

1) One of the most critical areas to learn

2) Problems may be caused by improper tone, wording, and not listening properly

3) Never say you cannot help someone, find someone who can.

d. Tone of voice

1) Your tone will convey a message and attitude about your work

2) You represent your place of business when talking on the phone

3) Be conscious of your mood, put personal or work related problems aside and out of your tone

e. Proper use also includes writing legible messages which should include:

1) Name of the person calling

2) Name of the person they wished to speak to

3) Date and time the call was received

4) Message

5) Name of the person taking the message

4. Confidentiality

a. Communication between patient and doctor is privileged and cannot be shared with other people without the patient’s consent.

b. Verbal and nonverbal (lab results, radiology, monitoring of patient, etc.) communication must be kept confidential.

c. Exceptions must involve legal consultation.

d. Phlebotomists with access to patient information must be careful not to disclose results or other information in a careless, casual, or unnecessary fashion

e. Don’t discuss patient’s condition unless it’s related to phlebotomy
f. Disclosure of confidentiality can lead to breach of patients’ rights and an invasion of privacy leading to litigation.

g. **Health Insurance Portability and Accountability Act (HIPPA)**

1) The first-ever federal privacy standards to protect the security and confidentiality of patients’ medical records and other health information provided to health plans, doctors, hospitals and other health care providers took effect on April 14, 2003.

2) Developed by the Department of Health and Human Services (HHS), these new standards provide patients with access to their medical records and more control over how their personal health information (PHI) is used and disclosed.

3) Represents a uniform, federal floor of privacy protections for consumers across the country

4) State laws providing additional protections to consumers are not affected by this new rule.

5) Visit: [http://www.hhs.gov/ocr/hipaa/](http://www.hhs.gov/ocr/hipaa/) for current information on this important regulation. **TIME TO DO ACC HIPPA training.**

5. Electronic transmission (facsimile/Fax) or email of laboratory requests or test results

a. Each institution must have clear policies related to use of test request or patient information that has been faxed or emailed, which must be in compliance with HIPPA.

b. Fax machines are an efficient, timely and cost effective way of communication and must be placed in room with limited access.

c. Precautions must be detailed out in procedure manual that relate to faxing official lab orders from requesting physician or test results to physicians.

d. Electronic Medical Record (EMR) becoming predominant method of sharing lab results with healthcare professionals.

E. Computerized Communications

1. Computers have become an essential instrument in all aspects of health care and can significantly decrease errors. Phlebotomist must possess basic computer skills.

2. Functions of a laboratory computer system include:

a. Entering of patient information: name, DOB, Doctor’s name, patient location

b. Entering patient test requests

c. Printing patient labels, collection lists and collection schedules

d. Updating lab accession records
e. Printing list of tests to be performed on patient samples.

f. Entering and storing results

g. Sending lab results to nursing floor or to doctor’s office

h. Analysis of results

i. Sending charges to billing office

j. Inventory management, personnel schedules

k. Quality control and quality assurance

F. Requisition forms used for transmitting the test request to the laboratory

1. Regardless of the method used, certain information is required for all laboratory requests

   a. Patient name

   b. Patient identification information, such as Date of Birth (DOB) or unique ID number

   c. Patient gender

   d. Name of doctor ordering the test

   e. Test(s) requested

2. For inpatients, additional information may be required, including:

   a. Location of patient (room number or patient care area—ER, OR, etc.)

   b. Specific time of collection or priority, i.e., STAT, Routine, PreOp, Medical Emergency, Priority One, Priority Two, etc.

   c. Name of institution must appear on the form

3. For outpatients, additional information may include:

   a. Requested patient status at time of collection, i.e., fasting, non-fasting, etc.

   b. Requested date and time of collection

   c. Phone or fax number to send report; address of requesting physician

   d. Patient insurance information and address for billing

4. Manual method – may be used in outpatient settings or when the laboratory computer system is down.

5. Computerized method – information is entered into a computer, which sends request to the lab. The advantages include:
Electronic based records are becoming the standard in both in and outpatient settings

Orders are directly transmitted to the lab.

Most error free means of making a request

Computer can perform automatic checks on input, will not accept a request for test that is not in its database

Allows user to obtain accurate, up-to-date information about specimen type, amount of specimens required, specimen collection process, reference values

Additional specifications or patient information can be added to request

Verbal test requests may be issued in cases of emergency, i.e., ER, ICU, surgery, etc

Should be documented on a standard lab form prior to collection by individual taking the order and include a patient name and identification number.

After blood is collected the request is entered into the computer system to generate a requisition or label.

Document name of person calling the order in along with date and time

**USE COMMON SENSE**

Specimen Labels and Blood Collection Lists

1. Labeling - specimen identification is essential
   a. Must be clear and accurate
   b. Begins immediately upon collection and continues through disposal
   c. Methods for labeling include handwritten or computer generated.
   d. Labels must include patient name and identification number, date and time of collection, and initials of phlebotomist collecting the sample

2. Manual labeling
   a. Is time consuming and prone to transcription errors
   b. Neat, legible handwriting is essential
   c. Serves as the back-up method when computers or printers are down

3. Computer Labels
   a. Most sophisticated, accurate and efficient method
b. Labels generated by the computer are put on specimens, phlebotomist adds date and time of collection and initials

c. Often extra labels are printed for labeling aliquot tubes, cuvettes, and slides

d. Computer generated labels may include Bar Code or Radio Frequency Identification (RFID) tags

e. Bar codes extremely useful in preventing transcription errors
   1) Series of light and dark bands representing alpha-numeric symbols
   2) Placed in a series to represent patient name, identification number and test ordered
   3) Bar code is scanned into computer and read by computer
   4) Example – Iatric Systems HealthCare Software (MobiLab® Specimen Collection and Phlebotomy Software)  http://www.iatric.com/MobiLab
      a) With the handheld mobile touchscreen computer, the phlebotomist scans the patient’s ID bracelet to obtain initial identification. Phlebotomist must obtain second identifier (birth date, etc.) according to facility’s protocol.
      b) Computer sends information to the companion mobile label printer which prints appropriate labels for tests ordered.
      c) Phlebotomist must still follow the facility’s protocol in adding date/time of collection and their initials.

f. RFID tags can also be used in place of bar codes
   1) Uses silicon chips that transmit data to a wireless receiver
   2) Unlike bar codes, does not require a line of sight

g. Both bar codes and RFID tags are very accurate and fast, aids in patient identification, test codes, billing codes and inventory records

h. Many lab instruments read the bar codes or RFID tags on the tube

4. Blood Collection List
   a. Utilized in hospital setting; helps to organize the morning collection, which is usually the largest collection time of the day in a hospital
   b. Aids in organizing collections by priority and location
   c. List will print labels for each specimen to be collected for each patient
   d. List can be shared with nursing staff for their records; are also kept for lab records

H. Specimen Handling Following Venipuncture

1. Basic steps for handling specimens immediately following venipuncture include:
a. Mix specimens by gentle inversion

b. Label the specimen correctly at the patient bedside or collection chair

c. Maintain microtainers and vacuum tubes in an upright, vertical position for two reasons
   1) Promotion of clot formation
   2) Reduce the possibility of hemolysis

2. **Chilled samples** – for thermolabile substances that are sensitive to higher temperatures, these specimens must be chilled immediately

   a. Use an ice slurry (crushed ice chips mixed with water) or a commercially available product to keep specimens upright and chilled; DO NOT FREEZE

   b. Blood gases – must be transported to lab within 10 minutes in airtight heparinized syringe and pack in ice water to prevent decrease in loss of gases from the specimen.

   c. Other thermolabile substances include: gastrin, ammonia, lactic acid, rennin, catecholamine, parathyroid hormone, ACTH, glucagon, and pyruvate.

3. **Warmed samples** – must be maintained at 37° C

   a. Use a commercially available controlled heat source or heating block

   b. Hemolysis will occur if temperature rises to 45° C or higher.

   c. Cold agglutinins, cryofibrinogen and cryoglobulin

4. **Protect from light** – specimens that are photosensitive

   a. Wrap light sensitive samples in foil or placing in a box.

   b. Bilirubin is a by-product of red cell breakdown
      1) If excessive amounts accumulate in babies, it can cause brain damage
      2) Exposure to light can cause falsely decreased results

   c. Samples which must be protected from the light include: Bilirubin, Vitamin A, Vitamin B6, Vitamin B12, Beta-carotene, folate and urine samples for porphyrin determination

5. **Microbiology samples** should be delivered to the department immediately to enhance ability to grow pathogenic organisms.

6. **Glycolysis** affects many laboratory analytes, affects will increase due to delays in transporting samples

   a. For in-patient setting, deliver blood samples to lab within 30-45 minutes
b. For out-patient settings, blood may need to be centrifuged and separated as soon as possible prior to transport

7. Plasma based coagulation assays can be very time-sensitive
   a. Depends on the substance being tested and the medication state of the patient
   b. Follow the procedure for your facility

8. DNA testing is best performed on fresh specimens. Check with the testing laboratory for the most up-to-date information

9. Collection at remote sites require phlebotomists to follow same handling procedures and safety guidelines as they would on-site in addition to appropriate sample storage and transport

1. Specimen Handling Following Microcollection
   1. Changes which occur over time
      a. Glycolysis is a process which utilizes glucose for energy
      b. RBCs and WBCs can cause a false decrease in blood glucose and Ph levels due to glycolysis. This can be detected after 20 minutes at room temperature
      d. Capillary blood gas specimens should be immersed in ice water to prevent these changes. Ice is available on the floors or in the lab and is put in a cup to be carried on the blood collection tray
   2. Microspecimens should be delivered to the lab ASAP if possible

I. Specimen Delivery and Transport
   1. Hand delivery – the most common method used for the in-patient setting
      a. Must have standards for assuring prompt delivery
      b. Phlebotomist may be responsible for collection and delivery of blood as well as other specimens
      c. Patient care areas should have a designated area for specimen delivery and a log which includes: patient name, ID number, room number, type of specimen or tests ordered, time of pick up and initials of individual transporting
   2. Large medical centers may have a transportation department which employ individuals to move patient around the hospital
      a. Delivery of lab specimens may be one of their duties
      b. Established protocols must be followed for specimen pick-up, documentation, and transport
c. This individual must take specimens to lab and log samples in following established protocol to document actual delivery time
d. STATE or timed requisition may be delivered by other healthcare members: nurses, clerks

3. Pneumatic tube systems
a. Very efficient, reliable method used to deliver all kinds of documents, medications, and requests to all major hospital departments, including tubes of blood
b. Samples must be properly cushioned by appropriate materials to prevent breakage and red blood cell hemolysis
c. Urine samples must be tightly capped
d. All samples must be enclosed in leak proof materials such as a zip-loc biohazard bag
e. Blood culture bottles must be sent separately due to weight and size
f. If leakage or breakage occurs, the part of the pneumatic tube system affected must be shut down for cleaning and disinfection

4. Transportation by vehicle requires specific protocols to follow when transporting specimens to a reference or centralized testing facility and are found in the Standard Operating Procedure (SOP) manual at each facility
a. Basic handling guidelines include the use of leak-proof plastic biohazard bags
   1) Biohazard labeled plastic bags with inner water tight sealable pouch for specimens and outer pouch for paperwork are routinely used for delivering out-patient specimens.
   2) This provides protection of the phlebotomist from potentially pathogenic organisms during transport, especially if inside of container is contaminated due to leakage or breakage of sample container.

b. Most facilities use coolers to load pre-packaged samples into for transport to maintain temperature.

5 Transportation to remote laboratories are done by vehicle or commercial carriers.
   a. Specific transportation protocols to follow will be found in the Standard Operating Procedure (SOP) manual at each facility
   b. Commercial shipping of biohazardous specimens to remote laboratories require very specific containers and protocols including:

      1) Biohazardous Specimens included in this classification is “any human or animal material such as excreta, secreta, blood and blood components, tissue, and tissue fluids being shipped for diagnostic or investigations purposes”.
1) Shipping methods must reduce possibility of sample breakage or leakage

2) Materials used must meet strength and absorbency requirements. Packaging must include inner or primary package (water tight), secondary container (water tight), absorbent material between primary and secondary containers and an outer package and must pass a drop test.

3) Name and telephone number of individual responsible for shipping.

4) Must be kept at appropriate temperature.

5) Mechanisms to verify receipt of specimen by receiving lab.

6) There are serious fines and legal ramifications for failure to comply with these requirements.

c. Local transport of samples usually use cooler with coolant if required

d. Transport containers should be evaluated for cost, protective ability, temperature control, sterilizing potential, appearance and labeling

J. Laboratory processing

1. May occur on-site or at satellite labs

2. Phlebotomist must learn the processing requirements of lab specimens as many labs use phlebotomists as “lab assistants”.

3. Prompt collection, delivery and processing of laboratory samples decreases turnaround times (TATs) and improves patient care.

4. Care must be taken to use the appropriate safety devices to prevent splashing and aerosol exposure.

5. All specimens that are received in a laboratory must be entered into a specimen log, which includes:

a. Date and time received

b. Patient name – name on all tubes must match name on lab requisition exactly

c. Patient identification number – must have exact match between all tubes and paperwork

d. Test(s) ordered

e. Tube(s) received

f. Initials or, if computer, identification code of individual logging in the specimen

g. If computer labels are used the unique lab accessioning number must be recorded and is also attached to all tubes of blood
h. Any problem(s) with the specimen or paperwork, and the resolution of the problem

6. Specimens that **do not** require centrifugation
   a. Should be delivered to the appropriate department as soon as they have been logged in
   b. Most hematology, microbiology and urinalysis specimens fall in this category

7. Specimens that **do** require centrifugation
   a. Anti-coagulated specimens (plasma specimens) may be centrifuged immediately
   b. Light blue coagulation and green are the two most commonly centrifuged plasma tubes
   c. Specimens without anti-coagulant additives (serum specimens in red or gold tubes) must be allowed to clot prior to centrifugation

8. Centrifugation of samples
   a. Clotting of serum specimens usually takes 30-60 minutes at room temperature
   b. Clotting may be affected (usually delayed) due to patient anticoagulant therapy
   c. Always balance the contents of the centrifuge before operating
   d. Do not remove the lids of specimens before centrifugation to avoid aerosols
   e. Do not open the lid of the centrifuge before the centrifuge comes to a complete stop
   f. Specimens should not be centrifuged more than once, this will affect some blood analytes

9. Be familiar with specimen processing guidelines for your facility – especially safety

10. Aliquoting of specimens
    a. Separate serum or plasma from their cells in accordance with laboratory safety guidelines and **should be done within 2 hours of collection**
    b. Specimens may be aliquoted for use in multiple departments or for multiple test or instrumentation within a single department
    c. The transfer tube into which the aliquot is placed is prepared **before** the aliquot is added to the tube and must be labeled with the following information:
       1) Two patient identifiers – name plus some other identification information, such as DOB or lab accessioning number with bar code or RFID tag
       2) Date and time of collection
       3) Initials of individual aliquoting the sample
4) Specimen type: citrate plasma, heparinized plasma, EDTA plasma, sodium fluoride plasma, or serum

5) Special information, such as a trough or peak drug level

d. Transfer the serum or plasma from the collection tube to the aliquot tube(s) using a clean disposable pipette, or if the collection tube contained a polymer separator gel, pour the specimen over into the aliquot tube. Follow your facilities policy.

1) Aliquots may be delivered to the appropriate lab department for immediate testing

2) For an outpatient setting, aliquots will be stored until transported to the final testing lab. Refer to the facilities SOP for the correct storage conditions.

e. Depending on the analysis to be performed, the storage may be:

1) At room temperature

2) In the refrigerator

3) In the freezer

4) In a dark place

K. Reporting Mechanisms and Distribution of Results

1. Written reports are the feedback mechanism for transmitting vital data from the lab to the reporting doctor.

   a. Joint Commission and CAP state that results should be confirmed, dated and accompany permanent copies that are kept in lab and on patient chart

   b. Should contain adequate information about patient ID, time in, time out, and be signed or initialed by lab worker.

2. Unique institutional requirements for acceptable results should be stated in the lab procedure manual and many include: QC limits, absolute limits and delta checks

3. Reports should contain a list of reference ranges and include normal, abnormal and critical values

4. Documentation of results in the lab, actual physical recording of results, may be one of the following:

   a. Manually recorded

   b. Lab instrument printed results

   c. Computer generated reports

5. Reporting results from lab to patient care unit or doctor
a. **Computer Report**

1) Computer generated reports are the most reliable and accurate method of reporting results; the most common method used today in hospitals, and for sending reports from outpatient laboratories to doctor’s offices.

2) Computer generated reports can be displayed in the appropriate patient care area and printed out to be placed in patient’s chart.

3) Care must be taken to insure patient privacy and confidentiality. Computer screen must not be visible to non-authorized individuals.

4) Doctor’s office may receive laboratory results by fax but must comply with patient privacy and confidentiality standards. Most reports are received electronically and are immediately transferred into the patient’s EMR.

b. **Verbal Reports**

1) Must be documented immediately with the date and time they were called, the name of the laboratory worker who called the results, and the name of the person taking the report.

2) Have declined because of easier, more reliable computer systems.

3) Verbal laboratory reports can only be given by laboratory personnel performing the tests, usually MLT or MLS, not phlebotomist. Useful for reporting STAT lab results or panic values, but must be very careful, as they are more prone to error than a computer generated report.

4) All verbal reports must be followed up with a written, computer generated report.

5) Care must be taken to maintain patient confidentiality.

c. **Manual, handwritten reports**

1) May be used for reporting of results from
   a) Point-of-Care Testing
   b) Doctor’s office lab performing in-house testing and waived test

2) **Legible handwriting is crucial**

5) Patient confidentiality must be maintained.

L. **Advanced Beneficiary Notification**

1. **Purpose**

   a. Medicare patients must be aware that some laboratory tests ordered may not be covered by Medicare and the patient will be responsible for paying.
b. The International Classification of Diseases (ICD) 10 must be included on all requisitions and is used to indicate a patient’s disease or condition for billing purposes.

c. Must look up ICD 10 code to review list of tests covered (reimbursed) by Medicare for that diagnosis.

d. If the laboratory test IS NOT listed, the patient MUST be informed that they may be responsible for payment and given the option of whether or not to have the test performed.

2. Depending on the clinical setting, the phlebotomist may be required to present and discuss the ABN form with the patient. It is critically important that the ABN form is properly filled out, signed and dated before collecting the required sample.

2. Basic Rules of Advanced Notices Beneficiary (ABN)

a. A laboratory should not do a Blanket Notice or do an ABN before every blood draw or procedure; it should only be done if it is believed the service will not be covered.

b. The ABN must be done in person, in writing, and not over the phone.

c. The patient must have the capacity to understand the notification (competency issues) and therefore, have it in their language, and must know that the patient is literate and able to hear and/or read well enough to understand the possibility of denial of payment for services.

d. Must use a font size of 12 or larger.