Advanced Beneficiary Notice (ABN)

An Advanced Beneficiary Notice (ABN) should be obtained anytime the provider is aware that services to be furnished to a patient will not be covered. Determination of when this applies is guided by National Coverage Decisions (NCD) published by Centers for Medicare and Medicaid Services (CMS). Copies of the NCD are provided to health care providers utilizing Regional West Laboratory Services (RWLS). An ABN is not required, but is desirable if the service is defined by Medicare as non-covered. Obtaining an ABN:

- An ABN may be obtained when a provider (clinician, laboratory staff, nurse, etc.) is aware that the services to be furnished to a patient will not be covered or when there is genuine doubt.
- To be valid, a patient or patient representative must be notified in writing at the time of, or prior to performance of the service. The clinician or a member of the clinician's staff should do this. However, if the laboratory does not receive written notice that the clinician or his/her designee has provided this notification to the patient or patient representative, RWLS staff will perform this notification. This, of course, applies only to those patients who present to the laboratory at Regional West Medical Center (RWMC) for specimen collection.
- Providers are not required to submit claims for non-covered services, but the patient can request that the provider submit a claim for reimbursement. RWLS will submit claims for potential non-covered services, but will maintain the signed ABN so that if payment is denied, the beneficiary can be billed for service. If a non-covered service is denied, RWMC will bill the beneficiary for the service even if an ABN has not been obtained.
- An ABN should only be obtained when there is a reasonable basis for the belief that a service is non-covered, i.e., the NCD indicates that the diagnosis provided does not document medical necessity or the test is ordered as a screening procedure (eg, Pap smear). It is not acceptable to use a blanket ABN for each patient to cover the possibility that a service may be regarded as non-covered. Therefore, every patient who receives any laboratory service cannot be asked to sign an ABN for any and all services. The exceptions to this rule are any screening tests that have frequency limitations defined by the CMS. This includes:
  - Screening Pap Smear-covered once every two years
  - Screening Prostate-Specific Antigen (PSA)-covered once every 12 months for male Medicare beneficiaries over the age of 50
  - Screening Occult Blood-1 to 3 determinations every 12 months for Medicare beneficiaries over the age of 50
  - Diabetes Screening Tests-Fasting Glucose, Post-Glucose Challenge Test for Medicare beneficiaries that meet eligibility requirements
  - Cardiovascular Disease Screening-Cholesterol, High-Density (HDL), Triglycerides for Medicare beneficiaries that meet eligibility requirements
- The ABN must document the patient's name as it appears on the Medicare/Medicaid card.
- The basis for believing that a service may not be covered (reason for denial) must be documented by the laboratory or other party obtaining the ABN.
- The ABN must be obtained prior to providing the service. This means that an ABN may be acceptable with a date after the specimen is collected, but prior to the test being performed.
- The ABN must designate the service that the provider believes will not be covered.
- The ABN must be signed by the patient or patient representative and must be dated to show that the ABN was obtained prior to performing service.
- A representative of the nursing home or beneficiary representative who signs on other matters may sign an ABN for a laboratory service for a mentally incompetent patient in a nursing home. The following individuals are permitted to sign for the beneficiary (42 CFR 424.36):
  - Legal guardian
  - Relative or other person who receives Social Security or other benefits on behalf of the beneficiary
  - Relative or other person who arranges treatments for the beneficiary
  - Representative of the nursing home
  - Representative of the provider, if the provider cannot have someone who meets the above requirements sign the claim
- Standing Orders-An ABN is required at the outset of the treatment for a non-covered service and is effective as long as no new services not specified in the standing order are provided. If new services are provided, then a new ABN is necessary.
Patient Refusal—A beneficiary has the choice to either refuse or obtain service. He/she does not have the choice to obtain the service, but refuse to sign an ABN and be responsible for payment if the service is non-covered. If beneficiary demands that a service be performed, but refuses to sign the ABN, a second person should witness the refusal and document this and his/her signature on the ABN statement. A note to the patient file should indicate the 2 persons present who witnessed the patient refusal. If only 1 person is present in the physical location with the patient, the second witness may be contacted by telephone to witness the refusal and then sign the ABN later. If the beneficiary refuses the service, the physician should be notified. This should be documented on the requisition.

Nursing homes may elect to perform testing on a resident based on state laws or quality of care practices as defined by the nursing home. In this case, medical necessity requirements may not be met and the nursing home may elect to have the services billed back to the nursing home rather than to the resident. In this case, the laboratory will bill the services as non-covered and bill the nursing home.

Format of an Advanced Beneficiary Form—Medicare has published acceptable formats for the ABN. The standard formats may not be modified except for the customizable boxes provided for listing the laboratory tests. Any change to the area of the ABN which is not customizable will result in a defective ABN. Contact Client Services at 888-522-7962, 308-630-1398, or clientservices@rwmc.net for a copy of an ABN form, showing all sections highlighted in yellow that must be completed.

Animal Specimens
We do accept animal specimens for limited laboratory testing.

Acceptable Specimen Volumes
Test entries list minimum acceptable volumes. The minimum volume is defined as the absolute minimum needed to run a validated test algorithm. If there is insufficient volume for testing, attempts will be made to locate any additional sample collected by your laboratory on the same date and time. If none are found, you will be contacted for recollection.

Billing
Client—Each month you will receive an itemized invoice/statement which will indicate the date of service, patient name, CPT code, test name, and test charge. Payment terms are net 30 days. When making payment, please include your account number on your check to ensure proper credit.

Patient—To allow Regional West Laboratory Services (RWLS) to bill patient’s insurance, please include the following required billing information: responsible party, patient’s name, current address, zip code, phone number, Social Security number, date of birth, gender, and diagnosis code, along with policy holder name, address, phone number, date of birth, and gender. Providing this information will avoid additional correspondence to your office at some later date. Please advise your patients that they will receive a bill for laboratory services from RWLS for any personal responsibility after insurance payment. VISA and MasterCard are acceptable forms of payment.

Billing Change Requests
Regional West Medical Center (RWMC) bills charges to clients, insurance companies, Federal programs (e.g., Medicaid, Medicare) or patients. Due to Federal regulation, the laboratory that performs the testing on a Medicare or Medicaid patient must bill that program for the testing. The exception is when a hospital refers a test to another laboratory in which case the referring hospital is still required to bill for testing done on its registered inpatient regardless of who did the testing. The laboratory bills, based on information provided on the requisition by requesting physician. Any requests for billing changes should be provided in writing by requesting the physician representative. See Special Instructions for a copy of the Billing Change Request form. All appropriate information must be provided to allow RWMC to bill charges. Requests must be received within 60 days of the date of service, and RWMC cannot accept requests for partial billing changes. All tests ordered on a single requisition, must be changed.

Blood Bank Specimens
The American Association of Blood Banks, in its Standards for Blood Banks and Transfusion Services (27th edition, 2011), requires that blood samples to be used in preparation of blood for transfusion: “be labeled in the presence of the intended recipient, that the sample label contain 2 independent patient identifiers plus collection date, and that there be a mechanism to identify the individual who drew the blood.” Samples sent to Regional West Laboratory for transfusion-associated tests, need to meet these requirements. In an emergency situation where no patient information is available, the green Securline blood bank
Armband number will be used for identification until patient information and history are available. If a trauma number is available, this number should also be recorded on the specimen tube.

Cancellation of Tests
Cancellations received prior to test setup will be honored at no charge. Requests received following test setup cannot be honored. A report will be issued automatically and charged appropriately.

Chain-of-Custody
Chain-of-custody, a record of disposition of a specimen to document who collected it, who handled it, and who performed the analysis, is necessary when results are to be used in a court of law. Mayo Medical Laboratories has developed packaging and shipping materials that satisfy legal requirements for chain-of-custody. This service is only offered for drug testing performed at Mayo Medical Laboratories.

Compliance Policies
Regional West Laboratory Services (RWLS) is committed to compliance with applicable laws and regulations such as the Clinical Laboratory Improvement Amendments (CLIA). Regulatory agencies that oversee our compliance include, but are not limited to, the Centers for Medicare or Medicaid Services (CMS), the Food and Drug Administration (FDA), and the Department of Transportation (DOT). RWLS develops, implements, and maintains policies, processes, and procedures throughout our organization which are designed to meet relevant requirements. We expect clients utilizing our services will ensure their compliance with patient confidentiality, diagnosis coding, anti-kick back statutes, professional courtesy, CPT-4 coding, CLIA proficiency testing, and other similar regulatory requirements.

CPT Coding
It is your responsibility to determine correct CPT codes to use for billing. While this directory lists CPT codes in an effort to provide some guidance, CPT codes listed only reflect our interpretation of CPT coding requirements and are not necessarily correct. Particularly, in the case of a test involving several component tests, this directory attempts to provide a comprehensive list of the CPT codes for all of the possible components of the test. Only a subset of component tests may be performed on your specimen. You should verify accuracy of codes listed. Where multiple codes are listed, you should select codes for tests actually performed on your specimen.

Regional West Laboratory Services assumes no responsibility for billing errors due to reliance on CPT codes listed in this directory. For further reference, please consult the CPT Coding Manual published by the American Medical Association. If you have any questions regarding the use of a code, please contact your local Medicare carrier.

Critical Values
The Notification of Critical Results policy of Regional West Laboratory Services (RWLS) is described below.

- Definition of Critical Value-A critical value is defined by RWLS as a value that represents a pathophysiological state at such variance with normal (expected values) as to be life-threatening.
- Abnormals are Not Considered Critical Values-Most laboratory tests have established reference ranges, which represent results that are typically seen in a group of healthy individuals. While results outside these reference ranges may be considered abnormal, abnormal results and critical values are not synonymous. Analytes on the RWLS Critical Values List represent a subgroup of tests that meet the above definition.
- Action Taken when a Result is Obtained that Exceeds the Limit Defined by RWLS Critical Values List-All critical results will be called to the appropriate nursing personnel responsible for the primary care of the patient or directly to the physician. Notification for in-house testing will be made within 30 minutes of test completion and within 60 minutes for testing sent to a referral laboratory. In the event that contact is not made within the 60-minute period, we continue to call, and will fax the results if telephone contact is deemed impossible.

The exceptions to this rule are those providers who have notified RWLS that they do not want critical values called to them outside their office hours. In these cases, the critical results will be called when the office reopens.

Disclosures of Results
Referral Specimens-Third party requests for laboratory results on specimens sent to Regional West Laboratory Services (RWLS) by other laboratories or physician offices will be referred back to the ordering entity.
Outpatient Requests-RWLS prefers the patient obtain laboratory results from the physician. However, results will be released directly to the patient under the following guidelines:

- There are certain tests that require interpretation by the physician and cannot be released to the patient. These are:
  - Chlamydia/GC testing
  - Cultures
  - Cytopathology results
  - Drug testing
  - Genetic testing (eg, Cystic Fibrosis, Quad Screen)
  - Hepatitis testing
  - HIV
  - Pregnancy testing
  - Surgical pathology

In these cases, the patient will be referred to the ordering physician.

- Verbal Results-The patient may call the laboratory for verbal results if he/she completes and signs an Authorization for Use and Disclosure of Protected Health Information form and establishes a password at the time of collection.

- Fax Results-Results will be faxed to a health care provider only if the fax number can be verified. Results cannot be faxed to a personal fax number.

- Mail Results-RWLS does not mail laboratory reports. The patient will be referred to either the Health Information Management Department or to their physician. Health Fair testing results may be obtained from either the draw site or the patient's physician.

Provider Requests-Results will be given on request, to any provider(s) involved with a patient's treatment or care.

**HIPAA Compliance**

Regional West Laboratory Services is fully committed to compliance with all privacy, security, and electronic transaction code requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). All services provided by Regional West Laboratory Services that involve joint efforts will be done in a manner which enables our clients to be HIPAA and the College of American Pathologists (CAP) compliant.

**Informed Consent Certification**

Submission of an order for any tests contained in this catalog constitutes certification to Regional West Laboratory Services and Mayo Medical Laboratories by ordering physician that: (1) ordering physician has obtained Informed Consent of subject patient as required by any applicable state or federal laws with respect to each test ordered; and (2) ordering physician has
obtained from subject patient authorization permitting RWLS and Mayo Medical Laboratories to report results of each test ordered directly to ordering physician. On occasion, Mayo Medical Laboratories will forward a specimen to an outside reference laboratory. The laws of the state where the reference laboratory is located may require written informed consent for certain tests. RWLS will request that ordering physician pursue and provide such consent. Test results may be delayed or denied if consent is not provided.

**Medicare Coverage of Laboratory Testing**

When ordering laboratory tests that are billed to Medicare/Medicaid or other federally-funded programs, the following requirements may apply:

- Only tests that are medically necessary for the diagnosis or treatment of the patient should be ordered. Medicare does not pay for screening tests, except for certain specifically approved tests and those tests considered experimental.
- If there is reason to believe that Medicare will not pay for a test, the patient should be informed. The patient should sign an Advance Beneficiary Notice (ABN) to indicate that he or she is responsible for the cost of the test if Medicare denies payment. See Advanced Beneficiary Notice (ABN).
- Organ- or disease-oriented panels should be billed to Medicare only when every component of the panel is medically necessary.
- RWLS- and client-customized panels should be billed to Medicare only when every component of the customized panel is medically necessary.
- Medicare National Limitation Amounts for CPT codes are available through Centers for Medicare and Medicaid Services (CMS) or its contractors. Medicaid reimbursement will be equal to or less than the amount of Medicare reimbursement.

**Verbal requests**

- Laboratory Outpatient or Non-patient-A verbal request will be followed with a request for written documentation of that order. Likewise, a verbal request for an add-on test to an order that has been received by the laboratory will be followed with a request for written documentation of that order.
- Hospital Inpatients-A verbal order label will be filled out and sent to the nursing unit when testing is completed (this includes CKM B performed automatically on the first elevated CK, and Kleihauer-Betke performed on all positive fetal bleed screens), along with instructions to have the doctor sign the label and attach it to the patient's chart.

Ambiguous or unclear orders will be clarified by contacting the ordering physician prior to performing the tests. Orders specifying, "Test if indicated" must include specific criteria to determine if the additional testing is required. Standing orders are accepted for a period of 6 months. At that time, a new order will be requested from the provider. Standing orders must have a start and stop date, as well as a diagnosis supporting medical necessity.

**Radioactive Specimens**

Specimens from patients receiving radioactive tracers or material should be labeled as such. Specimens are not routinely tested for background radioactivity. This radioactivity may invalidate the results of radioimmunoassays (RIA).
**Record Retention**

Regional West Laboratory Services retains all test requisitions for a minimum of seven years. Mayo Medical Laboratories retains all test requisitions for 25 years, and patient test results are retained indefinitely. A copy of the original report can be reconstructed including reference ranges, interpretive comments, flags, and footnotes with the source system as the Department of Laboratory Medicine's laboratory information system.

**Reflex Testing**

Both RWLS and Mayo Medical Laboratories identify tests that reflex when medically appropriate. In many cases, RWLS and Mayo Medical Laboratories offer components of reflex tests individually as well as together. Clients should familiarize themselves with the test offerings and make a decision whether to order a reflex test or an individual component.

**Reportable Disease**

State of Nebraska Public Health Department requires prompt and accurate reporting of all communicable diseases as required by law. When a reactive test result is obtained for a disease, which is listed by the Nebraska Public Health Department as a Reportable Disease, it shall be reported by Regional West Laboratory Services. Positive results are called to provider when the results are received. These test results are reported daily (Monday-Friday) to the Nebraska State Health Department.

**Retention of Specimens**

To allow for repeat testing for the purpose of confirmation, specimens received for testing are maintained for a temporary period of time depending on the specimen type.

<table>
<thead>
<tr>
<th>Blood Bank</th>
<th>Crossmatch specimens</th>
<th>4 days</th>
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<tbody>
<tr>
<td></td>
<td>Crossmatch segments</td>
<td>10 days</td>
</tr>
<tr>
<td></td>
<td>Cord blood</td>
<td>10 days</td>
</tr>
<tr>
<td></td>
<td>Type and screen</td>
<td>3 days</td>
</tr>
<tr>
<td></td>
<td>All other blood bank</td>
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<table>
<thead>
<tr>
<th>Urinalysis</th>
<th>Urine</th>
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<tbody>
<tr>
<td>Cytology</td>
<td>Urine, body fluid, etc.</td>
<td>3 days</td>
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<tr>
<td></td>
<td>GYN slides (positive or negative)</td>
<td>5 years</td>
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<tr>
<td></td>
<td>Non-GYN slides</td>
<td>10 years</td>
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</tbody>
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<table>
<thead>
<tr>
<th>Histology</th>
<th>Surgical specimens</th>
<th>2 weeks following final report</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Paraffin blocks-Surgical</td>
<td>10 years</td>
</tr>
<tr>
<td></td>
<td>Slides-Surgical</td>
<td>10 years</td>
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<tr>
<td></td>
<td>Autopsy slides-forensic</td>
<td>Indefinitely</td>
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<tr>
<td></td>
<td>A autopsy slides, Nonforensic</td>
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</tr>
<tr>
<td></td>
<td>Autopsy paraffin blocks-Nonforensic</td>
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<tr>
<td></td>
<td>A autopsy paraffin blocks-Nonforensic</td>
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<td></td>
<td>A autopsy specimens-Nonforensic</td>
<td>3 years</td>
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<tr>
<td></td>
<td>A autopsy specimens-Forensic</td>
<td>3 months after final report</td>
</tr>
<tr>
<td></td>
<td>Wet tissue</td>
<td>1 year</td>
</tr>
</tbody>
</table>

**Specimen Identification Policy**

Specimens must be clearly labeled and must meet labeling requirements in order to be acceptable for testing. Unacceptable specimen labeling may result in rejection of the specimen.

Inpatient Specimens: Collected by Nursing-Must be identified with a preprinted label or hand written with a minimum of first and last name and 1 other unique identifier.

Blood Bank Specimens: Intended for Compatibility Testing-Must be labeled according to standards set by AABB. Tubes should not be pre-labeled. Required information on the patient’s specimen (may be hand written or computer generated) is:

- Patient full name, including middle initial if available
- Collection date and time
- Phlebotomist’s initials
- Patient’s medical record number
- Green Blood Bank armband alphanumeric identification

All specimens must be identified and labeled at the patient’s bedside. Do not pre-label tubes or green armbands. Other transfusion specimens, such as obstetric panels are not considered specimens for compatibility testing and are labeled according to general laboratory requirements.
Cord Blood Specimen—Collected by nursing staff at time of delivery should have a cord blood label affixed to the tube with:

- Neonate’s last name
- Neonate’s gender
- Mother’s name and ABO/Rh type if available
- Collection date and time
- Individual who collected the specimen

Trauma Cases—Specimens collected/received from patients identified as trauma cases by the Emergency Department are labeled with the trauma number, date, time, and phlebotomist initials for general laboratory testing. Blood Bank specimens must also include blood bank armband number.

Cytology/Histology Specimens—Must be labeled at the time of collection. The minimum information required on the label is the patient’s name and a 2nd identifier. This must match the information on the requisition.

Specimens Submitted by Clinics, Hospitals, and Laboratories—

- Requisitions supplied by the laboratory may include crack and peel labels that may be used to label each specimen submitted for testing. The specimen must be related to that requisition. The label placed on the specimen matches the label on the requisition. The date and time of collection and initials of the person responsible for collection must be recorded on the requisition.
- All aliquots submitted for testing must be accurately and clearly labeled. In addition to unique patient identification information, labeling should include the source of the specimen (e.g., EDTA plasma, serum, urine).
- Specimens submitted for cytologic study must be labeled with the following:
  - Patient’s first and last name
  - Source of specimen
  - Patient ID number
  - Collection Date and Time
  - Initials of person collecting specimen
- Specimens submitted for histologic study must have complete patient billing and collecting facility information on requisition and a unique identifier on the specimen (name or SSN).

**Specimen Rejection**

All tests are unique in their testing requirements. To avoid specimen rejection or delayed turnaround times, please check the “Specimen Required” field within each test. You will be notified of rejected or problem specimens upon receipt.

Please review the following conditions prior to submitting a specimen to RWLS:

- Full 24 hours for timed urine collection
- pH of urine
- Lack of hemolysis/lipemia
- Specimen type (plasma, serum, whole blood, etc.)
- Specimen volume
- Patient information requested
- Proper identification of patient/specimen
- Specimen container (metal-free, separation gel, appropriate preservative, etc.)
- Transport medium
- Temperature (ambient, frozen, refrigerated)

**Specimen Volume**

The “Specimen Required” section of each test includes 2 volumes—preferred volume and minimum volume. Preferred volume has been established to optimize testing and allows the laboratory to quickly process specimen containers, present containers to instruments, perform test, and repeat test, if necessary. Many of our testing processes are fully automated; and as a result, this volume allows hands-free testing and our quickest turnaround time (TAT). Since patient values are frequently abnormal, repeat testing, dilutions, or other specimen manipulations often are required to obtain a reliable, reportable result. Our preferred specimen requirements allow expeditious testing and reporting. When venipuncture is difficult or patient is at risk of complications from blood loss (e.g., pediatric or intensive care patients), smaller volumes may be necessary. Specimen minimum volume is the amount required to perform an assay once, including instrument and container dead space.

When patient conditions do not mandate reduced collection volumes, we ask that our clients submit preferred volume to facilitate rapid, cost-effective, reliable test results. Submitting less than preferred volume may negatively impact quality of care by slowing TAT, increasing hands-on personnel time (and therefore cost) required to perform testing.

Both Mayo Medical Laboratories and RWLS make every possible effort to successfully test your patient’s specimen. If you have concerns about submitting a specimen for testing, please call RWLS Client Services at 888-522-7962 or 308-630-1398. Our staff will discuss the test and specimen you have available. While in some cases specimens are inadequate for the desired test, in other cases, testing can be performed using alternative techniques.
**Supplies**
Shipping boxes, specimen vials, special specimen collection containers, and request forms are supplied without charge. Supplies can be requested using 1 of the following methods:

- E-mail request to clientservices@rwmc.net
- Fax completed supply request form to 308-632-4745
- Call RWLS Client Services at 888-522-7962 or 308-630-1398.

For a copy of Request for Supplies form, see Special Instructions.

**Test Classifications**
Analytical tests offered by Mayo Medical Laboratories are classified according to the FDA status of the test kit or reagent and their usage. The classifications include:

- FDA exempt or cleared
- Analyte Specific Reagent
- Investigational Use Only
- Research Use Only

Where appropriate, analytical test listings contain a statement regarding these classifications, test development, and performance characteristics.

**Test Result Callbacks**
Results will be phoned to a client when requested from the client.

**Test Turnaround Time (TAT)**
This directory lists the days on which the test is set up as a guide to expected analytical turnaround times. Repeated tests take additional time. If defined analytical turnaround times will not be met by the testing laboratory, accessions could be released with a preliminary report stating that final result(s) are still pending.

**Unlisted Tests**
Regional West Laboratory Services does not list all available test offerings in the Directory of Services. For information about unlisted tests, please call Client Services at 888-522-7962 or 308-630-1398.

**Unsatisfactory Analytic Results**
If Regional West Laboratory Services is unable to obtain a satisfactory analytic result, there is no charge.