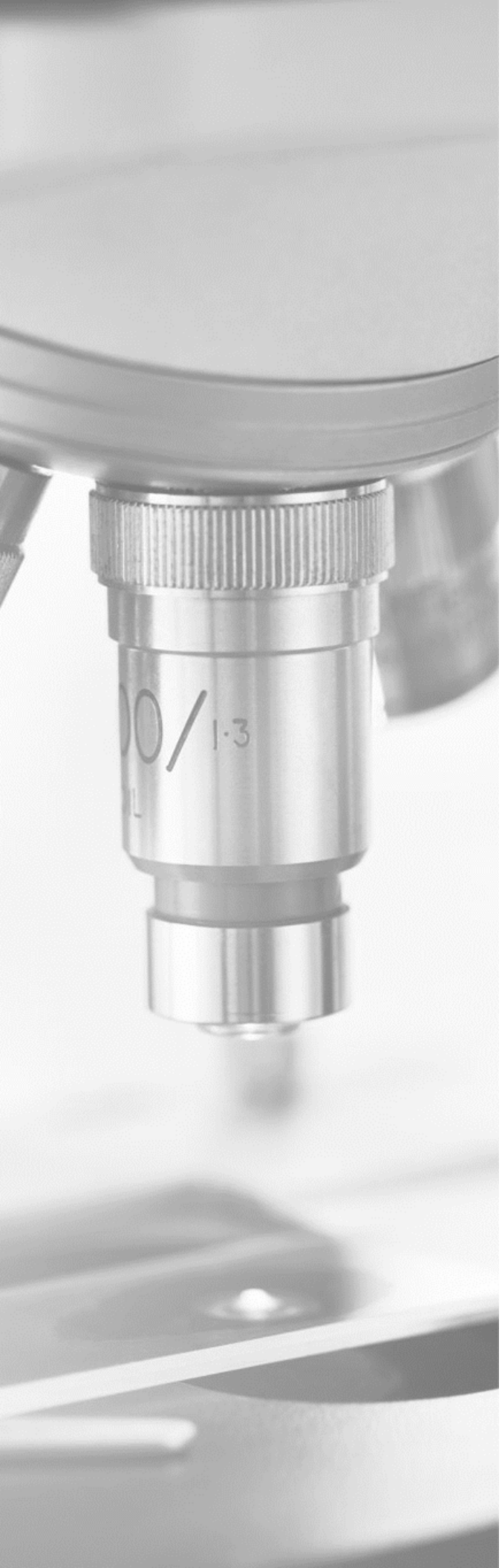

Clinical Laboratory Services Manual

MAWD LABORATORIES

11070 Strang Line Road | Lenexa Kansas 66215
Phone (913) 361-7127 | Toll Free (800) 933-6293
Fax (913) 361-8530 | mawdpathology.com

MAWD Laboratories

MAWD has served hospitals and physician practices in Kansas City and the surrounding region since 1969 and is one of the largest physician owned providers of pathology and laboratory services in the country. Our 58 pathologists care for over 250,000 patients a year and are available 24 hours per day, 7 days per week.

Client results are delivered in optimal turnaround time, with most routine pathology results available the day after specimen pickup. MAWD participates in all major insurance plans and offers a self-pay fee schedule for uninsured patients.

MAWD offers unmatched and diverse advanced subspecialty expertise and employs many of the region's recognized leaders in subspecialty pathology. Clients and patients benefit from the ability of our pathologists to consult directly within MAWD's extensive intra-organizational network of specialists.

We are committed to patient safety and excellence through:

- The pursuit of proven, state-of-the-art technology and accurate testing methods.
- Excellent professional staff, who at all times are aware of and concerned for the patient's welfare.
- Rapid and accurate reporting of patient diagnoses using secure, electronic methods.

Our quality diagnoses, commitment to patient care, and responsiveness to clinicians has established MAWD as a trusted provider of high-quality laboratory services.

Accreditation/Licensure

MAWD Laboratories is certified under the Clinical Laboratory Improvement Act of 1988 (CLIA-88) as qualified to perform high complexity testing. Additionally, MAWD Laboratories is accredited through the College of American Pathologists (CAP), the recognized global leader in established performance standards. For additional information or copies of certificates, please refer to MAWD's website at mawdpathology.com.

CAP ACCREDITED
COLLEGE of AMERICAN PATHOLOGISTS

MAWD LABORATORIES
11070 Strang Line Rd | Lenexa KS 66215
mawdpathology.com
Phone (913) 361-7127
Toll Free (800) 933-6293
Fax (913) 361-8530

Patient Privacy Policy

MAWD Laboratories takes patient privacy seriously and takes the necessary precautions to ensure we follow or exceed healthcare industry standards to secure that data. MAWD Laboratories is committed to compliance with the privacy standards outlined in the Health Insurance Portability and Accountability Act (HIPAA) and Health Information Technology for Economic and Clinical Health Act (HITECH).

MAWD Laboratories has implemented technical and organizational policies to ensure compliance with these standards. Additionally, we evaluate security audits regularly and conduct workforce training annually. The electronic patient information you provide is encrypted using secure socket layer (SSL) encryption technology and stored securely.

MAWD Laboratories reserves the right to change this notice and will promptly update this notice and post the information on the MAWD website at mawdpathology.com.

Referral Testing

MAWD Laboratories offer comprehensive clinical and anatomic pathology testing services. MAWD continues to strategically expand our in-house test menu to meet the needs of our clients. Additionally, MAWD partners with other laboratories who share a commitment to quality and service to provide testing not currently performed at MAWD.

Test Turnaround Time

Turnaround time is defined as the number of hours or days elapsed from the time a specimen is received at MAWD Laboratories to the time the result is released. Turn-around time expectations are defined in MAWD's Test Directory.

Laboratory Result Reporting

MAWD Laboratories can provide clients with laboratory results via several different mechanisms, including printed or faxed reports, electronic results via portal, and interfaced results.

Preliminary reports will be issued when clinically appropriate. Final reports are issued at the completion of testing.

MAWD Laboratories comply with local, state, and federal regulations regarding notifiable disease and condition reporting. Referring clients must follow applicable submission requirements, which includes providing all required patient demographic and client information to MAWD for such purposes.

Critical Reporting

MAWD Laboratories operate 24/7. Critical results are reported as soon as testing has been completed and identified. Critical results are called to the contact(s) provided by the referring client in accordance with all regulatory requirements.

Billing

When ordering laboratory tests that are billed to commercial payers, Medicare, Medicaid, or federally funded programs, *the following requirements and conditions may apply:*

- Tests should only be ordered when medically necessary.
- Payers may not approve tests considered medically unnecessary or experimental.
- If there is reason to believe Medicare will not pay for a test, the patient should be informed, and an Advance Beneficiary Notice (ABN) should be completed to indicate patient responsibility for the cost of the test if Medicare denies payment.
- The ordering provider must provide valid ICD-10 diagnosis code(s). Narrative descriptions and "rule-out" diagnoses are not sufficient.
- Organ or disease panels should only be billed when each component is medically necessary. Panel codes should be billed, when applicable.

CPT Codes

The Current Procedural Terminology (CPT) codes provided in MAWD's Test Directory are provided for informational purposes and reflect our interpretation of CPT coding requirements based on the American Medical Association's (AMA) and our understanding of payer guidelines. These are provided as a guide to assist with billing, though CPT coding is the sole responsibility of the billing party. MAWD encourages clients to confirm CPT codes with Medicare administrative contractors (MACs), as requirements may vary.

Supplies

MAWD Laboratories provides certain supplies necessary to collect and transport specimens to our laboratory for analysis, at no charge. Supplies provided by MAWD Laboratories are only to be used for specimens submitted to MAWD for analysis. The type and quantity of supplies ordered should correspond to the type and volume of testing referred. Due to regulatory requirements, MAWD Laboratories must monitor supply utilization.

Supplies may be ordered electronically using MAWD's portal or by contacting a client service representative.

Crisis Contingency and Business Continuity Plan

MAWD Laboratories maintains a corporate crisis contingency and business continuity plan to ensure an efficient and timely recovery of critical business functions in the event of a crisis impacting lab and/or business operations. In the event of a crisis that adversely impacts critical services, MAWD will notify clients of delays and coordinate alternative arrangements.

Patient and Specimen Preparation, Specimen Collection and Transport, and Packaging Guidelines

Patient Preparation

Many tests require patient preparation. This may include fasting, collecting specimens at specific timings or intervals, or ingesting a medication or substance for provocation prior to collection. Please see MAWD's Test Directory for additional information.

Specimen Submission

The quality and meaningfulness of laboratory results are directly related to the quality of the specimen submitted. All specimens submitted to MAWD Laboratories should be labeled, processed, and transported according to procedure to ensure optimal specimen quality. *Please review the appropriate container type, minimum volume, and special handling requirements needed, prior to submission*. While MAWD's exception handling team will contact the client for resolution, samples not meeting criteria may result in testing delays, specimen rejection, or test cancellation.

Potential causes for testing delays, specimen rejection, or test cancellation include but are not limited to the following:

- Specimen integrity issues (hemolyzed, lipemic, clotted, icteric)
- Improperly labeled specimen
- Inappropriate specimen type
- Inappropriate specimen container
- Insufficient volume
- Missing test order or requisition
- Missing required information
- Specimen leaked in transport
- Improper transport
- Sample received outside of stability
- Test order/requisition received without specimen

Irreplaceable Specimen Handling

MAWD Laboratories defines irreplaceable specimens as those that cannot be recollected or would require an additional invasive procedure to do so. *These include but are not limited to:*

- Cerebrospinal fluid
- Cavity body fluids (amniotic, ascites, pleural, synovial)
- Cord blood
- Kidney stones
- Lavages, washings, or brushings
- Meconium
- Products of conception
- Tissue or bone marrow biopsies

Due to the irreplaceable nature of these specimens, great care should be taken to ensure proper identification, processing, and transport. While every effort will be made by our Specimen Exception team to resolve labeling discrepancies and/or performing testing with a result disclaimer, this may result in testing delays and/or suboptimal results.

Minimum Specimen Volumes

MAWD's Test Directory defines the absolute minimum specimen volume required for each assay. While every attempt will be made to perform the requested testing on the provided sample volume and to locate additional specimen, if needed, insufficient volume may result in delays. Additionally, some testing scenarios may require more specimen volume than the minimum (repeat testing, aspiration errors, reflex testing, etc.).

Specimen Identification

All specimens must be labeled with **at least two unique patient identifiers** that match the accompanying requisition. Improperly labeled specimens will result in testing delays or rejection.

> ***The patient's full name and date of birth are the preferred identifiers*****,** though the following identifiers may also be used:
> - Unique patient identifier, such as medical record number.
> - Barcode labels embedded with at least two unique identifiers
>
> **NOTE:** Location-based identifiers are *not acceptable*, as these *are not unique.*
>
> ***Specimen identifiers must match exactly as they appear on the test requisition.***

If the specimen is hand-labeled, a ballpoint pen should be utilized. Felt-tip pens and gel pens are prone to smudging and may result in illegible identifiers.

Specimens should be labeled in such a way that does not prevent the visual inspection of the sample (e.g.: a sample window and fill lines should be visible when labeled). Additionally, barcodes should be oriented vertically to maintain scanability.

Test Requisition

Specimens must be accompanied by an electronic or paper requisition. ***At a minimum, the requisition must contain the following information:***

- Patient name
- Other unique identifier(s) (if name and date of birth were not utilized as specimen identifiers)
- Patient date of birth
- Patient gender
- Name of physician requesting the test
- Test(s) requested
- Date of specimen collection
- Time of collection, when appropriate
- Type of specimen and source, when appropriate
- Clinical information, as needed

If the requested testing is to be billed to a commercial or government payer, the requested demographic information, billing information, and ICD-10 diagnosis code *must* be submitted. See Billing and CPT Codes sections for more information.

Specimen Collection

Standard precautions should be observed during specimen collection and handling. Handle all samples, collection devices, sharps, and other hazards according to the policies and procedures of your facility. Safety engineered devices are encouraged and recapping of used needles should be prohibited to limit occupational risk. Biologic samples may transmit viral hepatitis, HIV, or other blood borne pathogens. Discard sharps and biohazard containers following facility policy. *Specimens received in syringes with needles attached will be rejected.*

Serum, Plasma, or Whole Blood Collection

Collect the preferred or defined alternative specimen tube. Consult the MAWD Test Directory to determine what tube/additive is required. Fill the tube completely, when possible, to prevent dilution.

For coagulation testing, it is imperative that a 9:1 ratio of blood to anticoagulant be maintained. Overfilled or underfilled citrate tubes will be rejected. In the event that a patient has a known elevated hematocrit above 55%, the citrate concentration must be adjusted. Please contact MAWD Laboratories Coagulation department for instruction.

Gently invert tubes to ensure mixing.

- *Citrate (light blue) tubes for coagulation testing:* Gently invert four (4) times. Avoid additional inversion, as this may cause activation of clotting factors.
- *Other tubes:* Gently invert eight (8) to ten (10) times.

Serum tubes should be allowed to clot in an upright position for at least 30 minutes prior to centrifugation. Separate plasma or serum by centrifugation for the appropriate interval and at the defined RPM. Gel barrier tubes are recommended. When tubes cannot be utilized, plasma or serum should be removed from cells and aliquoted into a transport container to preserve sample integrity. Gel barrier tubes should NOT be utilized for therapeutic drug monitoring or toxicological analysis.

Urine Collection

Many routine urine tests require a random or spot urine sample. First morning voided specimens are preferred for routine chemistry and immunoassay testing due to concentration and lower pH.

Urine samples should be collected in a way to avoid contamination. Urine for urinalysis or microbiology testing should have a collection method listed on the accompanying requisition.

Specimens for urinalysis testing *must* be submitted in a marble top preservative tube. This tube cannot be used for urine culture. If a urine culture or reflexive testing is required, an additional sample must be provided in the designated C&S (boric acid) preservative tube.

Some urine chemistry tests require a timed 12 or 24 hour collection. Preservative may be required. Consult the MAWD Test Directory for preservative requirements.

On the day of a timed urine collection, discard the first morning urine void. Begin the collection after this void and collect for the specified interval (12 or 24 hours). Measure and record the total urine volume collected on the accompanying test requisition. After mixing the container well, aliquot the requested volume into a labeled transport vial.

Specimen Collection | Microbiology

Critical to the isolation and identification of pathogenic organisms is the quality of the specimen received in the laboratory. The risk of contamination with normal flora makes it difficult for microbiology technologists to accurately determine the presence of a pathogenic organism possibly causing an infection. Methods of collection along with methods of transport and specimen stability are provided to assist with improving the efficiency, accuracy, and reliability of testing. All unlabeled specimens and syringes with needles attached will be rejected.

Blood for Culture

Collection

- Skin Antisepsis and Venipuncture: Follow instructions as provided on the procedure guide and gently mix to avoid clotting.
- Intravascular Catheter: Follow instructions as provided on the procedure guide and thoroughly mix the avoid clotting.
- Volume
  - Adult: 8-10 mL/bottle; 2 bottles per set
  - Pediatric: 2-5 mL/bottle; 1 or 2 bottles per set
- Timing
  - For acute sepsis, draw 2 sets from different anatomic sites prior to antimicrobial treatment.
  - For fever of unknown origin, subacute bacterial endocarditis, or other continuous bacteremia, draw a maximum of 3 sets.
  - When on antibiotics, draw cultures at the lowest concentration (trough level).

Transport

- Do not refrigerate blood culture bottles.
- Maximum of 24 hours held at room temperature.

Rejection/Comments

- Broken and cracked culture bottles will be rejected.

Body Fluid for Culture

Collection

- Percutaneous aspiration using syringe and needle prior to antimicrobial therapy.
- Clean needle puncture site with alcohol and disinfect with iodine solution or chlorhexidine.
- Optional: Immediately place a portion of fluid collected into blood culture bottles (at volume specified for age).
- Place remaining portion into container or capped syringe with the needle removed.

Transport

- Room temperature, store refrigerated if transport is delayed >8 hours.

Rejection/Comments

- Syringes with needles attached will be rejected.

Cerebrospinal Fluid (CSF) for Culture

Collection

- Collection should only be performed by a trained physician.
- Collect CSF prior to antimicrobial therapy and then every 2 to 3 days once antimicrobial therapy has begun.

Transport

- Do not refrigerate. Send as follows:
  - Tube 1 to Chemistry
  - Tube 2 or 3 to Microbiology
  - Tube 4 to Hematology

Rejection/Comments

- CSF is considered an irreplaceable specimen. See page 5 of this guide.

Urine for Culture

Collection

- Note collection method on the accompanying requisition.
- Clean Catch for females and uncircumcised males: Thoroughly cleanse the area with two successive BZK antiseptic wipes and collect urine directly into leakproof sterile container without stopping and restarting.
- Catheter: Using a needle and syringe, collect urine through the catheter port. Do not force fluids as this will dilute the urine and may prevent workup of pathogens.

Transport

- Sterile containers should be delivered within 2 hours of collection. If unable, refrigeration can occur for up to 24 hours.
- C&S (boric acid) preservative tubes can be stored at ambient or refrigerated temperatures for up to 96 hours.

Rejection/Comments

- Urine obtained with the same collection method within 48 hours of receipt of the first specimen will be rejected.
- Unpreserved urine specimens received >24 hours post collection will be rejected.

Throat for Culture

Collection

- Swab back and forth between the tonsillar pillars and behind the uvula.

Transport

- Ambient or refrigerated temperature up to 48 hours after collection.

Rejection/Comments

- Specimens exceeding stability limits will be rejected.

Lower Respiratory for Culture

Collection

- Sputum: Collect expectorated sputum into a sterile screw cap container.
- Induced Sputum (for AFB testing only): Brush the mouth with sterile water or saline 5-10 minutes prior to collection, then using an ultrasonic nebulizer, have the patient inhale 20-30 mL of 3% NaCl. Collect induced sputum into a sterile screw cap container.
- Endotracheal Aspirates: Collect into a sterile sputum trap and aseptically transfer into a sterile screw cap container.
- Lower Lung, Bronchial Wash, and Bronchioalveolar Lavage (BAL): Collected through bronchoscopy by a trained physician. Place specimens into a sterile container.
- Lower Lung, Bronchial brush: Collected by a trained physician. Place the protected brush sample in a sterile vial with 1 mL sterile saline.
- Lower Lung, Aspirate, or Tissue Biopsy: Obtained under surgery by a trained pulmonologist. Submit in a sterile container without formalin.

Transport

- Sputum can be refrigerated up to 24 hours.
- Bronchoscopy specimens should be sent immediately but can be refrigerated if transport is delayed >8 hours.

Rejection/Comments

- Expectorated sputum should be free of saliva or postnasal discharge.
- Induced sputum should only be used for AFB testing.
- Some lower respiratory specimens may be considered irreplaceable. See page 5 of this guide.

Genital for Culture

Collection

- Superficial female specimens and male lesions: Swab
- Male specimens for epididymitis or testicular abscess diagnosis: Urethral swab followed by aspiration of fluid.
- Amniotic fluid, Culdocentesis, Endometrium, Fallopian tubes, and pelvic cavity specimens: Aseptic or sterile technique by a trained physician.

Transport

- Transport fluid in sterile containers at ambient temperature; store refrigerated if transport is delayed >8 hours.
- Transport/Store swabs at ambient or refrigerated temperature for up to 48 hours after collection.

Rejection/Comments

- Specimens exceeding stability limits will be rejected.

Ear for Culture

Collection

- External specimen: Insert sterile swab into the ear canal until resistance is met, then rotate and allow fluid to collect on swab.
- Tympanocentesis fluid: Clean the external ear canal with mild detergent, then use a syringe to aspirate fluid from the ear drum.

Transport

- Ambient temperature or refrigerated for up to 24 hours.

Rejection/Comments

- Specimens exceeding stability limits will be rejected.
- Some ear specimens may be considered irreplaceable. See page 5 of this guide.

Eye for Culture

Collection

- Rinse conjunctival and corneal surfaces with sterile, non-bacteriostatic saline or water to remove any applied anesthetic before collection.
- Inner eye culture may be inoculated onto media at bedside or sent in sterile container.

Transport

- Transport/Store swabs at ambient or refrigerated temperature for up to 48 hours after collection.
- Other specimens may be transported at ambient temperature or refrigerated for up to 24 hours.

Rejection/Comments

- Specimens exceeding stability limits will be rejected.
- Some eye specimens may be considered irreplaceable. See page 5 of this guide.

Wound/Abscess, Tissue for Culture

Collection

- Wound: Prior to treatment with topical antimicrobial, cleanse the surface then roll the e-swab over the affected area.
- Aspirate: Aseptically remove using syringe and needle and submit in sterile container or capped syringe.
- Tissue: Aseptically removed by a trained physician and placed in a sterile cup or on gauze pad moistened with non-bacteriostatic saline in sterile container.

Transport

- For best results, deliver to the lab within 30 minutes of collection.
- Transport/Store swabs at refrigerated or ambient temperature up to 48 hours after collection.

Rejection/Comments

- Specimens exceeding stability limits will be rejected.
- Swabs cannot be processed for AFB Culture.
- Some specimens may be considered irreplaceable. See page 5 of this guide.

Stool for Culture

Collection

- Have patient obtain stool specimen by passing the stool into a clean, dry pan or special container mounted to the toilet for this purpose. Transfer at least 5 mL of diarrheal stool or 1 g material into one of the following:
  - Leakproof container with tight fitting lid
  - Modified Cary-Blair medium (do not fill above indicator line)
- Rectal swab (should be reserved for pediatric patients): Pass the tip of a sterile swab approximately 1 inch beyond the anal sphincter. Carefully rotate to sample the anal crypts.
- Duodenal, colostomy, or ileostomy contents: Leakproof cup or transport medium.

Transport

- Submit fresh stool within 2 hours of collection.
- Stool in Cary-Blair transport medium may be refrigerated and submitted within 24 hours of collection.
- Rectal swabs may be stored and transported at ambient temperature for up to 24 hours.

Rejection/Comments

- Multiple stool samples from the same patient on the same day will not be cultured.
- Stool for culture from hospitalized patients greater than three days will not be cultured unless specifically requested by provider.
- Stools with barium will not be processed.
- Specimens exceeding stability limits will be rejected.

Hair, Skin, and Nails for Fungal Culture

Collection

- Hair and Nails: Submit at least 10 broken hairs in a sterile container.
- Skin: Disinfect area with 70% alcohol prior to collection of scrapings to ensure the best possible recovery of fungi. Submit in a sterile container without preservative.
- Nails: Clippings are preferred over scrapings of the area. Submit in a sterile container.

Transport

- Transport and store at ambient temperature, submit within 24 hours of collection.

Rejection/Comments

- Specimens exceeding stability limits will be rejected.
- Some specimens may be considered irreplaceable. See page 5 of this guide.

Quality Control

Do not use collection supplies that exceed expiration dates, are improperly stored, or are visually defective.

Packaging

Specimens should be packaged in accordance with the following guidelines:

- Primary specimen container caps and lids are tightened properly to prevent leakage.
- No visible contamination is present outside of the specimen container.
- Primary specimen containers are placed in the primary chamber of a biohazard bag. If multiple specimens are submitted per bag, provided paperboard specimen transport racks are strongly encouraged.
    - MAWD Laboratories provides biohazard bags that are color-coded by transport temperature needs. This allows our courier team to quickly identify the transport conditions required.
- Biohazard bags should include an absorbent pad and be sealed prior to submission.
- Paper requisitions and/or transfer lists should be folded in half widthwise (top to bottom) and placed in the rear pocket of the biohazard bag.
- If packages are submitted via a carrier such as USPS, UPS, or FedEx, additional packaging and labeling is required to be compliant with federal and DOT/IATA/ICAO regulations.

Do NOT send any needles or sharps. This is in violation of transportation and disposal regulations and creates a safety hazard for our team members.

Holding and Securing Specimens

Specimens should be held in a secure location and at the appropriate temperature while awaiting pickup. A lock box will be provided, at client request. Cold packs or ice packs are encouraged to maintain temperature and will also be provided at client request.

Thank you for choosing MAWD Laboratories.

MAWD LABORATORIES

11070 Strang Line Road
Lenexa Kansas 66215
Phone (913) 361-7127
Toll Free (800) 933-6293
Fax (913) 361-8530
mawdpathology.com