



Client Resource Guide



**For Breast, Dermatology, Gastroenterology, Urology,
General Surgery, and Cytopathology**

Miraca Life Sciences
6655 N. MacArthur Blvd.
Irving, TX 75039

Copyright © 2016 Miraca Life Sciences, Inc.
All rights reserved, including the right of reproduction in whole or in part in any form.

Miraca Life Sciences™, EoGenius™, InformTx™, PathConnect™, and PINgenius™ are trademarks of Miraca Life Sciences, Inc.
All other trademarks are the property of their respective owners.

Printed in the United States of America.

Table of Contents

General Information.....	1
Contact Information	1
Client Services	1
Billing.....	1
Turnaround Time	1
Medical Records/Slide Release	2
Specimens Requiring Cultures.....	2
Accidental Receipt of Specimens.....	2
Radioactive Materials	2
Sharps	2
Consultations	2
Baylor Genetics.....	3
Specimen Collection, Labeling, and Submission	4
Items Supplied to Client/Clinician	4
Requisitions for all Miraca Specimens.....	4
Tissue Collection Instructions	5
Acceptable Transport Media.....	5
Labeling Specimen Containers	6
Specimen Packaging and Submission	6
Specimen Storage	6
Specimen Pick-Up	7
Breast.....	8
Tissue Types Accepted	8
Breast Specimens Not Accepted	8
Collection Instructions for Breast Specimens.....	8
Tissue Sample Information Requirements	8
Additional Tests (Prognostic and Predictive Markers)	9
Molecular/Genomic Testing.....	9
Dermatology	12
Tissue Types Accepted and Not Accepted.....	12
Fixative.....	12
Additional Diagnostic Offerings.....	12
Gastroenterology	14
Tissue Types Accepted and Not Accepted	14
Fixative.....	14
Additional Diagnostic Offerings.....	14

Urology.....	16
Tissue Types Accepted and Not Accepted	16
Collection Instructions for Kidney Stones	16
Collection Instructions for Prostate Biopsy Specimens	16
Collection Instructions for Urine Cytology and UroVysion FISH Requests	16
Voided Urine Fluid Specimen Collection and Handling	16
Catheterized Urine, Urine Collected after Irrigation or Instrumented Urine	17
Instructions for 3-Day Cytology Kit	17
Collection Instructions for Urinalysis Hematuria Profile with Urine Cytology.....	17
Additional Diagnostic Offerings.....	18
General Surgery.....	20
Tissue Types Accepted and Not Accepted.....	20
Cytopathology.....	22
Labeling and Preparing Slides	22
Tissue/Specimen Types Accepted and Not Accepted	22
Fine Needle Aspirations	22
Cytologic Brushings.....	23
Bile Aspirates for Cholesterol Crystals.....	23
Cytology Fluids.....	23
Appendix: Test Menu.....	26



General Information

Serving more than 5,500 patients each day, Miraca Life Sciences is a leading provider of expert pathology services in the fields of breast pathology, dermatopathology, gastrointestinal pathology, hematopathology, and urologic pathology.

In addition to pathology services, Miraca Life Sciences provides consulting services and technology solutions. Hundreds of practices have worked with Miraca to address everything from workflow efficiency to regulatory measures and compliance. Contact your Sales Director or our Client Services team for more information.

Contact Information

Client Services

Irving, Texas

Phone 866.588.3280
 Fax 866.688.3280

Union, N.J.

Phone 800.440.7284 Option 1
 Fax 908.349.3107

Newton, Mass.

Phone 866.969.4100
 Fax 617.969.3393

InformTx™ testing 844.305.2166

Billing

Local 972.331.3150
 Toll-free 888.344.1160
 Fax 866.724.0463



Turnaround Time

Miraca Life Sciences endeavors to provide the most rapid turnaround time possible without compromising quality. In general, anatomic pathology and cytopathology reports will be generated within one business day of receipt of the specimen. Any subsequent testing performed may delay release of the final report. Reports delivered electronically (to our online portal, a fax, secure printer or an interface) will transmit to client offices after sign out. If requested, hardcopy reports will be sent via overnight carrier and will arrive the day after sign out.

The chart below demonstrates the typical turnaround cycle for routine specimens. It assumes the specimen is packaged on the day of the procedure and successfully delivered to the lab the following business day via an overnight carrier, such as UPS.

Procedure Date	Accession Date	Sign-Out Date
Monday	Tuesday	Wednesday
Tuesday	Wednesday	Thursday
Wednesday	Thursday	Friday
Thursday	Friday	Monday
Friday*	Monday	Tuesday

* We can accept breast cases on Saturdays at our Irving (Texas) lab with prior notice. Please contact Client Services.

NOTE: Transportation or additional testing may impact turnaround time. Refer to specialty sections in this guide for turnaround times for certain tests.

Medical Records/Slide Release

For the release of medical records, please contact Client Services (see page one) and forward the patient's signed Release of Medical Records. Miraca Life Sciences only will release the patient's records to the person(s) named on the release form (physician/pathologist, legal counsel, insurance company).

For the release of slides or other pathology materials, Miraca requires a signed Record of Loan Form, which may be obtained from Client Services (see page one). Slides and other materials are released only to a patient's clinician or medical institution. Release of slides/materials requires the approval of a Miraca pathologist.

Allow 72 hours for laboratory processing before materials are shipped. Standard delivery is ground. For expedited delivery, requesters may provide a FedEx or UPS label or their carrier's account number. All materials must be returned intact within 14 days unless expressly allowed by Miraca Life Sciences in advance.

The slides/blocks are the property of Miraca Life Sciences and cannot be released to a third party without prior permission. The recipient must agree to take full responsibility and assume chain of custody of the specimen material until the materials are returned to Miraca Life Sciences.

Specimens Requiring Cultures

Miraca Life Sciences is an anatomic pathology laboratory. Specimens for cultures should be referred to a clinical reference laboratory specializing in microbiology. Miraca does not accept specimens requiring cultures, including stool samples, sputum and insulin/proinsulin testing.

Accidental Receipt of Specimens

Miraca occasionally receives time-sensitive specimens for testing that we do not perform, such as cultures and CLO testing. We will try to contact you for direction, but if we cannot reach you, we will send the specimen to an appropriate lab to preserve viability for your patient.

Radioactive Materials

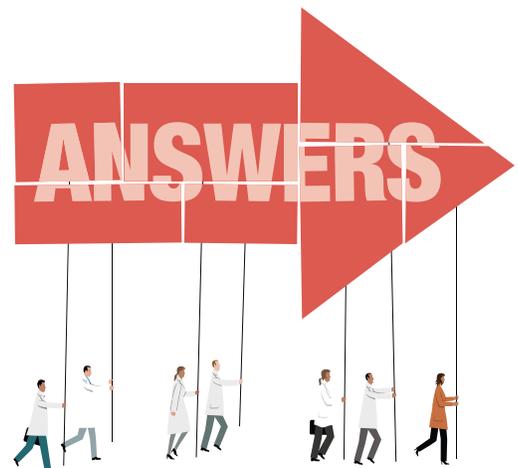
Miraca Life Sciences does not accept tissue containing radioactive materials.

Sharps

Specimens including blades and needles will not be accepted.

Consultations

The pathologists at Miraca Life Sciences are able to render an opinion on a case for which an expert opinion is desired. A copy of the outside pathology report, patient billing information, and pertinent clinical history should accompany the glass slides. Contact Miraca's Client Services department (see page one) to obtain a Surgical Pathology Consultation Form or for assistance.



Baylor Genetics

Genetic testing is provided by our sister company, Baylor Genetics—a joint venture between Baylor College of Medicine and Miraca Holdings. Initially launched as Baylor Miraca Genetics Laboratories, this venture was built on Baylor's existing Medical Genetics Laboratories, which engages in clinical laboratory genetic testing. Baylor has provided diagnostics

services for more than 35 years and is the no. 1 National Institutes of Health-funded genetics program. For more information, contact your Miraca Life Sciences sales representative.



When ordering any genetic tests by Baylor Genetics, please first contact our Client Services team (see page one).

Specimen Collection, Labeling, and Submission

Miraca Life Sciences is committed to providing clients and patients with the highest quality service through all phases of the laboratory experience. To help us provide the highest possible service, we ask clients to use certain supplies and follow general guidelines. This section describes client supplies, required patient requisition information, required specimen container labeling, and important packaging and shipping instructions.

Items Supplied to Client/Clinician

Miraca Life Sciences provides specimen collection and shipping supplies to clients. The following supplies are provided directly to clinicians:

Cytology Supplies

Slides, slide mailers, fixative, and containers

Surgical Biopsy Collection Vials

- 20, 40, and 60 ml biopsy containers. Larger containers (90, 120 and 240) are available
- upon request. For breast cases, 500 ml and 1 liter containers are available.
- Michel's medium
- Serum separator tubes
- Phlebotomy collection kits
- Prostate kits
- RPMI containers for lymphomas
- Urine cytology/FISH kits



Contact Client Services (see page three) to request supplies and to obtain a Client Supply Order Form.

Shipping Supplies

For your convenience, Miraca Life Sciences supplies carrier boxes, Lab Pack bags, Return Service Labels, UN3373 (Biological Substance) labels, formalin bottles, and zip-lock biohazard bags (with an absorbent liner for the 6"x9" and 8"x9" bags). **Please allow 4–5 business days from the time of request for supplies to arrive.**

Requisitions for all Miraca Specimens

Certain elements are required by regulatory agencies (such as CAP) when submitting specimens to a laboratory. All specimens must be accompanied by an adequately completed requisition. Please complete each requisition with the following information:

1. Miraca Life Sciences ID #
2. Patient's First and Last Name (no nicknames, no initials)
3. Date of birth
4. Patient gender
5. Address, including apartment # if applicable
6. Date of collection
7. Specimen source
8. Time of collection, when appropriate
9. Pertinent clinical history
10. Test requested

11. ICD code(s)
12. Name and address of ordering clinician
13. Authorized physician or legally authorized person requesting the test
14. The identity of the person collecting the specimen, if different from the physician or legally authorized person requesting the test

Incomplete information will delay processing of your patient's specimen. Client Services will call to resolve any discrepancies; however, a Discrepancy Resolution Form may be needed in order to complete specimen processing.

Tissue Collection Instructions

- Tissues should be placed in 10% buffered formalin without delay, unless a different or additional fixative is specified for a particular evaluation. The volume of formalin must completely cover the specimen and, should exceed the volume of the specimen at a ratio of 15:1.
- Do not wrap tissue in gauze or other type of toweling, as they absorb the fixative and parts of the tissue may not be covered by the fixative, causing the tissue to decompose.
- If re-biopsy of a lesion is performed, provide date and the specimen accession number of the previous biopsy.
- Tissues samples from different sites or lesions should be submitted in separate containers.
- **Tighten container lid to avoid loss of formalin.**

NOTE: Please review the relevant pathology specialty section of this Client Resource Guide for more specific collection and fixative instructions that may be applicable.

Acceptable Transport Media

The ideal transport medium is 10% neutral buffered formalin. Other media are acceptable depending on the specimen.

10% Neutral Buffered Formalin

This is the standard transport medium for all specimens requiring histopathological examination.

RPMI

RPMI is the standard transport medium for specimens requiring lymphoma work-up.

Red-top Michel's Media

Specimens requiring DIF (direct immunofluorescence) should be placed in a red-topped Michel's media bottle.

Serum Separator Tube

For InformTx therapeutic drug monitoring, use a tiger-top serum separator tube.

Cytofixatives

- Green-top cytology slide containers: Use these slide containers for cytology smears.
- Spray: Use for fresh specimen smear preparation.

Bouin's Fixative

Testis biopsy specimens performed for infertility evaluation should be collected preferably in Bouin's fixative for superior preservation of architectural details. If Bouin's fixative is not available, formalin fixation will be accepted.

100% Alcohol

Alcohol is recommended only when gout is suspected.

Saline/10% Formalin with Zinc

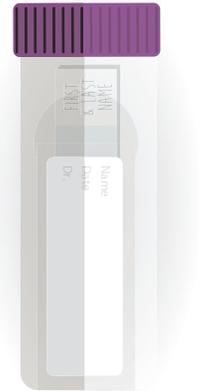
Neither are recommended. These are sub-optimal transport media. Please contact Miraca Client Services (see page one) to order supplies.

Labeling Specimen Containers

Use a chemical-resistant marker for all labeling. **DO NOT** label the container lid. Instead, label the body of the container with the following:

1. TWO unique identifiers, such as:
 - Patient First and Last Name (no nicknames, no initials)
 - Date of Birth
 - Medical Record Number
 - Unique specimen requisition number (labels provided on requisition)
2. Specific specimen site (this is NOT considered a unique identifier)

The absence of these elements on the specimen container(s) may delay specimen processing. A Discrepancy Resolution Form may need to be completed in order to complete specimen processing.



Additional Container Labeling

When affixing additional labeling to the specimen container, such as requisition labels, **please ensure the fixative type is not obscured.** This will allow our staff to handle the specimen appropriately and process the tissue accurately.

Specimen Packaging and Submission

Prior to packaging and sending to our lab, please ensure that the tissue processing requirements can be met if shipping on a Thursday, Friday or holiday. If you are unsure which location to send specimen, please contact Miraca Client Services.

- Place specimen in the larger pouch of the biohazard bag with absorbent pad and secure closure. **Take special care to secure the lid tightly.**
- Place folded requisition in the smaller pouch.
- Collect and secure all individual biohazard bags into a Miraca-branded Lab Pack bag. The Lab Pack bag ensures that your specimens will reach Miraca, even if the pack comes out of the outer box.
- Put the Lab Pack bag into the outer box.
- If shipping UPS, **you must use the yellow and white shipping labels.** This indicates to UPS that the box is being shipped to a Miraca lab. This label helps with tracking and research of misplaced packages.
- Affix a UN3373 label on the outside of the box if not already present. The courier requires this label in order to comply with DOT regulations.
- Prior to sealing the box, **include a Specimen Log that lists all enclosed specimens, and fax the Specimen Log to Miraca Life Sciences.** Faxing the Specimen Log notifies Miraca Life Sciences of expected incoming specimens. If expected specimens are not received, Miraca Life Sciences will notify the client. Contact Client Services (see page one) for a Specimen Log template.

Specimen Storage

All specimens in fixatives (other than RPMI) can be stored at room temperature. Specimens in Michel's medium can be stored at room temperature for up to five days (including transit time to lab).

During hot summer months, May 1 to September 30, store and ship all specimens, blocks and slides on ice, particularly paraffin blocks. Additionally, blocks should not be shipped on Fridays during these summer months, May through September. These requirements are critical for shipments to Miraca's labs in Arizona.

Specimens that are not in fixative must be refrigerated. This includes peripheral blood, serum, body fluids, urine, and specimens in RPMI for lymphoma studies.

On rare occasions, weather or other conditions prohibit routine courier transportation of specimens. The same storage requirements apply until routine courier systems resume.

Specimen Pick-Up

Specimens from physicians will be arranged to be picked up by UPS, FedEx or a local courier. Contact Client Services at (see page one) for more information.



Breast

Tissue Types Accepted

- Fine needle aspirations (FNAs)—see Cytopathology section
- Cyst aspirations
- Core needle biopsies (stereotactic, ultrasound or percutaneous)
- Core needle biopsies for microcalcifications
- Unoriented breast biopsies
- Oriented breast biopsies
- Wire localization biopsies for microcalcifications
- Wire localization excisions
- Lumpectomies
- Lymph node biopsies
- Lymph nodes
- Sentinel lymph nodes
- Male breast biopsies
- Reduction mastectomies
- Capsulectomies

Breast Specimens Not Accepted

- Any specimen that does not fit easily in the provided containers
- Mastectomies other than reductions
- Radical mastectomies

Collection Instructions for Breast Specimens

Breast specimens should be submitted in 10% neutral buffered formalin in a provided container large enough to **surround tissue with fixative at a ratio of at least 15:1**. Do not stuff tissue into container—the high amount of fixative volume ensures the fixation of the tissue.

Ideally, breast specimens should be sent only Mondays through Thursday to prevent over-fixation of breast carcinomas that may alter HER2/neu (c-erbB2) immunoreactivity.

To send cases obtained on Fridays, please contact Miraca Client Services to notify the lab, and please be sure to use the Saturday label. With notice, a lab team is available on Saturdays for accessioning and processing of breast specimens.

Tissue Sample Information Requirements

All shaded areas on the requisition form are required information.

- a. ICD codes
- b. Clinical history
- c. Date of collection MM/DD/YY
- d. Collection time
- e. Time placed in fixative

- f. Type of sample: tissue in fixative, peripheral blood, paraffin block or unstained slides
- g. Desired tests
- h. Indicate left or right side
- i. Site: breast, axilla, chest wall, lymph node, sentinel lymph node
- j. Nature of lesion: nodule, cyst, density, calcification, stellate mass, other
- k. Type of biopsy: FNA, core, wire-guided needle localization, lumpectomy
- l. Distance from nipple
- m. Orientation information with all sutures documented: double long, double short, single

Additional Tests (Prognostic and Predictive Markers)

- ER/PR/HER2/ Ki67/p53 (IHC)
- HER2 FISH
- HER2 CISH

Molecular/Genomic Testing

Genetic testing is provided by **Baylor Genetics**—a joint venture between Baylor College of Medicine and Miraca Holdings.

Cancer Gene Mutation Panel (50 genes) ABL1, AKT1, ALK, APC, ATM, BRAF, CDH1, CDKN2A, CSF1R, CTNNB1, EGFR, ERBB2, ERBB4, EZF2, FBXW7, FGFR1, FGFR2, FGFR3, FLT3, GNA11, GNAQ, GNAS, HNF1A, HRAS, IDH1, IDH2, JAK2, JAK3, KDR, KIT, KRAS, MET, MLH1, MPL, NOTCH1, NPM1, NRAS, PDGFRA, PIK3CA, PTEN, PTPN11, RB1, RET, SMAD4, SMARCB1, SMO, SRC, STK11, TP53, and VHL

Sample & Shipping Information

- Requirements:
Tumor Block: Paraffin-embedded, formalin-fixed tissue block containing adequate amounts of tumor to be analyzed with areas of tumor marked. Please include a copy of corresponding surgical pathology report. Can be performed on block from biopsy previously sent to and stored at Miraca Life Sciences.
or
Slides: 10 unstained 5um FFPE slides containing adequate amounts of tumor to be analyzed with areas of tumor marked. Please include a copy of corresponding surgical pathology report.
Unacceptable Conditions: No tumor in tissue. Frozen specimens and specimens fixed/processed in alternative fixatives.
Stability: Ambient—Indefinitely. Refrigerated—Acceptable.
- Documents:
Breast Pathology Requisition
Clinical notes
Patient insurance card and/or face sheet
Advanced Beneficiary Notice (ABN) (for Medicare patients only)
- Shipping Conditions: Send at ambient temperatures (18–25° C/64–77° F). Protect paraffin tissue from excessive heat. Ship in cooled container during summer months.
- Turnaround Time: 14 days.

BRCA1 and BRCA2 Screening (two genes: BRCA1, BRCA2)

Sample & Shipping Information

- Requirements:
3–5 mL **peripheral blood** in an EDTA (purple-top) tube.
or
Saliva collected with Oragene DNA Self-Collection kit
- Documents:
Breast Pathology Requisition
Clinical notes
Patient insurance card and/or face sheet
Aetna Prior Authorization Request Form (for Aetna patients only)
Advanced Beneficiary Notice (ABN) (for Medicare patients only)
- Insurance Requirements for Genetic Counseling: If patient's insurance provider is Cigna, United Healthcare or Aetna, genetic counseling is required prior to approving coverage for BRCA mutation testing and hereditary panels that include the BRCA gene. Miraca is proud to offer genetic counseling at no charge to patients through Baylor College of Medicine.
- Shipping Conditions: Ship at room temperature in an insulated container by overnight courier. Do not heat or freeze. Sample must arrive within 48 hours.
- Turnaround Time: 14 days.

High-Risk Hereditary Breast Cancer Panel (seven genes: BRCA1, BRCA2, CDH1, PALB2, PTEN, STK11, TP53)

Sample & Shipping Information

- Requirements:
3–5 mL **peripheral blood** in an EDTA (purple-top) tube.
or
Saliva collected with Oragene DNA Self-Collection kit
- Documents:
Breast Pathology Requisition
Clinical notes
Patient insurance card and/or face sheet
Aetna Prior Authorization Request Form (for Aetna patients only)
Advanced Beneficiary Notice (ABN) (for Medicare patients only)
- Insurance Requirements for Genetic Counseling: If patient's insurance provider is Cigna, United Healthcare or Aetna, genetic counseling is required prior to approving coverage for BRCA mutation testing and hereditary panels that include the BRCA gene. Miraca is proud to offer genetic counseling at no charge to patients through Baylor College of Medicine.
- Shipping Conditions: Ship at room temperature in an insulated container by overnight courier. Do not heat or freeze. Sample must arrive within 48 hours.
- Turnaround Time: 14 days.

Dermatology

Tissue Types Accepted and Not Accepted

Specimen types accepted:

- Skin
- Oral, vulvar, and penile mucosa
- Conjunctiva
- Nail clippings
- Hair shafts
- Insects for identification/classification
- Sentinel lymph nodes

Not accepted:

- All other tissue types

Fixative

All specimens must be placed in 10% buffered formalin. Exceptions are as follows:

- When the diagnosis of gout is suspected, the specimen must be placed in 100% alcohol or sent fresh. Specimens sent with a needle attached to the syringe will be sent back to the client.
- Nail clippings, skin scrapings, hair shafts, and insects should be placed in a dry container.
- Specimen for direct immunofluorescence (DIF) should be placed in a **red-topped Michel's media container**. The specimen cannot be processed for DIF if submitted in formalin.

Additional Diagnostic Offerings

- Melanoma FISH
- Direct immunofluorescence
- Entomologic species identification

Gastroenterology

Tissue Types Accepted and Not Accepted

Specimen types accepted:

- Endoscopic biopsies and polypectomies of the gastrointestinal tract
- Endoscopic mucosal resections
- Core and wedge biopsies of the liver, including non-transplant, transplant, and neoplastic disease
- Bile for cholesterol crystal examination
- Cytologic specimens of the GI tract, including brushings, washings, fine needle aspirates
- Previously prepared slides for second opinion (consultation)

Specimen types not accepted:

- Any specimen that does not appropriately fit into the provided 240 ml specimen jar

Fixative

- Biopsies and excisions for routine histologic examination: 10% neutral buffered formalin
- Colonic, esophageal, gastric washings, and brushings: 95% ethanol
- Flow cytometry specimens: submit fresh in RPMI
- Bile for cholesterol crystals: submit fresh

Additional Diagnostic Offerings

Testing is also available to screen for Lynch syndrome (HNPCC), as well as the tests described below and at right.

InformTx™ is a comprehensive **therapeutic drug monitoring** test that provides easy-to-interpret and actionable results. Testing is available for drug and anti-drug antibody levels for infliximab (Remicade®), adalimumab (Humira®), certolizumab pegol (Cimzia®), and vedolizumab (Entyvio®). Use the InformTx kit from Miraca Life Sciences.

Sample & Shipping Information for InformTx

- Requirements:
 - 5–7 mL **peripheral blood** in tiger-top serum separator tube.
 - Place SST upright; let stand undisturbed minimum 30 minutes.
 - Centrifuge at FULL SPEED (2200–2500 RPM) for minimum 15 minutes. Observe separation of the serum from the clot.
- Shipping instructions:
 - Package the labeled serum vial in biohazard bag. Place with completed requisition and **freezer brick (or Ice Brix or foam brick)** in Miraca InformTx Collection Kit. (See complete shipping instructions inside kit.)
 - Ship immediately or refrigerate overnight.
 - More than one patient sample may be shipped per kit—keep in separate biohazard bags and include separate requisition.
- Turnaround time: 3–5 days

EoGenius[™] RNA expression test helps to diagnose and monitor eosinophilic esophagitis. Exclusively available from Miraca Life Sciences, this test has been validated in both adult and pediatric populations. Use the EoGenius kit from Miraca Life Sciences.

Sample & Shipping Information for EoGenius

- Requirements:
 - **RNAlater-preserved tissue**
or
FFPE (formalin-fixed, paraffin-embedded) tissue; recommended within 12 months of biopsy date
or
Minimum of eight (8) 10 μ M **FFPE sections/curls**—must be sent within 24 hours of cut from block; recommended within 12 months of biopsy date
 - May be a single biopsy tissue from proximal, middle (preferred), or distal esophagus
- Shipping instructions:
 - Package fresh biopsy material in RNAlater vial.
 - Place blocks in the kit's plastic baggie.
 - Place tissue curls in the empty vial.
- Turnaround time: 7–10 days

Urology

Tissue Types Accepted and Not Accepted

Tissue/specimen types accepted:

- All types of biopsy and resection specimens
- Urine for cytologic evaluation
- Kidney biopsy performed for tumor (mass) evaluation

Tissue types not accepted:

- Kidney biopsy performed for renal disease is not accepted.

Collection Instructions for Kidney Stones

- Refer to the **Specimen Collection, Labeling, and Submission** section for labeling details.
- Kidney/renal stones—submit fresh.
- Refer to the **Specimen Packaging and Submission** section for further instructions.

Collection Instructions for Prostate Biopsy Specimens

- Refer to the **Specimen Collection, Labeling, and Submission** section for labeling details.
- Miraca Life Sciences will provide either 8-part, 12-part or 16-part kits. It is best practice to provide each biopsy core(s) from its individual site in its specific jar or biopsy site-labeled cassette to facilitate in providing optimal diagnostic and prognostic information.
- Perform biopsy procedure. Place biopsy specimen directly into labeled specimen vial. Secure cap tightly, and place vial into appropriate section of the specimen tray. Multiple core specimens from the same area should be placed in the same collection vial. Disregard any unused formalin collection vials.
- Refer to the **Specimen Packaging and Submission** section for further instructions.

Collection Instructions for Urine Cytology and UroVysion FISH Requests

- Collect urine specimens for cytology evaluation and UroVysion FISH examination in provided kit maintaining 2:1 ratio (2 parts urine and 1 part fixative). The Miraca-provided kit is preferred.
- If the UroVysion FISH test is requested, then if the urine volume is less than 33 ml, the assay will be attempted, however the cell yield may be insufficient for analysis, and a new specimen may be requested.
- In general, catheterized and neobladder specimens are not optimal for UroVysion test, because they may have an insufficient quantity of urothelial cells.
- The best practice and preferred range for urine samples requiring a UroVysion test is 72 hours. However, the specimen is still viable for this test for two weeks after receipt at Miraca if the recommended collection method was followed.
- Urine collected from individuals with bladder or urinary infection may exhibit extensive quantities of bacteria and/or neutrophils that may interfere with the assay.

Voided Urine Fluid Specimen Collection and Handling

- Refer to the **Specimen Collection, Labeling, and Submission** section for labeling details.
- Use the provided specimen kit.
- Clean catch urine collection is required.

- Use the white cap bottle from the Urine Collection Kit to collect urine specimen.
- Collect 40 cc of urine into white cap specimen jar. Discard any extra urine.
- Add the full container (20 cc) of preservative solution preservcyt to the urine in the specimen jar for a total of approximately 60 cc.
- If volume of urine is less than 40 cc, try to keep 2:1 ratio of urine and preservcyt fixative provided.
- Tighten the white cap on the specimen jar until you hear a click. Then tighten another quarter turn to complete the seal.
- Refer to the **Specimen Packaging and Submission** section for further instructions.

Catheterized Urine, Urine Collected after Irrigation or Instrumented Urine

- Refer to the **Specimen Collection, Labeling, and Submission** section for labeling details.
- Collect freshly obtained urine specimen in white cap jar and add provided preservcyt fixative keeping 2:1 ratio.
- Tighten the white cap on the specimen jar until you hear a click. Then tighten another ¼ turn to complete the seal.
- Refer to the **Specimen Packaging and Submission** section for further instructions.

Instructions for 3-Day Cytology Kit

- Use Miraca-provided kit; remove labels 1, 2, and 3 before giving kit to patient. Apply labels 1, 2, and 3 to three different Miraca Urologic Pathology Requisition forms, then hold until patient returns kit.
- Remind patient to use second urination of the morning each day and to use the jars in order.
- Remind patient to close each jar tightly after use, to record the date the specimen is collected on each jar, and to place each jar into one of the provided biohazard bags.
- Remind patient to keep specimens in refrigerator after each collection.
- When patient returns jar to office, place each requisition—with labels 1, 2, and 3—into the respective outside pockets of the biohazard bags containing the jars labeled 1, 2, and 3.

Collection Instructions for Urinalysis Hematuria Profile with Urine Cytology

- Use for the following test panels:
 - Cytology with hematuria analysis (urine cytology and hematuria analysis)
 - Cytology PLUS with hematuria analysis (urine cytology, Feulgen stain cytology, hematuria analysis)
 - Hematuria PLUS Profile (urine cytology, Feulgen stain cytology, UroVysion, hematuria analysis)
- Refer to **Specimen Collection, Labeling and Submission** section for labeling details.
- Use the provided hematuria specimen kit
- Collect specimen of first-voided urine, mid-stream, into plastic beaker with spout
- Volume requirements:
 - Optimum volume: 10.0 mL
 - Minimum volume: 1.0 mL
- Pour the specimen into the blue-capped jar.
 - Do not touch or remove the boric acid preservative tablet from the blue-capped jar.
 - Process urine sample with Vacutainer collection tube.
 - Submerge tip of transfer straw into specimen container.
 - Push UA tube into transfer straw.

- Hold in position until flow stops, then remove transfer straw.
- Invert the tube 8–10 times to mix; do not shake.
- Label tube with patient's full name, date of birth, date and time of collection.
- Discard transfer straw in sharps collector.
- Place the Vacutainer tube and absorbent pads inside the biohazard bag, place cold pack on top and seal.
- Store specimen in refrigerator pending shipment.
 - Specimen must be processed with 48 hours.
- Transport the specimen according to laboratory procedure.

Additional Diagnostic Offerings

Additional diagnostic offerings are available as standing orders. Contact Client Services (see page one) to request either an Additional Test Requisition form for individual cases, or an Advanced Protocol form to set up reflex testing.

- Urine **UroVysion™** FISH assay is available as a standalone test or reflex test with urine cytology examination. This test enhances the detection of urothelial carcinoma.
- **PINgenius™** is available as a reflex test on prostate biopsies with HGPIN. Developed by Miraca Life Sciences, this test predicts the risk of prostate cancer at re-biopsy.
- **PTEN & ERG IHC** is available as a reflex test on prostate biopsies with any Gleason scores, or specific Gleason scores of 3+3 or 3+4. This test improves prostate cancer risk stratification.
- **PTEN IHC only** is available as a reflex test on prostate biopsies with specific Gleason scores of 3+3 or 3+4. This test improves prostate cancer risk stratification.
- **PTEN by FISH** assay is available as a reflex test on prostate biopsies with HGPIN, cancer, Gleason score 3+3 or 3+4. This test helps in stratifying disease progression risk.
- **Confirm MDx™** epigenetic assay is available as a reflex test on negative prostate biopsies and prostate biopsies with HGPIN. This test addresses false-negative biopsy concerns.
- **KnowError®** is available for prostate biopsies—either for TWO specimen/cores (the highest Gleason score from each side of the prostate) or ONE specimen/core (with the highest Gleason score). This test verifies patient identification and prevents misidentification error.
- **Oncotype DX** is available as a reflex test on prostate biopsies.
- **Prolaris** is available as a reflex test on prostate biopsies.
- **Decipher** is available as a reflex test on prostate biopsies.

General Surgery

Tissue Types Accepted and Not Accepted

GYNECOLOGY

Cervical biopsy
Endometrial biopsy
Endocervical curettage/curettage
LEEP biopsy
CONE biopsy
Fallopian tubes

OPHTHALMOLOGY

Skin/lid
Lacrimal/meibomian gland
Lens/cornea/sclera
Evisceration (removal of ocular contents)
Enucleation (removal of eyeball)
Exenteration (removal of entire orbital contents)

ORTHOPEDICS

Bone fragments
Cartilage
Ligaments/tendons
Bone tumors with X-ray and/or radiology report
Soft-tissue tumors

- Lipomas, leiomyomas, angiomas, neuromas/
schwannomas

OTORHINOLARYNGOLOGY

Tonsils and adenoids
Oral and laryngeal tumors
Sinonasal polyps and mucosa

FINE NEEDLE ASPIRATIONS—See [Cytopathology section](#)

Adrenal
Bone
Kidney
Liver
Lung
Lymph node
Mediastinum
Pancreas
Parotid
Soft tissue
Thyroid

CYTOLOGIC BRUSHINGS—See [Cytopathology section](#)

Esophageal
Bronchial
Colon

FLUIDS—See [Cytopathology section](#)

Bladder washings
Bronchial washing and lavage fluid
Joint fluid
Pleural and ascitic fluid
Pelvic and abdominal fluid

NOT Accepted

Any specimen that does not fit easily in the 240 mL or 500 mL container (provided)
Cervical pap smears
Products of conception (with identifiable fetus)
Kidney biopsy for non-neoplastic disease
Muscle biopsy
Nerve biopsy
Tissue for culture

Cytopathology

It is known that formalin fumes may be extremely detrimental to cytology specimens. This exposure often occurs during transportation, when smears are shipped in the same container with biopsies. Miraca Life Sciences recommends that clients **ship cytology and surgical specimens in separate specimen bags** to minimize this potential problem.

Labeling and Preparing Slides

1. Slides are only required to have Patient Name written on the slide. Use chemical resistant marker or pencil for all labeling. Label on the frosted end of the slide.
2. Place specimen on the same side as the label side.
3. If multiple specimen sources are sent on the same patient, identify specimen source on each slide. (For example, for right thyroid, mark "R" on slide, and for left thyroid, mark "L" on slide).
4. Place slides into a slide holder.

Improperly labeled slides will result in delay of specimen processing. Discrepancy Resolution Form will need to be completed in order to complete specimen processing.

Tissue/Specimen Types Accepted and Not Accepted

- See specific procedure sections below (FNA, Cytologic Brushings, Bile Aspirates, Cytology Fluids) for further information.
- Cervical and endocervical smears (Pap smears) are not accepted for processing.

Fine Needle Aspirations

Specimen Types Accepted for FNA

Thyroid	Lung	Kidney	Adrenal
Pancreas	Lymph node	Mediastinum	Soft tissue
Breast	Liver	Prostate	Bone
Parotid			

Collection Instructions

- Refer to **Labeling and Preparing Slides** above for slide and labeling instructions.
- After aspiration, touch the end of the needle to the end of the glass slide and express one to two drops of material. (If too much material is expressed, the slides will be too thick for optimal interpretation. A thin monolayer of cells is desired.)
- Place a second slide on top of the first, allowing the drop to spread, and then gently pull slide apart toward opposite end.
- Immediately, fix one slide with spray or alcohol fixative and mark with "F."
- Allow the second slide to air-dry and mark it with "A."
- More slides may be prepared if material is available.
- Rinse the remaining material and the needle in a labeled tube/container containing alcohol fixative (not formalin).
- Rinsing FNA in fixative:
 - Rinse the specimen needle directly into a tube/container containing alcohol fixative.
 - If a needle core biopsy is also obtained; touch the core gently to at least two slides (one would be air-dried and the other spray or alcohol fixed), then place the needle core in a separate formalin-filled container.
 - In addition to smears, if large amounts of blood clots are in the syringe, the material can be rinsed in a formalin-filled container for cell block processing, labeled with the FNA site and "Cell Block."
- Refer to the **Specimen Packaging and Submission** section for further instructions.

Cytologic Brushings

Specimen Types Accepted

Esophageal
Bronchial
Colon
Rectum
Anal
Tzanck/skin

Collection Instructions

- Refer to **Labeling and Preparing Slides** in this section for slide labeling details.
- Refer to the **Specimen Collection, Labeling, and Submission** section for specimen labeling details.
- Prepare smears and put them immediately in a labeled tube/container containing alcohol fixative or spray fix.
- Put the brush (cut off the handle if necessary) immediately in a labeled tube/container containing alcohol fixative (not formalin). Placing the brush in a dry container will limit the number of viable cells due to the cells degenerating without fixative.
- Refer to the **Specimen Packaging and Submission** section for further instructions.

Bile Aspirates for Cholesterol Crystals

Collection Instructions

- Refer to the **Specimen Collection, Labeling, and Submission** section for specimen labeling details.
- Add aspirate to collection container. Note: The entire collected specimen should be submitted for cytological processing. It is the opinion of Miraca Life Sciences' pathologists that the yield and diagnostic sensitivity is increased when the entire specimen is received for cytological preparation and interpretation.
- DO NOT add fixative. The water content in the fixative will destroy any crystals that may be present.
- Refer to the **Specimen Packaging and Submission** section for further instructions.

Cytology Fluids

Fluids Accepted

Bladder washings
Bronchial washing and lavage fluid
Joint fluid
Pleural and ascitic fluid
Pelvic and abdominal fluid

Collection Instructions

- Refer to the **Specimen Collection, Labeling, and Submission** section for specimen labeling details.
- Fix fluid by mixing with equal amounts of 50% ethanol or 70% isopropyl alcohol (available in the hospital surgical area). Submit joint fluid in 10 mL purple-top tube containing anti-coagulant EDTA (provided by Miraca Life Sciences). Mix well by inverting tube several times.
- Refer to the **Specimen Packaging and Submission** section for further instructions.

Notes



Revisions

Revision Number	Effective Date	Reason for Change
0	05/09/2012	This document replaces the previously uncontrolled Client Resource Guide. Complete rewrite to conform to regulations and clarification.
1	08/20/2014	Changed document # from MLS-19-0100 to MLS-20-0100 to align with current numbering scheme. Added clarification to document.
2	07/31/2016	Added sections on Baylor Genetics and Breast pathology; revised all other sections. Created MLS 20-0100F1.0 for Test Menu.

Appendix: Test Menu

Miraca Life Sciences offers anatomic pathology, therapeutic drug monitoring, genomic testing, and non-gynecological cytopathology services.

Special Stains

AFB (Kinyoun's)
 Alcian Blue
 Alcian Blue PAS
 Alizarin Red S
 Auromine-Rhodamine
 CAE (Leder)
 Colloidal Iron
 Congo Red
 Copper
 Crystal Violet (Lieb's)
 Elastic
 Fite
 Fontana
 Giemsa
 GMS
 Gram
 Iron
 Melanin Bleach
 Mucin
 PAS
 PAS with Diastase
 PTAH
 Reticulin
 Steiner
 Thioflavin T
 Trichrome
 Von Kossa
 Warthin Starry

Antibodies

α-1 Antitrypsin
 Actin, Muscle Specific
 Actin, Smooth Muscle
 AE1/AE3 (Pan Cytokeratin)
 ALK-1
 AlphaFetoprotein (AFP)
 Annexin A1
 BCL2
 BCL6
 BerEP4
 Beta-catenin
 BRAF
 CA125
 Calcitonin
 Antibodies, continued
 Calponin
 Calretinin
 CD1a

Antibodies, continued

CD2
 CD3
 CD4
 CD5
 CD7
 CD8
 CD10
 CD15
 CD19
 CD20
 CD21
 CD23
 CD25
 CD30 (BER-H2)
 CD31
 CD34
 CD43
 CD44
 CD45 (LCA)
 CD56
 CD57
 CD61
 CD63 (NK1/C3)
 CD68 (KP-1)
 CD71
 CD79a
 CD99
 CD123
 CD138
 CD163
 CDX2
 CEA
 Chromogranin A
 CK 5/6
 CK 5/14
 CK8/18 (CAM 5.2)
 CK19
 CK20
 CK(HMW)
 C-kit/CD117
 CMV
 CK7
 Collagen
 Cyclin D1 (BCL-1)
 D2 40
 Desmin
 DOG-1
 E-Cadherin

Antibodies, continued

EGFR
 EMA
 ER
 ERG
 Factor VIII
 Factor XIII A
 FOX-P1
 Gastrin
 GATA-3
 GCDFP-15
 GCET1
 GFAP
 Glycophorin
 Granzyme B
 HCG
 Helicobacter pylori
 Hepatitis B Surface Antigen
 Hepatocyte
 HER2/Neu
 HHV8
 HMB45
 HSV I
 HSV II
 IgA
 IgD
 IgG
 IgG4
 IgM
 Inhibin, Alpha
 Kappa
 KBA62
 Ki-67
 Lambda
 Lysozyme
 Mammaglobin
 MART1/Melanin A
 MiTF
 MLH 1
 MSH 2
 MSH 6
 MUC-5AC
 MUC-6 Glycoprotein
 MUM-1
 Myeloperoxidase
 NKX3.1
 OCT-2
 OCT-3/4
 OCT-4

Antibodies, continued

p16
 p120
 p504s
 p53
 p63
 Pan Keratin (mnf116)
 PanKeratin (OSCAR)
 Parvovirus
 PAX-5
 PAX-8
 Perforin
 PHH3
 PLAP
 PMS 2
 PR
 PSA
 PSAP
 PSMA
 PTEN
 RCC
 S100
 Smooth Muscle Myosin
 Synaptophysin
 T Pallidium (Spirochete)
 TCR BF1
 TDT
 Thyroglobulin
 TIA-1
 Tryptase
 TSH
 TTF-1
 Tyrosinase
 Uroplakin
 Varicella Zoster
 Villin
 Vimentin
 WT-1

Antibody Cocktails

Basal Cell Cocktail
 CD3/CDX2
 CD31 & AE1/AE3
 CD56/Synaptophysin
 CD8/CDX2
 CYCLIN D1/CD138
 CYCLIN D1/CD20
 D2-40/AE1-AE3
 Harmony Cocktail (Mart1/Tyrosinase)
 HMW/p63
 HMW/S100
 Ki67/Mart-1
 Ki67/CD20
 Melanoma Cocktail/Tyrosinase
 PAX5/CD5
 PIN-4
 PIN-4 /ERG

ISH Antibodies

EBER
 HPV 6/11
 HPV 16/18
 KAPPA
 LAMBDA

Direct Immunofluorescent Stains

Albumin
 IgA
 IgG
 IgM
 C3
 Fibrin

Additional Tests

For Breast pathology:

ER/PR/HER2/ Ki67/p53 (IHC)
 HER2 FISH
 HER2 CISH
 BRCA1 and BRCA2 Screening
 Cancer Gene Mutation Panel
 High-Risk Hereditary Breast Cancer
 Panel

For GI pathology:

InformTx™ Therapeutic Drug
 Monitoring for IBD patients
 EoGenius™ RNA expression test for
 eosinophilic esophagitis

For Uropathology:

Urine UroVysion™ FISH assay
 PINgenius™ for HGPIIN
 PTEN & ERG IHC
 PTEN IHC only
 PTEN by FISH assay
 Confirm MDx™ epigenetic assay
 KnowError®
 Oncotype DX® (Miraca sends out)
 Prolaris® (Miraca sends out)
 Decipher® (Miraca sends out)

Contact Miraca Client Services for questions about new or discontinued tests.