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1. INTRODUCTION

- Scientific advances and achievements have made great demands upon the Laboratory to provide newer and more complex determinations. The Laboratory stands ready to meet the challenge of today's needs while looking ahead to meet the future demands of the medical profession and the patients they serve.
- Most sections of the Laboratory are undergoing continuous revision in both methodology and instrumentation. Practically every area of the Clinical Laboratory has been "automated". Our administrative management has been extremely responsive to the needs of the Laboratory Service in providing the necessary machines and manpower to help us face the challenge. We, in turn, welcome this challenge to be of service to those who served, and to provide to our patients medical care second to none.
- The Laboratory Manual is prepared for the physicians and health providers, so that an efficient service may be rendered to their patients. Complete Instructions regarding Laboratory procedure are contained herein. Our staff and their phone numbers are included are available to answer questions related to laboratory functions. We always welcome your comments and suggestions so that may continuously improve our service to all concerned.

MISSION:

- To partner with physicians in providing high quality, state-of-the-art, diagnostic services delivered in a timely manner.
- To partner with physicians in providing the most current material, resources to educate patients so that patients can understand their diseases, treatment, preventive measures, and well informed decisions can be made.
- To partner with health insurance plans in providing accurate and cost-effective laboratory results.

2. GENERAL INFORMATION OF LABORATORY

- Location of Laboratory: 4320 214th Place, Bayside, NY 11361
- Hours of Operation: Main Laboratory is opened 12:00-8:00 PM, Monday - Saturday
- Sites of Specimen Analysis:
 - ROUTINES: Tests listed on this category are analyzed in-house.

REFERENCES: Bendiner ACUPATH LABORATORIES, INC.
Laboratory located at 140 58th St, 28 S. Terminal Drive
Suite 8D, Brooklyn, NY 11220 Plainview, NY 11803
(Phone: 212-254-2300). Phone: (516) 775-8103
Fax: (516) 326-3452

- Specimens are transported at the pre-established courier service time interval.
- Staffing: The Laboratory is manned by license technical staff, and supported by non-technical staffs during operation.
- Pathology-Cytology laboratory is manned by pathologist, medical transcriptionist, and technologists.
- Table of Organization
 - The EastGene Laboratories organization is showed in the table below. The Director and Assistant Directors are certified by NYSDOH and Assistant Directors also provide additional coverage. The Directors supervises and monitors the day-to-day operation of the Laboratory with the help of the Laboratory Manager, Supervisors and Lead Technologist.
- The main contact information can be found at www.eastgene.com. The main fax number: 718-428-4889

3. SPECIMEN REQUISITION FORM

The anatomic and clinical requisition forms can be found at www.eastgene.com.

Requisition Slip:

1. All requisition slips are to be submitted to the laboratory.
2. All requisition slips should be placed in proper pigeon boxes labeled according to time of pick-up.
3. All requisition slips must be clocked in to indicate the date & time specimen/requisition slip is received by the laboratory from health providers.

Identification of Patient:

To avoid rejection or delay test, two patient indentifiers must be included in the requisition and sample labels: full name of the patient and date of birth.

4. PHYSICIAN'S ORDER

ROUTINE REQUEST:

Routine Test Request

- Written request is required for every test and test to be ordered should be checked on the requisition or written on the blank area if the test is not on the list.
- The samples should be accompanied with appreciate requisition as indicated above.

Add-On Test:

- Request for additional tests added on to the initial request and using the same specimen sent to the laboratory, the request must be written on the previous or new laboratory requisition slip and indicate:
 - **Add-on** specimen in laboratory; date & time, patient's full name, and date of birth.
 - Indicate clearly the name of the test(s)
- Add-on test is only valid for sample drawn within **24 hours** and there is enough sample to perform add-on tests. However, there are exceptions.
 - Acetone, alcohol, and ammonia cannot be

added on a sample more than 4 hours old in a recapped specimen.

- Written tests request MUST be faxed to the laboratory as soon as possible or within 24 hours.

5. SPECIMEN LABELING

Labeling of Specimen:

- Label sample while at patient's blood drawing site to avoid mislabeling. Label should include:
 - Patient's name.
 - Patient's date of birth.
- For timed specimen it should indicate: trough, peak, collection time in cases of glucose tolerance tests, etc.
- Any improper or unlabeled specimen will be rejected for analysis.
 - Exception: cerebrospinal fluid; knee fluid; pleural fluid; samples obtained from surgical procedure; timed specimen.
 - An ATTESTATION FORM should be filled up and signed by the person attesting that the specimen was obtained from such specific patient.
- All specimens should be accompanied by the appropriate requisition slip.
- The following common request form problems cause delays or specimen rejection:
 - Illegible patient demographics
 - Illegible name and ordering physician
 - Absent or incorrect time and date of request and/or specimen collection
 - Unclear or totally absent marking of test request boxes
 - Form contaminated by specimen

6. SPECIMEN PACKING

- Plastic specimen biohazard bags are required to help limit the danger of infection during handling the

specimen. Place the specimen container inside the pocket with zip-lock or seal and then securely seal the pocket. Place the requisition in the other side of pocket to avoid contamination.

- Specimens then transported to the Laboratory by Courier Service in a Biohazard Controlled Container.
 - Courier service: MedFleet Delivery

7. SPECIMEN CONTAINERS

The following containers may be used:

- For hematology tests: Lavender Top Tubes containing potassium EDTA
- For PT/PTT: Light Blue Top Tubes containing 1/2 cc 3.2% sodium citrate
- For most chemistry: Gold Top Tubes with Gel Barrier
- For HPV (cervical only): thinPrep PreservCyt vial
- For GC/CT (cervical only): GenProbe transport tube
- For biopsy: 10% Formalin container
- For urine cytology: 50% and 95% Ethyl Alcohol for cytology
- For cervical cytology: ThinPrep PreservCyt Solution vial
- For urine: sterile container

Please consult laboratory for appropriate tubes or container for specific sample type or test.

8. SPECIMEN PICK-UP AND TRANSPORTATION

- Pick up at each facility between 1:00 PM and 5:00 PM
 - After hours pick-ups are available providing there is access to the facility or lock-boxes and cut off times for shipping are met.
- Record specimen count and pick up time on Daily Specimen Log Sheet during each stop by courier.

- Log Sheet to include specimen counts, time of pick up, also pieces of package.
- The specimen should be kept in Thermal container during transportation to ensure the correct temperature

9. TURNAROUND TIME

The EastGene Laboratories will provide only ROUTINE tests. STAT/RAPID RESPONSE tests should be sent to other laboratories such as Bendiner Laboratory and Quest Laboratory directly.

- ROUTINE: Most test results (CBC, UA or Chemistry) will be available within 5-8 hours or the same shift that they are ordered.
 - However, some tests may take longer time either due to complexity of the assay or sending out to reference laboratory.
- For biopsy and cytology, the report will be available within 3 days.
 - However, it may take longer if special tests or consultation is needed.

10. CRITERIA OF SPECIMEN REJECTION

- Hematology and Coagulation
 - Clotted blood for an assay that need appropriate anticoagulant.
 - Quantity not sufficient.
 - Improper anticoagulant or preservative.
 - Contaminated.
 - Missing or improperly labeled.
 - Improper dilution of anticoagulant vs. blood (example. PT, PTT).
- Chemistry
 - Grossly hemolyzed.

Note: if the ordering physician wants the test done in spite of its condition, the test will be done with indication of the specimen condition that results might not be accurate. Example of a comment on the final laboratory result might be ... "Specimen grossly hemolyzed but analyzed per request of Dr._____. Results might not be accurate".

- For more detailed requirement of specimens please contact EastGene Laboratories.

11. CRITICAL TEST/CRITICAL VALUE RESULT (ALERT VALUE):

Definition:

- **CRITICAL TESTS REPORTING TIME FRAME (From Test to Results Available):**
 - **Critical Test:** are those tests that require rapid conduct and communication of results.
- **CRITICAL VALUES/TEST RESULTS REPORTING TIME FRAME (From Test To Results Available):**
 - **Critical Value/Test Results (Alert Value):** are results that, if left untreated, would be life threatening or place the patient at serious risk. The Laboratory will attempt to call the licensed caregiver (RN, NP, PA, or MD) within 2 hr of their determination, but not beyond 4 hr time-frame.

Verification:

- The laboratory technologist who obtains critical/absurd laboratory results should be verified FIRST before releasing the report and making a telephone call.
- Upon verification of the result, a telephone report shall be made ONLY to a licensed responsible care giver or his/her designee.

Notification:

- Physician office: report to ordering physician directly or office staff.
 - Off-Hours of Physician Offices: Answering Service or Physician's page
- Notification shall be made in the following manner:
 - SPELL the full name of the patient.
 - Give the date of birth of the patient.
 - Name of the test (s) and the result (s)
 - Ask the person receiving the call to READ BACK the information.

- Documentation on the laboratory computer system including: date and time call made, name and title of person receiving the call, READ BACK, and initial of laboratory staff who gave the result.
- Transmit hard copy report via fax if caregivers ask for it or have the caregivers can print it themselves from www.eastgene.com.
- Any problem in communicating the critical value/critical test the director/designee should be informed immediately.

Chemistry (some of the tests performed at reference laboratories)

Test Name	Less Than	Greater Than
Acetaminophen		50ug/ml
Alcohol mg/dl		200
Ammonia	150umol/L	
Amylase		500 U/L
Calcium mg/dl	6.5 mg/dl	13.0
Chloride mmol/L	80 mmol/L	120
CO2 mmol/L	12.0 mmol/L	40
Digoxin ng/inL		2.4
Dilantin ug/mL		20
Gentamicin ug/mL		12
Glucose mg/dL	40 mg/dL	500
Lactate mg/dL		4.0
Lithium mmol/L		2.0
Magnesium mg/dL	1.0 mg/dL	5.0

Phenobarbital ug/mL		40
Phosphorus mg/dL	1.7 mg/dL	10
Potassium mmol/dL	2.5 mmol/dL	7.5
Salicylate mg/dL		30
Sodium mmol/L	120 mmol/L	155
Theophylline ug/mL		25.0
Tobramycin ug/mL		12.0
Total Bilirubin mg/dL		15
Troponin I- ng/mL		0.5
Valproic Acid	100ug/mL	

Hematology (some of the tests performed at the reference laboratories)

Test name	Less Than	Greater Than
Hemoglobin	7.0 gm/dL	
Hematocrit	N/A	N/A
Platelets	30,000/ul	850,000/ul
White Blood Cells	1,500/ul	30,000/ul
Prothrombin time Seconds		30
APTT Seconds		100
Fibrinogen	100 mg/dL	
INR		4.0

12. REPORTS





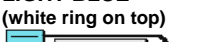


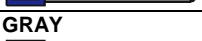



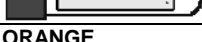
- The report can be printed at EastGene's website (www.eastgene.com) using assigned login name and password.
- If requested, results can be sent via fax or via regular mail.



- For reference tests, reports will send via internet (www.bendinerlab.com/web result) if an account is established or via fax by Bendiner Lab.

13. SPECIMEN REQUIREMENT: GENERAL

(For specific requirement of each test, please consult laboratory staff)

TUBE GUIDE

COLLECTION TUBES	ADDITIVE	USES
 GOLD/ SPECKLED (Serum separator tube)	None	- Chemistries - Immunology - Serology
 LIGHT GREEN (Plasma separator tube)	Lithium heparin	- Chemistries
 LAVENDER	EDTA	- Hematology (CBC) - Blood Bank (crossmatch) - Molecular testing
 LIGHT BLUE	Sodium citrate	- Coagulation tests (PT and PTT) - full draw
 LIGHT BLUE (white ring on top)	Sodium citrate	- For use with VerifyNow analyzers (physician must request these special tubes directly from the lab)
 DARK GREEN	Sodium heparin or Lithium heparin	- For lithium level, use sodium heparin
 DARK BLUE	EDTA	- Trace element testing (zinc, copper, lead, mercury) - Toxicology
 GRAY	Sodium fluoride and potassium oxalate	- Glucose (requires full draw)
 YELLOW	ACD (Acid-Citrate-Dextrose)	- HLA tissue typing - Paternity Testing - DNA studies
 YELLOW/BLACK	Broth mixture	- Microbiology – aerobes, anaerobes, fungi
 BLACK	Sodium citrate (buffered)	- Westergren Sedimentation Rate; requires full draw
 ORANGE	Thrombin	- STAT serum chemistries

		
BROWN 	Sodium heparin	- Serum lead determination

For a more detailed chart, please refer to:
http://www.bd.com/vacutainer/pdfs/plus_plastic_tubes_wallchart_tubeguide_VS5229.pdf

A. CHEMISTRY:

- For specimen collection and preparation, only use suitable tubes or collection containers.
- Only the specimens listed below were tested and found acceptable.
- Serum (free from gross hemolysis): Collect serum using standard sampling tubes.
- Plasma (free from hemolysis): Li-heparin or EDTA plasma. Do not use other anticoagulants.
- Nonhemolyzed serum is the specimen of choice.
- When processing samples in primary tubes (sample collection systems), follow the instructions of the tube manufacturer.
- Stability:
 - 3 days at 15-25 °C
 - 7 days at 2-8 °C
 - > 7 days at -70 °C

B. HEMATOLOGY

- Blood Counts:
 - Whole blood specimens containing clots
 - Blood specimens older than 48 hours
 - Other than EDTA anticoagulant

C. PATHOLGY SPECIMEN REQUIREMENT

- SURGICAL SPECIMEN:
 - All specimens are to be accompanied by "Pathology Requisition" completely and legibly filled

out. The form must include the patient's full name, date of birth, medical record number, type of specimen, clinical diagnosis, brief history, CPT code and the surgeon and attending physician's name.

- 2 No specimen will be accepted unless a completed form accompanies it.
- 3 Specimen will be submitted in plastic containers with lids, fixed in 10% Buffered Formalin.
- 4 The plastic specimen container must be clearly labeled with pre-established specimen ID code on the requisition form or labeled with patient's full name, patient's date of birth, medical record number, location, and the specimen contents.
- 5 If two or specimens are submitted for one patient, the container must be labeled "A" and "B" to correspond with the respective information supplied on the Surgical Pathology Requisition.
- 6 If there are any errors involving receipt of the specimen, these will be noted.

- **CYTOLOGY:**

- 1 All fluid specimens should be accompanied by "Pathology Requisition Form" with a short clinical history written for each specimen.
2. Urine specimen should be brought to the EastGene Laboratories within 4 hrs so the technologist may add the alcohol.

- **GYNECOLOGIC CYTOLOGY COLLECTION, PRESERVATION, TRANSPORTATION, RECEIPT & REPORTING:**

- **PATIENT PREPARATION:**

1. The patient should be informed of the following:
 - A. Ideal date for having a PAP smear taken is two weeks after the first day of the last menstrual period.
 - B. Avoid having the PAP smear taken during normal menses.

C. Do not use vaginal medication, vaginal contraceptives or douche for 48 hours prior to the examination.

- **LIQUID BASED PAP:**

1. Specimens can be obtained using spatula (ectocervix), brush (endocervix) or broom-like device (ecto-& endocervix).

- **PROCEDURES:**

1. Spatula:

- Obtain an adequate sampling from the ectocervix using a plastic spatula.
- Rinse the spatula into the PreserveCyt Solution vial by swirling the spatula vigorously in the vial 10 times.
- Discard the spatula.

2. Brush:

- Obtain an adequate sampling from the endocervix using an endocervical brush device.
- Insert the brush into the cervix until only the bottommost fibers are exposed. Slowly rotate 1/4 or 1/2 turn in one direction.
- Do not over-rotate.
- Rinse the brush in the PreserveCyt Solution by rotating the device in the solution 10 times while pushing against the PreserveCyt vial wall.
- Swirl the brush vigorously to further release material. Discard the brush.

3. Broom:

- Obtain an adequate sampling from the cervix using a broom-like device
- Insert the central bristles of the broom into the endocervical canal deep enough to allow the shorter

bristles to fully contact the ectocervix.

- Push gently and rotate the broom in a clockwise direction five times.
- Rinse the broom into the PreserveCyt solution vial by pushing the broom into the bottom of the vial 10 times, forcing the bristles apart.
- As a final step, swirl the broom vigorously to further release material.
- Discard the collection device.

As the final step tighten the cap so that the torque line on the cap passes the torque line on the vial. Label the vial with pre-established sticker on the requisition or record the patient's name, date of birth, and ID number on the vial. Complete the Pathology/Cytology requisition form with all patient information and medical history. Place the vial and requisition in a specimen bag for transporting to the Laboratory.

- **CONVENTIONAL PAP SMEAR:**

- A single slide technique is recommended.
- A well collected and prepared PAP smear should be taken from the ectocervix and the endocervix. If a quantitative maturation index is needed, take a sample from the lateral vaginal wall and smear on a separate slide labeled vaginal wall.
 - 1 Use pencil to label frosted edge of the slide the patient's name (Last Name and the initial of the First Name). A blank space should be left for the Laboratory to write accession number on the slide.
 - 2 Introduce an endocervical brush or an extended-tip spatula into the endocervix. Rotate the brush 90 to 180 degrees. Then smear the endocervical material onto the slide.

- 3 For ectocervical sample collection, scrape the entire ectocervix with a spatula.
- 4 Then smear the endocervical material on the section of the slide closest to the frosted edge, followed immediately by spreading the ectocervical specimen on the end farthest from the frosted edge of the slide.
- 5 Fix the slide immediately («1 second) by spraying with a spray fixative. Spray at a distance of approximately 12 inches away from the slide.
- 6 For patients requiring a maturation index:
 - I. Scrape the mid-lateral wall of the vagina very lightly with the spatula.
 - II. On a separate slide labeled vaginal wall, spread the vaginal material on the slide immediately.

14. LABORATORY INFORMATION SYSTEM (LIS)

- To view and print the results/report online, an account needs to be established. Please contact EastGene to set up an account.
- All users are required to enter their account ID and Password in order to log on EastGene web report.
 - Sign in ID: Account ID.
 - Password: Account specific one.
- No account should allow their access code to be used by someone who is not involved the patient care. It is against confidentiality law. It is the responsibility of each account to protect their web account. Hence it is very important to log out after using the LIS computer.