

SPECIMEN COLLECTION AND HANDLING GUIDE

Purpose of Specimen Collection and Handling Guide

Proper specimen collection and handling are essential parts of obtaining an accurate and timely laboratory test result. The purpose of this guide is to describe the proper procedure for specimen collection, labeling, storage, and shipping.

Patient Identification and Preparation Requirements

Patient Identification Requirements:

Personnel must confirm the patient's identity by checking at least two patient-specific identifiers before collecting the specimen and label the specimen in the presence of the patient.

- Acceptable identifiers include, but are not limited to: patient name, date of birth, hospital number, social security number, requisition number, accession number, or unique random number. A hospital room number is not an appropriate patient identifier.

Patient Preparation:

Many tests require proper patient preparation before collection to ensure a quality specimen for testing. Refer to collection facility's procedures for patient preparation requirements.

Specimen Labeling and Requisition Requirements

Specimen Labeling Requirements:

Label all primary specimen containers with at least two patient-specific identifiers.

- Label all specimens in the presence of the patient.
- Positive identification is the responsibility of the person collecting the sample.

Requisition Requirements:

Submit a completed order or requisition form with all specimens. Completed orders or requisition forms should contain the following information:

- Full name of patient
- Secondary unique identifier
- Date of Birth
- Sex of Patient
- Referring physician
- Facility name and address
- Date and time of specimen collection
- Specimen type
- Referring diagnoses
- ICD 10 Code
- Appropriate related patient history
- Test requested

Drug Interference

Tyrosine kinase inhibitors such as Gleevec may decrease mitotic index for chromosome studies.

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Isolated or Extracted Nucleic Acids Acceptance Policy

Genetics Associates, Inc. only accepts nucleic acid for clinical testing that was isolated or extracted in a CLIA-certified laboratory or a laboratory meeting equivalent requirements as determined by the CAP and/or the CMS.

Specimen Collection, Accepted Specimen Types, and Storage Requirements for Chromosome Analysis, FISH, ICP, and Microarray

Amniotic Fluid:

- Volume: 10 – 20 ml; discard the first ml of fluid or use for other testing
- Container: Sterile centrifuge tube or container
- Storage Conditions: Room temperature, 20 - 22°C (68 - 72°F)

Bone Core:

- Volume: Entire Biopsy
- Container: Sodium Heparin blood collection tube or a sterile tube containing sterile transport media
 - Invert tube 4 – 8 times to prevent formation of clots
- Storage Conditions: Room temperature, 20 - 22°C (68 - 72°F) or refrigerated temperature, 2 - 8°C (35.6 – 46.4°F).

Bone Marrow:

- **Adults**
 - Volume: 2 – 5 ml of bone marrow; from the first or, at least, the second tap
 - Container: Sodium Heparin blood collection tube
 - If Microarray is requested the preferred container is a purple top EDTA tube.
 - Do Not Use Lithium Heparin
 - Invert tube 4 – 8 time to prevent clots
 - Storage Conditions: Room temperature, 20 - 22°C (68 - 72°F) or refrigerated temperature, 2 - 8°C (35.6 – 46.4°F).
 - Do Not Freeze Specimen
- **Children > 8 Days Old**
 - Volume: 2 – 5 ml of bone marrow; from the first or, at least, the second tap
 - Container: Sodium Heparin blood collection tube
 - If Microarray is requested the preferred container is a purple top EDTA tube.
 - Do Not Use Lithium Heparin
 - Invert tube 4 – 8 times to prevent clots
 - Storage Conditions: Room temperature, 20 - 22°C (68 - 72°F) or refrigerated temperature, 2 - 8°C (35.6 – 46.4°F).
 - Do Not Freeze Specimen

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- **Newborn**
 - Volume: 1-2 ml of bone marrow; from the first or, at least, the second tap
 - Container: Sodium Heparin blood collection tube
 - If Microarray is requested the preferred container is a purple top EDTA tube.
 - Do Not Use Lithium Heparin;
 - Invert tube 4 – 8 times to prevent clots
 - Storage Conditions: Room temperature, 20 - 22°C (68 - 72°F) or refrigerated temperature, 2 - 8°C (35.6 – 46.4°F).
- Do Not Freeze Specimen

Chorionic Villi:

- Volume: 10 - 20 mg of chorionic villi, Additional 10mg for Microarray test requests
- Container: 15 ml sterile centrifuge tube containing sterile transport media
 - Sterile transport media provided by GAI upon request, sterile media such as RPMI, or sterile saline solution may be used.
- Storage Conditions: Room temperature, 20 - 22°C (68 - 72°F)
 - Do Not Freeze
- For locations in the Nashville area and with advanced notice, a cytogenetic technologist may be provided to verify that an adequate sample has been obtained.

Fine Needle Aspirate:

- Volume: Entire aspirate
- Container: 15 ml sterile centrifuge tube containing sterile transport media
 - Sterile transport media provided by GAI upon request, sterile media such as RPMI, or sterile saline solution may be used.
 - Do Not Use Formalin
- Storage Conditions: Room temperature, 20 - 22°C (68 - 72°F) or refrigerated temperature, 2 - 8°C (35.6 – 46.4°F)
 - Do Not Freeze

Fixed Pellet (Bone Marrow and Peripheral Blood):

- Volume: Pellet must be visible
 - Pellet must not be older than 1 week for Microarray
- Container: Sterile centrifuge tube with 3:1, Methanol:Acetic Acid
- Storage Conditions: Room temperature, 20 - 22°C (68 - 72°F)

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Lymph Node:

- Volume: Entire lymph node
- Container: Sterile container containing sterile transport media
 - Sterile transport media provided by GAI upon request, sterile media such as RPMI, or sterile saline solution may be used.
 - Do Not Use Formalin
- Rinse lymph nodes collected in non-sterile conditions with sterile balanced salts solution, Ringer's lactate, or sterile saline.
- Storage Conditions: Room temperature, 20 - 22°C (68 - 72°F) or refrigerated temperature, 2 - 8°C (35.6 – 46.4°F), Do not freeze

Masses / Tumors:

- Volume: Entire mass / tumor
- Container: Sterile specimen cup containing sterile transport media
 - Sterile transport media provided by GAI upon request, sterile media such as RPMI, or balanced salt solution may be used.
 - Do Not Use Formalin
- Storage Conditions: Room temperature, 20 - 22°C (68 - 72°F) or refrigerated temperature, 2 - 8°C (35.6 – 46.4°F)
 - Do Not Freeze

Peritoneal Fluid:

- Volume: 15 - 50 ml peritoneal fluid
- Container: 50 ml sterile centrifuge tube or specimen cup
- Storage Conditions: Room temperature, 20 - 22°C (68 - 72°F) or refrigerated temperature, 2 - 8°C (35.6 – 46.4°F)
 - Do Not Freeze

Peripheral Blood:

- **Children ≥8 days old – Adults**
 - Volume: 2 – 5 ml peripheral blood
 - Container: Sodium Heparin blood collection tube; invert tube 4 – 8 times to prevent clots
 - If Microarray is requested the preferred container is purple-top EDTA tube
 - Do Not Use Lithium
 - Invert tube 4 – 8 time to prevent clots
 - Storage Conditions: Room temperature, 20 – 22°C (68 - 72°F) or refrigerated temperature, 2 - 8°C (35.6 – 46.4°F)
 - Do Not Freeze

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- **Newborns (0 – 7 days)**
 - Volume: 1 – 2 ml peripheral blood
 - Container: Sodium Heparin blood collection tube; invert tube 4 – 8 times to prevent clots
 - If Microarray is requested the preferred container is a purple-top EDTA tube
 - Do Not Use Lithium
 - Storage Conditions: Room temperature, 20 – 22°C (68 - 72°F) or refrigerated temperature, 2 – 8°C (35.6 – 46.4°F)
 - Do Not Freeze

- **PUBS (Percutaneous Umbilical Blood Specimen/Cord Blood)**
 - Volume: 1 – 2 ml PUBS or cord blood
 - Container: Sodium Heparin blood collection tube; invert tube 4 – 8 times to prevent clots
 - If Microarray is requested the preferred container is a purple-top EDTA tube
 - Do Not Use Lithium
 - Storage Conditions: Room temperature, 20 - 22°C (68 - 72°F) or refrigerated temperature, 2 – 8°C (35.6 – 46.4°F), Do not freeze

Pleural Fluid:

- Volume: 15 -50 ml pleural fluid
- Container: Sterile centrifuge tube or specimen cup
- Storage Conditions: Room temperature, 20 - 22°C (68 - 72°F) or refrigerated temperature, 2 - 8°C (35.6 – 46.4°F)
 - Do Not Freeze

Products of Conception:

- Volume: 15-20 mg of appropriate tissue; Additional 10 mg for Microarray test requests.
- If volume is inadequate, all tests requested may not be performed.
 - Specimen collected should include, by order of preference, one or more of the following: villi, placenta or placental membrane, or recognizable fetal parts.
 - Stillborn: Placenta containing chorionic villi is the preferred tissue; include other tissue listed if possible
 - Stillborn or infant autopsy: Preferred tissues by order of preference: lung, kidney, thymus, skin.
- Rinse tissue collected in non-sterile conditions with sterile balanced salt solution, Ringer's lactate, or sterile saline.
- Container: Sterile container containing sterile transport media
 - Sterile transport media, provided by GAI upon request, sterile media such as RPMI, or sterile saline solution may be used
 - Carefully tighten the lid of container to prevent leakage
 - Do Not Use Formalin
- Storage Conditions: Room temperature, 20 -22°C (68 - 72°C) or refrigerated temperature, 2 - 8°C (35.6 – 46.4°F)
 - Do Not Freeze

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Slides (Paraffin Embedded Tissue):

- Volume: Submit 2 slides per probe requested
 - Cut specimen 3 – 4 μ thick.
 - Use positively charged slides.
- Submit H & E slide marked with the area of interest.
- Storage Conditions: Room temperature, 20 – 22°C (68 -72°F)

Tissue, Solid (Constitutional):

- Volume: 3mm³ tissue biopsy
- Container: Sterile specimen cup containing sterile transport media
 - Sterile transport media provided by GAI upon request, sterile media such as RPMI, or balanced salt solution may be used.
 - Do Not Use Formalin
- Storage Conditions: Room temperature, 20 - 22°C (68 - 72°F) or refrigerated temperature, 2 - 8°C (35.6 – 46.4°F)
 - Do Not Freeze

Urine:

- Volume: \geq 33 ml of urine
- Container: Sterile container containing Carbowax or PreserCyt
 - Carefully tighten the lid of the container to prevent leakage
 - Mix the urine at a 2:1 ratio with preservative
- Storage Conditions: Refrigerated temperature, 2 - 8°C (35.6 – 46.4°F)
 - Do Not Freeze

Specimen Collection, Accepted Specimen Types, and Storage Requirements for Molecular Testing

Special Instructions: Specimens for RNA based tests (PCR BCR/ABL1 p210 and p190) must be received in the lab within 72 hours of collection.

Bone Marrow:

- Volume: 2 – 5ml bone marrow; from the first or, at least, second tap
- Container: EDTA (purple top) blood collection tube
 - Invert tube 4 – 8 times to prevent clots
- Storage Conditions: Room temperature, 20 - 22°C (68-72°F) or Refrigerated temperature, 2 - 8°C (35.6 – 46.4°F)
 - Do Not Freeze

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Buccal Swab:

- Volume: Entire Swab (1)
- Container: Original collection tube, dry.
- Storage Conditions: Room temperature, 20 - 22°C (68-72°F) or refrigerated temperature, 2 - 8°C (35.6 - 46.6°F)
 - Do Not Freeze

Extracted DNA:

- Volume: 2 µg
- Container: DNA RNase-free microcentrifuge tube
- Storage Conditions: Refrigerated temperature, 2 - 8°C (35.6 - 46.6°F)

Fixed Pellets (Bone Marrow or Peripheral Blood):

- Volume: Pellet must be visible
 - Pellet must not be older than 1 week
- Container: Sterile centrifuge tube with 3:1, Methanol:Acetic Acid
- Storage Conditions: Refrigerated temperature, 2 - 8°C (35.6 - 46.6°F)

Peripheral Blood:

- Volume: 2 – 5 ml peripheral blood
- Container: EDTA (purple top) blood collection tube
 - Invert tube 4 – 8 times to prevent clots
- Storage Conditions: Room temperature, 20 - 22°C (68 - 72°F) or refrigerated temperature, 2 - 8°C (35.6 – 46.4°F)
 - Do Not Freeze

Specimen Collection, Accepted Specimen Types, and Storage Requirements for Molecular Testing DNA Based Testing (Breast Milk Identity)

Breast Milk:

- Volume: 5-10 mL
- Container: Sterile DNase/RNase free 15 mL centrifuge tube
- Storage Conditions: Refrigerated temperature, 2 - 8°C (35.6 - 46.4°F) or frozen temperature, -25 - 15°C (-13 to 5°F)
 - If specimen is frozen and thawed prior to preparing aliquot for GAI, do not re-freeze specimen, send at refrigerated temperature, 2 - 8°C (35.6 - 46.4 °F)

Buccal Swab:

- Volume: Entire Swab (1)
- Container: Original collection tube, dry.
- Storage Conditions: Room temperature, 20-22°C (68 - 72°F) or refrigerated temperature, 2 - 8°C (35.6 - 46.6°F)
 - Do Not Freeze

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Specimen Shipping

- Call Genetics Associates, Inc. at 615-327-4532 for pick up and additional information.
- Specimen Shipping Kits and FedEx Shipping Bags
 - Specimen shipping kits are provided by GAI.
 - FedEx overnight shipment will be provided for all outlying areas.
 - Mark the “Saturday Delivery” box on the FedEx airbill for all samples shipped on Friday.
 - Samples shipped on Saturday by FedEx will not be delivered until the next business day .
- Enclose completed requisition form with each specimen unless a electronic order has been sent.
- Enclose a refrigerated cold pack, during warmer weather, in the shipping box for overnight transportation for specimens requesting chromosome analysis, FISH, ICP, or microarray and avoid extreme temperatures to ensure specimen integrity.
- Enclose a frozen cool pack in the shipping box for overnight transportation for specimens requesting PCR testing and avoid temperature extremes to ensure specimen integrity.
- Store samples as stated above for each specific specimen type until pickup by courier.