

Specimen Requirements and Handling Procedures

The quality of laboratory results is highly dependent upon proper specimen collection and handling.

Listed below are specimen requirements and handling procedures for tests performed by siParadigm Laboratories



Specimen Type	Cytogenetics	FISH	Flow Cytometry	Bone Marrow Morphology	IHC	Molecular
Bone Marrow Aspirate★	<ul style="list-style-type: none"> ≥1.5 ml in Green top (Sodium Heparin). Room temperature. Good up to 72 hours from Collection. Sample should not be frozen, hemolyzed, washed, in syringe, in broken container, or in different anticoagulant other than sodium heparin. Maintain sterility of sample to prevent bacterial/fungal growth during culturing. 	<ul style="list-style-type: none"> 1 - 2 ml Green top (Sodium Heparin) tube OR Lavender top (EDTA) tube. Ship at room temperature. Sample considered acceptable up to 5 days from collection. Sample should not be frozen, hemolyzed, washed, in syringe, or sent in a broken container. 	<ul style="list-style-type: none"> 1 - 2 ml Green top (Sodium Heparin) tube OR Lavender top (EDTA) tube. Ship at room temperature. Sample considered acceptable up to 2 days from collection. Sample should not be hemolyzed, frozen or clotted. 	<ul style="list-style-type: none"> 3ml EDTA preferred, citrate (ACD) or Heparinized (acceptable) Ship at room temperature. 	NA	<ul style="list-style-type: none"> 3ml EDTA preferred, citrate (ACD) or Heparinized (acceptable) Ship at room temperature, must be received within 96 hrs for DNA or within 48 hrs for RNA.
Peripheral Blood★	<ul style="list-style-type: none"> Accepted in certain disease such as CLL or if circulating blood containing more than 10% blasts. Peripheral blood is ≥2 ml in Green top (Sodium Heparin). Room temperature. Good up to 72 hours from Collection. Sample should not be frozen, hemolyzed, washed, in syringe, in broken container, or in different anticoagulant other than sodium heparin. Maintain sterility of sample to prevent bacterial/fungal growth during culturing. 	<ul style="list-style-type: none"> 1 - 4 ml Green top (Sodium Heparin) tube OR Lavender top (EDTA) tube. Ship at room temperature. Sample considered acceptable up to 5 days from collection. Sample should not be frozen, hemolyzed, washed, in syringe, or sent in a broken container. 	<ul style="list-style-type: none"> 2-5 ml Green top (Sodium Heparin) tube OR Lavender top (EDTA) tube. Ship at room temperature. Sample considered acceptable up to 2 days from collection. Sample should not be hemolyzed, frozen or clotted. 	<ul style="list-style-type: none"> 3ml EDTA preferred, citrate (ACD) or Heparinized Ship at room temperature. 	NA	<ul style="list-style-type: none"> 3ml EDTA preferred, citrate (ACD) or Heparinized (acceptable) Ship at room temperature, received within 96 hrs for DNA or within 48 hrs for RNA. For liquid biopsy NGS assay, total 30ml peripheral blood in streck tubes (Blue top), 10ml per tube, transport at room temperature within 48 hrs (Include cold ischemic time and fixation time on the requisition).
Bone Marrow Core Biopsy and/ or Aspirate Clot (10% NBF)★	NA	<ul style="list-style-type: none"> Not preferred. Bone marrow core biopsy in 10% NBF must be decalcified to facilitate tissue sectioning. Use of decalcification solutions with strong acids is not recommended for FISH assay. Specimens decalcified using strong hydrochloric acid are subject to rejection. Specimens decalcified using EDTA are accepted but results should be interpreted with caution. If the decalcification chemical is unknown, testing will be attempted. Assay has not been validated on decalcified tissues. Results should be interpreted with caution given the possibility of false negative results on decalcified specimens. 	N/A	<ul style="list-style-type: none"> Saturate tissue completely with fixative (10%NBF) Ship at room temperature 	<ul style="list-style-type: none"> Saturate tissue completely with fixative (10%NBF) Ship at room temperature, 10:1 ratio is adequate for routine work Place into protective box and foam. 	N/A
Fresh Bone Marrow Core Biopsy★	NA	<ul style="list-style-type: none"> Not preferred. Fresh bone marrow core will be entirely consumed in the process, handled similar to fresh tissue. 1 - 2 cm core immersed in provided 5mL sterile transport media (RPMI 1640 & 1% penicillin-streptomycin). Ship to lab within 24 hours on cold pack. Label with patient name, DOB, and collection date. DO NOT use RPMI past expiration date. 	<ul style="list-style-type: none"> 1 - 2 cm core immersed in provided 5mL sterile transport media (RPMI 1640 & 1% penicillin-streptomycin). Ship to lab within 24 hours on cold pack. Label with patient name, DOB, and collection date. DO NOT use RPMI past expiration date. 	<ul style="list-style-type: none"> Saturate tissue completely with fixative (10%NBF) Ship at room temperature 	<ul style="list-style-type: none"> Saturate tissue completely with fixative (10%NBF) Ship at room temperature, 10:1 ratio is adequate for routine work Place into protective box and foam. 	<ul style="list-style-type: none"> 1-2cm core in RPMI

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Bone Marrow Morphology

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Fresh Unfixed Tissue ▲

N/A

- 1cm³ (marble-sized) piece of tissue immersed in provided 5mL sterile transport media (RPMI 1640 & 1% penicillin-streptomycin).
- Ship to lab within 24 hours on cold pack. Label with patient name, DOB, and collection date.
- DO NOT use RPMI past expiration date.

- 1 cm³ (marble-sized) piece of tissue immersed in provided 5mL sterile transport media (RPMI 1640 & 1% penicillin-streptomycin).
- Ship to lab within 24 hours on cold pack. Label with patient name, DOB, and collection date.
- DO NOT use RPMI past expiration date.

- Saturate tissue completely with fixative (10%NBF)
- Ship at room temperature

- Saturate tissue completely with fixative (10%NBF)
- Ship at room temperature, 10:1 ratio is adequate for routine work
- Place into protective box and foam.

- Fresh tissue in at least 5mm³ in RPMI or saline buffer
- Shipped at ambient temperature or on blue ice packs within 48 hrs .

Fluids ▲

N/A

- Fluids should be added to the provided 5mL sterile transport media (RPMI 1640 & 1% penicillin-streptomycin).
- Ship to lab within 24 hours on cold pack. Label with patient name, DOB, and collection date.
- DO NOT use RPMI past expiration date.

- Fluids should be added to the provided 5mL sterile transport media (RPMI 1640 & 1% penicillin-streptomycin).
- Ship to lab within 24 hours on cold pack. Label with patient name, DOB, and collection date.
- DO NOT use RPMI past expiration date.

N/A

N/A

- 5-10 ml Body fluids (CSF, pleural or ascetic fluid)
- Shipped at ambient temperature or on blue ice packs within 48 hrs.

Paraffin Block or Cut Slide ▲ (For cut slides, place sections from one block on each slide)

N/A

- Formalin Fixed Paraffin Embedded Tissue (FFPET):**
 - Block:** FFPE Cassette, ship in room temperature, include cold pack in extreme heat.
 - Stability:** Indefinite.
- Unstained, formalin-fixed slides:** One (1) slide per FISH probe and one (1) additional for Pathological evaluation.
- Ship in plastic slide holder at room temperature, include cold pack in extreme heat. Stability: Indefinite.
- For HER2 (ERBB2) by FISH:**
 - Block:** FFPE Cassette, ship in room temperature, include cold pack in extreme heat. Stability: Indefinite.
 - Specimens subject to HER2 (ERBB2) testing should be fixed in 10% neutral buffered formalin for at least six hours and up to 72 hours.
 - The volume of formalin should be at least 10 times the volume of the specimen. Decalcification solutions with strong acids should not be used.
 - Specimens should be immersed in fixative within one hour of the biopsy or resection.
- (Include cold ischemic time and fixation time on requisition).**
- Unstained, formalin-fixed slides:** Two (2) slides for FISH testing and one (1) additional for pathological evaluation.
- Ship in plastic slide holder at room temperature, include cold pack in extreme heat. Stability: Indefinite.

N/A

- FFPE Cassette at room temperature (Include cold pack in extreme heat.).
- Plastic slide holder for unstained slides

- FFPE Cassette at room temperature (Include cold pack in extreme heat).
- Plastic slide holder for unstained slides, plastic paraffin mailer is preferred to protect the block.

- Paraffin block preferred, or FFPE 5-10 sections at 4 to 10 micron each on positively charged slides.
- Shipped at ambient temperature.

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Voided Urine ▲	N/A	<ul style="list-style-type: none"> Minimum of 33cc of urine using the provided Urine Collection Kit. If Urine is not shipped immediately after collection, refrigerate immediately and ship via overnight courier within 24 hours. The preferred storage and shipping conditions are on ice packs, but specimens may be stored and shipped at temperatures up to 25°C. Must be processed within 48 hours of collection. Follow Urine Collection Kit Instructions 	N/A	N/A	N/A	<ul style="list-style-type: none"> 10ml Urine in sterile container or tube. Transport temperature should be 4C within 24-48 hrs, if there are no preservatives in the container. Ship urine at ambient temperature within 48-72 hrs for samples in container with preservatives. (Note: The specific sample collection devices will be determined.)
Decalcified Specimens	N/A	<ul style="list-style-type: none"> Use of decalcification solutions with strong acids is not recommended. Specimens decalcified using strong hydrochloric acid are subject to rejection. Specimens decalcified using EDTA are accepted but results should be interpreted with caution. If the decalcification chemical is unknown, testing will be attempted. Assay has not been validated on decalcified tissues. Results should be interpreted with caution given the possibility of false negative results on decalcified specimens. Formalin Fixed Paraffin Embedded Tissue (FFPET): Block: FFPE Cassette, ship in room temperature, include cold pack in extreme heat. Stability: Indefinite. Unstained, formalin-fixed slides: One (1) slide per FISH probe and one (1) additional for Pathological evaluation. Ship in plastic slide holder at room temperature, include cold pack in extreme heat. Stability: Indefinite. Decalcification solutions with strong acids should not be used for HER2(ERBB2) assay. 	N/A	<ul style="list-style-type: none"> Saturate tissue completely with fixative (10%NBF) Ship at room temperature 	<ul style="list-style-type: none"> Saturate tissue completely with fixative (10%NBF) Ship at room temperature, 10:1 ratio is adequate for routine work Place into protective box and foam. 10% neutral buffered EDTA and 5% nitric acid are the preferred decalcifying agents for IHC staining 	<ul style="list-style-type: none"> Not preferred

Storage and Transportation:

- ★ Use cold pack for transport, making sure cold pack is not in direct contact with specimen. For fresh specimens, ship same day as drawn whenever possible.
- ▲ Refrigerate and use cold pack for transport. For fresh specimens, ship same day as drawn whenever possible.