

Specimen Collection Manual

Patient Readiness & Specimen Collection	2
Specimen Storage and Shipment	4

HEMATOLOGICAL MALIGNANCIES

Anaplastic Large Cell Lymphoma (ALCL)	5
Acute Lymphocytic Leukemia (ALL)	5
Acute Myeloid Leukemia (AML)	5
Burkitt Lymphoma	5
Chronic Lymphocytic Leukemia (CLL)	6
Chronic Myelogenous Leukemia (CML)	6
Diffuse Large B-Cell Lymphoma (DLBCL)	7
Follicular Lymphoma (FL)	7
Lymphoma	8
MALT Lymphoma	8
Mantle Cell Lymphoma (MCL)	8
Myelodysplastic Syndrome (MDS)	9
Multiple Myeloma (MM)	9
Myeloproliferative Neoplasms (MPN)	9
Paroxysmal Nocturnal Hemoglobinuria (PNH)	10

SOLID TUMORS

Bladder Cancer	10
Brain Cancer	10
Breast Cancer	10
Cervical Cancer	11
Colorectal Cancer (CRC)	11
Gastric Cancer	11
Kidney Cancer	12
Melanoma	12
Thyroid Cancer	12
Non-Small Cell Lung Cancer (NSCLC)	13
Tissue of Origin® (TOO®)	13

CGI LABORATORIES

Client Services:
Tel: +1 201-528-9187
Toll Free: 888-334-4988
Fax: +1 201-933-0787

specimen@cgix.com
www.cancergenetics.com

PHARMACOGENOMICS AND HEREDITARY 14

Patient Readiness

Proper specimen collection is key to obtain accurate diagnostic test results. While information on handling human specimens can be obtained from the U.S. Occupational Safety and Health Administration (OSHA) and the Centers for Disease Control and Prevention (CDC), this manual is intended to provide basic instructions on proper collection as well as minimum specimen requirements.

In order to obtain diagnostic test results of the highest quality, the following steps must be completed with care:

Patient Readiness

Specimen Collection

Specimen Storage and Shipment

Patient Readiness

The patient should be provided ahead of time with relevant information pertaining to fasting, diet, and medication restrictions. The patient identity must be verified prior to specimen collection.

Specimen Collection

Prior to proceeding to specimen collection, review the specimen requirements. Specimen requirements include information such as specimen volume, collection and transport containers as well as transport temperature.

Labeling Instructions

Based on regulatory requirements, all specimen containers/slides must be labeled with at least two patient identifiers that must include patient name and at least one of the following date of birth, or chart/medical record number. Also, the collection dates and times must be on either the requisition or specimen container. All specimens received in the laboratory must have a completed requisition form with all appropriate information filled out, including:

- Patient name
- Patient DOB
- Collection date/time
- Specimen type/site
- Requesting physician
- Clinical data, when indicated

Specimen Collection

Handling of a Bone Marrow Specimen “Dry TAP”

CGI has a very high success rate with limited amounts of marrow as well as with more cellular aspirate specimens. The following specimen collection method can help our hematopathologists to reach a conclusive diagnosis on “dry tap” specimens that yield no bone marrow aspirate:

1. Collect 2 or more bone marrow core biopsies.
 - a. Make 5-10 touch imprint slides from the biopsies (for Cytology and Morphology).
 - Be sure to keep slides AWAY FROM FORMALIN.
 - Do not place open formalin jar anywhere near slides as the formalin fumes may affect the quality of morphologic evaluation.
 - Let all slides AIR DRY COMPLETELY before placing in the plastic container to prevent smudging.
 - b. Place the 1st bone marrow core biopsy in a Formalin jar (for Histology & IHC testing).
 - c. Place the 2nd biopsy in RPMI media (for Flow Cytometry and/or Cytogenetics testing). Store in refrigerator until shipped.
 - d. Additional samples/clot should be submitted for histology.
2. Indicate on REQUISITION that the specimen is a “DRY TAP”
3. Collect a peripheral blood specimen in a Sodium Heparin or green top tube (for possible Flow Cytometry and/or FISH testing, if indicated).
4. Collect a peripheral blood specimen in an EDTA or purple top tube (for possible molecular testing, if indicated).
5. Place each specimen in the Biohazard bag before placing in kit.
6. Call 888-334-4988 or 201-528-9187 for a specimen pickup or contact your local account representative or client services if you have any questions.

For general bone marrow requirements, refer to the Specimen Requirements section of this booklet or the back of the requisition form.

Blood Collection

1. Position the patient so that the arm extends to form a relatively straight line from shoulder to wrist.
2. Select a vein site. Whenever possible perform a venipuncture on the arm in which no IV is running.
3. Obtain the required amount in a vacuum tube, immediately invert the tube 8-10 times. Do not shake the tube.

Urine Collection

1. The sample must be obtained from a clean-catch, midstream flow using a big cup. First void of the day is preferred. Sample volume should be over 30 mL.
2. Slowly pour the sample into the smaller container up to 90 mL.
3. Tighten the lid until you hear a click in order to prevent leakage.
4. The sample should be received by CGI within 72 hours post-collection.
5. For further details about specimen shipment, please consult the section about Specimen Requirements.

FFPE Tissue

1. Tissue should be fixed in 10% neutral buffered formalin in a volume greater than 10 times the specimen volume.
2. Tissue should be fixed from 4 hours to 72 hours.
3. Breast tissue for Her2/ER/PR testing should be fixed at least 6 hours but no more than 72 hours.

Specimen Storage and Shipment

Specimen Storage and Shipment

The specimen should be properly packaged and transported to the laboratory in a timely manner and under environmental conditions that will not compromise the integrity of the specimen.

When you first sign up with CGI, your account representative will help you determine your specific courier needs, which are decided according to your geographical location FedEx is available for all clients outside of our local geographic region. Regardless of the method used, CGI will provide prompt and efficient service to ensure that clients receive results in a timely manner. Our accessioning office can be reached by phone at (888) 334-4988, or by email at salesupport@cgix.com.




Supplies and containers for our laboratory services are permitted by State and Federal laws. CGI will provide you, at no charge, with all the supplies you need: requisition forms, tubes, packaging transport forms, etc. Supply requests can be submitted to us by contacting your account manager or by contacting our accessioning department. You can reach the department by phone at (888) 334-4988 or by email at salesupport@cgix.com.





We request enough material for initial analysis as well as for any confirmatory tests. If an inadequate specimen is submitted, we may not be able to perform the initial test or required confirmatory procedures. If repeat or confirmatory tests cannot be performed, the report will indicate that the specimen quantity submitted was “QNS” (Quantity Not Sufficient) for additional testing.







Please contact the laboratory for clarifications, if needed, prior to specimen collection.




Specimen Requirements

Hematological Malignancies (ALCL, ALL, AML, Burkitt)

ANAPLASTIC LARGE CELL LYMPHOMA (ALCL)		
	IHC Evaluation	4-5 µm thick FFPE sections on positively coated slides at room temperature.
	Morphology	FFPE tissue block at room temp. or 0.5 cm ³ fresh tissue in RPMI on dry ice.
	Karyotype (G-banding)	1 Green/NaHeparin or 1 Lavender/EDTA tube (3-5 ml) peripheral blood, bone marrow or disaggregated tissue at room temperature.
	ALCL FISH Panel	1 Green/NaHeparin or 1 Lavender/EDTA tube (3-5 ml) peripheral blood, bone marrow or disaggregated tissue at room temperature.







ACUTE LYMPHOCYTIC LEUKEMIA (ALL)		
	IHC Evaluation	4-5 µm thick FFPE sections on positively coated slides at room temperature.
	Morphology	FFPE tissue block at room temp. or 0.5 cm ³ fresh tissue in RPMI on dry ice.
	Myeloid/Lymphoid/Acute Leukemia Flow Panel	1 Green/NaHeparin or 1 Lavender/EDTA tube (2 ml) peripheral blood or bone marrow at room temperature.
	Karyotype (G-banding)	1 Green/NaHeparin or 1 Lavender/EDTA tube (3-5 ml) peripheral blood, bone marrow or disaggregated tissue at room temperature.
	BM Transplant Monitoring	1 Green/NaHeparin or 1 Lavender/EDTA tube (3-5 ml) peripheral blood, bone marrow or disaggregated tissue at room temperature.
	B-ALL FISH Panel	
	T-ALL FISH Panel	






ACUTE MYELOID LEUKEMIA (AML)		
	IHC Evaluation	4-5 µm thick FFPE sections on positively coated slides at room temperature.
	Morphology	FFPE tissue block at room temp. or 0.5 cm ³ fresh tissue in RPMI on dry ice.
	Myeloid/Lymphoid/Acute Leukemia Flow Panel	1 Green/NaHeparin or 1 Lavender/EDTA tube (2 ml) peripheral blood or bone marrow at room temperature.
	Karyotype (G-banding)	1 Green/NaHeparin or 1 Lavender/EDTA tube (3-5 ml) peripheral blood, bone marrow or disaggregated tissue at room temperature.
	BM Transplant Monitoring	1 Green/NaHeparin or 1 Lavender/EDTA tube (3-5 ml) peripheral blood, bone marrow or disaggregated tissue at room temperature.
	AML FISH Panel	
	KIT Mutation (Exon 8 & 17)	1 Lavender/EDTA tube of peripheral blood or bone marrow aspirate (2-3 mL) at room temperature.
	CEBPA Mutation	
	FLT3 Mutation (ITD, D835)	
	NPM1 Mutation (Exon 12)	
	Focus::AML™ (NGS)	
	AML Complete™	1 Green/NaHeparin or 1 Lavender/EDTA tube (5-7 ml) peripheral blood or bone marrow at room temperature or 2-8°C; FFPE tissue block at room temperature.

BURKITT LYMPHOMA		
	IHC Evaluation	4-5 µm thick FFPE sections on positively coated slides at room temperature.
	Morphology	FFPE tissue block at room temp. or 0.5 cm ³ fresh tissue in RPMI on dry ice.
	Karyotype (G-banding)	1 Green/NaHeparin or 1 Lavender/EDTA tube (3-5 ml) peripheral blood, bone marrow or disaggregated tissue at room temperature.
	MYC/IGH DNA-FISH Probe	1 Green/NaHeparin or 1 Lavender/EDTA tube (3-5 ml) peripheral blood, bone marrow or disaggregated tissue at room temperature.

Specimen Requirements







Hematological Malignancies (CLL, CML)






CHRONIC LYMPHOCYTIC LEUKEMIA (CLL)		
	IHC Evaluation	4-5 µm thick FFPE sections on positively coated slides at room temperature.
	Morphology	FFPE tissue block at room temp. or 0.5 cm ³ fresh tissue in RPMI on dry ice.
	ZAP-70 Flow Panel	1 Green/NaHeparin or Lavender/EDTA tube 2 ml peripheral blood/bone marrow at room temp.
	MRD-CLL Flow Panel	1 Green/NaHeparin or 1 Lavender/EDTA tube peripheral blood (10 ml) or bone marrow (3 ml) at room temperature.
	Karyotype (G-banding)	1 Green/NaHeparin or 1 Lavender/EDTA tube (3-5 ml) peripheral blood, bone marrow or disaggregated tissue at room temperature.
	BM Transplant Monitoring	1 Green/NaHeparin or 1 Lavender/EDTA tube (3-5 ml) peripheral blood, bone marrow or disaggregated tissue at room temperature.
	CLL FISH Panel	
	IGHV Mutation	1 Lavender/EDTA tube (2-3 ml) peripheral blood or bone marrow at room temperature or 2-8°C.
	NOTCH1 Mutation	
	SF3B1 Mutation	
	TP53 Mutation	
	Focus::CLL™ (NGS)	
	MatBA®-CLL/SLL	1 Lavender/EDTA tube (2-3 ml) peripheral blood or bone marrow aspirate at room temperature or 3-5 FFPE sections at 10 µm thickness on regular slides at room temperature.
	CLL Complete™	1 Green/NaHeparin and 1 Lavender/EDTA tube (8-10 ml) peripheral blood or bone marrow at room temperature; FFPE tissue block at room temperature or 0.5 cm ³ fresh tissue in RPMI on ice.

CHRONIC MYELOGENOUS LEUKEMIA (CML)		
	IHC Evaluation	4-5 µm thick FFPE sections on positively coated slides at room temperature.
	Morphology	FFPE tissue block at room temp. or 0.5 cm ³ fresh tissue in RPMI on dry ice.
	Myeloid/Lymphoid/Acute Leukemia Flow Panel	1 Green/NaHeparin or 1 Lavender/EDTA tube (2 ml) peripheral blood or bone marrow at room temperature.
	Karyotype (G-banding)	1 Green/NaHeparin or 1 Lavender/EDTA tube (3-5 ml) peripheral blood, bone marrow or disaggregated tissue at room temperature.
	BM Transplant Monitoring	1 Green/NaHeparin or 1 Lavender/EDTA tube (3-5 ml) peripheral blood, bone marrow or disaggregated tissue at room temperature.
	CML FISH Panel	
	CML in Blast Crisis FISH Panel	
	ABL Kinase Domain	1 Lavender/EDTA tube peripheral blood or bone marrow (3-5 ml) at room temperature or 2-8°C within 48 hours after collection.
	BCR/ABL Qualitative	
	BCR/ABL Quantitative Major & Minor	

Specimen Requirements






Hematological Malignancies (DLBCL, FL)





DIFFUSE LARGE B-CELL LYMPHOMA (DLBCL)		
	IHC Evaluation	4-5 µm thick FFPE sections on positively coated slides at room temperature.
	cMYC, Ki-67 (IHC)	
	GCB vs. Non-GCB Subtyping (IHC)	
	Morphology	
	Lymphoid Flow Panel	1 Green/NaHeparin or 1 Lavender/EDTA tube (2 ml) peripheral blood or bone marrow at room temperature.
	Karyotype (G-banding)	1 Green/NaHeparin or 1 Lavender/EDTA tube (3-5 ml) peripheral blood, bone marrow or disaggregated tissue at room temperature.
	NHL FISH Panel	1 Green/NaHeparin or 1 Lavender/EDTA tube (3-5 ml) peripheral blood, bone marrow or disaggregated tissue at room temperature.
	B-Cell Clonality (IGH)	1 Lavender/EDTA tube (2-3 ml) peripheral blood or bone marrow at room temperature or 2-8°C or 30-50 µm total FFPE sections at room temperature.
	TP53 Mutation	1 Lavender/EDTA tube (2-3 ml) peripheral blood or bone marrow at room temperature or 2-8°C.
	Focus::DLBCL&FL™ (NGS)	
	MatBA®-DLBCL	FFPE: block containing ≥ 70% tumor. Minimum size: 2 mm x 2 mm tumor area, shipped at room temperature. Fresh-Frozen Tissue: 0.2 cm ³ minimum (in OCT is acceptable) containing ≥50% tumor. Stored at -80°C /-20°C, shipped on dry ice.
	DLBCL Complete™	1 Green/NaHeparin and 1 Lavender/EDTA tube (5-7 ml) peripheral blood or bone marrow aspirate at room temperature; FFPE tissue block at room temperature or 0.5 cm ³ fresh tissue in RPMI on ice.






FOLLICULAR LYMPHOMA (FL)		
	IHC Evaluation	4-5 µm thick FFPE sections on positively coated slides at room temperature.
	Morphology	FFPE tissue block at room temp. or 0.5 cm ³ fresh tissue in RPMI on dry ice.
	Lymphoid Flow Panel	1 Green/NaHeparin or 1 Lavender/EDTA tube (2 ml) peripheral blood or bone marrow at room temperature.
	Karyotype (G-banding)	1 Green/NaHeparin or 1 Lavender/EDTA tube (3-5 ml) peripheral blood, bone marrow or disaggregated tissue at room temperature.
	NHL FISH Panel	1 Green/NaHeparin or 1 Lavender/EDTA tube (3-5 ml) peripheral blood, bone marrow or disaggregated tissue at room temperature.
	Focus::DLBCL&FL™ (NGS)	1 Lavender/EDTA tube (2-3 ml) peripheral blood or bone marrow at room temperature or 2-8°C.
	MatBA®-FL	FFPE block containing ≥ 70% tumor (Min size: 2 mm ² tumor area) shipped at room temperature or 0.2 cm ³ fresh frozen tissue (Min >50% tumor, in OCT is acceptable) stored at -80°C /-20°C and shipped on dry ice.

Specimen Requirements

Hematological Malignancies (Lymphoma, MALT, MCL)

LYMPHOMA		
	IHC Evaluation	4-5 µm thick FFPE sections on positively coated slides at room temperature.
	Morphology	FFPE tissue block at room temp. or 0.5 cm ³ fresh tissue in RPMI on dry ice.
	Lymphoid Flow Panel	1 Green/NaHeparin or 1 Lavender/EDTA tube (2 ml) peripheral blood or bone marrow at room temperature.
	Karyotype (G-banding)	1 Green/NaHeparin or 1 Lavender/EDTA tube (3-5 ml) peripheral blood, bone marrow or disaggregated tissue at room temperature.
	NHL FISH Panel	1 Green/NaHeparin or 1 Lavender/EDTA tube (3-5 ml) peripheral blood, bone marrow or disaggregated tissue at room temperature.
	B-Cell Clonality (IGH)	1 Lavender/EDTA tube (2-3 ml) peripheral blood or bone marrow at room temperature or 2-8°C or 30-50 µm total FFPE sections at room temperature.
	BRAF Mutation	
	MatBA [®] -DLBCL	
	MatBA [®] -FL	
	MatBA [®] -MCL	
	MYD88 L265P Mutation	
	NOTCH1 Mutation	
	T-Cell Clonality (TCRβ & TCRγ)	
Focus::Lymphoma™ (NGS)	1 Lavender/EDTA tube (2-3 ml) peripheral blood or bone marrow at room temperature.	

MALT LYMPHOMA		
	IHC Evaluation	4-5 µm thick FFPE sections on positively coated slides at room temperature.
	Morphology	FFPE tissue block at room temp. or 0.5 cm ³ fresh tissue in RPMI on dry ice.
	Lymphoid Flow Panel	1 Green/NaHeparin or 1 Lavender/EDTA tube (2 ml) peripheral blood or bone marrow at room temperature.
	Karyotype (G-banding)	1 Green/NaHeparin or 1 Lavender/EDTA tube (3-5 ml) peripheral blood, bone marrow or disaggregated tissue at room temperature.
	NHL FISH Panel	1 Green/NaHeparin or 1 Lavender/EDTA tube (3-5 ml) peripheral blood, bone marrow or disaggregated tissue at room temperature.

MANTLE CELL LYMPHOMA (MCL)		
	IHC Evaluation	4-5 µm thick FFPE sections on positively coated slides at room temperature.
	Morphology	FFPE tissue block at room temp. or 0.5 cm ³ fresh tissue in RPMI on dry ice.
	Lymphoid Flow Panel	1 Green/NaHeparin or 1 Lavender/EDTA tube (2 ml) peripheral blood or bone marrow at room temperature.
	Karyotype (G-banding)	1 Green/NaHeparin or 1 Lavender/EDTA tube (3-5 ml) peripheral blood, bone marrow or disaggregated tissue at room temperature.
	NHL FISH Panel	1 Green/NaHeparin or 1 Lavender/EDTA tube (3-5 ml) peripheral blood, bone marrow or disaggregated tissue at room temperature.
	Focus::MCL™ (NGS)	1 Lavender/EDTA tube (2-3 ml) peripheral blood or bone marrow at room temperature.
	MatBA [®] -MCL	1 Green/NaHeparin or 1 Lavender/EDTA tube (3-5 ml) peripheral blood or bone marrow at room temperature; FFPE block containing ≥ 60% tumor (Min 2 mm ² tumor area) shipped at room temperature or fresh frozen tissue (Min 0.2 cm ³ , in OCT is acceptable) containing ≥50% tumor stored at -80°C /-20°C and shipped on dry ice.




Specimen Requirements

Hematological Malignancies (MDS, MM, MPN)




MYELOYDYSPLASTIC SYNDROME (MDS)		
	IHC Evaluation	4-5 µm thick FFPE sections on positively coated slides at room temperature.
	Morphology	FFPE tissue block at room temp. or 0.5 cm ³ fresh tissue in RPMI on dry ice.
	Karyotype (G-banding)	1 Green/NaHeparin or 1 Lavender/EDTA tube (3-5 ml) peripheral blood, bone marrow or disaggregated tissue at room temperature.
	BM Transplant Monitoring	1 Green/NaHeparin or 1 Lavender/EDTA tube (3-5 ml) peripheral blood, bone marrow or disaggregated tissue at room temperature.
	MDS FISH Panel	
	Focus::MDS™ (NGS)	1 Lavender/EDTA tube of peripheral blood or bone marrow aspirate (2-3 mL) at room temperature.
	MDS Complete™	1 Green/NaHeparin or 1 Lavender/EDTA tube (5-7 ml) peripheral blood or bone marrow at room temperature or 2-8°C; FFPE tissue block at room temperature.
MULTIPLE MYELOMA (MM)		
	IHC Evaluation	4-5 µm thick FFPE sections on positively coated slides at room temperature.
	Morphology	FFPE tissue block at room temp. or 0.5 cm ³ fresh tissue in RPMI on dry ice.
	MM Flow Panel	1 Green/NaHeparin or 1 Lavender/EDTA tube (2 ml) peripheral blood or bone marrow at room temperature.
	Karyotype (G-banding)	1 Green/NaHeparin or 1 Lavender/EDTA tube (3-5 ml) peripheral blood, bone marrow or disaggregated tissue at room temperature.
	MM with PPC FISH Panel	1 Green/NaHeparin or 1 Lavender/EDTA tube (3-5 ml) peripheral blood, bone marrow or disaggregated tissue at room temperature.
MYELOPROLIFERATIVE NEOPLASMS (MPN)		
	IHC Evaluation	4-5 µm thick FFPE sections on positively coated slides at room temperature.
	Morphology	FFPE tissue block at room temp. or 0.5 cm ³ fresh tissue in RPMI on dry ice.
	Myeloid/Lymphoid/Acute Leukemia Flow Panel	1 Green/NaHeparin or 1 Lavender/EDTA tube (2 ml) peripheral blood or bone marrow at room temperature.
	Karyotype (G-banding)	1 Green/NaHeparin or 1 Lavender/EDTA tube (3-5 ml) peripheral blood, bone marrow or disaggregated tissue at room temperature.
	BM Transplant Monitoring	1 Green/NaHeparin or 1 Lavender/EDTA tube (3-5 ml) peripheral blood, bone marrow or disaggregated tissue at room temperature.
	MPN FISH Panel	
	CALR Mutation	
	c-KIT Mutation (D816)	
	JAK2 Exon 12 Mutation	
	JAK2 V617F Mutation	
	MPL 515/505 Mutation	
Focus::MPN™ (NGS)	1 Lavender/EDTA tube of peripheral blood or bone marrow aspirate (2-3 mL) at room temperature.	
	MPN Complete™	1 Green/NaHeparin and 1 Lavender/EDTA tube (5-7 ml) peripheral blood or bone marrow aspirate at room temperature or 2-8°C; FFPE tissue block at room temperature.



Specimen Requirements





Hematological Malignancies (PNH)

PAROXYSMAL NOCTURNAL HEMOGLOBINURIA (PNH)		
	IHC Evaluation	4-5 µm thick FFPE sections on positively coated slides at room temperature.
	Morphology	FFPE tissue block at room temp. or 0.5 cm ³ fresh tissue in RPMI on dry ice.
	PNH Test (Flow)	1 Green/NaHeparin or 1 Lavender/EDTA tube (2 ml) peripheral blood or bone marrow at room temperature.
	Karyotype (G-banding)	1 Green/NaHeparin or 1 Lavender/EDTA tube (3-5 ml) peripheral blood, bone marrow or disaggregated tissue at room temperature.

Solid Tumors (Bladder, Brain, Breast)



BLADDER CANCER		
	IHC Evaluation	4-5 µm thick FFPE sections on positively coated slides at room temperature.
	Morphology	FFPE tissue block at room temp. or 0.5 cm ³ fresh tissue in RPMI on dry ice.
	PD-L1 SP142	FFPE block or a minimum of 3 FFPE sections at 3-5 µm thickness on positively coated slides at room temperature.
	UroVysion®	25-50 ml urine in a suitable container. Same day shipping or PreservCyt® should be used if the specimen will remain in transit for more than a day to ensure stability.
	Focus::Oncomine™ (NGS)	FFPE block or 5-10 FFPE sections at 10 µm thickness on positively coated slides shipped at room temperature, with H&E slide(s). Please submit 15 sections for small biopsies. The tumor tissue must be ≥ 20% tumor cells for accurate test results.





BRAIN CANCER		
	PTEN	Three 4 µm thick unstained sections on positively coated slides or FFPE tissue block at room temperature.
	1p/19q Deletion	
	Focus::Oncomine™ (NGS)	FFPE block or 5-10 FFPE sections at 10 µm thickness on positively coated slides shipped at room temperature, with H&E slide(s). Please submit 15 sections for small biopsies. The tumor tissue must be ≥ 20% tumor cells for accurate test results.
	EGFRvIII Mutation	
	IDH1 & IDH2 Mutations	
	MGMT Methylation	




BREAST CANCER		
	IHC Evaluation	4-5 µm thick FFPE sections on positively coated slides at room temperature.
	HER2 Pathway®	
	HER2 INFORM®	
	Morphology	
	HER2 PathVysion®	Three 4 µm thick unstained sections on positively coated slides or FFPE tissue block at room temperature.
	PTEN	
	Focus::Oncomine™ (NGS)	FFPE block or 5-10 FFPE sections at 10 µm thickness on positively coated slides shipped at room temperature, with H&E slide(s). Please submit 15 sections for small biopsies. The tumor tissue must be ≥ 20% tumor cells for accurate test results.
	EGFR Mutation	
	PIK3CA Mutation	
	Breast Complete™	Fifteen 4-5 µm thick FFPE unstained sections on positively coated slides or FFPE tissue block at room temperature.

Specimen Requirements

Solid Tumors (Cervical, Colorectal, Gastric)







CERVICAL CANCER		
	IHC Evaluation	4-5 µm thick FFPE sections on positively coated slides at room temperature.
	Morphology	FFPE tissue block at room temp. or 0.5 cm ³ fresh tissue in RPMI on dry ice.
	FHACT®	Liquid cytology in PreservCyt or SurePath. Specimens should be sent within 3 weeks after collection. Specimens may be shipped at room temperature (≤ 25°C). Specimen vol >10 mL.

COLORECTAL CANCER (CRC)		
	IHC Evaluation	4-5 µm thick FFPE sections on positively coated slides at room temperature.
	MMR Profile	
	Morphology	
	Focus::Oncomine™ (NGS)	FFPE block or 5-10 FFPE sections at 10 µm thickness on positively coated slides shipped at room temperature, with H&E slide(s). Please submit 15 sections for small biopsies. The tumor tissue must be ≥ 20% tumor cells for accurate test results.
	KRAS Mutation	
	NRAS Mutation	
	BRAF Mutation	
	EGFR Mutation	
	PIK3CA Mutation	
	UGT1A1 Mutation	
	cMET Gene Expression	
	EGFR Expression	
	ERCC1 Expression	
	TS Gene Expression	
	VEGFR2 Gene Expression	
	Micro-Satellite Instability	FFPE block or 10 4-5 µm thick FFPE sections on positively coated slides at room temp.
	CRC Complete™	FFPE block or 3-5 FFPE sections at 10 µm thickness containing at least 20% of tumor cells on regular unstained slides at room temperature with H&E slides.

GASTRIC CANCER		
	IHC Evaluation	3-5 µm thick FFPE sections on positively coated slides at room temperature.
	HER2 Amplification	Three 4 µm thick unstained sections on positively coated slides or FFPE tissue block at room temperature.
	Focus::Oncomine™ (NGS)	FFPE Block or 3-5 FFPE sections at 10 µm thickness containing at least 20% of tumor cells on regular unstained slides at room temperature with H&E slides.
	BRAF Mutation	
	CKIT Mutation	
	PDGFR α	
	cMET Gene Expression	
	ERCC1 Expression	
	TS Gene Expression	






Specimen Requirements

Solid Tumors (Kidney, Melanoma, Thyroid)

KIDNEY CANCER		
	IHC Evaluation	4-5 µm thick FFPE sections on positively coated slides at room temperature.
	Morphology	FFPE tissue block at room temp. or 0.5 cm ³ fresh tissue in RPMI on dry ice.
	Focus::Renal (NGS)	FFPE Tissue Block: 2 mm x 2 mm minimum tumor area, shipped at room temperature. Fresh Frozen Tissue Biopsy: minimum of 3-4 needle/core biopsies (18-gauge needle preferred) placed in a cryovial containing saline and transported in frozen condition. Fresh Frozen Tissue Resected Specimen: minimum of 0.2 cm ³ tissue, snap-frozen in a cryovial and transported in frozen condition.
	UroGenRA®-Kidney	Biopsy: minimum 3-4 needle/core biopsies (18-gauge needle) placed in a cryovial containing saline, transport frozen. (Minimum 70% tumor population). Resected Specimen: minimum of 0.2 cm ³ tissue, snap-frozen in a cryovial and transported in frozen condition. (Minimum 70% tumor population).
MELANOMA		
	IHC Evaluation	4-5 µm thick FFPE sections on positively coated slides at room temperature.
	Morphology	FFPE tissue block at room temp. or 0.5 cm ³ fresh tissue in RPMI on dry ice.
	PD-L1 28-8	FFPE block or a minimum of 3 FFPE sections at 3-5 µm thickness on positively coated slides at room temperature.
	Focus::Oncomine™ (NGS)	FFPE block or 5-10 FFPE sections at 10 µm thickness on positively coated slides shipped at room temperature, with H&E slide(s). Please submit 15 sections for small biopsies. The tumor tissue must be ≥ 20% tumor cells for accurate test results.
	BRAF cobas® Mutation	
	BRAF Mutation	
	NRAS Mutation	
	KIT Mutation	
THYROID CANCER		
	IHC Evaluation	4-5 µm thick FFPE sections on positively coated slides at room temperature.
	Morphology	FFPE tissue block at room temp. or 0.5 cm ³ fresh tissue in RPMI on dry ice.
	Focus::Oncomine™ (NGS)	FFPE block or 5-10 FFPE sections at 10 µm thickness on positively coated slides shipped at room temperature, with H&E slide(s). Please submit 15 sections for small biopsies. The tumor tissue must be ≥ 20% tumor cells for accurate test results.
	BRAF Mutation	
	KRAS Mutation	
	NRAS Mutation	


Specimen Requirements

Solid Tumors (NSCLC, TOO®)

NON-SMALL CELL LUNG CANCER (NSCLC)		
	IHC Evaluation	4-5 µm thick FFPE sections on positively coated slides at room temperature.
	Morphology	FFPE tissue block at room temp. or 0.5 cm ³ fresh tissue in RPMI on dry ice.
	ALK D5F3	FFPE block or a minimum of 3 FFPE sections at 3-5 µm thickness on positively coated slides at room temperature.
	PD-L1 28-8	
	PD-L1 22C3	
PD-L1 SP263		
	ALK Break Apart FISH Probe	FFPE block or sections at 3-5 µm thickness on positively coated slides at room temperature.
	FGFR1 (FISH)	
	MET (FISH)	
	RET (FISH)	
	ROS1 DNA-FISH Probe	
	cMET Gene Expression	FFPE block or 5-10 FFPE sections at 10 µm thickness on positively coated slides shipped at room temperature, with H&E slide(s). Please submit 15 sections for small biopsies. The tumor tissue must be ≥ 20% tumor cells for accurate test results.
	EGFR Mutation	
	EGFR cobas® Mutation	
	EML4-ALK RNA Fusion	
	ERCC1 Gene Expression	
	Focus::Oncomine™ (NGS)	
	HER2 Mutation	
	KRAS Mutation	
	ROS1 RNA Fusion	
	RRM1 Gene Expression	
	TS Gene Expression	
	VEGFR1 Gene Expression	
	Lung Complete™	FFPE tissue block or 3-5 FFPE sections at 10 µm thickness containing at least 20% of tumor cells and 5 FFPE sections at 3-5 µm thickness at room temperature.
TISSUE OF ORIGIN®		
	Tissue of Origin® [FDA-Cleared]	FFPE tissue block or one unbaked, unstained 3-5 µm section and ten unbaked, unstained 10 µm sections on positively charged glass slides, containing at least 1 mm ² of tumor at room temperature.
	Tissue of Origin® Endometrial	
	Tissue of Origin® Head & Neck	

Specimen Requirements

Pharmacogenomics and Hereditary

PHARMA GENOMICS AND HEREDITARY TESTS	
 APOE	Buccal Swabs: 3 buccal swab collection pads ejected into 2 mL cryovials labeled as 1st, 2nd, and 3rd according to collection order. Each swab should scrape all four quadrants of the patient's mouth during collection. Cryovials should be stored and shipped at -20°C.
APOL1	
CYP2C9	
CYP2C19	
CYP2D6	
UGT1A1*28	Peripheral Blood: 1 Lavender/EDTA tube (3-5 ml) peripheral blood stored and shipped at room temperature.