

Somatic Disease/Germline Comparator Exome (SDGC) Provider Guide



Introduction to Somatic Disease/Germline Comparator Exome (SDGC) Testing

The Steve and Cindy Rasmussen Institute for Genomic Medicine (IGM) Clinical Laboratory at Nationwide Children's Hospital now offers Somatic Disease/Germline Comparator Exome (Test Code: SDGC) testing for patients with known or suspected cancer, hematologic disease or somatic disorders.

Genomic characterization of a tumor or disease-involved tissue can aid in diagnosis, prognosis and medical management, helping providers make treatment decisions and evaluate eligibility for targeted therapies and clinical trials. SDGC testing can also identify germline disease predisposition.

This clinical assay returns information on small variants (single-nucleotide variants, small insertion-deletions), copy number variation (CNV), loss of heterozygosity (LOH), and tumor mutational burden (TMB).

The Institute for Genomic Medicine has optimized approaches to specimen processing, sequencing and variant interpretation in the context of pediatric and

adult cancer. Our team has analyzed thousands of individuals with cancer through clinical testing, yielding both germline and somatic medically meaningful findings to guide care.

Our expertise in performing clinical molecular characterization assays is nationally recognized, as evidenced by our selection as the testing laboratory for the Molecular Characterization Initiative, a project that aims to collect, analyze and report clinical molecular data to support Children's Oncology Group (COG)-affiliated clinicians in choosing the best treatment for each child as part of the National Cancer Institute (NCI) Childhood Cancer Data Initiative (CCDI).

The IGM Clinical Laboratory is accredited under the College of American Pathologists Laboratory Accreditation Program and certified by CLIA (Clinical Laboratory Improvement Amendments) for clinical testing.



NATIONWIDE CHILDREN'S®
When your child needs a hospital, everything matters.

Submission Requirements

DISEASE-INVOLVED AND GERMLINE SAMPLES

This test requires submission of both a disease-involved sample (somatic sample) and non-disease-involved sample (germline comparator sample) from the patient. Each submitted sample must be labeled with the full patient's name and at least one other unique patient identifier (i.e. DOB, MRN). For a complete list of genes analyzed, please see our website at <https://www.testmenu.com/nationwidechildrens>

Disease-Involved Sample(s)	Germline Sample
<i>Tumor percentage for malignant conditions:</i> The disease-involved sample must contain a minimum of 20% tumor or blast content for tumor mutational burden, single-nucleotide and small insertion-deletion variant resolution, and optimally, a minimum of 60% tumor or blast content for sensitive resolution of copy number variation (CNV) and loss of heterozygosity (LOH) to enable interpretation and reporting. Sensitivity in calling CNV and LOH will be limited, and at times, assay resolution of these events will preclude interpretation and reporting of CNV and LOH if the submitted specimen contains less than 60% disease-content. In some contexts, the ability to report TMB may be tumor specimen dependent. Please contact the laboratory for further information. <i>Specimen types:</i> One of the following types of specimens is required: • 10-15 FFPE slides (5-10 microns thick) and adjacent H&E slide (preferred). • Frozen tissue (30-50 mg). • Fresh tissue (30-50 mg). • FFPE tissue block. • 10-15 FFPE scrolls (5-10 microns thick) and adjacent H&E slide. • Involved bone marrow (4 mL EDTA). • Involved whole blood (4 mL EDTA). FFPE specimens processed using strong acid decalcification are not acceptable; EDTA and Formalin are accepted. Testing will be attempted on samples not meeting minimal tissue criteria if nucleic acid requirements are met. <i>Disease timepoints:</i> Multiple disease timepoints may be submitted for testing. Additional charges will be applied.	<i>Specimen type:</i> One of the following types of specimens is required: • Whole blood (4 mL EDTA). (This type is preferred.) • Saliva (two collection tubes). • Buccal swabs (four swabs). Please contact the laboratory if the patient has a history of allogeneic bone marrow transplantation to discuss options for the comparator normal sample.

REQUISITION

Please complete the Oncology Genetic Test Requisition Form in its entirety.

Prior Authorization/Billing

- For insurance preauthorization for SDGC testing, use CPT codes 81415 and 81416.
- Under billing information, select Institutional Bill and complete send-out laboratory information for billing.

PATHOLOGY REPORT

A pathology report is required for every disease-involved specimen. If multiple disease timepoints are submitted, multiple pathology reports are required.

Submission Checklist

Please ensure all the items below are completed and ready before submission.

✓ Completed	REQUIRED MATERIAL
	Disease-Involved Sample
	Germline Sample
	Requisition
	Pathology Report (for <u>EVERY</u> disease timepoint)

Submission Instructions

Once all required materials are gathered and completed, send them through your institution's send-out lab to Nationwide Children's Hospital Laboratory at the address below. Please contact the Institute for Genomic Medicine via phone or email to inform our team about your shipment.

Nationwide Children's Hospital Laboratory
700 Children's Drive
Room C1955
Columbus, OH 43205

Email: IGMCytoMGLAccessioning@NationwideChildrens.org

Phone: (614) 722-5321



NATIONWIDE CHILDREN'S

When your child needs a hospital, everything matters.™

Laboratory Client Services

Tel: (614) 722-5477 / (800) 934-6575

NationwideChildrens.org/Lab

Oncology Genetic Test Requisition Form

Institute for Genomic Medicine (IGM) Clinical Laboratory

Tel: (614) 722-5321 / Fax: (614) 722-5471

Ship Samples to: Nationwide Children's Laboratory Services

700 Children's Drive, Room C1955

Columbus, OH 43205 U.S.A.

PATIENT INFORMATION (Please Print or Place ID Label)

Last Name		First Name		MI
Date of Birth (DOB)	Sex Assigned at Birth Male Female Unknown	Gender Identity	Patient ID #/ MRN	
Street Address		City	State	Zip

ORDERING PHYSICIAN INFORMATION (Please Print)

Ordering Physician Name (REQUIRED)	Phone (REQUIRED)	Fax (REQUIRED)	NPI #
Attending Physician Information - REQUIRED if Ordering Physician is a Trainee (e.g. Resident, Fellow)			
Attending Physician Name	Phone	Fax	NPI#
Institution / Practice / Facility Name			
Street Address		City	State
			Zip/Postal Code
Physician Email (REQUIRED if sending from outside U.S.A.)		Country (if not U.S.A.)	
Ordering Physician Signature X		Date	

ADDITIONAL REPORT TO SENDOUT LABORATORY (Please Print):

Name	Phone	Fax
------	-------	-----

ICD-10 / CLINICAL DIAGNOSIS /SPECIAL INSTRUCTIONS

ICD-10 Codes (REQUIRED)	Clinical Diagnosis (REQUIRED)	Age of Onset
Special Instructions / Notes		Has the patient had a bone marrow transplant? (REQUIRED) No Yes - Autologous (self) Yes - Allogeneic (donor)

SAMPLE INFORMATION (Please List All Samples Being Submitted with This Form)

Please check sample requirements and exclusions for each test on website Nationwidechildrens.org/Lab.

Each submitted sample must be labeled with the name and at least one secondary identifier (e.g. MRN, DOB, SPID). Insufficiently labeled samples will require a signed specimen identification waiver and may result in delayed processing and/or reporting.

Submitted samples will be consumed as needed to complete the requested testing which may result in depletion of submitted samples.

- Bone marrow and Blood samples:** Collect 4 mL of bone marrow/disease involved blood sample in EDTA tube Ship overnight at room temperature. Samples must arrive in the laboratory within 48 hours from collection.
- Tissue samples:** Tissue scrolls must be accompanied by H&E slide. Any H&E slide submitted with tumor sample must be from a consecutive cut from the submitted tumor section. Fresh tissue sample must arrive the laboratory within 48 hours from collection.

New York State Collected Specimens:

Please select this box and include the New York State Required Healthcare Provider Statement if NY state approved test (see website).

Tumor / Involved Sample: Sample contains _____ % tumor nuclei / blasts ☐ Bone marrow ☐ Involved peripheral blood ☐ Fresh tissue ☐ Snap-frozen tissue ☐ OCT-embedded tissue ☐ FFPE tissue block ☐ FFPE tissue scrolls <u>and</u> consecutively cut H&E slide ☐ Other _____ ☐ FFPE unstained slides <u>and</u> consecutively cut H&E slide	Collection Date	Sample Time Point: ☐ Diagnosis ☐ Relapse ☐ Post-Treatment Day _____
Normal Sample: Normal sample must contain 0% tumor nuclei / blasts ☐ Uninvolved peripheral blood ☐ Saliva ☐ Buccal swab ☐ Other Tissue (specify): _____	Collection Date	Time

REQUIRED: A copy of the Pathology Report is required for each submitted tumor sample – if the report is not finalized, include a preliminary report with the sample submission and then fax the finalized report to 614-722-5471, once available. Failure to provide a finalized pathology report may result in a delayed test processing and/or result reporting.



NATIONWIDE CHILDREN'S

When your child needs a hospital, everything matters.™

Laboratory Client Services

Tel: (800) 934-6575 / NationwideChildrens.org/Lab

Patient Name (or place patient ID label)

Last, First _____

DOB or MRN _____

BILLING INFORMATION

■ INSTITUTIONAL BILL (Please Print)

Contact Name:	Phone	Fax	
Email Address (REQUIRED if sending from outside U.S.A.)			
Institution / Hospital / Laboratory Name			
Street Address			
City	State / Province	Zip Code	Country
☐ Send a result copy to sending institution via: ☐ Above Fax number ☐ Above Email address ☐ Other Fax/Email _____			
Other information:			

TEST SELECTION

*Internal pathology review by Nationwide Children's pathologist will be performed on submitted samples to assess for tumor/blast content.

CNS / BRAIN TUMOR

☐ CNS Tumor Classification by Methylation Array [CTCMA]

***At least 60% tumor** must be present in the submitted sample (based on internal pathology review).
FFPE tissue is Preferred

SOLID TUMOR

☐ Somatic Disease RNA Sequencing [SDRNA]

Diagnosis Category: ☐ Solid Tumor or ☐ CNS

Identifies gene fusions in CNS and non-CNS solid tumors (see website for additional information)..

***At least 10% tumor** must be present in the submitted **Fresh, Snap-frozen, OCT, or Bone marrow** samples.

***At least 25% tumor** must be present in the submitted **FFPE tissue block or unstained slides** (based on internal pathology review). Sample acquisition **PRIOR TO** receiving treatment is strongly preferred.

***For NY State Clients:**
Solid Tumor Fusion
Analysis performed
[TUMFUSN]

SOMATIC DISEASE/GERMLINE COMPARATOR EXOME

☐ Somatic Disease/Germline Comparator Exome [SDGC]

Submission of a disease-involved sample **AND** an unaffected comparator sample is **REQUIRED**.

***For malignant disease, at least 20% tumor content/blasts** must be present in the submitted affected sample for single-nucleotide and small insertion-deletion variant resolution and reporting (based on pathology review).

***For malignant disease, at least 60% tumor content/blasts** must be present in the submitted affected sample for sensitive resolution of copy number variation (CNV) and loss of heterozygosity (LOH) to enable interpretation (based on pathology review). Sensitivity in calling CNV and LOH will be limited, and at times, assay resolution of these events will preclude interpretation and reporting of CNV and LOH, if the submitted specimen contains less than 60% disease-content

Checklist of Required Items: ☐ Disease-involved sample ☐ Unaffected sample



NATIONWIDE CHILDREN'S

When your child needs a hospital, everything matters.™

Laboratory Client Services

Tel: (800) 934-6575 / NationwideChildrens.org/Lab

Patient Name (or place patient ID label)

Last, First _____

DOB or MRN _____

Please check sample requirements and exclusions for each test on website Nationwidechildrens.org/Lab.

Ship Samples and Completed Test Requisition Form to:

Nationwide Children's Hospital Laboratory

700 Children's Drive, Room C1955

Columbus, OH 43205 U.S.A.

- Ship samples via Overnight Courier. Samples must arrive at the laboratory within 48 hours. Saturday deliveries accepted. Please check "Saturday Delivery" on shipment label.
- For questions regarding testing, specimen requirements or transport, please call the IGM Clinical Laboratory at (614) 722-5321 or Lab Client Services at (800) 934-6575.

Sample Return Request:

Tissue blocks will be returned after testing is complete if there is remaining sample. Provide return details below:

Ship Back to: **Name:** _____ **Phone:** _____

Address: _____

Contact Us

**Steve and Cindy Rasmussen Institute for Genomic Medicine
Nationwide Children's Hospital**

Phone: (614) 722-5321

Email: IGMCytoMGLAccessioning@NationwideChildrens.org

Web: NationwideChildrens.org/Specialties/Institute-for-Genomic-Medicine





NATIONWIDE
CHILDREN'S®

When your child needs a hospital, everything matters.