

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 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.

Testing reports include details about copy number variation (CNV), regions demonstrating loss of heterozygosity (LOH), small single-nucleotide variants and small insertion-deletion events.

The Steve and Cindy Rasmussen Institute for Genomic Medicine has optimized approaches to specimen processing, sequencing and variant interpretation in

the context of pediatric 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 sequencing site 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.



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
<p><i>Tumor percentage for malignant conditions:</i> The disease-involved sample must contain a minimum of 20% tumor or blast content for single-nucleotide and small insertion-deletion variant resolution OR 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.</p> <p><i>Specimen types:</i> One of the following types of specimens is required:</p> <ul style="list-style-type: none"> • 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). <p style="margin-left: 20px;">Acid decalcified samples are not acceptable for this testing. Samples processed with EDTA decalcification can be attempted.</p> <p><i>Disease timepoints:</i> Multiple disease timepoints may be submitted for testing. Additional charges will be applied.</p>	<p><i>Specimen type:</i> One of the following types of specimens is required:</p> <ul style="list-style-type: none"> • Whole blood (4 mL EDTA). (This type is preferred.) • Saliva (two collection tubes). • Buccal swabs (four swabs). <p>Please contact the laboratory if the patient has a history of allogeneic bone marrow transplantation to discuss options for the comparator normal sample.</p>

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

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	SSN	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 (Please Print)					
Name <input type="checkbox"/> Physician <input type="checkbox"/> Lab <input type="checkbox"/> Other		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.					
<ul style="list-style-type: none"> Acid decalcified samples are NOT ACCEPTED. Bone marrow and Blood samples: Collect 4 mL of bone marrow or involved blood sample into 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/frozen tissue sample must arrive the laboratory within 48 hours from shipping. 					
Tumor / Involved Sample: Sample contains _____ % tumor/blasts <input type="checkbox"/> Bone marrow <input type="checkbox"/> Involved peripheral blood <input type="checkbox"/> Fresh tissue <input type="checkbox"/> Snap-frozen tissue <input type="checkbox"/> OCT-embedded tissue <input type="checkbox"/> FFPE tissue block <input type="checkbox"/> FFPE tissue scrolls <u>and</u> consecutively cut H&E slide <input type="checkbox"/> Other _____			Collection Date	Sample Time Point:	
			Time	<input type="checkbox"/> Diagnosis <input type="checkbox"/> Relapse <input type="checkbox"/> Post-Treatment Day _____	
Normal Sample: Normal sample must contain 0% tumor/blasts <input type="checkbox"/> Bone marrow <input type="checkbox"/> Peripheral blood <input type="checkbox"/> Fresh tissue <input type="checkbox"/> Snap-frozen tissue <input type="checkbox"/> OCT-embedded tissue <input type="checkbox"/> FFPE tissue block <input type="checkbox"/> FFPE tissue scrolls <u>and</u> consecutively cut H&E slide <input type="checkbox"/> Uninvolved peripheral blood <input type="checkbox"/> Other _____			Collection Date	Sample Time Point:	
			Time	<input type="checkbox"/> Diagnosis <input type="checkbox"/> Relapse <input type="checkbox"/> Post-Treatment Day _____	
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 can 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
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Email Address (REQUIRED if sending from outside U.S.A.)

Institution / Hospital / Laboratory Name

Street Address

City	State / Province	Zip Code	Country
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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 sample(s) for tumor content assessment.

CNS / BRAIN TUMOR

CNS Tumor Classification by Methylation Array [test code: CTCMA]
**At least 60% tumor must be present in the submitted sample (based on internal pathology review).
 Snap-frozen tissue is Preferred*

SOLID TUMOR

Solid Tumor Fusion Analysis by NGS [test code: TUMFUSN]
 Identifies gene fusions for 115 genes (see website for list of all gene partners).
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 FFPE tissue scrolls**
 (based on internal pathology review). Sample acquisition PRIOR TO receiving treatment is strongly preferred.*

SOMATIC DISEASE/GERMLINE COMPARATOR EXOME

Somatic Disease/Germline Comparator Exome [test code: SDGC]
 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



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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: _____

Lab Use Only — Sample Received by the Lab on:

Date: _____

Time _____

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



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