Laboratory Client Services
Tel: (614) 722-5477 / (800) 934-6575
NationwideChildrens.org/Lab

New York State 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	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 Physican 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 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 tissue sample must arrive the laboratory within 48 hours from collection.

Tumor / Involved Sample: Sample contains _____ % tumor nuclei / blasts	Collection Date Time	Sample Time Point:
☐ Bone marrow ☐ Involved peripheral blood ☐ Fresh tissue ☐ Snap-frozen tissue ☐ OCT-embedded tissue ☐ FFPE tissue block ☐ FFPE tissue scrolls and consecutively cut H&E slide ☐ Other_____ ☐ FFPE unstained slides and consecutively cut H&E slide		☐ Diagnosis ☐ Relapse ☐ Post-Treatment Day_____

Normal Sample: Normal sample must contain 0% tumor nuclei / blasts	Collection Date Time	Sample Time Point:
☐ Bone marrow ☐ Peripheral blood ☐ Fresh tissue ☐ Snap-frozen tissue ☐ OCT-embedded tissue ☐ FFPE tissue block ☐ FFPE tissue scrolls and consecutively cut H&E slide ☐ Uninvolved peripheral blood ☐ Other_____		☐ Diagnosis ☐ Relapse ☐ 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.

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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 _____

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 may be performed on submitted samples to assess for tumor/blast content.

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 151 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, scrolls, or unstained slides** *(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]
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

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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: _____

_____

_____

Nationwide Children's Laboratory Services
Institute for Genomic Medicine (IGM) Clinical Laboratory
700 Children's Drive, Columbus, OH 43240
Phone: (614) 722-5321 / FAX: (614) 722-5471
Website: NationwideChildrens.org/Lab

New York State Required Healthcare Provider Statement for Somatic Disease/Germline Comparator Paired Exome Genomic Profiling

This form is REQUIRED for New York State specimens and must be signed by the ordering Healthcare Provider to demonstrate consent for the comprehensive genomic sequencing analysis of a comparator sample and of a sample affected by acquired (somatic) disease, such as a tumor, diseases of blood cells, or suspected mosaicism.

Patient Name: _____

Patient DOB: _____

Patient MRN: _____

Or Place a Patient ID Label Here

(Label Must Contain the Name and DOB)

Note: The words "you" and "your" are used in this consent form. These words refer to the patient for which this test is being performed, whether a child or an adult.

Your healthcare provider has recommended a genetic test called Somatic Disease/Germline Comparator (SDGC) Paired Exome Genomic Profiling as part of a medical evaluation. This test is complex and can give you many types of results. **It is recommended to have genetic counseling prior to signing this informed consent form, and after results have been issued.** If you agree to have the test, you will be asked to sign at the end of this form to show that you understand the information. Although your healthcare provider suggested this testing, it is your choice to have the test. A copy of this signed form can be provided upon request.

Please review each statement below. If you have questions or need help understanding the information, please tell the healthcare provider ordering this test, so your questions can be answered.

What Is Somatic Disease Germline Comparator (SDGC) Genomic Profiling?

- SDGC looks for variants in a person's DNA that may cause or contribute to their medical condition.
- Everyone is born with variants in their DNA; these are called "germline" variants. Variants can also occur during fetal development or after birth. These variants are called "acquired" variants and may only be found in certain parts of the body, a concept known as "mosaicism". Acquired variants can also occur in cancers or blood disorders. These are called "somatic" variants.
- This SDGC test is interpreted by comparing a disease-involved (somatic) sample and a non-diseased (germline) sample.
- Finding a variant(s) in the disease-involved (somatic) sample may help diagnose or predict the course of the disease and may help you and your doctor decide on the best management or treatment of the disease.
- Finding a variant(s) in the non-diseased (germline) sample may also inform the need for follow-up testing and counseling of at-risk family members.
- For additional information about this test including sample requirements and turnaround time, visit https://www.testmenu.com/nationwidechildrens.

What Types of Results Will be Reported from SDGC Testing?

The test report will list and describe variants found in your DNA that may be related to the reason for testing. Based on what is known in the medical literature at the time of testing, variants are categorized into the following:

- ***Disease-associated findings*** — Somatic or germline variant(s) that are known to cause or contribute to your current medical condition, these are classified as pathogenic or likely pathogenic variants.
- ***Findings of uncertain significance*** — Somatic or germline variant(s) that are not known to cause or contribute to a current medical condition, these are classified as variants of uncertain significance (VUS).
- Additionally, it is possible that these tests may not find any variants related to your medical condition, a "negative" result. This does not rule out a genetic cause for your medical condition, but with current knowledge and technologies we cannot identify a specific genetic change(s) causing or contributing to your condition.

The following variants will NOT be reported:

- Variants in genes that are not directly related to the patient's clinical indication for testing.
- Variants in genes that cause adult-onset neurological disorders, such as dementia, unless the variant(s) may explain some or all the patient's current symptoms.
- Pharmacogenomic variants, which are findings in genes that affect a person's response to medications.
- Variants that are normal genetic variations in the population (benign or likely benign variants).

Place a Patient ID Label, or

Name: _____

DOB: _____

What Is the Accuracy and What Are Limitations of This Test?

Accuracy of these results depends on: (1) the quality and type of sample sent to the laboratory; (2) the way the test is performed and analyzed by the laboratory; (3) the accuracy of medical information provided to the laboratory. Inaccurate or incomplete medical information may lead to inaccurate results. ***The interpretation of the genetic variants is based on information available at the time of testing and may change in the future due to medical advancements.*** Limitations of testing include:

- A chance of error or test failure.
- Not all genes involved in human genetic disorders are known, and not all genetic variants can be found by this testing.
- All the genes present in human DNA are not tested, nor does SDGC test all parts of known genes.
- Certain types of genetic abnormalities cannot be found by this test but can still cause disease.
- It is possible that your medical condition has a non-genetic cause.

Possibility of Test Result Interpretation Changing Over Time

In the future, the laboratory may learn new information about variants, which may change the variant classification. If significant, the laboratory may issue an updated report to the ordering healthcare provider and/or other healthcare provider(s) involved in your medical care. Review of the entire test data (called reanalysis) will not be done for these updated reports. Full reanalysis is only available with additional charges and requires a new test order from a healthcare provider.

Who Will Receive the Results from This Test?

The patient's report will go into their confidential electronic medical records and sent to the ordering provider(s). Lab results may be available right away through MyChart and may be seen before a provider has reviewed them. With genetic testing, a provider often needs to do more investigation into the finding(s) to best explain them. You should always discuss the SDGC results with the ordering provider. All results are confidential and will not be reported to others without your written consent, unless otherwise required by law.

What Are Potential Risks and Consequences of This Test?

- Genetic test results could have importance for additional family members; testing of other family members may be recommended.
- It is possible to learn genetic information about you and/or your family that is not directly related to the reason for ordering SDGC testing. This information might relate to diseases with symptoms that may develop in the future in you or other family members, as well as conditions with no current treatment.
- The SDGC test results and data will be kept as part of the medical record in a secure computer environment. A very small risk exists for data to be unintentionally released to an unsecure environment.

Information about Genetic Discrimination

At this time, there are federal laws in place that prevent health insurers and most employers from discriminating based on genetic information, such as the Genetic Information Nondiscrimination Act (GINA) of 2008. It is possible that this law, like any other, may become less or more protective in the future. There are currently no federal laws that prohibit life insurance, long-term care, or disability insurance companies from discriminating based on genetic information. Different states may have more comprehensive laws about preventing discrimination based on genetic test results. GINA does not apply to the US armed forces or employers with fewer than 15 employees.

Cost and Financial Responsibility for This Test

The approximate cost of this test, the billing process, and the option of insurance preauthorization should be discussed with the ordering healthcare provider. Insurance plans may or may not cover this test or pay for this test depending on the individual insurance plan. Additional programs may be available to help pay for this test.

Information about Result Data Sharing and Publication

The SDGC results, data, and clinical information (such as age, sex, and medical symptoms) may be shared with the medical and scientific community **after all personal identifying information is removed**. Data sharing and publication are done to improve genetic test result interpretation for future patients and to help understand how different genetic variants relate to medical symptoms.

- Information on variant(s) and/or DNA sequencing data, along with patient clinical information, may be recorded in public databases and/or restricted controlled-access databases.
- Although all personal identifying information will be removed from shared data if sent to public and controlled-access databases, it may be possible to identify a person by comparing their DNA sequencing data to information available in genetic/ancestry databases.
- Results from this testing may be published in the medical literature, as well as the combined results from testing of many patients. These publications *will not* include any personal identifying information, unless a separate consent to allow this is obtained.

Nationwide Children's IGM may analyze compiled sequencing data from many patients for quality assurance or to assess test performance. Results may be published in the medical literature without personal identifying information.

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Place a Patient ID Label, or

Name: _____

DOB: _____

Option for Sample Retention

Please carefully read the statements below, check one box and initial next to it to make your choice. Testing cannot be processed until the reporting choice below is completed and submitted to the laboratory. **If the patient is under 18 years of age or is unable to give consent, then the "Patient" section must be initialed and signed by a parent or legal guardian.** If consented by phone or virtually, mark the box chosen by the family and put consenter's initials, and write "consented by phone" or "consented virtually" (i.e. telemedicine) on the signature line.

Check Box & Initial	**Sample Retention (Storage)**
☐_____	**YES**: I give permission for Nationwide Children's Hospital to store all samples remaining from this test (such as tissue, blood, DNA, and RNA from both somatic and germline samples) for possible future testing.
☐_____	**NO**: I DO NOT want Nationwide Children's Hospital to store any samples remaining from this test (including tissue, blood, DNA, or RNA). I understand that the remaining germline sample will be destroyed within 60 days from the collection date.

Signatures

Patient/Parent/Legal Guardian Signature to Consent for the Patient's Testing:

I have read or have had someone read to me all the above statements and understand the information about this testing. I have had the chance to ask questions about the test, the procedure, the risks, and the alternatives to this test before I give my informed consent. I hereby authorize Nationwide Children's Hospital to perform the SDGC test and retain the samples received according to the Sample Retention option that has been selected above.

Signature: _____ Date: _____ Time: _____

Printed Name: _____ Relationship to Patient: _____

Ordering Healthcare Provider or Qualified Healthcare Provider Signature:

I have explained the testing, limitations, consent, and implications of SDGC testing to the patient, parents, and/or legal guardians and have witnessed the consents documented above. I accept responsibility for receiving this test result and will ensure that genetic counseling is provided upon delivery of the test results.

Healthcare Provider Signature: _____ Date: _____ Time: _____

Printed Name: _____

Witness Healthcare Provider (required if consenting remotely): ☐ **N/A – consent obtained in person**

Witness Signature: _____ Date: _____ Time: _____

Printed Name: _____

A signed copy of this form should be given to the Patient/Parent/Guardian