# Pediatric Oncology
# Genetic Test Requisition Form

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

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

**Institute for Genomic Medicine (IGM) Clinical Laboratory**
Tel: (614) 722-2866 / Fax: (614) 722-2887

**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 ☐ Male ☐ Female | 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 |
|---|---|---|---|
| | | | |

Physician Email **(REQUIRED if sending from outside U.S.A.)**

| Physican Signature<br>**X** | Date |
|---|---|
| | |

## ADDITIONAL REPORT TO (Please Print)

| Name<br>☐ Physician ☐ Lab ☐ Other | Phone | Fax |
|---|---|---|
| | | |

## DIAGNOSIS / ICD-10 / CLINICAL INFORMATION

Diagnosis / ICD-10

Other Clinical Information / Special Instructions

## SAMPLE INFORMATION (List each sample submitted with this form) - REQUIRED

| | | | |
|---|---|---|---|
| **SAMPLE 1**<br>**Type:** _____<br>☐ Tumor sample with _____ % tumor/blasts<br>☐ Normal sample<br>❑ This sample may be depleted for testing if necessary | Time Point (diagnosis, relapse, day 28, etc) | Collection Date: | ☐ This is a banked COG sample<br>COG #: _____ |
| **SAMPLE 2**<br>**Type:** _____<br>☐ Tumor sample with _____ % tumor/blasts<br>☐ Normal sample<br>❑ This sample may be depleted for testing if necessary | Time Point (diagnosis, relapse, day 28, etc) | Collection Date: | ☐ This is a banked COG sample<br>COG #: _____ |
| **SAMPLE 3**<br>**Type:** _____<br>☐ Tumor sample with _____ % tumor/blasts<br>☐ Normal sample<br>❑ This sample may be depleted for testing if necessary | Time Point (diagnosis, relapse, day 28, etc) | Collection Date: | ☐ This is a banked COG sample<br>COG #: _____ |

**REQUIRED: A copy of *Pathology Report* is required for each submitted tumor sample – attach a preliminary report if final report is not available. *Failure can result in a delayed test processing and/or result reporting*.**

**To request a return of submitted tissue blocks/unused samples/slides, complete all fields below:**

Ship Back to: **Name**: _____ **Phone**: _____
**Address**: _____
_____
**FedEx Account # to use for bill for shipping (REQUIRED):** _____

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**Patient Name (or place patient ID label)**

Last, First_____

DOB or MRN_____

# BILLING INFORMATION

- Insurance bill option is only available for patients/insurance plans within the state of Ohio. For insurance bill, please attach the front and back copy of the patient's insurance card and complete the "Ohio Insurance Bill" section below
- For out-of-Ohio patients/insurance plans, we only accept institutional bill. We **DO NOT** insurance bill for patients/insurance plans outside of Ohio
- For **INTERNATIONAL** samples referred from outside the U.S.A. or Canada, we only accept institutional bill. Pre-payment or agreement of payment must be made **PRIOR TO** sending the sample. Payment can be made by wire transfer or by credit card. To arrange payment, please email *LaboratoryBilling@NationwideChildrens.org*
- We **DO NOT** offer Self-pay option at this time
- Please contact Laboratory Client Services for more information at 1-800-934-6575

## ☐ INSTITUTIONAL BILL (Please Print) – REQUIRED for *Out-of-State* and *International* Samples

| Contact Name: | Phone | Fax |
|---|---|---|
| Email Address **(REQUIRED if sending from outside U.S.A.)** | | |
| Institution / Hospital / Laboratory Name | | |
| Street Address | | |

| City | State | Zip Code | Country |
|---|---|---|---|
| | | | |

☐ **Send a result copy to sending institution via:**
☐ Above Fax number ☐ Above Email address ☐ Other Fax/Email_____

Other information:

## ☐ OHIO INSURANCE BILL (Please Print) – Option Only for Ohio Patients/Insurance Plans
Please Attach a Front and Back Copy of Insurance Card

| Legal Guardian Last Name | Legal Guardian First Name, MI | Legal Guardian DOB |
|---|---|---|
| Legal Guardian SSN | Relationship to Patient ☐ Self ☐ Spouse ☐ Parent ☐ Other_____ | |
| Subscriber Last Name | Subscriber First Name, MI | Subscriber DOB |
| Subscriber SSN | Employer | |
| Insurance Co. Name | Policy # | Group # |

| Insurance Address | City | State | Zip |
|---|---|---|---|
| | | | |

Secondary Insurance Co. Name

## PATIENT CONSENT FOR INSURANCE BILL

I will fully abide with Nationwide Children's Hospital Laboratory Services by providing all necessary documents needed for insurance billing and appeals. I understand that I am responsible for the payment of this test whether through my insurance company or myself.

**Patient Signature:** X_____

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## ACUTE LYMPHOBLASTIC LEUKEMIA (ALL) TESTING

### B-ALL Fusion Detection Tests

☐ **Targeted B-ALL Fusion Analysis** (ALLFUSN)
This test detects gene fusions that have the following genes as the 3' kinase fusion partner: *ABL1, ABL2, BLNK, CSF1R, EPOR, FGFR1, FLT3, JAK2, NTRK3, PDGFRA, PDGFRB, PTK2B* and *TYK2*. This test will also detect some, but not all, *IGH-CRLF2* gene fusion. *Detected fusion partners are confirmed by singleplex RT-PCR with Sanger sequencing.*

☐ **Single Kinase Fusion Detection by Singleplex RT-PCR** (KINFS)
This test detects a specific single gene fusion.
**Specify gene fusion — Gene #1 (5' Fusion Partner):**_____
**Gene #2 (3' Fusion Partner):**_____

**At least 10% blasts must be present in the submitted sample (based on internal pathology review)*

Liquid Tumor Type:
☐ *Banked COG sample (provide COG # on page 1)*
☐ *Bone marrow (4mL EDTA)†*
☐ *Involved peripheral blood (4mL EDTA)†*

† **Bone marrow and Blood samples:** Collect 4 mL of bone marrow or involved peripheral blood into EDTA tube. Transfer sample into conical vial containing 2 mL of COG ALL shipping media. If COG ALL shipping media is unavailable please send in tissue culture or transport media. Ship overnight at room temperature. Must arrive the lab within 48 hours from collection.

☐ ***IL7R* Targeted Sequencing** (IL7R)
**At least 50% blasts must be present in the submitted tumor sample (based on internal pathology review). Submission of a normal sample (containing 0% tumor) is recommended but not required.*

1) Liquid Tumor Type:
☐ *Banked COG sample (provide COG # on page 1)*
☐ *Bone marrow (4 mL EDTA)*
☐ *Involved peripheral blood (4 mL EDTA)*

2) Normal Sample Type:
☐ *Banked COG (provide COG # on page 1)*
☐ *Uninvolved peripheral blood (4 mL EDTA)*
☐ *Other (specify):*_____

☐ ***JAK1 & JAK2* Targeted Sequencing** (JAK12)
Please note: this test does **NOT** include the JAK2 V617F mutation commonly seen in myeloproliferative disorders.

**At least 50% blasts must be present in the submitted tumor sample (based on internal pathology review). Submission of a normal sample (containing 0% blast) is recommended but not required.*

1) Liquid Tumor Type:
☐ *Banked COG sample*
☐ *Bone marrow (4 mL EDTA)*
☐ *Involved peripheral blood (4 mL EDTA)*

2) Normal Sample Type:
☐ *Banked COG sample*
☐ *Uninvolved peripheral blood (4 mL EDTA)*
☐ *Other (specify):*_____

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FFPE = Formalin-fixed Paraffin-embedded ; Tissue scrolls *MUST* be accompanied by H&E slide from a consecutive cut

## GLIOMA TESTING

☐ ***BRAF V600 Mutation Analysis*** (BRAFV600)
**At least 40% tumor* must be present in the submitted tumor sample (based on internal pathology review).*

Tumor Tissue Type: ☐ *Snap-frozen (preferred)* ☐ *Fresh*
☐ *FFPE tissue block* ☐ *FFPE tissue scrolls **AND** H&E slide*
☐ *OCT-embedded tissue block*

***NOTE:** Our lab does not offer BRAF-KIAA1549 fusion detection test unless the patient had previous positive result from another research/clinical lab. We only offer confirmatory testing, done under "RT-PCR Fusion Confirmation" test.*

## MEDULLOBLASTOMA TESTING

☐ ***CTNNB1* (Beta-Catenin) Exon 3 Sequencing** (CTNE3)
**At least 40% tumor* must be present in the submitted tumor sample (based on internal pathology review). Submission of a normal sample (containing 0% tumor) is recommended but not required.*

1) Tumor Tissue Type: ☐ *Banked COG sample (provide COG # on page 1)*
☐ *Snap-frozen (preferred)* ☐ *Fresh*
☐ *FFPE tissue block* ☐ *FFPE tissue scrolls **AND** H&E slide*
☐ *OCT-embedded tissue block*

2) Normal Sample Type: ☐ *Banked COG sample (provide COG # on page 1)*
☐ *Uninvolved peripheral blood (4 mL EDTA)*
☐ *Other (specify):*_____

☐ ***MYCN (N-MYC)* and *MYC (C-MYC)* Amplification by FISH** (FISHTUMOR)

Tumor Tissue Type: ☐ *Banked COG sample (provide COG # on page 1)*
☐ *Snap-frozen* ☐ *Fresh*
☐ *FFPE tissue block (undecalcified)* ☐ *FFPE unstained slides (6 slides, 3 micron, undecalcified)*
☐ *OCT-embedded tissue block* ☐ *Involved bone marrow (4 mL EDTA)*

## SOFT TISSUE SARCOMA TESTING

**Soft Tissue Sarcoma Tumor Analysis by RT-PCR** (RTPCR)
**Fusion partners are confirmed by DNA sequence analysis of the RT-PCR product*

☐ **Full Panel (includes all listed below)**

or Specific RT- PCR for the following selected sarcoma types:

☐ **Ewing sarcoma** *EWS-FLI-1* and *EWS-ERG* fusions [t(11;22)(q24;q12) and t(21;22)(q22;q12)]
☐ **Alveolar rhabdomyosarcoma** *PAX3-FOXO1* and *PAX7-FOXO1* fusions [t(2;13)(q35;q14) and t(1;13)(p36;q14)]
☐ **Synovial sarcoma** *SYT-SSX1/SSX2* fusion [t(X;18)(p11.2;q11.2)]
☐ **Desmoplastic small round cell tumor** *EWS-WT1* fusion [t(11;22)(p13;q12)]
☐ **Congenital fibrosarcoma/cellular mesoblastic nephroma** *ETV6-NTRK3* fusion [t(12;15)(p13;q25)]

Tumor Tissue Type: ☐ *Snap-frozen (preferred)* ☐ *Fresh* ☐ *OCT-embedded tissue block*
** FFPE tissues are **NOT ACCEPTED** for this test*

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## NEUROBLASTOMA TESTING

☐ **Targeted Oncology Microarray Analysis** (TONCMA) — LOH and Copy Number Abnormality Detection
***Both tumor sample AND normal sample (containing 0% tumor) are REQUIRED.**
**At least 40% tumor must be present in the submitted tumor sample (based on internal pathology review)*

1) Tumor Tissue Type:
- ☐ *Banked COG sample (provide COG # on page 1)*
- ☐ *Snap-frozen (preferred)*
- ☐ *Fresh*
- ☐ *FFPE tissue block*
- ☐ *FFPE tissue scrolls **AND** H&E slide*
- ☐ *OCT-embedded tissue block*
- ☐ *Involved bone marrow (4 mL EDTA)*

2) Normal Sample Type:
- ☐ *Banked COG sample (provide COG # on page 1)*
- ☐ *Uninvolved peripheral blood (preferred; 4 mL EDTA)*
- ☐ *Snap-frozen*
- ☐ *Fresh*
- ☐ *FFPE tissue block*
- ☐ *FFPE tissue scrolls **AND** H&E slide*
- ☐ *OCT-embedded tissue block*
- ☐ *Other (specify):*_____

☐ ***MYCN (N-MYC)* Amplification by FISH** (FISHTUMOR)

Tumor Tissue Type:
- ☐ *Banked COG sample (provide COG # on page 1)*
- ☐ *Snap-frozen*
- ☐ *Fresh*
- ☐ *FFPE tissue block (undecalcified)*
- ☐ *FFPE unstained slides (6 slides, 3 micron, undecalcified)*
- ☐ *OCT-embedded tissue block*
- ☐ *Involved bone marrow (4 mL EDTA)*

☐ ***ALK* Amplification by FISH** (FISHALK) **& *ALK* Targeted Sequencing** (ALK)
**At least 40% tumor must be present in the submitted tumor sample (based on internal pathology review).* Submission of a normal sample (containing 0% tumor) is recommended but not required.

1) Tumor Tissue Type:
- ☐ *Banked COG sample (provide COG # on page 1)*
- ☐ *Snap-frozen (preferred)*
- ☐ *Fresh*
- ☐ *FFPE tissue block (undecalcified)*
- ☐ *OCT-embedded tissue block*
- ☐ *Involved bone marrow (4 mL EDTA)*

2) Normal Sample Type:
- ☐ *Banked COG sample (provide COG # on page 1)*
- ☐ *Uninvolved peripheral blood (preferred; 4 mL EDTA)*
- ☐ *Snap-frozen (preferred)*
- ☐ *Fresh*
- ☐ *FFPE tissue block (undecalcified)*
- ☐ *OCT-embedded tissue block*
- ☐ *Other (specify):*_____

☐ **DNA Ploidy Analysis** (DNAP)

Tumor Tissue Type:
- ☐ *Banked COG sample (provide COG # on page 1)*
- ☐ *Snap-frozen*
- ☐ *Fresh*
- ☐ *FFPE tissue block*
- ☐ *FFPE tissue scrolls*
- ☐ *OCT-embedded tissue block*
- ☐ *Involved bone marrow (4 mL EDTA)*

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## WILMS TUMOR TESTING

☐ **Targeted Oncology Microarray Analysis** (TONCMA) — LOH and Copy Number Abnormality Detection
***Both tumor sample AND normal sample (containing 0% tumor) are REQUIRED.**
**At least 40% tumor must be present in the submitted tumor sample (based on internal pathology review)*

1) Tumor Tissue Type:
- ☐ *Banked COG sample (provide COG # on page 1)*
- ☐ *Snap-frozen (preferred)*
- ☐ *Fresh*
- ☐ *FFPE tissue block*
- ☐ *FFPE tissue scrolls **AND** H&E slide*
- ☐ *OCT-embedded tissue block*

2) Normal Sample Type:
- ☐ *Banked COG sample (provide COG # on page 1)*
- ☐ *Uninvolved peripheral blood (preferred; 4 mL EDTA)*
- ☐ *Snap-frozen*
- ☐ *Fresh*
- ☐ *FFPE tissue block*
- ☐ *FFPE tissue scrolls **AND** H&E slide*
- ☐ *OCT-embedded tissue block*
- ☐ *Other (specify):*_____

# CAUTION for Following Tests:

**Following tests are only available as *CONFIRMATORY TESTS* and only offered to patients who have a known gene fusion or somatic sequence variant(s) detected by previous research/clinical testing.** If patient does not have a previously detected gene fusion or somatic variant(s), then below tests cannot be ordered and samples will be rejected.

## TARGETED TUMOR FUSION ANALYSIS - Confirmatory Test for a Known Gene Fusion

☐ **RT-PCR Fusion Confirmation** (FUSNCON)
A copy of the previous research/clinical tumor fusion result is **REQUIRED**.
*At least 10% tumor must be present in the submitted liquid/solid tumor sample (based on internal pathology review)*

**Test for fusion between these 2 genes:** Gene #1 (5' Fusion Partner):_____

Gene #2 (3' Fusion Partner):_____

Test for additional gene fusions (specificy):_____

**Previous tumor fusion analysis performed at (Lab Name):** _____
**Previous tumor fusion analysis performed as a** ☐ *Clinical testing* ☐ *Research testing*

☐ Liquid Tumor: **specify tumor diagnosis**: _____
Sample Type:
- ☐ *Bone marrow (4 mL EDTA):* Blast %:_____
- ☐ *Involved peripheral blood (4 mL EDTA):* Blast %:_____
- ☐ *Other (specify):*_____

☐ Solid Tumor: **specify tumor diagnosis**: _____
Sample Type:
- ☐ *Snap-frozen (preferred)*
- ☐ *Fresh*
- ☐ *OCT-embedded tissue block*
- ☐ *Other (specify):*_____

** FFPE tissues are **NOT ACCEPTED** for this test*

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# Please Read CAUTION on Previous Page for Following Test

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## TARGETED TUMOR VARIANT ANALYSIS - Confirmatory Test for a Known Somatic Variant

☐ **Targeted Tumor Variant Analysis** (TTVA)
A copy of the previous research/clinical tumor sequencing result is **REQUIRED**.

1. Gene Name:_____ Mutation/Variant:_____
2. Gene Name:_____ Mutation/Variant:_____
3. Gene Name:_____ Mutation/Variant:_____

**Previous tumor sequencing performed at** _____
**Previous tumor sequencing performed as a** ☐ *Clinical testing* ☐ *Research testing*

***Submission of tumor sample is REQUIRED; Submission of a normal sample (containing 0% tumor) is recommended but not required.**

☐ Liquid Tumor: **specify tumor diagnosis**: _____
*Must contain at least 50% blasts (based on internal pathology review)*
Sample Type: ☐ *Bone marrow (4 mL EDTA):* Blast %:_____
☐ *Involved peripheral blood (4 mL EDTA):* Blast %:_____

☐ Solid Tumor: **specify tumor diagnosis**: _____
*Must contain at least 40% tumor (based on internal pathology review)*
Tissue Type: ☐ *Snap-frozen (preferred)* ☐ *Fresh*
☐ *FFPE tissue block* ☐ *FFPE tissue scrolls **AND** H&E slide*
☐ *OCT-embedded tissue block*

☐ Normal Sample Type: ☐ *Peripheral blood (preferred; 4 mL EDTA)*
☐ *Other:* _____

## Please Ship Samples and Completed Test Requisition Form to:

**Nationwide Children's Hospital Laboratory**
**700 Children's Drive, Room C1961**
**Columbus, OH 43205 U.S.A.**

**Ship samples via Overnight Courier. Samples must arrive in the laboratory within 48 hours. Saturday deliveries accepted. Please check "Saturday Delivery" on shipment label.**

For testing requested on banked COG samples, please FAX the completed Test Requisition Form to FAX number (614) 722-2887.

For questions regarding testing, specimen requirements or transport, please call IGM Clinical Laboratory at (614) 722-2866 or Lab Client Services at (800) 934-6575.

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**Institute for Genomic Medicine (IGM) Clinical Laboratory**
700 Children's Drive, Columbus, OH 43205
Phone: (614) 722-2866 / Fax: (614) 722-2887

# Informed Consent for Genetic Testing

**Patient Name** _____ **Date of Birth** _____

**Testing to be Performed** _____

Purpose of Testing
I understand that blood/tumor/bone marrow samples from me/my child will be tested to determine the presence or absence of certain genetic characteristics associated with a particular genetic disorder or diagnosis (germline), or associated with my/my child's cancer. It is the responsibility of the referring physician to ensure that I understand the implications of this testing. I understand that participation in this testing is voluntary.

Accuracy of Testing
I understand that the accuracy of the testing is limited to the techniques used. I understand that, as with all complex testing, there is always a chance of error or test failure. It is the responsibility of the referring physician to explain the limitations of the testing.

☐ **Germline (Constitutional) Testing**
The tests that will be performed on the samples aims to identify genetic features I (my child) was born with and are present in all of my (child's) cells. I understand that the accuracy of the testing is influenced by the information that I provide regarding myself (my child), the medical history of family members, and biological relationships in my family. Testing may also reveal that my (child's) parents are related by blood. In addition, non-paternity may be detected in some family-based studies, and this result may be reported to the referring health care provider.

☐ **Cancer (Tumor) Testing**
The primary aim of testing is to identify genetic changes in the cancer cells. The tests that will be performed on the samples can, in rare cases, identify genetic changes I (my child) was born with and are present in all of my (child's) cells (not just the cancer cells). This could include a genetic disorder caused by gene mutation, gain or loss of DNA, or determination that my (child's) parents are related by blood. If changes in the non-cancer cells are found that are thought by the testing laboratory to have significant clinical importance, the results may be communicated to the referring physician for consideration of follow-up testing.

Reporting of Results
I understand that the results of this testing will be reported only to the referring healthcare provider, or to a designated professional. All results are confidential and will be reported to other individuals only with my written consent, unless otherwise required by law.

Disposition of Samples
I understand that a portion (an aliquot) of my (child's) sample will be kept with identifiers intact, and it may be available for additional testing as ordered by my healthcare provider. I will not consider this as a banking procedure, and the laboratory will not be responsible for ensuring that the sample is available in the future. The remainder of the sample can be used for research-based testing with the option that I have checked below.
I give the following permission regarding research use of the unused portion of my (child's) sample **(please choose ONE):**
[Please note: if neither option is marked, the first option will apply and consent to research will be implied.]

☐ **Can be used for research purposes including studies designed to investigate the cause of my (child's) condition without removing the identifying information on the sample. Results, at the discretion of the laboratory, may be communicated through the referring physician.**

☐ **Can be used for research purposes only after the identifying information is removed from the sample. I understand that I will not be given any results from the testing, because the sample will be anonymous.**

☐ **Cannot be used for research purposes.**

**Signature of Signature of Patient/Parent/Guardian:** Signature of Patient/Parent/Guardian: I consent to participate (or have my child participate) in genetic testing for the above mentioned scenario. The testing has been explained to me, including its limitations and implications, and I have been given the opportunity to ask questions which have been answered in a satisfactory manner.

_____ Date/Time_____

**Signature of Ordering Clinician:** I have explained the testing, limitations, consent, and implications to the patient/parent and accept responsibility for ensuring genetic counseling is provided.

_____Date/Time_____

A signed copy should be provided to the Patient/Parent/Guardian.

LA-90 Informed Consent for Genetic Testing 2/07; 12/15