bionano laboratories
www.bionanolaboratories.com
Phone: 801.931.6200
Fax: 801.931.6201
Email: clinicalsupport@bionanogenomics.com

OGM-Dx™ HemeOne Test Requisition Form

ORDERING PROVIDER INFORMATION

Provider Name: _____

NPI#: _____

Clinic Name: _____

Clinic Address: _____

City: _____ State: _____ ZIP: _____

Phone: _____

Fax (for Report Delivery): _____

E-mail (for eReport Delivery): _____

Additional Provider Name: _____

Additional Provider E-mail (for eReport Delivery): _____

BIONANO LABORATORIES TEST REQUEST

☐ OGM-Dx™ HemeOne

DIAGNOSIS/INDICATION

Please include progress notes with sample.

Please select one of the cancers below and list any other applicable diagnoses

- ☐ Acute Lymphoblastic Leukemia
- ☐ Acute Myeloid Leukemia
- ☐ B-Cell Lymphoma
- ☐ Chronic Lymphocytic Leukemia
- ☐ Chronic Myelogenous Leukemia
- ☐ Multiple Myeloma
- ☐ Myelodysplastic Syndrome
- ☐ Myeloproliferative Neoplasms
- ☐ Other/Unknown hematological malignancy

Other Clinical Information: _____

_____

_____

Has the patient had a blood marrow transplant? ☐ Yes ☐ No

Has the patient had a blood transfusion in the last two weeks? ☐ Yes ☐ No

SAMPLE REQUIREMENTS, SHIPPING INFORMATION, AND COLLECTION DATE

- **Please indicate sample type and number of tubes**
  - ☐ Peripheral blood in purple top (EDTA) tube ____
  - ☐ Bone marrow aspirate in EDTA tube ____
  - ☐ Bone marrow aspirate in heparin tube ____
  - ☐ Other, please specify: _____
- All samples should be shipped the same day as the draw preferably at 2-8°C.
- The sample must arrive to the lab within 4 days of draw.
- Samples should be packed with absorptive materials and either:
  1) Placed into the shipping container at ambient temperature with an ambient temperature gel pack.
  2) Placed in a styrofoam box, packed with sufficient insulation between the blood tube and 1-2 ice packs so that they are physically separated from one another. **DO NOT FREEZE SPECIMEN.**
- Samples can only be received by our laboratory Monday-Friday

Shipping Address: Bionano Laboratories
6777 Nancy Ridge Drive
San Diego, CA 92121

Sample Collection Date & Time: ____/____/____ ____:____ ☐ AM ☐ PM

HEALTHCARE PROVIDER AUTHORIZATION, STATEMENT OF MEDICAL NECESSITY, AND INFORMED CONSENT

I am authorized by law to order the test(s) requested herein. I certify that this is medically necessary for the diagnosis, detection of a disease/illness/impairment/symptom/syndrome/disorder, and that the result will be used to inform the patient's medical management and treatment. I authorize such testing and have explained it to the patient (or the parent/guardian) who has provided consent (an informed consent form is available on the back of this document for my convenience). I agree to release this patient's medical records (clinical information/progress notes) including a summary of the indication for testing to Bionano Laboratories for purposes of optimized test interpretation and insurance correspondence, if applicable.

Authorized Signature: _____

Date (MM/DD/YY): _____

Place sticker from sample collection kit here

PATIENT INFORMATION

Patient Name: _____

Date of Birth (MM/DD/YY): _____

Gender: ☐ Male ☐ Female

Patient Address: _____

City: _____ State: _____ ZIP: _____

*NY residents: Check box to consent for your sample to be kept longer than 60 Days. ☐

Ethnic Background *(mark all that apply)*: ☐ African American ☐ Asian ☐ Pacific Islander ☐ White ☐ Hispanic ☐ Native American ☐ Alaskan ☐ Ashkenazi Jewish ☐ Other: _____

GUARDIAN INFORMATION

Guardian Name (if different from above): _____

Guardian Relationship to Patient: _____

Guardian Phone: _____

Guardian Email: _____

Spoken Language (if other than English): _____

BILLING INFORMATION

☐ **Institutional Billing Information**

Facility Name: _____

Facility Account Number: _____

Phone: _____

☐ **Patient Payment Information**

Please ensure the Patient Information box above is complete. The Bionano Laboratories team will call the patient within days of the order and sample reception to discuss the out of pocket cost.

We do not bill insurance for the OGM-Dx™ HemeOne

PATIENT AUTHORIZATION AND INFORMATION CONSENT

I understand and agree that: (1) I consent to this testing which has been authorized and explained to me by my healthcare provider. (2) I can schedule a session with a genetic counselor to further discuss this testing service. (3) Any personal financial responsibility will be based upon the final Explanation of Benefits (EOB) from my insurer, and Bionano Laboratories personnel will be available to discuss my financial responsibility. (4) I authorize any holder of my/the patient's medical information to release those records for this testing to Bionano Laboratories and my insurer. (5) Bionano Laboratories is authorized to represent myself/the patient in any and all interactions with my insurer for this test order. (6) My personal health information will be treated confidentially, in accordance with applicable state and federal law. (7) I have access to a copy of Bionano Laboratories' Notice of Privacy Practices at www.bionanolaboratories. com. (8) A copy of this authorization may be used in place of the original.

By signing this I acknowledge I have read, or have had read to me, and understand the Informed Consent statements on the back of this document, and have been provided the opportunity to ask questions of my healthcare provider or Bionano Laboratories, and received answers to my questions. By signature below, I hereby authorize Bionano Laboratories to conduct the genetic testing as described herein.

Patient Name: _____

Signature of Patient or Parent/Legal Guardian on behalf of Patient (if applicable):

_____

Date of Signature: _____

Patient Informed Consent

Bionano Laboratories requires a completed "Informed Consent" for testing to be performed. This Informed Consent describes the benefits, risks, and limitations of genetic testing to be performed using a biological sample obtained from me. I may wish to obtain professional genetic counseling prior to signing this Informed Consent. The use of "I" and "my" in this document refers to the person for whom testing was ordered on by an authorized healthcare provider.

Purpose of Testing

I understand that the purpose of the testing is to identify if I have a genetic variant (i.e., a genetic change) causing or contributing to a genetic disorder and/or to assess the chance of passing on a genetic disorder to any children or descendants I may have.

Description of the Genetic Disorder

Genetic disorders can be caused by many different types of variants, including, but not limited to, structural variants (SV) and single nucleotide variants. There are thousands of known genetic disorders with different symptoms presenting depending on the gene(s) involved and the type of variant. This test may be helpful in identifying genetic disorders that arise due to SV in my chromosomes. Information about the tests are available from my healthcare provider and can also be found on the Bionano Laboratories website (www.bionanolaboratories.com).

Description of the Test

Different genetic tests assess for different types of genetic variants and different number of genes. Each test offered by Bionano Laboratories is unique in its methodology and scope and may use optical genome mapping to identify SV. A description of each test offered by Bionano Laboratories can be found at www.bionanolaboratories.com.

What are the Expected Results from Genetic Testing?

1. Positive: A variant meeting reporting criteria was identified. This result: (a) may contribute to or cause my symptoms; (b) may mean that I am a carrier for a genetic condition, have a predisposition to the genetic condition tested for, or that the metabolism of certain medications is affected; (c) may be associated with disease, in other cases it may be a predictor of disease which may or may not present with symptoms; (d) may provide information helpful to making predictions on the chance to develop certain symptoms associated with a genetic disorder (but is dependent on what is known at the time the variant is identified); or may have implications for other family members. Upon receiving a positive result, you may wish to consider further independent testing, consult your physician, or pursue genetic counseling.
2. Negative: No variants meeting reporting criteria were identified. This result does not exclude the possibility that I have a genetic condition as the test that was ordered may have technical limitations. This result may lead my healthcare provider to discuss more genetic testing.
3. Uncertain: A variant was identified; however, it is unknown if this variant is the cause of or contributing to my symptoms. Over time the classification of these uncertain variants may be updated (clarified) due to the availability of additional information, such as updates to medical and scientific literature and/or familial segregation data accumulated through testing select family members.

Risks and Limitations of Genetic Testing

1. This testing may be negative, which could be due to my clinical status (e.g., stem cell or bone marrow transplantation, post-transfusion, etc.) or technical limitations of the testing.
2. This testing may identify genetic information that is not related to the clinical reasons for why testing was ordered, which may impact my health (unexpected findings). I agree to have these findings reported to the healthcare provider who ordered the test.
3. This testing may reveal that my parents are related or clarify/uncover family relationships (e.g., paternity/maternity). I agree to have these findings reported to the healthcare provider who ordered the test.
4. Clinical information and family history may be necessary for optimal test interpretation; furthermore, the results may prompt a recommendation for additional testing.
5. Several sources of delay and/or error are possible, including but not limited to sample mishandling, misidentification, and contamination; an additional sample may be requested

Genetic counseling is encouraged to further understand the purpose, benefits, and limitations of the specific test(s) ordered by my healthcare provider. Please contact Bionano Laboratories (previously Lineagen, Inc.) for details on how to access a licensed/certified genetic counselor.

Patient Confidentiality and Results Disclosure

I have the right to confidential treatment of the sample I provide for testing and my Protected Health Information (PHI) consistent with applicable laws, including the HIPAA Privacy Rules. Bionano Laboratories employs a number of organizational, technical, and physical safeguards designed to protect the confidentiality of the PHI it collects, and will not use or disclose my PHI without my consent, except as permitted by law. My healthcare provider will provide Bionano Laboratories with PHI such as my name, date of birth, gender and clinical symptoms to help track my sample and results report. I agree that Bionano Laboratories may disclose my results to the ordering provider and to the parent(s)/legal guardian(s) for minors I agree that Bionano Laboratories may also send results to additional healthcare providers that are treating me or upon my request. I also authorize Bionano Laboratories to disclose my PHI, which may include my results, for payment purposes to my insurer (if I am not paying for my testing directly). A copy of Bionano Laboratories' Notice of Privacy Practices is available at www.bionanolaboratories.com.

De-identified Sample Policies

Non-New York State Residents

Bionano Laboratories' practice is to retain samples in accordance with CAP, CLIA, state laws, and federal laws. In addition, after testing is complete, my sample may be de-identified (i.e., removal of all identifiers that connect the sample with the individual from which it was derived), retained and used by Bionano Laboratories (including its contractors and affiliates) for future testing in connection with commercial or non-commercial research and development purposes (including, without limitation, the improvement, enhancement or modification of existing tests, and the development of new tests), the development and commercialization of intellectual property, internal or external validation, quality control and assurance, education, publication, and/or research (including, without limitation, basic or clinical and commercial or non-commercial genome analysis utilizing cytogenetic and/or molecular genetics techniques).
If no initials are provided this will be interpreted as 'consent given'.

_____ By initialing here, I hereby authorize Bionano Laboratories to retain and use my de-identified sample for the purposes described in this section. I understand that I may withdraw my consent at any time, without prejudice to me, by contacting Bionano Laboratories at 801.931.6200.

_____ By initialing here, I DO NOT authorize Bionano Laboratories to retain and use my de-identified sample for the purposes described in this section. I understand that I may consent to be contacted in the future for any or all purposes including provision of general information about research findings or information about the test that may benefit me or my family in relation to preventive or clinical care choices.

_____ By initialing here, I give permission to be contacted in the future for any or all purposes as described above. I understand the risks of consenting to future contact, including learning information about myself or my family that might cause anxiety and psychological stress.

_____ By initialing here, I DO NOT give permission to be contacted in the future. I understand this means that information about specific test results for general research purposes will not be disclosed to me.

New York State Residents

No tests other than those described herein and authorized by this Informed Consent shall be performed using my sample. Unless I consent to storage and de-identification of my sample by Bionano Laboratories, my sample will be destroyed upon completion of testing or within 60 days following the date of collection.
If no initials are provided this will be interpreted as "consent not given."

_____ By initialing here, I confirm that I am a New York state resident, and I give permission for Bionano Laboratories to retain my de-identified sample for as long as necessary for general research purposes or internal validation and quality assurance testing. I understand that I may withdraw my consent at any time by contacting Bionano Laboratories at 801-931-6200, and any remaining portions of my sample will be destroyed.

_____ By initialing here , I confirm that I am a New York state resident, and I DO NOT give permission for Bionano Laboratories to retain my de-identified sample. My sample will be destroyed upon completion of testing or within 60 days following the date of collection. I understand that I may consent to be contacted in the future for any or all purposes including provision of general information about research findings or information about the test that may benefit me or my family in relation to preventive or clinical care choices.

_____ By initialing here, I confirm that I am a New York state resident, and I give permission to be contacted in the future for any or all purposes as described above. I understand the risks of consenting to future contact, including learning information about myself or my family that might cause anxiety and psychological stress.

_____ By initialing here, I confirm that I am a New York state resident, and I DO NOT give permission to be contacted in the future. I understand this means that information about specific test results for general research purposes will not be disclosed to me.

Use of De-Identified Data

Bionano Laboratories' practice is to retain data in accordance with CAP, CLIA, state laws, and federal laws. After testing is complete, I understand that data concerning my genetic testing results or clinical history may be deidentified and used by Bionano Laboratories (including its contractors or affiliates) for commercial or non- commercial research and development purposes (including, without limitation, the improvement, enhancement or modification of existing tests, and the development of new tests), the development and commercialization of intellectual property, internal or external validation, quality control and assurance, education, publication, and/or research (including, without limitation, basic or clinical and commercial or non-commercial genome analysis utilizing cytogenetic and/or molecular genetics techniques). **If no initials are provided this will be interpreted as 'consent given'.**

_____By initialing here, I hereby authorize Bionano Laboratories to retain and use my de-identified data for the purposes described in this section. I understand that I may withdraw my consent at any time, without prejudice to me, by contacting Bionano Laboratories at 801.931.6200.

_____By initialing here, I DO NOT authorize Bionano Laboratories to retain and use my de-identified data for the purposes described in this section.

Database Participation

The use of de-identified patient information (such as, clinical history and genetic information) may assist scientists, researchers, and healthcare providers understand how genes and variants can affect human health.
If no initials are provided this will be interpreted as 'consent given'.

_____By initialing here, I hereby authorize Bionano Laboratories to share de-identified patient information with databases, scientists, researchers, and healthcare providers. I or my parent/legal guardian may request disposal of my de-identified patient information upon request at any time following the completion of the indicated tests by contacting Bionano Laboratories at 801-931-6200. However, if my de-identified information has already been shared, I understand that it may not be possible to have it removed or returned.

_____By initialing here, I DO NOT authorize Bionano Laboratories to share my de-identified patient information with databases, scientists, researchers, and healthcare providers.

Financial Agreement

For insurance billing cases, I authorize Bionano Laboratories to bill my health insurance plan on my behalf, to release any information required for billing, and to be my designated representative for purposes of appealing any denial of benefits. I understand that Bionano Laboratories will call me if my out-of-pocket cost will be more than $100 USD and that testing will not be initiated until I agree to any out-of-pockets costs in excess of $100 USD. If my insurance provider sends a payment directly to me for services performed by Bionano Laboratories on my behalf, I agree to endorse the insurance check and forward it to Bionano Laboratories within 30 days of receipt of such payment.

Familial Samples

If my family members submit samples as part of testing (including, but not limited to, whole exome sequencing and variant resolution program), their results and data will be used to assist with the interpretation of my results. Their samples are considered supplementary and they will not receive a separate report; however, information on the segregation analysis might be included in my report. If my family members would like their own report, their healthcare provider(s) would need to place a separate order.

Acknowledgement

By signing the Patient Authorization and Informed Consent section on page 1, I acknowledge that I have read, or have had read to me, and understand all of the statements listed above and have been provided the opportunity to ask questions of my healthcare provider or Bionano Laboratories and receive answers to my questions. By my signature on page 1, I hereby authorize Bionano Laboratories to conduct the genetic testing as described herein.