

## CONSENT TO USE PARENT/RELATIVE SAMPLE

This form must be completed by each parent/relative who will be providing a cheek swab sample to assist with the patient's NextStep<sup>Dx</sup> PLUS testing (whole exome sequencing). Bionano Laboratories uses the genetic information from relative samples (typically biological parent samples) to aid in our analysis of the patient's NextStep<sup>Dx</sup> PLUS results (there is no separate report for relatives). Use of relative data reduces the time to get results, improves the clinical information/understanding in the results, and informs genetic counseling.

*Please note: information within boxes is required.*

### PARENT/RELATIVE INFORMATION

Relative Name: \_\_\_\_\_ Date of Birth (MM/DD/YY): \_\_\_\_\_ Gender: \_\_\_\_\_

Relative Address: \_\_\_\_\_ City: \_\_\_\_\_ State: \_\_\_\_\_ ZIP: \_\_\_\_\_

Relationship to patient: ☐ Mother ☐ Father ☐ Other\*: \_\_\_\_\_

\*If samples from one or both biological parents are not available, a sample from another biological family member (e.g., a sibling) may be accepted.

### PATIENT INFORMATION

Patient Name: \_\_\_\_\_ Date of Birth (MM/DD/YY): \_\_\_\_\_ Gender: \_\_\_\_\_

### PARENT/RELATIVE DEVELOPMENT & HEALTH HISTORY

Have you ever had, or do you currently have, any similar symptoms to the patient?

☐ YES, similar symptoms are: \_\_\_\_\_

☐ NO

### PARENT/RELATIVE SAMPLE INFORMATION

Sample Collection Date (MM/DD/YY): \_\_\_\_\_

### PARENT/RELATIVE INFORMED CONSENT

I understand that this test analysis can reveal information about how individuals are related to each other. For example, this test may suggest that the family relationship is different from what is reported, such as non-paternity. If the stated relationship between the patient and the relative is inaccurate, the test may not be as informative as possible and the relationship between the tested relatives may be revealed on the test results. **Initials:** \_\_\_\_\_

I understand that this test could reveal that I am at risk for developing symptoms associated with a genetic condition or that I am a carrier for a genetic condition. **Initials:** \_\_\_\_\_

### AUTHORIZATION

Please contact Bionano Laboratories at 1.888.888.6736 with any questions.

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 call and schedule a time to speak with a Bionano Laboratories genetic counselor. (3) My personal health information will be treated confidentially, in accordance with applicable state and federal law. (4) I have access to a copy of Bionano Laboratories' Notice of Privacy Practices at [www.bionanolaboratories.com](http://www.bionanolaboratories.com) (5) A copy of this authorization may be used in place of the original. I understand and agree to the test service being performed.

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.

**Authorized Signature:** \_\_\_\_\_ **Date (MM/DD/YY):** \_\_\_\_\_

# Patient Informed Consent

Lineagen Inc. (d/b/a 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 (a) to identify if I have a genetic variant (i.e., a genetic change) causing or contributing to a genetic disorder; (b) to assess the chance of passing on a genetic disorder to any children or descendants I may have; and (c) to provide information about individualized metabolism of medications.

### Description of the Genetic Disorder

Genetic disorders can be caused by many different types of variants, including, but not limited to, structural variants 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 structural variation(s) 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](http://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 structural variants. A description of each test offered by Bionano Laboratories can be found at [www.bionanolaboratories.com](http://www.bionanolaboratories.com).

### What are the Expected Results from Genetic Testing?

1. Positive: A variant 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 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 indeterminate or falsely 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](http://www.bionanolaboratories.com).

### Sample Retention and Future Testing

#### Non-New York State Residents

After testing is complete, my sample and data 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'.

#### Sample Retention

\_\_\_\_\_ 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.

#### Data Retention

\_\_\_\_\_ 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.

### Use of De-Identified Data

After testing is complete, I understand that data concerning my genetic testing results or clinical history may be de-identified 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).

### 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.

#### 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.