www.bionanolaboratories.com
Phone: 801.931.6200
Fax: 801.931.6201
Email: clinicalsupport@bionanogenomics.com
Investigator: Alka Chaubey | Lineagen Inc. d/b/a Bionano Laboratories

Variant Resolution Program 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

To qualify for this study, the Parent (Research Participant) must have a biological child who had genetic testing completed at Bionano Laboratories (formerly Lineagen). The Research Participant will only be tested for variants that meet inclusion criteria, as noted on the child's Bionano Laboratories genetic test result.

☐ Targeted Variant Testing (as specified in proband report)

PHENOTYPIC INFORMATION

The following must be filled out for the Parent (Research Participant). Please select any clinical features that the parent has, if any.

☐ Developmental delay or intellectual disability
☐ Autism spectrum Disorder
☐ Congenital Anomalies (if yes, please list below)
☐ Similar features or symptoms to the biological child tested at Bionano Laboratories (if yes, please list below)
☐ Other Features:

_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

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/impair-ment/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): _____

RESEARCH PARTICIPANT INFORMATION

Name and Date of Birth of Child Tested:

_____

Parent (Research Participant) Name:

_____

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

Gender: ☐ Male ☐ Female

Has a sample been collected or sample collection kit provided to participant?

☐ Yes ☐ No

If no, provide a current address for the kit to be shipped. Testing cannot begin until sample is received. Return of the sample to Bionano Laboratories is the responsibility of the research participant or order provider.

Address:_____

City:_____ State:_____ ZIP:_____

Contact information for the Research Participant is required. Testing will not proceed if documentation is not complete.

Phone Number: _____

Email Address: _____

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

TESTING CONSENT

You are being asked to participate in a research study that includes providing a sample for genetic testing. You qualify for this study if your biological child had genetic testing through Bionano Laboratories (formerly Lineagen) and there was one or more qualifying variants reported with uncertain significance. The goal of this study is to help determine if knowing parental inheritance of these variants clarifies the clinical significance of the variant(s) for the child. Your sample will only be tested for the variant(s) that meet inclusion criteria for this study. You will not receive a personal result from this study; however, your child's test result will be updated with inheritance information for the variant(s) tested.

Participation in this study is optional. You may choose not to participate, or there are options to receive genetic testing through non-research related methods. You or your insurance will not be charged for participation in this study and there is no compensation provided.

You may not receive direct benefit from this study, but the results may impact the understanding of your child's genetic test result and should be discussed with a healthcare provider. You may contact our study team with any additional questions at 801-931-6191

PATIENT AUTHORIZATION AND INFORMED 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 speak with a research team member or genetic counselor at Bionano Laboratories about this testing. (3) There is no financial cost to me or insurance billing from Bionano Laboratories for this testing. (4) I authorize any holder of my/the patient's medical information to release those records for this testing to Bionano Laboratories. (5) My personal health information will be treated confidentially, in accordance with applicable state and federal law. (6) I have access to a copy of Bionano Laboratories' Notice of Privacy Practices at www.bionanolaboratories.com. (7) 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: _____

Sample Collection Date: _____

Patient Informed Consent

Parental Testing: How Inheritance Testing Impacts Reclassification for Variants Classified as Uncertain Significance or Likely Pathogenic
IRB Approved: 07/02/2023

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 this testing is for research purposes. Parental testing may help clarify the clinical significance of some variants. These such variants, typically classified as uncertain significance, qualify for parental testing through this study. Eligibility is at the discretion of Bionano Laboratories clinical team and will be described on the proband's original genetic test result. Additional eligibility criteria includes test orders and samples for both biological parents being received within one year of the proband test result and phenotypic information for each parent being provided with the test order.

Description of the Test
Different genetic tests assess for different types of genetic variants and different number of genes. The analysis performed under this research protocol is limited to the variants that meet inclusion criteria for the study.

What are the Expected Results from Genetic Testing?
Personal results will not be issued through this study. The proband's original test result will be updated with inheritance information. If the classification of the proband's variant(s) has changed as a result of the information obtained through this research study, an updated report will be issued with this information.

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. Targeted testing through this study does not determine biological relationships between the proband and family member. Therefore, misattributed familial relationships are possible.
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. 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'. Participation in this study is contingent on consent for research use of sample/data.

_____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." Participation in this study is contingent on consent for research use of sample/data.

_____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 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). **If no initials are provided this will be interpreted as 'consent given'.** Participation in this study is contingent on consent for research use of sample/data.

_____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'. Participation in this study is contingent on consent for research use of sample/data.

_____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.

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.