Patient Informed Consent for OncoNext Liquid™ Scan test

The accuracy of the genetic testing and reporting methods have been determined and verified to meet required regulatory performance standards by GENOMA Group Lab ("Genoma"), a licensed and accredited laboratory.

I understand the following information regarding the general purpose and benefits of testing:

The purpose of this genetic test is to identify somatic cancer derived hotspot mutations in cancer driver genes involved primarily in melanoma, and lung, colorectal and gastric, prostate, breast and ovarian cancers. The test method used for detecting these somatic mutations is known as

a liquid biopsy. This test is being offered as preventative surveillance for individuals at high-risk for developing cancer, and as a screening tool for early detection of disease. Identification of any of the somatic mutations could potentially help indicate that a patient may have a malignant tumor, personalize disease management by providing tumor profiling, monitor disease progression and tumor evolution, and provide options for treatment if necessary.

I understand the following information regarding OncoNext Liquid™ Scan results:

- The OncoNext Liquid™ Scan test uses a method for isolating circulating tumor DNA (ctDNA) in blood. This ctDNA is analyzed for somatic mutations in genes commonly mutated in tumor tissue of patients with specific types of cancer. Identification of a mutation could have implications for my healthcare management and cancer surveillance or treatment.
- A positive result indicates one or more somatic mutations was identified. Identification of a mutation in my specimen will have different implications depending on the variant(s) detected. This screening test is not designed to diagnose cancer. Additional testing, including imaging studies, may be required as a follow up to a positive result. Recommendations about follow up testing will be made by my primary healthcare provider.
- A negative result indicates none of the somatic mutations analyzed were identified in my specimen. A negative result does not mean that I do not currently have a tumor or a risk of cancer in the future. This result only indicates that tumor DNA associated with one of the mutations analyzed was not detected. Other tumors that are not associated with the mutations analyzed are not detected by this test.
- Occasionally, a test result will be at the lowest point of the test's ability to detect a mutation described above. If this happens, the results will be considered indeterminate, and a second specimen will be requested for reanalysis at no additional charge. After reanalysis of the second blood sample, a negative or positive result will be reported.
- Knowing this information may help me and my healthcare provider make informed choices about my health care, including additional screening tests and medical management based on what is known about the mutations identified and the type of cancers associated with them.
- Genoma may contact me for additional information or follow-up clinical history at any point after I undergo this testing.

I understand the general risks and limitations of genetic testing including the following:

- One tube of blood (10 mL each) will be collected to perform the liquid biopsy. Risks of having blood drawn are uncommon, but may include dizziness, fainting, soreness, pain, bleeding, bruising, and rarely, infection.
- Genetic testing should not be used as a substitute for treating and diagnosing conditions, or for the provision of health care services by a physician or other qualified healthcare professional.
- The lack of detection of any mutations does not mean that I definitively do not have a cancer tumor currently nor does it mean that I will not develop cancer at a later time. The OncoNext Liquid™ Scan test only analyzes mutations associated with some common tumor types. There may be tumors of the types usually associated with these mutations that have not developed the specific mutations tested which will be missed as well as tumors that are not yet shedding DNA into the blood stream that cannot be detected. Other tumors not associated with the somatic mutations analyzed will not be identified by this test.
- This test may not provide informative results for other reasons, such as: (1) non-genetic factors, (2) individual genetic variation, (3) insufficient scientific information about the relationship between genetic information and health outcomes, (4) various laboratory and non- laboratory technical reasons, and (5) incomplete gene sequence information.
- This test does not test for hereditary cancer syndromes. The test is designed to detect only somatic mutations in ctDNA.
- Other risks that may be experienced as a result of this testing include: unjustified alarm and/or false reassurance that can discourage preventive measures, related emotional issues, impact on life-changing decisions, potential genetic discrimination, and loss of confidentiality. The testing results and information may become part of my permanent medical record and may be available to individuals and organizations with legal access to such records.

Informed Consent Acknowledgement

I understand that this testing is voluntary and freely consent to this testing. My signature below acknowledges that:

- I understand written English
- I have read and understood the front and back of this consent, all of my questions have been asked and answered to my satisfaction, and I agree to this testing. I understand that I can receive a copy of this consent by calling Client Services. (See "Questions").
- I am 18 years of age or older and have the legal authority to provide this consent and authorization for genetic testing, under all applicable laws.

Eurofins Genoma Group S.r.l a socio unico

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00138 Roma - Via di Castel Giubileo, 11
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REA: 883.955
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CHIAMATA GRATUITA NUMEROVERDE 800-501651

• I understand Genoma may use my DNA and clinical information in medical research studies and for publication, if appropriate, unless I opt-out by initialing below. I understand that my name or other personally identifiable information will not be used in or linked by Genoma to the results of any studies and publications.

_____(**initial to opt-out**) **I do NOT consent** to the use of my extracted DNA sample and clinical information for anonymous medical research purposes. I understand this is deemed useful by Genoma and explained on the other side of this Consent.

_____(**initial to opt-in**)**:** My DNA, extracted from my original specimen, and my clinical information can be retained for greater than 60 days and up to ten (10) years after the completion of testing for anonymized medical research purposes as described above.

Signature of Patient or Legally Authorized Representative _____ Signature Date _____

☐ Check one ☐ Self ☐ Parent ☐ Legal Guardian ☐ Durable Power of Attorney for Health Care

I understand that it is strongly recommended that I obtain pre-testing and post-testing counseling from someone professionally trained in cancer genetics or oncology to consider the purpose, meaning, risks, benefits, and limitations of, as well as any alternatives to, genetic testing in my particular situation, including medical issues based on my personal medical history. Counseling may be provided by an advanced practice oncology nurse, doctor, or other qualified healthcare professional. Pre-test counseling may help me better prepare to receive the test results and allow for advance consideration of medical options and the impact test results may have on me and my health. Post- test counseling provides a valuable opportunity to understand the medical interpretations of detected mutations, the psychological risks and benefits of learning my genetic test results, options for additional independent testing, and the importance of continuing cancer surveillance and prevention activities, among other things.

I understand that if testing results are inconclusive that I may be asked for an additional specimen(s). This consent is effective for any such additional specimen(s).

I understand the following information about confidentiality and disclosure of my personal information:

• My personal information and test results are confidential. While there can be no guarantee of privacy, Genoma has established reasonable safeguards to protect it. This information and the test results will be released to the ordering healthcare professional. I may request a copy of my lab results from Genoma' Client Services (see "Questions" below for contact information). For more information about my rights and Genoma' privacy practices, see Notice of Privacy Practices.
• This information and the results may also be disclosed if required by law, such as in response to a subpoena.
• I understand that if I share this information or these test results with anyone, I am responsible for any compromise of confidentiality that may result from such sharing.
• If I have opted out of allowing storage of my sample for research, the original specimen(s) may be securely stored for sixty (60) days from the date of collection and any remaining isolated DNA may be securely stored in accordance with applicable laws, regulations and standards. After such storage, the specimen(s) and the isolated DNA will be properly destroyed in accordance with applicable laws and regulations and the testing laboratory's standard operating procedures.

I understand the following regarding specimens for Medical Research Purposes: I understand that, unless I opt-out, as checked above, I am authorizing that my DNA extracted from my original specimen may be retained up to 10 years by Genoma as deemed useful for medical research purposes to develop new genetic tests. I understand that I may opt-in for this retention of my original specimen for up to 10 years by checking the correct box above. I understand that to protect my identity: a unique identifier will be assigned to my specimen and all resulting research data will be recorded, handled, and stored using this unique identifier. My name will be unavailable to any member of the research team and my identity will not be released or disclosed to others outside of Genoma. No compensation will be given me nor will I be owed any funds due to any invention(s) resulting from research and development using my specimen(s). I may refuse to submit my specimen for use in this way and this will not affect my results. Unless I indicate in the front page that I do not consent to anonymous medical research, I understand that my specimen(s) may be used in this manner.

I understand I may withdraw my consent: Under Italian regulations, Genoma cannot destroy medical records. However, at my written request and according to my instructions, Genoma can: a) destroy my DNA specimen(s) at the next regularly scheduled destruction cycle, b) delete my account, and c) move all medical information, including results report(s), into a into a secure, offline storage area with limited access. This means my account and results report(s) will not be searchable in Genoma systems by regular means and I, and my healthcare professional, will not be able to obtain a copy of my account information and results report(s) from Genoma. A request to withdraw my consent may be made to Genoma' Client Services (see phone number under "Questions" below).

Questions: If I have further questions about this testing, I understand that I can either contact a genetic counselor, other qualified healthcare professional or Genoma' Client Services at +39068811270, 8:00 AM to 8:00 PM, Monday through Friday. I may also call this number to set up an appointment to speak with a Genoma genetic counselor.

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