GOPATH®
LABORATORIES
Global Pathology Services

INFORMED CONSENT

Instructions for Healthcare Providers:

INTRODUCTION: Before a person has a genetic test, it is important that he or she fully understands the testing procedure, the benefits and limitations of the test, and the possible consequences of the test results. The process of educating a person about the test and obtaining permission to carry out testing is called informed consent. "Informed" means that the person has enough information to make an educated decision about testing; "consent" refers to a person's voluntary agreement to have the test done. An informed consent is provided to adults competent to make decisions for themselves and for children or patients unable to comprehend the document and make informed medical decisions, the consent form can be signed by parent, guardian, or legally responsible person qualified to make decisions on the patient's behalf. In general, informed consent can only be given by adults who are competent to make medical decisions for them. For children and others who are unable to make their own medical decisions (such as people with impaired mental status), informed consent can be given by a parent, guardian, or other person legally responsible for making decisions on that person's behalf. GoPath Laboratory's Informed Consent for genetic testing is available for doctors or genetic counselor to share with patients during an office visit and will discuss the test and answer any questions. If a person wishes to have the test, he or she will read and sign the consent form.

TESTING PURPOSE: The Hereditary Cancer Panel™ test performed at GoPath Laboratories analyzes the genes for abnormal genetic changes identified as mutations and are associated with specific hereditary cancers. Findings can indicate a significantly increased risk of developing tumors because of the cancer-risk mutation(s). Genetic testing for hereditary cancers helps determine an individual's risk for developing a hereditary cancer supplementing personal and family history findings.
TEST PROCEDURE AND METHADOLOGY: The Hereditary Cancer Panel™ test uses a simple blood test obtained through a venous blood collection and sent to GoPath Laboratories for testing. GoPath's expert scientific team will analyze the sample using the DNA to look for MMR mutations associated with an increased risk of colon, gastric, and other hereditary cancers. (For additional information, please visit https://www.gopathlabs.com).
TEST RESULTS AND INTERPRETATION: Results are best evaluated by your healthcare provider in conjunction with family and personal health history, physical examination, laboratory and any other testing, the clinical impression based on physician analysis. Possible result possibilities for the Hereditary Cancer Panel™ test include: Positive, Negative, and Variant of Unknown Significance
(VUS).
Positive: Results indicates an identified genetic alteration (mutation or deletion) that is clinically significant and is either pathologic or likely pathogenic, resulting in abnormal function of coded proteins. Such mutation(s) are associated with significantly increased risk in developing colon, gastric, and other hereditary cancers.
Negative: The variants have sufficient reported evidence and observation to be considered of no clinical significance. The changes are classified as harmless and confer no risk associated with cancer. A negative test result could also be considered likely benign. This means the variants are strongly suggestive of having no effect on the gene function and are unlikely to have an increased risk for cancer.
Variant of Unknown Significance: The variants have unknown effects on gene function, have not been previously reported or have been reported with inadequate or conflicting evidence regarding pathogenicity. The genetic change is not scientifically linked to increased risk currently and may also be a normal variant not associated with an increased risk of colon, gastric and other hereditary cancers.

Your physician or genetic counselor will help you understand the significance of each category. If there is a strong family history of ovarian or breast cancer, other family members may also be tested at GoPath Laboratories.

RISKS: The physical risks are minimal with the blood sample collection; however, some people may experience discomfort, slight bruising, or lightheadedness. If you take blood thinners, bruising may be more severe, it is important to share any past history of complications with the phlebotomist.

LIMITATIONS: Not all results will identify a genetic abnormality even though one may exist due to limitations of current knowledge and available genetic correlation to hereditary cancers. I understand that GoPath's methodology and process using the Hereditary Cancer Panel™ test is performed in a quality laboratory and are accurate. However, some false-positive or false-negative results may occur due to laboratory error in testing process or because of patient history of bone marrow transplantation, blood trans-fusion, non-detectable changes in cells or error/omission in family history cannot be excluded. Because of the dynamic nature of the genetic testing field, it is recommended to keep in contact with your healthcare provider on an annual basis to learn about any updates in genetic testing availability and/or to update your family history which may affect cancer risk.

FINANCIAL INFORMATION: In general, genetic testing of at-risk individuals is covered and reimbursed by insurance companies, Medicare, and HMO plans. Some insurance plans require additional supportive documentation however, GoPath's pre-authorization process will determine what documentation is needed, if the testing is covered, and what balance will be the patient's responsibility based on annual deductable, co-pays, co-insurance, or non-coverage and for any amount greater than $100.00, GoPath will contact you for approval prior to moving forward with testing.

CONFIDENTIALITY: GoPath Laboratories is committed to protecting patient privacy and will only release results to ordering physician (or qualified healthcare professional), ordering hospital laboratory, or ordering reference laboratory. Report copies may be sent to additional providers indicated on the requisition for convenience. Only upon written authorization from patient will any additional report copies be generated and sent to requested individual (s). Genetic testing is also protected under the Genetic Non-Discrimination Act (GINA) of 2008 which prohibits any form of discrimination by employers or insurers. In addition, genetic testing results are considered "protected health information" covered under the Health Insurance Portability and Accountability Act of 1996 commonly known as HIPAA which prohibits unauthorized release of results. Some states may have additional regulations and requirements regarding genetic testing results. Information obtained from testing may be used for scientific publications or teaching presentations however, identify is always excluded and protected.

GENETIC COUNSELING: It is highly recommended that patients receive genetic counseling prior to and after genetic testing as counselors in conjunction with physicians offer not only scientific information but are available to answer any questions and guide patients through testing process and any next steps. Continued visits with physicians may be necessary dependant on results. GoPath Laboratories offers comprehensive counseling services as a part of our genetic testing program.

SPECIMEN RETENTION:

- GoPath Laboratories follows all state and federal regulations regarding specimen retention and does not use submitted samples for banking purposes.
- Genetic testing samples are not returned to ordering physician or their patients
- Referring physician may request additional testing on previously submitted sample (additional charges apply) but will not be performed without written request from an authorized provider.
- GoPath may wish to use anonymized samples to develop new tests in the laboratory or for required quality assurance testing purposes, however, all pertinent patient information is removed _____ please initial
- For New York patients, I authorize GoPath Laboratory to retain my samples for greater than the allowable 60 days_____ please intial.

PATIENT CONSENT ATTESTATION:

By signing below, I (patient, parent, or legal guardian) acknowledge the following:

- I asked questions and discussed the benefits and limitations of the Hereditary Cancer Panel test to be performed as indicated on the Go-Path Hereditary Cancer Test Requisition with my healthcare provider
- I discussed the reliability of the Hereditary Cancer Panel test results (negative or positive) with my healthcare provider and the level of certainty regarding a positive result and the predictability of related cancer potential.
- I was informed about the importance of and offered genetic counseling services and provided written documentation inden-tifying appropriate genetic counseling services to choose from
- I read this document completely, had all questions answered, and understand I may keep a copy for my records
- I consent to be tested for hereditary cancer screening using the Hereditary Cancer Panel testing offered exclusively at GoPath Laboratories.

Name of Patient being tested (please print) _____ Date of Birth _____

Signature of Patient (or legal guardian) _____ Date _____

Instructions:
Provider, please review form with patient and offer copy for their retention
Patient (or legal guardian) initial boxes and print, sign, and date, keep copy for your records.

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