MAINSTREAM DIAGNOSTIC LABORATORY

GENETIC TESTING

Toll Free: (844) 995-5227
Phone: (727) 203-8391
5354 Gulf Drive, New Port Richey, FL 34652

Fax: (844) 452-2329
Email: info@mainstreamlab.com
www.mainstreamlab.com

PATIENT INFORMATION (REQUIRED)

Last Name: _____ First Name: _____

Street Address: _____ Apt#: _____

City: _____ State: _____ Zip: _____

Phone: _____ DOB: ___/___/___ SSN: _____ Gender: F ☐ M ☐

Primary Ethnicity: ☐ African ☐ European (Finnish) ☐ Latino
☐ Ashkenazi Jewish ☐ East Asian ☐ South Asian
☐ European (Non-Finnish) ☐ Near/Middle Eastern ☐ Other

SPECIMEN INFORMATION

Date Collected: ___/___/___ Time Collected : _____

Collected and Registered By: _____ Specimen Type: ☐ Saliva ☐ Blood

ICD10 CODES						

It is the ordering party's responsibility to order only those tests medically necessary for the diagnosis and treatment of the patient.

ADDITIONAL RESULTS RECIPIENT

Health Care Professional Name: _____

Phone: _____ Fax: _____

Email (for notification of results): _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

CHART NOTES / MEDICAL NECESSITY (REQUIRED)

*attach additional supporting documentation if needed

_____

_____

_____

_____

TEST(S) REQUESTED (REQUIRED)

COLORECTAL

☐ COLODx CLEAR
(APC,ATM, BMPR1A, EPCAM (CNV only), MLH1, MSH2, MSH6, MUTYH, PMS2, POLD1, POLE, PTEN, MDLD4, STK11, TP53)
SimplOFy Saliva collection device or Peripheral Blood Container (Lavender Top Tube)

PROSTATE

☐ PROSTATEDx CLEAR
(ATM, BRCA1, BRCA2, BRIP1, CHEK2, EPCAM (CNV only), MLH1, MRE11A, MSH2, MSH6, NBN, PALB2, PMS2, RAD51C, RAD51D, TP53)
SimplOFy Saliva collection device or Peripheral Blood Container (Lavender Top Tube)

BREAST & OVARIAN

☐ BRCADx C LEAR
(BRCA1, BRCA2)

☐ BREASTDx CLEAR
(ATM, BARD1, BRCA1, BRCA2, BRIP1, CDH1, CHEK2, FANCC, MRE11A, NBN, PALB2, PTEN, RAD51C, RAD51D, STK11, TP53)
SimplOFy Saliva collection device or Peripheral Blood Container (Lavender Top Tube)

CARRIER SCREENING

☐ CYSTIC FIBROSIS CARRIER SCREEN ASSAY
(CFTR - 139 clinically relevant variants in the gene) Peripheral Blood Container (Lavender Top Tube)

☐ EXPANDED CARRIER SCREEN
SimplOFy Saliva collection device or Peripheral Blood Container (Lavender Top Tube)

_____

PATIENT PAYMENT OPTIONS (SIGNATURE REQUIRED)

☐ OPTION 1: CREDIT CARD (MDL Mainstream Diagnostic Laboratorywill contact youfor additional information)
☐ OPTION 2: INVOICE PRACTICE / INSTITUTIONAL BILL / FACILITY BILL
☐ OPTION 3: BILL INSURANCE (attach front andback copy of insurance card)

Insurance Company Name: _____

Policy Number / Member ID: _____

I understand that if I have enrolled in an FSA/HSA or other medical spending account with my employer or my insurance carrier, that the provision on coordination of benefits in my coverage policy may result in an automatic deduction of out of pocket costs directly from that fund by the carrier or my employer. I understand that Mainstream Diagnostic Laboratory is in no way responsible or liable for that deduction, and will not reverse it, refund it or otherwise reimburse me for those amounts. I understand that it is my responsibility to contact my insurance carrier or employer in advance of services regarding coordination of benefits issues that may impact such an account.

➤ Patients Initials: _____

Patient Acknowledgment and Authorization: I acknowledge that I have provided accurate and true information to the best of my knowledge. If I have provided my insurance information for direct insurance / 3rd party billing: I hereby authorize my insurance benefits to be paid directly to Mainstream Diagnostic Laboratory (MDL) and authorize MDL to release medical information concerning my testing, including upon request my genetic testing results, to my insurer and any business associate of insurer (Medicare, Medicaid, etc.) I authorize MDL to be my Designated Representative for purposes of appealing any denial of health benefits. I understand that I am responsible for any amounts that my insurer determines are my responsibility after calculating deductibles, co-payments and co-insurance due under my policy. **I understand that I am legally responsible for sending Mainstream Diagnostic Laboratory any money received from my health insurance company for performance of this genetic test.**

➤ Patients Signature: _____ Date: _____

ORDERING HEALTH CARE PROFESSIONAL (SIGNATURE REQUIRED)

Informed Consent and Statement of Medical Necessity:
I affirm that I am legally authorized to order laboratory tests OR that I am an authorized representative of a health care professional legally authorized to order laboratory tests; and hereby order the tests requested above, which includes any collection device necessary to obtain the samples for testing. I hereby confirm that the test(s) are medically necessary for the treatment and/or plan of care for patient, and that the information supplied on this form is accurate to the best of my knowledge. I further hereby confirm that the information has been supplied about genetic testing and that an appropriate Mainstream Diagnostic Laboratory (MDL) informed consent has been signed by the patient and is on file with a copy returned to MDL.

Did the patient opt-out for the use of their sample for research purposes in the consent? ☐ Yes ☐ No

➤ Physicians Signature: _____ Date: _____

Clinical History Questionnaire

5354 Gulf Drive, New Port Richey, FL 34652 | Toll Free: (844) 995-5227 • Fax: (844) 452-2329

Patient Name_____

Date of Birth_____

Personal History of Cancer ☐ No personal history of cancer

Cancer / Tumor	Age of Diagnosis	Pathology and Other Info
Breast		Type: ☐ Invasive Ductal ☐ Invasive Lobular ☐ DCIS ☐ Bilateral ☐ Other Hormonal Status: **ER** ☐ (+) ☐ (-) **PR** ☐ (+) ☐ (-) **HER2/neu** ☐ (+) ☐ (-)
2nd primary breast		Type: ☐ Invasive Ductal ☐ Invasive Lobular ☐ DCIS ☐ Bilateral ☐ Other/Unknown Hormonal Status: **ER** ☐ (+) ☐ (-) **PR** ☐ (+) ☐ (-) **HER2/neu** ☐ (+) ☐ (-)
Ovarian		Indicate if: ☐ Primary ovarian ☐ Fallopian Tube Cancer ☐ Primary peritoneal
Endometrial		
Colorectal		Location: ☐ Cecum / ascending ☐ Transverse ☐ Descending ☐ Sigmoid ☐ Rectal *Tumor Studies Performed?* ☐ Yes (please attach the report and/or fill info below) ☐ No Microsatellite instability (MSI): ☐ Not done ☐ Stable (MSS) ☐ Unstable (MSI-H) IHC (MLH1, MSH2, MSH6, PMS2): ☐ Normal ☐ Absence of staining for _____ BRAF V600E: ☐ Not done ☐ Present ☐ Absent MLH1 Methylation Status: ☐ Not done ☐ Positive ☐ Negative
2nd primary colorectal		
GI Polyps		☐ Adenomatous Polyp #: ☐ 1 ☐ 2-5 ☐ 6-99 ☐ 100+ ☐ Other type Polyp #: ☐ 1 ☐ 2-5 ☐ 6-99 ☐ 100+
Brain		
Hematologic		Type: ☐ Allogenic bone marrow or stem cell transplant
Melanoma/skin		
Pancreatic		
Prostate		Gleason Score: Metastatic?: ☐ Yes ☐ No
Other cancer or relevant clinical history		Personal history of blood transfusion: ☐ Yes ☐ No Date of last transfusion _____

Previous Genetic Testing (Please include a copy of test results if performed at another laboratory) ☐ No previous genetic testing

Patient or family member previously tested at another laboratory? ☐ YES ☐ NO A copy of the test results provided? ☐ YES ☐ NO

Patient previously tested at Mainstream Diagnostic Laboratory? ☐ YES ☐ NO Family member previously tested at Mainstream Diagnostic Laboratory? ☐ YES ☐ NO

Name: _____ DOB: _____ Relation: _____

Family History ☐ No known family history ☐ Limited Family Structure

Relationship (indicate if maternal or paternal)	Cancer or Polyp History	Age at Diagnosis

Patient Informed Consent for Genetic Testing

The accuracy of the genetic testing and reporting methods have been determined and verified to meet required regulatory performance standards by Mainstream Diagnostic Laboratory ("MDL"), a licensed and CLIA (U.S. government) accredited laboratory.

PLEASE INITIAL NEXT TO EACH STATEMENT AS ACKNOWLEDGMENT THAT YOU HAVE READ AND UNDERSTAND THE INFORMATION

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

- Saliva or blood specimens are used for testing. Side effects 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 the provision of health care services by a physician or other qualified healthcare professional.
- Even if a mutation or variant is present in a family, it does not mean that everyone in the family inherited this mutation or variant. The pattern of inheritance can be explained by a genetic counselor or qualified healthcare professional. Understanding this can help me and my family members prepare for varying and complicated outcomes. I understand that a genetic counselor or qualified healthcare professional can help me consider the pros and cons of speaking first with family members before being tested to find out if they want to know my results. I understand that sometimes family secrets, such as paternity, adoptions, or other difficult issues may come up.
- This testing 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.
- 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 (e.g., in employment and insurance areas) 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.

____ **I understand that it is strongly recommended that I obtain pre-testing and post-testing counseling from someone professionally trained in genetics to consider the purpose, meaning, risks, benefits, and limitations of, as well as any alternatives to, genetic testing in my particular situation, including my personal and family medical history.** Counseling may be provided by a genetic counselor (such as those found on the National Society of Genetic Counseling website), advanced practice oncology nurse, doctor and 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 myself and my family members. Post-test counseling provides a valuable opportunity to understand the medical interpretations of detected mutations and variants, the psychological risks and benefits of learning my genetic test results, how families inherited conditions and the risk of passing an inherited variant on to my children, options for additional independent testing, and the importance of continuing regular 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).

If a minor will be tested, I understand the following: While genetic report information may be similar for adults and minors, the consequences of genetic testing of minors are relatively new and less understood. The National Society of Genetic Counselors recommends that the social and psychological risks and benefits of early identification of genetic issues from the perspective of the minor and parent/guardian be carefully considered and include genetic counseling when discussing genetic testing of children for inherited cancer risk.

____ **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, MDL Mainstream Diagnostic Laboratory 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 Mainstream Diagnostic Laboratory' Client Services (see "Questions" below for contact information).

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. 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 authorize that my DNA extracted from my original specimen may be retained up to 10 years by Mainstream Diagnostic Laboratory as deemed useful for medical research purposes to develop new genetic tests. I understand that to protect my identity: a unique identifier will be assigned to my specimen 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 Mainstream Diagnostic Laboratory. No compensation will be given me nor will I be owed any funds due to any inventions(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 on the front that I do not consent to anonymous medical research, I understand that my specimen(s) may be used in this manner.

If you are a Florida state resident YOU MUST CHECK ONE:

☐ I do not wish for my specimen to be retained for Medical Research Purposes; discard within 60 days of collection.

☐ I agree to use of my de-identified biospecimen for medical research to improve genetic testing for all patients. I consent to my sample being retained beyond 60 days of collection; the retained sample will be de-identified by having all identifiers removed prior to re-testing. The de-identified sample and results obtained will remain anonymous.

____ **I understand I may withdraw my consent: Under CLIA regulations, MDL Mainstream Diagnostic Laboratory cannot destroy medical records.**

However at my written request and according to my instructions, Mainstream Diagnostic Laboratory 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 secure, offline storage area with limited access. This means my account and results report(s) will not be searchable in MDL Mainstream Diagnostic Laboratory 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 MDL Mainstream Diagnostic Laboratory. A request to withdraw my consent may be made to MDL Specialty Medical Lab' Client Services (see phone number under "Questions" below).

If you are requesting one of the <u>Cancer Panels</u> please read and initial the following statements:

____ **I understand the following information regarding the general purpose of testing for inherited cancer risk.**

• Depending upon the specific genetic testing ordered by the healthcare professional on the Mainstream Diagnostic Laboratory (MDL)' requisition form, I understand my specimen is being tested for my genetic makeup related only to my inherited cancer risk. Many cancers are not inherited but occur during a person's lifetime which is why continuing regular prevention activities is important. I understand what MDL includes in its reports is determined at MDL's discretion.

____ **I understand the risks and limitations of hereditary cancer testing** including the following:

- The existence of a mutation or variant does not mean I will develop cancer. The lack of mutations or variants does not mean I will not develop cancer. For some cancers, genetic causes have not been determined. The severity of the symptoms may vary from person to person.
- Genes are one of many things that may contribute to development of cancer. Other factors, such as exposures to cancer-causing substances, diet, personal and family medical history and lifestyle or behavioral choices, also contribute to risk for the development of cancer.
- Cancer can appear to "run in families", even though it may not be caused by a mutation or variant detectable by this test. This could, for example, be caused by a shared environment or lifestyle, such as tobacco use.

____ **I understand that the results from genetic testing for hereditary cancer may** help a qualified healthcare professional and me learn more about my susceptibility to certain cancers and how I may reduce my cancer risk through screening and medical management. I understand that there are several types of results that can be generated, including:

- Pathogenic variant detected - A pathogenic variant could be identified in my genetic makeup that is associated with an increased risk of hereditary cancer. Knowing this information may help me and my healthcare professional make more informed choices about my health care, including screening and medical management based on what is known about the gene(s) in which a variant was found and the cancer associated with it.
- Likely pathogenic variant detected - A likely pathogenic variant could be identified in my genetic makeup that could be associated with an increased risk of hereditary cancer. Knowing this information may help me and my healthcare professional make more informed choices about my health care, including screening and medical management based on what is known about the gene(s) in which a variant was found and the cancer associated with it.
- Variant of uncertain significance detected – A variant of uncertain significance could be detected. This type of change may or may not be associated with an increased risk for cancer. I understand I may have at least the same risk of cancer as the general population, and may still be at greater than average risk due to a genetic predisposition that cannot be detected by this test. As clinical or scientific information evolves, I understand that I may receive updated information about the interpretation of my results.
- Negative - No variant of clinical or uncertain significance was detected. If no one in my family, including me, has ever had cancer, I still have at least the same risk of cancer as does a person in the general population. I may still be at greater than average risk for hereditary cancer due to a genetic predisposition that cannot be detected by this test, either in the gene(s) I am tested for or in another gene linked to hereditary cancer.

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 sufficiently well enough, I have read and understood the front and back of this Consent, all of my questions have been answered to my satisfaction, and I agree to have the testing completed. I understand that I can receive a copy of this Consent.

I have reached 18 years of age or older OR have the legal authority to provide this Consent and authorization for genetic testing, under all applicable laws.

I understand Mainstream Diagnostic Laboratory 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 Mainstream Diagnostic Laboratory to the results of any studies and publications.

I **consent** to the use of my DNA extracted from my original specimen, clinical information and information provided herein for anonymized medical and research purposes. I understand this is deemed useful by MDL and explained in this Consent.

Release of Information for Insurance Claims Processing: I understand that by requesting payment by my insurance company, Medicare or other third-party payor that I specifically authorize the release of my Protected Health Information ("PHI"), including my lab test results, to such third-party payor or its authorized agents or representatives, as necessary for the purpose of determining coverage and facilitating payment. This authorization is valid for one year. I may revoke this authorization at any time by sending a written notice to Mainstream Diagnostic Laboratory' Client Services.

_____ _____

Signature of Patient or Legally Authorized Representative | Signature Date

_____ _____

Patient Name (Print) | Name and Relationship (Parent/Guardian if patient is a minor)

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

Questions: If I have further questions about this testing, I understand that I can either contact a genetic counselor, other qualified healthcare professional or Mainstream Diagnostic Laboratory' Client Services at (727)-203-8391, 9:00 AM to 5:00 PM Eastern Time, Monday through Friday to speak to MDL Genetic Department.