MEDICAL LABS UNLIMITED

1508200300 (EX)

Molecular Diagnostics Requisition

FIRST NAME	LAST NAME	MIDDLE INITIAL	CLINIC INFORMATION

SS #	D.O.B.	SEX	RACE
		☐ M ☐ F	

ADDRESS	CITY	STATE	ZIP	PHONE

BILLING: ☐ MEDICARE ☐ MEDICAID ☐ PRIVATE ☐ SELF PAY ☐ CLIENT BILL ☐ WC/AUTO _____ *(DATE OF INJURY)*

ICD-10 DIAGNOSIS CODES: Additional documents supporting medical necessity may be attached.

(1) _____ (2) _____ (3) _____ (4) _____ (5) _____ (6) _____

PROVIDER NAME (PRINT)	PROVIDER SIGNATURE
X	X

COLLECTOR NAME (please print)	DATE COLLECTED	TIME COLLECTED	FASTING
			☐ Yes ☐ No

TUBE TYPE & COUNT	SPECIMEN STORAGE:	SPECIMEN SHIPPING:
☐ Dry Buccal Swab: _____ ☐ EDTA: _____ ☐ Mouthwash: _____ ☐ Cell-Free DNA BCT: _____ ☐ Saliva Collection: _____ ☐ Nasopharyngeal Swab: _____	☐ Room temperature ☐ Frozen ☐ Refrigerated	☐ Room temperature ☐ Cooling/Ice Pack

MOLECULAR DIAGNOSTIC TESTING OPTIONS

KEY: E = EDTA | DB = Dry Buccal Swab | CD = Cell-Free DNA BCT | MW = Mouthwash | SC = Saliva Collection | NS = Nasopharyngeal Swab

☐ **Hereditary Cancer Risk Assessment** (E SC MW) – *APC, ATM, BARD1, BMPR1A, BRCA1, BRCA2, BRIP1, CDH1, CDK4, CDKN2A, CHEK2, EPCAM, FANCC, MEN1, MET, MLH1, MRE11A, MSH2, MSH6, NBN, NF1, NTRK1, PALB2, PMS2, PTCH1, PTEN, RAD50, RAD51C, RAD51D, RET, SMAD4, STK11, PT53, VHL*

☐ **Personal Breast-Ovarian Cancer ONLY** (E SC MW) – *APC, BARD1, BMPR1A, BRCA1, BRCA2, CDK4, CDKN2A, CHEK2, EPCAM, FANCC, MEN1, MET, MRE11A, NF1, NTRK1, PMS2, PTCH1, RAD50, RAD51D, RET, SMAD4, VHL*

☐ **Respiratory Pathogen Panel:** (NS) – ***Viruses:*** *Adenovirus, Coronavirus HKU1, Coronavirus NL63, Coronavirus 229E, Coronavirus OC43, Human Metapneumovirus, Human Rhinovirus/Enterovirus Influenza A, Influenza A/H1, Influenza A/H1-2009, Influenza A/H3, Influenza B, Parainfluenza 1, Parainfluenza 2, Parainfluenza 3, Parainfluanza 4, Respiratory Syncytical Virus;* ***Bacteria:*** *Bordetella pertussis, Chlamydophila pneumoniae, Mycoplasma pneumoniae*

Pharmacogenetic Test (DB) *Please attach patient medication list*

☐ Comp
ANKK1/DRD2, APOE, COMT, CYPs: 1A2, 2B6, 2C19, 2C8, 2C9, 2D6 (Copy Number), 3A4, 3A5, DPYD, Factor II, Factor V Leiden, HCP5, MTHFR, OPRM1, SLCO1B1, TPMT, UGT2B15, VKORC1

☐ cardio
APOE, Factor II, FactorV Leiden, MTHFR, SLCO1B1, VKORCI, and CYPs: 1A2, 2C9, 2C19, 2D6, 3A4, 3A5,

☐ psych/ADHD
ANKKI/DRD2, COMT, MTHFR, and CYPs: 1A2, 2C9, 2C19, 2D6, 3A4, 3A5

☐ pain
COMT, OPRM1 and CYPs: 1A2, 2B6, 2C9, 2C19, 2D6, 3A4, 3A5

☐ cancer
COMT, DPYD, TPMT, MTHFR, OPRMI, and CYPs: 2B6, 2C8, 2C9, 2D6, 3A4, 3A5

Non-Invasive Prenatal Test (CD)

The DISCOVER™ prenatal test is validated for singleton and twin pregnancies with gestational age of at least 10 weeks 0 days, as estimated by last menstrual period, crown rump length, or other appropriate method (equivalent to 8 weeks fetal age as determined by date of conception).

Choose Either Test (NIPT or NIPT Plus) and All Options That Apply

Prenatal Test (chromosomes 21, 18, 13) OR **Prenatal Plus Test** (chromosomes 21, 18, 13)

☐ Singleton	☐ Twin	Singleton
Additional option: ☐ Sex Chromosome aneuploidies option	Additional option: ☐ Presence of Y chromosome options	Additional options: ☐ Microdeletions *1p36 deletion, 4p- (Wolf-Hirschhorn), 5p- (Cri-du-chat), 15q11.2 deletion (Prader-Willi/Angelman), 22q11.2 deletion (DiGeorge)* ☐ *Sex chromosome aneuploidies (MX, XXX, XXY, and XYY)* ☐ All Chromosomes (including sex chromosome aneuploidies [MX, XXX, XXY, and XYY])

Test Indications
(Choose at least one):

☐ Advanced Maternal Age
☐ Positive Serum Screen
☐ Abnormal Ultrasound
☐ Hx suggestive of increased risk for the specified chromosome aneuploidies
☐ Low risk/maternal anxiety
☐ Other: _____

Clinical Information

GESTATIONAL AGE: WKS / DAYS ON MM / DD / YYYY

DATING METHOD:
☐ LMP ☐ CRL
☐ Date of Implantation ☐ Other: _____

DATE OF DRAW: MM / DD / YYYY

MATERNAL HEIGHT: ☐ cm ☐ ft in

MATERNAL WEIGHT: ☐ kgs ☐ lbs

MOLECULAR TESTING INFORMED PATIENT CONSENT

See reverse side for extended Patient Informed Consent

Please attach a copy of the insurance card/ID. *I voluntarily consent to the collection and testing of my specimen. I certify that the specimen is fresh and has not been adulterated in any manner. I authorize the laboratory to release the results of this testing to the ordering provider. I further authorize my insurance benefits to be paid directly to the lab for services rendered . I acknowledge that the Lab may be treated as an out-of network provider. In the event I receive payment for laboratory services from my insurer, I will remit said payment to the Lab within 14 days of receipt. I will either endorse the original check, or produce a personal check for the entire payment amount, and forward it to the lab. When selecting "self- pay" above, I acknowledge financial responsibility for all lab charges associated with the processing of this test requisition. All rights to the samples will belong to the laboratory conducting the testing. There will be no compensation in the event of an invention resulting from research and development using this sample.*

☐ *I agree to allow my provided specimen to be used for the purpose of (diagnosis/research) (development/quality control). I understand that if I agree, any information identifying me will be kept confidential so that it will not be possible to determine from whom the sample was drawn.*

☐ *I request that the sample be destroyed after testing. I understand that it will not be available if retesting is required.*

Your signature on this form indicates that you understand to your satisfaction the information about testing and agree to have the test done. In no way does this waive your legal rights or release anyone from their legal and professional responsibilities. If you have further questions concerning matters related to this consent, you may wish to seek professional genetic counseling prior to signing this form. Consultation with a medical geneticist, genetic counselor, or your referring healthcare provider also may be warranted after the test has been completed.

SIGNATURE OF PATIENT OR LEGAL GUARDIAN	DATE
X	

OFFICE USE ONLY LIS Profile Number: _____ Reviewed and processed by: Signature _____ Date _____

1508200300 (EX)	1508200300 (EX)	1508200300 (EX)	1508200300 (EX)
Pt. Name: _____ Date of Birth: _____	Pt. Name: _____ Date of Birth: _____	Pt. Name: _____ Date of Birth: _____	Pt. Name: _____ Date of Birth: _____

WHITE COPY: LAB YELLOW COPY: CLINIC PINK COPY: PATIENT

Molecular Genetics Informed Consent

Background on Testing
Molecular Risk Panels are designed to evaluate multiple genes that have been reported to be associated with an increased risk of developing one or more pathologic disease states. While LS is NOT *diagnosing* any specific condition, we do investigate for any changes in the specific genes that have been shown to increase the risk for molecular illness to develop, so as to help the patient and their physician make better informed choices, if necessary.

Potential limits of Molecular Risk Panels
- Med Labs partners do not look for all genetic causes of cancer. It is designed to study a set panel of genes known to cause certain inherited cancers.
- Med Labs partners do not provide any risk information for genes that we do not explicitly evaluate for.
- Med Labs partners require a minimum amount of sufficient DNA. Patients should not be concerned if the laboratory, or their physician, requests additional samples to complete the testing in a satisfactory manner.

Who may benefit from Molecular Risk Testing?
For benefits associated with each specific molecular assay kindly refer to our website: www.MedLabsUnlimited.com

Should my child (under 18 years old) have testing?
Genetic testing for children under 18 years old is not recommended except when an inherited condition is known to cause signs or symptoms that are recognized in childhood. You should talk with your health care provider and/or a genetic counselor about whether our testing or other genetic testing is right for your child.

How is testing performed?
Next generation sequencing (NGS), a technique that allows our group to interrogate a large amount of genetic information very quickly, enabling us to reliably identify very small changes in the implicated genes. Another technique is used to find any large missing or extra pieces of a gene. The clinical staff at the testing laboratory – which may include scientists, doctors, and genetic counselors – review any changes (called variants) found to determine if a variant might be benign (unlikely to cause harm) or pathogenic (known to be associated with an increased risk for genetic disease).

What can I learn from the report?
The report should ideally be interpreted in concert with a heath care professional qualified to assist you in understanding the results we provide, such as a certified genetic counselor. These professionals are trained to give unbiased and neutral details about your report information. You may learn if you have a higher potential risk to develop certain conditions compared to others in the general population. The results of this genetic test may change the way your healthcare provider chooses to manage your usual treatment. If you are found to have a variant (a change in the DNA sequence) that increases your risk to develop certain types of conditions, this information is important for your biologic (related by blood) relatives to know as well. They share some of the same DNA as you, which means that they might also have the same variant and may carry similar risk (either increased or decreased). If they are found to have the same variant, they may also benefit from multiple potential therapeutic options.

After you receive your results, you may have questions. Your healthcare provider can answer your questions and/or refer you to a genetic counselor for additional information.

What will happen to my specimen?
Specimens are stored according to all applicable federal, state and professional regulations. If no regulation applies, specimens will be stored no longer than 60 days from the collection date. The data generated by the test will be saved for at least one year after testing is completed. To continually improve the analysis process, your test results may be shared with a HIPAA-compliant public database in a way that is de-identified, so that no one else may know that the results came from you. The confidentiality of each specimen is of the utmost priority, and will be maintained in perpetuity, to the best of our ability.

Genetic Test Consent

- I understand the following and freely give my consent to have this genetic test performed.
- I have had an opportunity to read the information provided above and/or my healthcare provider has explained the risks, benefits, and limitations for the test ordered below. I am aware that genetic counseling is an option available to me both before and after testing.
- The test may provide me additional information about my inherited risk for diseases which may also have consequences for my blood relatives.
- The ability of genetic testing to provide risk information or a diagnosis varies with the type of test. I have been provided with information about LabSolutions' ability to detect changes in the genes tested, and/or my healthcare provider has discussed it with me in detail.
- I understand that I may have variants in genes that increase my risk of genetic disease that are not tested by LabSolutions at the time my test is performed.
- This test may not provide reliable information, regardless of the results for a number of reasons. Some of the reasons include: 1) the need to test other family members; 2) no information known about the variant detected; 3) technical reasons.
- All test results are confidential and will be released only to the ordering healthcare provider or that healthcare provider's designated representative. I understand that in some states I may have to disclose this information to third parties, such as life, disability, or health insurers.
- Procedures to obtain blood specimens may have associated risks, such as bruising from blood collection.
- An additional blood specimen may have to be obtained in the absence of results, or if the results are inconclusive.
- All specimens are coded with unique identifying information to assure quality and, to the extent humanly possible, prevent error.
- My specimen will be securely stored in case retesting is necessary. Specimens are stored according to applicable federal, state, and professional regulations. If no regulation applies, specimens will be stored no longer than 60 days from the collection date. At the end of that time, the specimen will be destroyed unless otherwise instructed below.