ELITE CLINICAL LABORATORY

OHIO RIVER LABORATORIES

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PLEASE SUBMIT THE FOLLOWING WITH REQUISITION FORM

- ☐ Letter of Medical Necessity (Signed by Physician)
- ☐ Informed Consent Form (Signed by Pt & Physician)
- ☐ SOAP & Progress Note (Signed by Physician)
- ☐ Summary of Active Medications
- ☐ Scanned Insurance Card Copy

PRIMARY IMMUNODEFICIENCY TESTING REQUISITION FORM

PATIENT INFORMATION

Patient First Name	Patient Last Name	Biological Sex ☐ F ☐ M
Date of Birth (MM/DD/YYYY)	Phone Number	Email Address
Address	City	State / Zip

Ethnicity: ☐ African American ☐ Asian ☐ Caucasian ☐ Hispanic ☐ Jewish(Ashkenazi) ☐ Portuguese ☐ Other

PATIENT INSURANCE INFORMATION

☐ Insurance ☐ Self-Pay ☐ Client Bill

Name of the insurance	Secondary Insurance, If any
Insurance Policy/ID number	Name of the insured
Insurance Group number	Date of Birth of Insured

SPECIMEN INFORMATION

Date Sample Collected (mm/dd/yy) (required)

Medical Record#

☐ Buccal Swab

☐ Other (specify source)

ORDERING PHYSICIAN/SENDING FACILITY (Each Listed person will receive a copy of the report)

Facility Name (Facility Code):	Address:	City:	
State/Country :	Zip:	Phone:	
Ordering Licensed Provider Name (Last, First)(Code)	NPI#	Phone	Fax/Email

STATEMENT OF MEDICAL NECESSITY

By submission of this test requisition and accompanying sample(s), I: (i) authorize and direct to perform the testing indicated; (ii) certify that the person listed as the ordering provider is authorized by law to order the test(s) requested; (iii) certify that any custom panel and/or ordered test(s) requested on this test requisition form are reasonable and medically necessary for the diagnosis and/or treatment of a disease, illness, impairment, symptom, syndrome or disorder; (iv) the test results will determine my patient's medical management and treatment decisions of this patient's condition on this date of service; (v) have obtained this patient's and relatives', when applicable, written informed consent to undergo any genetic testing requested; and (vi) that the full and appropriate diagnosis code(s) are indicated to the highest level of specificity.

Signature of Provider (required) Date:

INDICATIONS FOR TESTING (CHECK ALL THAT APPLY)

☐ Diagnostic ☐ Family history ☐ Positive or normal control ☐ Other.....

Will Patient management be changed depending on the test results? ☐ Yes ☐ No

CLINICAL PRESENTATION

Please indicate any clinical presentations and /or findings that may be relavant to genetic testing:

- Behavior
- Conditions
- Pedigree/Family History
- Phenotypes
- Physical
- Symptoms

There are many presentations which may not seem like a direct association for disease. Please List the most suspected presentations and attach detailed medical records and/or pedigree.

Panel ID: FT-TP01366 - COMPREHENSIVE PRIMARY IMMUNODEFICIENCY - 471 GENES

ACD, ACP5, ACTB, ADA, ADA2, ADAM17, ADAMTS13, ADAR, AICDA, AIRE, AK2, AP1S3, AP3B1, AP3D1, APOL1, ARMC4, ARPC1B, ATM, ATP6AP1, B2M, BACH2, BCL10, BCL11B, BLM, BLNK, BLOC1S3, BLOC1S6, BRCA2, BRIP1, BTK, C1QA, C1QB, C1QC, C1R, C1S, C2, C3, C4BPA, C5, C6, C7, C8A, C8B, C8G, C9, CARD11, CARD14, CARD9, CARMIL2, CASP10, CASP8, CAVIN1, CCBE1, CCDC103, CCDC114, CCDC39, CCDC40, CCDC65, CCNO, CD19, CD247, CD27, CD3D, CD3E, CD3G, CD40, CD40LG, CD46, CD55, CD59, CD70, CD79A, CD79B, CD81, CD8A, CDCA7, CEBPE, CENPF, CFAP298, CFB, CFD, CFH, CFHR1, CFHR2, CFHR3, CFHR4, CFHR5, CFI, CFP, CFTR, CHD7, CIITA, CLCN7, CLEC7A, CLPB, COG6, COLEC11, COPA, CORO1A, CR2, CREBBP, CSF2RA, CSF2RB, CSF3R, CTC1, CTLA4, CTPS1, CTSC, CXCR4, CYBA, CYBB, DCLRE1B, DCLRE1C, DDX58, DGKE, DHFR, DKC1, DNAAF1, DNAAF2, DNAAF3, DNAAF4, DNAAF5, DNAH1, DNAH11, DNAH5, DNAI1, DNAI2, DNAJC21, DNAL1, DNASE1L3, DNASE2, DNMT3B, DOCK2, DOCK8, DRC1, DTNBP1, ELANE, EPG5, ERCC2, ERCC3, ERCC4, ERCC6L2, ETV6, EXTL3, F11, F13A1, F13B, F5, F7, F8, F9, FAAP24, FADD, FANCA, FANCB, FANCC, FANCD2, FANCE, FANCF, FANCG, FANCI, FANCL, FANCM, FAS, FASLG, FAT4, FCGR3A, FCN3, FERMT3, FGA, FGB, FOXN1, FOXP3, FPR1, G6PC, G6PC3, G6PD, GAS8, GATA1, GATA2, GFI1, GINS1, GP1BA, GP1BB, GP9, GTF2H5, HAX1, HELLS, HPS1, HPS3, HPS4, HPS5, HPS6, HYDIN, HYOU1, ICOS, IFIH1, IFNAR2, IFNGR1, IFNGR2, IGHM, IGLL1, IKBKB, IKZF1, IL10, IL10RA, IL10RB, IL12RB1, IL17F, IL17RA, IL17RC, IL1RN, IL2, IL21, IL21R, IL2RA, IL2RG, IL36RN, IL7R, INO80, INSR, INVS, IRAK1, IRAK4, IRF2BP2, IRF3, IRF7, IRF8, ISG15, ITCH, ITGAM, ITGB2, ITK, JAGN1, JAK1, JAK2, JAK3, KDM6A, KMT2D, KRAS, LAMTOR2, LAT, LCK, LIG1, LIG4, LPIN2, LRBA, LRRC6, LRRC8A, LYST, MAGT1, MALT1, MAN2B1, MANBA, MAP3K14, MASP1, MASP2, MBL2, MC2R, MCM4, MEFV, MKL1, MLPH, MOGS, MPL, MPO, MRE11, MS4A1, MSH6, MSN, MTHFD1, MVK, MYD88, MYH9, MYO5A, MYSM1, NBAS, NBN, NCF1, NCF2, NCF4, NCSTN, NFAT5, NFKB1, NFKB2, NFKBIA, NHEJ1, NHP2, NKX2-5, NLRC4, NLRP1, NLRP12, NLRP3, NME8, NOD2, NOP10, NRAS, NSMCE3, OFD1, ORAI1, OSTM1, OTULIN, PALB2, PARN, PCCA, PCCB, PEPD, PGM3, PI4KA, PIGA, PIH1D3, PIK3CD, PIK3R1, PLCG2, PLEKHM1, PLG, PMM2, PMS2, PNP, POLA1, POLE, POLE2, PRF1, PRKCD, PRKDC, PROC, PROS1, PSENEN, PSMB8, PSTPIP1, PTEN, PTPRC, RAB27A, RAC2, RAD50, RAD51C, RAG1, RAG2, RANBP2, RASGRP1, RBCK1, RBM8A, RECQL4, RELB, RFX5, RFXANK, RFXAP, RHOH, RMRP, RNASEH2A, RNASEH2B, RNASEH2C, RNF168, RNF31, RNU4ATAC, RORC, RPGR, RPL11, RPL15, RPL26, RPL35A, RPL36, RPL5, RPS10, RPS15, RPS15A, RPS17, RPS19, RPS24, RPS26, RPS27A, RPS28, RPS29, RPS7, RPSA, RSPH1, RSPH3, RSPH4A, RSPH9, RTEL1, RUNX1, SAMD9, SAMD9L, SAMHD1, SBDS, SEMA3E, SERPING1, SH2D1A, SH3BP2, SKIV2L, SLC29A3, SLC35A1, SLC35C1, SLC37A4, SLC39A4, SLC46A1, SLC7A7, SLX4, SMARCAL1, SMARCD2, SNX10, SP110, SPAG1, SPINK5, SRP54, SRP72, STAT1, STAT2, STAT3, STAT5B, STIM1, STK4, STN1, STX11, STXBP2, TAP1, TAP2, TAPBP, TAZ, TBK1, TBX1, TCF3, TCIRG1, TCN2, TERC, TERT, TFRC, THBD, TICAM1, TINF2, TIRAP, TLR3, TMC6, TMC8, TMEM173, TNFAIP3, TNFRSF11A, TNFRSF13B, TNFRSF13C, TNFRSF1A, TNFRSF4, TNFSF11, TNFSF12, TPP1, TPP2, TRADD, TRAF3, TRAF3IP2, TREX1, TRNT1, TTC37, TTC7A, TYK2, UNC119, UNC13D, UNC93B1, UNG, USB1, USP18, VPS13B, VPS45, WAS, WDR1, WIPF1, WRAP53, XIAP, XK, ZAP70, ZBTB24, ZMYND10, ZNF341

INDICATION (S) FOR TESTING — ICD-10 Codes

INFECTIOUS DISEASES

ICD	Description
☐ B20	Human immunodeficiency virus [HIV] disease
☐ B59	Pneumocystosis

MALIGNANT NEOPLASMS OF LYMPHOID, HEMATOPOIETIC AND RELATED TISSUE

ICD	Description
☐ C80.2	Malignant neoplasm associated with transplanted organ
☐ C88.8	Other malignant immunoproliferative diseases
☐ C94.40	Acute panmyelosis with myelofibrosis not having achieved remission
☐ C94.41	Acute panmyelosis with myelofibrosis in remission
☐ C94.42	Acute panmyelosis with myelofibrosis in relapse
☐ C94.6	Myelodysplastic disease not classified

MYELODYSPLASTIC SYNDROMES

ICD	Description
☐ D46.22	Refractory anemia with excess of blasts 2
☐ D47.1	Chronic myeloproliferative disease
☐ D47.9	Neoplasm of uncertain behavior of lymphoid hematopoietic and related tissue unspecified
☐ D47.Z1	Post-transplant lymphoproliferative disorder (PTLD)
☐ D47.Z9	Other specified neoplasms of uncertain behavior of lymphoid hematopoietic and related tissue

APLASTIC AND OTHER ANEMIAS AND OTHER BONE MARROW FAILURE SYNDROMES

ICD	Description
☐ D61.09	Other constitutional aplastic anemia
☐ D61.810	Antineoplastic chemotherapy induced pancytopenia
☐ D61.811	Other drug-induced pancytopenia
☐ D61.818	Other pancytopenia

OTHER DISORDERS OF BLOOD AND BLOOD-FORMING ORGANS

ICD	Description
☐ D70.0	Congenital agranulocytosis
☐ D70.1	Agranulocytosis secondary to cancer chemotherapy
☐ D70.2	Other drug-induced agranulocytosis
☐ D70.4	Cyclic neutropenia
☐ D70.8	Other neutropenia
☐ D70.9	Neutropenia unspecified
☐ D71	Functional disorders of polymorphonuclear neutrophils
☐ D72.0	Genetic anomalies of leukocytes
☐ D72.810	Lymphocytopenia
☐ D72.818	Other decreased white blood cell count
☐ D72.819	Decreased white blood cell count unspecified
☐ D73.81	Neutropenic splenomegaly
☐ D75.81	Myelofibrosis
☐ D76.1	Hemophagocytic lymphohistiocytosis
☐ D76.2	Hemophagocytic syndrome infection-associated
☐ D76.3	Other histiocytosis syndromes

DISORDERS INVOLVING THE IMMUNE MECHANISM

ICD	Description
☐ D80.0	Hereditary hypogammaglobulinemia
☐ D80.1	Nonfamilial hypogammaglobulinemia
☐ D80.2	Selective deficiency of immunoglobulin A [IgA]
☐ D80.3	Selective deficiency of immunoglobulin G [IgG] subclasses
☐ D80.4	Selective deficiency of immunoglobulin M [IgM]
☐ D80.5	Immunodeficiency with increased immunoglobulin M [IgM]
☐ D80.6	Antibody deficiency with near-normal immunoglobulins or with hyperimmunoglobulinemia
☐ D80.7	Transient hypogammaglobulinemia of infancy
☐ D80.8	Other immunodeficiencies with predominantly antibody defects
☐ D80.9	Immunodeficiency with predominantly antibody defects unspecified
☐ D81.0	Severe combined immunodeficiency [SCID] with reticular dysgenesis
☐ D81.1	Severe combined immunodeficiency [SCID] with low T- and B-cell numbers
☐ D81.2	Severe combined immunodeficiency [SCID] with low or normal B-cell numbers
☐ D81.4	Nezelof's syndrome
☐ D81.6	Major histocompatibility complex class I deficiency
☐ D81.7	Major histocompatibility complex class II deficiency
☐ D81.89	Other combined immunodeficiencies
☐ D81.9	Combined immunodeficiency unspecified
☐ D82.0	Wiskott-Aldrich syndrome
☐ D82.1	Di George's syndrome
☐ D82.2	Immunodeficiency with short-limbed stature
☐ D82.3	Immunodeficiency following hereditary defective response to Epstein-Barr virus
☐ D82.4	Hyperimmunoglobulin E [IgE] syndrome
☐ D82.8	Immunodeficiency associated with other specified major defects
☐ D82.9	Immunodeficiency associated with major defect unspecified
☐ D83.0	Common variable immunodeficiency with predominant abnormalities of B-cell numbers and function
☐ D83.1	Common variable immunodeficiency with predominant immunoregulatory T-cell disorders
☐ D83.2	Common variable immunodeficiency with autoantibodies to B- or T-cells
☐ D83.8	Other common variable immunodeficiencies
☐ D83.9	Common variable immunodeficiency unspecified
☐ D84.0	Lymphocyte function antigen-1 [LFA-1] defect
☐ D84.1	Defects in the complement system
☐ D84.8	Other specified immunodeficiencies
☐ D84.9	Immunodeficiency unspecified
☐ D89.3	Immune reconstitution syndrome
☐ D89.810	Acute graft-versus-host disease
☐ D89.811	Chronic graft-versus-host disease
☐ D89.812	Acute on chronic graft-versus-host disease
☐ D89.813	Graft-versus-host disease unspecified
☐ D89.82	Autoimmune lymphoproliferative syndrome [ALPS]
☐ D89.89	Other specified disorders involving the immune mechanism not elsewhere classified
☐ D89.9	Disorder involving the immune mechanism unspecified

POSTSURGICAL MALABSORPTION & CONNECTIVE TISSUE RELATED DISORDER

	ICD	Description
☐	T86.00	Unspecified complication of bone marrow transplant
☐	T86.01	Bone marrow transplant rejection
☐	T86.02	Bone marrow transplant failure
☐	T86.03	Bone marrow transplant infection
☐	T86.09	Other complications of bone marrow transplant
☐	T86.10	Unspecified complication of kidney transplant
☐	T86.11	Kidney transplant rejection
☐	T86.12	Kidney transplant failure
☐	T86.13	Kidney transplant infection
☐	T86.19	Other complication of kidney transplant
☐	T86.20	Unspecified complication of heart transplant
☐	T86.21	Heart transplant rejection
☐	T86.22	Heart transplant failure
☐	T86.23	Heart transplant infection
☐	T86.290	Cardiac allograft vasculopathy
☐	T86.298	Other complications of heart transplant
☐	T86.30	Unspecified complication of heart-lung transplant
☐	T86.31	Heart-lung transplant rejection
☐	T86.32	Heart-lung transplant failure
☐	T86.33	Heart-lung transplant infection
☐	T86.39	Other complications of heart-lung transplant
☐	T86.40	Unspecified complication of liver transplant
☐	T86.41	Liver transplant rejection
☐	T86.42	Liver transplant failure
☐	T86.43	Liver transplant infection
☐	T86.49	Other complications of liver transplant
☐	T86.5	Complications of stem cell transplant
☐	T86.810	Lung transplant rejection
☐	T86.811	Lung transplant failure
☐	T86.812	Lung transplant infection
☐	T86.818	Other complications of lung transplant
☐	T86.819	Unspecified complication of lung transplant
☐	T86.830	Bone graft rejection
☐	T86.831	Bone graft failure
☐	T86.832	Bone graft infection
☐	T86.838	Other complications of bone graft
☐	T86.839	Unspecified complication of bone graft
☐	T86.850	Intestine transplant rejection
☐	T86.851	Intestine transplant failure
☐	T86.852	Intestine transplant infection
☐	T86.858	Other complications of intestine transplant
☐	T86.859	Unspecified complication of intestine transplant
☐	T86.890	Other transplanted tissue rejection
☐	T86.891	Other transplanted tissue failure
☐	T86.892	Other transplanted tissue infection
☐	T86.898	Other complications of other transplanted tissue
☐	T86.899	Unspecified complication of other transplanted tissue
☐	T86.90	Unspecified complication of unspecified transplanted organ and tissue
☐	T86.91	Unspecified transplanted organ and tissue rejection
☐	T86.92	Unspecified transplanted organ and tissue failure
☐	T86.93	Unspecified transplanted organ and tissue infection
☐	T86.99	Other complications of unspecified transplanted organ and tissue

MALNUTRITION

	ICD	Description
☐	E40	Kwashiorkor
☐	E41	Nutritional marasmus
☐	E42	Marasmic kwashiorkor
☐	E43	Unspecified severe protein-calorie malnutrition

HYPERTENSIVE & KIDNEY RELATED DISEASES

	ICD	Description
☐	I12.0	Hypertensive chronic kidney disease with stage 5 chronic kidney disease or end stage renal disease
☐	I13.11	Hypertensive heart and chronic kidney disease without heart failure with stage 5 chronic kidney disease or end stage renal disease
☐	I13.2	Hypertensive heart and chronic kidney disease with heart failure and with stage 5 chronic kidney disease or end stage renal disease
☐	N18.5	Chronic kidney disease stage 5
☐	N18.6	End stage renal disease

ENCOUNTER FOR OTHER POSTPROCEDURAL AFTERCARE

	ICD	Description
☐	Z48.21	Encounter for aftercare following heart transplant
☐	Z48.22	Encounter for aftercare following kidney transplant
☐	Z48.23	Encounter for aftercare following liver transplant
☐	Z48.24	Encounter for aftercare following lung transplant
☐	Z48.280	Encounter for aftercare following heart-lung transplant
☐	Z48.290	Encounter for aftercare following bone marrow transplant
☐	Z48.298	Encounter for aftercare following other organ transplant

ENCOUNTER FOR CARE INVOLVING RENAL DIALYSIS

	ICD	Description
☐	Z49.01	Encounter for fitting and adjustment of extracorporeal dialysis catheter
☐	Z49.02	Encounter for fitting and adjustment of peritoneal dialysis catheter
☐	Z49.31	Encounter for adequacy testing for hemodialysis
☐	Z99.2	Dependence on renal dialysis

TRANSPLANTED ORGAN AND TISSUE STATUS

	ICD	Description
☐	Z94.0	Kidney transplant status
☐	Z94.1	Heart transplant status
☐	Z94.2	Lung transplant status
☐	Z94.3	Heart and lungs transplant status
☐	Z94.4	Liver transplant status
☐	Z94.81	Bone marrow transplant status
☐	Z94.82	Intestine transplant status
☐	Z94.83	Pancreas transplant status
☐	Z94.84	Stem cells transplant status
☐	Z94.89	Other transplanted organ and tissue status

Additional ICD-10 codes: .....

INFORMED CONSENT

For the purposes of this consent, "I", "my", and "your" will refer to me or to my child, including my unborn child, if my child is the person for whom the healthcare provider has ordered testing.

PURPOSE OF THIS TEST

The purpose of this test is (a) to see if I may have a genetic variant or chromosome rearrangement causing a genetic disorder; or (b) to evaluate the chance that I will develop or passon a genetic disorder in the future. If I already know the specific gene variant(s) or chromosome rearrangement that causes the genetic disorder in my family, I agree to inform the laboratory of this information.

WHAT TYPE OF TEST RESULTS CAN I EXPECT FROM GENETIC TESTING?

1. Positive: A change in your DNA was found, which is very likely the cause of your features/symptoms. This is the most straightforward test result, which can be used as the basis to test other family members to determine their chances of having either the disease or a child with the disease.

2. Negative: No variants were found to explain your symptoms. This does not mean that you do not have a genetic condition. It is still possible that there is a genetic variant not found by the test that was ordered. Your healthcare provider or genetic counselor may discuss more testing either now or in the future.

3. Variant of Uncertain Significance (VUS): A change in a gene was found. However, we are not sure whether this variant is the cause of your symptoms/-features. More information is needed. We may suggest testing other family members to help figure out the meaning of the test result.

4. Unexpected Results: In rare instances, this test may reveal an important genetic change that is not directly related to the reason for ordering this test. For example, this test may find you are at risk for another genetic condition I am not aware of or it may indicate differences in the number or rearrangement of sex chromosomes. We may disclose this information to the ordering healthcare provider if it likely affects medical care. Because medical and scientific knowledge is constantly changing, new information that becomes available may supplement the information **Elite Clinical Laboratory** used to interpret my results.

Healthcare providers can contact **Elite Clinical Laboratory** at any time to discuss the classification of an identified variant.

WHAT IS TRIO/DUO-BASED GENETIC TESTING?

For some genetic tests, including samples from the biological parents and/or other biological relatives along with the patient's sample can help with the interpretation of the test results. These tests are often referred to as "trio tests" since they typically include samples from the patient and both parents. Samples from relatives should be submitted with the patient's sample. Clinical information must be provided for the patient and any relative who submits a sample.

I understand that **Elite Clinical Laboratory** will use the relative sample(s) when needed for the interpretation of my test results and that my test report may include clinical and genetic information abouta relative when it is relevant to the interpretation of the test results. I further understand that relatives will not receive an independent analysis of data nor a separate report.

RISKS AND LIMITATIONS OF GENETIC TESTING

1. In some cases, testing may not identify a genetic variant even though one exists. This may be due to limitations in current medical knowledge or testing technology.

2. Accurate interpretation of test results may require knowing the true biological relationships in a family. I understand that if I fail to accurately state the biological relationships in my family, it could lead to incorrect interpretation of the test results, incorrect diagnoses, and/or inconclusive test results. If genetic testing reveals that the true biological relationships in a family are not as I reported them, including non-paternity (the reported father is not the biological father) and consanguinity (the parents are related by blood), I agree to have these findings reported to the healthcare provider who ordered the test.

3. Although genetic testing is highly accurate, inaccurate results may occur. These reasons include, but are not limited to mislabeled samples, inaccurate reporting of clinical/medical information, rare technical errors, or other reasons.

4. I understand that this test may not detect all of the long-term medical risks that I might experience. The result of this test does not guarantee my health and that additional diagnostic tests may still need to be done.

5. I agree to provide an additional sample if the initial sample is not adequate.

PATIENT CONFIDENTIALITY AND GENETIC COUNSELING

It is recommended that I receive genetic counseling before and after having this genetic test. I can find a genetic counselor in my area at www.nsgc.org. Further testing or additional consultations with a healthcare provider may be necessary.

To maintain confidentiality, test results will only be released to the referring healthcare provider, the ordering laboratory, to me, to other healthcare providers involved in my care, diagnosis and treatment, or to others with my consent or as permitted or required by law. Federal laws prohibit unauthorized disclosure of this information. More information can be found at: www.genome.gov/10002077

INTERNATIONAL SAMPLES

If I reside outside the United States, I attest that by providing a sample for testing, I am not knowingly violating any export ban or other legal restriction in the country of my residence.

SAMPLE RETENTION

After testing is complete, my sample may be de-identified and be used for test development and improvement, internal validation, quality assurance, and training purposes. **Elite Clinical Laboratory** will not return DNA samples to you or to referring healthcare providers, unless specific prior arrangements have been made. I understand that samples from residents of New York State will not be included in the de-identified research studies described in this authorization and will not retain them for more than 60 days after test completion, unless specifically authorized by my selection. The authorization is optional, and testing will be unaffected if I do not check the box for the New York authorization language. **Elite Clinical Laboratory** will not perform any tests on the biological sample other than those specifically authorized.

DATABASE PARTICIPATION

De-identified health history and genetic information can help healthcare providers and scientists understand how genes affect human health. Sharing this de-identified information helps healthcare providers to provide better care for their patients and researchers to make new discoveries. **Elite Clinical Laboratory** shares this type of information with healthcare providers, scientists, and healthcare databases. **Elite Clinical Laboratory** will not share any personally identifying information and will replace the identifying information with a unique code not derived from any personally identifying information. Even with a unique code, there is a risk that I could be identified based on the genetic and health information that is shared. **Elite Clinical Laboratory** believes that this is unlikely, though the risk is greater if I have already shared my genetic or health information with public resources, such as genealogy websites.

EXOME/GENOME SEQUENCING SECONDARY FINDINGS

Applicable Only for Full Exome Sequencing and Genome Sequencing Tests. • Does not pertain to Xpanded® or Slice tests

As many different genes and conditions are analyzed in an exome or genome sequencing test, these tests may reveal some findings not directly related to the reason for ordering the test. Such findings are called "incidental" or "secondary" and can provide information that was not anticipated.

Secondary findings are variants, identified by an exome or genome sequencing test, in genes that are unrelated to the individual's reported clinical features.

The American College of Medical Genetics and Genomics (ACMG) has recommended that secondary findings identified in a specific subset of medically actionable genes associated with various inherited disorders be reported for all probands undergoing exome or genome sequencing. Please refer to the latest version of the ACMG recommendations for reporting of secondary findings in clinical exome and genome sequencing for complete details of the genes and associated genetic disorders. Reportable secondary findings will be confirmed by an alternate test method when needed.

WHAT WILL BE REPORTED FOR THE PATIENT? - All pathogenic and likely pathogenic variants associated with specific genotypes identified in the genes (for which a minimum of 10X coverage was achieved by exome sequencing or a minimum of 15X coverage was achieved by genome sequencing), as recommended by the ACMG.

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WHAT WILL BE REPORTED FOR RELATIVES? - The presence or absence of any secondary finding(s) reported for the proband will be provided for all relatives analyzed by an exome or genome sequencing test.

LIMITATIONS - Pathogenic and/or likely pathogenic variants may be present in a portion of the gene not covered by this test and therefore are not reported. The absence of reportable secondary findings for any particular gene does not mean there are no pathogenic and/or likely pathogenic variants in that gene. Pathogenic variants and/or likely pathogenic variants that may be present in a relative, but are not present in the proband, will not be identified, or reported. Only changes at the sequence level will be reported in the secondary findings report. Larger deletions/duplications, abnormal methylation, triplet repeat or other expansion variants, or other variants not routinely identified by clinical exome and genome sequencing will not be reported.

FINANCIAL AGREEMENT AND GUARANTEE - For insurance billing, I understand and authorize **Elite Clinical Laboratory** to bill my health insurance plan on my behalf, to release any information required for billing, and to be my designated representative for purposes of appealing any denial of benefits. I irrevocably assign to and direct that payment be made directly to I understand that my out-of-pocket costs may be different than the estimated amount indicated to me by **Elite Clinical Laboratory** as part of a benefit investigation. I agree to be financially responsible for any and all amounts as indicated on the explanation of benefits issued by my health insurance plan. If my insurance provider sends a payment directly to me for services performed by **Elite Clinical Laboratory** on my behalf, I agree to endorse the insurance check and forward it to **Elite Clinical Laboratory** within 30 days of receipt as payment towards **IElite Clinical Laboratory** claim for services rendered.

MEDICARE

A completed Advance Beneficiary Notice (ABN) is required for Medicare patients.

DIGITAL PATIENT LETTER CONSENT

• Applicable Only for Commercial Insurance

• Estimate is provided by your health insurance company and therefore NO estimate will be sent for any orders placed with federal or state-funded insurance plans (e.g. Medicare, Medicaid, Tricare, etc.), institutional bill, or patient bill (self-pay).

To provide you with the estimated out-of-pocket expenses related to your test, **Elite Clinical Laboratory** will send you an email and/or text with the link to access your personalized Digital Patient Letter.

In order to send this information, we need your consent and agreement to the following items:

1. can use your email address or mobile phone number solely for the purpose of **Elite Clinical Laboratory** sending your estimated financial obligation. Text message data rates may apply. is not responsible for undelivered messages due to incorrect or illegible contact information.

2. will send you an email and/or text message containing a link to view your personalized Patient Letter that includes the test out-of-pocket estimate. The link is time-sensitive and will only be available for 72 hours from the time the message is sent. In order to view the estimate, you must click the link in the message.

3. If you take no action, **Elite Clinical Laboratory** will assume that you agree to move ahead with testing and will bill your health insurance. You can approve testing with insurance, switch to self-pay, or cancel the test via the link within the given 72-hour window. In turn, **Elite Clinical Laboratory** if receives your sample(s) and the billing method hasn't been changed, or the test hasn't been cancelled, we will move ahead with testing as ordered, and you will be responsible for any out-of-pocket costs for the completion of the test(s).

STOP Patient Signature

I hereby assign all rights and benefits under my health plan and all rights and obligations that I and my dependents have under my health plan to **Elite Clinical Laboratory** its assigned affiliates and authorized representatives for laboratory services furnished to me by **Elite Clinical Laboratory** I irrevocably designate, authorize and appoint **Elite Clinical Laboratory** or its assigned affiliates and their authorized representatives as my true and lawful attorney-in-fact for the purpose of submitting my claims, obtain a copy of my health plan document, Summary Plan Description, disclosure, appeal, litigation or other remedies in accordance with the benefits and rights under my health plan and in accordance with federal or state laws. If my health plan fails to abide by my authorization and makes payment directly to me, I agree to endorse the insurance check and forward it to **Elite Clinical Laboratory** immediately upon receipt. I hereby authorize **Elite Clinical Laboratory** its assigned affiliates and authorized representatives to contact me or my health Plan/administrator for billing or payment purposes by phone, text message, or email with the contact information that I have provided to **Elite Clinical Laboratory**, in compliance with federal and state laws. **Elite Clinical Laboratory**, its assigned affiliates and their authorized representatives may release to my health plan administrator, my employer, and my authorized representative my personal health information for the purpose of procuring payment of **Elite Clinical Laboratory** and for all the laboratory services. I understand the acceptance of insurance does not relieve me from any responsibility concerning payment for laboratory services and that I am financially responsible for all charges whether or not they are covered by my insurance.

Signature of Patient or Patient Representative / Relationship to Patient Date:

STOP ORDERING PHYSICIAN SIGN HERE

Physician must only order tests that are medically necessary for the diagnosis or treatment of a patient

I attest that this test is medically necessary for the diagnosis or detection of a disease or disorder and that the results will be used in medical management and care decisions for the patient. Furthermore, all information on this Requisition Form is true to the best of my knowledge. I agree to provide the Care Plan notes and Letter of Intent for this order if the insurance requests the lab to gather the medical necessity for any reason

Ordering Physician Signature Date: