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Instructions:

- Physician **must** sign Physician Consent.
- Patient Informed Consent signature **Required only** for Genetics testing orders.
- All items identified as ***Required** (Listed in the Test Name and/or Informational panels) **must** be provided/attached to the requisition.

Facility Code	Facility Name	
Ordering Physician (Last Name, First)		NPI
Facility Address (Address, State, Zip)		

PATIENT INFORMATION

Patient First Name	Patient Last Name	Biological Sex <input type="checkbox"/> M <input type="checkbox"/> F	Date of Birth (mm/dd/yyyy)	Phone Number
Address		City	State	Zip

Gender Identity	Sexual Orientation	Race	Ethnicity
<input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Female-to-Male <input type="checkbox"/> Male-to-Female <input type="checkbox"/> Genderqueer <input type="checkbox"/> Other (Specify) _____ <input type="checkbox"/> Choose not to Disclose	<input type="checkbox"/> Lesbian, gay, or homosexual <input type="checkbox"/> Straight or heterosexual <input type="checkbox"/> Bisexual <input type="checkbox"/> Something else (Describe) _____ <input type="checkbox"/> Don't know <input type="checkbox"/> Choose not to disclose	<input type="checkbox"/> American Indian or Alaska Native <input type="checkbox"/> Asian <input type="checkbox"/> Black or African American <input type="checkbox"/> Native Hawaiian or Other Pacific Islander <input type="checkbox"/> White <input type="checkbox"/> Other <input type="checkbox"/> Unknown <input type="checkbox"/> Asked but unknown <input type="checkbox"/> Choose not to disclose	<input type="checkbox"/> Hispanic or Latino <input type="checkbox"/> Non-Hispanic/Non-Latino <input type="checkbox"/> Other <input type="checkbox"/> Unknown <input type="checkbox"/> Asked but unknown <input type="checkbox"/> Choose not to disclose

PATIENT INSURANCE INFORMATION

(*Required: Copy of Patient Insurance Card)

Primary Insurance	Insurance Policy / ID Number	Group Number
Secondary Insurance (if any)	Insurance Policy / ID Number	Group Number
Name of Insured	Date of Birth of Insured	

SPECIMEN INFORMATION

 Date Sample Collected (mm/dd/yyyy)
 (Required)

Specimen Type

Specimen Quantity

ICD-10 CODES - Indications for Testing

ICD-10 Codes:

TEST MENU

Genetics (*Required: SOAP & Progress Notes)

 (34) Comprehensive Metabolic Disorder NGS

ABCA1, ABCB4, ABCC2, ABCD1, ABCD3, ABCD4, ABCG5, ABCG8, ACACA, ACADM, ACADS, ACADVL, APOE, ARSA, ASPA, ASS1, ATP7B, BCKDHA, BCKDHB, BLM, BSCL2, BTB, CACNA1A, CBS, CFTR, CLCNKB, COX10, COX15, CPOX, CPT1A, CSTB, DGUOK, DHCR7, DLD, DPYD, F9,FAH, FANCC, FH, G6PC, G6PD, GAA, GALNS, GALT, GALC, GAMT, GATM, GBA, GBE1, GLUD1, GCDH, GCK, GLA, GNE, GYS1, GYS2, HADH, HADHA, HADHB, HBB, HEXA, HFE, HMGCL, HPRT1, HSD17B10, HYAL1, IDH2, IDS, LCT, LIPA, LPL, MAN2B1, IKBKAP, ISCU, MCCC1, MCCC2, MCOLN1, MMAB, MMACHC, MMAA, MMADHC, MTHFR, MUT, NAGA, NAGLU, OTC, PAH, NHEG1, PCCA, PC, PCCB, PCK1,PCK2, PDHA1, PDHX, PEPD, PEX1, PEX10, PEX12, PEX13, PEX14, PEX16, PEX19, PEX2, PEX26, PEX3, PEX5, PEX6, PEX7, PHKA1, PHKA2, PHKB, PHKG1, PHKG2, PHYH, POLG, PPARG, PRKAG2, PRPS1, PTS, PYGL, PYGM, QDPR, RBCK1, RFT1, RNASEH2A, RNASEH2B, RNASEH2C, SAMHD1, SEC23B, SERPINA1, SGSH, SLC12A3, SLC16A1, SLC17A5, SLC22A5, SLC25A13, SLC25A15, SLC25A20, SLC25A26, SLC25A4, SLC2A1, SLC2A2, SLC30A10, SLC35A1, SLC35A2, SLC35C1, SLC39A4,SLC3A1, SLC40A1, SLC41A2, SLC41A3, SLC46A1, SLC5A1, SLC6A19, SLC6A8, SLC6A9, SLC7A7, SLCO1B1, SMPD1, SSR4, STT3A, STT3B, SUCLA2, SUGL1, SUOX, SURF1, TALDO1, TAT, TBC1D4, TCN2, TFR2, TIMM8A, TMEM126A, TMEM165, TNPO3, TMEM70, TPMT, TPP1, TREX1, TRIM32, TRIM37, TRMU, TRPM6, TRPM7, TSFM, TTC19, TUFM, TUSC3, TYMP,UGT1A1, UMPS, UCP2,UPB1, UQCRB, UQCRQ, UROD, WFS1, XDH, YARS2, ZMPSTE24

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 pass on 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 Amerilab Diagnostics Center used to interpret my results.
5. Healthcare providers can contact Amerilab Diagnostics Center at any time to discuss the classification of an identified variant. 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 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.

INFORMED CONSENT

I understand that Amerilab Diagnostics Center 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 about a 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. Amerilab Diagnostics Center 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. Amerilab Diagnostics Center 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. Amerilab Diagnostics Center shares this type of information with healthcare providers, scientists, and healthcare databases. Amerilab Diagnostics Center 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. Amerilab Diagnostics Center 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.

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 Amerilab Diagnostics Center 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 Amerilab Diagnostics Center 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 Amerilab Diagnostics Center on my behalf, I agree to endorse the insurance check and forward it to Amerilab Diagnostics Center within 30 days of receipt as payment towards Amerilab Diagnostics Center 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, Amerilab Diagnostics Center will send you an email and/or text with the link to access your personalized Digital Patient Letter.

In order to send this information, Amerilabs needs your consent and agreement to the following items:

1. Can use your email address or mobile phone number solely for the purpose of Amerilab Diagnostics Center 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, Amerilab Diagnostics Center 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, Amerilab Diagnostics Center 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).

PATIENT INFORMED CONSENT SIGNATURE

I certify my understanding and acceptance of the Patient Informed Consent. I also 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 Amerilab Diagnostics Center its assigned affiliates and authorized representatives for laboratory services furnished to me by Amerilab Diagnostics Center I irrevocably designate, authorize and appoint Amerilab Diagnostics Center 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 Amerilab Diagnostics Center immediately upon receipt. I hereby authorize Amerilab Diagnostics Center 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 Amerilab Diagnostics Center , in compliance with federal and state laws. Amerilab Diagnostics Center , 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 Amerilab Diagnostics Center 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

PHYSICIAN SIGNATURE

Amerilab Diagnostics Center continually updates its panels based on the most recent evidence. If an order is placed using an outdated test requisition form, Amerilab Diagnostics Center reserves the right to upgrade ordered tests to their current versions. Test IDs containing add-on codes will include the original panel as well as the add-on. By signing this form, the medical professional attests that they are authorized under applicable law to order this test(s) and acknowledge that the (i) the individual/family member authorized to make decisions for the individual (collectively, the "Patient") has been supplied information regarding and consented to undergo genetic testing, (ii) the test(s) ordered are medically necessary for the diagnosis and/or treatment/management of the patient, (iii) the results will be used to determine my patients medical management and treatment decisions. The medical professional will retain evidence that the patient consented to genetic testing. The medical professional consents to the sharing of organization and clinician contact information with third parties, including commercial organizations, who may contact the medical professional directly in connection with the Program. A list of third party partners will be provided upon request. I and further certify that.

Medical Professional Signature (Required)

Date