

- Statement of Medical Necessity (Signed by Physician)
- Informed Consent Form (Signed by Pt & Physician)
- SOAP & Progress Note (Signed by Physician)
- Scanned Insurance Card Copy

TESTING REQUISITION FORM - THYROID GENETIC DISEASE

PATIENT INFORMATION

Patient First Name		Patient Last Name		Biological Sex <input type="checkbox"/> F <input type="checkbox"/> M
Date of Birth (MM/DD/YYYY)	Phone Number	Email Address		
Address	City	State	Zip	
Ethnicity: <input type="checkbox"/> African American <input type="checkbox"/> Asian <input type="checkbox"/> Caucasian <input type="checkbox"/> Hispanic <input type="checkbox"/> Jewish(Ashkenazi) <input type="checkbox"/> Portuguese <input type="checkbox"/> Other				

PATIENT INSURANCE INFORMATION

SPECIMEN INFORMATION

<input type="checkbox"/> Insurance <input type="checkbox"/> Self-Pay <input type="checkbox"/> Client Bill		Date Sample Collected (mm/dd/yy) (required)		
Name of the insurance	Secondary Insurance, If any			
Insurance Policy/ID number	Name of the insured			
Insurance Group number	Date of Birth of Insured			
		<input type="checkbox"/> Buccal Swab <input type="checkbox"/> 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 relevant 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.

- | | | | | | | | |
|---------------------------------|----------------------------------|-----------------------------------|--------------------------------|---------------------------------|----------------------------------|----------------------------------|--------------------------------|
| <input type="checkbox"/> PIK3CA | <input type="checkbox"/> SLC5A5 | <input type="checkbox"/> PAX8 | <input type="checkbox"/> TGFBI | <input type="checkbox"/> ATP1A2 | <input type="checkbox"/> PLN | <input type="checkbox"/> IRAK1 | <input type="checkbox"/> CST3 |
| <input type="checkbox"/> TRH | <input type="checkbox"/> CACNA1A | <input type="checkbox"/> GLIS3 | <input type="checkbox"/> TG | <input type="checkbox"/> HRAS | <input type="checkbox"/> TFR2 | <input type="checkbox"/> G6PD | <input type="checkbox"/> CST1 |
| <input type="checkbox"/> THRB | <input type="checkbox"/> PRKCG | <input type="checkbox"/> FOXE1 | <input type="checkbox"/> THRA | <input type="checkbox"/> TTR | <input type="checkbox"/> SLC26A4 | <input type="checkbox"/> SLC16A2 | <input type="checkbox"/> CSTB |
| <input type="checkbox"/> CTNNB1 | <input type="checkbox"/> HAMP | <input type="checkbox"/> SECISBP2 | <input type="checkbox"/> TP53 | <input type="checkbox"/> IYD | <input type="checkbox"/> TSHR | <input type="checkbox"/> IGSF1 | <input type="checkbox"/> DUOX2 |
| <input type="checkbox"/> KRAS | <input type="checkbox"/> SLC40A1 | <input type="checkbox"/> GNAQ | <input type="checkbox"/> TSHB | <input type="checkbox"/> HFE | <input type="checkbox"/> NKX2-1 | <input type="checkbox"/> TBL1X | |
| <input type="checkbox"/> DUOX1 | <input type="checkbox"/> TPO | <input type="checkbox"/> PLCG2 | <input type="checkbox"/> NRAS | <input type="checkbox"/> ESR1 | <input type="checkbox"/> MECP2 | <input type="checkbox"/> IRS4 | |

INDICATION (S) FOR TESTING

ICD-10 Codes

Category - 1: ICD10 codes

- | | |
|--|--|
| <input type="checkbox"/> E06.0 Acute thyroiditis | <input type="checkbox"/> E05.11 Thyrotoxicosis with toxic single thyroid nodule with thyrotoxic crisis or storm |
| <input type="checkbox"/> E06.1 Subacute thyroiditis | <input type="checkbox"/> E05.20 Thyrotoxicosis with toxic multinodular goiter without thyrotoxic crisis or storm |
| <input type="checkbox"/> E06.2 Chronic thyroiditis with transient thyrotoxicosis | <input type="checkbox"/> E05.21 Thyrotoxicosis with toxic multinodular goiter with thyrotoxic crisis or storm |
| <input type="checkbox"/> E06.3 Autoimmune thyroiditis | <input type="checkbox"/> E05.30 Thyrotoxicosis from ectopic thyroid tissue without thyrotoxic crisis or storm |
| <input type="checkbox"/> E06.4 Drug-induced thyroiditis | <input type="checkbox"/> E05.31 Thyrotoxicosis from ectopic thyroid tissue with thyrotoxic crisis or storm |
| <input type="checkbox"/> E06.5 Other chronic thyroiditis | <input type="checkbox"/> E05.40 Thyrotoxicosis factitia without thyrotoxic crisis or storm |
| <input type="checkbox"/> E06.9 Thyroiditis, unspecified | <input type="checkbox"/> E05.41 Thyrotoxicosis factitia with thyrotoxic crisis or storm |
| <input type="checkbox"/> E03.0 Congenital hypothyroidism with diffuse goiter | <input type="checkbox"/> E05.80 Other thyrotoxicosis without thyrotoxic crisis or storm |
| <input type="checkbox"/> E03.1 Congenital hypothyroidism without goiter | <input type="checkbox"/> E05.81 Other thyrotoxicosis with thyrotoxic crisis or storm |
| <input type="checkbox"/> E03.2 Hypothyroidism due to medicaments and other exogenous substances | <input type="checkbox"/> E05.90 Thyrotoxicosis, unspecified without thyrotoxic crisis or storm |
| <input type="checkbox"/> E03.3 Postinfectious hypothyroidism | <input type="checkbox"/> E05.91 Thyrotoxicosis, unspecified with thyrotoxic crisis or storm |
| <input type="checkbox"/> E03.4 Atrophy of thyroid (acquired) | <input type="checkbox"/> E07.0 Hypersecretion of calcitonin |
| <input type="checkbox"/> E03.5 Myxedema coma | <input type="checkbox"/> E07.1 Dysormogenetic goiter |
| <input type="checkbox"/> E03.8 Other specified hypothyroidism | <input type="checkbox"/> E07.81 Sick-euthyroid syndrome |
| <input type="checkbox"/> E03.9 Hypothyroidism, unspecified | <input type="checkbox"/> E07.89 Other specified disorders of thyroid |
| <input type="checkbox"/> E01.0 Iodine-deficiency related diffuse (endemic) goiter | <input type="checkbox"/> E07.9 Disorder of thyroid, unspecified |
| <input type="checkbox"/> E01.1 Iodine-deficiency related multinodular (endemic) goiter | <input type="checkbox"/> E20.1 Pseudohypoparathyroidism |
| <input type="checkbox"/> E01.2 Iodine-deficiency related (endemic) goiter, unspecified | <input type="checkbox"/> Z85.8 Personal history of malignant neoplasms of other organs and systems |
| <input type="checkbox"/> E01.8 Other iodine-deficiency related thyroid disorders and allied conditions | <input type="checkbox"/> D02.0 Carcinoma in situ of larynx |
| <input type="checkbox"/> E04.0 Nontoxic diffuse goiter | <input type="checkbox"/> D09.3 Carcinoma in situ of thyroid and other endocrine glands |
| <input type="checkbox"/> E04.1 Nontoxic single thyroid nodule | <input type="checkbox"/> D14.1 Benign neoplasm of larynx |
| <input type="checkbox"/> E04.2 Nontoxic multinodular goiter | |
| <input type="checkbox"/> E04.8 Other specified nontoxic goiter | |
| <input type="checkbox"/> E04.9 Nontoxic goiter, unspecified | |
| <input type="checkbox"/> E05.00 Thyrotoxicosis with diffuse goiter without thyrotoxic crisis or storm | |
| <input type="checkbox"/> E05.01 Thyrotoxicosis with diffuse goiter with thyrotoxic crisis or storm | |
| <input type="checkbox"/> E05.10 Thyrotoxicosis with toxic single thyroid nodule without thyrotoxic crisis or storm | |

Category - 2: ICD10 codes

- | | |
|---|--|
| <input type="checkbox"/> C17.0 Malignant neoplasm of duodenum | <input type="checkbox"/> C34.80 Malignant neoplasm of overlapping sites of unspecified bronchus and lung |
| <input type="checkbox"/> C17.1 Malignant neoplasm of jejunum | <input type="checkbox"/> C34.81 Malignant neoplasm of overlapping sites of right bronchus and lung |
| <input type="checkbox"/> C17.2 Malignant neoplasm of ileum | <input type="checkbox"/> C34.82 Malignant neoplasm of overlapping sites of left bronchus and lung |
| <input type="checkbox"/> C17.3 Meckel's diverticulum, malignant | <input type="checkbox"/> C34.90 Malignant neoplasm of unspecified part of unspecified bronchus or lung |
| <input type="checkbox"/> C17.8 Malignant neoplasm of overlapping sites of small intestine | <input type="checkbox"/> C34.91 Malignant neoplasm of unspecified part of right bronchus or lung |
| <input type="checkbox"/> C17.9 Malignant neoplasm of small intestine, unspecified | <input type="checkbox"/> C34.92 Malignant neoplasm of unspecified part of left bronchus or lung |
| <input type="checkbox"/> C18.0 Malignant neoplasm of cecum | <input type="checkbox"/> C38.4 Malignant neoplasm of pleura |
| <input type="checkbox"/> C18.1 Malignant neoplasm of appendix | <input type="checkbox"/> C45.0 Mesothelioma of pleura |
| <input type="checkbox"/> C18.2 Malignant neoplasm of ascending colon | <input type="checkbox"/> C45.1 Mesothelioma of peritoneum |
| <input type="checkbox"/> C18.3 Malignant neoplasm of hepatic flexure | <input type="checkbox"/> C48.1 Malignant neoplasm of specified parts of peritoneum |
| <input type="checkbox"/> C18.4 Malignant neoplasm of transverse colon | <input type="checkbox"/> C48.2 Malignant neoplasm of peritoneum, unspecified |
| <input type="checkbox"/> C18.5 Malignant neoplasm of splenic flexure | <input type="checkbox"/> C48.8 Malignant neoplasm of overlapping retroperitoneum and peritoneum |
| <input type="checkbox"/> C18.6 Malignant neoplasm of descending colon | <input type="checkbox"/> C54.0 Malignant neoplasm of isthmus uteri |
| <input type="checkbox"/> C18.7 Malignant neoplasm of sigmoid colon | <input type="checkbox"/> C54.1 Malignant neoplasm of endometrium |
| <input type="checkbox"/> C18.8 Malignant neoplasm of overlapping sites of colon | <input type="checkbox"/> C54.2 Malignant neoplasm of myometrium |
| <input type="checkbox"/> C18.9 Malignant neoplasm of colon, unspecified | <input type="checkbox"/> C54.3 Malignant neoplasm of fundus uteri |
| <input type="checkbox"/> C19 Malignant neoplasm of rectosigmoid junction | <input type="checkbox"/> C54.8 Malignant neoplasm of overlapping sites of corpus uteri |
| <input type="checkbox"/> C20 Malignant neoplasm of rectum | <input type="checkbox"/> C54.9 Malignant neoplasm of corpus uteri, unspecified |
| <input type="checkbox"/> C21.0 Malignant neoplasm of anus, unspecified | <input type="checkbox"/> C55 Malignant neoplasm of uterus, part unspecified |
| <input type="checkbox"/> C21.1 Malignant neoplasm of anal canal | <input type="checkbox"/> C56.1 Malignant neoplasm of right ovary |
| <input type="checkbox"/> C21.2 Malignant neoplasm of cloacogenic zone | <input type="checkbox"/> C56.2 Malignant neoplasm of left ovary |
| <input type="checkbox"/> C21.8 Malignant neoplasm of overlapping of rectum, anus and anal canal | <input type="checkbox"/> C56.3 Malignant neoplasm of bilateral ovaries |
| <input type="checkbox"/> C33 Malignant neoplasm of trachea | <input type="checkbox"/> C56.9 Malignant neoplasm of unspecified ovary |
| <input type="checkbox"/> C34.00 Malignant neoplasm of unspecified main bronchus | <input type="checkbox"/> C57.00 Malignant neoplasm of unspecified fallopian tube |
| <input type="checkbox"/> C34.01 Malignant neoplasm of right main bronchus | <input type="checkbox"/> C57.01 Malignant neoplasm of right fallopian tube |
| <input type="checkbox"/> C34.02 Malignant neoplasm of left main bronchus | <input type="checkbox"/> C57.02 Malignant neoplasm of left fallopian tube |
| <input type="checkbox"/> C34.10 Malignant neoplasm of upper lobe, unspecified bronchus or lung | <input type="checkbox"/> C57.10 Malignant neoplasm of unspecified broad ligament |
| <input type="checkbox"/> C34.11 Malignant neoplasm of upper lobe, right bronchus or lung | <input type="checkbox"/> C57.11 Malignant neoplasm of right broad ligament |
| <input type="checkbox"/> C34.12 Malignant neoplasm of upper lobe, left bronchus or lung | <input type="checkbox"/> C57.12 Malignant neoplasm of left broad ligament |
| <input type="checkbox"/> C34.2 Malignant neoplasm of middle lobe, bronchus or lung | <input type="checkbox"/> C57.20 Malignant neoplasm of unspecified round ligament |
| <input type="checkbox"/> C34.30 Malignant neoplasm of lower lobe, unspecified bronchus or lung | <input type="checkbox"/> C57.21 Malignant neoplasm of right round ligament |
| <input type="checkbox"/> C34.31 Malignant neoplasm of lower lobe, right bronchus or lung | <input type="checkbox"/> C57.22 Malignant neoplasm of left round ligament |
| <input type="checkbox"/> C34.32 Malignant neoplasm of lower lobe, left bronchus or lung | <input type="checkbox"/> C57.3 Malignant neoplasm of parametrium |

Continued

INDICATION (S) FOR TESTING**ICD-10 Codes**

- C57.4 Malignant neoplasm of uterine adnexa, unspecified
- C73* Malignant neoplasm of thyroid gland
- C92.00 Acute myeloblastic leukemia, not having achieved remission
- C92.01 Acute myeloblastic leukemia, in remission
- C92.02 Acute myeloblastic leukemia, in relapse
- C92.10 Chronic myeloid leukemia, BCR/ABL-positive, not having achieved remission
- C92.11 Chronic myeloid leukemia, BCR/ABL-positive, in remission
- C92.12 Chronic myeloid leukemia, BCR/ABL-positive, in relapse
- C92.40 Acute promyelocytic leukemia, not having achieved remission
- C92.41 Acute promyelocytic leukemia, in remission
- C92.42 Acute promyelocytic leukemia, in relapse
- C92.50 Acute myelomonocytic leukemia, not having achieved remission
- C92.51 Acute myelomonocytic leukemia, in remission
- C92.52 Acute myelomonocytic leukemia, in relapse
- C92.60 Acute myeloid leukemia with 11q23-abnormality not having achieved remission
- C92.61 Acute myeloid leukemia with 11q23-abnormality in remission
- C92.62 Acute myeloid leukemia with 11q23-abnormality in relapse
- C92.A0 Acute myeloid leukemia with multilineage dysplasia, not having achieved remission
- C92.A1 Acute myeloid leukemia with multilineage dysplasia, in remission
- C92.A2 Acute myeloid leukemia with multilineage dysplasia, in relapse
- C93.10 Chronic myelomonocytic leukemia not having achieved remission
- C93.11 Chronic myelomonocytic leukemia, in remission
- C93.12 Chronic myelomonocytic leukemia, in relapse
- D34 Benign neoplasm of thyroid gland
- D44.0 Neoplasm of uncertain behavior of thyroid gland

- D44.2* Neoplasm of uncertain behavior of parathyroid gland
- D44.9 Neoplasm of uncertain behavior of unspecified endocrine gland
- D46.0 Refractory anemia without ring sideroblasts, so stated
- D46.1 Refractory anemia with ring sideroblasts
- D46.20 Refractory anemia with excess of blasts, unspecified
- D46.21 Refractory anemia with excess of blasts 1
- D46.22 Refractory anemia with excess of blasts 2
- D46.4 Refractory anemia, unspecified
- D46.9 Myelodysplastic syndrome, unspecified
- D46.A Refractory cytopenia with multilineage dysplasia
- D46.B Refractory cytopenia with multilineage dysplasia and ring sideroblasts
- D46.C Myelodysplastic syndrome with isolated del(5q) chromosomal abnormality
- D46.Z Other myelodysplastic syndromes
- E01.0 Iodine-deficiency related diffuse (endemic) goiter
- E01.1 Iodine-deficiency related multinodular (endemic) goiter
- E01.2 Iodine-deficiency related (endemic) goiter, unspecified
- E04.0 Nontoxic diffuse goiter
- E04.1 Nontoxic single thyroid nodule
- E04.2 Nontoxic multinodular goiter
- E04.8 Other specified nontoxic goiter
- E04.9 Nontoxic goiter, unspecified
- Z85.030 Personal history of malignant carcinoid tumor of large intestine
- Z85.038 Personal history of other malignant neoplasm of large intestine
- Z85.040 Personal history of malignant carcinoid tumor of rectum
- Z85.048 Personal history of other malignant neoplasm of rectum, rectosigmoid junction, and anus

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 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 **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 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. **Elite Clinical Laboratory** will not return DNA samples to you or 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.

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 **Elite 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: