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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

DIABETES-OBESITY GENETIC TESTING REQUISITION FORM

COMPLETE ENTIRE FORM AND SUBMIT PEDIGREE/CLINIC NOTES TO AVOID DELAYS

	IMPORTANT I I								
PATIENT INFORMATION	IMPORTANT - Include a cu	urrent m	nedicatio phot	on list AND a patier cocopy of insurance	it face shee card (fron	et OR complete next t and back).	two se	ections below and include	
Patient First Name		F	Patient	Last Name				Biological Sex F M	
Date of Birth (MM/DD/YYYY)	Date of Death (if applica	ble)		Phone Number			Em	ail Address	
Address				City		State		Zip	
Ethnicity: African American	Asian 🗌 Caucasia	an 🗌	Hispar	nic	hkenazi)	Portuguese	Otl	ner	
PATIENT INSURANCE INFORMATION - Attach patient demographics and copy of insurance card			SPECIMEN INFORMATION*						
☐ Insurance ☐ Self-Pay ☐ Client Bill				Date Sample Collected (mm/dd/yy) (required)					
Name of the insurance	Secondary Insurance, If any		Medical Record#						
Insurance Policy/ID number	Name of the insured			☐ Buccal Swab					
Insurance Group number	Date of Birth of Insur	ed		Other (specify source)					
ORDERII	NG PHYSICIAN/SEND	DING	FACIL	LITY (Each Listed	l person wi	ll receive a copy of t	he rep	ort)	
Facility Name (Facility Code):		A	Address	:		City:			
State/Country :			ip:			Phone:	Phone:		
Ordering Licensed Provider Name (Last, First)(Code)			IPI#		Phone		Fax/Email		
	STATEME	NT O	F ME	DICAL NEC	SSITY				
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 TEST	ING (CHECK ALL THAT APP	PLY)							
☐ Diagnostic ☐ Family history ☐ I	Positive or normal control	Other	ſ						
Will Patient management be changed depending on the test results? Tes No STATTEST: Date results needed (if Known):									
CLINICAL HISTORY			1	Attach any ava	ilable d	etailed medica	l reco	ords and clinical notes	

Please indicate any clinical presentations and/or Endings that may be relevant to genetic testing:

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.

FAMILY HISTORY Please give age at diagnosis and current treatment (Diet/OHA/Ins)							
DIABETIC GRANDPARENT(S)?:	FATHER'S FATHER:		FATHER'S MOTHER:				
MOTHER'S FATHER:			MOTHER'S MOTHER:				
DIABETIC PARENT(S)?:	FATHER:		MOTHER:				
DIABETIC SIBLING(S)?:	NUMBER AND AGE AT DIAGNOSIS:						
DIABETIC CHILDREN?:	NUMBER AND AGE AT DIAGNOSIS:						
OTHER DIABETIC RELATIVES (N.B. A FAMII	Y TREE SHOWING AGE AT DIAGNOSIS AND CU	JRRENTTRE	EATMENT O	F AFFECTED FAMILY M	1EMBERS WOULD	BE VERY HELPFUL):	
FAMILY HISTORY OF RENAL DISEASE (CY	STS, PROTEINURIA, RENAL FAILURE, RENAL	L DYSPLASI	IA, RENAL	AGENESIS) Y/N PLEA	SE GIVE DETAILS	S:	
FAMILY HISTORY OF DEAFNESS Y/N PLE	ASE GIVE DETAILS:						
IF SAMPLES FROM OTHER FAMILY MEM	BERS HAVE BEEN SENT PREVIOUSLY PLEASE	E GIVE DET	AILS:				
PATIENT VISIT HISTORY	Date of the Previous Pa	tient Visit	t	Date of the	Last Genetic	Testing, if any	
	TARGETED SINGLE GE	NE TES	TING P	ANEL			
□ ABCC8 □ GATA6 □ BLK □ GCK □ CAPN10 □ GLIS3 □ EIF2AK3 □ GLUD □ FOXP3 □ HADH	☐ HNF1B☐ HNF4A☐ INS☐ INSR☐ Code Used to repor	t type 1		DD1	PDX1 PPARG PTF1A RFX6 SLC16A1	□ SLC2A2□ TCF7L2□ UCP2□ WFS1□ ZFP57	
□ E10.1X With the presence of diabetic ketoacidosis □ E10.10 With diabetic ketoacidosis without coma □ E10.11 With diabetic ketoacidosis with coma □ E10.2X With renal disease □ E10.21 With diabetic nephropathy □ E10.22 With diabetic chronic kidney disease □ E10.29 With other diabetic kidney □ E10.3X With eye disease □ E10.311 With ophthalmic complications without macular edema □ E10.319 With ophthalmic complications with macular edema □ E10.329 With mild nonproliferative diabetic retinopathy with macular edema □ E10.329 With mild nonproliferative diabetic retinopathy without macular edema □ E10.339 Without macular edema □ E10.339 Without macular edema □ E10.349 With severe nonproliferative diabetic retinopathy with macular edema □ E10.359 With proliferative diabetic retinopathy with macular edema □ E10.359 With proliferative diabetic retinopathy without macular edema □ E10.36 With diabetic cataract □ E10.39 With other diabetic ophthalmic complication □ E10.4X With nerve disease □ E10.40 With diabetic neuropathy, unspecified □ E10.41 With diabetic mononeuropathy □ E10.42 With diabetic polyneuropathy		 □ E10.43 With diabetic autonomic (poly)neuropathy □ E10.44 With diabetic amyotrophy □ E10.59 With other diabetic neurological complication □ E10.51 With diabetic peripheral angiopathy without gangrene □ E10.52 With diabetic peripheral angiopathy with gangrene □ E10.59 With other circulatory complications □ E10.6X With diabetes-related musculoskeletal, oral, or skin complications; hypoglycemia; or hyperglycemia □ E10.61 With diabetic arthropathy □ E10.610 With diabetic arthropathy □ E10.618 With other diabetic arthropathy □ E10.620 With diabetic dermatitis □ E10.621 With foot ulcer □ E10.622 With other skin ulcer □ E10.638 With other skin complications □ E10.638 With other oral complications □ E10.641 With hypoglycemia with coma □ E10.649 With hypoglycemia without coma or with hypoglycemia unawareness □ E10.65 With hyperglycemia □ E10.69 With complications, unspecified □ E10.9 Without complications 					
Code Used to report type 2 diabetes:							
□ E11.0X With hyperosmolarity □ E11.00 Without nonketotic hyperglycem □ E11.01 With nonketotic hyperglycem □ E11.2X With kidney complications □ E11.21 With diabetic nephropathy □ E11.22 With diabetic chronic kidney co □ E11.3Y With other diabetic kidney co □ E11.3X With eye complications □ E11.31 With diabetic retinopathy, unit	ic hyperosmolar coma disease mplications	E11.4 E11.5 E11.5 E11.5 E11.6 comp	19 With ot 5X With p 51 With dia 52 With dia 59 With ot 6X With d plications	ntonomic neuropath her diabetic neurolo peripheral vascular abetic peripheral ar abetic peripheral ar her circulatory com liabetes-related m s; hypoglycemia; o abetic arthropathy	ogical complica r disease ngiopathy with ngiopathy with plications usculoskeletal	ations out gangrene gangrene I, oral, or skin	

 E11.311 With diabetic retinopathy with macular edema E11.319 With diabetic retinopathy without macular edema E11.32 With mild nonproliferative diabetic retinopathy E11.321 With mild nonproliferative diabetic retinopathy with macular edema E11.329 With mild nonproliferative diabetic retinopathy without macular edema E11.33 With moderate nonproliferative diabetic retinopathy with macular edema E11.331 With moderate nonproliferative diabetic retinopathy without macular edema E11.339 With moderate nonproliferative diabetic retinopathy without macular edema E11.34 With severe nonproliferative diabetic retinopathy with macular edema E11.349 With severe nonproliferative diabetic retinopathy without macular edema E11.36 With diabetic cataract E11.39 With other diabetic ophthalmic complication E11.4X With nerve complications E11.40 With diabetic neuropathy, unspecified E11.41 With mononeuropathy E11.42 With diabetic polyneuropathy 	 E11.610 With diabetic neuropathic arthropathy E11.62 With skin complications E11.62 With diabetic dermatitis E11.621 With foot ulcer E11.622 With other skin ulcer E11.638 With other skin complications E11.63 With periodontal disease E11.638 With other oral complications E11.638 With other oral complications E11.649 With hypoglycemia E11.649 Without hypoglycemia with coma E11.65 With hypoglycemia E11.65 With hyperglycemia E11.69 With other complications E11.8X With other non-specified complication E11.9X Well controlled without hyperglycemia, hypoglycemia, or complications
□ Dermatology	□ N18.6 End-stage renal disease
□ S81.801 Open wound, unspecified, right lower leg	□ R80.9 Microalbuminuria
□ L97.X–L98.X Site of ulceration	□ Z99.2 Dependence on renal dialysis
☐ L97.411 Non-pressure chronic ulcer of right heel and mid-foot l	☐ E10.42 Presence of AV shunt for dialysis Hypoglycemia
imited to breakdown of skin	□ E10.649 Type 1 diabetes with hypoglycemia without coma
□ L97.5 Non-pressure chronic ulcer of other part of the foot	☐ E11.649 Type 2 diabetes with hypoglycemia without coma
□ L97.533 Non-pressure chronic ulcer of other part of left foot	☐ E08.64 Diabetes due to underlying condition with hypoglycemia
with necrosis of muscle Nephrology	☐ E09.64 Drug- or chemical-induced diabetes with hypoglycemia
□ N18.1 Chronic kidney disease (CKD) stage I	□ E16.0 Drug-induced hypoglycemia without coma
□ N18.2 CKD stage II	☐ E16.1 Other hypoglycemia
□ N18.3 CKD stage III	☐ E16.2 Hypoglycemia, unspecified
□ N18.4 CKD stage IV	EXX.641 Fill in with code for type of diabetes with hypoglycemia
□ N18.5 CKD stage V	and coma
☐ F17.210 Nicotine dependence, cigarettes, uncomplicated	☐ Also utilize a Z68 code with obesity for BMI:
☐ K31.84 Gastroparesis	□ Z68.30 BMI 30.0–30.9 kg/m2
□ I10 Essential hypertension	□ Z68.31 BMI 31.0–31.9 kg/m2
□ Hyperlipidemia:	□ Z68.32 BMI 32.0–32.9 kg/m2
□ E78.0 Pure hypercholesterolemia	□ Z68.33 BMI 33.0–33.9 kg/m2
□ E78.1 Pure hypertriglyceridemia	□ Z68.34 BMI 34.0–34.9 kg/m2
□ E78.2 Mixed hyperlipidemia	□ Z68.35 BMI 35.0–35.9 kg/m2
☐ E78.5 Hyperlipidemia, unspecified	□ Z68.36 BMI 36.0–36.9 kg/m2
☐ Hypothyroidism:	□ Z68.37 BMI 37.0–37.9 kg/m2
☐ E06.3 Due to Hashimoto's disease	☐ Z68.38 BMI 38.0–38.9 kg/m2
☐ E89.0 Postoperative or postablative	□ Z68.39 BMI 39.0–39.9 kg/m2
□ E03.9 Acquired	☐ Z68.41 BMI 40.0–44.9 kg/m2
□ Z13.29 Thyroid disorder screen	☐ Z68.42 BMI 45.0–49.9 kg/m2
☐ R94.6 Abnormal thyroid blood test or screen	□ Z68.43 BMI 50.0–59.9 kg/m2 □ Z68.44 BMI 60.0–69.9 kg/m2
☐ E66.0 Obesity due to excess calories	□ Z68.45 BMI >70.0 kg/m2
☐ E66.01 Morbid severe obesity due to excess calories	G47.33 Obstructive sleep apnea
☐ E66.9 Obesity, unspecified	☐ E28.2 Polycystic ovarian syndrome
	- L20.2 i diyeyane ovanan symatome
ICD-10 code(s):	

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 about 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.

INFORMED CONSENT

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.

Signature of Patient or Patient Representative / Relationship to Patient:

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

Ordering Physician 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.

STOP	ORDERING PHYSICIAN SIGN HERE Physician must only order tests that are medically necessory for the diagnosis or treatment of a patient
patient. F	at 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 urthermore, 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 the lab to gather the medical necessity for any reason

Date:

Date: