YALE DIAGNOSTIC LABORATORY

SAMPLE SUBMISSION FORM

c/o Allen E. Bale, M.D.
Yale Univ. School of Medicine
Dept. Genetics, I-323
333 Cedar Street
New Haven, CT 06520-8005
Tel (203) 785-5745 Fax (203) 785-5729
CLIA ID# 07D0098275 CAP Lab# 11910-07
http://dnalab.sites.yale.edu/

Patient Name: _____

Date of birth: _____ *Date of sample:* _____ *Sex: M F*

MRN#: _____

*DIAGNOSIS (Yale Physicians)*_____

OUTPATIENT LOCATION_____

DNA Lab Use Only:

DDL #_____ **PED#**_____

Type of Sample:

Blood_____
1 to 5 ml in EDTA tube

Chorionic villus, uncultured_____
10-20 mg in tissue culture medium

Cultured cells_____
One T25, save backup flask
Please specify cell type

Other _____(please specify)

********PLEASE INCLUDE CLINICAL INFORMATION AND PEDIGREE CHART ON THE FAMILY HISTORY FORM IF MORE THAN ONE SAMPLE IS BEING SUBMITTED FROM THE SAME FAMILY.**

CPT	*Reason for Referral/Hereditary Disorder:*	*cost/sample*	*CPT*	*Reason for Refferal/Hereditary Disorder*	*cost/sample*
81212	Ashkenazi BRCA 1 and 2 mutations	$535*	81215 81217	Familial BRCA 1 or 2 mutation (non-Ashkenazi)	$535*
81243	Fragile X	$515	81405	Multiple endocrine neoplasia type IIa, IIb, FMTC (MEN2)	$1450**
81331	Prader-Willi/Angelman MSPCR (SNRPN)	$460	81405	Ornithine transcarbamylase deficiency, specify:	$1450**
			81402	Uniparental Disomy	$760
81479	Gorlin (nevoid basal cell carcinoma syndrome)	$2400**	81321	Cowden Syndrome (PTEN)	$1660**
81406	Medium chain acyl dehydrogenase deficiency		81479	DNA preparation alone	$90
	_____Full sequence	$2400**	81265	Prenatal (MCC study) Required for any prenatal testing	$760
81404	Melanoma (P16(CDKN2a), CDK4)	$775		**By special arrangement the lab will test for other**	
81405	Multiple endocrine neoplasia *type* 1 (MEN1), specify:	$1450**		**rare diseases.**	
				Extended Genetic Panel	Up to $7410

*per licensing agreement with Myriad, routine testing for these mutations from blood or cheek brushes is available to physicians at Yale and affiliated hospitals only.

**$420 for subsequent samples

Information that should be conveyed to patients: *Testing is for the disorder listed above, only. This is not a general screen for genetic disorders and other birth defects. This type of test can provide a diagnosis with at least 99% accuracy for most patients, but it is possible that no answer or a less accurate answer will be provided. An error in diagnosis may occur due to sample mix-ups or laboratory error (less than 1% of the time). The DNA Diagnostic Laboratory will preserve anonymized excess sample material, not needed for diagnosis, to be used in scientific research or teaching purposes unless the following box is checked.*
Please dispose of excess sample and do not preserve it for scientific or teaching purposes____

READ THIS PLEASE: TO PROTECT PATIENT CONFIDENTIALITY, RESULTS WILL BE REPORTED ONLY TO HEALTH CARE PROVIDERS AND REFERRAL LABORATORIES LISTED BELOW OR ON ACCOMPANYING PAGES.

Name	**Name**
Address	**Address**
Fax:	**Fax:**
Phone: **Email:**	**Phone:** **Email:**

Request for Clinical Information for Genetic Testing

Please complete the following information:

Clinical Reason for ordering this test (symptoms, family history, etc.):

_____
_____
_____
_____
_____

Explain how test results will directly impact treatment of this patient:

_____
_____
_____
_____
_____
_____

Yale University DNA Diagnostics Laboratory

FAMILY HISTORY FORM

(Please complete when samples from more than one family member are being submitted.)

PEDIGREE CHART

Samples to be submitted:

Name (include Jr. or Sr.)	*Affected?*	*Requested study*[1]
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		

1 Carrier detection; Pre-pregnancy informativeness; Prenatal diagnosis; Presymptomatic diagnosis; Other, please specify.

❖ 333 Cedar Street, Room I-321 SHM, New Haven, CT 06520 ❖ Phone (203) 785-5745 ❖ Fax (203) 785-7227

Yale University DNA Diagnostics Laboratory

PROCEDURE FOR SUBMITTING SAMPLES

1.) **BLOOD SAMPLES:** Send 10ml for each adult or child over 10 years old and 5ml for each younger child. Smaller samples will be accepted but may not yield sufficient DNA in some cases. Use purple top (EDTA) tubes. Label with patient's full name, date of birth, and date drawn. Samples are stable for at least five days at room temperature in purple top tubes.

2.) **SALIVA SAMPLES**: Submit 1Oragene (OGR-500 or OGR-250) kit per patient. Closely follow directions included with the kit. Samples should be kept at room temperature before and during shipping.

3.) **CHORIONIC VILLOUS SAMPLES:** Send 10-20 mg of villi, free of maternal cells, in tissue culture medium in a screw cap eppendorf tube labelled with the **fetus's last name**, ***LMP date***, and **date sample was obtained**. Samples should be kept at room temperature before and during shipping. Save a backup culture.

4.) **FIBROBLAST OR AMNIOCENTESIS SAMPLES:** Send 2 T-25 flasks with confluent cells labelled with the **fetus's last name**, ***LMP date***, and **date sample was obtained**. Flasks should be filled to the top with tissue culture medium before shipping. Samples should be kept at room temperature before and during shipping. Save a backup culture.

5.) **REQUISITION FORM:** For simple testing involving one patient, submit only the one-page Sample Submission Form. For more complex testing that involves several family members, submit the Family History Form with pedigree chart. Place forms in plastic bag.

6.) **SHIPPING:** Pack samples and completed forms in a strong styrofoam box. Packaging must indicate the nature of materials being shipped, such as “biohazard” or “diagnostic specimens” labels. Ship at room temperature to:

DNA Diagnostics Laboratory
c/o Allen E. Bale, M.D.
Yale University School of Medicine
Department of Genetics
Room I-323, SHM
333 Cedar Street
New Haven, CT 06520
Phone (203) 785-5745

******DO NOT FREEZE, REFRIGERATE, OR EXPOSE TO HEAT OR COLD.******
Samples should be shipped by **overnight mail** so as to arrive on any weekday. Saturday or holiday delivery requires special arrangements.

7.) **For prenatal samples, inform the laboratory (203-785-5745) that the sample has been shipped.**

8.) **APPROXIMATE TURNAROUND TIME:**

- Prenatal Diagnosis 4 - 14 days (depending on the type of analysis to be done)
- Fragile X 2 weeks
- Gorlin syndrome 8 - 12 weeks
- BRCA, Ashkenazi mutations 2 - 4 weeks
- OTC, MEN 1 and 2, MCAD Hemophilia A, Melanoma, Extended Genetic Panel 8 weeks

PAYMENT REQUIREMENTS

Samples sent to the Yale University DNA Diagnostic Lab will **NOT** be processed without one of the following:

If patient would like insurance billed, call Central Registration 888-639-9253 to input patient information. **Patient is responsible for obtaining insurance authorization and pre-registration.** If patient is not registered at time of billing, the facility sending the sample will be responsible for payment. Please make sure that it is indicated on the form that patient has pre-registered.

OR

The Laboratory or Hospital sending the sample agrees to be responsible for the payment.
Laboratory or Hospital Billing Address:

_____

_____

_____

_____

_____

OR

In the case of uninsured patients, prior arrangements can be made with the lab director.
E-mail to allen.bale@yale.edu