MAYO
Mayo Medical Laboratories
1-800-533-1710

NEW TEST ANNOUNCEMENT
REFERRAL
NOTIFICATION DATE: May 16, 2012
EFFECTIVE DATE: Immediately

ASHKENAZI JEWISH FLEX PANEL (8 CONDITIONS)
Test ID: FAJFP

EXPLANATION: The following new orderable unit code, referred to Ambry Genetics, is available immediately for temporary referral during test down for Mayo test(s).

NOTE: This test will become obsolete when Mayo Test ID: AJPWO, Ashkenazi Jewish Mutation Analysis Panel Without Cystic Fibrosis (CF) and AJP, Ashkenazi Jewish Mutation Analysis Panel With Cystic Fibrosis (CF) resumes.

NOTE: This panel does not include Cystic Fibrosis (CFPB) or Hexosaminidase A and Total (NAGW), testing. Both of these tests will have to be ordered individually.

REFERRAL LAB CODE: 1804

METHODOLOGY: DNA Sequencing

REFERENCE VALUES:
An interpretive report will be provided.

SPECIMEN REQUIREMENTS:
Draw blood in a lavender-top (EDTA) or yellow-top (ACD) tube(s) send 5 mL of EDTA or ACD whole blood refrigerate in plastic vial.

Note: Complete Ambry Ashkenazi Jewish Panel request form

SPECIMEN STABILITY INFORMATION:

Specimen Type	Temperature	Time
Blood	Refrigerate (preferred)	14 days
	Ambient	5 days

LIST FEE: $ 520.00

CPT CODE: 83891 X 1; 83894 X 8; 83898 X 24; 83904 X 16; 83909 X 16; 83912 X 8

DAY(S) SET UP: Monday through Friday   **ANALYTIC TIME**: 10 - 14 days

QUESTIONS: Contact Mary Erath, MML Laboratory Technologist Resource Coordinator
Telephone: 800-533-1710

Ambry Genetics™

General Test Requisition

*Required for processing

PATIENT INFORMATION

*DOB (MM/DD/Year)	*Last Name	*First Name	Middle Initial

*Gender ☐ F ☐ M

*Ethnicity
☐ African American
☐ Asian
☐ Caucasian
☐ Hispanic
☐ Jewish (Ashkenazi)
☐ Specify: _____

*Street Address, City, State, Zip

*Home Phone   Work/Cell

*Specimen Collection Date: _____   Specimen ID: _____

MR# _____   Specimen Type ☐ Blood ☐ DNA ☐ Saliva (Adult)
☐ Saliva (Pediatric) ☐ Other _____

CONTACT AND ORGANIZATION INFORMATION

*Authorized Ordering Physician   NPI#

*PH 800-533-1710	*FX 507-538-5340

*Ordering Clinician Email

*Facility Name and Address   ID#

Mayo Medical Laboratories
3050 Superior Drive NW
Rochester, MN 55904

ADDITIONAL RESULTS RECIPIENT

Medical Professional Name:

Facility Name and Address   ☐ Same As Above

*Preferred Contact   *Phone

*Statement of Medical Necessity
By ordering testing, the medical professional or authorized person acknowledges the patient has been supplied information regarding genetic testing and the patient has given consent for genetic testing to be performed and the signed consent form is on file. I confirm that this is medically necessary for the diagnosis or detection of a disease, illness, impairment, syndrome or disorder, and that these results will be used in the medical management and treatment decisions for this patient. Does this patient give consent to the use of their sample for research?

☐ Yes ☐ No Consent is implied if a box is not marked

*Medical Professional Signature _____ Date: _____
(MD/DO, Clinical Nurse Specialist, Nurse-Midwives, Nurse Practitioner, Physician Assistant)
Mandatory for Medicare/Medicaid

ADDITIONAL INFORMATION

*Indication for Testing: (please list clinical findings)
☐ Diagnostic ☐ Carrier Screening ☐ Research
☐ Positive Newborn Screen ☐ Family History
☐ Other _____
ICD-9 Codes _____

Reason for Referral / Testing

Additional Clinical Findings

*Family History (or attach pedigree) relevant to clinical indication

Maternal (Mother's side)

Relation to Patient	Gender	Health History

Paternal (Father's side)

Additional/Other (Siblings/Children)

General Test Requisition

FAMILIAL HYPERCHOLESTEROLEMIA - (EDTA TUBE)

☐ 8680 Familial Hypercholesterolemia Comprehensive Evaluation (*LDLR* and *PCSK9* gene sequence and *APOB* partial gene sequence with *LDLR* deletion/duplication)
☐ 8582 Familial Hypercholesterolemia (*LDLR* and *APOB* partial gene sequence reflex to *LDLR* deletion/duplication)
☐ 2780 *LDLR* gene sequence
☐ 2784 *LDLR* deletion/duplication
☐ 2800 *APOB* partial gene sequence
☐ 2804 *PCSK9* gene sequence

GASTROENTEROLOGY - (EDTA TUBE)

☐ 8022 Pancreatitis Plus (*CFTR, PRSS1, SPINK1, CTRC* gene sequence)
☐ 8020 Pancreatitis (*CFTR, PRSS1, SPINK1* gene sequence)
☐ 8040 Pancreatitis Amplified (*CFTR, PRSS1, SPINK1* with *CFTR* del/dup)
☐ 1100 *PRSS1* gene sequence
☐ 1120 *SPINK1* gene sequence
☐ 1660 *CTRC* gene sequence
☐ 1840 Wilson Disease (*ATP7B* gene sequence)
☐ 1440 Shwachman-Diamond Syndrome (*SBDS* gene sequence)

GENETICS - (EDTA TUBE)

☐ 8641 AmbrySCREEN™
☐ 1640 Alagille (*JAG1* gene sequence and deletion/duplication)
☐ 1641 Alagille (*JAG1* deletion/duplication)
☐ 8642 Amyotrophic Lateral Sclerosis (*SOD1, ANG, FIG4, FUS* and *TARDBP* gene sequence) (concurrent)
☐ 8620 Amyotrophic Lateral Sclerosis (*SOD1* reflex to *ANG, FIG4, FUS, TARDBP* gene sequence)
☐ 8622 Amyotrophic Lateral Sclerosis (*SOD1* gene sequence)
☐ 1320 Aminoglycoside-Related Hearing Loss (*MT-RNR1* gene sequence)
☐ 5280 Andermann Syndrome (*SLC12A6* gene sequence)
☐ 8520 Angelman Syndrome (*SNRPN* methylation reflex to *UBE3A* gene sequence)
☐ 2400 Angelman Syndrome (*UBE3A* gene sequence)
☐ 2420 Angelman-like Syndrome (*SLC9A6* gene sequence)
☐ 2440 Angelman/Prader-Willi Syndrome (*SNRPN* methylation)
☐ 1808 Ashkenazi Jewish Panel™ with all 16 conditions
☑ 1804 Ashkenazi Jewish FlexPanel™ as marked below:
  ☑ Bloom (*BLM*) ☐ Glycogen Storage Disease 1a (*G6PC*) ☐ Cystic Fibrosis (*CFTR*)
  ☐ Maple Syrup Urine Disease (*BCKDHA/B*) ☐ Maple Syrup Urine Disease Type 3 (*DLD*)
  ☑ Mucolipidosis Type IV (*MCOLN1*) ☑ Canavan (*ASPA*) ☐ Joubert Syndrome (*TMEM216*)
  ☑ Familial Dysautonomia (*IKBKAP*) ☑ Niemann-Pick A (*SMPD1*) ☑ Gaucher (*GBA*)
  ☑ Fanconi Anemia Type C (*FANCC*) ☑ Tay-Sachs (*HEXA*) ☐ Nemaline Myopathy (*NEB*)
  ☐ Usher Syndrome Type 1F (*PCDH15*) ☐ Usher Syndrome Type III (*CLRN1*)
☐ 4940 Aspartylglucosaminuria (*AGA* gene sequence)
☐ 1040 Beta Thalassemia Plus (*HBB* gene sequence with 619del check)
☐ 1226 Canavan (*ASPA* gene sequence and deletion/duplication) (concurrent)
☐ 1220 Canavan (*ASPA* gene sequence reflex deletion/duplication)
☐ 1370 Congenital Hyperinsulinism-Hyperammonemia (*GLUD1* gene sequence)
☐ 1364 Congenital Hyperinsulinism (*KCNJ11* gene sequence)
☐ 2380 CHARGE Syndrome (*CHD7* gene sequence)
☐ 4960 Dihydropyrimidine Deyhydrogenase Deficiency (*DPYD* gene sequence)
☐ 1720 Fabry Disease (*GLA* gene sequence)
☐ 5000 Familial Mediterranean Fever (*MEFV* gene sequence)
☐ 1820 Gaucher Disease (*GBA* gene sequence)
☐ 1600 Glutaric Acidemia Type 1 (*GCDH* gene sequence)
☐ 4880 Glutathione Synthetase Deficiency (*GSS* gene sequence)
☐ 1880 Glycogen Storage Disease Type Ia (*G6PC* gene sequence)
☐ 1900 Glycogen Storage Disease Type Ib (*SLC37A4* gene sequence)
☐ 2746 Hereditary Angioedema (*SERPING1* gene sequence and deletion/duplication)
☐ 2708 Hirschsprung Disease (*RET* gene sequence) (concurrent)
☐ 2700 Hirschsprung Disease Steps 1 and 2 (*RET*)
  Step 1 only: exons 2,3,5,6,9,10,12,13,17 gene sequence
  Step 2 only: rest of gene sequence
☐ 1940 Hunter Syndrome (*IDS* gene sequence)
☐ 2160 Hurler Syndrome (*IDUA* gene sequence)
☐ 5020 Hyperoxaluria Type 2 (*GRHPR* gene sequence)
☐ 3200 Infantile Spasms (*CDKL5* gene sequence)
☐ 4860 Lysosomal Free Sialic Acid-Storage (Salla) Diseases (*SLC17A5* gene sequence)
☐ 4900 MCAD - Medium-chain acyl-CoA dehydrogenase (*ACADM* gene sequence)
☐ 5180 Mucolipidosis Type IV (*MCOLN1* gene sequence)
☐ 1360 Neonatal Diabetes (*KCNJ11* gene sequence)
☐ 1620 Neonatal Diabetes (*INS* gene sequence)
☐ 1860 Niemann-Pick Disease Types A & B (*SMPD1* gene sequence)

(right column)

☐ 4680 Niemann-Pick Disease Types C1 (*NPC1* gene sequence)
☐ 4684 Niemann-Pick Disease Types C2 (*NPC2* gene sequence)
☐ 8122 Primary Ciliary Dyskinesia NextGen Sequencing Panel (*DNAH5, DNAI1, DNAI2, DNAH11, TXNDC3, RSPH4A, RSPH9, DNAAF1, DNAAF2, RPGR, OFD1, CFTR*)
☐ 4840 Rhizomelic Chondrodysplasia Punctata Type 1 (*PEX7* gene sequence)
☐ 1760 Phenylketonuria - PKU (*PAH* gene sequence)
☐ 1740 Pompe Disease (*GAA* gene sequence)
☐ 2180 Smith-Lemli-Opitz Syndrome (*DHCR7* gene sequence)
☐ 1240 Tay-Sachs Plus (*HEXA* gene sequence)
☐ 5240 Tay-Sachs Enzyme Assay (*HEXA* Leukocytes)
☐ 1560 Transthyretin Amyloidosis (*TTR* gene sequence)
☐ 4920 VLCAD - Very long-chain acyl-CoA dehydrogenase (*ACADVL* gene sequence)
☐ 1700 Warfarin Sensitivity (*CYP2C9* & *VKORC1* SNP analysis)
☐ 5220 Y Chromosome Microdeletion Analysis

Thrombophilia (5140) (1 EDTA Lavender Top)
☐ 5141 Factor II (Prothrombin G20210A)
☐ 5143 Factor V (Leiden)
☐ 5145 *MTHFR* (C677T and A1298C)

HEREDITARY HEMORRHAGIC TELANGIECTASIA (HHT) - (EDTA TUBE)

☐ 8662 HHT *ACVRL1, ENG* and *SMAD4* gene sequence with *ACRL1* and *ENG* deletion/duplication (concurrent)
☐ 1680 HHT *ACVRL1* & *ENG* gene sequence and deletion/duplication
☐ 8660 HHT Steps 1 through 3
  ☐ 1683 Step 1 *ACVRL1* & *ENG* gene sequence
  ☐ 1681 Step 2 *ACVRL1* & *ENG* deletion/duplication
  ☐ 1684 Step 3 *SMAD4* gene sequence
Call HHT Single Gene Deletion/Duplication   GENE _____

MARFAN SYNDROME - (EDTA TUBE)

☐ 8780 Marfan Syndrome NextGen Sequencing Panel (concurrent)
  ACTA2, CBS, FBN1, FBN2, MYH11, COL3A1, SLC2A10, SMAD3, TGFBR1, TGFBR2 gene sequence
☐ 8782 Marfan Syndrome NextGen Sequencing Panel Steps 1 and 2
  Step 1 *FBN1* gene sequence
  Step 2 *ACTA2, CBS, FBN2, MYH11, COL3A1, SLC2A10, SMAD3, TGFBR1, TGFBR2* gene sequence
☐ 8784 *FBN1* gene sequence
☐ 8788 *FBN1, TGFBR1* and *TGFBR2* gene sequence

NEUROLOGY / INTELLECTUAL DISABILITY

☐ 8630 XLMR Evaluation Steps 1 and 2 (reflex to next step when negative)
  Step 1 Ambry CMA: 180K Oligo Array (EDTA + Na Heparin)
    Note: This CMA has increased coverage on X chromosome
  Step 2 XLMR Next-Gen SuperPanel™ (sequencing panel for 81 genes) (EDTA)
☐ 8628 XLMR Comprehensive Evaluation Steps 1-3 (reflex to next step when negative)
  Step 1 Routine Chromosome Analysis/Karyotype and Fragile X DNA Analysis(EDTA + Na Heparin)
  Step 2 Ambry CMA: 180K Oligo Array (EDTA + Na Heparin)
    Note: This CMA has increased coverage on X chromosome
  Step 3 XLMR Next-Gen SuperPanel™ (sequencing panel for 81 genes) (EDTA)
☐ 8626 XLMR Next Gen SuperPanel™ (1 EDTA)
  ABCD1, ACSL4, AGTR2, AP1S2, ARHGEF6, ARHGEF9, ARX, ATP6AP2, ATP7A, ATRX, BCOR, BRWD3, CASK, CDKL5, CUL4B, DCX, DKC1, DLG3, FANCB, FGD1, FLNA, FMR1, FTSJ1, GDI1, GJB1, GK, GPC3, GRIA3, HCCS, HPRT1, HSD17B10, HUWE1, IDS, IL1RAPL1, KDM5C, KIAA2022, L1CAM, LAMP2, MAOA, MECP2, MED12, MID1, MTM1, NDP, NDUFA1, NHS, NLGN3, NLGN4X, OCRL, OFD1, OPHN1, OTC, PAK3, PDHA1, PGK1, PHF6, PHF8, PLP1, PORCN, PQBP1, PRPS1, RPL10, RPS6KA3, SHROOM4, SLC16A2, SLC9A6, SMC1A, SMS, SOX3, SRPX2, SYN1, SYP, TIMM8A, TSPAN7, UBE2A, UPF3B, ZDHHC9, ZNF41, ZNF674, ZNF711, ZNF81

Single Gene Sequence Analysis is also available for all 81 genes on XLMR Next-Gen panels. To order single gene testing check box below and list gene name.

☐ Single Gene Sequence Analysis   Gene: _____

☐ 4544 Fragile X DNA Analysis (1 EDTA)
☐ 3020 FRAXE (FMR2) DNA Analysis (1 EDTA)
☐ 3664 Routine Chromosome Analysis/Karyotype (1 Na Heparin)

☐ 3002 180K Oligo Array (1 EDTA)
☐ 5480 SNP+CGH Array (1 EDTA)
Note: These microarrays have increased coverage on X chromosome

Billing Information (Mandatory for Processing)

Patient Name_____

☐ PERFORM PRE-VERIFICATION OF BENEFITS PRIOR TO TESTING

AMBRY GENETICS provides a selection of convenient billing options. Please choose an option below and supply all requested information for your selection. Please note that all non-fetal testing is held until billing requirements have been met.

Preferred contact at ordering physician's office for insurance updates (preverification, patient OOP, bill holds):

Name:_____

Contact info:_____

Circle preferred contact method:

Call | e-mail | Fax

☐ BILL INSURANCE Include card copy (both sides)

A completed Advance Beneficiary Notice (ABN) of coverage is required for Medicare patients who do not meet medical criteria for testing

Name of Insured	Relation to patient? ☐ Self ☐ Parent ☐ Spouse

Insurance Company Name and Address

Insurance Phone

Member ID #	Group #

Authorization #	Date

☐ PRE-PAYMENT

Payment Type
☐ Check   ☐ Mastercard   ☐ Discover
☐ Visa   ☐ American Express

Card Number	Exp. Date

Cardholder Name	Amount $

Signature X	Date

☐ BILL FACILITY   ☐ same as ordering facility

Facility Name   (or place billing stamp here)

Mayo Medical Laboratories

Adress, City, State, Zip

PO Box 4100
Rochester, MN 55901

Contact Person

Business Office

Contact Person Phone

800-447-6424 ⊞

☐ GRATIS (FREE OF CHARGE)

☐ Pre-approved family studies sample

☐ Positive control sample

If pre-verification of benefits is requested prior to sample submission, please retain this form (pages 1-3) and include a copy with the sample shipment. To initiate a pre-verification request, please fax this completed form to 949-900-5501 with a copy of the patient's insurance card. For assistance, please call 949-900-5500 ext#5992 or email preverification@ambrygen.com.

Importance of complete clinical information:
The clinical information provided on page 1 of this form will assist in determination of insurance coverage. Complete, detailed clinical information provides a clear indication for testing (i.e. medical necessity). A patient-specific letter of medical necessity (LMN) from the ordering clinician may be requested if incomplete/limited clinical information is included on this form.

Out-of-Pocket Expense Policy:
Ambry genetics will contact the above patient if the out-of-pocket (OOP) amount for this test order is estimated to exceed $300. For any tests priced under $300, pre-verification of insurance coverage will not be performed.

Patient Acknowledgement: (Applies for direct insurance/3rd party billing)
I hereby authorize my insurance benefits to be paid directly to Ambry Genetics Corporation and authorize them to release medical information concerning my testing to my insurer. I hereby acknowledge that I am financially responsible for any amounts not covered by my insurer for this test order.

Patient Signature:_____   Date:_____