GENESYS Diagnostics INC.

# Carrier Screening Requisition Form

*Information required for testing

## Patient Information

LAST NAME* | FIRST NAME* | MI | DOB* (MM/DD/YYYY) | SEX

ADDRESS | CITY | STATE | ZIPCODE | PHONE NUMBER | EMAIL ADDRESS

## Billing Information (Please include a copy of insurance card(s) for billing purposes.)

*☐ CLIENT BILL ☐ INSURANCE ☐ SELF PAY ☐ MEDICARE/MEDICAID (☐ PRIMARY ☐ SECONDARY) RELATIONSHIP: ☐ SELF ☐ SPOUSE ☐ DEPENDENT

INSURANCE NAME | MEMBER/POLICY ID | GROUP #

POLICY HOLDER NAME | POLICY HOLDER DOB (MM/DD/YYYY) | TEST INDICATION/ICD-10 CODE(S)*

## Account Information

FACILITY/PRACTICE NAME* | PHONE NUMBER | FAX NUMBER | ORDERING PHYSICIAN NAME*

## Specimen Information PREFERRED SPECIMEN IS BUCCAL SWAB

☐ BLOOD IN EDTA (5ml MINIMUM) ☐ BUCCAL SWAB ☐ DNA (10 ug MIN) COLLECTION DATE:_____MM/DD/YYYY____ COLLECTION TIME:____00:00 AM/PM____

## Background Information (Please check all that apply)

RACE AND ETHNICITY: ☐ WHITE ☐ ASIAN ☐ HISPANIC ☐ AFRICAN AMERICAN ☐ ASHKENAZI JEWISH ☐ OTHER (PLEASE SPECIFY):_____

| GENE PANEL NAME* (Must choose at least one) | GENES ** |
|---|---|
| ☐ COMPREHENSIVE PANEL (145 GENES) INCLUDES ALL BELOW PANELS | ABCA3, ABCC8, ABCD1, ACADM, ACADS, ACADVL, ACAT1, ACSF3, AFF2, AGA, AGXT, AHI1, AIRE, ALDOB, ALMS1, ALPL, ANO10, ARSA, ARX, ASL, ASPA, ATM, ATP7B, BBS1, BBS2, BCKDHA, BCKDHB, BLM, BTD, CAPN3, CBS, CC2D2A, CCDC88C, CDH23, CEP290, CFTR (ALL MUTATIONS), CHRNE, CLCN1, CLRN1, CNGB3, COL7A1, CPT2, CYP11A1, CYP1B1, CYP21A2, CYP27A1, CYP27B1, DBT, DHCR7, DHDDS, DLD, DMD, DNAH5, DYNC2HI, DYSF, ELP1, ERCC2, EVC2, EYS, F11, F8, F9, FAH, FANCA, FANCC, FANCG, FKRP, FKTN, FMO3, FMR1, FXN, G6PC, GAA, GALC, GALT, GBA, GBE1, GJB2, GLA, GNE, GNPTAB, GRIP1, HBA1, HBA2, HBB, HEXA, HFE, HOGA1, HPS1, HPS3, IDUA, L1CAM, LDLR, LOXHD1, LRP2, MCCC2, MCOLN1, MCPH1, MEFV, MID1, MLC1, MMACHC, MMUT, MVK, MYO7A, NAGA, NEB, NPC1, NPC2, NPHS1, NPHS2, NR0B1, OCA2, OTC, PAH, PCDH15, PEX6, PKHD1, PLP1, PMM2, POLG, PRF1, PYGM, RARS2, RMRP, RNASEH2B, RPGR, RS1, SCO2, SERPINA1, SLC12A3, SLC19A3, SLC22A5, SLC26A2, SLC26A4, SLC37A4, SLC6A8, SMN1, SMPD1, TF, TMEM216, TNXB, TYR, USH2A, XPC FMR1 |
| ☐ HIGH-FREQUENCY PAN-ETHNIC PANEL (11 GENES) | HBA1, HBA2, HBB, PMM2, CFTR, DMD, FMR1, ACADM, PAH, DHCR7, SMN1 |
| ☐ FRAGILE X (1 GENE) | FMR1 |
| ☐ DUCHENNE MUSCULAR DYSTROPHY (1 GENE) | DMD |
| ☐ SPINAL MUSCULAR ATROPHY (1 GENE) | SMN1 |
| ☐ ALPHA THALASSEMIA (2 GENES) | HBA1, HBA2 |
| ☐ CYSTIC FIBROSIS (1 GENE) | CFTR (74 MUTATIONS) |
| ☐ INDIVIDUAL GENE TESTING | INDICATE BY CIRCLING GENES ABOVE OR LISTING_____ |

## Patient Authorization and Consent

It has been explained to me and I understand that I am voluntarily providing a specimen for a genetic test. I will provide the specimen in a collection device provided by GDI. My DNA will be extracted from my specimen at GDI, and the test will evaluate how my genome variance may affect the risk associated with genetically linked disorders. However, carriers for certain disease genes or variants may show mild phenotypes themselves. Proper pre-test and post-test genetic counseling should be provided. The test identifies the most common variants of these genes but is not designed to identify some rare mutations. The test is a clinical laboratory test and may aid in my treatment plan; therefore, I or my health insurer will be billed for this test. A written report of the test results will be provided to my health care provider who will inform me of the results. GDI will keep all of my medical information confidential and only disclose it to pursuant to applicable state and federal laws. I understand that I am responsible for providing accurate information about my insurance to Genesys Diagnostics Inc. I understand that Genesys Diagnostics Inc. will be providing testing service and billing my insurance. However, I understand that charges that are not covered by my insurance, including any applicable copayments and deductibles are my responsibility and I agree to pay such charges promptly.

Patient/Guardian Signature:* Date:*

☐ I do not consent to having my deidentified DNA sample used for internal research purposes.

## Healthcare Provider Authorization

I certify that (i) this test is medically necessary, (ii) the patient (or authorized representative on the patient's behalf) has given informed consent (which includes written informed consent or written authorization when required by law) to have this testing performed, and (iii) the informed consent obtained from the patient meets the requirements of applicable law. I agree to provide Genesys, or its designee, any and all additional information reasonably required for this testing to be performed.

Healthcare Provider Signature:* Date:*

GENESYS Diagnostics INC.

# Carrier Screening Requisition Form

| ICD 10 CODES* | | | |
|---|---|---|---|
| ☐Z13.0 | Encounter for screening for diseases of the blood and blood-forming organs and certain disorders involving immune mechanism | ☐Z34.03 | Encounter for supervision of normal first pregnancy, third trimester |
| ☐Z13.228 | Encounter for screening for other metabolic disorders | ☐Z34.81 | Encounter for supervision of other normal pregnancy, first trimester |
| ☐Z13.71 | Encounter for nonprocreative screening for genetic disease carrier status | ☐Z34.82 | Encounter for supervision of other normal pregnancy, second trimester |
| ☐Z13.89 | Encounter for screening for other disorder | ☐Z34.83 | Encounter for supervision of other normal pregnancy, third trimester |
| ☐Z14.8 | Other genetic carrier status | ☐Z81.0 | Family history of intellectual disabilities |
| ☐Z15.89 | High risk ethnicity | ☐Z84.3 | Consanguinity |
| ☐Z31.430 | Encounter of female for testing for genetic disease carrier status for procreative management | ☐Z84.81 | Family history of carrier of genetic disease |
| ☐Z34.01 | Encounter for supervision of normal first pregnancy, first trimester | ☐Z84.89 | Family history of other specified conditions |
| ☐Z34.02 | Encounter for supervision of normal first pregnancy, second trimester | ☐Z84.99 | Family history of related disorder. Please describe:_____ |

**Medical Necessity Statement:** Tests ordered on Medicare patients must follow CMS rules regarding medical necessity and FDA approval guidelines and must include diagnosis, symptoms and reason for testing as indicated in the medical record. If testing does not come under Medicare guidelines for payment a 'signed' Advanced Beneficiary Notice must be included.

**Certain regions in various genes have poor coverage and are not included in the panel (if you would like more coverage information regarding any specific genes of interest, please contact Genesys Diagnostics Inc.). All genes that have pseudogenes will have poorer performance on the MiSeq instrument. Variants in genes with pseudogenes may not be reliably detected. DNA alterations in regions not covered by this test such as deep intronic or regulatory regions, or in poorly covered regions will not be detected using Next Generation Sequencing analysis. There are technical limitations on the ability of Next Generation Sequencing to detect small insertions and deletions and these types of alterations are not detected as reliably as single nucleotide variants. This assay is not designed or validated for the detection of low-level mosaicism or somatic mutations.