EGL Genetics | Eurofins Clinical Diagnostics

2460 Mountain Industrial Boulevard | Tucker, Georgia 30084
855-831-7447 | 470-378-2200
Fax: 470-378-2250

NGS PANEL EXPAND REQUISITION AND CONSENT FORM

PATIENT INFORMATION

Last Name

First Name MI

Patient ID DOB (mm/dd/yyyy)

Sex

❍ F ❍ M ❍ Unknown ❍ Ambiguous

Street Address

City

State Zip

Country

Preferred Phone

Ethnicity (check all that apply)

❑ African-American ❑ Asian
❑ Caucasian/NW European ❑ E. Indian
❑ Hispanic ❑ Jewish-Ashkenazi
❑ Jewish-Sephardic ❑ Mediterranean
❑ Native American ❑ Adopted
❑ Other

ORDERING ENTITY & REPORT DISTRIBUTION *(Indicate Preferred Distribution Method)

❑ PHYSICIAN

Name

Phone

❑ Fax (required to receive a report by fax)

Street Address

City State

Zip Country

❑ Email (required to receive a report by email)

NPI

❑ INSTITUTION

Name

Phone

❑ Fax (required to receive a report by fax)

Street Address

City State

Zip Country

❑ Email (required to receive a report by email)

❑ GENETIC COUNSELOR

Name

Phone

❑ Fax (required to receive a report by fax)

❑ Email (required to receive a report by email)

IDENTIFYING NUMBER NEEDED TO APPEAR ON REPORT AND/OR INVOICE

Ref ID

ORDERING CHECKLIST

Please makes sure to complete and/or submit the following:
(All are required to perform testing)

❑ Patient information (pg. 1) ❑ Billing Information (pg. 2)
❑ Informed Consent Seq. Proband (pgs. 3-4)
❑ Medical Record (please attach)
❑ Detailed Family History Including Pedigree (please attach)

ICD-10 Codes

Please check all of the following that apply:

❑ Patient has had transfusion within the past 30 days
❑ Patient has had bone marrow transplant
❑ Patient or family member is pregnant LMP/EDD
❑ Results will directly impact patient treatment

TEST SELECTION

❑ NGS Panel Expand*

This test is appropriate for individuals with emerging and/or complex phenotypes.

*An eligible NGS panel must have been previously performed at EGL Genetics in order to request this test. (Eligible panels include most NGS panels performed January 2016 or later; sponsored testing does not apply.) Please contact the laboratory with any questions regarding panel eligibility.

LAB USE ONLY

Received Unboxed by

Sender

TEMP	SPEC	COL	#TUBES	VOL
RCF				
RCF				
RCF				
RCF				

BILLING

❑ Facility Bill Acct. No.
❑ Insurance Bill
❑ Self Pay

	COMP.	INCOMP.
PT. DATA	❑	❑
TEST DATA	❑	❑
PHYSICIAN DATA	❑	❑
BILLING DATA	❑	❑

Hold Billing

QC

Reflex

Specimen

Accessioned by

Labeled by

Accessioning Label

Accessioning Label

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Patient Name: Last _____ First _____ MI _____

Submit this completed payment options form with the specimen. Testing is not initiated until billing information is received. Billing policy is available at http://eglgenetics.com/billing.

INTERNATIONAL SAMPLES

Payment in full must be made before samples will be processed. Banker's checks or money orders **must** be made payable to EGL Genetic Diagnostics LLC. Please contact the EGL billing office for further arrangements or when you make an electronic fund payment at 816-251-0395 or 888-875-7307.

Visit our website for more information: http://eglgenetics.com/billing/international-billing/.

PAYMENT OPTIONS (please fill out one of the following options)

1 - INSTITUTION

To establish an institutional account, new clients must complete an Institutional Account Request Form prior to submitting an order. The form can be downloaded at http://eglgenetics.com/billing. For any questions or to confirm whether you have an account or what your account number is, please contact the EGL billing office at 816-251-0395 or 888-875-7307.

Institution _____ Account Number _____

The following information is not required if account number is provided above:

Contact Name _____ Email _____

Billing Address _____

City _____ State _____ Zip _____

Phone _____ Fax _____

EGL Genetics Billing Label
Please call to request labels

2 - INSURANCE (Also includes GA Medicaid, Wellcare, Amerigroup, Peachstate for GA Residents and Medicare). EGL Genetics does not accept non-Georgia Medicaid

*A **legible** copy of the front and back of the insurance card is required as well as any applicable insurance authorizations. A completed and signed Advance Beneficiary Notice of coverage (ABN) is required for Medicare patients.*

ICD-10 Diagnosis Code(s) *Required _____

PRIMARY

Policy Holder Name _____

DOB (mm/dd/yyyy) _____ Gender ❍ Female ❍ Male

Relationship to patient
❍ Self ❍ Spouse ❍ Dependent ❍ Other _____

Insurance Company Name _____ Policy Number _____

Group Number _____ Address _____

City _____ State _____ Zip _____

Phone _____ Authorization No. (copy of auth. letter required) _____

SECONDARY

Policy Holder Name _____

DOB _____ Gender ❍ Female ❍ Male

Relationship to patient
❍ Self ❍ Spouse ❍ Dependent ❍ Other _____

Insurance Company Name _____ Policy Number _____

Group Number _____ Address _____

City _____ State _____ Zip _____

Phone _____ Authorization No. (copy of auth. letter required) _____

Authorization to assign benefits, accept financial responsibility, and disclose health records

If I am entitled to benefits under the Medicare program, the Medicaid program, or any insurance policy or other health benefit plan, in consideration for services provided to me by EGL Genetics, I assign, transfer and convey the benefits payable under such program, policy or plan for such services to EGL Genetics. I authorize payment of benefits directly to EGL Genetics, with such benefits applied to my bill. I understand and acknowledge that this assignment does not relieve me of financial responsibility for charges incurred by me and I agree to pay charges not paid under this assignment, including any coinsurance amounts and deductibles and any charges for services deemed to be non-covered, not pre-certified or not preauthorized by my insurance plan. I understand that EGL Genetics is permitted to disclose my health information for purposes of payment of bills (if I filled out section 2 above), my continued care or treatment, and healthcare operations. I authorize my physicians or any facility to release my health information to EGL Genetics for the purposes of payments of bills or claims.

_____ _____

Signature of patient, parent, of Guardian (required) **Date**

3 - SELF PAY

Payment Method ❍ Cashier Check ❍ VISA ❍ MasterCard ❍ Discover

Amount $ _____ (include discount if applicable)

Credit Card No. _____ Expiration Date _____

CVV _____ Cardholder Billing Address _____

City _____ State _____

Zip _____ Cardholder Phone _____

Required for credit card payments

_____
Cardholder Printed Name as it Appears on Card

_____
Cardholder Signature

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Informed Consent – NGS Panel Expand Testing

NGS Panel Expand (NGSExpand) - Informed Consent Document

I, (name)_____, voluntarily request EGL Genetics to perform NGSExpand testing in myself/my child (child's name) _____

Given the complexity of this analysis, **genetic counseling and informed consent by a trained medical geneticist or genetic counselor is strongly recommended prior to and after undergoing this testing**. Informed consent is a process that provides education about genetics, and the options, benefits, limitations, and consequences of genetic testing. Genetic counseling provides the patient with informed consent prior to the decision to undergo testing and with the opportunity to review the results of the test in detail. If a signed consent is not submitted, only variants related to or possibly related to phenotype will be reported.

What is the NGSExpand?

- The Next-Generation Sequencing (NGS) Panel Expand (NGSExpand) includes analysis of approximately 5,000 genes associated or implicated with Mendelian disease. These genes may include:
  - Genes possibly associated with this patient's phenotype
  - Genes associated with disease but may not be associated with this patient's phenotype
  - Genes newly identified to be associated with disease
  - Genes that are not definitively associated with disease

How is the NGSExpand performed?

- This test requires that an eligible NGS panel have been previously run at EGL Genetics (e.g. epilepsy, autism, macrocephaly).
- The panel is performed using next generation sequencing (NGS) technology and bioinformatic analysis.
- A broad analysis is performed to match genes/variants with phenotype (phenotype driven analysis).

Limitations of analysis by NGS

- Not all genes associated with disease will be included as part of the NGSExpand analysis. Genes not currently associated with disease may be included in this analysis. A fraction of the genes in the NGSExpand Analysis will not have sufficient coverage to accurately determine if a pathogenic variant is present. Therefore, pathogenic variants in these regions will not be detected by this analysis.
- NGS cannot accurately sequence repetitive regions, such as trinucleotide repeats. This means that NGS cannot provide data on regions such as the fragile X syndrome repeat region, the Huntington disease repeat region, or the myotonic dystrophy repeat region.
- Results from this testing may indicate that additional testing, such as full gene sequencing to fill-in exons with poor coverage or deletion/duplication analysis, is recommended.
- Copy number variation (CNV) is not evaluated in the NGSExpand test.

Potential risks associated with NGSExpand:

- Pathogenic variants in genes that lead to conditions for which the patient currently has no features may be discovered. For some conditions, the option of knowing if pathogenic variants are present is available.
- Uncertainty - We may not be able to tell you with certainty whether the variant(s) we find are directly related to the patient's phenotype. The interpretation of variants will evolve over time as we learn more about normal and abnormal human variation.
- Anxiety - Patients and family members may experience anxiety before, during, and/or after testing.

What will and will not be reported?

- Any variants in genes that are considered to be related to phenotype will be reported.
- Upon request EGL Genetics will report only pathogenic or likely pathogenic variants in childhood-onset conditions or carrier status for recessive conditions.
- Upon request, EGL Genetics will tell you what genes were included as part of the NGSExpand analysis and a list of low coverage exons can be requested. Please
- note that for minors information regarding variants in adult-onset conditions that are not related to phenotype will NOT be reported as part of this testing.
- Pharmacogenetic variants will not be reported as part of this testing.

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Mandatory Disclosures (for both minors and adult patients):
These are variants that will be reported in all patients.

1. **Diagnostic findings related to phenotype** - pathogenic variant(s), likely pathogenic variants(s), and variant(s) of uncertain significance in genes interpreted to be responsible for, or contributing to the patient's phenotype will be reported.
2. **Diagnostic findings not related to phenotype in childhood onset conditions** - pathogenic variant(s) and likely pathogenic variant(s) in genes that are known to cause childhood onset conditions, even if they are unrelated to the patient's phenotype, will be reported.

Optional Disclosures:
Individuals can choose to receive findings in regions other than those related to phenotype.

For All Patients (minors and adults)
1. **Carrier Status for Autosomal Recessive Conditions (ex. cystic fibrosis):**
A recessive condition is one in which two pathogenic variants in the same gene are required in order to show symptoms of the disease (one variant is inherited from each parent). Someone who has only one pathogenic variant does not show symptoms and is called a carrier. However, if we find a pathogenic variant in a recessive gene that is related to the patient's phenotype, we will report it as a diagnostic finding. Further testing may be necessary to look for a second pathogenic variant in that gene not identified by NGSExpand.

Pathogenic variants in genes that are not related to the patient's phenotype and would give information about the patient's carrier status for autosomal recessive conditions will only be reported if requested.

❑ YES, report information regarding carrier status. _____Patient/Guardian Initials

❑ NO, please DO NOT report information regarding carrier status. _____Patient/Guardian Initials

For Adult Patients (over 18 years of age): Answer the following questions only if an adult is receiving NGSExpand testing, does not apply to minors.
1. **Diagnostic Findings Not Related to Phenotype in Adult-onset Medically Actionable Disorders**:
Medically actionable conditions are those for which there is currently recommended treatment or preventative actions that can be taken to reduce the risk of developing the disease. An example would be hereditary cancer syndromes such as Lynch syndrome. Pathogenic and likely pathogenic variants in medically actionable conditions will only be reported if requested.

❑ YES, report information regarding adult onset conditions. _____Patient/Guardian Initials

❑ NO, please DO NOT report information adult onset conditions. _____Patient/Guardian Initials

2. **Diagnostic Findings Not Related to Phenotype in Adult-onset Not Currently Medically Actionable Disorders**:
Conditions that are not currently medically actionable do not have recommended treatment or preventative measures. An example would be Alzheimer's disease. Pathogenic variants in conditions that are not currently medically actionable (do not have recommended treatment or preventative measures) will only be reported if requested.

❑ YES, report information regarding adult onset conditions. _____Patient/Guardian Initials

❑ NO, please DO NOT report information adult onset conditions. _____Patient/Guardian Initials

PLEASE NOTE
The NGSExpand test is not designed to be a comprehensive test to identify carrier status or findings in conditions not part of the original panel. We are unable to guarantee that all conditions for which the individual is a carrier for or all conditions for which the individual has a pathogenic variant in will be determined by this test. Additional testing for health or reproductive purposes should be discussed with your doctor or genetic counselor. Also, variants of unknown significance will not be reported when they fall under categories not related to phenotype. Requests for raw data from this analysis are available only as VCF files.

The risks, benefits, and limitation of the NGSExpand testing have been explained to me and I have had a chance to have my questions answered. I have read and will receive a copy of this consent form. I understand that diagnostic findings related to adult onset conditions (e.g. cancer predispositions syndromes) will not be reported for minors as part of this testing.

_____ _____ _____ _____
Patient Signature Date Parent/Guardian Signature Date

Physician/Counselor/Clinician Statement:
I have provided genetic counseling and have explained the NGSExpand test to the patient/parent/guardian. The consent form and limitations of genetic testing were reviewed with the patient/guardian. I accept responsibility for pre- and post-test genetic counseling.

Note to Ordering Clinician:
EGL Genetics encourages the discussion of the limitations and utility of a genetic test with the patient prior to specimen collection. This form is provided to address pertinent issues regarding this test.

_____ _____
Clinician Signature Date