Ambry Genetics

Clinical Genomics Test Requisition Form - Page 1 of 5
(Exome Sequencing and Microarray)

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

To submit an order via email, please send the completed test requisition form to info@ambrygen.com

PATIENT INFORMATION

Name (Last, First, MI)	Sex at Birth ☐F ☐M	Date of Birth (MM/DD/YY)	MRN

Ethnicity: ☐ Asian ☐ Ashkenazi Jewish ☐ Black/African American ☐ White ☐ French Canadian/Cajun ☐ Hispanic/Latino ☐ Mediterranean ☐ Middle Eastern ☐ Native American ☐ Pacific Islander ☐ Portuguese ☐ Unknown ☐ Other:

Address	City	State	Zip

Phone	Email	Preferred Billing ☐ Insurance ☐ Self-pay ☐ Institutional

SPECIMEN INFORMATION* (For phlebotomy service, select all services you are requesting)

Type(s) ☐ Blood *(EDTA preferred)* ☐ Saliva ☐ Buccal Swab ☐ DNA, Source**: ☐ Cultured CVS ☐ Cultured amniocytes ☐ Other:

☐ Personal history of allogenic bone marrow or peripheral stem cell transplant* ☐ Current diagnosis of heme malignancy, Type:

Collection Date	Specimen ID ☐ Send saliva kit to patient	Medical Record #

**Blood/saliva/buccal swab sample from patients with a history of allogenic bone marrow or stem cell transplant cannot be used for genetic testing. Blood/saliva/buccal swab sample from patients with active hematological disease is not recommended. An alternative specimen may be needed. See ambrygen.com/specimen-requirements for details.*

***Fetal specimens, cord blood and POC will have maternal cell contamination studies added for a charge. Maternal and fetal specimen required. Please see page 4 for Maternal Cell Contamination sample submission test codes*

Phlebotomy Services Request: ☐ Phlebotomy draw ☐ Send blood kit to patient^^ ☐ Send saliva kit to patient | ☐ Insurance preverification first (available for ExomeNext and SNP array only)

^As the patient's clinician, I am unaware of any potential for complication or difficulty in drawing blood for the listed patient(s). I understand that the phlebotomist has full authority to refuse to draw any patient if the safety of the phlebotomist and/or patient(s) are in question.

ORDERING PHYSICIAN/SENDING FACILITY (Each listed person will receive a copy of the report)

Facility Name (Facility Code)	Address	City	State /Country	Zip	Phone

Ordering Licensed Provider Name (Last, First)(Code)	NPI#	Phone	Fax	Fax/Email

ADDITIONAL RESULTS RECIPIENTS

Genetic Counselor or Other Medical Provider Name (Last, First) (Code)	Phone/Fax/Email

CONFIRMATION OF INFORMED CONSENT AND MEDICAL NECESSITY FOR GENETIC TESTING

The undersigned person (or representative thereof) ensures he/she is a licensed medical professional authorized to order genetic testing and confirms that the patient has given appropriate consent. I confirm that testing is medically necessary and that test results may impact medical management for the patient. I agree to allow Ambry Genetics to facilitate the provision of pre-test genetic counseling services by a third-party service, as required by the patient's insurance provider. Furthermore, all information on this TRF is true to the best of my knowledge. My signature applies to the attached letter of medical necessity.

Signature Required for Processing Medical Professional Signature: Date:

☐ INSURANCE BILLING (Include copy of both sides of insurance card)

Patient Relation to Policy Holder? ☐Self ☐Spouse ☐Child	Name and DOB of Policy Holder (if not self)	
Insurance Company	Policy #	HMO Auth #

Out of Pocket:
In many cases, we will start testing immediately (may vary by test or insurance provider). We will attempt to contact the patient if the estimated out-of-pocket costs are > USD $100.

Special Billing Notes:

☐ INSTITUTIONAL BILLING

Facility Name ☐ *Send invoice to facility address above*

Address

Contact Name

Phone Number	E-mail/Fax

☐ PATIENT PAYMENT

☐ Check (Payable to Ambry Genetics)
☐ Credit Card (Call 949-900-5795)

Patient Acknowledgement: I acknowledge that the information provided by me is true and correct. For direct insurance billing: I authorize my insurance benefits to be paid directly to Ambry Genetics Corporation (Ambry), authorize Ambry to release medical information concerning my testing to my insurer, to be my designated representative for purposes of appealing any denial of benefits as needed and to request additional medical records for this purpose. I understand that I am financially responsible for any amounts not covered by my insurer and responsible for sending Ambry money received from my health insurance company.
For patient payment by credit card: I hereby authorize Ambry Genetics Corporation to bill my credit card as indicated above. In order to expedite consideration for eligibility for **Ambry's Patient Assistance Program**, please provide the total annual gross household income: $_____ and the number of family members in the household supported by the listed income: _____. I authorize Ambry Genetics Corporation to verify the above information for the sole purpose of assessing financial need, including the right to seek supporting documentation.

For NY Residents:
☐ I am a New York resident and I give Ambry Genetics permission to store my sample for longer than 60 days. **NOTE:** If left blank, consent is interpreted as "NO".

Signature Required For Insurance/Self-Pay Patients and NY Sample Storage Consent: Date:

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Patient Name: _____ DOB: _____

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ONLY COMPLETE FOR EXOMENEXT-DUO/TRIO ORDERS OR IF FAMILY MEMBERS WILL BE SUBMITTED FOR CO-SEGREGATION.
All family member specimens must be received within 4 weeks of order. Otherwise test will be run as proband only.

FAMILY MEMBER #1 INFORMATION

Name (Last, First, MI)	Date of Birth (MM/DD/YY)	Date of Death (If applicable)	Phone Number/Email

Biological Sex: ☐F ☐M

Ethnicity: ☐Asian ☐Ashkenazi Jewish ☐Jewish (non-Ashkenazi) ☐Black/African American ☐White ☐French Canadian/Cajun ☐Hispanic/Latino ☐Mediterranean ☐Middle Eastern ☐Native American ☐Pacific Islander ☐Portuguese ☐Unknown ☐Other:

Address: ☐ Same as Proband	Address	City	State	Zip	Relationship to proband

SPECIMEN INFORMATION* (For phlebotomy service, select all services you are requesting)

Type(s) ☐Blood (EDTA preferred) ☐Saliva ☐DNA, Source: ☐Other:

☐Personal history of allogenic bone marrow or peripheral stem cell transplant ☐Current diagnosis of heme malignancy, Type:

Collection Date	Specimen ID	Medical Record #

**Blood/saliva from patients with a history of allogenic bone marrow or stem cell transplant cannot be used for genetic testing. Blood/saliva from patients with active hematological disease is not recommended. An alternative specimen may be needed. See ambrygen.com/specimen-requirements for details.*

Phlebotomy Services Request: ☐Phlebotomy draw ☐Insurance preverification first ☐Send blood kit to patient^ ☐Send saliva kit to patient

^As the patient's clinician, I am unaware of any potential for complication or difficulty in drawing blood for the listed patient(s). I understand that the phlebotomist has full authority to refuse to draw any patient if the safety of the phlebotomist and/or patient(s) are in question.

CLINICAL INFORMATION

Does the family member have any features similar to the proband? ☐Yes ☐No ☐Partially ☐Possibly

Describe:

SECONDARY FINDINGS

Secondary findings results are available for each family member sequenced as part of the trio. Check below to opt-out of the ACMG Recommended List of secondary findings. If left unchecked, secondary findings will be reported.

☐Opt-out: I choose to decline the ACMG Recommended List of secondary findings.

FAMILY MEMBER #2 INFORMATION

Name (Last, First, MI)	Date of Birth (MM/DD/YY)	Date of Death (If applicable)	Phone Number/Email

Biological Sex: ☐F ☐M

Ethnicity: ☐Asian ☐Ashkenazi Jewish ☐Jewish (non-Ashkenazi) ☐Black/African American ☐White ☐French Canadian/Cajun ☐Hispanic/Latino ☐Mediterranean ☐Middle Eastern ☐Native American ☐Pacific Islander ☐Portuguese ☐Unknown ☐Other:

Address: ☐ Same as Proband	Address	City	State	Zip	Relationship to proband

SPECIMEN INFORMATION* (For phlebotomy service, select all services you are requesting)

Type(s) ☐Blood (EDTA preferred) ☐Saliva ☐DNA, Source: ☐Other:

☐Personal history of allogenic bone marrow or peripheral stem cell transplant ☐Current diagnosis of heme malignancy, Type:

Collection Date	Specimen ID	Medical Record #

**Blood/saliva from patients with a history of allogenic bone marrow or stem cell transplant cannot be used for genetic testing. Blood/saliva from patients with active hematological disease is not recommended. An alternative specimen may be needed. See ambrygen.com/specimen-requirements for details.*

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CLINICAL INFORMATION

Does the family member have any features similar to the proband? ☐Yes ☐No ☐Partially ☐Possibly

Describe:

SECONDARY FINDINGS

Secondary findings results are available for each family member sequenced as part of the trio. Check below to opt-out of the ACMG Recommended List of secondary findings. If left unchecked, secondary findings will be reported.

☐Opt-out: I choose to decline the ACMG Recommended List of secondary findings.

Note: Additional relatives may be submitted for co-segregation analysis, free of charge. Please complete "Clinical Genomics Family Member TRF" if additional relatives will be included.

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Patient Name: _____ DOB: _____

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INDICATION(S) FOR TESTING

ICD-10 code(s):	Will medical management change depending upon the results of the test? ☐ Yes ☐ No

PROBAND'S PRIMARY INDICATION FOR TESTING

Please describe in a few words the main reason for ordering exome testing (Please also provide clinic notes and pedigree):

PROBAND'S CLINICAL OVERVIEW (Check all that apply)

- ☐ Audiologic/Otolaryngologic
- ☐ Cardiovascular
- ☐ Craniofacial
- ☐ Dental
- ☐ Dysmorphic Features
- ☐ Dermatologic
- ☐ Endocrine
- ☐ Fetal (*Please complete and attach "ExomeNext Prenatal Form"*)
- ☐ Gastrointestinal
- ☐ Genitourinary
- ☐ Growth Disorders:
  - ☐ Undergrowth
  - ☐ Overgrowth
  - ☐ Failure to thrive
- ☐ Hematologic
- ☐ Immunologic/Infectious/Allergy
- ☐ Metabolic/Biochemical
- ☐ Movement Disorder
- ☐ Musculoskeletal/Structural
- ☐ Multiple Congenital Anomalies
- ☐ Neurologic
  - ☐ Seizures/Epilepsy
  - ☐ Autism Spectrum Disorder
  - ☐ Developmental Delay/Intellectual disability
  - ☐ Ataxia/Spasticity
  - ☐ Psychiatric
  - ☐ Abnormal brain MRI
- ☐ Obstetric
- ☐ Oncologic
- ☐ Ophthalmologic
- ☐ Pulmonary
- ☐ Renal
- ☐ Tone abnormalities
  - ☐ Hypotonia
  - ☐ Hypertonia

ADDITIONAL CLINICAL DETAILS

Autism: ☐ no autistic behaviors ☐ autistic behaviors (describe): _____

Dysmorphic Features (describe): _____

Congenital Anomalies (describe): _____

History of Seizures ☐ Yes ☐ No ☐ diagnosed epilepsy Seizure type(s):_____

Progressive disease ☐ Yes ☐ No

Previous Studies

MRI/CT studies (findings): _____

Chromosome analysis: _____ Microarray analysis:_____

Other molecular studies:_____

Growth Indices (current): Head circumference: _____% Weight: _____ % Height: _____%

Differential diagnosis/Genes of interest:_____

FAMILY HISTORY (Please attach pedigree)

Is anyone in the family affected with a similar phenotype as the proband? ☐ NO ☐ YES, please list exact relationship to proband, symptoms and age of onset of symptoms:

_____

_____

Is there any consanguinity (conception between blood relatives) in the family? ☐ NO ☐ YES If yes please describe: _____

_____

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Patient Name: _____ DOB: _____

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Please check the box next to the test(s) being ordered below. If this TRF is sent to Ambry without or ahead of the sample, it will be treated as a preverification. If test ordered is different than the test preverified, we will honor what is on the TRF order form with the sample. Preverification will only be performed for ExomeNext or SNP Array testing.

For multiple test orders, testing will be run concurrently (multiple tests initiated at the same time) unless otherwise specified. To order reflexive testing (second test starts pending first test outcome), please clearly indicate the order of reflexive tests in the notes section or next to the test check box. For reflex test orders, any positive findings (pathogenic/likely pathogenic) in the first test will be reported out to the clinician, and the requested second test will be canceled; all other findings will automatically reflex (including VUS).

Check to order	Test Name	Test Code	Description
Chromosomal Microarray Analysis			
☐	SNP Array^^	5490	Chromosomal microarray (>2.6 million copy number probes and 750,000 SNP probes)
☐	Familial targeted microarray^^	5495	Paid option. Only available following SNP Array (5490) completed at Ambry. Incidental findings unrelated to the variant(s) detected in the proband, will NOT be reported. Name of proband tested at Ambry: _____
Exome Sequencing			
☐	ExomeNext®-*Proband*	9993	Proband only exome sequencing Secondary Findings†: ☐ Opt-out
☐	ExomeNext®-*Proband* plus mtDNA	9994	Proband only exome sequencing plus mtDNA sequencing Secondary Findings†: ☐ Opt-out
☐	ExomeNext®-*Duo*	9991	Duo exome sequencing Secondary Findings†: ☐ Opt-out
☐	ExomeNext®-*Duo* plus mtDNA	9992	Duo exome sequencing plus mtDNA sequencing Secondary Findings†: ☐ Opt-out
☐	ExomeNext®-*Trio*	9995	Trio exome sequencing Secondary Findings†: ☐ Opt-out
☐	ExomeNext®-*Trio* plus mtDNA	9996	Trio exome sequencing plus mtDNA sequencing Secondary Findings†: ☐ Opt-out
☐	ExomeNext-*Rapid*® *(Institutional billing or patient payment only)*	9999R	Rapid Trio exome sequencing plus mtDNA sequencing Secondary Findings†: ☐ Opt-out
Order through AmbryPort®	ExomeNext®-*Select*	9500	Up to 500 gene custom exome sequencing test

^^*Buccal swab accepted for SNP Array*
†*Secondary Findings: If box is left unchecked, the ACMG recommended list of Secondary Findings will be reported. Secondary Findings are not available for ExomeNext-Select orders.*

SINGLE SITE ANALYSIS (Please include a copy of relative's report)

Gene(s): _____ Mutation(s): _____

Relative Name: _____

Relationship to Relative:_____ Accession # (If tested at Ambry): _____

Positive control sample: ☐ will be provided ☐ already at Ambry ☐ not available

FOR PRENATAL SPECIMENS, POC OR CORD BLOOD: MATERNAL CELL CONTAMINATION ANALYSIS REQUIRED

Both test codes required for fetal specimens.

☐ 1260 MCC for amniotic fluid culture or CVS

☐ 1262 MCC Reference for maternal blood sample (No Charge)

OTHER ORDER

Please visit ambrygen.com/tests for details.

Test Code: _____Test Name: _____

Notes:

ORDERING CHECKLIST (Required†)

☐ Proband specimen

☐ Clinical Genomics TRF with patient & clinician signatures

☐ Clinical history (attach clinic notes)

☐ Medical Necessity Form (insurance orders only) (see page 5)

☐ Copy of Insurance Card (insurance orders only)

Orders with missing requirements will be placed on hold until all requirements are received.

ORDERING CHECKLIST (Highly Recommended)

☐ Family member specimens *Please send all first degree and other informative relatives within 4 weeks of the order.*

☐ Family history or pedigree

☐ Previous test results

CONTACT INFORMATION

For ExomeNext preverification requests please send the Medical Necessity Form and Clinical Genomics TRF to preverification@ambrygen.com or fax to 949-900-5501.

All other documents can be secure uploaded at ambrygen.com/secure-upload, or faxed to 949-900-5501.

AmbryPort is a secure client portal that allows order submission, test status updates, insurance authorization status and report downloads. All required documents can be completed and directly uploaded through AmbryPort during the ordering process or after order submission. Please visit portal.ambrygen.com/signup to sign up.

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Patient Name: _____ DOB: _____

ExomeNext Medical Necessity Form - Page 5 of 5

REQUIRED FOR INSURANCE ORDERS ONLY (NOT REQUIRED FOR CIGNA MEMBERS)

This form is required if you are ordering Exome testing and wish to have the patient's insurance billed. Please complete and submit with the TRF and a copy of clinical notes. This form replaces the Letter of Medical Necessity.

1. Has the patient had previous Whole Exome Sequencing (WES) performed?

   ☐ Yes, date performed: _____

   ☐ No

2. Does this patient have a clinical presentation consistent with the following (select all that apply):

   ☐ Multiple abnormalities affecting unrelated organ systems (please specify): _____

   OR two of the following:

   ☐ Abnormality affecting a single organ system(specify): _____

   ☐ Significant intellectual disability, symptoms of a complex neurodevelopmental disorder (i.e. self-injurious behavior, reverse sleep-wake cycle, or seizure/epilepsy), or severe neuropsychiatric condition (e.g. schizophrenia, bipolar, Tourette syndrome)

   ☐ Family history strongly implicating a genetic etiology (please specify findings and relationships): _____

   ☐ Period of unexplained developmental regression (unrelated to autism or epilepsy)

3. Are the results of this WES test expected to directly influence this patient's medical management recommendations and clinical outcome?

   ☐ Yes (please describe): _____

   ☐ No

4. Please describe the genetic tests that would be indicated if WES were NOT performed (i.e., single gene tests, gene panels, etc.):

   ☐ Chromosomal microarray

   ☐ Single gene test(s): _____

   ☐ Multigene panel(s): _____

   ☐ Other genetic test(s): _____

5. Please describe follow-up procedures & frequency that would be needed if WES were NOT performed (i.e., lumbar puncture, imaging studies, brain MRI, etc.):

   ☐ Imaging study: _____

   ☐ Surgery: _____

   ☐ Biopsy: _____

   ☐ Other: _____

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