Ambry Genetics

Clinical Genomics Test Requisition Form - Page 1 of 6
(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

COLLECTION DATE (REQUIRED)

If date of collection is not provided, three calendar days before specimen receipt will be used (for specimens stored longer than 30 days, the day of archive retrieval will be used as the date of service)

2. PATIENT INFORMATION

Legal Name (Last, First, MI)	Date of Birth (MM/DD/YY)	Sex Assigned at Birth ☐F ☐M	Gender (optional) ☐Man ☐Woman ☐Nonbinary ☐Self-described

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

Address	City	State	Zip

Mobile #	Email	Preferred Billing ☐Insurance ☐Self-pay ☐Institutional

SPECIMEN INFORMATION* (Please see ambrygen.com/specimen-requirements for details)

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

Specimen ID:	Medical Record #

**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*

Collection Assistance: ☐Phlebotomy draw** ☐ Send saliva kit to patient ☐ Send buccal 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 #

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.

☐ I agree to be contacted regarding future research studies for which I may be a candidate. Any future research projects will be subject to a separate informed consent process and participation is voluntary. Learn more about Ambry's privacy practices at https://www.ambrygen.com/legal/notice-of-privacy-practices.

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:

☐ By checking this box, I agree that Ambry Genetics will retain my sample for 6 months after the testing above has been completed. By not checking this box, I understand that under New York State law, Ambry Genetics must discard my sample after the longer of (a) testing completion and (b) 60 days after the Date of Collection above.

Patient Signature (I agree to terms above): 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

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

Sex Assigned at Birth: ☐F ☐M

Gender (optional) ☐Man ☐Woman ☐Nonbinary ☐Self-described

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

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

SPECIMEN INFORMATION* (Please see ambrygen.com/specimen-requirements for details)

☐ 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.*

Collection Assistance: ☐Phlebotomy draw** ☐ Send saliva kit to patient ☐ Send buccal 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.*

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

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

Sex Assigned at Birth: ☐F ☐M

Gender (optional) ☐Man ☐Woman ☐Nonbinary ☐Self-described

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

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

SPECIMEN INFORMATION* (Please see ambrygen.com/specimen-requirements for details)

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

Collection Date	Specimen ID	Medical Record #

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Collection Assistance: ☐Phlebotomy draw** ☐ Send saliva kit to patient ☐ Send buccal kit to patient | ☐ Insurance preverification first (available for ExomeNext and SNP array only)

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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 yes for all that apply)

☐ Yes ☐ No Audiologic/Otolaryngologic
☐ Yes ☐ No Cardiovascular
☐ Yes ☐ No Craniofacial
☐ Yes ☐ No Dental
☐ Yes ☐ No Dysmorphic Features
☐ Yes ☐ No Dermatologic
☐ Yes ☐ No Endocrine
☐ Yes ☐ No Fetal (*Please complete and attach "ExomeNext Prenatal Form"*)
☐ Yes ☐ No Gastrointestinal
☐ Yes ☐ No Genitourinary
☐ Yes ☐ No Growth Disorders:
  ☐ Yes ☐ No Undergrowth
  ☐ Yes ☐ No Overgrowth
  ☐ Yes ☐ No Failure to thrive
☐ Yes ☐ No Hematologic
☐ Yes ☐ No Immunologic/Infectious/Allergy
☐ Yes ☐ No Metabolic/Biochemical
☐ Yes ☐ No Movement Disorder
☐ Yes ☐ No Musculoskeletal/Structural
☐ Yes ☐ No Multiple Congenital Anomalies
☐ Yes ☐ No Neurologic
  ☐ Yes ☐ No Seizures/Epilepsy
  ☐ Yes ☐ No Autism Spectrum Disorder
  ☐ Yes ☐ No Developmental Delay/Intellectual disability
  ☐ Yes ☐ No Ataxia/Spasticity
  ☐ Yes ☐ No Psychiatric
  ☐ Yes ☐ No Abnormal brain MRI
☐ Yes ☐ No Obstetric
☐ Yes ☐ No Oncologic
☐ Yes ☐ No Ophthalmologic
☐ Yes ☐ No Pulmonary
☐ Yes ☐ No Renal
☐ Yes ☐ No Tone abnormalities
  ☐ Yes ☐ No Hypotonia
  ☐ Yes ☐ No 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:_____

Known Familial Variant: ☐ Family ☐ Self Gene: _____ Variant (c. and/or p.): _____ Testing Lab: _____ Ambry ID: _____

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 Reflex or Concurrent Testing:

Test 1: _____ ☐ Reflex to ☐ Concurrent with Test 2: _____ ☐ Reflex to ☐ Concurrent with Test 3: _____

See Reflex or Concurrent Testing section of the Supplemental Information page.

Check	Test Name	Test Code	Description
Exome			
!	**REQUIRED: Select a Primary Test Order**		
☐	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
ExomeNext Supplemental Test Options			
☐	ExomeReveal™	9990	RNA analysis available with all ExomeNext orders except for ExomeNext-*Rapid*, EDTA and PAX-gene RNA tubes required
Fragile X syndrome and Chromosomal Microarray			
☐	Fragile X syndrome	4544	*FMR1* repeat expansion analysis and methylation studies
☐	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: _____

**Secondary Findings: If box is left unchecked, the ACMG recommended list of Secondary Findings will be reported.*

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.

Specimen Requirements

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.

Specific site analysis for variants identified at an external laboratory must be accompanied by a copy of the original testing report. A positive control from a known positive family member is recommended (required for prenatal testing).

Reflex or Concurrent Testing

Concurrent testing is when multiple tests are initiated at the same time. When multiple tests are ordered on the same test requisition form, testing will be run concurrently unless otherwise specified.

Reflex testing is when a subsequent test is initiated pending the outcome of the initial test. Reflex testing may result in delayed reporting of results.

For reflex test orders:

- Any diagnostic finding at any step will result in cancellation of any subsequent reflex tests.
- Non-diagnostic findings (including VUS or Uncertain results) will automatically reflex to the subsequent test.
- Secondary findings results do not impact whether a subsequent test is initiated or canceled.

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Patient Name: _____ DOB: _____

ExomeNext Medical Necessity Form - Page 6 of 6

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: _____

7 Argonaut, Aliso Viejo, CA 92656 USA Toll Free +1.866.262.7943 Fax +1.949.900.5501 **ambrygen.com**

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