



Clinical Genome Center
 7910 Frost Street, Suite 240
 San Diego, CA 92123
E: RCIGM_rWGS@rchsd.org
P: 858 / 966-8127 **F:** 858 / 966-8092
CLIA ID# 05D2129627 CAP ID# 9487427

Place ordering provider label with patient identifier here

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RCIGM-CGC Test Requisition Form

Patient Information

Last Name _____ First Name _____
 Middle Name _____ Alias Name (optional) _____
 Patient ID/MRN _____
 Sex: Female _____ Male _____ Ambiguous _____
 DOB (MM/DD/YYYY) _____

Race and Ethnicity: *(Check all that apply)*

Caucasian	Middle Eastern
African-American	Ashkenazi Jewish
Asian	Native American
Hispanic	Other _____

Ordering Provider and Report Distribution

Institution _____
 Street _____
 City _____ State _____
 Zip _____ Country _____

Ordering Provider

Last Name _____ First Name _____
 Role/Title _____
 Phone _____
 Email (Institutional email required for return of results) _____

Patient's Physician Same as Ordering Provider (*if yes, skip below)

Last Name _____ First Name _____
 Role/Title _____
 Phone _____
 Email (Institutional email required for return of results) _____
 Additional Report Distribution Instructions (optional) _____

Specimen And Sample Type

Label sample tubes with at least two identifiers listed on Requisition Form. *see pg. 7 for additional Specimen and Shipping Requirements

Date Collected (MM/DD/YYYY) _____ AM _____ PM _____
 Time Collected _____
 Specimen ID (ID associated with specific sample container) _____

Sample Type:
 *see pg. 7 for Specimen Requirements Clinical

Whole blood (EDTA)
 Please make every effort to provide two whole blood EDTA tubes for Whole Genome Sequencing (WGS)

DNA, Extracted from EDTA Blood in a CLIA accredited laboratory

CLIA Laboratory Name _____

Order Type
 Please indicate the urgency of medical management on pg 2 to assist RCIGM prioritizing testing.
 *See page 6 for test types and ordering information.

Ultra Rapid Whole Genome Sequencing (urWGS) (F11-03)

Rapid Whole Genome Sequencing (rWGS)
 rWGS Patient Only (one individual) (F10-01)
 rWGS Duo (two individuals) (F10-02)
 rWGS Trio (three individuals) (F10-03)
 rWGS Additional Family Member (F10-05)

Standard Whole Genome Sequencing (WGS)
 WGS Patient Only (one individual) (D12-01)
 WGS Duo (two individuals) (D12-02)
 WGS Trio (three individuals) (D12-03)
 WGS Additional Family Member (D12-05)

DNA Isolation Hold and Storage (F30-01)
 If a Duo, Trio and/or Additional Family Member test is ordered, please fill out the Biological Family Sample Information on pg. 1 and additional family member information on pg. 3.

Biological Parent Sample included in shipment

If sending biological parent samples for testing, please provide additional family members information sheet (pg. 3). If sending more than 3 samples, print and complete additional copy of this page (additional fees may apply).

Mother	Included in Shipment	Not Available
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First Name _____ Last Name _____ DOB (MM/DD/YYYY) _____
 MRN _____

Father	Included in Shipment	Not Available
--------	----------------------	---------------

First Name _____ Last Name _____ DOB (MM/DD/YYYY) _____
 MRN _____

Other	Included in Shipment	Not Available
-------	----------------------	---------------

First Name _____ Last Name _____ DOB (MM/DD/YYYY) _____
 MRN _____

Consent and Test Requisition Form Information

The undersigned person (or representative thereof) certifies as follows: 1) I am a licensed medical professional authorized to order genetic testing; 2) appropriate informed consent by the patient and/or parent/guardian has been obtained and documented; 3) testing as ordered is medically necessary; 4) all information on this Test Requisition Form is true and correct to the best of my knowledge; and 5) I agree to the attached Terms and Conditions for invoicing, billing and payment.

Medical Professional NPI # *(required)* _____
 Medical Professional Name Print *(required)* _____
 Medical Professional Signature *(required)* _____
 Today's Date (MM/DD/YYYY) *(required)* _____

RCIGM Clinical Genome Center Use Only

Received by _____ Date _____
 Received from Sender (Name, Title & Organization/Hospital) _____
 RCIGM Case ID _____





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Clinical Information

Clinical Diagnosis/Reason for Testing

ICD-10 Codes

REQUIRED: Enter additional relevant information below, for example, patient phenotype information and detailed family history. If available, list differential diagnosis, add medical history, specialists' notes (i.e. neurology, cardiology, immunology, etc.) and family pedigree as attachments. Clinical information is crucial for accurate interpretation of results.

Large empty rectangular box for clinical information input.



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Additional Family Member Samples

Instructions: Please complete the following section if submitting samples from family members to assist with interpretation of the patient's genome. Separate reports will not be issued for these family members. Label sample tubes with at least two identifiers as listed on requisition form. See pages 6 and 7 for specimen requirements and test descriptions.

Additional Family Member 1

_____ First Name		_____ Last Name		_____ DOB (MM/DD/YYYY)		_____ Relationship to Patient (e.g. mother)	
_____ MRN		Sex: Female Male Ambiguous					
Clinically Unaffected Clinically Affected		Briefly list phenotype		AM PM		Sample Type: Whole blood (EDTA) Saliva (confirmatory testing only) DNA, Extracted from EDTA Blood in a CLIA accredited laboratory *see pg. 7 for Specimen Requirements	
_____ Date Collected (MM/DD/YYYY)		_____ Time Collected				_____ CLIA Laboratory Name	

Additional Family Member 2

_____ First Name		_____ Last Name		_____ DOB (MM/DD/YYYY)		_____ Relationship to Patient (e.g. mother)	
_____ MRN		Sex: Female Male Ambiguous					
Clinically Unaffected Clinically Affected		Briefly list phenotype		AM PM		Sample Type: Whole blood (EDTA) Saliva (confirmatory testing only) DNA, Extracted from EDTA Blood in a CLIA accredited laboratory *see pg. 7 for Specimen Requirements	
_____ Date Collected (MM/DD/YYYY)		_____ Time Collected				_____ CLIA Laboratory Name	

Additional Family Member 3

_____ First Name		_____ Last Name		_____ DOB (MM/DD/YYYY)		_____ Relationship to Patient (e.g. mother)	
_____ MRN		Sex: Female Male Ambiguous					
Clinically Unaffected Clinically Affected		Briefly list phenotype		AM PM		Sample Type: Whole blood (EDTA) Saliva (confirmatory testing only) DNA, Extracted from EDTA Blood in a CLIA accredited laboratory *see pg. 7 for Specimen Requirements	
_____ Date Collected (MM/DD/YYYY)		_____ Time Collected				_____ CLIA Laboratory Name	



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RCIGM-CGC Notice of Use and Disclosure of Samples & Information; Incidental Findings

Samples will be sent to RCIGM laboratories in California for testing. RCIGM acknowledges the confidentiality and privacy rights of the patient, parents and other family members tested. In accordance with its policies and applicable law, RCIGM will retain samples, the results of testing, associated data and reports. Identifiable samples and information will be kept confidential and accessible only to RCIGM clinical staff. Unless required or permitted by law, RCIGM will not disclose identifiable samples or information to any person or entity without your written authorization. For the limited purposes of treatment, payment, healthcare operations and on a restricted need-to-know basis, RCIGM may share your samples and/or data with your provider(s).

Additional Use of De-identified Information and/or Samples. RCIGM may use De-identified Information and Samples for research, scientific and technical development, and internal statistical and program operations analysis ("Additional Use"). De-identified data may be submitted to rare disease databases such as GeneMatcher to help identify new disease causing genes and aid in the ability to identify a genetic diagnosis in the individual. Additionally, samples may be sent de-identified to external clinical laboratories to resolve any analytical discrepancies that occur during testing at the discretion of RCIGM. Additional Use of De-identified Information and Samples for these purposes may improve identification and development of the therapies for existing and new diseases now or in the future. At the time of placing an order and prior to testing, RCIGM offers patients/guardians and/or individuals tested the ability to prohibit RCIGM additional use of De-identified information and samples. No response will be treated as Opt-In (except for New York residents).

For New York Residents: If no selection is marked below, RCIGM laboratory will select Opt-Out by default. If Opt-In for additional use is not selected, New York law requires RCIGM to destroy samples 60 days after completion of testing.

Data Release: RCIGM can provide the release of raw sequence data from WGS for patients and/or family members to the healthcare provider on record, upon request. Data will be provided as BAM and/or VCF files. For data release requests, the ordering provider can contact RCIGM_rWGS@rchsd.org.

Incidental Findings. In rare cases, RCIGM may also report an incidental finding during routine analysis. Incidental findings are pathogenic variants identified in genes not related to the patient's phenotype that are considered medically actionable and the results are significant for the health of the patient or family members tested.

What will be reported for relatives: The presence of any incidental findings reported for the proband may be provided for relatives included in this testing, unless they opt-out of receiving such results.

Limitations: Pathogenic variants that may be present in a relative, but not present in the proband, will not be identified or reported.

Please mark the appropriate boxes below to Opt-In or Opt-Out.

If no selection is marked, RCIGM laboratory will select Opt-In by default (except for New York residents).

Use of De-identified Information and/or Samples		Incidental Findings		Proband and Family Member Names	
Opt-In	Opt-Out	Opt-In	Opt-Out	Relationship	Print Name
				Proband	
				Mother	
				Father	
				Sibling	
				Other _____	

By signing below you are acknowledging that you have reviewed the WGS test information and authorize the completion of the described test. Your signature(s) confirm that you Opt-In or Opt-Out of incidental findings and sharing of de-identified data for each participant as selected above. Print the name of the person signing. Parent/Guardian(s) must sign below for minors. Each adult (age 18 and older) must sign for themselves. If parent is under 18, parent guardian signature may be required.

 Proband/Proband Guardian Name (Print)

 Proband/Proband Guardian Signature

 Date (MM/DD/YYYY)

 Mother/Mother Guardian Name (Print)

 Mother/Mother Guardian Signature

 Date (MM/DD/YYYY)

 Father/Father Guardian Name (Print)

 Father/Father Guardian Signature

 Date (MM/DD/YYYY)

 Sibling/Sibling Guardian Name (Print)

 Sibling/Sibling Guardian Signature

 Date (MM/DD/YYYY)

 Other Family Member Name (Print)

 Other Family Member Signature

 Date (MM/DD/YYYY)



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Financial Responsibility and Payment Information

Please provide account and billing contact information below.

Form with fields for Institution, Contact Name, Billing Address, City, State, ZIP, Phone, Fax, and Federal Tax Identification Number (if applicable).

Fees:

Attach written acceptance from Ordering Provider's authorized representative (e.g. E-mail)

Payment:

See attached Terms and Conditions for invoicing, billing and payment

Contact Us:

For invoice and billing questions, email RCIGM_Accounting@rchsd.org
For test fee information, email RCIGM_rWGS@rchsd.org or call us at (858) 966-8127.



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RCIGM-CGC Test Description

Ordering Provider Consent Certification: Given the complexity of the Testing and the nature of the potential results, RCIGM strongly recommends the Ordering Provider ensure genetic counseling by a trained medical geneticist or genetic counselor is offered concurrent with the informed consent process, as well as after the Test is ordered and results are received. This Test Description is intended to be used as a resource for the consent process, in the Ordering Provider's professional judgment and discretion. The information in the Test Requisition Form is provided as guidance only, to facilitate informed consent and genetic counseling procedures. See www.nsgc.org to locate a genetic counselor in your area.

Ultra-Rapid WGS (URWGS): *If a provider has questions about ordering Ultra-rapid Whole Genome Sequencing for the purpose of urgent medical management, please call (858) 966-8127.*

rWGS Background and Methodology: Sequence via next generation sequencing (NGS) technology is generated from genomic DNA. PCR-free library preparation is performed prior to whole genome sequencing (WGS). An average genomic coverage of at least 35x is obtained for each proband genome. Alignment and variant calling are performed using the Edico DRAGEN pipeline using the official reference build 37.1. Copy number variation (CNV) calling is performed using a combination of CNV callers. Interpretation of CNVs is focused on variants that overlap or have a boundary that lies within 1 kb of an exon in one of approximately 8000 genes known to have a gene-disease association. The current version of this test assesses single nucleotide variants (SNVs), small deletions and insertions, and larger deletions and duplications. This test is validated for copy number analysis of exons 7 and 8 of the SMN1 and SMN2 genes. Single nucleotide variants in the mitochondrial genome down to 1% heteroplasmy can be detected. RCIGM is also validated to detect large deletions and duplications in the mitochondrial DNA. Likely pathogenic and pathogenic reported variants may be confirmed using orthogonal technologies in instances where the variant does not meet internal RCIGM quality control thresholds.

Rapid Whole Genome Sequencing (rWGS): RCIGM has pioneered an integrated rapid Whole Genome Sequencing process to deliver high quality clinical results posthaste. Our optimized process enables us to deliver a preliminary diagnosis in under a week and final clinical reports within 7-14 days, compared to the typical 6 weeks. RCIGM offers multiple testing options. For all rWGS order types, it is recommended that samples from biological parents be sent in addition to the patient's sample, when available. If Patient Only WGS is selected, patient's sample will undergo whole genome sequencing and biological parent samples will be used for phasing and confirmation of compelling variants. If Duo, Trio or Additional Family Member WGS is selected, patient and familial samples will undergo concurrent whole genome sequencing.

Standard Whole Genome Sequencing: Samples will be processed in the order they are received (non-rapid) and a final clinical report will be issued ≤ 30 days. If diagnostic information is available that will immediately impact medical management of the patient, a preliminary report will be issued immediately when available.

DNA Isolation and Hold: Order extraction of DNA from Specimens for possible add-on testing. Genomic DNA will be frozen and stored according to RCIGM retention policies.

Why Parental Samples Are Needed: In order to interpret results, other family members may also need to have the testing or to have targeted testing depending on who in the family is affected and is available for testing. Parents are often the most informative family members to test for interpreting patient results; therefore, parental samples are often sent along with the patient's sample for testing.

How RCIGM Performs Testing: WGS sequencing requires ≥ 0.5ml (cc) of blood, which has risks associated with obtaining the sample, such as bruising and bleeding from a blood draw. DNA will be extracted from the blood sample and sequencing of the genome will be performed using next generation sequencing (NGS) technology. A list of sequence variants that potentially could be important to the patient's condition will be generated. NGS has a small false positive rate, therefore some variants may need to be confirmed by a second detection method, such as Sanger sequencing or MLPA (Multiplex Ligation-dependent Probe Amplification).

Test Limitations: A fraction of the genome cannot be sequenced with accuracy sufficient to determine if a pathogenic variant is present. Therefore, pathogenic variants in these regions will not be detected by this analysis. Results from the testing may indicate that additional testing, such as full gene sequencing to fill-in exons with poor coverage or deletion/duplication analysis, is recommended. Not all large deletions and duplications are evaluated in the testing. Genetic changes identified may not necessarily predict the prognosis or severity of disease and it is possible that the genetic change may not affect management or treatment. Full coverage of the genome is not currently possible due to technically challenging repetitive elements and duplicated regions within the genome. Thus, not all regions of the genome are sequenced and/or uniquely aligned to the reference genome. Certain genomic alterations may not be detected with the current version of this test. For example, genomic alterations such as trinucleotide repeat expansions and translocations will not be identified with the current version of the test. This test is set up to evaluate the potential contribution of rare disease causing variants in known disease genes. It is not designed to evaluate for common variants in genes that might contribute to disease risk nor for disorders that have a multi-genic inheritance. Based on current knowledge, potential disease causing variants may not always be recognized at the time of testing.

What RCIGM Reports: Diagnostic findings related to phenotype - pathogenic variant(s), likely pathogenic variants(s), variant(s) of uncertain significance – suspicious, in genes interpreted to be responsible for, or contributing to, the patient's phenotype will be reported. RCIGM will report Incidental findings for patients and tested family members who opt-in to receive them. Incidental findings include pathogenic variants in genes that do not appear to be related to patient's phenotype, but are considered medically-actionable. If a patient or tested family member opts-out to receive incidental findings or does not specify a preference, these findings will not be reported.

Test Change or Cancellations: If you wish to change or cancel a test or have any questions, you may contact the laboratory via email at RCIGM_rWGS@rchsd.org and by phone at (858) 966-8127.

Testing Fees: For pricing, please email RCIGM at RCIGM_rWGS@rchsd.org or call us at (858) 966-8127.

State Licensure Notice: RCIGM is not currently licensed to perform genetic testing for samples originating in New York unless New York Exemption Form has been completed and sent to NYS Department of Health to obtain case-by-case permission before shipping specimen to RCIGM.



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DOB (MM/DD/YYYY)

Patient ID/MRN

Shipping and Specimen Requirements

Shipping Address:

Attn: Clinical Genome Center
Rady Children's Institute for Genomic Medicine
7910 Frost St, Suite 240
San Diego, CA 92123

Specimen Requirements:

Whole Blood (EDTA): Minimum requirement is one tube of ≥ 0.5 mL (cc) whole blood in an Ethylenediaminetetraacetic acid (EDTA) tube. Two tubes are strongly preferred to allow for identity confirmation check. One tube will be used for Whole Genome Sequencing and one for an orthogonal specimen identity check to ensure accuracy in sample collection and processing.

Extracted DNA: DNA extracted from whole blood in a CLIA lab, collected in an EDTA tube may be sent instead of whole blood. Minimum DNA yield of 2 µg and a 20 ng/µL concentration is required.

DNA Isolation and Storage: Minimum requirement is one tube of ≥ 0.3 mL (cc) peripheral blood in an Ethylenediaminetetraacetic acid (EDTA) tube.

Saliva: Saliva may be sent for confirmatory testing only and must be collected using an Oragene DX OGD-500 collection kit. RCIGM is not validated to perform testing on saliva collected using other collection kits. Contact RCIGM Clinical Genome Center for additional ordering information and to request a kit. Donor must not eat, drink, smoke or chew gum for 30 minutes prior to collection. Collection instructions must be followed: https://www.dnagenotek.com/US/support/collection-instructions/oragene-dx/OGD-500andOGD-600.html

In the event that the Clinical Genome Center does not receive sufficient sample material to complete the testing, the ordering party will be notified to provide an additional sample.

Labeling Requirements: Label sample tubes with at least two identifiers. Patient's full name and date of birth, preferred. We strongly recommend including the medical record number and/or specimen ID number also.

Shipping Conditions: Do not freeze. Refrigerate until time of shipment at 2-8°C. Whole blood may refrigerated up to five days before shipping. Ship overnight delivery with a cold pack. Do not place cold pack in direct contact with sample. Shipping overnight at room temperature is acceptable if cold pack is not available.

Result Delivery: Results are typically delivered within 7 to 14 days for rWGS, or ≤ 30 days for standard WGS. Urgent, clinically actionable results will be communicated by phone, followed by electronic notification. If clarification of the test order or an additional specimen are needed, the ordering provider will be contacted. Please provide phone and email for communication (page 1).



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_____,
Patient Last Name, First Name
_____,
DOB (MM/DD/YYYY)
_____,
Patient ID/MRN

REFERENCE LABORATORY TERMS AND CONDITIONS

In consideration of the terms, conditions, and mutual covenants set forth herein, and intending to be legally bound hereby, the health care provider placing an order for clinical reference laboratory testing ("Ordering Provider") and Rady Children's Institute for Genomic Medicine ("RCIGM") agree as follows:

- 1. RCIGM operates a Clinical Genome Center with unusual clinical capabilities including but not limited to whole genome sequencing and bioinformatics analysis services of a nature and quality not generally available from commercial sources.
2. Until such time that a Laboratory Services Agreement is entered into between Ordering Provider's Organization and RCIGM these Terms and Conditions, and the applicable test requisition form, shall together constitute the complete and exclusive statement of the agreement between Ordering Provider and RCIGM with respect to the Services ("Agreement").
3. Upon RCIGM's receipt of a completed test requisition form ("Order"), any related information, and specimens in the required format ("Specimens"), RCIGM shall provide testing and results reporting to Ordering Provider in accordance with RCIGM's established procedures ("Services").
4. Upon delivery of results to Ordering Provider, RCIGM shall submit an invoice to Ordering Provider pursuant to the rates established by RCIGM and agreed upon by Ordering Provider's authorized representative ("Fees").
5. The Agreement shall commence on the date the Order is received by RCIGM ("Effective Date") and continue in full force for a two (2) year ("Term"), unless earlier terminated.
6. To the extent applicable, in the performance of the Agreement the parties shall abide by all state and federal laws and regulations governing the confidentiality, privacy, and security of medical information and/or personally identifiable information ("Patient Information").



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- 7. Ordering Provider shall indemnify, defend and hold harmless RCIGM, its affiliates, subsidiaries, parent company, directors, officers, employees, professional staff, and agents, against any loss, cost, damage, award, liability, claim, counterclaim, judgment or expense of every kind including injury to person or property (including reasonable attorneys' and other consultancy fees and court costs) arising out of Ordering Provider's obligations under the Agreement, the negligent use of the Services including test results provided by RCIGM, and Ordering Provider's gross negligence or willful misconduct.
8. RCIGM may use test results and any patient information disclosed hereunder for any purposes as permitted by applicable law, including without limitation, quality monitoring. Neither party shall, without the other party's written consent, advertise, publish or release any statement mentioning the other party with respect to the Agreement or the existence of the Agreement.
9. Neither party will hire, arrange for or contract with any individual or entity that is suspended, excluded, or otherwise debarred from participation in a state or federal health care program, or a program that receives federal funding for the provision of items or services for which payment may be made by a federal or state health care program.
10. Without the prior written consent of the other party, neither party may assign, transfer, or delegate its rights, duties or obligations hereunder, except to (i) a successor by merger or sale of substantially all of its business to which the Agreement relates, or (ii) an affiliate or subsidiary, under common ownership and control with the assigning party.
11. To the extent the Agreement is subject to Section 1861(v)(I)(91) of the Social Security Act, RCIGM agrees to make available upon written request of the Secretary of Health and Human Services or the United States Comptroller General or their duly authorized representatives, the Agreement, and any books, documents and records of RCIGM that are necessary to certify the nature and extent of costs incurred by Ordering Provider hereunder until the expiration of four (4) years after the last date of Services performed under the Agreement.
12. TO THE MAXIMUM EXTENT ALLOWED BY LAW, RCIGM DISCLAIMS ALL WARRANTIES AND REPRESENTATIONS OF ANY KIND, WHETHER EXPRESS OR IMPLIED, RELATING TO THE SERVICES, WITH RESPECT TO ANY TEST RESULT, THE TESTING OF ANY SPECIMEN, OR THE USE BY ORDERING PROVIDER OF ANY TEST RESULTS PROVIDED UNDER THE AGREEMENT.