RCIGM-CGC Whole Genome Sequencing

Rady Children's Institute
Genomic Medicine

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 her

Place ordering provider label with patient identifier her

RCIGM-CGC Test Requisition Form

Patient Information

Last Name First Name

Middle Name Alias Name (optional)

Patient ID/MRN

DOB (MM/DD/YYYY)

Sex: ☐ Female ☐ Male ☐ Ambiguous

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 Sampl 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

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 medica 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

CGC Accessioning Label

CGC Accessioning Label

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_____,
Patient Last Name, First Name

DOB (MM/DD/YYYY)

Patient ID/MRN

Clinical Information

Clinical Diagnosis/Reason for Testing

ICD-10 Codes

REQUIRED: Enter additional relevent 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.

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_____,
Patient Last Name, First Name

_____
DOB (MM/DD/YYYY)

_____
Patient ID/MRN

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 re uisition 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)

_____ Sex: ☐ Female ☐ Male ☐ Ambiguous
MRN

☐ Clinically Unaffected
☐ Clinically Affected
_____
Briefly list phenotyp

_____ _____ ☐ AM ☐ PM
Date Collected (MM/DD/YYYY) Time Collected

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

_____
CLIA Laboratory Name

Additional Family Member 2

First Name Last Name DOB (MM/DD/YYYY) Relationship to Patient (e.g. mother)

_____ Sex: ☐ Female ☐ Male ☐ Ambiguous
MRN

☐ Clinically Unaffected
☐ Clinically Affected
_____
Briefly list phenotyp

_____ _____ ☐ AM ☐ PM
Date Collected (MM/DD/YYYY) Time Collected

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

_____
CLIA Laboratory Name

Additional Family Member 3

First Name Last Name DOB (MM/DD/YYYY) Relationship to Patient (e.g. mother)

_____ Sex: ☐ Female ☐ Male ☐ Ambiguous
MRN

☐ Clinically Unaffected
☐ Clinically Affected
_____
Briefly list phenotyp

_____ _____ ☐ AM ☐ PM
Date Collected (MM/DD/YYYY) Time Collected

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

_____
CLIA Laboratory Name

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_____,
Patient Last Name, First Name

_____
DOB (MM/DD/YYYY)

_____
Patient ID/MRN

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, or as otherwise permitted by HIPAA, to external clinical laboratories, providers, and specialists for consultation on complex, rare, and difficult cases and/or to resolve any analytical discrepancies that occur during testing at the discretion of RCIGM. Additional Use of De-identified Information and Samples for the purposes of research, development, and analysis may improve identification and development of 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 that no tests other than those authorized shall be performed on the biological sample and RCIGM is required to destroy samples no more than sixty (60) days after sample collection or at the end of the testing process. If Opt-In is selected for Additional Use, De-Identified samples may be stored and used longer than 60 days.

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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_____,
Patient Last Name, First Name

_____
DOB (MM/DD/YYYY)

_____
Patient ID/MRN

Financial Responsibility and Payment Information

Please provide account and billing contact information below.

Institution	Federal Tax Identification Number (if applicable
Contact Name	Email
Billing Address	
City / State / ZIP	
Phone	Fax

Please provide insurance information below.
Please note that RCIGM can currently only bill institutionally. Please call (858) 966-8127 with any questions.

Insurance Provider

- ☐ Medicaid/MediCal
- ☐ Commercial
- ☐ Tricare
- ☐ Other: _____

If none of the above options apply (e.g., patient is uninsured or using self-pay), please state the reason.

_____
Name of Insurance Carrier

_____
Insurance ID

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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_____,
Patient Last Name, First Name

_____
DOB (MM/DD/YYYY)

_____
Patient ID/MRN

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. A positive result is an indication that the individual may be predisposed to or have the specific disease or condition tested for and may want to consider further independent testing, consult their physician or pursue genetic counseling. 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 Amplificaion).

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 be 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.

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_____,_____
Patient Last Name, First Name

_____
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 chec . 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 b 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 day 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 a 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"). Once a Laboratory Services Agreement is entered into those terms will control but the test requisition form will still be required as part of the intake process due to the necessary patient –specific information and consents it provides. Ordering Provider's placement of an Order constitutes acceptance of the Agreement. The Agreement may only be modified pursuant to written agreement by authorized representatives of RCIGM and Ordering Provider. To the extent that Ordering Provider's purchase order or other document provided by Ordering Provider to RCIGM, if any, conflicts with the Agreement, the Agreement shall control and such different, additional, or conflicting terms are hereby rejected. Ordering Provider waives the right to assert that matters of contract interpretation should be construed against the drafter.

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"). The Services include return of results and reporting as specified in the applicable Order. RCIGM will maintain and make available such records and specimens related to the Services in conformity with applicable laws and regulations. Services shall be furnished at a CLIA licensed and CAP accredited laboratory owned and operated by RCIGM, and in accordance with applicable state and federal law and regulations, and RCIGM's policies and procedures. RCIGM makes no representation that its Services procedures and methods satisfy any FDA, HHS, international, or state law requirements for device studies, trials, or human subjects' research. Ordering Provider acknowledges that not all specimens may be of adequate quantity or quality to be successfully tested. If RCIGM determines a specimen does not meet the quality criteria established by RCIGM for the particular test, RCIGM will notify Ordering Provider. Ordering Provider will have the option to replace the specimen or proceed with the testing of such specimen. If Ordering Provider elects to proceed with the testing Ordering Provider is responsible for the full test fee, even if the testing of the specimen does not generate successful results.

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"). No later than thirty (30) days following invoice receipt, Ordering Provider shall reimburse RCIGM via payment method specified in the Order. Additional, subsequent, or follow-up testing performed at Ordering Provider's request, other than as may be specified by the Order, will incur additional fees to be agreed upon by RCIGM and the Ordering Provider. RCIGM reserves the right to refuse to provide Services to Ordering Provider if payment on any invoice is more than sixty (60) days overdue. Ordering Provider and RCIGM agree the Fees represent fair market value for the Services, have been negotiated in an arms' length transaction, and have not been determined in any manner with regard to the volume or value of any potential business or referrals generated between them.

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. Either party may terminate the Agreement early by providing sixty (60) days written notice of termination to the other party. Upon termination by Ordering Provider for any reason, RCIGM shall cease further processing of any specimens; provided that, Ordering Provider shall continue to be responsible for paying test Fees for completed Services. Upon termination by RCIGM for any reason, RCIGM shall complete processing of any Services requested prior to the effective date of such termination, unless RCIGM terminated the Agreement due to Ordering Provider's failure to timely pay invoices when due. If a Laboratory Services Agreement (LSA) is subsequently entered into between Ordering Provider's Organization and RCIGM the LSA (together with the test requisition form) shall apply with respect to any Orders submitted after the effective date of the LSA while these Terms and Conditions (together with the test requisition form) shall continue to apply to any Orders submitted prior to the effective date of the LSA.

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"). RCIGM agrees to employ physical, technical, and administrative controls consistent with HIPAA standards to ensure the confidentiality, integrity, and privacy of Patient Information. In addition, each party shall treat as confidential all non-public information not already in its possession and disclosed by the other party in connection with the Agreement ("Confidential Information"), and shall only disclose such Confidential Information (i) to those individuals who need to use it in performance of the Agreement, (ii) as authorized by the disclosing party, or (iii) as required by law. This obligation regarding Confidential Information shall survive for a period of five (5) years following termination of the Agreement. Either party may request return or destruction of Confidential Information at any time, in its discretion and at its sole expense.

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_____,
Patient Last Name, First Name

_____
DOB (MM/DD/YYYY)

_____
Patient ID/MRN

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. Ordering Provider hereby expressly consents to allow RCIGM to identify Ordering Provider as a clinical reference laboratory services customer. Ordering Provider acknowledges that Rady Children's has a Corporate Compliance Program which includes, but is not limited to, policies pertaining to Section 6032 of the Deficit Reduction Act of 2005 (available electronically at http://www.rchsd.org/deficit-reduction-act-dra-notice/). If Ordering Provider becomes aware of any fraud or abuse in the use of public funds, Ordering Provider will make reasonable efforts to report such abuse accordingly.

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. Each party shall comply with the provisions of Title VII of the Civil Rights Act of 1964 (42 U.S.C. § 2000 a amended by the Equal Opportunity Act of March 24, 1972, Public Law No. 92-261), Title I and Title V of the Americans with Disabilities Act of 1990 ("ADA") (42 U.S.C. § 12101 as amended by the ADA Amendments Act of 2008, Public Law No. 110-325), the Vietnam Era Veterans' Readjustment Assistance Act of 1974 ("VEVRAA") (38 U.S.C. § 4212 as amended by the Jobs for Veterans Act of 2002, Public Law No. 107-288) and as applicable the California Fair Employment and Housing Act (Cal. Gov. Code § 12900) in that neither party shall discriminate against any individual with respect to his or her compensation, terms, conditions, or privileges of employment; or discriminate in any way that would deprive or intend to deprive any individual of employment opportunities or otherwise adversely affect his or her status as an employee because of such individual's race, color, religion, sex, national origin, age, disability, protected veteran status, medical condition, or marital status. Each party shall ensure that services and benefits are provided without regard to race, color, religion, sex, age, or national origin in accordance with Title VII of the Civil Rights Act of 1964. Each party shall comply with Section 504 of the Rehabilitation Act of 1973, as amended (29 U.S.C. § 794), pertaining to the prohibition of discrimination against qualified disabled persons. Required contract laws relative to Equal Employment Opportunity/Affirmative Action are incorporated herein by specific reference to Executive Order 11246, as amended; 41 C.F.R. § 60-1.4 (Equal Opportunity Clause); 41 C.F.R. §§ 60-300.4, 60-300.5 (Protected Veterans"); and 41 C.F.R. §§ 60-741.4, 60-741.5 (Disabled Workers). To the extent applicable, each party also agrees to comply with 29 C.F.R. Part 470 (Notice of Employee Rights Concerning Payment of Union Dues).

10. Without the prior written consent of the other party, neither party may assign or transfer 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. Additionally, RCIGM may engage subcontractors hereunder as necessary while assuming full responsibility for them and their compliance with the terms of this Agreement. Any attempted assignment, transfer or delegation in violation of this provision shall be void and of no effect. Ordering Provider and RCIGM are independent contractors. Neither party shall have the power or authority to bind, nor to obligate the other party, except as may be expressly set forth in the Agreement. The failure of a party to insist upon strict adherence to any term hereof on any occasion shall not be considered a waiver or deprive that party of the right thereafter to that term or any other term hereof. If any of the terms hereof shall be held unenforceable, the remainder of the terms hereof shall nevertheless remain in full force and effect. All notices required or permitted hereunder shall be deemed given when delivered by hand, mailed, first class postage prepaid, to either party at its address appearing on the Order or to such other address as said party may have designated in writing. RCIGM shall not be liable for costs incurred by Ordering Provider if RCIGM's failure to perform hereunder arises out of causes beyond the control and without the fault or negligence of RCIGM, including but not limited to acts of God, acts of Ordering Provider, acts of government, fires, floods, epidemics, strikes, or freight embargoes. The Agreement shall not be construed as creating any rights or benefits in any third party, including Ordering Provider's patients. Paragraphs 2, 4, 6, 7, 8, 11, and 12 shall survive termination of the Agreement.

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. RCIGM agrees that if it carries out any obligations hereunder through a contract with a value of $10,000 or more over a twelve (12) month period, such contract will require the same access to records as stated herein.

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. ORDERING PROVIDER AGREES THAT RCIGM SHALL NOT BE LIABLE FOR ANY DAMAGES, LIABILITIES, OR COST, OF ANY KIND THAT MAY ARISE FROM OR IN CONNECTION WITH ORDERING PROVIDER'S USE OF TEST RESULTS. RCIGM, AND ITS AFFILIATES, OFFICERS, DIRECTORS, EMPLOYEES, AGENTS AND LICENSORS, SHALL NOT BE LIABLE FOR ANY INDIRECT, INCIDENTAL, SPECIAL, CONSEQUENTIAL, PUNITIVE OR EXEMPLARY DAMAGES, WHETHER IN CONTRACT, WARRANTY, TORT, STRICT LIABILITY, OR OTHERWISE, ARISING OUT OF OR IN CONNECTION WITH ORDERING PROVIDER'S USE OF THE SERVICES OR RESULTS, EVEN IF RCIGM HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. IN NO EVENT, EXCEPT WHERE PROHIBITED BY LAW, WILL ETHER PARTY'S LIABILITY HEREUNDER EXCEED THE TOTAL AMOUNT OF FEES PAID TO RCIGM BY ORDERING PROVIDER.