PREVENTION GENETICS

Rhythm PHARMACEUTICALS

For questions related to the Uncovering Rare Obesity Program, Sponsored by Rhythm Pharmaceuticals, call PreventionGenetics at (844) 513-3994

☐ Please ship one Buccal OCD-100 Kit to patient's home address.

PREVENTIONGENETICS USE ONLY

**THIS FORM MUST ACCOMPANY ALL SPECIMENS**

# UNCOVERING RARE OBESITY GENE PANEL

## TEST REQUISITION FORM - SP068

| PERSON COMPLETING FORM | PHONE AND EMAIL | DATE OF REQUEST |
|---|---|---|
| | | ____/____/____ MONTH DAY YEAR |

## PATIENT INFORMATION

| LAST (FAMILY) NAME | FIRST NAME | MI | DATE OF BIRTH |
|---|---|---|---|
| | | | ____/____/____ MONTH DAY YEAR |

| STREET ADDRESS *(MUST BE US, US TERRITORIES OR CANADIAN ADDRESS)* | CITY | GEOANCESTRY / ETHNICITY |
|---|---|---|
| | | ☐ Hispanic or Latino |
| STATE / PROVINCE: | ZIP / POSTAL CODE: | ☐ White |
| | COUNTRY CODE (US / US TERRITORY, CANADA): | ☐ Black or African American |
| EMAIL (PATIENT OR PARENT / GUARDIAN): | PATIENT ID CODE (i.e. EMR #): | ☐ East Asian |
| FOR MINORS - LIST PARENT OR GUARDIAN NAME AND RELATIONSHIP: | BIOLOGICAL SEX: ☐ Male ☐ Female ☐ Other _____ | ☐ South Asian |
| | | ☐ First Nations |
| | | ☐ Native Hawaiian or Other Pacific Islander |
| | | ☐ Other: _____ |

| SPECIMEN SOURCE | SPECIMEN COLLECTION DATE | BLOOD TRANSFUSION | BONE MARROW TRANSPLANT |
|---|---|---|---|
| ☐ Whole Blood<br>☐ Buccal (OCD-100) Swab<br>☐ DNA at Laboratory | *If no collection date is provided, date of receipt will be used.*<br>____/____/____ MONTH DAY YEAR | ☐ NO<br>☐ Within Last 30 Days, Date and Type<br>____/____/____ MONTH DAY YEAR<br>TYPE _____ | ☐ NO<br>☐ Within Last 30 Days, Date and Type<br>____/____/____ MONTH DAY YEAR<br>TYPE _____ |

## TEST SELECTION

| TEST CODE | TEST NAME | DESCRIPTION | SPECIAL INSTRUCTIONS |
|---|---|---|---|
| ☑ 15187 | Uncovering Rare Obesity Gene Panel | Gene variants that may cause rare genetic diseases of obesity. | **SP068** |

## PROGRAM ELIGIBILITY AND PROVIDER AUTHORIZATION

### FOR NEW PATIENTS

☐ **Age of ≥19 years of age, BMI ≥40, and a history of childhood obesity.**
**BMI:** _____ **Age of onset:**_____ (if unknown, request exception below)

☐ **Age of ≤18 years of age, BMI ≥97th percentile.**
**BMI:** _____ **Age of onset:**_____

☐ **Clinical or suspected diagnosis of Bardet Biedl Syndrome (BBS)**

☐ **Exception Requested.** In rare situations, patients present with compelling reasons for testing but do not meet above criteria. All exception requests are subject to sponsor approval. We will notify you if the exception is not approved.
**BMI:** _____ **Age of onset:**_____ (if unknown, leave blank)
**Explain clinical presentation and reason for requesting exception**

_____

_____

**OR**

### FOR FAMILY MEMBERS OF SELECT PATIENTS PREVIOUSLY TESTED

Test eligibility for first degree relatives will be indicated in the notes section of the proband report. If eligible, a full gene panel analysis will be performed.
**Call PreventionGenetics at (844) 513-3994 to confirm eligibility prior to test submission.**

**Proband PGID #** ☐☐☐☐-☐☐☐☐-☐☐☐

**Proband Name** _____

**Relationship to Affected Patient (Proband)**
☐ Mother ☐ Father ☐ Sibling

**BMI of Family Member:** _____

**Childhood Obesity of Family Member**
☐ No ☐ Yes, Age of onset:_____ ☐ Unknown

I understand that it is my responsibility to ensure that the patient has been adequately informed and provided all necessary consents for collecting the specimen sample, genetic testing, and disclosing genetic information in accordance with applicable laws. By ordering this test, I acknowledge that I am authorized under applicable law to order this test and that the patient has been supplied information regarding the purpose, capabilities, and limitations of the genetic test and voluntarily consented to undergo genetic testing.

I hereby attest the patient meets the criteria for and is a candidate for the Uncovering Rare Obesity Program, sponsored by Rhythm Pharmaceuticals, Inc. ("Rhythm"). I understand the diagnostic testing services offered under this program are directional in nature and they do not eliminate the need for additional medical management or replace any existing diagnostic methods. I further understand neither Rhythm nor PreventionGenetics, LLC ("PG") makes any claims as to the usefulness of this test.

I certify I am a licensed healthcare provider currently authorized under applicable law to practice medicine. I have explained the purpose of the requested testing and potential results, and have provided appropriate genetic counseling to my patient.

As the ordering licensed healthcare provider, I hereby authorize PG to share my name, institution, address, and contact information with Rhythm, and I consent to Rhythm contacting me about the Uncovering Rare Obesity Program and other programs sponsored by Rhythm.

I understand the Uncovering Rare Obesity Program covers only the cost of the genetic test but does not cover the cost of any ancillary services, including but not limited to office visits. I also understand and agree that I may not bill, charge, seek credit, payment, or reimbursement for the genetic testing from my patient or another third-party payer.

HEALTHCARE PROVIDER SIGNATURE _____ PRINTED NAME _____ SPECIALITY _____ DATE _____

CONTINUE TO PAGE 2

3800 South Business Park Avenue, Marshfield, Wisconsin 54449 USA • www.PreventionGenetics.com
Phone: (715) 387-0484 • General Fax: (715) 384-3661 • Billing Fax: (715) 207-6602 • Email: support@preventiongenetics.com
CLIA 52D2065132 • CAP 7185561 • NPI 1114140571 • ISO 15189:2012 #3950.01

PREVENTION GENETICS

Rhythm PHARMACEUTICALS

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**THIS FORM MUST ACCOMPANY ALL SPECIMENS**

## CLINICAL INFORMATION

***• • SHADED AREAS MUST BE COMPLETED TO BE ELIGIBLE • •***

Height _____ft. _____in. Weight _____lbs. _____ oz.

Childhood obesity? ☐ NO ☐ YES ☐ Unknown

Hyperphagia? ☐ NO ☐ YES Age of onset: _____ ☐ Unknown

Clinical or suspected diagnosis of Bardet Biedl Syndrome (BBS)? ☐ NO ☐ YES ☐ Unknown

Failure to thrive before the age of 2? ☐ NO ☐ YES ☐ Unknown

History of thyroid conditions? ☐ NO ☐ YES ☐ Unknown

History of prior anti-obesity medications? ☐ NO ☐ YES ☐ Unknown

Family history of obesity? ☐ Father ☐ Mother ☐ Sibling(s) ☐ Unknown

Bariatric surgery: ☐ NO ☐ YES, Bariatric surgery failure: ☐ NO ☐ YES ☐ Unknown

Family history of genetic disease and/or earlier testing ☐ NO ☐ YES ☐ Unknown

Results_____

_____

## PROVIDER INFORMATION

***Our preferred method of report transmission is uploading to our secure web portal, myPrevent.***
***Please provide an email address, when possible. If you have additional specific reporting requests, indicate them below.***

INSTITUTION

ADDRESS (Street, City, State / Province, Country and Zip / Postal Code) *(MUST BE A US, US TERRITORY OR CANADIAN ADDRESS)*

| REQUESTING PHYSICIAN OR PROVIDER (First, Last, Credentials) | SPECIALITY |
|---|---|
| | |

| PHONE NUMBER | NPI# | EMAIL ADDRESS (FOR REPORT ACCESS) |
|---|---|---|
| | | |

IF YOU REQUIRE REPORTS TO BE TRANSMITTED ANOTHER WAY, SPECIFY INSTRUCTIONS HERE.

LIST ADDITIONAL EMAILS TO HAVE ACCESS TO REPORTS

## SPECIMEN REQUIREMENTS

**WHOLE BLOOD**
Collect 3 ml - 5 ml of whole blood in EDTA (purple top tube) or ACD (yellow top tube), minimum 1 ml for small infants.

**OCD-100 BUCCAL SWAB**
OCD-100 Buccal Swab used according to manufacturer instructions.

## SHIPPING AND HANDLING INSTRUCTIONS

**Label all specimen containers with the patient's name, date of birth and/or ID number. At least two identifiers should be listed on specimen containers.** We accept specimen deliveries Monday-Saturday. Holiday schedules will be posted on our website at least one week prior to major holidays.

**BLOOD**
At room temperature or refrigerated, a blood specimen is stable for up to 8 days. Include a refrigerated gel pack in the shipping container.

Fresh blood specimens are preferred. If frozen, a blood specimen is stable for up to 1 month before shipping. Frozen blood specimens should be shipped frozen (preferably on dry ice) overnight.

**BUCCAL**
At room temperature, an OCD-100 buccal specimen is stable for up to 80 days. Specimens may be shipped at room temperature.

**DNA GENOTYPING PANEL**
For quality control purposes, the PreventionGenetics DNA Genotyping Panel is performed on all clinical specimens. Genotyping results are not included in test reports.

**CONTACT US**
For additional questions or concerns, contact a Client Service Representative at (844) 513-3994, or email: support@preventiongenetics.com.

**Comment SP068**

**ADDRESS**
PreventionGenetics - Diagnostic Lab
3800 S. Business Park Ave.
Marshfield, Wisconsin 54449
USA

UNCOVERING RARE OBESITY®

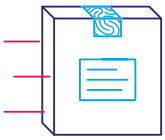
# Consent form instructions

PREVENTION GENETICS

## COMPLETE YOUR CONSENT FORMS IN 3 EASY STEPS

1 | Review the forms on pages 2-4.

2 | Complete, sign, and date the form on pages 2-3. You may also choose to complete, sign, and date the form on page 4.



3 | Include your completed forms in the box with your genetic test sample.

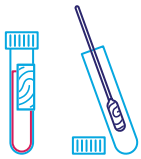
## RHYTHM IS COMMITTED TO ADVANCING THE UNDERSTANDING OF RARE GENETIC DISEASES OF OBESITY

At Rhythm, we believe it's important to:

- Ask for your consent to collect or share your information
- Give you the choice to decide whether your identifiable information may be shared with us

**Your consent is requested in two areas.**

The first form gives your permission to conduct the test and is required for participation in the program. The second form is optional and allows the lab to share your identifiable information with Rhythm to help determine your eligibility for research studies. It also enables Rhythm to contact you about potential research opportunities.



### 1 | Consent for genetic testing and participation

With this required consent, you give your permission for an independent certified laboratory, PreventionGenetics, to analyze your (or your child's) genetic information through the test sample provided. The lab may remove your personally identifying information in a process called "de-identification" and share your results with Rhythm Pharmaceuticals for the purposes of carrying out the program and advancing research efforts.

### 2 | Authorization to use and disclose identifiable information

With this optional authorization, you allow the laboratory to share your Identifiable Health Information with Rhythm Pharmaceuticals so that Rhythm may help determine your eligibility for trials and contact you about clinical research and other potential research opportunities.

UNCOVERING RARE OBESITY®

# Consent for genetic testing and participation in sponsored testing program

PREVENTION GENETICS

Rhythm Pharmaceuticals, Inc. ("Rhythm") is providing the Uncovering Rare Obesity Gene Panel ( "the Genetic Test") under a sponsored genetic testing program ("the Program") to healthcare providers and their patients to help identify rare genetic diseases of obesity. Rare genetic diseases of obesity are associated with early-onset, severe obesity that may be accompanied by insatiable hunger. The Genetic Test will be performed by PreventionGenetics, LLC ("PG") in a CLIA-accredited clinical DNA testing laboratory. Under the Program, the Genetic Test will be provided at no charge to patients, excluding the cost of office visits, sample collection, and any other related costs, which shall be the patient's responsibility.

I/MY CHILD, _____ , agree to participate in the Program and request and permit PG to analyze MY/MY CHILD'S genetic information in the buccal or blood sample provided to PG in connection with the Program as described in this Consent Form.

## I UNDERSTAND AND AGREE THAT:

1 | The purpose of the Genetic Test, which will be conducted by PG and is sponsored by Rhythm, is to identify gene variants that may cause or predispose an individual to rare genetic diseases of obesity. This test analyzes the sequence of specific genes for variants that may cause or predispose an individual to rare genetic diseases of obesity. No other tests other than those authorized in this Consent Form shall be performed on the blood, saliva, or buccal samples provided.

2 | My/my child's healthcare provider has advised me that he/she would like to order the Genetic Test and has confirmed that I/my child meets one of the eligibility criteria below:

- Age of ≥19 years of age, BMI ≥40, and a history of childhood obesity
- Age of ≤18 years of age, BMI ≥97th percentile
- Family testing for previously reported Uncovering Rare Obesity Gene Panel positive findings
- Suspected or clinical diagnosis of Bardet-Biedl syndrome
- Other clinical justification to support exemption from eligibility criteria; approved by Rhythm

3 | The Genetic Test provided under the Program requires that I/my child provide a blood, saliva, or buccal specimen for testing, which will be conducted by PG. My healthcare provider has explained the risks associated with a blood draw (if applicable), and I consent to the specimen being collected and shared with, and analyzed by, PG.

4 | My healthcare provider has also discussed the following with me:

- The Genetic Test will include gene variants that may cause or predispose an individual to certain rare genetic diseases of obesity
- The limitations of genetic testing; some genetic test results may not necessarily be conclusive for purposes of establishing a diagnosis of a rare genetic disease of obesity in all individuals
- The meaning of a negative genetic test result (where nothing is reported back to me from the test) and what the negative result may mean for me/my child, along with the limitations of negative results
- The meaning of a positive result; as the Genetic Test looks for a variant associated with a rare genetic disease of obesity, the likelihood of a positive result in any individual patient may be low. I may consult with my healthcare provider or ask to be referred to a geneticist, genetic counselor, or other qualified healthcare provider to discuss any additional testing or counseling that may be helpful. I understand that I would be responsible for the costs associated with such counseling, except where I use the no-charge genetic counseling offered under the Program
- Learning about test results may be stressful and upsetting for me and my family
- It is my responsibility to consider the possible impact of my/my child's test results as they relate to insurance rates, obtaining disability or life insurance, and employment. I may consult with other professionals or genetic counselors who are experts in this area to counsel me

*(continued on next page)*

# Consent for genetic testing and participation in sponsored testing program (continued)

- Errors or incorrect results may occur; however, control measures are in place to limit them to the extent possible. Sources of error may include, but are not limited to: specimen contamination, technical laboratory mistakes, presence of DNA variants that compromise data analysis, inconsistent scientific classification systems, and inaccurate reporting of family relationships or clinical diagnosis information
- Reports are current as of the date provided. However, as genetic knowledge and understanding increases and evolves, it is possible that the clinical significance of the genetic variant(s) identified in my/my child's sample will change over time, at PG's and Rhythm's sole discretion. To the extent such additional interpretive information is provided, I should discuss with my/my child's healthcare provider

5 | The results of the Genetic Test in the form of a clinical report will be released to the healthcare provider(s) listed on the test requisition form. My/my child's healthcare provider may communicate with me about possible eligibility for future clinical trials or other research opportunities based on my/my child's Genetic Test results.

6 | I/my child may be offered no-charge genetic counseling with a genetic counselor who can answer questions and provide information and advice about testing before and after having the Genetic Test. I authorize PG to release a copy of my/my child's Genetic Test results to the genetic counseling provider under the Program.

7 | PG may disclose my Genetic Test results after stripping them of personal identifying information ("De-identified Results") to Rhythm for the purposes of carrying out the Program, including potentially contacting my healthcare provider to discuss treatment options or to discuss my/my child's possible eligibility for clinical trials or other research opportunities. Rhythm may store, use, and disclose De-identified Results for its business purposes, research, and publication, and to conduct other analyses. My/my child's name or other personal identifying information will not be used in or connected to the results in any educational materials, presentations, or other publications. Rhythm will take steps to protect my De-identified Results from use or disclosure in a manner not permitted under applicable laws and regulations.

8 | The use of my/my child's De-identified Results may lead to commercial products in the future. Neither I nor my child will receive compensation or any rights or interests in those products.

9 | If I do not sign this form, I understand this means I will not be able to participate in the Program.

**New York residents only:**

10 | I authorize PG to retain my/my child's sample for potential future testing, for research ordered by my healthcare professional, and/or for quality control purposes. (If this statement is not signed, unused sample will be destroyed 60 days after testing is completed.)

INITIAL HERE >

_____
INITIALS

## BY SIGNING BELOW, I AGREE TO THE FOLLOWING:

I, the undersigned, have reviewed the information referenced above, including information regarding the possible benefits and risks of the Genetic Test. I have reviewed this informed consent. I have been given the opportunity to ask questions before I sign this document, and I have been told that I can ask additional questions at any time.

I consent to the Genetic Test and participation in the Program as described in this Consent Form.

SIGN HERE >

| _____ | _____ | _____ |
|---|---|---|
| PATIENT SIGNATURE | PATIENT NAME (PLEASE PRINT) | DATE |
| _____ | _____ | _____ |
| PARENT / GUARDIAN SIGNATURE, IF PATIENT IS A MINOR | PARENT / GUARDIAN NAME (PLEASE PRINT) | DATE |

UNCOVERING RARE OBESITY®

# Optional authorization to use and disclose Identifiable Health Information

PREVENTION GENETICS

Rhythm Pharmaceuticals, Inc. ("Rhythm") is providing the Uncovering Rare Obesity Gene Panel ("the Genetic Test") under a sponsored genetic testing program ("the Program") to healthcare providers and their patients to help identify rare genetic diseases of obesity. Rare genetic diseases of obesity are associated with early-onset, severe obesity that may be accompanied by insatiable hunger. The Genetic Test will be performed by PreventionGenetics, LLC ("PG") in a CLIA-accredited clinical DNA testing laboratory.

## IF I CHOOSE TO SIGN THIS AUTHORIZATION, I UNDERSTAND AND AGREE THAT:

1 | Rather than disclose to Rhythm only my Genetic Test results that have been stripped of personal identifying information as described in the Consent for Genetic Testing and Participation in Sponsored Testing Program, PG may use and disclose to Rhythm and others working for or with Rhythm my identifiable Genetic Test results, my contact information, and other clinical information provided by my doctor on the form to request Genetic Testing (collectively, "**Identifiable Health Information**").

2 | The purposes for PG's use and disclosure of my Identifiable Health Information to Rhythm is to help determine my eligibility for clinical trials and other research studies that are conducted on behalf of Rhythm or other entities, including research about my experience with the Sponsored Testing Program, and to contact me about potential research opportunities for which I may be eligible. I am under no obligation to participate in any of the research opportunities that I may be contacted about.

☐ By checking this box, I also authorize PG to disclose my Identifiable Health Information to Rhythm so that Rhythm may send me disease education materials or information about Rhythm Pharmaceuticals and its programs. I understand I can opt out of these communications at any time via the contact information provided in these communications.

3 | This authorization will remain in effect for five years from the date of my signature below unless a shorter period is provided for by state law.

4 | Once my Identifiable Health Information is disclosed to Rhythm, it may be re-disclosed by Rhythm and may no longer be protected by federal health privacy laws.

5 | This authorization is voluntary, and I am not required to sign this authorization. PG cannot condition my treatment, payment, enrollment, or eligibility for benefits on whether I sign this authorization.

6 | I may revoke (take back) this authorization at any time in writing by sending a letter to PG at the address listed below. If I revoke my authorization, it will not affect uses and disclosures of my Identifiable Health Information that were already made before PG received my authorization revocation. In addition, PG will not be able to take back my Identifiable Health Information that it has already shared with Rhythm before it received my authorization revocation. If I revoke my authorization, PG may still use the Identifiable Health Information for certain purposes, such as to comply with the law.

**To revoke this authorization or to change your contact information, please call PreventionGenetics at 1-715-387-0484 or submit a written request to:** PreventionGenetics, LLC, 3800 South Business Park Avenue, Marshfield, WI 54449.

## BY SIGNING BELOW, I AGREE TO THE FOLLOWING:

I, the undersigned, have read and understand this authorization. I authorize the use and disclosure of my Identifiable Health Information as described above.

SIGN HERE ›

| PATIENT SIGNATURE | PATIENT NAME (PLEASE PRINT) | DATE |
|---|---|---|
| PARENT / GUARDIAN SIGNATURE, IF PATIENT IS A MINOR | PARENT / GUARDIAN NAME (PLEASE PRINT) | DATE |