Phosphorus Diagnostics

# Infertility Test Requisition Form

LEAVING ANY SECTION BLANK OR INCOMPLETE WILL RESULT IN A DELAY OR CANCELLATION OF TESTING

## PATIENT INFORMATION

First Name ______ Last Name ______

DOB (mm/dd/yy) ______

Biological Sex: ☐ Male ☐ Female

Ethnicity: ☐ African ☐ Native American ☐ European ☐ French Canadian ☐ Jewish ☐ Latin American ☐ Mediterranean ☐ Middle Eastern ☐ East Asian ☐ Southeast Asian ☐ South Asian ☐ Other

Address ______

City ______ State ______ Zip ______

Country ______ Phone ______

Email ______

## CLINIC INFORMATION

Clinic Name ______ ID # ______

Address ______

City ______ State ______ Zip ______

Phone ______ Extension ______

### ORDERING PROVIDER

Name ______ NPI # ______

Email ______ Phone ______

Clinical Contact ______ Role Title ______

Email ______ Phone ______

Report sending preference: ☐ Email ☐ Regular mail ☐ Fax ______

## BILLING INFORMATION

☐ **Option A: Commercial Insurance** ☐ **Option B: Medicare/Medicaid/Other Government Insurance** ☐ **Option C: Self Pay/No Insurance**

In addition to completing the fields below, please attach a copy of the front and back of patient's insurance card or email a picture to billing@phosphorus.com.

### PRIMARY INSURANCE INFORMATION

Insurance Company Name ______

Policy Number/Member ID ______

Policyholder Name ______

Relation to Patient ______ Policyholder DOB ______

### SECONDARY INSURANCE INFORMATION

Insurance Company Name ______

Policy Number/Member ID ______

Policyholder Name ______

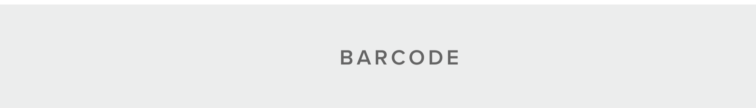
Relation to Patient ______ Policyholder DOB ______

## SPECIMEN INFORMATION

Collection Date (mm/dd/yy) ______

Specimen Type: ☐ Saliva ☐ Blood ☐ Extracted DNA

Sample Redraw: ☐ Yes ☐ No




## TEST TYPE

☐ Diagnostic ☐ Family Testing

If family testing, please complete the below fields.

Gene ______ Variant ______ (Attach proband report if not tested at Phosphorus)

If the family member received testing at Phosphorus, please complete the following:

Family member's name ______

Family member's DOB (mm/dd/yy) ______ Relation to current patient ______

## TEST INDICATIONS

Select ICD-10 code(s) below.

**FEMALE:**

- ☐ E28.39 Other primary ovarian failure
- ☐ E28.2 Polycystic ovarian syndrome
- ☐ O22.3 Deep phlebothrombosis in pregnancy
- ☐ N97.9 Female infertility, unspecified

**MALE:**

- ☐ N46.0 Azoospermia
- ☐ Q55.4 Other congenital malformations of vas deferens
- ☐ N46.1 Oligospermia
- ☐ N46.9 Male infertility, unspecified

**Other:** ______

## CLINICAL VARIABLES

**FEMALE:**

- Previous Prenancy Losses ______
- Day 3 FSH ______
- AMH ______

**MALE:**

- Sperm Count: ______ million / mL
- Motility: ______ %

## TEST ORDER

Select your core test panel below (select one core panel).

☐ **Female Panel** (Includes: sex chromosome aneuploidy, premature ovarian insufficiency, polycystic ovary syndrome, ovarian hyperstimulation syndrome, and recurrent pregnancy loss)

☐ **Full Male Panel** (Includes: sex chromosome aneuploidy, azoospermia, oligospermia, CAVD, and Y-chromosome microdeletions)

- ☐ **Non-obstructive azoospermia only** (Excludes: CFTR testing for CAVD)
- ☐ **Obstructive azoospermia** (CAVD only)

☐ **Add Emerging Evidence Genes**

☐ **Karyotype Add-On** (A green top heparin collection tube is required in addition to the purple top EDTA tube.)

## TEST AUTHORIZATION AND PATIENT CONSENT

By signing below, I certify that I have carefully read, understand, and agree to the attached patient consent form for genetic testing, have discussed the benefits, risks, and limitations of genetic testing with my or my child's provider, and consent for Phosphorus Diagnostics to perform the genetic test(s) ordered by my or my child's provider. By signing this consent, I acknowledge that I am the patient providing the sample or the parent/guardian of the child providing the sample, and I am either (1) at least 18 years of age or (2) I am legally recognized as an 'emancipated minor' by the state in which I reside.

I acknowledge that Phosphorus Diagnostics is a non-participating provider and my physician has determined that this test is medically relevant to my or my child's care.

**NY State Residents - Please Read Carefully:** Unless you check the box below, you authorize Phosphorus Diagnostics to de-identify your or your child's sample and indefinitely retain, store, and use your de-identified sample for research, education, and other purposes as permitted by applicable law.

☐ I do not provide authorization for Phosphorus Diagnostics to retain my or my child's sample for the above purposes.

**Patient Signature** ______ **Date** ______

## ORDERING HEALTHCARE PROVIDER AUTHORIZATION

I hereby order Phosphorus Diagnostics to conduct the above tests, which I have determined to be medically necessary. I have explained genetic testing (including the risks, benefits, and alternatives) to this individual or this child's parent/guardian. I have addressed the limitations outlined in the patient consent form, and I have answered this person's questions to the best of my ability.

If requested or required by a third party payer, I will work with Phosphorus Diagnostics to provide an appropriate Pre-Authorization and/or Medical Necessity Letter, as well as relevant medical records for the purpose of seeking reimbursement for these services.

**Provider Signature** ______ **Date** ______

## SAMPLE REQUIREMENTS

- Blood: EDTA Lavender top tube, 6 µL for adults and 2-3 µL suggested for infants
- Saliva: collect sample according to kit specifications
- Extracted DNA: minimum 50uL volume and 50 mg/µL concentration

## UNACCEPTABLE SPECIMENS

- Hemolyzed or clotted blood
- Blood and saliva from patient after allogenic bone marrow transplant
- Blood or saliva collected less than two weeks after blood transfusion
- Buccal swabs and mouthwash specimens
- Saliva in non-Oragene collection kit
- Chorionic villus and amniotic samples

Ship overnight at room temperature, or cold pack (blood) to the following address:

400 Plaza Drive
Suite 401
Secaucus, NJ 07094

| FOR SAMPLE COLLECTION TUBE | EXTRA STICKER, IF NEEDED | EXTRA STICKER, IF NEEDED | EXTRA STICKER, IF NEEDED |
|---|---|---|---|
| **Patient First & Last Name** ______ | **Patient First & Last Name** ______ | **Patient First & Last Name** ______ | **Patient First & Last Name** ______ |
| **Date of Birth (mm/dd/yy)** ______ | **Date of Birth (mm/dd/yy)** ______ | **Date of Birth (mm/dd/yy)** ______ | **Date of Birth (mm/dd/yy)** ______ |

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Diagnostics

# Patient Consent Form

## INFERTILITY

### PURPOSE
I understand that the purpose of this test is to determine if I (my child) carry changes in my (his/her) DNA, called pathogenic variant(s), in the disease genes ordered by my (my child's) provider. If detected, the presence of pathogenic variant(s) may be associated with a disease.

### TEST INFORMATION
I understand that this test is a diagnostic genetic test for detecting genetic variants associated with reproductive health conditions. This test can determine if an individual is at an increased risk for developing specific reproductive health conditions. For more information on genetic conditions included in this test, please visit www.phosphorus.com. My (my child's) healthcare provider has determined that this test is appropriate for me (my child) and can also provide more information about this test.

### TEST RESULTS AND INTERPRETATION
I understand that test results can provide information that has implications for my (my child's) health and/or my family members' health. I understand that if a pathogenic variant(s) is/are found, I (my child) may be affected with, or at risk for, the disease(s) caused by that/those gene(s). As not every disease causing variant in each gene is studied, negative test results reduce, but do not eliminate, the chance that I am (my child is) affected with or predisposed to having said disease(s). Test results may not provide definitive conclusions regarding risk for developing the condition. I understand that results returned from this analysis will not include likely benign or benign variants unless specifically requested. I understand that all disease causing variants, identified in the specified genes/regions tested in the current analysis, are reported, and that these variants may cause, or predispose me (my child) to, a disease other than that for which testing was initiated. I understand that upon a positive or inconclusive test result, I may wish to consider further testing, and I may consult my (my child's) provider or genetic counselor to consider my (my child's) options.

### FAMILY MEMBER TESTING AND RESULTS
I understand that if my family members undergo genetic testing, Phosphorus Diagnostics may disclose my (my child's) results to my family members, unless I make a request in writing for Phosphorus Diagnostics to only disclose my (my child's) results to me. As with any genetic test, results may reveal incidental and unsought information, such as non-paternity.

### LIMITATIONS
I understand that this test is designed to detect specific genetic changes associated with reproductive health conditions. It cannot detect every pathogenic variant associated with each disease, nor does it look for all known genetic diseases. Therefore, a negative result on this test is risk reducing but not risk eliminating. I understand that a normal result therefore does not guarantee a healthy outcome. Phosphorus Diagnostics offers the option to design custom panels as a special service to ordering providers. As such, I understand that Phosphorus Diagnostics cannot be held liable for any missed disease causing variant(s) due to omission of a disease from a clinic's custom panel. I understand that though this test is highly accurate, no genetic test is 100% accurate. Reasons for inaccurate results include but are not limited to: biological factors (e.g. recent blood transfusions or history of bone marrow transplantation), poor DNA quality, technical issues, inaccurately marked samples, and sample mix-up. I understand that it is possible that no results will be obtained from a sample. In such cases, another sample will be requested.

## GENERAL

### SAMPLE COLLECTION AND PROCEDURE
Testing is performed on saliva or blood samples obtained via the collection kit. I understand that Phosphorus Diagnostics has no obligation to retain my (my child's) sample indefinitely or return my (my child's) sample to me, and may destroy it once it no longer has a legal duty to retain it. I also understand that adequate DNA in the sample provided is required to complete the test. As a result, additional samples may be needed if the sample is damaged in shipment, incorrectly submitted, or if no results are obtained.

### SAMPLE TRANSPORT
The samples obtained for this test will be sent to Phosphorus Diagnostics for analysis. I understand that issues with transport such as delivery delays, lost packages, or damage to sample packaging are not the responsibility of Phosphorus Diagnostics.

### GENETIC COUNSELING
Genetic counselors are available by phone to answer questions prior to testing and to review test results after testing. Once results are available, I may be contacted by email or phone to schedule a phone consultation with a genetic counselor to review my (my child's) test results, depending on my healthcare provider's preferences. Genetic counselors may recommend further testing as needed based on my (my child's) initial test results and/or family history information.

### RESULTS AND DISCLOSURE
I understand that my (my child's) test results will be disclosed only to the healthcare provider named on the test order, the healthcare provider's agent, and/or my family members as indicated above. I understand that I can contact my doctor's office to obtain a copy of my (my child's) test results. In order to have my (my child's) results released to any other healthcare provider, person, or organization, I must provide the appropriate authorization. I understand that if I schedule a genetic consultation with a genetic counselor, Phosphorus Diagnostics will send me my (my childs') test results by email. I understand that email communications from Phosphorus Diagnostics, including my (my child's) test results, may not be encrypted and/or secure. Should I wish to receive the results through a different method, I understand I may contact Phosphorus Diagnostics by phone, email, or standard mail with my request. If I do not schedule an appointment with a genetic counselor, I can also receive a copy of my (my child's) test results from Phosphorus Diagnostics by submitting a written request by email, fax, or standard mail. I understand that Phosphorus Diagnostics does not have a responsibility to contact me in the future if new tests are added to the menu or when additional disease causing variants are added to the tests offered.

### VARIANT CLASSIFICATION
Genetic variant(s) identified during testing are assessed and classified according to American College of Medical Genetics (ACMG) guidelines. Understanding of these variants can change over time, which may impact their classification. Variants are reassessed, and clinicians are notified of changes in variant classification according to Phosphorus's Variant Re-classification policy.

### GENETIC TESTING RISKS AND BENEFITS
No clinical tests other than those I have authorized shall be performed on my (my child's) sample for purposes of my (my child's) diagnosis and treatment. I understand that the results of this test may help me make more informed decisions regarding my (my child's) health. My (my child's) results may also benefit other family members. I understand that the physical risk of having a blood draw is minimal, but may include dizziness, fainting, soreness, bleeding, bruising and, rarely, infection. I understand that genetic information obtained through this test could be used as a basis for discrimination. To address concerns regarding possible health insurance and employment discrimination, some countries, including the United States, have enacted laws to prohibit genetic discrimination in those circumstances. I understand that these laws may not protect against genetic discrimination in other circumstances such as when applying for life insurance or long-term disability insurance.

### CONFIDENTIALITY
I understand that confidentiality of my (my child's) information and results will be maintained at all times as required by law and in accordance with Phosphorus Diagnostics' Notice of Privacy Practices, which Phosphorus Diagnostics has made available to me on its website at www.phosphorus.com/notice-of-privacy-practices/.

### DATA AND SAMPLE RETENTION AND USE
Upon completion of my (my child's) genetic testing, any remaining saliva or blood samples may be discarded or held indefinitely for research, educational, and other purposes as permitted by applicable law. Phosphorus Diagnostics will remove all of my (my child's) personally identifiable information from my (my child's) sample in accordance with applicable law prior to using my (my child's) sample for such purposes.

In addition, after completion of my (my child's) testing and in accordance with applicable law, Phosphorus Diagnostics may de-identify my (my child's) test data, and any genetic information extracted from my (my child's) sample, for use for research, educational, and other purposes as permitted by applicable law.

My (my child's) name or other personally identifiable information will not be included in or linked to the results of any research studies and publications. I hereby disclaim any and all rights to, ownership of, and interest in any samples obtained by Phosphorus Diagnostics, and grant Phosphorus Diagnostics (and any third-party collaborators) all rights to use my samples, data, information, and results to conduct research, develop commercial products, and obtain intellectual property rights as permitted by applicable law. I acknowledge that neither I nor my heirs will acquire any rights or license to, ownership of, or interest in any research, commercial products, techniques, inventions, discoveries or intellectual property arising or derived from or relating to the use of any of my samples, data, or information gained from my genetic testing. I further acknowledge that neither I nor my heirs will receive any compensation or share in any profits relating to any such commercial or research activities.

I understand Phosphorus Diagnostics may also contact me in the future about research opportunities. I understand that I am not required to participate in these future research opportunities.

### SAMPLES COLLECTED IN NEW YORK STATE ONLY
If my (my child's) sample will be collected in New York State, I authorize Phosphorus Diagnostics to indefinitely retain, store, and use any of my (my child's) de-identified sample for research, educational, and other purposes as permitted by applicable law, unless I selected the box to opt out from the authorization. This consent will not expire, but I may revoke my consent at any time by contacting Phosphorus Diagnostics at 1-855-746-7423. Any revocation of this consent will not affect any action Phosphorus Diagnostics has taken in reliance on my consent before my revocation.

### FINANCIAL RESPONSIBILITY AND ASSIGNMENT OF BENEFITS
I authorize my insurance company to directly pay my insurance benefits to Phosphorus Diagnostics and agree to endorse and forward any payments received from my insurance company. I acknowledge that I am financially responsible for any amounts not paid by my insurance company. I have been given the opportunity to ask my provider and Phosphorus Diagnostics questions concerning the payment terms outlined within this document. I agree that all of my questions have been answered to my satisfaction and I accept the payment terms. Information regarding costs of services, and financial hardship policies can be found at www.phosphorus.com and are subject to terms and conditions.