



Physician Requisition Form for the No Cost to Patient *APOL1* Genotyping Program

Please complete every field.

Arkana Laboratories and Vertex Pharmaceuticals are working together to make it possible to provide *APOL1*-risk variant testing at no cost to patients who meet all four of the following criteria:

1. African ancestry including those who self-identify as Black, African American, African, Afro-Caribbean, Hispanic, or Latino
2. History of any level of proteinuria - or - decreased renal function (CKD stages 1-4)
3. Absence of diabetes mellitus
4. No history of dialysis or kidney transplant

Specimen Information: Buccal Swab (included in kit) Kidney biopsy previously processed at Arkana

Laboratory Test Values: 24 hour urine protein or urine prot:Cr ratio: _____ CKD Stage: _____ eGFR: _____

Self-reported race/ethnicity: Check all that apply

Black/African American Afro-Caribbean African Hispanic Latino Other _____

Patient Information:

Patient Name: _____ Date of Birth (MM/DD/YYYY): _____ Gender: M F

Address: _____ City: _____ State: _____ Zip Code: _____

Phone #: _____ Email: _____ Medical Record #: _____

Referring Physician Information:

Name: _____ MD DO Phone #: _____ Fax #: _____

Institution: _____ Address: _____

City: _____ State: _____ Zip Code: _____ Email: _____

Arkana Laboratories Agreement for *APOL1* Sponsored Testing

By requesting testing from Arkana Laboratories, the ordering physician indicates that they understand and agree with the following:

- A. Should required information not be provided in the test requisition form, lab personnel may contact the clinical office or patient directly to obtain or verify information required to complete the form.
- B. Results will only be released to the providers listed on the requisition form and a genetics counselor (if requested).
- C. It is the responsibility of the ordering physician to disclose test results and direct the patient's care as appropriate.
- D. The ordering provider's name and institution name may be shared with Vertex Pharmaceuticals to track test utilization.
- E. The patient fulfills criteria for no cost testing by fulfilling all four criteria listed at the top of this form and the test is clinically appropriate for the patient.
- F. A genetic counselor will reach out to discuss results with patients who have two risk alleles (if requested) via Metis Genetics at no cost to the patient.
- G. The patient has been informed that Arkana may de-identify information obtained from the test and share that information with Vertex Pharmaceuticals.

Ordering Provider Signature

I, _____ (Print Name), as ordering physician, certify that the patient being tested and/or their legal guardian have been informed of the risks, benefits, and limitations of the testing ordered. I have obtained informed consent, as required by my own state and/or federal laws. In addition, I assume responsibility for returning the results of genetic testing to my patient and/or their legal guardian.

Signature (Ordering Physician)

Date



NOTE: Please obtain patient/guardian signature on the consent form below. Failure to submit a completed consent may delay initiation of testing.

I, (name) _____, voluntarily request for Arkana Laboratories to perform the genetic test for *APOL1*-mediated kidney disease for myself/my child (child's name if <18 years of age _____).

General Description and Purpose of the Test:

Kidney failure occurs in Black Americans about three times as much as it does in white Americans. There are many reasons for this increased risk, including genetic causes. One gene called *APOL1* is the cause of a rapidly progressive form of chronic kidney disease for some people of African ancestry if they have genetic changes known as "*APOL1* risk variants" confirmed by genetic testing. Not all people with the *APOL1* risk variants develop kidney disease, and people can still develop kidney disease without any genetic variants.

Reason for Testing:

Genetic testing for *APOL1* risk variants is recommended to further determine what is causing non-diabetic kidney disease in those with African ancestry before attributing it to other causes, like high blood pressure. While there aren't yet specific treatments for *APOL1*-mediated kidney disease (AMKD), *APOL1* genetic testing can provide predictive information about your kidney disease and which treatments might or might not help. Research studies to test new treatments for *APOL1*-mediated kidney disease, also known as clinical trials, could also be considered if they are available. Lastly, a better understanding of the genetic cause of your disease may help inform family members who may also be at risk for kidney disease.

Meaning of a Positive Test Result:

People who have two copies of *APOL1* risk variants are at increased risk of kidney disease.

Meaning of a Negative Test Result:

Individuals with no risk alleles (or a single risk allele) are currently considered to have a "low risk genotype" and are currently considered to have no increased risk of kidney disease due to the *APOL1* gene. This test is only for the *APOL1* gene and a negative result does not exclude the possibility of other genetic diseases.

Qualifications for Sponsored Testing Program:

Arkana Laboratories and Vertex Pharmaceuticals are working together to make it possible to provide *APOL1*-risk variant testing at no cost to eligible patients. Patients must fulfill all four of the criteria listed below to be eligible for this program:

- African ancestry including those who self-identify as Black, African American, African, Afro-Caribbean, Hispanic, or Latino
- Presence of either protein in urine or decreased kidney function (CKD Stages 1-4)
- Absence of diabetes
- Not currently on dialysis and no history of kidney transplant

Additional Information:

- Additional samples may be needed if the sample is damaged in shipment or inaccurately submitted.
- As with any complex test, there is a small chance of a failure or error in sample analysis. Many measures are taken to avoid these errors. Uncommonly, an additional sample may be needed.
- Due to the complexity and potential implications of DNA testing, results are only directly reported to the ordering provider and/or the assigned genetic counselor. Patient results and information are private and confidential, and will only be released to other parties with written consent from the patient.



- Arkana Laboratories may de-identify information obtained from the test and share that information with Vertex Pharmaceuticals.
- No tests other than those authorized shall be performed.
- Residual sample and/or extracted DNA will be destroyed within 45 days of result reporting.

Professional Genetic Counseling:

In order to derive the most meaningful benefit from this testing, it is recommended that the results be discussed with your healthcare provider and/or a trained genetics professional. Genetic counseling from Metis Genetics is available at no cost for all patients who test positive for the *APOL1* high risk variants. Please indicate below if you would like a genetic counselor to contact you to discuss your result should you test positive. If this section is left blank, a genetic counselor will reach out.

- I would like a professional genetic counselor from Metis Genetics to contact me if I am positive for AMKD.
- Please do not contact me to offer genetic counseling (*patient must check box and initial below to opt out of genetic counseling*).

Patient initials: _____

Patient Signature:

I understand the benefits, risks, and limitations of the above requested testing and wish to proceed with it.

Patient/Patient Guardian Signature

Date

Patient/Patient Guardian Print Name



Please scan the QR code to watch a video about this informed consent.