Arkana Laboratories

APOL1 Consent and Requisition Form

Affix patient sticker here

Specimen Type (Arkana Use Only)**:** ☐ Blood ☐ FFPE ☐ Frozen Block ☐ DNA ☐ Buccal Swab

Test requested (if no selection made, standard test will be performed):

☐ Standard Test - *G1* and *G2* risk variants with *M1* (p.N264K) testing if *G1/G2 or G2/G2* genotypes identified

☐ *M1* (p.N264K) variant only, for previously identified *G1/G2* or *G2/G2* genotypes

Laboratory test values:

☐ Creatinine ☐ Levels not elevated Current: _____ Baseline: _____

☐ Protein ☐ Not present ☐ Macro ☐ Micro

Is patient being tested for living kidney donation? ☐ Yes ☐ No

Patient or family memeber previously tested for disease? ☐ Yes ☐ No If yes, please describe results and/or attach report.

Reason(s) for testing:

☐ Diagnosis ☐ Family History ☐ Assess risk ☐ Other: _____

Prior renal biopsy evaluated at Arkana? ☐ Yes ☐ No

Patient Information:

Patient Name: _____ Date of Birth (MMDDYYYY): _____ Gender: ☐ M ☐ F

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

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

Is the patient adopted? ☐ Yes ☐ No Has the patient received a bone marrow or kidney transplant? ☐ Yes ☐ No

Race & Ethnicity: Check all that apply

☐ Black/African American ☐ Asian ☐ White/Non-Hispanic Caucasian ☐ Ashkenazi Jewish ☐ Other: _____

☐ Hispanic ☐ American Indian ☐ Native Hawaiian or Pacific Islander ☐ Native Alaskan

Referring Physician Information:

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

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

Email: _____

Institution: _____ City: _____ State: _____ Zip Code: _____

Specimen and Shipping Information:

Please contact Arkana Laboratories at (501) 604-2695 to request a kit.

10810 Executive Center Drive, Suite 100 Little Rock, Arkansas 72211
Telephone +1 501 604 2695 Fax +1 501 604 2699 support@arkanalabs.com
arkanalabs.com

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Patient Name: _____

Date of Birth (MMDDYYYY): _____

Arkana Laboratories Molecular Policies

By requesting testing from Arkana Laboratories Molecular Division (ALMD), the ordering physician indicates that they understand and accept the policies of the ALMD, as listed below, and has communicated these policies to the patient.

A. The laboratory testing performed in ALMD requires advanced technology and is performed by highly skilled doctors and technicians. As in any laboratory, despite our best and diligent efforts there is a small possibility that a test will not work or that an error may occur.

B. Should required information not be provided in the test requisition form, lab personnel may contact patients directly to obtain or verify information required to complete the
form.

C. Results will only be released to the ordering physician and other providers listed on the requisition form.

D. It is the responsibility of the ordering physician to disclose test results and direct the patient's care as appropriate.

E. Turnaround times (TAT) for testing represent an estimate of the typical turnaround time for the test, but are not guaranteed.

Ordering Provider Signature

I, _____ (Print Name), as ordering physician, certify that the patient being treated and/or their legal guardian have been informed of the risks, benefits, and limitations of the testing ordered, as well as the policies of ALMD listed above. 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 and for ensuring that my patient receives appropriate genetic counseling to understand the implications of their test results.

_____ _____

Signature (Ordering Physician) Date

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

I, (name)_____ , voluntarily request for Arkana Molecular Diagnostic Laboratory to perform the genetic test for APOL1-related nephropathy for myself/my child (child's name_____).

The following information was explained and I understand that:

General description and purpose of the test:

Black/African Americans have a much higher rate of kidney disease than other populations without recent African ancestry. Almost all of this increased risk is associated with two different DNA mutations in the APOL1 gene (called G1 and G2). Both copies of the APOL1 gene must be affected by a mutation for an individual to have a higher risk of kidney disease (i.e. autosomal recessive inheritance pattern). The test detects the presence of the APOL1 G1 [c.1024A>G; p.Ser342Gly (rs73885319)] and G2 [c.1169delATAATT; p.Asn388_Tyr389del (rs71785313)] risk alleles, as well as the APOL1 modifier variant (c.792C>A; p.N264K (rs73885316), designated M1) that is protective against the G2 risk variant, using polymerase chain reaction (PCR) test methodology.

Reason for testing:

- Determining risk status in a Black/African-American patient, particularly in patients with systemic lupus erythematosus (SLE), collapsing or membranous glomerulopathy, HIV, or renal failure in the setting of COVID-19 infection
- Individuals being considered for kidney donation
- Determination of carrier status in a family member
- Clinical features of nephrotic syndrome and/or renal biopsy findings of collapsing glomerulopathy which is commonly seen in APOL1-related glomerulopathy

Meaning of a positive test result:

Individuals with two risk alleles (G1/G1, G1/G2, or G2/G2) are said to have a "high-risk genotype". This genotype is characterized by a 7- to 10-fold increased risk for hypertension-associated end-stage renal disease (ESRD); 10- to 17-fold increased risk for focal segmental glomerulosclerosis (FSGS), and a 29-fold increased risk for HIV-associated nephropathy. These APOL1 risk variants are also associated with progression to ESRD in African American patients with SLE and COVID-19 infection.

Meaning of a negative test result:

Individuals with no risk alleles (G0/G0) are considered to have no risk of kidney disease due to the APOL1 gene; while those with a single risk allele (G0/G1 or G0/G2) are said to have a "low-risk genotype" and have no increased risk of kidney disease due to the APOL1 gene. Recent studies have identified the M1 variant in the coding region is protective against the G2 risk variant when present on the same allele (i.e. in cis). This combination is designated G2-M1. Testing for this variant is warranted in patients initially identified to have G1/G2 or G2/G2 high-risk genotypes because G1/G2-M1, G2-M1/G2 and G2-M1/G2-M1 genotypes clinically behave as low-risk/single-risk variant genotypes.

Professional genetic counseling

Individuals considering genetic testing may wish to consult with a Certified Genetics Counselor or Geneticist prior to signing this consent.

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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. Patient results and information are private and confidential, and will only be released to other parties with written consent from the patient.

Research consent:

Research at Arkana Laboratories has advanced the understanding of kidney diseases, including features of chronic kidney disease associated with APOL1. Thus, we request research consent from all patients to allow the use of their samples for future possible research studies. However, no other tests than those authorized shall be performed on your sample and any samples received solely for genetic testing will be destroyed within 45 days of sample receipt without your consent below. The patient can choose whether or not their leftover sample can be de-identified, retained beyond 45 days, and used for research purposes. If no choice is indicated below it is assumed that the patient opted-out, the sample will not be used for research purposes, and the sample will be destroyed within 45 days.

I consent for the use of my sample for research: ☐ Yes ☐ No Patient initials: _____

Financial responsibility:

Test cancellation:

If testing is canceled prior to test set-up, processing will be discontinued and there will be no charge. If a test cancellation is received after set-up, a cancellation report will be generated and a set-up fee will be charged. Test cancellations received after the test assay has been started will be charged a technical fee.

Coverage or noncoverage by insurance:

Some insurance companies do not cover genetic testing as they regard it as unnecessary or experimental. In the event that a patient's healthcare plan does not reimburse Arkana Laboratories for genetic testing, the patient is held responsible for test charges and will be contacted to make arrangements for payment. If your insurance is covered under Medicare please complete the attached advanced Beneficiary Notice of Noncoverage (ABN: form CMS-R-131) on pages 3 and 4, and please select an option for billing. For non-Medicare patients, compassionate use, partial down-payment and/or payment plans can be negotiated by contacting Arkana Laboratories (Toll Free phone number for Billing Manager: 866-269-9819).

Signatures:

Genetic testing may be delayed pending receipt of the following documents; completed test requisition signed by the healthcare provider responsible for the patient's care and signatures from the patient/guardian; and a completed ABN if your healthcare costs are covered under Medicare.

Patient Signature:

Patient/Patient Guardian Print Name	Patient/Patient Guardian Signature	Date

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