Arkana Laboratories

Genetic Test Consent and Requisition Form

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 Molecular Diagnostic Laboratory to perform the following genetic test(s) for:

- ☐ APOL1-related nephropathy
- ☐ Alport syndrome
- ☐ Steroid resistant nephrotic syndrome (SRNS)
- ☐ Autosomal dominant polycystic kidney disease (PKD1)
- ☐ C3 glomerulopathy (C3G) Dense Deposit Disease (DDD)
- ☐ Thrombiotic microangiopathy (TMA)
- ☐ LIMS1 Genotyping Assay

for myself/my child (child's name _____), in an attempt to determine whether I/my child have a genetic explanation for kidney disease.

The following information was explained and I understand that:

- This testing requires DNA obtained from a blood sample or prior fresh frozen renal biopsy tissue. Additional samples may be needed if the sample is damaged in shipment or inaccurately submitted.
- Sometimes in order to make sense of a mutation in one person, samples from their parents or additional family members may be required.
- These DNA-based studies are specific to the condition(s) listed above. These genetic tests use some of the newest clinical laboratory test methods. However, even these methods are not 100% accurate. Some changes in DNA are not well-detected; in a few cases the test may be unable to detect an abnormality even though one may still be present. In addition, due to limitations in current knowledge, a DNA change may be detected but we will not be able to tell with certainty whether or not this change is the cause of a person's disease. It is likely that these limitations will improve as scientific knowledge advances.
- 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.
- Interpretation of genetic tests depends upon an accurate clinical diagnosis, family medical history, and knowledge about a family's true biologic relationships. An incorrect diagnosis in the patient or relative may lead to an incorrect interpretation of a laboratory test result. In addition, genetic testing of family members can sometimes reveal true biological relationships that do not match the reported biological relationships. For example a genetic test result may show that the stated father of an individual is not the true biological father (non-paternity).
- 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.
- Arkana Laboratories is not a DNA banking facility and does not guarantee the future availability of extracted DNA. Requests for additional studies must be ordered by the referring provider and charges will be incurred. Once the test is complete, identifying information may be removed and remaining DNA may be used for de-identified laboratory purposes. These samples will not be available for future clinical studies. Any results obtained cannot be traced back to the original source, so no results can be reported.
- The patient can choose whether or not their leftover sample can be de-identified and used for research purposes. If no choice is indicated below it is assumed that the patient opted-out, and the sample will not be used for research purposes.

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

Financial responsibility:

Test cancellation:

If testing is cancelled 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 Laboratory (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; this consent document with signatures from the patient/guardian; and a completed ABN if your healthcare costs are covered under Medicare.

Patient/Guardian signature:

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

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

Physician/Counselor/Clinician Statement:

It is the responsibility of the referring physician or health care provider to understand the specific utility and limitations of the testing ordered, and to educate the patient regarding these limitations. Specific information describing indications, methodology and detection can be found on the Arkana Laboratories website at arkanalabs.com or by contacting Arkana Laboratories Molecular Diagnostics.

I have explained the above points regarding genetic testing to the patient/parent/guardian. The consent form and limitations of genetic testing were reviewed with the patient or parent/guardian. I accept responsibility for either preforming or arranging for pre- and post- test genetic counseling.

Clinician Print Name	Date	Clinician Signature	Date

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Affix patient sticker here

Specimen Information: ☐ Kidney biopsy tissue ☐ DNA ☐ Blood

Nephrology Gene Panel Ordered:

☐ Steroid resistant nephrotic syndrome/FSGS panel ☐ PKD1 ☐ Apolipoprotein (APOL1) genotyping

☐ Alport panel ☐ C3 glomerulopathy (C3G) ☐ LIMS1 genotyping Assay ☐ Thrombotic microangiopathy (TMA) / atypical HUS panel

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 member 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

Third-Party Billing Information: Complete or attach a copy of insurance card and authorization

Insured/Responsible Party: _____ Date of Birth (MMDDYYYY): _____ Gender: M F

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

Phone #: _____ Patient's relationship to insured: ☐ Self ☐ Spouse ☐ Dependent ☐ Other

Member ID #: _____ ☐ Medicare ☐ Medicaid ☐ HMO ☐ PPO ☐ Other

Policy #: _____ Group #: _____

Insurance Co Name: _____ Insurance Co Address: _____ Insurance Co Phone #: _____

Employer Name: _____ Employer Phone #: _____

Referral Authorization/Precertification #: _____

Print Name: _____ Signature: _____ Date: _____

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Patient Name: _____

Date of Birth: (MMDDYYYY): _____

Referring Physician Information:

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

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

Email: _____

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

Patient seen by Genetic Counselor? If yes, please provide contact information. Name: _____

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

Phone #: _____ Fax #: _____

Institution: ☐ Same as referring physician ☐ See below

Name: _____ Phone #: _____ Fax #: _____

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

Specimen and Shipping Information:

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

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 tested 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

Arkana Laboratories

Nephrology Genetic Panels

Full Steroid Resistant Nephrotic Syndrome/FSGS gene sequencing panel (all genes listed below)

ACTN4	ADCK3	ADCK4	ANLN	APOL1	APRT	ARHGAP24	ARHGDIA	CD2AP	CLCN5	XPO5
COL4A3	COL4A4	COL4A5	COQ2	COQ4	COQ6	CRB2	DLC1	DDX53	DGKE	
FAT1	IL15RA	INF2	ITGA3	ITGB4	LAMB2	MAG12	MYH9	MYO1E	NEIL1	
NPHS1	NPHS2	NUP205	NUP93	NXF5	OCRL1	PAX2	PDSS2	PLCE1	PODXL	
PDSS1	PTPRO	SCARB2	SMARCAL1	SHROOM3	TNS2	TTC21B	TRPC6	VEGFA	WT1	

Full Alport syndrome gene sequencing panel (all genes listed below)

COL4A1	COL4A3	COL4A4	COL4A5	COL4A6	FN1	LMX1B	MYH9	MYO1E

Complement component 3 glomerulopathy (C3G) panel (all genes listed below)

C3	C8A	CD46 (MCP)	CFB	CFH	CFHR1	CFHR2	CFHR3	CFHR4	CFHR5	CFI

Thrombotic microangiopathy (TMA) panel (all genes listed below)

ADAMTS13	C3	CD46	CFB	CFH	CFHR1	CFHR2	CFHR3	CFHR4	CFHR5	CFI	DGKE
MMACHC	PLG	THBD									

Autosomal Dominant Polycystic Kidney Disease (ADPKD)

PKD1

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A. Notifier:

B. Patient Name: **C. Identification Number:**

Advance Beneficiary Notice of Non-coverage (ABN)

NOTE: If Medicare doesn't pay for **D.**_____ below, you may have to pay. Medicare does not pay for everything, even some care that you or your health care provider have good reason to think you need. We expect Medicare may not pay for the **D.**_____ below.

D.	E. Reason Medicare May Not Pay:	F. Estimated Cost

WHAT YOU NEED TO DO NOW:

- Read this notice, so you can make an informed decision about your care.
- Ask us any questions that you may have after you finish reading.
- Choose an option below about whether to receive the **D.**_____ listed above.
  Note: If you choose Option 1 or 2, we may help you to use any other insurance that you might have, but Medicare cannot require us to do this.

G. OPTIONS: Check only one box. We cannot choose a box for you.

☐ **OPTION 1.** I want the **D.**_____ listed above. You may ask to be paid now, but I also want Medicare billed for an official decision on payment, which is sent to me on a Medicare Summary Notice (MSN). I understand that if Medicare doesn't pay, I am responsible for payment, but I can appeal to Medicare by following the directions on the MSN. If Medicare does pay, you will refund any payments I made to you, less co-pays or deductibles.

☐ **OPTION 2.** I want the **D.**_____ listed above, but do not bill Medicare. You may ask to be paid now as I am responsible for payment. I cannot appeal if Medicare is not billed.

☐ **OPTION 3.** I don't want the **D.**_____ listed above. I understand with this choice I am **not** responsible for payment, and I cannot appeal to see if Medicare would pay.

H. Additional Information:

This notice gives our opinion, not an official Medicare decision. If you have other questions on this notice or Medicare billing, call **1-800-MEDICARE** (1-800-633-4227/**TTY:** 1-877-486-2048). Signing below means that you have received and understand this notice. You also receive a copy.

I. Signature:	J. Date:

CMS does not discriminate in its programs and activities. To request this publication in an alternative format, please call: 1-800-MEDICARE or email: AltFormatRequest@cms.hhs.gov.

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