Arkana Laboratories

Informed Consent for Molecular Genetic Testing

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)
- ☐ C3 glomerulopathy (C3G) Dense Deposit Disease (DDD)
- ☐ Thrombiotic microangiopathy (TMA)
- ☐ Extended complement panel gene

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.

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

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arkanalabs.com

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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

Arkana Laboratories

Renal Molecular Genetics Sequencing Test Requisition

Affix patient sticker here

Specimen Information: ☐ Kidney biopsy tissue ☐ DNA ☐ Blood (lavender top/EDTA tube)

Reason(s) for testing:

☐ Diagnosis ☐ Family history

☐ Assess risk ☐ Other:

Prior renal biopsy evaluated at Arkana?

☐ Yes ☐ No

Nephrology Gene Panel Ordered:

☐ Steroid resistant nephrotic syndrome/FSGS panel ☐ Extended Complement Panel ☐ Apolipoprotein (APOL1) genotyping

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

☐ Other:_____

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.

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:

Acceptable specimens include:

Peripheral blood (preferred):	At least 2 ml in Lavender top (EDTA) tube <5 days old (typically 1 tube) or DNA PaxGene tube Shipped overnight at room temperature
Previously extracted DNA:	10ul suspended in TE buffer at 10-100ng/ul

All samples must have two patient identifiers, preferably the patient's name and date of birth. Please contact Arkana for more details.
Each sample must be accompanied by a requisition form. The ordering provider must sign the declaration below.

Sample (with forms) should be shipped to:

Arkana Laboratories ATTN: Molecular Division
10810 Executive Center Drive, Suite 100
Little Rock, AR 72211

Please contact Arkana Laboratories Molecular Diagnostics Lab at (501) 604-2695 if you have further questions.

Arkana Laboratories Molecular Division 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. Once stripped of all patient identifiers, including name, SSN, medical record number, and any other information required to protect the confidentiality of your results and your privacy, ALMD may share your test results with other clinical laboratories for the purpose of improving test methodologies and to enable a better understanding of the relationship between genetic changes and the diseases they cause.

F. 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

Select full panel(s) and/or individual genes to be tested

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

☐ ACTN4 ☐ ADCK3 ☐ ADCK4 ☐ ANLN ☐ APOL1 ☐ APRT ☐ ARHGAP24 ☐ ARHGDIA ☐ CD2AP ☐ CLCN5
☐ 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
☐ XPO5

☐ 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

☐ Extended Complement panel (all genes listed below)

☐ ADAMTS13 ☐ C1QA ☐ C1QB ☐ C1S ☐ C2 ☐ C3 ☐ C8A ☐ C9
☐ CD46 ☐ CFB ☐ CFH ☐ CFHR1 ☐ CFHR2 ☐ CFHR3 ☐ CFHR4 ☐ CFHR5
☐ CFI ☐ CR2 ☐ DGKE ☐ F12 ☐ FCN1 ☐ MASP1 ☐ MASP2 ☐ MMACHC
☐ PLG ☐ THBD

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