



# 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:

- |  |  |
|--|--|
| <input type="checkbox"/> APOL1-related nephropathy                   | <input type="checkbox"/> C3 glomerulopathy (C3G) Dense Deposit Disease (DDD) |
| <input type="checkbox"/> Alport syndrome                             | <input type="checkbox"/> Thrombotic microangiopathy (TMA)                    |
| <input type="checkbox"/> Steroid resistant nephrotic syndrome (SRNS) | <input type="checkbox"/> Extended complement panel gene                      |
| <input type="checkbox"/> 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.





# Renal Molecular Genetics Sequencing Test Requisition

Affix patient sticker here

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

**Nephrology Gene Panel Ordered:**

- Steroid resistant nephrotic syndrome/FSGS panel
- Alport panel
- Thrombotic microangiopathy (TMA) / atypical HUS panel
- Extended Complement Panel
- C3 glomerulopathy (C3G)
- LIMS1 Genotyping Assay
- Other: \_\_\_\_\_
- Apolipoprotein (APOL1) genotyping

Reason(s) for testing:

- Diagnosis
- Assess risk
- Family history
- Other:

Prior renal biopsy evaluated at Arkana?

- Yes
- No

**Laboratory test values:**

- Creatinine
- Protein
- Levels not elevated
- Not present
- Current: \_\_\_\_\_ Baseline: \_\_\_\_\_
- 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
- Hispanic
- Asian
- American Indian
- White/Non-Hispanic Caucasian
- Native Hawaiian or Pacific Islander
- Ashkenazi Jewish
- Native Alaskan
- Other:

**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: \_\_\_\_\_



# Arkana Laboratories

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

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    ARHGDI1A    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