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)

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

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

Genetic Test Consent and Requisition Form

Specimen Information:  
- Kidney biopsy tissue  
- DNA  
- Blood

Nephrology Gene Panel Ordered:
- Steroid-resistant nephrotic syndrome/FSGS panel
- Alport panel
- C3 glomerulopathy (C3G)
- Apolipoprotein (APOL1) genotyping
- Thrombotic microangiopathy (TMA)/atypical HUS panel

Laboratory test values:
- Creatinine Levels not elevated
- Protein 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

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: ____________________________

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
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 #: __________________________

Instution:  [ ] 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.

______________________________  __________________________
Signatur (Ordering Physician)  Date
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  XPOS
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  SMARCA1  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