

REFERRING LABORATORY USE ONLY: please complete below section			FOR MORL USE ONLY:		
Requisition Date: _____		Completed by: _____		Accn#: _____	
Collection Dates Blood: _____		Serum: _____		Plasma: _____	
Part A) Patient Information (Required)			Part A,) Patient Demographic Information (Required)		
Name: _____ Last First DOB: ____/____/____ month day year Sex: <input type="checkbox"/> Male <input type="checkbox"/> Female MRN: _____			Ethnicity: <input type="checkbox"/> Hispanic <input type="checkbox"/> Not Hispanic Race: <input type="checkbox"/> Caucasian <input type="checkbox"/> Black or African American <input type="checkbox"/> Asian <input type="checkbox"/> American Indian/Alaska Native <input type="checkbox"/> Native Hawaiian or Other Pacific Islander <input type="checkbox"/> More Than One Race _____		
- OR Place patient ID sticker here -			Please note: We request extensive patient demographic and clinical information. This information is required as it is very valuable in the interpretation of your patient's results. Please check this requisition form. Did you provide the following? <input type="checkbox"/> Patient date of birth and gender; <input type="checkbox"/> Patient ethnicity and race; <input type="checkbox"/> Patient's clinical info and family history of kidney disease.		
Part B) Reporting Information (Required)			Part C) Payment Information (Required)		
Health Care Provider: _____			***The MORL will NOT submit to insurance.		
E-mail address: _____			Billing Contact: _____		
Institution: _____			Institution: _____		
Street Address: _____			Street Address: _____		
City: _____	State: _____	Zip: _____	City: _____	State: _____	Zip: _____
Phone: () _____		FAX: () _____	Phone: () _____		FAX: () _____
If you or your patient would like to pay by credit card please contact Jori Hendon at 319-335-6653					
Part D) Pertinent Clinical Information (Required) – Complete the section below					
* Diagnosis: <input type="checkbox"/> DDD; <input type="checkbox"/> C3GN; <input type="checkbox"/> TTP; <input type="checkbox"/> aHUS; <input type="checkbox"/> Other (complete): _____ Date of onset: _____ Family history of renal disease? <input type="checkbox"/> Yes <input type="checkbox"/> No					
Renal biopsy: <input type="checkbox"/> Yes <input type="checkbox"/> No Hematuria: <input type="checkbox"/> Yes <input type="checkbox"/> No Diarrhea: <input type="checkbox"/> Yes <input type="checkbox"/> No Schistocytes: <input type="checkbox"/> Yes <input type="checkbox"/> No Hg/Hct: _____ Haptoglobin: _____ Platelets: _____ sCr/BUN: _____ LDH: _____ uProt/uCr: _____		C3 Level: _____ nl range: _____ C4 Level: _____ nl range: _____ ADAMTS13 Level: _____ nl range: _____ Is Specimen: Eculizumab: <input type="checkbox"/> Pre <input type="checkbox"/> Post <input type="checkbox"/> N/A PLEX: <input type="checkbox"/> Pre <input type="checkbox"/> Post <input type="checkbox"/> N/A Renal Tx: <input type="checkbox"/> Pre <input type="checkbox"/> Post <input type="checkbox"/> N/A BMT: <input type="checkbox"/> Pre <input type="checkbox"/> Post <input type="checkbox"/> N/A Liver Tx: <input type="checkbox"/> Pre <input type="checkbox"/> Post <input type="checkbox"/> N/A		Comments: _____ _____ _____	
Part E1) Comprehensive Panel Tests—Serum & plasma samples MUST arrive frozen & LABELED as SERUM or PLASMA (EDTA or Citrate) or they will be rejected for testing. Do NOT freeze blood. Sample requirements on page 3					
<input type="checkbox"/> Genetic Renal Panel (DNA test for TTP, aHUS, HUS, DDD, C3G and other complement diseases)		The Genetic Renal Panel requires 1 sample <input type="checkbox"/> 8-10 cc EDTA whole blood (or 10 µg DNA, minimum concentration 50ng/ul) for panel: <i>CFH, CFI, MCP, CFB, CFHR5, C3, THBD, ADAMTS13, PLG, DGKE, MMACHC and MLPA.</i>			
<input type="checkbox"/> TMA Functional Panel (Serologies for TTP, aHUS, HUS)		Panel requires 2 samples: <input type="checkbox"/> 2ml frozen serum for: FH autoantibody, Hemolytic, CH50, APFA; <input type="checkbox"/> 2ml frozen EDTA plasma for: Bb, FH, FI, FB, C3, C4, soluble C5b-9 (sMAC)			
<input type="checkbox"/> C3G Functional Panel (Serologies for DDD, C3GN)		Panel requires 2 samples: <input type="checkbox"/> 2ml frozen serum for: FH autoantibody, FB autoantibody, Hemolytic, Nephritic Factors (Nef Activity Assay (IFE), C3Nef (C3CSA), C4Nef & C5Nef (C3CSAP)), CH50, APFA; <input type="checkbox"/> 2ml frozen EDTA plasma for: C3, C3c, C4, FB, FH, FI, Bb, Ba, C5, Properdin levels & soluble C5b-9 (sMAC)			

*** Diagnosis & Clinical Information are Required to Perform Testing**

Please see page 2 for MicroPanels, a la carte and Custom Tests

Specimen and shipping requirements along with CPT codes and prices can be found on our website: <https://morl.lab.uiowa.edu>.

Patient Name: _____ DOB: _____ MRN: _____

Part E2) Micro-Panel Tests – Serum & plasma samples MUST arrive frozen & LABELED as SERUM or PLASMA (EDTA or Citrate) or they will be rejected for testing. Sample requirements on page 3

Autoantibodies (also included on the TMA and C3G Functional Panels)

Autoantibody Micro-Panel (FH autoantibody, FB autoantibody, Nef Activity Assay (IFE), C3Nef (C3CSA), C4Nef, C5Nef (C3CSAP))
 requires 1 sample: 2ml frozen **serum**

Complement Biomarkers (also included on the TMA and C3G Functional Panels)

Complement Biomarker Micro-Panel (Ba, Bb, C3, C3c, C4, C5, FB, FH, FI, Properdin levels and soluble C5b-9)
 requires 1 sample: 2ml frozen **EDTA plasma**

Complement Pathway Function (also included on the TMA and C3G Functional Panels)

Complement Activity Micro-Panel (CH50, APFA, Hemolytic Assay)
 requires 1 sample: 2ml frozen **serum**

ADAMTS-13

ADAMTS-13 Activity (1ml frozen **Citrate plasma**) **ADAMTS-13 Inhibitor** (1ml frozen **Citrate plasma**) **ADAMTS-13 Activity with Inhibitor** (1ml frozen **Citrate plasma**)

Part E3) a la carte Autoantibody Tests – Serum samples MUST arrive frozen & LABELED as SERUM or they will be rejected for testing. Sample requirements on page 3

FH autoantibody – (appropriate for aHUS) - requires 1 sample:
 1ml frozen **serum**

Nef Activity Assay (IFE) – (appropriate for C3G) - requires 1 sample:
 1ml frozen **serum**

C4Nef – (appropriate for C3G) - requires 1 sample:
 1ml frozen **serum**

FB autoantibody – (appropriate for aHUS) - requires 1 sample:
 1ml frozen **serum**

C3Nef (C3CSA) – (appropriate for C3G) - requires 1 sample:
 1ml frozen **serum**

C5Nef (C3CSAP) – (appropriate for C3G) - requires 1 sample:
 1ml frozen **serum**

Part E4) a la carte Complement Proteins/Split Products Tests – Plasma samples MUST arrive frozen & LABELED as PLASMA (EDTA or Citrate) or they will be rejected for testing. Sample requirements on page 3

Ba (1ml frozen **EDTA plasma**) **Bb** (1ml frozen **EDTA plasma**) **C3** (1ml frozen **EDTA plasma**) **C3c** (1ml frozen **EDTA plasma**) **C4** (1ml frozen **EDTA plasma**)

C5 (1ml frozen **EDTA plasma**) **FB** (1ml frozen **EDTA plasma**) **FH** (1ml frozen **EDTA plasma**) **FI** (1ml frozen **EDTA plasma**) **Properdin** (1ml frozen **EDTA plasma**)

Soluble C5b-9 (sMAC) (1ml frozen **EDTA plasma**)

Part E5) a la carte Complement Pathway Function Tests – Plasma samples MUST arrive frozen & LABELED as SERUM or they will be rejected for testing. Sample requirements on page 3

CH50 (1ml frozen **serum**) **AP Functional Assay (APFA)** (1ml frozen **serum**) **Hemolytic Assay** (1ml frozen **serum**)

Part E6) A la carte Gene & CustomTests – requires 8-10 cc EDTA whole blood – Do NOT freeze blood

MLPA Testing **Familial Testing** Gene: _____ Mutation: _____

Custom Testing (Please contact Amy Weaver at 319-335-6623 or amy-weaver@uiowa.edu prior to order)

Details of request: _____

Ship all samples to:

Dr. Richard Smith
 Molecular Otolaryngology & Renal Research Laboratories
 The University of Iowa
 285 Newton Rd., 5270 CBRB
 Iowa City, IA 52242
 Phone: 319-335-6623

If serum and plasma samples do not arrive in the laboratory frozen OR labeled as to the type of sample they are (serum or type of plasma) they will be rejected for testing.

**PLEASE SEE PAGE 3 FOR SPECIMEN COLLECTION PROTOCOL AND REQUIREMENTS
 PLEASE SEE PAGE 4 FOR OTHER PERTINENT INFORMATION**

*** Diagnosis & Clinical Information are Required to Perform Testing**

Please see page 2 for MicroPanels, a la carte and Custom Tests

Specimen and shipping requirements along with CPT codes and prices can be found on our website: <https://morl.lab.uiowa.edu>.

Molecular Otolaryngology & Renal Research Laboratories Sample Requirements

CLIA#: 16D0966193

Please contact Amy Weaver at 319-335-6623 or amy-weaver@uiowa.edu if you have any questions

Genetic Renal Panel/MLPA/DNA Testing Sample Requirements: (shipping address at the bottom of page 2)

- 8-10 cc. EDTA whole blood (minimum amount of 3-4 cc. is accepted for children under age 4)
- **OR** 10 µg DNA, minimum concentration 50ng/ul (A260/A280 1.8-2) resuspended in 0.1mM EDTA (10mM Tris HCl, 0.1mM EDTA, pH 8, Teknova Cat# T0220)
Note: MORL is not responsible for broken tubes.
- Overnight delivery, Room temperature (**DO NOT FREEZE WHOLE BLOOD**)
- Samples are accepted Monday-Friday.
- Samples may be refrigerated if delivery is delayed (stability – 1 week)

Serum (FB & FH autoantibody, Hemolytic Assay, APFA, CH50, Nef Activity, C3Nef, C4Nef, C5Nef) Collection Protocol (minimum volume 2ml):

1. Follow standard phlebotomy techniques to collect at least **6 cc** of whole blood drawn in a red-top vacutainer tube.
 - a. *Note: Serum separators with “clot activators” should **not** be used for the serum samples.*
2. Allow the blood in the **red-top** tube to clot at room temperature for 30 minutes.
3. Centrifuge the clotted blood at room temperature (1000 x g for 10 minutes).
4. **Label “Serum” or “Red-top”** on 4 clean cryovial screw top tubes.
5. Pipette aliquots of 0.5ml - 1ml cell-free supernatant to each labeled tube.
6. **Place the tube immediately at -80°C (or on dry ice). Sample must remain frozen.**
Note: Do not transfer cells with serum. If necessary centrifuge a second time.

Plasma (sMAC - also called sC5b-9; C3, C3c, Ba, Bb, Properdin, C4, C5, FB, FH, FI levels) Collection Protocol (minimum volume: 2ml):

1. Follow standard phlebotomy techniques to collect at least **6 cc** of whole blood drawn in a **lavender-top** vacutainer tube.
2. Centrifuge at room temperature immediate after blood draw (1000 x g for 10 minutes).
3. **Label “Plasma” or “Lavender-top”** on 4 clean cryovial screw top tubes.
4. Pipette aliquots of 0.5ml - 1ml cell-free supernatant to each labeled tube.
5. **Place the tube immediately at -80°C (or on dry ice). Sample must remain frozen.**
Note: Do not transfer cells with plasma. If necessary centrifuge a second time.

Plasma (ADAMTS-13 Activity/Inhibitor) Collection Protocol (minimum volume: 0.5ml):

1. Follow standard phlebotomy procedure to collect blood in buffered sodium citrate (**light blue-top**, 3.2%) plastic tubes (available in 4.5 mL, 2.7 mL or 1.8 mL full draw tubes).
2. After collection, invert the tube gently 5 to 6 times.
3. **Label “Citrate Plasma” or “Blue-top”** on clean cryovial screw top tubes.
4. Store the blue-top tube upright at room temperature until centrifugation. Samples should be centrifuged between 15 to 60 minutes after blood collection for best results.
5. Re-mix the blood sample immediately prior to centrifugation by gently inverting the tube 5 to 6 times.
6. Centrifuge blood sample at room temperature in a horizontal rotor (swinging bucket rotor) for 15-20 minutes at 1500 to 1800 x g with the *brake off*.
7. Following centrifugation, transfer the top two-thirds of the plasma layer into a new plastic tube.
8. Re-centrifuge the collected plasma at 1500 to 1800 x g with the *brake off* for an additional 15-20 minutes to remove any red cells or platelets.
9. Transfer the top two-thirds of the plasma into the previously labeled cryovials, taking care not to disturb any cells at the bottom of the tube.
10. **Place the tube immediately at -80°C (or on dry ice). Sample must remain frozen.**
NOTE: if the sample arrives at room temperature a new sample will be required.

Serum & Plasma Shipping Requirements: (shipping address at the bottom of page 2)

- Serum and plasma must be **frozen** and shipped with a **minimum** of 2 kg (or 5 lbs) of dry ice.
- Cryovials should be put in zip lock bags and completely covered in dry ice to keep the sample frozen until it arrives in the lab.
- Delivery: Monday-Friday.
- **Thawed OR unlabeled samples will be rejected for testing.**

*** Diagnosis & Clinical Information are Required to Perform Testing**

Please see page 2 for MicroPanels, a la carte and Custom Tests

Specimen and shipping requirements along with CPT codes and prices can be found on our website: <https://morl.lab.uiowa.edu>.

DISCLAIMER:

This request to order molecular diagnostic tests from the MORL certifies to the MORL that the ordering physician has obtained informed consent from the patient as required by applicable state or federal laws for each test ordered, that the ordering physician has authorization from the patient permitting the MORL to report results for each test ordered to the ordering physician, and that the ordering physician assumes responsibility for providing the patient with all associated guidance and counseling regarding the test results.

ALL requested information must be provided or testing will not be performed

Specimen information: Patient identifiers (full name, date of birth, sex and medical record number)
Date of collection
Sample type – frozen samples must be CLEARLY labeled as either serum or plasma (and type, EDTA or Citrate)
Ordering physician

Billing information: We will **NOT** bill insurance, Medicare or patient directly.
Institutional billing accepted. Visa and Master Card accepted.
Personal checks **NOT** accepted.
Please include contact information including phone & fax number for billing questions.

Reporting Information: Because of confidentiality issues reports will only be released to the individual indicated on the page 1 of the testing requisition form.

Research Participation: If your patient's genetic and functional testing results are inconclusive they may qualify for research studies on complement mediated renal diseases that are ongoing at the MORL. If you would like your patient to be considered for this opportunity please contact Amy Weaver at amy-weaver@uiowa.edu.

IMPORTANT INFORMATION FOR PHYSICIAN OR GENETIC COUNSELOR:

DNA tests may detect an abnormality. Detection methods are greater than 99% accurate. Many of these tests are relatively new. The analysis and interpretation represents our best knowledge and understanding of the genetics of these diseases.

There is a small possibility that a test may not work properly or an error may occur. You may be asked for an additional sample if it is felt that confirmatory testing is needed.

An error in diagnosis may occur if incorrect information is provided with the sample.

Kidney diseases are complex disorders and penetrance of a phenotype (the degree of kidney disease, for example) may be variable. Research to determine whether a genotype-phenotype correlation exists is ongoing.

Because of the complexity of DNA testing, results should be discussed with a genetic counselor or physician.

Note: Kidney diseases are very complex disorders. This complexity means that mutations in many different genes can lead to kidney disease. It is possible that no mutations will be detected in the mutation screens (the genes) you have requested.

*** Diagnosis & Clinical Information are Required to Perform Testing**

Please see page 2 for MicroPanels, a la carte and Custom Tests

Specimen and shipping requirements along with CPT codes and prices can be found on our website: <https://morl.lab.uiowa.edu>.