Molecular Otolaryngology & Renal Research Laboratories
For test inquiries please call: 319-335-6623 • For billing inquiries call: 319-467-1647
Fax: 319-353-5869 or 319-335-9890
Email: morl@uiowa.edu • https://morl.lab.uiowa.edu
CLIA: 16D0966193

Clear Form

MORL - Kidney Testing Requisition Form

REFERRING LABORATORY USE ONLY: *please complete below section*

Requisition Date: Completed by: Accn#:

FOR MORL USE ONLY:
MORL Case #:

Collection: Blood Date/Time: _____ #Tubes:_____ Serum Date/Time: _____ #Tubes: _____ Plasma Date/Time: _____ #Tubes: _____

Part A) Patient Information or ID Sticker *(Required)*

Name: _____
Last First

DOB: _____ / _____ / _____ **Sex**: ☐ Male ☐ Female
month day year *(please check sex assigned at birth)*

Height: _____ **BMI**: _____

MRN: _____

Part A$_1$) Patient Demographic Information *(Required)*

Ethnicity: ☐ Hispanic ☐ Not Hispanic

Race: ☐ White ☐ Black or African American
☐ Asian ☐ American Indian/Alaska Native
☐ Native Hawaiian or Other Pacific Islander
☐ More Than One Race _____

Part B) Reporting Information *(Required)*

Healthcare Provider:

E-mail Address:

Institution:

Street Address:

City: State: Zip:

Phone: ( ) FAX: ( )

Part C) Payment Information (*Required*)

Institutional billing or payment by Visa or MasterCard is accepted.

***The MORL will NOT submit to insurance.**

Billing Contact:

Institution:

Street Address:

City: State: Zip:

Phone: ( ) FAX: ( )

If you or your patient would like to pay by credit card, please contact us at morl@uiowa.edu for instructions

Part D) Pertinent Clinical Information (*Required*) – Complete the section below

Diagnosis: ☐ aHUS: Trigger? ☐ **No** ☐ **Yes** *(if **yes**, describe trigger, eg. BMT, pregnancy, pneumococcal)*: _____
☐ DDD ☐ C3GN ☐ PIGN ☐ TTP ☐ STEC-HUS ☐ Other (complete): _____

Family history of renal disease? ☐ **No** ☐ **Yes** *(if **yes**, please provide details in comment & attach a pedigree if available)*

Disease History **Date of symptom onset:** _____

Renal Biopsy: ☐ **Yes** ☐ **No** **Date:** _____
Hematuria: ☐ **Yes** ☐ **No**
Diarrhea: ☐ **Yes** ☐ **No**
Schistocytes: ☐ **Yes** ☐ **No**

Current Lab Values

	Value	Normal Range	Test Date
Hg/Hct:			
Haptoglobin:			
Platelets:			
sCr/BUN:			
eGFR:			
LDH:			
uProt/uCr:			
Urine Blood:			
C3 Level:			
C4 Level:			
ADAMTS13:			

Specimen Information:

Was specimen drawn pre or post:	Procedure date:	Pre	Post	N/A
Eculizumab:		☐	☐	☐
PLEX (*affects serologies):		☐	☐	☐
Renal Tx:		☐	☐	☐
BMT (*affects genetics):		☐	☐	☐
Liver Tx:		☐	☐	☐

Comments:

MORL Molecular Otolaryngology & Renal Research Laboratories | IOWA HEALTH CARE

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Patient Name: _____ **DOB:** _____ **MRN:** _____

Please see page 3 for sample processing & handling requirements - No Weekend Deliveries

Genetic Testing

☐ **Genetic Renal Panel (GRP) with MLPA**
(Next Generation Sequencing (NGS) Testing for TTP, aHUS, HUS, DDD, C3G and other complement diseases)
(CFH, CFI, MCP, CFB, CFHR5, C3, THBD, ADAMTS13, PLG, DGKE, G6PD, MMACHC, WT1, C5, c.2653C>T, p.Arg885Cys and c.2654G>A, p.Arg885His, MLPA testing is included with this panel*)*

Sample Collection Information (see page 3, # 1)

Genetic Testing requirements:
- 3-5 cc EDTA whole blood (room temp or refrigerated)
OR
- Saliva (OraGene OGR-500 kit) – ***recommended for BMT recipients***
OR
- Buccal swabs, no less than 4 swabs (OraCollect OCD-100)
OR
- 5 µg DNA, minimum concentration 50 ng/µl

Functional Testing

Sample Collection Information see page 3, # 2 and #3)

☐ **C3 Glomerulopathy Complement Panel (C3G-CP)**
(Serologies for complement-mediated renal diseases) (CH50, APFA, C3b Deposition Assay, FHAA, FBAA, Fluid Phase Activity Assay (IFE), Nephritic Factors (C3Nef, C5Nef, C4Nef), C3, C3c, C4, FB, Ba, Bb, FD, Properdin, C5, Soluble C5b-9, FH and FI levels)

☐ **aHUS (complement-mediated TMA) Panel (aHUS-FP)**
(This panel includes all tests on the C3G-CP Panel except for C3Nef, C5Nef and C4Nef)

C3 Glomerulopathy Complement Panel (C3G-CP) and aHUS (complement mediated TMA) Panel (aHUS-FP) requirements:
- 2 mL frozen serum (red-top)
AND
- 2 mL frozen EDTA plasma (lavender-top)

Any request for these panels without both serum (red-top) & plasma (lavender-top) will be rejected

☐ **Complement Biomarker Panel (CBP)**
(C3, C3c, C4, FB, Ba, Bb, FD, Properdin, C5, Soluble C5b-9, FH and FI levels)

Complement Biomarker Panel (CBP) requirements:
- 2 mL frozen EDTA plasma (lavender-top)

☐ **Autoantibody Panel (AAP)**
(FHAA, FBAA, Fluid Phase Activity (IFE), Nephritic Factors (C3NeF, C5Nef, C4Nef)

☐ **Complement Pathway Activity Panel (CPAP)**
(CH50, APFA, C3b Deposition Assay)

Autoantibody Panel (AAP) and Complement Pathway Activity Panel (CPAP) requirements:
- 2 mL frozen serum (red-top)

a La Carte Tests

Autoantibody Tests – 1 mL Frozen Serum

☐ **FH Autoantibody (FHAA)** ☐ **FB Autoantibody (FBAA)**
☐ **Fluid Phase Activity (IFE)** ☐ **C3Nef (C3CSA)**
☐ **C5Nef (C3CSAP)** ☐ **C4Nef**

Biomarker Tests – 1 mL Frozen EDTA Plasma

☐ **C3 Level** ☐ **C4 Level** ☐ **C3c Level ***
☐ **FD Level** ☐ **FB Level** ☐ **Ba Level ***
☐ **Properdin Level** ☐ **C5 Level** ☐ **Bb Level ***
☐ **FH Level** ☐ **FI Level** ☐ **Soluble C5b-9 ***

* Indicates complement activation products

Complement Pathway Function Tests – 1 mL Frozen Serum

☐ **CH50** ☐ **C3b Deposition Assay**
☐ **APFA (Alternative Pathway Functional Assay)**

ADAMTS-13 Tests – 1 mL Frozen Citrate Plasma ***(see page 3, # 4)***

☐ **ADAMTS-13 Activity**
☐ **ADAMTS-13 Activity with reflex to Inhibitor** (when activity <25%)

Genetic Tests – Whole Blood, Saliva, DNA

☐ **MLPA Testing ONLY** (CNVs in *CFH-CFHR5* genomic region)
☐ **Familial Testing** (site specific analysis for variants previously identified in a family member)

Familial Testing Details, Gene/s: _____
MORL ID# or Variant/s: _____
Relationship to previously tested person: _____

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Molecular Otolaryngology & Renal Research Laboratories Sample Requirements

*Questions? Tel: 319-335-6623 or **morl@uiowa.edu***

1) Genetic Testing Requirements – If minimum volume/concentration of blood and/or DNA not set, sample will be REJECTED

- **3**-5 cc. EDTA whole blood – *MORL not responsible for broken tubes*
- Saliva (OraGene OGR-500 kit) OR Buccal swabs, no less than 4 swabs (OraCollect OCD-100)
- 5 µg DNA, minimum concentration 50ng/µl (A260/A280 1.8-2) resuspended in 0.1mM EDTA (10mM Tris HCl, 0.1mM EDTA, pH 8, Teknova Cat# T0220)
- ***Please note: blood samples drawn from a bone marrow transplant patient will result in genetic results for the donor rather than the patient, saliva samples are recommended.**
- Overnight delivery, Room temperature or refrigerated (DO NOT FREEZE WHOLE BLOOD)
- Samples are accepted Monday-Friday.
- Samples may be refrigerated if delivery is delayed (stability – 1 week)

2) Serum Collection Protocol (minimum volume 2ml)

***PLEX treatments will affect serum tests, please wait ~14 days after PLEX to draw samples**

1. Follow standard phlebotomy techniques to collect at least **6 cc** of whole blood drawn in a **red-top** vacutainer tube.
   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 clean screw top-tube (s).
5. Pipette **cell-free supernatant** (at least 2 mL) to each labeled tube (s).
6. **Place the tube immediately at -80°C (or on dry ice). Sample must remain deep frozen.**
   Note: Do not transfer cells with serum. If necessary, centrifuge a second time.

3) Plasma Collection Protocol (minimum volume: 2ml)

***PLEX treatments will affect plasma tests, please wait ~14 days after PLEX to draw samples**

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

4) 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*.

1. Following centrifugation, transfer the top two-thirds of the plasma layer into a new plastic tube.
2. 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.
3. 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.
7. **Place the tube immediately at -80°C (or on dry ice). Sample must remain deep frozen.**

Note: if the sample arrives at room temperature a new sample will be required.

Serum & Plasma Shipping Requirements:

- **Serum and plasma must be frozen and shipped OVERNIGHT with a minimum of 3 kg (or 6 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. NO WEEKEND DELIVERIES**
- **Thawed OR unlabeled samples will be REJECTED for testing.**

Ship all samples to:

Dr. Richard Smith
Molecular Otolaryngology & Renal Research Laboratories
The University of Iowa
285 Newton Rd., 5270 CBRB
Iowa City, IA 52242-1078
Phone: 319-335-6623

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Complement Panel tests offered by the MORL:	Test Code:
C3 Glomerulopathy Complement Panel (serologies for DDD, C3GN), Serum and Plasma - CH50, APFA, C3b Deposition Assay, FHAA, FBAA, Fluid Phase Activity Assay-IFE, Nephritic Factors (C3Nef-C3CSA, C5Nef-C3CSAP, C4Nef), C3, C3c, C4, FB, Ba, Bb, FD, Properdin, C5, Soluble C5b-9, FH and FI levels	C3G-CP
aHUS (complement-mediated TMA Functional Panel (serologies for TTP, aHUS, HUS), Serum and Plasma - CH50, APFA, C3b Deposition, FHAA, FBAA, Fluid Phase Activity-IFE, C3, C3c, C4, FB, Ba, Bb, FD, Properdin, C5, Soluble C5b-9, FH and FI levels	aHUS-FP
Autoantibody Panel, Serum - FHAA, FBAA, Fluid Phase Activity-IFE, Nephritic Factors (C3Nef-C3CSA, C5Nef-C3CSAP, C4Nef)	AAP
Complement Biomarker Panel, Plasma - C3, C3c, C4, FB, Ba, Bb, FD, C5, Properdin levels, soluble C5b-9, FH and FI levels	CBP
Complement Pathway Activity Panel, Serum - CH50, APFA, C3b Deposition Assay	CPAP

Autoantibodies to Complement Components	Test Code:
Fluid Phase Activity Assay, Serum (IFE)	07FPA
FH Autoantibody, Serum (ELISA)	07FHAA
FB autoantibody, Serum (ELISA)	07FBAA
C3Nef, Serum (Hemolytic)	06C3NEF
C5Nef, Serum (Hemolytic)	06C5NEF
C4Nef, Serum (Hemolytic)	06C4NEF

Functional Assays of Complement Activity - Pathways	Test Code:
CH50, Serum (Liposome-based method)	07CH50
Alternative Pathway Functional Assay (APFA), Serum (ELISA)	06APFA
C3b Deposition Assay (Hemolytic)	01C3BDA

Complement Protein Biomarkers (including split products)	Test Code:
C3 Level, Serum or Plasma (Turbidmetry)	07C3L
C3c Level, Plasma (ELISA)	06C3CL
C4 Level, Serum or Plasma (Turbidmetry)	07C4L
FB Level, Plasma (ELISA)	07FBL
Ba Level, Plasma (ELISA)	06BAL
Bb Level, Plasma (ELISA)	06BBL
FD Level, Plasma (ELISA)	06C5L
Properdin Level, Plasma (ELISA)	06PL
C5 Level, Plasma (ELISA)	06C5L
Soluble C5b-9, Plasma (ELISA)	06SMAC
FI Level, Plasma (ELISA)	07FIL
FH Level, Plasma (ELISA)	06FHL

ADAMTS-13	Test Code:
ADAMTS-13 Activity (a la carte only), Citrate Plasma (FRET)	01ATS13
ADAMTS-13 Activity with reflex to Inhibitor Assay (if activity is <25%), Citrate Plasma (FRET)	01ATS13RFX

Genetic Tests Offered by the MORL:	Test Code:
Genetic Renal Panel: NGS + MLPA (CNVs) for Complement-Mediated Kidney Disease	GRP08
MLPA (*CFH-CFHR5*): Multiplex Ligation Dependent Probe Amplification	MLPA02

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DISCLAIMER:
This request to order molecular diagnostic tests from the MORL certifies to the MORL that the ordering healthcare provider has obtained informed consent from the patient as required by applicable state or federal laws for each test ordered, that the ordering healthcare provider has authorization from the patient permitting the MORL to report results for each test ordered to the ordering physician, and that the ordering healthcare provider 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

Patient information:	Patient date of birth and gender Patient ethnicity and race Patient's clinical information and family history of kidney disease
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 Healthcare Provider
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**.

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.

IMPORTANT INFORMATION FOR HEALTHCARE PROVIDERS:

DNA tests may detect an abnormality. Detection methods are greater than 99% accurate. Many of these tests are relatively new. The analysis and interpretation represent 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 variants in many different genes can lead to kidney disease. It is possible that no variants will be detected in the variant screens (the genes) you have requested.