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# Molecular Otolaryngology & Renal Research Laboratories

For test inquiries please call: 319-335-6623 • For billing inquiries call: 319-335-6653

Fax: 319-353-5869 or 319-335-9890

Email: morl@uiowa.edu • https://morl.lab.uiowa.edu
CLIA: 16D0966193

# **MORL - Kidney Testing Requisition Form**

REFERRING LABORATORY USE ONLY: please complete below section		FOR MORL USE ONLY	:	
Requisition Date: Completed by: Accn#:		MORL Case #:		
Collection: Blood Date: #Tubes: Serum Date:	#Tubes: Plasma Date:	#Tubes		
Part A) Patient Information or ID Sticker (Required)	Part A <sub>1</sub> ) Patient Demogra			
Name:	Ethnicity: Hispanic	Not Hispanio	-	
Last First				
DOB:/	Race: Caucasian Asian	<b>=</b>	can American	
month day year	Asian American Indian/Alaska Native Native Hawaiian or Other Pacific Islander			
Sex: ☐ Male ☐ Female				
MRN:	iviore inan	One Race		
Part B) Reporting Information ( <u>Required</u> )	Part C) Payment Information ( <u>Required</u> ) Institutional billing or payment by Visa or MasterCard is accepted.			
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: St	ate:	Zip:	
Phone: ( ) FAX: ( )	Phone: ( )	FAX: ( )		
If you or your patient would like to pay by o	redit card please contact Jori I	lendon at 319-335-	6653	
Part D) Pertinent Clinical Information (Required) – Comple	te the section below			
Diagnosis: aHUS: Trigger? No Yes (if <u>yes</u> , describe trig	gger, eg. BMT, pregnancy, pneumococ	cal):		-
	TEC-HUS	e):		
Family history of renal disease? No Yes (if <u>yes</u> , please provide	details in comment & attach a pedigre	e if available)		
Disease History Date of onset of symptoms:	Specimen Information:			_
os zeven Date	Was specimen drawn Proc pre or post:	edure date: Pre-Pro	cedure Post- Procedure	N/A
C4 Level: nl range: Date:	Eculizumab:			
	PLEX (*affects serologies):			
. — —	Renal Tx:			
Schistocytes: D. D.	BMT(*affects genetics):			
Command Lab Malura	Liver Tx:		]	
Value Normal Range Test Date			<b>-</b>	Ш
Hg/Hct:	Comments:			
Haptoglobin:				
Platelets:				
sCr/BUN:				
LDH:				
uProt/uCr:				
Urine Blood:				
C3 Level:				
C4 Level:				



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DOB: Patient Name: MRN: Please see page 3 for sample handling requirements - No Weekend Deliveries **Functional Testing Panels Requested Genetic Testing Requested** C3 Glomerulopathy Complement Panel (C3G-CP) Genetic Renal Panel (DNA test for TTP, aHUS, HUS, DDD, C3G and (serologies for complement-mediated renal diseases) other complement diseases) (CH50, APFA, C3b Deposition Assay, Fluid Phase Activity (CFH, CFI, MCP, CFB, CFHR5, C3, THBD, ADAMTS13, PLG, (IFE), FHAA, FBAA, Nephritic Factors (C3Nef (C3CSA), DGKE, G6PD, MMACHC, WT1 and MLPA analysis) C5Nef (C3CSAP) C4Nef), C3, C3c, C4, FD, FB, Ba, Bb, C5, • 8-10 cc EDTA whole blood (room temp or refrigerated) Properdin, Soluble C5b-9, FI and FH levels) • 2 mL frozen serum • 10 μg DNA, minimum concentration 50 ng/μl • 2 mL frozen EDTA plasma П MLPA Testing ONLY (screening for copy number variations in the CFH-CFHR5 genomic region) aHUS (complement-mediated TMA) Panel (aHUS-FP) • 8-10 cc EDTA whole blood (room temp or refrigerated) (CH50, APFA, C3b Deposition Assay, FHAA, FBAA, Fluid Phase Activity (IFE), C3, C3c, C4, FD, FB, Ba, Bb, C5, Properdin, • 10 μg DNA, minimum concentration 50 ng/μl Soluble C5b-9, FI and FH levels) • 2 mL frozen serum • 2 mL frozen EDTA plasma Familial Testing (site specific analysis to screen for variants previously identified in a family member) Autoantibody Panel (AAP) **Familial Testing Details:** (FHAA, FBAA, Fluid Phase Activity (IFE), Nephritic Factors (C3Nef (C3CSA), C5Nef (C3CSAP), C4Nef)) Gene/s: • 2 mL frozen serum MORL ID# or Variant/s: \_\_\_\_\_ Complement Biomarker Panel (CBP) (C3, C3c, C4, FD, FB, Ba, Bb, C5, Properdin levels, Soluble Relationship to C5b-9, FH and FI levels) previously tested person: • 2 mL frozen serum • 2 mL frozen EDTA plasma **Complement Pathway Activity Panel (CPAP)** If you are interested in ordering Custom Testing please contact (CH50, APFA, C3b Deposition Assay) Amy Weaver at 319-335-6623 or amy-weaver@uiowa.edu 2 mL frozen serum a la carte Testing Requested Important Information for <u>ALL</u> Requests Autoantibody Tests - 1 mL Frozen Serum All serum and plasma samples MUST be processed and frozen down ☐ FH autoantibody (FHAA) ☐ FB autoantibody (FBAA) to -80°C immediately after collection (please see instructions on page 3). Sample type must be clearly labeled (either serum or ☐ Fluid Phase Activity (IFE) ☐ C3Nef (C3CSA) plasma) and shipped out overnight on at least 5 lb dry ice ☐ C5Nef (C3CSAP) ☐ C4Nef (Monday - Thursday). Biomarker Tests - 1 mL Frozen EDTA Plasma If samples arrive thawed they will be REJECTED. ☐ **C3 Level** (1 mL frozen serum) ☐ C3c Level **No Weekend Deliveries** ☐ **C4 Level** (1 mL frozen serum) ☐ FD Level ☐ FB Level ☐ Ba Level ☐ Bb Level Molecular Otolaryngology & Renal Research Laboratories ☐ C5 Level Properdin Level ☐ Soluble C5b-9 For test inquiries please call: 319-335-6623 • Fax: 319-353-5869 For billing inquiries please call: 319-335-6653 • Fax: 319-353-5869 ☐ FH Level ☐ FI Level Email: morl@uiowa.edu • https://morl.lab.uiowa.edu Complement Pathway Function Tests - 1 mL Frozen Serum Ship to: ☐ CH50 ☐ C3b Deposition Assay Dr. Richard Smith ■ APFA (Alternative Pathway Functional Assay) Molecular Otolaryngology & Renal Research Laboratories The University of Iowa ADAMTS-13 Tests - 1 mL Frozen Citrate Plasma 285 Newton Rd., 5270 CBRB □ ADAMTS-13 Activity Iowa City, IA 52242-1078 ADAMTS-13 Activity with reflex to Inhibitor (when activity <25%) Monday — Friday ONLY – No Weekend Deliveries



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## Molecular Otolaryngology & Renal Research Laboratories Sample Requirements

Questions? Contact Amy Weaver at 319-335-6623 or amy-weaver@uiowa.edu

## **Genetic Renal Panel/MLPA/DNA Testing Sample Requirements:**

- 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/μl (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.
- \*Please note: blood samples drawn from a bone marrow transplant patient will result in genetic results for the <u>donor</u> rather than the patient.
- 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)

Serum (FB & FH autoantibody, C3b Deposition, APFA, CH50, Fluid Phase Activity (IFE), C3Nef (C3CSA), C5Nef (C3CSAP), C4Nef, C3 and C4 Levels) Collection Protocol (minimum volume 2ml) \*PLEX treatments will affect serum tests, please wait ~14 days after PLEX to draw samples:

- 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).
- 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.

### Plasma (soluble C5b-9, C3c, Ba, Bb, Properdin, C5, FD, FB, FH, FI levels) 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 immediately 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.

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

- 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.
- Label "Citrate Plasma" or "Blue-top" on clean cryovial screwtop 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.
- 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*.

- Following centrifugation, transfer the top two-thirds of the plasma layer into a new plastic tube.
- 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.
- 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.
- 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 <u>frozen</u> 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, Fluid Phase Activity (IFE), FHAA, FBAA, Nephritic Factors (C3Nef (C3CSA), C5Nef (C3CSAP), C4Nef), C3, C3c, C4, FD, FB, Bb, Ba, C5, Properdin, Soluble C5b-9 (sC5b-9), FI and FH levels	
<b>aHUS (complement-mediated TMA) Panel (serologies for TTP, aHUS, HUS), Serum and Plasma -</b> CH50, APFA, C3b Deposition Assay, FHAA, FBAA, Fluid Phase Activity (IFE), C3, C3c C4, FD, FB, Ba, Bb, C5, Properdin, Soluble C5b-9 (sC5b-9), FI and FH levels	aHUS-FP
<b>Autoantibody Panel, Serum</b> - Fluid Phase Activity Assay (IFE), FHAA, FBAA, Nephritic Factors (C3Nef (C3CSA), C5Nef (C3CSAP), C4Nef)	AAP
<b>Complement Biomarker Panel, Serum and Plasma -</b> C3, C3c, C4, FB, Ba, Bb, C5, FD, Properdin levels, Soluble C5b-9 (sC5b-9), FI and FH levels	
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)	
C3Nef (C3CSA), Serum (Hemolytic)	
C5Nef (C3CSAP), 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 (Cell-based assay)	01C3BDA
Complement Protein Biomarkers (including split products)	Test Code:
C3 Level, Serum (Turbidimetry)	07C3L
C3c Level, Plasma (ELISA)	06C3CL
C4 Level, Serum (Turbidimetry)	07C4L
FD Level, Plasma (ELISA)	01FDL
FB Level, Plasma (RID)	07FBL
Ba Level, Plasma (ELISA)	06BAL
Bb Level, Plasma (ELISA)	06BBL
C5 Level, Plasma (ELISA)	06C5L
Properdin Level, Plasma (ELISA)	06PL
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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# ALL requested information must be provided or testing will not be performed

We request extensive patient demographic and clinical information. This information is <u>required</u> as it is very valuable in the interpretation of your patient's results.

**Patient information:** 

- Patient date of birth and gender
- Patient ethnicity and race
- Patient's clinical information and family history of kidney disease
- Patient identifiers (full name, date of birth, sex and medical record number)
- Date of collection

**Specimen information:** 

- Sample type frozen samples must be CLEARLY LABELED as either serum or plasma and type (i.e. EDTA or Citrate)
- Ordering physician
- We are not able to bill insurance, Medicare or patient directly.
- Institutional billing accepted. Visa and Mastercard accepted.
- Personal checks NOT accepted
- Please include contact information including phone and fax number for billing questions.

**Reporting Information:** 

**Billing 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 <a href="may-weaver@uiowa.edu">amy-weaver@uiowa.edu</a>.

# 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 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.

### **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.