

DENSE DEPOSIT DISEASE AND C3 GLOMERULONEPHRITIS TEST REQUISITION

All Information Must Be Completed Before Sample Can Be Processed

PATIENT INFORMATION

Patient Name: _____, _____, _____
Last First MI

Address: _____

Home Phone: _____

MR# _____ Date of Birth ____/____/____

Gender: Male Female

ETHNIC/RACIAL BACKGROUND (Choose All)

- European American (White) African-American (Black)
 Native American or Alaskan Asian-American
 Pacific Islander Ashkenazi Jewish ancestry
 Latino-Hispanic _____
 (specify country/region of origin)
 Other _____
 (specify country/region of origin)

BILLING INFORMATION (Choose ONE method of payment)

REFERRING INSTITUTION

Institution: _____

Address: _____

City/State/Zip: _____

Accounts Payable Contact Name: _____

Phone: _____

Fax: _____

Email: _____

COMMERCIAL INSURANCE*

Insurance can only be billed if requested at the time of service.

Policy Holder Name: _____

Gender: _____ Date of Birth ____/____/____

Authorization Number: _____

Insurance ID Number: _____

Insurance Name: _____

Insurance Address: _____

City/State/Zip: _____

Insurance Phone Number: _____

* PLEASE NOTE:

- We will not bill Medicaid, Medicaid HMO, or Medicare except for the following: CCHMC Patients, CCHMC Providers, or Designated Regional Counties.
- Commercial Insurance Precertification for genetic testing available upon request. Test(s) will not be started until authorization is obtained.
- If you have questions, please call 1-866-450-4198 for complete details.

REFERRING PHYSICIAN

Physician Name (print): _____

Address: _____

Phone: (____) _____ Fax: (____) _____ Email: _____

Genetic Counselor/Lab Contact Name: _____

Phone: (____) _____ Fax: (____) _____ Email: _____

Date: ____/____/____

Referring Physician Signature (REQUIRED)

Patient signed completed ABN

Medical Necessity Regulations: At the government's request, the Molecular Genetics Laboratories would like to remind all physicians that when ordering tests that will be paid under federal health care programs, including Medicare and Medicaid programs, that these programs will pay only for those tests the relevant program deems to be (1) included as covered services, (2) reasonable, (3) medically necessary for the treatment and diagnosis of the patient, and (4) not for screening purposes.

CLINICAL AND LABORATORY INFORMATION (If Available)

Is the patient receiving plasma infusion or plasmapheresis? Yes No

Creatinine: _____

If yes, date: _____

C3: _____ C4: _____

Proband Family

Has the patient had a kidney biopsy (Y/N)? _____

If so, what was the diagnosis? _____

- | | | |
|--------------------------|--------------------------|----------------------|
| <input type="checkbox"/> | <input type="checkbox"/> | Renal disease |
| <input type="checkbox"/> | <input type="checkbox"/> | Macular degeneration |
| <input type="checkbox"/> | <input type="checkbox"/> | Other: _____ |

SAMPLE/SPECIMEN INFORMATION

Collection Date: _____

Has patient received a bone marrow transplant? Yes No

Time: _____

If yes, date of bone marrow transplant _____

Percent engraftment _____

Please send saliva kit and two cytobrushes. Note: STR analysis at an additional charge is required on cytobrushes and saliva samples obtained on all patients post BMT.

TEST(S) REQUESTED

Please see page 3 of requisition for sample requirements.

QUANTITATIVE COMPLEMENT TESTING

- Complete Complement Profile
(Includes C3, C4, C1q, C2, C5, C6, C7, C8, C9, Factor H, Factor I, Factor B, Properdin, C1 Inhibitor, and C4 Binding Protein)
- Factor B
- Factor H
- Factor I
- C5
- C6
- C7
- C8
- C9
- Properdin

GENETIC TESTING

- Dense Deposit Disease/C3 Glomerulonephritis Sequencing Panel**
(Includes sequence analysis of C3, CD46 (MCP), CFB, CFD, CFH, CFHR5, CFI, and CFHR2)
- Reflex to deletion/duplication of C3, CD46 (MCP), CFB, CFD, CFH, CFHR5 and CFI

CUSTOM GENE SEQUENCING AND DEL/DUP

Gene(s) to be sequenced (specify): _____

Suspected syndrome/ condition: _____

Please choose one of the following:

- Full gene(s) sequencing
- Full gene(s) sequencing with reflex to deletion and duplication analysis, if indicated¹
- Reflex to deletion/duplication of single gene(s)¹ (specify): _____

¹Deletion/Duplication analysis of CFHR2 is not available at this time. Please see list of genes available for del/dup at www.cincinnatichildrens.org/deldup

- Familial variant analysis
Proband's name: _____
Proband's DOB: _____
Proband's variant: _____
Patient's relation to proband: _____

If testing was not performed at Cincinnati Children's, please include proband's report and at least 100ng of proband's DNA to use as a positive control.

AUTOANTIBODY TESTING

- Factor H Autoantibody
- C3 Nephritic Factor

COMPLEMENT ACTIVATION MARKERS

- C3a (0.5 mL EDTA plasma - frozen sep. aliq.)
- C5a (0.5 mL EDTA plasma - frozen sep. aliq.)
- sC5b-9 (sMAC) (0.5 mL EDTA plasma - frozen sep. aliq.)
- Bb (0.5 mL plasma [serum also accepted] - frozen sep. aliq.)

ECULIZUMAB MONITORING

- Eculizumab Pharmacokinetic Assay**
(Includes Eculizumab level and CH50. For assessing complement activity to monitor patients on eculizumab therapy)
- Eculizumab Level
- CH50

DENSE DEPOSIT DISEASE AND C3 GLOMERULOPATHY TESTING INFORMATION SHEET

SHIP SAMPLES TO: 3333 Burnet Avenue NRB 1042, Cincinnati, OH 45229
LOCAL OR COURIER SAMPLES: deliver to NRB 1013

Test Name	Performing Lab	Specimen Requirements	TAT/ Days Performed	CPT Codes
Complete complement profile	Nephrology 513-636-4530	1 mL red top serum- spun, separated, frozen within 2 hrs of collection; ship on dry ice	2 weeks	86160 x15
Single complement component (C3, C4, C1q, C2, C5, C6, C7, C8, C9, Factor H, Factor I, Factor B, Properdin)	Nephrology 513-636-4530	0.5 mL red top serum- spun, separated, frozen within 2 hrs of collection; ship on dry ice	2 weeks	86160
Eculizumab Level	Nephrology 513-636-4530	0.5 mL red top serum- spun, separated, frozen within 2 hrs of collection; ship on dry ice	24 hours/ Mon, Wed, Fri	80299
CH50	Nephrology 513-636-4530	0.5 mL red top serum- spun, separated, frozen within 2 hrs of collection; ship on dry ice	24 hours/ Mon, Wed, Fri	86162
Factor B	Nephrology 513-636-4530	0.5 mL red top serum- spun, separated, frozen within 2 hrs of collection; ship on dry ice	3 days, Mon, Fri	86160
Factor H	Nephrology 513-636-4530	0.5 mL red top serum- spun, separated, frozen within 2 hrs of collection; ship on dry ice	3 days/ Mon, Fri	86160
Factor I	Nephrology 513-636-4530	0.5 mL red top serum- spun, separated, frozen within 2 hrs of collection; ship on dry ice	3 days/ Mon, Fri	86160
Factor H Autoantibody	Nephrology 513-636-4530	0.5 mL red top serum- spun, separated, frozen within 2 hrs of collection; ship on dry ice	24 hours/ Mon, Thurs stat available	83516
C3 Nephritic Factor	Nephrology 513-636- 4530	1 mL red top serum- spun, separated, frozen within 2 hrs of collection; ship on dry ice	2 weeks	86160 x4
Bb	Nephrology 513-636-4530	0.5 mL EDTA plasma-spun, separated, frozen within 2 hrs of collection; ship on dry ice	1 week	86160
sC5b-9 (sMAC)	Cancer and Blood Disease Institute 513-803-3503	0.5 mL EDTA plasma – spun, separated, frozen within 2 hrs of collection, separate aliquot each test; ship on dry ice	1 week	86160
C3a	Cancer and Blood Disease Institute 513-803-3503	0.5 mL EDTA plasma – spun, separated, frozen within 2 hrs of collection, separate aliquot each test; ship on dry ice	2 weeks	86160
C5a	Cancer and Blood Disease Institute 513-803-3503	0.5 mL EDTA plasma – spun, separated, frozen within 2 hrs of collection, separate aliquot each test; ship on dry ice	2 weeks	86160
Dense Deposit Disease/C3 Glomerulonephritis Sequencing Panel (C3, CD46 (MCP), CFB, CFH, CFHR5, CFI, CFD, and CFHR2)	Laboratory of Genetics and Genomics 513-636-4474	3 mL EDTA – whole blood- room temperature*	28–42 days	81479 x4
Custom Gene Sequencing for C3, CD46 (MCP), CFB, CFH, CFHR5, CFI, CFD, and CFHR2	Laboratory of Genetics and Genomics 513-636-4474	3 mL EDTA – whole blood- room temperature*	28–42 days	81479
Deletion/duplication analysis of C3, CFB, CFI, and/or CFD	Laboratory of Genetics and Genomics 513-636-4474	3 mL EDTA – whole blood- room temperature* for each gene tested	28 days	81479 for each gene tested
Any other single gene sequencing test	Laboratory of Genetics and Genomics 513-636-4474	3 mL EDTA – whole blood- room temperature*	28 days	81479
Targeted mutation analysis	Laboratory of Genetics and Genomics 513-636-4474	3 mL EDTA – whole blood- room temperature*	2 weeks	86160 x4

DO NOT FREEZE SAMPLES FOR GENETIC TESTING.

*Call for other acceptable specimen types.