

THROMBOTIC MICROANGIOPATHY (aHUS and TTP) TEST REQUISITION

All Information Must Be Completed Before Sample Can Be Processed

PATIENT INFORMATION

Patient Name: _____, _____, _____
Last First MI

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)

SAMPLE/SPECIMEN INFORMATION

Collection Date: _____ / _____ / _____

Collection Time: _____

Has patient received a bone marrow transplant? ☐ Yes ☐ No

If yes, date of bone marrow transplant _____ Percent engraftment _____

Please send saliva kit and two cytobrushes. For Post-BMT Genetic Testing, please see specimen requirements on page 2.

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

BILLING INFORMATION

☐ REFERRING INSTITUTION

Institution: _____

Address: _____ City/State/Zip: _____

Accounts Payable Contact Name: _____

Phone: _____ Fax: _____

Email: _____

* PLEASE NOTE:

- We do not third-party bill patient insurance.
- Please call the laboratory for international billing and with any billing questions.
- Genetic testing: 1-866-450-4198, other testing: 513-636-4530

REFERRING PHYSICIAN

Physician Name (print): _____

Address: _____

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

Genetic Counselor/Lab Contact Name: _____

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

_____ Date: _____ / _____ / _____

Referring Physician Signature

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.

TEST(S) REQUESTED

TESTING PANELS

- ☐ **TMA Profile aHUS/TPP**
(Includes C3, C4, Factor H, Factor I, Factor B, Factor H autoantibody, and ADAMTS13 activity)
• 1 mL SER
• 1 mL PPP[†] (no EDTA)
- ☐ **TMA Complement Panel**
(Includes C3, C4, Factor H, Factor I, Factor B, Factor H autoantibody)
• 1 mL SER
- ☐ **Ecuzumab Pharmacokinetic Panel**
(Includes Ecuzumab level and CH50. For assessing complement activation and to assist in monitoring patients on ecuzumab therapy)
• 1 mL SER
- ☐ **ADAMTS13 Activity (STAT available**)**
If ADAMTS13 Activity is <30%, ADAMTS13 Inhibition Assay is added.
If the Inhibition test is >30%, ADAMTS13 Inhibitor Antibody test is added.
• 1 mL SER
• 1 mL PPP[†] (Li Hep/Cit plasma, no EDTA)
- ☐ **Complement System Screen**
Test for the function of the complement system via Classical, Alternative and Lectin pathways
• 0.5 mL serum (separate aliquot)
- ☐ **Anti-C5 Therapeutic Monitoring**
(Includes anti-C5 (Ecuzumab) level, C5, C5 functional, and CH50. For assessing complement activation to monitor patients on C5 inhibitor therapy)
• 1 mL SER

INDIVIDUAL TESTS

- | | |
|--|---------------------------------|
| ☐ Alternative Pathway Functional Assay | 0.5 mL SER |
| ☐ ADAMTS13 Activity (STAT available**) | 1 mL PPP [†] (no EDTA) |
| ☐ ADAMTS13 Inhibition Test | 1 mL PPP [†] (no EDTA) |
| ☐ ADAMTS13 Inhibitor Ab Test | 1 mL SER |
| ☐ C3a | 0.5 mL EDTA P separate aliquot |
| ☐ C5a | 0.5 mL EDTA P separate aliquot |
| ☐ C5 Functional | 0.5 mL SER |
| ☐ CH50 Complement Total | 0.5 mL SER |
| ☐ Complement Bb Level | 0.5 mL SER / EDTA P |
| indicate specimen: ☐ serum
☐ plasma | |
| ☐ Ecuzumab Level | 0.5 mL SER |
| ☐ Factor B | 0.5 mL SER |
| ☐ Factor H Auto-Ab | 0.5 mL SER |
| ☐ Factor H | 0.5 mL SER |
| ☐ Factor I | 0.5 mL SER |
| ☐ Lectin Pathway Functional Assay | 0.5 mL SER |
| ☐ SC5b-9 Level (MAC) | 0.5 mL EDTA P separate aliquot |

SER = serum P = plasma

PPP[†] = platelet poor plasma; See page 3 for instructions.

All serum, plasma, and PPP samples should be processed within 2 hours of collection, frozen, and shipped frozen on dry ice.

CELLULAR PROTEIN EXPRESSION

- ☐ **CD46 Expression/Membrane Cofactor Protein (MCP)**
by Flow Cytometry
• 3 mL ACD A/B whole blood room temp.
Note: If ordered, sample must be sent by next-day shipping for Monday – Friday delivery only.

GENETIC TESTING

- ☐ **ADAMTS13 Full gene sequencing**
• 3 mL EDTA whole blood, room temp*
- ☐ **aHUS Genetic Susceptibility Panel**
(Includes sequence analysis of ADAMTS13, C3, C4BPA, CD46 (MCP), CD59, CFB, CFH, CFHR1, CFHR2, CFHR3, CFHR4, CFHR5, CFI, DGKE, MMACHC, PLG, THBD and deletion/duplication analysis of CFHR1, CFHR2, CFHR3 and CFHR4 via MLPA. Also includes analysis of variants c.2653C>T and c.2654G>A in the C5 gene, which are associated with poor response to ecuzumab.)
• 3 mL EDTA whole blood, room temp*
☐ Reflex to del/dup of ADAMTS13, C3, C4BPA, CD46 (MCP), CD59, CFB, CFH, CFI, CHFR5, DGKE, MMACHC, PLG, and THBD
☐ Reflex to del/dup of single gene(s)[†] (Specify): _____
- ☐ **CFHR1/CFHR3 deletion analysis by MLPA**
Includes deletion/duplication analysis of CFHR1, CFHR2, CFHR3 and CHFR4

Each gene listed above is also available for order as an individual test

- 3 mL EDTA whole blood room temp*

- ☐ **Custom Gene Sequencing**
• Full Gene Sequencing for _____ gene
• Targeted (family-specific) variant analysis for _____ gene
Proband's name: _____
Proband's DOB: _____
Proband's variant: _____

Please call 513-636-4474 to discuss any family specific mutation analysis with genetic counselor prior to shipment.

*For Genetic Testing (germline), a pre-BMT sample is the optimum specimen for a post-BMT patient. If not available, fibroblasts are the preferred specimen type for Genetic Testing on a post-BMT specimen. Saliva and Cytobrushes can be sent as a last resort for Genetic Testing. A donor sample should be sent with all post-BMT specimens. Please call for other acceptable specimen types. Do not spin or freeze samples for Flow Cytometry or Genetic Testing.

Cincinnati Children's Clinical Laboratories

For test inquiries please call: 513.636.4530 • Fax: 513.803.5056
Email: nephclinlab@cchmc.org • www.cchmc.org/tma

Ship to (Monday – Friday ONLY):

CCHMC SDOCK- Dock 1
Nephrology Clinical Lab T6-325
240 Albert Sabin Way
Cincinnati, OH 45229-3039

****ADAMTS13 Activity STAT testing:** please call (513) 636-4530 for special weekend and holiday shipping instructions.

TMA TESTING INFORMATION SHEET

Test Name	Performing Lab	Specimen Requirements	TAT/ Days Performed	CPT Codes
ADAMTS13 Activity	Nephrology 513-636-4530	1 mL platelet poor plasma Na Cit/Li Hep only (no EDTA) — spun, separated, frozen; ship on dry ice. If you have STAT/critical requests for ADAMTS13 Activity, call 513-636-4530.	24 hours— available on weekends and holidays	85397
ADAMTS13 Antibody Quant	Nephrology 513-636-4530	1 mL red top serum spun, separated, frozen; ship on dry ice*	1 week	85320
ADAMTS13 Inhibition Test	Nephrology 513-636-4530	1 mL platelet poor plasma Na Cit/Li Hep only (no EDTA)-spun, separated, frozen; ship on dry ice	24 hours	85335
ADAMTS13 Panel	Nephrology 513-636-4530	1 mL red top serum — spun, separated, frozen; ship on dry ice	24 hours	85397 +85335 +85320
Alternative Pathway Functional Assay	Nephrology 513-636-4530	0.5 mL serum-spun, separated, frozen within 2 hours of collection, ship on dry ice	1 week	86161
Anti-C5 Therapeutic Monitoring	Nephrology 513-636-4530	1 mL red top serum — spun, separated in two 0.5mL aliquots, frozen within 2hrs; ship on dry ice	2-4 days/Mon-Fri	80299, 86162, 86160, 86161
C3, C4	Nephrology 513-636-4530	0.5 mL red top serum — spun, separated, frozen; ship on dry ice	24 hours	86160
CH50	Nephrology 513-636-4530	0.5 mL red top serum — spun, separated, frozen within 2 hrs of collection; ship on dry ice	Monday, Wednesday, Friday	86162
C5 Functional	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-Fri	86161
Complement System Screen	Nephrology 513-636-4530	1.5 mL serum 3 aliquots — spun separated, frozen within 2 hours of collection, ship on dry ice	1 week	86161x2 +86162
Eculizumab Level	Nephrology 513-636-4530	0.5 mL red top serum — spun, separated, frozen within 2 hour of collection; ship on dry ice	Monday	80299
Factor B, Factor H, Factor I	Nephrology 513-636-4530	0.5 mL red top serum — spun, separated, frozen; ship on dry ice	3 days	86160
Factor H Auto-Antibody	Nephrology 513-636-4530	0.5 mL red top serum — spun, separated, frozen; ship on dry ice	1 week — STAT available	83516
Bb	Nephrology 513-636-4530	0.5 mL EDTA plasma — spun, separated, frozen within 2 hours of collection, separate aliquot each test; ship on dry ice	1 week	86160
Lectin Pathway Functional Assay	Nephrology 513-636-4530	0.5 mL EDTA plasma — spun, separated, frozen within 2 hours of collection, ship on dry ice	1 week	86161
Membrane Cofactor Protein (MCP)/CD46 by Flow	Cancer and Blood Disease Institute 513-636-4685	3mL ACD (A or B) whole blood — room temperature, MUST be delivered within 24 hours of collection Monday — Friday only	24 hours	86356x3
SC5b-9 (MAC Complex)	Cancer and Blood Disease Institute 513-803-3503	0.5 mL EDTA plasma — spun, separated, frozen within 2 hours 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 hours 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 hours of collection, separate aliquot each test; ship on dry ice	2 weeks	86160
ADAMTS13 Gene Sequencing	Molecular Genetics 513-636-4474	3mL EDTA — whole blood; room temperature*	4 weeks	81479
aHUS Genetic Susceptibility Panel	Molecular Genetics 513-636-4474	3 mL EDTA — whole blood- room temperature*	28–42 days	81443
Any single gene sequencing test	Molecular Genetics 513-636-4474	3 mL EDTA — whole blood– room temperature*	28 days	Call lab
Targeted variant analysis	Molecular Genetics 513-636-4474	3 mL EDTA — whole blood- room temperature*	4 weeks	Call lab