Clinical suspicion for Multi-System Inflammatory Syndrome in Children (MIS-C): Fever ≥100.4°F for ≥24 hours, no alternative plausible diagnosis. AND any one of the following:
- GI: abdominal pain, diarrhea, vomiting
- CV: chest pain, arrhythmia, signs of shock, hypotension
- Musculoskeletal: rash, oral changes, conjunctivitis, extremity swelling/peeling
- Resp: cough, shortness of breath, difficulty breathing
- Neuro: altered mental status, headache, irritability

Initial Work Up and Management:
- Prompt recognition of shock is crucial. Rapid push/pull administration of 10 ml/kg aliquots of fluid as tolerated with frequent reassessment for signs of worsening heart failure, such as hepatomegaly, crackles, gallop, and other signs of fluid overload. Strong consideration should be given for early initiation of inotropic support.

1st Tier Labs/Studies (of patients):
- CBC with differential, hepatic function panel (no coags), chem 10, CRP, ESR, troponin, NT-proBNP, CK/CIMB
- Extra red top tube to hold for further studies; consider drawing and holding blood culture
- Additional labs/studies may be added based upon clinical presentation (e.g. ECG, CXR for patient with chest pain)

2nd Tier Labs/Studies (if appearing patients, abnormal 1st tier labs1, strong possibility of MIS-C based upon clinical presentation): (see Appendix B for blood volumes and required tubes)
- blood with lactate, coags, cortisol, fibrinogen, D-dimer, LDH, ferritin, procalcitonin, blood culture, urinalysis, urine culture
- Obtain COVID-19 PCR (Appendix C: Instructions for Collection and Sending of COVID-19 Specimens), respiratory BIOFF, and enter order as “add-on” for SARS-CoV-2 IgG antibodies (can be run from lavender top tube sent for CBC/CRP)
- EKG, CXR

PPE: Full COVID-19 Special Precautions PPE until COVID-19 PCR results return

Disposition Considerations:
- Consider discharge from ED if: well appearing, no or mild elevation in labs, concrete plan in place for lab trending/follow up (may return to ED for lab follow up). For patients with normal labs and no clinical suspicion for MIS-C, Ifu not necessarily required.
- Consider admission if: ill-appearing; clinical or laboratory picture strongly suggestive of MIS-C; markedly elevated inflammatory markers and/or lab or clinical evidence of end organ dysfunction; tachycardia out of proportion to clinical picture; abnormal ECG; altered mental status; patient indicates for Complete or Incomplete Kawasaki Disease; clinical need to closely monitor disease progression; if unable to arrange outpatient follow up
- Consider admission to PICU if: signs of shock and/or multi-system organ involvement
- If admitted: consult Infectious Diseases and Cardiology services to discuss additional work up and management. Consider consulting Rheumatology if diagnostic question or 2nd line agents are required. *Unless ED has specific questions or concerns, consults should be placed by receiving service.

Additional Work Up per Consultant Recommendations
- Labs above, if not already completed
- Type and screen, triglycerides
- Cytokine studies (see Appendix D): IL-6, soluble IL-2, IL-1, IL-20, NK Function, Soluble CD-163, Soluble IL-2R
- Studies to obtain prior to NG administration if feasible: CMV, EBV, parvovirus antibodies for immunocompetent patients; add PCR studies for immunocompromised patients
- Trend labs2
- Consider echocardiogram abdominal ultrasound, chest/abdominal CT based upon clinical presentation

Treatment and Management:
- Treatment may be started prior to COVID-19 PCR and serology tests result.

1st line agents:
- ASA
  - Low dose 3.5 mg/kg/day (max 81 mg/day) if diagnosed MIS-C and KD-like features and/or thrombocytosis (platelet ≥ 500,000/uL)
  - Continue ASA until normalization of platelet count and confirmed normal coronary arteries 6 weeks after diagnosis
  - Avoid ASA if platelet count ≤ 50,000/uL
  - If coronary arteriopathy: follow Kawasaki Clinical Pathway in discussion with cardiologist
  - If other cardiac abnormalities present, or doesn’t meet above criteria, cardiac-derivation antplatelet/anticoagulation management
- Methylprednisolone IV 2 mg/kg x 1 dose (max 80 mg) – give first and then start IVIG
  - Then 2 mg/kg/day IV/IVig (max 40 mg/dose)
  - When signs of clinical and laboratory improvement, transition to PO steroids 2mg/kg/day divided BID (max 30mg/dose)
  - Upon discharge, follow up should be scheduled in outpatient Rheumatology for further steroid tapering plan
  - IVIG 2 g/kg x 1 (max 100 g/dose)
  - Consider 2nd IVIG dose if continues to be febrile at 36 hours after completion of first IVIG dose
- Antibiotics x 48 hrs (modify antibiotic selection based on clinical situation, patient allergy; consider discontinuing if cultures are negative):
  - Ceftriaxone 100 mg/kg/day divided q12hr (max 2,000 mg/dose)
  - If signs of septic shock: add Vancomycin IV (<52 weeks PMA – 200 mg/kg/day divided q6hr) or as determined by pharmacy based on estimated AUC; ≤ 52 weeks PMA: 100 mg/kg/day divided q6hr; ≥ 12 weeks PMA: 75 mg/kg/day divided q6hr)
  - If signs of KD: administer aspirin 3 mg/kg/day divided q4hr (max 81 mg/day)
  - Lamivudine 1 mg/kg/day PO once daily (max 30 mg/dose) or Protenons 1 mg/kg/day IV once daily (max 40 mg/dose)

2nd line agents (consult Rheumatology for discussion of initiation of 2nd line medications as follows):
- Consider Anakinra 2 mg/kg/day IV q12hr (max 100 mg/dose)
- If patient still without improvement, discuss alternative immunomodulator therapy with Rheumatology

Other considerations:
- If COVID-19 PCR positive: Follow COVID-19 VTE Pathway
  - If COVID-19 PCR negative: consider anticoagulation based on clinical picture

MIS-C is suspected if all of the following are met (CDC case definition):
- Fever ≥100.4°F for ≥24 hrs
- Laboratory evidence of inflammation
  - Can include any of the following: CRP, ESR, fibrinogen, procalcitonin, D-Dimer, ferritin, LDH, IL-6, elevated neutrophils, low lymphocytes, low albumin
- Resistant hospitalization with multisystem (≥2) organ involvement (cardiac, renal, respiratory, hematologic, GI, dermatologic, or neurologic)
- No alternative plausible diagnosis
- Current/recent SARS-CoV-2 infection (symptoms, positive PCR, serology, or COVID-19 exposure within the 4 weeks prior to the onset of symptoms
- Any patient that meets MIS-C diagnostic criteria, should be reported to the DPH Epidemiology Program at (860) 508-7994.

Abnormal labs values:
- Absolute lymphocyte count < 1000
- Platelets < 100
- CRP > 3
- ESR > 40
- Neutrophils < 125
- ALT > 45
- NT-proBNP > 800
- CKMB/Ck CK > 5%
- Troponin > 0.03

Lab Trending:
- Daily: CBC, CRP, ESR, PCT, BMP, LFTs, ferritin, NT-proBNP (gas/lactate if on D/P)
- If cardiac involvement: troponin, CKMB/CK, EKG
- Consider procalcitonin every other day
- May trend other labs depending on clinical situation (e.g. triglycerides if cytokine storm syndrome)

Discharge:
- D/C meds,IV/IVs and tests per consultants on case-by-case basis
- If discharged on steroids: Give 4 week supply; Obtain lab studies (to be placed by Rheum) 4-7 days after D/C and call Rheum for results/initial taper; Schedule 1/u appt with rheum in ~2 weeks

CONTACTS: ROBERT PARKER, MD | HEATHER SCHLOTT, MD | JOHN SCHREIBER, MD | ALEX GOLDEN, MD | HEATHER TORY, MD
This pathway is subject to change, based on evolving recommendations from the CDC and CT DPH.
LAST UPDATED: 02.17.21
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CLINICAL PATHWAY: Multi-System Inflammatory Syndrome in Children (MIS-C)
Clinical Pathway
Appendix A: MIS-C Infographic

MIS-C Case Ranges by Territory, State, New York City, and Washington, DC
539 Cases in 44 States
March 11 – September 11, 2020

Any Positive Test (PCR/Serology): 100%
- Sars-CoV-2 PCR Pos/lgG neg or not done: 26%
- Sars-CoV-2 PCR Pos/lgG pos: 27%
- Sars-CoV-2 PCR neg/lgG pos: 46%

Epidemiologic Link: 0.9%

MIS-C Cases (7-Day Moving Average)

Pharmacologic
- Vasoactive Support (41%)
- Intravenous Immune Globulin (IVIG) (80%)
- Second dose IVIG (21%)
- Systemic Steroids (62%)
- IL-6 Inhibitors [tocilizumab and sarilumab] (85%)
- IL-1Ra Inhibitor [anakinra] (13%)
- Systemic Anticoagulation (47%)
- Antiglomerel (59%)

Respiratory
- Mechanical Ventilation (13%)
- Usually used for offloading myocardium
- Non-invasive 30-80%

Extracorporeal Support
- ECMO (4%) with median duration of 4.5 days
- Dialysis (0.4%)

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Initial Work Up:

- CBC with differential: Whole blood, Lavender EDTA, Minimum 1 mL, 4mL collection tube or microtainer
- “Liver function panel” (includes GGT and coags): Green top Lithium Heparin with gel-barrier, minimum 2mL whole blood, 1mL plasma (liver function) AND Full Blue top sodium citrate tube (coags)
- Chem 10: Green top Lithium Heparin with gel-barrier, minimum 2mL whole blood, 1 mL plasma.
- Blood gas with lactate: 1mL of whole blood into a heparin syringe on ice or full Green Lithium Heparin tube (blood gas); Grey top or Li Heparin on ice (lactate)
- Cortisol: Green top Lithium Heparin with gel-barrier, minimum 2mL whole blood, 1 mL plasma.
- Fibrinogen: Full Blue top sodium citrate tube
- D-dimer: Full Blue top sodium citrate tube
- CRP: Green top Lithium Heparin with gel-barrier, minimum 2mL whole blood, 1 mL plasma.
- ESR: Whole blood, Lavender EDTA, Minimum 1 mL, 4mL collection tube
- Procalcitonin: Green top Lithium Heparin with gel-barrier, minimum 2mL whole blood, 1 mL plasma.
- LDH: Green top Lithium Heparin with gel-barrier, minimum 2mL whole blood, 1 mL plasma.
- Ferritin: Green top Lithium Heparin with gel-barrier, minimum 2mL whole blood, 1 mL plasma.
- Troponin: Green top Lithium Heparin with gel-barrier, minimum 2mL whole blood, 1 mL plasma.
- NT-proBNP: Green top Lithium Heparin with gel-barrier, minimum 2mL whole blood, 1 mL plasma.
- CKMB: Green top Lithium Heparin with gel-barrier, minimum 2mL whole blood, 1 mL plasma.
- Blood culture: Bactec pedi bottle (no minimum amount needed)
- Hold extra red top tube for future studies, if able

**all tubes being sent need to be full if you wish the lab to run multiple tests off of the same tube – minimum volumes added together will not suffice**

- Lavender top EDTA tube (not the bullet):
  - Amount of blood: needs to be full
    - can run: CBC w diff, ESR (can also add on SARS-CoV-2 antibody if requiring admission)
- Green top lithium heparin with gel barrier tube:
  - Amount of blood: needs to be full
    - Can run: liver function panel, chem 10, CRP, LDH, procalcitonin, ferritin, triglyceride, troponin, NT-proBNP, CKMB, cortisol
Blue top sodium citrate tube:
  o Amount of blood: needs to be full
    ▪ Can run: coagulation tests, fibrinogen, D-dimer

If patient requires admission, add:

  • COVID-19 antibodies (IgG): Can be run off of full Lavender tube with CBC/ESR; Call lab to determine if this can be added on; otherwise, will require serum or Lavender EDTA plasma, Minimum volume 0.5 mL

Additional Work Up:

  • Type and Screen
  • Triglycerides: Green top Lithium Heparin with gel-barrier, minimum 2 ml whole blood, 1 ml plasma
  • Cytokine studies:
    o IL-6, Soluble IL-2, Soluble IL-2R, IL-1, IL-10 (sent as cytokine panel): Red top, preferred 1 ml serum
    o NK Function (not part of cytokine panel above): Green top, 10 ml whole blood
    o Soluble CD-163 (not part of cytokine panel above and is sent separately to Cincinnati): see Appendix D Cytokine Studies Cincinnati Lab Requisition Form

  • CMV:
    o Serology:
      • Cytomegalovirus (CMV) Antibody, IgG: Red top serum, 1.0 mL (0.5 mL) min required
      • Cytomegalovirus (CMV) Antibody, IgM: Red top serum, 1.0 mL (0.5 mL) min required
    o PCR:
      • Cytomegalovirus DNA, QUANT, PCR: Send out to Quest, EDTA Lavender plasma, -1.0 mL

  • EBV:
    o Serology:
      • All EBV serological testing: Red top serum, 1.0 mL (0.5 mL) min required
    o Molecular
      • EBV DNA, PCR, QUALITATIVE: Send out to Quest, 1 mL (0.3 mL minimum) serum from red gel barrier or red non-gel barrier tube or 1 mL Lavender EDTA plasma
      • EBV DNA, PCR, Quantitative: Send out to Quest, 1 mL (0.5 mL minimum) EDTA Lavender plasma or 1 mL (0.5 mL minimum) serum

  • Parvovirus:
    o Antibodies: Send out to Quest, 2 mL (1 mL minimum) serum from a red top or SST tube
    o PCR: Send out to Quest, 1 mL (0.5 mL minimum) EDTA plasma
INSTRUCTIONS FOR COLLECTION AND SENDING COVID-19 SPECIMEN

Hartford Hospital Specimen

- Specimens must be collected in a viral transport tube
  - Both BIOFIRE and COVID-19 specimens may be sent with 1 single swab
    (reserve respiratory BIOFIRE for critically ill patients)
- Place COVID-19 sample in a green irreplaceable biohazard bag
- Patient’s COVID-19 test requisition form (will have printed when COVID-19 test was ordered)
- Must hand carry sample to the HH Lab; **DO NOT** use the tube system
- When walking samples to Hartford Hospital, the staff member will **only** need to wear gloves for PPE. There is no need to don full PPE for sample transport.

LIAT Specimen

- Specimen must be collected in viral transport medium
- Label sample with barcoded patient demographic label that includes: the initials of the person collecting the sample, date and time of collection
- Patient sample should be placed in a green irreplaceable biohazard bag
- Must hand carry sample to COVID-19 specimen drop-off room (1C, room #1693) and fill out the log
- When walking samples to COVID-19 specimen drop-off room, the staff member will only need to wear gloves for PPE. There is no need to don full PPE for sample transport.
### DIAGNOSTIC IMMUNOLOGY LABORATORY

**Phone:** 513-636-4685  •  **Fax:** 513-636-3861

**Lab Hours:** Monday–Friday 8:00 AM – 5:00 PM EST

www.cincinnatichildrens.org/DIL  •  CBDILabs@cchmc.org

**Ship First Overnight to:**
- CCHMC - Julie Beach
- DIL - Rm R2328
- 3333 Burnet Avenue
- Cincinnati, OH 45229-3039

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**DIL — TEST REQUISITION FORM**

**MUST BE RECEIVED MONDAY – FRIDAY WITHIN 1 DAY OF COLLECTION UNLESS OTHERWISE INDICATED**

**PATIENT INFORMATION (STICKER ALSO ACCEPTED)**

- **Patient Name (Last, First, MI):** __________________________, __________________________, _______  **DOB (MM/DD/YYYY):** _______/_______/________
- **Medical Record #:** __________________________  **Collection Date (MM/DD/YYYY):** ______/______/______  **Time of Sample(HH:MM):** ___________________
- **Legal Sex:**
  - ☐ Male
  - ☐ Female
  - ☐ BMT:
    - ☐ Yes – Date: ______/______/_______
    - ☐ No ☐ Unknown
- **Relevant Medications:** ______________________________
- **Diagnosis or reason for testing:** ____________________________________________________________________________________________________

**REFERRING PHYSICIAN**

- **Physician Name (print):** __________________________________________
- **Phone:** (_____)  __________________  **Fax:** (_____)  ___________________
- **Email:** _______________________________________________________
- **Date:** _____/ _____/ _____

**BILLING & REPORTING INFORMATION**

- **Institution:** ____________________________________________________
- **Address:** _____________________________________________________
- **City/State/ZIP:** _________________________________________________
- **Phone:** (_____)  __________________  **Fax:** (_____)  ___________________

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**TESTS OFFERED: THE MAX VOLUME LISTED IS THE PREFERRED WHOLE BLOOD VOLUME**

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<thead>
<tr>
<th>Test Description</th>
<th>Volume/Type</th>
<th>Notes</th>
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</thead>
<tbody>
<tr>
<td>Alemtuzumab Plasma Level</td>
<td>2-3mL Sodium Heparin</td>
<td>See #5 on page 2</td>
</tr>
<tr>
<td>ALPS Panel by Flow Need CBC/Diff result</td>
<td>1-3mL EDTA – See #2 on page 2</td>
<td></td>
</tr>
<tr>
<td>Antigen Stimulation</td>
<td>See #1 Below</td>
<td></td>
</tr>
<tr>
<td>Apoptosis (Fas, mediated) Note: Only draw Apoptosis on Wednesday for Thursday delivery</td>
<td>10-20mL ACD-A</td>
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<tr>
<td>B Cell Panel Need CBC/Diff result</td>
<td>1-3mL EDTA – See #2 on page 2</td>
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<tr>
<td>BAFF</td>
<td>1-3mL EDTA – See #4 on page 2</td>
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<tr>
<td>CD40L / CD40FP / ICOS</td>
<td>3-5mL Sodium Heparin</td>
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<tr>
<td>CD45RA/RO</td>
<td>1-3mL EDTA</td>
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<tr>
<td>CD52 Expression</td>
<td>1-3mL EDTA</td>
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<tr>
<td>CD107a Mobilization (NK Cell Degran) Note: Only draw CD107a Monday – Wednesday</td>
<td>See #1 on page 2</td>
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<tr>
<td>CXCL9</td>
<td>2 (0.5mL) EDTA plasma aliquots, frozen w/in 8 hours of collection</td>
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<tr>
<td>Cytokines, Intracellular</td>
<td>2-3mL Sodium Heparin</td>
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<tr>
<td>Cytokines (Circle One): Plasma or CSF Includes: IL-1β, 2, 4, 5, 6, 8, 10, IFN-γ, TNF-α, and GM-CSF</td>
<td>3-5mL EDTA or 0.5-1mL CSF – See #3 or #4 on page 2</td>
<td></td>
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<tr>
<td>If sending frozen, 2 (0.5mL) EDTA plasma aliquots frozen, preferred</td>
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<tr>
<td>Foxp3 Need CBC/Diff result</td>
<td>1-3mL EDTA – See #2 on page 2</td>
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<td>GM-CSF Autoantibody (GMAb)</td>
<td>1-3mL Red/Gold - See #4 on page 2</td>
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<td>GM-CSF Receptor Stimulation</td>
<td>1-3mL Sodium Heparin</td>
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<td>INKT</td>
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<tr>
<td>Interleukin-18 (IL-18)</td>
<td>3mL Red/Gold - See #4 on page 2</td>
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<td>If sending frozen, 2 (0.3mL) red/gold serum aliquots frozen, preferred</td>
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<td>Lymphocyte Activation Markers</td>
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<tr>
<td>Lymphocyte Subsets</td>
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<td>MHC Class I &amp; II</td>
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<td>Mitogen Stimulation</td>
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<td>Neopterin (Circle One): Plasma or CSF</td>
<td>1-3mL EDTA or 0.5-1mL CSF – See #3 or #4 on page 2</td>
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<tr>
<td>Antigen Stimulation</td>
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<td>Neutrophil Adhesion Mkrs: CD18/11b</td>
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<td>Neutrophil Oxidative Burst (DHR)</td>
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<td>NK Function (STRICT 24 HOUR CUT-OFF)</td>
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<td>Perforin/Granzyme B</td>
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<td>pSTAT5</td>
<td>1-3mL EDTA</td>
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<tr>
<td>S100A8/A9 Heterodimer</td>
<td>2 (0.3mL) Gold serum aliquots, frozen w/in 4 hours of collection</td>
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<tr>
<td>S100A12</td>
<td>2 (0.3mL) Gold serum aliquots, frozen w/in 4 hours of collection</td>
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<tr>
<td>Soluble CD163</td>
<td>1-2mL EDTA - See #4 on page 2</td>
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<td>Soluble IL-2R (Soluble CD25)</td>
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<td>Soluble TCR γ/δ</td>
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<tr>
<td>Soluble TCR α/β</td>
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<td>T Cell Degranulation Assay Note: Only draw T Cell Degran Monday – Wednesday</td>
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<td>Th-17 Enumeration</td>
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<td>WASP Transplant Monitor</td>
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**Page 1 of 2**
**ADDITIONAL BILLING INFORMATION – CONTINUED FROM PAGE 1**

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**SEND ADDITIONAL REPORTS TO:**

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<td>Name:</td>
<td></td>
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<tr>
<td>Fax Number:</td>
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</tr>
</tbody>
</table>

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**Laboratory Information**

1. 5-10ml Sodium Heparin blood per test should be adequate for most patients unless they are lymphopenic. If you have volume constraints or an absolute lymphocyte count (ALC) of <1.0 K/uL, please see the Customized Volume Sheet on our website (www.cchmc.org/DIL) or call for adjusted volume requirements for the following tests: Antigen Stimulation, Mitogen Stimulation, CTL Function, NK Function, CD107a, or T Cell Degran.

2. Results of a concurrent CBC/Diff must accompany ALPS Panel, B Cell Panel, or Foxp3. Results will be used to calculate absolute cell counts.

3. CSF Samples:
   a) Fresh Specimens: Ship with frozen ice packs to keep at refrigeration temp (2-8°C/35-46°F) for receipt within 48 hours of collection.
   b) Frozen Specimens: Freeze within 48 hours of collection. Ship samples frozen on dry ice.

4. Specimen Processing and Shipping Instructions only for tests marked with “See #4”:
   a) Unspun whole blood: Ship as unspun whole blood at Room Temperature for receipt within 24 hours of collection.
   b) Spun Specimens: See test line for acceptable specimen types. Spin and remove test-required serum or plasma from cells within 24 hours of collection. Freeze the separated plasma or serum immediately. Two aliquots per test are preferred. Ship frozen on dry ice. Once separated from cells, the serum or plasma must stay frozen until received by the DIL. Thawed samples will be rejected.

5. Specimen Processing and Shipping Instructions only for tests marked with “See #5”:
   a) Unspun whole blood: Ship as unspun whole blood at Room Temperature (20-25 °C) for receipt within 5 days of collection. Chilled specimens will be rejected.
   b) Spun Specimens: Spin at 2000 g for 10 min and remove test-required plasma from cells in 500 μL aliquots within 5 days of collection. Freeze the separated plasma immediately. Two aliquots are preferred. Ship frozen on dry ice. Once separated from cells, the plasma must stay frozen until received by the DIL. Thawed samples will be rejected.

Visit our Clinical Lab Index at [www.testmenu.com/cincinnatichildrens](http://www.testmenu.com/cincinnatichildrens) for detailed processing and testing information.

**Additional Shipping & Handling Information**

- **Testing is not performed and samples cannot be received on Saturdays/Sundays and certain holidays.**
- Samples should be sent as whole blood at room temperature and received in our laboratory within 1 day of collection, unless otherwise indicated.
  - We recommend using a Diagnostic Specimen pack to ensure proper processing and timely delivery of samples to the lab.
  - Call with any questions or help with minimizing collection requirements.
  - Package securely to avoid breakage and extreme weather conditions.
  - Include a completed copy of our test requisition form with each sample.
  - First Overnight shipping is strongly recommended. Please call, email or fax the tracking number so that we may better track your specimen.

**Billing Information**

- The institution sending the sample is responsible for payment in full.
- We do not third-party bill patient insurance.

**Laboratory Information**

- Hours: Monday through Friday, 8:00 AM to 5:00 PM (Eastern Standard Time). Closed on Weekends and some major holidays.
- Phone: 513-636-4685
- Fax: 513-636-3861
- Email: CBDILabs@cchmc.org

**Questions?**

Please call 513-636-4685 with any questions regarding collection or billing.

**THE REQUISITION MUST BE FILLED OUT COMPLETELY. INCOMPLETE FORMS MAY RESULT IN THE COMPROMISE OF THE SPECIMEN INTEGRITY WHILE THE MISSING INFORMATION IS BEING OBTAINED**