IMPAACT Lab Processing Chart

IMPAACT [Protocol Number]

[IMPAACT Protocol Name]

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| --- | --- | --- |
| Protocol Version: [#.#] | Protocol Version Date: [ddMmmyyyy] | Protocol Memo(s): [N/A or LOA# [ddMmmyyyy] and/or CM# [ddMmmyyyy]] |
| LPC Version: [#.#] | LPC Creation Date: [ddMmmyyyy] | LPC Revision Date: [ddMmmyyyy] |
| Lab Technologist: [Name]  | Email: [Email address]  | Phone: [###-###-####] |
| Lab Technologist: [Name] | Email: [Email address] | Phone: [###-###-####] |
| IMPAACT Lab Center Specialist: [Name] | Email: [Email address] | Phone: [###-###-####] |
| Westat Lab Center Specialist: [Name] | Email: [Email address] | Phone: [###-###-####] |
| Lab Data Manager: [Name] | Email: [Email address] | Phone: [###-###-####] |

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| Data Handling: All specimens must be logged into the LDMS specimen management and storage modules. LDMS data must be updated so the number of aliquots and the volumes must accurately reflect what has been prepared and stored.  Specimen condition codes must be updated if they are not available.Blood Volume Disclaimer: Blood collection volumes for standard-of-care testing provided in this LPC are based upon generalized recommendations. Sites must confirm actual blood volume requirements for local standard-of-care testing and ensure the blood volumes included in the informed consent for the protocol match the actual blood volumes collected by the site since your laboratory may use a different size tube or require additional tubes for all the analytes listed.Pediatric Blood Volume Limit: Per IMPAACT [Protocol Number] Section [#.#.#], and in accordance with US NIH recommendations, pediatric (less than 18 years) blood collection will not exceed 5 mL/kg in a single day or 9.5 mL/kg over any eight-week period. ORBlood Volume Limit: Per IMPAACT [Protocol Number] Section [#.#.#], and in accordance with U.S. National Institutes of Health (NIH) recommendations, adult blood collection will not exceed 10.5 mL/kg or 550 mL, whichever is smaller, over any eight-week period, and pediatric blood collection will not exceed 5 mL/kg in a single day or 9.5 mL/kg in any eight-week period. [Add any study specific details or major LPC changes here.] |

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| Protocol-Required Non-Standard Reagents and Supplies |
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| Evaluation | Reagent or Supply  | Order Information |
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| Section 1: Schedule of Laboratory Evaluations  |
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| Evaluation | Screen | Pre-Entry | Weeks | After 96 Weeks | Virologic Failure Confirm. | Eval. After Virologic Failure Confirmed | Prem D/C Study Tx | Final Study Eval. |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 0 (Entry) | 2 | 4 | 8 | 16 | 24 | 36 | 48 | 64 | 80 | 96 | Q16 | Q32 | Q48 |
|  | ± 7 days | ± 14 days | ± 28 days |
| Urinalysis | X |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Hematology | 1 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Chemistry | 2 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Pregnancy Testing | X |  |  |  |
| CD4+/CD8+ | 2 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Genotype | 3 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Plasma HIV-1 RNA  | 3 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Stored Plasma  | 3 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Stored PBMC  | 3 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Total Blood Volume per visit (mL) | 17 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| *Approximate TBSP equivalent* | 1.1 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

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| Prioritization of Collection of Blood Tubes and Processing for Short Draws, by Visit |

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| Visit | Tube type  | Purpose |
| [Specify visit here if applicable] |  |  |
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| Section 2: Safety/Clinical Laboratory Evaluations |
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| Evaluation | Tube type | Tests | eCRF # |
| Hematology | EDTA  | [List applicable hematology tests here] |  |
| Chemistry | SST or NON | [List applicable chemistry tests here] |  |
| Urinalysis | Sterile cup | [List applicable urinalysis tests here] |  |
| Pregnancy | Urine or SST/NON  | β HCG (pregnancy test) with a sensitivity of <25 mIU/mL |  |
| CD4+/CD8+ | EDTA | CD4/CD8 cell counts and percentages  | Dual platform labs only must also have a WBC and diff. |  |

| Section 3: Specimen Processing (Refer to Section 4 below for collection volumes) |
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| Evaluation | Tube Type | Special Collection Notes  | CRF #DMC Test Code | Processing | Shipping |
| HIV-1 RNA*Note: This applies to blood sent to a processing lab. Confirm with protocol team which assay should be used.*  | EDTA*Note: Combine blood whenever possible.* | Invert tubes per the manufacturers instructions and transport to the local processing lab ambient. | *Note: Obtain the correct eCRF# from the protocol LDM* | Spin blood at 800xg for 10 min (or at 400xg if blood is being used for PBMC processing). Remove plasma, re-spin at 800xg for 10 min. Freeze plasma aliquots at -80°C (-65°C to -95°C).*Note: Specimens should be handled/processed according to local testing lab requirements.* | Send to local CLIA (US) or VQA (non-US) certified testing lab. *Note: Include appropriate testing requisition and note if expedited testing is required.* |
| Stored Plasma *Note: List the purpose or refer to the protocol section* | EDTA | Invert tubes per the manufacturers instructions and transport to the local processing lab ambient. | *Note: Obtain the correct eCRF# from the protocol LDM* | Spin blood at 800xg for 10 min (or at 400xg if blood is being used for PBMC processing). Remove plasma, re-spin at 800xg for 10 min. Freeze plasma aliquots at -80°C (-65°C to -95°C).*Note: Confirm the processing and storage instructions with the protocol team.* | Ship to NIAID or the NICHD Repository.*Note: Confirm shipping instructions with the protocol team and include any additional shipping information in Section 5 of the LPC.* |
| Stored Plasma and PBMCs*Note: List the purpose or refer to the protocol section* | EDTA*Note: Confirm the additive with the protocol team. Combine blood whenever possible.* | Invert tubes per the manufacturers instructions and transport to the local processing lab ambient. | *Note: Obtain the correct eCRF# from the protocol LDM* | Spin blood at 400xg for 10 min. Remove plasma, re-spin at 800xg for 10 minutes. Freeze plasma at at -80°C (-65°C to -95°C). Ficoll cells according to Cross-Network Consensus Cryopreservation SOP. Freeze PBMCs viably at -80°C (-65°C to -95°C); transfer to LN2 vapor phase if cells cannot be shipped and received within 5 weeks of collection.*Note: Confirm the processing and storage instructions with the protocol team.* | Ship to NIAID or the NICHD Repository.*Note: Confirm shipping instructions with the protocol team and include any additional shipping information in Section 5 of the LPC.* |
| Stored Serum *Note: List the purpose or refer to the protocol section* | SST or NON | Invert tubes per the manufacturers instructions and transport to the local processing lab ambient. | *Note: Obtain the correct eCRF# from the protocol LDM* | Allow SST or red top blood to clot, upright, for at least 30 min. Spin at 1100-1300xg for 10 min. (horizontal rotor centrifuge) or 15 min. (fixed angle rotor centrifuge). Freeze aliquots at -80°C (-65°C to -95°C).*Note: Confirm the processing and storage instructions with the protocol team.* | Ship to NIAID or the NICHD Repository.*Note: Confirm shipping instructions with the protocol team and include any additional shipping information in in Section 5 of the LPC.* |
| Stored Plasma for PK (drugs requiring temperature and light control) | K2 EDTA (spray dried)*Note: Confirm the anticoagulant with the testing lab* | Immediately after collection, invert tube 8-10 times gently and protect from light by wrapping blood collection tube in foil and place collection tube(s) at appropriate temperature. Maintain appropriate temperature during transport to local processing lab. | *Note: Obtain the correct eCRF# from the protocol LDM* | Process within \_\_\_ of collection. Spin blood at \_\_\_ g for \_\_\_ min under refrigerated conditions. Samples should be kept at the appropriate temperature during processing. Remove plasma and aliquot into 2 mL amber screw-capped cryovials. Freeze immediately after processing in an upright position at -80°C (-65°C to -95°C). Plasma samples should be placed in freezer within \_\_\_ of blood collection. Document processing and freezing times in LDMS and change condition code as appropriate.*Note: Confirm any special processing instructions with the protocol team and/or testing lab (e.g. double spun plasma).*  | *Note: Confirm shipping instructions with the protocol team and include any additional shipping information in Section 5 of the LPC.* |

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| Section 4: Evaluations by Visit |

| Screen: Must be completed within [#] days prior to study entryLDMS Visit Code = A5### 0/SCR |
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| Evaluation | Specimen | Aliquots | LDMS Code | Special Notes |
| HIV-1 RNA | EDTA blood ([#] mL) | [#] x [#] mL | BLD/DPE/PL2 | Ship one aliquot to designated network testing lab. |
| Stored Plasma | EDTA blood ([#] mL) | [#] x [#] mL | BLD/DPE/PL2 | Ship to NIAID or the NICHD Repository |
| Stored Plasma and PBMC | EDTA blood ([#] mL) |  [#] x [#] mL[#] @ [#] x 106 CEL | BLD/DPE/PL2BLD/DPE/CEL/DMS | Ship to NIAID or the NICHD Repository |
| Stored Serum | SST or NON blood ([#] mL) | [#] x [#] mL | BLD/SST or NON/SER | Ship to NIAID or the NICHD Repository |
| Stored Plasma for PK | Spray dried EDTA blood ([#] mL) | [#] x [#] mL | BLD/DPE/PL1 | *Note: Confirm shipping instructions with the protocol team and include any additional shipping information in Section 5 of the LPC.* |

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| Section 5: Helpful Links and Shipping Addresses*Ship overnight Monday through Wednesday preferred; Thursday OK unless otherwise specified. Mark Thursday shipments as “OK to deliver on Saturday.”* |
| ACTG/IMPAACT Laboratory Manual, Shipping Information and other useful information: <http://www.hanc.info/labs/labresources/Pages/informationActgImpaactLabs.aspx> BRI Shipments: All shipments to BRI must be made in accordance with current repository policies in SOP ACTG-144: <https://member.mis.s-3.net/cms/fpage/6172/1290> |
| **[EVALUATION]**Attention: [Name][Institution][Address] Phone: [###-###-####] Fax: [###-###-####] Email [LDMS batch file, Excel file or other required document] to: [Email address]Include LDMS Manifest [and appropirate requisition if applicable] in the shipment.LDMS lab code (if applicable): [###] | **REPOSITORY SPECIMENS (NIAID Sites)**Attention: John WardBiomedical Research Institute9410 Key West Avenue, First FloorRockville, MD 20850Phone: 301-881-7636Fax: 301-770-9811LDMS contact: John WardEmail LDMS batch file and Ambient/Refrigerated/Frozen Shipment Notice to: brirepository@afbr-bri.org Include LDMS Manifest and Shipping Container Report in the shipment.LDMS lab code: 999 | **REPOSITORY SPECIMENS (NICHD Sites)**Attention: Ryan Patrick BabayFisher Bioservices - NICHD Repository625 Lofstrand LaneRockville, MD 20850 USAPhone: 301-354-0325Fax: 301.838.9753LDMS contact: Ryan Patrick BabayEmail LDMS batch file and Ambient/Refrigerated/Frozen Shipment Notice to: fbs.gbo@thermo.com; ryan.busa-babay@thermofisher.com Include LDMS Manifest and Shipping Container Report in the shipment.LDMS lab code: 243  |

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| Section 6: Revision History |
| Protocol Version | LPC Change Date | Page(s) | Description |
|  | [ddMmmyyyy] |  |  |
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| Section 7: Appendices |

***Instructions for draft LPC review and final posting:***

* *Review the draft LPC for readability.*
* *Submit the draft LPC to the co-LT or LTC for initial review.*
* *Send the LPC to the protocol Lab Specialist for the final team review and sign-off.*
* *The Lab Specialist will submit the final LPC to the protocol CTS for posting.*