



Lab Processing Chart

IMPAACT 2002

Combined Cognitive Behavioral Therapy and a Medication Management Algorithm for Treatment of Depression
Among Youth Living with HIV in the United States

Protocol Version: 1.0 Protocol Version Date: 19/AUG/2016 LPC Edited/Updated: 28/JAN/2017
Lab Technologist: Bill Kabat Email: bkabat@luriechildrens.org Phone: 312-227-6290

Table of Contents

All Participants

Section 1: Schedule of Evaluation	2
Section 2: Safety/Clinical Laboratory Evaluations Appendix I	3
Section 3: Specimen Processing	4
Section 4: Evaluations by Visit	5-6
Section 5: Shipping Information	7
Section 6: Revision History	7

Section I: IMPAACT 2002 Schedule of Evaluations for All Participants								
Study Visit	Screening/ Entry Visit	Week 1	Week 6	Week 12	Week 24	Week 36	Week 48/Study Exit/Early Discontinuation	Interim Visit
Visit Window	—	-7/+14 d	±14 d	±14 d	±14 d	±14 d	±14 d	—
Laboratory								
CD4+ T-Cell Count (4mL)	4.0mL				4.0mL		4.0mL	
HIV-1 RNA (4mL)	4.0mL				4.0mL		4.0mL	
Plasma for inflammatory/biomarkers (5 mL)	5.0mL				5.0mL		5.0mL	
HIV-1 test (confirmatory tests as needed) (5mL estimate) [#]	*							
Total blood volumes (may vary depending on local laboratory requirements)	13-18mL				13mL		13mL	

* - if indicated,

1.) If HIV RNA PCR is used to establish HIV status at screening /entry, it may be also used as the viral load measure for study entry

Note: Week 1 procedures may be combined with the Screening and Enrollment Visit if convenient for the participant and study staff

For insufficient blood draws, priorities are as follows:

- 1) Safety labs as clinically indicated
- 2) Virology
- 3) Immunology
- 4) Plasma for inflammatory biomarkers

Section 2: Safety/Clinical Laboratory Evaluations			
Appendix I: All Participants.			
<i>Defer to local clinical specimen collection guidelines for tube types and collection volumes as needed.</i>			
Evaluation	Tube Type	Test(s)	CRF #/ DMC Test Code
Lymphocyte subsets	EDTA Blood	Send ambient Lymphocytes subsets (CD4+/CD8+ percentages and absolute counts) to local CLIA/CAP testing lab.	LBW0054
HIV Confirmatory Testing as needed per local laboratory requirements.¹	EDTA or NON Blood	Send to local CLIA/CAP testing lab.	F3008, F3111

1.) If HIV RNA PCR is used to establish HIV status at screening /entry, it may also be used as the viral load measure for study entry

Section 3: Specimen Processing					
Appendix I: All Participants					
Refer to Section 4 for tube types and collection volumes.					
Evaluation	Tube Type	Special Collection Notes	DMC Test Code	Processing	Shipping
Plasma HIV-1 RNA PCR	Plasma HIV-1 RNA PCR	Process sample as required by local site practices using any FDA Approved Quantitative HIV-1 RNA PCR. Send to local CLIA/CAP lab ambient for testing or use processing instructions here if sending frozen plasma for testing.	HIVRNA	Spin blood at 400 x g for 10 minutes. Remove plasma, transfer to new tube and respin at 800xg for 10 min. Prepare 2 x (1.0 -1.5 mL) aliquots in LDMS labeled cryovial. Store on site at -70°C or lower until shipped for testing. Adjust plasma volume in LDMS as needed.	As needed per local site practices.
Plasma for Inflammatory Biomarkers	EDTA Blood	Send to processing lab ambient. Process within one hour of collection if possible.	STORIMM	Spin blood at 800 x g for 10 minutes. Prepare 2 x (1.0 -1.5 mL) aliquots in LDMS labeled cryovial. Store on site at -70°C or lower until requested by the protocol team. Adjust plasma volume in LDMS as needed.	See Section 5 for shipping instructions.

Section 4: Evaluations by Visit						
All Participants						
Screen/Entry:						
<p><i>May be completed on the same day or within 30 days prior to study entry.</i></p> <p><i>LDMS preloads will be triggered when a patient visit of 0 ENT is entered.</i></p>						
Evaluation	Patient Subset	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Lymphocytes subsets (CD4+/CD8+)	All Participants	4.0 mL EDTA Blood	LBW0054	NA	NA	Send to local clinical lab.
Plasma HIV-1 RNA PCR	All Participants	4.0 mL EDTA Blood	F3008 and F3111	If sending plasma: Prepare 2 x 1.0-1.5mL aliquots	BLD/EDT or DPE/PL2	Send to local clinical lab ambient or freeze at -70°C or lower until shipped to testing lab. Adjust plasma volume in LDMS as needed.
Plasma for inflammatory biomarkers.	All Participants	5.0 mL EDTA Blood	F3008	Prepare 2 x 1.0-1.5mL aliquots	BLD/EDT or DPE/PL1	Store @ -70 C or lower until shipping requested by protocol team. See Section 5 for shipping instructions Adjust plasma volume in LDMS as needed.
HIV-1 Confirmatory Test(s) per local requirements. Note that HIV RNA PCR above may serve as confirmatory test.	For participants that require HIV-1 confirmatory test documentation Only	5.0mL EDTA or NON Blood collection as required for local lab.	F3008	NA	NA	Send to local clinical lab.

Week 24 (\pm 14 days): All Participants						
LDMS preloads will be triggered when a patient visit of 24 WK is entered.						
Evaluation	Patient Subset	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Lymphocytes subsets (CD4+/CD8+)	All Participants	4.0 mL EDTA Blood	LBW0054	NA	NA	Send to local clinical lab.
Plasma HIV-1 RNA PCR	All Participants	4.0 mL EDTA Blood	F3008 and F3111	If sending plasma: Prepare 2 x 1.0-1.5mL aliquots	BLD/EDT or DPE/PL2	Send to local clinical lab ambient or freeze at -70°C or lower until shipped to testing lab. Adjust plasma volume in LDMS as needed.
Plasma for inflammatory biomarkers.	All Participants	5.0 mL EDTA Blood	F3008	Prepare 2 x 1.0-1.5mL aliquots	BLD/EDT or DPE/PL1	Store @ -70 C or lower until shipping requested by protocol team. See Section 5 for shipping instructions. Adjust plasma volume in LDMS as needed.

Week 48/Study Exit/Early Discontinuation (\pm 14 Days): All Participants						
LDMS preloads will be triggered when a patient visit unit of EXT is entered.						
Evaluation	Patient Subset	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Lymphocytes subsets (CD4+/CD8+)	All Participants	4.0 mL EDTA Blood	LBW0054	NA	NA	Send to local clinical lab.
Plasma HIV-1 RNA PCR	All Participants	4.0 mL EDTA Blood	F3008 and F3111	If sending plasma: Prepare 2 x 1.0-1.5mL aliquots	BLD/EDT or DPE/PL2	Send to local clinical lab ambient or freeze at -70°C or lower until shipped to testing lab. Adjust plasma volume in LDMS as needed.
Plasma for inflammatory biomarkers.	All Participants	5.0 mL EDTA Blood	F3008	Prepare 2 x 1.0-1.5mL aliquots	BLD/EDT or DPE/PL1	Store @ -70 C or lower until shipping requested by protocol team. See Sec. 5 for shipping instructions. Adjust plasma volume in LDMS as needed.

Section 5: Helpful Links and Shipping Addresses		
ACTG/IMPAACT Laboratory Manual, Shipping Information and other useful information: http://www.hanc.info/labs/labresources/Pages/informationActgImpaactLabs.aspx		
<p>Inflammatory Biomarkers</p> <p>Dr. Adriana Weinberg MD University of Colorado Denver 12700 E. 19th Avenue Research 2, P15 Room 11480 Aurora, CO 80045 Phone: 303-724-4481 Fax: 303-724-4485 Email: adriana.tovarsalazar@ucdenver.edu</p> <p>Lab 174</p>	<p>NICHD Repository Specimens</p> <p>Maria Wolff Biological Services Division, Fisher Bioservices 625 Lofstrand Lane Rockville, MD 20850 Phone: 301-340-1620 Fax: 301-838-9753 Email: maria.wolff@themofisher.com LDMS lab code: 243</p>	<p>NIAID Repository Specimens</p> <p>Biomedical Research Institute (BRI) c/o John C. Ward, Jr. Shipping address: 9410 Key West Avenue, First Floor Rockville, MD 20850 Phone: 301-881-7636 Fax: 301-770-9811 Email: brirepository@sfbr-bri.com LDMS lab code: 999</p>

Section IV: Revision History	
Version & Date (dd/mmm/yy)	Comments
V1.1 05/DEC/2016	Updated shipping address for Inflammatory Biomarkers
V1.2 28/JAN/2017	Added NIAID and NICHD shipping information; reworded instructions for HIV RNA collection and processing