HALT-C Specimen Collection and Processing: Blood Specimens

I. Blood Specimen Collection:

Blood will be collected at every HALT-C Trial study visit. The schedule of collection is detailed in the Blood Draw Protocol (Attachment A). The Blood Draw Protocol illustrates the Vacutainer tubes to be collected and the tests to be performed from each tube by study visit. This Blood draw protocol is generic and can be modified based on clinical center local lab requirements.

The blood tests that should be performed at local and central labs will also be detailed on the Visit Control Sheet that can be generated by the Data Management System (DMS) before each patient study visit.

The Blood Draw Protocol includes the blood to be collected for the Steatosis and Iron and HFE Gene Mutation Ancillary Studies, as all patients enrolled into HALT-C will participate in these studies.

There are several additional Ancillary Studies that require collection of blood that are not included in the Blood Draw protocol as not all centers will participate. These include the Immunology/Virology AS, Quantitative Liver Function Test AS, Serum Fibrosis Marker AS and Cognition AS. Please see the Ancillary study section (Section K) of this manual for the specimen collection requirements of these studies.

II. Blood Specimen Processing:

A. Local lab testing:

Blood collected for local testing should be labeled and processed per each clinical center's standard procedure. Results of these assays should be recorded on Form #30: Local Lab, Form #35: Screen 2 Local Lab, and Form #34: AFP.

B. Central lab/Repository:

Blood collected for testing or storage at the BBI Repository or Virology Lab (marked as REPO on Blood Draw Protocol) must be processed and labeled prior to shipment. BBI will supply packets of labels to be used for specimens that will be shipped to the Repository. These label packets will be specific for Screen 1, Screen 2, Lead in Phase, Randomized Phase, Week 20 Responder, R00 visit, Immunology/Virology AS, QLFT AS and Serum Fibrosis Marker AS study visits. A new packet should be used for each patient visit. For Screening, Lead in Phase and the R00 visit, an additional label with the patient ID must be attached with the study visit written on the label.

The Visit Control Sheet will include information on the specimens to be collected for the Repository, including volumes and sequence numbers. See Attachment B for the table of sequence numbers to be used for specimens shipped to the Repository.

1.) Fresh Blood:

Fresh blood will be collected at Screen 2, and when applicable at M21 and M45 (see the Form #73 QxQ for details). The Visit Control Sheet will list the fresh blood specimens to be aliquotted for each study visit. The Vacutainer tubes should be shipped at room temperature to the Repository via overnight delivery on the date collected. These specimens should be held at room temperature prior to shipping. See Section E.4 for shipping procedures.

The Vacutainer tubes must be labeled with the labels supplied by the Repository. The patient's name must not be written on the tube. For Screen 2, the Vacutainer tubes should be labeled with sequence number 003 and 004 (EBV) and 001 and 002 (PBMC). A second

label, supplied by the DCC, with the patient ID should be attached for the S00 visits. For M21 and M45, the tubes should be labeled with sequence number 001 and 002 (PBMC).

Collection of these tubes should be recorded on the appropriate Aliquot Form (Form #71 for Screen 2 and Form #73 for M21 and M45). This form must be data entered prior to shipping these specimens.

2.) Serum:
Blood will be collected in Red top or Tiger top Vacutainer tubes at every visit for serum. Serum must be separated within 2-4 hours of collection. The Visit Control Sheet will list the serum specimens to be aliquotted for each study visit.

Serum Processing Procedures:
a.) Allow blood to clot at room temperature for approximately 30 minutes.
b.) Centrifuge the Vacutainer tubes @ 2,500- 3,500 rpm for 10-15 minutes.
c.) Aliquot 1ml of serum into aliquot tubes supplied by the Repository.
d.) Aliquot tubes should be labeled with the appropriate labels supplied by the Repository.
e.) A second label, supplied by the DCC, with the patient ID should be attached to each aliquot tube. The study visit should be written on these labels.
f.) Tubes should be frozen immediately at -20^0C or -70^0C until ready to ship these specimens to the Repository.
g.) Collection of these specimens must be recorded on the Aliquot Form for this visit: Form #70: Screen 1 Aliquot Form, Form #71: Screen 2 Aliquot Form, Form #72: Lead in Phase Aliquot Form, Form #73: Randomized Phase Aliquot Form, Form ##74: Week 20 Responder Aliquot Form, Form 77: R00 Visit Aliquot Form. These forms must be data entered prior to shipping.
h.) See Section E-4 for shipping procedures.

3.) Whole Blood for DNA:
Whole Blood for DNA will be collected in Yellow top Vacutainer tubes at the following visits; 20ml should be collected at M09, M15, M18, M27, W30, W42 and W60, 10ml should be collected at W36 and W72.

BBI will be providing large 10ml aliquot tubes to the clinical centers. The whole blood for DNA specimens should be transferred directly from the ACD yellow top tubes to these large 10ml aliquot tubes.
- Tubes should be frozen immediately at -20°C or -70°F until ready to ship these specimens to the Repository.
- These specimens should be included in the weekly frozen shipments to the Repository.

4.) Repeat HCV-RNA
Once a patient has a positive HCV-RNA at W36, W48, W60 or W72 the patient will have the option to come in for a repeat HCV-RNA. Use Form #76: Repeat HCV-RNA Aliquot to list the serum aliquots will be shipped to the Virology lab via BBI for RNA testing. Results will be reported on Form #37: Repeat HCV-RNA Results.

The patient might not come in for the repeat blood draw but wait until the next scheduled visit with HCV-RNA testing to have the confirmatory HCV-RNA test. In these cases the standard procedures will be used i.e.: Form #74: W20 Responder aliquot form and Form #31: HCV-RNA Form.

ATTACHMENT A

HALT-C Trial Blood Draw Protocol
Screening and Lead-in Phases

	Scr1	Scr2	W00	W02	W04	W08	W12	W16	W20	W24
Red Top	**34ml**	**20ml**	**45ml**	**18ml**	**15ml**	**15ml**	**30ml**	**15ml**	**38ml**	**32ml**
Remove serum for tests:										
[1]Liver Function Test	5	5	5	5	5	5	5	5	5	5
Uric Acid	5		5						5	
Alpha-fetoprotein (AFP)	3		3						3	
Thyroid-stimulating hormone (TSH)		5					5		5	
Repository (REPO)	10	10	17	10	10	10	10	10	10	17
HCV-RNA (REPO)	10		10				10		10	10
Fasting Insulin-Steatosis (REPO)			5							
Genotyping (REPO)				3						
Serum ferritin	1									
[4]Serologic assays	X									
Lavender Top	**7ml**		**3ml**	**3ml**	**3ml**	**3ml**	**3ml**	**3ml**	**3ml**	**3ml**
Remove whole blood for tests:										
[5]Complete Blood Count (CBC)	3		3	3	3	3	3	3	3	3
HIV	4									
[3]Glycosylated hemoglobin (HgbA1c)	X									
Blue Top	**3ml**		**3ml**				**3ml**		**3ml**	
Remove whole blood for tests:										
[7] Prothrombin Time (INR)	3	3	3				3		3	
Green Top	**5ml**		**3ml**						**3ml**	
Remove whole blood for tests:										
[2] Fasting Chemistry	3		3						3	
Serum Iron	1									
Total Iron Binding Capacity	1									
Yellow Top		**40ml**								
For overnight shipment to Repository:										
PBMC/Future Use (REPO)		20								
[8] EBV Cell lines (REPO)		20								

[1] Liver Function Tests to include: AST, ALT, Alkaline Phosphatase, Total bilirubin, Total protein or globulin, Albumin
[2] Fasting Chemistries to include: BUN, creatinine, glucose, triglycerides
[3] To be performed on known diabetics only
[4] Serologic assays to include HBsAg + ANA, Hepatitis B surface antigen, Ceruloplasmin, Alpha-1 antitrypsin if previous results of these assays are not available
[5] CBC to include platelets
[7] For Express patients only at S02
[8] Collected only if patient consented for genetic testing

HALT-C Trial Blood Draw Protocol
Randomized Phase

	M09	M12	M15	M18	M21	M24	M27	M30	M33	M36	M39	M42	M45	M48	M54
Red Top	**18ml**	**40ml**	**18ml**	**33ml**	**18ml**	**46ml**	**18ml**	**33ml**	**18ml**	**40ml**	**18ml**	**33ml**	**18ml**	**41ml**	**35ml**
Remove serum for tests:															
[1]Liver Function Test	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
Uric Acid															
Alpha-fetoprotein (AFP)	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
Thyroid-stimulating hormone (TSH)		5		5		5		5		5		5		5	
Repository (REPO)	10	17	10	10	10	17	10	10	10	17	10	10	10	17	17
HCV-RNA (REPO)		10		10		10		10		10		10		10	10
Fasting Insulin-Steatosis (REPO)						5									
Serum ferritin						1								1	
Lavender Top	**3ml**	**3ml**	**3ml**	**3ml**	**3ml**	**3ml**	**3ml**	**3ml**	**3ml**	**3ml**	**3ml**	**3ml**	**3ml**	**7ml**	**3ml**
Remove whole blood for tests:															
[5]Complete Blood Count (CBC)	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
HIV														4	
Blue Top	**3ml**	**3ml**	**3ml**	**3ml**	**3ml**	**3ml**	**3ml**	**3ml**	**3ml**	**3ml**	**3ml**	**3ml**	**3ml**	**3ml**	**3ml**
Remove whole blood for tests:															
Prothrombin Time (INR)	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
Green Top		**3ml**		**3ml**		**5ml**		**3ml**		**3ml**		**3ml**		**5ml**	
Remove whole blood for tests:															
[2]Fasting Chemistry		3		3		3		3		3		3		3	
Fasting Iron						1								1	
Total Iron Binding Capacity						1								1	
Yellow Top	**20 ml**		**20 ml**	**20 ml**	**30 ml**		**20 ml**						**30 ml**		
For overnight shipment to Repository:															
PBMC/Future use (REPO)					30ml								30ml		
Aliquoted and frozen at site and shipped in weekly frozen shipments:															
[8]Whole Blood for DNA (REPO)	20ml		20ml	20ml			20ml								

[1] Liver Function Tests to include: AST, ALT, Alkaline Phosphatase, Total bilirubin, Total protein or globulin, Albumin
[2] Fasting Chemistries to include: BUN, creatinine, glucose, triglycerides
[5] CBC to include platelets
[8] Collected only if patient consented for genetic testing

HALT-C Trial Blood Draw Protocol
Responder Phase

	W30	W36	W42	W48	W60	W72
Red Top	**15ml**	**33ml**	**15ml**	**38ml**	**28ml**	**33ml**
Remove serum for tests:						
[1]Liver Function Test	5	5	5	5	5	5
Uric Acid				5		
Alpha-fetoprotein (AFP)		3		3	3	3
Thyroid-stimulating hormone (TSH)		5		5		5
Repository (REPO)	10	10	10	10	10	10
HCV-RNA (REPO)		10		10	10	10
[6] Repeat HCV-RNA (REPO)		(10)		(10)	(10)	(10)
Lavender Top	**3ml**	**3ml**	**3ml**	**3ml**	**3ml**	**3ml**
Remove whole blood for tests:						
[5]Complete Blood Count (CBC)	3	3	3	3	3	3
Blue Top		**3ml**		**3ml**	**3ml**	**3ml**
Remove whole blood for tests:						
Prothrombin Time (PT)		3		3	3	3
Green Top				**3ml**	**3ml**	**3ml**
Remove whole blood for tests:						
[2]Fasting Chemistries				3	3	3
Yellow Top	**20ml**	**10ml**	**20ml**		**20ml**	**10ml**
Remove whole blood for tests:						
Whole Blood for DNA (REPO)	20ml	10ml	20ml		20ml	10ml

[1] Liver Function Tests to include: AST, ALT, Alkaline Phosphatase, Total bilirubin, Total protein or globulin, Albumin
[2] Fasting Chemistries to include: BUN, creatinine, glucose, triglycerides
[5] CBC to include platelets
[6] Repeat HCV-RNA taken at one of the 4 visits, after having the first positive HCV-RNA and distinguished as a Breakthrough/Relapse patient.

HALT-C Trial Blood Draw Protocol
R00 visit
Breakthrough/Relapser & Express Patients

	R00
Total	**20 or23 ml**
Red Top	
Remove serum for tests:	
[1]Liver Function Test	5
Uric Acid	5
HCV-RNA (REPO)	10
Alpha-fetoprotein (AFP)[3]	3
Total	**3ml**
Lavender Top	
Remove whole blood for tests:	
[5]Complete Blood Count (CBC)	3
Total	**3ml**
Blue Top	
Remove whole blood for tests:	
Prothrombin Time (PT)	3
Total	**3ml**
Green Top	
Remove whole blood for tests:	
[2]Fasting Chemistries	3

[1] Liver Function Tests to include: AST, ALT, Alkaline Phosphatase, Total bilirubin, Total protein or globulin, Albumin
[2] Fasting Chemistries to include: BUN, creatinine, glucose, triglycerides
[3] Express patients only
[5] CBC to include platelets

ATTACHMENT B

Repository Specimen Table

Description of Material				Screen		Lead in Phase								R00 Visit	Randomized Phase															W20 Responder Phase					
Material	Purpose	Vol (ml)	Seq #	S 00	S 00	W 00	W 02	W 04	W 08	W 12	W 16	W 20	W 24	R 00	M 09	M 12	M 15	M 18	M 21	M 24	M 27	M 30	M 33	M 36	M 39	M 42	M 45	M 48	M 54	W 30	W 36	W 42	W 48	W 60	W 72
Vacutainers																																			
ACD	blood for PBMC	10	001		X														[2]X								[2]X								
ACD	blood for PBMC	10	002		X														[2]X								[2]X								
ACD	blood for PBMC	10	007																[2]X								[2]X								
ACD	blood for EBV	10	003		X																														
ACD	blood for EBV	10	004		X																														
ACD	spare	10	005																																
ACD	spare	10	006																																
Aliquot tubes for Main Trial																																			
Serum	AFP	1.0	100																																
Serum	HCV-RNA-S00/W20	1.0	101	X								X																							
Serum	HCV-RNA-S00/W20	1.0	102	X								X																							
Serum	HCV-RNA-S00/W20	1.0	103	X								X																							
Serum	HCV-RNA-S00/W20	remain	104	X								X																							
Serum	HCV-RNA-other visits	1.0	105			X				X			X	X		X		X		X		X		X		X		X	X		X		X	X	X
Serum	HCV-RNA-other visits	1.0	106			X				X			X	X		X		X		X		X		X		X		X	X		X		X	X	X
Serum	HCV-RNA-other visits	1.0	107			X				X			X	X		X		X		X		X		X		X		X	X		X		X	X	X
Serum	HCV-RNA-other visits	remain	108			X				X			X	X		X		X		X		X		X		X		X	X		X		X	X	X
Serum	Repeat HCV-RNA	1.0	150																																
Serum	Repeat HCV-RNA	1.0	151																																
Serum	Repeat HCV-RNA	1.0	152																																
Serum	Repeat HCV-RNA	1.0	153																																
Serum	serum for Genotype	1.0	109				X							[3]X																					
Serum	Long-term storage	1.0	110	X		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Serum	Long-term storage	1.0	111	X		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

[2] Only if Baseline specimens were collected.
[3] Express patients only

Description of Material				Screen		Lead in Phase								R00 Visit	Randomized Phase														W20 Responder Phase					
Material	Purpose	Vol (ml)	Seq #	S 00	S 00	W 00	W 02	W 04	W 08	W 12	W 16	W 20	W 24	R 00	M 09	M 12	M 15	M 18	M 21	M 24	M 27	M 30	M 33	M 36	M 39	M 42	M 45	M 48	M 54	W 30	W 36	W 42	W 48	W 60	W 72
Aliquot tubes for Main Trial																																		
Serum	Long-term storage	1.0	112			X							X	X		X				X				X				X	X					
Serum	Long-term storage	1.0	113			X							X	X		X				X				X				X	X					
Serum	Long-term storage	1.0	114			X							X	X		X				X				X				X	X					
Serum	Long-term storage*	1.0	115	X		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Serum	Long-term storage*	1.0	116	X		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Serum	Long-term storage	1.0	117		X																													
Serum	Long-term storage	1.0	118		X																													
Serum	Long-term storage*	1.0	119		X																													
Serum	Long-term storage*	1.0	120		X																													
Serum	Steatosis	1.0	121			X														X														
Serum	Steatosis	1.0	122			X														X														
Serum	Spare	1.0	123																															
Serum	Spare	1.0	124																															
Serum	Spare	1.0	125																															
Serum	Spare	1.0	126																															
Serum	Spare	1.0	127																															
Serum	Repeat AFP	1.0	129																															
Liver	Long-term storage	2.5cm	130		X															X								X						
Liver OCT	Long-term storage	0.4cm	132																	X								X						
	*stored locally until notified to ship to Repository																																	

Description of Material				Screen		Lead in Phase								R00 Visit	Randomized Phase															W20 Responder Phase						
Material	Purpose	Vol (ml)	Seq #	S 00	S 00	W 00	W 02	W 04	W 08	W 12	W 16	W 20	W 24	R 00	M 09	M 12	M 15	M 18	M 21	M 24	M 27	M 30	M 33	M 36	M 39	M 42	M 45	M 48	M 54	W 30	W 36	W 42	W 48	W 60	W 72
Aliquot tubes for Randomized and Responder Phase																																				
Whole Blood	DNA	10	140												X		X	X			X									X	X	X		X	X
Whole Blood	DNA	10	141												X		X	X			X									X		X		X	
Whole Blood	spare	10	143																																	
Whole Blood	spare	10	144																																	
Aliquot tubes for Ancillary Studies																																				
Serum	Immunology-NA	1.0	301			X								[1, 2] X		X				X				X				X							
Serum	Virology-QUASI	1.0	302			X							X	[1, 2] X		X				X				X				X	X						
Serum	Virology-QUASI	1.0	303			X							X	[1, 2] X		X				X				X				X	X						
Serum	Fibrosis	0.5	305			X							X	[1] X		X				X				X				X					X		X
Serum	Fibrosis	0.5	306			X							X	[1] X		X				X				X				X					X		X
Serum	Fibrosis	0.5	307			X							X	[1] X		X				X				X				X					X		X
Serum	Fibrosis	0.5	308			X							X	[1] X		X				X				X				X					X		X
Serum	Fibrosis	0.5	309			X							X	[1] X		X				X				X				X					X		X
Serum	Fibrosis	0.5	310			X							X	[1] X		X				X				X				X					X		X
Serum	Fibrosis	0.5	311			X							X	[1] X		X				X				X				X					X		X
Serum	Fibrosis	0.5	312			X							X	[1] X		X				X				X				X					X		X
Serum	Fibrosis	0.5	313			X							X	[1] X		X				X				X				X					X		X
Serum	Fibrosis	0.5	314			X							X	[1] X		X				X				X				X					X		X
Serum	Fibrosis	1.0	315			X							X	[1] X		X				X				X				X					X		X
Serum	Fibrosis	1.0	316			X							X	[1] X		X				X				X				X					X		X
Serum	Fibrosis	1.0	317			X							X	[1] X		X				X				X				X					X		X
Serum	Fibrosis	1.0	318			X							X	[1] X		X				X				X				X					X		X
Serum	Fibrosis	remain	319			X							X	[1] X		X				X				X				X					X		X
Liver-OCT	Virology-Replication	2.5cm	320		X															X								X							

[1] Breakthrough/Relapse patients only.
[2] Only if Baseline specimens were collected.

Description of Material				Screen		Lead in Phase								R00 Visit	Randomized Phase													W20 Responder Phase						
Material	Purpose	Vol (ml)	Seq #	S 00	S 00	W 00	W 02	W 04	W 08	W 12	W 16	W 20	W 24	R 00	M 09	M 12	M 15	M 18	M 21	M 24	M 27	M 30	M 33	M 36	M 39	M 42	M 45	M 48	M 54	W 30	W 36	W 42	W 48	W 60	W 72
Aliquot tubes for Ancillary Studies (AS)-QLFT																																		
Serum	QLFT-Lidocaine/T=0	2.0	330			X								[3] X						X								X						
Serum	QLFT-Lidocaine/T=15	2.0	331			X								[3] X						X								X						
			332											[3] X																					
Serum	QLFT-cholate/T=0	2.0	333			X								[3] X						X								X						
Serum	QLFT-cholate/T=5	2.0	334			X								[3] X						X								X						
Serum	QLFT-cholate/T=10	2.0	335			X								[3] X						X								X						
Serum	QLFT-cholate/T=15	2.0	336			X								[3] X						X								X						
Serum	QLFT-cholate/T=20	2.0	337			X								[3] X						X								X						
Serum	QLFT-cholate/T=30	2.0	338			X								[3] X						X								X						
Serum	QLFT-cholate/T=45	2.0	339			X								[3] X						X								X						
Serum	QLFT-cholate/T=60	2.0	340			X								[3] X						X								X						
Serum	QLFT-cholate/T=75	2.0	341			X								[3] X						X								X						
Serum	QLFT-cholate/T=90	2.0	342			X								[3] X						X								X						
Serum	QLFT-cholate/T=105	2.0	343			X								[3] X						X								X						
Serum	QLFT-cholate/T=120	2.0	344			X								[3] X						X								X						
Serum	QLFT-cholate/T=150	2.0	345			X								[3] X						X								X						
Serum	QLFT-cholate/T=180	2.0	346			X								[3] X						X								X						
Plasma	QLFT-galactose/T=0	2.0	347			X								[3] X						X								X						
Plasma	QLFT-galactose/T=20	2.0	348			X								[3] X						X								X						
Plasma	QLFT-galactose/T=40	2.0	349			X								[3] X						X								X						
Plasma	QLFT-galactose/T=60	2.0	350			X								[3] X						X								X						
Plasma	QLFT-galactose/T=80	2.0	351			X								[3] X						X								X						
Saliva	QLFT-saliva/T=0	2.0	352			X								[3] X						X								X						
Saliva	QLFT-saliva/T=6	2.0	353			X								[3] X						X								X						
Saliva	QLFT-saliva/T=12	2.0	354			X								[3] X						X								X						
Saliva	QLFT-saliva/T=24	2.0	355			X								[3] X						X								X						
Saliva	QLFT-saliva/T=36	2.0	356			X								[3] X						X								X						
Saliva	QLFT-saliva/T=48	2.0	357			X								[3] X						X								X						
Saliva	QLFT-saliva/T=60	2.0	358			X								[3] X						X								X						

[3] Express patients only.

Description of Material				Screen		Lead in Phase								R00 Visit	Randomized Phase															W20 Responder Phase					
Material	Purpose	Vol (ml)	Seq #	S 00	S 00	W 00	W 02	W 04	W 08	W 12	W 16	W 20	W 24	R 00	M 09	M 12	M 15	M 18	M 21	M 24	M 27	M 30	M 33	M 36	M 39	M 42	M 45	M 48	M 54	W 30	W 36	W 42	W 48	W 60	W 72
Aliquot tubes for Ancillary Studies (AS)-QLFT																																			
Breath	QLFT-MBT/00-1	10.0	30			X								[3] X						X															
Breath	QLFT-MBT/00-2	10.0	31			X								[3] X						X															
Breath	QLFT-MBT/T=10	10.0	32			X								[3] X						X															
Breath	QLFT-MBT/T=20	10.0	33			X								[3] X						X															
Breath	QLFT-MBT/T=30	10.0	34			X								[3] X						X															
Breath	QLFT-MBT/T=40	10.0	35			X								[3] X						X															
Breath	QLFT-MBT/T=50	10.0	36			X								[3] X						X															
Breath	QLFT-MBT/T=60	10.0	37			X								[3] X						X															

[3] Express patients only.

HALT-C Trial Local Lab Blood Collection

Local Lab Blood Collection	Screening Phase (S00)			Lead In Phase							
Visit Number →	Screen1		Screen2	W00	W02	W04	W08	W12	W16	W20	W24
CBC											
WBC	X			X	X	X	X	X	X	X	X
Neutrophils	X			X	X	X	X	X	X	X	X
Hematocrit	X			X	X	X	X	X	X	X	X
Hemoglobin	X			X	X	X	X	X	X	X	X
Platelets	X			X	X	X	X	X	X	X	X
Fasting Serum Chemistries											
BUN	X			X						X	
Creatinine	X			X						X	
Glucose	X			X						X	
Triglycerides	X			X						X	
Serum Uric Acid											
Uric Acid	X			X						X	
Liver Chemistries											
AST	X	&	X	X		X	X	X	X	X	X
ALT	X	&	X	X		X	X	X	X	X	X
Alkaline phosphatase	X	&	X	X		X	X	X	X	X	X
Total bilirubin	X	&	X	X		X	X	X	X	X	X
Albumin	X	&	X	X		X	X	X	X	X	X
Globulin or Total Protein	X	&	X	X		X	X	X	X	X	X
Protrombin Time											
Prothrombin Time (INR)	X		X	X				X		X	
TSH											
TSH			X					X		X	
AFP											
AFP	X			X						X	
Urinalysis											
Urinalysis (heme & protein)			X								

Study-Wide Trial Forms	Randomized Phase																
Local Lab Blood Collection	**R00**		**M09**	**M12**	**M15**	**M18**	**M21**	**M24**	**M27**	**M30**	**M33**	**M36**	**M39**	**M42**	**M45**	**M48**	**M54**
Visit Number ➔	*Exp.*	*Bt/R*															
CBC																	
WBC	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Neutrophils	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Hematocrit	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Hemoglobin	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Platelets	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Fasting Serum Chemistries																	
BUN	X	X		X		X		X		X		X		X		X	
Creatinine	X	X		X		X		X		X		X		X		X	
Glucose	X	X		X		X		X		X		X		X		X	
Triglycerides	X	X		X		X		X		X		X		X		X	
Serum Uric Acid																	
Uric Acid	X	X															
Liver Chemistries																	
AST	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
ALT	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Alkaline phosphatase	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Total bilirubin	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Albumin	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Globulin or Total Protein	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Protrombin Time																	
Prothrombin Time (INR)	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
TSH																	
TSH				X		X		X		X		X		X		X	
AFP																	
AFP	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Urinalysis																	
Urinalysis (heme & protein)				X				X				X				X	

Local Lab Blood Collection	Responder Phase					
Visit Number ➔	**W30**	**W36**	**W42**	**W48**	**W60**	**W72**
CBC						
WBC	X	X	X	X	X	X
Neutrophils	X	X	X	X	X	X
Hematocrit	X	X	X	X	X	X
Hemoglobin	X	X	X	X	X	X
Platelets	X	X	X	X	X	X
Fasting Serum Chemistries						
BUN				X	X	X
Creatinine				X	X	X
Glucose				X	X	X
Triglycerides				X	X	X
Serum Uric Acid						
Uric Acid				X		
Liver Chemistries						
AST	X	X	X	X	X	X
ALT	X	X	X	X	X	X
Alkaline phosphatase	X	X	X	X	X	X
Total bilirubin	X	X	X	X	X	X
Albumin	X	X	X	X	X	X
Globulin or Total Protein	X	X	X	X	X	X
Protrombin Time						
Prothrombin Time (INR)		X		X	X	X
TSH						
TSH		X		X		X
AFP						
AFP		X		X	X	X
Urinalysis						
Urinalysis (heme & protein)				X		