

Sample Availability and Location

Table 1 lists the status and location of all HALT-C samples (blood, breath, liver) that have been collected. Samples typically are collected and stored for a short period at the clinical center, then shipped to the SeraCare (BBI) repository. SeraCare stores certain samples and ships other samples to laboratories for HCV RNA or ancillary study testing. Samples sent to a lab may have been returned to SeraCare after testing was completed. A small percentage of samples have not been located at the site or at SeraCare. Some samples were destroyed because they were broken, damaged, or thawed during shipment or because there was lack of consent to collect the specimen.

Table 1: Status and Location of Samples

Purpose	Sample Location				Not counted			Total
	At CC	Shipped	At Sera-Care	Shipped to Lab	Not found at CC	Not found ship	Broken	
001-002, 005-006: Fresh Blood For PBMC	0	0	4,288	0	16	0	7	4,311
003-004, 007: Fresh Blood for EBV	0	0	3,622	0	9	1	8	3,640
030-037: QLFT M Breath Test	0	0	0	3,400	0	8	0	3,408
100: AFP	0	0	27	1,789	0	1	2	1,819
101-104: HCV RNA S00, W20	0	0	0	11,412	4	4	26	11,446
105-108: HCV RNA other	0	0	0	47,890	17	10	73	47,990
109: HCV Genotype	0	0	22	1,348	0	0	4	1,374
110-120, 123-127: Spare Serum	0	0	126,836	24,710	140	19	372	152,077
121-122: Steatosis	0	0	2,065	2,079	2	0	4	4,150
129: Repeat AFP	0	0	1	28	1	0	0	30
130-131: Frozen liver storage	0	0	1,670	175	20	5	8	1,878
132: Liver tissue in OCT for Main Trial	0	0	238	0	5	0	1	244
140-143: Frozen Whole Blood	0	0	8,490	404	15	0	83	8,992
150-153: Repeat HCV RNA	0	0	0	430	0	0	1	431
210-215: Serum for Extended Follow-up (1 ml)	0	0	2,423	35	15	0	6	2,479
220-231: Serum for Extension 2007 (0.5 ml)	283	0	29,317	0	145	0	11	29,756
301: Neutralizing Antibodies	0	0	698	710	2	1	8	1,419
302-303: Quasispecies	0	0	2,056	1,101	8	0	16	3,181
305-319: Serum Fibrosis Markers	0	0	22,200	8,755	49	3	29	31,036
320: Liver in OCT for replication	0	0	413	191	5	1	2	612
330-358: QLFT Ancillary	0	0	0	7,702	3	0	5	7,710
400-429: Serum for EDRN	0	0	4,382	4,366	0	0	0	8,748
500-504: Plasma	0	0	12,969	10	0	0	0	12,979
505-515: PBMC	0	0	8,278	742	0	0	1	9,021
520-539: EBV Cells	0	0	4,584	668	0	0	68	5,320
540-569: DNA from EBV (10 µg)	0	0	6,662	2,794	0	0	16	9,472
570-599: DNA from Froz Whole Blood (10 µg)	0	0	2,129	356	0	0	0	2,485
650-654: IMM AS Extra PBMC	0	0	477	7	0	0	0	484
655-659: IMM AS Extra BLCL	0	0	272	3	0	0	0	275
660-664: IMM AS Extra Plasma	0	0	2	0	0	0	0	2
800-829: DNA from PBMC (10 µg)	0	0	278	98	0	0	0	376
900-919: DNA from PBMC (1 µg)	0	0	474	260	0	0	0	734
940-959: DNA from EBV (1 µg)	0	0	6,094	3,457	0	0	0	9,551
960-999: DNA from Froz Whole Blood (1 µg)	0	0	1,825	753	0	0	0	2,578
Total:	283	0	252,792	125,673	456	53	751	380,008

Randomized Patients: Serum Sample Availability

Table 2 lists the estimated number of vials containing serum samples for randomized patients currently stored at the repository and available for further testing. All visits are included, from Screening through Lead-in, W20 Responder Phase, through the Randomized Phase up to the final Extension 2007 visits.

Table 2: Randomized Patients: Serum Sample Availability

Visit	Total Patients with Vials Available	Patients with specified number of vials available											
		1	2	3	4	5	6	7	8	9	10	11	>=12
S00	1050	1	7	21	42	125	205	285	197	118	30	17	2
W00	810	3	2	7	15	83	385	85	163	39	17	11	0
W02	788	0	8	12	490	29	249	0	0	0	0	0	0
W04	805	0	7	82	462	57	197	0	0	0	0	0	0
W08	804	0	4	4	528	39	228	0	1	0	0	0	0
W12	808	0	9	76	420	89	214	0	0	0	0	0	0
W16	800	0	2	6	507	34	251	0	0	0	0	0	0
W20	810	6	88	387	61	268	0	0	0	0	0	0	0
W24	798	1	6	2	16	80	246	212	161	44	18	11	1
W30	150	0	0	0	98	9	43	0	0	0	0	0	0
W36	150	1	1	5	84	11	48	0	0	0	0	0	0
W42	147	1	0	3	89	15	39	0	0	0	0	0	0
W48	142	0	2	61	37	39	3	0	0	0	0	0	0
W60	132	0	5	18	67	14	28	0	0	0	0	0	0
W72	61	0	0	35	4	22	0	0	0	0	0	0	0
R00	383	1	2	10	37	144	45	78	49	3	3	11	0
M09	995	0	11	251	288	167	278	0	0	0	0	0	0
M12	978	1	6	23	65	389	106	247	51	38	52	0	0
M15	946	0	20	381	197	302	46	0	0	0	0	0	0
M18	951	2	35	458	125	323	7	1	0	0	0	0	0
M21	929	0	40	424	130	335	0	0	0	0	0	0	0
M24	938	2	4	7	7	44	371	62	257	58	60	64	2
M27	875	0	157	317	174	227	0	0	0	0	0	0	0
M30	881	1	56	392	136	279	7	10	0	0	0	0	0
M33	853	0	51	388	111	303	0	0	0	0	0	0	0
M36	890	1	9	42	61	322	31	232	58	49	81	2	2
M39	796	0	50	358	103	284	1	0	0	0	0	0	0
M42	822	7	60	387	106	246	9	7	0	0	0	0	0
M45	762	1	157	270	155	179	0	0	0	0	0	0	0
M48	839	2	5	37	55	290	59	216	66	37	60	5	7
M54	729	2	4	6	14	33	28	261	44	214	26	86	11
M60	697	0	0	20	148	34	175	1	17	6	80	16	200
M66	427	0	1	0	0	2	3	2	5	5	112	15	282
M72	583	0	3	6	43	14	46	3	6	9	132	11	310
M78	536	0	0	0	2	1	3	0	5	9	145	13	358
M84	386	0	1	0	0	0	1	1	5	3	114	8	253
M90	250	0	0	0	0	1	3	1	2	2	70	4	167
M96	139	0	0	0	0	0	0	1	1	3	42	1	91
M102	65	0	0	0	1	0	0	0	1	1	21	1	40
M108	14	0	0	0	0	0	0	0	0	0	3	1	10
Total	24,919	33	813	4,496	4,878	4,833	3,355	1,705	1,089	638	1,066	277	1,736

Genetic Sample Availability

Tables 3A and 3B summarize the number of vials available at the repository for specific genetic samples for patients who gave genetic consent. Of 1,382 enrolled patients, 1,263 (91%) gave genetic consent. Of 1,050 randomized patients, 950 (91%) gave genetic consent.

Table 3A: All Patients: Genetic Sample Availability

All patients	Patients with specified number of vials available								Total patients with vials available
	0	1	2	3	4	5-9	10-19	20+	
DNA in 1ug vial	241	2	0	3	3	1005	9	0	1022
DNA in 10ug vial	70	86	94	119	109	466	298	21	1193
Frozen whole blood	143	22	40	27	34	844	150	3	1120
EBV cells	255	10	3	11	719	265	0	0	1008
PBMC	19	66	246	205	137	417	165	8	1244
Any genetic	1	0	0	0	0	26	189	1047	1262

Table 3B: Randomized Patients: Genetic Sample Availability

All randomized patients	Patients with specified number of vials available								Total patients with vials available
	0	1	2	3	4	5-9	10-19	20+	
DNA in 1ug vial	104	2	0	3	2	836	4	0	847
DNA in 10ug vial	47	66	65	82	83	340	249	19	904
Frozen whole blood	31	11	26	8	30	704	138	3	920
EBV cells	74	3	2	5	613	254	0	0	877
PBMC	16	52	195	120	92	310	158	8	935
Any genetic	1	0	0	0	0	0	42	908	950

Liver Specimen Sample Availability

Table 4 lists the number of liver specimens available at the repository for all patients. Liver specimens were collected by two methods: flash frozen and maintained in OCT.

Table 4: Liver Specimen Sample Availability, All Patients

	Visit			Total
	S00	M24	M48	
Flash Frozen liver	578	602	489	1669
OCT Liver for Main Trial	0	84	154	238
OCT Liver for Repl Study	142	150	121	413
Any OCT	142	234	275	651

Liver slides for patients in the HALT-C Trial have been stored at the Armed Forces Institute of Pathology (AFIP) and will be transferred to the NIDDK Sample Repository in January 2010. Slide sets (slides from a single biopsy) were sent to the DCC by clinical sites, marked with a masked ID number, and then transferred to AFIP. Slide sets typically contained 10 unstained slides. Slides were requested at the Screening (S00), Month 24 (M24), and Month 48 (M48) study visits. In addition, slides were requested from patients with confirmed HCC (listed as "Other" in the tables). At AFIP, four of the slides in each set were stained to allow central review. The remaining slides in the set were left unstained. Table 5 provides information on the number of unstained liver slides available.

Table 5: All Patients: Unstained Liver Slide Availability

Visit	Total Patients with Unstained Slides Available	Patients with specified number of unstained liver slides available											
		1	2	3	4	5	6	7	8	9	10	11	>=12
S00	1219	2	3	7	20	23	1139	12	4	1	0	1	7
M24	843	1	1	1	6	24	767	37	3	0	1	0	2
M48	718	0	3	2	2	22	675	4	4	0	0	2	4
Other	21	1	0	0	3	0	9	3	0	1	0	1	3
Total	2801	4	7	10	31	69	2590	56	11	2	1	4	16

Table 6 provides information on the number of stained liver slides available. For patients with 4 or more slides, it should be assumed that at least one of the following types of stains is available: Masson (Trichome); Sirius red; Mallory's iron; H & E (Hematoxylin & Eosin).

Table 6: All Patients: Stained Liver Slide Availability

Visit	Total Patients with Stained Slides Available	Patients with specified number of stained liver slides available											
		1	2	3	4	5	6	7	8	9	10	11	>=12
S00	1227	0	0	3	1183	9	3	1	23	0	3	0	2
M24	845	0	1	0	837	2	0	1	3	0	0	0	1
M48	719	0	0	0	713	0	0	2	4	0	0	0	0
Other	31	0	2	2	19	2	1	0	2	2	0	1	0
Total	2822	0	3	5	2752	13	4	4	32	2	3	1	3