

Sample Availability and Location

Table 1 lists the status and location of all HALT-C samples (blood, DNA, breath, liver) that have been collected. Samples typically were collected and stored for a short period at the clinical center, then shipped to the SeraCare 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
	Sera-Care QC	Shipped	At Sera-Care	Shipped to Lab	Not found at CC	Not found ship	Broken/Relabel	
001-002, 005-006: Fresh Blood For PBMC	1	0	4,288	0	16	0	7	4,312
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	2	0	27	1,789	0	1	2	1,821
101-104: HCV RNA S00, W20	0	0	0	11,412	4	4	26	11,446
105-108: HCV RNA other	1	0	0	47,890	17	10	73	47,991
109: HCV Genotype	0	0	22	1,348	0	0	4	1,374
110-120, 123-127: Spare Serum	544	0	124,408	27,138	140	19	372	152,621
121-122: Steatosis	2	0	2,065	2,079	2	0	4	4,152
129: Repeat AFP	0	0	1	28	1	0	0	30
130-131: Frozen liver storage	1	0	1,665	179	20	6	8	1,879
132: Liver tissue in OCT for Main Trial	0	0	235	3	5	0	1	244
140-143: Frozen Whole Blood	12	0	8,490	404	15	0	83	9,004
150-153: Repeat HCV RNA	0	0	0	430	0	0	1	431
210-215: Serum for Extended Follow-up (1 ml)	0	0	2,347	111	15	0	6	2,479
220-231: Serum for Extension 2007 (0.5 ml)	291	0	28,835	490	137	0	11	29,764
301: Neutralizing Antibodies	0	0	685	723	2	1	8	1,419
302-303: Quasispecies	0	0	2,043	1,114	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	393	211	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	4,201	4,531	0	0	16	8,748
500-504: Plasma	0	0	12,949	30	0	0	0	12,979
505-515: PBMC	0	0	8,057	963	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	6,642	2,795	0	0	45	9,482
570-599: DNA from Froz Whole Blood (10 µg)	0	0	1,998	356	0	0	366	2,720
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	231	98	0	0	80	409
900-919: DNA from PBMC (1 µg)	0	0	489	359	0	0	0	848
940-959: DNA from EBV (1 µg)	0	0	4,849	4,722	0	0	0	9,571
960-999: DNA from Froz Whole Blood (1 µg)	0	0	2,126	1,159	0	0	0	3,285
Total:	854	0	248,203	130,897	448	54	1,242	381,698

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	1049	1	8	25	51	133	195	259	184	142	33	16	2
W00	810	5	1	10	20	127	344	91	150	37	16	9	0
W02	788	0	7	13	430	89	243	6	0	0	0	0	0
W04	805	0	7	80	435	84	191	8	0	0	0	0	0
W08	804	0	4	4	503	63	216	13	1	0	0	0	0
W12	808	0	7	77	393	110	215	6	0	0	0	0	0
W16	800	0	1	7	484	55	237	16	0	0	0	0	0
W20	810	6	86	388	61	268	1	0	0	0	0	0	0
W24	798	1	6	6	25	109	229	204	149	41	17	10	1
W30	150	0	0	0	98	9	42	1	0	0	0	0	0
W36	150	1	1	5	83	11	48	1	0	0	0	0	0
W42	147	1	0	3	87	17	39	0	0	0	0	0	0
W48	142	0	2	60	38	38	3	1	0	0	0	0	0
W60	132	0	4	19	67	14	27	1	0	0	0	0	0
W72	61	0	0	35	4	22	0	0	0	0	0	0	0
R00	383	2	4	12	50	133	45	72	48	3	3	11	0
M09	995	3	43	249	279	172	249	0	0	0	0	0	0
M12	978	2	6	43	106	343	127	215	46	45	45	0	0
M15	944	12	55	372	182	280	43	0	0	0	0	0	0
M18	951	26	62	423	141	287	11	1	0	0	0	0	0
M21	929	32	54	412	134	293	4	0	0	0	0	0	0
M24	938	2	5	12	31	63	336	83	226	63	56	59	2
M27	868	28	171	298	171	197	3	0	0	0	0	0	0
M30	881	37	64	369	145	248	8	10	0	0	0	0	0
M33	851	34	53	379	118	266	1	0	0	0	0	0	0
M36	888	6	16	61	57	305	51	205	61	47	75	2	2
M39	794	29	48	357	107	252	1	0	0	0	0	0	0
M42	816	31	56	386	107	222	8	6	0	0	0	0	0
M45	760	27	160	266	144	163	0	0	0	0	0	0	0
M48	839	3	13	48	58	284	64	199	70	33	56	4	7
M54	728	1	5	10	16	37	35	259	44	205	28	77	11
M60	697	3	5	27	156	29	161	2	18	7	91	15	183
M66	428	0	1	0	1	2	9	3	14	5	119	15	259
M72	588	0	6	7	44	18	42	3	19	7	147	11	284
M78	540	0	0	1	2	1	9	2	19	7	156	12	331
M84	388	0	1	0	0	0	4	4	13	3	120	8	235
M90	256	0	0	1	0	2	7	1	10	2	72	4	157
M96	140	0	0	0	0	0	1	1	5	3	42	1	87
M102	67	0	0	0	2	0	1	0	1	1	21	1	40
M108	14	0	0	0	0	0	0	0	0	0	3	1	10
Total	24,915	293	962	4,465	4,830	4,746	3,250	1,673	1,078	651	1100	256	1611

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	3	1	25	174	71	911	76	2	1260
DNA in 10ug vial	15	135	106	122	135	475	254	21	1248
Frozen whole blood	144	23	38	31	31	844	149	3	1119
EBV cells	255	10	3	16	714	265	0	0	1008
PBMC	19	128	223	184	139	405	157	8	1244
Any genetic	1	0	0	0	0	23	177	1062	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	3	1	25	137	56	677	50	2	948
DNA in 10ug vial	5	89	69	83	104	352	230	19	946
Frozen whole blood	31	13	24	12	27	704	137	3	920
EBV cells	74	3	2	7	611	254	0	0	877
PBMC	16	108	175	100	96	298	150	8	935
Any genetic	1	0	0	0	0	1	60	889	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	573	602	489	1664
OCT Liver for Main Trial	0	81	154	235
OCT Liver for Repl Study	136	136	121	393
Any OCT	136	217	275	628

Liver slides for patients in the HALT-C Trial were stored at the Armed Forces Institute of Pathology (AFIP) until they were transferred to the NIDDK Sample Repository in April 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