

HALT-C Trial Visit Schedule

Study-Wide Trial Forms	Form #	Screening Phase (S00)		Lead In Phase							
		Screen1	Screen2	W00	W02	W04	W08	W12	W16	W20	W24
Screening & Baseline											
Trial ID Assignment	1	X									
Trial Consent	2	X ¹	or X ¹								
Screening Medical History Interview	3	X									
Screening Checklist (Lead-in pts)	4		X ^{Lead-in}								
Trial Ineligibility	5	X ¹	or X ¹								
Baseline History	6	X	or X	or X							
Baseline Medications Interview	7			X							
Baseline Visit Date	8			X							
Screening Checklist (Express pts)	94		X ^{Express}								
Interview & Exam											
Study Visit	10				X	X	X	X	X	X	X
Physical Exam	11	X						X		X	
Medications Interview	12				X	X	X	X	X	X	X
Specimen Collection	14		X								
CTP Score	15	X	and X	X				X		X	
Early Term. Peginterferon Treatment	19				X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹
Randomization Checklist I (Lead-in pts)	21									X	
Ultrasound, MRI, CT ²	22		X ²							X	
Endoscopy ³	23										X ³
Missed Visit	24				X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹
Early Termination from Trial	25			X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹
Randomization Checklist II	99		X ^{Express}								
Study Medication Logs											
Peginterferon Accountability Log	26			X ⁴	X ⁴	X ⁴	X ⁴	X ⁴	X ⁴	X ⁴	X ⁴
Ribavirin Accountability Log	27			X ⁵	X ⁵	X ⁵	X ⁵	X ⁵	X ⁵	X ⁵	X ⁵
Peginterferon Dose Adjustments	28			X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ⁷
Ribavirin Dose Adjustments	29			X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ⁷
Lost Drug Accountability	926			X ⁶	X ⁶	X ⁶	X ⁶	X ⁶	X ⁶	X ⁶	X ⁶
Laboratory Results											
Local Lab	30	X		X	X	X	X	X	X	X	X
Central HCV RNA / Repeat HCV RNA ¹	31 / 37 ¹	V		V				V		V	V
HCV Genotype	33	V	or		V						
AFP / Repeat AFP ¹	34 / 36 ¹	X		X						X	
Screening Visit 2 Local Lab	35		X								
Pre-treatment Blood Work (Express pts)	38	X ^{Express}									

Data Entry Codes:

X = Data entered at the clinical site

V = Data entered at the Central Virology Lab

N = Data entered at NERI

Page 1 and 2 Footnotes:

1 To be completed as necessary.

2 Screening ultrasound must be performed for patients with no ultrasound in past 6 months.

3 Endoscopy must be performed for randomized patients with no endoscopy in past 12 months.

4 To be completed any time that interferon is dispensed or returned.

5 To be completed any time that ribavirin is dispensed or returned.

6 To be completed any time interferon or ribavirin is not returned to site for accountability.

7 To be completed for Lead-In patients who are entering the Randomized Phase.

8 To be completed by Sites 17 and 18 only.

9 Liver biopsy must be performed for patients with no biopsy in past 12 months.

Continued

HALT-C Trial Visit Schedule

Study-Wide Trial Forms Visit Number →	Form #	Screening Phase (S00)		Lead In Phase							
		Screen1	Screen2	W00	W02	W04	W08	W12	W16	W20	W24
Symptoms & Life Events											
Quality of Life	40	X									
Skinner	41		X								
Alcohol Use Questionnaire	42			X							X
Symptoms Form	43	X		X			X			X	
Beck Depression Inventory II	44		X or	X		X ⁸		X		X	X ⁸
Life Events Status Interview	45			X							
Pathology											
Screening Biopsy Evaluation	50		X								
Central Pathology Biopsy Review	51		N								
Histopathology	181		N								
Histology Log	505		X								
Adverse Events & Outcomes											
Adverse Event Report	60	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹
Serious Adverse Event Report	61	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹
Clinical Outcome	63			X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹
Death Report	64			X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹
Clinical Outcome Review	65			N ¹	N ¹	N ¹	N ¹	N ¹	N ¹	N ¹	N ¹
Liver Transplant Information	67			X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹
Pregnancy Report	68	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹
Aliquot Forms											
Screening 1 Aliquot Form	70	X									
Screening 2 Aliquot Form	71		X								
Lead In Phase Aliquot Form	72			X	X	X	X	X	X	X	X
Other Study-Wide Forms											
Central Endoscopy Review	110										N
Glycosylated Hemoglobin (diabetics only)	121	X ^{Diabetics}	or X ^{Diabetics}								
Physical Activity	140			X							
Analgesic Medications	141			X							
Cigarette Smoking History	142						X				
Hormone Use (female patients only)	144						X ^{Females}				
Weight History	146						X				
Block Food Frequency Questionnaire	Block		X								
Composite Int'l Diagnostic Interview	CIDI	X ¹	or X ¹								

Data Entry Codes:

X = Data entered at the clinical site

V = Data entered at the Central Virology Lab

N = Data entered at NERI

Page 1 and 2 Footnotes:

1 To be completed as necessary.

2 Screening ultrasound must be performed for patients with no ultrasound in past 6 months.

3 Endoscopy must be performed for randomized patients with no endoscopy in past 12 months.

4 To be completed any time that interferon is dispensed or returned.

5 To be completed any time that ribavirin is dispensed or returned.

6 To be completed any time interferon or ribavirin is not returned to site for accountability.

7 To be completed for Lead-In patients who are entering the Randomized Phase.

8 To be completed by Sites 17 and 18 only.

9 Liver biopsy must be performed for patients with no biopsy in past 12 months.

HALT-C Manual of Operations

Study-Wide Trial Forms	Form #	Randomized Phase																
		R00		M09	M12	M15	M18	M21	M24	M27	M30	M33	M36	M39	M42	M45	M48	M54
		Exp.	Bt/R															
Screening & Baseline																		
Baseline Medications Interview	7	X																
Genetic Status Change	9			X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	
Interview & Exam																		
Study Visit	10			X	X	X	X	X	X	X	X	X	X	X	X	X	X	
Physical Exam	11			X	X	X	X	X	X	X	X	X	X	X	X	X	X	
Medications Interview	12		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
Specimen Collection	14								X								X	
CTP Score	15	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
Early Term. Peginterferon Treatment	19	X ²	X ²	X ²	X ²	X ²	X ²	X ²	X ²	X ²	X ²	X ²	X ²	X ²	X ²	X ²	X ²	
Ultrasound, MRI, CT	22				X				X				X				X	
Endoscopy	23	X ⁶	X ⁶						X ⁷								X	
Missed Visit	24	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	
Early Termination from Trial	25	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	
Randomization Visit Date Form	98	X	X															
Alternative Study Visit	924			X ⁵	X ⁵	X ⁵	X ⁵	X ⁵	X ⁵	X ⁵	X ⁵	X ⁵	X ⁵	X ⁵	X ⁵	X ⁵	X ⁵	
Study Medication Logs																		
Peginterferon Accountability Log	26	X ³	X ³	X ³	X ³	X ³	X ³	X ³	X ³	X ³	X ³	X ³	X ³	X ³	X ³	X ³	X ³	
Peginterferon Dose Adjustments	28	X ²	X ²	X ²	X ²	X ²	X ²	X ²	X ²	X ²	X ²	X ²	X ²	X ²	X ²	X ²	X	
Lost Drug Accountability	926		X ⁴	X ⁴	X ⁴	X ⁴	X ⁴	X ⁴	X ⁴	X ⁴	X ⁴	X ⁴	X ⁴	X ⁴	X ⁴	X ⁴	X ⁴	
Laboratory Results																		
Local Lab	30	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
Central HCV RNA / Repeat HCV RNA ¹	31 / 37 ¹	V	V		V		V		V		V		V		V		V	
AFP / Repeat AFP ¹	34 / 36 ¹	X		X	X	X	X	X	X	X	X	X	X	X	X	X	X	
HIV Test Results	39																X	
Symptoms & Life Events																		
Quality of Life	40				X				X				X				X	
Alcohol Use Questionnaire	42	X	X		X		X		X		X		X		X		X	
Symptoms Form	43	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
Beck Depression Inventory II	44		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
Life Events Status Interview	45	X			X				X				X				X	
Pathology																		
Central Pathology Biopsy Review	51								N								N	
Clinical Center Biopsy	52								X								X	
HCC Pathology	56	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	
Histopathology	181								N								N	

Data Entry Codes:

X = Data entered at the clinical site

V = Data entered at the Central Virology Lab

N = Data entered at NERI

Page 3 and 4 Footnotes:

1 To be completed as necessary.

2 To be completed for treatment group patients as necessary.

3 To be completed any time that interferon is dispensed or returned.

4 To be completed any time interferon is not returned to site for accountability.

5 To be completed if randomized patient misses two consecutive study visits.

6 Endoscopy must be performed for randomized patients with no endoscopy in past 12 months.

7 M24 endoscopy to be performed on patients with varices detected at W24/R00 endoscopy.

8 To be completed at Month 9 for Express patients only

HALT-C Manual of Operations

Continued

Study-Wide Trial Forms	Form #	Randomized Phase																	
		R00		M09	M12	M15	M18	M21	M24	M27	M30	M33	M36	M39	M42	M45	M48	M54	
		Exp.	Bt/R																
Adverse Events & Outcomes																			
Adverse Event Report	60	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	
Serious Adverse Event Report	61	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	
Clinical Outcome	63	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	
Death Report	64	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	
Clinical Outcome Review	65	N ¹	N ¹	N ¹	N ¹	N ¹	N ¹	N ¹	N ¹	N ¹	N ¹	N ¹	N ¹	N ¹	N ¹	N ¹	N ¹	N ¹	
HCC Diagnosis	66	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	
Liver Transplant Information	67	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	
Pregnancy Report	68	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹	
Aliquot Forms																			
Randomized Phase Aliquot Form	73			X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
Repeat HCV RNA Aliquot Form	76					X ¹		X ¹		X ¹		X ¹		X ¹		X ¹			
R00 Visit Aliquot Form	77	X	X																
Other Study-Wide Forms																			
Central Endoscopy Review	110	N	N						N ⁷									N	
Physical Activity	140	X			X				X										X
Analgesic Medications	141	X																	
Cigarette Smoking History	142			X ⁸															
Current Cigarette Smoking	143								X									X	
Hormone Use (female patients only)	144			X ⁸															
Weight History	146			X ⁸															
Serum Iron	183								X									X	
Block Food Frequency Questionnaire	Block							X											

Data Entry Codes:

X = Data entered at the clinical site

V = Data entered at the Central Virology Lab

N = Data entered at NERI

Page 3 and 4 Footnotes:

- | | |
|--|---|
| <ul style="list-style-type: none"> 1 To be completed as necessary. 2 To be completed for treatment group patients as necessary. 3 To be completed any time that interferon is dispensed or returned. 4 To be completed any time interferon is not returned to site for accountability. | <ul style="list-style-type: none"> 5 To be completed if randomized patient misses two consecutive study visits. 6 Endoscopy must be performed for randomized patients with no endoscopy in past 12 months. 7 M24 endoscopy to be performed on patients with varices detected at W24/R00 endoscopy. 8 To be completed at Month 9 for Express patients only |
|--|---|

HALT-C Manual of Operations

Study-Wide Trial Forms	Form #	Week 20 Responder Phase					
		W30	W36	W42	W48	W60	W72
Interview & Exam							
Study Visit	10	X	X	X	X	X	X
Physical Exam	11		X		X		X
Medications Interview	12	X	X	X	X	X	X
CTP Score	15		X		X		X
Early Term. Peginterferon Treatment	19	X ¹	X ¹	X ¹	X ¹		
Ultrasound, MRI, CT	22		X ⁵		X	X ⁵	X
Missed Visit	24	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹
Early Termination from Trial	25	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹
Randomization Checklist II	99		X ^{Breakthrough}	X ^{Breakthrough}	X ^{Breakthrough}	X ^{Relapser}	X ^{Relapser}
Study Medication Logs							
Peginterferon Accountability Log	26	X ²	X ²	X ²	X ²		
Ribavirin Accountability Log	27	X ³	X ³	X ³	X ³		
Peginterferon Dose Adjustments	28	X ¹	X ¹	X ¹	X		
Ribavirin Dose Adjustments	29	X ¹	X ¹	X ¹	X		
Lost Drug Accountability	926	X ⁴	X ⁴	X ⁴	X ⁴	X ⁴	X ⁴
Laboratory Results							
Local Lab	30	X	X	X	X	X	X
Central HCV RNA / Repeat HCV RNA ¹	31 / 37 ¹		V		V	V	V
AFP / Repeat AFP ¹	34 / 36 ¹		X		X	X	X
Symptoms & Life Events							
Quality of Life	40						X
Alcohol Use Questionnaire	42				X		X
Symptoms Form	43	X	X	X	X	X	X
Beck Depression Inventory II	44		X		X	X	X
Life Events Status Interview	45						X
Adverse Events & Outcomes							
Adverse Event Report	60	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹
Serious Adverse Event Report	61	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹
Clinical Outcome	63	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹
Death Report	64	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹
Clinical Outcome Review	65	N ¹	N ¹	N ¹	N ¹	N ¹	N ¹
Liver Transplant Information	67	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹
Pregnancy Report	68	X ¹	X ¹	X ¹	X ¹	X ¹	X ¹
Aliquot Forms							
Week 20 Responders Aliquot Form	74	X	X	X	X	X	X
Repeat HCV RNA Aliquot Form	76		X ¹	X ¹	X ¹	X ¹	X ¹

Data Entry Codes:

X = Data entered at the clinical site

V = Data entered at the Central Virology Lab

N = Data entered at NERI

Page 5 Footnotes:

1 To be completed as necessary.

2 To be completed any time that interferon is dispensed or returned.

3 To be completed any time that ribavirin is dispensed or returned.

4 To be completed any time interferon or ribavirin is not returned to site for accountability.

5 Ultrasound to be completed if patient is to be randomized after W36 or W60.

HALT-C Trial Ancillary Studies Visit Schedule

Ancillary Studies Forms Visit Number →	Form #	Data Entry	Lead In Phase					Responder Phase	
			S00	W00	W04	W08	W24	W48	W72
Serum Fibrosis Markers									
Serum TGF-B1	100	SITE 18 LAB		18			18	18	18
Serum Fibrosis Aliquot Form	102	SITES		11,13,19			11,13,19	11,13,19	11,13,19
SFM Specimen Collection Log	503	DCC		18			18	18	18
Steatosis									
Glycosylated Hemoglobin (diabetics only)	121	SITES	ALL						
Risk Factors									
Physical Activity	140	SITES		ALL					
Analgesics Medications	141	SITES		ALL					
Cigarette Smoking History	142	SITES				ALL			
Hormone Use (female patients only)	144	SITES				ALL FEMALES			
Weight History	146	SITES				ALL			
Cognitive Effects									
Cortisol Results	150	SITE 18 LAB		18	18		18	18	18
ShIPLEY	151	SITES		17, 18					
Neuropsych Test Results	152	SITES		17, 18			17, 18	17, 18	17, 18
CIDI-12	153	SITES					17, 18	17, 18	17, 18
Brief Symptom Inventory (BSI)	154	SITES		17, 18	17, 18		17, 18	17, 18	17, 18
Cognition AS withdrawal ¹	155	SITES							
Serotonin Results	156	SITE 18 LAB		18	18		18	18	18
Years of Education	157	SITES		17, 18					
Occupational Status	158	SITES		17, 18					
Scoring Sheet for NTP batteries	159	DCC		17, 18					
Immunology/Virology									
CTL	170	CTL LABS	11,12,16,17						
Neutralizing Antibody	171	DCC		11,12,16,17					
Quasispecies	172	VIR. LAB					11,12,16,17		
Lymphoproliferation	173	VIR. LAB		11,12,16,17			11,12,16,17		
Replication	174	VIR. LAB	11,12,16,17						
Immunology/Virology Aliquot	175	SITES	11,12,16,17	11,12,16,17			11,12,16,17		
Immunology / Virology Withdrawal ¹	176	SITES							
HCV Quasispecies CFA	177	VIR. LAB		11,12,16,17					
CTL Serum Aliquot	270 (501)	SITES	11,12,16,17						
CTL Liver Aliquot	271 (501)	SITES	11,12,16,17						
LP Aliquot	273 (503)	SITES		11,12,16,17			11,12,16,17		
Iron & HFE Gene Testing									
Histopathology	181	DCC	ALL						
Hepatic Iron Concentration	182	UCONN LAB	11, 15						
Iron & HFE Aliquot Form	184	SITES	11, 15						
QLFT									
QLFT Test Record	190	SITES		14, 15, 19					
QLFT Results	191	SITE 14 LAB		14, 15, 19					
SPECT scan	192	SITE 15 LAB		14, 15, 19					
QLFT Aliquot Form	193	SITES		15, 19					
QLFT Withdrawal Form ¹	194	SITES							
QLFT MBT Aliquot Form	195	SITES		14, 15, 19					
QLFT MBT Results	196	DCC		14, 15, 19					

¹ To be completed as necessary when a patient withdraws from the Ancillary Study.

HALT-C Manual of Operations

Ancillary Studies Forms	Form #	Data Entry	Randomized Phase										
			Visit Number →	R00 Express	R00 BT/R	M09	M12	M18	M24	M30	M36	M42	M48
Serum Fibrosis Markers													
Serum TGF-B1	100	SITE 18 LAB				18		18		18		18	
Serum Fibrosis Aliquot Form	102	SITES				11,13,19		11,13,19		11,13,19		11,13,19	
SFM Specimen Collection Log	503	DCC				18		18		18		18	
Risk Factors													
Physical Activity	140	SITES	EXPRESS			ALL		ALL					ALL
Analgesics Medications	141	SITES	EXPRESS										
Cigarette Smoking History	142	SITES			EXPRES								
Current Cigarette Smoking	143	SITES						ALL				ALL	
Hormone Use (female patients only)	144	SITES			EXPRES								
Weight History	146	SITES			EXPRES								
Cognitive Effects													
Cortisol Results	150	SITE 18 LAB		* 18		18		18		18		18	18
Neuropsych Battery	152	SITES		* 17, 18		17, 18		17, 18		17, 18		17, 18	17, 18
CIDI-12	153	SITES		* 17, 18		17, 18		17, 18		17, 18		17, 18	17, 18
Brief Symptom Inventory (BSI)	154	SITES		* 17, 18		17, 18	17,18	17, 18	17, 18	17, 18	17, 18	17, 18	17, 18
Cognition AS withdrawal ¹	155	SITES											
Serotonin Results	156	SITE 18 LAB		* 18		18		18		18		18	18
Immunology/Virology													
CTL	170	CTL LABS						11,12,16,17				11,12,16,17	
Neutralizing Antibody	171	DCC		11,12,16,17		11,12,16,17		11,12,16,17		11,12,16,17		11,12,16,17	
Quasispecies	172	VIR. LAB		11,12,16,17		11,12,16,17		11,12,16,17		11,12,16,17		11,12,16,17	11,12,16,17
Lymphoproliferation	173	VIR. LAB		11,12,16,17		11,12,16,17		11,12,16,17		11,12,16,17		11,12,16,17	11,12,16,17
Replication	174	VIR. LAB						11,12,16,17				11,12,16,17	
Immunology/Virology Aliquot	175	SITES		11,12,16,17		11,12,16,17		11,12,16,17		11,12,16,17		11,12,16,17	11,12,16,17
Immunology / Virology Withdrawal ¹	176	SITES											
CTL Serum Aliquot ¹	270 (501)	SITES											
CTL Liver aliquot	271 (501)	SITES						11,12,16,17				11,12,16,17	
LP Aliquot	273 (503)	SITES		11,12,16,17		11,12,16,17		11,12,16,17		11,12,16,17		11,12,16,17	11,12,16,17
Iron & HFE Gene Testing													
Histopathology	181	DCC						ALL				ALL	
Hepatic Iron Concentration	182	UCONN LAB						11, 15				11, 15	
Serum Iron	183	SITES						ALL				ALL	
Iron & HFE Aliquot Form	184	SITES						11, 15				11, 15	
QLFT													
QLFT Test Record	190	SITES	14, 15, 19					14, 15, 19				14, 15, 19	
QLFT Results	191	SITE 14 LAB	14, 15, 19					14, 15, 19				14, 15, 19	
SPECT scan	192	SITE 15 LAB	14, 15, 19					14, 15, 19				14, 15, 19	
QLFT Aliquot Form	193	SITES	15, 19					15, 19				15, 19	
QLFT Withdrawal Form ¹	194	SITES											
QLFT MBT Aliquot Form	195	SITES	14, 15, 19					14, 15, 19					
QLFT MBT Results	196	DCC	14, 15, 19					14, 15, 19					

¹ To be completed as necessary when a patient withdraws from the Ancillary Study.

* If R00 visit more than 1 month since the last NPT then Cortisol, Serotonin testing, CIDI-12, BSI, BDI-II, NPT test battery should be repeated again.