MRC Clinical Trials Unit | UCL

STOP-HCV
Stratified Medicine for HepC

Attach Participant ID label

Visit Date: ☐d ☐d ☐m ☐m ☐m ☐y ☐y ☐y ☐y

Unscheduled ☑

Screening ☑ First line ☑ Retreatment ☑

Day ☐☐ Week ☐☐ EOT ☑ EOT+week ☐☐

☞ **Return completed CRFs by secure email to mrcctu.stophcv1@ucl.ac.uk or by fax 0207 670 4817.**

A. HAEMATOLOGY

1. Specimen Date ☐d ☐d ☐m ☐m ☐m ☐y ☐y ☐y ☐y

Required at: Screening, First line: day 0, 14, 28; EOT, EOT+12 weeks, EOT+24 weeks
Retreatment: week 0, 2, 4, 8, 12(EOT), EOT+12 weeks, EOT+24 weeks

	Result	Unit of Assay		Result	Unit of Assay
2. Haemoglobin	☐☐ • ☐	g/dL	3. Haematocrit	0 • ☐☐	fraction (proportion)
4. White blood cell count	☐☐ • ☐	10^9/L	5. Neutrophils	☐☐ • ☐	10^9/L
6. Lymphocytes	☐☐ • ☐	10^9/L	7. Platelets	☐☐☐☐	10^9/L

B. BIOCHEMISTRY

1. Specimen Date ☐d ☐d ☐m ☐m ☐m ☐y ☐y ☐y ☐y

Required at: Screening, First line: day 0, 14, 28; EOT, EOT+12 weeks, EOT+24 weeks
Retreatment: week 0, 2, 4, 8, 12(EOT), EOT+12 weeks, EOT+24 weeks

	Result	Unit of Assay		Result	Unit of Assay
2. ALT	☐☐☐	U/L	3. AST	☐☐☐	U/L
4. ALP	☐☐☐	U/L	5. Total Bilirubin	☐☐☐ • ☐	µmol/L
6. Albumin	☐☐ • ☐	g/L	7. Creatinine	☐☐☐ • ☐	µmol/L
8. eGFR	☐☐☐	mL/min (calculate using Cockcroft Gault. See online tools)			

C. HCV VIRAL LOAD

1. Specimen Date ☐d ☐d ☐m ☐m ☐m ☐y ☐y ☐y ☐y

☞ **If the HCV viral load is:**
(i) detectable after the participant has initiated treatment and the viral load has been undetectable.
(ii) >2000 IU/mL and > $1\log_{10}$ above nadir on treatment.
Please ask the participant to return for a repeat test 1 week or more after the first test. Please complete Form 02 - Laboratory Tests for confirmatory HCV viral load regardless of the result. If failure is confirmed please complete Form 14 - Treatment Failure.

Required at: Screening, First line: day 0, 3, 7, 14, 28, EOT, EOT+4 weeks, EOT+8 weeks, EOT+12 weeks, EOT+24 weeks
Retreatment: week 0, 2, 4, 8, 12(EOT), EOT+4 weeks, EOT+8 weeks, EOT+12 weeks, EOT+24 weeks

	Absolute result or limit of quantification (IU/mL)	Mark which is recorded	Type of assay used
2a. Viral Load	☐☐ , ☐☐☐ , ☐☐☐	b. ☐ Absolute result ☐ Assay lower limit	c. ☐ Cobas Amplicor v2 (Roche) ☐ Realtime HCV (Abbott) ☐ Aptima QuantDX (Hologic) ☐ Versant HCV assay v2 (Siemens) ☐ Other

e. If the Viral Load is below the lower limit of quantification is it reported as:

☐ Detected, below LLOQ   ☐ Not Detected   ☐ Not Specified

d. Please specify _____

☞ **If the HCV viral load is the only Laboratory result required at this visit please sign, print name, date and submit this page only to the STOP-HCV-1 co-ordinating centre.**

Signature:	Printed Name:	Date Completed:
		☐d ☐d ☐m ☐m ☐m ☐y ☐y ☐y ☐y

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D. COAGULATION MARKERS

1. Specimen Date ☐d ☐d ☐m ☐m ☐m ☐y ☐y ☐y ☐y

Required at: Screening
  Retreatment: week 0

2. INR result (ratio) ☐ • ☐

E. POC IL28 (EPISTEM) TEST

☞ **If the participant consented to POC IL28 test, did not have a test at enrolment but has had a test since the last visit, please record the results below.**

1a. Date of test: ☐d ☐d ☐m ☐m ☐m ☐y ☐y ☐y ☐y   b. result: ☐ IL28 CC ☐ IL28 TT ☐ IL28 CT ☐ No result

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F. GENETIC TESTING

☞ **If the participant consented to genetic testing and the EDTA whole blood sample was not taken at enrolment, please complete below if this sample has been taken since the last visit.**

1. 2.5 ml whole blood for EDTA DNA

Size of collection tubes	**Number of tubes collected**	**Date specimen obtained**	**Time of collection** (use 24 hour clock)
a. ☐☐ • ☐ ml	b. ☐☐	c. ☐d ☐d ☐m ☐m ☐m ☐y ☐y ☐y ☐y	d. ☐h ☐h : ☐m ☐m

☞ **If not HIV infected stop here, sign and send.**

G. HIV VIRAL LOAD

1. Specimen Date ☐d ☐d ☐m ☐m ☐m ☐y ☐y ☐y ☐y

If HIV infected required at: Screening, First line: EOT, EOT+24 weeks
  Retreatment: week 0, 12(EOT), EOT+24 weeks

2a. Viral Load	**Absolute result or limit of quantification (copies/mL)**	**Mark which is recorded**	**Type of assay used**
	☐☐ , ☐☐☐ , ☐☐☐	b. ☐ Absolute result ☐ Assay lower limit	d. ☐ TaqMan® 2.0 ☐ Aptima QuantDX (Hologic) ☐ Other e. Please specify _____

H. IMMUNOLOGY

1.Specimen Date ☐d ☐d ☐m ☐m ☐m ☐y ☐y ☐y ☐y

If HIV infected required at: Screening, First line: EOT, EOT+24 weeks
  Retreatment: week 0, 12(EOT), EOT+24 weeks

2. CD4+ cell count ☐☐☐☐ cells/mm^3

Signature: _____

Printed Name: _____

Date Completed: ☐d ☐d ☐m ☐m ☐m ☐y ☐y ☐y ☐y

☞ *Please return by secure email to: mrcctu.stophcv1@ucl.ac.uk or by fax 0207 670 4817*

For office use only:

Date form received at CTU: ___ dd - mmm - yyyy ___

Date form entered onto database : ___ dd - mmm - yyyy ___

Initials of data enterer: ☐☐☐☐