

Supplementary Table 1. FDA-Approved HCV Encoded Antibody Testing (Anti-HCV Assay)

| Trade name | Format | Sample | Use | Specificity/ sensitivity | Whole blood vol.* | Manufacturer |
|--------------------------------|------------------------------------|-------------------------------|-----------------------------------|--------------------------|-------------------|--|
| Abbott PRISM HCV | CIA (c100-3, HCr43, NS5) | Serum/Plasma/ Cadaveric serum | Clinical; blood/ organ donors | 99.89%/ 100% | 1.4 ml | Abbott |
| HCV EIA, Version 3.0 | EIA (c-22-3, c200, NS5) | Serum/plasma | Clinical; blood/ organ donors | 99.95%/ 100% | 0.08 ml | Ortho-Clinical Diagnostics, Inc |
| RIBA HCV 3.0 Strip Immuno-blot | SIA (NS5, c33c,c100, 5-1-1p, c22p) | Serum/plasma | Suppl. Ab testing of HCV antigens | 96.7%/ 96.4% | 0.08 ml | Novartis Vaccines and Diagnostics, Inc |

(Modified from reference #77); *assuming duplicate assays and serum or plasma being ~50% of whole blood

Supplementary Table 2. FDA-Approved Hepatitis C Virus Nucleic Acid Assays

| Qualitative Assays: Trade Name | Format | Sample | Use | LLD IU/ml | Blood vol.* | Manufacturer |
|---|--------------------------|--------------------------------|----------------------------|------------------|--------------------|-----------------------------|
| COBAS Amplicor HCV Test (v 2.0) | Manual RT-PCR | Plasma; Cadaveric serum/plasma | Qualitative HCV RNA | 50 | 0.8 ml | Roche Molecular Diagnostics |
| COBAS Ampliprep/COBAS Amplicor HCV Test (v 2.0) | Semi-automated RT-PCR | Plasma; Cadaveric serum/plasma | Qualitative HCV RNA | 50 | 4 ml | Roche Mol. Diagnostics |
| COBAS Ampli-Screen HCV Test(v2.0) | Semi-automated RT-PCR | Plasma | Qualitative HCV RNA | <10 | N.A. | Roche Mol. Diagnostics |
| Versant HCV RNA Qualitative Assay | Semi-automated RT-PCR | Plasma | Qualitative HCV RNA | 50 | 2 ml | Versant |
| Quantitative Assays: Trade name | Format | Sample | Dynamic range IU/ml | LLD IU/ml | Blood vol.* | Manufacturer |
| HCV RNA 3.0 assay | DNA signal amplification | serum | 615- 7.7x 10 ⁶ | 615 | 0.2 ml | Versant |
| COBAS Ampliprep/COBAS TaqMan HCV Test | Fully automated RT-PCR | Plasma, serum | 43- 6.9 x 10 ⁷ | 15 | 4 ml | Roche Mol. Diagnostics |
| COBAS TaqMan HCV Test v2.0 (High Pure System) | Semiautomated RT-PCR | Plasma, serum | 25- 3 x 10 ⁸ | 25 | 2 ml | Roche Mol. Diagnostics |
| Abbott RealTime HCV | Semiautomated RT-PCR | plasma | 12- 1 x 10 ⁸ | 12 | 0.8 ml | Abbott |

(Modified from reference #77)

*assuming duplicate assays and serum or plasma being ~50% of whole blood

Supplementary Table 3. Dose Reductions of PEG-IFN Based on Abnormal Laboratory Values (adapted from Ref. #101)

Weekly PEG IFN- α -2a Dosing

| Original dose | Level 1 Decrease | Level 2 Decrease | Level 3 Decrease |
|----------------------------|----------------------------|---------------------------|---------------------------|
| 180 mcg/1.73m ² | 135 mcg/1.73m ² | 90 mcg/1.73m ² | 45 mcg/1.73m ² |

Weekly PEG IFN- α -2b Dosing

| Original dose | Level 1 Decrease | Level 2 Decrease | Level 3 Decrease |
|-----------------------|-----------------------|-----------------------|-----------------------|
| 60 mcg/m ² | 45 mcg/m ² | 30 mcg/m ² | 15 mcg/m ² |

| Parameter | Action |
|---|--|
| Absolute Neutrophil Count (cells/mm³) | |
| 750-999 | Wk. 1-2: Level 1 Decrease Wk. 3-48: none |
| 500-749 | Wk. 1-2: delay dose until \geq 750, then resume with Level 1 Decrease Wk 3-48: Level 1 Decrease |
| 250-499 | Wk. 1-2: delay dose until \geq 750, then resume with Level 2 Decrease Wk 3-48: delay dose until \geq 750, then resume with Level 1 Decrease |
| <250 or febrile neutropenia | Stop drug |
| Platelets (cells/mm³) | |
| 35,000-49,000 | Delay dose until \geq 50,000, then resume dose with Level 1 Decrease |
| 25,000-34,000 | Delay dose until \geq 50,000, then resume dose with Level 2 Decrease |
| <25,000 | Stop drug |
| ALT | |
| \geq 5x but <10x ULN | -Repeat ALT in 1 wk -If ALT decreasing then continue at present dose. Follow ALT q1-2 wks. to assure stability -If ALT increased but <10x ULN, Level 1 Decrease and weekly ALT until decreasing |
| \geq 10x ULN | -Repeat ALT in 1 wk -If ALT decreasing but between 5-10x ULN then Level 1 Decrease and weekly ALT until decreasing -If ALT still \geq 10x ULN, stop drug |

Ribavirin Dosing

| Original dose | Dose Reduction |
|---------------------------|--|
| 15 mg/kg/day, divided BID | 7.5 mg/kg/day, divided QD or BID (based on dose) |
| Hemoglobin (gm/dL) | Action |
| <10 | -Decrease ribavirin dose by 50% -Follow weekly and increase to original dose when >10 gm/dL |
| <8.5 | Permanent discontinuation of ribavirin |