CPAL
Central **P**ennsylvania **A**lliance **L**aboratory

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Reporting Change for HCV Real Time PCR Viral Load Assay

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Effective Date:

June 28, 2011

Performed:

Tuesday and Thursday (days)

Specimen:

2mL K2/K3 EDTA Plasma Frozen Aliquot
(Separate plasma within 6 hours, store 2-8C, freeze @ -70C within 72hr)

Summary:

CPAL has made a change to the format of the HCV Viral Load result report. This change is in conjunction with the recent FDA approval of INCIVEK ™ (telaprevir) and VICTRELIS™ (boceprevir) which may be indicated in combination with peginterferon alfa and ribavirin for the treatment of chronic hepatitis C **genotype 1** infection. HCV viral load monitoring plays a significant role in the management of patients under these therapies.

- Quantitative results will be reported for HCV viral loads ranging from 43 IU/mL to 6,900,000,000 IU/mL (1.63 Log_{10} IU/mL to 9.83 Log_{10} IU/mL).

- Results reported as <43 IU/mL (<1.63 Log_{10} IU/mL) should be interpreted as **Detected**, but below the limit of quantification.

- Results reported as **Not Detected** are below the limit of detection. The overall limit of detection for this assay is 18 IU/mL. The specific limit of detection for genotype 1 is 7.1 IU/mL and the results provided may be useful in therapeutic decisions involving the treatment of chronic hepatitis C genotype 1 infection with INCIVEK ™ (telaprevir) and/or VICTRELIS™ (boceprevir).

The following tables are provided as general information. Consult VICTRELIS™ (boceprevir) prescribing information (issued May 2011) and the INCIVEK™ (telaprevir) prescribing information (issued May 2011) for specific information and instructions.

How do viral load results lead to clinical decisions for patients undergoing VICTRELIS™ therapy?[1]

Treatment Week	Clinical Rationale	Clinical Decision
Baseline	Predictor of response	SVR higher when baseline viral load is ≤ 800,000 IU/mL
Week 4	Predictor of response	< 0.5log10IU/mL decline predicted to have null response
Week 8	Indicates treatment duration	Undetectable indicates 28-36 week regimen Detectable indicates 48 week regimen
Week 12	Indicates treatment futility	≥ 100 IU/mL indicates treatment futility, discontinue
Week 24	Indicates treatment duration	Undetectable indicates 28-48 week regimen Detectable indicates futility, discontinue
End of Treatment	Assess treatment efficacy	Undetectable requires additional assessment at FT24 Detectable indicates partial response
24 Week Follow Up	Assess treatment efficacy	<25 IU/mL indicates SVR is achieved >25 IU/mL indicates relapse, SVR not achieved

How do viral load results lead to clinical decisions for patients undergoing INCIVEK™ therapy?[2]

Treatment Week	Clinical Rationale	Clinical Decision
Week 4	Indicates treatment duration and/or futility	Undetectable indicates 12 triple + 12 dual = 24 weeks Detectable <1000 IU/mL indicates 12 triple + 24 dual = 36 weeks Detectable >1000 IU/mL indicates futility, discontinue
Week 12	Indicates treatment duration and/or futility	Undetectable indicates more weeks of dual therapy Detectable <1000 IU/mL indicates 24 more weeks of dual therapy Detectable >1000 IU/mL indicates futility, discontinue
Week 24	Indicates treatment futility	Detectable indicates futility, discontinue
End of Treatment	Assess treatment efficacy	Undetectable requires additional assessment at FT24 Detectable indicates partial response
24 Week Follow Up	Assess treatment efficacy	<25 IU/mL indicates SVR is achieved >25 IU/mL indicates relapse, SVR not achieved

Notes:

1. Quantitation of HCV RNA is dependant on the number of virus particles present in the specimen and may be affected by specimen collection methods, patient factors (e.g. age, presence of symptoms) and stage of infection.
2. The *COBAS® AmpliPrep/COBAS® TaqMan® HCV Test* is not intended for use as a screening test for the presence of HCV in blood or blood products or as a diagnostic test to confirm the presence of HCV infection.
3. Though rare, mutations in the highly conserved regions of the viral genome covered by the *COBAS® AmpliPrep/COBAS® TaqMan® HCV Test* primers and/or probe may result in the under-quantitation of or failure to detect the presence of the virus in this circumstance.
4. Results will be reported as HCV RNA IU/mL and Log_{10} IU/mL.

References

1. VICTRELIS™ (boceprevir) prescribing information issued May 2011
2. INCIVIK™ (telaprevir) prescribing information issued in May 2011
3. Cobas® AmpliPrep/Cobas® TaqMan® HCV Test package insert, 10/2008, Doc Rev 1.0