

Diagnostic Testing and Reporting Practices: Quest Diagnostics

Rick L. Pesano, MD, PhD

Medical Director, Infectious Diseases

Anti-HCV Result Interpretation

- Inclusion of interpretation of anti-HCV test results in reports
 - Positive test results cannot be interpreted with signal to cut-off (s/co) ratio value alone
- Quest Diagnostics uses the following:
 - Low s/co ratio (≥ 1 to < 8): reflex to RIBGA or recommend supplemental testing with RIBA or NAAT
 - High s/co ratio (≥ 8): additional testing for verification of the result is not recommended

HCV RNA Tests at Quest Diagnostics

Test name	Test code	Sensitivity/Range
Qualitative		
HCV RNA QL, TMA	37273X	7.5 IU/mL
HCV RNA QL, PCR	34024X	50 IU/mL
Quantitative		
HCV RNA QN, Real-Time PCR (Roche/LOD 7.1IU/mL GT1)	35645X	43-69,000,000 IU/mL 1.70-7.70 log IU/mL
HEPTIMAX® HCV RNA	10565X	5-69,000,000 IU/mL 0.70-7.70 log IU/mL
HCV RNA QN, bDNA	27271X	615-7,700,000 IU/mL 2.79-6.89 log IU/mL
HCV RNA QN, TMA	10073X	5-7500 IU/mL 0.70-3.88 log IU/mL
Genotype		
HCV RNA Genotype, LiPA	37811X	>300 IU/mL
QN rfl to Genotype		
HEPTIMAX® rfl to Genotype, LiPA	19702X	5-69,000,000 IU/mL Rfl to genotype if VL ≥300 IU/mL
HCV RNA QN, Real-Time PCR rfl to Genotype	11348X	43-69,000,000 IU/mL Rfl to genotype if VL ≥300 IU/MI
New Test		
AccuType(R) IL28B (IL28B Polymorphism) Specimen type: Whole blood	90251	Homozygous C/C : highest response to IFN Heterozygous T/C : intermediary response Homozygous T/T : poorest response

Laboratory Monitoring

- Telaprevir (INCIVEK™)

*“HCV-RNA levels should be monitored at weeks 4 and 12 and as clinically indicated. Use of a sensitive real-time RT-PCR assay for monitoring HCV-RNA levels during treatment is recommended. The assay should have a lower limit of HCV-RNA quantification equal to or less than 25 IU/mL, and a limit of HCV-RNA detection of approximately 10-15 IU/mL. For the purpose of assessing response-guided therapy eligibility, an “undetectable” HCV-RNA result is required; a confirmed “detectable but below limit of quantification” HCV-RNA result should not be considered equivalent to an “undetectable” HCV-RNA result.” **

*Incivek package insert

Laboratory Monitoring

- Boceprevir (VICTRELIS™)

“HCV-RNA levels should be monitored at treatment weeks 4, 8, 12, and 24, at the end treatment, during treatment follow-up, and for other time points as clinically indicated. Use of a sensitive real-time reverse transcription polymerase chain reaction (RT-PCR) assay for monitoring HCV-RNA levels during treatment is recommended. The assay should have a lower limit of HCV-RNA quantification of equal to or less than 25 IU/mL, and a limit of HCV-RNA detection of approximately 10-15 IU/mL. For the purposes of assessing Response-Guided Therapy milestones, a confirmed “detectable, but below limit of quantification” HCV-RNA result should not be considered equivalent to an “undetectable” HCV-RNA result.”

*Victrelis package insert

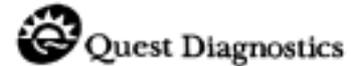
Hepatitis Surveillance Laboratory Testing and Reporting Objectives

- Establish standardized hepatitis lab reporting state wide (with some state requirement differences)
 - Produce complete and easily interpretable test results
 - Identify acute cases of hepatitis in a manner timely enough to allow for public health intervention activities
 - Hepatitis laboratory reports consistently include complete patient information including name, address, telephone number, date of birth/ or age, ordering physician contact information, and available demographics
 - Race
 - Ethnicity
- (Note: State reporting requirements are not harmonized)

Viral Hepatitis Reportable Markers by Standard Abbreviations

- When at least one reportable marker is positive, report all results (positive or negative) for additional serologic markers of HCV and liver function tests, including:
 - Alanine aminotransferase (ALT [SGPT])
 - To date only two states (New York and Florida) require the ALT test result

Sample Report



Quest Diagnostics - Nichols Institute
HEPATITIS C - FROM 11/18/2011 TO 11/21/11

PAGE 25

FROM HISTORY
CONFIDENTIAL - for Public Health Reporting only

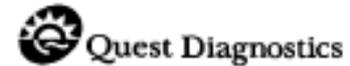
Submitting Facility: 53914 -

For: CALIFORNIA State Department of Health

Lab/Testing Facility: Quest Diagnostics - Nichols Institute
33608 Ortega Hwy
San Juan Capistrano, CA 92675
(800) 553-5445

Accn#	PATIENT NAME	DOB	Sex	PAT.ID	DOCTOR	DOS	Unit Code	Analyte	Result	RSLT DATE
-------	--------------	-----	-----	--------	--------	-----	-----------	---------	--------	-----------

Sample Report



Quest Diagnostics - Nichols Institute
 HEPATITIS C - FROM 11/18/2011 TO 11/21/11

PAGE 18

FROM HISTORY
 CONFIDENTIAL - for Public Health Reporting only

Submitting Facility: For: CALIFORNIA State Department of Health
 Lab/Testing Facility: Quest Diagnostics - Nichols Institute
 33608 Ortega Hwy
 San Juan Capistrano, CA 92675
 (800) 553-5445

Accn#	PATIENT NAME	DOB	Sex	PAT.ID	DOCTOR	DDS	Unit Code	Analyte	Result	RSLT DATE
						11/14/2011	44263N	HCV RNA, Quant, bDNA	2014000	11-19-2011
						11/17/2011	8472	Hepatitis C Antibody	REACTIVE	11-19-2011
						11/17/2011	8472	Signal to Cutoff	11.70	11-19-2011
						11/17/2011	8472	Hepatitis C Antibody	REACTIVE	11-19-2011
						11/17/2011	8472	Signal to Cutoff	5.00	11-19-2011
						11/17/2011	8472	Hepatitis C Antibody	REACTIVE	11-19-2011
						11/17/2011	8472	Signal to Cutoff	38.30	11-19-2011

QUESTIONS