

Client: Example Client ABC123
123 Test Drive
Salt Lake City, UT 84108
UNITED STATES

Physician: Doctor, Example

Patient: Patient, ExampleDOB: 3/27/1954
Gender: Female
Patient Identifiers: 01234567890ABCD, 012345
Visit Number (FIN): 01234567890ABCD
Collection Date: 01/01/2017 12:34**Interleukin 28 B (IL28B)-Associated Variants, 2 SNPs**

ARUP test code 2004680

IL28B-Assoc Variants, 2 SNPs Specimen	Whole Blood
IL28B rs12979860	C/T
IL28B rs8099917	T/G
IL28B-Assoc Variants, 2 SNPs Interp	See Note

Section 79-1 of New York State Civil Rights Law requires informed consent be obtained from all patients (or their legal guardians) prior to pursuing any diagnostic genetic testing or testing to assess carrier status. These forms must be kept on file by the ordering physician. Biochemical and DNA testing patient consent forms can be accessed from ARUP's web site: www.aruplab.com.

IL28B rs12979860: Unfavorable Genotype C/T
IL28B rs8099917: Unfavorable Genotype T/G

IL28B Interpretation:

The unfavorable C/T genotype for IL28B-associated SNP rs12979860 was detected and the unfavorable T/G genotype for IL28B-associated SNP rs8099917 was detected. The combination of detected genotypes is a risk factor for unfavorable treatment outcome or decreased likelihood of sustained virologic response with peginterferon/ribavirin therapy for hepatitis C, genotype 1 (HCV-1).

Recommendations:

Genotyping results should be interpreted along with clinical information. Other genetic and non-genetic factors may influence an individual's response to peginterferon/ribavirin HCV therapy. Individuals lacking favorable genetic factors should not be denied therapy. Genetic testing does not eliminate the need to monitor the clinical response to peginterferon/ribavirin therapy.

This result has been reviewed and approved by Rong Mao, M.D.

H – high L – low * – abnormal C – critical

Background Information for Interleukin 28B-Associated Variants, IL28B, 2 SNPs:
 Characteristics: Hepatitis C is an infectious disease that can result in cirrhosis, liver failure, and hepatocellular carcinoma in chronically infected individuals. Hepatitis C virus (HCV) is categorized into six genotypes; HCV genotype 1 (HCV-1) accounts for 75 percent of U.S. cases. Therapy for chronic infection consists of a combination of peginterferon (PEG-IFN alpha) and ribavirin (RBV), which is effective in eliminating HCV-1 in 40 to 50 percent of individuals. Single nucleotide polymorphisms (SNPs) rs12979860 C/T and rs8099917 T/G located upstream of the IL28B gene (encoding for lambda or type III interferons), have been associated with both spontaneous clearance and response to PEG-IFN alpha/RBV therapy in individuals infected with HCV-1. For SNP rs12979860, the CC genotype is associated with a two- to threefold greater rate of sustained virological response (SVR) following PEG-IFN alpha/RBV therapy, while the TC and TT genotypes are less likely to respond to treatment. For SNP rs8099917, the TT genotype is associated with a higher rate of SVR after PEG-IFN alpha/RBV therapy, while the GT and GG genotypes are less likely to respond to treatment and achieve SVR.
 Prevalence: 4.1 million Americans (1.6 percent of the U.S. population) have anti-HCV antibodies.
 Allele Frequency: SNP rs12979860 favorable C allele: East Asian 0.90, Caucasian 0.75, Hispanic 0.70, and African American 0.50. SNP rs8099917 favorable T allele: Caucasian 0.75, Asian 0.88, and unknown in other ethnicities.
 Variants Tested: SNP rs12979860 C/T and SNP rs8099917 T/G.
 Clinical Sensitivity: Unknown.
 Methodology: Polymerase chain reaction followed by single nucleotide extension (SNE) and capillary electrophoresis.
 Analytical Sensitivity & Specificity: 99 percent.
 Limitations: SNPs other than those targeted will not be detected. Mutations in other genes and non-genetic factors that may affect response to hepatitis C therapy are not detected. For HCV genotypes other than type 1, the usefulness of these SNPs for predicting response to therapy is unknown. Diagnostic errors can occur due to rare sequence variations.

See Compliance Statement C: www.aruplab.com/CS

VERIFIED/REPORTED DATES

Procedure	Accession	Collected	Received	Verified/Reported
IL28B-Assoc Variants, 2 SNPs Specimen	17-045-131665	2/14/2017 12:25:00 PM	2/16/2017 3:17:52 AM	2/19/2017 11:38:10 AM
IL28B rs12979860	17-045-131665	2/14/2017 12:25:00 PM	2/16/2017 3:17:52 AM	2/19/2017 11:38:10 AM
IL28B rs8099917	17-045-131665	2/14/2017 12:25:00 PM	2/16/2017 3:17:52 AM	2/19/2017 11:38:10 AM
IL28B-Assoc Variants, 2 SNPs Interp	17-045-131665	2/14/2017 12:25:00 PM	2/16/2017 3:17:52 AM	2/19/2017 11:38:10 AM

END OF CHART

H - high L - low * - abnormal C - critical