

LABORATORY REPORT

Example Client, XYZ123 1234 Warde Road Ann Arbor MI 48108 **EXAMPLE, REPORT W**

WX0000003827 M 07/08/1978 45 Y

Referral Testing

Collected: 09/25/2023 11:45 Received: 09/25/2023 11:45

<u>Test Name</u> <u>Result</u> <u>Flag Ref-Ranges</u> <u>Units</u> <u>Site</u>

Interleukin 28B (IL28B) Variant (rs12979860),

See Below

WMMR

Varies

Test Result Flag Ref Range

IL28B Genotype C/C

response

Interpretation

This patient has a genotype that has been associated with an approximately 2- to 3-fold greater rate of sustained virologic response (SVR) in HCV genotype 1-infected individuals treated with combined pegylated-interferon and ribavirin therapy as compared to either the CT or TT genotypes. Similar SVR have been observed across various racial groups including European Americans, African Americans, and Hispanics. CC genotype has also been associated with a 3-fold increase in rate of spontaneous clearance of HCV. IL28B genotype is only one of many factors that can influence response related to pegylated interferon/ribavirin combination therapy in HCV genotype 1 infection and should be interpreted in the context of other clinical factors.

Met.hod

Genotyping is performed using a PCR-based 5'-nuclease assay. Fluorescently labeled detection probes anneal to the target DNA. PCR is used to amplify the segment of DNA that contains the polymorphism. If the detection probe is an exact match to the target DNA, the 5'-nuclease polymerase degrades the probe, the reporter dye is released from the effects of the quencher dye, and a fluorescent signal is detected. Genotypes are assigned based on the allele-specific fluorescent signals that are detected. (TaqMan SNP Genotyping Assays User Guide, Applied Biosystems)

Disclaimer

Targeted variant analysis is performed for the IL28B-related rs12979860 (c.-3180G>A). Note that IL28B is now known as IFNL3. This test will not detect other IL28B (IFNL3) variants. Absence of this variant does not rule out the possibility that a patient has that or another variation that can impact the response to treatment of a hepatitis C viral infection.

The SNP in IL28B is used to predict response to pegylated-interferon and ribavirin combination therapy for hepatitis

LAB: L - LOW, H - HIGH, AB - ABNORMAL, C - CRITICAL, $\,$. - NOT TESTED

F325000042 WX0000003827 Printed D&T: 09/25/23 11:45 Ordered By: KAJAL SITWALA, MD, PhD WX00000000002365



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C, genotype 1 infections. IL28B is only one factor that can influence response rates to pegylated-interferon and ribavirin combination therapy.

CAUTIONS:

Samples may contain donor DNA if obtained from patients who have recently received non-leukoreduced blood transfusions or allogeneic hematopoietic stem cell transplantation. Results from samples obtained under these circumstances may not accurately reflect the recipient's genotype. For individuals who have received blood transfusions, the genotype usually reverts to that of the recipient within 6 weeks. For individuals who have received allogeneic hematopoietic stem cell transplantation, a pretransplant DNA specimen is recommended for testing.

For liver transplant patients, the IL28B genotype of the recipient and the donor are independent predictors of sustained virologic response with combined pegylated-interferon and ribavirin therapy.

Reviewed by

Laboratory Notes

This test was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration.

Test(s) performed at Mayo Clinic Laboratories - Rochester Main Campus 200 First Street SW, Rochester, MN 55905 Lab Director William G. Morice M.D., Ph.D.

Performing Site:

WMMR: MAYO CLINICAL LABS 3050 Superior Drive NW Rochester MN 55901

Reported Date: 2023.09.25 11:45

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Kajal V. Sitwala, MD, PhD - Medical Director Form: MM RL1 PAGE 2 OF 2