Patient ID	Patient Name		Birth Date	Sex	Age
SA00175244	TESTINGRNV, 3A5Q ABNORMAL		2005-06-06	M	19
Order Number	Client Order Number	Ordering Physician	Report Notes		
SA00175244	SA00175244	CLIENT,CLIENT			
Account Information		Collected			
C7028846 DLMP Rochester		15 Apr 2025 00:00			

Results

Analyte	Result	Performing Site
CYP3A5 Genotype	*1/*3	MCR
CYP3A5 Phenotype	⚠ Intermediate metabolizer	MCR

Interpretation

MCR

This patient is expected to be an increased CYP3A5 metabolizer compared to CYP3A5*3/*3. This phenotype is also known as CYP3A5 expresser. For patients taking tacrolimus with this genotype, the literature indicates that higher doses may be required presumably because original dosing guidelines were determined on patients who were poor metabolizers (i.e. CYP3A5*3/*3). This may also be true of other medications that are CYP3A5 substrates. Therapeutic drug monitoring is recommended where possible.

Method

MCR

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

1 MCR

Targeted variant analysis was used to test for the presence of specific CYP3A5 variants: *3 (c.219–237A>G), *6 (c.624G>A), *7 (c.1035dup), *8 (c.82C>T), and *9 (c.1009G>A), based on GRCh37 NM_000777.4.

This test will not detect all CYP3A5 genetic variants. If no detectable CYP3A5 variant is found, a presumed *1 allele is assigned. Therefore, absence of a detectable gene variant does not rule out the possibility that a patient has an altered CYP3A5 metabolism status due to other CYP3A5 variants that cannot be detected with this method. Furthermore, when two or more gene variants are identified, the cis-trans status (whether the variants are on the same or opposite chromosomes) is not always known.

The CYP3A5 enzyme is involved in the metabolism of a large number of medications, including tacrolimus. The CYP3A5 genotype explains about 30% of variability in dosing of tacrolimus, but it is only one factor that should be taken into consideration for tacrolimus dosing. Other factors include age, race, and concomitant use of medications that inhibit CYP3A5 which may further increase variability in dosing. Absence of a variant allele does not rule out the possibility that a patient harbors another genetic variant that can impact the function of this enzyme, drug response, or drug side effects.

CAUTIONS:

Rare variants may be present that could lead to false negative or positive results. If results obtained do not match the clinical findings (phenotype), additional testing should be considered.

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 pre-transplant DNA specimen is recommended for testing.

Performing Site Legend

Code	Laboratory	Address	Lab Director	CLIA Certificate
MCR	Mayo Clinic Laboratories - Rochester Main Campus	200 First Street SW, Rochester, MN 55905	Nikola Baumann Ph.D.	24D0404292

MAYO CLINIC LABORATORIES

Patient ID	Patient Name		Birth Date	Sex	Age
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Order Number	**Client Order Number**	**Ordering Physician**	**Report Notes**		
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Account Information		**Collected**			
C7028846 DLMP Rochester		15 Apr 2025 00:00			

CYP3A5 genetic test results in patients who have undergone liver transplantation may not accurately reflect the patient's CYP3A5 status.

Reviewed by MCR

Ann Marie Moyer, M.D., Ph.D.

Received: 15 Apr 2025 10:48 **Reported:** 16 Apr 2025 17:23

Laboratory Notes

1 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.

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