

|                                                       |                                               |                                            |                 |                  |
|-------------------------------------------------------|-----------------------------------------------|--------------------------------------------|-----------------|------------------|
| Patient ID<br><b>SA00178892</b>                       | Patient Name<br><b>TESTINGHL57R, ABNORMAL</b> | Birth Date<br><b>2005-06-06</b>            | Sex<br><b>M</b> | Age<br><b>20</b> |
| Order Number<br><b>SA00178892</b>                     | Client Order Number<br><b>SA00178892</b>      | Ordering Physician<br><b>CLIENT,CLIENT</b> | Report Notes    |                  |
| Account Information<br><b>C7028846 DLMP Rochester</b> |                                               | Collected<br><b>15 Jan 2026 00:00</b>      |                 |                  |

## HLA-B 5701 Genotype, V

### HLA-B \*57:01 Genotype


**Positive**

Abn

MCR

Reference Value  
Negative

### HLA-B \*57:01 Phenotype

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Significant risk of abacavir hypersensitivity reactions (HSR) and increased risk of pazopanib-induced elevation in alanine aminotransferase (ALT).

### Interpretation

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Treatment with abacavir is not recommended and should be considered only under exceptional circumstances when the potential benefits outweigh the risk. Should abacavir hypersensitivity reaction develop, therapy should be discontinued immediately and permanently.

There is an increased risk of elevated ALT levels in patients taking pazopanib who are HLA-B\*57:01 carriers. Patients who are HLA-B\*57:01 carriers should be managed according to the pazopanib FDA label. Note that pazopanib therapy may also result in hyperbilirubinemia and is associated with genetic variation in UGT1A1.

### Method

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Amplification for the HLA-B\*57:01 allele and an internal control gene is performed by real-time PCR in the presence of SYBR Green, which fluoresces when bound to double-stranded DNA. A genotype is assigned based on the allele-specific SYBR Green fluorescent signals that are detected. (Hammond E, Mamotte C, Nolan D, Mallal S: HLA-B\*5701 typing: evaluation of an allele-specific polymerase chain reaction melting assay. Tissue Antigens 2007 Jul;70[1]:58-61)

### Disclaimer

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The HLA-B\*57:01 allele is detected by allele specific amplification (IMGT/HLA accession number HLA00381).

Screening for the HLA-B\*57:01 allele is recommended by the

FDA before initiating therapy with abacavir. Genotyping is also critical when there is a clinical history of, or when the physician suspects, an abacavir hypersensitivity reaction. However, FDA guidance states that, regardless of HLA-B\*57:01 status, abacavir should be permanently discontinued if hypersensitivity cannot be ruled out, even when other diagnoses are possible. Since symptoms of abacavir hypersensitivity are often variable and non-specific and can imitate other conditions commonly seen in HIV patients on antiretroviral therapy, the phenotypic diagnosis of abacavir hypersensitivity can be challenging.

HLA-B\*57:01 carriers who are taking pazopanib are at increased risk of elevated alanine aminotransferase (ALT) levels. According to the FDA label for pazopanib, in an analysis of data from 31 clinical studies of pazopanib administered as either monotherapy or in combination with other agents, elevation of ALT greater than 3 times the upper limit of normal occurred in 32% (42/133) of HLA-B\*57:01 allele carriers compared to 19% (397/2101) of non-carriers. Elevation of ALT levels greater than 5 times the upper limit of normal occurred in 19% (25/133) of HLA-B\*57:01 allele carriers and in 10% (213/2101) of non-carriers. Hepatic function should be monitored during pazopanib therapy, regardless of HLA-B\*57:01 carrier status and administration of pazopanib should be interrupted, reduced, or discontinued according to recommendations in the FDA label if hepatic function is impaired.

### CAUTIONS:

Rare or novel variants may be present that could lead to false negative or false positive results. There may be rare or novel HLA-B alleles which could interfere with this assay. There are currently no data indicating whether any other alleles or subtypes are associated with abacavir hypersensitivity. 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 received heterologous 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. The impact of allogeneic hematopoietic

### Performing Site Legend

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| MCR  | Mayo Clinic Laboratories - Rochester Main Campus | 200 First Street SW, Rochester, MN 55905 | Nikola Baumann Ph.D. | 24D0404292       |



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stem cell transplantation on risk of abacavir hypersensitivity reactions is not defined in the literature.

**Reviewed by**  
BENJAMIN VANSTEINBURG

MCR

**Received:** 15 Jan 2026 13:48

**Reported:** 15 Jan 2026 13:51

Laboratory Notes

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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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