SYNLAB Diagnostics Europe
Certified Medical Laboratory - ISO 15189:2012 Accredited
593 Laboratory Way, Berlin, Germany | Tel: +49 30 6474510 | www.synlab.de

Laboratory Report

Patient Copy

Patient Information

Patient Name: Alexander Mueller	Patient ID: 9347821
Date of Birth: 1985-04-12	Gender: Male
Sample Collection Date: 2025-07-04	Report Date: 2025-07-05

Test Details

Test Name: HLA-B*57:01 Typing (Genetic Test for Abacavir Hypersensitivity)
Method: PCR-based Genotyping
Sample Type: Whole Blood (EDTA)

Result Summary

HLA-B*57:01 Genotype: POSITIVE

Clinical Interpretation

The presence of the HLA-B*57:01 allele is associated with a significantly increased risk of developing a severe hypersensitivity reaction to abacavir-containing medications. In accordance with EMA and FDA guidelines, abacavir should not be prescribed to patients who test positive for this allele. Alternative antiretroviral therapy should be considered.

This test result should be interpreted in the context of the patient's clinical history and other diagnostic findings. Genetic counseling may be appropriate.

Test Methodology

The detection of the HLA-B57:01 allele was performed using **polymerase chain reaction (PCR)** with **sequence-specific primers (SSP)**.
DNA was extracted from whole blood collected in EDTA tubes, using automated magnetic bead-based isolation (Qiagen EZ1 system).
Amplification and allele detection were carried out using the Inno-Train HLA-B57:01 Genotyping Kit on a **Thermo Fisher Veriti® PCR system**.
Post-amplification analysis was conducted via agarose gel electrophoresis and visual inspection under UV light.

The test has a reported sensitivity and specificity >99% for detection of HLA-B*57:01. This assay is intended for in vitro diagnostic use and is CE-IVD certified in accordance with European regulatory standards.

Supervising Pathologist / Medical Director

Name: **Dr. Markus Klein, MD**

Signature: 

Date: **2025-07-05**

Time: **15:05**

SYNLAB
Diagnostics Europe
123 Laboratory Way
Berlin, Germany
ISO 15189:2012 Accredited