

Patient Name:	Mr. M1	Booking ID:	XXX
Age:	40 Years	Sample Type:	Whole Blood EDTA
Gender:	Male	Sample collection date:	08-05-2024
Referring doctor:	XXX	Sample receiving date:	09-05-2024
Test Requested:	HLA Celiac Disease (DQ2 & DQ8) by SSO-Luminex	Reporting date:	15-05-2024

HLA CELIAC DISEASE (DQ2 & DQ8) REPORT

CLINICAL INDICATION

NA

RESULTS SUMMARY

Allele I For HLA - DQB1*	02:01
Allele II For HLA - DQB1*	06:03
Allele I For HLA - DQA1*	01:03
Allele II For HLA - DQA1*	05:01

REMARKS

HLA-DQ*02 was detected

(HLA-DQ*02 and or HLA-DQ*08 are known associations with celiac disease)

DISCLAIMER

The above four digit HLA typing report is based on the probe-based HLA typing method (SSO-Luminex). Once in a while, the third and fourth digit of HLA alleles may change when the reporting has done based on NGS.

INTERPRETATION

Please note that approximately 95% of patients with Celiac Disease have the HLA-DQ2 heterodimer encoded by the DQA1*05 and DQB1*02 alleles, while close to 5% have the HLA-DQ8 heterodimer encoded by the DQA1*03 and DQB1*0302 alleles.

CLINICAL DESCRIPTION

HLA antigens are cell membrane glycoproteins with key roles in the initiation of the immune response. Current methods for HLA typing define HLA alleles and allele groups using DNA-based methods. Different DNA-based molecular techniques are used depending on the clinical application. Solid-organ transplantation requires a low- to intermediate-level typing resolution to determine an individual's HLA antigens. Bone marrow transplantation requires a high-resolution typing to determine the HLA alleles. Determination of HLA phenotypes is also applied to vaccine development, studies of disease associations and as companion diagnostics for the safe and effective use of therapeutic products.

A high-resolution typing result is defined as a set of alleles that specify and encode the same protein sequence for the peptide binding region of an HLA molecule and that excludes alleles that are not expressed as cell surface proteins. This test is used for HLA typing at a minimum of 4 digits in Bone Marrow Transplants. In low resolution typing result is defined as a set of alleles of HLA molecule, this test is used for HLA typing of 2 digits.

METHODOLOGY AND DATA ANALYSIS

- ✧ This assay was carried out by sequence typing of exons 2 & 3 for HLA Class I and exon 2 for HLA Class II.
- ✧ This test has been conducted by Sanger Sequencing/Luminex using the Secore sequencing Kit/Immucor kit.
- ✧ All efforts are made to resolve ambiguities. However, in certain cases, this is not possible, and therefore ambiguous alleles for the same loci may be reported. In cases where special sequencing can be done to resolve ambiguities, the patient/physician will be consulted and a special sequencing test will be carried out for a fee.
- ✧ SOFTWARE AND ALLELE DATABASE VERSION; IMGT/HLA DATABASE RELEASE: 3.14.0 2013 OCT 11

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LIMITATIONS OF THE PROCEDURE

- ✧ In cases of ambiguities of low-resolution HLA typing, Sequence-based HLA Typing is Advised to confirm the Results. This Report will not be valid for assessing the relationship between two individuals. For Relationship assessment between individuals, Autosomal STR testing is advised.
- ✧ These tests do not in any way imply or confirm the identity of the sample. Rare primer site mutations or sequence variations in the genome might result in an erroneous report.
- ✧ If the Recipient / Donor has undergone blood transfusion than the results may vary and give ambiguous results. In this type of matter, the laboratory gives the advice to resolve by NGS platform method.
- ✧ Although all precautions are taken, available data indicate a technical error rate of approximately 2% for all molecular tests. It is important that any individual interpreting these tests is aware of this data before acting upon their results.
- ✧ This report will not be valid for assessing the relationship between two individuals without the attachment of the photographs of the concerned individuals and a valid form-3 signed by a qualified immunologist.
- ✧ Alleles with ambiguities in intronic regions will not be resolved. This report is to be interpreted by a Transplant physician/surgeon only.
- ✧ The alleles that are in italics and underlined are RARE alleles. NMDP biannual rare alleles list comprises of class I alleles observed at a frequency of less than 1/50,000 and DRB1 alleles observed at a frequency of less than 1/100,000 in the NMDP registry. Rare alleles have extremely low frequencies and are not likely to be found repeatedly in a significant number of unrelated subjects.

DISCLAIMER

This test has not been cleared or approved by the U.S.FDA. The test results are for RUO (research use only) and relate specifically to the sample received in the lab and are presumed to have been collected and transported per specific instructions given by the physicians/laboratory and belongs to the patient named or identified in the test requisition form. All reports have limitation imposed by sensitivity and specificity of the assay and should be interpreted in conjunction with clinical presentation and other related investigations. Results of this test could be affected by interfering substances (endogenous and exogenous)/contamination during specimen collection, inappropriate specimen storage and transport and thereby lead to occasional assay failure. The said report is strictly not a medical/medical laboratory/diagnostic report and/or an opinion with regard to test results. The authorized signatories are only responsible for signing Technical report/Test report i.e a report stating the test results and the processes, if any, indicating the analysis of sample without recording any medical opinion or diagnosis of any medical condition.

----- End Of Report -----



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2. It is to be presumed that the tests performed pertain to the specimen/sample attributed to the Customer's name or identification. It is presumed that the verification particulars have been cleared out by the customer or his/her representation at the point of generation of said specimen / sample. It is hereby clarified that the reports furnished are restricted solely to the given specimen only.
3. It is to be noted that variations in results may occur between different laboratories and over time, even for the same parameter for the same Customer. The assays are performed and conducted in accordance with standard procedures, and the reported outcomes are contingent on the specific individual assay methods and equipment(s) used, as well as the quality of the received specimen.
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DISCLAIMER

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