MAYO CLINIC LABORATORIES

# Test Definition: 2DIS

Human Leukocyte Antigens (HLA)-DR-DQ Disease Association Typing Low Resolution, Blood

## Overview

### Useful For

Determining class II human leukocyte antigens (HLA) to identify potential disease associations or markers for drug hypersensitivity

### Method Name

Polymerase Chain Reaction (PCR)/Next-Generation Sequencing (NGS)

### NY State Available

Yes

## Specimen

### Specimen Type

Whole Blood ACD

### Specimen Required

**Container/Tube:** Yellow top (ACD solution A or B)
**Specimen Volume:** 6 mL
**Collection Instructions:** Send whole blood in original tube. **Do not aliquot**.
**Additional Information:** Specimen acceptability is based on extracted DNA concentration and not sample age.

### Forms

If not ordering electronically, complete, print, and send a Hematopathology/Cytogenetics Test Request (T726) with the specimen.

### Specimen Minimum Volume

3 mL

### Reject Due To

All specimens will be evaluated at Mayo Clinic Laboratories for test suitability.

### Specimen Stability Information

| Specimen Type | Temperature | Time | Special Container |
|---|---|---|---|
| Whole Blood ACD | Ambient (preferred) | | |
| | Refrigerated | | |

## Clinical & Interpretive

### Clinical Information

Human leukocyte antigen (HLA) class II genes (*HLA-DRB1, -DRB3/4/5, -DQA1, -DQB1, -DPA1, -DPB1*) are a part of the major histocompatibility gene complex that encodes for proteins involved in immune recognition.

This assay is designed to provide low-to-medium resolution for HLA class II typing. Low-to-medium resolution defines the typing at first field (antigen or allele group level). This contrasts with high-resolution typing, which defines typing at second field or higher (allele level).

### Reference Values

Not applicable

### Interpretation

Interpretation depends on the rationale for ordering the test.

### Cautions

No significant cautionary statements.

### Clinical Reference

1. Terasaki PI, Bernoco D, Park MS, Ozturk G, Iwaki Y. Microdroplet testing for HLA-A, B, C and D antigens. The Phillip Levine Award Lecture. Am J Clin Pathol. 1978;69(2):103-120
2. Colinas RJ, Bellisario R, Pass KA. Multiplexed genotyping of beta-globin variants form PCR-amplified newborn blood spot DNA by hybridization with allele-specific oligodeoxynucleotides coupled to an array of fluorescent microspheres. Clin Chem. 2000;46(7):996-998
3. Kennedy AE, Ozbek U, Dorak MT. What has GWAS done for HLA and disease associations? Int J Immunogenet. 2017;44(5):195-211. doi:10.1111/iji.12332
4. Caillat-Zucman S. New insights into the understanding of MHC associations with immune-mediated disorders. HLA. 2017;89(1):3-13. doi:10.1111/tan.12947
5. Howell WM. HLA and disease: guilt by association. Int J Immunogenet. 2014;41(1):1-12. doi:10.1111/iji.12088
6. Profaizer T, Pole A, Monds C, Delgado JC, Lazar-Molnar E. Clinical utility of next generation sequencing based HLA typing for disease association and pharmacogenetic testing. Hum Immunol. 2020;81(7): 354-360

## Performance

### Method Description

Next-generation sequencing is used to type for Class II alleles (DRB1, DRB3/4/5, DQB1, DQA1, DPB1, and DPA1) from genomic DNA. This method uses strictly controlled polymerase chain reaction (PCR) conditions for DNA amplification. The PCR amplicons are processed and sequenced via the Illumina MiSeq instrument. The output files are analyzed in provided software, which compares the data against the IMGT/HLA database to assign the molecular typing.(Package

inserts: Holotype HLA Kit. Omixon; v3.0.1, 08/16/2019; NGSgo HLA Kit. GenDx; v2, 02/2021)

For resolution of an allelic ambiguity or in select cases, the following additional methodologies may be utilized:
-Sequence-based typing (SBT) by Sanger sequencing(Package insert: SeCore Sequencing and GSSP Kits. One Lambda, Inc; Rev 3, 02/06/2021)
-SBT by sequence-specific primers (SSP)(Package insert: Olerup SSP HLA typing kits including Taq Polymerase. CareDx; Rev 04, 12/2020)
-Reverse sequence-specific oligonucleotides (SSO)(Package insert: LABType SSO Typing Test. One Lambda, Inc.; Rev 04, 11/11/2019)

### PDF Report
No

### Day(s) Performed
Monday, Thursday

### Report Available
7 to 17 days

### Specimen Retention Time
14 days

### Performing Laboratory Location
Rochester

## Fees & Codes

### Fees
- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their account representative. For assistance, contact Customer Service.

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

### CPT Code Information
81375
81376 x3

### LOINC® Information

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# Test Definition: 2DIS

Human Leukocyte Antigens (HLA)-DR-DQ Disease Association Typing Low Resolution, Blood

| Test ID | Test Order Name | Order LOINC® Value |
|---|---|---|
| 2DIS | HLA-DR-DQ DisAssoc Typing LowRes,B | 96640-8 |

| Result ID | Test Result Name | Result LOINC® Value |
|---|---|---|
| 2DA02 | DRDQ DisAssoc Comment | 96625-9 |
| 2DA03 | DRB1 - 1 Equivalent | 57298-2 |
| 2DA04 | DRB1 - 2 Equivalent | 57298-2 |
| 2DA05 | DRB1 - 1 Molecular | 96664-8 |
| 2DA06 | DRB1 - 2 Molecular | 96664-8 |
| 2DA07 | DRB345 - 1 Equivalent | 96673-9 |
| 2DA08 | DRB345 - 2 Equivalent | 96673-9 |
| 2DA09 | DRB345 - 1 Molecular | 96672-1 |
| 2DA10 | DRB345 - 2 Molecular | 96672-1 |
| 2DA11 | DQB1 - 1 Equivalent | 53938-7 |
| 2DA12 | DQB1 - 2 Equivalent | 53938-7 |
| 2DA13 | DQB1 - 1 Molecular | 78017-1 |
| 2DA14 | DQB1 - 2 Molecular | 78017-1 |
| 2DA15 | DQA1 - 1 Molecular | 96654-9 |
| 2DA16 | DQA1 - 2 Molecular | 96654-9 |
| 2DA17 | DPB1 - 1 Molecular | 96648-1 |
| 2DA18 | DPB1 - 2 Molecular | 96648-1 |
| 2DA19 | DPA1 - 1 Molecular | 96643-2 |
| 2DA20 | DPA1 - 2 Molecular | 96643-2 |
| LRTM2 | Test Method | 85069-3 |