

## 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

Extracted DNA	Reject
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### 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.

### 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 from 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 insert: NGSgo HLA Kit. GenDx; v3, 06/2022)

For resolution of an allelic ambiguity or in select cases, the following additional methodologies may be utilized:

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- Sequence-based typing (SBT) by Sanger sequencing(Package insert: SeCore Sequencing and GSSP Kits. One Lambda, Inc; Rev 3, 02/06/2021)
  - 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, Wednesday

**Report Available**

7 to 17 days

**Specimen Retention Time**

14 days

**Performing Laboratory Location**

Mayo Clinic Laboratories - Rochester Main Campus

**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**

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