MAYO CLINIC LABORATORIES

Test Definition: DIS

Human Leukocyte Antigens (HLA) Class I and II Disease Association Typing, Low Resolution, Blood

Overview

Useful For

Identifying class I and II human leukocyte antigens (HLA) for potential disease associations or markers for drug hypersensitivity

Profile Information

Test Id	Reporting Name	Available Separately	Always Performed
1DIS	HLA-A-B-C DisAssoc Typing LowRes,B	Yes	Yes
2DIS	HLA-DR-DQ DisAssoc Typing LowRes,B	Yes	Yes

Method Name

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

NY State Available

Yes

Specimen

Specimen Type

Whole Blood ACD

Ordering Guidance

This test should be ordered if both human leukocyte antigen (HLA) class I and class II results are wanted for disease association.

If only needing patient's HLA class I typing for disease association, order 1DIS / Human Leukocyte Antigens (HLA)-A-B-C Disease Association Typing Low Resolution, Blood.

If only needing patient's HLA class II typing for disease association, order 2DIS / Human Leukocyte Antigens (HLA)-DR-DQ Disease Association Typing Low Resolution, Blood.

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.

Specimen Minimum Volume
3 mL

Reject Due To

Extracted DNA	Reject

Specimen Stability Information

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

Clinical & Interpretive

Clinical Information
Human leukocyte antigens (HLA) class I and II genes (*A*, *B*, *C*, *DRB1*, *DRB3/4/5*, *DQB1*, *DQA1*, *DPB1*, *DPA1*) are a part of the major histocompatibility gene complex that encodes for proteins involved in immune recognition and are regulators of the immune response.

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 I alleles (A, B, and C) and 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:
-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

81370
81376 x3

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
DIS	HLA CI-CII DisAssoc Typing LowRes,B	98005-2

Result ID	Test Result Name	Result LOINC® Value
1DA02	ABC DisAssoc Comment	96625-9
1DA03	A - 1 Equivalent	13298-5
1DA04	A - 2 Equivalent	13298-5
1DA05	A - 1 Molecular	78014-8
1DA06	A - 2 Molecular	78014-8
1DA07	B - 1 Equivalent	13299-3
1DA08	B - 2 Equivalent	13299-3
1DA09	B - 1 Molecular	78015-5
1DA10	B - 2 Molecular	78015-5
1DA11	Bw - 1 Equivalent	96633-3
1DA12	Bw - 2 Equivalent	96633-3
1DA13	C - 1 Equivalent	13302-5
1DA14	C - 2 Equivalent	13302-5
1DA15	C - 1 Molecular	96636-6
1DA16	C - 2 Molecular	96636-6
LRTM1	Test Method	85069-3
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