

Overview

Useful For

Determining class II human leukocyte antigens to identify potential disease association and as markers for drug hypersensitivity

Method Name

[Polymerase Chain Reaction \(PCR\)/Sequence-Specific Oligonucleotide Probes \(SSO\)](#)

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. *Am J Clin Pathol.* 1978 Feb;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 Jul;46(7):996-998
3. Kennedy AE, Ozbek U, Dorak MT: What has GWAS done for HLA and disease associations? *Int J Immunogenet.* 2017 Oct;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 Jan;89(1):3-13. doi: 10.1111/tan.12947
5. Howell WM: HLA and disease: guilt by association. *Int J Immunogenet.* 2014 Feb;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 Jul;81(7): 354-360

Performance

Method Description

[The reverse sequence-specific oligonucleotide DNA typing method consists of using polymerase chain reaction \(PCR\) to amplify target DNA with group specific primers. The PCR product is denatured and allowed to rehybridize to complementary DNA probes bound to fluorescently coded microspheres. The mixture is labeled with a fluorescent dye that is able to detect biotinylated protein and nucleic acids. A flow analyzer detects the fluorescent emission on each](#)

[probe and the reaction pattern is analyzed and interpreted. The assignment of the human leukocyte antigen \(HLA\) typing is based on the reaction pattern compared to patterns associated with published HLA gene sequences. \(Package insert: LABType SSO Typing Test. One Lambda, Inc.; Rev 04, 11/11/2019\)](#)

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)

-SBT by next-generation sequencing (NGS) (Package inserts: Holotype HLA Kit. Omixon; v3.0.1, 08/16/2019; NGSgo HLA Kit. GenDx; v2, 02/2021)

PDF Report

No

Day(s) Performed

Monday

Report Available

3 to 16 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 Regional Manager. For assistance, contact [Customer Service](#).

Test Classification

This test has been cleared, approved, or is exempt by the US Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

CPT Code Information

81375

81376 (as appropriate)

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
LRTMB	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