

RHD and RHCE Technical Brief

RH is the most complex blood group system, with over 40 antigens encoded by two highly homologous genes: RHCE and RHD. Because of RH's high immunogenicity, this system is critical in blood banking and is associated with transfusion reactions and hemolytic disease of the newborn.

Background

Applications of RH variant typing by DNA analysis may include:

- providing prospective determination of RH variants in patients who will be multiply transfused

- identifying clinically significant RH polymorphisms undetectable by current serological techniques
- investigating anomalous or ambiguous serological typings (e.g. unexpected RH antibodies, weak reactions, variations in reactivity across reagents)
- conducting detailed RH variant analysis in pregnant women (e.g. partial D, weak D)
- selectively testing donors or patients for altered or variant expressions of RH

RHCE Assay Variant Coverage

Detects C, c, E, e, VS, and V antigens along with **44+ RHCE variants** including ceAR, ceBI or ceSM, ceCF, CeCW, CeCX, ceEK, cEEW, cEFM, CeFV, ceHAR, ceJAL, cEKH, CeMA, ceMO, ceRA, CeRN, ceRT, ceSL, ceTI, CeVA, r's, ce(1025T), cE(344C), Ce(344G), cE(365T), Ce(365T), cE(602C), Ce(667T), ce(697G,733G), ce(733G), ce(733G,1006T), ce(733G,748A), ce(48C), ce(48C,106A), ce(48C,122G), ce(48C,340T,733G)



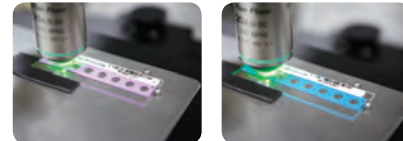
RHD Assay Variant Coverage

Weak D type: 1, 1.1, 2, 3, 5, 14, 17, 29, 34, 40, 41, 47, 51

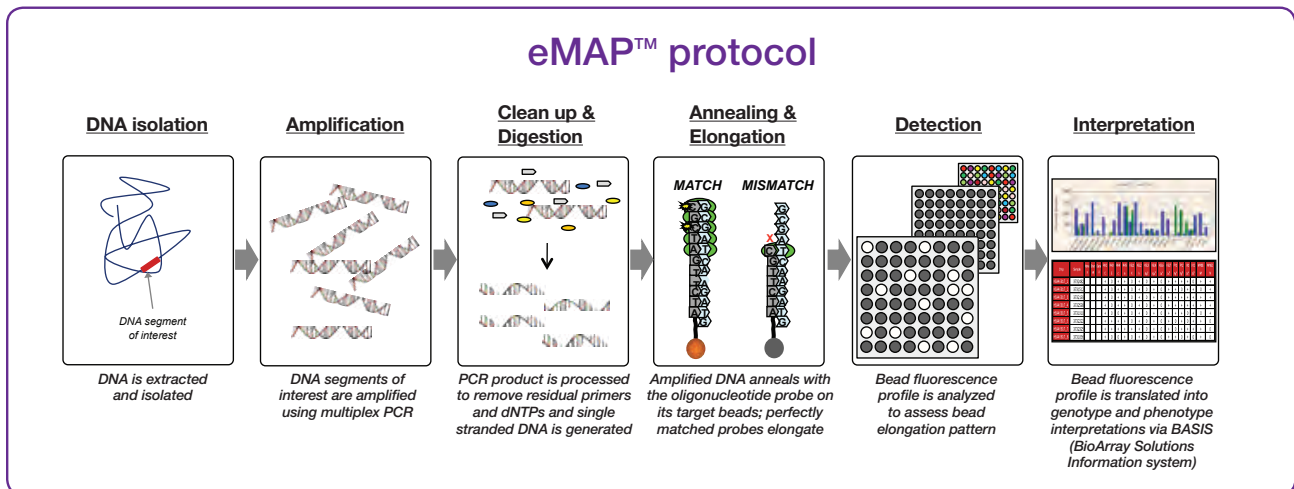
D negative: RHD deletion, RHD Ψ , RHD-CE(3-9)-D, RHD-CE(3-7)-D, RHD-CE(4-7)-D, 48A (W16X), 807G (Y269X), DIIIa-CE(4-7)-D, RHCE(1-3)-D(4-10)

D_{el}: 1227A, IVS3+1G>A

Partial D: DBS0,1,2; DAR, DAR-E, DAU 1,2,3,4,5; DOL 1,2,3; DBT1,2; DIIIa,b,c; DIII type 4,6,7; DIVa,b; DIVa-2, DIV type 3,4,5; DV type 1,2,4,5,6,7,8,9; DVI, DCS1,2; DFR1,2,3,4; DHMi, DNB, DUC2, ceHAR, DFV, Weak D type 4.0, 4.1, 4.3, 11, 15



Method:



RHD Validation Summary:

Validation of the RHD BeadChip assay included an evaluation of accuracy, precision, sensitivity, specificity and interfering substances. Accuracy of the RHD assay demonstrated 99.9% concordance between the Immucor DX Laboratory, a reference laboratory, and BioArray Solutions Research and Development Laboratory. The RHD Beadchip assay demonstrated 92.6% sensitivity and 96.1% specificity when compared with established reference methods. Interference testing of common

endogenous interfering substances as well as exogenous substances and microorganisms demonstrated no impact on the performance of the RHD BeadChip assay.

Accuracy*	99.9%
Sensitivity	92.6%
Specificity	96.1%
Interfering Substances	No Impact

*Genotype Accuracy

RHCE Validation Summary:

Validation of the RHCE BeadChip assay included an evaluation of accuracy, precision, sensitivity, specificity and interfering substances. Accuracy of the RHCE assay demonstrated 100% concordance between the Immucor DX Laboratory, a reference laboratory, and BioArray Solutions Research and Development Laboratory. The RHCE BeadChip assay demonstrated 99.0% sensitivity and 99.0% specificity when compared with established reference methods. Interference testing of common endogenous interfering substances as well as exogenous substances and microorganisms demonstrated no impact on the performance of the RHCE BeadChip assay.

Accuracy*	100%
Sensitivity	99%
Specificity	99%
Interfering Substances	No Impact

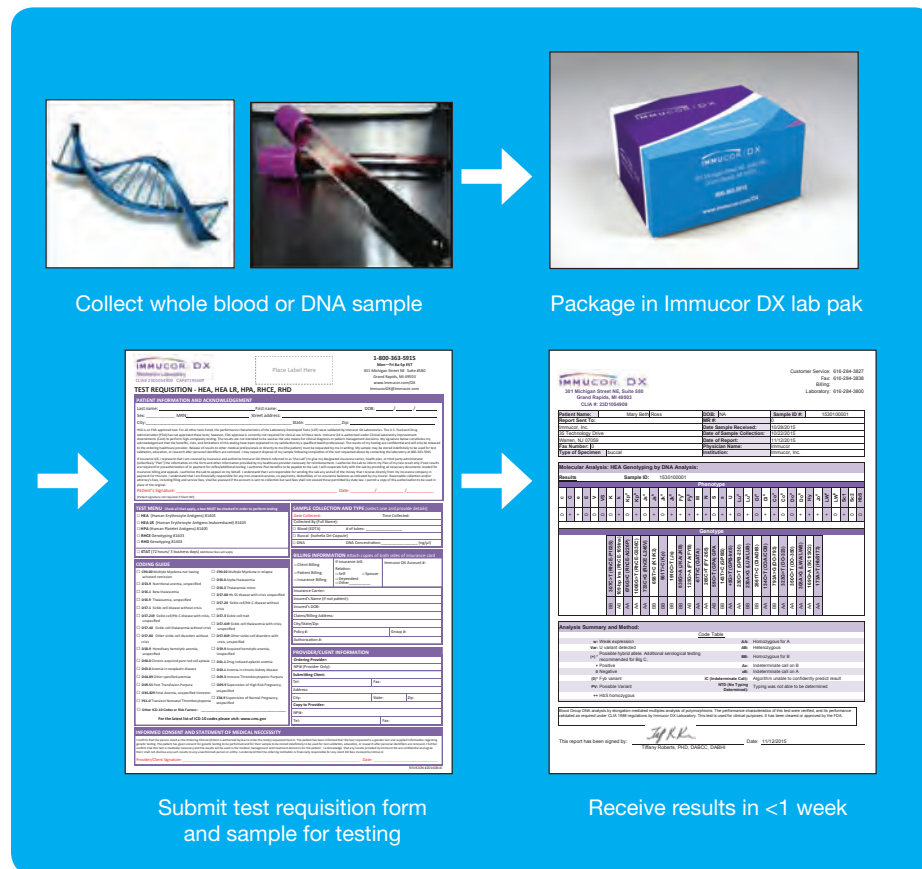
*Genotype Accuracy

CPT Code	Description
81403	Molecular pathology procedure

Complementing Your Organization's Capability

- Laboratories without onsite molecular immunohematology capabilities can now effectively reflex testing to the Immucor DX Reference Laboratory.
- Leverage the capabilities of molecular diagnostics without the capital outlay and maintenance of an onsite molecular laboratory.

The process is quick and simple:



ImmucorDX has achieved both CLIA certification and CAP accreditation!

CLIA Number: 23D1054909

CAP Number: 7195469

