

BLOODchip^{ID}

Efficient blood group
genotyping for
extended matching



TYPING

The same commitment as the first day

At Grifols, we know the primary concern in blood transfusion is patient safety. With more than 100 years of experience in the field of transfusion medicine, safety is also our number one priority.

Blood Group Genotyping (BGG) takes safety a step further. Grifols launched its first BGG product in 2007.¹ For more than ten years, our products have been used worldwide to extensively type donors and patients, with excellent performance.²

100+ **YEARS**
of experience
in transfusion
medicine

10+ **YEARS**
of BGG product
availability



¹. Product registration and availability vary by country. To know whether a product is available in your country, please kindly contact your Grifols representative.
². Finning et al. *Blood Transfus.* 2016 Mar;14(2):160-7, 2 (study supported with a research grant from Grifols)

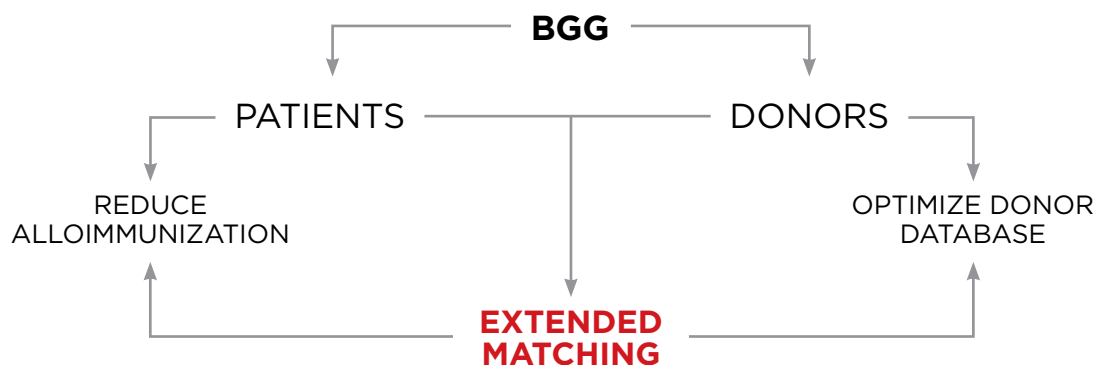
Genotyping: when and why?

Molecular typing has been proven very effective in overcoming some well-known serology limitations such as:¹

- Typing recently and chronically transfused patients
- DAT positive samples
- Weak expressions
- When antisera is not available

Main applications and benefits of BGG

	CLINICAL SITUATION	BENEFITS
PATIENTS	• Chronically transfused patients (SCD, thalassemia, cancer patients) • Autoimmune hemolytic anemia • Pregnancy • Patients under monoclonal treatments such as anti-CD38	• Prospective extended matching has been shown to reduce alloimmunization rates^{2,3} • Reduction of alloimmunization rates is associated with: - Increased patient survival^{4,5} - Expansion of period between transfusions⁶
DONORS	• When antisera is not available • To build extensively typed donor databases	• Reduction of costs to provide antigen negative units⁷ • Save in reagent and labor cost⁸ • Reduction of time to provide antigen negative units⁷ • Better management of negative units stocks (ie, Duffy b and D neg)^{9,10,11}



1. Jungbauer. *ISBT Science Series* (2011) 6, 399-403; **2.** Lasalle-Williams et al. *Transfusion*. 2011 Aug;51(8):1732-9. **3.** Tahhan et al. *Transfusion*. 1994 Jul;34(7):562-9. **4.** Telen et al. *Transfusion*. 2015 Jun;55(6 Pt 2):1378-87; **5.** Nickel et al. *Transfusion*. 2016 Jan;56(1):107-14. **6.** Da Costa et al. *Rev Bras Hematol Hemoter*. 2013;35(1):35-8. **7.** Shafi et al. *Transfusion*. 2014 May;54(5):1212-9; **8.** Winkler et al. *Immunohematology*. 2012;28(1):24-6. **9.** Sandler et al. *Transfusion*. 2015 Mar;55(3):680-9. **10.** Flegel. *Transfus Apher Sci*. 2011 Feb;44(1):81-91. **11.** Pelpier et al. *J Exp Med*. 1995 Apr 1;181(4):1311-7

Easy and fast process

FEATURES

EASY

- Only 4 tubes to pipette
- No washing steps
- Ready-to-use reagents

FAST

- 4 hr from DNA to results^{1,2}
- 30 min hands-on time^{1,2}

FLEXIBLE

- 1-96 tests per run
- Multiple batch: ID CORE XT, ID HPA XT, and ID RHD XT can be performed in the same run
- Open technology: standard Luminex® equipment can be used for other products

BENEFITS

- Easy for technicians of all levels
- Reduces human errors

- Results are obtained quickly
- Technicians are available to perform other activities

- Results obtained when needed without running full batches
- Different product results can be obtained simultaneously, which improves efficiency and reduces time and resources
- Efficient equipment investment



BLOODchip ID analytical procedure

1. AMPLIFICATION

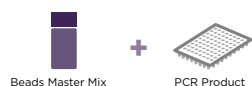


15 min



2.5 hr

2. HYBRIDIZATION



10 min



30 min

3. LABELING

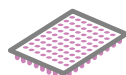


5 min



10 min

4. DATA ACQUISITION + ANALYSIS



Hands-on time
30 min



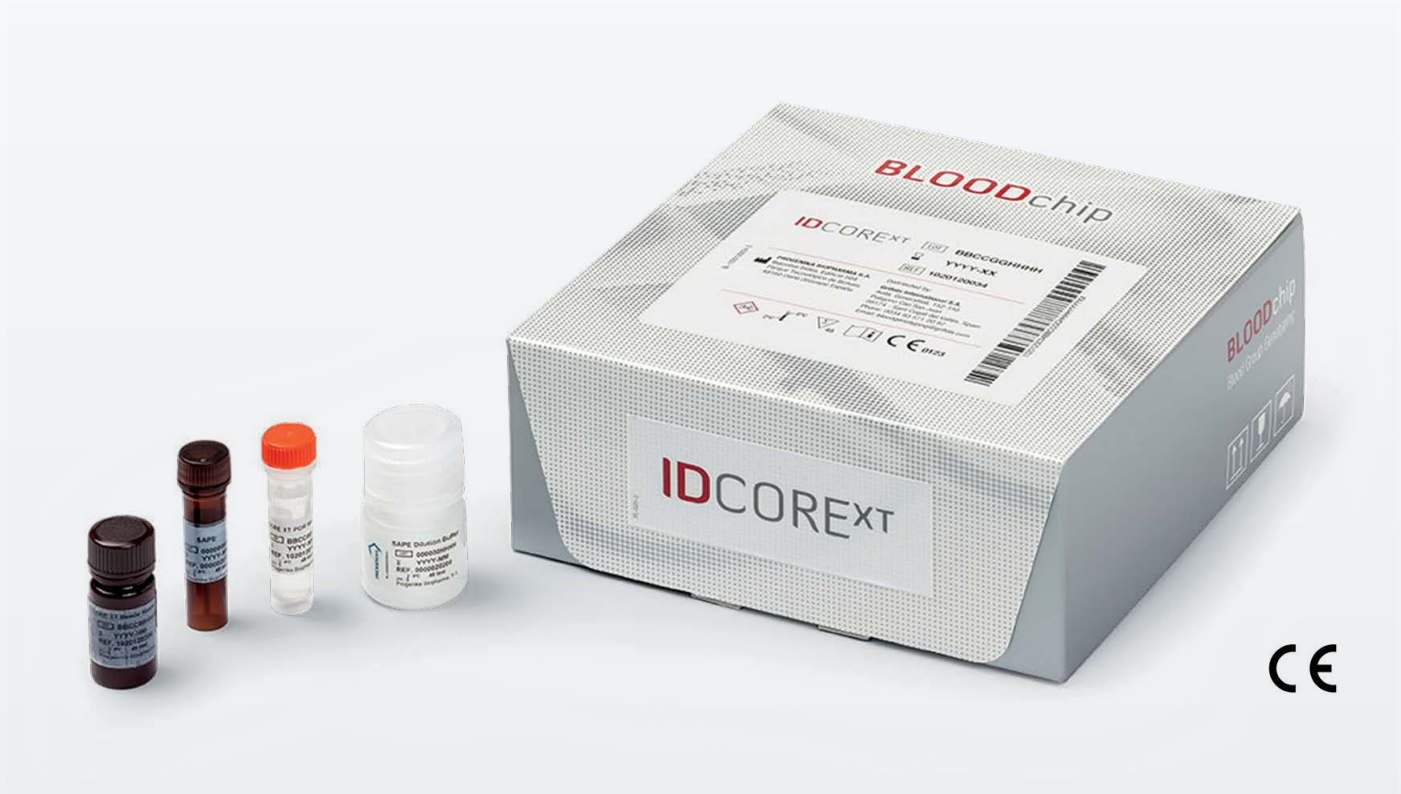
Automated time
3.5 hr

Overall time 4 hr

1. Finning et al. Blood Transfus. 2016 Mar;14(2):160-7, 2 (study supported with a research grant from Grifols).
2. ID CORE XT package insert, page 10.

Accurate and reliable performance

PARAMETER	RESULT	STUDY DESCRIPTION	REFERENCE
ACCURACY (SPECIFICITY AND SENSITIVITY)	100%	- Multi-center study: Milan (Italy), Barcelona (Spain), Bristol and Aberdeen (UK) 519 samples compared with reference methods	Finning et al. Blood Transfus. 2016 Mar;14(2):160-7, 2 (study supported with a research grant from Grifols)
	100%	Study performed in Brazil. 242 samples compared with Open Array and with sequencing if discrepant results	Bianchi et al. ISBT Science Series Volume 10, Issue 1, pages 45-51 (Grifols supplied the inputs for the assays ID CORE XT and ID HPA XT)
	100%	1000 samples tested at 2 sites were compared with CE marked serology assays following Directive 98/79/CE. Antigens were compared with molecular reference methods when serology wasn't available	ID CORE XT package insert (pages 18-19)
	100%	283 samples tested at 1 site were compared with established molecular genotyping reference methods	ID HPA XT package insert (pages 16-17)
	100%	1000 samples were processed with ID RHD XT following Directive 98/79/CE. Results were compared with RHD serology in every case and with bidirectional sequencing in the case of Weak D samples (n=163). Discrepancies were resolved with bi - directional sequencing	ID CORE XT package insert (pages 18-19)
r'S ACCURACY	99%	Study performed in US. 125 possible r'S samples were tested with HEA beadchip (Immucor) and with ID CORE XT. ID CORE XT could accurately detect r'S type 1 haplotype in a single test	Moulds et al. Transfusion. 2015 Jun;55(6 Pt 2):1418-22 (Joann M. Moulds and Katrina L. Billingsley were consultants for Novartis and Grifols)
PRECISION	100%	Use of the analytical procedure in different laboratories, and use of analytical procedure on different days, with different operators and different equipment within the same laboratory	ID CORE XT (pages 18-19) and ID HPA XT (page 17) package inserts



ID CORE XT

- Analyzes 29 polymorphisms determining 37 RBC antigens
- 48 tests per kit

Main applications^{1,2}

- Assess the presence/absence of blood groups in chronically transfused patients
- Screen routine donors
- Select compatible donors for alloimmunized patients
- Complement serological panel with further antigen identification
- Type patients treated with drugs such as daratumumab, which interfere with blood typing methods



1. Jungbauer. *ISBT Science Series* (2011) 6, 399-403.
2. *AABB Association Bulletin* #16-02.

ID CORE XT antigen panel

BLOOD GROUPS	ALLELES ASSAYED	PHENOTYPES (ANTIGENS)
RHCE	<i>RHCE*CeCW</i> ; <i>RHCE*ceCW</i> <i>RHCE*CECW</i> ; <i>RHCE*ce</i> ; <i>RHCE*cE</i> ; <i>RHCE*Ce</i> ; <i>RHCE*CE</i> ; <i>RHCE*ceAR</i> <i>RHCE*ce</i> [712G]; <i>RHCE*CeFV</i> <i>RHCE*cEFM</i> ; <i>RHCE*ce</i> [733G] <i>RHCE*ce</i> [733G,1006T] <i>RHCE*CeVG</i> ; <i>RHCE*cE</i> [712G,733G] <i>RHCE*Ce</i> [733G]; <i>RHD*r's-</i> <i>RHCE*ce</i> [733G,1006T] <i>RHCE*CE-D</i> [5, 7]- <i>CE</i>	C (RH2) E (RH3) c (RH4) e (RH5) CW (RH8) V (RH10) hrS (RH19) VS (RH20) hrB (RH31)
KELL	<i>KEL*K_KPB_JSB</i> ; <i>KEL*k_KPB_JSB</i> <i>KEL*k_KPA_JSB</i> ; <i>KEL*k_KPB_JSA</i>	K (KEL1) k (KEL2) Kpa (KEL3) Kpb (KEL4) Jsa (KEL6) Jsb (KEL7)
KIDD	<i>JK*B_null(IVS5-1a)</i> <i>JK*A_null(IVS5-1a)</i> ; <i>JK*A</i> ; <i>JK*B</i> <i>JK*B_null(871C)</i>	Jka (JK1) Jkb (JK2)
DUFFY	<i>FY*A_GATA</i> ; <i>FY*B_GATA</i> ; <i>FY*A FY*B</i> <i>FY*A</i> [265T] <i>FY*B</i> [265T]_FY*X	Fya (FY1) Fyb (FY2)
MNS	<i>GYP*A*M</i> ; <i>GYP*A*N</i> ; <i>GYPB*S</i> ; <i>GYPB*s</i> <i>GYPB*S_null(230T)</i> <i>GYPB*S_null(IVS5+5t)</i> <i>GYPMur</i> ; <i>GYPB*deletion</i>	M (MNS1) N (MNS2) S (MNS3) s (MNS4) U (MNS5) Mia (MNS7)
DIEGO	<i>DI*A</i> ; <i>DI*B</i>	Dia (DI1) Dib (DI2)
DOMBROCK	<i>DO*A</i> ; <i>DO*B</i> ; <i>DO*B_HY</i> <i>DO*A_JO</i>	Doa (DO1) Dob (DO2) Hy (DO4) Joa (DO5)
COLTON	<i>CO*A</i> ; <i>CO*B</i>	Coa (CO1) Cob (CO2)
CARTWRIGHT	<i>YT*A</i> ; <i>YT*B</i>	Yta (YT1) Ytb (YT2)
LUTHERAN	<i>LU*A</i> ; <i>LU*B</i>	Lua (LU1) Lub (LU2)



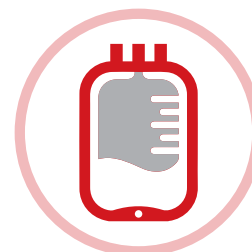


ID HPA XT

- Analyzes 13 polymorphisms determining 12 HPA systems
- 48 tests per kit

Main applications¹

- Platelet antigen typing in donors and patients
- Perform large-scale donor typing for provision of antigen-negative platelets
- Help to select compatible platelet donors for refractory or alloimmunized patients
- Complement clinical history of alloimmune platelet disorders, such as fetal and neonatal alloimmune thrombocytopenia (FNAIT), post-transfusion purpura, and platelet transfusion refractoriness

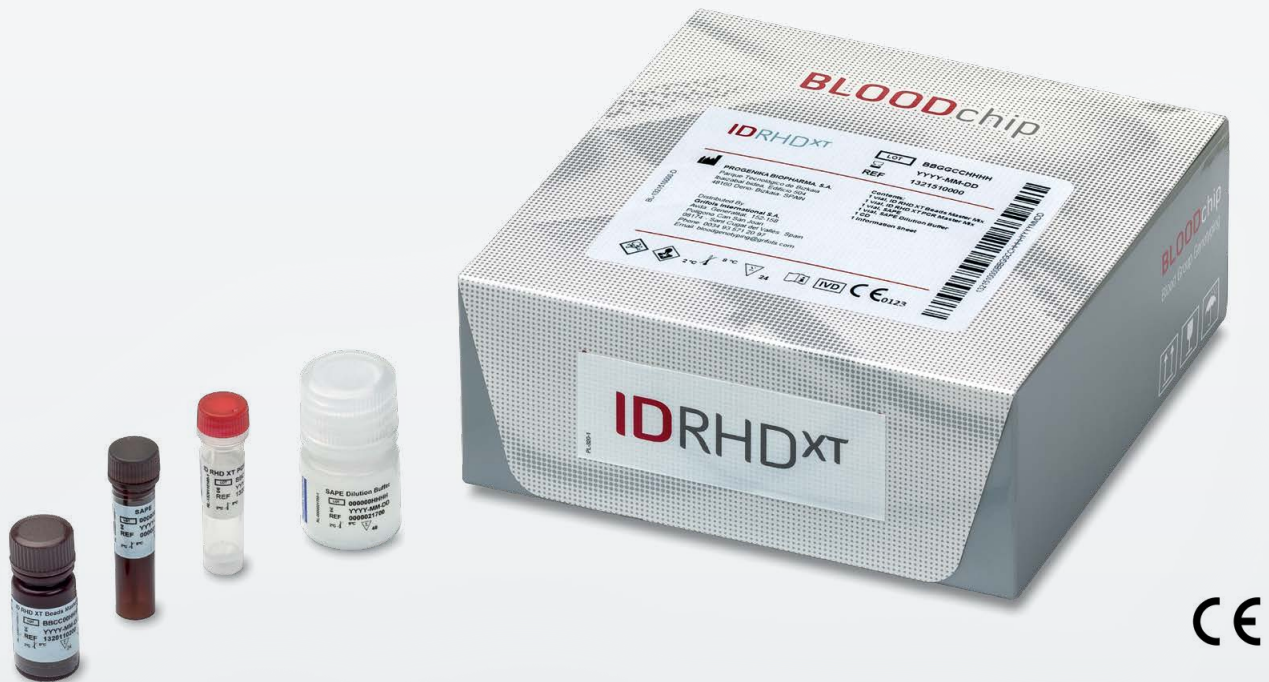


¹. Hurd et al. Vox Sanguinis 2022;83:1-12.

ID HPA XT antigen panel

HUMAN PLATELET ANTIGENS	ALLELES ASSAYED	PHENOTYPES (ANTIGENS)
HPA-1	HPA1a; HPA1b	HPA-1a; HPA-1b
HPA-2	HPA2a; HPA2b	HPA-2a; HPA-2b
HPA-3	HPA3a; HPA3b	HPA-3a; HPA-3b
HPA-4	HPA4a; HPA4b	HPA-4a; HPA-4b
HPA-5	HPA5a; HPA5b	HPA-5a; HPA-5b
HPA-6	HPA6a; HPA6b	HPA-6bw
HPA-7	HPA7a; HPA7b	HPA-7bw
HPA-8	HPA8a; HPA8b	HPA-8bw
HPA-9	HPA9a; HPA9b	HPA-9bw
HPA-10	HPA10a; HPA10b	HPA-10bw
HPA-11	HPA11a; HPA11b	HPA-11bw
HPA-15	HPA15a; HPA15b	HPA-15a; HPA-15b





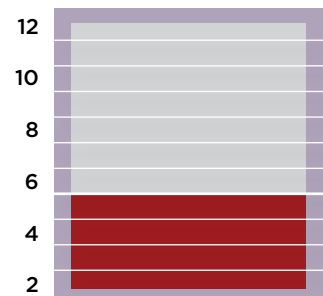
ID RHD XT

- Analyzes 7 polymorphisms determining 6 RHD variants and HPA-1
- 24 tests per kit

Main applications^{1,2}

- Weak D patient subtyping to rationalize the use of D neg blood units
- Weak D pregnant women subtyping to avoid unnecessary RhIG injections
- Confirmation of D neg donors

Blood stocks: O-



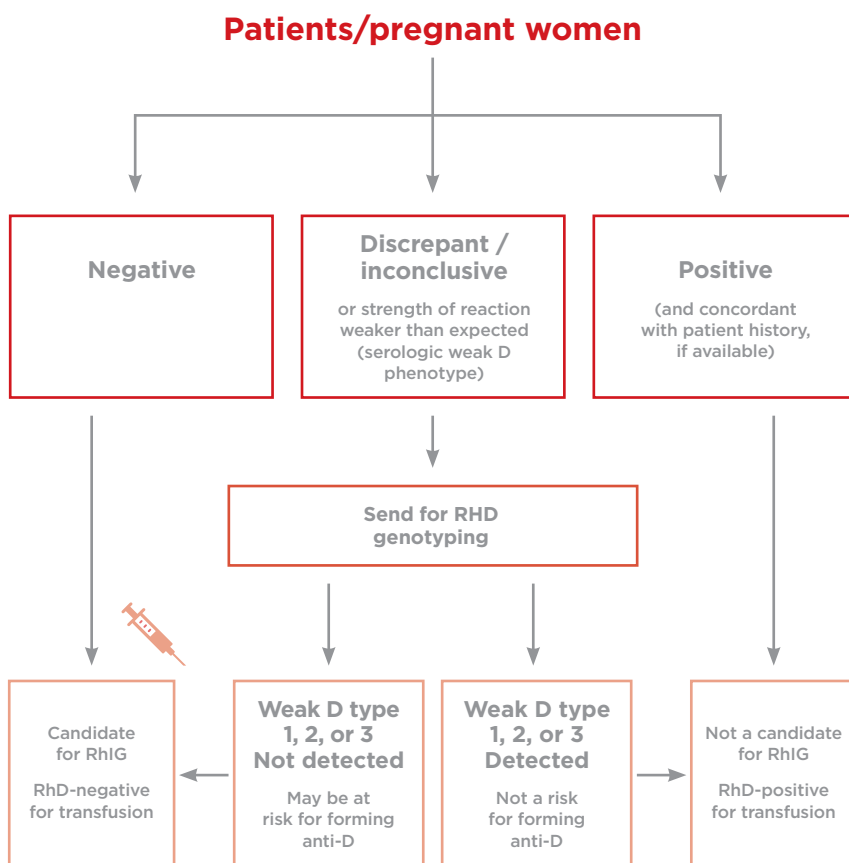
D neg units are scarce

1. Sandler et al. *Transfusion*. 2015 Mar;55(3):680-9.
2. Lopez et al. *Vox Sanguinis*, 2016;111(S1):234

ID RHD XT variant panel

BLOOD GROUP SYSTEM	PREDICTED PHENOTYPE	ALLELES ASSAYED	ISBT NAME
RH	Weak D Type 1	<i>RHD*weak D type 1</i>	RHD*01W.1
RH	Weak D Type 2	<i>RHD*weak D type 2</i>	RHD*01W.2
RH	Weak D Type 3	<i>RHD*weak D type 3</i>	RHD*01W.3
RH	D-	<i>RHD*Pseudogene</i>	RHD*04N.01
RH	D-	<i>RHD*DIlla-CE (3-7)-D</i>	RHD*03N.01
RH	D-	<i>RHD deletion</i>	RHD*01N.01
HPA-1	HPA-1a; HPA-1b	<i>HPA1a; HPA1b</i>	Not applicable

Recommended algorithm for resolving serologic weak D phenotype test results by RHD genotyping to determine candidacy for RhIG and RhD type for transfusions¹.



1. Sandler et al. *Transfusion*. 2015 Mar;55(3):680-9.



ID CORE CONTROL is a positive control for ID CORE XT

- 2 clones tested in ID CORE XT, including testing for all alleles A and B of all polymorphisms
- 25 tests per kit

Main benefits

- Standardization of the system quality control processes
- Practical: already commercially available, the laboratory does not have to produce their own controls
- Allows control of all tested alleles







BLOODchip ID software efficiently handles the genotyping procedure and data

Workflow traceability

- Plate configuration, kit, and enzyme lot registration
- Worksheet print-outs with calculated volumes to pipette

Database and multiple-search function

- Comprehensive database for samples, clinical information, and test results
- Multiple-search function, including phenotypes and genotypes

Clear results

- Friendly and detailed reports
- Results by sample or batch of samples
- Multiple report formats (.xls, .pdf)
- Results are generated automatically, no user intervention for interpretation

Connectivity

- Connection with LIS
- Connection with Luminex

Performance and quality control

- Provides management of positive and negative controls
- Provides performance statistics
- Provides raw data graphs for troubleshooting

Audits

- Registers all actions performed by users

Configurable
Comprehensive
Flexible

BIDS XT results window

Assists the user throughout the analytical procedure. Results are automatically shown on screen following Luminex quantification.

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BIDSXT

Batch #: 2016_11_07_0002
Date: 07/11/2016

DNA Extraction → Amplification → Hybridization → Labeling → Quantification → Results

Test Id: ID_CORE_XT_IgH1_0001
Loca...: A01
Page: 1
Status: Confirmed
Result comments: Confirmed

Test Id: ID_CORE_XT_IgH2_0001
Loca...: B01
Page: 1
Status: Confirmed
Result comments: Confirmed

Test Id: ID_CORE_XT_IgH3_0001
Loca...: C01
Page: 1
Status: Confirmed
Result comments: Confirmed

Test Id: ID_CORE_XT_IgH4_0001
Loca...: D01
Page: 1
Status: Confirmed
Result comments: Confirmed

Test Id: ID_CORE_XT_IgH5_0001
Loca...: E01
Page: 1
Status: Confirmed
Result comments: Confirmed

Test Id: ID_CORE_XT_ICC1_0001
Loca...: F01
Page: 1
Status: Confirmed
Result comments: Confirmed

Test Id: ID_CORE_XT_ICC2_0001
Loca...: G01
Page: 1
Status: Confirmed
Result comments: Confirmed

Test Id: ID_CORE_XT_H2O_H2O_0005
Loca...: H01
Page: 1
Status: Confirmed
Result comments: Confirmed

Test Id: ID_HPA_XT_IgH1_0001
Loca...: A02
Page: 1
Status: Confirmed
Result comments: Confirmed

Test Id: ID_HPA_XT_IgH2_0001
Loca...: B02
Page: 1
Status: Confirmed
Result comments: Confirmed

Test Id: ID_HPA_XT_IgH3_0001
Loca...: C02
Page: 1
Status: Confirmed
Result comments: Confirmed

Test Id: ID_HPA_XT_IgH4_0001
Loca...: D02
Page: 1
Status: Confirmed
Result comments: Confirmed

Test Id: ID_HPA_XT_IgH5_0001
Loca...: E02
Page: 1
Status: Confirmed
Result comments: Confirmed

Test Id: ID_HPA_XT_ICC1_0001
Loca...: F02
Page: 1
Status: Confirmed
Result comments: Confirmed

Test Id: ID_HPA_XT_ICC2_0001
Loca...: G02
Page: 1
Status: Confirmed
Result comments: Confirmed

Test Id: ID_HPA_XT_H2O_H2O_0004
Loca...: H02
Page: 1
Status: Confirmed
Result comments: Confirmed

Test Id: ID_RHD_XT_IgH1_0001
Loca...: A03
Page: 1
Status: Confirmed
Result comments: Confirmed

Test Id: ID_RHD_XT_IgH2_0001
Loca...: B03
Page: 1
Status: Confirmed
Result comments: Confirmed

Test Id: ID_RHD_XT_IgH3_0001
Loca...: C03
Page: 1
Status: Confirmed
Result comments: Confirmed

Product: ID CORE XT
Software version: ID CORE XT ANALYSIS SOFTWARE v3.0.2.7
Test Id: ID_CORE_XT_IgH2_0001 Lot #: 0203000000

Blood Grp: Rh
Antibodies Assayed: RhCEcDe
Genotype Result: RhCEcDe
Antigens (RBT): C (RH2)
Predicted Phenotype Result: +

Antigens (RBT): E (RH3) 0, c (RH4) 0, s (RH5) +, CW (RH8) 0, V (RH10) 0, R1S (RH19) +, VS (RH20) 0

BIDS XT worksheet

Provides printable worksheets, which include plate design, reagent lot numbers, and automatic calculation of volumes to facilitate the process and avoid errors.

Batch #: 2016_11_07_0002

Comments:

AMPLIFICATION

	1	2	3	4	5	6	7	8	9	10	11	12
A	IgH1 ID CORE XT	IgH1 ID HPA XT	IgH1 ID RHD XT									
B	IgH2 ID CORE XT	IgH2 ID HPA XT	IgH2 ID RHD XT									
C	IgH3 ID CORE XT	IgH3 ID HPA XT	IgH3 ID RHD XT									
D	IgH4 ID CORE XT	IgH4 ID HPA XT	IgH4 ID RHD XT									
E	IgH5 ID CORE XT	IgH5 ID HPA XT	IgH5 ID RHD XT									
F	ICC1 ID CORE XT	ICC1 ID HPA XT	ICC1 ID RHD XT									
G	ICC2 ID CORE XT	ICC2 ID HPA XT	ICC2 ID RHD XT									
H	H2O ID CORE XT	H2O ID HPA XT	H2O ID RHD XT									

PRODUCT Kit # Tests #				ID CORE XT 0203000000 8				PRODUCT Kit # Tests #				ID HPA XT 0102000000 8							
REAGENTS				LOT #		Volume (µl)		Check		REAGENTS				LOT #		Volume (µl)		Check	
ID CORE XT PCR Master Mix				0203000006		180.0				ID HPA XT PCR Master Mix				0102000014		180.0			
HotStarTaq DNA Polymerase (5 U/µL)				HEA16-12A		4.0				HotStarTaq DNA Polymerase (5 U/µL)				HEA16-12A		4.0			

BIDS XT search function

Allows performing complex searches in the database, selecting the desired number of antigens.

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Search Advanced search Reported parameters Results

Date: [] - []

Result type: Predicted Phenotype Result

Product: ID CORE XT

1. Group/System: C (RH2)
Result: 0

2. Group/System: E (RH3)
Result: 0

3. Group/System: K (KEL1)
Result: 0

4. Group/System: Fyb (FY2)
Result: 0

5. Group/System: Lub (LU2)
Result: 0

6. Group/System: []
Result: []

7. Group/System: []
Result: []



BLOODchip^{ID}

Reagents and software

REFERENCE	PRODUCT NAME	PRODUCT DESCRIPTION	SIZE
221239	ID CORE XT*	Genetic identification panel for 37 RBC antigens by DNA analysis	48 tests
221238	ID HPA XT*	Genetic identification panel for 12 HPA systems by DNA analysis	48 tests
730001	ID RHD XT*	Genetic identification panel for 6 RHD variants and HPA-1	24 tests
730285	ID CORE CONTROL*	Positive control for ID CORE XT	25 tests
221240	BIDS XT*	BLOODchip ID software XT	1 unit

Equipment

REFERENCE	PRODUCT NAME	PRODUCT DESCRIPTION	SIZE
220973	Luminex 200™ system with xPONENT® software	Luminex 200 system with xPONENT software and PC/flat panel monitor	1 unit

* ID CORE XT, ID HPA XT, ID RHD XT, ID CORE CONTROL, and BIDS XT comply with the Directive 98/79/EC of the European Parliament and of the Council on in vitro diagnostic medical devices. CE mark certification.
ID CORE XT and ID CORE CONTROL are sold in US as IVD (FDA).
BIDS XT is not an in vitro medical device neither in EU nor US.
ID HPA XT and ID RHD XT are sold in the US for research use only. Not for use in diagnostic procedures.
Product registration and availability vary by country. Ask your local Grifols representative for more information.

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