

101.117-12/03 – including *Taq* polymerase
101.117-12u/03u – without *Taq* polymerase

Visit www.caredx.com for
“Instructions for Use” (IFU)

Lot No.: **4R8**

Lot-specific information
Olerup SSP® DRB1*14

Product number: 101.117-12/03 – including *Taq* pol.
101.117-12u/03u – without *Taq* pol.
Lot number: 4R8
Expiry date: 2026-12-01
Number of tests: 12 tests – Product No. 101.117-12/12u
3 tests – Product No. 101.117-03/03u
Number of wells per test: 47+1
Storage - pre-aliquoted primers: dark, between -15°C and -25°C
- PCR Master Mix: between -15°C and -25°C
- Adhesive PCR seals RT

This Product Description is only valid for Lot No. 4R8.

Complete product documentation consists of generic Instructions for Use (IFU), lot specific Product Insert, Worksheet and Certificate.

**CHANGES COMPARED TO THE PREVIOUS OLERUP SSP®
DRB1*14 LOT (6N0)**

- The product documentation has been updated for new alleles of IMGT 3.50.0
- The kit resolution focuses on common and well documented (CWD) alleles¹.

¹As described in section Uniquely Identified Alleles.

The DRB1*14 primer set, specificity and interpretation tables have been updated for the DRB1 alleles reported since the previous *Olerup SSP®* DRB1*14 lot (**Lot No. 6N0**) was made.

The primers of the wells detailed below have been exchanged, added or modified compared to the previous lot (**Lot No. 6N0**).

Well	5'-primer	3'-primer	rationale
11	-	Exchanged	3'-primer added for improved allelic resolution.

¹S. J. Mack, P. Cano, J. A. Hollenbach¹ et al.
Common and well-documented HLA alleles: 2012 update to
the CWD catalogue. Tissue Antigens, 2013, 81, 194–203

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Well **48** contains Negative Control primer pairs, that will amplify the majority of the *Olerup* SSP® HLA Class I, DRB, DQB1, DPB1 and DQA1 amplicons as well as all the amplicons generated by the control primer pairs matching the human growth hormone gene.

HLA-specific PCR product sizes range from 75 to 200 base pairs.
The PCR product generated by the positive control primer pair is 200 base pairs.

Length of PCR product	105	200	105	80	75	80	85
5'-primer¹	164	340	440	45	45	43	36
	5'-CAC ^{3'}	5'-Agg ^{3'}	5'-TTA ^{3'}	5'-Tgg ^{3'}	5'-Tgg ^{3'}	5'-Tgg ^{3'}	5'-TAC ^{3'}
							36
							5'-TAT ^{3'}
3'-primer²	231	2nd I	507	59	58	57	47
	5'-TgC ^{3'}	5'-AAA ^{3'}	5'-TTg ^{3'}	5'-CTC ^{3'}	5'-ggC ^{3'}	5'-CTC ^{3'}	5'-ACA ^{3'}
							48
							5'-gCA ^{3'}
							48
							5'-gCC ^{3'}
							52
							5'-TgT ^{3'}
A*	+	+	+				
B*	+	+	+				
C*	+	+	+				
DRB1				+	+		
DRB3				+	+		
DRB5				+			
DQB1					+		
DPB1						+	
DQA1							+

¹The nucleotide position for HLA class I genes and the codon for HLA class II genes, in the 2nd or 3rd exon, matching the specificity-determining 3'-end of the primer is given. Nucleotide and codon numbering as on the www.ebi.ac.uk/imgt/hla web site. The sequence of the 3 terminal nucleotides of the primer is given.

²The nucleotide position for HLA class I genes and the codon for HLA class II genes, in the 2nd or 3rd exon or the 2nd intron, matching the specificity-determining 3'-end of the primer is given in the anti-sense direction. Nucleotide and codon numbering as on the www.ebi.ac.uk/imgt/hla web site. The sequence of the 3 terminal nucleotides of the primer is given.

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Lot-specific information

PRODUCT DESCRIPTION

DRB1*14 SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for identifying the DRB1*14:01 to DRB1*14:247 alleles.

PLATE LAYOUT

Each test consists of 48 PCR reactions in a 48 well cut PCR plate.

1	2	3	4	5	6	7	8
9	10	11	12	13	14	15	16
17	18	19	20	21	22	23	24
25	26	27	28	29	30	31	32
33	34	35	36	37	38	39	40
41	42	43	44	45	46	47	NC

The 48 well cut PCR plate is marked with 'DRB1*14' in silver/gray ink.

Well No. 1 is marked with the Lot No. '4R8'.

Wells 1 to 47 – DRB1*14 high resolution primers.

Well 48 – Negative Control (NC).

A faint row of numbers is seen between wells 1 and 2 or wells 7 and 8 of the PCR trays. These stem from the manufacture of the trays, and should be disregarded. The PCR plates are covered with a PCR-compatible foil.

Please note: When removing each 48 well PCR plate, make sure that the remaining plates stay covered. Use a scalpel or a similar instrument to carefully cut the foil between the plates.

INTERPRETATION

Due to the sharing of sequence motifs between DRB1 alleles, non-DRB1*14 alleles will be amplified by some primer mixes. For further details see Specificity Table.

UNIQUELY IDENTIFIED ALLELES

All the DRB1*14 alleles, i.e. **DRB1*14:01 to DRB1*14:247**, recognized by the HLA Nomenclature Committee in October 2022^{1,2} will be amplified by the primers in the DRB1*14 subtyping kit³.

The DRB1*14 kit enables separation of the confirmed DRB1*14 alleles as listed in the IMGT/HLA database 3.27.0. An HLA allele is listed as confirmed by IMGT/HLA if it has been sequenced by more than a single laboratory or from multiple sources. Current allele confirmation status for DRB1*14 alleles is listed below.

The DRB1*14 kit also enables identification of many null and alternatively expressed alleles.



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For *In Vitro* Diagnostic Use
MA123 v02 SSP PI Template
Date: January 2023, Rev. No: 00

101.117-12/03 – including *Taq* polymerase
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Lot-specific information

The following DRB1*14 alleles can be distinguished by the different sizes of the HLA-specific PCR product:

Alleles	Primer mix
DRB1*14:01:02-14:01:04, 14:86	26
DRB1*14:26, 14:110	24

¹DRB1 alleles listed on the IMGT/HLA web page 2022-October-12, release 3.50.0, www.ebi.ac.uk/imgt/hla.

²Alleles that have been deleted from or renamed in the official WHO HLA Nomenclature up to and including the last IMGT/HLA database release can be retrieved from web page <http://hla.alleles.org/alleles/deleted.html>.

³The DRB1*14 primer set cannot separate the following alleles. These alleles can be distinguished by the DR low resolution and/or DRB1*03 and DRB1*13 kits:

Alleles

DRB1*14:21, DRB1*03:76, DRB1*03:174N, DRB1*13:178

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Lot-specific information
ALLELE CONFIRMATION STATUS

Allele	Status ¹	Allele	Status ¹	Allele	Status ¹	Allele	Status ¹
DRB1*14:01:01	Confirmed	DRB1*14:32:01	Unconfirmed	DRB1*14:73	Unconfirmed	DRB1*14:123	Confirmed
DRB1*14:01:02	Confirmed	DRB1*14:32:02	Unconfirmed	DRB1*14:74	Confirmed	DRB1*14:124	Unconfirmed
DRB1*14:01:03	Unconfirmed	DRB1*14:32:03	Unconfirmed	DRB1*14:75	Unconfirmed	DRB1*14:125	Unconfirmed
DRB1*14:01:04	Unconfirmed	DRB1*14:33	Confirmed	DRB1*14:76	Confirmed	DRB1*14:126:01	Unconfirmed
DRB1*14:02:01	Confirmed	DRB1*14:34	Unconfirmed	DRB1*14:77	Unconfirmed	DRB1*14:126:02	Unconfirmed
DRB1*14:02:02	Unconfirmed	DRB1*14:35	Confirmed	DRB1*14:78	Unconfirmed	DRB1*14:127:01	Unconfirmed
DRB1*14:02:03	Unconfirmed	DRB1*14:36	Unconfirmed	DRB1*14:79	Unconfirmed	DRB1*14:127:02	Unconfirmed
DRB1*14:03:01	Confirmed	DRB1*14:37	Unconfirmed	DRB1*14:80	Unconfirmed	DRB1*14:128	Unconfirmed
DRB1*14:03:02	Unconfirmed	DRB1*14:38:01	Unconfirmed	DRB1*14:81	Unconfirmed	DRB1*14:129	Confirmed
DRB1*14:04:01	Confirmed	DRB1*14:38:02	Unconfirmed	DRB1*14:82	Confirmed	DRB1*14:130	Unconfirmed
DRB1*14:04:02	Unconfirmed	DRB1*14:39	Unconfirmed	DRB1*14:83	Unconfirmed	DRB1*14:131	Unconfirmed
DRB1*14:04:03	Unconfirmed	DRB1*14:40	Unconfirmed	DRB1*14:84	Confirmed	DRB1*14:132	Unconfirmed
DRB1*14:05:01	Confirmed	DRB1*14:41	Confirmed	DRB1*14:85	Unconfirmed	DRB1*14:133	Unconfirmed
DRB1*14:05:02	Unconfirmed	DRB1*14:42	Confirmed	DRB1*14:86	Unconfirmed	DRB1*14:134	Unconfirmed
DRB1*14:05:03	Unconfirmed	DRB1*14:43	Unconfirmed	DRB1*14:87	Confirmed	DRB1*14:135	Unconfirmed
DRB1*14:05:04	Unconfirmed	DRB1*14:44:01	Unconfirmed	DRB1*14:88	Unconfirmed	DRB1*14:136	Confirmed
DRB1*14:06:01	Confirmed	DRB1*14:44:02	Unconfirmed	DRB1*14:89	Confirmed	DRB1*14:137N	Unconfirmed
DRB1*14:06:02	Confirmed	DRB1*14:44:03	Unconfirmed	DRB1*14:90	Confirmed	DRB1*14:138	Confirmed
DRB1*14:06:03	Unconfirmed	DRB1*14:45	Unconfirmed	DRB1*14:91	Unconfirmed	DRB1*14:139	Unconfirmed
DRB1*14:07:01	Confirmed	DRB1*14:46	Confirmed	DRB1*14:92N	Unconfirmed	DRB1*14:140	Unconfirmed
DRB1*14:07:02	Unconfirmed	DRB1*14:47	Confirmed	DRB1*14:93	Unconfirmed	DRB1*14:141	Confirmed
DRB1*14:08	Confirmed	DRB1*14:48	Confirmed	DRB1*14:94	Confirmed	DRB1*14:142	Unconfirmed
DRB1*14:09	Confirmed	DRB1*14:49	Confirmed	DRB1*14:95	Confirmed	DRB1*14:143	Confirmed
DRB1*14:10	Confirmed	DRB1*14:50	Unconfirmed	DRB1*14:96	Unconfirmed	DRB1*14:144	Unconfirmed
DRB1*14:11	Confirmed	DRB1*14:51	Unconfirmed	DRB1*14:97	Confirmed	DRB1*14:145	Confirmed
DRB1*14:12:01	Confirmed	DRB1*14:52	Confirmed	DRB1*14:98	Unconfirmed	DRB1*14:146	Unconfirmed
DRB1*14:12:02	Unconfirmed	DRB1*14:53	Confirmed	DRB1*14:99	Confirmed	DRB1*14:147	Unconfirmed
DRB1*14:13	Confirmed	DRB1*14:54:01	Confirmed	DRB1*14:100	Unconfirmed	DRB1*14:148	Unconfirmed
DRB1*14:14	Confirmed	DRB1*14:54:02	Unconfirmed	DRB1*14:101	Confirmed	DRB1*14:149	Unconfirmed
DRB1*14:15	Confirmed	DRB1*14:54:03	Unconfirmed	DRB1*14:102	Unconfirmed	DRB1*14:150	Unconfirmed
DRB1*14:16	Confirmed	DRB1*14:54:04	Unconfirmed	DRB1*14:103	Confirmed	DRB1*14:151	Unconfirmed
DRB1*14:17	Confirmed	DRB1*14:54:05	Unconfirmed	DRB1*14:104	Unconfirmed	DRB1*14:152N	Confirmed
DRB1*14:18	Confirmed	DRB1*14:55	Unconfirmed	DRB1*14:105	Unconfirmed	DRB1*14:153	Unconfirmed
DRB1*14:19	Confirmed	DRB1*14:56	Unconfirmed	DRB1*14:106	Confirmed	DRB1*14:154	Unconfirmed
DRB1*14:20	Confirmed	DRB1*14:57	Unconfirmed	DRB1*14:107	Unconfirmed	DRB1*14:155	Unconfirmed
DRB1*14:21	Confirmed	DRB1*14:58	Unconfirmed	DRB1*14:108	Unconfirmed	DRB1*14:156	Unconfirmed
DRB1*14:22	Confirmed	DRB1*14:59	Unconfirmed	DRB1*14:109	Confirmed	DRB1*14:157	Confirmed
DRB1*14:23:01	Confirmed	DRB1*14:60	Unconfirmed	DRB1*14:110	Unconfirmed	DRB1*14:158	Confirmed
DRB1*14:23:02	Unconfirmed	DRB1*14:61	Confirmed	DRB1*14:111	Unconfirmed	DRB1*14:159	Unconfirmed
DRB1*14:23:03	Unconfirmed	DRB1*14:62	Unconfirmed	DRB1*14:112	Unconfirmed	DRB1*14:160	Unconfirmed
DRB1*14:23:04	Confirmed	DRB1*14:63	Unconfirmed	DRB1*14:113	Confirmed	DRB1*14:161	Unconfirmed
DRB1*14:24	Confirmed	DRB1*14:64	Unconfirmed	DRB1*14:114	Unconfirmed	DRB1*14:162	Unconfirmed
DRB1*14:25	Confirmed	DRB1*14:65	Unconfirmed	DRB1*14:115	Unconfirmed	DRB1*14:163	Confirmed
DRB1*14:26	Unconfirmed	DRB1*14:67	Unconfirmed	DRB1*14:116	Unconfirmed	DRB1*14:164	Unconfirmed
DRB1*14:27:01	Unconfirmed	DRB1*14:68:01	Confirmed	DRB1*14:117	Unconfirmed	DRB1*14:165	Unconfirmed
DRB1*14:27:02	Unconfirmed	DRB1*14:68:02	Unconfirmed	DRB1*14:118	Unconfirmed	DRB1*14:166N	Unconfirmed
DRB1*14:28	Unconfirmed	DRB1*14:69	Unconfirmed	DRB1*14:119	Confirmed	DRB1*14:167	Unconfirmed
DRB1*14:29	Confirmed	DRB1*14:70	Confirmed	DRB1*14:120	Unconfirmed	DRB1*14:168	Unconfirmed
DRB1*14:30	Confirmed	DRB1*14:71	Confirmed	DRB1*14:121	Unconfirmed	DRB1*14:169	Unconfirmed
DRB1*14:31	Unconfirmed	DRB1*14:72	Confirmed	DRB1*14:122	Confirmed	DRB1*14:170	Unconfirmed

Allele	Status ¹	Allele	Status ¹
DRB1*14:171	Unconfirmed	DRB1*14:181	Unconfirmed
DRB1*14:172	Unconfirmed	DRB1*14:182	Unconfirmed
DRB1*14:173	Unconfirmed	DRB1*14:183	Unconfirmed
DRB1*14:174	Unconfirmed	DRB1*14:184	Confirmed
DRB1*14:175	Unconfirmed		
DRB1*14:176	Unconfirmed		
DRB1*14:177	Unconfirmed		
DRB1*14:178	Unconfirmed		
DRB1*14:179	Unconfirmed		
DRB1*14:180	Unconfirmed		



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Lot-specific information

¹Allele status “confirmed” or “unconfirmed” as listed on the IMGT/HLA web page 2017-January-20, release 3.27.0, www.ebi.ac.uk/imgt/hla.

RESOLUTION IN HOMO- AND HETEROZYGOTES

Results file with resolution in DRB1*14 homo- and heterozygotes is available upon request.



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For *In Vitro* Diagnostic Use
MA123 v02 SSP PI Template
Date: January 2023, Rev. No: 00

101.117-12/03 – including *Taq* polymerase
101.117-12u/03u – without *Taq* polymerase

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Lot-specific information
SPECIFICITY TABLE

DRB1*14 SSP subtyping

Specificities and sizes of the PCR products of the 47+1 primer mixes used for
DRB1*14 SSP subtyping

Primer Mix	Size of spec. PCR product ¹	Size of contr. band ²	Amplified DRB1*14 alleles ³	Other amplified DRB alleles
1	215 bp	515 bp	*14:01:01-14:01:05, 14:05:01:01-14:05:05, 14:07:01-14:08, 14:14, 14:18, 14:23:01:01-14:23:04, 14:26, 14:32:01-14:32:03, 14:34-14:36, 14:38:01-14:39, 14:42-14:45, 14:54:01:01-14:54:12, 14:56, 14:58-14:60, 14:62, 14:64-14:65, 14:70, 14:72, 14:75, 14:81-14:82, 14:86-14:88, 14:90-14:92N, 14:95-14:97, 14:99-14:101, 14:103, 14:110, 14:112-14:114, 14:117-14:118, 14:122-14:125, 14:127:01-14:127:02, 14:129-14:134, 14:139-14:140, 14:142, 14:147, 14:149-14:151, 14:153-14:155, 14:157-14:158, 14:160-14:163, 14:166N-14:169, 14:172, 14:178, 14:184-14:193, 14:197N, 14:202, 14:204, 14:207-14:208, 14:211, 14:213-14:217, 14:219, 14:225, 14:227-14:228, 14:230, 14:232, 14:234, 14:236-14:238, 14:240, 14:243-14:246	*11:01:03, 11:01:10-11:01:11, 11:04:07, 11:08:03, 11:13:01-11:13:02, 11:17, 11:19:02, 11:42:02, 11:52, 11:89, 11:159, 11:202, 11:266, 11:283, 13:02:02, 13:12:05, 13:26:01, 13:42:02, 13:49:02, 13:60, 13:77, 13:163, 13:181, 13:289N
2	180 bp	430 bp	*14:01:01-14:01:05, 14:07:01-14:08, 14:16, 14:22, 14:25:01-14:26, 14:32:01-14:32:03, 14:34-14:35, 14:38:01-14:39, 14:49, 14:53-14:55, 14:58, 14:60, 14:62, 14:69-14:70, 14:72, 14:74-14:75, 14:82, 14:86-14:88, 14:90, 14:92N, 14:97, 14:99, 14:101, 14:104-14:105, 14:110-14:114, 14:117-14:119, 14:122, 14:124-14:125, 14:128-14:133, 14:137N, 14:139-14:140, 14:142, 14:146-14:147, 14:149-14:151, 14:153, 14:157-14:158, 14:162-14:164, 14:166N, 14:168, 14:171-14:173, 14:178, 14:184-14:186, 14:189-14:193, 14:197N, 14:200, 14:202-14:204, 14:207-14:208, 14:211, 14:213-14:217, 14:219, 14:225, 14:227-14:228, 14:230, 14:232, 14:234-14:238, 14:240, 14:243-14:245	*03:10, 11:31, 11:52, 11:96, 11:148, 11:293, 13:43, 13:45, 13:159, 13:171:01, 13:179, 13:191, 13:197, 13:217



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3	140 bp	430 bp	*14:02:01:01-14:02:09, 14:06:01-14:06:06, 14:09, 14:13, 14:17, 14:19, 14:21, 14:29-14:30, 14:33, 14:46-14:48, 14:51-14:52, 14:80, 14:83, 14:106, 14:108-14:109, 14:121, 14:165, 14:170, 14:176-14:177, 14:179, 14:194-14:195N, 14:198, 14:200, 14:209, 14:212, 14:242	*03:76, 03:126, 03:174N, 03:177, 04:211, 04:230, 13:10, 13:85, 13:120, 13:170, 13:176, 13:178, 13:193, 13:196
4⁴	85 bp	430 bp	*14:02:01:01-14:03:02, 14:06:01-14:06:06, 14:12:01-14:13, 14:18-14:20, 14:24, 14:27:01-14:27:02, 14:29, 14:40-14:41, 14:47-14:49, 14:51, 14:63, 14:67, 14:77-14:78, 14:81, 14:83, 14:85, 14:89, 14:94, 14:98, 14:106, 14:108-14:109, 14:115, 14:135, 14:154, 14:156, 14:159-14:160, 14:165, 14:170, 14:174, 14:176-14:177, 14:181, 14:194-14:195N, 14:198, 14:200, 14:209, 14:212, 14:218, 14:222N-14:223, 14:226, 14:239, 14:242	*03:02:01:01-03:03, 03:27, 03:29, 03:38, 03:53, 03:74, 03:88, 03:90, 03:102-03:103, 03:115, 03:119, 03:131, 03:154, 03:167, 03:176, 03:179, 13:15, 13:19, 13:26:01-13:26:02, 13:53, 13:57, 13:85, 13:104, 13:198, 13:235
5	260 bp	515 bp	*14:02:01:01-14:02:07, 14:02:09-14:03:02, 14:07:01-14:07:03, 14:09, 14:13-14:14, 14:19, 14:22, 14:24-14:25:02, 14:27:01-14:27:02, 14:30, 14:36, 14:40-14:42, 14:44:01-14:44:03, 14:47-14:49, 14:51, 14:53, 14:63, 14:67, 14:69, 14:77, 14:85, 14:89, 14:94, 14:98, 14:102, 14:109, 14:115-14:116, 14:119, 14:134-14:135, 14:144, 14:159, 14:164, 14:174, 14:179, 14:181, 14:194, 14:198, 14:200, 14:208-14:209, 14:218, 14:222N-14:223, 14:226, 14:239, 14:242, 14:244	*03:02:01:01-03:02:06, 03:05:01-03:05:03, 03:09, 03:14, 03:17, 03:27, 03:29, 03:35, 03:38, 03:40-03:41:02, 03:53, 03:74, 03:81, 03:88, 03:90, 03:102-03:103, 03:115, 03:122, 03:130-03:131, 03:154-03:155, 03:167, 03:176, 03:178-03:179, 03:188, 11:01:01:01, 11:01:01:03-11:01:27, 11:01:28 ² , 11:01:29-11:01:47, 11:08:01-11:11:01, 11:11:03-11:12:03, 11:14:01:01-11:15:02, 11:19:01-11:20, 11:23:01-11:24:02, 11:26-11:29:02, 11:31-11:33, 11:37:01-11:37:02, 11:39, 11:45, 11:49:01-11:49:02, 11:51, 11:53, 11:61-11:62:02, 11:64, 11:66:01-11:66:02, 11:68-11:69, 11:72-11:75, 11:79-11:82, 11:87, 11:90-11:91, 11:93-11:97, 11:99-11:101:03, 11:103:01-11:103:02, 11:105-11:112, 11:114, 11:117:01-11:117:02, 11:120-11:122, 11:125-11:126, 11:128, 11:133-11:134, 11:136, 11:140-11:145, 11:147:01-11:147:02, 11:149-11:150, 11:152, 11:154-11:155, 11:157-11:158, 11:162, 11:164, 11:166-11:170, 11:172, 11:175, 11:177-11:178, 11:183-11:186, 11:188, 11:191-11:192, 11:195, 11:197, 11:199, 11:204-11:205, 11:208, 11:212, 11:215, 11:219, 11:222, 11:225-11:226, 11:228, 11:232, 11:234-11:240, 11:243, 11:245, 11:247-11:248Q, 11:250N, 11:252, 11:254, 11:257, 11:259, 11:262-11:263, 11:265-11:266, 11:268-11:269, 11:271-11:275,



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28⁵	170 bp 215 bp	430 bp	*14:11:01:01-14:11:01:02, 14:148 *14:50:01-14:50:02, 14:76, 14:79, 14:93, 14:152N	*08:31, 08:41, 08:63, 08:75, 11:67, 11:193:01-11:193:02, 11:209, 11:229, 11:270, 12:04, 12:49 *03:92, 08:67, 12:22, 12:88



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	190 bp		*14:06:01-14:06:06, 14:12:01-14:12:02, 14:17-14:18, 14:21, 14:29, 14:33, 14:52, 14:59, 14:64, 14:78, 14:80-14:81, 14:83, 14:95, 14:106, 14:108, 14:121, 14:132-14:133, 14:154, 14:165, 14:170, 14:176-14:177, 14:195N, 14:212, 14:246	*03:01:01:01-03:01:41, 03:03, 03:06-03:08, 03:10-03:11:01, 03:11:03-03:13:02, 03:15:01:01-03:16, 03:18-03:20, 03:22-03:24, 03:26, 03:28, 03:32-03:34, 03:36-03:37, 03:39, 03:42, 03:45-03:48, 03:50-03:51, 03:52:02, 03:54-03:56, 03:58-03:62, 03:64-03:73, 03:76-03:80, 03:82-03:87, 03:89, 03:91-03:101, 03:104, 03:106-03:114, 03:116-03:117, 03:119-03:121, 03:124-03:129, 03:132-03:153, 03:156N-03:166, 03:168-03:175, 03:177, 03:180-03:187, 03:189N-03:203, 04:211, 04:230, 11:16:01:01-11:16:01:02, 11:40, 11:58:01, 11:59, 11:83, 11:113, 11:115, 11:182, 11:280, 12:58, 13:01:01:01-13:01:39, 13:06, 13:09-13:10, 13:15, 13:18, 13:20:01:01-13:20:01:03, 13:27:01-13:28:02, 13:32, 13:35, 13:40, 13:42:01-13:43, 13:51, 13:53, 13:59, 13:61:01-13:61:02, 13:69, 13:71, 13:77-13:80, 13:87, 13:91-13:93, 13:98, 13:102, 13:105, 13:110-13:114, 13:117:01:01-13:117:01:02, 13:121, 13:125, 13:127, 13:129-13:131, 13:137N-13:138, 13:141, 13:144, 13:146, 13:148, 13:153, 13:156, 13:160, 13:163, 13:166, 13:173, 13:176-13:178, 13:181, 13:183-13:187, 13:190-13:193, 13:200N-13:201, 13:205, 13:213-13:215, 13:217-13:218, 13:221-13:223, 13:226, 13:233, 13:238, 13:242:01-13:242:02, 13:245, 13:248-13:249N, 13:251-13:252N, 13:254, 13:256, 13:258-13:263, 13:266-13:267, 13:270-13:274, 13:279, 13:281, 13:283, 13:287, 13:291, 13:294, 13:299-13:300, 13:303-13:305, 13:308-13:309, 13:311, 13:313, 13:322N-13:324N, 13:326-13:328, 15:32, 15:192, DRB3*03:10



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31⁴	80 bp	515 bp	*14:35, 14:53, 14:72, 14:128, 14:132, 14:138, 14:186, 14:208	*03:10, 11:31, 11:96, 11:148, 11:293, 12:96, 13:43, 13:45, 13:179, 13:217, 15:187
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33	175 bp	430 bp	*14:01:01-14:01:05, 14:07:01- 14:08, 14:16, 14:22, 14:25:01- 14:26, 14:32:01-14:32:03, 14:34- 14:35, 14:38:01-14:39, 14:49, 14:53-14:55, 14:58, 14:60, 14:62, 14:69-14:70, 14:74-14:75, 14:82, 14:86-14:88, 14:90, 14:92N, 14:97, 14:99, 14:104-14:105, 14:110- 14:114, 14:117-14:119, 14:122, 14:124-14:125, 14:128-14:129, 14:131-14:133, 14:137N, 14:139- 14:140, 14:142, 14:146-14:147, 14:149-14:151, 14:153, 14:157- 14:158, 14:162-14:164, 14:166N, 14:168, 14:171-14:173, 14:184- 14:186, 14:189-14:193, 14:197N, 14:200, 14:202-14:204, 14:207- 14:208, 14:211, 14:213-14:217, 14:219, 14:225, 14:227-14:228, 14:230, 14:232, 14:234-14:238, 14:240, 14:243-14:245	*03:10, 11:293, 13:43, 13:45, 13:159, 13:179, 13:191, 13:217
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39	200 bp	430 bp	*14:01:01-14:01:05, 14:07:01-14:08, 14:14, 14:18, 14:23:01:01-14:23:04, 14:26, 14:32:01-14:32:02, 14:34-14:36, 14:38:01-14:38:02, 14:42, 14:54:01:01-14:54:12, 14:58-14:60, 14:62, 14:64-14:65, 14:70, 14:72, 14:75, 14:81-14:82, 14:86-14:88, 14:90, 14:92N, 14:95, 14:97, 14:99, 14:101, 14:110, 14:112-14:114, 14:117-14:118, 14:122-14:125, 14:129, 14:131-14:134, 14:139, 14:142, 14:147, 14:149-14:151, 14:153-14:155, 14:157-14:158, 14:160, 14:162-14:163, 14:166N, 14:168-14:169, 14:172, 14:178, 14:184-14:186, 14:190-14:193, 14:197N, 14:202, 14:204, 14:207-14:208, 14:211, 14:213-14:217, 14:219, 14:225, 14:227-14:228, 14:230, 14:232, 14:234, 14:236-14:238, 14:240, 14:243-14:246, 14:247?	*11:13:01-11:13:02, 11:17, 11:52, 11:89, 11:159, 11:202, 11:266, 11:283
40	210 bp 250 bp	430 bp	*14:107, 14:152N *14:71	
41⁴	115 bp	515 bp	*14:91, 14:94, 14:97, 14:162, 14:185, 14:221	*03:04:01-03:04:02, 03:26, 03:33, 03:44, 11:29:01-11:29:02, 11:44, 11:47, 11:49:01-11:50, 11:63:01-11:63:02, 11:85, 11:127, 11:165:01-11:165:02, 11:249, 11:273, 11:278, 11:286, 13:60, 13:84, 13:106, 13:216, 13:229, 13:266
	140 bp 165 bp 245 bp		*14:129 *14:90, 14:198 *14:75, 14:103	
42⁵	235 bp	515 bp	*14:01:01, 14:01:02 [?] -14:01:04 [?] , 14:01:05, 14:02:02 [?] -14:02:03 [?] , 14:02:06 [?] , 14:03:02 [?] , 14:04:01:01-14:04:01:03, 14:04:02 [?] -14:04:03 [?] , 14:04:04-14:04:06, 14:04:09-14:05:01:04, 14:05:02 [?] -14:05:04 [?] , 14:05:05, 14:06:02 [?] -14:06:03 [?] , 14:07:01-14:08, 14:10:01:01-14:11:01:02, 14:12:02 [?] , 14:14-14:16, 14:18, 14:22 [?] , 14:23:01:01-14:23:01:03, 14:23:02 [?] -14:23:04 [?] , 14:25:01 [?] -14:41 [?] , 14:43 [?] -14:45 [?] , 14:48 [?] -14:52 [?] , 14:54:01:01-14:54:06, 14:54:08-14:54:12, 14:55 [?] -14:56 [?] , 14:57, 14:58 [?] -14:65 [?] , 14:67 [?] -14:69 [?] , 14:70, 14:71 [?] -14:81 [?] , 14:82, 14:83 [?] -14:110 [?] , 14:111, 14:112 [?] -14:136 [?] , 14:137N, 14:138 [?] -14:140 [?] , 14:141, 14:142 [?] -14:143 [?] , 14:145 [?] -14:151 [?] , 14:152N, 14:153 [?] -14:161 [?] , 14:162, 14:163 [?] -14:170 [?] ,	*08:09:02, 11:03:04, 11:04:17, 11:13:01-11:13:02, 11:17, 11:149, 11:202, 11:264, 13:01:27, 13:02:21, 13:08



101.117-12/03 – including *Taq* polymerase
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Lot No.: **4R8**

Lot-specific information

			14:171, 14:172 [?] -14:176 [?] , 14:178 [?] - 14:190 [?] , 14:191-14:193, 14:196- 14:197N, 14:199, 14:201-14:202, 14:203 [?] , 14:204-14:207, 14:210Q- 14:211, 14:213-14:217, 14:219, 14:220 [?] , 14:222N [?] , 14:224, 14:225 [?] , 14:227-14:228, 14:229 [?] , 14:230- 14:232, 14:234-14:237, 14:239 [?] , 14:240-14:241, 14:243-14:247	
43⁴	65 bp 95 bp 200 bp 225 bp	430 bp	*14:107, 14:111, 14:137N, 14:152N *14:101, 14:178, 14:205:01 *14:82, 14:95, 14:132 *14:188N	*03:01:17, 03:15:02, 03:97, 03:145 *03:01:17, 03:15:02, 03:145
44⁵	215 bp	515 bp	*14:70, 14:83, 14:155	*03:200, 13:328, 15:03:01:01-15:03:05, 15:23, 15:54, 15:57, 15:94, 15:130, 15:137N, 15:142, 15:163N, 15:165, 15:178, 15:185
	280 bp		*14:113	*04:85
45⁴	65 bp	430 bp	*14:98	*08:67, 11:27:01, 11:84:01, 11:124:01, 11:138, 12:22, 12:88, 13:33:02- 13:33:03, 13:61:01, 13:94:02, 13:96:02, 16:46
	190 bp 225 bp		*14:45 *14:127:01	*03:35
46⁴	105 bp 135 bp 165 bp 220 bp	515 bp	*14:92N *14:129, 14:158 *14:88 *14:87, 14:89, 14:197N	*03:153, 13:95 *03:157
47⁴	75 bp 215 bp 275 bp	430 bp	*14:153, 14:184 *14:163, 14:197N *14:114	*03:165
48⁶	-	-	Negative Control	

¹Alleles are assigned by the presence of specific PCR product(s). However, the sizes of the specific PCR products may be helpful in the interpretation of DRB1*14 SSP typings.

When the primers in a primer mix can give rise to HLA-specific PCR products of more than one length this is indicated if the size difference is more than 20 base pairs. Size differences of 20 base pairs or less are not given. For high resolution SSP kits, the alleles listed are specified according to amplicon length.

Nonspecific amplifications, i.e. a ladder or a smear of bands, may sometimes be seen. GC-rich primers have a higher tendency of giving rise to nonspecific amplifications than other primers.

PCR fragments longer than the control bands may sometimes be observed. Such bands should be disregarded and do not influence the interpretation of the SSP typings.

PCR fragments migrating faster than the control bands, but slower than a 400 bp fragment may be seen in some gel read-outs. Such bands can be disregarded and do not influence the interpretation of the SSP typings.

Some primers may give rise to primer oligomer artifacts. Sometimes this phenomenon is an inherent feature of the primer pair(s) of a primer mix. More often it is due to other factors such as too low amount of DNA in the PCR reactions, taking too long time in setting up the PCR reactions, working at elevated room temperature or using thermal cyclers that are not pre-heated.

²The internal positive control primer pairs amplify segments of the human growth hormone gene. The internal positive control bands are 430 or 515 base pairs respectively, well distribution as outlined in the table. Well number 1 contains the longer, 515 bp, internal positive control band. The well distribution of the internal controls can help in orientation of the kit on gel photo, as well as allow for kit identification. In the presence of a specific amplification the intensity of the control band often decreases.

³For several DRB1 alleles 1st and/or 3rd exon(s) and beyond, as well as intron nucleotide sequences, are not available. In these instances it is not known whether some of the primers of the SSP sets are completely matched



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Lot-specific information

with the target sequences or not. Assumption is made that unknown sequences in these regions are conserved within allelic groups.

⁴HLA-specific PCR products shorter than 125 base pairs have a lower intensity and are less sharp than longer PCR products.

⁵Primer mixes 23, 28, 42 and 44 may have tendencies of unspecific amplifications.

⁶Primer mix 48 contains a negative control, which will amplify the majority of HLA amplicons as well as the amplicons generated by the control primer pairs matching the human growth hormone gene. HLA-specific PCR product sizes range from 75 to 200 base pairs and the PCR product generated by the HGH positive control primer pair is 200 base pairs.

Abbreviations

w: might be weakly amplified.

?: nucleotide sequence information not available for the primer matching sequence.

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Lot No.: **4R8**

Lot-specific information

PRIMER SPECIFICATION

Well No.	1	2	3	4	5	6	7	8	9	10	11	12
Length of spec. PCR product	215	180	140	85	260	260	200	170	130	180	85	225
							225		250			
Length of int. pos. control ¹	515	430	430	430	515	515	430	430	430	430	430	515
5'-primer(s) ²	13(125) 5'-gTC 3'	13(125) 5'-gTC 3'	37(196) 5'-AgA 3'	13(125) 5'-gTC 3'	13(125) 5'-gTC 3'	13(125) 5'-gTC 3'	13(125) 5'-gTC 3'	13(125) 5'-ggg 3'	16(135) 5'-CAA 3'	6(103) 5'-CAT 3'	60(265) 5'-AgC 3'	13(125) 5'-gTC 3'
								16(133) 5'-gTT 3'	57(256) 5'-CTA 3'	11(118) 5'-ACC 3'		
										13(125) 5'-ACA 3'		
3'-primer(s) ³	70(296) 5'-TCC 3'	57(257) 5'-CAG 3'	70(295) 5'-CTg 3'	28(171) 5'-CTC 3'	86(344) 5'-CAC 3'	86(344) 5'-CCA 3'	67(286) 5'-gAT 3'	57(257) 5'-CAG 3'	86(344) 5'-CCA 3'	57(257) 5'-CAG 3'	74(308) 5'-CCg 3'	74(308) 5'-CCT 3'
	72(303) 5'-gCg 3'	60(265) 5'-gTg 3'	71(298) 5'-CTT 3'				74(307) 5'-CAG 3'					74(308) 5'-CCT 3'
												74(308) 5'-CCT 3'
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

Well No.	13	14	15	16	17	18	19	20	21	22	23	24
Length of spec. PCR product	115	60	185	105	220	85	145	110	170	145	75	85
		130						160	215		155	125
								215	275			165
Length of int. pos. control ¹	430	515	430	430	430	430	430	430	515	430	430	430
5'-primer(s) ²	34(189) 5'-CAG 3'	37(196) 5'-AgA 3'	37(196) 5'-AgA 3'	57(258) 5'-gAT 3'	13(125) 5'-gTC 3'	13(125) 5'-gTC 3'	37(197) 5'-gTT 3'	16(133) 5'-gTT 3'	13(125) 5'-gTC 3'	13(125) 5'-gTC 3'	13(125) 5'-gTC 3'	13(125) 5'-gTC 3'
		37(196) 5'-AgA 3'	37(197) 5'-gTT 3'	57(258) 5'-gAC 3'				34(189) 5'-CAA 3'				
		60(265) 5'-AgC 3'										
3'-primer(s) ³	60(265) 5'-gTg 3'	67(286) 5'-gAA 3'	85(341) 5'-CAG 3'	78(321) 5'-CAA 3'	69(292) 5'-CTg 3'	28(171) 5'-CTg 3'	71(298) 5'-CTC 3'	57(257) 5'-CAG 3'	57(256) 5'-gCT 3'	47(227) 5'-ggT 3'	24(157) 5'-CAA 3'	25(161) 5'-ACT 3'
					71(298) 5'-CTT 3'	28(171) 5'-CTg 3'	74(307) 5'-CAG 3'	74(307) 5'-CAG 3'	71(298) 5'-CgC 3'		47(227) 5'-ggA 3'	29(172) 5'-TCT 3'
					77(316) 5'-ggC 3'	30(177) 5'-AAA 3'			91(359) 5'-gCg 3'		55(251) 5'-gCT 3'	38(199) 5'-CAG 3'
												45(220) 5'-CCg 3'
												55(250) 5'-CCC 3'
Well No.	13	14	15	16	17	18	19	20	21	22	23	24



101.117-12/03 – including *Taq* polymerase
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Lot No.: **4R8**

Lot-specific information

Well No.	25	26	27	28	29	30	31	32	33	34	35	36
Length of spec.	85	125	165	170	115	160	80	100	175	205	250	120
PCR product	120	250	220	215	130	190		150			280	155
	210				180							
	250				220							
Length of int.	430	515	515	430	515	430	515	430	430	515	430	515
pos. control ¹												
5'-primer(s) ²	16(135) 5'-CAA 3'	51(239) 5'-gAg 3'	10(116) 5'-gCT 3'	16(133) 5'-gTT 3'	13(125) 5'-gTC 3'	37(196) 5'-AgA 3'	47(227) 5'-gTT 3'	37(196) 5'-AgA 3'	13(125) 5'-gTC 3'	16(133) 5'-gTT 3'	6(103) 5'-CAA 3'	37(196) 5'-AgA 3'
	60(265) 5'-AgC 3'	112(421) 5'-ACT 3'									16(133) 5'-gTT 3'	
3'-primer(s) ³	73(304) 5'-ggA 3'	78(321) 5'-CAA 3'	51(239) 5'-CCC 3'	58(260) 5'-CCT 3'	38(200) 5'-gCg 3'	77(317) 5'-AAT 3'	60(265) 5'-gTg 3'	57(256) 5'-gCT 3'	58(260) 5'-CCg 3'	70(296) 5'-TCC 3'	86(344) 5'-CCA 3'	60(266) 5'-Agg 3'
	74(308) 5'-CCA 3'	181(630) 5'-CTT 3'	70(295) 5'-CTg 3'	72(301) 5'-CCg 3'	43(214) 5'-gTA 3'	86(344) 5'-CCA 3'		71(298) 5'-CTT 3'				67(286) 5'-gAT 3'
	86(344) 5'-CAC 3'			77(317) 5'-AgT 3'	45(220) 5'-CCT 3'			77(317) 5'-AAT 3'				67(286) 5'-gAT 3'
				77(318) 5'-TAA 3'	57(257) 5'-CgA 3'							67(286) 5'-gAA 3'
					60(267) 5'-CAC 3'							74(308) 5'-CCT 3'
					72(301) 5'-CCg 3'							
					73(305) 5'-ggC 3'							
Well No.	25	26	27	28	29	30	31	32	33	34	35	36

Well No.	37	38	39	40	41	42	43	44	45	46	47
Length of spec.	90	165	200	210	115	235	65	215	65	105	75
PCR product	175	215		250	140		95	280	190	135	215
					165		200		225	165	275
					245		225			220	
Length of int.	430	515	430	430	515	515	430	515	430	515	430
pos. control ¹											
5'-primer(s) ²	13(125) 5'-gTC 3'	16(135) 5'-CAA 3'	16(135) 5'-CAT 3'	16(133) 5'-gTT 3'	13(125) 5'-gTC 3'	114(429) 5'-CTg 3'	16(135) 5'-TAA 3'	6(103) 5'-CAA 3'	16(135) 5'-CAA 3'	13(125) 5'-gTC 3'	13(125) 5'-gTC 3'
							26(164) 5'-gTA 3'	27(166) 5'-TCA 3'	70(295) 5'-AAG 3'		
							60(265) 5'-AgT 3'	30(175) 5'-gAC 3'			
							71(299) 5'-gAA 3'				
3'-primer(s) ³	29(172) 5'-TCT 3'	58(261) 5'-TCA 3'	70(296) 5'-TCC 3'	72(301) 5'-CCg 3'	37(197) 5'-Cgg 3'	179(624) 5'-ACg 3'	78(321) 5'-CAA 3'	86(344) 5'-CCA 3'	67(286) 5'-gAT 3'	35(190) 5'-CTA 3'	24(157) 5'-CAA 3'
	58(260) 5'-CCT 3'	74(308) 5'-CCg 3'		73(305) 5'-ggC 3'	38(200) 5'-gCg 3'				77(317) 5'-AAT 3'	43(214) 5'-gTA 3'	69(292) 5'-CTg 3'
	58(260) 5'-CCT 3'			86(343) 5'-CAT 3'	46(224) 5'-ACC 3'					46(224) 5'-ACC 3'	74(307) 5'-CTA 3'
	58(260) 5'-CCT 3'				55(250) 5'-CCC 3'					55(251) 5'-gCT 3'	91(359) 5'-gCg 3'
					81(328) 5'-gTA 3'					70(295) 5'-CTg 3'	
										74(307) 5'-CTA 3'	
										75(310) 5'-CAT 3'	
Well No.	37	38	39	40	41	42	43	44	45	46	47



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Lot-specific information

¹The internal positive control primer pairs amplify segments of the human growth hormone gene. The internal positive control bands are 430 or 515 base pairs respectively, well distribution as outlined in the table. Well number 1 contains the longer, 515 bp, internal positive control band. The well distribution of the internal controls can help in orientation of the kit on gel photo, as well as allow for kit identification. In the presence of a specific amplification the intensity of the control band often decreases.

²The nucleotide position matching the specificity-determining 3'-end of the primer is given. Nucleotide numbering as on the www.ebi.ac.uk/imgt/hla web site. The sequence of the 3 terminal nucleotides of the primer is given.

³The nucleotide position matching the specificity-determining 3'-end of the primer is given in the anti-sense direction. Nucleotide numbering as on the www.ebi.ac.uk/imgt/hla web site. The sequence of the 3 terminal nucleotides of the primer is given.



0197

For *In Vitro* Diagnostic Use
MA123 v02 SSP PI Template
Date: January 2023, Rev. No: 00

101.117-12/03 – including *Taq* polymerase
101.117-12u/03u – without *Taq* polymerase

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Lot No.: 4R8

Lot-specific information

[illegible]

0197

For *In Vitro* Diagnostic Use
MA123 v02 SSP PI Template
Date: January 2023, Rev. No: 00

101.117-12/03 – including *Taq* polymerase
101.117-12u/03u – without *Taq* polymerase

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Lot No.: **4R8**

Lot-specific information

CELL LINE VALIDATION SHEET																																					
DRB1*14 SSP subtyping kit ²																																					
					Well ³																																
					Prod. No.:	202246017	202246018	202246019	202246020	202246021	202246022	202246023	202246024	202246025	202246026	202246027	202246028	202246029	202246030	202246031	202246032																
	IHCW cell line ¹			DRB1																																	
1	9001	SA	*01:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
2	9280	LK707	*15:02	*04:05		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
3	9011	E4181324	*15:02			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
4	9275	GU373	*03:01			-	+	-	-	-	-	+	-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-	-	-	-		
5	9009	KAS011	*16:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
6	9353	SM	*04:07	*08:03		-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
7	9020	QBL	*03:01			-	+	-	-	-	-	+	-	-	-	+	-	-	-	+	-	-	-	+	-	-	-	+	-	-	+	-	-	-	-		
8	9025	DEU	*04:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
9	9026	YAR	*04:02			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
10	9107	LKT3	*04:05			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
11	9051	PITOUT	*07:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
12	9052	DBB	*07:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
13	9004	JESTHOM	*01:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
14	9071	OLGA	*08:02			-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
15	9075	DKB	*09:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
16	9037	SWEIG007	*11:01			-	+	-	-	-	-	+	-	-	-	+	-	-	-	+	-	-	-	+	-	-	-	+	-	-	-	-	-	-	-		
17	9282	CTM3953540	*03:01	*13:01		-	+	-	-	-	-	+	-	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-	+	-	-	-	-	-		
18	9257	32367	*09:01	*11:01		-	+	-	-	-	-	+	-	-	-	+	-	-	-	+	-	-	-	-	-	+	-	-	-	-	-	-	-	-	-		
19	9038	BM16	*12:01			-	-	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-	-	-		
20	9059	SLE005	*13:02			-	+	-	-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
21	9064	AMALA	*14:02			-	-	-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
22	9056	KOSE	*13:02	*14:54		-	+	-	-	-	+	+	-	-	-	+	-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
23	9124	IHL	*08:03	*14:14		-	+	-	+	-	+	-	-	-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
24	9035	JBUSH	*11:01			-	+	-	-	-	-	+	-	-	-	+	-	-	+	-	-	-	-	-	+	-	-	-	-	-	-	-	-	-	-		
25	9049	IBW9	*07:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
26	9285	WT49	*03:01			-	+	-	-	-	-	+	-	-	-	+	-	-	+	-	-	+	-	-	+	-	-	+	-	-	+	-	-	-	-		
27	9191	CH1007	*04:05	*10:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
28	9320	BEL5GB	*04:16	*07:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
29	9050	MOU	*07:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
30	9021	RSH	*03:02			-	-	-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
31	9019	DUCAF	*03:01			-	+	-	-	-	-	+	-	-	-	+	-	-	-	+	-	-	+	-	-	+	-	-	+	-	-	-	-	-	-		
32	9297	HAG	*13:03			+	+	-	-	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
33	9098	MT14B	*04:04			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
34	9104	DHIF	*11:01			-	+	-	-	-	-	+	-	-	-	+	-	-	+	-	-	-	-	-	+	-	-	-	-	-	-	-	-	-	-		
35	9302	SSTO	*04:03			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
36	9024	KT17	*04:03	*04:06		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
37	9065	HHKB	*13:01			-	+	-	-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-		
38	9099	LZL	*14:02			-	-	-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
39	9315	CML	*03:01	*04:01		-	+	-	-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-		
40	9134	WHONP199	*07:01	*09:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
41	9055	H0301	*13:02			-	+	-	-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
42	9066	TAB089	*08:03			-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
43	9076	T7526	*09:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
44	9057	TEM	*14:01			-	+	-	-	-	+	-	-	-	+	-	-	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
45	9239	SHJO	*07:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
46	9013	SCHU	*15:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
47	9045	TUBO	*11:04	*12:01		-	+	-	-	-	-	+	-	-	-	+	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
48	9303	TER-ND	*01:03			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		

101.117-12/03 – including *Taq* polymerase
101.117-12u/03u – without *Taq* polymerase

Visit www.caredx.com for
“Instructions for Use” (IFU)

Lot No.: 4R8

Lot-specific information

[illegible]

For *In Vitro* Diagnostic Use
MA123 v02 SSP PI Template
Date: January 2023, Rev. No: 00

101.117-12/03 – including *Taq* polymerase
101.117-12u/03u – without *Taq* polymerase

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Lot No.: **4R8**

Lot-specific information

¹The provided cell line HLA specificities are retrieved from the <http://www.ihwg.org/hla> web site. The specificity of an individual cell line may thus be subject to change.

²The specificity of each primer solution in the kit has been tested against 48 well characterized cell line DNAs and where applicable, additional cell line DNAs.

³Primer mix 27 will amplify the DRB3*02:02 alleles in the GU373, QBL, SWEIG007, CH1007, DUCAF, DHIF, TEM and TUBO cell lines.

No DNAs carrying the alleles to be amplified by primer solutions 10, 11, 14, 15, 19, 24, 29, 31, 40, 43 and 45 to 47 were available. The specificities of the primers in primer solutions 10, 11, 14, 15, 19, 24, 29, 31, 43 and 45 were tested by separately adding one or two additional 5'-primers, and one or two additional 3'-primers accordingly. In primer solutions 40, 46 and 47 it was only possible to test the 5'-primer, the 3'-primers were not possible to be tested. In primer solutions 10, 14, 35, 43 and 44 one or two of the 5'-primers were not possible to be test, and in primer solutions 7, 17, 18, 21 to 25, 28, 29, 36, 37, 41 and 45 one or more of the 3'-primers were not possible to be tested. In addition, one or more 5'- and/or 3'-primers in primer solutions 1, 12, 16, 21, 25 to 28, 30, 32, 36, 38 and 41 were tested by separately adding one or two 3'-primers and/or one 5'-primer respectively.



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101.117-12/03 – including *Taq* polymerase
101.117-12u/03u – without *Taq* polymerase

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“Instructions for Use” (IFU)

Lot No.: **4R8**

Lot-specific information

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