

101.128-12 – including *Taq* polymerase
101.128-12u – without *Taq* polymerase

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

Lot No.: 1R1

Lot-specific information

Olerup SSP[®] DRB1*12

Product number:	101.128-12 – including <i>Taq</i> polymerase 101.128-12u – without <i>Taq</i> polymerase
Lot number:	1R1
Expiry date:	2026-09-01
Number of tests:	12
Number of wells per test:	23+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. 1R1.

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*12 LOT (5L4)

- The product documentation has been updated for new alleles of IMGT 3.49.0.
- The kit resolution focuses on common and well documented (CWD) alleles¹.

¹As described in section Uniquely Identified Alleles.

The DRB1*12 specificity and interpretation tables have been updated for the DRB1 alleles described since the previous *Olerup SSP[®]* DRB1*12 lot was made (**Lot No. 5L4**).

The DRB1*12 primer set is unchanged compared to the previous *Olerup SSP[®]* DRB1*12 (**Lot No. 5L4**).

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



0197

For *In Vitro* Diagnostic Use
MA123 v02 SSP PI Template
Date: September 2022, Rev. No: 00

101.128-12 – including *Taq* polymerase

101.128-12u – without *Taq* polymerase

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

Lot No.: 1R1

Lot-specific information

Well **24** contains Negative Control primer pairs, that will amplify a majority of *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'-CAC3'	5'-Agg3'	5'-TTA3'	5'-Tgg3'	5'-Tgg3'	5'-Tgg3'	5'-TAC3'
							36
							5'-TAT3'
3'-primer²	231	2nd I	507	59	58	57	47
	5'-TgC3'	5'-AAA3'	5'-TTg3'	5'-CTC3'	5'-ggC3'	5'-CTC3'	5'-ACA3'
							48
							5'-gCA3'
							48
							5'-gCC3'
							52
							5'-TgT3'
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.



0197

For *In Vitro* Diagnostic Use
MA123 v02 SSP PI Template
Date: September 2022, Rev. No: 00

101.128-12 – including *Taq* polymerase
101.128-12u – without *Taq* polymerase

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

Lot No.: **1R1**

Lot-specific information

PRODUCT DESCRIPTION

DRB1*12 SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for identifying the DRB1*12:01 to DRB1*12:98N alleles.

PLATE LAYOUT

Each test consists of 24 PCR reactions in a 24 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	NC

The 24 well cut PCR plate is marked with 'DRB1*12' in silver/gray ink.

Well No. 1 is marked with the Lot No. '1R1'.

Wells 1 to 23 – DRB1*12 high resolution primers.

Well 24 – 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 24 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*12 alleles will be amplified by some primer mixes. For further details see Specificity Table.

UNIQUELY IDENTIFIED ALLELES

All the phenotypically different DRB1*12 alleles, i.e. **DRB1*12:01 to DRB1*12:98N**, recognized by the HLA Nomenclature Committee in July 2022^{1,2} will be amplified by the primers in the DRB1*12 subtyping kit.

The DRB1*12 kit enables separation of the confirmed DRB1*12 alleles as listed in the IMGT/HLA database 3.32.0. 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*12 alleles is listed below.

The DRB1*12 kit also enables identification of many null and alternatively expressed alleles.



0197

For *In Vitro* Diagnostic Use
MA123 v02 SSP PI Template
Date: September 2022, Rev. No: 00

101.128-12 – including *Taq* polymerase
101.128-12u – without *Taq* polymerase

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

Lot No.: **1R1**

Lot-specific information

¹DRB alleles listed on the IMGT/HLA web page 2022-July-12, release 3.49.0, 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>.

ALLELE CONFIRMATION STATUS

Allele	Status ¹	Allele	Status ¹	Allele	Status ¹	Allele	Status ¹
DRB1*12:01:01:01	Confirmed	DRB1*12:08	Confirmed	DRB1*12:36	Unconfirmed	DRB1*12:66	Unconfirmed
DRB1*12:01:01:02	Unconfirmed	DRB1*12:09	Unconfirmed	DRB1*12:37	Unconfirmed	DRB1*12:67	Unconfirmed
DRB1*12:01:01:03	Unconfirmed	DRB1*12:10	Unconfirmed	DRB1*12:38	Unconfirmed	DRB1*12:68	Unconfirmed
DRB1*12:01:01:04	Unconfirmed	DRB1*12:11	Confirmed	DRB1*12:39	Unconfirmed	DRB1*12:69	Unconfirmed
DRB1*12:01:01:05	Unconfirmed	DRB1*12:12	Unconfirmed	DRB1*12:40	Unconfirmed		
DRB1*12:01:01:06	Unconfirmed	DRB1*12:13	Unconfirmed	DRB1*12:41	Unconfirmed		
DRB1*12:01:02	Unconfirmed	DRB1*12:14	Unconfirmed	DRB1*12:42	Unconfirmed		
DRB1*12:01:03	Unconfirmed	DRB1*12:15	Unconfirmed	DRB1*12:43	Unconfirmed		
DRB1*12:01:04	Confirmed	DRB1*12:16:01	Unconfirmed	DRB1*12:44	Unconfirmed		
DRB1*12:01:05	Unconfirmed	DRB1*12:16:02	Unconfirmed	DRB1*12:45	Confirmed		
DRB1*12:01:06	Unconfirmed	DRB1*12:16:03	Unconfirmed	DRB1*12:46	Unconfirmed		
DRB1*12:01:07	Unconfirmed	DRB1*12:17	Unconfirmed	DRB1*12:47	Unconfirmed		
DRB1*12:01:08	Unconfirmed	DRB1*12:18	Unconfirmed	DRB1*12:48	Confirmed		
DRB1*12:01:09	Unconfirmed	DRB1*12:19	Unconfirmed	DRB1*12:49	Unconfirmed		
DRB1*12:02:01:01	Confirmed	DRB1*12:20	Confirmed	DRB1*12:50	Unconfirmed		
DRB1*12:02:01:02	Unconfirmed	DRB1*12:21	Unconfirmed	DRB1*12:51	Unconfirmed		
DRB1*12:02:01:03	Unconfirmed	DRB1*12:22	Unconfirmed	DRB1*12:52	Unconfirmed		
DRB1*12:02:01:04	Unconfirmed	DRB1*12:23	Unconfirmed	DRB1*12:53	Unconfirmed		
DRB1*12:02:02	Confirmed	DRB1*12:24N	Confirmed	DRB1*12:54	Unconfirmed		
DRB1*12:02:03	Unconfirmed	DRB1*12:25	Unconfirmed	DRB1*12:55	Unconfirmed		
DRB1*12:02:04	Unconfirmed	DRB1*12:26	Unconfirmed	DRB1*12:56	Unconfirmed		
DRB1*12:02:05	Unconfirmed	DRB1*12:27	Confirmed	DRB1*12:57	Unconfirmed		
DRB1*12:02:06	Unconfirmed	DRB1*12:28	Unconfirmed	DRB1*12:58	Unconfirmed		
DRB1*12:02:07	Unconfirmed	DRB1*12:29	Unconfirmed	DRB1*12:59	Unconfirmed		
DRB1*12:03:02	Confirmed	DRB1*12:30	Unconfirmed	DRB1*12:60N	Unconfirmed		
DRB1*12:03:03	Unconfirmed	DRB1*12:31N	Unconfirmed	DRB1*12:61	Unconfirmed		
DRB1*12:04	Confirmed	DRB1*12:32	Unconfirmed	DRB1*12:62	Unconfirmed		
DRB1*12:05	Unconfirmed	DRB1*12:33	Unconfirmed	DRB1*12:63	Unconfirmed		
DRB1*12:06	Unconfirmed	DRB1*12:34	Unconfirmed	DRB1*12:64	Unconfirmed		
DRB1*12:07	Unconfirmed	DRB1*12:35	Unconfirmed	DRB1*12:65	Unconfirmed		

¹Allele status “confirmed” or “unconfirmed” as listed on the IMGT/HLA web page 2018-April-16, release 3.32.0, www.ebi.ac.uk/imgt/hla.

RESOLUTION IN HOMO- AND HETEROZYGOTES

Results file with resolution in DRB1*12 homo- and heterozygotes is available upon request.



0197

For *In Vitro* Diagnostic Use
MA123 v02 SSP PI Template
Date: September 2022, Rev. No: 00

101.128-12 – including *Taq* polymerase
101.128-12u – without *Taq* polymerase

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

Lot No.: **1R1**

Lot-specific information

SPECIFICITY TABLE

DRB1*12 SSP subtyping

Specificities and sizes of the PCR products of the 23+1 primer mixes used for
DRB1*12 SSP subtyping

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified DRB1*12 alleles ³	Other amplified DRB1 alleles
1	135 bp	515 bp	*12:01:01:01-12:20, 12:22-12:37, 12:39:01-12:41, 12:43-12:52, 12:54-12:56, 12:58-12:75, 12:77-12:82, 12:84-12:98N	*03:92, 08:17, 08:28, 08:37, 08:45:01-08:45:02, 08:63, 08:103, 08:113, 11:67, 11:193:01-11:193:02, 11:209, 11:229, 11:270, 13:17, 13:175, 13:214, 14:138, 14:175
2	215 bp	430 bp	*12:01:01:01-12:21, 12:23-12:41, 12:44-12:56, 12:58-12:65, 12:67-12:82, 12:84-12:87, 12:89-12:98N	*08:05, 08:18, 08:24:01-08:25, 08:31, 08:40-08:41, 08:47, 08:92, 08:102, 11:193:01-11:193:02, 11:209, 11:229, 11:270, 13:17, 13:116, 13:175, 13:214, 14:31, 14:52
3	165 bp	430 bp	*12:09, 12:48, 12:62	*03:92, 08:02:01:01-08:02:04, 08:04:01:01-08:04:05, 08:04:07, 08:09:01-08:09:02, 08:13, 08:21, 08:24:01-08:24:02, 08:28, 08:30:01, 08:30:03, 08:42, 08:44-08:45:02, 08:59, 08:67, 08:72-08:73, 08:81-08:85, 08:89N, 08:94, 08:98-08:99, 08:101, 08:103, 08:106, 13:17, 13:116, 13:175, 13:214, 14:15, 14:52, 14:126:01, 14:175
4⁴	105 bp	430 bp	*12:01:01:01-12:04, 12:06-12:13, 12:16:01-12:37, 12:39:01-12:41, 12:43-12:55, 12:59-12:82, 12:84-12:98N	*08:32, 08:53, 08:87
5	170 bp	515 bp	*12:01:01:01-12:03:03, 12:05-12:08, 12:10-12:17, 12:19:01-12:32, 12:34-12:41, 12:43-12:45, 12:50-12:56, 12:58-12:61, 12:63-12:75, 12:77-12:82, 12:84-12:95, 12:97-12:98N	*08:19, 08:25, 08:34, 08:52, 08:113
6	250 bp	430 bp	*12:01:01:01-12:02:12, 12:04-12:15, 12:17-12:18, 12:20-12:21, 12:23-12:38, 12:40-12:41, 12:43-12:56, 12:58-12:82, 12:84-12:98N	*08:12, 08:22, 14:28
7	225 bp	430 bp	*12:01:01:01-12:02:12, 12:04-12:07, 12:09-12:12,	



0197

For *In Vitro* Diagnostic Use
MA123 v02 SSP PI Template
Date: September 2022, Rev. No: 00

101.128-12 – including *Taq* polymerase
101.128-12u – without *Taq* polymerase

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

Lot No.: **1R1**

Lot-specific information

			12:13 ^w , 12:14-12:15, 12:17-12:18, 12:20-12:21, 12:24N-12:26, 12:28-12:36, 12:38, 12:40-12:56, 12:58-12:59, 12:61-12:63, 12:66-12:98N	
8	195 bp	430 bp	*12:01:01:01-12:01:11, 12:03:02-12:06, 12:08-12:11, 12:14, 12:17, 12:22, 12:24N-12:25, 12:28-12:30, 12:34-12:36, 12:38-12:41, 12:46-12:48, 12:53-12:54, 12:58-12:59, 12:63, 12:68, 12:70, 12:72N, 12:77, 12:79, 12:82, 12:84, 12:86N-12:91, 12:95	*08:03:02:01-08:03:13, 08:10, 08:12, 08:15, 08:18-08:19, 08:23, 08:25, 08:27, 08:29-08:30:03, 08:32-08:38, 08:40, 08:45:01-08:47, 08:49, 08:51, 08:53, 08:56, 08:58, 08:60N-08:63, 08:65-08:66, 08:68:01-08:69, 08:71, 08:74, 08:76, 08:91, 08:95, 08:97, 08:104, 08:110
9	165 bp	430 bp	*12:01:01:01-12:01:01:11, 12:01:04-12:02:01:08, 12:02:03-12:02:12, 12:03:03-12:04, 12:06-12:13, 12:16:02, 12:17-12:19:01, 12:20-12:21, 12:23-12:37, 12:39:01, 12:40-12:42, 12:44-12:54, 12:59-12:61, 12:63-12:65, 12:67-12:72N, 12:74N-12:80, 12:82-12:87, 12:89-12:98N	
10	195 bp	430 bp	*12:02:01:01-12:02:12, 12:13, 12:15-12:16:03, 12:18-12:21, 12:23, 12:26-12:27, 12:31N-12:33, 12:37, 12:43-12:45, 12:49-12:52, 12:55-12:56, 12:60N-12:61, 12:64-12:65, 12:67, 12:69, 12:71, 12:74N-12:76, 12:78, 12:80-12:81, 12:85, 12:92-12:94, 12:97-12:98N	*08:01:01:01-08:01:02, 08:01:04-08:01:05, 08:01:07-08:02:04, 08:04:01:01-08:09:02, 08:11:01:01-08:11:01:02, 08:16-08:17, 08:21-08:22, 08:24:01-08:24:02, 08:26, 08:28, 08:31, 08:39, 08:41-08:44, 08:50, 08:52, 08:54-08:55, 08:59, 08:64, 08:67, 08:70, 08:72-08:73, 08:75, 08:77-08:79, 08:82-08:90, 08:93-08:94, 08:96, 08:98-08:101, 08:103, 08:105-08:109, 08:111-08:114, 11:67, 11:193:01-11:193:02, 11:209, 14:15, 14:73
11	250 bp	430 bp	*12:03:02-12:03:03, 12:19:01-12:19:02	*03:92, 08:04:01:01-08:04:01:04, 08:04:02 ^w -08:04:03 ^w , 08:04:04-08:04:07, 08:06:01:01-08:06:01:02, 08:10, 08:28, 08:31, 08:54, 08:59, 08:67, 08:70, 08:75, 08:83, 08:94, 08:98-08:99, 11:67, 11:209, 11:229, 11:270, 13:17, 13:116, 13:175, 13:214, 14:04:01:01-14:04:09, 14:11:01:01-14:11:01:02, 14:15, 14:31, 14:50:01-14:50:02, 14:52, 14:73, 14:76, 14:79, 14:107, 14:120, 14:126:01-14:126:02, 14:138, 14:145, 14:148, 14:152N,



0197

For *In Vitro* Diagnostic Use
MA123 v02 SSP PI Template
Date: September 2022, Rev. No: 00

101.128-12 – including *Taq* polymerase

101.128-12u – without *Taq* polymerase

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

Lot No.: **1R1**

Lot-specific information

				14:175, 14:180, 14:196, 14:201, 14:205:01-14:206, 14:210Q, 14:220, 14:224, 14:229, 14:233, 14:241
12⁵	170 bp	430 bp	*12:04, 12:49	*08:31, 08:41, 08:63, 08:75, 11:67, 11:193:01-11:193:02, 11:209, 11:229, 11:270, 14:11:01:01-14:11:01:02, 14:148
13⁴	115 bp 185 bp 255 bp	515 bp	*12:24N-12:25 *12:05, 12:14-12:15, 12:56 *12:20	
14	135 bp	515 bp	*12:06	*03:124 ^w , 04:05:22 ^w , 15:01:01:01 ^w -15:01:16 ^w , 15:01:18 ^w -15:01:37 ^w , 15:01:39 ^w , 15:01:41 ^w -15:03:02 ^w , 15:03:04 ^w - 15:209N ^w , 16:01:01:01 ^w - 16:05:02 ^w , 16:07 ^w -16:53 ^w , 16:55N ^w -16:73 ^w , DRB3*02:02:24
15	170 bp 200 bp	515 bp	*12:18, 12:47 *12:07	
16⁴	80 bp	430 bp	*12:08, 12:23, 12:27	*08:53, 08:87, 11:76, 11:114, 11:183, 11:196, 11:302, 13:34, 13:64, 13:136, 13:174, 13:204, 13:221, 13:250, 14:41, 14:77, 14:110, 14:218, 15:102, DRB3*01:36, DRB3*02:37, DRB3*02:83, DRB3*02:112, DRB3*03:12
	115 bp		*12:31N	
17^{4,6}	80 bp 110 bp 225 bp	430 bp	*12:10 *12:25, 12:48 *12:60N	*01:26, 13:163 DRB5*02:07
18^{4,6}	85 bp 135 bp	515 bp	*12:26, 12:28 *12:11	
19⁴	75 bp 115 bp 195 bp	430 bp	*12:28 *12:45 *12:12, 12:62	*08:13, 08:48
20	175 bp 220 bp	430 bp	*12:13, 12:23 *12:57	
21⁴	110 bp	430 bp	*12:01:01:01-12:02:06, 12:02:08-12:13, 12:15-12:28, 12:30-12:35, 12:37, 12:39:01-12:41, 12:43-12:44, 12:46-12:50, 12:53-12:55, 12:59-12:62, 12:64-12:82, 12:84-12:98N	*08:32, 08:53, 08:87
22⁴	105 bp 220 bp	430 bp	*12:21, 12:38, 12:53, 12:76 *12:16:01-12:16:03, 12:22, 12:39:01-12:39:02	*08:32 *08:32, 13:145
23⁴	120 bp	430 bp	*12:17	*01:01:01:01-01:01:38, 01:01:40- 01:125, 01:127-01:136
24⁷	-	-	Negative Control	



0197

For *In Vitro* Diagnostic Use

MA123 v02 SSP PI Template

Date: September 2022, Rev. No: 00

101.128-12 – including *Taq* polymerase
101.128-12u – without *Taq* polymerase

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

Lot No.: 1R1

Lot-specific information

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*12 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 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 mix 12 has a tendency to giving rise to primer oligomer formation.

⁶Primer mixes 17 and 18 may have tendencies of unspecific amplifications.

⁷Primer mix 24 contains a negative control which will amplify a 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: may be weakly amplified.



0197

For *In Vitro* Diagnostic Use
MA123 v02 SSP PI Template
Date: September 2022, Rev. No: 00

101.128-12 – including *Taq* polymerase

101.128-12u – without *Taq* polymerase

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

Lot No.: **1R1**

Lot-specific information

PRIMER SPECIFICATION

Well No.	1	2	3	4	5	6	7	8	9	10	11	12
Length of spec. PCR product	135	215	165	105	170	250	225	195	165	195	250	170
Length of int. pos. control ¹	515	430	430	430	515	430	430	430	430	430	430	430
5'-primer(s) ²	16(133) 5'-gTT 3'	16(133) 5'-gTT 3'	16(133) 5'-gTT 3'	16(133) 5'-gTT 3'	16(133) 5'-gTT 3'	16(133) 5'-gTT 3'	23(154) 5'-AgA 3'	16(133) 5'-gTT 3'	37(196) 5'-AgC 3'	16(133) 5'-gTT 3'	16(133) 5'-gTT 3'	16(133) 5'-gTT 3'
							25(162) 5'-CgA 3'					
							26(165) 5'-TTA 3'					
3'-primer(s) ³	47(227) 5'-ggA 3'	74(307) 5'-CgC 3'	57(257) 5'-CAT 3'	37(196) 5'-gAg 3'	57(257) 5'-CgA 3'	85(341) 5'-CAG 3'	85(341) 5'-CAG 3'	67(286) 5'-gAT 3'	78(321) 5'-CAA 3'	67(286) 5'-gAA 3'	85(341) 5'-CAA 3'	58(260) 5'-CCT 3'
			57(257) 5'-CAT 3'		57(257) 5'-CgA 3'							
					58(261) 5'-TCC 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
Length of spec. PCR product	115	135	170	80	80	85	75	175	110	105	120
	185		200	115	110	135	115	220		220	
	255				225		195				
Length of int. pos. control ¹	515	515	515	430	430	515	430	430	430	430	430
5'-primer(s) ²	13(125) 5'-gTg 3'	149(534) 5'-CAG 3'	16(133) 5'-gTT 3'	14(127) 5'-gTT 3'	-17(40) 5'-CAA 3'	16(133) 5'-gTT 3'	16(133) 5'-gTT 3'	11(119) 5'-gCT 3'	16(133) 5'-gTT 3'	26(165) 5'-TTA 3'	152(543) 5'-gAT 3'
	37(197) 5'-gTT 3'			25(160) 5'-TgT 3'	24(158) 5'-g.T 3'			25(160) 5'-TgT 3'			
	61(269) 5'-CTA 3'			26(165) 5'-TTC 3'	60(266) 5'-gTC 3'			25(161) 5'-gCT 3'			
	65(280) 5'-AgC 3'				65(280) 5'-AgC 3'						
3'-primer(s) ³	85(341) 5'-CAG 3'	181(630) 5'-CTT 3'	59(262) 5'-CTg 3'	38(199) 5'-CAG 3'	-4(79) 5'-AgC 3'	28(169) 5'-CTg 3'	28(169) 5'-CTg 3'	70(296) 5'-TgT 3'	38(199) 5'-CAG 3'	47(227) 5'-ggT 3'	179(624) 5'-ACA 3'
			69(293) 5'-CTC 3'		85(341) 5'-CAG 3'	32(182) 5'-TAC 3'	40(205) 5'-gAC 3'		42(213) 5'-TCA 3'	86(344) 5'-CAC 3'	
						47(226) 5'-gAg 3'	67(286) 5'-gAg 3'				
Well No.	13	14	15	16	17	18	19	20	21	22	23

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. Wellnumber 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: September 2022, Rev. No: 00

101.128-12 – including *Taq* polymerase

101.128-12u – without *Taq* polymerase

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

Lot No.: **1R1**

Lot-specific information

CELL LINE VALIDATION SHEET																				
DRB1*12 SSP subtyping kit ²																				
					Well															
					1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
				Prod. No.:	201890701	201890702	201890703	201890704	201890705	201890706	201890707	201890708	201890709	201890710	201890711	201890712	201890713	201890714	201890715	201890716
	IHWC cell line ¹		DRB1																	
1	9001	SA	*01:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2	9280	LK707	*15:02	*04:05	-	-	-	-	-	-	-	-	-	-	-	-	-	W	-	-
3	9011	E4181324	*15:02		-	-	-	-	-	-	-	-	-	-	-	-	-	W	-	-
4	9275	GU373	*03:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
5	9009	KAS011	*16:01		-	-	-	-	-	-	-	-	-	-	-	-	-	W	-	-
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		-	-	-	-	-	-	-	-	-	-	-	-	-	W	-	-
47	9045	TUBO	*11:04	*12:01	+	+	-	+	+	+	+	+	+	-	-	-	-	-	-	-
48	9303	TER-ND	*01:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-



0197

For *In Vitro* Diagnostic Use
MA123 v02 SSP PI Template
Date: September 2022, Rev. No: 00

101.128-12 – including *Taq* polymerase

101.128-12u – without *Taq* polymerase

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

Lot No.: **1R1**

Lot-specific information

CELL LINE VALIDATION SHEET												
DRB1*12 SSP subtyping kit ²												
					Well							
					17	18	19	20	21	22	23	
				Prod. No.:	201890717	202024118	202024119	201890720	201890721	201890722	201890723	
	IHWC 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		-	-	-	-	-	-	-	+



0197

For *In Vitro* Diagnostic Use
MA123 v02 SSP PI Template
Date: September 2022, Rev. No: 00

101.128-12 – including *Taq* polymerase

101.128-12u – without *Taq* polymerase

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

Lot No.: **1R1**

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.

No DNAs carrying the alleles to be amplified by primer solutions 13, 15, 16, 18 to 20 and 22 were available. The specificities of the primers in primer solutions 16, 19, 20 and 22 were tested by separately adding one or two additional 5'-primers, respectively one or two additional 3'-primers. In primer solutions 15 and 18 it was only possible to test the 5'-primer, the 3'-primers were not possible to test. In primer solution 13 it was only possible to test the 3'-primer, the 5'-primers were not possible to test. In primer solutions 7, 16, 17 and 20 one, two or three 5'-primers were not possible to test. In primer solutions 5, 19 and 21 one 3'-primer was not possible to test. In addition, one 3'-primer in primer solutions 5 and 17 was tested by separately adding one additional 5'-primer.



0197

For *In Vitro* Diagnostic Use

MA123 v02 SSP PI Template

Date: September 2022, Rev. No: 00

101.128-12 – including *Taq* polymerase

101.128-12u – without *Taq* polymerase

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

Lot No.: **1R1**

Lot-specific information

ADDRESSES:

Manufacturer:

CareDx AB, Franzengatan 5, SE-112 51 Stockholm, Sweden.

Tel: +46-8-508 939 00

Fax: +46-8-717 88 18

E-mail: orders-se@caredx.com

Web page: www.caredx.com

Distributed by:

CareDx Lab Solutions Inc., 901 S. Bolmar St., Suite R, West Chester, PA 19382

Tel: 1-877-653-78171

Fax: 610-344-7989

E-mail: orders-us@caredx.com

Web page: www.caredx.com

For information on CareDx distributors worldwide, contact **CareDx AB**.



0197

For *In Vitro* Diagnostic Use

MA123 v02 SSP PI Template

Date: September 2022, Rev. No: 00