

101.123-24/06 – including *Taq* polymerase
101.123-24u/06u – without *Taq* polymerase

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

Lot No.: 8N2

Lot-specific information
Olerup SSP® DRB5

Product number:	101.123-24/06 – including <i>Taq</i> pol. 101.123-24u/06u – without <i>Taq</i> pol.
Lot number:	8N2
Expiry date:	2026-09-01
Number of tests:	24 tests – Product No. 101.123-24/24u 6 tests – Product No. 101.123-06/06u
Number of wells per test:	21+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. 8N2.

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

CHANGES COMPARED TO THE PREVIOUS OLERUP SSP® DRB5 LOT (1N4)

- 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 DRB5 primer set, specificity and interpretation tables have been updated for the HLA-DRB alleles described since the previous *Olerup SSP®* DRB5 lot was made (**Lot No. 1N4**).

The DRB5 primer set is unchanged compared to the previous *Olerup SSP®* DRB5 (**Lot No. 1N4**).



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Well **22** contains Negative Control primer pairs, that will amplify a 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

DRB5 SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for identifying the DRB5*01:01:01 to DRB5*01:126 and the DRB5*02:02 to DRB5*02:33 alleles.

PLATE LAYOUT

Each test consists of 22 PCR reactions in a 24 well cut PCR plate. Wells 23 to 24 are empty.

1	2	3	4	5	6	7	8
9	10	11	12	13	14	15	16
17	18	19	20	21	NC	empty	empty

The 24 well cut PCR plate is marked with ‘DRB5’ in silver/gray ink.

Well No. 1 is marked with the Lot No. ‘8N2’.

Wells 1 to 21 – DRB5 primers.

Well 22 – 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 DRB5 alleles, non-DRB5 alleles will be amplified by some primer mixes. For further details see Specificity Table.

UNIQUELY IDENTIFIED ALLELES

All the DRB5 alleles, i.e. **DRB5*01:01:01 to DRB5*01:126 and DRB5*02:02 to DRB5*02:33**, recognized by the HLA Nomenclature Committee in July 2022^{1,2} will be amplified by the primers in the DRB5 subtyping kit.

The DRB5 kit enables separation of the confirmed DRB5 alleles as listed in the IMGT/HLA database 3.28.0. 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 DRB5 alleles is listed below.

The DRB5 kit also enables identification of many null and alternatively expressed alleles.



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¹DRB5 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
DRB5*01:01	Confirmed	DRB5*01:19	Unconfirmed	DRB5*02:09	Unconfirmed
DRB5*01:01:02	Unconfirmed	DRB5*01:20	Confirmed	DRB5*02:10	Confirmed
DRB5*01:01:03	Unconfirmed	DRB5*01:21	Confirmed	DRB5*02:11	Unconfirmed
DRB5*01:02	Confirmed	DRB5*01:22	Unconfirmed	DRB5*02:12	Confirmed
DRB5*01:03	Confirmed	DRB5*01:23	Unconfirmed	DRB5*02:13	Confirmed
DRB5*01:04	Unconfirmed	DRB5*01:24	Unconfirmed	DRB5*02:14	Unconfirmed
DRB5*01:05	Unconfirmed	DRB5*01:25	Unconfirmed	DRB5*02:15	Unconfirmed
DRB5*01:06	Unconfirmed	DRB5*01:26	Unconfirmed	DRB5*02:16	Unconfirmed
DRB5*01:07	Unconfirmed	DRB5*01:27N	Unconfirmed		
DRB5*01:08N	Confirmed	DRB5*01:28	Unconfirmed		
DRB5*01:09	Unconfirmed	DRB5*01:29	Unconfirmed		
DRB5*01:10N	Confirmed	DRB5*01:30	Unconfirmed		
DRB5*01:11	Unconfirmed	DRB5*01:31	Unconfirmed		
DRB5*01:12	Unconfirmed	DRB5*02:02	Confirmed		
DRB5*01:13	Confirmed	DRB5*02:03	Confirmed		
DRB5*01:14	Unconfirmed	DRB5*02:04	Unconfirmed		
DRB5*01:15	Unconfirmed	DRB5*02:05	Unconfirmed		
DRB5*01:16	Unconfirmed	DRB5*02:06	Unconfirmed		
DRB5*01:17	Confirmed	DRB5*02:07	Confirmed		
DRB5*01:18	Confirmed	DRB5*02:08	Unconfirmed		

¹Allele status “confirmed” or “unconfirmed” as listed on the IMGT/HLA web page 2017-April-13, release 3.28.0, www.ebi.ac.uk/imgt/hla.

RESOLUTION IN HOMO- AND HETEROZYGOTES

Results file with resolution in DRB5 homo- and heterozygotes is available upon request.



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Lot-specific information
SPECIFICITY TABLE

DRB5 SSP subtyping

Specificities and sizes of the PCR products of the 21+1 primer mixes used for
DRB5 SSP subtyping

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified DRB5 alleles ³	Other amplified DRB alleles
1	255 bp	515 bp	*01:01:01:01-01:05, 01:07-01:20, 01:22-01:01:30, 01:32-01:38, 01:40-01:42, 01:45-01:54, 01:56-01:78, 01:80-01:96, 01:99, 01:101N-01:126, 02:03, 02:31	DRB1*09:07
2	210 bp	515 bp	*01:01:01:01-01:05, 01:07-01:10N, 01:12-01:20, 01:22-01:01:38, 01:40-01:70, 01:72-01:78, 01:80-01:96, 01:99, 01:101N-01:126, 02:04, 02:08, 02:12, 02:25N-02:26N	DRB1*09:07
3	225 bp	430 bp	*01:01:01:01-01:02:02, 01:04-01:05, 01:07-01:10N, 01:12-01:20, 01:22-01:01:38, 01:40-01:42, 01:44-01:54, 01:56-01:68N, 01:70, 01:72-01:78, 01:80-01:81N, 01:83N-01:96, 01:99, 01:101N-01:126, 02:05, 02:08, 02:12, 02:25N-02:26N, 02:31	DRB1*09:07
4⁴	100 bp	515 bp	*01:01:01:01-01:01:09, 01:01:11-01:01:12, 01:04, 01:06-01:07, 01:09, 01:11, 01:15-01:19, 01:21-01:24, 01:26, 01:29-01:31, 01:33-01:34, 01:36-01:38, 01:40, 01:42-01:45, 01:47-01:50, 01:53N-01:55, 01:57-01:58N, 01:62-01:63:01, 01:65-01:66, 01:71N, 01:75, 01:79Q-01:86, 01:88-01:89, 01:91-01:101N, 01:104-01:109, 01:111-01:112, 01:114-01:119, 01:121N-01:122, 01:124, 01:126	DRB1*16:60
5	150 bp 150 bp	515 bp	*02:06 *01:01:01:01-01:01:01:06, 01:01:04-01:01:07, 01:01:09-01:01:12, 01:05, 01:07, 01:09, 01:13, 01:16-01:19, 01:22-01:01:24, 01:26, 01:29-01:31, 01:33-01:34, 01:36-01:38, 01:40-01:42, 01:44-01:45, 01:47-01:51, 01:53N-01:54, 01:57-01:58N, 01:62-01:63:02, 01:65, 01:73, 01:78-01:85, 01:87-01:89, 01:91-01:99, 01:101N, 01:104-01:109,	DRB1*16:60



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			01:111-01:112, 01:114-01:119, 01:121N-01:124, 01:126	
6	145 bp	430 bp	*01:02:01-01:03, 01:05, 01:08:01N- 01:08:02N, 01:10N, 01:20, 01:25, 01:27N-01:28, 01:32, 01:35, 01:39, 01:46, 01:56, 01:59-01:60, 01:64, 01:67N-01:70, 01:72, 01:74, 01:76, 01:90, 01:102-01:103, 01:110, 01:113, 01:120N, 01:125N, 02:08, 02:12, 02:25N-02:26N	
7	145 bp	430 bp	*01:02:01-01:03, 01:08:01N- 01:08:02N, 01:10N, 01:17, 01:20, 01:25, 01:27N-01:28, 01:32, 01:35, 01:39, 01:46, 01:56, 01:59-01:61, 01:64, 01:67N-01:70, 01:72, 01:74, 01:76, 01:90, 01:102-01:103, 01:110, 01:113, 01:120N, 01:125N, 02:05, 02:08, 02:12, 02:25N- 02:26N	
8	215 bp	430 bp	*01:03, 01:06, 01:09, 01:11, 01:21, 01:43, 01:55, 01:69, 01:100, 02:02:01-02:04, 02:06-02:07, 02:09-02:11, 02:13-02:24, 02:27- 02:33	
9 ⁴	85 bp	430 bp	*01:16	
	175 bp		*01:13, 01:41	
	225 bp		*01:04	
10 ⁴	110 bp	430 bp	*01:48N	
	130 bp		*01:07	
	160 bp		*01:12, 01:15	
11 ⁴	110 bp	430 bp	*01:14	
	200 bp		*01:06, 01:11, 01:21, 01:100, 02:02:01-02:03, 02:06-02:07, 02:09-02:11, 02:13-02:23, 02:27- 02:33	
12	185 bp	515 bp	*02:02:01-02:02:04, 02:04-02:12, 02:14-02:16, 02:18-02:30, 02:33	
13	150 bp	430 bp	*01:01:02 [?] , 01:07 [?] , 01:09 [?] , 01:18, 01:56, 02:04 [?]	DRB1*15:02:03 [?] , DRB1*15:86, DRB1*16:01:02 [?] , DRB1*16:02:02 [?] , DRB4*01:05 [?] , DRB4*01:07:01 [?]
	195 bp		*01:08:01N-01:08:02N, 02:26N	
14	145 bp	430 bp	*02:07	
15	235 bp	430 bp	*01:10N, 01:12, 01:15, 02:31	DRB1*09:07
16 ⁴	125 bp	430 bp	*01:21, 01:43, 01:47, 02:10	
	225 bp		*01:20, 01:47, 02:08	DRB1*08:59, DRB1*11:210
17	130 bp	430 bp	*01:46, 01:69, 02:12	
	180 bp		*01:27N, 02:19N	



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18	185 bp	430 bp	*02:13, 02:19N	DRB1*03:112, DRB1*09:06, DRB4*01:117
19	195 bp	430 bp	*01:49N	
20	185 bp	430 bp	*01:48N	
21	230 bp	430 bp	*01:01:01:01-01:01:01:06, 01:01:03-01:01:07, 01:01:09-01:03, 01:05, 01:07-01:10N, 01:13-01:14, 01:16-01:20, 01:22:01-01:42, 01:44-01:54, 01:56-01:70, 01:72- 01:73, 01:75-01:99, 01:101N- 01:126, 02:08, 02:12, 02:25N- 02:26N	
22⁵	-	-	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 DRB5 SSP subtypings. 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 DRB alleles 1st and/or 3rd exon(s) and above, 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 and that unknown sequences of codons 87 to 92 are identical with the DRB1*01:01 consensus sequence.

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

⁵Primer mix 22 contains a negative control, which will amplify a majority of the 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

‘?’ , nucleotide sequence information not available for the primer matching sequence.



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PRIMER SPECIFICATION

Well No.	1	2	3	4	5	6	7	8	9	10	11	12
Length of spec. PCR product(s)	255	210	225	100	150	145	145	215	85	110	110	185
				150					175	130	200	
									225	160		
Length of int. pos. control ¹	515	515	430	515	515	430	430	430	430	430	430	515
5'-primer(s) ²	13(125) 5'-gTA 3'	13(125) 5'-gTA 3'	13(125) 5'-gTA 3'	38(199) 5'-ACT 3'	37(196) 5'-Agg 3'	38(199) 5'-ACg 3'	37(196) 5'-AgA 3'	13(125) 5'-gTA 3'	13(125) 5'-gTA 3'	38(199) 5'-ACT 3'	13(125) 5'-gTA 3'	37(196) 5'-AgA 3'
				98(379) 5'-CTg 3'		38(199) 5'-ACg 3'	41(209) 5'-Cgg 3'		120(446) 5'-gAC 3'			
3'-primer(s) ³	85(341) 5'-CAA 3'	67(286) 5'-gAA 3'	71(299) 5'-gCC 3'	57(258) 5'-gCg 3'	72(303) 5'-gCg 3'	72(303) 5'-gCg 3'	70(295) 5'-CTg 3'	70(295) 5'-gTT 3'	58(260) 5'-CCT 3'	60(267) 5'-CAC 3'	37(196) 5'-gTA 3'	85(341) 5'-CAg 3'
		67(286) 5'-gAA 3'	74(307) 5'-CAg 3'	135(490) 5'-gCC 3'			72(303) 5'-gCg 3'	71(299) 5'-gCg 3'	74(307) 5'-CAg 3'	67(286) 5'-gAT 3'	67(286) 5'-gAT 3'	
		70(296) 5'-TCC 3'	78(319) 5'-CAC 3'					71(299) 5'-gCg 3'	135(490) 5'-gCT 3'	78(319) 5'-CAC 3'		
		72(303) 5'-gCg 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
Length of spec. PCR product(s)	150	145	235	125	130	185	195	185	230
	195			225	180				
Length of int. pos. control ¹	430	430	430	430	430	430	430	430	430
5'-primer(s) ²	57(258) 5'-gAC 3'	24(157) 5'-ggT 3'	13(125) 5'-gTA 3'	6(103) 5'-CAT 3'	37(196) 5'-AgA 3'	37(196) 5'-AgA 3'	104(397) 5'-CTg 3'	13(125) 5'-gTA 3'	9(112) 5'-TgC 3'
	108(409) 5'-AgA 3'								
3'-primer(s) ³	93(365) 5'-gCg 3'	58(261) 5'-TCA 3'	78(319) 5'-CAC 3'	30(176) 5'-TgT 3'	67(286) 5'-gAT 3'	78(321) 5'-CAT 3'	156(553) 5'-CTA 3'	60(267) 5'-CAC 3'	72(303) 5'-gCg 3'
	160(565) 5'-CAT 3'		79(323) 5'-TgC 3'	38(199) 5'-CAA 3'	78(321) 5'-CAT 3'	85(341) 5'-CAA 3'			
				67(286) 5'-gAA 3'	83(336) 5'-CCC 3'				
Well No.	13	14	15	16	17	18	19	20	21

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 or the 3 terminal nucleotides of the primer is given.



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For *In Vitro* Diagnostic Use

MA123 v02 SSP PI Template

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CELL LINE VALIDATION SHEET																
DRB5 SSP subtyping kit																
				Prod. No.:	Well ²											
					1	2	3	4	5	6	7	8	9	10	11	12
					202130601	202130602	202130603	202130604	202130605	202130606	202130607	202130608	202130609	202130610	202130611	202130612
					202130613	202130614	202130615	202130616								
	IHWC cell line ¹	DRB5														
1	9001 SA				-	-	-	-	-	-	-	-	-	-	-	-
2	9280 LK707	*01:02			+	+	+	-	-	+	+	-	-	-	-	-
3	9011 E4181324	*01:02			+	+	+	-	-	+	+	-	-	-	-	-
4	9275 GU373				-	-	-	-	-	-	-	-	-	-	-	-
5	9009 KAS011	*02:02			-	-	-	-	-	-	-	+	-	+	+	-
6	9353 SM				-	-	-	-	-	-	-	-	-	-	-	-
7	9020 QBL				-	-	-	-	-	-	-	-	-	-	-	-
8	9025 DEU				-	-	-	-	-	-	-	-	-	-	-	-
9	9026 YAR				-	-	-	-	-	-	-	-	-	-	-	-
10	9107 LKT3				-	-	-	-	-	-	-	-	-	-	-	-
11	9051 PITOUT				-	-	-	-	-	-	-	-	-	-	-	-
12	9052 DBB				-	-	-	-	-	-	-	-	-	-	-	-
13	9004 JESTHOM				-	-	-	-	-	-	-	-	-	-	-	-
14	9071 OLGA				-	-	-	-	-	-	-	-	-	-	-	-
15	9075 DKB				-	-	-	-	-	-	-	-	-	-	-	-
16	9037 SWEIG007				-	-	-	-	-	-	-	-	-	-	-	-
17	9282 CTM3953540				-	-	-	-	-	-	-	-	-	-	-	-
18	9257 32367				-	-	-	-	-	-	-	-	-	-	-	-
19	9038 BM16				-	-	-	-	-	-	-	-	-	-	-	-
20	9059 SLE005				-	-	-	-	-	-	-	-	-	-	-	-
21	9064 AMALA				-	-	-	-	-	-	-	-	-	-	-	-
22	9056 KOSE				-	-	-	-	-	-	-	-	-	-	-	-
23	9124 IHL				-	-	-	-	-	-	-	-	-	-	-	-
24	9035 JBUSH				-	-	-	-	-	-	-	-	-	-	-	-
25	9049 IBW9				-	-	-	-	-	-	-	-	-	-	-	-
26	9285 WT49				-	-	-	-	-	-	-	-	-	-	-	-
27	9191 CH1007				-	-	-	-	-	-	-	-	-	-	-	-
28	9320 BEL5GB				-	-	-	-	-	-	-	-	-	-	-	-
29	9050 MOU				-	-	-	-	-	-	-	-	-	-	-	-
30	9021 RSH				-	-	-	-	-	-	-	-	-	-	-	-
31	9019 DUCAF				-	-	-	-	-	-	-	-	-	-	-	-
32	9297 HAG				-	-	-	-	-	-	-	-	-	-	-	-
33	9098 MT14B				-	-	-	-	-	-	-	-	-	-	-	-
34	9104 DHIF				-	-	-	-	-	-	-	-	-	-	-	-
35	9302 SSTO				-	-	-	-	-	-	-	-	-	-	-	-
36	9024 KT17				-	-	-	-	-	-	-	-	-	-	-	-
37	9065 HHKB				-	-	-	-	-	-	-	-	-	-	-	-
38	9099 LZL				-	-	-	-	-	-	-	-	-	-	-	-
39	9315 CML				-	-	-	-	-	-	-	-	-	-	-	-
40	9134 WHONP199				-	-	-	-	-	-	-	-	-	-	-	-
41	9055 H0301				-	-	-	-	-	-	-	-	-	-	-	-
42	9066 TAB089				-	-	-	-	-	-	-	-	-	-	-	-
43	9076 T7526				-	-	-	-	-	-	-	-	-	-	-	-
44	9057 TEM				-	-	-	-	-	-	-	-	-	-	-	-
45	9239 SHJO				-	-	-	-	-	-	-	-	-	-	-	-
46	9013 SCHU	*01:01			+	+	+	+	+	-	-	-	-	-	-	-
47	9045 TUBO				-	-	-	-	-	-	-	-	-	-	-	-
48	9303 TER-ND				-	-	-	-	-	-	-	-	-	-	-	-



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For *In Vitro* Diagnostic Use

MA123 v02 SSP PI Template

Date: October 2022, Rev. No: 00

101.123-24/06 – including *Taq* polymerase
101.123-24u/06u – without *Taq* polymerase

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

Lot No.: **8N2**

Lot-specific information

CELL LINE VALIDATION SHEET					
DRB5 SSP subtyping kit					
				Well ²	
				17	18 19 20 21
				202130617	202130618 202130619 202130620 202130621
				Prod. No.:	
IHCW cell line ¹		DRB5			
1	9001 SA		-	-	-
2	9280 LK707	*01:02	-	-	+
3	9011 E4181324	*01:02	-	-	+
4	9275 GU373		-	-	-
5	9009 KAS011	*02:02	-	-	-
6	9353 SM		-	-	-
7	9020 QBL		-	-	-
8	9025 DEU		-	-	-
9	9026 YAR		-	-	-
10	9107 LKT3		-	-	-
11	9051 PITOUT		-	-	-
12	9052 DBB		-	-	-
13	9004 JESTHOM		-	-	-
14	9071 OLGA		-	-	-
15	9075 DKB		-	-	-
16	9037 SWEIG007		-	-	-
17	9282 CTM3953540		-	-	-
18	9257 32367		-	-	-
19	9038 BM16		-	-	-
20	9059 SLE005		-	-	-
21	9064 AMALA		-	-	-
22	9056 KOSE		-	-	-
23	9124 IHL		-	-	-
24	9035 JBUSH		-	-	-
25	9049 IBW9		-	-	-
26	9285 WT49		-	-	-
27	9191 CH1007		-	-	-
28	9320 BEL5GB		-	-	-
29	9050 MOU		-	-	-
30	9021 RSH		-	-	-
31	9019 DUCAF		-	-	-
32	9297 HAG		-	-	-
33	9098 MT14B		-	-	-
34	9104 DHIF		-	-	-
35	9302 SSTO		-	-	-
36	9024 KT17		-	-	-
37	9065 HHKB		-	-	-
38	9099 LZL		-	-	-
39	9315 CML		-	-	-
40	9134 WHONP199		-	-	-
41	9055 H0301		-	-	-
42	9066 TAB089		-	-	-
43	9076 T7526		-	-	-
44	9057 TEM		-	-	-
45	9239 SHJO		-	-	-
46	9013 SCHU	*01:01	-	-	+
47	9045 TUBO		-	-	-
48	9303 TER-ND		-	-	-



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

101.123-24/06 – including *Taq* polymerase
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Lot No.: **8N2**

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 9, 10 and 14 to 20 were available. The specificities of the primers in primer solutions 9, 10, 15, 17 and 18 were tested by separately adding one, two or three additional 5'-primers, respectively one or two additional 3'-primers. In primer solutions 14 and 16 it was only possible to test the 3'-primer, the 5'-primer was not possible to test. In primer solutions 19 and 20 it was only possible to test the 5'-primers, the 3'-primers were not possible to test. In primer solutions 4, 7 and 9 one 5'-primer was not possible to test, and in primer solutions 2, 8, 10, 13 and 15 to 18 one or two 3'-primers were not possible to test. Additional primers in primer solutions 1 to 4, 7, 8, 11 and 13 were tested by separately adding additional 5'-primers and/or 3'-primers.



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

101.123-24/06 – including *Taq* polymerase
 101.123-24u/06u – without *Taq* polymerase

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

Lot No.: **8N2**

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

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**.



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For *In Vitro* Diagnostic Use

MA123 v02 SSP PI Template

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