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

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"Instructions for Use" (IFU)

Lot No.: 0V1

Lot-specific information

Olerup SSP® DRB5

Product number:	**101.123-24/06 – including *Taq* pol.** **101.123-24u/06u – without *Taq* pol.**
Lot number:	**0V1**
Expiry date:	**2028-11-01**
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. 0V1.

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 (0S2)

- The product documentation has been updated for new alleles of IMGT 3.56.0
- The kit resolution focuses on common and well documented (CWD) alleles[1].

[1]As 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. 0S2)**.

The DRB5 primer set is unchanged compared to the previous *Olerup* SSP® DRB5 **(Lot No. 0S2)**.

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For *In Vitro* Diagnostic Use

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'-primer[1]	**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'-primer[2]	**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							**+**

[1]The 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.

[2]The 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.

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

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Lot No.: 0V1 **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*01:138 and the DRB5*02:02 to DRB5*02:39 alleles.

PLATE LAYOUT

Each test consists of 22 PCR reactions in a 24 well cut PCR plate. Wells 23 and 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. '0V1'.
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*01:138 and DRB5*02:02 to DRB5*02:39**, recognized by the HLA Nomenclature Committee in April 2024[1,2,3] 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.

101.123-24/06 – including *Taq* polymerase
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Lot No.: 0V1 **Lot-specific information**

[1]DRB5 alleles listed on the IMGT/HLA web page 2024-April-10, release 3.56.0, www.ebi.ac.uk/imgt/hla.
[2]Alleles 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.
[3]The primers in this kit do not amplify the DRB5*01:131N allele.

ALLELE CONFIRMATION STATUS

Allele	Status[1]	Allele	Status[1]	Allele	Status[1]
DRB5*01:01:01	**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		

[1]Allele 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.

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

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Lot No.: 0V1

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-01:130, 01:132-01:135, 01:137-01:138, 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-01:130, 01:132-01:135, 01:137-01:138, 02:04, 02:08, 02:12, 02:25N-02:26N	**DRB1*09:07**
3	225 bp	430 bp	*01:01:01:01-01:02:04, 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-01:128, 01:130, 01:132-01:135, 01:137-01:138, 02:05, 02:08, 02:12, 02:25N-02:26N, 02:31, 02:34	**DRB1*09:07**
4[4]	100 bp 150 bp	**515 bp**	*01:01:01:01-01:01:09, 01:01:11-01:01:13, 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, 01:128-01:129, 01:132-01:138 *02:06	**DRB1*16:60**
5[5]	150 bp	**515 bp**	*01:01:01:01-01:01:01:06, 01:01:04-01:01:07, 01:01:09-01:01:13, 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, 01:111-01:112, 01:114-01:119, 01:121N-01:124, 01:126, 01:128-01:129, 01:132-01:135, 01:137-01:138	**DRB1*16:60**

101.123-24/06 – including *Taq* polymerase
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Lot No.: 0V1 **Lot-specific information**

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, 01:127N, 01:130, 02:08, 02:12, 02:25N-02:26N	**DRB1*09:53**
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, 01:127N, 01:130, 02:05, 02:08, 02:12, 02:25N-02:26N	**DRB1*09:53**
8	215 bp	430 bp	*01:03, 01:06, 01:09, 01:11, 01:21, 01:43, 01:55, 01:69, 01:100, 01:136, 02:02:01-02:04, 02:06-02:07, 02:09-02:11, 02:13-02:24, 02:27-02:39	
9[4]	85 bp 175 bp 225 bp	430 bp	*01:16 *01:13, 01:41 *01:04	
10[4]	110 bp 130 bp 160 bp	430 bp	*01:48N *01:07 *01:12, 01:15	
11[4]	110 bp 200 bp	430 bp	*01:14 *01:06, 01:11, 01:21, 01:100, 01:136, 02:02:01-02:03, 02:06-02:07, 02:09-02:11, 02:13-02:23, 02:27-02:39	
12[6]	185 bp	**515 bp**	*02:02:01-02:02:04, 02:04-02:12, 02:14-02:16, 02:18-02:30, 02:33-02:39	
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, 01:127N, 02:26N	
14	145 bp	430 bp	*02:07	
15	235 bp	430 bp	*01:10N, 01:12, 01:15, 02:31, 02:34	**DRB1*09:07**
16[4]	125 bp 225 bp	430 bp	*01:21, 01:43, 01:47, 01:136, 02:10 *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	
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	

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

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			Lot-specific information
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-01:130, 01:132-01:135, 01:137-01:138, 02:08, 02:12, 02:25N-02:26N
22[7]	-	-	**Negative Control**

[1]Alleles 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 inherit 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.

[2]The 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.

[3]For 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.

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

[5]Primer mix 5 may have tendency of unspecific amplification.

[6]In primer mix 12 the positive control band may be weaker than for the other DRB5 primer mixes.

[7]Primer 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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Lot No.: 0V1

Lot-specific information

PRIMER SPECIFICATION

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

[1]The 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.

[2]The 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.

[3]The 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.

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

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Lot No.: 0V1 **Lot-specific information**

CELL LINE VALIDATION SHEET

DRB5 SSP subtyping kit

				Well[2]															
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
			Prod. No.:	202130601	202130602	202459503	202130604	202459505	202459506	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		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

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

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Lot No.: 0V1 **Lot-specific information**

CELL LINE VALIDATION SHEET

DRB5 SSP subtyping kit

				Well[2]				
				17	18	19	20	21
			Prod. No.:	202459517	202130618	202130619	202130620	202459521
	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		-	-	-	-	-

CE
0197
For *In Vitro* Diagnostic Use
MA123 v02 SSP PI Template
Date: November 2024, Rev. No: 00

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

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Lot No.: 0V1 **Lot-specific information**

[1]The 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.

[2]The 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.

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.: 0V1 **Lot-specific information**

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Web page: www.caredx.com

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Web page: www.caredx.com

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

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