

101.122-24/06 – including *Taq* polymerase  
101.122-24u/06u – without *Taq* polymerase

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“Instructions for Use” (IFU)

Lot No.: **8R9**

Lot-specific information  
**Olerup SSP® DRB4**

<b>Product number:</b>	101.122-24/06 – including <i>Taq</i> pol. 101.122-24/06u – without <i>Taq</i> pol.
<b>Lot number:</b>	8R9
<b>Expiry date:</b>	2027-06-01
<b>Number of tests:</b>	24 tests – Product No. 101.122-24/24u 6 tests – Product No. 101.122-06/06u
<b>Number of wells per test:</b>	31+1
<b>Storage - pre-aliquoted primers:</b>	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. 8R9.**

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

**CHANGES COMPARED TO THE PREVIOUS OLERUP SSP®  
DRB4 LOT (6N2)**

- The product documentation has been updated for new alleles of IMGT 3.52.0.
- The kit resolution focuses on common and well documented (CWD) alleles<sup>1</sup>.

<sup>1</sup>As described in section Uniquely Identified Alleles.

The DRB4 specificity and interpretation tables have been updated for the DRB alleles described since the previous *Olerup SSP®* DRB4 lot was made (**Lot No. 6N2**).

The DRB4 primer set is unchanged compared to the previous *Olerup SSP®* DRB4 (**Lot No. 6N2**).

<sup>1</sup>S. 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: June 2023, Rev. No:00

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Well **32** 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
<b>5'-primer<sup>1</sup></b>	<b>164</b>	<b>340</b>	<b>440</b>	<b>45</b>	<b>45</b>	<b>43</b>	<b>36</b>
	5'-CAC <sup>3'</sup>	5'-Agg <sup>3'</sup>	5'-TTA <sup>3'</sup>	5'-Tgg <sup>3'</sup>	5'-Tgg <sup>3'</sup>	5'-Tgg <sup>3'</sup>	5'-TAC <sup>3'</sup>
							36
							5'-TAT <sup>3'</sup>
<b>3'-primer<sup>2</sup></b>	<b>231</b>	<b>2<sup>nd</sup> I</b>	<b>507</b>	<b>59</b>	<b>58</b>	<b>57</b>	<b>47</b>
	5'-TgC <sup>3'</sup>	5'-AAA <sup>3'</sup>	5'-TTg <sup>3'</sup>	5'-CTC <sup>3'</sup>	5'-ggC <sup>3'</sup>	5'-CTC <sup>3'</sup>	5'-ACA <sup>3'</sup>
							48
							5'-gCA <sup>3'</sup>
							48
							5'-gCC <sup>3'</sup>
							52
							5'-TgT <sup>3'</sup>
<b>A*</b>	<b>+</b>	<b>+</b>	<b>+</b>				
<b>B*</b>	<b>+</b>	<b>+</b>	<b>+</b>				
<b>C*</b>	<b>+</b>	<b>+</b>	<b>+</b>				
<b>DRB1</b>				<b>+</b>	<b>+</b>		
<b>DRB3</b>				<b>+</b>	<b>+</b>		
<b>DRB5</b>				<b>+</b>			
<b>DQB1</b>					<b>+</b>		
<b>DPB1</b>						<b>+</b>	
<b>DQA1</b>							<b>+</b>

<sup>1</sup>The nucleotide position for HLA class I genes and the codon for HLA class II genes, in the 2<sup>nd</sup> or 3<sup>rd</sup> 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](http://www.ebi.ac.uk/imgt/hla) web site. The sequence of the 3 terminal nucleotides of the primer is given.

<sup>2</sup>The nucleotide position for HLA class I genes and the codon for HLA class II genes, in the 2<sup>nd</sup> or 3<sup>rd</sup> exon or the 2<sup>nd</sup> 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](http://www.ebi.ac.uk/imgt/hla) web site. The sequence of the 3 terminal nucleotides of the primer is given.



0197

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## PRODUCT DESCRIPTION

### DRB4 SSP subtyping

#### CONTENT

The primer set contains 5'- and 3'-primers for identifying the DRB4\*01:01:01:01 to DRB4\*03:01N alleles.

#### PLATE LAYOUT

Each test consists of 32 PCR reactions in a 32 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	NC

The 32 well cut PCR plate is marked with ‘DRB4’ in silver/gray ink.  
Well No. 1 is marked with the Lot No. ‘8R9’.

Wells 1 to 31 – DRB4 high resolution primers.

Well 32 – 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 32 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 DRB alleles, non-DRB4 alleles will be amplified by some primer mixes. For further details see Specificity Table.

#### UNIQUELY IDENTIFIED ALLELES

All the DRB4 alleles, i.e. **DRB4\*01:01:01:01 to DRB4\*03:01N**, recognized by the HLA Nomenclature Committee in April 2023<sup>1,2</sup> will be amplified by the primers in the DRB4 subtyping kit.

The DRB4 kit enables separation of the confirmed DRB4 alleles as listed in the IMGT/HLA database 3.29.0. 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 DRB4 alleles is listed below.

The DRB4 kit also enables identification of many null and alternatively expressed alleles.



0197

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Lot No.: **8R9**

Lot-specific information

The following DRB4 alleles can be distinguished by the different sizes of the HLA-specific PCR product:

Alleles	Primer mix	Alleles	Primer mix
DRB4*01:08, 01:39	13	DRB4*01:32, 01:43, 01:54:01N-01:54:02N	24
DRB4*01:20, 01:36	21	DRB4*01:33, 01:38N, 01:40	22
DRB4*01:24, 01:37	23		

<sup>1</sup>DRB4 alleles listed on the IMGT/HLA web page 2023-April-17, release 3.52.0, [www.ebi.ac.uk/imgt/hla](http://www.ebi.ac.uk/imgt/hla).

<sup>2</sup>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>.

### ALLELE CONFIRMATION STATUS

Allele	Status <sup>1</sup>	Allele	Status <sup>1</sup>	Allele	Status <sup>1</sup>	Allele	Status <sup>1</sup>
DRB4*01:01:01:01	Confirmed	DRB4*01:13	Confirmed	DRB4*01:33	Unconfirmed	DRB4*01:53	Confirmed
DRB4*01:01:02	Confirmed	DRB4*01:14	Confirmed	DRB4*01:34	Unconfirmed	DRB4*01:54N	Unconfirmed
DRB4*01:02	Confirmed	DRB4*01:15	Unconfirmed	DRB4*01:35	Unconfirmed	DRB4*01:55	Unconfirmed
DRB4*01:03:01:01	Confirmed	DRB4*01:16N	Confirmed	DRB4*01:36	Confirmed	DRB4*01:56N	Unconfirmed
DRB4*01:03:01:02N	Confirmed	DRB4*01:17	Confirmed	DRB4*01:37	Unconfirmed	DRB4*02:01N	Unconfirmed
DRB4*01:03:01:03	Unconfirmed	DRB4*01:18	Unconfirmed	DRB4*01:38N	Unconfirmed	DRB4*03:01N	Unconfirmed
DRB4*01:03:02	Unconfirmed	DRB4*01:19	Unconfirmed	DRB4*01:39	Confirmed		
DRB4*01:03:03	Confirmed	DRB4*01:20	Unconfirmed	DRB4*01:40	Confirmed		
DRB4*01:03:04	Unconfirmed	DRB4*01:21	Unconfirmed	DRB4*01:41	Confirmed		
DRB4*01:03:05	Unconfirmed	DRB4*01:22	Confirmed	DRB4*01:42	Unconfirmed		
DRB4*01:04	Confirmed	DRB4*01:23	Unconfirmed	DRB4*01:43	Unconfirmed		
DRB4*01:05	Unconfirmed	DRB4*01:24	Unconfirmed	DRB4*01:44	Confirmed		
DRB4*01:06	Unconfirmed	DRB4*01:25	Unconfirmed	DRB4*01:45	Confirmed		
DRB4*01:07:01	Confirmed	DRB4*01:26	Unconfirmed	DRB4*01:46	Unconfirmed		
DRB4*01:07:02	Confirmed	DRB4*01:27	Unconfirmed	DRB4*01:47	Unconfirmed		
DRB4*01:08	Unconfirmed	DRB4*01:28	Confirmed	DRB4*01:48	Unconfirmed		
DRB4*01:09	Unconfirmed	DRB4*01:29	Unconfirmed	DRB4*01:49	Unconfirmed		
DRB4*01:10	Unconfirmed	DRB4*01:30	Unconfirmed	DRB4*01:50	Unconfirmed		
DRB4*01:11	Confirmed	DRB4*01:31	Unconfirmed	DRB4*01:51	Unconfirmed		
DRB4*01:12	Unconfirmed	DRB4*01:32	Unconfirmed	DRB4*01:52	Unconfirmed		

<sup>1</sup>Allele status “confirmed” or “unconfirmed” as listed on the IMGT/HLA web page 2017-August-10, release 3.29.0, [www.ebi.ac.uk/imgt/hla](http://www.ebi.ac.uk/imgt/hla).

### RESOLUTION IN HOMO- AND HETEROZYGOTES

Results file with resolution in DRB4 homo- and heterozygotes is available upon request.



0197

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Lot-specific information  
**SPECIFICITY TABLE**

**DRB4 SSP subtyping**

**Specificities and sizes of the PCR products of the 31+1 primer mixes used for DRB4 SSP subtyping**

Primer Mix	Size of spec. PCR product <sup>1</sup>	Size of control band <sup>2</sup>	Amplified DRB4 <sup>3</sup> alleles	Other amplified DRB alleles
<b>1</b>	185 bp	<b>515 bp</b>	*01:01:01:01, 01:01:01:03-01:01:04, 01:01:06-01:01:10, 01:03:01:01-01:03:18, 01:03:20-01:03:32, 01:05-01:26, 01:28-01:66, 01:68-01:69, 01:71N-01:91, 01:93-01:138, 01:140-01:162N, 01:164-01:171	
<b>2<sup>5</sup></b>	140 bp	430 bp	*01:02	
<b>3</b>	130 bp	430 bp	*01:01:01:01, 01:01:01:03-01:01:01:04, 01:01:02 <sup>?</sup> , 01:01:03-01:01:10, 01:04 <sup>?</sup> -01:05 <sup>?</sup> , 01:06, 01:07:01 <sup>?</sup> -01:08 <sup>?</sup> , 01:11 <sup>?</sup> -01:13 <sup>?</sup> , 01:15 <sup>?</sup> -01:43 <sup>?</sup> , 01:45 <sup>?</sup> -01:62 <sup>?</sup> , 01:64 <sup>?</sup> , 01:66 <sup>?</sup> -01:69 <sup>?</sup> , 01:70, 01:71N <sup>?</sup> , 01:73 <sup>?</sup> , 01:75, 01:78-01:79, 01:82 <sup>?</sup> -01:83 <sup>?</sup> , 01:91 <sup>?</sup> -01:93 <sup>?</sup> , 01:95, 01:98 <sup>?</sup> -01:102 <sup>?</sup> , 01:106 <sup>?</sup> , 01:108N <sup>?</sup> -01:111 <sup>?</sup> , 01:113N <sup>?</sup> -01:116 <sup>?</sup> , 01:125, 01:127, 01:133 <sup>?</sup> , 01:136, 01:139 <sup>?</sup> -01:140 <sup>?</sup> , 01:141, 01:144, 01:151, 01:156, 01:164, 01:168-01:169, 01:170 <sup>?</sup> , 02:01N, 03:01N	<b>DRB1*01:139, DRB1*10:19, DRB1*14:217, DRB1*15:141</b>
<b>4</b>	245 bp	<b>515 bp</b>	*01:01:01:01, 01:01:01:03-01:03:01:01, 01:03:01:03-01:03:01:12, 01:03:01:14-01:04, 01:05 <sup>?</sup> , 01:06-01:13, 01:15-01:172, 02:01N	
<b>5</b>	155 bp	430 bp	*01:03:01:02N, 01:03:01:13N, 01:14N	
<b>6<sup>4</sup></b>	115 bp 200 bp	430 bp	*01:12 *01:04, 01:14N	
<b>7</b>	155 bp	430 bp	*01:02-01:03:14, 01:03:16-01:03:32, 01:04 <sup>?</sup> -01:05 <sup>?</sup> , 01:07:01 <sup>?</sup> -01:08 <sup>?</sup> , 01:09-01:10, 01:11 <sup>?</sup> -01:13 <sup>?</sup> , 01:14N, 01:15 <sup>?</sup> -01:43 <sup>?</sup> , 01:44, 01:45 <sup>?</sup> -01:62 <sup>?</sup> , 01:63, 01:64 <sup>?</sup> , 01:65N, 01:66 <sup>?</sup> -01:69 <sup>?</sup> , 01:71N <sup>?</sup> , 01:72, 01:73 <sup>?</sup> , 01:74, 01:76-01:77, 01:80N-01:81, 01:82 <sup>?</sup> -01:83 <sup>?</sup> , 01:84N-01:89, 01:91 <sup>?</sup> -01:93 <sup>?</sup> , 01:94, 01:96-01:97, 01:98 <sup>?</sup> -01:102 <sup>?</sup> ,	<b>DRB1*15:01:01:01<sup>w</sup>-15:01:30<sup>w</sup>, DRB1*15:01:32<sup>w</sup>-15:02:17<sup>w</sup>, DRB1*15:02:19<sup>w</sup>-15:140<sup>w</sup>, DRB1*15:142<sup>w</sup>-15:179<sup>w</sup>, DRB1*15:181<sup>w</sup>-15:200:01:02N<sup>w</sup>, DRB1*15:202<sup>w</sup>-15:216<sup>w</sup>, DRB1*16:01:01:01<sup>w</sup>-16:05:02<sup>w</sup>, DRB1*16:07<sup>w</sup>-16:73<sup>w</sup></b>



**0197**

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Lot No.: **8R9**

Lot-specific information

			01:103-01:105, 01:106 <sup>?</sup> , 01:107, 01:108N <sup>?</sup> -01:111 <sup>?</sup> , 01:112, 01:113N <sup>?</sup> -01:116 <sup>?</sup> , 01:117- 01:124, 01:126, 01:128N- 01:132, 01:133 <sup>?</sup> , 01:134-01:135, 01:137-01:138, 01:139 <sup>?</sup> -01:140 <sup>?</sup> , 01:142-01:143, 01:145N-01:150, 01:152-01:155, 01:157-01:163, 01:166-01:167, 01:170 <sup>?</sup> , 01:171- 01:172	
<b>8</b>	150 bp	430 bp	*03:01N	
<b>9</b>	200 bp	<b>515 bp</b>	*01:05	
<b>10<sup>4</sup></b>	85 bp	<b>515 bp</b>	*02:01N	
<b>11<sup>4</sup></b>	110 bp	430 bp	*01:06	
<b>12</b>	210 bp	430 bp	*01:07:01-01:07:02, 01:14N	
<b>13<sup>4</sup></b>	110 bp 140 bp 215 bp	430 bp	*01:12, 01:39 *01:45 *01:08	
<b>14</b>	220 bp	430 bp	*01:09	
<b>15</b>	190 bp 245 bp	430 bp	*01:10, 01:30 *01:02 <sup>?</sup> , 01:21	
<b>16<sup>4</sup></b>	125 bp 200 bp 265 bp	430 bp	*01:13 *01:57N *01:17	
<b>17</b>	255 bp	430 bp	*01:02 <sup>?</sup> , 01:17, 01:21-01:22, 01:26	
<b>18</b>	200 bp	430 bp	*01:29-01:31	
<b>19</b>	210 bp 230 bp	430 bp	*01:27-01:29 *01:65N	<b>DRB1*03:109, DRB1*12:64, DRB1*13:187, DRB1*15:93</b>
<b>20</b>	225 bp	430 bp	*01:23, 01:27, 01:65N	<b>DRB1*03:109, DRB1*04:109, DRB1*12:64- 12:65, DRB1*13:187, DRB1*13:258, DRB1*15:42, DRB1*15:93</b>
<b>21<sup>4</sup></b>	250 bp 105 bp 220 bp 235 bp	430 bp	*01:22 *01:20 *01:42 *01:05 <sup>?</sup> , 01:07:01 <sup>?</sup> , 01:36	
<b>22<sup>4</sup></b>	100 bp 230 bp	430 bp	*01:33, 01:40 *01:38N	
<b>23<sup>4</sup></b>	105 bp 200 bp 240 bp	430 bp	*01:24 *01:61N *01:37	
<b>24<sup>4</sup></b>	75 bp 175 bp 240 bp	430 bp	*01:32 *01:35, 01:43 *01:54:01N-01:54:02N	
<b>25<sup>4</sup></b>	75 bp 160 bp	430 bp	*01:44 *01:15, 01:35, 01:56N	
<b>26</b>	135 bp 160 bp	430 bp	*01:25 *01:18, 01:34, 01:56N	



0197

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<b>27</b>	160 bp 210 bp	430 bp	*01:19, 01:34 *01:42, 01:61N
<b>28</b>	140 bp	430 bp	*01:16N, 01:25, 01:45
<b>29</b>	140 bp	430 bp	*01:11
<b>30</b>	185 bp 220 bp	430 bp	*01:57N *01:41
<b>31<sup>4</sup></b>	125 bp	430 bp	*01:53
<b>32<sup>6</sup></b>	-	-	<b>Negative Control</b>

<sup>1</sup>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 DRB4 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 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.

<sup>2</sup>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. In the presence of a specific amplification the intensity of the control band often decreases.

<sup>3</sup>For 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. The complete 2nd exon nucleotide sequence of the DRB4\*01:05 allele is not known. Thus, it is not known whether the DRB4\*01:05 allele will be amplified by primer mix 4 or not.

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

<sup>5</sup>Primer mix 2 has a tendency to give rise to primer oligomer formation.

<sup>6</sup>Primer mix 32 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.

'w', may be weakly amplified.



0197

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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	185	140	130	245	155	115	155	150	200	85	110	210
Length of int. pos. control <sup>1</sup>	515	430	430	515	430	430	430	430	515	515	430	430
5'-primer(s) <sup>2</sup>	28(170) 5'-gAT 3'	42(213) 5'-AgT 3'	105(401) 5'-AAA 3'	1 <sup>st</sup> I 5'-ggg 3'	5(101) 5'-CAA 3'	28(170) 5'-gAT 3'	96(375) 5'-CAA 3'	2 <sup>nd</sup> I 5'-... 3'	28(170) 5'-gAT 3'	28(170) 5'-gAT 3'	112(421) 5'-ACT 3'	28(170) 5'-gAT 3'
3'-primer(s) <sup>3</sup>	76(314) 5'-TgT 3'	76(314) 5'-TgC 3'	135(490) 5'-gCT 3'	1 <sup>st</sup> I 5'-TgC 3'	42(213) 5'-TCA 3'	53(244) 5'-CAT 3'	135(490) 5'-gCC 3'	2 <sup>nd</sup> I 5'-ggA 3'	81(328) 5'-gTg 3'	42(213) 5'-TCA 3'	135(490) 5'-gCT 3'	83(335) 5'-CgC 3'
						77(317) 5'-AgT 3'						84(337) 5'-CCg 3'
						83(335) 5'-CgC 3'						84(337) 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	110	220	190	125	255	200	210	225	105	100	105	75
			245	200			230	250	220	230	200	175
				265					235		240	240
Length of int. pos. control <sup>1</sup>	430	430	430	430	430	430	430	430	430	430	430	430
5'-primer(s) <sup>2</sup>	28(170) 5'-gAT 3'	96(375) 5'-CAA 3'	17(138) 5'-TTg 3'	12(121) 5'-CTg 3'	12(121) 5'-CTg 3'	30(175) 5'-gAg 3'	23(154) 5'-AgT 3'	17(137) 5'-TTC 3'	28(170) 5'-gAT 3'	28(170) 5'-gAT 3'	28(170) 5'-gAT 3'	28(170) 5'-gAT 3'
			36(195) 5'-gAC 3'	32(183) 5'-TAG 3'	15(131) 5'-gTA 3'	36(195) 5'-gAC 3'	28(170) 5'-gAg 3'	23(154) 5'-AgT 3'				
			38(199) 5'-ACA 3'	58(259) 5'-ACC 3'	17(137) 5'-TTC 3'	37(196) 5'-AgC 3'	30(175) 5'-gAC 3'	23(155) 5'-gCA 3'				
				17(138) 5'-TTg 3'		30(175) 5'-gAg 3'	28(170) 5'-gAg 3'					
3'-primer(s) <sup>3</sup>	51(239) 5'-CCA 3'	156(555) 5'-gTA 3'	86(344) 5'-CCA 3'	86(344) 5'-CCA 3'	86(344) 5'-CCA 3'	86(344) 5'-CCA 3'	86(344) 5'-CCA 3'	86(344) 5'-CCA 3'	49(233) 5'-CCA 3'	46(223) 5'-CTT 3'	49(232) 5'-CgT 3'	39(203) 5'-AgT 3'
	53(244) 5'-CAT 3'								88(350) 5'-Agg 3'	48(230) 5'-CCC 3'	81(330) 5'-TTC 3'	71(299) 5'-gCT 3'
	61(270) 5'-TTg 3'								93(365) 5'-gCT 3'	92(361) 5'-CTA 3'	94(368) 5'-CTT 3'	74(309) 5'-ACA 3'
	87(346) 5'-CTT 3'											94(367) 5'-TCA 3'
Well No.	13	14	15	16	17	18	19	20	21	22	23	24

Well No.	25	26	27	28	29	30	31
Length of spec. PCR product	75	135	160	140	140	185	125
	160	160	210			220	
Length of int. pos. control <sup>1</sup>	430	430	430	430	430	430	430
5'-primer(s) <sup>2</sup>	28(170) 5'-gAT 3'	28(170) 5'-gAT 3'	28(170) 5'-gAT 3'	28(170) 5'-gAT 3'	15(130) 5'-AgC 3'	21(149) 5'-gAT 3'	28(170) 5'-gAT 3'
						32(183) 5'-TAg 3'	
3'-primer(s) <sup>3</sup>	39(202) 5'-gCA 3'	60(266) 5'-AgC 3'	68(290) 5'-CCg 3'	60(266) 5'-AgC 3'	48(230) 5'-CCT 3'	81(328) 5'-gTA 3'	56(253) 5'-AgT 3'
	64(277) 5'-CTA 3'	64(277) 5'-CTA 3'	70(295) 5'-CCC 3'	60(267) 5'-CAC 3'			
	71(299) 5'-gCT 3'	68(290) 5'-CCg 3'	81(330) 5'-TTC 3'	61(270) 5'-TTg 3'			
	72(301) 5'-CCA 3'	70(295) 5'-CTg 3'	88(350) 5'-Agg 3'				
Well No.	25	26	27	28	29	30	31



0197

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



101.122-24/06 – including *Taq* polymerase  
101.122-24u/06u – without *Taq* polymerase

Visit [www.caredx.com](http://www.caredx.com) for  
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Lot No.: **8R9**

#### Lot-specific information

<sup>1</sup>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.

<sup>2</sup>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](http://www.ebi.ac.uk/imgt/hla) web site. The sequence of the 3 terminal nucleotides of the primer is given.

<sup>3</sup>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](http://www.ebi.ac.uk/imgt/hla) web site. The sequence of the 3 terminal nucleotides of the primer is given.



0197

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Lot No.: **8R9**

Lot-specific information

CELL LINE VALIDATION SHEET																				
DRB4 SSP kit <sup>2</sup>																				
				Well																
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	
				Prod. No.:	201777101	201777102	201777103	201777104	201777105	201777106	201777107	202136108	202136109	201777110	201777111	201777112	201788213	201777114	201777115	202136116
IHWC cell line <sup>1</sup>		DRB4																		
1	9001	SA		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2	9280	LK707	*01:03	+	-	-	+	-	-	+	-	-	-	-	-	-	-	-	-	-
3	9011	E4181324		-	-	-	-	-	-	-	W	-	-	-	-	-	-	-	-	-
4	9275	GU373		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
5	9009	KAS011		-	-	-	-	-	-	-	W	-	-	-	-	-	-	-	-	-
6	9353	SM	*01:03	+	-	-	+	-	-	W	-	-	-	-	-	-	-	-	-	-
7	9020	QBL		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
8	9025	DEU	*01:03	+	-	-	+	-	-	+	-	-	-	-	-	-	-	-	-	-
9	9026	YAR	*01:03	+	-	-	+	-	-	+	-	-	-	-	-	-	-	-	-	-
10	9107	LKT3	*01:03	+	-	-	+	-	-	+	-	-	-	-	-	-	-	-	-	-
11	9051	PITOUT	*01:01	+	-	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-
12	9052	DBB	*01:03N	+	-	-	-	+	-	+	-	-	-	-	-	-	-	-	-	-
13	9004	JESTHOM		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
14	9071	OLGA		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
15	9075	DKB	*01:03	+	-	-	+	-	-	+	-	-	-	-	-	-	-	-	-	-
16	9037	SWEIG007		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
17	9282	CTM3953540		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
18	9257	32367	*01:01	+	-	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-
19	9038	BM16		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
20	9059	SLE005		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
21	9064	AMALA		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
22	9056	KOSE		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
23	9124	IHL		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
24	9035	JBUSH		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
25	9049	IBW9	*01:01	+	-	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-
26	9285	WT49		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
27	9191	CH1007	*01:03	+	-	-	+	-	-	+	-	-	-	-	-	-	-	-	-	-
28	9320	BEL5GB	*01:01	+	-	+	+	-	-	+	-	-	-	-	-	-	-	-	-	-
29	9050	MOU	*01:01	+	-	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-
30	9021	RSH		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
31	9019	DUCAF		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
32	9297	HAG		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
33	9098	MT14B	*01:03	+	-	-	+	-	-	+	-	-	-	-	-	-	-	-	-	-
34	9104	DHIF		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
35	9302	SSTO	*01:03	+	-	-	+	-	-	+	-	-	-	-	-	-	-	-	-	-
36	9024	KT17	*01:03	+	-	-	+	-	-	+	-	-	-	-	-	-	-	-	-	-
37	9065	HHKB		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
38	9099	LZL		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
39	9315	CML	*01:02	-	+	-	+	-	-	+	-	-	-	-	-	-	-	-	-	-
40	9134	WHONP199	*01:03	+	-	-	+	-	-	+	-	-	-	-	-	-	-	-	-	-
41	9055	H0301		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
42	9066	TAB089		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
43	9076	T7526	*01:03	+	-	-	+	-	-	+	-	-	-	-	-	-	-	-	-	-
44	9057	TEM		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
45	9239	SHJO	*01:01	+	-	+	+	-	-	+	-	-	-	-	-	-	-	-	-	-
46	9013	SCHU		-	-	-	-	-	-	-	W	-	-	-	-	-	-	-	-	-
47	9045	TUBO		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
48	9303	TER-ND		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-



0197

101.122-24/06 – including *Taq* polymerase  
101.122-24u/06u – without *Taq* polymerase

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Lot No.: **8R9**

Lot-specific information

<b>CELL LINE VALIDATION SHEET</b>																			
<b>DRB4 SSP kit<sup>2</sup></b>																			
			Prod. No.:	Well															
				17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	
				201777117	202136118	201896119	201896120	201777121	201777122	202136123	201788224	201788225	201788226	201896127	201788228	202136129	202136130	201788231	
	<b>IHWC cell line<sup>1</sup></b>	<b>DRB4</b>																	
1	9001 SA			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2	9280 LK707	*01:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3	9011 E4181324			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4	9275 GU373			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
5	9009 KAS011			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
6	9353 SM	*01:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
7	9020 QBL			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
8	9025 DEU	*01:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
9	9026 YAR	*01:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
10	9107 LKT3	*01:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
11	9051 PITOUT	*01:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
12	9052 DBB	*01:03N		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
13	9004 JESTHOM			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
14	9071 OLGA			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
15	9075 DKB	*01:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
16	9037 SWEIG007			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
17	9282 CTM3953540			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
18	9257 32367	*01:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
19	9038 BM16			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
20	9059 SLE005			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
21	9064 AMALA			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
22	9056 KOSE			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
23	9124 IHL			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
24	9035 JBUSH			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
25	9049 IBW9	*01:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
26	9285 WT49			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
27	9191 CH1007	*01:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
28	9320 BEL5GB	*01:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
29	9050 MOU	*01:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
30	9021 RSH			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
31	9019 DUCAF			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
32	9297 HAG			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
33	9098 MT14B	*01:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
34	9104 DHIF			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
35	9302 SSTO	*01:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
36	9024 KT17	*01:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
37	9065 HHKB			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
38	9099 LZL			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
39	9315 CML	*01:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
40	9134 WHONP199	*01:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
41	9055 H0301			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
42	9066 TAB089			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
43	9076 T7526	*01:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
44	9057 TEM			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
45	9239 SHJO	*01:01	*01:03	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
46	9013 SCHU			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
47	9045 TUBO			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
48	9303 TER-ND			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-



0197

101.122-24/06 – including *Taq* polymerase  
101.122-24u/06u – without *Taq* polymerase

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**Lot No.: 8R9**

**Lot-specific information**

<sup>1</sup>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.

<sup>2</sup>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 6 and 9 to 31 were available.

The specificities of the primers in primer solutions 6, 9, 22 and 24 to 26 were tested by separately adding one additional 5'-primer, respectively, one additional 3'-primer.

In primer solutions 10, 11, 15 to 20, 29 and 30 it was only possible to test the 3'-primers, the 5'-primers were not possible to test.

In primer solutions 12 to 14, 21, 23, 27, 28 and 31 it was only possible to test the 5'-primer, the 3'-primers were not possible to test.

In primer solutions 6, 22, 24 to 26 two or three of the 3'-primers were not possible to test.

In addition, one 3'-primer in primer solution 1 was tested separately by adding one additional 5'-primer.



**0197**

For *In Vitro* Diagnostic Use  
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101.122-24/06 – including *Taq* polymerase  
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“Instructions for Use” (IFU)

Lot No.: **8R9**

Lot-specific information

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



**0197**

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