

101.121-24/04 – including *Taq* polymerase  
101.121-24u/04u – without *Taq* polymerase

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“Instructions for Use” (IFU)

Lot No.: **2S6**

Lot-specific information

## Olerup SSP® DRB3

<b>Product number:</b>	101.121-24/04 – including <i>Taq</i> pol. 101.121-24u/04u – without <i>Taq</i> pol.
<b>Lot number:</b>	2S6
<b>Expiry date:</b>	2027-07-01
<b>Number of tests:</b>	24 tests – Product No. 101.121-24/24u 4 tests – Product No. 101.121-04/04u
<b>Number of wells per test:</b>	47+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. 2S6.**

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

### CHANGES COMPARED TO THE PREVIOUS OLERUP SSP® DRB3 Lot (7N9)

- 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 DRB3 specificity and interpretation tables have been updated for the DRB alleles described since the previous *Olerup SSP®* DRB3 lot (**Lot No. 7N9**) was made.

The DRB3 primer set is unchanged compared to the previous *Olerup SSP®* DRB3 (**Lot No. 7N9**).

<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



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Well **48** contains Negative Control primer pairs, that will amplify the majority of the *Olerup* SSP<sup>®</sup> 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>
							<b>36</b>
							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>
							<b>48</b>
							5'-gCA <sup>3'</sup>
							<b>48</b>
							5'-gCC <sup>3'</sup>
							<b>52</b>
							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.



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## PRODUCT DESCRIPTION

### DRB3 SSP subtyping

#### CONTENT

The primer set contains 5'- and 3'-primers for identifying the DRB3\*01:01 to DRB3\*03:62 alleles.

#### PLATE LAYOUT

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

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

The 48 well cut PCR plate is marked with ‘DRB3’ in silver/gray ink.

Well No. 1 is marked with the Lot No. ‘2S6’.

Wells 1 to 47 – DRB3 high resolution primers.

Well 48 – Negative Control (NC).

A faint row of numbers is seen between wells 1 and 2 or wells 7 and 8 of the PCR trays. These stem from the manufacture of the trays, and should be disregarded.

The PCR plates are covered with a PCR-compatible foil.

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

#### INTERPRETATION

Due to the sharing of sequence motifs between DRB3, DRB1 and DRB4 alleles some primer mixes will amplify DRB1 and DRB4 alleles. For further details see Specificity Table.

#### UNIQUELY IDENTIFIED ALLELES

All the DRB3 alleles, i.e. **DRB3\*01:01 to DRB3\*01:114, DRB3\*02:01 to DRB3\*02:191 and DRB3\*03:01 to DRB3\*03:62**, recognized by the HLA Nomenclature Committee in April 2023<sup>1,2</sup> will be amplified by the primers in the DRB3 subtyping kit.

The DRB3 kit enables separation of the confirmed DRB3 alleles as listed in the IMGT/HLA database 3.34.0. An HLA allele is listed as confirmed by IMGT/HLA if



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it has been sequenced by more than a single laboratory or from multiple sources. Current allele confirmation status for DRB3 alleles is listed below.

The DRB3 kit also enables identification of many null and alternatively expressed alleles.

The following DRB3 alleles can be distinguished by the different sizes of the HLA-specific PCR product:

Alleles	Primer mix
DRB3*02:12, 02:67N	22
DRB3*02:32, 02:34	38

<sup>1</sup>DRB 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>.

## RESOLUTION IN HOMO- AND HETEROZYGOTES

Results file with resolution in DRB3 homo- and heterozygotes is available upon request.



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**ALLELE CONFIRMATION STATUS**

Allele	Status <sup>1</sup>	Allele	Status <sup>1</sup>	Allele	Status <sup>1</sup>	Allele	Status <sup>1</sup>
DRB3*01:01:02:01	Confirmed	DRB3*01:43	Unconfirmed	DRB3*02:30	Confirmed	DRB3*02:79	Unconfirmed
DRB3*01:01:02:02	Confirmed	DRB3*01:44	Unconfirmed	DRB3*02:31:01	Unconfirmed	DRB3*02:80N	Unconfirmed
DRB3*01:01:03	Confirmed	DRB3*01:45	Confirmed	DRB3*02:31:02	Confirmed	DRB3*02:81	Unconfirmed
DRB3*01:01:04	Unconfirmed	DRB3*01:46	Unconfirmed	DRB3*02:32	Confirmed	DRB3*03:01:01	Confirmed
DRB3*01:01:05	Confirmed	DRB3*01:47	Unconfirmed	DRB3*02:33	Confirmed	DRB3*03:01:02	Unconfirmed
DRB3*01:01:06	Unconfirmed	DRB3*01:48	Unconfirmed	DRB3*02:34	Confirmed	DRB3*03:01:03	Confirmed
DRB3*01:01:07	Unconfirmed	DRB3*01:49	Unconfirmed	DRB3*02:35	Confirmed	DRB3*03:01:04	Unconfirmed
DRB3*01:01:08	Unconfirmed	DRB3*02:01	Confirmed	DRB3*02:36	Confirmed	DRB3*03:01:05	Confirmed
DRB3*01:02	Unconfirmed	DRB3*02:02:01:01	Confirmed	DRB3*02:37	Confirmed	DRB3*03:02	Unconfirmed
DRB3*01:03	Unconfirmed	DRB3*02:02:01:02	Unconfirmed	DRB3*02:38	Unconfirmed	DRB3*03:03	Confirmed
DRB3*01:04	Unconfirmed	DRB3*02:02:02	Unconfirmed	DRB3*02:39	Confirmed	DRB3*03:04	Confirmed
DRB3*01:05	Unconfirmed	DRB3*02:02:03	Unconfirmed	DRB3*02:40	Unconfirmed	DRB3*03:05	Confirmed
DRB3*01:06	Unconfirmed	DRB3*02:02:04	Unconfirmed	DRB3*02:41	Unconfirmed	DRB3*03:06	Confirmed
DRB3*01:07	Unconfirmed	DRB3*02:02:05	Unconfirmed	DRB3*02:42	Unconfirmed	DRB3*03:07	Unconfirmed
DRB3*01:08	Unconfirmed	DRB3*02:02:06	Confirmed	DRB3*02:43	Confirmed	DRB3*03:08	Confirmed
DRB3*01:09	Unconfirmed	DRB3*02:02:07	Unconfirmed	DRB3*02:44	Unconfirmed	DRB3*03:09	Unconfirmed
DRB3*01:10	Unconfirmed	DRB3*02:02:08	Confirmed	DRB3*02:45	Unconfirmed	DRB3*03:10	Unconfirmed
DRB3*01:11	Unconfirmed	DRB3*02:02:09	Confirmed	DRB3*02:46	Unconfirmed	DRB3*03:11	Unconfirmed
DRB3*01:12	Unconfirmed	DRB3*02:02:10	Confirmed	DRB3*02:47	Confirmed	DRB3*03:12	Unconfirmed
DRB3*01:13	Unconfirmed	DRB3*02:02:11	Unconfirmed	DRB3*02:48	Confirmed	DRB3*03:13	Unconfirmed
DRB3*01:14	Unconfirmed	DRB3*02:02:12	Unconfirmed	DRB3*02:49	Unconfirmed	DRB3*03:14	Unconfirmed
DRB3*01:15	Unconfirmed	DRB3*02:02:13	Unconfirmed	DRB3*02:50	Confirmed	DRB3*03:15	Confirmed
DRB3*01:16	Confirmed	DRB3*02:03	Unconfirmed	DRB3*02:51	Confirmed	DRB3*03:16	Unconfirmed
DRB3*01:17	Unconfirmed	DRB3*02:04	Unconfirmed	DRB3*02:52	Unconfirmed	DRB3*03:17	Unconfirmed
DRB3*01:18	Confirmed	DRB3*02:05	Unconfirmed	DRB3*02:53	Unconfirmed	DRB3*03:18	Unconfirmed
DRB3*01:19	Unconfirmed	DRB3*02:06	Unconfirmed	DRB3*02:54	Unconfirmed		
DRB3*01:20	Unconfirmed	DRB3*02:07	Unconfirmed	DRB3*02:55N	Confirmed		
DRB3*01:21	Unconfirmed	DRB3*02:08	Unconfirmed	DRB3*02:56	Confirmed		
DRB3*01:22	Unconfirmed	DRB3*02:09	Confirmed	DRB3*02:57	Confirmed		
DRB3*01:23	Confirmed	DRB3*02:10	Confirmed	DRB3*02:58	Unconfirmed		
DRB3*01:24	Unconfirmed	DRB3*02:11	Unconfirmed	DRB3*02:59	Unconfirmed		
DRB3*01:25	Unconfirmed	DRB3*02:12	Unconfirmed	DRB3*02:60	Confirmed		
DRB3*01:26N	Confirmed	DRB3*02:13	Unconfirmed	DRB3*02:61Q	Unconfirmed		
DRB3*01:27	Unconfirmed	DRB3*02:14	Confirmed	DRB3*02:62	Unconfirmed		
DRB3*01:28	Unconfirmed	DRB3*02:15	Confirmed	DRB3*02:63	Unconfirmed		
DRB3*01:29	Unconfirmed	DRB3*02:16	Unconfirmed	DRB3*02:64	Unconfirmed		
DRB3*01:30	Confirmed	DRB3*02:17	Confirmed	DRB3*02:65	Unconfirmed		
DRB3*01:31	Confirmed	DRB3*02:18	Unconfirmed	DRB3*02:66	Unconfirmed		
DRB3*01:32	Unconfirmed	DRB3*02:19	Unconfirmed	DRB3*02:67N	Unconfirmed		
DRB3*01:33	Unconfirmed	DRB3*02:20	Confirmed	DRB3*02:68	Unconfirmed		
DRB3*01:34	Confirmed	DRB3*02:21	Unconfirmed	DRB3*02:69	Unconfirmed		
DRB3*01:35	Confirmed	DRB3*02:22:01	Unconfirmed	DRB3*02:70	Confirmed		
DRB3*01:36	Unconfirmed	DRB3*02:22:02	Confirmed	DRB3*02:71	Unconfirmed		
DRB3*01:37	Confirmed	DRB3*02:23	Unconfirmed	DRB3*02:72	Unconfirmed		
DRB3*01:38	Unconfirmed	DRB3*02:24	Confirmed	DRB3*02:73	Confirmed		
DRB3*01:39	Unconfirmed	DRB3*02:25	Unconfirmed	DRB3*02:74	Unconfirmed		
DRB3*01:40:01N	Unconfirmed	DRB3*02:26	Unconfirmed	DRB3*02:75	Unconfirmed		
DRB3*01:40:02N	Confirmed	DRB3*02:27	Unconfirmed	DRB3*02:76	Unconfirmed		
DRB3*01:41	Unconfirmed	DRB3*02:28	Unconfirmed	DRB3*02:77	Unconfirmed		
DRB3*01:42	Unconfirmed	DRB3*02:29N	Confirmed	DRB3*02:78	Confirmed		

<sup>1</sup>Allele status “confirmed” or “unconfirmed” as listed on the IMGT/HLA web page 2018-October-18, release 3.34.0, [www.ebi.ac.uk/imgt/hla](http://www.ebi.ac.uk/imgt/hla).



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## SPECIFICITY TABLE

### DRB3 SSP subtyping

Specificities and sizes of the PCR products of the 47+1 primer mixes used for DRB3 SSP subtyping

Primer Mix	Size of spec. PCR product <sup>1</sup>	Size of control band <sup>2</sup>	Amplified DRB3 alleles <sup>3</sup>	Amplified DRB1 alleles
1 <sup>4</sup>	100 bp	515 bp	*01:01:02:01-01:08, 01:10-01:13, 01:15-01:21, 01:23, 01:25, 01:27-01:55, 01:57-01:114, 02:05:01-02:05:02, 02:38, 02:112, 02:130, 03:01:01:01-03:01:15, 03:03-03:19, 03:21, 03:23-03:54, 03:57Q-03:62	*03:42, 03:87, 11:30 <sup>w</sup> , 12:57, 13:67, 13:195, 14:46, 14:247
2 <sup>4</sup>	125 bp	430 bp	*01:01:02:01-01:01:07, 01:01:09-01:06, 01:08, 01:10-01:14, 01:16-01:36, 01:38-01:40:02N, 01:43-01:49, 01:51-01:54, 01:57-01:74, 01:77N-01:114, 03:01:01:01-03:01:09, 03:01:11, 03:01:13-03:01:15, 03:03-03:08, 03:10-03:17, 03:19-03:21, 03:24-03:35, 03:37-03:54, 03:57Q-03:58, 03:60-03:62	*03:38, 03:79, 03:85, 03:96, *04:82 <sup>w</sup> , 04:99 <sup>w</sup> , 07:09 <sup>w</sup> , 08:07 <sup>w</sup> , 08:19 <sup>w</sup> , 08:25 <sup>w</sup> , 08:34 <sup>w</sup> , 08:52 <sup>w</sup> , 08:113 <sup>w</sup> , 12:27 <sup>w</sup> , 12:57, 13:31 <sup>w</sup> , 13:46 <sup>w</sup> , 13:54 <sup>w</sup> , 13:77 <sup>w</sup> , 13:100 <sup>w</sup> , 13:162 <sup>w</sup> , 13:180 <sup>w</sup> , 13:260 <sup>w</sup> , 13:330 <sup>w</sup> , 14:48 <sup>w</sup> , 14:174 <sup>w</sup> , 14:177 <sup>w</sup> , 15:135
3 <sup>4</sup>	95 bp	430 bp	*01:01:02:01-01:02, 01:04-01:08, 01:10-01:13, 01:15-01:21, 01:23, 01:27 <sup>w</sup> , 01:28-01:38, 01:40:01N-01:40:02N, 01:42-01:55, 01:57-01:66, 01:68-01:70, 01:72-01:114	*03:42
4 <sup>7</sup>	240 bp	430 bp		*08:09:02, 11:03:04, 11:04:17, 11:13:01-11:13:02, 11:17, 11:149, 11:202, 11:264, 13:01:27, 13:02:21, 13:08, 14:01:01:01-14:01:01:03, 14:01:02 <sup>?</sup> -14:01:04 <sup>?</sup> , 14:01:05, 14:02:02 <sup>?</sup> -14:02:03 <sup>?</sup> , 14:02:06 <sup>?</sup> , 14:04:01:01-14:04:01:03, 14:04:02 <sup>?</sup> -14:04:03 <sup>?</sup> , 14:04:04-14:04:06, 14:04:09-14:05:01:04, 14:05:02 <sup>?</sup> -14:05:04 <sup>?</sup> , 14:05:05, 14:06:02 <sup>?</sup> -14:06:03 <sup>?</sup> , 14:07:01, 14:07:02 <sup>?</sup> , 14:07:03-14:08, 14:10:01:01-14:11:01:02, 14:12:02 <sup>?</sup> , 14:14-14:15, 14:16 <sup>?</sup> , 14:18, 14:19 <sup>?</sup> -14:20 <sup>?</sup> , 14:22 <sup>?</sup> , 14:23:01:01-14:23:01:03, 14:23:02 <sup>?</sup> -14:23:04 <sup>?</sup> , 14:25:01 <sup>?</sup> -14:41 <sup>?</sup> ,



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				14:43 <sup>?</sup> -14:45 <sup>?</sup> , 14:48 <sup>?</sup> -14:52 <sup>?</sup> , 14:54:01:01-14:54:06, 14:54:08- 14:54:12, 14:55 <sup>?</sup> -14:56 <sup>?</sup> , 14:57, 14:58 <sup>?</sup> - 14:65 <sup>?</sup> , 14:67 <sup>?</sup> -14:69 <sup>?</sup> , 14:70, 14:71 <sup>?</sup> - 14:81 <sup>?</sup> , 14:82, 14:83 <sup>?</sup> -14:110 <sup>?</sup> , 14:111, 14:112 <sup>?</sup> -14:136 <sup>?</sup> , 14:137N, 14:138 <sup>?</sup> - 14:140 <sup>?</sup> , 14:141, 14:142 <sup>?</sup> -14:143 <sup>?</sup> , 14:145 <sup>?</sup> -14:151 <sup>?</sup> , 14:152N, 14:153 <sup>?</sup> - 14:161 <sup>?</sup> , 14:162, 14:163 <sup>?</sup> -14:170 <sup>?</sup> , 14:171, 14:172 <sup>?</sup> -14:176 <sup>?</sup> , 14:178 <sup>?</sup> - 14:190 <sup>?</sup> , 14:191-14:193, 14:196- 14:197N, 14:199, 14:201-14:202, 14:203 <sup>?</sup> , 14:204-14:207, 14:210Q- 14:211, 14:213-14:217, 14:219, 14:220 <sup>?</sup> , 14:222N <sup>?</sup> , 14:224, 14:225 <sup>?</sup> , 14:227- 14:228, 14:229 <sup>?</sup> , 14:230-14:238, 14:239 <sup>?</sup> , 14:240-14:241, 14:243-14:247, 14:248 <sup>?</sup> , 14:249, 14:250 <sup>?</sup> -14:251 <sup>?</sup> , 14:253
<b>5<sup>4</sup></b>	95 bp 125 bp	430 bp	*01:03, 01:71 *01:10	*14:46
<b>6</b>	190 bp	430 bp	*01:04	
<b>7<sup>4,6</sup></b>	90 bp 150 bp 180 bp	<b>515 bp</b>	*01:05 *01:23, 01:46 *01:07, 01:15, 01:50, 01:75 <sup>w</sup> , 01:76, 02:42	*03:42 *03:42, 14:46
<b>8<sup>4</sup></b>	120 bp 150 bp	430 bp	*01:06, 01:08, 01:46, 01:71 *01:23, 01:46	*03:42, 14:46 *03:42
<b>9<sup>5</sup></b>	165 bp	<b>515 bp</b>	*01:07, 01:21, 01:41, 01:50, 01:76, 02:01-02:08, 02:11- 02:37, 02:39-02:43, 02:45- 02:77, 02:79-02:80:02N, 02:82, 02:84-02:92, 02:94- 02:99, 02:101-02:103, 02:105, 02:107-02:114, 02:116-02:118, 02:120- 02:130, 02:132-02:145N, 02:147-02:170, 02:172, 02:174-02:191, 03:17	*14:141
<b>10<sup>5,7</sup></b>	185 bp	<b>515 bp</b>	*01:09, 02:01-02:04, 02:06- 02:14, 02:16-02:26, 02:28- 02:37, 02:39-02:57, 02:59- 02:110, 02:113-02:129, 02:132-02:136, 02:138- 02:159, 02:161-02:162, 02:164-02:191, 03:02, 03:55-03:56	*03:101, 03:120, 12:22, 12:88, 14:141
<b>11<sup>6</sup></b>	270 bp	<b>515 bp</b>	*01:34, 02:01, 02:04, 02:24, 02:48, 02:58, 02:89, 02:103-02:104, 02:141, 02:171, 02:173:01- 02:173:02, 02:175, 02:181,	*03:42, 03:87, 11:288, 12:57, 14:247, <b>DRB4*01:105</b>



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			03:01:01:01-03:02, 03:04:01-03:05, 03:07- 03:21, 03:23-03:55, 03:57Q-03:62	
<b>12<sup>4</sup></b>	90 bp 145 bp	<b>515 bp</b>	*02:17 *02:01, 02:04, 02:24, 02:48, 02:58, 02:89, 02:103, 02:141, 02:175, 02:181, 03:17	*03:37, 03:80, 03:140, 04:183, 11:43:01:01-11:43:01:02, 11:50, 11:115, 11:151, 11:171, 11:174, 12:34, 13:131, 13:150, 13:262, 14:59, 14:86, 14:96, 14:145, 14:153-14:154, 14:251, 15:65
<b>13<sup>5</sup></b>	270 bp	<b>515 bp</b>	*01:01:02:01-01:13, 01:15- 01:33, 01:35-01:114, 02:02:01:01-02:03, 02:05:01-02:13, 02:15- 02:23, 02:25-02:47, 02:49- 02:57, 02:59-02:77, 02:79- 02:88, 02:90-02:102, 02:105-02:140, 02:142- 02:170, 02:172, 02:174, 02:176-02:180, 02:182- 02:191, 03:03, 03:06, 03:56	*11:30, 13:67, 13:195, 14:46, 14:141
<b>14</b>	185 bp	<b>515 bp</b>	*01:07, 01:09, 02:02:01:01- 02:02:18, 02:02:20- 02:02:35, 02:05:01- 02:05:02, 02:07-02:13, 02:15-02:19, 02:21-02:23, 02:25-02:36, 02:39-02:47, 02:49, 02:53-02:57, 02:60, 02:62-02:69, 02:71-02:82, 02:84-02:88, 02:90-02:99, 02:101-02:102, 02:105- 02:106, 02:108-02:111, 02:113-02:114, 02:116- 02:118, 02:121N-02:135, 02:137N-02:139, 02:142- 02:170, 02:172, 02:174, 02:176-02:180, 02:182- 02:191	*10:01:01:01 <sup>w</sup> , 10:01:01:03 <sup>w</sup> -10:01:18 <sup>w</sup> , 10:03 <sup>w</sup> -10:11 <sup>w</sup> , 10:13 <sup>w</sup> , 10:15 <sup>w</sup> -10:16 <sup>w</sup> , 10:18 <sup>w</sup> -10:34 <sup>w</sup> , 10:36 <sup>w</sup> -10:46 <sup>w</sup> , 13:216, 14:141, 15:212, 16:30
<b>15<sup>4</sup></b>	265 bp 120 bp	<b>430 bp</b>	*01:02 *02:03, 02:38, 02:50, 02:100, 02:115, 02:119, 03:01:01:01-03:09, 03:11, 03:13-03:21, 03:23-03:34, 03:36-03:40, 03:42-03:45, 03:47-03:62	*12:57, 13:195, 14:247
<b>16</b>	180 bp 210 bp 150 bp	<b>430 bp</b>	*02:16 *02:17 *01:09, 02:04, 02:19, 02:22:01-02:22:02, 02:56, 02:146	*14:247 *03:44



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17 <sup>4</sup>	120 bp	430 bp	*01:08, 01:46, 01:71, 02:06, 02:20, 03:10	*03:42, 03:87, 13:67, 14:46
	180 bp		*02:16, 02:23	*14:247
18 <sup>4</sup>	100 bp	430 bp	*01:09, 02:07, 02:09, 02:21, 02:44, 02:56, 02:89, 02:146, 02:171, 02:173:01-02:173:02, 03:41	
	170 bp		*01:18	
19 <sup>6</sup>	180 bp	<b>515 bp</b>	*01:42, 02:08, 02:18, 02:23, 02:131	*11:30, 11:288
	270 bp		*02:14	
20	175 bp	430 bp	*01:01:02:01-01:06, 01:08-01:13, 01:15-01:20, 01:22-01:28, 01:30-01:34, 01:36-01:40:02N, 01:42-01:49, 01:51-01:75, 01:77N-01:114, 02:09-02:10, 02:16, 02:38, 02:44, 02:81, 02:83, 02:100, 02:104, 02:106, 02:115, 02:119, 02:131, 02:146, 02:171, 02:173:01-02:173:02, 03:01:01:01-03:06, 03:08-03:16, 03:18-03:21, 03:23-03:24, 03:26-03:53, 03:55-03:62	*03:42, 03:87, 11:30, 11:288, 12:57, 13:67, 13:195, 14:46, 14:247, <b>DRB4*01:105</b>
21 <sup>4</sup>	120 bp	430 bp	*01:13	<b>DRB4*01:105</b>
	155 bp		*02:43, 02:141	
	210 bp		*01:19, 01:31, 02:11, 03:15	
22 <sup>4,6</sup>	80 bp	430 bp	*02:67N	
	185 bp		*01:11	
	240 bp		*01:02, 02:12, 03:46	
23	195 bp	430 bp	*02:13	
	240 bp		*01:02, 03:46	
24	185 bp	430 bp	*01:67, 02:09, 02:18-02:19, 02:21, 02:25, 02:48, 02:56, 02:89, 02:100, 02:146, 02:171, 02:173:01-02:173:02, 03:01:01:01-03:15, 03:17-03:21, 03:23-03:45, 03:47-03:54, 03:56-03:62	*11:30, 11:288, 12:57
25	150 bp	430 bp	*02:60	
	220 bp		*01:19, 02:26, 02:143	
	260 bp		*01:12, 02:31:01	
26	235 bp	430 bp	*01:14	*03:01:02:01-03:01:02:02, 03:02:02, 03:05:03, 03:11:03, 03:13:02, 03:17, 03:24, 03:27, 03:35, 03:81, 03:130, 03:167, 03:188, 08:67, 11:07:02, 11:27:01, 11:27:04, 11:84:01, 11:124:01, 11:136, 11:138, 12:22, 12:88, 13:33:02-13:33:03, 13:61:01, 13:94:02, 13:96:02, :38:01, 14:47,



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				14:50:01, 14:98, 14:127:01, 14:165, 14:244
27 <sup>4</sup>	90 bp	430 bp	*02:01	
28 <sup>4</sup>	110 bp	430 bp	*02:36	
	235 bp		*02:27, 02:111, 02:160	*11:30, 11:288, 12:57, 13:67, 13:195, 14:46
	260 bp		*01:12, 01:40:02N, 02:31:01, 02:55N	
29 <sup>7</sup>	160 bp	430 bp	*02:15, 02:27, 02:58, 02:111, 02:131, 02:137N, 02:160	*10:01:01:01 <sup>w</sup> , 10:01:01:03 <sup>w</sup> -10:01:04 <sup>w</sup> , 10:01:05, 10:01:06 <sup>w</sup> -10:06 <sup>w</sup> , 10:08 <sup>w</sup> -10:10 <sup>w</sup> , 10:12 <sup>w</sup> -10:13 <sup>w</sup> , 10:15 <sup>w</sup> -10:16 <sup>w</sup> , 10:18 <sup>w</sup> -10:46 <sup>w</sup> , 13:106, 13:216, 14:221, 15:212, 16:30
30	210 bp	430 bp	*02:28	
31 <sup>4</sup>	70 bp	430 bp	*01:21, 02:19, 02:21, 02:25, 02:48, 02:56, 02:89, 03:17	*12:34
	95 bp		*01:16, 02:29N	*01:77 <sup>w</sup> , 01:119 <sup>w</sup>
32 <sup>4</sup>	85 bp	430 bp	*01:39, 01:41, 01:67, 02:130, 03:33	*03:87
	230 bp		*01:67, 02:04, 02:19, 02:22:01-02:22:02, 02:56, 02:146, 03:03-03:04:02	*03:87
33 <sup>7</sup>	150 bp	430 bp	*01:32, 01:39, 01:41, 01:50, 02:37-02:38, 02:50, 02:83, 02:100, 02:107, 02:112, 02:115, 02:119, 03:01:01:01-03:02, 03:05-03:09, 03:11-03:21, 03:23-03:34, 03:36-03:40, 03:42-03:49, 03:51-03:61	*03:35, 07:04, 14:38:01-14:38:02, 14:50:01-14:50:02, 14:93, 14:127:01-14:127:02, 14:244
	180 bp		*01:20	
34 <sup>5</sup>	130 bp	515 bp	*01:43, 02:139	
	170 bp		*03:05	*04:148, 15:64
35 <sup>4</sup>	115 bp	430 bp	*02:51	
	250 bp		*01:17, 02:33, 02:127	
36 <sup>4</sup>	105 bp	430 bp	*01:22	
	155 bp		*02:43, 02:141	<b>DRB4*01:105</b>
	185 bp		*01:35, 02:35, 03:25	
37	155 bp	430 bp	*02:30	
	215 bp		*01:31, 01:45, 01:109, 02:11, 02:47, 02:97, 03:15	
38 <sup>4,5</sup>	70 bp	430 bp	*02:32, 02:81, 02:146	*03:44, 10:13, 13:106, 14:221, 15:212
	205 bp		*01:07 <sup>?</sup> , 02:02:02 <sup>?</sup> , 02:05:01 <sup>?</sup> , 02:07 <sup>?</sup> -02:08 <sup>?</sup> , 02:34	
39	190 bp	430 bp	*02:39	
	260 bp		*01:40:01N	
40	130 bp	430 bp	*03:13	
	190 bp		*01:07, 01:15, 01:30, 01:42, 01:49-01:50, 01:76, 02:42	*03:42, 14:46



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41 <sup>4</sup>	110 bp 140 bp	430 bp	*02:36 *02:57, 02:60
42	165 bp 205 bp 230 bp	430 bp	*02:61Q *01:37, 03:08 *02:73
43 <sup>8</sup>	140 bp	430 bp	*02:47
44 <sup>4</sup>	100 bp 195 bp 260 bp	430 bp	*01:26N *02:80:01N *01:40:02N, 02:55N
45 <sup>4</sup>	70 bp	430 bp	*02:31:02
46 <sup>6</sup>	145 bp	430 bp	*02:70, 02:175, 03:35
47	245 bp	430 bp	*02:78
48 <sup>9</sup>	-	-	<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 DRB3 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.

<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.

<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 mixes 9, 10, 13, 34 and 38 may have tendencies of unspecific amplifications.

<sup>6</sup>Primer mixes 7, 11, 19, 22 and 46 have a tendency giving rise to primer oligomer formation.

<sup>7</sup>Primer mixes 4, 10, 29 and 33 may give rise to a lower yield of HLA-specific PCR product than the other DRB3 primer mixes.

<sup>8</sup>In primer mix 43 the positive control band may be weaker than for other DRB3 primer mixes.

<sup>9</sup>Primer mix 48 contains a negative control, which will amplify the majority of HLA amplicons as well as the amplicons generated by the control primer pairs matching the human growth hormone gene. HLA-



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

Abbreviations

w: might be weakly amplified.

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



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### PRIMER SPECIFICATION

Well No.	1	2	3	4	5	6	7	8	9	10	11	12
Length of spec. PCR product	100	125	95	240	95	190	90	120	165	185	270	90
					125		150	150				145
							180					
Length of int. pos. control <sup>1</sup>	515	430	430	430	430	430	515	430	515	515	515	515
5'-primer(s) <sup>2</sup>	10(116) 5'-gCT <sup>3'</sup>	30(175) 5'-gAT <sup>3'</sup>	11(119) 5'-gCg <sup>3'</sup>	114(429) 5'-CTg <sup>3'</sup>	11(119) 5'-gCg <sup>3'</sup>	8(110) 5'-CTC <sup>3'</sup>	11(119) 5'-gCg <sup>3'</sup>	11(119) 5'-gCg <sup>3'</sup>	10(116) 5'-gCT <sup>3'</sup>	30(175) 5'-gAC <sup>3'</sup>	10(116) 5'-gCT <sup>3'</sup>	51(239) 5'-gAg <sup>3'</sup>
		30(175) 5'-gAT <sup>3'</sup>	11(119) 5'-gTg <sup>3'</sup>						10(116) 5'-gCT <sup>3'</sup>			
3'-primer(s) <sup>3</sup>	30(175) 5'-gTA <sup>3'</sup>	57(257) 5'-CgA <sup>3'</sup>	28(171) 5'-CTg <sup>3'</sup>	181(630) 5'-CTT <sup>3'</sup>	28(171) 5'-CTC <sup>3'</sup>	57(257) 5'-CgA <sup>3'</sup>	28(169) 5'-gTT <sup>3'</sup>	38(199) 5'-CAC <sup>3'</sup>	51(239) 5'-CCC <sup>3'</sup>	77(317) 5'-AgT <sup>3'</sup>	86(344) 5'-CCA <sup>3'</sup>	67(286) 5'-gAA <sup>3'</sup>
	30(175) 5'-gTA <sup>3'</sup>	57(257) 5'-CAA <sup>3'</sup>	28(171) 5'-ATg <sup>3'</sup>		39(202) 5'-gCT <sup>3'</sup>		47(227) 5'-ggA <sup>3'</sup>	47(227) 5'-ggA <sup>3'</sup>		77(318) 5'-TAA <sup>3'</sup>		86(344) 5'-CCA <sup>3'</sup>
							57(257) 5'-CAT <sup>3'</sup>					
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	270	185	120	150	120	100	180	175	120	80	195	185
		265	180		180	170	270		155	185	240	
			210						210	240		
Length of int. pos. control <sup>1</sup>	515	515	430	430	430	430	515	430	430	430	430	430
5'-primer(s) <sup>2</sup>	10(116) 5'-gCT <sup>3'</sup>	11(118) 5'-TgT <sup>3'</sup>	11(119) 5'-gCT <sup>3'</sup>	38(200) 5'-CgC <sup>3'</sup>	10(116) 5'-gCT <sup>3'</sup>	15(130) 5'-Agg <sup>3'</sup>	10(116) 5'-gCT <sup>3'</sup>	10(116) 5'-gCT <sup>3'</sup>	10(116) 5'-gCT <sup>3'</sup>	9(112) 5'-TgC <sup>3'</sup>	11(118) 5'-TgT <sup>3'</sup>	11(119) 5'-gCT <sup>3'</sup>
	10(116) 5'-gCT <sup>3'</sup>	38(200) 5'-CgC <sup>3'</sup>				38(200) 5'-CgC <sup>3'</sup>				11(118) 5'-TgT <sup>3'</sup>	11(119) 5'-gTg <sup>3'</sup>	
		38(200) 5'-CgC <sup>3'</sup>								11(119) 5'-gTg <sup>3'</sup>	26(163) 5'-ggC <sup>3'</sup>	
										29(173) 5'-CAT <sup>3'</sup>		
										64(277) 5'-gCT <sup>3'</sup>		
3'-primer(s) <sup>3</sup>	86(344) 5'-CAC <sup>3'</sup>	86(344) 5'-CAC <sup>3'</sup>	37(197) 5'-Cgg <sup>3'</sup>	74(308) 5'-CCC <sup>3'</sup>	37(196) 5'-gTT <sup>3'</sup>	57(257) 5'-CgA <sup>3'</sup>	55(251) 5'-gCA <sup>3'</sup>	51(239) 5'-CCg <sup>3'</sup>	37(196) 5'-gAg <sup>3'</sup>	77(318) 5'-TAA <sup>3'</sup>	77(318) 5'-TAA <sup>3'</sup>	58(260) 5'-CCT <sup>3'</sup>
			37(197) 5'-CgA <sup>3'</sup>		37(196) 5'-gTT <sup>3'</sup>		57(256) 5'-gCT <sup>3'</sup>	57(257) 5'-CAg <sup>3'</sup>	48(230) 5'-CCT <sup>3'</sup>			60(266) 5'-Agg <sup>3'</sup>
			57(257) 5'-CAg <sup>3'</sup>		55(251) 5'-gCA <sup>3'</sup>		58(260) 5'-CCT <sup>3'</sup>	58(261) 5'-TCC <sup>3'</sup>	67(286) 5'-gAT <sup>3'</sup>			
			67(286) 5'-gAA <sup>3'</sup>		57(257) 5'-CAg <sup>3'</sup>		86(344) 5'-CAg <sup>3'</sup>		69(294) 5'-TgA <sup>3'</sup>			
Well No.	13	14	15	16	17	18	19	20	21	22	23	24



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Well No.	25	26	27	28	29	30	31	32	33	34	35	36
Length of spec.	150	235	90	110	160	210	70	85	150	130	115	105
PCR product	220			235			95	230	180	170	250	155
	260			260								185
Length of int. pos. control <sup>1</sup>	430	430	430	430	430	430	430	430	430	515	430	430
5'-primer(s) <sup>2</sup>	10(116) 5'-gCT 3'	12(122) 5'-TAC 3'	164(577) 5'-CAT 3'	10(116) 5'-gCT 3'	38(200) 5'-CgC 3'	123(455) 5'-CTg 3'	51(239) 5'-gAg 3'	11(119) 5'-gCT 3'	37(197) 5'-gTT 3'	44(217) 5'-ACA 3'	10(116) 5'-gCT 3'	10(116) 5'-gCT 3'
							149(534) 5'-CAg 3'			149(534) 5'-CAg 3'		
3'-primer(s) <sup>3</sup>	46(224) 5'-ACA 3'	77(317) 5'-AAT 3'	179(624) 5'-ACg 3'	33(186) 5'-TgC 3'	77(317) 5'-Agg 3'	179(624) 5'-ACg 3'	60(266) 5'-Agg 3'	26(164) 5'-ggT 3'	74(308) 5'-CCT 3'	86(344) 5'-CCA 3'	34(188) 5'-CCC 3'	31(180) 5'-TgC 3'
	69(294) 5'-TgA 3'			74(308) 5'-CCg 3'			166(583) 5'-CCg 3'	74(308) 5'-CCC 3'	84(338) 5'-CCA 3'	180(625) 5'-TAT 3'	77(316) 5'-ATC 3'	48(230) 5'-CCT 3'
	71(299) 5'-gCC 3'			83(336) 5'-CCC 3'			170(595) 5'-AAA 3'				81(329) 5'-Tgg 3'	55(251) 5'-gCA 3'
	84(337) 5'-CCg 3'			84(337) 5'-CCg 3'								61(270) 5'-TTA 3'
Well No.	25	26	27	28	29	30	31	32	33	34	35	36

Well No.	37	38	39	40	41	42	43	44	45	46	47
Length of spec.	155	70	190	130	110	165	140	100	70	145	245
PCR product	215	205	260	190	140	205		195			
						230		260			
Length of int. pos. control <sup>1</sup>	430	430	430	430	430	430	430	430	430	430	430
5'-primer(s) <sup>2</sup>	10(116) 5'-gCT 3'	15(130) 5'-AgC 3'	10(116) 5'-gCT 3'	11(119) 5'-gCg 3'	10(116) 5'-gCT 3'	15(130) 5'-AgC 3'	38(200) 5'-CgC 3'	10(116) 5'-gCT 3'	84(337) 5'-ACA 3'	38(200) 5'-CgT 3'	9(114) 5'-gAT 3'
		38(200) 5'-CgC 3'		152(542) 5'-AgT 3'		20(146) 5'-TgA 3'					
						24(157) 5'-ggT 3'					
						37(196) 5'-..T 3'					
3'-primer(s) <sup>3</sup>	48(230) 5'-CCg 3'	47(227) 5'-ggA 3'	60(265) 5'-gTC 3'	60(266) 5'-AgT 3'	33(186) 5'-TgC 3'	77(318) 5'-TAA 3'	72(301) 5'-CCA 3'	30(177) 5'-AAT 3'	93(364) 5'-CCg 3'	73(305) 5'-ggC 3'	77(317) 5'-AAT 3'
	64(278) 5'-TCC 3'	93(365) 5'-gCg 3'	83(336) 5'-CCT 3'	181(630) 5'-CTT 3'	40(207) 5'-TCC 3'			61(270) 5'-TTT 3'			
	67(286) 5'-gAT 3'				46(224) 5'-ACA 3'			83(336) 5'-CCC 3'			
	72(301) 5'-CCA 3'										
Well No.	37	38	39	40	41	42	43	44	45	46	47

<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.



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

101.121-24/04 – including *Taq* polymerase  
101.121-24u/04u – without *Taq* polymerase

Visit [www.caredx.com](http://www.caredx.com) for  
“Instructions for Use” (IFU)

Lot No.: **2S6**

Lot-specific information

<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

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

101.121-24/04 – including *Taq* polymerase  
101.121-24u/04u – without *Taq* polymerase

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Lot No.: **2S6**

Lot-specific information

CELL LINE VALIDATION SHEET																		
DRB3 SSP subtyping kit <sup>2</sup>																		
			Well <sup>3</sup>															
			1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
		Prod. No.	202355001	202355002	202355003	202355004	202355005	202355006	202355007	202355008	202355009	202355010	202355011	202355012	202355013	202355014	202355015	202355016
	IHWC cell line <sup>1</sup>	DRB3																
1	9001 SA		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2	9280 LK707		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3	9011 E4181324		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4	9275 GU373	*02:02	-	-	-	-	-	-	-	-	+	+	-	-	+	+	-	-
5	9009 KAS011		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
6	9353 SM		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
7	9020 QBL	*02:02	-	-	-	-	-	-	-	-	+	+	-	-	+	+	-	-
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	*02:02	-	-	-	-	-	-	-	-	+	+	-	-	+	+	-	-
17	9282 CTM3953540	*01:01	+	+	+	-	-	-	-	-	-	-	-	-	+	-	-	-
18	9257 32367	*02:02	-	-	-	-	-	-	-	-	+	+	-	-	+	+	-	-
19	9038 BM16	*02:02	-	-	-	-	-	-	-	-	+	+	-	-	+	+	-	-
20	9059 SLE005	*03:01	+	+	-	-	-	-	-	-	-	-	+	-	-	-	+	-
21	9064 AMALA	*01:01	+	+	+	-	-	-	-	-	-	-	-	-	+	-	-	-
22	9056 KOSE	*02:02	+	+	-	+	-	-	-	-	+	+	+	-	+	+	+	-
23	9124 IHL	*02:02	-	-	-	+	-	-	-	-	+	+	-	-	+	+	-	-
24	9035 JBUSH	*02:02	-	-	-	-	-	-	-	-	+	+	-	-	+	+	-	-
25	9049 IBW9		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
26	9285 WT49	*02:02	-	-	-	-	-	-	-	-	+	+	-	-	+	+	-	-
27	9191 CH1007		-	-	-	-	-	-	-	-	-	-	-	-	-	w	-	-
28	9320 BEL5GB		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
29	9050 MOU		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
30	9021 RSH	*01:01	+	+	+	-	-	-	-	-	-	-	-	-	+	-	-	-
31	9019 DUCAF	*02:02	-	-	-	-	-	-	-	-	+	+	-	-	+	+	-	-
32	9297 HAG	*01:01	+	+	+	-	-	-	-	-	-	-	-	-	+	-	-	-
33	9098 MT14B		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
34	9104 DHIF	*02:02	-	-	-	-	-	-	-	-	+	+	-	-	+	+	-	-
35	9302 SSTO		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
36	9024 KT17		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
37	9065 HHKB	*01:01	+	+	+	-	-	-	-	-	-	-	-	-	+	-	-	-
38	9099 LZL	*01:01	+	+	+	-	-	-	-	-	-	-	-	-	+	-	-	-
39	9315 CML	*01:01	+	+	+	-	-	-	-	-	-	-	-	-	+	-	-	-
40	9134 WHONP199		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
41	9055 H0301	*03:01	+	+	-	-	-	-	-	-	-	-	+	-	-	-	+	-
42	9066 TAB089		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
43	9076 T7526		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
44	9057 TEM	*02:24	-	-	-	+	-	-	-	-	+	+	+	+	-	-	-	-
45	9239 SHJO		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
46	9013 SCHU		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
47	9045 TUBO	*02:02	-	-	-	-	-	-	-	-	+	+	-	-	+	+	-	-
48	9303 TER-ND		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-



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



101.121-24/04 – including *Taq* polymerase  
101.121-24u/04u – without *Taq* polymerase

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“Instructions for Use” (IFU)

Lot No.: **2S6**

Lot-specific information

CELL LINE VALIDATION SHEET																				
DRB3 SSP subtyping kit <sup>2</sup>																				
				Well <sup>3</sup>																
				17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	
				Prod. No.	202355017	202355018	202355019	202355020	202355021	202355022	202355023	202355024	202355025	202355026	202355027	202355028	202355029	202355030	202355031	202355032
	IHWC cell line <sup>1</sup>	DRB3																		
1	9001 SA			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
2	9280 LK707			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
3	9011 E4181324			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
4	9275 GU373	*02:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
5	9009 KAS011			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
6	9353 SM			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
7	9020 QBL	*02:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
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	*02:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
17	9282 CTM3953540	*01:01		-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	
18	9257 32367	*02:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
19	9038 BM16	*02:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
20	9059 SLE005	*03:01		-	-	-	+	-	-	-	+	-	-	-	-	-	-	-	-	
21	9064 AMALA	*01:01		-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	
22	9056 KOSE	*02:02	*03:01	-	-	-	+	-	-	-	+	-	-	-	-	-	-	-	-	
23	9124 IHL	*02:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
24	9035 JBUSH	*02:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
25	9049 IBW9			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
26	9285 WT49	*02:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
27	9191 CH1007			-	-	-	-	-	-	-	-	-	-	-	-	W	-	-	-	
28	9320 BEL5GB			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
29	9050 MOU			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
30	9021 RSH	*01:01		-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	
31	9019 DUCAF	*02:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
32	9297 HAG	*01:01		-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	
33	9098 MT14B			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
34	9104 DHIF	*02:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
35	9302 SSTO			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
36	9024 KT17			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
37	9065 HHKB	*01:01		-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	
38	9099 LZL	*01:01		-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	
39	9315 CML	*01:01		-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	
40	9134 WHONP199			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
41	9055 H0301	*03:01		-	-	-	+	-	-	-	+	-	-	-	-	-	-	-	-	
42	9066 TAB089			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
43	9076 T7526			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
44	9057 TEM	*02:24		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
45	9239 SHJO			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
46	9013 SCHU			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
47	9045 TUBO	*02:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
48	9303 TER-ND			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	



0197

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

101.121-24/04 – including *Taq* polymerase  
101.121-24u/04u – without *Taq* polymerase

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“Instructions for Use” (IFU)

Lot No.: **2S6**

Lot-specific information

CELL LINE VALIDATION SHEET															
DRB3 SSP subtyping kit <sup>2</sup>															
Well <sup>3</sup>															
Prod. No.															
202355033															
202355034															
202355035															
202355036															
202355037															
202355038															
202355039															
202355040															
202355041															
202355042															
202355043															
202355044															
202355045															
202355046															
202355047															
IHC cell line <sup>1</sup>		DRB3													
1	9001 SA			-	-	-	-	-	-	-	-	-	-	-	-
2	9280 LK707			-	-	-	-	-	-	-	-	-	-	-	-
3	9011 E4181324			-	-	-	-	-	-	-	-	-	-	-	-
4	9275 GU373	*02:02		-	-	-	-	-	-	-	-	-	-	-	-
5	9009 KAS011			-	-	-	-	-	-	-	-	-	-	-	-
6	9353 SM			-	-	-	-	-	-	-	-	-	-	-	-
7	9020 QBL	*02:02		-	-	-	-	-	-	-	-	-	-	-	-
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	*02:02		-	-	-	-	-	-	-	-	-	-	-	-
17	9282 CTM3953540	*01:01		-	-	-	-	-	-	-	-	-	-	-	-
18	9257 32367	*02:02		-	-	-	-	-	-	-	-	-	-	-	-
19	9038 BM16	*02:02		-	-	-	-	-	-	-	-	-	-	-	-
20	9059 SLE005	*03:01		+	-	-	-	-	-	-	-	-	-	-	-
21	9064 AMALA	*01:01		-	-	-	-	-	-	-	-	-	-	-	-
22	9056 KOSE	*02:02	*03:01	+	-	-	-	-	-	-	-	-	-	-	-
23	9124 IHL	*02:02		-	-	-	-	-	-	-	-	-	-	-	-
24	9035 JBUSH	*02:02		-	-	-	-	-	-	-	-	-	-	-	-
25	9049 IBW9			-	-	-	-	-	-	-	-	-	-	-	-
26	9285 WT49	*02:02		-	-	-	-	-	-	-	-	-	-	-	-
27	9191 CH1007			-	-	-	-	-	-	-	-	-	-	-	-
28	9320 BEL5GB			-	-	-	-	-	-	-	-	-	-	-	-
29	9050 MOU			-	-	-	-	-	-	-	-	-	-	-	-
30	9021 RSH	*01:01		-	-	-	-	-	-	-	-	-	-	-	-
31	9019 DUCAF	*02:02		-	-	-	-	-	-	-	-	-	-	-	-
32	9297 HAG	*01:01		-	-	-	-	-	-	-	-	-	-	-	-
33	9098 MT14B			-	-	-	-	-	-	-	-	-	-	-	-
34	9104 DHIF	*02:02		-	-	-	-	-	-	-	-	-	-	-	-
35	9302 SSTO			-	-	-	-	-	-	-	-	-	-	-	-
36	9024 KT17			-	-	-	-	-	-	-	-	-	-	-	-
37	9065 HHKB	*01:01		-	-	-	-	-	-	-	-	-	-	-	-
38	9099 LZL	*01:01		-	-	-	-	-	-	-	-	-	-	-	-
39	9315 CML	*01:01		-	-	-	-	-	-	-	-	-	-	-	-
40	9134 WHONP199			-	-	-	-	-	-	-	-	-	-	-	-
41	9055 H0301	*03:01		+	-	-	-	-	-	-	-	-	-	-	-
42	9066 TAB089			-	-	-	-	-	-	-	-	-	-	-	-
43	9076 T7526			-	-	-	-	-	-	-	-	-	-	-	-
44	9057 TEM	*02:24		-	-	-	-	-	-	-	-	-	-	-	-
45	9239 SHJO			-	-	-	-	-	-	-	-	-	-	-	-
46	9013 SCHU			-	-	-	-	-	-	-	-	-	-	-	-
47	9045 TUBO	*02:02		-	-	-	-	-	-	-	-	-	-	-	-
48	9303 TER-ND			-	-	-	-	-	-	-	-	-	-	-	-



0197

**101.121-24/04 – including *Taq* polymerase**  
**101.121-24u/04u – without *Taq* polymerase**

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“Instructions for Use” (IFU)

**Lot No.: 2S6**

**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.

<sup>3</sup>Cell line TEM, IHW 9057, is profiled as DRB3\*02:01 by ECACC ((European Collection of Cell Cultures)). However, Olerup SSP AB has shown that this cell line includes the exon 3 polymorphism corresponding to DRB3\*02:24. Primer mix 4 amplifies DRB1\*14 alleles in the KOSE, IHL and TEM cell lines. The DRB1\*10:01 allele is weakly amplified by primer mixes 14 and 29 in the CH1007 cell line.

No DNAs carrying the alleles to be amplified by primer solutions 5 to 8, 16 to 19, 21 to 23, 25 to 28, 30 to 32 and 34 to 47 were available. The specificities of the primers in primer solutions 5, 7, 8, 16 to 19, 21, 22, 25, 26, 28, 31, 32, 34, 36, 38 and 40 were tested by separately adding additional 5'-primers, and additional 3'-primers accordingly. In primer solutions 6, 23, 27, 30, 42 and 45 to 47 it was only possible to test the 3'-primer, the 5'-primers were not possible to be tested. In primer solutions 35, 37, 39, 41, 43 and 44 it was only possible to test the 5'-primer, the 3'-primers were not possible to be tested.

In primer solutions 1 to 3, 5, 7, 12, 15, 17, 19, 21, 25, 28, 31, 33, 34, 36 and 38 one or more 3'-primers were not possible to be tested. In primer solutions 2, 3, 14, 18, 22, 34, 38 and 40 one or two of the 5'-primers were not possible to be tested. In addition, one or more 3'-primers in primer solutions 15, 20 and 24 were tested by separately adding one or more 5'-primers.



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101.121-24/04 – including *Taq* polymerase  
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