

101.215-12 – including *Taq* pol., IFU-01  
101.215-12u – without *Taq* pol., IFU-02

Visit <https://labproducts.caredx.com> for  
“Instructions for Use” (IFU)

Lot No.: **2L9**

Lot-specific Information

**Olerup SSP® DQB1\*04**

Product number:	101.215-12 – including <i>Taq</i> polymerase 101.215-12u – without <i>Taq</i> polymerase
Lot number:	2L9
Expiry date:	2024-08-01
Number of tests:	12
Number of wells per test:	21+1
Storage - pre-aliquoted primers:	dark at -20°C
- PCR Master Mix:	-20°C
- Adhesive PCR seals	RT
- Product Insert	RT

**This Product Description is only valid for Lot No. 2L9.**

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

**CHANGES COMPARED TO THE PREVIOUS OLERUP SSP®  
DQB1\*04 Lot (7H9)**

- The product documentation has been updated for new alleles of IMGT 3.40.0.
- The kit resolution focuses on common and well documented (CWD) alleles<sup>1</sup>.
- One new well was added to the DQB1\*04 primer tray, well **22**.

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

The DQB1\*04 primer set, specificity and interpretation tables have been updated with the DQB1 alleles described since the previous *Olerup SSP®* DQB1\*04 lot (**Lot No. 7H9**) was made.

<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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The primers of the wells detailed below have been exchanged, added or modified compared to the previous lot.

Well	5'-primer	3'-primer	rationale
12	Moved	Moved	Primer pair moved to primer mix 21 for reducing tendency of primer oligomer formation.
19	-	Added	3'-primer added for the DQB1*04:02:19 allele.
21	Added	Added, exchanged	Primer pair added from primer mix 12. 3'-primer was exchanged for reducing tendency of primer oligomer formation.
22	-	-	Negative control primer pair moved from primer mix 21.

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Well **22** 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

### DQB1\*04 SSP subtyping

#### CONTENT

The primer set contains 5'- and 3'-primers for identifying the DQB1\*04:01 to DQB1\*04:77 alleles.

*Please note that DQB1 amplifications usually are somewhat less pronounced than e.g. DRB and DQA1 amplifications even when using the same DNA preparation and exactly the same experimental procedures.*

#### PLATE LAYOUT

Each test consists of 22 PCR reactions in a 24 well 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 PCR plate is marked with 'DQB1\*04' in silver/gray ink.

Well No. 1 is marked with the Lot No. '2L9'.

Wells 1 to 21 – DQB1\*04 high resolution 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 DQB1 alleles, non-DQB1\*04 alleles will be amplified by some primer mixes.

The interpretation of DQB1\*04 subtypings is not influenced by the DQB2 and DQB3 genes.

For further details see Specificity Table.

#### UNIQUELY IDENTIFIED ALLELES

All the DQB1\*04 alleles, i.e. **DQB1\*04:01 to DQB1\*04:77**, recognized by the HLA Nomenclature Committee in April 2020<sup>1,2</sup> will be amplified by the primers in the DQB1\*04 subtyping kit.

The DQB1\*04 kit enables separation of the confirmed DQB1\*04 alleles as listed in the IMGT/HLA database 3.25.0. An HLA allele is listed as confirmed by IMGT/HLA

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if it has been sequenced by more than a single laboratory or from multiple sources. Current allele confirmation status for DQB1\*04 alleles is listed below.

The DQB1\*04 kit also enables identification of many null and alternatively expressed alleles.

<sup>1</sup>HLA-DQB1 alleles listed on the IMGT/HLA web page 2020-April-20, release 3.40.0, [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>
DQB1*04:01:01	Confirmed	DQB1*04:08	Unconfirmed	DQB1*04:28	Unconfirmed
DQB1*04:01:02	Unconfirmed	DQB1*04:09	Unconfirmed	DQB1*04:29	Unconfirmed
DQB1*04:01:03	Unconfirmed	DQB1*04:10	Unconfirmed	DQB1*04:30	Unconfirmed
DQB1*04:01:04	Unconfirmed	<b>DQB1*04:11</b>	<b>Confirmed</b>	DQB1*04:31	Unconfirmed
<b>DQB1*04:02:01</b>	<b>Confirmed</b>	<b>DQB1*04:12</b>	<b>Confirmed</b>	DQB1*04:32	Unconfirmed
DQB1*04:02:02	Unconfirmed	DQB1*04:13	Unconfirmed	<b>DQB1*04:33</b>	<b>Confirmed</b>
<b>DQB1*04:02:03</b>	<b>Confirmed</b>	DQB1*04:14	Unconfirmed	DQB1*04:34	Unconfirmed
<b>DQB1*04:02:04</b>	<b>Confirmed</b>	DQB1*04:15	Unconfirmed	DQB1*04:35	Unconfirmed
DQB1*04:02:05	Unconfirmed	DQB1*04:16	Unconfirmed	DQB1*04:36N	Unconfirmed
DQB1*04:02:06	Unconfirmed	DQB1*04:17	Unconfirmed		
<b>DQB1*04:02:07</b>	<b>Confirmed</b>	<b>DQB1*04:18</b>	<b>Confirmed</b>		
DQB1*04:02:08	Unconfirmed	DQB1*04:19	Unconfirmed		
<b>DQB1*04:02:09</b>	<b>Confirmed</b>	DQB1*04:20	Unconfirmed		
DQB1*04:02:10	Unconfirmed	DQB1*04:21	Unconfirmed		
DQB1*04:03:01	Unconfirmed	DQB1*04:22	Unconfirmed		
DQB1*04:03:02	Unconfirmed	DQB1*04:23	Unconfirmed		
DQB1*04:04	Unconfirmed	DQB1*04:24	Unconfirmed		
DQB1*04:05	Unconfirmed	DQB1*04:25N	Unconfirmed		
DQB1*04:06	Unconfirmed	DQB1*04:26	Unconfirmed		
DQB1*04:07	Unconfirmed	<b>DQB1*04:27</b>	<b>Confirmed</b>		

<sup>1</sup>Allele status “confirmed” or “unconfirmed” as listed on the IMGT/HLA web page 2016-July-14, release 3.25.0, [www.ebi.ac.uk/imgt/hla](http://www.ebi.ac.uk/imgt/hla).

**RESOLUTION IN HOMO- AND HETEROZYGOTES**

Results file with resolution in DQB1\*04 homo- and heterozygotes is available upon request.

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Lot-specific Information  
**SPECIFICITY TABLE**

**DQB1\*04 SSP subtyping**

Specificities and sizes of the PCR products of the 21+1 primer mixes used for DQB1\*04 SSP subtyping

Primer Mix	Size of spec. PCR product <sup>1</sup>	Size of control band <sup>2</sup>	Amplified DQB1*04 alleles <sup>3</sup>	Amplified non-DQB1*04 alleles
<b>1<sup>5,6</sup></b>	160 bp	<b>515 bp</b>	*04:01:01:01-04:01:02, 04:01:04-04:02:01:01, 04:02:01:04-04:02:07, 04:02:09-04:02:15, 04:02:17-04:03:02, 04:04- 04:29, 04:31-04:47, 04:49- 04:77	*03:132
	205 bp		*04:01:01:01-04:01:05, 04:05-04:08, 04:14-04:17, 04:38, 04:42, 04:61-04:62, 04:69, 04:71, 04:73N-04:74	
<b>2<sup>5,6</sup></b>	205 bp	<b>515 bp</b>	*04:01:01:01-04:01:05, 04:05-04:08, 04:14-04:17, 04:38, 04:42, 04:61-04:62, 04:69, 04:71, 04:73N-04:74	
<b>3</b>	180 bp	430 bp	*04:02:01:01, 04:02:01:04- 04:02:18, 04:02:20- 04:03:01, 04:04, 04:09- 04:13, 04:18-04:19, 04:21, 04:22 <sup>w</sup> , 04:23, 04:24 <sup>w</sup> , 04:25N-04:32, 04:34-04:37, 04:39-04:41N, 04:43-04:48, 04:50-04:60, 04:63-04:68N, 04:70, 04:72, 04:75-04:77	
<b>4</b>	195 bp	430 bp	*04:03:01-04:03:03	*03:06, 03:25:01
<b>5<sup>4</sup></b>	110 bp	430 bp	*04:06, 04:12	*03:06, 03:25:01
	245 bp		*04:04-04:05	
<b>6<sup>4</sup></b>	95 bp	430 bp	*04:16	
	210 bp		*04:20	
<b>7<sup>7</sup></b>	245 bp	430 bp	*04:02:08	*03:30, 03:72, 03:100, 03:215, 06:02:01:01-06:02:32, 06:02:34-06:02:44, 06:10, 06:13:01-06:16, 06:19:01- 06:20, 06:22:01-06:24, 06:29, 06:33, 06:37, 06:46-06:51:02, 06:68-06:84, 06:95-06:97, 06:106-06:107, 06:109, 06:111-06:117, 06:119, 06:122-06:123, 06:125- 06:127, 06:130, 06:136, 06:138-06:139, 06:146:01- 06:147, 06:150-06:152,

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				06:156, 06:159, 06:161-06:163, 06:166, 06:173-06:175, 06:178-06:179N, 06:182-06:183, 06:188, 06:192, 06:197-06:198, 06:200, 06:206:01-06:206:02, 06:208, 06:211, 06:213, 06:215-06:216N, 06:219, 06:224-06:228, 06:232, 06:235-06:237, 06:240, 06:242, 06:249, 06:255-06:256, 06:262, 06:264, 06:270:02-06:271, 06:273, 06:284, 06:286, 06:289-06:290, 06:293-06:298, 06:300, 06:304N, 06:306N, 06:308N, 06:311, 06:314-06:315, 06:317N, 06:322, 06:324, 06:326, 06:333, 06:335, 06:337-06:338, 06:341N, 06:344, 06:347, 06:354-06:357, 06:363-06:364, 06:366, 06:368, 06:370
8 <sup>4</sup>	95 bp	430 bp	*04:08	*03:06 <sup>?</sup> -03:07 <sup>?</sup> , 03:14:01 <sup>?</sup> -03:15 <sup>?</sup> , 03:17:01 <sup>?</sup> -03:18 <sup>?</sup> , 03:19:01:01, 03:19:01:02Q <sup>?</sup> , 03:19:02-03:19:04, 03:20 <sup>?</sup> , 03:23:01 <sup>?</sup> , 03:23:03 <sup>?</sup> , 03:25:02 <sup>?</sup> -03:26 <sup>?</sup> , 03:37 <sup>?</sup> , 03:48 <sup>?</sup> , 03:52 <sup>?</sup> -03:54 <sup>?</sup> , 03:56 <sup>?</sup> -03:71 <sup>?</sup> , 03:74 <sup>?</sup> -03:78 <sup>?</sup> , 03:81 <sup>?</sup> -03:82 <sup>?</sup> , 03:101 <sup>?</sup> -03:104 <sup>?</sup> , 03:106 <sup>?</sup> -03:112 <sup>?</sup> , 03:118N <sup>?</sup> , 03:120 <sup>?</sup> -03:131 <sup>?</sup> , 03:133 <sup>?</sup> -03:135 <sup>?</sup> , 03:137 <sup>?</sup> , 03:140 <sup>?</sup> -03:149 <sup>?</sup> , 03:150, 03:151 <sup>?</sup> -03:163 <sup>?</sup> , 03:165 <sup>?</sup> -03:167 <sup>?</sup> , 03:170 <sup>?</sup> -03:179 <sup>?</sup> , 03:183 <sup>?</sup> , 03:185 <sup>?</sup> , 03:187 <sup>?</sup> -03:189 <sup>?</sup> , 03:192 <sup>?</sup> -03:194 <sup>?</sup> , 03:201 <sup>?</sup> -03:205 <sup>?</sup> , 03:207 <sup>?</sup> -03:210 <sup>?</sup> , 03:212 <sup>?</sup> -03:221 <sup>?</sup> , 03:223 <sup>?</sup> -03:230 <sup>?</sup> , 03:232 <sup>?</sup> -03:238 <sup>?</sup> , 03:240 <sup>?</sup> , 03:244 <sup>?</sup> , 03:255 <sup>?</sup> -03:262 <sup>?</sup> , 03:263, 03:267 <sup>?</sup> -03:270 <sup>?</sup> , 03:273 <sup>?</sup> -03:275 <sup>?</sup> , 03:278 <sup>?</sup> , 03:286, 03:335, 03:351 <sup>?</sup> -03:353 <sup>?</sup> , 03:356N <sup>?</sup> , 03:359 <sup>?</sup> , 03:360, 03:376N, 03:381, 03:387 <sup>?</sup> , 03:394, 03:401, 03:425 <sup>?</sup>
9	140 bp	430 bp	*04:09, 04:14	

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<b>10</b>	145 bp	430 bp	*04:10	*05:01:19 <sup>w</sup> , 06:03:03 <sup>w</sup>
<b>11<sup>4</sup></b>	120 bp 160 bp	430 bp	*04:11, 04:15 *04:23	*02:108, 02:144, 03:22:01- 03:22:02, 03:96, 03:251, 05:226, 05:231 <sup>w</sup> , 06:04:01:01 <sup>w</sup> -06:05:02 <sup>w</sup> , 06:06 <sup>?</sup> , 06:07:01 <sup>w</sup> -06:07:02 <sup>w</sup> , 06:08:02 <sup>?</sup> -06:08:03 <sup>?</sup> , 06:09:01:01 <sup>w</sup> -06:09:11 <sup>w</sup> , 06:09:12 <sup>?</sup> , 06:11:02 <sup>?</sup> - 06:11:03 <sup>?</sup> , 06:12 <sup>w</sup> , 06:13:02 <sup>?</sup> - 06:13:03 <sup>?</sup> , 06:15:01 <sup>?</sup> , 06:17 <sup>?</sup> - 06:18:01 <sup>?</sup> , 06:18:02 <sup>w</sup> , 06:19:01 <sup>?</sup> , 06:21 <sup>w</sup> , 06:22:01 <sup>?</sup> - 06:25 <sup>?</sup> , 06:27:01 <sup>?</sup> -06:27:02 <sup>?</sup> , 06:29 <sup>?</sup> -06:32:02 <sup>?</sup> , 06:34 <sup>w</sup> , 06:35 <sup>?</sup> , 06:36 <sup>w</sup> , 06:38 <sup>w</sup> , 06:40 <sup>?</sup> , 06:41 <sup>w</sup> -06:42 <sup>w</sup> , 06:45 <sup>?</sup> , 06:50 <sup>?</sup> , 06:51:02 <sup>?</sup> , 06:52 <sup>w</sup> , 06:53:01 <sup>?</sup> - 06:54N <sup>?</sup> , 06:56 <sup>?</sup> -06:57 <sup>?</sup> , 06:58 <sup>w</sup> , 06:59 <sup>?</sup> -06:61 <sup>?</sup> , 06:63 <sup>?</sup> - 06:67 <sup>?</sup> , 06:69:01 <sup>?</sup> -06:76 <sup>?</sup> , 06:79:02 <sup>?</sup> -06:83 <sup>?</sup> , 06:84 <sup>w</sup> , 06:85 <sup>?</sup> , 06:89 <sup>?</sup> , 06:91 <sup>?</sup> - 06:92:01 <sup>?</sup> , 06:93 <sup>?</sup> -06:97 <sup>?</sup> , 06:118:01 <sup>w</sup> , 06:118:02 <sup>?</sup> - 06:124 <sup>?</sup> , 06:126 <sup>?</sup> , 06:128 <sup>?</sup> , 06:129 <sup>w</sup> , 06:131 <sup>?</sup> -06:147 <sup>?</sup> , 06:149 <sup>?</sup> -06:153:01 <sup>?</sup> , 06:154 <sup>?</sup> - 06:184 <sup>?</sup> , 06:186 <sup>w</sup> , 06:189 <sup>w</sup> , 06:190:01 <sup>?</sup> -06:199 <sup>?</sup> , 06:201 <sup>?</sup> - 06:204 <sup>?</sup> , 06:206:01 <sup>?</sup> , 06:206:02 <sup>w</sup> , 06:207 <sup>?</sup> -06:208 <sup>?</sup> , 06:210 <sup>?</sup> -06:215 <sup>?</sup> , 06:217 <sup>w</sup> , 06:229 <sup>?</sup> -06:236 <sup>?</sup> , 06:238 <sup>?</sup> , 06:241 <sup>?</sup> , 06:244 <sup>?</sup> , 06:246 <sup>?</sup> - 06:247 <sup>?</sup> , 06:249 <sup>?</sup> , 06:252N <sup>?</sup> , 06:254 <sup>w</sup> , 06:260 <sup>?</sup> , 06:261 <sup>w</sup> , 06:263 <sup>?</sup> , 06:265 <sup>w</sup> -06:267 <sup>w</sup> , 06:268 <sup>?</sup> , 06:275 <sup>w</sup> , 06:277 <sup>?</sup> , 06:280 <sup>w</sup> -06:283 <sup>w</sup> , 06:287 <sup>w</sup> - 06:288 <sup>w</sup> , 06:291 <sup>w</sup> -06:292 <sup>w</sup> , 06:299 <sup>w</sup> , 06:301 <sup>w</sup> , 06:303N <sup>w</sup> , 06:313 <sup>w</sup> , 06:318 <sup>w</sup> -06:319 <sup>w</sup> , 06:320 <sup>?</sup> , 06:325 <sup>w</sup> , 06:332 <sup>w</sup> , 06:339 <sup>w</sup> , 06:343 <sup>w</sup> , 06:348 <sup>w</sup> - 06:349 <sup>w</sup> , 06:351 <sup>w</sup> , 06:353 <sup>?</sup> , 06:358 <sup>?</sup> , 06:361 <sup>?</sup> , 06:368 <sup>?</sup> - 06:369 <sup>?</sup>
<b>12</b>	160 bp	430 bp	*04:07	
<b>13</b>	185 bp	430 bp	*04:13	
<b>14<sup>6</sup></b>	160 bp	430 bp	*04:17	*03:395
<b>15</b>	150 bp	430 bp	*04:23, 04:25N	*03:96, 03:251



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<b>16</b>	200 bp	430 bp	*04:27
<b>17</b>	195 bp	430 bp	*04:33
<b>18</b>	245 bp	430 bp	*04:36N
<b>19</b>	200 bp	430 bp	*04:01:01:01-04:02:01:01, 04:02:01:04-04:02:02, 04:02:05-04:03:03, 04:06- 04:31, 04:33-04:77
	225 bp		*04:01:01:01-04:02:01:01, 04:02:01:04-04:02:18, 04:02:20-04:03:03, 04:06- 04:21, 04:22 <sup>w</sup> , 04:23, 04:24 <sup>w</sup> , 04:25N-04:32, 04:34-04:37, 04:38 <sup>w</sup> , 04:39- 04:48, 04:50-04:77
<b>20<sup>4</sup></b>	105 bp	430 bp	*04:41N
<b>21<sup>8</sup></b>	185 bp	430 bp	*04:18
<b>22<sup>9</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 DQB1\*04 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.

<sup>3</sup>For several DQB1 alleles 1<sup>st</sup> and/or 3<sup>rd</sup> 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 1 and 2 may give rise to a lower yield of HLA-specific PCR product than the other DQB1\*04 primer mixes.

<sup>6</sup>Primer mixes 1, 2 and 14 may have tendencies of unspecific amplifications.

<sup>7</sup>In primer mix 7 the positive control band may be weaker than for other DQB1\*04 primer mixes.

<sup>8</sup>Primer mix 21 may have a tendency for primer oligomer formation.

<sup>9</sup>Primer mix 22 contains a negative control, which will amplify the majority of the HLA amplicons as

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well as the amplicons generated by the control primer pairs matching the human growth hormone gene. HLA-specific PCR product sizes range from 75 to 200 base pairs and the PCR product generated by the HGH positive control primer pair is 200 base pairs.

Abbreviations

w: 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	160 205	205	180	195	110 245	95 210	245	95	140	145	120 160	160
Length of int. pos. control <sup>1</sup>	515	515	430	430	430	430	430	430	430	430	430	430
5'-primer(s) <sup>2</sup>	23(164) 5'-gCT 3'	23(164) 5'-gCT 3'	23(164) 5'-gCg 3'	26(173) 5'-TCT 3'	9(122) 5'-gTA 3'	22(160) 5'-CCA 3'	9(122) 5'-gTT 3'	167(596) 5'-gCA 3'	44(226) 5'-ACA 3'	23(164) 5'-gCg 3'	49(241) 5'-ggA 3'	145(529) 5'-CCg 3'
	38(210) 5'-gCg 3'		23(164) 5'-gCg 3'		55(259) 5'-ggT 3'	59(272) 5'-CgT 3'			45(230) 5'-ggA 3'		52(251) 5'-gCT 3'	
											130(485) 5'-CCA 3'	
3'-primer(s) <sup>3</sup>	77(327) 5'-ACg 3'	77(327) 5'-ACg 3'	70(304) 5'-CTC 3'	77(327) 5'-ACg 3'	77(327) 5'-ACg 3'	77(327) 5'-ACg 3'	77(326) 5'-CCg 3'	185(650) 5'-CgA 3'	77(327) 5'-ACg 3'	57(267) 5'-gCA 3'	77(327) 5'-ACg 3'	185(650) 5'-CgA 3'
											170(604) 5'-gAC 3'	
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

Well No.	13	14	15	16	17	18	19	20	21
Length of spec. PCR product	185	160	150	200	195	245	200	105	185
Length of int. pos. control <sup>1</sup>	430	430	430	430	430	430	430	430	430
5'-primer(s) <sup>2</sup>	140(514) 5'-CAA 3'	146(533) 5'-CCT 3'	26(173) 5'-ggg 3'	24(166) 5'-gCT 3'	23(164) 5'-gCg 3'	26(173) 5'-ggg 3'	9(122) 5'-gTT 3'	102(400) 5'-TCT 3'	15(140) 5'-gTA 3'
			130(485) 5'-CCA 3'						
3'-primer(s) <sup>3</sup>	187(656) 5'-ACA 3'	185(650) 5'-CgA 3'	59(271) 5'-CTA 3'	77(327) 5'-ACg 3'	74(316) 5'-CgC 3'	94(376) 5'-TCA 3'	62(282) 5'-CTA 3'	123(465) 5'-ggC 3'	62(282) 5'-CTA 3'
			185(650) 5'-CgA 3'				70(304) 5'-CTC 3'		
Well No.	13	14	15	16	17	18	19	20	21

<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.

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**Lot-specific Information**

<b>CELL LINE VALIDATION SHEET</b>																			
<b>DQB1*04 SSP subtyping kit<sup>2</sup></b>																			
				<b>Well</b>															
				<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>7</b>	<b>8</b>	<b>9</b>	<b>10</b>	<b>11</b>	<b>12</b>	<b>13</b>	<b>14</b>	<b>15</b>	<b>16</b>
				202021101	202021102	202021103	202021104	202021105	202021106	202021107	202021108	202021109	202021110	202021111	202021112	202021113	202021114	202021115	202021116
			<b>Production No.</b>																
<b>IHWC cell line<sup>1</sup></b>			<b>DQB1</b>																
1	9001	SA	*05:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2	9280	LK707	*06:01	*02:02	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3	9011	E4181324	*06:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4	9275	GU373	*02:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
5	9009	KAS011	*05:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
6	9353	SM	*03:02	*06:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
7	9020	QBL	*02:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
8	9025	DEU	*03:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
9	9026	YAR	*03:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
10	9107	LKT3	*04:01		+	+	-	-	-	-	-	-	-	-	-	-	-	-	-
11	9051	PITOUT	*02:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
12	9052	DBB	*03:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
13	9004	JESTHOM	*05:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
14	9071	OLGA	*04:02		+	-	+	-	-	-	-	-	-	-	-	-	-	-	-
15	9075	DKB	*03:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
16	9037	SWEIG007	*03:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
17	9282	CTM3953540	*02:01	*06:03	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
18	9257	32367	*06:02	*02:02	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-
19	9038	BM16	*03:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
20	9059	SLE005	*06:04		-	-	-	-	-	-	-	-	-	W	-	-	-	-	-
21	9064	AMALA	*03:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
22	9056	KOSE	*05:03	*06:04	-	-	-	-	-	-	-	-	-	W	-	-	-	-	-
23	9124	IHL	*05:03	*06:01	-	-	-	-	-	-	-	-	-	W	-	-	-	-	-
24	9035	JBUSH	*03:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
25	9049	IBW9	*02:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
26	9285	WT49	*02:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
27	9191	CH1007	*04:01	*05:01	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-
28	9320	BEL5GB	*02:02	*03:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
29	9050	MOU	*02:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
30	9021	RSH	*04:02		+	-	+	-	-	-	-	-	-	-	-	-	-	-	-
31	9019	DUCAF	*02:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
32	9297	HAG	*03:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
33	9098	MT14B	*03:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
34	9104	DHIF	*03:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
35	9302	SSTO	*03:05		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
36	9024	KT17	*03:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
37	9065	HHKB	*06:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
38	9099	LZL	*03:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
39	9315	CML	*02:01	*03:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
40	9134	WHONP199	*02:02	*03:03	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
41	9055	H0301	*06:09		-	-	-	-	-	-	-	-	-	W	-	-	-	-	-
42	9066	TAB089	*06:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
43	9076	T7526	*03:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
44	9057	TEM	*05:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
45	9239	SHJO	*02:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
46	9013	SCHU	*06:02		-	-	-	-	-	-	+	-	-	-	-	-	-	-	-
47	9045	TUBO	*03:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
48	9303	TER-ND	*05:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-



**101.215-12 – including *Taq* pol., IFU-01**  
**101.215-12u – without *Taq* pol., IFU-02**

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**Lot-specific Information**

<b>CELL LINE VALIDATION SHEET</b>									
<b>DQB1*04 SSP subtyping kit<sup>2</sup></b>									
					<b>Well</b>				
					<b>17</b>	<b>18</b>	<b>19</b>	<b>20</b>	<b>21</b>
					202021117	202021118	202021119	202021120	202021121
				<b>Production No.</b>					
	<b>IHWC cell line<sup>1</sup></b>			<b>DQB1</b>					
1	9001 SA			*05:01	-	-	-	-	-
2	9280 LK707			*06:01 *02:02	-	-	-	-	-
3	9011 E4181324			*06:01	-	-	-	-	-
4	9275 GU373			*02:01	-	-	-	-	-
5	9009 KAS011			*05:02	-	-	-	-	-
6	9353 SM			*03:02 *06:01	-	-	-	-	-
7	9020 QBL			*02:01	-	-	-	-	-
8	9025 DEU			*03:01	-	-	-	-	-
9	9026 YAR			*03:02	-	-	-	-	-
10	9107 LKT3			*04:01	-	-	+	-	-
11	9051 PITOUT			*02:02	-	-	-	-	-
12	9052 DBB			*03:03	-	-	-	-	-
13	9004 JESTHOM			*05:01	-	-	-	-	-
14	9071 OLGA			*04:02	-	-	+	-	-
15	9075 DKB			*03:03	-	-	-	-	-
16	9037 SWEIG007			*03:01	-	-	-	-	-
17	9282 CTM3953540			*02:01 *06:03	-	-	-	-	-
18	9257 32367			*06:02 *02:02	-	-	-	-	-
19	9038 BM16			*03:01	-	-	-	-	-
20	9059 SLE005			*06:04	-	-	-	-	-
21	9064 AMALA			*03:01	-	-	-	-	-
22	9056 KOSE			*05:03 *06:04	-	-	-	-	-
23	9124 IHL			*05:03 *06:01	-	-	-	-	-
24	9035 JBUSH			*03:01	-	-	-	-	-
25	9049 IBW9			*02:02	-	-	-	-	-
26	9285 WT49			*02:01	-	-	-	-	-
27	9191 CH1007			*04:01 *05:01	-	-	+	-	-
28	9320 BEL5GB			*02:02 *03:01	-	-	-	-	-
29	9050 MOU			*02:02	-	-	-	-	-
30	9021 RSH			*04:02	-	-	+	-	-
31	9019 DUCAF			*02:01	-	-	-	-	-
32	9297 HAG			*03:01	-	-	-	-	-
33	9098 MT14B			*03:02	-	-	-	-	-
34	9104 DHIF			*03:01	-	-	-	-	-
35	9302 SSTO			*03:05	-	-	-	-	-
36	9024 KT17			*03:02	-	-	-	-	-
37	9065 HHKB			*06:03	-	-	-	-	-
38	9099 LZL			*03:01	-	-	-	-	-
39	9315 CML			*02:01 *03:01	-	-	-	-	-
40	9134 WHONP199			*02:02 *03:03	-	-	-	-	-
41	9055 H0301			*06:09	-	-	-	-	-
42	9066 TAB089			*06:01	-	-	-	-	-
43	9076 T7526			*03:03	-	-	-	-	-
44	9057 TEM			*05:03	-	-	-	-	-
45	9239 SHJO			*02:02	-	-	-	-	-
46	9013 SCHU			*06:02	-	-	-	-	-
47	9045 TUBO			*03:01	-	-	-	-	-
48	9303 TER-ND			*05:01	-	-	-	-	-



**101.215-12 – including *Taq* pol., IFU-01**  
**101.215-12u – without *Taq* pol., IFU-02**

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**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 4 to 6, 9, 10, 12 to 18, 20 and 21 were available. The specificities of the primers in primer solutions 4, 5, 9, 10 and 15 were tested by separately adding one additional 5'-primer, and one additional 3'-primer respectively.

In primer solutions 6, 12, 14, 16 and 21 it was only possible to test the 3'-primers, the 5'-primers were not possible to be tested. In primer solutions 13, 17, 18 and 20 it was only possible to test the 5'-primer, the 3'-primer was not possible to be tested. In primer solutions 3, 5, 9 and 11 one or more 5'-primers were not possible to be test, and in primer solution 15 one 3'-primer was not possible to be tested. In addition, one 3'-primer in primer solution 11 was tested by separately adding one 5'-primer.

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Lot No.: **2L9**

Lot-specific Information

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