

## Olerup SSP<sup>®</sup> DQB1\*03

Product number:	101.214-24/06 – including <i>Taq</i> pol.
Lot number:	22G
Expiry date:	2011-October-01
Number of tests:	24 test – Product No. 101.214-24 6 tests – Product No. 101.214-06
Number of wells per test:	23
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. 22G.**

### CHANGES COMPARED TO THE PREVIOUS *OLERUP SSP*<sup>®</sup> DQB1\*03 LOT

The DQB1\*03 specificity and interpretation tables have been updated for the HLA-DQB1 alleles described since the previous *Olerup SSP*<sup>®</sup> DQB1\*03 lot was made (Lot No. 15F).

Two wells have been added to the DQB1\*03 kit,  
wells **22 and 23**.

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

Well	5'-primer	3'-primer	rationale
22	New	New	New primer pair for the DQB1*0323 allele.
23	New	New	New primer pair for the DQB1*0324 allele.

## PRODUCT DESCRIPTION

### DQB1\*03 SSP subtyping

#### CONTENT

The primer set contains 5'- and 3'-primers for identifying the DQB1\*0301 to DQB1\*0325 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 23 PCR reactions in a 24 well PCR plate. Well 24 is empty.

1	2	3	4	5	6	7	8
9	10	11	12	13	14	15	16
17	18	19	20	21	22	23	empty

The 24 well cut PCR plate is marked with 'DQB1\*03' in silver/gray ink.

Well No. 1 is marked with the Lot No. '22G'.

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

The interpretation of DQB1\*03 SSP subtypings will be influenced by the DQB1\*02, the DQB1\*04 and by many DQB1\*06 alleles, when present on the other haplotype. The interpretation of DQB1\*03 subtypings is not influenced by the DQB2 and DQB3 genes.

#### UNIQUELY IDENTIFIED ALLELES

All the DQB1\*03 alleles, i.e. **DQB1\*0301 to DQB1\*0325**, recognized by the HLA Nomenclature Committee in July 2009<sup>1</sup> will give rise to unique amplification patterns by the primers in the DQB1\*03 subtyping kit.

The DQB1\*03 subtyping kit cannot distinguish the DQB1\*030101, DQB1\*030102 and DQB1\*030104 alleles or the DQB1\*030201 to DQB1\*030204 alleles or the DQB1\*030302 and DQB1\*030303 alleles or the DQB1\*030501 to DQB1\*030504 alleles.

<sup>1</sup>HLA-DQB1 alleles listed on the IMGT/HLA web page 2009-July-17, release 2.26.0, [www.ebi.ac.uk/imgt/hla](http://www.ebi.ac.uk/imgt/hla).

### RESOLUTION IN HOMO- AND HETEROZYGOTES

The 25 DQB1\*03 alleles give rise to 26 different amplification patterns that can be combined in 351 homozygous and heterozygous combinations. 150 of these genotypes do not give rise to unique amplification patterns. The different lengths of the specific PCR products generated by primer mixes 6, 8 and 10 were not considered in these calculations.

++++----+ ---+----- -+-----	0301, 0307 = 0307, 0319
++++----+ ---+----- -+-----	0302, 0316 = 0307, 0316
++++----+ +---+----- -+-----	0301, 0308 = 0308, 0319
++++----+ -+---+----- -+-----	0301, 0311 = 0302, 0309 = 0309, 0311 = 0311, 0319
++++----+ -----+---+ +---+-----	0301, 0318 = 0318, 0319
+---+-----+ ---+----- -+-----	0301, 0320 = 030103, 0320 = 0319, 0320
+---+-----+ -+---+----- -+-----	0306, 0309 = 0309, 0325
+---+-----+ -----+---+ -+-----	0306, 0313 = 0313, 0325
+---+-----+ ---+-----+ -+-----	0306, 0321 = 0321, 0325
+---+-----+ ---+-----+ -+---+-----	0306, 0322 = 0322, 0325
+---+-----+ ---+-----+ -+-----+	0306, 0324 = 0324, 0325
+---+-----+ ---+-----+ -+-----	0301, 0306 = 0301, 0325 = 030103, 0306 = 0306, 0319
+---+-----+ ---+-----+ -+-----	0301, 0315 = 030103, 0315 = 0315, 0319
+---+-----+ ---+-----+ -+-----	0303, 0316 = 0315, 0316
+---+-----+ ---+-----+ -+-----	0301, 0312 = 030103, 0312 = 0312, 0319
+---+-----+ ---+-----+ -+-----+	0301, 0323 = 030103, 0323 = 0319, 0323
+---+-----+ ---+-----+ -+-----	0301, 0303 = 030103, 0303
+---+-----+ ---+-----+ -+-----	0301, 0314 = 0314, 0319
+---+-----+ ---+-----+ -+-----	030103, 0314 = 0304, 0314
+---+-----+ ---+-----+ -+-----	030103, 0304 = 0304, 0304
+---+-----+ ---+-----+ -+-----	0305, 0316 = 0316, 0317
+---+-----+ -+---+----- -+-----	0305, 0309 = 0309, 0317
+---+-----+ -----+---+ -+-----	0305, 0313 = 0313, 0317
+---+-----+ ---+-----+ -+-----	0305, 0321 = 0317, 0321
+---+-----+ ---+-----+ -+---+-----	0305, 0322 = 0317, 0322
+---+-----+ ---+-----+ -+-----+	0305, 0324 = 0317, 0324
+---+-----+ ---+-----+ -+-----	0301, 0305 = 0301, 0317 = 030103, 0317 = 0317, 0319
+---+-----+ ---+-----+ -+-----	0301, 0316 = 030103, 0316 = 0316, 0319
+---+-----+ -+---+----- -+-----	0301, 0309 = 030103, 0309 = 0309, 0309
+---+-----+ ---+-----+ -+-----	0301, 0310 = 030103, 0310
+---+-----+ -----+---+ -+-----	0301, 0313 = 030103, 0313 = 0313, 0313 = 0313, 0319
+---+-----+ ---+-----+ -+-----	0301, 0319 = 030103, 0319
+---+-----+ ---+-----+ -+---+-----	0301, 0321 = 030103, 0321 = 0321, 0321
+---+-----+ ---+-----+ -+---+-----	0301, 0322 = 030103, 0322 = 0322, 0322
+---+-----+ ---+-----+ -+-----+	0301, 0324 = 030103, 0324 = 0324, 0324
+---+-----+ ---+-----+ -+-----	0301, 0301 = 0301, 030103
-+---+-----+ ---+-----+ -+-----	0303, 0314 = 0312, 0314
-+---+-----+ ---+-----+ -+-----	0306, 0310 = 0310, 0325
-+---+-----+ ---+-----+ -+-----	0303, 0310 = 0310, 0312
-+---+-----+ ---+-----+ -+-----	0305, 0310 = 0310, 0317
---+---+-----+ -----+---+ -+-----	0307, 0317 = 0307, 0320
---+---+-----+ +-----+---+ -+-----	0308, 0317 = 0308, 0320

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Lot-specific Information

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--++-+-	-+-----	-+-----	0311, 0317 = 0311, 0320
--++-+-	-----	+++-----	0317, 0318 = 0318, 0320
--++-+-	-----	-+-----	0302, 0317 = 0302, 0320
--++-+-	-----	-+-----	0302, 0315 = 0303, 0307 = 0307, 0315
--++-+-	-----	-+-----	0302, 0307 = 0307, 0307
--++-+-	+-----	-+-----	0302, 0308 = 0308, 0308
--++-+-	-+-----	-+-----	0302, 0311 = 0311, 0311
--++-+-	-----	+++-----	0302, 0318 = 0318, 0318
----+---	-----	-+-----	0305, 0306 = 0306, 0317 = 0306, 0320 = 0317, 0325 = 0320, 0325
----+---	-----	-+-----	0305, 0315 = 0315, 0317 = 0315, 0320
----+---	--++-+-	-+-----	0305, 0312 = 0312, 0317 = 0312, 0320
----+---	-----	-+-----	0305, 0323 = 0317, 0323 = 0320, 0323
----+---	-----	-+-----	0303, 0317 = 0303, 0320 = 0305, 0320 = 0317, 0320 = 0320, 0320
----+---	-----	-+-----	0306, 0315 = 0315, 0325
----+---	--++-+-	-+-----	0306, 0312 = 0312, 0325
----+---	-----	-+-----	0303, 0306 = 0306, 0306 = 0306, 0325
----+---	-----	-+-----	0303, 0315 = 0315, 0315
----+---	--++-+-	-+-----	0303, 0312 = 0312, 0312
-----	-----	-+-----	0305, 0317 = 0317, 0317

0301 = 030101, 030102 and 030104  
0302 = 030201 to 030204  
0303 = 030302 and 030303  
0305 = 030501 to 030504

## SPECIFICITY TABLE

### DQB1\*03 SSP subtyping

Specificities and sizes of the PCR products of the 23 primer mixes used for DQB1\*03 SSP subtyping

Primer Mix	Size of spec. PCR product <sup>1</sup>	Size of control band <sup>2</sup>	Amplified DQB1*03 alleles <sup>3</sup>	Other amplified DQB1 alleles <sup>4</sup>
1	165 bp	<b>515 bp</b>	*030101-030104, 0304, 0309, 0313, 0316, 0319, 0321, 0322, 0324	
2	220 bp	<b>515 bp</b>	*030101-030104, 0304, 0309, 0310, 0313, 0314, 0316, 0319, 0321, 0322, 0324	
3 <sup>5</sup>	135 bp	<b>515 bp</b>	*030201-030204, 0307, 0308, 0311, 0318	*020101-0202, 0204, 0205, 0629
4	220 bp	<b>515 bp</b>	*030201-030303, 0306-0308, 0311, 0312, 0315, 0318, 0320, 0323, 0325	*020101-0205, 0403
5 <sup>5</sup>	135 bp	430 bp	*0304, 0314	
6 <sup>5,7</sup>	95 bp, 130 bp	430 bp	*030501-030504, 0317, 0320	
7 <sup>5</sup>	115 bp	430 bp	*0306, 0325	
8 <sup>5,8</sup>	110 bp, 140 bp	430 bp	*0307, 0315, 0316	
9 <sup>5</sup>	135 bp	430 bp	*0308	*060202, 060302
10 <sup>5,9</sup>	135 bp, 260 bp	430 bp	*0309, 0311	
11 <sup>5,6</sup>	135 bp	430 bp	*0310, 0312, 0314	*060101-060104
12	260 bp	<b>515 bp</b>	*030101-030104, 0304, 0309, 0310, 0312-0314, 0316, 0319, 0321, 0322, 0324	
13	165 bp	430 bp	*0313	
14 <sup>5</sup>	130 bp	<b>515 bp</b>	*030101-030104, 0304, 0309, 0310, 0313, 0314, 0319, 0321, 0322, 0324	
15 <sup>5</sup>	135 bp	<b>515 bp</b>	*030101-0315, 0317-0322, 0324	

<b>16<sup>5</sup></b>	130 bp	430 bp	*030101, 030102, 030104, 030302, 030303, 0306, 0309, 0310, 0312, 0313, 0315-0317, 0319-0324	*0203
<b>17</b>	220 bp	430 bp	*0318	
<b>18</b>	175 bp	<b>515 bp</b>	*030201-030303, 030501-030504, 0306 <sup>?</sup> -0308 <sup>?</sup> , 0311 <sup>?</sup> - 0318 <sup>?</sup> , 0319, 0320 <sup>?</sup> , 0323 <sup>?</sup> , 0325	*040101-0403
<b>19<sup>6</sup></b>	175 bp	<b>515 bp</b>	*030101-030104, 0304, 0306 <sup>?</sup> -0308 <sup>?</sup> , 0309, 0310, 0311 <sup>?</sup> - 0318 <sup>?</sup> , 0320 <sup>?</sup> , 0321, 0322, 0323 <sup>?</sup> , 0324	
<b>20</b>	150 bp	430 bp	*0321	
<b>21</b>	160 bp	<b>515 bp</b>	*0322	
<b>22</b>	160 bp	<b>515 bp</b>	*0323	*060301, 060302, 060402, 0607, 060801, 061101, 061102, 0626N, 0628, 0630-0632
<b>23<sup>5</sup></b>	130 bp	430 bp	*0324	

<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\*03 SSP typings.

When the primers in a primer mix can give rise to specific PCR products of more than one length this is indicated if the size difference is 20 base pairs or more. Size differences shorter than 20 base pairs are not given. For high resolution SSP kits the respective lengths of the specific PCR product(s) of the alleles amplified by these primer mixes are given.

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 two different control primer pairs give rise to either an internal positive control band of 430 base pairs, for most wells, or a band of 515 base pairs, for some wells.

Well number 1 contains the primer pair giving rise to the longer, 515 bp, internal positive control band in order to help in the correct orientation of the DQB1\*03 subtyping.

In addition, wells number 2, 3, 4, 12, 14, 15, 18, 19, 21 and 22 contain the primer pair giving rise to the longer, 515 bp, internal positive control band in order to allow kit identification.

In the presence of a specific amplification the intensity of the control band often decreases.

<sup>3</sup>For several DQB1 alleles only partial second exon nucleotide sequences are 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. We assume that unknown sequences of DQB1 alleles are conserved within allelic groups.

<sup>4</sup>Due to the sharing of sequence motifs, non-DQB1\*03 alleles will be amplified by primer mixes 3, 4, 9, 11, 16, 18 and 22.

<sup>5</sup>Specific PCR fragments shorter than 150 base pairs are less intense and not as sharp as longer specific bands.

<sup>6</sup>Primer mixes 11 and 19 may give rise to nonspecific amplifications.

<sup>7</sup>Primer mix 6: Specific PCR fragment of 95 bp in the DQB1\*0320 allele. Specific PCR fragment of 130 bp in the DQB1\*030501-030504 and 0317 alleles.

<sup>8</sup>Primer mix 8: Specific PCR fragment of 110 bp in the DQB1\*0315 allele. Specific PCR fragment of 140 bp in the DQB1\*0307 and 0316 alleles.

<sup>9</sup>Primer mix 10: Specific PCR fragment of 135 bp in the DQB1\*0309 allele. Specific PCR fragment of 260 bp in the DQB1\*0311 allele.

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

<b>INTERPRETATION TABLE</b>												
<b>DQB1*03 SSP subtyping</b>												
<b>Amplification patterns of the DQB1*0301 to DQB1*0325 alleles</b>												
	Well <sup>5</sup>											
	1	2	3	4	5	6	7	8	9	10	11	12
Length of spec. PCR product(s)	165	220	135	220	135	95	115	110	135	135	135	260
Length of int.	515	515	515	515	430	430	430	430	430	430	430	515
pos. control <sup>1</sup>												
5'-primer(s) <sup>2</sup>	45(230)	26(173)	26(173)	26(173)	26(173)	26(173)	38(210)	49(242)	38(210)	14(136)	13(134)	13(134)
	5' -ggA 3' -TTA 3' -TCT 3' -TCT 3' -TTA 3' -ggg 3' -gCA 3' -ggT 3' -gCA 3' -gCC 3' -ggC 3' -ggC 3'											
						38(208)		55(260)		135(500)		
							5' -ACA 3'	5' -gCA 3'		5' -TgA 3'		
								63(285)				
									5' -Agg 3'			
3'-primer(s) <sup>3</sup>	86(353)	86(353)	57(266)	86(353)	57(266)	55(260)	62(282)	86(353)	70(304)	86(353)	45(230)	86(353)
	5' -gCT 3' -gCT 3' -Cgg 3' -gCT 3' -Cgg 3' -gCg 3' -CTA 3' -gCT 3' -CCC 3' -gCT 3' -CCC 3' -gCT 3'											
										167(596)		
											5' -CAT 3'	
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
DQB1 allele <sup>4</sup>												
*030101, 030102, 030104	1	2										12
*030103	1	2										12
*030201-030204			3	4								
*030302, 030303				4								
*0304	1	2			5							12
*030501-030504						6						
*0306				4			7					
Well No.	1	2	3	4	5	6	7	8	9	10	11	12



INTERPRETATION TABLE											
DQB1*03 SSP subtyping											
Amplification patterns of the DQB1*0301 to DQB1*0325 alleles											
Well <sup>5</sup>											
13	14	15	16	17	18	19	20	21	22	23	
165	130	135	130	220	175	175	150	160	160	130	Length of spec. PCR product(s)
430	515	515	430	430	515	515	430	515	515	430	Length of int. pos. control <sup>1</sup>
26(173)	26(173)	55(260)	57(266)	27(175)	140(514)	140(514)	133(493)	130(485)	9(122)	140(514)	5'-primer(s) <sup>2</sup>
5'-TTA 3'	5'-TTA 3'	5'-gCC 3'	5'-TgA 3'	5'-TTC 3'	5'-CAA 3'	5'-CAA 3'	5'-TTT 3'	5'-CCA 3'	5'-gTA 3'	5'-CAA 3'	
67(296)	55(260)	86(353)	86(353)	86(353)	185(650)	185(650)	170(604)	170(604)	48(240)	170(604)	3'-primer(s) <sup>3</sup>
5'-ggT 3'	5'-gCg 3'	5'-gCT 3'	5'-gCT 3'	5'-gCT 3'	5'-CgA 3'	5'-Cgg 3'	5'-gAC 3'	5'-gAC 3'	5'-gCg 3'	5'-gAT 3'	
	55(260)										
	5'-gCg 3'										
	55(260)										
	5'-ggg 3'										
13	14	15	16	17	18	19	20	21	22	23	Well No.
											DQB1 allele <sup>4</sup>
	14	15	16			19					*030101, 030102, 030104
	14	15				19					*030103
		15			18						*030201-030204
		15	16		18						*030302, 030303
	14	15				19					*0304
		15			18						*030501-030504
		15	16		?	?					*0306
13	14	15	16	17	18	19	20	21	22	23	Well No.

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Length of spec. PCR product(s)	165	220	135	220	135	95	115	110	135	135	135	260
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
*0307			3	4				8				
*0308			3	4					9			
*0309	1	2								10		12
*0310		2									11	12
*0311			3	4						10		
*0312				4							11	12
*0313	1	2										12
*0314		2			5						11	12
*0315				4				8				
*0316	1	2						8				12
*0317						6						
*0318			3	4								
*0319	1	2										12
*0320				4		6						
*0321	1	2										12
*0322	1	2										12
*0323				4								
*0324	1	2										12
*0325				4			7					
*020101-0202, 0204, 0205			3	4								
*0203				4								
*040101-0402												
*0403				4								
*060101-060104											11	
*060202									9			
*060301, 060402, 0607, 060801, 061101, 061102, 0626N, 0628, 0630- 0632												
*060302									9			
*0629			3									
DQB1 allele <sup>4</sup>												
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

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165	130	135	130	220	175	175	150	160	160	130	Length of spec. PCR product(s)
13	14	15	16	17	18	19	20	21	22	23	Well No.
		15			?	?					*0307
		15			?	?					*0308
	14	15	16			19					*0309
	14	15	16			19					*0310
		15			?	?					*0311
		15	16		?	?					*0312
13	14	15	16		?	?					*0313
	14	15			?	?					*0314
		15	16		?	?					*0315
			16		?	?					*0316
		15	16		?	?					*0317
		15		17	?	?					*0318
	14	15	16		18						*0319
		15	16		?	?					*0320
	14	15	16			19	20				*0321
	14	15	16			19		21			*0322
			16		?	?			22		*0323
	14	15	16			19				23	*0324
					18						*0325
											*020101-0202, 0204, 0205
			16								*0203
					18						*040101-0402
					18						*0403
											*060101-060104
											*060202
									22		*060301, 060402, 0607, 060801, 061101, 061102, 0626N, 0628, 0630- 0632
									22		*060302
											*0629
											DQB1 allele <sup>4</sup>
13	14	15	16	17	18	19	20	21	22	23	Well No.

Lot No.: **22G**

Lot-specific Information

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<sup>1</sup>The internal positive control primer pairs amplify segments of the human growth hormone gene. The two different control primer pairs give rise to either an internal positive control band of 430 base pairs, for most wells, or a band of 515 base pairs, for some wells.

Well number 1 contains the primer pair giving rise to the longer, 515 bp, internal positive control band in order to help in the correct orientation of the DQB1\*03 subtyping.

In addition, wells number 2, 3, 4, 12, 14, 15, 18, 19, 21 and 22 contain the primer pair giving rise to the longer, 515 bp, internal positive control band in order to allow kit identification.

<sup>2</sup>The codon, and in parenthesis the nucleotide, in the 2<sup>nd</sup> or 3<sup>rd</sup> exon, matching the specificity-determining 3'-end of the primer is given. Codon and 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 codon, and in parenthesis the nucleotide, in the 2<sup>nd</sup> or 3<sup>rd</sup> exon, matching the specificity-determining 3'-end of the primer is given in the anti-sense direction. Codon and 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>4</sup>The sequence of the DQB1\*030301 allele has been shown to be identical to DQB1\*030302.

<sup>5</sup>Primer mix 6: Specific PCR fragment of 95 bp in the DQB1\*0320 allele. Specific PCR fragment of 130 bp in the DQB1\*030501-030504 and 0317alleles.

Primer mix 8: Specific PCR fragment of 110 bp in the DQB1\*0315 allele. Specific PCR fragment of 140 bp in the DQB1\*0307 and 0316 alleles.

Primer mix 10: Specific PCR fragment of 135 bp in the DQB1\*0309 allele. Specific PCR fragment of 260 bp in the DQB1\*0311 allele.

'?', nucleotide sequence information not available for the primer matching region.

CELL LINE VALIDATION SHEET																			
DQB1*03 SSP subtyping kit																			
			Production No.	Well															
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
	IHWC cell line	DQB1		200963001	200963002	200963003	200963004	200963005	200963006	200963007	200963008	200963009	200963010	200963011	200963012	200963013	200963014	200963015	200963016
1	9001 SA	*0501		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2	9280 LK707	*0601	*0202	-	-	+	+	-	-	-	-	-	-	-	-	-	-	-	-
3	9011 E4181324	*0601		-	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-
4	9275 GU373	*0201		-	-	+	+	-	-	-	-	-	-	-	-	-	-	-	-
5	9009 KAS011	*0502		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
6	9353 SM	*0302	*0601	-	-	+	+	-	-	-	-	-	-	+	-	-	-	+	-
7	9020 QBL	*0201		-	-	+	+	-	-	-	-	-	-	-	-	-	-	-	-
8	9025 DEU	*0301		+	+	-	-	-	-	-	-	-	-	-	+	-	+	+	+
9	9026 YAR	*0302		-	-	+	+	-	-	-	-	-	-	-	-	-	-	+	-
10	9107 LKT3	*0401		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
11	9051 PITOUT	*0202		-	-	+	+	-	-	-	-	-	-	-	-	-	-	-	-
12	9052 DBB	*0303		-	-	-	+	-	-	-	-	-	-	-	-	-	-	+	+
13	9004 JESTHOM	*0501		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
14	9071 OLGA	*0402		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
15	9075 DKB	*0303		-	-	-	+	-	-	-	-	-	-	-	-	-	-	+	+
16	9037 SWEIG007	*0301		+	+	-	-	-	-	-	-	-	-	-	+	-	+	+	+
17	9282 CTM3953540	*0201	*0603	-	-	+	+	-	-	-	-	-	-	-	-	-	-	-	-
18	9257 32367	*0602	*0202	-	-	+	+	-	-	-	-	-	-	-	-	-	-	-	-
19	9038 BM16	*0301		+	+	-	-	-	-	-	-	-	-	-	+	-	+	+	+
20	9059 SLE005	*0604		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
21	9064 AMALA	*0301		+	+	-	-	-	-	-	-	-	-	-	+	-	+	+	+
22	9056 KOSE	*0503	*0604	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
23	9124 IHL	*0503	*0601	-	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-
24	9035 JBUSH	*0301		+	+	-	-	-	-	-	-	-	-	-	+	-	+	+	+
25	9049 IBW9	*0202		-	-	+	+	-	-	-	-	-	-	-	-	-	-	-	-
26	9285 WT49	*0201		-	-	+	+	-	-	-	-	-	-	-	-	-	-	-	-
27	9191 CH1007	*0401	*0501	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
28	9320 BEL5GB	*0202	*0301	+	+	+	+	-	-	-	-	-	-	-	+	-	+	+	+
29	9050 MOU	*0202		-	-	+	+	-	-	-	-	-	-	-	-	-	-	-	-
30	9021 RSH	*0402		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
31	9019 DUCAF	*0201		-	-	+	+	-	-	-	-	-	-	-	-	-	-	-	-
32	9297 HAG	*0301		+	+	-	-	-	-	-	-	-	-	-	+	-	+	+	+
33	9098 MT14B	*0302		-	-	+	+	-	-	-	-	-	-	-	-	-	-	+	-
34	9104 DHIF	*0301		+	+	-	-	-	-	-	-	-	0301	-	+	-	+	+	+
35	9302 SSTO	*0305		-	-	-	-	-	+	-	-	-	-	-	-	-	-	+	-
36	9024 KT17	*0302		-	-	+	+	-	-	-	-	-	-	-	-	-	-	+	-
37	9065 HHKB	*0603		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
38	9099 LZL	*0301		+	+	-	-	-	-	-	-	-	-	-	+	-	+	+	+
39	9315 CML	*0201	*0301	+	+	+	+	-	-	-	-	-	-	-	+	-	+	+	+
40	9134 WHONP199	*0202	*0303	-	-	+	+	-	-	-	-	-	-	-	-	-	-	+	+
41	9055 H0301	*0609		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
42	9066 TAB089	*0601		-	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-
43	9076 T7526	*0303		-	-	-	+	-	-	-	-	-	-	-	-	-	-	+	+
44	9057 TEM	*0503		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
45	9239 SHJO	*0202		-	-	+	+	-	-	-	-	-	-	-	-	-	-	-	-
46	9013 SCHU	*0602		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
47	9045 TUBO	*0301		+	+	-	-	-	-	-	-	-	-	-	+	-	+	+	+
48	9303 TER-ND	*0501		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

CELL LINE VALIDATION SHEET											
DQB1*03 SSP subtyping kit											
				Production No.	Well						
					17	18	19	20	21	22	23
					200963017	200963018	200963019	200963020	200963021	200963022	200963023
	IHWC cell line		DQB1								
1	9001 SA		*0501		-	-	-	-	-	-	-
2	9280 LK707		*0601	*0202	-	-	-	-	-	-	-
3	9011 E4181324		*0601		-	-	-	-	-	-	-
4	9275 GU373		*0201		-	-	-	-	-	-	-
5	9009 KAS011		*0502		-	-	-	-	-	-	-
6	9353 SM		*0302	*0601	-	+	-	-	-	-	-
7	9020 QBL		*0201		-	-	-	-	-	-	-
8	9025 DEU		*0301		-	-	+	-	-	-	-
9	9026 YAR		*0302		-	+	-	-	-	-	-
10	9107 LKT3		*0401		-	+	-	-	-	-	-
11	9051 PITOUT		*0202		-	-	-	-	-	-	-
12	9052 DBB		*0303		-	+	-	-	-	-	-
13	9004 JESTHOM		*0501		-	-	-	-	-	-	-
14	9071 OLGA		*0402		-	+	-	-	-	-	-
15	9075 DKB		*0303		-	+	-	-	-	-	-
16	9037 SWEIG007		*0301		-	-	+	-	-	-	-
17	9282 CTM3953540		*0201	*0603	-	-	-	-	-	+	-
18	9257 32367		*0602	*0202	-	-	-	-	-	-	-
19	9038 BM16		*0301		-	-	+	-	-	-	-
20	9059 SLE005		*0604		-	-	-	-	-	-	-
21	9064 AMALA		*0301		-	-	+	-	-	-	-
22	9056 KOSE		*0503	*0604	-	-	-	-	-	-	-
23	9124 IHL		*0503	*0601	-	-	-	-	-	-	-
24	9035 JBUSH		*0301		-	-	+	-	-	-	-
25	9049 IBW9		*0202		-	-	-	-	-	-	-
26	9285 WT49		*0201		-	-	-	-	-	-	-
27	9191 CH1007		*0401	*0501	-	+	-	-	-	-	-
28	9320 BEL5GB		*0202	*0301	-	-	+	-	-	-	-
29	9050 MOU		*0202		-	-	-	-	-	-	-
30	9021 RSH		*0402		-	+	-	-	-	-	-
31	9019 DUCAF		*0201		-	-	-	-	-	-	-
32	9297 HAG		*0301		-	-	+	-	-	-	-
33	9098 MT14B		*0302		-	+	-	-	-	-	-
34	9104 DHIF		*0301		-	-	+	-	-	-	-
35	9302 SSTO		*0305		-	+	-	-	-	-	-
36	9024 KT17		*0302		-	+	-	-	-	-	-
37	9065 HHKB		*0603		-	-	-	-	-	+	-
38	9099 LZL		*0301		-	-	+	-	-	-	-
39	9315 CML		*0201	*0301	-	-	+	-	-	-	-
40	9134 WHONP199		*0202	*0303	-	+	-	-	-	-	-
41	9055 H0301		*0609		-	-	-	-	-	-	-
42	9066 TAB089		*0601		-	-	-	-	-	-	-
43	9076 T7526		*0303		-	+	-	-	-	-	-
44	9057 TEM		*0503		-	-	-	-	-	-	-
45	9239 SHJO		*0202		-	-	-	-	-	-	-
46	9013 SCHU		*0602		-	-	-	-	-	-	-
47	9045 TUBO		*0301		-	-	+	-	-	-	-
48	9303 TER-ND		*0501		-	-	-	-	-	-	-

## CERTIFICATE OF ANALYSIS

### **Olerup SSP<sup>®</sup> DQB1\*03 SSP**

**Product number:** 101.214-24/06 – including *Taq* pol.  
**Lot number:** 22G  
**Expiry date:** 2011-October-01  
**Number of tests:** 24 test – Product No. 101.214-24  
6 tests – Product No. 101.214-06  
**Number of wells per test:** 23

#### **Well specifications:**

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2009-630-01	9	2009-630-09	17	2009-630-17
2	2009-630-02	10	2009-630-10	18	2009-630-18
3	2009-630-03	11	2009-630-11	19	2009-630-19
4	2009-630-04	12	2009-630-12	20	2009-630-20
5	2009-630-05	13	2009-630-13	21	2009-630-21
6	2009-630-06	14	2009-630-14	22	2009-630-22
7	2009-630-07	15	2009-630-15	23	2009-630-23
8	2009-630-08	16	2009-630-16		

The specificity of each primer solution of the kit has been tested against 48 well characterized IHWC cell line DNAs.

No DNAs carrying the alleles to be amplified by primer solutions 7 to 10, 13, 17, 20, 21 and 23 were available. The specificities of the primers in primer solutions 7, 9 and 10 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer solutions 8, 17, 20 and 21 it was only possible to test the 3'-primer, the 5'-primers were not possible to test. In primer solutions 13 and 23 it was only possible to test the 3'-primers, the 5'-primers were not possible to test. In primer solutions 10 and 14 one of the 3'-primers was not possible to test, and in primer solution 6 one of the 5'-primers was not possible to test.

**Results:** No false positive or false negative amplifications were obtained.

**Date of approval:** 2009-October-08

**Approved by:**

**Quality Control, Supervisor**

## Declaration of Conformity

**Product name:** *Olerup* SSP® DQB1\*03  
**Product number:** 101.214-24/06  
**Lot number:** 22G

**Intended use:** DQB1\*03 resolution histocompatibility testing

**Manufacturer:** *Olerup* SSP AB  
Hasselstigen 1  
SE-133 33 Saltsjöbaden, Sweden  
**Phone:** +46-8-717 88 27  
**Fax:** +46-8-717 88 18

We, *Olerup* SSP AB, hereby declare that this product, to which this Declaration of Conformity relates is in conformity with the following Standard(s) and other normative document(s) ISO 9001:2000 and ISO 13485:2003, following the provisions of the 98/79/EC Directive on *in vitro* diagnostic medical devices, Annex III, as transposed into the national laws of the Member States of the European Union.

The Technical Documentation File is maintained at *Olerup* SSP AB, Hasselstigen 1, SE-133 33 Saltsjöbaden, Sweden.

The Authorized Representative located within the Community is: *Olerup* SSP AB.

Saltsjöbaden, Sweden  
2009-October-08

Olle Olerup  
Managing Director









Lot No.: **22G**

Lot-specific Information

[www.olerup.com](http://www.olerup.com)

**ADDRESSES:**

**Manufacturer:**

**Olerup SSP AB**, Hasselstigen 1, SE-133 33 Saltsjöbaden, Sweden.

**Tel:** +46-8-717 88 27

**Fax:** +46-8-717 88 18

**E-mail:** [info-ssp@olerup.com](mailto:info-ssp@olerup.com)

**Web page:** <http://www.olerup.com>

**Distributed by:**

**Olerup GmbH**, Löwengasse 47 / 6, AT-1030 Vienna, Austria.

**Tel:** +43-1-710 15 00

**Fax:** +43-1-710 15 00 10

**E-mail:** [support-at@olerup.com](mailto:support-at@olerup.com)

**Web page:** <http://www.olerup.com>

**Olerup Inc.**, 901 S. Bolmar St., Suite R, West Chester, PA 19382

**Tel:** 1-877-OLERUP1

**Fax:** 610-344-7989

**E-mail:** [info.us@olerup.com](mailto:info.us@olerup.com)

**Web page:** <http://www.olerup.com>

For information on *Olerup* SSP distributors worldwide, contact **Olerup GmbH**.