Olerup SSP® DQB1*06

Product number:	**101.212-24/04 – including *Taq* pol.**
Lot number:	**02G**
Expiry date:	**2011-June-01**
Number of tests:	**24**
Number of wells per test:	**29**
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. 02G.

CHANGES COMPARED TO THE PREVIOUS *OLERUP* SSP® DQB1*06 LOT

The DQB1*06 specificity and interpretation tables have been updated for the DQB1 alleles described since the previous *Olerup* SSP® DQB1*06 lot **(Lot No. 61E)**.

One well have been added to the DQB1*06 kit,
well **29**.

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

Well	5'-primer	3'-primer	rationale
8	-	Added	Primer added for increased yield of specific PCR product.
14	Exchanged	-	New primer to decrease formation of primer dimers.
15	-	Added	New primer for the DQB1*061402 allele.
29	New	New	New primer pair for improved resolution of the DQB1*0603 and *0604 alleles.

Change in revision R01 compared to R00:

1. The DQB1*0615 and DQB1*0622 alleles are weakly amplified by primer mix 11. This has been changed in the Specificity and Interpretation Tables.

PRODUCT DESCRIPTION

DQB1*06 SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for identifying the DQB1*0601 to DQB1*0634 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.

STRIP LAYOUT

Each test consists of 29 PCR reactions in a 32 well cut PCR plate. Wells 30 to 32 are empty.

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**	**empty**	**empty**	**empty**

The 32 well cut PCR plate is marked with 'DQB1*06' in silver/gray ink.
Well No. 1 is marked with the Lot No. '02G'.
The PCR plates are covered with a PCR-compatible foil.
Please note: When removing each 32 well PCR plate, make sure that the remaining plates stay covered. Use a scalpel or a similar instrument to carefully cut the foil between the plates.

INTERPRETATION

Only the DQB1*06 alleles will be amplified by the DQB1*06 subtyping kit, except that the DQB1*0323 allele will be amplified by primer mix 5, and DQB1*0401, 0402 and 0403 alleles will be amplified by primer mix 24. Thus, the interpretation of DQB1*06 subtypings is only influenced by these four non-DQB1*06 alleles and not by other groups of DQB1 alleles or the DQB2 and DQB3 genes.

UNIQUELY IDENTIFIED ALLELES

All the DQB1*06 alleles, i.e. **DQB1*0601 to DQB1*0634**, recognized by the HLA Nomenclature Committee in May 2009[1] will give rise to unique amplification patterns by the primers in the DQB1*06 subtyping kit.
The DQB1*06 subtyping kit cannot distinguish the DQB1*060101 to 060104 alleles, the DQB1*060201 and 060202 alleles, the DQB1*060301 and 060302 alleles or the DQB1*060401 and DQB1*060403 alleles.

[1]HLA-B alleles listed on the IMGT/HLA web page 2009-May-09, release 2.25.2, www.ebi.ac.uk/imgt/hla.

RESOLUTION IN HOMO- AND HETEROZYGOTES

The 34 DQB1*06 alleles give rise to 39 different amplification patterns can be combined in 780 homozygous and heterozygous combinations[1]. 120 of these genotypes do not give rise to unique amplification patterns. The different lengths of the specific PCR products generated by primer mix 15 have not been considered in these calculations.

```
-++++++- -+------ ----+-+- +---- 0602,0631 = 0603,0620 =
                                 0620,0631
-++++++- ------+- ----+-+- +---- 061101,061401 = 061102,061401 =
                                 061102,061402
-+++++-- -------- -+--+--- +---- 0602,0630 = 0624,0630
-+++-+-- ------+- ----+-+- +---- 0602,061401 = 061401,0629
-++----+- +------- -+--+--- ----- 0602,0617 = 0617,0624
-++-----+ ++------ ----+--- ----+ 0602,0606 = 0606,0620
-++-----+ ++------ ----+--- ----+ 0602,060501 = 060501,0620 =
                                 0609,0620
-++-----+ -++----- ----+--- ----+ 0602,060502 = 060502,0620
-++----- -+------ ----+--- ----- 0602,0620 = 0620,0620
-++----- ------+- ----+-+- +---- 0602,061402 = 061402,0629
-++----- -------+ ----+--- ----- 0602,0616 = 0616,0616
-++----- -------- -+--+--- ----- 0602,0624 = 0624,0624
-++----- -------- ----+--- --+-- 0602,0633 = 0633,0633
-+-+++++ +------- -------- ----+ 0604,061102 = 060402,061102
-+-++-+ ++------ ------+- +---+ 0603,0606 = 0606,0631
-+-++-+ -++----- ------+- +---+ 0603,060502 = 060502,0631
-+-+++-- +------- ------+- +---- 060801,061102 = 060802,061102
-+-+++-- -+------ ------+- +---- 061101,0631 = 061102,0631
-+-+++-- -------- ---+---- ----- 061101,0626N = 061102,0626N
-+-+++-- -------- ------+- ++--- 061101,0628 = 061102,0628
-+-+++-- -------- ------+- +---- 0603,061101 = 0603,061102
-+-+++-- -------- -------- ----- 061101,061102 = 061102,061102
-+--++-- +------- ------+- +---- 060801,061101 = 060802,061101
-+--+-++ +------- -------- ----+ 0604,061101 = 060402,061101 =
                                 060402,0618
-+-----+ ++------ -------- ----+ 060501,0606 = 060502,0606 =
                                 0606,0606 = 0606,0609 =
                                 0606,0618
-+-----+ ++----- -------- ----+ 060501,060502 = 060501,0618 =
                                 060502,0609 = 060502,0618
--++++-- -+----+- ----+-+- +---- 061401,0631 = 061402,0631
--++++-- ------+- ---++-+- +---- 061401,0626N = 061402,0626N
--++++-- ------+- ----+-+- ++--- 061401,0628 = 061402,0628
--++++-- ------+- ----+-+- +---- 0603,061401 = 0603,061402
--++-+-- ------+- ----+-+- +---- 061401,061401 = 061401,061402
---++++- ++------ ------+- +---+ 0604,0631 = 060402,0631
---++++- +------- ---+---- ----+ 0604,0626N = 060402,0626N
---++++- +------- -----++- +---+ 0607,060801 = 0607,060802
---++++- +------- ------+- ++--+ 0604,0628 = 060402,0628
---++++- +------- ------+- +---+ 0603,0604 = 0603,060402
---+++-- +------- -+----+- +---- 0603,0617 = 0621,0630
---+++-+ ++------ ------+- +---+ 0603,060501 = 060501,0631 =
                                 0609,0631
```

---++++-+	+-------	------+-	+---- 0603,0627 = 060801,0632 = 060802,0632
---++++-	++------	------+-	+---- 060801,0631 = 060802,0631
---++++-	+-------	-+----+-	+---- 060801,0630 = 060802,0630
---++++-	+-------	---+--+-	+---- 060801,0626N = 060802,0626N
---++++-	+-------	------+-	++--- 060801,0628 = 060802,0628
---++++-	+-------	------+-	+---- 0603,060801 = 0603,060802
---++++-	-+------	------+-	+---- 0603,0631 = 0631,0631
---++++-	--------	------+-	++--- 0603,0628 = 0628,0628
---+++-++	+-------	-+------	+---+ 0604,0630 = 060402,0630
---+++-++	+-------	-----+--	----+ 0604,0607 = 060402,0607
---+++-++	+-------	--------	+---+ 0604,0632 = 060402,0632
----++++	+-------	------+-	+---+ 0604,060801 = 060402,060801 = 060402,060802
----++--	+-------	------+-	+---- 060801,060801 = 060801,060802
----+-++	+-------	--------	----+ 0604,060402 = 060402,060402
------++	+-------	--------	---++ 0604,0634 = 0634,0634
-------+	++-----	--------	----+ 060501,060501 = 060501,0609

[1]The two different amplification patterns of the DQB1*060401/060403 and DQB1*060402 alleles, the DQB1*050101 and DQB1*050102 alleles, the DQB1*060801 and DQB1*060802 alleles, the DQB1*061101 and DQB1*061102 alleles and the DQB1*061401 and DQB1*061402 alleles have been considered in these calculations.

SPECIFICITY TABLE

DQB1*06 SSP subtyping

Specificities and sizes of the PCR products of the 29 primer mixes used for DQB1*06 SSP subtyping

Primer Mix	Size of spec. PCR product[1]	Size of control band[2]	Amplified DQB1 alleles[3]
1	220 bp	**515 bp**	060101-060104
2	210 bp	430 bp	060101-060202, 060502[?], 0606[?], 0610-061102, 0613, 0616, 0618-0620, 0624, 0629, 0633
3	185 bp	430 bp	060201-060202, 061401-0616, 0619, 0620, 0623, 0624, 0633
4	130 bp	430 bp	060301-060302, 0607, 061102, 061401, 0626N, 0628, 0630-0632
5	160 bp	430 bp	060301-060302, 060402, 0607, 060801, 061101-061102, 0626N, 0628, 0630-0632, 0323
6	170 bp	**515 bp**	060301-060302, 060801-060802, 061102, 0612, 061401, 0621, 0626N, 0628, 0631
7	210 bp	**515 bp**	060401-060403, 0607, 0617, 0621, 0625, 0634
8	170 bp	430 bp	060401-060501, 060502, 0606, 0607, 0609, 0618, 0625, 0627, 0632, 0634
9[5]	130 bp	430 bp	060401-060501, 0606, 060801-0609, 0612, 0617, 0618, 0621, 0627, 0634
10[6]	260 bp	**515 bp**	060501, 060502[?], 0606[?], 0620, 0631
11	210 bp	430 bp	060501, 060502[?], 0606[?], 0609, 0612, 0615[w], 0622[w]
12	180 bp	430 bp	0606
13	185 bp	430 bp	0610
14	130 bp	430 bp	0613, 0622
15[4,8]	100, 185 bp	430 bp	061401-061402, 0629
16	195 bp	430 bp	0616
17[4]	110 bp	430 bp	0623
18[7]	175 bp	430 bp	0617, 0624, 0630
19	135 bp	430 bp	0610, 0625
20	215 bp	**515 bp**	0626N

21	160 bp	430 bp	060201-060202, 0610, 0613-0616, 0620, 0623, 0624, 0629, 0633
22	130 bp	**515 bp**	0607, 0615
23	160 bp	**515 bp**	060301-060302, 060801-060802, 061401-061402, 0621, 0628, 0631
24	155 bp	430 bp	0619, 0401- 0403
25	210 bp	430 bp	060301-060302, 060801-060802, 061401-061402, 0627, 0628, 0630-0632
26	190 bp	430 bp	0628
27	265 bp	430 bp	0633
28	300 bp	430 bp	0634
29[4]	90 bp	430 bp	060401-060501, 060502[?], 0606[?], 0607, 0609, 0615, 0622, 0625, 0634

[1]Alleles are assigned by the presence of specific PCR product(s). However, the sizes of the specific PCR products may be helpful in the interpretation of DQB1*06 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 inherit feature of the primer pair(s) of a primer mix. More often it is due to other factors such as too low amount of DNA in the PCR reactions, taking too long time in setting up the PCR reactions, working at elevated room temperature or using thermal cyclers that are not pre-heated
[2]The internal positive control primer pairs amplify segments of the human growth hormone gene. The 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*06 subtyping.
In addition, wells number 6, 7, 10, 20, 22 and 23 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.
[3]Due to the sharing of sequence motif between DQB1 alleles, the DQB1*0323 alleles will be amplified by primer mix 5, and the DQB1*0401 to 0403 alleles will be amplified by primer mix 24.
[4]Specific PCR fragments shorter than 125 base pairs have a lower intensity than longer PCR bands.
[5]Primer mix 9 may yield somewhat less intense specific PCR fragments than the other DQB1*06 primer mixes.
[6]The nucleotide sequence of codon 14 of the DQB1*060502 allele is not yet known. If codon 14 is CTg, then the DQB1*060502 allele will retain its name and will be amplified by the primer pair in well No. 10. If the sequence of codon 14 is ATg, then DQB1*060502 will be renamed to DQB1*060902 (Steven Marsh personal communication), and will not be amplified by the primer pair in well No. 10.
[7]Primer mix 18 may give rise to primer dimer formation.

[8]Primer mix 15: Specific PCR fragment of 100 bp in the DQB1*061401 and *061402 alleles. Specific PCR fragment of 185 bp in the DQB1*0629 allele.
"?", nucleotide sequence information is not available for the primer matching sequence.
'w', might be weakly amplified.

INTERPRETATION TABLE

DQB1*06 SSP subtyping

Amplification patterns of the DQB1*0601 to 0634 alleles

	Well[4]															
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**
Length of spec.	**220**	**210**	**185**	**130**	**160**	**170**	**210**	**170**	**130**	**260**	**210**	**180**	**185**	**130**	**100**	**195**
PCR product															**185**	
Length of int. pos. control[1]	**515**	**430**	**430**	**430**	**430**	**515**	**515**	**430**	**430**	**515**	**430**	**430**	**430**	**430**	**430**	**430**
5'-primer(s)[2]	**26**	**30**	**9**	**27**	**9**	**27**	**30**	**27**	**27**	**14**	**30**	**27**	**9**	**27**	**9**	**9**
	5'-T TA 3'	5'-gA T 3'	5'-g TT 3'	5'-gTA 3'	5'-g TA 3'	5'-gTA 3'	5'-gA C 3'	5'-gTA 3'	5'-gTA 3'	5'-gC C 3'	5'-gA T 3'	5'-gTA 3'	5'-g TT 3'	5'-gTg 3'	5'-g TT 3'	5'-g TT 3'
		30														
		5'-gA T 3'														
3'-primer(s)[3]	**86**	**86**	**57**	**57**	**48**	**70**	**86**	**70**	**57**	**86**	**86**	**74**	**57**	**57**	**27**	**60**
	5'-A Cg 3'	5'-A Cg 3'	5'-C AT 3'	5'-C AT 3'	5'-gC g 3'	5'-CCC 3'	5'-A CC 3'	5'-CCT 3'	5'-C AA 3'	5'-AC C 3'	5'-A CC 3'	5'-C Cg 3'	5'-gC T 3'	5'-C AA 3'	5'-gT T 3'	5'-gTT 3'
								74		**87**					**30**	
								5'-C Cg 3'		5'-gg A 3'					5'-gTg 3'	
															57	
															5'-C gg 3'	
Well No.	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**
DQB1 allele																
***060101-060104**	**1**	**2**														
***060201-060202**		**2**	**3**													
***060301-060302**				**4**	**5**	**6**										
***060401, 060403**							**7**	**8**	**9**							
***060402**					**5**		**7**	**8**	**9**							
***060501**								**8**	**9**	**10**	**11**					
***060502**		**?**						**8**		**?**	**?**					
***0606**		**?**						**8**	**9**	**?**	**?**	**12**				
***0607**				**4**	**5**		**7**	**8**								
***060801**					**5**	**6**			**9**							
***060802**						**6**			**9**							
***0609**								**8**	**9**		**11**					
***0610**		**2**											**13**			
***061101**		**2**			**5**											
***061102**		**2**		**4**	**5**	**6**										
***0612**						**6**			**9**		**11**					
***0613**		**2**												**14**		
***061401**			**3**	**4**		**6**									**15**	
***061402**			**3**												**15**	
***0615**			**3**								**w**					
***0616**		**2**	**3**													**16**
Well No.	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**

INTERPRETATION TABLE

DQB1*06 SSP subtyping

Amplification patterns of the DQB1*0601 to 0634 alleles

Well[4]													
17	18	19	20	21	22	23	24	25	26	27	28	29	
110	175	135	215	160	130	160	155	210	190	265	300	90	Length of spec. PCR product
430	430	430	515	430	515	515	430	430	430	430	430	430	Length of int. pos. control[1]
26	26	26	29	9	57	30	9	30	38	11	102	70	5'-primer(s)[2]
5'-g gg 3'	5'-T CT 3'	5'-T CT 3'	5'-CC T 3'	5'-g TT 3'	5'-T gA 3'	5'-gA C 3'	5'-g TT 3'	5'-gA C 3'	5'-C gT 3'	5'-TTA 3'	5'-TC T 3'	5'-Ag A3'	
48	71	57	86	48	86	70	47	86	87	86	189	86	3'-primer(s)[3]
5'-gC g 3'	5'-ggT 3'	5'-gC T 3'	5'-A Cg 3'	5'-gC g 3'	5'-A CC 3'	5'-CCC 3'	5'-Cg A 3'	5'-A Cg 3'	5'-gg A 3'	5'-A Cg 3'	5'-CCA 3'	5'-ACC3'	
17	18	19	20	21	22	23	24	25	26	27	28	29	Well No.
													DQB1 allele
													*060101-060104
				21									*060201-060202
						23		25					*060301-060302
												29	*060401, 060403
												29	*060402
												29	*060501
												?	*060502
												?	*0606
					22							29	*0607
						23		25					*060801
						23		25					*060802
												29	*0609
		19		21									*0610
													*061101
													*061102
													*0612
				21									*0613
				21		23		25					*061401
				21		23		25					*061402
				21	22							29	*0615
				21									*0616
17	18	19	20	21	22	23	24	25	26	27	28	29	Well No.

Length of spec.	**220**	**210**	**185**	**130**	**160**	**170**	**210**	**170**	**130**	**260**	**210**	**180**	**185**	**130**	**100**	**195**
PCR product															**185**	
Well No.	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**
***0617**							**7**		**9**							
***0618**		**2**						**8**	**9**							
***0619**		**2**	**3**													
***0620**		**2**	**3**							**10**						
***0621**						**6**	**7**		**9**							
***0622**											**w**			**14**		
***0623**			**3**													
***0624**		**2**	**3**													
***0625**							**7**	**8**								
***0626N**				**4**	**5**	**6**										
***0627**								**8**	**9**							
***0628**				**4**	**5**	**6**										
***0629**		**2**													**15**	
***0630**				**4**	**5**											
***0631**				**4**	**5**	**6**				**10**						
***0632**				**4**	**5**			**8**								
***0633**		**2**	**3**													
***0634**							**7**	**8**	**9**							
***0323**					**5**											
***0401-0403**																
DQB1 allele																
Well No.	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**

[1]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*06 subtyping.
In addition, wells number 6, 7, 10, 20, 22 and 23 contain the primer pair giving rise to the longer, 515 bp, internal positive control band in order to allow kit identification.

110	175	135	215	160	130	160	155	210	190	265	300	90	Length of spec.
													PCR product
17	18	19	20	21	22	23	24	25	26	27	28	29	Well No.
	18												*0617
													*0618
							24						*0619
				21									*0620
						23							*0621
												29	*0622
17				21									*0623
	18			21									*0624
		19										29	*0625
			20										*0626N
								25					*0627
						23		25	26				*0628
				21									*0629
	18							25					*0630
						23		25					*0631
								25					*0632
				21						27			*0633
											28	29	*0634
													*0323
							24						*0401-0403
													DQB1 allele
17	18	19	20	21	22	23	24	25	26	27	28	29	Well No.

[2]The nucleotide position, in the 2nd or 3rd exons, matching the specificity-determining 3'-end of the primer is given. Nuclotide numbering as on the www.ebi.ac.uk/imgt/hla web site. The sequence of the 3 terminal nucleotides of the primer is given. Empty spaces indicate codon boundaries.

[2]The nucleotide position, in the 2nd or 3rd exons, matching the specificity-determining 3'-end of the primer is given. Nuclotide numbering as on the www.ebi.ac.uk/imgt/hla web site. The sequence of the 3 terminal nucleotides of the primer is given. Empty spaces indicate codon boundaries.

[4]Primer mix 15: Specific PCR fragment of 100 bp in the DQB1*061401 and *061402 alleles. Specific PCR fragment of 185 bp in the DQB1*0629 allele.

"?", nucleotide sequence information is not available for the primer matching sequence.

'w', might be weakly amplified.

CELL LINE VALIDATION SHEET

DQB1*06 SSP subtyping kit

					Well															
					1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
				Prod. No.	200732001	200732002	200732003	200732004	200732005	200732006	200732007	200961108	200732009	200846310	200732011	200732012	200732013	200961114	200961115	200732016
	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		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

CELL LINE VALIDATION SHEET

DQB1*06 SSP subtyping kit

					Well												
					17	18	19	20	21	22	23	24	25	26	27	28	29
				Prod. No.	200732017	200961118	200732019	200732020	200732021	200732022	200846323	200732024	200846325	200846326	200846327	200846328	200961129
	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® DQB1*06 SSP

Product number: **101.212-24/04 – including *Taq* pol.**
Lot number: **02G**
Expiry date: **2011-June-01**
Number of tests: **24 test – Product No. 101.212-24**
4 tests – Product No. 101.212-04
Number of wells per test: **29**

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2007-320-01	11	2007-320-11	21	2007-320-21
2	2007-320-02	12	2007-320-12	22	2007-320-22
3	2007-320-03	13	2007-320-13	23	2008-463-23
4	2007-320-04	14	2009-611-14	24	2007-320-24
5	2007-320-05	15	2009-611-15	25	2008-463-25
6	2007-320-06	16	2007-320-16	26	2008-463-26
7	2007-320-07	17	2007-320-17	27	2008-463-27
8	2009-611-08	18	2009-611-18	28	2008-463-28
9	2007-320-09	19	2007-320-19	29	2009-611-29
10	2008-463-10	20	2007-320-20		

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

No DNAs carrying the alleles to be amplified by primer solutions 10, 12 to 20, 22 and 26 to 28 were available. The specificities of the primers in primer solutions 10, 12 to 15, 17, 19, 22 and 26 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer solutions 16, 18 and 28 it was only possible to test the 5'-primers, the 3'-primers were not possible to test. . In primer solutions 20 and 27 it was only possible to test the 3'-primer, the 5'-primer was not possible to test.

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

Date of approval: 2009-June-24

Approved by:

Quality Control, Supervisor

Declaration of Conformity

Product name: *Olerup* SSP™ DQB1*06
Product number: 101.212-24/04
Lot number: 02G

Intended use: DQB1*06 high 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-June-24

Olle Olerup
Managing Director

ADDRESSES:

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