

Olerup SSP[®] DQB1*06

Product number:	101.212-24/04 – including <i>Taq</i> pol. 101.212-24u/04u – without <i>Taq</i> pol.
Lot number:	61E
Expiry date:	2010-May-01
Number of tests:	24
Number of wells per test:	28
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. 61E.

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. X59**).

Four wells have been added to the DQB1*06 kit,
wells **25 to 28**

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

Well	5'-primer	3'-primer	rationale
10	Removed	-	Primer pair moved to well 26.
23	-	Removed	Primer pair moved to well 25.
25	New	New	Primer pair moved from well 23.
26	New	New	Primer pair moved from well 10
27	New	New	Primer pair added for the DQB1*0633 allele
28	New	New	Primer pair added for the DQB1*0634 allele

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 28 PCR reactions in a 32 well cut PCR plate. Wells 29 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	empty	empty	empty	empty

The 32 well cut PCR plate is marked with 'DQB1*06'.

Well No. 1 is marked with the Lot No. '61E'.

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*0401, 0402 and 0403 alleles will be amplified by the primers in primer mix 24. Thus, the interpretation of DQB1*06 subtypings is only influenced by these three 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 April 2008¹ 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 060103 alleles, the DQB1*060201 and 060202 alleles, the DQB1*060301 and 060302 alleles or the DQB1*060401 and DQB1*060403 alleles.

¹HLA-B alleles listed on the IMGT/HLA web page 2008-April-08, release 2.21.0, www.ebi.ac.uk/imgt/hla.

RESOLUTION IN HOMO- AND HETEROZYGOTES

The 34 DQB1*06 alleles give rise to 38 different amplification patterns can be combined in 741 homozygous and heterozygous combinations¹. 128 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
-+++++-- -----+- -----+-+ +--- 061101,0614 = 061102,0614
-+++++-- -----+- -+-----+ +--- 0602,0630 = 0624,0630
-+++++-- -----+- -----+-+ +--- 0602,0614 = 0614,0629
-+-----+ +-----+ -+-----+ +--- 0602,0617 = 0617,0624
-+-----+ ++++++-- -----+--- +--- 0602,0606 = 0606,0620
-+-----+ ++++++-- -----+--- +--- 0602,060501 = 060501,0620 =
0609,0620
-+-----+ -+-----+ -----+--- +--- 0602,060502 = 060502,0620
-+-----+ -+-----+ -----+--- +--- 0602,0620 = 0620,0620
-+-----+ -----+--- -----+--- +--- 0602,0616 = 0616,0616
-+-----+ -----+--- -+-----+ +--- 0602,0624 = 0624,0624
-+-----+ -----+--- -----+--- --+- 0602,0633 = 0633,0633
-+-----+ +-----+ -----+--- +--- 0604,061102 = 060402,061102
-+-----+ +-----+ -----+--- +--- 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
-+-----+ ++++++-- -----+--- +--- 060501,0618 = 060502,0618
-----+--- ++++++-- -----+--- +--- 0604,0631 = 060402,0631
-----+--- +-----+ -----+--- +--- 0604,0626N = 060402,0626N
-----+--- +-----+ -----+--- +--- 0607,060801 = 0607,060802
-----+--- +-----+ -----+--- ++- 0604,0628 = 060402,0628
-----+--- +-----+ -----+--- +--- 0603,0604 = 0603,060402 =
0621,0632
-----+--- +-----+ -+-----+ +--- 0603,0617 = 0621,0630
-----+--- ++++++-- -----+--- +--- 0603,0606 = 0606,0631
-----+--- ++++++-- -----+--- +--- 0603,060501 = 060501,0631 =
0609,0631
-----+--- +-----+ -----+--- +--- 0603,0627 = 060801,0632 =
060802,0632
-----+--- -+-----+ -----+--- +--- 0603,060502 = 060502,0631
-----+--- ++++++-- -----+--- +--- 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



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Lot-specific information

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----+--+ +----- -+----- +---- 0604,0630 = 060402,0630 =
                                         0617,0632
----+--+ +----- -----+-- ---- 0604,0607 = 060402,0607
----+--+ +----- -----+-- +---- 0604,0632 = 060402,0632
-----+++ +----- -----+-- +---- 0604,060801 = 060402,060801 =
                                         060402,060802
-----+++ +----- -----+-- +---- 060501,060801 = 060502,060801
-----+++ +----- -----+-- +---- 060801,060801 = 060801,060802
-----+--+ +----- -----+-- ---- 060402,060501 = 060402,060502
-----+--+ +----- -----+-- ---- 0604,060402 = 060402,060402
-----+++ +----- -----+-- ---- 060501,0621 = 060502,0621
-----+++ +----- -----+-- +---- 0604,060802 = 0621,0627
-----+--+ +----- -----+-- +---- 060501,060802 = 060502,060802
-----+--+ +----- -----+-- ---- 060501,0612 = 060502,0612
-----+++ +----- -+----- ---- 060501,0617 = 060502,0617
-----+++ +----- -----+-- + 060501,0634 = 060502,0634
-----+++ +----- -----+-- ---- 0604,060501 = 0604,060502
-----+++ +----- -----+-- + 0604,0634 = 0634,0634
-----+--+ +----- -----+-- ---- 060501,0606 = 060502,0606 =
                                         0606,0606 = 0606,0609
-----+--+ +----- -----+-- +---- 060501,0627 = 060502,0627
-----+--+ +----- -----+-- ---- 060501,060501 = 060501,060502 =
                                         060501,0609 = 060502,0609
  
```

¹The 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 and the DQB1*061101 and DQB1*061102 alleles have been considered in these calculations.



SPECIFICITY TABLE

DQB1*06 SSP subtyping

Specificities and sizes of the PCR products of the 28 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	060101-060103
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, 0614- 0616, 0619, 0620, 0623, 0624, 0633
4	130 bp	430 bp	060301-060302, 0607, 061102, 0614, 0626N, 0628, 0630-0632
5	160 bp	430 bp	060301-060302, 060402, 0607, 060801, 061101-061102, 0626N, 0628, 0630-0632
6	170 bp	515 bp	060301-060302, 060801-060802, 061102, 0612, 0614, 0621, 0626N, 0628, 0631
7	210 bp	515 bp	060401-060403, 0607, 0617, 0621, 0625, 0634
8	170 bp	430 bp	060401-0607, 0609, 0618, 0625, 0627, 0632, 0634
9 ⁴	130 bp	430 bp	060401-060501, 0606, 060801-0609, 0612, 0617, 0618, 0621, 0627, 0634
10	260 bp	515 bp	060501, 060502 [?] , 0606 [?] , 0620, 0631
11	210 bp	430 bp	060501, 060502 [?] , 0606 [?] , 0609, 0612, 0615, 0622
12	180 bp	430 bp	0606
13	185 bp	430 bp	0610
14	185 bp	430 bp	0613, 0622
15 ⁷	95, 185 bp	430 bp	0614, 0629
16	195 bp	430 bp	0616
17	110 bp	430 bp	0623
18 ⁶	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,

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			0620, 0623, 0624, 0629, 0633
22	130 bp	515 bp	0607, 0615
23	160 bp	515 bp	060301-060302, 060801-060802, 0614, 0621, 0628, 0631
24	155 bp	430 bp	0619, 0401- 0403
25	210 bp	430 bp	060301-060302, 060801-060802, 0614, 0627, 0628, 0630-0632
26	190 bp	430 bp	0628
27	265	430 bp	0633
28	300	430 bp	0634

¹Alleles 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 length 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

²The 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.

³Due to the sharing of sequence motif between DQB1 alleles, the DQB1*0401, 0402 and 0403 alleles will be amplified by primer mix 24.

⁴Primer mix 9 may yield somewhat less intense specific PCR fragments than the other DQB1*06 primer mixes.

⁵The 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.

⁶Primer mix 18 may give rise to primer dimer formation.

⁷Primer mix 15: Specific PCR fragment of 95 bp in the DQB1*0614 allele. Specific PCR fragment of 185 bp in the DQB1*0629 allele.

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

DQB1*06

Product Insert

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Lot-specific information

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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
Length of spec.	220	210	185	130	160	170	210	170	130	260	210	180	185	185
PCR product														
Length of int.	515	430	430	430	430	515	515	430	430	515	430	430	430	430
pos. control ¹														
5'-primer(s) ²	26	30	9	27	9	27	30	27	27	14	30	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'-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
	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'}
										87				
										5'-gg A ^{3'}				
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14
DQB1 allele														
*060101-060103	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
*0614			3	4		6								
*0615			3								11			
*0616		2	3											
*0617							7		9					
*0618		2						8	9					
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14

INTERPRETATION TABLE

DQB1*06 SSP subtyping

Amplification patterns of the DQB1*0601 to 0634 alleles

Well ⁴														
15	16	17	18	19	20	21	22	23	24	25	26	27	28	
95	195	110	175	135	215	160	130	160	155	210	190	265	300	Length of spec.
185														PCR product
430	430	430	430	430	515	430	515	515	430	430	430	430	430	Length of int.
														pos. control ¹
9	9	26	27	26	29	9	57	30	9	30	38	11	102	5'-primer(s) ²
5'-g TT ^{3'}	5'-g TT ^{3'}	5'-g gg ^{3'}	5'-gTA ^{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'}	5'-C gT 3 ^{5'}	5'-TTA ^{3'}	5'-TC T 3 ^{5'}	
27	60	48	71	57	86	48	86	70	47	86	87	86	189	3'-primer(s) ³
5'-gT T ^{3'}	5'-gTT ^{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'}	5'-gg A 3 ^{5'}	5'-A Cg 3 ^{5'}	5'-C CA 3 ^{5'}	
57														
5'-C gg ^{3'}														
15	16	17	18	19	20	21	22	23	24	25	26	27	28	Well No.
														DQB1 allele
														*060101-060103
						21								*060201-060202
								23		25				*060301-060302
														*060401, 060403
														*060402
														*060501
														*060502
														*0606
							22							*0607
								23		25				*060801
								23		25				*060802
														*0609
				19		21								*0610
														*061101
														*061102
														*0612
						21								*0613
15						21		23		25				*0614
						21	22							*0615
	16					21								*0616
			18											*0617
														*0618
15	16	17	18	19	20	21	22	23	24	25	26	27	28	Well No.



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

¹The 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.

95	195	110	175	135	215	160	130	160	155	210	190	265	300	Length of spec. PCR product
15	16	17	18	19	20	21	22	23	24	25	26	27	28	Well No.
									24					*0619
						21								*0620
								23						*0621
														*0622
		17				21								*0623
			18			21								*0624
				19										*0625
					20									*0626N
										25				*0627
								23		25	26			*0628
15						21								*0629
			18							25				*0630
								23		25				*0631
										25				*0632
						21						27		*0633
													28	*0634
									24					*0401-0403
														DQB1 allele
15	16	17	18	19	20	21	22	23	24	25	26	27	28	Well No.

²The 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.

²The 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.

⁴Primer mix 15: Specific PCR fragment of 95 bp in the DQB1*0614 allele. Specific PCR fragment of 185 bp in the DQB1*0629 allele.

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

CELL LINE VALIDATION SHEET																			
DQB1*06 SSP subtyping kit																			
			Prod. No.	Well															
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
				200732001	200732002	200732003	200732004	200732005	200732006	200732007	200732008	200732009	200846310	200732011	200732012	200732013	200732014	200732015	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	9007 DEM	*0302	*0502	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
9	9026 YAR	*0302		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
10	9107 LKT3	*0401		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
11	9051 PITOUT	*0202		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
12	9052 DBB	*0303		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
13	9067 BTB	*0402		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
14	9071 OLGA	*0402		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
15	9075 DKB	*0303		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
16	9037 SWEIG007	*0301		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
17	9008 WILJON	*0602	*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	
				Prod. No.	200732017	200732018	200732019	200732020	200732021	200732022	200846323	200732024	200846325	200846326	200846327	200846328
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	9007	DEM	*0302	*0502	-	-	-	-	-	-	-	-	-	-	-	-
9	9026	YAR	*0302		-	-	-	-	-	-	-	-	-	-	-	-
10	9107	LKT3	*0401		-	-	-	-	-	-	-	+	-	-	-	-
11	9051	PITOUT	*0202		-	-	-	-	-	-	-	-	-	-	-	-
12	9052	DBB	*0303		-	-	-	-	-	-	-	-	-	-	-	-
13	9067	BTB	*0402		-	-	-	-	-	-	-	+	-	-	-	-
14	9071	OLGA	*0402		-	-	-	-	-	-	-	+	-	-	-	-
15	9075	DKB	*0303		-	-	-	-	-	-	-	-	-	-	-	-
16	9037	SWEIG007	*0301		-	-	-	-	-	-	-	-	-	-	-	-
17	9008	WILJON	*0602	*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.
101.212-24u/04u – without *Taq* pol.

Lot number: 61E

Expiry date: 2010-May-01

Number of tests: 24 test – Product No. 101.212-24
4 tests – Product No. 101.212-04

Number of wells per test: 28

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	2007-320-14	24	2007-320-24
5	2007-320-05	15	2007-320-15	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	2007-320-08	18	2007-320-18	28	2008-463-28
9	2007-320-09	19	2007-320-19		
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, 26, 27 or 28 were available. The specificities of the primers in primer solutions 10, 12, 13, 14, 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: 2008-May-30

Approved by:

Quality Control, Supervisor

Declaration of Conformity

Product name: *Olerup* SSP™ DQB1*06
Product number: 101.212-24/04, 101.212-24u/04u
Lot number: 61E

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
2008-May-30

Olle Olerup
Managing Director

101.212-24/04 – including *Taq* polymerase101.212-24u/04u – without *Taq* polymeraseLot No.: **61E**

Lot-specific information

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**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**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**Web page:** <http://www.olerup.com>For information on *Olerup* SSP distributors worldwide, contact **Olerup GmbH**.