

Lot No.: **96K**

Lot-specific information

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Olerup SSP[®] DQB1*06:02,DQA1*01:02 - SSP

Product number: 101.901-24u – without *Taq* polymerase
Lot number: 96K
Expiry date: 2013-July-01
Number of tests: 24
Number of wells per test: 8
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. 96K.

CHANGES COMPARED TO THE PREVIOUS *OLERUP SSP*[®] DQB1*06:02,DQA1*01:02 Lot

The DQB1*06:02,DQA1*01:02 specificity and interpretation tables have been updated for the DQB1 and DQA1 alleles described since the previous *Olerup SSP*[®] DQB1*06:02,DQA1*01:02 lot (**Lot No. 17G**) was made.

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

Well	5'-primer	3'-primer	rationale
7	Added	-	Primers added for the DQB1*06:23 and *06:37 alleles.
8	-	Added	Primers added for the DQB1*06:14:01-06:14:02 and *06:15 alleles.

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PRODUCT DESCRIPTION

DQB1*06:02,DQA1*01:02 - SSP

CONTENT

The primer set contains 5'- and 3'-primers for identifying the DQB1*06:02 and DQA1*01:02 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 8 PCR reactions dispensed in an 8 well cut PCR plate

1	2	3	4	5	6	7	8
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The 8 well PCR plate is marked with '96K' in silver/gray ink.

Well No. 1 is marked with the Lot No. '96K'.

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 8 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 DQB1*03:30 allele and seven DQB1*04 alleles will be amplified by the primers in vial 6. Thus, the interpretation is only marginally influenced by other groups of DQB1 alleles, and not by the DQB2 and DQB3 genes.

Only DQA1*01 alleles will be amplified by the primers in vials 3, 4 and 5. Thus, the interpretation is not influenced by other groups of DQA1 alleles or the DQA2 gene.

UNIQUELY IDENTIFIED ALLELES

All the DQB1*06 alleles, i.e. **DQB1*06:01 to DQB1*06:39**, and all the DQA1*01 alleles, i.e. **DQA1*01:01 to DQA1*01:07**, recognized by the HLA Nomenclature Committee in October 2010¹ have been considered in the specificity and interpretation tables of the DQB1*06:02,DQA1*01:02 primer set.

The DQB1*06:02,DQA1*01:02 kit cannot distinguish the DQB1*06:02:01-06:02:02 alleles or the DQA1*01:02:01-01:02:04 alleles.

¹DQB1 and DQA1 alleles listed on the IMGT/HLA web page 2010-October-15, release 3.2.0, www.ebi.ac.uk/imgt/hla.

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SPECIFICITY TABLE

DQB1*06:02,DQA1*01:02 - SSP

Specificities and sizes of the PCR products of the 8 primer mixes used for DQB1*06:02,DQA1*01:02 SSP typing

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified alleles ³
1	210 bp	515 bp	DQB1*06:01:01-06:02:02, 06:05:02 [?] -06:06 [?] , 06:10-06:11:02, 06:13, 06:16, 06:18-06:20, 06:24, 06:29, 06:33, 06:35, 06:37
2	185 bp	430 bp	DQB1*06:02:01-06:02:02, 06:14:01-06:16, 06:19-06:20, 06:23-06:24, 06:33, 06:37
3⁵	170 bp	430 bp	DQA1*01:01:01-01:02:04, 01:04:01-01:07
4	145 bp	430 bp	DQA1*01:02:01-01:03, 01:06
5⁴	95 bp	430 bp	DQA1*01:06
6⁶	155 bp, 195 bp	430 bp	DQB1*06:01:01 ^w -06:01:06 ^w , 06:16, 06:19, DQB1*03:30, 04:01:01-04:03:02, 04:06
7^{4,7}	115 bp, 225 bp, 265 bp	430 bp	DQB1*06:20, 06:23, 06:31, 06:33, 06:37
8^{4,5,8}	60 bp, 175 bp, 220 bp	430 bp	DQB1*06:03:01-06:05:01, 06:05:02 [?] -06:06 [?] , 06:07:01-06:09, 06:12, 06:14:01-06:15, 06:17, 06:21-06:22, 06:24-06:28, 06:30-06:32, 06:34, 06:36, 06:38-06:39

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 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.

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*06:02,DQA1*01:02 subtyping.

³Due to sharing of sequence motifs, the DQB1*03:30 as well as some DQB1*04 allele are amplified by primer mix 6.

⁴Short specific PCR fragments are less intense and not as sharp as longer specific bands.

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⁵Primer mixes 3 and 8 may give rise to a primer dimer artifact.

⁶Primer mix 6: Specific PCR product of 155 bp in the DQB1*06:01:01^w-06:01:06^w and 06:19 and in the DQB1*03:30, 04:01:01-04:03:02 and 04:06 alleles. Specific PCR product of 195 bp in the DQB1*06:16 allele.

⁷Primer mix 7: Specific PCR product of 115 bp in the DQB1*06:37 allele. Specific PCR product of 225 bp in the DQB1*06:23 allele. Specific PCR product of 265 bp in the DQB1*06:20, 06:31 and 06:33 alleles.

⁸Primer mix 8: Specific PCR product of 60 bp in the DQB1*06:03:01-06:03:02, 06:08:01-06:08:02, 06:14:01-06:14:02, 06:26-06:28, 06:31-06:32

allele. Specific PCR product of 175 bp in the DQB1*06:24 alleles. Specific PCR product of 220 bp in the DQB1*06:05:01, 06:05:02?-06:06?, 06:09, 06:12, 06:15, 06:22 allele. Specific PCR product of 60 and 175 bp the DQB1*06:30 allele. Specific PCR product of 60 and 220 bp in the DQB1*06:04:01-06:04:03, 06:07:01-06:07:02, 06:21, 06:25, 06:34, 06:36, 06:38-06:39 allele. Specific PCR product of 60, 175 and 220 bp in the DQB1*06:17 allele. All specific bands may not always be visible.

'?', nucleotide sequence of the primer matching region is not available for this allele.

'w', might be weakly amplified.

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INTERPRETATION TABLE						
DQB1*06:02 SSP						
	Well⁴					
	1	2		6	7	8
Length of spec.	210	185		155	115	60
PCR product				195	225	175
					265	220
Length of int.	515	430		430	430	430
pos. control¹						
5'-primer²	30(184)	9(122)		9(122)	11(129)	26(173)
	5' -gAT 3'	5' -gTT 3'		5' -gTT 3'	5' -TTA 3'	5' -TCT 3'
	30(184)				14(136)	
	5' -gAT 3'				5' -gCC 3'	
					26(173)	
					5' -ggg 3'	
					62(282)	
					5' -AAg 3'	
3'-primer³	86(353)	57(266)		47(237)	87(356)	30(184)
	5' -ACg 3'	5' -CAT 3'		5' -CgA 3'	5' -ggA 3'	5' -gTg 3'
				60(274)		71(307)
				5' -gTT 3'		5' -ggC 3'
						86(353)
						5' -ACC 3'
Well No.	1	2		6	7	8
DQB1 allele						
DQB1*06:01:01-06:01:06	1			w		
DQB1*06:02:01-06:02:02	1	2				
DQB1*06:03:01-06:05:01, 06:07:01-06:09, 06:12, 06:17, 06:21-06:22, 06:25-06:28, 06:30, 06:32, 06:34, 06:36, 06:38-06:39						8
DQB1*06:05:02-06:06	?					?
DQB1*06:10-06:11:02, 06:13, 06:18, 06:29, 06:35	1					
DQB1*06:14:01-06:15		2				8
DQB1*06:16, 06:19	1	2		6		
DQB1*06:20, 06:33, 06:37	1	2			7	
DQB1*06:23		2			7	
DQB1*06:24	1	2				8
DQB1*06:31					7	8
DQB1*03:30, 04:01:01-04:03:02, 04:06				6		
DQB1 allele						
Well No.	1	2		6	7	8

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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*06:02,DQA1*01:02 subtyping.

²The codon, and in parenthesis the nucleotide, in the 2nd 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 web site. The sequence of the 3 terminal nucleotides of the primer is given.

³The codon, and in parenthesis the nucleotide, in the 2nd 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 web site. The sequence of the 3 terminal nucleotides of the primer is given.

⁴Primer mix 6: Specific PCR product of 155 bp in the DQB1*06:01:01^w-06:01:06^w and 06:19 and in the DQB1*03:30, 04:01:01-04:03:02 and 04:06 alleles. Specific PCR product of 195 bp in the DQB1*06:16 allele.

Primer mix 7: Specific PCR product of 115 bp in the DQB1*06:37 allele. Specific PCR product of 225 bp in the DQB1*06:23 allele. Specific PCR product of 265 bp in the DQB1*06:20, 06:31 and 06:33 alleles.

Primer mix 8: Specific PCR product of 60 bp in the DQB1*06:03:01-06:03:02, 06:08:01-06:08:02, 06:14:01-06:14:02, 06:26-06:28, 06:31-06:32

allele. Specific PCR product of 175 bp in the DQB1*06:24 alleles. Specific PCR product of 220 bp in the DQB1*06:05:01, 06:05:02?-06:06?, 06:09, 06:12, 06:15, 06:22 allele. Specific PCR product of 60 and 175 bp the DQB1*06:30 allele. Specific PCR product of 60 and 220 bp in the DQB1*06:04:01-06:04:03, 06:07:01-06:07:02, 06:21, 06:25, 06:34, 06:36, 06:38-06:39 allele. Specific PCR product of 60, 175 and 220 bp in the DQB1*06:17 allele. All specific bands may not always be visible.

'?', nucleotide sequence of the primer matching region is not available for this allele.

'w', might be weakly amplified.

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INTERPRETATION TABLE			
DQA1*01:02 SSP			
	Well		
	3	4	5
Length of spec.	170	145	95
PCR product			
Length of int.	430	430	430
pos. control¹			
5'-primer²	25(143)	34(169)	25(143)
	5' -gTA 3'	5' -AgC 3'	5' -gTA 3'
3'-primer³	69(274)	69(274)	44(199)
	5' -TgC 3'	5' -TgC 3'	5' -AgC 3'
Well No.	3	4	5
DQA1 allele			
DQA1*01:01:01-01:01:02, 01:04:01-01:05, 01:07	3		
DQA1*01:02:01-01:02:04	3	4	
DQA1*01:03		4	
DQA1*01:06	3	4	5
DQA1 allele			
Well No.	3	4	5

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*06:02,DQA1*01:02 subtyping.

²The codon, and in parenthesis the nucleotide, in the 2nd 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 web site. The sequence of the 3 terminal nucleotides of the primer is given.

³The codon, and in parenthesis the nucleotide, in the 2nd 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 web site. The sequence of the 3 terminal nucleotides of the primer is given.

'?', nucleotide sequence of the primer matching region is not available for this allele.

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CELL LINE VALIDATION SHEET										
DQB1*06:02										
					Well					
					1	2		6	7	8
				Prod. No.	200962601	200962602		200962606	201081507	201081508
	IHWC cell line		DQB1							
1	9001	SA	*05:01		-	-		-	-	-
2	9280	LK707	*06:01	*02:02	+	-		W	-	-
3	9011	E4181324	*06:01		+	-		W	-	-
4	9275	GU373	*02:01		-	-		-	-	-
5	9009	KAS011	*05:02		-	-		-	-	-
6	9353	SM	*03:02	*06:01	+	-		W	-	-
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	+	-		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		-	-		-	-	+
42	9066	TAB089	*06:01		+	-		W	-	-
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		-	-		-	-	-



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CELL LINE VALIDATION SHEET								
DQA1*01:02								
					Well			
					3	4	5	
					Prod. No.:	200962603	200962604	200962505
IHC cell line			DQA1*					
1	9001	SA	*01:01		+	-	-	
2	9280	LK707	*01:03	*03:03	-	+	-	
3	9011	E4181324	*01:03		-	+	-	
4	9275	GU373	*05:01		-	-	-	
5	9009	KAS011	*01:02		+	+	-	
6	9353	SM	*01:03	*03:01	-	+	-	
7	9020	QBL	*05:01		-	-	-	
8	9025	DEU	*03		-	-	-	
9	9026	YAR	*03:01		-	-	-	
10	9107	LKT3	*03:03		-	-	-	
11	9051	PITOUT	*02:01		-	-	-	
12	9052	DBB	*02:01		-	-	-	
13	9004	JESTHOM	*01:01		-	-	-	
14	9071	OLGA	*04:01		-	-	-	
15	9075	DKB	*03:02		-	-	-	
16	9037	SWEIG007	*05:05		-	-	-	
17	9282	CTM3953540	*01:03	*05:01	-	+	-	
18	9257	32367	*01:02	*03:03	+	+	-	
19	9038	BM16	*05:05		-	-	-	
20	9059	SLE005	*01:02		+	+	-	
21	9064	AMALA	*05:03		-	-	-	
22	9056	KOSE	*01:02	*01:04	+	+	-	
23	9124	IHL	*01:03	*01:04	+	+	-	
24	9035	JBUSH	*05:05		-	-	-	
25	9049	IBW9	*02:01		-	-	-	
26	9285	WT49	*05:01		-	-	-	
27	9191	CH1007	*03:03	*01:05	+	-	-	
28	9320	BEL5GB	*02:01	*03:03	-	-	-	
29	9050	MOU	*02:01		-	-	-	
30	9021	RSH	*04:01		-	-	-	
31	9019	DUCAF	*05:01		-	-	-	
32	9297	HAG	*05:05		-	-	-	
33	9098	MT14B	*03:01		-	-	-	
34	9104	DHIF	*05:05		-	-	-	
35	9302	SSTO	*03:01		-	-	-	
36	9024	KT17	*03:01		-	-	-	
37	9065	HHKB	*01:03		-	+	-	
38	9099	LZL	*05:03		-	-	-	
39	9315	CML	*03:03	*05:01	-	-	-	
40	9134	WHONP199	*02:01	*03:02	-	-	-	
41	9055	H0301	*01:02		+	+	-	
42	9066	TAB089	*01:03		-	+	-	
43	9076	T7526	*03:02		-	-	-	
44	9057	TEM	*01:04		+	-	-	
45	9239	SHJO	*02:01	*03:03	-	-	-	
46	9013	SCHU	*01:02		+	+	-	
47	9045	TUBO	*05:05		-	-	-	
48	9303	TER-ND	*01:01		+	-	-	



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CERTIFICATE OF ANALYSIS

Olerup SSP® DQB1*06:02,DQA1*01:02 - SSP

Product number: 101.901-24u – without Taq polymerase
Lot number: 96K
Expiry date: 2013-July-01
Number of tests: 24
Number of wells per test: 8

Well specifications:

Well No.	Production No.
1	2009-626-01
2	2009-626-02
3	2009-626-03
4	2009-626-04
5	2009-626-05
6	2009-626-06
7	2010-815-07
8	2010-815-08

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 5 and 7 were available. The specificities of the primers in primer solutions 7 were tested by separately adding one additional 5'-primer, respectively, one additional 3'-primer. In primer solution 5 it was only possible to test the 5'-primer, the 3'-primer was not possible to test. In primer solutions 6 and 8 one 3'-primer was not possible to test, and in primer solution 7 two 5'-primers were not possible to test.

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

Date of approval: 2011-February-04

Approved by:

Quality Control, Supervisor

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Declaration of Conformity

Product name: *Olerup* SSP® DQB1*06:02,DQA1*01:02
Product number: 101.901-24u
Lot number: 96K

Intended use: DQB1*06:02,DQA1*01:02 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 9001:2008 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
2011-February-04

Olle Olerup
Managing Director

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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-ssp.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**.