

Lot No.: **17G**

Lot-specific information

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Olerup SSP® DQB1*0602,DQA1*0102 - SSP

Product number: 101.901-24 – including *Taq* polymerase
Lot number: 17G
Expiry date: 2011-August-01
Number of tests: 24
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. 17G.

CHANGES COMPARED TO THE PREVIOUS OLERUP SSP® DQB1*0602,DQA1*0102 LOT

The DQB1*0602,DQA1*0102 specificity and interpretation tables have been updated for the DQB1 and DQA1 alleles described since the previous *Olerup SSP®* DQB1*0602,DQA1*0102 lot (Lot No. 37E) was made.

Four wells have been added to the
DQB1*0602,DQA1*0102 kit,
wells **5 to 8**.

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

Well	5'-primer	3'-primer	rationale
5	New	New	New primer pair for the DQA1*0106 allele.
6	New	New	New primer pair for the DQB1*0616 and *0619 alleles.
7	New	New	New primer pair for the DQB1*0620 and *0633 alleles.
8	New	New	New primer pair for the DQB1*0624 allele.

PRODUCT DESCRIPTION

DQB1*0602,DQA1*0102 - SSP

CONTENT

The primer set contains 5'- and 3'-primers for identifying the DQB1*0602 and DQA1*0102 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 a 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 '17G'.

Well No. 1 is marked with the Lot No. '17G'.

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

Four 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*0601 to DQB1*0635**, and all the DQA1*01 alleles, i.e. **DQA1*0101 to DQA1*0107**, recognized by the HLA Nomenclature Committee in July 2009¹ have been considered in the specificity and interpretation tables of the DQB1*0602,DQA1*0102 primer set.

The DQB1*0602,DQA1*0102 kit cannot distinguish the DQB1*060201 and DQB1*060202 alleles or the DQA1*010201 to DQA1*010204 alleles.

¹DQB1 and DQA1 alleles listed on the IMGT/HLA web page 2009-July-17, release 2.26.0, www.ebi.ac.uk/imgt/hla.

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SPECIFICITY TABLE

DQB1*0602,DQA1*0102 - SSP

Specificities and sizes of the PCR products of the 8 primer mixes used for DQB1*0602,DQA1*0102 SSP typing

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified alleles ³
1	210 bp	515 bp	DQB1*060101-060202, 060502 [?] , 0606 [?] , 0610-061102, 0613, 0616, 0618-0620, 0624, 0629, 0633, 0635
2	185 bp	430 bp	DQB1*060201, 060202, 061401-0616, 0619, 0620, 0623, 0624, 0633
3	170 bp	430 bp	DQA1*010101-010204, 010401-0107
4	145 bp	430 bp	DQA1*010201-0103, 0106
5	95 bp	430 bp	DQA1*0106
6 ⁵	155 bp, 195 bp	430 bp	DQB1*040101-0403, DQB1*060101 ^w -060104 ^w , 0616, 0619
7	270 bp	430 bp	DQB1*0620, 0631, 0633
8 ⁴	175 bp	430 bp	DQB1*0617, 0624, 0630

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*0602,DQA1*0102 subtyping.

³Due to sharing of sequence motifs, some DQB1*04 allele are amplified by primer mix 6.

⁴Primer mix 8 may give rise to a primer dimer artifact.

⁵Primer mix 6: Specific PCR product of 155 bp in the DQB1*040101-0403, DQB1*060101^w-060104^w and 0619 alleles. Specific PCR product of 195 bp in the DQB1*0616 allele.

‘?’ , 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*0602 SSP						
	Well⁴					
	1	2		6	7	8
Length of spec.	210	185		155	270	175
PCR product				195		
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'	
3'-primer³	86(353)	57(266)		47(237)	87(356)	71(307)
	5'-ACg 3'	5'-CAT 3'		5'-CgA 3'	5'-ggA 3'	5'-ggC 3'
				60(274)		
				5'-gTT 3'		
Well No.	1	2		6	7	8
DQB1 allele						
DQB1*060101-060104	1			w		
DQB1*060201, 060202	1	2				
DQB1*060502, 0606	?					
DQB1*0610-061102, 0613, 0618, 0629, 0635	1					
DQB1*061401-0615, 0623		2				
DQB1*0616, 0619	1	2		6		
DQB1*0617, 0630						8
DQB1*0620, 0633	1	2			7	
DQB1*0624	1	2				8
DQB1*0631					7	
DQB1*040101-0403				6		
DQB1 allele						
Well No.	1	2		6	7	8

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*0602,DQA1*0102 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*040101-0403, DQB1*060101^w-060104^w and 0619 alleles. Specific PCR product of 195 bp in the DQB1*0616 allele.

'?', 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*0102 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*010101, 010102, 010401-0105, 0107	3		
DQA1*010201-010204	3	4	
DQA1*0103		4	
DQA1*0106	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*0602,DQA1*0102 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*0602										
					Well					
					1	2		6	7	8
				Prod. No.	200962601	200962602		200962606	200962607	200962608
	IHC cell line		DQB1							
1	9001	SA	*0501		-	-		-	-	-
2	9280	LK707	*0601	*0202	+	-		w	-	-
3	9011	E4181324	*0601		+	-		w	-	-
4	9275	GU373	*0201		-	-		-	-	-
5	9009	KAS011	*0502		-	-		-	-	-
6	9353	SM	*0302	*0601	+	-		w	-	-
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	+	-		w	-	-
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		+	-		w	-	-
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		-	-		-	-	-



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CELL LINE VALIDATION SHEET								
DQA1*0102								
					Well			
					3	4	5	
					Prod. No.:	200962603	200962604	200962505
IHCW cell line			DQA1*					
1	9001	SA	*0101		+	-	-	
2	9280	LK707	*0103	*0303	-	+	-	
3	9011	E4181324	*0103		-	+	-	
4	9275	GU373	*0501		-	-	-	
5	9009	KAS011	*0102		+	+	-	
6	9353	SM	*0103	*0301	-	+	-	
7	9020	QBL	*0501		-	-	-	
8	9025	DEU	*03		-	-	-	
9	9026	YAR	*0301		-	-	-	
10	9107	LKT3	*0303		-	-	-	
11	9051	PITOUT	*0201		-	-	-	
12	9052	DBB	*0201		-	-	-	
13	9004	JESTHOM	*0101		-	-	-	
14	9071	OLGA	*0401		-	-	-	
15	9075	DKB	*0302		-	-	-	
16	9037	SWEIG007	*0505		-	-	-	
17	9282	CTM3953540	*0103	*0501	-	+	-	
18	9257	32367	*0102	*0303	+	+	-	
19	9038	BM16	*0501		-	-	-	
20	9059	SLE005	*0102		+	+	-	
21	9064	AMALA	*0503		-	-	-	
22	9056	KOSE	*0102	*0104	+	+	-	
23	9124	IHL	*0103	*0104	+	+	-	
24	9035	JBUSH	*0501		-	-	-	
25	9049	IBW9	*0201		-	-	-	
26	9285	WT49	*0501		-	-	-	
27	9191	CH1007	*0303	*0105	+	-	-	
28	9320	BEL5GB	*0201	*0303	-	-	-	
29	9050	MOU	*0201		-	-	-	
30	9021	RSH	*0401		-	-	-	
31	9019	DUCAF	*0501		-	-	-	
32	9297	HAG	*0501		-	-	-	
33	9098	MT14B	*0301		-	-	-	
34	9104	DHIF	*0501		-	-	-	
35	9302	SSTO	*0301		-	-	-	
36	9024	KT17	*0301		-	-	-	
37	9065	HHKB	*0103		-	+	-	
38	9099	LZL	*0503		-	-	-	
39	9315	CML	*0303	*0501	-	-	-	
40	9134	WHONP199	*0201	*0302	-	-	-	
41	9055	H0301	*0102		+	+	-	
42	9066	TAB089	*0103		-	+	-	
43	9076	T7526	*0302		-	-	-	
44	9057	TEM	*0104		+	-	-	
45	9239	SHJO	*0201	*0303	-	-	-	
46	9013	SCHU	*0102		+	+	-	
47	9045	TUBO	*0501		-	-	-	
48	9303	TER-ND	*0101		+	-	-	



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CERTIFICATE OF ANALYSIS

Olerup SSP[®] DQB1*0602,DQA1*0102 - SSP

Product number: 101.901-24 – including *Taq* polymerase
Lot number: 17G
Expiry date: 2011-August-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	2009-626-07
8	2009-626-08

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 No. 5, 7 and 8 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 and 8 it was only possible to test the 5'-primer, the 3'-primer was not possible to test. In primer solution 6 one 3'-primer was not possible to test, and in primer solution 7 one 5'-primer was not possible to test.

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

Date of approval: 2009-August-25

Approved by:

Quality Control, Supervisor

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Declaration of Conformity

Product name: *Olerup* SSP® DQB1*0602,DQA1*0102
Product number: 101.901-24
Lot number: 17G

Intended use: DQB1*0602,DQA1*0102 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-August-25

Olle Olerup
Managing Director

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