101.901-24 – including *Taq* polymerase, IFU-01
101.901-24u – without *Taq* polymerase, IFU-02

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"Instructions for Use" (IFU)

Lot No.: 33S **Lot-specific information**

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

Product number:	**101.901-24 – including *Taq* polymerase** **101.901-24u – without *Taq* polymerase**
Lot number:	**33S**
Expiry date:	**2015-October-01**
Number of tests:	**24**
Number of wells per test:	**11+1**
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. 33S.

CHANGES COMPARED TO THE PREVIOUS *OLERUP* SSP®
DQB1*06:02,DQA1*01:02 LOT (64M)

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. 64M)** was made.

The DQB1*06:02,DQA1*01:02 kit has been updated:

The order of the primer mixes has been changed compared to the previous lot.

Four wells have been added to DQB1*06:02,DQA1*01:02kit, wells **9 to 12**.

A well containing Negative Control primer pairs has been added.

The Lot-specific information for DQB1*06:02,DQA1*01:02 including and without *Taq* polymerase is now described in one common Product Insert.

Lot No.: 33S **Lot-specific information**

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

Well	5'-primer	3'-primer	rationale
1	Moved, added	Moved, added	Primer pair moved to well 7, primer pair added from well 3.
2	Moved, added	Moved, added	Primer pair moved to well 8, primer pair added from well 4.
3	Moved, added	Moved, added	Primer pair moved to well 1, primer pair added from well 5.
4	New, moved	New, moved	New primer pair for improved resolution of DQA1*01:01 and DQA1*01:02 alleles, primer pair moved to well 2.
5	New, moved	New, moved	New primer pair for the DQA1*01:08 and DQA1*01:09 alleles, primer pair moved to well 3.
6	New, moved	New, moved	New primer pair for the DQA1*01:11 allele, primer pair moved to well 9.
7	Moved, added	Moved, added	Primer pair moved to well 10, primer pair added from well 1.
8	Moved, added	Moved, added	Primer pair moved to well 11, primer pair added from well 2.
9	Added	Added	3'-primers added for the DQB1*06:48 and DQB1*06:50 alleles, primer pair added from well 6.
10	Added	Added	5'-primers added for the DQB1*06:49 allele, primer pair added from well 7.
11	Added	Added	Primer pair added for the DQB1*06:47 allele, primer pair added from well 8.
12	New	New	Negative Control.

Change in revision R01 compared to R00:

1. The Interpretation Table has been corrected for the DQB1*06:01:01, 06:01:03-06:01:06, 06:10-06:11:02, 06:13, 06:18, 06:29, 06:35 and 06:43 and the DQB1*06:01:02 amplification patterns.

Lot No.: 33S **Lot-specific information**

Well **12** contains Negative Control primer pairs, that will amplify more than 95% of the *Olerup* SSP® HLA Class I, DRB, DQB1 and DPB1 amplicons as well as amplicons generated by a control primer pair.

PCR product sizes range from 75 to 430 base pairs.
The PCR product generated by the control primer pair is 430 base pairs.

Length of PCR product	**105**	**200**	**105**	**80**	**75**	**80**
5'-primer[1]	**164**	**340**	**440**	**45**	**45**	**43**
	5'-CAC3'	**5'-Agg3'**	**5'-TTA3'**	**5'-Tgg3'**	**5'-Tgg3'**	**5'-Tgg3'**
3'-primer[2]	**231**	**2nd I**	**507**	**59**	**58**	**57**
	5'-TgC3'	**5'-AAA3'**	**5'-TTg3'**	**5'-CTC3'**	**5'-ggC3'**	**5'-CTC3'**
A*	**+**	**+**	**+**			
B*	**+**	**+**	**+**			
C*	**+**	**+**	**+**			
DRB1				**+**	**+**	
DRB3				**+**	**+**	
DRB5				**+**		
DQB1					**+**	
DPB1						**+**

[1]The nucleotide position for HLA class I genes and the codon for HLA class II genes, in the 2nd or 3rd exon, matching the specificity-determining 3'-end of the primer is given. Nucleotide and codon numbering as on the www.ebi.ac.uk/imgt/hla web site. The sequence of the 3 terminal nucleotides of the primer is given.

[2]The nucleotide position for HLA class I genes and the codon for HLA class II genes, in the 2nd or 3rd exon or the 2nd intron, matching the specificity-determining 3'-end of the primer is given in the anti-sense direction. Nucleotide and codon numbering as on the www.ebi.ac.uk/imgt/hla web site. The sequence of the 3 terminal nucleotides of the primer is given.

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Lot No.: 33S **Lot-specific information**

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 12 PCR reactions dispensed in a 16 well cut PCR plate.
Wells 13 to 16 are empty.

1	2	3	4	5	6	7	8
9	10	11	12	empty	empty	empty	empty

The 16 well PCR plate is marked with '33S' in silver/gray ink.
Well No. 1 is marked with the Lot No. '33S'.
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.
Wells 1 to 6: DQA1 primers.
Wells 7 to 11: DQB1 primers.
Well 12 : Negative Control
The PCR plates are covered with a PCR-compatible foil.
Please note: When removing each 16 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 nine DQB1*04 alleles will be amplified by the primers in vial 9 and the DQB1*03:38 allele is amplified by primer mix 11. 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 1 to 6. 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*06:52**, and all the DQA1*01 alleles, i.e. **DQA1*01:01 to DQA1*01:11**, recognized by the HLA Nomenclature Committee in Janaury 2013[1] have been considered in the specificity and interpretation tables of the DQB1*06:02,DQA1*01:02 primer set.

Lot No.: 33S **Lot-specific information**

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.

[1]DQB1 and DQA1 alleles listed on the IMGT/HLA web page 2013-Janaury-11, release 3.11.0, www.ebi.ac.uk/imgt/hla.

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Lot No.: 33S **Lot-specific information**

SPECIFICITY TABLE

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

Specificities and sizes of the PCR products of the 11+1 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 HLA class I alleles[3]
1[5]	170 bp	430 bp	DQA1*01:01:01-01:02:04, 01:04:01:01-01:09, 01:11
2	145 bp	430 bp	DQA1*01:02:01:01-01:03:01:02, 01:06, 01:08-01:11
3[4,5]	95 bp	430 bp	DQA1*01:06
4	170 bp	430 bp	DQA1*01:03:01:01-01:03:01:02, 01:10
5[4,6]	120 bp, 210 bp	430 bp	DQA1*01:08-01:09
6	135 bp	430 bp	DQA1*01:11
7	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, 06:43, 06:45, 06:47-06:51
8[5]	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, 06:46-06:50
9[7]	155 bp, 195 bp, 230 bp	430 bp	DQB1*06:01:02[w], 06:05:02, 06:15-06:16, 06:19, 06:22, 06:37, 06:48, 06:50-06:51, **DQB1*03:30, DQB1*04:01:01-04:03:02, DQB1*04:06-04:08**
10[4,8]	115 bp, 225 bp, 265 bp	430 bp	DQB1*06:20, 06:23, 06:31, 06:33, 06:37, 06:45, 06:49
11[4,9]	50 bp, 100 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, 06:41-06:42, 06:44, 06:46-06:47, 06:52, **DQB1*03:38**
12[10]	-	-	**Negative Control**

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

Lot No.: 33S **Lot-specific information**

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 7 contains the primer pair giving rise to the longer, 515 bp, internal positive control band.
[3]Due to sharing of sequence motifs, the DQB1*03:30 as well as some DQB1*04 allele are amplified by primer mix 9, and the DQB1*03:38 allele is amplified by primer mix 11.
[4]HLA-specific PCR products shorter than 125 base pairs have a lower intensity and are less sharp than longer PCR products.
[5]Primer mixes 1, 3 and 8 have a tendency to giving rise to primer oligomer formation.
[6]Primer mix 5: Specific PCR product of 120 bp in the DQA1*01:08 allele. Specific PCR product of 210 bp in the DQA1* 01:09 allele.
[7]Primer mix 9: Specific PCR product of 155 bp in the DQB1*06:01:02[w] and 06:19 and in the DQB1*04:01:01-04:03:02 and 04:06-4:08 alleles. Specific PCR product of 195 bp in the DQB1*06:16 allele. Specific PCR product of 230 bp in the DQB1*06:05:02, 06:15, 06:22, 06:37, 06:48 and 06:50-06:51 alleles. Specific PCR product of 155 bp and 230 bp in the DQB1*03:30 allele.
[8]Primer mix 10: 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 06:33, 06:45 and 06:49 alleles.
[9]Primer mix 11: Specific PCR product of 50 bp in the DQB1*06:03:01-06:03:02, 06:08:01-06:08:02, 06:14:01-06:14:02, 06:21, 06:26-06:28, 06:31-06:32, 06:38-06:39 and 06:41 and the DQB1*03:38 alleles. Specific PCR product of 100 bp in the DQB1*06:47 allele. Specific PCR product of 175 bp in the DQB1*06:24 and 06:42 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, 06:42 and 06:46 alleles. Specific PCR product of 50 and 100 bp the DQB1*06:44 allele Specific PCR product of 50 and 175 bp the DQB1*06:30 allele. Specific PCR product of 50 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 and 06:52 alleles. Specific PCR product of 175 and 220 bp in the DQB1*06:42 allele.Specific PCR product of 50, 175 and 220 bp in the DQB1*06:17 allele. All specific bands may not always be visible.
[10]Primer mix 12 contains a negative control, which will amplify more than 95% of HLA amplicons as well as the amplicons generated by control primer pairs. PCR product sizes range from 75 to 200 base pairs. The PCR product generated by the control primer pair is 430 base pairs.
'?', nucleotide sequence of the primer matching region is not available for this allele.
'w', might be weakly amplified.

Lot No.: 33S **Lot-specific information**

INTERPRETATION TABLE DQA1*01:02 SSP						
	Well[4]					
	1	2	3	4	5	6
Length of spec.	170	145	95	170	120	135
PCR product					210	
Length of int.	430	430	430	430	430	430
pos. control[1]						
5'-primer[2]	25(143)	33(169)	25(143)	25(143)	103(377)	186(626)
	5' -gTA 3'	5' -AgC 3'	5' -gTA 3'	5' -gTT 3'	5' -ggA 3'	5' -TCT 3'
					134(470)	
					5' -AgC 3'	
3'-primer[3]	68(274)	68(274)	43(199)	68(274)	160(548)	218(722)
	5' -TgC 3'	5' -TgC 3'	5' -AgC 3'	5' -TgC 3'	5' -CAg 3'	5' -CTT 3'
Well No.	1	2	3	4	5	6
DQA1 allele						
DQA1*01:02:01:01-01:02:04	1	2				
DQA1*01:01:01-01:01:02, 01:04:01:01-01:05, 01:07	1					
DQA1*01:03:01:01-01:03:01:02, 01:10		2		4		
DQA1*01:06:00	1	2	3			
DQA1*01:08-01:09	1	2			5	
DQA1*01:11:00	1	2				6
DQA1 allele						
Well No.	1	2	3	4	5	8

[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 7 contains the primer pair giving rise to the longer, 515 bp, internal positive control band.
[2]The 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.
[3]The 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.
'w', might be weakly amplified

Lot No.: 33S **Lot-specific information**

INTERPRETATION TABLE

DQB1*06:02 SSP

	Well[4]					
	7	8	9	10	11	12
Length of spec.	210	185	155	115	50	Negative Control
PCR product			195	225	100	
			230	265	175	
					220	
Length of int.	515	430	430	430	430	
pos. control[1]						
5'-primer[2]	29(184)	9(122)	9(122)	11(129)	26(173)	
	5' -gAT 3'	5' -gTT 3'	5' -gTT 3'	5' -TTA 3'	5' -TCT 3'	
	29(184)			13(134)	154(558)	
	5' -gAT 3'			5' -ggT 3'	5' -ACT 3'	
				13(136)		
				5' -gCC 3'		
				26(173)		
				5' -ggg 3'		
				62(282)		
				5' -AAg 3'		
3'-primer[3]	86(353)	57(266)	47(237)	87(356)	29(184)	
	5' -ACg 3'	5' -CAT 3'	5' -CgA 3'	5' -ggA 3'	5' -gTg 3'	
			59(274)		70(307)	
			5' -gTT 3'		5' -ggC 3'	
			69(304)		86(353)	
			5' -CCT 3'		5' -ACC 3'	
			75(322)		174(618)	
			5' -gTg 3'		5' -ACT 3'	
Well No.	7	8	9	10	11	12
DQB1 allele						
DQB1*06:02:01-06:02:02	7	8				Negative Control
DQB1*06:01:01, 06:01:03-06:01:06, 06:10-06:11:02, 06:13, 06:18, 06:29, 06:35, 06:43	7					
DQB1*06:01:02	7		w			
DQB1*06:03:01-06:05:01, 06:07:01-06:09, 06:12, 06:17, 06:21, 06:25-06:28, 06:30, 06:32, 06:34, 06:36, 06:38-06:39, 06:41-06:42, 06:44, 06:52, *DQB1*03:38*					11	
DQB1*06:05:02	?		9		?	
DQB1*06:06	?				?	
DQB1*06:14:01-06:14:02, 06:46		8			11	
DQB1*06:15		8	9		11	
DQB1*06:16, 06:19, 06:48, 06:50	7	8	9			
DQB1*06:20, 06:33, 06:49	7	8		10		
DQB1*06:22			9		11	
DQB1*06:23		8		10		
DQB1*06:24, 06:47	7	8			11	
DQB1*06:31				10	11	
DQB1*06:37	7	8	9	10		
DQB1*06:45	7			10		
DQB1*06:51	7		9			
*DQB1*03:30, 04:01:01-04:03:02, 04:06-04:08*			9			
DQB1 allele						
Well No.	7	8	9	10	11	12

Lot No.: 33S **Lot-specific information**

[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 7 contains the primer pair giving rise to the longer, 515 bp, internal positive control.
[2]The 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.
[3]The 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.
[4]Primer mix 5: Specific PCR product of 120 bp in the DQA1*01:08 allele. Specific PCR product of 210 bp in the DQA1* 01:09 allele.
Primer mix 9: Specific PCR product of 155 bp in the DQB1*06:01:02[w] and 06:19 and in the DQB1*04:01:01-04:03:02 and 04:06-4:08 alleles. Specific PCR product of 195 bp in the DQB1*06:16 allele. Specific PCR product of 230 bp in the DQB1*06:05:02, 06:15, 06:22, 06:37, 06:48 and 06:50-06:51 alleles. Specific PCR product of 155 bp and 230 bp in the DQB1*03:30 allele.
Primer mix 10: 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 06:33, 06:45 and 06:49 alleles.
Primer mix 11: Specific PCR product of 50 bp in the DQB1*06:03:01-06:03:02, 06:08:01-06:08:02, 06:14:01-06:14:02, 06:21, 06:26-06:28, 06:31-06:32, 06:38-06:39 and 06:41 and the DQB1*03:38 alleles. Specific PCR product of 100 bp in the DQB1*06:47 allele. Specific PCR product of 175 bp in the DQB1*06:24 and 06:42 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, 06:42 and 06:46 alleles. Specific PCR product of 50 and 100 bp the DQB1*06:44 allele Specific PCR product of 50 and 175 bp the DQB1*06:30 allele. Specific PCR product of 50 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 and 06:52 alleles. Specific PCR product of 175 and 220 bp in the DQB1*06:42 allele.Specific PCR product of 50, 175 and 220 bp in the DQB1*06:17 allele. All specific bands may not always be visible.
Primer mix 12 contains a negative control, which will amplify more than 95% of HLA amplicons as well as the amplicons generated by control primer pairs. PCR product sizes range from 75 to 200 base pairs. The PCR product generated by the control primer pair is 430 base pairs.
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Lot No.: 33S

Lot-specific information

CELL LINE VALIDATION SHEET

DQA1*01:02

					Well					
					1	2	3	4	5	6
				Prod. No.	201190103	201190104	201190105	201318409	201318410	201318411
	IHWC cell line		DQB1							
1	9001	SA	*05:01		+	-	-	-	-	-
2	9280	LK707	*06:01	*02:02	-	+	-	+	-	-
3	9011	E4181324	*06:01		-	+	-	+	-	-
4	9275	GU373	*02:01		-	-	-	-	-	-
5	9009	KAS011	*05:02		+	+	-	-	-	-
6	9353	SM	*03:02	*06:01	-	+	-	+	-	-
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	+	+	-	+	-	-
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		-	+	-	+	-	-
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		+	-	-	-	-	-

101.901-24 – including *Taq* polymerase, IFU-01
101.901-24u – without *Taq* polymerase, IFU-02

Visit www.olerup-ssp.com for
"Instructions for Use" (IFU)

Lot No.: 33S **Lot-specific information**

CELL LINE VALIDATION SHEET

DQB1*06:02

				Well					
					7	8	9	10	11
				Prod. No.	201190101	201190102	201318406	201318407	201318408
	IHWC cell line		DQB1						
1	9001	SA	*05:01		-	-	-	-	-
2	9280	LK707	*06:01	*02:02	+	-	-	-	-
3	9011	E4181324	*06:01		+	-	-	-	-
4	9275	GU373	*02:01		-	-	-	-	-
5	9009	KAS011	*05:02		-	-	-	-	-
6	9353	SM	*03:02	*06:01	+	-	-	-	-
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		+	-	-	-	-
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		-	-	-	-	-

Lot No.: 33S **Lot-specific information**

CERTIFICATE OF ANALYSIS

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

Product number:	**101.901-24 – including *Taq* polymerase** **101.901-24u- without *Taq* polymerase**
Lot number:	**33S**
Expiry date:	**2015-October-01**
Number of tests:	**24**
Number of wells per test:	**11+1**

Well specifications:

Well No.	Production No.	Well No.	Production No.
1	2011-901-03	9	2013-184-06
2	2011-901-04	10	2013-184-07
3	2011-901-05	11	2013-184-08
4	2013-184-09		
5	2013-184-10		
6	2013-184-11		
7	2011-901-01		
8	2011-901-02		

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 3, 5, 6 and 10 were available. The specificities of the primers in primer solution 10 were tested by separately adding one additional 5'-primer, respectively, one additional 3'-primer. In primer solution 3 it was only possible to test the 5'-primer, the 3'-primer was not possible to test. In primer solution 5 and 6 it was only possible to test the 3'-primer, the 5'-primer was not possible to test. In primer solutions 9 and 11 two 3'-primer was not possible to test, and in primer solutions 5 and 10 two respective three 5'-primers were not possible to test.
One additional 3'-primer in primer mix 9 and one additional 5'-primer in primer mix 11 were tested by separately adding one 3'-primer respective one 5'-primer.

The negative control primer pairs, **Production No. 2013-165-01**, can detect contamination with PCR products diluted 10^{-7}.

Lot No.: 33S **Lot-specific information**

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

Date of approval: 2013-May-23

Approved by:

Production Quality Control

Lot No.: 33S **Lot-specific information**

Declaration of Conformity

Product name: *Olerup* SSP® DQB1*06:02,DQA1*01:02
Product number: 101.901-24/24u
Lot number: 33S

Intended use: DQB1*06:02,DQA1*01:02 histocompatibility testing

Manufacturer: *Olerup* SSP AB
Franzengatan 5
SE-112 51 Stockholm, 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 13485:2012, 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, Franzengatan 5, SE-112 51 Stockholm, Sweden.

Stockholm, Sweden
2013-May-23

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs

Lot No.: 33S **Lot-specific information**

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