

Olerup SSP® DRB1*01

Product number:	101.111-24u/06u – without <i>Taq</i> pol.
Lot number:	90G
Expiry date:	2012-March-01
Number of tests:	24 test – Product No. 101.111-24u 6 tests – Product No. 101.111-06u
Number of wells per test:	19
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. 90G.

**CHANGES COMPARED TO THE PREVIOUS *OLERUP SSP*®
DRB1*01 Lot**

The DRB1*01 specificity and interpretation tables have been updated for the DRB1 alleles described since the previous *Olerup SSP*® DRB1*01 lot was made (Lot No. 50F).

Three wells have been added to the DRB1*01 kit,
wells **17 to 19**.

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	-	Added	Primer added for the DRB1*0129 allele.
6	-	Added	Primer added for the DRB1*0129 and DRB1*0131 alleles.
8	Added	-	Primer added for the DRB1*0127 allele.
12	-	Added	Primer added for the DRB1*0126 and DRB1*0131 alleles.
13	-	Added	Primer added for the DRB1*0123 and DRB1*0128 alleles.
14	-	Added	Primer added for the DRB1*0123 and DRB1*0124 alleles.

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15	-	Added	Primer added for the DRB1*0121 and DRB1*0128 alleles.
16	-	Added	Primer added for the DRB1*0121 and DRB1*0124 alleles.
17	New	New	New primer pair for the DRB1*0122 and DRB1*0127 alleles.
18	New	New	New primer pair for the DRB1*0125 allele.
19	New	New	New primer pair for the DRB1*0130 allele.

PRODUCT DESCRIPTION

DRB1*01 SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for identifying the DRB1*0101 to DRB1*0131 alleles.

STRIP LAYOUT

Each test consists of 19 PCR reactions in a 24 well PCR plate. Wells 20 to 24 are empty.

1	2	3	4	5	6	7	8
9	10	11	12	13	14	15	16
17	18	19	empty	empty	empty	empty	empty

The 24 well PCR plate is marked with 'DRB1*01' in silver/gray ink.

Well No. 1 is marked with the Lot No. '90G'.

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 24 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 DRB1*01 alleles will be amplified by the DRB1*01 subtyping kit. Thus, the interpretation of DRB1*01 subtypings is not influenced by other groups of DRB1 alleles.

UNIQUELY IDENTIFIED ALLELES

All the DRB1*01 alleles, i.e. **DRB1*0101 to DRB1*0131**, recognized by the HLA Nomenclature Committee in January 2010¹ will give rise to unique amplification patterns by the primers in the DRB1*01 subtyping kit.

The DRB1*01 subtyping kit cannot distinguish the DRB1*010101 to DRB1*010117 alleles or the DRB1*010201 to DRB1*010205 alleles.

¹DRB1 alleles listed on the IMGT/HLA web page 2010-January-15, release 2.28.0, www.ebi.ac.uk/imgt/hla.

RESOLUTION IN HOMO- AND HETEROZYGOTES

The 31 DRB1*01 alleles can be combined in 496 homozygous and heterozygous combinations. 157 of these genotypes do not give rise to unique amplification patterns. The different sizes of the specific PCR products generated by primer mixes 6, 8, 9 and 11 to 17 have not been considered in this calculation.

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+++--+--	---+-----	---	0102,0131 = 0105,0126 = 0126,0131
+++-----	---+-----	---	0101,0126 = 0102,0112 = 0112,0126
+++-----	-----+++-	---	0116,0123 = 0123,0128
+++-----	-----+++-	---	0101,0123 = 0113,0123 = 0114,0123
+--+--+--	+-----	---	0103,0108 = 0103,0120
+--+--+--	---+-----	---	0103,0110 = 0103,0118 = 0110,0117
+--+--+--	-----	---	0101,0103 = 0103,0117
+--+--+--	+--+-----	---	0108,0110 = 0110,0120
+--+--+--	---+-----	---	0101,0110 = 0110,0110 = 0110,0118
+--+--+--	+-----	---	0104,0105 = 0104,0129 = 0108,0129
			= 0120,0129
+--+--+--	---+-----	---	0111,0131 = 0112,0129 = 0129,0131
+--+--+--	-----	---	0101,0129 = 0105,0111 = 0105,0129
			= 0111,0129 = 0129,0129
+--+--+--	++-----	---	0104,0109 = 0106,0111
+--+--+--	+-----	---	0101,0104 = 0104,0108 = 0104,0111
			= 0108,0111 = 0111,0120
+--+--+--	-----	---	0101,0111 = 0111,0111
+--+--+--	+--+-----	---	0108,0131 = 0120,0131
+--+--+--	+-----	---	0105,0108 = 0105,0120
+--+--+--	---+-----	---	0101,0131 = 0105,0112 = 0105,0131
			= 0112,0131 = 0131,0131
+--+--+--	-----	---	0101,0105 = 0105,0105
+--+--+--	++-----	---	0106,0115 = 0106,0117 = 0108,0115
			= 0115,0120
+--+--+--	+-----	---	0108,0117 = 0117,0120
+--+--+--	+-----	---	0101,0115 = 0109,0115 = 0109,0117
			= 0115,0117
+--+--+--	-----	---	0101,0117 = 0117,0117
+--+--+--	+-----	+--	0108,0127 = 0120,0127
+--+--+--	+-----	---	0107,0108 = 0107,0120
+--+--+--	-----	+--	0101,0127 = 0107,0122 = 0107,0127
			= 0122,0127 = 0127,0127
+--+--+--	-----	---	0101,0107 = 0107,0107
+--+--+--	++-----	---	0101,0106 = 0106,0108 = 0106,0109
			= 0108,0109 = 0109,0120
+--+--+--	+--+-----	---	0108,0118 = 0118,0120
+--+--+--	+--+-----	---	0108,0112 = 0112,0120
+--+--+--	+--+--+--	---	0108,0128 = 0120,0128
+--+--+--	+--+--+--	---	0108,0113 = 0113,0120
+--+--+--	+--+--+--	---	0108,0124 = 0120,0124
+--+--+--	+--+--+--	---	0108,0114 = 0114,0120
+--+--+--	+--+--+--	---	0108,0121 = 0120,0121
+--+--+--	+--+--+--	---	0108,0116 = 0116,0120
+--+--+--	+--+--+--	---	0108,0119 = 0119,0120
+--+--+--	+--+--+--	+--	0108,0122 = 0120,0122
+--+--+--	+--+--+--	+--	0108,0125 = 0120,0125
+--+--+--	+--+--+--	---	0108,0130 = 0120,0130

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+--+----- +----- ---	0101,0108 = 0101,0120 = 0108,0108 = 0108,0120
+--+----- -+----- ---	0101,0109 = 0109,0109
+--+----- --+----- ---	0101,0118 = 0118,0118
+--+----- ---+----- ---	0101,0112 = 0112,0112
+--+----- -----++ ---	0113,0121 = 0119,0128 = 0121,0128
+--+----- -----+-+ ---	0101,0128 = 0113,0116 = 0113,0128 = 0116,0128 = 0128,0128
+--+----- -----+--- ---	0101,0113 = 0113,0113
+--+----- -----+++ ---	0114,0121 = 0116,0124 = 0121,0124
+--+----- -----+-+ ---	0101,0124 = 0114,0119 = 0114,0124 = 0119,0124
+--+----- -----+-- ---	0101,0114 = 0114,0114
+--+----- -----++ ---	0101,0121 = 0116,0119 = 0116,0121 = 0119,0121 = 0121,0121
+--+----- -----+- ---	0101,0116 = 0116,0116
+--+----- -----+ ---	0101,0119 = 0119,0119
+--+----- -----+- ---	0101,0122 = 0122,0122
+--+----- -----+- ---	0101,0125 = 0125,0125
+--+----- -----++ ---	0101,0130 = 0130,0130
+--+----- ---+----- ---	0102,0126 = 0126,0126
+--+----- +----- ---	0104,0104 = 0104,0120
+--+----- ++----- ---	0106,0106 = 0106,0120

0101 = 010101-010117

0102 = 010201-010205

SPECIFICITY TABLE

DRB1*01 SSP subtyping

Specificities and sizes of the PCR products of the 19 primer mixes used for DRB1*01 SSP subtyping

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified DRB1*01 ³ alleles
1⁵	255 bp	515 bp	*010101-010117, 0103, 0105, 0107-0119, 0121, 0122 ^w , 0124, 0125, 0127-0131
2	235 bp	430 bp	*010201-010205, 0123, 0126
3	200 bp	515 bp	*010101-010205, 0104-0114, 0116-0121, 0122 ^w , 0125-0131
4	210 bp	430 bp	*0103, 0110
5	220 bp	430 bp	*0104, 0111, 0129
6^{6,7}	135 bp, 210 bp	430 bp	*0105, 0129, 0131
7	210 bp	430 bp	*0103, 0115, 0117
8⁸	175 bp, 210 bp	430 bp	*0107, 0127
9^{4,9}	110 bp, 255 bp	430 bp	*0104, 0106, 0108, 0120
10	210 bp	430 bp	*0106, 0109, 0115
11^{5,7,10}	140 bp, 210 bp	430 bp	*0110, 0118
12¹¹	140 bp, 180 bp, 215 bp	430 bp	*0112, 0126, 0131
13^{4,12}	85 bp, 150 bp, 215 bp	430 bp	*0113, 0123, 0128
14¹³	170 bp, 210 bp	430 bp	*0114, 0123, 0124
15¹⁴	150 bp, 220 bp	430 bp	*0116, 0121, 0128
16¹⁵	200 bp, 230 bp	430 bp	*0119, 0121, 0124
17¹⁶	230 bp, 260 bp	430 bp	*0122, 0127
18	230 bp	430 bp	*0125
19⁴	125 bp	430 bp	*0130

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 DRB1*01 SSP subtypings.

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.

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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 DRB1*01 subtyping.

In addition, well number 3 contains 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.

³For several DRB alleles only partial second exon nucleotide sequences are available. In these instances it is not known whether some of the primers of the SSP sets are completely matched with the target sequences or not. We assume that unknown sequences in the first hyperpolymorphic region of the second exon of DRB alleles are conserved within allelic groups and that unknown sequences of codons 87 to 92 are identical with the DRB1*0101 consensus sequence.

⁴Specific PCR fragments shorter than 125 base pairs have a lower intensity and are less sharp than longer PCR bands.

⁵Primer mixes 1 and 11 have a tendency of giving rise to primer oligomer formation.

⁶Primer mix 6 has a tendency of giving rise to non-specific amplification.

⁷Primer mix 6: Specific PCR fragment of 135 bp in the DRB1* 0105 and DRB1*0131 alleles. Specific PCR fragment of 210 bp in the DRB1* 0129 allele.

⁸Primer mix 8: Specific PCR fragment of 175 bp in the DRB1*0127 allele. Specific PCR fragment of 210 bp in the DRB1*0107 allele.

⁹Primer mix 9: Specific PCR fragment of 110 bp in the DRB1*0108 allele. Specific PCR fragment of 255 bp in the DRB1*0104, 0106 and 0120 alleles.

¹⁰Primer mix 11: Specific PCR fragment of 140 bp in the DRB1*0118 allele. Specific PCR fragment of 210 bp in the DRB1*0110 allele.

¹¹Primer mix 12: Specific PCR fragment of 140 bp in the DRB1*0131 allele. Specific PCR fragment of 180 bp in the DRB1*0126 allele. Specific PCR fragment of 215 bp in the DRB1*0112 allele.

¹²Primer mix 13: Specific PCR fragment of 85 bp in the DRB1*0113 allele. Specific PCR fragment of 150 bp in the DRB1*0128 allele. Specific PCR fragment of 215 bp in the DRB1*0123 allele.

¹³Primer mix 14: Specific PCR fragment of 170 bp in the DRB1*0114 allele. Specific PCR fragment of 210 bp in the DRB1* 0123 and DRB1*0124 alleles.

¹⁴Primer mix 15: Specific PCR fragment of 150 bp in the DRB1*0128 allele. Specific PCR fragment of 220 bp in the DRB1*0116 and DRB1*0121 alleles.

¹⁵Primer mix 16: Specific PCR fragment of 200 bp in the DRB1*0124 allele. Specific PCR fragment of 230 bp in the DRB1* 0119 and DRB1*0121 alleles.

¹⁶Primer mix 17: Specific PCR fragment of 230 bp in the DRB1*0127 allele. Specific PCR fragment of 260 bp in the DRB1*0122 allele.

'w', might be weakly amplified.

INTERPRETATION TABLE**DRB1*01 SSP subtyping****Amplification patterns of the DRB1*0101 to 0131 alleles**

	Well ⁴											
	1	2	3	4	5	6	7	8	9	10	11	12
Length of spec. PCR product(s)	255	235	200	210	220	135	210	175	110	210	140	140
						210		210	255		210	180
												215
Length of int. pos. control ¹	515	430	515	430	430	430	430	430	430	430	430	430
5'-primer ²	14 (129)	14 (129)	14 (129)	14 (129)	14 (129)	14 (129)	14 (129)	10 (115)	14 (129)	14 (129)	14 (129)	14 (129)
	5' -gAA 3'	5' -gAA 3'	5' -gAA 3'	5' -gAA 3'	5' -gAA 3'	5' -gAA 3'	5' -gAA 3'	5' -ggg 3'	5' -gAA 3'	5' -gAA 3'	5' -gAA 3'	5' -gAA 3'
								23 (154)				
								5' -A gg 3'				
3'-primer(s) ³	86 (344)	78 (321)	67 (286)	71 (299)	70 (296)	45 (220)	67 (286)	67 (286)	37 (197)	71 (298)	47 (227)	48 (230)
	5' -CAC 3'	5' -CAA 3'	5' -gAg 3'	5' -gCT 3'	5' -TCC 3'	5' -CCT 3'	5' -gAT 3'	5' -gAg 3'	5' -CgT 3'	5' -CgC 3'	5' -ggA 3'	5' -CCT 3'
			67 (286)		77 (317)	48 (230)	67 (286)		85 (341)		71 (298)	60 (266)
			5' -gAg 3'		5' -AAT 3'	5' -CCT 3'	5' -gAT 3'		5' -CAA 3'		5' -CTT 3'	5' -Agg 3'
						70 (296)	74 (308)					72 (302)
						5' -TCC 3'	5' -CCT 3'					5' -CCA 3'
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
DRB1 allele												
*010101-010117	1		3									
*010201-010205		2	3									
*0103	1			4			7					
*0104			3		5				9			
*0105	1		3			6						
*0106			3						9	10		
*0107	1		3					8				
*0108	1		3						9			
*0109	1		3							10		
*0110	1		3	4							11	
*0111	1		3		5							
*0112	1		3									12
*0113	1		3									
*0114	1		3									
*0115	1						7			10		
*0116	1		3									
*0117	1		3				7					
*0118	1		3								11	
*0119	1		3									
*0120			3						9			
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

INTERPRETATION TABLE							
DRB1*01 SSP subtyping							
Amplification patterns of the DRB1*0101 to 0131 alleles							
Well ⁴							
13	14	15	16	17	18	19	
85	170	150	200	230	230	125	Length of spec.
150	210	220	230	260			PCR product(s)
215							
430	430	430	430	430	430	430	Length of int.
							pos. control ¹
14 (129)	14 (129)	14 (129)	14 (129)	12 (123)	23 (154)	59 (262)	5'-primer ²
5' -gAA 3'	5' -gAA 3'	5' -gAA 3'	5' -gAA 3'	5' -AAC 3'	5' -AGT 3'	5' -CCA 3'	
				23 (154)			
				5' -A gg 3'			
30 (175)	57 (257)	51 (239)	67 (286)	86 (344)	86 (344)	86 (344)	3'-primer(s) ³
5' -gAg 3'	5' -CAg 3'	5' -CCA 3'	5' -gAT 3'	5' -CAC 3'	5' -CAC 3'	5' -CAC 3'	
51 (239)	67 (286)	73 (305)	76 (313)				
5' -CCA 3'	5' -gAT 3'	5' -ggC 3'	5' -gTT 3'				
72 (303)	72 (303)	78 (319)	78 (319)				
5' -gCg 3'	5' -gCg 3'	5' -CAC 3'	5' -CAC 3'				
13	14	15	16	17	18	19	Well No.
							DRB1 allele
							*010101-010117
							*010201-010205
							*0103
							*0104
							*0105
							*0106
							*0107
							*0108
							*0109
							*0110
							*0111
							*0112
13							*0113
	14						*0114
							*0115
		15					*0116
							*0117
							*0118
			16				*0119
							*0120
13	14	15	16	17	18	19	Well No.

Length of spec.	255	235	200	210	220	135	210	175	110	210	140	140
PCR product(s)						210		210	255		210	180
												215
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
*0121	1		3									
*0122	w		w									
*0123		2										
*0124	1											
*0125	1		3									
*0126		2	3									12
*0127	1		3					8				
*0128	1		3									
*0129	1		3		5	6						
*0130	1		3									
*0131	1		3			6						12
DRB1 allele												
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

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 DRB1*01 subtyping.

In addition, well number 3 contains the primer pair giving rise to the longer, 515 bp, internal positive control band in order to allow kit identification.

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 in the anti-sense direction. 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.

85	170	150	200	230	230	125	Length of spec.
150	210	220	230	260			PCR product(s)
215							
13	14	15	16	17	18	19	Well No.
		15	16				*0121
				17			*0122
13	14						*0123
	14		16				*0124
					18		*0125
							*0126
				17			*0127
13		15					*0128
							*0129
						19	*0130
							*0131
							DRB1 allele
13	14	15	16	17	18	19	Well No.

⁴Primer mix 6: Specific PCR fragment of 135 bp in the DRB1* 0105 and DRB1*0131 alleles. Specific PCR fragment of 210 bp in the DRB1* 0129 allele.

Primer mix 8: Specific PCR fragment of 175 bp in the DRB1*0127 allele. Specific PCR fragment of 210 bp in the DRB1*0107 allele.

Primer mix 9: Specific PCR fragment of 110 bp in the DRB1*0108 allele. Specific PCR fragment of 255 bp in the DRB1*0104, 0106 and 0120 alleles.

Primer mix 11: Specific PCR fragment of 140 bp in the DRB1*0118 allele. Specific PCR fragment of 210 bp in the DRB1*0110 allele.

Primer mix 12: Specific PCR fragment of 140 bp in the DRB1*0131 allele. Specific PCR fragment of 180 bp in the DRB1*0126 allele. Specific PCR fragment of 215 bp in the DRB1*0112 allele.

Primer mix 13: Specific PCR fragment of 85 bp in the DRB1*0113 allele. Specific PCR fragment of 150 bp in the DRB1*0128 allele. Specific PCR fragment of 215 bp in the DRB1*0123 allele.

Primer mix 14: Specific PCR fragment of 170 bp in the DRB1*0114 allele. Specific PCR fragment of 210 bp in the DRB1* 0123 and DRB1*0124 alleles.

Primer mix 15: Specific PCR fragment of 150 bp in the DRB1*0128 allele. Specific PCR fragment of 220 bp in the DRB1*0116 and DRB1*0121 alleles.

Primer mix 16: Specific PCR fragment of 200 bp in the DRB1*0124 allele. Specific PCR fragment of 230 bp in the DRB1* 0119 and DRB1*0121 alleles.

Primer mix 17: Specific PCR fragment of 230 bp in the DRB1*0127 allele. Specific PCR fragment of 260 bp in the DRB1*0122 allele.

'w', might be weakly amplified.

CELL LINE VALIDATION SHEET																
DRB1*01 SSP subtyping kit																
						Well										
						1	2	3	4	5	6	7	8	9	10	11
					Production No.	200842401	200842402	200842403	200842404	201070305	201070306	201070307	201070308	200855509	200842410	201070311
						201070312	201070313	201070314	201070315	201070316						
	IHWC cell line	DRB1	DRB1													
1	9001 SA	*0101				+	-	+	-	-	-	-	-	-	-	-
2	9280 LK707	*1502	*0405			-	-	-	-	-	-	-	-	-	-	-
3	9011 E4181324	*1502				-	-	-	-	-	-	-	-	-	-	-
4	9275 GU373	*0301				-	-	-	-	-	-	-	-	-	-	-
5	9009 KAS011	*1601				-	-	-	-	-	-	-	-	-	-	-
6	9353 SM	*0407	*0803			-	-	-	-	-	-	-	-	-	-	-
7	9020 QBL	*0301				-	-	-	-	-	-	-	-	-	-	-
8	9025 DEU	*0401				-	-	-	-	-	-	-	-	-	-	-
9	9026 YAR	*0402				-	-	-	-	-	-	-	-	-	-	-
10	9107 LKT3	*0405				-	-	-	-	-	-	-	-	-	-	-
11	9051 PITOUT	*0701				-	-	-	-	-	-	-	-	-	-	-
12	9052 DBB	*0701				-	-	-	-	-	-	-	-	-	-	-
13	9004 JESTHOM	*0101				+	-	+	-	-	-	-	-	-	-	-
14	9071 OLGA	*0802				-	-	-	-	-	-	-	-	-	-	-
15	9075 DKB	*0901				-	-	-	-	-	-	-	-	-	-	-
16	9037 SWEIG007	*1101				-	-	-	-	-	-	-	-	-	-	-
17	9282 CTM3953540	*0301	*1301			-	-	-	-	-	-	-	-	-	-	-
18	9257 32367	*0901	*1101			-	-	-	-	-	-	-	-	-	-	-
19	9038 BM16	*1201				-	-	-	-	-	-	-	-	-	-	-
20	9059 SLE005	*1302				-	-	-	-	-	-	-	-	-	-	-
21	9064 AMALA	*1402				-	-	-	-	-	-	-	-	-	-	-
22	9056 KOSE	*1302	*1401			-	-	-	-	-	-	-	-	-	-	-
23	9124 IHL	*0803	*1414			-	-	-	-	-	-	-	-	-	-	-
24	9035 JBUSH	*1101				-	-	-	-	-	-	-	-	-	-	-
25	9049 IBW9	*0701				-	-	-	-	-	-	-	-	-	-	-
26	9285 WT49	*0301				-	-	-	-	-	-	-	-	-	-	-
27	9191 CH1007	*0405	*1001			-	-	-	-	-	-	-	-	-	-	-
28	9320 BEL5GB	*0416	*0701			-	-	-	-	-	-	-	-	-	-	-
29	9050 MOU	*0701				-	-	-	-	-	-	-	-	-	-	-
30	9021 RSH	*0302				-	-	-	-	-	-	-	-	-	-	-
31	9019 DUCAF	*0301				-	-	-	-	-	-	-	-	-	-	-
32	9297 HAG	*1303				-	-	-	-	-	-	-	-	-	-	-
33	9098 MT14B	*0404				-	-	-	-	-	-	-	-	-	-	-
34	9104 DHIF	*1101				-	-	-	-	-	-	-	-	-	-	-
35	9302 SСТО	*0403				-	-	-	-	-	-	-	-	-	-	-
36	9024 KT17	*0403	*0406			-	-	-	-	-	-	-	-	-	-	-
37	9065 HHKB	*1301				-	-	-	-	-	-	-	-	-	-	-
38	9099 LZL	*1402				-	-	-	-	-	-	-	-	-	-	-
39	9315 CML	*0301	*0401			-	-	-	-	-	-	-	-	-	-	-
40	9134 WHONP199	*0701	*0901			-	-	-	-	-	-	-	-	-	-	-
41	9055 H0301	*1302				-	-	-	-	-	-	-	-	-	-	-
42	9066 TAB089	*0803				-	-	-	-	-	-	-	-	-	-	-
43	9076 T7526	*0901				-	-	-	-	-	-	-	-	-	-	-
44	9057 TEM	*1401				-	-	-	-	-	-	-	-	-	-	-
45	9239 SHJO	*0701				-	-	-	-	-	-	-	-	-	-	-
46	9013 SCHU	*1501				-	-	-	-	-	-	-	-	-	-	-
47	9045 TUBO	*1104	*1201			-	-	-	-	-	-	-	-	-	-	-
48	9303 TER-ND	*0103				+	-	-	+	-	-	+	-	-	-	-

CELL LINE VALIDATION SHEET					
DRB1*01 SSP subtyping kit					
					Well
					17 18 19
				Production No.	201070317 201070318 201070319
	IHWC cell line	DRB1	DRB1		
1	9001 SA	*0101		-	-
2	9280 LK707	*1502	*0405	-	-
3	9011 E4181324	*1502		-	-
4	9275 GU373	*0301		-	-
5	9009 KAS011	*1601		-	-
6	9353 SM	*0407	*0803	-	-
7	9020 QBL	*0301		-	-
8	9025 DEU	*0401		-	-
9	9026 YAR	*0402		-	-
10	9107 LKT3	*0405		-	-
11	9051 PITOUT	*0701		-	-
12	9052 DBB	*0701		-	-
13	9004 JESTHOM	*0101		-	-
14	9071 OLG A	*0802		-	-
15	9075 DKB	*0901		-	-
16	9037 SWEIG007	*1101		-	-
17	9282 CTM3953540	*0301	*1301	-	-
18	9257 32367	*0901	*1101	-	-
19	9038 BM16	*1201		-	-
20	9059 SLE005	*1302		-	-
21	9064 AMALA	*1402		-	-
22	9056 KOSE	*1302	*1401	-	-
23	9124 IHL	*0803	*1414	-	-
24	9035 JBUSH	*1101		-	-
25	9049 IBW9	*0701		-	-
26	9285 WT49	*0301		-	-
27	9191 CH1007	*0405	*1001	-	-
28	9320 BEL5GB	*0416	*0701	-	-
29	9050 MOU	*0701		-	-
30	9021 RSH	*0302		-	-
31	9019 DUCAF	*0301		-	-
32	9297 HAG	*1303		-	-
33	9098 MT14B	*0404		-	-
34	9104 DHIF	*1101		-	-
35	9302 S8TO	*0403		-	-
36	9024 KT17	*0403	*0406	-	-
37	9065 HHKB	*1301		-	-
38	9099 LZL	*1402		-	-
39	9315 CML	*0301	*0401	-	-
40	9134 WHONP199	*0701	*0901	-	-
41	9055 H0301	*1302		-	-
42	9066 TAB089	*0803		-	-
43	9076 T7526	*0901		-	-
44	9057 TEM	*1401		-	-
45	9239 SHJO	*0701		-	-
46	9013 SCHU	*1501		-	-
47	9045 TUBO	*1104	*1201	-	-
48	9303 TER-ND	*0103		-	-

CERTIFICATE OF ANALYSIS**Olerup SSP® DRB1*01 SSP**

Product number: 101.111-24u/06u – without *Taq* pol.
Lot number: 90G
Expiry date: 2012-March-01
Number of tests: 24 test – Product No. 101.111-24u
6 tests – Product No. 101.111-06u
Number of wells per test: 19

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2008-424-01	9	2008-555-09	17	2010-703-17
2	2008-424-02	10	2008-424-10	18	2010-703-18
3	2008-424-03	11	2010-703-11	19	2010-703-19
4	2008-424-04	12	2010-703-12		
5	2010-703-05	13	2010-703-13		
6	2010-703-06	14	2010-703-14		
7	2010-703-07	15	2010-703-15		
8	2010-703-08	16	2010-703-16		

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, 6 and 8 to 19 were available. The specificities of the primers in primer solutions 5, 6 and 9 to 16 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer solution 8 and 17 to 19 it was only possible to test the 3'-primer, the 5'-primer was not possible to test. In primer solutions 6, and 12 to 16 one or two 3'-primers were not possible to test. Additional 3'-primers in primer solution 7 were tested by separately adding one additional 5'-primer.

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

Date of approval: 2010-April-01

Approved by:

Quality Control, Supervisor

Declaration of Conformity

Product name: *Olerup* SSP® DRB1*01

Product number: 101.111-24u/06u

Lot number: 90G

Intended use: DRB1*01 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 9001:2008 and ISO 13485:2003, following the provisions of the 98/79/EC Directive on *in vitro* diagnostic medical devices, Annex II List B, conformity assessed using Annex IV, 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.

Notified Body: Lloyd's Register Quality Assurance Limited, Hiramford, Middlemarch Office Village, Siskin Drive, Coventry CV3 4FJ, United Kingdom. (Notified Body number: 0088.)

Saltsjöbaden, Sweden
2010-April-01

Olle Olerup
Managing Director

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**.