

Olerup SSP[®] DRB1*12

Product number:	101.128-12 – including <i>Taq</i> polymerase
Lot number:	89G
Expiry date:	2012-March-01
Number of tests:	12
Number of wells per test:	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. 89G.

CHANGES COMPARED TO THE PREVIOUS *OLERUP SSP*[®] DRB1*12 LOT

The DRB1*12 specificity and interpretation tables have been updated for the DRB1 alleles described since the previous *Olerup SSP*[®] DRB1*12 lot was made (Lot No. 44F).

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

Well	5'-primer	3'-primer	rationale
12	-	-	Exchanged positive control primer pair.
13	Modified, added	-	Modified 5'-primer for increased specificity, 5'-primer added for the DRB1*1220 allele.
16	-	Modified	Modified 3'-primer for increased specificity, to exclude amplification of DRB5 alleles.

Changes in revision R01 compared to R00:

1. The DRB1*1210 allele is weakly amplified by primer mix 17. This has been corrected in the Specificity and Interpretation Tables.

PRODUCT DESCRIPTION

DRB1*12 SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for identifying the DRB1*1201 to DRB1*1220 alleles.

PLATE LAYOUT

Each test consists of 24 PCR reactions in a 24 well cut PCR plate.

1	2	3	4	5	6	7	8
9	10	11	12	13	14	15	16
17	18	19	20	21	22	23	24

The 24 well cut PCR plate is marked with 'DRB1*12' in silver/gray ink.

Well No. 1 is marked with the Lot No. '89G'.

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

The interpretation of DRB1*12 SSP subtypings will be influenced by all DRB1*01 alleles, most DRB1*08 alleles, two DRB1*11 alleles, three DRB1*13 alleles and twelve DRB1*14 alleles when present on the other haplotype. In addition, the DRB1*15 and DRB1*16 alleles will be weakly amplified by primer mix 14.

UNIQUELY IDENTIFIED ALLELES

All the phenotypically different DRB1*12 alleles alleles, i.e. **DRB1*1201 to DRB1*1220**, recognized by the HLA Nomenclature Committee in January 2010¹ will give rise to unique amplification patterns by the primers in the DRB1*12 subtyping kit.

The DRB1*12 kit cannot distinguish the DRB1*120102 and 120103 alleles, and the DRB1*120201, 120203 and 120204 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 20 DRB1*12 alleles can generate 22 amplification patterns that may be combined in 253 homozygous and heterozygous combinations. 137 of these genotypes do not give rise to unique amplification patterns.

+++++++ +----- ----- 1209,1215 = 1209,1220
+++++++ +----- ----- 1202,1209 = 120202,1209
+++++++ +----- ----- 1205,1209 = 1209,1214

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+++++++ +----- +---+--- 120101,1209 = 120102,1209
++-+++++ ++++---- +---+--- 120302,1220 = 1205,1219 = 1214,1219
++-+++++ ++++---- +---+--- 120101,1219 = 120102,1219 = 1202,120302
++-+++++ ++-+---- +---+--- 1204,1215 = 1204,1220
++-+++++ ++-+---- +---+--- 1202,1204 = 120202,1204
++-+++++ ++++---- +---+--- 1206,1215 = 1206,1220
++-+++++ ++++---- +---+--- 1208,1215 = 1208,1220
++-+++++ ++++---- +---+--- 1210,1215 = 1210,1220
++-+++++ ++-+---- -+---+--- 1211,1215 = 1211,1220
++-+++++ ++-+---- -+---+--- 1205,1213 = 1213,1214
++-+++++ ++++---- +---+--- 1215,1217 = 1217,1220
++-+++++ ++++---- +---+--- 1205,1218 = 1214,1218
++-+++++ ++++---- +---+--- 120101,1215 = 120101,1220 = 120102,1220 =
1202,1205 = 1202,1214 = 1205,1220 =
1214,1220
++-+++++ ++-+---- +---+--- 1202,1206 = 120202,1206
++-+++++ ++-+---- +---+--- 1202,1208 = 120202,1208
++-+++++ ++-+---- +---+--- 1202,1210 = 120202,1210
++-+++++ ++-+---- -+---+--- 1202,1211 = 120202,1211
++-+++++ ++-+---- -+---+--- 120101,1213 = 120102,1213
++-+++++ ++-+---- -+---+--- 1202,1217 = 120202,1217
++-+++++ ++++---- +---+--- 120101,1218 = 120102,1218
++-+++++ ++-+---- +---+--- 120101,1202 = 120101,120202 = 120102,1202
++-+++++ ++-+---- +---+--- 1204,1205 = 1204,1214
++-+++++ ++-+---- +---+--- 120101,1204 = 120102,1204
++-+++++ ++++---- +---+--- 1205,1206 = 1206,1214
++-+++++ ++++---- +---+--- 1205,1207 = 1207,1214
++-+++++ ++++---- +---+--- 1205,1208 = 1208,1214
++-+++++ ++++---- +---+--- 1205,1210 = 1210,1214
++-+++++ ++++---- -+---+--- 1205,1211 = 1211,1214
++-+++++ ++++---- -+---+--- 1205,1212 = 1212,1214
++-+++++ ++++---- +---+--- 1205,1217 = 1214,1217
++-+++++ ++-+---- +---+--- 120101,1205 = 120101,1214
++-+++++ ++-+---- +---+--- 120101,1206 = 120102,1206 = 1206,1206
++-+++++ ++-+---- +---+--- 120101,1207 = 120102,1207
++-+++++ ++++---- +---+--- 120101,1208 = 120102,1208
++-+++++ ++++---- +---+--- 120101,1210 = 120102,1210 = 1210,1210
++-+++++ ++++---- -+---+--- 120101,1211 = 120102,1211 = 1211,1211
++-+++++ ++++---- -+---+--- 120101,1212 = 120102,1212
++-+++++ ++++---- -+---+--- 120101,1217 = 120102,1217 = 1217,1217
++-+++++ ++++---- +---+--- 120101,120101 = 120101,120102
++-+++++ -+---+--- +---+--- 1205,1216 = 1214,1216
++-+++++ -+---+--- +---+--- 120102,1215 = 120202,1205 = 120202,1214
++-+++++ -+---+--- +---+--- 120302,1205 = 120302,1214
++-+++++ ++++---- +---+--- 120102,1205 = 120102,1214
++-+++++ ++++---- +---+--- 1215,1219 = 1219,1220
++-+++++ ++++---- +---+--- 1202,1219 = 120202,1219
++-+++++ ++-+---+--- +---+--- 1207,1215 = 1207,1220
++-+++++ ++-+---+--- -+---+--- 1212,1215 = 1212,1220
++-+++++ ++-+---+--- -+---+--- 1213,1215 = 1213,1220
++-+++++ ++++---- +---+--- 1215,1218 = 1218,1220
++-+++++ ++-+---+--- +---+--- 1202,1215 = 1202,1220 = 120202,1220 =
1215,1220 = 1220,1220
++-+++++ ++-+---+--- +---+--- 1202,1207 = 120202,1207
++-+++++ ++-+---+--- -+---+--- 1202,1212 = 120202,1212
++-+++++ ++-+---+--- -+---+--- 1202,1213 = 120202,1213 = 1213,1213
++-+++++ ++-+---+--- -+---+--- 1202,1218 = 120202,1218
++-+++++ ++-+---+--- -+---+--- 1202,1202 = 1202,120202
++-+++++ -+---+--- +---+--- 1205,1215 = 1214,1215
++-+++++ -+---+--- +---+--- 1205,1205 = 1205,1214

120102 = 120102 and 120103; 1202 = 120201, 120203 and 120204



SPECIFICITY TABLE

DRB1*12 SSP subtyping

Specificities and sizes of the PCR products of the 24 primer mixes used for DRB1*12 SSP subtyping

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified DRB1*12 alleles ³	Other amplified DRB1 alleles ⁴
1	135 bp	515 bp	*120101-1220	*0817, 0828, 0837, 1167, 1317
2	215 bp	430 bp	*120101-1220	*0805, 0818, 0824, 0825, 0831, 1317, 1431, 1452
3	165 bp	430 bp	*1209	*080201-080203, 080401-080404, 0809, 0813, 0821, 0824, 0828, 083001, 1317, 1415, 1452
4⁵	105 bp	430 bp	*120101-1204, 1206-1213, 1216-1220	*0832
5	165 bp	515 bp	*120101-120302, 1205-1208, 1210-1217, 1219, 1220	*0819, 0825, 0834
6	250 bp	430 bp	*120101-120204, 1204-1215, 1217, 1218, 1220	*0812, 0822, 1428
7	215 bp	430 bp	*120101-120204, 1204-1207, 1209-1212, 1213 ^w , 1214, 1215, 1217, 1218, 1220	
8	195 bp	430 bp	*120101-120103, 120302-1206, 1208-1211, 1214, 1217	*080302, 0810, 0812, 0814, 0815, 0818, 0819, 0823, 0825, 0827, 0829-083002, 0832-0838
9	165 bp	430 bp	*120101, 120201, 120203, 120204, 1204, 1206-1213, 1217-1220	
10	195 bp	430 bp	*120201-120204, 1213, 1215, 1216, 1218-1220	*080101-080203, 080401-0809, 0811, 0816, 0817, 0821, 0822, 0824, 0826, 0828, 0831, 0839, 1167, 1415, 1473
11	250 bp	430 bp	*120302, 1219	*080401, 080402 ^w , 080403 ^w , 080404, 0806, 0810, 0828, 0831, 1167, 1317, 1404, 1411,

				1415, 1431, 1450, 1452, 1473, 1476, 1479
12	170 bp	430 bp	*1204	*0831, 1167, 1411
13⁶	185 bp, 255 bp	515 bp	*1205, 1214, 1215, 1220	
14⁷	135 bp	515 bp	*1206	*15010101 ^w -1543 ^w , 160101 ^w - 160502 ^w , 1607 ^w -1615 ^w
15	200 bp	515 bp	*1207	
16⁵	75 bp	430 bp	*1208	*1176, 1334, 1364, 1441, 1477
17⁵	80 bp	430 bp	*1210 ^w	
18	135 bp	515 bp	*1211	
19	195 bp	430 bp	*1212	*0813
20	220 bp	430 bp	*1213	
21⁵	105 bp	430 bp	*120101-1213, 1215-1220	*0832
22	220 bp	430 bp	*1216	*0832
23⁵	120 bp	430 bp	*1217	*010101-0131
24	170 bp	430 bp	*1218	

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*12 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 DRB1*12 subtyping.

In addition, wells number 5, 13 to 15 and 18 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.

³For several DRB alleles only partial second exon and third 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.

⁴Due to the sharing of sequence motifs, all DRB1*01 alleles, most DRB1*08 alleles, two DRB1*11 alleles, three DRB1*13 alleles and twelve DRB1*14 alleles will be amplified by some of the DRB1*12 primer mixes. In addition, the DRB1*15 and DRB1*16 alleles will be weakly amplified by primer mix 14.

⁵Short specific PCR fragments have a lower intensity than longer PCR bands.

⁶Primer mix 13: Specific PCR fragment of 185 bp in the DRB1*1205, DRB1*1214 and DRB1*1215 alleles. Specific PCR fragment of 255 bp in the DRB1*1220 allele.

⁷Primer mix 14 may give rise to a primer dimer artefact.

'w', may be weakly amplified.

INTERPRETATION TABLE

DRB1*12 SSP subtyping

Amplification patterns of the DRB1*1201 to 1220 alleles

	Well ⁵											
	1	2	3	4	5	6	7	8	9	10	11	12
Length of spec.	135	215	165	105	165	250	215	195	165	195	250	170
PCR product												
Length of int.	515	430	430	430	515	430	430	430	430	430	430	430
pos. control ¹												
5'-primer ²	16 (133)	16 (133)	16 (133)	16 (133)	16 (133)	16 (133)	26 (165)	16 (133)	37 (196)	16 (133)	16 (133)	16 (133)
	5'-gTT 3'	5'-gTT 3'	5'-gTT 3'	5'-gTT 3'	5'-gTT 3'	5'-gTT 3'	5'-TTA 3'	5'-gTT 3'	5'-AgC 3'	5'-gTT 3'	5'-gTT 3'	5'-gTT 3'
3'-primer ³	47 (227)	74 (307)	57 (257)	37 (196)	57 (257)	85 (341)	85 (341)	67 (286)	78 (321)	67 (286)	85 (341)	58 (260)
	5'-ggA 3'	5'-CgC 3'	5'-CAT 3'	5'-gAg 3'	5'-CgA 3'	5'-CAg 3'	5'-CAg 3'	5'-gAT 3'	5'-CAA 3'	5'-gAA 3'	5'-CAA 3'	5'-CCT 3'
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
DRB1 allele ⁴												
*120101	1	2		4	5	6	7	8	9			
*120102, 120103	1	2		4	5	6	7	8				
*120201, 120203, 120204	1	2		4	5	6	7		9	10		
*120202	1	2		4	5	6	7			10		
*120302	1	2		4	5			8			11	
*1204	1	2		4		6	7	8	9			12
*1205	1	2			5	6	7	8				
*1206	1	2		4	5	6	7	8	9			
*1207	1	2		4	5	6	7		9			
*1208	1	2		4	5	6		8	9			
*1209	1	2	3	4		6	7	8	9			
*1210	1	2		4	5	6	7	8	9			
*1211	1	2		4	5	6	7	8	9			
*1212	1	2		4	5	6	7		9			
*1213	1	2		4	5	6	w		9	10		
*1214	1	2			5	6	7	8				
*1215	1	2			5	6	7			10		
*1216	1	2		4	5					10		
*1217	1	2		4	5	6	7	8	9			
*1218	1	2		4		6	7		9	10		
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

INTERPRETATION TABLE												
DRB1*12 SSP subtyping												
Amplification patterns of the DRB1*1201 to 1220 alleles												
Well⁵												
13	14	15	16	17	18	19	20	21	22	23	24	
185	135	200	75	80	135	195	220	105	220	120	170	Length of spec. PCR product(s)
255												
515	515	515	430	430	515	430	430	430	430	430	430	Length of int. pos. control ¹
13 (125)	149 (534)	16 (133)	26 (165)	-16 (40)	16 (133)	16 (133)	25 (161)	16 (133)	26 (165)	152 (543)	16 (133)	5'-primer ²
5' -gTg 3'	5' -CAg 3'	5' -gTT 3'	5' -TTC 3'	5' -CAA 3'	5' -gTT 3'	5' -gTT 3'	5' -gCT 3'	5' -gTT 3'	5' -TTA 3'	5' -gAT 3'	5' -gTT 3'	
37 (197)												
5' -gTT 3'												
85 (341)	181 (630)	69 (293)	38 (199)	-3 (79)	47 (226)	67 (286)	85 (341)	38 (199)	86 (344)	179 (624)	59 (262)	3'-primer ³
5' -CAg 3'	5' -CTT 3'	5' -CTC 3'	5' -CAg 3'	5' -AgC 3'	5' -gAg 3'	5' -gAg 3'	5' -CAg 3'	5' -CAg 3'	5' -CAC 3'	5' -ACA 3'	5' -CTg 3'	
13	14	15	16	17	18	19	20	21	22	23	24	Well No. DRB1 allele ⁴
								21				*120101
								21				*120102, 120103
								21				*120201, 120203, 120204
								21				*120202
								21				*120302
								21				*1204
13								21				*1205
	14							21				*1206
		15						21				*1207
			16					21				*1208
								21				*1209
				w				21				*1210
					18			21				*1211
						19		21				*1212
							20	21				*1213
13												*1214
13								21				*1215
								21	22			*1216
								21		23		*1217
								21			24	*1218
13	14	15	16	17	18	19	20	21	22	23	24	Well No.

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Length of spec. PCR product	135	215	165	105	165	250	215	195	165	195	250	170
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
*1219	1	2		4	5				9	10	11	
*1220	1	2		4	5	6	7		9	10		
*010101-0131												
*080101-080105, 0807, 0808, 0811, 0816, 0826, 0839										10		
*080201-080203, 0809, 0821			3							10		
*080302, 0814, 0815, 0823, 0827, 0829, 083002, 0833, 0835, 0836, 0838								8				
*080401, 080404, 1415			3							10	11	
*080402, 080403			3							10	w	
*0805		2								10		
*0806, 1473										10	11	
*0810								8			11	
*0812						6		8				
*0813			3									
*0817	1									10		
*0818		2						8				
*0819, 0834					5			8				
*0822						6				10		
*0824		2	3							10		
*0825		2			5			8				
*0828	1		3							10	11	
*083001			3					8				
*0831		2								10	11	12
*0832				4				8				
*0837	1							8				
*1167	1									10	11	12
*1176, 1334, 1364, 1441, 1477												
*1317	1	2	3								11	
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

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Lot-specific information

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185	135	200	75	80	135	195	220	105	220	120	170	Length of spec. PCR product
255												Well No.
13	14	15	16	17	18	19	20	21	22	23	24	
								21				*1219
13								21				*1220
										23		*010101-0131
												*080101-080105, 0807, 0808, 0811, 0816, 0826, 0839
												*080201-080203, 0809, 0821
												*080302, 0814, 0815, 0823, 0827, 0829, 083002, 0833, 0835, 0836, 0838
												*080401, 080404, 1415
												*080402, 080403
												*0805
												*0806, 1473
												*0810
												*0812
						19						*0813
												*0817
												*0818
												*0819, 0834
												*0822
												*0824
												*0825
												*0828
												*083001
												*0831
								21	22			*0832
												*0837
												*1167
			16									*1176, 1334, 1364, 1441, 1477
												*1317
13	14	15	16	17	18	19	20	21	22	23	24	Well No.

Lot No.: **89G**

Lot-specific information

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Length of spec.	135	215	165	105	165	250	215	195	165	195	250	170
PCR product												
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
*1404, 1450, 1476, 1479											11	
*1411											11	12
*1428						6						
*1431		2									11	
*1452		2	3								11	
*15010101-1543, 160101-160502, 1607-1615												
DRB1 allele ⁴												
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

185	135	200	75	80	135	195	220	105	220	120	170	Length of spec. PCR product
255												Well No.
13	14	15	16	17	18	19	20	21	22	23	24	
												*1404, 1450, 1476, 1479
												*1411
												*1428
												*1431
												*1452
	w											*15010101-1543, 160101-160502, 1607-1615
												DRB1 allele ⁴
13	14	15	16	17	18	19	20	21	22	23	24	Well No.

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*12 subtyping.

In addition, wells number 5, 13 to 15 and 18 contain 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 1st, 2nd or 3rd 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 1st, 2nd or 3rd 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.

⁴The sequence of the DRB1*120301 allele has been shown to be identical to DRB1*1201.

⁵Primer mix 13: Specific PCR fragment of 185 bp in the DRB1*1205, DRB1*1214 and DRB1*1215 alleles. Specific PCR fragment of 255 bp in the DRB1*1220 allele.

'w', may be weakly amplified.

CELL LINE VALIDATION SHEET																				
DRB1*12 SSP subtyping kit																				
					Well															
					1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
					201071501	201071502	201071503	201071504	201071505	201071506	201071507	201071508	201071509	201071510	201071511	201071512	201071513	201071514	201071515	201071516
				Prod. No.:																
	IHWC cell line		DRB1																	
1	9001 SA		*0101		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2	9280 LK707		*1502	*0405	-	-	-	-	-	-	-	-	-	-	-	-	-	-	W	-
3	9011 E4181324		*1502		-	-	-	-	-	-	-	-	-	-	-	-	-	-	W	-
4	9275 GU373		*0301		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
5	9009 KAS011		*1601		-	-	-	-	-	-	-	-	-	-	-	-	-	-	W	-
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 SSTO		*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		-	-	-	-	-	-	-	-	-	-	-	-	-	-	W	-
47	9045 TUBO		*1104	*1201	+	+	-	+	+	+	+	+	+	-	-	-	-	-	-	-
48	9303 TER-ND		*0103		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

CELL LINE VALIDATION SHEET												
DRB1*12 SSP subtyping kit												
				Well								
				17	18	19	20	21	22	23	24	
				Prod. No.:	201071517	201071518	201071519	201071520	201071521	201071522	201071523	201071524
	IHWC cell line	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 SSTO	*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*12 SSP

Product number: 101.128-12 – including *Taq* polymerase
Lot number: 89G
Expiry date: 2012-March-01
Number of tests: 12
Number of wells per test: 24

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2010-715-01	9	2010-715-09	17	2010-715-17
2	2010-715-02	10	2010-715-10	18	2010-715-18
3	2010-715-03	11	2010-715-11	19	2010-715-19
4	2010-715-04	12	2010-715-12	20	2010-715-20
5	2010-715-05	13	2010-715-13	21	2010-715-21
6	2010-715-06	14	2010-715-14	22	2010-715-22
7	2010-715-07	15	2010-715-15	23	2010-715-23
8	2010-715-08	16	2010-715-16	24	2010-715-24

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 13, 15 to 20, 22 and 24 were available. The specificities of the primers in primer solutions 16, 19 and 22 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer solutions 15, 18 and 24 it was only possible to test the 5'-primer, the 3'-primers were not possible to test. In primer solutions 13 and 20 it was only possible to test the 3'-primer, the 5'-primer was not possible to test. In primer solution 17, it was neither possible to test the 5'-primer nor the 3'-primer.

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

Date of approval: 2011-March-18

Approved by:

Quality Control, Supervisor

Lot No.: **89G**

Lot-specific information

www.olerup-ssp.com

Declaration of Conformity

Product name: *Olerup* SSP® DRB1*12
Product number: 101.128-12
Lot number: 89G

Intended use: DRB1*12 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
2011-March-18

Olle Olerup
Managing Director

Lot No.: **89G**

Lot-specific information

www.olerup-ssp.com

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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**.