

Lot No.: **44F**

Lot-specific information

Olerup SSP[®] DRB1*12

Product number: 101.128-12u – without *Taq* polymerase
Lot number: 44F
Expiry date: 2011-February-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. 44F.

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. 25E).

Two wells has been added to the DRB1*12 kit,
wells **23** and **24**.

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

Well	5'-primer	3'-primer	rationale
13	Exchanged	Exchanged	Exchanged primer pair for improved specificity.
23	New	New	New primer pair for the DRB1*1217 allele.
24	New	New	New primer pair for the DRB1*1218 allele.

Changes in revision R02 compared to R01:

1. The DRB1*1115, 1362 and eight DRB5*01 alleles are faintly amplified by primer mix 16.
2. A footnote stating that short specific PCR fragments are less intense has been added to the specificity table.

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PRODUCT DESCRIPTION

DRB1*12 SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for identifying the DRB1*1201 to DRB1*1218 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. '44F'.

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, four 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, and eight DRB5 alleles will be faintly amplified by primer mix 16.

UNIQUELY IDENTIFIED ALLELES

All the phenotypically different DRB1*12 alleles, i.e. **DRB1*1201 to DRB1*1218**, recognized by the HLA Nomenclature Committee in January 2009¹ will give rise to unique amplification patterns by the primers in the DRB1*12 subtyping kit.

The DRB1*12 kit cannot distinguish the DRB1*120201, 120203 and 120204 alleles.

¹DRB1 alleles listed on the IMGT/HLA web page 2009-January-16, release 2.24.0, www.ebi.ac.uk/imgt/hla.

RESOLUTION IN HOMO- AND HETEROZYGOTES

The 18 DRB1*12 alleles can generate 20 amplification patterns that may be combined in 210 homozygous and heterozygous combinations. Ninety-six of these genotypes do not give rise to unique amplification patterns.

+++++++	++-----	----+---	1202,1209 = 120202,1209
+++++++	+----+---	----+---	1205,1209 = 1209,1214
+++++++	+-----	----+---	120101,1209 = 120102,1209
+++++++	++-+-----	----+---	1202,1204 = 120202,1204

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++-+++++	++---+---	----+---	1205,1213 = 1213,1214
++-+++++	++---+---	----+---	1205,1218 = 1214,1218
++-+++++	++---+---	----+---	120101,1215 = 1202,1205 = 1202,1214
++-+++++	++---+---	----+---	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
++-+++++	++---+---	----+---	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

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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	120101-120204, 120302-1218	0817, 0828, 1167, 1317
2	215 bp	430 bp	120101-120204, 120302-1218	0805, 0818, 0824, 0825, 0831, 1317, 1431, 1452
3	165 bp	430 bp	1209	080201-080203, 080401-080404, 0809, 0813, 0821, 0824, 0828, 0830, 1317, 1415, 1452
4 ⁵	105 bp	430 bp	120101-120204, 120302, 1204, 1206-1213, 1216-1218	0832
5	165 bp	515 bp	120101-120204, 120302, 1205-1208, 1210-1217	0819, 0825, 0834
6	250 bp	430 bp	120101-120204, 1204-1215, 1217, 1218	0812, 0822, 1428
7	215 bp	430 bp	120101-120204, 1204-1207, 1209-1212, 1213 ^{weakly} , 1214, 1215, 1217, 1218	
8	195 bp	430 bp	120101-120102, 120302-1206, 1208-1211, 1214, 1217	080302, 0810, 0812, 0814, 0815, 0818, 0819, 0823, 0825, 0827, 0829, 0830, 0832-0836
9	165 bp	430 bp	120101, 120201, 120203, 120204, 1204, 1206-1213, 1217, 1218	
10	195 bp	430 bp	120201-120204, 1213, 1215, 1216, 1218	080101-080203, 080401-0809, 0811, 0816, 0817, 0821, 0822, 0824, 0826, 0828, 0831, 1167, 1415, 1473
11	250 bp	430 bp	120302	080401, 080402-080403 ^{weakly} , 080404, 0806, 0810, 0828,

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				0831, 1167, 1317, 1404, 1411, 1415, 1431, 1450, 1452, 1473, 1476, 1479
12	170 bp	515 bp	1204	0831, 1167, 1411
13	185 bp	515 bp	1205, 1214, 1215	1428
14	135 bp	515 bp	1206	15010101-1531 ^{weakly} , 160101-160502 ^{weakly} , 1607-1613N ^{weakly}
15	200 bp	515 bp	1207	
16⁵	75 bp	430 bp	1208	1115 ^f , 1334, 1362 ^f , 1364, 1441, 1477, DRB5*0101^f, 0104^f, 0106^f, 0107^f, 0109^f, 0111-0113^f
17⁵	80 bp	430 bp	1210	
18	135 bp	515 bp	1211	
19	195 bp	430 bp	1212	0813
20	220 bp	430 bp	1213	
21⁵	105 bp	430 bp	120101-120204, 120302-1213, 1215-1218	0832
22	220 bp	430 bp	1216	0832
23⁵	120 bp	430 bp	1217	010101-0120
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, 12 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 within the DR52 group of DRB1 alleles, all DRB1*01 alleles, most DRB1*08 alleles, two DRB1*11 allele, four 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, and eight DRB5 alleles will be faintly amplified by primer mix 16.

⁵Short specific PCR fragments are less intense and not as sharp as longer specific bands.

^f, may be faintly amplified.

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INTERPRETATION TABLE												
DRB1*12 SSP subtyping												
Amplification patterns of the DRB1*1201 to 1218 alleles												
	Well											
	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	515
pos. control ¹												
5'-primer ²	16	16	16	16	16	16	26	16	37	16	16	16
	5'-gT T 3' 5'-gT T 3' 5'-gT T 3' 5'-gT T 3'	5'-gT T 3' 5'-gT T 3' 5'-gT T 3' 5'-gT T 3'	5'-gT T 3' 5'-gT T 3' 5'-gT T 3' 5'-gT T 3'	5'-gT T 3' 5'-gT T 3' 5'-gT T 3' 5'-gT T 3'	5'-gT T 3' 5'-gT T 3' 5'-gT T 3' 5'-gT T 3'	5'-gT T 3' 5'-gT T 3' 5'-gT T 3' 5'-gT T 3'	5'-gT T 3' 5'-gT T 3' 5'-gT T 3' 5'-gT T 3'	5'-gT T 3' 5'-gT T 3' 5'-gT T 3' 5'-gT T 3'	5'-gT T 3' 5'-gT T 3' 5'-gT T 3' 5'-gT T 3'	5'-gT T 3' 5'-gT T 3' 5'-gT T 3' 5'-gT T 3'	5'-gT T 3' 5'-gT T 3' 5'-gT T 3' 5'-gT T 3'	5'-gT T 3' 5'-gT T 3' 5'-gT T 3' 5'-gT T 3'
3'-primer ³	47	74	57	37	57	85	85	67	78	67	85	58
	5'-g gA 3' 5'-C gC 3' 5'-C AT 3' 5'-gAg 3'	5'-g gA 3' 5'-C gC 3' 5'-C AT 3' 5'-gAg 3'	5'-g gA 3' 5'-C gC 3' 5'-C AT 3' 5'-gAg 3'	5'-g gA 3' 5'-C gC 3' 5'-C AT 3' 5'-gAg 3'	5'-g gA 3' 5'-C gC 3' 5'-C AT 3' 5'-gAg 3'	5'-g gA 3' 5'-C gC 3' 5'-C AT 3' 5'-gAg 3'	5'-g gA 3' 5'-C gC 3' 5'-C AT 3' 5'-gAg 3'	5'-g gA 3' 5'-C gC 3' 5'-C AT 3' 5'-gAg 3'	5'-g gA 3' 5'-C gC 3' 5'-C AT 3' 5'-gAg 3'	5'-g gA 3' 5'-C gC 3' 5'-C AT 3' 5'-gAg 3'	5'-g gA 3' 5'-C gC 3' 5'-C AT 3' 5'-gAg 3'	5'-g gA 3' 5'-C gC 3' 5'-C AT 3' 5'-gAg 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	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		
*010101-0120												
*080101-080103, 0807, 0808, 0811, 0816, 0826										10		
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

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INTERPRETATION TABLE												
DRB1*12 SSP subtyping												
Amplification patterns of the DRB1*1201 to 1218 alleles												
Well												
13	14	15	16	17	18	19	20	21	22	23	24	
105	135	200	75	80	135	195	220	105	220	120	170	Length of spec. PCR product
515	515	515	430	430	515	430	430	430	430	430	430	Length of int. pos. control ¹
16	149	16	26	-16	16	16	25	16	26	152	16	5'-primer ²
5'-gT T 3' 5'-CAg 3' 5'-gT T 3' 5'-TTC 3' 5'-CA A 3' 5'-gT T 3' 5'-gT T 3' 5'-g CT 3' 5'-gT T 3' 5'-TTA 3' 5'-gAT 3' 5'-gT T 3'												
37	181	69	38	-2	47	67	85	38	86	179	59	3'-primer ³
5'-gAA 3' 5'-CT T 3' 5'-C TC 3' 5'-CAg 3' 5'-AgC 3' 5'-gAg 3' 5'-gAg 3' 5'-C Ag 3' 5'-CAg 3' 5'-C AC 3' 5'-A CA 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
								21				*120201, 120203-120204
								21				*120202
								21				*120302
								21				*1204
13								21				*1205
	14							21				*1206
		15						21				*1207
			16					21				*1208
								21				*1209
				17				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
										23		*010101-0120
												*080101-080103, 0807, 0808, 0811, 0816, 0826
13	14	15	16	17	18	19	20	21	22	23	24	Well No.

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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
*080201-080203, 0809, 0821			3							10		
*080302, 0814, 0815, 0823, 0827, 0829, 0833, 0835,								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	
*0830			3					8				
*0831		2								10	11	12
*0832				4				8				
*1115, 1362, <i>DRB5*0101, 0104, 0106, 0107, 0109, 0111-0113</i>												
*1167	1									10	11	12
*1317	1	2	3								11	
*1334, 1364, 1441, 1477												
*1404, 1450, 1476, 1479											11	
*1411											11	12
*1428						6						
*1431		2									11	
*1452		2	3								11	
*15010101-1531, 160101-160502, 1607-1613N												
DRB1 allele ⁴												
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

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105	135	200	75	80	135	195	220	105	220	120	170	Length of spec. PCR product
13	14	15	16	17	18	19	20	21	22	23	24	Well No.
												*080201-080203, 0809, 0821
												*080302, 0814, 0815, 0823, 0827, 0829, 0833, 0835, *080401, 080404, 1415
												*080402, 080403 *0805
												*0806, 1473 *0810 *0812 *0813
						19						*0817 *0818 *0819, 0834 *0822
												*0824 *0825 *0828 *0830
								21	22			*0831 *0832
			f									*1115, 1362, <i>DRB5</i> *0101, 0104, 0106, 0107, 0109, 0111-0113 *1167
			16									*1317 *1334, 1364, 1441, 1477 *1404, 1450, 1476, 1479 *1411
13												*1428 *1431 *1452
	w											*15010101-1531, 160101-160502, 1607-1613N
13	14	15	16	17	18	19	20	21	22	23	24	DRB1 allele ⁴ Well No.

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¹The internal positive control primer pairs amplify segments of the human growth hormone gene. The two different control primer pairs give rise to either an internal positive control band of 430 base pairs, for most wells, or a band of 515 base pairs, for some wells.

Well number 1 contains the primer pair giving rise to the longer, 515 bp, internal positive control band in order to help in the correct orientation of the DRB1*12 subtyping.

In addition, wells number 5, 12 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, in the 1st, 2nd or 3rd exon matching the specificity-determining 3'-end of the primer is given. 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. Empty spaces indicate codon boundaries.

³The codon, in the 1st, 2nd or 3rd exon, matching the specificity-determining 3'-end of the primer is given in the anti-sense direction. 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. Empty spaces indicate codon boundaries.

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

'w', may be weakly amplified.

'f', may be faintly amplified.

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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	
				Prod. No.:	200848001	200848002	200848003	200848004	200848005	200848006	200848007	200848008	200848009	200848010	200848011	200848012	200854713	200848014	200848015	200848016
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	9007	DEM	*0401	*1602	-	-	-	-	-	-	-	-	-	-	-	-	-	W	-	-
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	-	-	-	-	-	-	-	-	-	-	-	-	-	W	-	-
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		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

Lot No.: 44F

Lot-specific information

CELL LINE VALIDATION SHEET												
DRB1*12 SSP subtyping kit												
				Well								
				17	18	19	20	21	22	23	24	
				Prod. No.:	200848017	200848018	200848019	200848020	200848021	200848022	200854723	200854324
	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	9007	DEM	*0401	*1602	-	-	-	-	-	-	-	-
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		-	-	-	-	-	-	+	-

Lot No.: **44F**

Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP[®] DRB1*12 SSP

Product number: 101.128-12u – without *Taq* polymerase
Lot number: 44F
Expiry date: 2011-February-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	2008-480-01	9	2008-480-09	17	2008-480-17
2	2008-480-02	10	2008-480-10	18	2008-480-18
3	2008-480-03	11	2008-480-11	19	2008-480-19
4	2008-480-04	12	2008-480-12	20	2008-480-20
5	2008-480-05	13	2008-547-13	21	2008-480-21
6	2008-480-06	14	2008-480-14	22	2008-480-22
7	2008-480-07	15	2008-480-15	23	2008-547-23
8	2008-480-08	16	2008-480-16	24	2008-547-24

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 12, 13, 15 to 20, 22 and 24 were available. The specificities of the primers in primer solutions 12, 13, 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 solution 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: 2009-November-23

Approved by:

Quality Control, Supervisor

Lot No.: **44F**

Lot-specific information

Declaration of Conformity

Product name: *Olerup* SSP® DRB1*12
Product number: 101.128-12u
Lot number: 44F

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 9001:2000 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
2009- November-23

Olle Olerup
Managing Director

Lot No.: **44F**

Lot-specific information

Lot No.: **44F**

Lot-specific information

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Fax: 610-344-7989

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