

Olerup SSP[®] DRB1*12

Product number:	101.128-12 – including <i>Taq</i> polymerase 101.128-12u – without <i>Taq</i> polymerase
Lot number:	25E
Expiry date:	2010-March-01
Number of tests:	12
Number of wells per test:	22
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. 25E.

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. X21).

One well has been added to the DRB1*12 kit,
well **22**.

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

Well	5'-primer	3'-primer	rationale
22	New	New	New primer pair for the DRB1*1216 allele.

PRODUCT DESCRIPTION

DRB1*12 SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for identifying the DRB1*1201 to DRB1*1216 alleles.

PLATE LAYOUT

Each test consists of 22 PCR reactions in a 24 well cut PCR plate. Wells 23 to 24 are empty.

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

The 24 well cut PCR plate is marked with 'DRB1*12'.

Well No. 1 is marked with the Lot No. '25E'.

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 most DRB1*08 alleles, one DRB1*11 allele, three DRB1*13 alleles and nine 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, i.e. **DRB1*1201 to DRB1*1216**, recognized by the HLA Nomenclature Committee in January 2008¹ will give rise to unique amplification patterns by the primers in the DRB1*12 subtyping kit.

¹DRB1 alleles listed on the IMGT/HLA web page 2008-January-11, release 2.20.0, www.ebi.ac.uk/imgt/hla.

RESOLUTION IN HOMO- AND HETEROZYGOTES

The 16 DRB1*12 alleles can generate 18 amplification patterns that be combined in 171 homozygous and heterozygous combinations. Eighty-three of these genotypes do not give rise to unique amplification patterns.

+++++++	++-----	-----+	120201,1209 = 120202,1209
+++++++	++-----	-----+	1205,1209 = 1209,1214
+++++++	++-----	-----+	120101,1209 = 120102,1209
++-----	++++-----	-----+	120201,1204 = 120202,1204
++-----	++++-----	-----+	1205,1213 = 1213,1214

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++-+++++	++-+----	-----+	120101,1215 = 120201,1205 = 120201,1214
++-+++++	++-+----	-----+	120201,1206 = 120202,1206
++-+++++	++-+----	-----+	120201,1208 = 120202,1208
++-+++++	++-+----	-----+	120201,1210 = 120202,1210
++-+++++	++-+----	-----+	120201,1211 = 120202,1211
++-+++++	++-+----	-----+	120101,1213 = 120102,1213
++-+++++	++-+----	-----+	120101,120201 = 120101,120202 = 120102,120201
++-+++++	++-+----	-----+	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
++-+++++	++-+----	-----+	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
++-+++++	++-+----	-----+	120101,120101 = 120101,120102
++-+++++	++-+----	-----+	1205,1216 = 1214,1216
++-+++++	++-+----	-----+	120102,1215 = 120202,1205 = 120202,1214
++-+++++	++-+----	-----+	120302,1205 = 120302,1214
++-+++++	++-+----	-----+	120102,1205 = 120102,1214
++-+++++	++-+----	-----+	120201,1207 = 120202,1207
++-+++++	++-+----	-----+	120201,1212 = 120202,1212
++-+++++	++-+----	-----+	120201,1213 = 120202,1213 = 1213,1213
++-+++++	++-+----	-----+	120201,120201 = 120201,120202
++-+++++	++-+----	-----+	1205,1215 = 1214,1215
++-+++++	++-+----	-----+	1205,1205 = 1205,1214

SPECIFICITY TABLE

DRB1*12 SSP subtyping

Specificities and sizes of the PCR products of the 22 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	120101-120202, 120302-1216	0817, 0828, 1167, 1317
2	215 bp	430 bp	120101-120202, 120302-1216	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	105 bp	430 bp	120101-120202, 120302, 1204, 1206-1213, 1216	0832
5	165 bp	515 bp	120101-120202, 120302, 1205-1208, 1210-1216	0819, 0825, 0834
6	250 bp	430 bp	120101-120202, 1204-1215	0812, 0822, 1428
7	215 bp	430 bp	120101-120202, 1204-1207, 1209-1212, 1213 ^{weakly} , 1214, 1215	
8	195 bp	430 bp	120101-120102, 120302-1206, 1208-1211, 1214	080302, 0810, 0812, 0814, 0815, 0818, 0819, 0823, 0825, 0827, 0829, 0830, 0832-0834, 1317
9	165 bp	430 bp	120101, 120201, 1204, 1206-1213	
10	195 bp	430 bp	120201-120202, 1213, 1215, 1216	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, 0831, 1167, 1317, 1404, 1411, 1415, 1431, 1450, 1452, 1473

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12	170 bp	515 bp	1204	0831, 1167, 1411
13	105 bp	515 bp	1205, 1214, 1215	0809, 0821, 1404, 1411, 1415, 1428, 1431, 1450
14	135 bp	515 bp	1206	150101-1527 ^{weakly} , 160101- 160502 ^{weakly} , 1607- 1613N ^{weakly}
15	200 bp	515 bp	1207	
16	75 bp	430 bp	1208	1334, 1364, 1441
17	80 bp	430 bp	1210	
18	135 bp	515 bp	1211	
19	195 bp	430 bp	1212	0813
20	220 bp	430 bp	1213	
21	105 bp	430 bp	120101-120202, 120302-1213, 1215, 1216	0832
22	220	430 bp	1216	0832

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 length 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 fourth 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, most DRB1*08, one DRB1*11, three DRB1*13 and nine 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.

INTERPRETATION TABLE

DRB1*12 SSP subtyping

Amplification patterns of the DRB1*1201 to 1216 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'-TTA ^{3'}	5'-gT T ^{3'}	5'-Ag C ^{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'-CgC ^{3'}	5'-C AT ^{3'}	5'-gAg ^{3'}	5'-C gA ^{3'}	5'-C Ag ^{3'}	5'-C Ag ^{3'}	5'-gAT ^{3'}	5'-CA A ^{3'}	5'-gAA ^{3'}	5'-C AA ^{3'}	5'-C CT ^{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	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		
*080101-080103, 0807, 0808, 0811, 0816, 0826										10		
*080201-080203			3							10		
*080302, 0814, 0815, 0823, 0827, 0829, 0833								8				
*080401, 080404			3							10	11	
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 1216 alleles										
Well										
13	14	15	16	17	18	19	20	21	22	
105	135	200	75	80	135	195	220	105	220	Length of spec. PCR product
515	515	515	430	430	515	430	430	430	430	Length of int. pos. control ¹
16	149	16	26	-16	16	16	25	16	26	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'}	
37	181	69	38	-2	47	67	85	38	86	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'}	
13	14	15	16	17	18	19	20	21	22	Well No. DRB1 allele ⁴
								21		*120101
								21		*120102
								21		*120201
								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
										*080101-080103, 0807, 0808, 0811, 0816, 0826
										*080201-080203
										*080302, 0814, 0815, 0823, 0827, 0829, 0833
										*080401, 080404
13	14	15	16	17	18	19	20	21	22	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
*080402-080403			3							10	w	
*0805		2								10		
*0806, 1473										10	11	
*0809, 0821			3							10		
*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				
*1167	1									10	11	12
*1317	1	2	3					8			11	
*1334, 1364, 1441												
*1404, 1450											11	
*1411											11	12
*1415			3							10	11	
*1428						6						
*1431		2									11	
*1452		2	3								11	
*150101-1527, 160101-160502, 1607-1613N												
DRB1 allele ⁴												
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*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.

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105	135	200	75	80	135	195	220	105	220	Length of spec. PCR product Well No.
13	14	15	16	17	18	19	20	21	22	
										*080402-080403
										*0805
										*0806, 1473
13										*0809, 0821
										*0810
										*0812
						19				*0813
										*0817
										*0818
										*0819, 0834
										*0822
										*0824
										*0825
										*0828
										*0830
										*0831
								21	22	*0832
										*1167
										*1317
			16							*1334, 1364, 1441
13										*1404, 1450
13										*1411
13										*1415
13										*1428
13										*1431
										*1452
	w									*150101-1527, 160101-160502, 1607-1613N
										DRB1 allele ⁴
13	14	15	16	17	18	19	20	21	22	Well No.

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.

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.

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

'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	
				Prod. No.:	200848001	200848002	200848003	200848004	200848005	200848006	200848007	200848008	200848009	200848010	200848011	200848012	200848013	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	9067	BTB	*0801		-	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-
14	9071	OLGA	*0802		-	-	+	-	-	-	-	-	+	-	-	-	-	-	-	-
15	9075	DKB	*0901		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
16	9037	SWEIG007	*1101		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
17	9008	WILJON	*1501		-	-	-	-	-	-	-	-	-	-	-	-	-	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		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

CELL LINE VALIDATION SHEET										
DRB1*12 SSP subtyping kit										
				Well						
				17	18	19	20	21	22	
				Prod. No.:	200848017	200848018	200848019	200848020	200848021	200848022
	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	9067 BTB	*0801			-	-	-	-	-	-
14	9071 OLGA	*0802			-	-	-	-	-	-
15	9075 DKB	*0901			-	-	-	-	-	-
16	9037 SWEIG007	*1101			-	-	-	-	-	-
17	9008 WILJON	*1501			-	-	-	-	-	-
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
101.128-12u – without *Taq* polymerase
Lot number: 25E
Expiry date: 2010-March-01
Number of tests: 12
Number of wells per test: 22

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	2008-480-13	21	2008-480-21
6	2008-480-06	14	2008-480-14	22	2008-480-22
7	2008-480-07	15	2008-480-15		
8	2008-480-08	16	2008-480-16		

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 11, 12, 13, 15 to 20 and 22 were available. The specificities of the primers in primer solutions 11, 12, 13, 16, 18, 19 and 22 were tested by separately adding one additional 5'-primer, respectively, one additional 3'-primer. In primer solutions 15 and 16 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.

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

Date of approval: 2008-March-11

Approved by:

Quality Control, Supervisor

Lot No.: **25E**

Lot-specific information

www.olerup.com

Declaration of Conformity

Product name: *Olerup* SSP® DRB1*12
Product number: 101.28-12, 101.128-12u
Lot number: 25E

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
2008-March-11

Olle Olerup
Managing Director

DRB1*12
101.128-12 – including *Taq* polymerase
101.128-12u – without *Taq* polymerase

Product Insert

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Lot No.: **25E**

Lot-specific information

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