Olerup SSP® DRB1*15

Product number:	**101.125-24/06 – including *Taq* pol.** **101.125-24u/06u – without *Taq* pol.**
Lot number:	**35E**
Expiry date:	**2010-April-01**
Number of tests:	**24 test – Product No. 101.125-24** **6 tests – Product No. 101.125-06**
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. 35E.

CHANGES COMPARED TO THE PREVIOUS *OLERUP* SSP® DRB1*15 LOT

The DRB1*15 specificity and interpretation tables have been updated for the DRB1 alleles described since the previous *Olerup* SSP® DRB1*15 lot was made **(Lot No. X37)**.

Four wells have been added to the DRB1*15 kit,
wells **21 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
8	New	New	Primer added for the DRB1*1527 allele.
21	New	New	New primer pair for the DRB1*1523 allele.
22	New	New	New primer pair for the DRB1*1524 allele.
23	New	New	New primer pair for the DRB1*1525 allele.
24	New	New	New primer pair for the DRB1*1526 allele.

PRODUCT DESCRIPTION

DRB1*15 SSP subtyping

CONTENT
The primer set contains 5'- and 3'-primers for identifying the DRB1*1501 to DRB1*1527 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*15 '.
Well No. 1 is marked with the Lot No. '35E'.
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*15 and DRB1*16 alleles will be amplified by the DRB1*15 subtyping kit, except that the DRB1*0473, DRB1*1309 and DRB1*1437 alleles will be amplified by primer mix 3. Thus, the interpretation of DRB1*15 subtypings is only influenced by the DRB1*16 alleles and the DRB1*0473, DRB1*1309 and DRB1*1437 alleles when present on the other haplotype but not by other groups of DRB1 alleles or other DRB genes.

UNIQUELY IDENTIFIED ALLELES
All the DRB1*15 alleles, i.e. **DRB1*1501 to DRB1*1527**, recognized by the HLA Nomenclature Committee in January 2008[1] will give rise to unique amplification patterns by the primers in the DRB1*15 subtyping kit.
The DRB1*15 subtyping kit cannot distinguish the DRB1*150101 to DRB1*150106 alleles or the DRB1*150201 to DRB1*150204 alleles.

[1]DRB1 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 27 DRB1*15 alleles can be combined in 378 homozygous and heterozygous combinations. Ninety-eight of these genotypes do not give rise to unique amplification patterns. The different sizes of the specific PCR products generated by primer mixes 6, 9, 14 and 16 were not considered in these calculations.

```
++++++-- -----+-- -------- 1513,1514 = 1514,1517N
++++++-- -------- ----+--- 1502,1503 = 1503,1514
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+++++-++ -------- -------- 1505,1511 = 1507,1527
+++++-+- +------- -------- 1506,1511 = 1507,1519
+++++-+- -+------ -------- 1504,1511 = 1507,1515
+++++-+- -----+-- -------- 1511,1513 = 1511,1517N
+++++-+- -------+ -------- 1507,1508 = 1511,1516
+++++-+- -------- -------- 1501,1511 = 1502,1507
++++++-+ +------- -------- 1505,1519 = 1506,1527
++++++-+ -------+ -------- 1505,1508 = 1516,1527
++++++-+ -------- -------- 1501,1527 = 1502,1505
+++++--- ++------ -------- 1504,1519 = 1506,1515
+++++--- +----+-- -------- 1513,1519 = 1517N,1519
+++++--- +------+ -------- 1506,1508 = 1516,1519
+++++--- +------- -------- 1501,1519 = 1502,1506 = 1506,1519
+++++--- -+-----+ -------- 1504,1508 = 1515,1516
+++++--- -+------ -------- 1501,1515 = 1502,1504
+++++--- -----+-+ -------- 1508,1513 = 1508,1517N
+++++--- -----+-- -------+ 1513,1526 = 1517N,1526
+++++--- -----+-- -------- 1502,1513 = 1502,1517N
+++++--- -------+ -------- 1501,1508 = 1502,1516 = 1508,1516
++++--+- -----+-- -------- 1507,1513 = 1507,1517N
+++++--- +----+-- -------- 1506,1513 = 1506,1517N
+++++--- +------- -------- 1501,1506 = 1506,1506
+++++--- --+--+-- -------- 1512,1513 = 1512,1517N
+++++--- --+----- -------- 1501,1512 = 1512,1512
+++++--- ---+-+-- -------- 1509,1513 = 1509,1517N
+++++--- ---+---- -------- 1501,1509 = 1509,1509
+++++--- -----+-+ -------- 1513,1516 = 1516,1517N
+++++--- -----+-- +------- 1513,1518 = 1517N,1518
+++++--- -----+-- -+------ 1513,1520 = 1517N,1520
+++++--- -----+-- ---+---- 1513,1522 = 1517N,1522
+++++--- -----+-- -----+-- 1513,1524 = 1517N,1524
+++++--- -----+-- -------- 1501,1513 = 1501,1517N = 1513,1513 =
                           1513,1517N
+++++--- -------+ -------- 1501,1516 = 1516,1516
+++++--- -------- +------- 1501,1518 = 1518,1518
+++++--- -------- -+------ 1501,1520 = 1520,1520
+++++--- -------- ---+---- 1501,1522 = 1522,1522
+++++--- -------- -----+-- 1501,1524 = 1524,1524
+++-++-- -------- -------- 1502,1514 = 1514,1514
+++-+--- +------- -------- 1502,1519 = 1519,1519
+++-+--- -------+ -------- 1502,1508 = 1508,1508
+++-+--- -------- -------+ 1502,1526 = 1526,1526
++-+-+-+ -------- ----+--- 1503,1505 = 1503,1523
+--++--+ -+------ -------- 1504,1527 = 1505,1515
+--+---+ -------- ----+--- 1505,1523 = 1523,1523
+--+---+ -------- ------+- 1505,1525 = 1525,1525
```

SPECIFICITY TABLE

DRB1*15 SSP subtyping

Specificities and sizes of the PCR products of the 24 primer mixes used for DRB1*15 SSP subtyping

Primer Mix	Size of spec. PCR product[1]	Size of control band[2]	Amplified DRB1*15 alleles[3]	Other amplified DRB1 Alleles[4]
1	140 bp	**515 bp**	150101-1506, 1508-1510, 1512-1527	1609, 1610
2	200 bp	**515 bp**	150101-1503, 1506-1509, 1511-1514, 1516, 1518-1520, 1522, 1524, 1526	
3	150 bp	430 bp	150101-150204, 1506-1509, 1511-1514, 1516, 1518-1520, 1522, 1524, 1526	0473, 1309, 1437
4	260 bp	430 bp	150101-150106, 1503-1507, 1509, 1510, 1512, 1513, 1516-1518, 1520-1525	
5	260 bp	430 bp	150201-150204, 1508, 1511, 1514, 1515, 1519, 1526, 1527	160101-160502, 1607-1611, 1613N
6[6]	150, 180 bp	430 bp	1503, 1514	
7	140 bp	430 bp	1507, 1511	160101-160502, 1607, 1608, 1611, 1613N
8	200 bp	430 bp	1505, 1523, 1525, 1527	
9[5,7]	90, 225 bp	430 bp	1506, 1519	
10	200 bp	430 bp	1504, 1515	
11	170 bp	430 bp	1512	
12[5]	95 bp	430 bp	1509	
13	215 bp	430 bp	1510	
14[8]	190, 210 bp	430 bp	1513, 1517N	
15	200 bp	**515 bp**	1510, 1521	160501-160502, 1607

16[9]	135, 200 bp	430 bp	1508, 1516	
17	160 bp	430 bp	1518	
18	250 bp	**515 bp**	1520	
19	220 bp	430 bp	1521	1604
20	165 bp	430 bp	1522	
21	165 bp	430 bp	1503, 1523	
22	165 bp	430 bp	1524	
23	220 bp	430 bp	1525	
24	190 bp	430 bp	1526	

[1]Alleles are assigned by the presence of specific PCR product(s). However, the sizes of the specific PCR products may be helpful in the interpretation of DRB*15 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 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 inherit feature of the primer pair(s) of a primer mix. More often it is due to other factors such as too low amount of DNA in the PCR reactions, taking too long time in setting up the PCR reactions, working at elevated room temperature or using thermal cyclers that are not pre-heated.
[2]The internal positive control primer pairs amplify segments of the human growth hormone gene. The two different control primer pairs give rise to either an internal positive control band of 430 base pairs, for most wells, or a band of 515 base pairs, for some wells.
Well number 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*15 subtyping.
In addition, wells number 2, 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.
[3]For 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.
[4]Due to the sharing of sequence motifs between DRB1 alleles, primer mix 3 will amplify the DRB1*0473, 1309 and 1437 alleles.
[5]Specific PCR fragments shorter than 125 base pairs have a lower intensity and are less sharp than longer PCR bands.
[6]Primer mix 6: Specific PCR fragment of 150 bp in the DRB1*1503 allele. Specific PCR fragment of 180 bp in the DRB1*1514 allele.
[7]Primer mix 9: Specific PCR fragment of 90 bp in the DRB1*1506 allele. Specific PCR fragment of 225 bp in the DRB1*1519 allele.
[8]Primer mix 14: Specific PCR fragment of 190 bp in the DRB1*1513 allele. Specific PCR fragment of 210 bp in the DRB1*1517N allele.
[9]Primer mix 16: Specific PCR fragment of 135 bp in the DRB1*1516 allele. Specific PCR fragment of 200 bp in the DRB1*1508 allele.

INTERPRETATION TABLE

DRB1*15 SSP subtyping

Amplification patterns of the DRB1*1501 to 1527 alleles

	Well[4]											
	1	2	3	4	5	6	7	8	9	10	11	12
Length of spec.	140	200	150	260	260	150	140	200	90	200	170	95
PCR product						180			225			
Length of int.	515	515	430	430	430	430	430	430	430	430	430	430
pos. control[1]												
5'primer(s)[2]	13	13	30	13	13	20	13	13	6	13	13	30
	5'-Agg3'	5'-Agg3'	5'-gA T3'	5'-Agg3'	5'-Agg3'	5'-T gC3'	5'-Agg3'	5'-Agg3'	5'-CA g3'	5'-Agg3'	5'-Agg3'	5'-gA T3'
						30			50			
						5'-gA C3'			5'-g gC3'			
3'primer(s)[3]	47	67	67	86	86	67	47	67	67	67	57	48
	5'-g gA3'	5'-gAT3'	5'-gAT3'	5'-C CA3'	5'-C AC3'	5'-gAT3'	5'-g gT3'	5'-gAg3'	5'-gAT3'	5'-gAA3'	5'-gCT3'	5'-C CT3'
								67				
								5'-gAg3'				
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
DRB1 allele												
*150101-150106	1	2	3	4								
*150201-150204	1	2	3		5							
*1503	1	2		4		6						
*1504	1			4						10		
*1505	1			4				8				
*1506	1	2	3	4					9			
*1507		2	3	4			7					
*1508	1	2	3		5							
*1509	1	2	3	4								12
*1510	1			4								
*1511		2	3		5		7					
*1512	1	2	3	4							11	
*1513	1	2	3	4								
*1514	1	2	3		5	6						
*1515	1				5					10		
*1516	1	2	3	4								
*1517N	1			4								
*1518	1	2	3	4								
*1519	1	2	3		5				9			
*1520	1	2	3	4								
*1521	1			4								
*1522	1	2	3	4								
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

INTERPRETATION TABLE

DRB1*15 SSP subtyping

Amplification patterns of the DRB1*1501 to 1527 alleles

Well[4]												
13	14	15	16	17	18	19	20	21	22	23	24	
215	190	200	135	160	250	220	165	165	165	220	190	Length of spec.
	210		200									PCR product
430	430	515	430	430	515	430	430	430	430	430	430	Length of int.
												pos. control[1]
13	13	13	13	30	13	13	13	30	25	13	21	5'primer(s)[2]
5'-Agg3'	5'-Agg3'	5'-Agg3'	5'-Agg3'	5'-gA T3'	5'-Agg3'	5'-Agg3'	5'-Agg3'	5' -gA C 3'	5' -g CA 3'	5' -Agg 3'	5' -gg T 3'	
71	64	67	45	70	84	74	55	71	67	73	71	3'primer(s)[3]
5'-g CT3'	5'-C Tg3'	5'-gAT3'	5'-CCT3'	5'-CTC3'	5'-CCT3'	5'-CAg3'	5'-g CA3'	5' -CgC 3'	5' -gAT 3'	5' -g gC 3'	5' -CgC 3'	
	69		66									
	5'-Tg T3'		5'-gTT3'									
13	14	15	16	17	18	19	20	21	22	23	24	Well No.
												DRB1 allele
												*150101-150106
												*150201-150204
								21				*1503
												*1504
												*1505
												*1506
												*1507
			16									*1508
												*1509
13		15										*1510
												*1511
												*1512
	14											*1513
												*1514
												*1515
			16									*1516
	14											*1517N
				17								*1518
												*1519
					18							*1520
		15				19						*1521
							20					*1522
13	14	15	16	17	18	19	20	21	22	23	24	Well No.

Length of spec.	140	200	150	260	260	150	140	200	90	200	170	95
PCR product						180			225			
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
*1523	1			4				8				
*1524	1	2	3	4								
*1525	1			4				8				
*1526	1	2	3		5							
*1527	1				5			8				
*0473, 1309, 1437			3									
*160101-1603, 1608, 1611, 1613N					5		7					
*1604					5		7					
*160501-160502, 1607					5		7					
*1609, 1610	1				5							
DRB1 allele												
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

[1]The internal positive control primer pairs amplify segments of the human growth hormone gene. The two different control primer pairs give rise to either an internal positive control band of 430 base pairs, for most wells, or a band of 515 base pairs, for some wells.
Well number 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*15 subtyping.
In addition, wells number 2, 15 and 18 contain the primer pair giving rise to the longer, 515 bp, internal positive control band in order to allow kit identification.
[2]The codon, in the 2nd 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.
[3]The codon, in the 2nd 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.

215	190	200	135	160	250	220	165	165	165	220	190	Length of spec.
	210		200									PCR product
13	14	15	16	17	18	19	20	21	22	23	24	Well No.
								21				*1523
									22			*1524
										23		*1525
											24	*1526
												*1527
												*0473, 1309, 1437
												*160101-1603, 1608, 1611, 1613N
						19						*1604
		15										*160501-160502, 1607
												*1609, 1610
												DRB1 allele
13	14	15	16	17	18	19	20	21	22	23	24	Well No.

[4]Primer mix 6: Specific PCR fragment of 150 bp in the DRB1*1503 allele. Specific PCR fragment of 180 bp in the DRB1*1514 allele.
Primer mix 9: Specific PCR fragment of 90 bp in the DRB1*1506 allele. Specific PCR fragment of 225 bp in the DRB1*1519 allele.
Primer mix 14: Specific PCR fragment of 190 bp in the DRB1*1513 allele. Specific PCR fragment of 210 bp in the DRB1*1517N allele.
Primer mix 16: Specific PCR fragment of 135 bp in the DRB1*1516 allele. Specific PCR fragment of 200 bp in the DRB1*1508 allele.

CELL LINE VALIDATION SHEET

DRB1*15 SSP subtyping kit

					Well															
					1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
				Prod. No.:	200730101	200730102	200730103	200730104	200730105	200730106	200730107	200844008	200730109	200730110	200730111	200730112	200730113	200730114	200730115	200730116
	IHWC cell line		DRB1																	
1	9001	SA	*0101		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2	9002	MZ0707082	*0102		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3	9011	E4181324	*1502		+	+	+	-	+	-	-	-	-	-	-	-	-	-	-	-
4	9010	AMAI	*1503		+	+	-	+	-	+	-	-	-	-	-	-	-	-	-	-
5	9009	KAS011	*1601		-	-	-	-	+	-	+	-	-	-		-	-	-	-	-
6	9016	RML	*1602		-	-	-	-	+	-	+	-	-	-	-	-	-	-	-	-
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	9067	BTB	*0801		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
14	9071	OLGA	*08022		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
15	9075	DKB	*09012		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
16	9036	SPO010	*1101		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
17	9039	JVM	*1102		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
18	9089	BOB	*1104		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
19	9038	BM16	*1201		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
20	9059	SLE005	*1302		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
21	9064	AMALA	*1402		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
22	9056	KOSE	*1302	*1401	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
23	9061	31227ABO	*1401		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
24	9035	JBUSH	*11xx		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
25	9049	IBW9	*0701		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
26	9285	WT49	*0301		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
27		MAM	*0101	*0102	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
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	9062	WDV	*1302		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
41	9055	H0301	*1302		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
42	9066	TAB089	*08032		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
43	9076	T7526	*0901		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
44	9057	TEM	*1401		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
45	9058	OMV	*1301		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
46	9013	SCHU	*1501		+	+	+	+	-	-	-	-	-	-	-	-	-	-	-	-
47	9045	TUBO	*1104	*1201	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
48	9303	TER-ND	*0103		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

CELL LINE VALIDATION SHEET

DRB1*15 SSP subtyping kit

					Well							
					17	18	19	20	21	22	23	24
				Prod. No.:	200730117	200730118	200730119	200730120	200844021	200844022	200844023	200844024
	IHWC cell line		DRB1									
1	9001	SA	*0101		-	-	-	-	-	-	-	-
2	9002	MZ0707082	*0102		-	-	-	-	-	-	-	-
3	9011	E4181324	*1502		-	-	-	-	-	-	-	-
4	9010	AMAI	*1503		-	-	-	-	-	-	-	-
5	9009	KAS011	*1601		-	-	-	-	-	-	-	-
6	9016	RML	*1602		-	-	-	-	-	-	-	-
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	9067	BTB	*0801		-	-	-	-	-	-	-	-
14	9071	OLGA	*08022		-	-	-	-	-	-	-	-
15	9075	DKB	*09012		-	-	-	-	-	-	-	-
16	9036	SPO010	*1101		-	-	-	-	-	-	-	-
17	9039	JVM	*1102		-	-	-	-	-	-	-	-
18	9089	BOB	*1104		-	-	-	-	-	-	-	-
19	9038	BM16	*1201		-	-	-	-	-	-	-	-
20	9059	SLE005	*1302		-	-	-	-	-	-	-	-
21	9064	AMALA	*1402		-	-	-	-	-	-	-	-
22	9056	KOSE	*1302	*1401	-	-	-	-	-	-	-	-
23	9061	31227ABO	*1401		-	-	-	-	-	-	-	-
24	9035	JBUSH	*11xx		-	-	-	-	-	-	-	-
25	9049	IBW9	*0701		-	-	-	-	-	-	-	-
26	9285	WT49	*0301		-	-	-	-	-	-	-	-
27		MAM	*0101	*0102	-	-	-	-	-	-	-	-
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	9062	WDV	*1302		-	-	-	-	-	-	-	-
41	9055	H0301	*1302		-	-	-	-	-	-	-	-
42	9066	TAB089	*08032		-	-	-	-	-	-	-	-
43	9076	T7526	*0901		-	-	-	-	-	-	-	-
44	9057	TEM	*1401		-	-	-	-	-	-	-	-
45	9058	OMV	*1301		-	-	-	-	-	-	-	-
46	9013	SCHU	*1501			-	-	-	-	-	-	-
47	9045	TUBO	*1104	*1201	-	-	-	-	-	-	-	-
48	9303	TER-ND	*0103		-	-	-	-	-	-	-	-

CERTIFICATE OF ANALYSIS

Olerup SSP® DRB1*15 SSP

Product number: **101.125-24/06 – including *Taq* pol.**
101.125-24u/06u – without *Taq* pol.
Lot number: **35E**
Expiry date: **2010-April-01**
Number of tests: **24 test – Product No. 101.125-24**
6 tests – Product No. 101.125-06
Number of wells per test: **24**

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2207-301-01	9	2207-301-09	17	2007-301-17
2	2207-301-02	10	2207-301-10	18	2007-301-18
3	2207-301-03	11	2207-301-11	19	2007-301-19
4	2207-301-04	12	2207-301-12	20	2007-301-20
5	2007-301-05	13	2007-301-13	21	2008-440-21
6	2007-301-06	14	2007-301-14	22	2008-440-22
7	2007-301-07	15	2007-301-15	23	2008-440-23
8	2008-440-08	16	2007-301-16	24	2008-440-24

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 8 to 24 were available. The specificities of the primers in primer solutions 8, 11, 13, 15, 19, 21, 22 and 23 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer solutions 10, 12, 14, 16, 17, 18 and 20 it was only possible to test the 5'-primers, the 3'-primers were not possible to test. An additional 5'-primer in primer solution 6 was not possible to test. In primer solutions 9 and 24 it was only possible to test the 3'-primers, the 5'-primers were not possible to test.

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

Date of approval: 2008-April-06

Approved by:

Quality Control, Supervisor

Declaration of Conformity

Product name: *Olerup* SSP® DRB1*15
Product number: 101.125-24/06, 101.125-24u/06u
Lot number: 35E

Intended use: DRB1*15 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 13485:2005, 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-April-06

Olle Olerup
Managing Director

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