

Olerup SSP[®] HLA-Cw*06

Product number:	101.614-12 – including <i>Taq</i> polymerase
Lot number:	95F
Expiry date:	2011-June-01
Number of tests:	12
Number of wells per test:	16
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. 95F.

**CHANGES COMPARED TO THE PREVIOUS *OLERUP SSP[®]*
HLA-Cw*06 LOT**

The HLA-Cw*06 specificity and interpretation tables have been updated for the HLA-Cw alleles described since the previous *Olerup SSP[®]* HLA-Cw*06 lot was made (**Lot No. 01F**).

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

Well	5'-primer	3'-primer	rationale
3	Added	-	Primer added for the Cw*0618 allele.
5	Added	Added	Primer pairs added for the Cw*0618 and Cw*0623 alleles
7	Added	-	Primer added for the Cw*0619 allele.
9	Added	-	Primer added for the Cw*0623 allele.
10	Added	Added	Primer pair added for the Cw*0622 allele.
11	Added	Added	Primer pair added for the Cw*0622 allele.
12	Added	Added	Primer pairs added for the Cw*0619 and Cw*0620 alleles
16	Added	-	Primer added for the Cw*0620 allele.

PRODUCT DESCRIPTION

HLA-Cw*06 SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for identifying the HLA-Cw*0602 to HLA-Cw*0623 alleles.

PLATE LAYOUT

Each test consists of 16 PCR reactions in a 16 well PCR plate.

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

The 16 well cut PCR plate is marked with 'Cw*06' in silver/gray ink.

Well No. 1 is marked with the Lot No. '95F'.

The PCR plates are covered with a PCR-compatible foil.

Please note: When removing each 16 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 HLA-Cw*06 SSP subtypings will be influenced by the Cw*01 alleles, four Cw*02 alleles, the Cw*03 alleles, most Cw*04 alleles, the Cw*05 alleles, twelve Cw*07 alleles, the Cw*08 alleles, most Cw*12 alleles, the Cw*14 alleles, the Cw*15 alleles, the Cw*160401 allele, the Cw*17 alleles and the Cw*18 alleles when present on the other haplotype. In addition, the B*5802 allele will be amplified by primer mix 4 and the B*9537 will be amplified by the primer mix 9.

UNIQUELY IDENTIFIED ALLELES

All the HLA-C*06 alleles, i.e. **Cw*0602 to Cw*0623**, recognized by the HLA Nomenclature Committee in May 2009¹ will give rise to unique amplification patterns by the primers in the HLA-Cw*06 subtyping kit.

The HLA-Cw*06 SSP subtyping kit cannot distinguish the Cw*06020101, Cw*06020102 and Cw*060203 alleles.

¹HLA-Cw alleles listed on the IMGT/HLA web page 2009-May-09, release 2.25.2, www.ebi.ac.uk/imgt/hla.

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Lot-specific information

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RESOLUTION IN HOMO- AND HETEROZYGOTES

The 21 HLA-Cw*06 alleles can be combined in 231 homozygous and heterozygous combinations. Eighty-six of these genotypes do not give rise to unique amplification patterns. The different lengths of the specific PCR products generated by primer mixes 5, 7, 9, 11, 12 and 16 were not considered in these calculations.

+++--+-	-----	0603,0605 = 0605,0618 = 0606,0618
+++--+-	+-----	0603,0623 = 0609,0618 = 0617,0618 =
		0618,0623
+++--+-	-----	0602,0618 = 0603,0618 = 0618,0618
++-+--	+-----	0604,0609 = 0604,0617
++-+--	+-----	0605,0609 = 0605,0617 = 0605,0623 =
		0606,0623
++-+--	+-----	0602,0623 = 0609,0623 = 0617,0623 =
		0623,0623
++-+--	+-----	0606,0609 = 0606,0617
++-+--	+-----	0609,0619 = 0617,0619
++-+--	+-----	0607,0609 = 0607,0617
++-+--	---+---	0607,0620 = 0616N,0619 = 0619,0620
++-+--	---+---	0602,0619 = 0607,0612 = 0607,0619 =
		0612,0619 = 0619,0619
++-+--	-----	0602,0607 = 0607,0607
++-+--	+-----	0608,0609 = 0608,0617
++-+--	-----	0602,0608 = 0608,0608
++-+--	+++-----	0609,0622 = 0617,0622
++-+--	+++-----	0609,0610 = 0610,0617
++-+--	+-----	0609,0611 = 0611,0617
++-+--	+-----	0609,0620 = 0617,0620
++-+--	+-----	0609,0612 = 0612,0617
++-+--	+-----	0609,0613 = 0613,0617
++-+--	+-----	0609,0614 = 0614,0617
++-+--	+-----	0609,0615 = 0615,0617
++-+--	+-----	0609,0616N = 0616N,0617
++-+--	+-----	0602,0609 = 0602,0617 = 0609,0609 =
		0609,0617
++-+--	-++-----	0602,0622 = 0610,0611 = 0610,0622 =
		0611,0622 = 0622,0622
++-+--	-+-----	0602,0610 = 0610,0610
++-+--	---+---	0602,0611 = 0611,0611
++-+--	---+---	0602,0620 = 0612,0616N = 0612,0620 =
		0616N,0620 = 0620,0620
++-+--	---+---	0602,0612 = 0612,0612
++-+--	---+---	0602,0613 = 0613,0613
++-+--	---+---	0602,0615 = 0615,0615
++-+--	-----	0602,0616N = 0616N,0616N
++-+--	-----	0605,0605 = 0605,0606

SPECIFICITY TABLE

HLA-Cw*06 SSP subtyping

Specificities and sizes of the PCR products of the 16 primer mixes used for HLA-Cw*06 SSP subtyping

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified HLA-Cw*06 alleles	Other amplified HLA Class I alleles ³
1	240 bp	800 bp	06020101-06020102, 060203, 0604-0616N, 0618-0620, 0622, 0623	0339, 1216
2	220 bp	800 bp	06020101-06020102, 060203, 0603, 0607-0613, 0615-0620, 0622, 0623	0104, 0109, 0205, 0217, 12030101-1207, 1211-1213, 1215, 160401
3⁴	135 bp	1070 bp	0603, 0618	030201-0317, 0319-033802, 0340-0350, 0357, 0358
4	250 bp	1070 bp	0604	0122, 0511, 0517, 080101-080102, 0803, 0804, 0806, 0808-0811, 0813, 0814, 0816, 0820-0822, 121401-121402, 1218, 1220, 1406, 150201-1507, 1509-1513, 1515-1521, 1701-1705, B*5802
5⁶	165, 220 bp	800 bp	0605, 0618, 0623	0104, 0109, 0221, 05010101-050104, 0503-0525, 0810, 1221, 1705
6⁵	250 bp	1070 bp	0605, 0606	010201-0103, 0105-0108, 0110-0120, 0123-0127, 04010101-040106, 0403, 0405, 0407-0412, 041501-0420, 0423-0433, 0435-0438, 0440, 050101-050104, 0503-0507N, 0509, 0510,

				0512-0516, 0518-0525, 0802, 0805, 0807, 0812, 0815, 0817-0819, 0823, 1209, 140201-1405, 1407N-1411, 1508, 1801, 1802
7^{4,7}	110, 185 bp	1070 bp	0607, 0619	
8	240 bp	1070 bp	0608	0110, 0205, 0217
9⁸	165, 210, 435 bp	1070 bp	0609, 0617, 0623	0104, 0109, 0222, 0508, 0707, 0709, 1801-1803, B*9537
10⁵	190 bp	800 bp	0610, 0622	
11^{4,9}	130, 185 bp	1070 bp	0611, 0622	070401-070403, 0711, 0712, 0745, 0763, 0768
12¹⁰	200, 275 bp	1070 bp	0612, 0619, 0620	
13	155 bp	1070 bp	0613	
14	295 bp	1070 bp	0614	0332, 0345, 0710, 0743
15	360 bp	800 bp	0615	
16¹¹	235, 275 bp	1070 bp	0616N, 0620	

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 HLA-Cw*06 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 1070 base pairs, for most wells, or a band of 800 base pairs, for some wells.

Well number 1 contains the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to help in the correct orientation of the HLA-Cw*06 subtyping.

In addition, wells number 2, 5, 10 and 15 contain the primer pair giving rise to the shorter, 800 bp, internal positive control in order to allow kit identification.

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In the presence of a specific amplification the intensity of the control band often decreases.

³Due to the sharing of sequence motifs between HLA-Cw alleles non-HLA-Cw*06 alleles will be amplified by primer mixes 1 to 6, 8, 9, 11 and 14. In addition, the B*5802 allele will be amplified by primer mix 4 and the B*9537 allele will be amplified by primer mix 9.

⁴Short specific PCR fragments are less intense and not as sharp as longer specific bands.

⁵Primer mixes 6 and 10 have a tendency of giving rise to non-specific amplifications.

⁶Primer mix 5: Specific PCR fragment of 165 bp in the Cw*0605 and Cw*050101 to 050104, 0503 to 0525, 0810, 1221 and 1705 alleles. Specific PCR fragment of 220 bp in the Cw*0618 and 0623 and Cw*0104, 0109 and 0221 alleles.

⁷Primer mix 7: Specific PCR fragment of 110 bp in the Cw*0607 allele. Specific PCR fragment of 185 bp in the Cw*0619 allele.

⁸Primer mix 9: Specific PCR fragment of 165 bp in the Cw*0609 and Cw*0222, 0508 and B*9537 alleles. Specific PCR fragment of 210 bp in the Cw*0623 and Cw*0104 and 0109 alleles.

Specific PCR fragment of 435 bp in the Cw*0617 and Cw*0707, 0709, 1801 and 1802 alleles. Specific PCR fragments of 165 and 435 bp in the Cw*1803 allele.

⁹Primer mix 11: Specific PCR fragment of 130 bp in the Cw*0611 and Cw*070401 to 070403, 0711, 0712, 0745, 0763 and 0768 alleles. Specific PCR fragment of 185 bp in the Cw*0622 allele.

¹⁰Primer mix 12: Specific PCR fragment of 200 bp in the Cw*0612 and 0619 alleles. Specific PCR fragment of 275 bp in the Cw*0620 allele.

¹¹Primer mix 16: Specific PCR fragment of 235 bp in the Cw*0616N allele. Specific PCR fragment of 275 bp in the Cw*0620 allele.

INTERPRETATION TABLE								
HLA-Cw*06 SSP subtyping								
Amplification patterns of the Cw*0602 to Cw*0623 alleles								
	Well⁵							
	1	2	3	4	5	6	7	8
Length of spec.	240	220	135	250	165	250	110	240
PCR product(s)					220		185	
Length of int. pos. control¹	800	800	1070	1070	800	1070	1070	1070
5'-primer(s)²	28	361	105	2nd I	113	2nd I	157	361
	5'-TCA ^{3'}	5'-AgT ^{3'}	5'-gCT ^{3'}	5'-CCA ^{3'}	5'-CCA ^{3'}	5'-CCA ^{3'}	5'-TgA ^{3'}	5'-AgT ^{3'}
			113		176		232	
			5'-CCA ^{3'}		5'-gCA ^{3'}		5'-AgA ^{3'}	
					368			
					5'-gTg ^{3'}			
3'-primer(s)³	97	538	201	539	302	538	302	559
	5'-gTC ^{3'}	5'-CCA ^{3'}	5'-CTC ^{3'}	5'-TCA ^{3'}	5'-ggT ^{3'}	5'-CCg ^{3'}	5'-ggT ^{3'}	5'-CTC ^{3'}
					538			
					5'-CCA ^{3'}			
Well No.	1	2	3	4	5	6	7	8
HLA-Cw allele⁴								
*06020101-060203	1	2						
*0603		2	3					
*0604	1			4				
*0605	1				5	6		
*0606	1					6		
*0607	1	2					7	
*0608	1	2						8
*0609	1	2						
*0610	1	2						
*0611	1	2						
*0612	1	2						
*0613	1	2						
*0614	1							
*0615	1	2						
*0616N	1	2						
*0617		2						
*0618	1	2	3		5			
*0619	1	2					7	
*0620	1	2						
Well No.	1	2	3	4	5	6	7	8

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Length of spec.	240	220	135	250	165	250	110	240
PCR product(s)					220		185	
Well No.	1	2	3	4	5	6	7	8
*0622	1	2						
*0623	1	2			5			
*010201-0103, 0105-0108, 0111-0120, 0123-0127, 04010101-040106, 0403, 0405, 0407-0412, 041501-0420, 0423-0433, 0435-0438, 0440, 0802, 0805, 0807, 0812, 0815, 0817-0819, 0823, 1209, 140201-1405, 1407N-1411, 1508						6		
*0104, 0109		2			5			
*0110						6		8
*0122, 080101-080102, 0803, 0804, 0806, 0808, 0809, 0811, 0813, 0814, 0816, 0820-0822, 121401-121402, 1218, 1220, 1406, 150201-1507, 1509-1513, 1515-1521, 1701-1704				4				
*0205, 0217		2						8
*0221, 1221					5			
*0222, 0707, 0709, 1803								
*030201-0317, 0319-0331, 0333-033802, 0340-0344, 0346-0350, 0357, 0358			3					
*0332, 0345			3					
*0339, 1216	1							
*05010101-050104, 0503-0507N, 0509, 0510, 0512-0516, 0518-0525					5	6		
*0508					5			
*0511, 0517, 0810, 1705				4	5			
*070401-070403, 0711, 0712, 0745, 0763, 0768								
*0710, 0743								
*12030101-1207, 1211-1213, 1215, 160401		2						
*1801, 1802						6		
HLA-Cw allele ⁴								
Well No.	1	2	3	4	5	6	7	8
B*5802				4				
B*9537								
Well No.	1	2	3	4	5	6	7	8

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165	190	130	200	155	295	360	235	Length of spec.
210		185	275				275	PCR product(s)
435								
9	10	11	12	13	14	15	16	Well No.
	10	11						*0622
9								*0623
								*010201-0103, 0105-0108, 0111-0120, 0123-0127, 04010101-040106, 0403, 0405, 0407-0412, 041501-0420, 0423-0433, 0435-0438, 0440, 0802, 0805, 0807, 0812, 0815, 0817-0819, 0823, 1209, 140201-1405, 1407N-1411, 1508
9								*0104, 0109
								*0110
								*0122, 080101-080102, 0803, 0804, 0806, 0808, 0809, 0811, 0813, 0814, 0816, 0820-0822, 121401-121402, 1218, 1220, 1406, 150201-1507, 1509-1513, 1515-1521, 1701-1704
								*0205, 0217
								*0221, 1221
9								*0222, 0707, 0709, 1803
								*030201-0317, 0319-0331, 0333-033802, 0340-0344, 0346-0350, 0357, 0358
				14				*0332, 0345
								*0339, 1216
								*05010101-050104, 0503-0507N, 0509, 0510, 0512-0516, 0518-0525
9								*0508
								*0511, 0517, 0810, 1705
		11						*070401-070403, 0711, 0712, 0745, 0763, 0768
				14				*0710, 0743
								*12030101-1207, 1211-1213, 1215, 160401
9								*1801, 1802
								HLA-Cw allele ⁴
9	10	11	12	13	14	15	16	Well No.
								B*5802
9								B*9537
9	10	11	12	13	14	15	16	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 1070 base pairs, for most wells, or a band of 800 base pairs, for some wells.

Well number 1 contains the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to help in the correct orientation of the HLA-Cw*06 subtyping.

In addition, wells number 2, 5, 10 and 15 contain the primer pair giving rise to the shorter, 800 bp, internal positive control in order to allow kit identification.

²The nucleotide position, in the 1st, 2nd or 3rd exons or the 2nd intron, matching the specificity-determining 3'-end of the primer is given. 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 nucleotide position, in the 2nd or 3rd exons or the 3rd intron, matching the specificity-determining 3'-end of the primer is given in the anti-sense direction. 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 Cw*0601 allele has been shown to be identical to Cw*0602.

The sequence of the Cw*060202 allele has been renamed to Cw*0617.

⁵Primer mix 5: Specific PCR fragment of 165 bp in the Cw*0605 and Cw*050101 to 050104, 0503 to 0525, 0810, 1221 and 1705 alleles. Specific PCR fragment of 220 bp in the Cw*0618 and 0623 and Cw*0104, 0109 and 0221 alleles.

Primer mix 7: Specific PCR fragment of 110 bp in the Cw*0607 allele. Specific PCR fragment of 185 bp in the Cw*0619 allele.

Primer mix 9: Specific PCR fragment of 165 bp in the Cw*0609 and Cw*0222, 0508 and B*9537 alleles. Specific PCR fragment of 210 bp in the Cw*0623 and Cw*0104 and 0109 alleles.

Specific PCR fragment of 435 bp in the Cw*0617 and Cw*0707, 0709, 1801 and 1802 alleles. Specific PCR fragments of 165 and 435 bp in the Cw*1803 allele.

Primer mix 11: Specific PCR fragment of 130 bp in the Cw*0611 and Cw*070401 to 070403, 0711, 0712, 0745, 0763 and 0768 alleles. Specific PCR fragment of 185 bp in the Cw*0622 allele.

Primer mix 12: Specific PCR fragment of 200 bp in the Cw*0612 and 0619 alleles. Specific PCR fragment of 275 bp in the Cw*0620 allele.

Primer mix 16: Specific PCR fragment of 235 bp in the Cw*0616N allele. Specific PCR fragment of 275 bp in the Cw*0620 allele.

CELL LINE VALIDATION SHEET																					
HLA-Cw*06 SSP subtyping kit																					
					Well																
					1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	
				Prod. No.:	200960501	200734402	200960503	200734404	200960505	200734406	200960507	200734408	200960509	200960510	200960511	200960512	200734413	200734414	200734415	200960516	
	IHWC cell line		Cw*																		
1	9001	SA	*0702		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
2	9280	LK707	*0701	*1505	-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	
3	9011	E4181324	*1202		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
4	9275	GU373	*0304	*0401	-	-	+	-	-	+	-	-	-	-	-	-	-	-	-	-	
5	9009	KAS011	*0602		+	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
6	9353	SM	*0304	*0702	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	
7	9020	QBL	*0501		-	-	-	-	+	+	-	-	-	-	-	-	-	-	-	-	
8	9025	DEU	*0401		-	-	-	-	-	+	-	-	-	-	-	-	-	-	-	-	
9	9026	YAR	*1203		-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
10	9107	LKT3	*0102		-	-	-	-	-	+	-	-	-	-	-	-	-	-	-	-	
11	9051	PITOUT	*1601		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
12	9052	DBB	*0602		+	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
13	9004	JESTHOM	*0102		-	-	-	-	-	+	-	-	-	-	-	-	-	-	-	-	
14	9071	OLGA	*0102	*0304	-	-	+	-	-	+	-	-	-	-	-	-	-	-	-	-	
15	9075	DKB	*0304		-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	
16	9037	SWEIG007	*0202		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
17	9282	CTM3953540	*0303	*0701	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	
18	9257	32367	*0102	*0705	-	-	-	-	-	+	-	-	-	-	-	-	-	-	-	-	
19	9038	BM16	*0701		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
20	9059	SLE005	*0304		-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	
21	9064	AMALA	*0303		-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	
22	9056	KOSE	*1203		-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
23	9124	IHL	*0102	*1502	-	-	-	+	-	+	-	-	-	-	-	-	-	-	-	-	
24	9035	JBUSH	*1203		-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
25	9049	IBW9	*0802		-	-	-	-	-	+	-	-	-	-	-	-	-	-	-	-	
26	9285	WT49	*0701		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
27	9191	CH1007	*0704	*1505	-	-	-	+	-	-	-	-	-	-	+	-	-	-	-	-	
28	9320	BEL5GB	*0501	*1601	-	-	-	-	+	+	-	-	-	-	-	-	-	-	-	-	
29	9050	MOU	*1601		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
30	9021	RSH	*1701		-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	
31	9019	DUCAF	*0501		-	-	-	-	+	+	-	-	-	-	-	-	-	-	-	-	
32	9297	HAG	*1701	*1703	-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	
33	9098	MT14B	*0304		-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	
34	9104	DHIF	*1203		-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
35	9302	SSTO	*0501		-	-	-	-	+	+	-	-	-	-	-	-	-	-	-	-	
36	9024	KT17	*0303	*0401	-	-	+	-	-	+	-	-	-	-	-	-	-	-	-	-	
37	9065	HHKB	*0702		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
38	9099	LZL	*0303		-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	
39	9315	CML	*0202	*0701	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
40	9134	WHONP199	*0602		+	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
41	9055	H0301	*0802		-	-	-	-	-	+	-	-	-	-	-	-	-	-	-	-	
42	9066	TAB089	*0102		-	-	-	-	-	+	-	-	-	-	-	-	-	-	-	-	
43	9076	T7526	*0102	*0801	-	-	-	+	-	+	-	-	-	-	-	-	-	-	-	-	
44	9057	TEM	*1203		-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
45	9239	SHJO	*0602	*17	+	+	-	+	-	-	-	-	-	-	-	-	-	-	-	-	
46	9013	SCHU	*0702		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
47	9045	TUBO	*0704	*1502	-	-	-	+	-	-	-	-	-	-	+	-	-	-	-	-	
48	9303	TER-ND	*0401	*1601	-	-	-	-	-	+	-	-	-	-	-	-	-	-	-	-	

CERTIFICATE OF ANALYSIS**Olerup SSP® HLA-Cw*06 SSP****Product number:** 101.614-12 – including *Taq* polymerase**Lot number:** 95F**Expiry date:** 2011-June-01**Number of tests:** 12**Number of wells per test:** 16**Well specifications:**

Well No.	Production No.	Well No.	Production No.
1	2009-605-01	9	2009-605-09
2	2007-344-02	10	2009-605-10
3	2009-605-03	11	2009-605-11
4	2007-344-04	12	2009-605-12
5	2009-605-05	13	2007-344-13
6	2007-344-06	14	2007-344-14
7	2009-605-07	15	2007-344-15
8	2007-344-08	16	2009-605-16

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 7, 8, 10, 12 to 16 were available. In primer solutions 8 and 14 it was possible to test both the 5'-primer and the 3'-primer. The specificity of the primers in primer solutions 8 and 14 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer solution 13 it was only possible to test the 5'-primer, the 3'-primer was not possible to test. In primer solution 7 and 15 it was only possible to test the 3'-primer, the 5'-primer was not possible to test. In primer solution 3, 5, 10, 12 and 16 one or two 5'-primers was not possible to test, and in primer solutions 10 and 11 one 3'-primer was not possible to test. Additional primers in primers solutions 5 and 9 were tested by separately adding one 5'-primer or one 3'-primer.

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

Date of approval: 2009-June-08

Approved by:

Quality Control, Supervisor

Declaration of Conformity

Product name: Olerup SSP[®] HLA-Cw*06
Product number: 101.614-12
Lot number: 95F

Intended use: HLA-Cw*06 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, ISO 17025:1999 and ISO 13485:2000, following the provisions of the 98/79/EC Directive on *in vitro* diagnostic medical devices, Annex III.

The Technical Construction 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.

Saltsjöbaden, Sweden
2009-June-08

Olle Olerup

Lot No.: **95F**

Lot-specific information

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