

Lot No.: **34F**

Lot-specific information

Olerup SSP[®] HLA-C low resolution

Product number: 101.601-24u/12u – without *Taq* pol.
Lot number: 34F
Expiry date: 2010-November-01
Number of tests: 24 tests – Product No. 101.601-24u
 12 tests – Product No. 101.601-12u
Number of wells per test: 23 + 1
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. 34F.

CHANGES COMPARED TO THE PREVIOUS *OLERUP SSP[®]* HLA-C LOW RESOLUTION LOT

The HLA-C low resolution specificity and interpretation tables have been updated for the HLA-Cw alleles described since the previous *Olerup SSP[®]* HLA-C low resolution lot was made (**Lot No. Y22**).

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

Well	5'-primer	3'-primer	rationale
1	-	Added	Primer added for the Cw*0121 allele.
2	-	Removed	Increased resolution.
5	Removed	Removed	Primer pair moved to vial 19 and internal positive control primer pair changed to decrease primer dimer formation tendency.
9	-	-	Changed internal positive control primer pair to decrease primer dimer formation tendency.
10	Added	1 added 1 exchanged	Primer pair added for the Cw*0813 allele. Primer exchanged to not amplify the Cw*0520 allele. Changed internal positive control primer pair.
12	Exchanged	-	Primer exchanged to not amplify the Cw*040105 allele.
13	Exchanged	-	Primer exchanged to not amplify the

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			Cw*0753 allele.
15	Modified	-	Primer improved for increased specificity. Changed internal positive control primer pair.
19	1 exchanged 1 added	1 exchanged 1 added	Primer pair moved from vial 5. Primer pair added for the Cw*0433 allele.
22	1 removed 1 added	1 removed 1 added	Primer pair for Cw*0804 removed to decrease primer dimer formation tendency. Primer pair added for the Cw*0432 allele.

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Well **24** contains Negative Control primer pairs, that will amplify more than 95% of the *Olerup* SSP[®] HLA Class I, DRB, DQB1 and DPB1 amplicons as well as the amplicons generated by control primer pairs.

PCR product sizes range from 75 to 430 base pairs.

The PCR product generated by the control primer pair is 430 base pairs.

Length of PCR product	105	200	105	80	75	80
5'-primer¹	164	340	440	45	45	43
	5'-CAC ^{3'}	5'-Agg ^{3'}	5'-TTA ^{3'}	5'-Tg g ^{3'}	5'-Tg g ^{3'}	5'-Tg g ^{3'}
3'-primer²	231	2nd I	507	59	58	57
	5'-TgC ^{3'}	5'-AAA ^{3'}	5'-TTg ^{3'}	5'-CTC ^{3'}	5'-ggC ^{3'}	5'-CTC ^{3'}
A*	+	+	+			
B*	+	+	+			
Cw*	+	+	+			
DRB1				+	+	
DRB3				+	+	
DRB5				+		
DQB1					+	
DPB1						+

¹The nucleotide position for HLA class I genes and the codon for HLA class II genes, in the 2nd or 3rd exon 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.

²The nucleotide position for HLA class I genes and the codon for HLA class II genes, in the 2nd or 3rd exon, 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.

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PRODUCT DESCRIPTION

HLA-C-low resolution SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for grouping the HLA-Cw*0102 to Cw*1803 alleles into the groups Cw*01xx to Cw*18xx.

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

Wells 1 to 23 – HLA-Cw low resolution primers.

Well 24 – Negative Control.

The 24 well cut PCR plate is marked with 'HLA-C low' in silver/gray ink.

Well No. 1 is marked with the Lot No. '34F'.

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 sealed. Use a scalpel or a similar instrument to carefully cut the foil between the plates.

INTERPRETATION

Only HLA-Cw alleles will be amplified by the HLA-C low resolution typing kit, except that primer mix 13 will amplify the B*6702 allele and primer mix 20 will amplify the B*1403 allele. Thus, the interpretation of HLA-C low resolution typings is only influenced by these HLA-B alleles and not by other HLA class I genes.

UNIQUELY IDENTIFIED ALLELES

All the HLA-Cw alleles, i.e. **Cw*0102 to Cw*1803**, recognized by the HLA Nomenclature Committee in October 2008¹ will be amplified by the primers in the HLA-C low resolution SSP kit. The HLA-Cw alleles will be grouped into the Cw*01xx to Cw*18xx groups.

¹HLA-Cw alleles listed on the IMGT/HLA web page 2008-October-10, release 2.23.0, www.ebi.ac.uk/imgt/hla.

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SPECIFICITY TABLE

HLA-C low resolution SSP typing

Specificities and sizes of the PCR products of the 23 primer mixes used for HLA-C low resolution SSP typing

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified HLA class I ³ alleles
1⁴	155, 370 bp	800 bp	010201-0122
2	270 bp	800 bp	0110, 020201-020203, 020205-0222, 0432, 0608, 1701-1704, 1803
3	280 bp	800 bp	020201-020203, 020205-0203, 0204 ^{weakly} , 0205-0213, 0214 ^{weakly} , 0215-0222, 030201-030203, 030401-0310, 0314-0317, 0319, 0323-0329, 0332-033802, 0340-0342, 0344-0348, 0403, 0406, 0416, 0603, 150201-1509, 151002, 1511, 1513, 1515-1521
4⁹	155 bp	1070 bp	030201-030406, 0305-0315, 0317-0340, 0342-0350
5	280 bp	800 bp	030301-030305, 031101-0313, 0320N-0322Q, 0330, 0331, 0343, 0349, 0350, 1512
6	125 bp	1070 bp	020201-020203, 020205-0220, 0222, 04010101-040106, 0403-041502, 0417-0420, 0423-0436, 1511
7	165 bp	1070 bp	050101-050104, 0503-0521, 0605, 0810, 1221
8	130, 240, 355 bp	800 bp	0206, 0339, 06020101-06020102, 060203-0616N, 0618, 1215, 1216, 150201-1503, 1507, 1508, 151001-1513, 1515-1518, 1521
9⁵	245, 425 bp	800 bp	070101-0733N, 0735-0764
10^{6,9}	115, 170, 260, 390 bp	1070 bp	080101-0819
11	340 bp	1070 bp	0114, 020201-020203, 020205-0211, 0213-0222, 0307, 0315, 0345, 04010101-040106, 0403-0410, 0412-0420, 0423-0428, 0430-0435, 050101-050104, 0503-0521, 06020101-06020102, 060203-0610, 0612-0618,

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			0707, 0709, 0749, 0810, 120401-1205, 1209, 1221, 1404, 150201-1506, 1508-1513, 1515-1520, 1602, 1609, 1612, 1701-1704, 1801-1803
12	100, 160, 220 bp	1070 bp	0104, 0121, 120201-12030102, 120303-120306, 120402-1208, 1210-1213, 1215-1221
13^{8,9}	130, 250 bp	800 bp	0121, 0212, 04010101-040106, 0403-0409N, 0412-0420, 0423-0435, 0805, 120201-120303, 120305-120306, 120402, 1206-1208, 1210-1220, 1503, 1516, 160101-1602, 1606-1612, B*6702
14¹⁰	220 bp	800 bp	0104, 0109, 0205, 0217, 06020101-06020102, 060203, 0603, 0607-0613, 0615-0618, 12030101-1207, 1211-1213, 1215, 1219, 160401
15⁹	255 bp	1070 bp	020201 ^{weakly} , 020202-020203, 020205-0213, 0215-0222, 0307, 0310, 0315, 0329, 0345, 0403, 0406, 0416, 050101-050104, 0503-0519, 0521, 0603, 0810, 120401-1205, 1209, 1221, 150201-1506, 1508-1513, 1515-1521, 1602, 1609, 1612, 1701-1704
16⁹	95, 255 bp	1070 bp	0411, 0429, 0436, 0511, 0517, 0764, 0804, 0813, 140201-1411
17^{7,9}	110, 335 bp	1070 bp	0206, 1208, 1215, 150201-1513, 1515-1521
18⁸	190, 250 bp	1070 bp	0213, 0218, 04010101-040106, 0403-0410, 0412-0420, 0423-0432, 0434-0436, 0517, 0605, 0731, 080101-080102, 0803, 0806, 0808-0811, 0814, 0816, 1214, 160101-1602, 160401, 1606-1612
19	225, 260 bp	800 bp	0433, 0807, 1214, 1701-1704
20	220, 425 bp	800 bp	010201-0103, 0106-0108, 0110-0120, 0516, 0605, 0606, 0707, 0709, 0749, 0812, 1209, 140201-1405, 1407N, 1410, 1411, 1801-1803, B*1403
21	325, 380 bp	1070 bp	0103, 0222, 030301-030407, 0306-0312, 0314, 0318-0324, 0326, 0328-0332, 0334, 0337-0350, 04010101-040106, 0403-0420, 0424-0436, 050101-050104, 0503, 0505-0521, 0609, 0614, 0710, 0728, 0741, 0743, 080101-0808, 0810,

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			0812-0819, 150201-1513, 1515-1521, 1701-1704, 1801-1803
22⁸	135 bp	1070 bp	030201-0317, 0319-033802, 0340-0350, 0432, 0603, 1803
23	160, 235 bp	1070 bp	06020101-06020102, 060203, 0604, 0606-0618, 070101-0725, 072701-0732N, 0735-0738, 0741-0763, 1216, 160101-1602, 1606-1612, 1801-1803

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-C low resolution 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-C low resolution typing.

In addition, wells number 2, 3, 5, 8, 9, 13, 14, 19 and 20 contain the primer pair giving rise to the shorter, 800 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 HLA-C alleles only partial 1st and 4th exon nucleotide sequences are available. In these instances it is not known whether some of the primers of the HLA-C low resolution SSP sets are completely matched with the target sequences or not. We assume that unknown sequences are conserved within allelic groups.

⁴Primer mix 1 will for most Cw*01 alleles give rise to two specific PCR fragments.

⁵Primer mix 9 will for most Cw*07 alleles give rise to two specific PCR fragments.

⁶Primer mix 10 will for most Cw*08 alleles give rise to multiple specific PCR fragments.

⁷Primer mix 17 will for most Cw*15 alleles give rise to two specific PCR fragments.

⁸Primer mixes 13, 18 and 22 have a tendency of giving rise to primer oligomer artifacts.

⁹Primer mixes 4, 10, 13, 15, 16 and 17 yield somewhat less intense specific PCR fragments than the other HLA-C low resolution primer mixes.

¹⁰Primer mix 14 might faintly amplify the Cw*0102 to 0103, the Cw*0105 to Cw*0119 and the Cw*140201 to 1409 alleles.

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INTERPRETATION TABLE												
HLA-Cw low resolution SSP typing												
Amplification patterns of the Cw*0102 to Cw*1803 alleles												
	Well											
	1	2	3	4	5	6	7	8	9	10	11	12
Length of spec.	155	270	280	155	280	125	165	130	245	115	340	100
PCR product(s)	370							240	425	170		160
								355		260		220
										390		
Length of int.	800	800	800	1070	800	1070	1070	800	800	1070	1070	1070
pos. control¹												
5'-primer(s)²	89	2nd I	105	477	105	112	176	28	47	1st I	1st I	361
	5'-gAA ^{3'}	5'-CCA ^{3'}	5'-gCT ^{3'}	5'-gCC ^{3'}	5'-gCT ^{3'}	5'-CCT ^{3'}	5'-gCA ^{3'}	5'-TCA ^{3'}	5'-Agg ^{3'}	5'-CgA ^{3'}	5'-CgA ^{3'}	5'-AgT ^{3'}
	368					118		2nd I	648	176		419
	5'-gTg ^{3'}					5'-CCA ^{3'}		5'-CCA ^{3'}	5'-CAC ^{3'}	5'-gCA ^{3'}		5'-gTC ^{3'}
										527		
										5'-TAC ^{3'}		
3'-primer(s)³	201	559	343	589	343	201	302	97	302	175	302	474
	5'-CTC ^{3'}	5'-CTC ^{3'}	5'-ACC ^{3'}	5'-CTT ^{3'}	5'-ACT ^{3'}	5'-CTT ^{3'}	5'-ggT ^{3'}	5'-gTC ^{3'}	5'-ggC ^{3'}	5'-CCg ^{3'}	5'-ggT ^{3'}	5'-gCA ^{3'}
	201							213	853	302		477
	5'-CTT ^{3'}							5'-Cgg ^{3'}	5'-CAT ^{3'}	5'-ggC ^{3'}		5'-gCA ^{3'}
	3rd I							420		601		538
	5'-CTC ^{3'}							5'-gCT ^{3'}		5'-CTT ^{3'}		5'-gCA ^{3'}
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
HLA-Cw allele⁴												
*010201-010206, 0106-0108, 0111-0113, 0115-0120	1											
*0103	1											
*0104	1											12
*0105, 0122	1											
*0109	1											
*0110	1	2										
*0114	1										11	
*0121	1											12
*020201		2	3			6					11	
*020202-020203, 020205-0203, 0207-0211, 0215, 0216, 0219, 0220		2	3			6					11	
*0204		2	w			6					11	
*0205, 0217		2	3			6					11	
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

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INTERPRETATION TABLE											
HLA-Cw low resolution SSP typing											
Amplification patterns of the Cw*0102 to Cw*1803 alleles											
Well											
13	14	15	16	17	18	19	20	21	22	23	
130	220	255	95	110	190	225	220	325	135	160	Length of spec. PCR product(s)
250			255	335	250	260	425	380		235	
800	800	1070	1070	1070	1070	800	800	1070	1070	1070	Length of int. pos. control¹
201	361	98	98	201	201	112	47	355	105	97	5'-primer(s)²
5'-CCA ^{3'}	5'-AgT ^{3'}	5'-CTA ^{3'}	5'-CTC ^{3'}	5'-CCA ^{3'}	5'-CCA ^{3'}	5'-CCT ^{3'}	5'-Agg ^{3'}	5'-TCA ^{3'}	5'-gCT ^{3'}	5'-TCg ^{3'}	
2nd I			485	409	2nd I	2nd I	361	412	459	418	
5'-CCA ^{3'}			5'-CAA ^{3'}	5'-ggC ^{3'}	5'-CCA ^{3'}	5'-CCA ^{3'}	5'-AgT ^{3'}	5'-ATA ^{3'}	5'-gAT ^{3'}	5'-Agg ^{3'}	
					361					419	
					5'-AgT ^{3'}					5'-gTC ^{3'}	
289	538	312	311	270	341	341	302	3rd I	201	289	3'-primer(s)³
5'-AgC ^{3'}	5'-CCA ^{3'}	5'-AgT ^{3'}	5'-ggT ^{3'}	5'-TAg ^{3'}	5'-CgT ^{3'}	5'-Cgg ^{3'}	5'-ggT ^{3'}	5'-CTC ^{3'}	5'-CTC ^{3'}	5'-AgC ^{3'}	
539	538		539	3rd I	341	512	538		559	539	
5'-TCT ^{3'}	5'-gCA ^{3'}		5'-TCA ^{3'}	5'-CTC ^{3'}	5'-ggT ^{3'}	5'-CCA ^{3'}	5'-CCg ^{3'}		5'-CTC ^{3'}	5'-TCT ^{3'}	
					527						
					5'-CCg ^{3'}						
13	14	15	16	17	18	19	20	21	22	23	Well No. HLA-Cw allele⁴
							20				
							20	21			*0103
	14										*0104
											*0105, 0122
	14										*0109
							20				*0110
							20				*0114
13											*0121
		w									*020201
		15									*020202-020203, 020205
		15									0203, 0207-0211, 0215,
		14	15								0216, 0219, 0220
											*0204
											*0205, 0217
13	14	15	16	17	18	19	20	21	22	23	Well No.



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Well No.	1	2	3	4	5	6	7	8	9	10	11	12
*0206		2	3			6		8			11	
*0212		2	3			6						
*0213, 0218		2	3			6					11	
*0214		2	w			6					11	
*0221		2	3								11	
*0222		2	3			6					11	
*030201-030203, 0305, 0317, 0325, 0327, 0333, 0335, 0336			3	4								
*030301-030305, 031101- 031102, 0312, 0320N- 0322Q, 0330, 0331, 0343, 0349, 0350				4	5							
*030401-030406, 0306, 0308, 0309, 0314, 0319, 0323, 0324, 0326, 0328, 0332, 0334, 0337- 033802, 0340, 0342, 0344, 0346-0348			3	4								
*030407, 0341			3									
*0307, 0345			3	4							11	
*0310, 0329			3	4								
*0313				4	5							
*0315			3	4							11	
*0316			3									
*0318				4								
*0339				4				8				
*04010101-040106, 040401-0405, 0407- 0409N, 0412-041502, 0417-0420, 0424-0428, 0430, 0431, 0434, 0435						6					11	
*0403, 0406			3			6					11	
*0410						6					11	
*0411						6						
*0416			3								11	
*0423						6					11	
*0429						6						
*0432		2				6					11	
*0433						6					11	
*0436						6						
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

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13	14	15	16	17	18	19	20	21	22	23	Well No.
		15		17							*0206
13		15									*0212
		15			18						*0213, 0218
											*0214
		15									*0221
		15						21			*0222
									22		*030201-030203, 0305, 0317, 0325, 0327, 0333, 0335, 0336
								21	22		*030301-030305, 031101, 031102, 0312, 0320N- 0322Q, 0330, 0331, 0343, 0349, 0350
								21	22		*030401-030406, 0306, 0308, 0309, 0314, 0319, 0323, 0324, 0326, 0328, 0332, 0334, 0337- 033802, 0340, 0342, 0344, 0346-0348
								21	22		*030407, 0341
		15						21	22		*0307, 0345
		15						21	22		*0310, 0329
									22		*0313
		15							22		*0315
									22		*0316
								21			*0318
								21			*0339
13					18			21			*04010101-040106, 040401-0405, 0407- 0409N, 0412-041502, 0417-0420, 0424-0428, 0430, 0431, 0434, 0435
13		15			18			21			*0403, 0406
					18			21			*0410
			16			19		21			*0411
13		15			18			21			*0416
13					18						*0423
13			16		18			21			*0429
13					18			21	22		*0432
13						19		21			*0433
			16		18			21			*0436
13	14	15	16	17	18	19	20	21	22	23	Well No.



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Well No.	1	2	3	4	5	6	7	8	9	10	11	12
*050101-050104, 0503, 0505-0510, 0512-0515, 0518, 0519, 0521							7				11	
*0504							7				11	
*0511							7				11	
*0516							7				11	
*0517							7				11	
*0520							7				11	
*06020101-06020102, 060203, 0607, 0610, 0612, 0613, 0615, 0616N, 0618								8			11	
*0603			3					8			11	
*0604								8			11	
*0605							7	8			11	
*0606								8			11	
*0608		2						8			11	
*0609								8			11	
*0611								8				
*0614								8			11	
*0617											11	
*070101-0706, 0708, 0711-0725, 072701-072702, 0729, 0730, 0732N, 0735-0738, 0742, 0744-0748, 0750-0763									9			
*0707, 0709, 0749									9		11	
*0710, 0728, 0741, 0743									9			
*0726, 0733N, 0739, 0740									9			
*0731									9			
*0764									9			
*080101-080102, 0803, 0806, 0808, 0814, 0816										10		
*0802, 0815, 0817-0819										10		
*0804, 0813										10		
*0805										10		
*0807										10		
*0809, 0811										10		
*0810							7			10	11	
*0812										10		
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

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13	14	15	16	17	18	19	20	21	22	23	Well No.
		15						21			*050101-050104, 0503, 0505-0510, 0512-0515, 0518, 0519, 0521
		15									*0504
		15	16					21			*0511
		15					20	21			*0516
		15	16		18			21			*0517
								21			*0520
	14									23	*06020101-06020102, 060203, 0607, 0610, 0612, 0613, 0615, 0616N, 0618
	14	15							22		*0603
										23	*0604
					18		20				*0605
							20			23	*0606
	14									23	*0608
	14							21		23	*0609
	14									23	*0611
								21		23	*0614
	14									23	*0617
										23	*070101-0706, 0708, 0711-0725, 072701- 072702, 0729, 0730, 0732N, 0735-0738, 0742, 0744-0748, 0750-0763
							20			23	*0707, 0709, 0749
								21		23	*0710, 0728, 0741, 0743
											*0726, 0733N, 0739, 0740
					18					23	*0731
			16								*0764
					18			21			*080101-080102, 0803, 0806, 0808, 0814, 0816
								21			*0802, 0815, 0817-0819
			16					21			*0804, 0813
13								21			*0805
						19		21			*0807
					18						*0809, 0811
		15			18			21			*0810
							20	21			*0812
13	14	15	16	17	18	19	20	21	22	23	Well No.



Lot No.: **34F**

Lot-specific information

Well No.	1	2	3	4	5	6	7	8	9	10	11	12
*120201-120203, 1210, 1217, 1218, 1220												12
*12030101-12030102, 120303, 120305-120306, 1206, 1207, 1211-1213, 1219												12
*120302												
*120304												12
*120401											11	
*120402											11	12
*1205											11	12
*1208												12
*1209											11	
*1214												
*1215								8				12
*1216								8				12
*1221							7				11	12
*140201-1403, 1405, 1407N, 1410, 1411												
*1404											11	
*1406, 1408, 1409												
*150201-150204, 1508, 151002, 1513, 1515, 1517, 1518			3					8			11	
*1503, 1516			3					8			11	
*1504-1506, 1509, 1519, 1520			3								11	
*1507			3					8				
*151001								8			11	
*1511			3			6		8			11	
*1512					5			8			11	
*1521			3					8				
*160101-160103, 1606-1608, 1610, 1611												
*1602, 1609, 1612											11	
*160401												
*1701-1704		2									11	
*1801, 1802											11	
*1803		2									11	
HLA-Cw allele ⁴												
B*1403												
B*6702												
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

Lot No.: **34F**

Lot-specific information

13	14	15	16	17	18	19	20	21	22	23	Well No.	
13											*120201-120203, 1210, 1217, 1218, 1220	
13	14										*12030101-12030102, 120303, 120305-120306, 1206, 1207, 1211-1213, 1219	
13	14										*120302	
	14										*120304	
	14	15										*120401
13	14	15									*120402	
	14	15										*1205
13				17							*1208	
		15					20				*1209	
13					18	19					*1214	
13	14			17							*1215	
13										23	*1216	
		15										*1221
			16				20				*140201-1403, 1405, 1407N, 1410, 1411	
			16			20					*1404	
			16								*1406, 1408, 1409	
		15			17			21			*150201-150204, 1508, 151002, 1513, 1515, 1517, 1518	
13		15		17				21			*1503, 1516	
		15			17			21			*1504-1506, 1509, 1519, 1520	
				17				21			*1507	
		15			17			21			*151001	
		15		17				21			*1511	
		15			17			21			*1512	
		15		17				21			*1521	
13					18						23	*160101-160103, 1606- 1608, 1610, 1611
13		15			18						23	*1602, 1609, 1612
	14			18								*160401
		15				19		21				*1701-1704
								20	21		23	*1801, 1802
								20	21	22	23	*1803
											HLA-Cw allele ⁴	
								20				B*1403
13											B*6702	
13	14	15	16	17	18	19	20	21	22	23	Well No.	



Lot No.: 34F

Lot-specific information

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-C low resolution SSP typing.

In addition, wells number 2, 3, 5, 8, 9, 13, 14, 19 and 20 contain the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to allow kit identification.

²The nucleotide position, in the 1st, 2nd, 3rd or 4th exon or the 1st or 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 1st, 2nd, 3rd or 4th exon 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*0101 allele has been shown to be identical to Cw*0102.

The sequence of the Cw*0201 allele has been shown to be identical to Cw*02022.

The sequence of the Cw*020204 allele has been shown to be identical to Cw*0210.

The sequence of the Cw*0301 allele has been shown to be identical to Cw*0304.

The sequence of the Cw*0402 allele has been shown to be identical to Cw*04011.

The sequence of the Cw*0421 allele has been shown to be identical to Cw*041502.

The sequence of the Cw*0422 allele has been shown to be identical to Cw*0421.

The sequence of the Cw*0502 allele has been shown to be identical to Cw*0509.

The sequence of the Cw*0601 allele has been shown to be identical to Cw*0602.

The sequence of the Cw*060202 allele has been shown to be identical to Cw*0617.

The sequence of the Cw*0734 allele has been shown to be identical to Cw*072702.

The sequence of the Cw*1101 allele has been shown to be in error.

The sequence of the Cw*1201 allele has been shown to be identical to Cw*12022.

The sequence of Cw*1301 has been shown to be in error.

The sequence of the Cw*1401 allele has been shown to be identical to Cw*1402.

The sequence of the Cw*1501 allele has been shown to be identical to Cw*1502.

The sequence of the Cw*1514 allele has been shown to be identical to Cw*151002.

The sequence of the Cw*1603 allele has been shown to be identical to Cw*1403.

The sequence of the Cw*16042 allele has been shown to be identical to Cw*16041.

The sequence of the Cw*1605 allele has been shown to be identical to Cw*16041.

Lot No.: **34F**

Lot-specific information

CELL LINE VALIDATION SHEET																				
HLA-C low resolution SSP primer set																				
				Well																
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	
				Prod. No.:	200848401	200848402	200848403	200848404	200848405	200848406	200848407	200848408	200848409	200853710	200848411	200848412	200848413	200848414	200853715	200848416
IHCW 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	9007	DEM	*0602		-	-	-	-	-	-	-	+	-	-	+	-	-	+	-	-
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	CTM395354	*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	*0102	*0602	+	-	-	-	-	-	-	+	-	-	+	-	-	+	-	-
41	9055	H0301	*0802		-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-
42	9066	TAB089	*0102		+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
43	9076	T7526	*0102	*0801	+	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-
44	9057	TEM	*1203		-	-	-	-	-	-	-	-	-	-	-	+	+	+	-	-
45	9239	SHJO	*0602	*1701	-	+	-	-	-	-	-	+	-	-	+	-	-	+	+	-
46	9013	SCHU	*0702		-	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-
47	9045	TUBO	*0704	*1502	-	-	+	-	-	-	-	+	+	-	+	-	-	-	+	-
48	9303	TER-ND	*0401	*1601	-	-	-	-	-	+	-	-	-	-	+	-	+	-	-	-



Lot No.: **34F**

Lot-specific information

CELL LINE VALIDATION SHEET					Well							
HLA-C low resolution SSP primer set					17	18	19	20	21	22	23	
				Prod. No.:	200848417	200848418	200853719	200848420	200848421	200848422	200848423	
	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	9007 DEM		*0602		-	-	-	-	-	-	+	
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 CTM395354		*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		*0102	*0602	-	-	-	+	-	-	+	
41	9055 H0301		*0802		-	-	-	-	+	-	-	
42	9066 TAB089		*0102		-	-	-	+	-	-	-	
43	9076 T7526		*0102	*0801	-	+	-	+	+	-	-	
44	9057 TEM		*1203		-	-	-	-	-	-	-	
45	9239 SHJO		*0602	*1701	-	-	+	-	+	-	+	
46	9013 SCHU		*0702		-	-	-	-	-	-	+	
47	9045 TUBO		*0704	*1502	+	-	-	-	+	-	+	
48	9303 TER-ND		*0401	*1601	-	+	-	-	+	-	+	



Lot No.: **34F**

Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP[®] HLA-C low resolution SSP

Product number: 101.601-24u/12u – without Taq pol.
Lot number: 34F
Expiry date: 2010-November-01
Number of tests: 24 tests – Product No. 101.601-24u
12 tests – Product No. 101.601-12u
Number of wells per test: 23 + 1

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2008-484-01	9	2008-484-09	17	2008-484-17
2	2008-484-02	10	2008-537-10	18	2008-484-18
3	2008-484-03	11	2008-484-11	19	2008-537-19
4	2008-484-04	12	2008-484-12	20	2008-484-20
5	2008-484-05	13	2008-484-13	21	2008-484-21
6	2008-484-06	14	2008-484-14	22	2008-484-22
7	2008-484-07	15	2008-537-15	23	2008-484-23
8	2008-484-08	16	2008-484-16		

The specificity of each primer solution of the kit has been tested against 48 well characterized IHWC cell line DNAs.

Additional 5'-primers in primer solution 23 were tested by separately adding one 3'-primer. Additional 3'-primers in primer solutions 1 and 10 were tested by separately adding one 5'-primer. Additional 5'- and 3'-primers in primer solutions 19 and 22 were tested by separately adding one 3'-primer, respectively one 5'-primer.

The negative control primer pairs, **Production No. 2008-495-01**, can detect contamination with PCR products diluted 10^{-7} .

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

Date of approval: 2009-May-25

Approved by:

Quality Control, Supervisor

Lot No.: **34F**

Lot-specific information

Declaration of Conformity

Product name: *Olerup* SSP® HLA-C low resolution
Product number: 101.601-24u/12u
Lot number: 34F

Intended use: HLA-C low 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 13485:2004, following the provisions of the 98/79/EC Directive on *in vitro* diagnostic medical devices, Annex III, as transposed into the national laws of the Member States of the European Union.

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-May-25

Olle Olerup
Managing Director

Lot No.: **34F**

Lot-specific information

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Lot-specific information

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Lot No.: **34F**

Lot-specific information

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Fax: 610-344-7989

E-mail: info.us@olerup.com

Web page: <http://www.olerup.com>

For information on *Olerup* SSP distributors worldwide, contact **Olerup GmbH**.