Lot No.: 38F **Lot-specific information**

Olerup SSP® HLA-Cw*12

Product number:	**101.624-12u – without *Taq* polymerase**
Lot number:	**38F**
Expiry date:	**2010-November-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. 38F.

CHANGES COMPARED TO THE PREVIOUS *OLERUP* SSP® HLA-CW*12 LOT

The HLA-Cw*12 specificity and interpretation tables have been updated for the HLA-Cw alleles described since the previous *Olerup* SSP® HLA-Cw*12 lot was made **(Lot No. 04E)**.

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	-	Modified	Modified 3'-primer to increase specificity.
21	Exchanged	-	Changed to a more specific 5-primer.

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PRODUCT DESCRIPTION

HLA-Cw*12 SSP typing

INTENDED USE

The primer set contains 5'- and 3'-primers for identifying the Cw*1202 to Cw*1221 alleles.

PLATE LAYOUT

Each HLA-Cw*12 test consists of twenty-two 10 µl 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 PCR plate is marked with 'HLA-Cw*12' in silver/gray ink.
Well No. 1 is marked with the Lot No. '38F'.
The PCR plates are heat-sealed 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

The interpretation of HLA-Cw*12 SSP subtypings will be influenced by other HLA-Cw alleles, as primer mixes 1 to 7, 9, 11, 12, 14 to 16 and 21 amplify non-HLA-Cw*12 alleles. In addition, primer mix 1 amplifies the B*0713, B*0715 and B*6702 alleles, primer mix 9 amplifies the B*0713 and B*6702 alleles, primer mix 11 amplifies the B*1403 allele, primer mix 12 amplifies the B*350802 and B*6702 alleles, primer mix 14 amplifies the B*6702, primer mix 15 amplifies the B*350802 and primer mix 21 amplifies the B*5802 allele.

UNIQUELY IDENTIFIED ALLELES

All the HLA-Cw*12 alleles, i.e. **Cw*1202 to Cw*1221**, recognized by the HLA Nomenclature Committee in October 2008[1] will be amplified by the primers in the HLA-Cw*12 SSP kit[2].
The HLA-Cw*12 subtyping kit cannot distinguish the Cw*120201 to Cw*120203 alleles or the Cw*12030101, Cw*12030102, Cw*120303, Cw*120305 and the Cw*120306 alleles.

[1]HLA-Cw alleles listed on the IMGT/HLA web page 2008-October-10, release 2.23.0, www.ebi.ac.uk/imgt/hla.
[2]The HLA-Cw*12 primer set cannot separate the Cw*1209 and Cw*0516 alleles. These two alleles can be distinguished by the HLA-Cw low resolution and/or HLA-Cw*05 kits.

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RESOLUTION IN HOMO- AND HETEROZYGOTES

The twenty phenotypically different HLA-Cw*12 alleles give rise to 23 different amplification patterns and these can be combined in 327 homozygous and heterozygous combinations. Fifty-four of these genotypes do not give rise to unique amplification patterns. In these calculations the different sizes of the PCR products obtained by primer mixes 6, 8, 14, 15 and 16 have not been considered.

```
+++--+-- ++-+-+-- ------   1206,1216 = 1208,1211
+++--+-- ++-+---- ------   1202,1206 = 1203,1208 = 1206,1208
+++----- ++-+-+-- ------   1202,1211 = 1203,1216 = 1211,1216
++---+-- +--+---- ------   1202,1208 = 1208,1208
++------ +--++--- ------   1202,1210 = 1210,1210
++------ +--+---- -+----   1202,1217 = 1217,1217
++------ +--+---- --+-+-   1202,1218 = 1218,1218
+-+++-+- ++-+---- ------   1203,1205 = 120302,1205
+-+++-+- ++------ ------   120401,1205 = 120402,1205
+-++--+- ++-+---- ------   1203,120402 = 120302,120402
+-++--+- ++------ ------   120401,120402 = 120402,120402
+-+--+-- ++-+---- ------   1203,1206 = 120302,1206 = 1206,1206
+-+----+ ++-+--+- ------   1203,1215 = 120302,1215 = 1207,1212 =
                           1207,1215 = 1212,1215 = 1215,1215
+-+----+ ++-+---- ------   1203,1207 = 120302,1207 = 1207,1207
+-+----- ++-+-+-- ------   1203,1211 = 120302,1211 = 1211,1211
+-+----- ++-+--+- ------   1203,1212 = 120302,1212 = 1212,1212
+-+----- ++-+---+ ----+-   1203,1214 = 1213,1214 = 1213,1220
+-+----- ++-+---+ ------   1203,1213 = 120302,1213 = 1213,1213
+-+----- ++-+---- +-----   1203,120304 = 120302,120304
+-+----- ++-+---- ----+-   1203,1220 = 120302,1220
+-+----- ++-+---- ------   1203,1203 = 1203,120302

1202 = 120201-120203
1203 = 12030101-12030102, 120303, 120305-120306
```

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SPECIFICITY TABLE

HLA-Cw*12 SSP subtyping

Specificities and sizes of the PCR products of the 22 primer mixes used for HLA-Cw*12 SSP subtyping

Primer Mix	Size of spec. PCR product[1]	Size of control band[2]	Amplified HLA-Cw*12 alleles	Other amplified HLA Class I alleles[3]
1	235 bp	**800 bp**	120201-120402, 1206-1208, 1210-1215, 1217-1220	0212, 0315, 0327, 033801-033802, 0403, 0406, 0416, 0603, 0726, 0805, 1503, 1516, 1701-1704, **B*0713, B*0715, B*6702**
2[4,5]	100 bp	1070 bp	120201-120203, 1208, 1210, 1216-1218	0104, 0121
3	220 bp	**800 bp**	12030101-1207, 1211-1213, 1215	0104, 0109, 0205, 0217, 06020101-0603, 0607-0613, 0615-0618, 160401
4	340 bp	1070 bp	120401-1205, 1209, 1221	0114, 020201-020203, 020205-0211, 0213-0222, 0307, 0315, 0345, 04010101-040106, 0403-0410, 0412-0420, 0423-0428, 0430-0435, 050101-050104, 0503-0521, 06020101-0610, 0612-0618, 0707, 0709, 0749, 0810, 1404, 150201-1506, 1508-1513, 1515-1520, 1602, 1609, 1612, 1701-1704, 1801-1803
5[4,5]	130 bp	1070 bp	1205, 1209, 1221	020201-020203, 020205-0211, 0213-0222, 0410, 0411, 0436, 050101-050104, 0503-0521, 0605, 080101-0804, 0806-0819, 140203, 1403, 1408, 1410, 150201-

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				150204, 1504-1513, 1515, 1517-1521, 160101, 160103, 1602, 160401, 1606-1612
6[6]	150, 410 bp	1070 bp	1206, 1208	0308, 0329, 0331
7[4]	140 bp	**800 bp**	120402, 1205, 1209, 1221	020201-020203, 020205-0211, 0213-0222, 04010101-040106, 0403-0410, 0412-0420, 0423-0428, 0430-0435, 050101-050104, 0503-0521, 0605, 0810, 150201-1506, 1508-1513, 1515-1520, 1602, 1609, 1612
8[4,7]	95, 245 bp	1070 bp	1207, 1215	
9[4]	95 bp	1070 bp	120201-120402, 1206-1208, 1210-1220	0117, 0121, 0212, 0327, 033801-033802, 0433, 0707, 0716, 0751, 0805, 1404, 1503, 1516, 1701-1704, **B*0713, B*6702**
10	155 bp	1070 bp	12030101-12030102, 120303-120306, 120402-1207, 1211-1213, 1215, 1220	
11	220 bp	1070 bp	1209	010201-0103, 0106-0108, 0110-0120, 0516, 0605, 0606, 0812, 140201-1405, 1407N, 1410, 1411, **B*1403**
12[4]	140 bp	1070 bp	120201-120303, 120305, 120306, 1206-1208, 1210-1220	0121, 0212 weakly, 0411, 0429, 0436, 080101-0809, 0811-0819, 140203, 1403, 1408, 1410, 1507, 1521 weakly, 160101, 160103, 160401, 1606-1608, 1610, 1611, **B*350802, B*6702**
13	150 bp	1070 bp	1210	
14[4,8]	100, 145 bp	1070 bp	1211, 1216	0121, 0605 weakly, 0814, **B*6702**

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15[4,9]	95, 140 bp	**800 bp**	1212, 1215	**B*350802**
16[10]	185, 225 bp	1070 bp	1213, 1214	0807, 1701-1704
17	555 bp	1070 bp	120304	
18	240 bp	1070 bp	1217	
19[4]	105 bp	1070 bp	1218	
20	220 bp	1070 bp	1219	
21	250 bp	1070 bp	1214, 1218, 1220	0122, 0511, 0517, 0604, 080101-080102, 0803, 0804, 0806, 0808-0811, 0813, 0814, 0816, 1406, 150201-1507, 1509-1513, 1515-1521, 1701-1704, **B*5802**
22	580 bp	1070 bp	1221	

[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 HLA-Cw*12 high 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 length of the specific PCR product(s) of the alleles amplified by these primer mixes is 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 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*12 SSP subtyping.
In addition, wells number 3, 7 and 15 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.
[3]The HLA-Cw*12 primer set cannot separate the Cw*1209 and Cw*0516 alleles. These two alleles can be distinguished by the HLA-Cw low resolution and/or HLA-Cw*05 kits.
Due to the sharing of sequence motifs between HLA Class I alleles some non-HLA-Cw*12 alleles will be amplified by primer mixes 1 to 7, 9, 11, 12, 14 to 16 and 21. In addition, primer mix 1 amplifies the B*0713, B*0715 and B*6702 alleles, primer mix 9 amplifies the B*0713 and B*6702 alleles, primer mix 11 amplifies the B*1403 allele, primer mix 12 amplifies the B*350802 and B*6702 alleles, primer mix 14 amplifies the B*6702 allele, primer mix 15 amplifies the B*350802 allele and primer mix 21 amplifies the B*5802 allele.
[4]Specific PCR fragments shorter than 150 base pairs have a lower intensity and are less sharp than longer PCR bands.
[5]Primer mixes 2 and 5 have a tendency of giving rise to nonspecific amplifications.

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[6]Primer mix 6: Specific PCR fragment of 150 bp in the Cw*1206 allele. Specific PCR fragment of 410 bp in the Cw*1208 and Cw*0308, Cw*0329 and Cw*0331 alleles.
[7]Primer mix 8: Specific PCR fragment of 95 bp in the Cw*1215 allele. Specific PCR fragment of 245 bp in the Cw*1207 allele.
[8]Primer mix 14: Specific PCR fragment of 100 bp in the Cw*1216 and Cw*0121, Cw*0605, Cw*0814 and B*6702 alleles. Specific PCR fragment of 145 bp in the Cw*1211 allele.
[9]Primer mix 15: Specific PCR fragment of 95 bp in the Cw*1215 allele. Specific PCR fragment of 140 bp in the Cw*1212 and B*350802 alleles.
[10]Primer mix 16: Specific PCR fragment of 185 bp in the Cw*1213 allele. Specific PCR fragment of 225 bp in Cw*1214 and Cw*0807 and Cw*1701 to 1704 alleles.

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INTERPRETATION TABLE

HLA-Cw*12 SSP subtyping

Amplification patterns of the Cw*1202 to 1221 alleles

	Well[5]											
	1	2	3	4	5	6	7	8	9	10	11	12
Length of spec.	235	100	220	340	130	150	140	95	95	155	220	140
PCR product						410		245				
Length of int.	800	1070	800	1070	1070	1070	800	1070	1070	1070	1070	1070
pos. control[1]												
5'-primer(s)[2]	98	419	361	1st I	201	28	201	98	289	361	361	201
	5'-CTA3'	5'-gTC3'	5'-AgT3'	5'-CgA3'	5'-CCA3'	5'-TCA3'	5'-CCA3'	5'-CTA3'	5'-Agg3'	5'-AgT3'	5'-AgT3'	5'-CCA3'
						431		420				
						5'-CgT3'		5'-TTA3'				
3'-primer(s)[3]	289	477	538	302	289	270	302	301	341	474	538	302
	5'-AgC3'	5'-gCA3'	5'-CCA3'	5'-ggT3'	5'-AgT3'	5'-TAg3'	5'-ggT3'	5'-gCC3'	5'-Cgg3'	5'-gCA3'	5'-CCg3'	5'-ggC3'
	295					538		474				
	5'-TCC3'					5'-CCA3'		5'-gCA3'				
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
HLA-Cw allele[4]												
*120201-120203	1	2							9			12
*12030101-12030102, 120303, 120305-120306	1		3						9	10		12
*120302	1		3						9			12
*120304	1		3						9	10		
*120401	1		3	4					9			
*120402	1		3	4			7		9	10		
*1205			3	4	5		7			10		
*1206	1		3			6			9	10		12
*1207	1		3					8	9	10		12
*1208	1	2				6			9			12
*1209, 0516				4	5		7				11	
*1210	1	2							9			12
*1211	1		3						9	10		12
*1212	1		3						9	10		12
*1213	1		3						9	10		12
*1214	1								9			12
*1215	1		3					8	9	10		12
*1216		2							9			12
*1217	1	2							9			12
*1218	1	2							9			12
*1219	1								9			12
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

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INTERPRETATION TABLE

HLA-Cw*12 SSP subtyping

Amplification pattern of the Cw*1202 to 1219 alleles

Well[5]										
13	14	15	16	17	18	19	20	21	22	
150	100	95	185	555	240	105	220	250	580	Length of spec.
	145	140	225							PCR product
1070	1070	800	1070	1070	1070	1070	1070	1070	1070	Length of int.
										pos. control[1]
368	142	201	2nd I	201	98	477	361	2nd I	176	5'-primer(s)[2]
5'-gTT3'	5'-TCT3'	5'-CCA3'	5'-CCA3'	5'-CCg3'	5'-CTA3'	5'-gCT3'	5'-AgT3'	5'-CCA3'	5'-gCA3'	
	368	420								
	5'-gTC3'	5'-TTA3'								
477	201	299	473	474	295	539	538	539	474	3'-primer(s)[3]
5'-gCA3'	5'-CTT3'	5'-TCT3'	5'-CAA3'	5'-gCA3'	5'-TCC3'	5'-TCA3'	5'-gCA3'	5'-TCA3'	5'-gCA3'	
	474	474	512							
	5'-gCA3'	5'-gCA3'	5'-CCA3'							
13	14	15	16	17	18	19	20	21	22	Well No.
										HLA-Cw allele[4]
										*120201-120203
										*12030101-12030102, 120303, 120305-120306
										*120302
				17						*120304
										*120401
										*120402
										*1205
										*1206
										*1207
										*1208
										*1209, 0516
13										*1210
	14									*1211
		15								*1212
			16							*1213
			16					21		*1214
		15								*1215
	14									*1216
					18					*1217
						19		21		*1218
							20			*1219
13	14	15	16	17	18	19	20	21	22	Well No.

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Length of spec.	235	100	220	340	130	150	140	95	95	155	220	140
PCR product						410		245				
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
*1220	1								9	10		12
*1221				4	5		7					
*010201-0103, 0106-0108, 0110-0113, 0115, 0116, 0118-0120, 140201-140202, 140204, 1405, 1407N, 1411											11	
*0104		2	3									
*0109, 0611			3									
*0114, 0606				4							11	
*0117									9		11	
*0121		2							9			12
*0122, 1406												
*020201-020203, 020205-0204, 0206-0211, 0213-0216, 0218-0222, 0410, 050101-050104, 0503-0510, 0512-0515, 0518-0521, 1508, 1602, 1609, 1612				4	5		7					
*0205, 0217			3	4	5		7					
*0212	1								9			w
*0307, 0345, 0614, 0709, 0749, 1801-1803				4								
*0308, 0329, 0331						6						
*0315	1			4								
*0327, 033801-033802	1								9			
*04010101-040106,040401-0405, 0407-0409N, 0412-041502, 0417-0420, 0423-0428, 0430-0432, 0434, 0435				4			7					
*0403, 0406, 0416	1			4			7					
*0411, 0436, 0802, 0815, 0817-0819, 1408, 160101, 160103, 1606-1608, 1610, 1611					5							12
*0429												12
*0433				4			7		9			
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

Lot No.: 38F **Lot-specific information**

150	100	95	185	555	240	105	220	250	580	Length of spec.
	145	140	225							PCR product
13	14	15	16	17	18	19	20	21	22	Well No.
								21		*1220
									22	*1221
										*010201-0103, 0106-0108, 0110-0113, 0115, 0116, 0118-0120, 140201-140202, 140204, 1405, 1407N, 1411
										*0104
										*0109, 0611
										*0114, 0606
										*0117
	14									*0121
								21		*0122, 1406
										*020201-020203, 020205-0204, 0206-0211, 0213-0216, 0218-0222, 0410, 050101-050104, 0503-0510, 0512-0515, 0518-0521, 1508, 1602, 1609, 1612
										*0205, 0217
										*0212
										*0307, 0345, 0614, 0709, 0749, 1801-1803
										*0308, 0329, 0331
										*0315
										*0327, 033801-033802
										*04010101-040106,040401 0405, 0407-0409N, 0412-041502, 0417-0420, 0423-0428, 0430-0432. 0434, 0435
										*0403, 0406, 0416
										*0411, 0436, 0802, 0815, 0817-0819, 1408, 160101, 160103, 1606-1608, 1610, 1611
										*0429
										*0433
13	14	15	16	17	18	19	20	21	22	Well No.

Lot No.: 38F **Lot-specific information**

Length of spec.	235	100	220	340	130	150	140	95	95	155	220	140
PCR product						410		245				
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
*0511, 0517, 0810, 150201-150204, 1504-1506, 1509-1513, 1515, 1517-1520				4	5		7					
*06020101-060203, 0607-0610, 0612, 0613, 0615-0618			3	4								
*0603	1		3	4								
*0604				4								
*0605				4	5		7				11	
*0707				4					9			
*0716, 0751									9			
*0726	1											
*080101-080102, 0803, 0804, 0806, 0808, 0809, 0811, 0813, 0816, 1507					5							12
*0805	1								9			12
*0807					5							12
*0812, 140203, 1403, 1410					5						11	12
*0814					5							12
*1404				4					9		11	
*1503, 1516	1			4			7		9			
*1521					5							w
*160401			3		5							12
*1701-1704	1			4					9			
HLA-Cw allele[4]												
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
B*0713	1								9			
B*0715	1											
B*1403											11	
B*350802												12
B*5802												
B*6702	1								9			12
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

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150	100	95	185	555	240	105	220	250	580	Length of spec.
	145	140	225							PCR product
13	14	15	16	17	18	19	20	21	22	Well No.
								21		*0511, 0517, 0810, 150201 150204, 1504-1506, 1509-1513, 1515, 1517-1520
										*06020101-060203, 0607-0610, 0612, 0613, 0615-0618
										*0603
								21		*0604
	w									*0605
										*0707
										*0716, 0751
										*0726
								21		*080101-080102, 0803, 0804, 0806, 0808, 0809, 0811, 0813, 0816, 1507
										*0805
			16							*0807
										*0812, 140203, 1403, 1410
	14							21		*0814
										*1404
								21		*1503, 1516
								21		*1521
										*160401
			16					21		*1701-1704
										HLA-Cw allele[4]
13	14	15	16	17	18	19	20	21	22	Well No.
										B*0713
										B*0715
										B*1403
		15								B*350802
								21		B*5802
	14									B*6702
13	14	15	16	17	18	19	20	21	22	Well No.

Lot No.: 38F Lot-specific information

[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 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*12 SSP subtyping.
In addition, wells number 3, 7 and 15 contain the primer pair giving rise to the shorter, 800 bp, internal positive control band.
[2]The nucleotide position, in the 2nd or 3rd 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.
[3]The nucleotide position, in the 2nd or 3rd exon, matching the specificity-determining 3'-end of the primer is given in the anti-sense direction. Nuclotide numbering as on the www.ebi.ac.uk/imgt/hla web site. The sequence of the 3 terminal nucleotides of the primer is given.
[4]The HLA-Cw*1201 nucleotide sequence has been shown to be identical to Cw*120202.
The HLA-Cw*12 primer set cannot separate the Cw*1209 and Cw*0516 alleles. These two alleles can be distinguished by the HLA-Cw low resolution and/or HLA-Cw*05 kits.
[5]Primer mix 6: Specific PCR fragment of 150 bp in the Cw*1206 allele. Specific PCR fragment of 410 bp in the Cw*1208 and Cw*0308, Cw*0329 and Cw*0331 alleles.
Primer mix 8: Specific PCR fragment of 95 bp in the Cw*1215 allele. Specific PCR fragment of 245 bp in the Cw*1207 allele.
Primer mix 14: Specific PCR fragment of 100 bp in the Cw*1216 and Cw*0605, Cw*0121, Cw*0814 and B*6702 alleles. Specific PCR fragment of 145 bp in the Cw*1211 allele.
Primer mix 15: Specific PCR fragment of 95 bp in the Cw*1215 allele. Specific PCR fragment of 140 bp in the Cw*1212 and B*350802 alleles.
Primer mix 16: Specific PCR fragment of 185 bp in the Cw*1213 allele. Specific PCR fragment of 225 bp in Cw*1214 and Cw*0807 and Cw*1701 to 1704 alleles.
'w', might only be weakly amplified.

Lot No.: 38F **Lot-specific information**

CELL LINE VALIDATION SHEET

HLA-Cw*12 SSP primer set

					Well															
					1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
				Prod. No.:	200854101	200627602	200615303	200615304	200854105	200615306	200615307	200615308	200615309	200627610	200854111	200615312	200615313	200615314	200615315	200627616
	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	9067	BTB	*0102		-	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-
14	9071	OLGA	*0102	*0304	-	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-
15	9075	DKB	*0304		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
16	9037	SWEIG007	*0202		-	-	-	+	+	-	+	-	-	-	-	-	-	-	-	-
17	9008	WILJON	*1203		+	-	+	-	-	-	-	-	+	+	-	+	-	-	-	-
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	*1701	+	-	+	+	-	-	-	-	+	-	-	-	-	-	-	+
46	9013	SCHU	*0702		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
47	9045	TUBO	*0704	*1502	-	-	-	+	+	-	+	-	-	-	-	-	-	-	-	-
48	9303	TER-ND	*0401	*1601	-	-	-	+	+	-	+	-	-	-	-	+	-	-	-	-

Lot No.: 38F **Lot-specific information**

CELL LINE VALIDATION SHEET

HLA-Cw*12 SSP primer set

					Well					
					17	18	19	20	21	22
				Prod. No.:	200627617	200627618	200627619	200627620	200854121	200740722
	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	9067	BTB	*0102		-	-	-	-	-	-
14	9071	OLGA	*0102	*0304	-	-	-	-	-	-
15	9075	DKB	*0304		-	-	-	-	-	-
16	9037	SWEIG007	*0202		-	-	-	-	-	-
17	9008	WILJON	*1203		-	-	-	-	-	-
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	*1701	-	-	-	-	+	-
46	9013	SCHU	*0702		-	-	-	-	-	-
47	9045	TUBO	*0704	*1502	-	-	-	-	+	-
48	9303	TER-ND	*0401	*1601	-	-	-	-	-	-

Lot No.: 38F **Lot-specific information**

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-Cw*12 SSP

Product number: **101.624-12u – without *Taq* polymerase**
Lot number: **04E**
Expiry date: **2010-November-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	2008-541-01	9	2006-153-09	17	2006-276-17
2	2006-276-02	10	2006-276-10	18	2006-276-18
3	2006-153-03	11	2008-541-11	19	2006-276-19
4	2006-153-04	12	2006-153-12	20	2006-276-20
5	2008-541-05	13	2006-153-13	21	2008-541-21
6	2006-153-06	14	2006-153-14	22	2007-407-22
7	2006-153-07	15	2006-153-15		
8	2006-153-08	16	2006-276-16		

The specificity of each primer solution of the HLA-Cw*12 primer set has been tested against 48 well characterized IHWC cell line DNAs.

No DNAs carrying the alleles to be amplified by primer solutions 6, 8, 13 to 15, 17 to 20 and 22 were available. The specificities of the primers in primer solutions 13, 17, 19 and 22 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer solutions 6 and 14 it was only possible to test the two 3'-primers and one of the 5'-primers, one of the 5'-primers was not possible to test. In primer solutions 8 and 15 it was only possible to test the two 5'-primers and one of the 3'-primers, one of the 3'-primers was not possible to test.
In primer solutions 18 and 20 it was only possible to test the 5'-primer, the 3'-primer was not possible to test.

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

Date of approval: 2009-May-25

Approved by:

Quality Control, Supervisor

Lot No.: 38F **Lot-specific information**

Declaration of Conformity

Product name: *Olerup* SSP® HLA-Cw*12
Product number: 101.624-12u
Lot number: 38F

Intended use: HLA-Cw*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 III, 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.

Saltsjöbaden, Sweden
2009-May-25

Olle Olerup
Managing Director

Lot No.: 38F **Lot-specific information**

Lot No.: 38F **Lot-specific information**

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