

Olerup SSP® HLA-Cw*12

Product number:	101.624-12 – including <i>Taq</i> polymerase
Lot number:	75G
Expiry date:	2012-January-01
Number of tests:	12
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. 75G.

**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. 38F).

Two wells have been added to the HLA-Cw*12 kit,
wells **23 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
5	Modified	-	Modified 5'-primer to increase specificity.
18	Added	Added	Primer pair added for the Cw*1227 allele.
19	Added	Added	Primer pair added for the Cw*1225 allele.
20	Added	Added	Primer pair added for the Cw*1222 allele.
22	Added	Added	Primer pair added for the Cw*1223 allele and exchanged positive control primer pair.
23	New	New	New primer pair for the Cw*1226 allele.
24	New	New	New primer pair for the Cw*1228 allele.

PRODUCT DESCRIPTION

HLA-Cw*12 SSP typing

INTENDED USE

The primer set contains 5'- and 3'-primers for identifying the Cw*1202 to Cw*1228 alleles.

PLATE LAYOUT

Each HLA-Cw*12 test consists of twenty-four 10 µl 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 PCR plate is marked with 'HLA-Cw*12' in silver/gray ink.

Well No. 1 is marked with the Lot No. '75G'.

A faint row of numbers is seen between wells 1 and 2 or wells 7 and 8 of the PCR trays. These stem from the manufacture of the trays, and should be disregarded. The PCR plates are covered with a PCR-compatible foil.

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, 16, 18, 21 and 24 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, primer mix 19 amplifies the B*4029 and B*4432 alleles and primer mix 21 amplifies the B*5802 allele.

UNIQUELY IDENTIFIED ALLELES

All the HLA-Cw*12 alleles, i.e. **Cw*1202 to Cw*1228**, recognized by the HLA Nomenclature Committee in October 2009¹ will be amplified by the primers in the HLA-Cw*12 SSP kit².

The HLA-Cw*12 subtyping kit cannot distinguish the Cw*120201 to Cw*120203 alleles, the Cw*12030101, Cw*12030102, Cw*120303, Cw*120305 and Cw*120306 alleles or the Cw*120302 and Cw*120308 alleles.

¹HLA-Cw alleles listed on the IMGT/HLA web page 2009-October-19, release 2.27.0, www.ebi.ac.uk/imgt/hla.

² The HLA-Cw*12 primer set cannot separate the Cw*1209 and Cw*0516 alleles or the Cw*1216 and Cw*0121 alleles. These alleles can be distinguished by the HLA-Cw low resolution kit and the HLA-Cw*05 or HLA-Cw*01 kit, respectively.

RESOLUTION IN HOMO- AND HETEROZYGOTES

The twenty-seven phenotypically different HLA-Cw*12 alleles give rise to 31 different amplification patterns. These can be combined in 496 homozygous and heterozygous combinations. 142 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 to 16, 18, 20 and 22 have not been considered.

```

+++---+--- ++-+-+--- -----1206,1216 = 1208,1211
+++---+--- ++-+----- -+-----1206,1217 = 1206,1227
+++---+--- ++-+----- -----1202,1206 = 1203,1208 = 1206,1208
+++-----+ ++-+-+--- -+-----1215,1217 = 1215,1227
+++-----+ ++-+----- -+-----1207,1217 = 1207,1227
+++-----+ ++-+-+--- -+-----1211,1217 = 1211,1227
+++-----+ ++-+-+--- -----1202,1211 = 1203,1216 = 1211,1216
+++-----+ ++-+-+--- -+-----1212,1217 = 1212,1227
+++-----+ ++-+----- -+-----1213,1217 = 1213,1227
+++-----+ ++-+----- --+---+---1203,121402 = 1213,121402 =
                                     1213,1218 = 121402,1225
+++-----+ ++-+----- -+---+---1217,1225 = 1225,1227
+++-----+ ++-+----- -+---+---1217,1223 = 1223,1227
+++-----+ ++-+----- -+-----+1217,1228 = 1227,1228
+++-----+ ++-+----- -+-----1203,1217 = 1203,1227
+++-----+ ++-+----- --+---+---1203,1218 = 1218,1225
+++-----+ +-+-----+ -+-----+1217,1226 = 1226,1227
+++-----+ +-+-----+ -+-----120302,1217 = 120302,1227
+++---+--- +-+-----+ -+-----1208,1217 = 1208,1227
+++---+--- +-+-----+ ---+-----1208,1219 = 1208,1222
+++---+--- +-+-----+ -----1202,1208 = 1208,1208
+++-----+ ++++----- -+-----1217,1224 = 1224,1227
+++-----+ ++-+----- -+---+---1217,1220 = 1220,1227
+++-----+ +-+---+--- -+-----1210,1217 = 1210,1227
+++-----+ +-+---+--- ---+-----1210,1219 = 1210,1222
+++-----+ +-+---+--- -----1202,1210 = 1210,1210
+++-----+ +-+---+--- -+-----1216,1217 = 1216,1227
+++-----+ +-+---+--- ---+-----1216,1219 = 1216,1222
+++-----+ +-+---+--- -+---+---121402,1217 = 121402,1227
+++-----+ +-+---+--- -+---+---121401,1217 = 121401,1227
+++-----+ +-+---+--- ---++---121402,1219 = 121402,1222
+++-----+ +-+---+--- --+---+---1202,121402 = 121401,121402 =
                                     121401,1218 = 121402,121402 =
                                     121402,1218
+++-----+ +-+---+--- -+---+---1217,1218 = 1218,1227
+++-----+ +-+---+--- -+---+---1217,1219 = 1217,1222 = 1219,1227 =
                                     1222,1227
+++-----+ +-+---+--- -+-----1202,1217 = 1202,1227 = 1217,1217 =
                                     1217,1227
+++-----+ +-+---+--- ---++---1218,1219 = 1218,1222
+++-----+ +-+---+--- --+---+---1202,1218 = 1218,1218
+++-----+ +-+---+--- ---+-----1202,1219 = 1202,1222 = 1219,1222 =
                                     1222,1222
+-+++++--- +++++----- -----1203,1209 = 1205,1224

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Lot No.: **75G**

Lot-specific information

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+ - + + + - + -	+ + - + - - - -	- - - - - + - -	1203,1221 = 1205,1223 = 1221,1223
+ - + + + - + -	+ + - + - - - -	- - - - - - - -	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
+ - + - - - - -	+ + + + - - - -	- - - - - - - -	1203,1224 = 120302,1224
+ - + - - - - -	+ + - + - + - -	- - - - - - - -	1203,1211 = 120302,1211 = 1211,1211
+ - + - - - - -	+ + - + - - + -	- - - - - - - -	1203,1212 = 120302,1212 = 1212,1212
+ - + - - - - -	+ + - + - - - +	- - - - - + - -	1203,121401 = 1213,121401 =
			1213,1220
+ - + - - - - -	+ + - + - - - +	- - - - - - - -	1203,1213 = 120302,1213 = 1213,1213
+ - + - - - - -	+ + - + - - - -	+ - - - - - - -	1203,120304 = 120302,120304
+ - + - - - - -	+ + - + - - - -	- - + - - - - -	1203,1225 = 120302,1225 = 1225,1225
+ - + - - - - -	+ + - + - - - -	- - - - - + - -	1203,1220 = 120302,1220
+ - + - - - - -	+ + - + - - - -	- - - - - + - -	1203,1223 = 120302,1223 = 1223,1223
+ - + - - - - -	+ + - + - - - -	- - - - - - - +	1203,1228 = 120302,1228
+ - + - - - - -	+ + - + - - - -	- - - - - - - -	1203,1203 = 1203,120302
+ - + - - - - -	+ - - + - - - -	- - - - - - - +	120302,1226 = 1226,1226

1202 = 120201-120203

1203 = 12030101-12030102, 120303, 120305-120307

120302 = 120302, 120308

SPECIFICITY TABLE

HLA-Cw*12 SSP subtyping

Specificities and sizes of the PCR products of the 24 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
1⁵	235 bp	800 bp	*120201-120402, 1206-1208, 1210-1215, 1217-1220, 1222-1228	*0212, 0315, 0327, 033801, 033802, 0353, 0369, 0403, 0406, 0416, 0603, 0726, 0805, 0821, 0825, 1503, 1516, 1615, 17010101-1705, B*0713, B*0715, B*6702
2^{4,6}	100 bp	1070 bp	*120201-120203, 1208, 1210, 121402, 1216-1218, 1222, 1227	*0104, 0121
3	220 bp	800 bp	*12030101-1207, 1211-1213, 1215, 1223, 1225, 1226, 1228	*0104, 0109, 0205, 0217, 06020101, 06020102, 060203-0603, 0607-0613, 0615-0628, 160401
4	340 bp	1070 bp	*120401-1205, 1209, 1221	*0114, 020201-020203, 020205-0211, 0213-0226, 0228-0231, 0307, 0315, 0345, 04010101-040112, 0403-0410, 0412-0420, 0423-0428, 0430-0435, 0437-0448, 05010101-050110, 0503-0530, 06020101, 06020102, 060203-0610, 0612-0628, 0707, 0709, 0749, 0776, 0810, 1404, 1412, 150201-1506, 1508-1513, 1515-1520, 1522, 1523, 1602, 1609, 1612, 17010101-1705, 1801-1803
5⁴	130 bp	1070 bp	*1205, 1209, 1221	*020201-020203, 020205-020207, 0203-0211, 0213-0231, 0410, 0411, 0436, 05010101-050110, 0503-0530, 0605, 080101-0804,

Lot No.: **75G**

Lot-specific information

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				0806-0820, 0822-0824, 0826N-0829, 140203, 1403, 1408, 1410, 150201- 150204, 1504-1513, 1515, 1517-1523, 160101, 160103, 1602, 160401, 1606-1614, 1616, 1617
6⁸	150 bp, 415 bp	1070 bp	*1206, 1208	*0308, 0329, 0331
7⁴	140 bp	800 bp	*120402, 1205, 1209, 1221	*020201-020203, 020205- 020207, 0203-0211, 0213- 0226, 0228-0231, 04010101-040109, 040111, 040112, 0403-0410, 0412- 0420, 0423-0428, 0430- 0435, 0437-0448, 05010101-050110, 0503- 0530, 0605, 0810, 150201- 1506, 1508-1513, 1515- 1520, 1522, 1523, 1602, 1609, 1612
8^{4,9}	95 bp, 245 bp	1070 bp	*1207, 1215	
9⁴	95 bp	1070 bp	*120201- 120402, 1206- 1208, 1210- 1220, 1222- 1227	*0117, 0121, 0212, 0327, 033801, 033802, 0433, 0707, 0716, 0751, 0805, 0821, 0825, 1404, 1503, 1516, 1615, 17010101- 1705, B*0713, B*6702
10	155 bp	1070 bp	*12030101, 12030102, 120303-120307, 120402-1207, 1211-1213, 1215, 1220, 1223-1225, 1228	
11	220 bp	1070 bp	*1209, 1224	*010201-0103, 0106-0108, 0110-0120, 0123-0133, 0358, 0437, 0516, 0605, 0606, 0812, 140201-1405, 1407N, 1410-1414, B*1403
12⁴	140 bp	1070 bp	*120201- 120303, 120305-120308,	*0121, 0212 ^w , 0227, 0411, 0429, 0436, 070209, 080101-0809, 0811-0829,

			1206-1208, 1210-1220, 1222-1226, 1228	140203, 1403, 1408, 1410, 1507, 1521 ^w , 160101, 160103, 160401, 1606- 1608, 1610, 1611, 1613- 1617, B*350802, B*6702
13	150 bp	1070 bp	*1210	
14 ^{4,10}	100 bp, 145 bp	1070 bp	*1211, 1216	*0121, 0605 ^w , 070209, 0814, B*6702
15 ^{4,7,11}	95 bp, 140 bp	800 bp	*1212, 1215	B*350802
16 ¹²	185 bp, 225 bp	1070 bp	*1213-121402	*0523, 0807, 17010101- 1705
17	555 bp	1070 bp	*120304	
18 ^{4,13}	140 bp, 245 bp	1070 bp	*1217, 1227	*0353, 0412
19 ⁴	100 bp	1070 bp	*121402, 1218, 1225	B*4029, B*4432
20 ¹⁴	170 bp, 220 bp	1070 bp	*1219, 1222	
21	250 bp	1070 bp	*121401, 121402, 1218, 1220	*0122, 0511, 0517, 0527, 0604, 080101, 080102, 080301-0804, 0806, 0808- 0811, 0813, 0814, 0816, 0820-0822, 0824, 0826N, 1406, 150201-1507, 1509- 1513, 1515-1523, 17010101-1705, B*5802
22 ^{4,15}	110 bp, 580 bp	800 bp	*1221, 1223	
23	150 bp	1070 bp	*1226	
24	425 bp	1070 bp	*1228	*040105

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*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 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*12 SSP subtyping.

In addition, wells number 3, 7, 15 and 22 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.

³The HLA-Cw*12 primer set cannot separate the Cw*1209 and Cw*0516 alleles or the Cw*1216 and Cw*0121 alleles. These alleles can be distinguished by the HLA-Cw low resolution kit and the HLA-Cw*05 or HLA-Cw*01 kit, respectively.

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, 16, 18, 21 and 24. 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, primer mix 19 amplifies the B*4029 and B*4432 alleles and primer mix 21 amplifies the B*5802 allele.

⁴Specific PCR fragments shorter than 150 base pairs have a lower intensity and are less sharp than longer PCR bands.

⁵Primer mix 1 may yield less specific PCR products than the other Cw*12 primer mixes.

⁶Primer mixes 2 has a tendency of giving rise to nonspecific amplifications.

⁷Primer mix 15 may give rise to a long unspecific amplification product. This band should be disregarded when interpreting the typing results.

⁸Primer mix 6: Specific PCR fragment of 150 bp in the Cw*1206 allele. Specific PCR fragment of 415 bp in the Cw*1208 and Cw*0308, Cw*0329 and Cw*0331 alleles.

⁹Primer mix 8: Specific PCR fragment of 95 bp in the Cw*1215 allele. Specific PCR fragment of 245 bp in the Cw*1207 allele.

¹⁰Primer mix 14: Specific PCR fragment of 100 bp in the Cw*1216 and Cw*0121, Cw*0605^w, Cw*070209, Cw*0814 and B*6702 alleles. Specific PCR fragment of 145 bp in the Cw*1211 allele.

¹¹Primer 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.

¹²Primer mix 16: Specific PCR fragment of 185 bp in the Cw*1213 allele. Specific PCR fragment of 225 bp in Cw*121401 and Cw*121402 and the Cw*0523, Cw*0807 and Cw*17010101-1705 alleles.

¹³Primer mix 18: Specific PCR fragment of 140 bp in the Cw*0412 allele. Specific PCR fragment of 245 bp in Cw*0353 allele. Specific PCR fragments of 140 bp and 245 bp in the Cw*1217 and Cw*1227 alleles

¹⁴Primer mix 20: Specific PCR fragment of 170 bp in the Cw*1222 allele. Specific PCR fragment of 220 bp in Cw*1219 allele.

¹⁵Primer mix 22: Specific PCR fragment of 110 bp in the 1223 allele. Specific PCR fragments of 110 bp and 580 bp in Cw* 1221 allele.

^w, might be weakly amplified.

INTERPRETATION TABLE

HLA-Cw*12 SSP subtyping

Amplification patterns of the Cw*1202 to 1228 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						415		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	1 st	201	28	201	98	289	361	361	201
	5' -CTA 3'	5' -gTC 3'	5' -AgT 3'	5' -CgA 3'	5' -CCA 3'	5' -TCA 3'	5' -CCA 3'	5' -CTA 3'	5' -Agg 3'	5' -AgT 3'	5' -AgT 3'	5' -CCA 3'
						431		420				
						5' -CgT 3'		5' -TTA 3'				
3'-primer(s) ³	289	477	538	302	289	270	302	301	341	474	538	302
	5' -AgC 3'	5' -gCA 3'	5' -CCA 3'	5' -ggT 3'	5' -AgT 3'	5' -TAG 3'	5' -ggT 3'	5' -gCC 3'	5' -Cgg 3'	5' -gCA 3'	5' -CCg 3'	5' -ggC 3'
	289				289	538		474				
	5' -AgC 3'				5' -AgT 3'	5' -CCA 3'		5' -gCA 3'				
	295											
	5' -TCC 3'											
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, 120305-120307	1		3						9	10		12
*120302, 120308	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
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

CE

Lot No.: **75G**

Lot-specific information

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Length of spec.	235	100	220	340	130	150	140	95	95	155	220	140
PCR product						415		245				
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
*1212	1		3						9	10		12
*1213	1		3						9	10		12
*121401	1								9			12
*121402	1	2							9			12
*1215	1		3					8	9	10		12
*1216, 0121		2							9			12
*1217	1	2							9			12
*1218	1	2							9			12
*1219	1								9			12
*1220	1								9	10		12
*1221				4	5		7					
*1222	1	2							9			12
*1223	1		3						9	10		12
*1224	1								9	10	11	12
*1225	1		3						9	10		12
*1226	1		3						9			12
*1227	1	2							9			
*1228	1		3							10		12
*010201-0103, 0106-0108, 0110-0113, 0115, 0116, 0118-0120, 0123-0133, 0358, 140201, 140202, 140204, 1405, 1407N, 1411, 1413, 1414, <i>B*1403</i>											11	
*0104		2	3									
*0109, 0611			3									
*0114, 0606, 1412				4							11	
*0117									9		11	
*0122, 1406, <i>B*5802</i>												
*020201-020203, 020205- 020207, 0203, 0204, 0206- 0211, 0213-021602, 0218- 0226, 0228-0231, 0410, 05010101-050110, 0503- 0510, 0512-0515, 0518- 0522, 0524-0526, 0528- 0530, 1508, 1602, 1609, 1612				4	5		7					
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

Lot No.: **75G**

Lot-specific information

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150	100	95	185	555	140	100	170	250	110	150	425	Length of spec.
	145	140	225		245		220		580			PCR product
13	14	15	16	17	18	19	20	21	22	23	24	Well No.
		15										*1212
			16									*1213
			16					21				*121401
			16			19		21				*121402
		15										*1215
	14											*1216, 0121
					18							*1217
						19		21				*1218
							20					*1219
								21				*1220
									22			*1221
							20					*1222
									22			*1223
												*1224
						19						*1225
										23		*1226
					18							*1227
											24	*1228
												*010201-0103, 0106-0108, 0110-0113, 0115, 0116, 0118-0120, 0123-0133, 0358, 140201, 140202, 140204, 1405, 1407N, 1411, 1413, 1414, B*1403
												*0104
												*0109, 0611
												*0114, 0606, 1412
												*0117
								21				*0122, 1406, B*5802
												*020201-020203, 020205- 020207, 0203, 0204, 0206- 0211, 0213-021602, 0218- 0226, 0228-0231, 0410, 05010101-050110, 0503- 0510, 0512-0515, 0518- 0522, 0524-0526, 0528- 0530, 1508, 1602, 1609, 1612
13	14	15	16	17	18	19	20	21	22	23	24	Well No.

Lot No.: **75G**

Lot-specific information

www.olerup-ssp.com

Length of spec.	235	100	220	340	130	150	140	95	95	155	220	140
PCR product						415		245				
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
*020208, 0307, 0345, 040110, 0614, 0709, 0749, 0776, 1801-1803				4								
*0205, 0217			3	4	5		7					
*0212	1								9			w
*0227, 0411, 0436, 080201, 080202, 0815, 0817-0819, 0823, 0827-0829, 1408, 160101, 160103, 1606- 1608, 1610, 1611, 1613, 1614, 1616, 1617					5							12
*0308, 0329, 0331						6						
*0315	1			4								
*0327, 033801, 033802, B*0713	1								9			
*0353	1											
*0369, 0726, B*0715	1											
*04010101-040104, 040106- 040109, 040111, 040112, 040401-0405, 0407-0409N, 0413-041502, 0417-0420, 0423-0428, 0430-0432, 0434, 0435, 0438-0448				4			7					
*040105				4			7					
*0403, 0406, 0416	1			4			7					
*0412				4			7					
*0429												12
*0433				4			7		9			
*0437				4			7				11	
*0511, 0517, 0527, 0810, 150201-150204, 1504- 1506, 1509-1513, 1515, 1517-1520, 1522, 1523				4	5		7					
*0523				4	5		7					
*06020101, 06020102, 060203-060205, 0607- 0610, 0612, 0613, 0615- 0628			3	4								
*0603	1		3	4								
*0604				4								
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

Lot No.: **75G**

Lot-specific information

www.olerup-ssp.com

150	100	95	185	555	140	100	170	250	110	150	425	Length of spec.
	145	140	225		245		220		580			PCR product
13	14	15	16	17	18	19	20	21	22	23	24	Well No.
												*020208, 0307, 0345, 040110, 0614, 0709, 0749, 0776, 1801-1803
												*0205, 0217
												*0212
												*0227, 0411, 0436, 080201, 080202, 0815, 0817-0819, 0823, 0827-0829, 1408, 160101, 160103, 1606- 1608, 1610, 1611, 1613, 1614, 1616, 1617
												*0308, 0329, 0331
												*0315
												*0327, 033801, 033802, <i>B</i> *0713
					18							*0353
												*0369, 0726, <i>B</i> *0715
												*04010101-040104, 040106- 040109, 040111, 040112, 040401-0405, 0407-0409N, 0413-041502, 0417-0420, 0423-0428, 0430-0432, 0434, 0435, 0438-0448
											24	*040105
												*0403, 0406, 0416
					18							*0412
												*0429
												*0433
												*0437
								21				*0511, 0517, 0527, 0810, 150201-150204, 1504- 1506, 1509-1513, 1515, 1517-1520, 1522, 1523
			16									*0523
												*06020101, 06020102, 060203-060205, 0607- 0610, 0612, 0613, 0615- 0628
												*0603
								21				*0604
13	14	15	16	17	18	19	20	21	22	23	24	Well No.

Length of spec.	235	100	220	340	130	150	140	95	95	155	220	140
PCR product						415		245				
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
*0605				4	5		7				11	
*070209												12
*0707				4					9			
*0716, 0751									9			
*080101, 080102, 080301-0804, 0806, 0808, 0809, 0811, 0813, 0816, 0820, 0822, 0824, 0826N, 1507					5							12
*0805, 0825, 1615	1								9			12
*0807					5							12
*0812, 140203, 1403, 1410					5						11	12
*0814					5							12
*0821	1								9			12
*1404				4					9		11	
*1503, 1516	1			4			7		9			
*1521					5							w
*160401			3		5							12
*17010101-1705	1			4					9			
HLA-Cw allele ⁴												
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
<i>B*350802</i>												12
<i>B*4029, B*4432</i>												
<i>B*6702</i>	1								9			12
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

¹The internal positive control primer pairs amplify segments of the human growth hormone gene. The two different control primer pairs give rise to either an internal positive control band of 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, 15 and 22 contain the primer pair giving rise to the shorter, 800 bp, internal positive control band.

²The nucleotide position, in the 2nd or 3rd exon or the 1st, 2nd or 3rd 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, 3rd or 4th 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.

⁴The 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 or the Cw*1216 and Cw*0121 alleles. These alleles can be distinguished by the HLA-Cw low resolution kit and the HLA-Cw*05 or HLA-Cw*01 kit, respectively.

Lot No.: **75G**

Lot-specific information

www.olerup-ssp.com

150	100	95	185	555	140	100	170	250	110	150	425	Length of spec.
	145	140	225		245		220		580			PCR product
13	14	15	16	17	18	19	20	21	22	23	24	Well No.
	w											*0605
	14											*070209
												*0707
												*0716, 0751
								21				*080101, 080102, 080301- 0804, 0806, 0808, 0809, 0811, 0813, 0816, 0820, 0822, 0824, 0826N, 1507
												*0805, 0825, 1615
			16									*0807
												*0812, 140203, 1403, 1410
	14							21				*0814
								21				*0821
												*1404
								21				*1503, 1516
								21				*1521
												*160401
			16					21				*17010101-1705
												HLA-Cw allele ⁴
13	14	15	16	17	18	19	20	21	22			Well No.
		15										B*350802
						19						B*4029, B*4432
	14											B*6702
13	14	15	16	17	18	19	20	21	22			Well No.

⁵Primer mix 6: Specific PCR fragment of 150 bp in the Cw*1206 allele. Specific PCR fragment of 415 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*0121, Cw*0605^w, Cw*070209, 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*121401 and Cw*121402 and the Cw*0523, Cw*0807 and Cw*17010101-1705 alleles.

Primer mix 18: Specific PCR fragment of 140 bp in the Cw*0412 allele. Specific PCR fragment of 245 bp in Cw*0353 allele. Specific PCR fragments of 140 bp and 245 bp in the Cw*1217 and Cw*1227 alleles

Primer mix 20: Specific PCR fragment of 170 bp in the Cw*1222 allele. Specific PCR fragment of 220 bp in Cw*1219 allele.

Primer mix 22: Specific PCR fragment of 110 bp in the 1223 allele. Specific PCR fragments of 110 bp and 580 bp in Cw* 1221 allele.

^w, might be weakly amplified.

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.:	200968401	200968402	200968403	200968404	200968405	200968406	200968407	200968408	200968409	200968410	200968411	200968412	200968413	200968414	200968415	200968416
	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	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	*1701	+	-	+	+	-	-	-	-	+	-	-	-	-	-	-	+
46	9013	SCHU	*0702		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
47	9045	TUBO	*0704	*1502	-	-	-	+	+	-	+	-	-	-	-	-	-	-	-	-
48	9303	TER-ND	*0401	*1601	-	-	-	+	+	-	+	-	-	-	-	+	-	-	-	-

CELL LINE VALIDATION SHEET													
HLA-Cw*12 SSP primer set													
					Prod. No.:	Well							
						17	18	19	20	21	22	23	24
						200968417	200968418	200968419	200968420	200968421	200968422	200968423	200968424
	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		*1701	-	-	-	-	+	-	-	-
46	9013	SCHU	*0702			-	-	-	-	-	-	-	-
47	9045	TUBO	*0704		*1502	-	-	-	-	+	-	-	-
48	9303	TER-ND	*0401		*1601	-	-	-	-	-	-	-	-

CERTIFICATE OF ANALYSIS**Olerup SSP® HLA-Cw*12 SSP**

Product number: 101.624-12 – including *Taq* polymerase
Lot number: 75G
Expiry date: 2012-January-01
Number of tests: 12
Number of wells per test: 24

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2009-684-01	9	2009-684-09	17	2009-684-17
2	2009-684-02	10	2009-684-10	18	2009-684-18
3	2009-684-03	11	2009-684-11	19	2009-684-19
4	2009-684-04	12	2009-684-12	20	2009-684-20
5	2009-684-05	13	2009-684-13	21	2009-684-21
6	2009-684-06	14	2009-684-14	22	2009-684-22
7	2009-684-07	15	2009-684-15	23	2009-684-23
8	2009-684-08	16	2009-684-16	24	2009-684-24

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 to 24 were available. The specificities of the primers in primer solutions 6, 8, 13 to 15, 17, 19, 22 and 24 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer.

In primer solutions 18, 20 and 23 it was only possible to test the 5'-primer, the 3'-primer was not possible to test. In primer solutions 6, 14 and 19 one 5'-primer was not possible to test, and in primer solutions 8, 16 and 22 one 3'-primer was not possible to test.

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

Date of approval: 2010-February-05

Approved by:

Quality Control, Supervisor

Declaration of Conformity

Product name: *Olerup* SSP® HLA-Cw*12
Product number: 101.624-12
Lot number: 75G

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 9001:2008 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
2010-February-05

Olle Olerup
Managing Director



Lot No.: **75G**

Lot-specific information

www.olerup-ssp.com

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