

Olerup SSP[®] HLA-Cw*02

Product number:	101.622-12 – including <i>Taq</i> polymerase 101.622-12u – without <i>Taq</i> polymerase
Lot number:	12E
Expiry date:	2010-January-01
Number of tests:	12
Number of wells per test:	16
Storage - pre-aliquoted primers:	dark at -20°C
- PCR Master Mix:	-20°C
- Adhesive PCR seals	RT
- Product Insert	RT

This Product Description is only valid for Lot No. 12E.

CHANGES COMPARED TO THE PREVIOUS **OLERUP SSP[®]** **HLA-Cw*02** LOT

The HLA-Cw*02 specificity and interpretation tables have been updated for the HLA-Cw alleles described since the previous *Olerup SSP[®]* HLA-Cw*02 lot was made (**Lot No. X08**).

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

Well	5'-primer	3'-primer	rationale
3	-	Added	Primer added for the Cw*0220 allele.
6	Added	-	Primer added for the Cw*0219 allele.
8	Modified	-	Primer modified in order to decrease primer dimer formation tendency.
11	-	Added	Primer added for the Cw*0218 allele.
12	Added	-	Primer added for the Cw*0217 allele.
14	Exchanged	-	Primer exchanged for a more specific primer pair.

Changes in revision R01 compared to R00:

1. The Cw*160401 allele is not amplified by primer mix 14, corrected in the Specificity and Interpretation Tables.

PRODUCT DESCRIPTION

HLA-Cw*02 SSP typing

INTENDED USE

The primer set contains 5'- and 3'-primers for identifying the Cw*0202 to Cw*0220 alleles.

PLATE LAYOUT

Each HLA-Cw*02 test consists of sixteen 10 µl PCR reactions in a 16 well cut PCR plate.

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

The 16 well PCR plate is marked with 'Cw*02'.

Well No. 1 is marked with the Lot No. '12E'.

The PCR plates are heat-sealed with a PCR-compatible foil.

Please note: When removing each 16 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*02 SSP subtypings will be influenced by other HLA-Cw alleles, as primer mixes 1, 5 to 8, 10, 12 and 16 amplify non-HLA-Cw*02 alleles. In addition, primer mix 3 will amplify the B*2734, the B*400602 and also weakly the B*570302 allele. In addition, primer mix 3 will amplify the B*2734 and B*400602 alleles and also weakly the B*570302 allele. Primer mix 16 will amplify the B*5802 allele.

UNIQUELY IDENTIFIED ALLELES

All the HLA-Cw*02 alleles, i.e. **Cw*0202 to Cw*0220**, recognized by the HLA Nomenclature Committee in January 2008¹ will be amplified by the primers in the HLA-Cw*02 SSP kit.

The HLA-Cw*02 subtyping kit cannot distinguish the Cw*020201 to Cw*020203 and Cw*020206 alleles.

¹HLA-Cw alleles listed on the IMGT/HLA web page 2008-January-11, release 2.20.0, www.ebi.ac.uk/imgt/hla.

RESOLUTION IN HOMO- AND HETEROZYGOTES

The 19 phenotypically different HLA-Cw*02 alleles give rise to 20 different amplification patterns that can be combined in 210 homozygous and heterozygous combinations. 115 of these genotypes do not give rise to unique amplification patterns. The different lengths of the specific PCR products generated by primer mixes 3, 11 and 12 were not considered in these calculations.

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Lot-specific information

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+++---+--	++-----	0206,0220 = 0219,0220
+++-----	+++-----+	0202,0218 = 0203,0209 = 0209,0218 = 0218,0220
+++-----	++-+-----	0211,0220 = 0214,0220
+++-----	++-----+	0202,0203 = 0203,0220 = 0216,0220
+++-----	++-----	0202,0220 = 020205,0220 = 0210,0220 = 0220,0220
++-+---+--	++-----	0204,0206 = 0204,0219
++-+-----	++-+-----	0204,0211 = 0204,0214
++-+-----	++-----	0202,0204 = 020205,0204 = 0204,0204 = 0204,0210
++-+---+--	++-+-----	0202,0217 = 0205,0211 = 0211,0217
++-+---+-	++-----	0206,0207 = 0207,0219
++-+---+-	++-----	0206,0208 = 0208,0219
++-+---+-	+++-----	0206,0209 = 0209,0219
++-+---+-	++-+-----	0206,0211 = 0211,0219 = 0214,0219
++-+---+-	++-+---+-	0206,0213 = 0213,0219
++-+---+-	++-+---+-	0206,0215 = 0215,0219
++-+---+-	++-----	0202,0206 = 0202,0219 = 020205,0219 = 0206,0219 = 0210,0219 = 0219,0219
++-+---+-	++-+-----	0207,0211 = 0207,0214
++-+---+-	++-----	0202,0207 = 020205,0207 = 0207,0207 = 0207,0210
++-+---+-	++-+-----	0208,0211 = 0208,0214
++-+---+-	++-----	0202,0208 = 020205,0208 = 0208,0208 = 0208,0210
++-+---+-	++++-----	0209,0211 = 0209,0214
++-+---+-	+++-----	0202,0209 = 020205,0209 = 0209,0209 = 0209,0210
++-+---+-	++-+---+-	0211,0213 = 0213,0214
++-+---+-	++-+---+-	0211,0215 = 0214,0215
++-+---+-	++-+---+-	0202,0211 = 0202,0214 = 020205,0211 = 0210,0211 = 0211,0211 = 0211,0214
++-+---+-	++-+---+-	0202,0213 = 020205,0213 = 0210,0213 = 0213,0213
++-+---+-	++-+---+-	0202,0215 = 020205,0215 = 0210,0215 = 0215,0215
++-+---+-	++-----	0202,0202 = 0202,020205 = 0202,0210
+-+-----	+++-----+	020205,0218 = 0210,0218
+-+-----	+++-----+	020205,0203 = 0203,0210
+-+-----	++-+-----	020205,0217 = 0205,0214 = 0205,0217 = 0210,0217 = 0214,0217 = 0217,0217
+-----+--	++-----	020205,0205 = 0205,0205 = 0205,0210
+-----+--	++-----	020205,0206 = 0206,0206 = 0206,0210
+-----+--	++-+-----	020205,0214 = 0210,0214 = 0214,0214
+-----+--	++-+-----	020205,0212 = 0210,0212 = 0212,0212
+-----+--	++-----+	020205,0216 = 0210,0216
+-----+--	++-----	020205,020205 = 020205,0210
--+-----	+++-----+	0203,0218 = 0216,0218 = 0218,0218
--+-----	++-+-----	0203,0203 = 0203,0216

(0201 = 020201-020203 and 020206)

SPECIFICITY TABLE

HLA-Cw*02 SSP subtyping

Specificities and sizes of the PCR products of the 16 primer mixes used for HLA-Cw*02 SSP subtyping

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified HLA-Cw*02 alleles	Other amplified HLA-Cw alleles ³
1	250 bp	800 bp	020201-020203, 020205-020206, 0204-0215, 0217, 0219, 0220	0104, 0109, 0508, 06020101-0603, 0607-0616N, 120201-1208, 1210-1213, 1215-1217, 1221, 160401, 1803
2 ⁴	95 bp	800 bp	020201-020203, 020206, 0204, 0207-0209, 0211, 0213, 0215, 0219, 0220	
3 ^{4,6}	95, 135 bp	800 bp	0203, 0218, 0220	B*2734, B*400602, B*570302^{weakly}
4	150 bp	1070 bp	0204	
5	240 bp	1070 bp	0205, 0217	0110, 0608
6	160 bp	800 bp	0206, 0219	0109, 0321, 1215
7 ⁴	130 bp	800 bp	0207	1610
8 ^{4,5}	70 bp	1070 bp	0208	151002
9	200 bp	1070 bp	020201-020203, 020205-0209, 0211-0220	
10 ⁴	125 bp	1070 bp	020201-020203, 020205-0220	0403, 0406, 1511
11 ^{4,7}	80, 170 bp	1070 bp	0209, 0218	
12 ⁸	150, 230 bp	1070 bp	0211, 0214, 0217	0605 ^{weakly} , 1216
13	225 bp	1070 bp	0212	
14 ⁴	80 bp	800 bp	0213	
15	190 bp	1070 bp	0215	
16	230bp	1070 bp	0203, 0216, 0218	040401-040402, 0406, 0413, 0511, 0517, 0604, 080101-080102, 0803, 0804, 0806, 0808-0811, 0813,

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0814, 1214, 1218,
1220, 1406,
150201-1507,
1509-1513, 1515-
1521, 1701-1704,
B*5802

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 DR 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 length of the specific PCR product(s) of the alleles amplified by these primer mixes are given.

Nonspecific amplifications, i.e. a ladder or a smear of bands, may sometimes be seen. GC-rich primers have a higher tendency of giving rise to nonspecific amplifications than other primers.

PCR fragments longer than the control bands may sometimes be observed. Such bands should be disregarded and do not influence the interpretation of the SSP typings.

PCR fragments migrating faster than the control bands, but slower than a 400 bp fragment may be seen in some gel read-outs. Such bands can be disregarded and do not influence the interpretation of the SSP typings.

Some primers may give rise to primer oligomer artifacts. Sometimes this phenomenon is an 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.

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 tubes, or a band of 800 base pairs, for some tubes.

Tube 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*02 SSP subtyping.

In addition, tubes number 2, 3, 6, 7 and 14 contain the primer pair giving rise to the shorter, 800 bp, internal positive control band.

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

³ Due to the sharing of sequence motifs between HLA Class I alleles some non-HLA-Cw*02 alleles will be amplified by primer mixes 1, 5 to 8, 10, 12 and 16. In addition, the B*2734 and the B*400602 and B*570302^{weakly} alleles will be amplified by primer mix 3 and the B*5802 allele by primer mix 16.

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

⁵ Primer mix 8 has a tendency of primer oligomer formation.

⁶ Primer mix 3: Specific PCR fragment of 95 bp in the Cw*0203 and Cw*0218 and the B*2734, B*400602 and B*570302^{weakly} alleles. Specific PCR fragment of 135 bp in the Cw*0220 allele.

⁷ Primer mix 11: Specific PCR fragment of 80 bp in the Cw*0218 allele. Specific PCR fragment of 170 bp in the Cw*0209 allele.

⁸ Primer mix 12: Specific PCR fragment of 150 bp in the Cw*0211, and Cw*0214 and the Cw*0605^{weakly} and Cw*1216 alleles. Specific PCR fragment of 230 bp in the Cw*0217 allele.

INTERPRETATION TABLE								
HLA-Cw*02 SSP subtyping								
Amplification patterns for the HLA-Cw*0202 to 0220 alleles								
	Well⁵							
	1	2	3	4	5	6	7	8
Length of spec.	250	95	95	150	240	160	130	70
PCR product			135					
Length of int.	800	800	800	1070	1070	800	800	1070
pos. control¹								
5'-primer(s)²	2nd I	486	486	92	361	419	2nd I	105
	^{5'} -CCA ^{3'}	^{5'} -ACA ^{3'}	^{5'} -ACA ^{3'}	^{5'} -gTg ^{3'}	^{5'} -AgT ^{3'}	^{5'} -gTA ^{3'}	^{5'} -CCA ^{3'}	^{5'} -gCT ^{3'}
						420		
						^{5'} -TTA ^{3'}		
3'-primer(s)³	538	538	538	201	559	538	418	134
	^{5'} -CCA ^{3'}	^{5'} -CCA ^{3'}	^{5'} -CAg ^{3'}	^{5'} -CTT ^{3'}	^{5'} -CTC ^{3'}	^{5'} -CCA ^{3'}	^{5'} -gTC ^{3'}	^{5'} -AgC ^{3'}
			578					
			^{5'} -TgT ^{3'}					
Well No.	1	2	3	4	5	6	7	8
HLA-Cw allele⁴								
*020201-020203, 020206	1	2						
*020205	1							
*0203			3					
*0204	1	2		4				
*0205	1				5			
*0206	1					6		
*0207	1	2					7	
*0208	1	2						8
*0209	1	2						
*0210	1							
*0211	1	2						
*0212	1							
*0213	1	2						
*0214	1							
*0215	1	2						
*0216								
*0217	1				5			
*0218			3					
*0219	1	2				6		
*0220	1	2	3					
Well No.	1	2	3	4	5	6	7	8

INTERPRETATION TABLE							
HLA-Cw*02 SSP subtyping							
Amplification patterns for the HLA-Cw*0202 to 0220 alleles							
Well⁵							
9	10	11	12	13	14	15	16
200	125	80	150	225	80	190	230
		170	230				
1070	1070	1070	1070	1070	800	1070	1070
703	118	486	97	118	486	369	350
5'-CTA ^{3'}	5'-CCA ^{3'}	5'-ACA ^{3'}	5'-TCg ^{3'}	5'-CCA ^{3'}	5'-ACA ^{3'}	5'-TAC ^{3'}	5'-TCA ^{3'}
			368				
			5'-gTT ^{3'}				
			449				
			5'-CCA ^{3'}				
861	201	527	201	302	527	518	539
5'-TCg ^{3'}	5'-CTT ^{3'}	5'-CCg ^{3'}	5'-CTT ^{3'}	5'-ggC ^{3'}	5'-CCg ^{3'}	5'-CCA ^{3'}	5'-TCA ^{3'}
		613	559				
		5'-gCA ^{3'}	5'-CTC ^{3'}				
9	10	11	12	13	14	15	16
9	10						
9	10						
9	10					16	
9	10						
9	10						
9	10						
9	10						
9	10						
9	10	11					
	10						
9	10		12				
9	10			13			
9	10				14		
9	10		12				
9	10					15	
9	10						16
9	10		12				
9	10	11					16
9	10						
9	10						
9	10						
9	10	11	12	13	14	15	16



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Well No.	1	2	3	4	5	6	7	8
*0104, 0508, 06020101-0603, 0607, 0609-0616N, 120201-1208, 1210-1213, 1217, 1221, 160401, 1803	1							
*0109, 1215	1					6		
*0110					5			
*0321						6		
*0403								
*040401-040402, 0413, 0511, 0517, 0604, 080101-080102, 0803, 0804, 0806, 0808-0811, 0813, 0814, 1214, 1218, 1220, 1406, 150201-1507, 1509, 151001, 1512, 1513, 1515-1521, 1701-1704								
*0406, 1511								
*0605								
*0608	1				5			
*1216	1							
*151002								8
*1610							7	
HLA-Cw allele ⁴								
Well No.	1	2	3	4	5	6	7	8
B*2734, B*400602			3					
B*570302			w					
B*5802								
Well No.	1	2	3	4	5	6	7	8

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 tubes, or a band of 800 base pairs, for some tubes.

Tube 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*02 SSP subtyping. In addition, tubes number 2, 3, 6, 7 and 14 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 2nd intron, matching the specificity-determining 3'-end of the primer is given. Nucleotide numbering as on the www.ebi.ac.uk/imgt/hla web site. The sequence of the 3 terminal nucleotides of the primer is given.

³The nucleotide position, in the 2nd or 3rd 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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9	10	11	12	13	14	15	16	Well No.
								*0104, 0508, 06020101-0603, 0607, 0609-0616N, 120201-1208, 1210-1213, 1217, 1221, 160401, 1803
								*0109, 1215
								*0110
								*0321
	10							*0403
							16	*040401-040402, 0413, 0511, 0517, 0604, 080101-080102, 0803, 0804, 0806, 0808-0811, 0813, 0814, 1214, 1218, 1220, 1406, 150201-1507, 1509, 151001, 1512, 1513, 1515-1521, 1701-1704
	10						16	*0406, 1511
			w					*0605
			12					*0608
							16	*1216
								*151002
								*1610
								HLA-Cw allele ⁴
9	10	11	12	13	14	15	16	Well No.
								B*2734, B*400602
								B*570302
							16	B*5802
9	10	11	12	13	14	15	16	Well No.

⁴Cw*0201 has been deleted as it was identical to Cw*020202.

Cw*02024 has been deleted as it was identical to Cw*0210

⁵Primer mix 3: Specific PCR fragment of 95 bp in the Cw*0203 and Cw*0218 and the B*2734, B*400602 and B*570302^{weakly} alleles. Specific PCR fragment of 135 bp in the Cw*0220 allele.

Primer mix 11: Specific PCR fragment of 80 bp in the Cw*0218 allele. Specific PCR fragment of 170 bp in the Cw*0209 allele.

Primer mix 12: Specific PCR fragment of 150 bp in the Cw*0211, and Cw*0214 and the Cw*0605^{weakly} and Cw*1216 alleles. Specific PCR fragment of 230 bp in the Cw*0217 allele.

'w', might be weakly amplified.

CELL LINE VALIDATION SHEET																				
HLA-Cw*02 SSP primer set																				
				Well																
				Prod. No.:																
				200512901	200627402	200841403	200512904	200512905	200841406	200512907	200841408	200512909	200512910	200841411	200841412	200512913	200841414	200627415	200627416	
IHW 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	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

CERTIFICATE OF ANALYSIS

Olerup SSP[®] HLA-Cw*02 SSP

Product number: 101.622-12 – including *Taq* polymerase
101.622-12u – without *Taq* polymerase
Lot number: 12E
Expiry date: 2010-January-01
Number of tests: 12
Number of wells per test: 16

Well specifications:

Well No.	Production No.	Well No.	Production No.
1	2005-129-01	9	2005-129-09
2	2006-274-02	10	2005-129-10
3	2008-414-03	11	2008-414-11
4	2005-129-04	12	2008-414-12
5	2005-129-05	13	2005-129-13
6	2008-414-06	14	2008-414-14
7	2005-129-07	15	2006-274-15
8	2008-414-08	16	2006-274-16

The specificity of each primer solution of the HLA-Cw*02 primer set has been tested against 48 well characterized IHWC cell line DNAs.

No DNAs carrying the alleles to be amplified by primer solutions 3 to 8 and 11 to 15 were available. The specificity of the primers in primer solutions 3, 5, 6, 7, 8, 12, 13 and 14 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer solution 4 it was only possible to test the 3'-primer, the 5'-primer was not possible to test. In primer solutions 11 and 15 it was only possible to test the 3'-primers, the 5'-primers were not possible to test.

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

Date of approval: 2007-February-01

Approved by:

Quality Control, Supervisor

Lot No.: **12E**

Lot-specific information

www.olerup.com

Declaration of Conformity

Product name: *Olerup* SSP[®] HLA-Cw*02
Product number: 101.622-12, 101.622-12u
Lot number: 12E

Intended use: HLA-Cw*02 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
2008-February-01

Olle Olerup
Managing Director

HLA-Cw*02
101.622-12 – including *Taq* polymerase
101.622-12u – without *Taq* polymerase

Product Insert

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Lot No.: **12E**

Lot-specific information

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Product Insert

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Lot No.: **12E**

Lot-specific information

www.olerup.com

HLA-Cw*02
101.622-12 – including *Taq* polymerase
101.622-12u – without *Taq* polymerase

Product Insert

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Lot No.: **12E**

Lot-specific information

www.olerup.com

Lot No.: **12E**

Lot-specific information

www.olerup.com

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