

Lot No.: **79F**

Lot-specific information

Olerup SSP[®] HLA-Cw*08

Product number: 101.623-12u – without *Taq* polymerase
Lot number: 79F
Expiry date: 2011-May-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. 79F.

CHANGES COMPARED TO THE PREVIOUS *OLERUP SSP[®]* HLA-Cw*08 LOT

The HLA-Cw*08 specificity and interpretation tables have been updated for the HLA-Cw alleles described since the previous *Olerup SSP[®]* HLA-Cw*08 lot was made (**Lot No. 23E**).

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

Well	5'-primer	3'-primer	rationale
6	-	Added	New primer added for the Cw*0823 allele.
9	Exchanged	Exchanged	New primer pair for improved resolution.
10	Added	Added	New primer pair for the Cw*0817 allele.
11	Added	Added	New primer pair for the Cw*0820 allele.
14	Added	Added	New primer pair for the Cw*0818 allele.
15	Added	Added	New primer pair for the Cw*0819 allele.
16	Added	Added	New primer pair for the Cw*0822 allele.

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PRODUCT DESCRIPTION

HLA-Cw*08 SSP typing

CONTENT

The primer set contains 5'- and 3'-primers for identifying the Cw*0801 to Cw*0823 alleles.

PLATE LAYOUT

Each HLA-Cw*08 test consists of 16 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*08' in silver/gray ink.

Well No. 1 is marked with the Lot No. '79F'.

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*08 SSP subtypings will be influenced by other HLA-Cw alleles, as primer mixes 1, 3, 5, 7, 8, 11, 13 and 16 amplify non-HLA-Cw*08 alleles. In addition, primer mix 1 will amplify the B*5802 allele, primer mix 5 will amplify the B*1533 allele and primer mix 16 will amplify B*6702.

UNIQUELY IDENTIFIED ALLELES

All the HLA-Cw*08 alleles, i.e. **Cw*0801 to Cw*0823**, recognized by the HLA Nomenclature Committee in May 2009¹ will be amplified by the primers in the HLA-Cw*08 SSP kit.

The HLA-Cw*08 subtyping kit cannot distinguish the Cw*080101 to Cw*080102 alleles.

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

RESOLUTION IN HOMO- AND HETEROZYGOTES

The twenty-three HLA-Cw*08 alleles can be combined in 276 homozygous and heterozygous combinations. 106 of these genotypes do not give rise to unique amplification patterns. The different sizes of the specific PCR products generated by primer mixes 6, 10, 11, 14 to 16 were not considered in these calculations.

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+++++---- -++----- 0802,0806 = 0803,0823 = 0806,0823
+++------ -++----- 0805,0820 = 0812,0821
+++------ -++----- 0805,0808 = 0818,0821
+++------ -++----- 0805,0816 = 0819,0821
+++------ -++----- 0801,0805 = 0802,0821 = 0805,0821
+++----- +----- 0802,0809 = 0809,0817 = 0811,0817
+++----- -++----- 0808,0812 = 0818,0820
+++----- -++----- 0812,0816 = 0819,0820
+++----- -++----- 0801,0812 = 0802,0820 = 0812,0820
+++----- -++----- 0801,0818 = 0802,0808 = 0808,0818
+++----- -++----- 0801,0819 = 0802,0816 = 0816,0819
+++----- -++----- 0801,0813 = 0804,0816
+-++++- -++----- 0806,0815 = 0806,0821
+-++++- -++----- 0814,0815 = 0814,0821
+-++++- -++----- 0803,0815 = 0803,0821
+-++++- -++----- 0806,0814 = 0806,0822
+-++++- -++----- 0801,0806 = 0803,0806 = 0806,0806
+-++++- -++----- 0801,0814 = 0803,0814 = 0803,0822 = 0814,0814
= 0814,0822
++++----- -++----- 0801,0803 = 0803,0803
+-++++- +----- 0809,0815 = 0809,0821
+-++++- -++----- 0811,0815 = 0811,0821
+-++++- +----- 0810,0815 = 0810,0821
+-++++- -++----- 0815,0820 = 0820,0821
+-++++- -++----- 0808,0815 = 0808,0821
+-++++- -++----- 0815,0816 = 0816,0821
+-++++- -++----- 0815,0822 = 0821,0822
+-++++- -++----- 0801,0815 = 0801,0821 = 0815,0821 = 0821,0821
+-++++- +----- 0801,0809 = 0809,0809 = 0809,0811
+-++++- -++----- 0801,0811 = 0811,0811
+-++++- -++----- 0801,0820 = 0820,0820
+-++++- -++----- 0801,0808 = 0808,0808
+-++++- -++----- 0801,0822 = 0822,0822
+-++++- -++----- 0802,0813 = 0804,0819 = 0813,0819
--++++- -++----- 0805,0823 = 0815,0823
--++++- -++----- 0805,0807 = 0807,0815
--++++- +----- 0805,0817 = 0815,0817
--++++- -++----- 0805,0812 = 0812,0815
--++++- -++----- 0805,0818 = 0815,0818
--++++- -++----- 0805,0819 = 0815,0819
--++++- -++----- 0802,0805 = 0802,0815 = 0805,0805 = 0805,0815
--++++- -++----- 0802,0823 = 0823,0823
--++++- -++----- 0802,0807 = 0807,0807
--++++- +----- 0802,0817 = 0817,0817
--++++- -++----- 0802,0812 = 0812,0812
--++++- -++----- 0802,0819 = 0819,0819

0801 = 080101-080102

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SPECIFICITY TABLE

HLA-Cw*08 SSP subtyping

Specificities and sizes of the PCR products of the 16 primer mixes used for HLA-Cw*08 SSP subtyping

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified HLA-Cw*08 alleles	Other amplified HLA Class I alleles ³
1⁵	250 bp	800 bp	080101-080102, 0803, 0804, 0806, 0808-0811, 0813, 0814, 0816, 0820-0822	0122, 0203, 021601-021602, 0218, 040401-040402, 0406, 0413, 0434, 0511, 0517, 0604, 121401-121402, 1218, 1220, 1406, 150201-1507, 1509-1513, 1515-1521, 1701-1705, B*5802
2⁴	115 bp	1070 bp	080101-080102, 0803, 0806, 0808-0811, 0814, 0816, 0820-0822	
3⁴	115 bp	800 bp	0802, 0804, 0805, 0807, 0812, 0813, 0817-0819, 0823	05010101-050104, 0503-0508, 0510, 0511, 0513-0516, 0518-0525, 0741
4⁴	110 bp	1070 bp	0803, 0806, 0814	
5	155 bp	1070 bp	0805, 0815, 0821	0113, 0509, 0517, 1705, B*1533
6⁶	270, 310 bp	1070 bp	0806, 0823	
7⁴	100 bp	1070 bp	0807	0523
8	225 bp	1070 bp	0809, 0811	0504, 0768
9	495 bp	1070 bp	0810	
10^{4,5,7}	110, 140 bp	800 bp	0809, 0817	
11⁸	280, 465 bp	800 bp	0812, 0820	0516
12	165 bp	800 bp	080101-0809, 0811, 0812, 0814, 0815, 0817, 0819-0823	
13⁴	105 bp	800 bp	0802, 0805, 0807, 0812, 0817-0819, 0823	05010101-050104, 0503-0508, 0510, 0512-0516, 0518-0525, 0741
14⁹	170, 280 bp	1070 bp	0808, 0818	
15¹⁰	260, 490 bp	1070 bp	0813, 0816, 0819	
16^{4,5,11}	100, 540 bp	1070 bp	0814, 0822	0121, 0605, 1216, B*6702

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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*08 SSP subtypings.

When the primers in a primer mix can give rise to specific PCR products of more than one length this is indicated if the size difference is 20 base pairs or more. Size differences shorter than 20 base pairs are not given. For high resolution SSP kits the respective lengths of the specific PCR product(s) of the alleles amplified by these primer mixes are given.

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

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

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

Some primers may give rise to primer oligomer artifacts. Sometimes this phenomenon is an inherent feature of the primer pair(s) of a primer mix. More often it is due to other factors such as too low amount of DNA in the PCR reactions, taking too long time in setting up the PCR reactions, working at elevated room temperature or using thermal cyclers that are not pre-heated.

²The internal positive control primer pairs amplify segments of the human growth hormone gene. The two different control primer pairs give rise to either an internal positive control band of 1070 base pairs, for most wells, or a band of 800 base pairs, for some wells.

Well number 1 contains the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to help in the correct orientation of the HLA-Cw*08 SSP subtyping.

In addition, wells number 3 and 10 to 13 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.

³Due to the sharing of sequence motifs between HLA-Cw alleles some non-HLA-Cw*08 alleles will be amplified by primer mixes 1, 3, 5, 7, 8, 11, 13 and 16. In addition, primer mix 1 will amplify the B*5802 allele, primer mix 5 will amplify the B*1533 allele and primer mix 16 will amplify B*6702.

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

⁵Primer mixes 1, 11 and 16 have a tendency of giving rise to non-specific amplifications.

⁶Primer mix 6: Specific PCR fragment of 270 bp in the Cw*0806 allele. Specific PCR fragment of 310 bp in the Cw*0823 allele.

⁷Primer mix 10: Specific PCR fragment of 110 bp in the Cw*0809 allele. Specific PCR fragment of 140 bp in the Cw*0817 allele.

⁸Primer mix 11: Specific PCR fragment of 280 bp in the Cw*0812 and in the Cw*0516 allele. Specific PCR fragment of 465 bp in the Cw*0820 allele.

⁹Primer mix 14: Specific PCR fragment of 170 bp in the Cw*0818 allele. Specific PCR fragment of 280 bp in the Cw*0808 allele.

¹⁰Primer mix 15: Specific PCR fragment of 260 bp in the Cw*0813 and *0816 alleles. Specific PCR fragment of 490 bp in the Cw*0819 allele.

¹¹Primer mix 16: Specific PCR fragment of 100 bp in the Cw*0814 and Cw*0121, 0605, 1216 and in the B*6702 allele. Specific PCR fragment of 540 bp in the Cw*0822 allele.

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INTERPRETATION TABLE								
HLA-Cw*08 SSP subtyping								
Amplification patterns of the HLA-Cw*0801 to 0823 alleles								
	Well⁴							
	1	2	3	4	5	6	7	8
Length of spec.	250	115	115	110	155	270	100	225
PCR product						310		
Length of int.	800	1070	800	1070	1070	1070	1070	1070
pos. control¹								
5'-primer²	2nd I	527	527	527	176	2nd I	453	419
	<small>5'-CCA^{3'}</small>	<small>5'-TAC^{3'}</small>	<small>5'-TgA^{3'}</small>	<small>5'-TAC^{3'}</small>	<small>5'-gCA^{3'}</small>	<small>5'-CCA^{3'}</small>	<small>5'-AAT^{3'}</small>	<small>5'-gTC^{3'}</small>
					485			
					<small>5'-CAA^{3'}</small>			
3'-primer³	539	601	601	595	289	559	512	601
	<small>5'-TCA^{3'}</small>	<small>5'-CTT^{3'}</small>	<small>5'-CTT^{3'}</small>	<small>5'-CCT^{3'}</small>	<small>5'-AgC^{3'}</small>	<small>5'-CgC^{3'}</small>	<small>5'-CCA^{3'}</small>	<small>5'-CTT^{3'}</small>
					601	599		
					<small>5'-CTC^{3'}</small>	<small>5'-TCC^{3'}</small>		
Well No.	1	2	3	4	5	6	7	8
HLA-Cw allele								
*080101-080102	1	2						
*0802			3					
*0803	1	2		4				
*0804	1		3					
*0805			3		5			
*0806	1	2		4		6		
*0807			3				7	
*0808	1	2						
*0809	1	2						8
*0810	1	2						
*0811	1	2						8
*0812			3					
*0813	1		3					
*0814	1	2		4				
*0815					5			
*0816	1	2						
*0817			3					
*0818			3					
*0819			3					
*0820	1	2						
*0821	1	2			5			
*0822	1	2						
*0823			3			6		
Well No.	1	2	3	4	5	6	7	8

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INTERPRETATION TABLE								
HLA-Cw*08 SSP subtyping								
Amplification patterns of the HLA-Cw*0801 to 0823 alleles								
Well⁴								
9	10	11	12	13	14	15	16	
495	110	280	165	105	170	260	100	Length of spec.
	140	465			280	490	540	PCR product
1070	800	800	800	800	1070	1070	1070	Length of int. pos. control¹
312	176	361	176	539	173	1st 	142	5'-primer²
<small>5'-AAA^{3'}</small>	<small>5'-gCA^{3'}</small>	<small>5'-AgT^{3'}</small>	<small>5'-gCA^{3'}</small>	<small>5'-gCg^{3'}</small>	<small>5'-CgC^{3'}</small>	<small>5'-CgA^{3'}</small>	<small>5'-TCT^{3'}</small>	
	527	652			363	176	972	
	<small>5'-TAC^{3'}</small>	<small>5'-CCA^{3'}</small>			<small>5'-AgC^{3'}</small>	<small>5'-gCA^{3'}</small>	<small>5'-CTA^{3'}</small>	
526	277	601	302	601	302	175	201	3'-primer³
<small>5'-CgT^{3'}</small>	<small>5'-gCA^{3'}</small>	<small>5'-CTT^{3'}</small>	<small>5'-ggC^{3'}</small>	<small>5'-CTT^{3'}</small>	<small>5'-ggC^{3'}</small>	<small>5'-CCg^{3'}</small>	<small>5'-CTT^{3'}</small>	
	598	956			601	387	1034	
	<small>5'-CTC^{3'}</small>	<small>5'-CAG^{3'}</small>			<small>5'-CTT^{3'}</small>	<small>5'-TCC^{3'}</small>	<small>5'-AgT^{3'}</small>	
9	10	11	12	13	14	15	16	Well No.
								HLA-Cw allele
			12					*080101-080102
			12	13				*0802
			12					*0803
			12					*0804
			12	13				*0805
			12					*0806
			12	13				*0807
			12		14			*0808
	10		12					*0809
9								*0810
			12					*0811
		11	12	13				*0812
						15		*0813
			12				16	*0814
			12					*0815
						15		*0816
	10		12	13				*0817
				13	14			*0818
			12	13		15		*0819
		11	12					*0820
			12					*0821
			12				16	*0822
			12	13				*0823
9	10	11	12	13	14	15	16	Well No.

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Length of spec.	250	115	115	110	155	270	100	225
PCR product						310		
Well No.	1	2	3	4	5	6	7	8
*0113, 0509					5			
*0122, 0203, 021601, 021602, 0218, 040401, 040402, 0406, 0413, 0434, 0604, 121401-121402, 1218, 1220, 1406, 150201-1507, 1509-1513, 1515-1521, 1701-1704	1							
*0121, 0605, 1216								
*05010101-050104, 0503, 0505-0508, 0510, 0513-0515, 0518-0522, 0524, 0525, 0741			3					
*0504			3					8
*0511	1		3					
*0512								
*0516			3					
*0517, 1705	1				5			
*0523			3			7		
*0768								8
HLA-Cw allele								
Well No.	1	2	3	4	5	6	7	8
B*1533					5			
B*5802	1							
B*6702								
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 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*08 SSP subtyping.

In addition, wells number 3 and 10 to 13 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 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 2nd or 3rd exon, matching the specificity-determining 3'-end of the primer is given in the anti-sense direction. The sequence of the 3 terminal nucleotides of the primer is given.

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495	110	280	165	105	170	260	100	Length of spec.
	140	465			280	490	540	PCR product
9	10	11	12	13	14	15	16	Well No.
								*0113, 0509
								*0122, 0203, 021601, 021602, 0218, 040401, 040402, 0406, 0413, 0434, 0604, 121401-121402, 1218, 1220, 1406, 150201-1507, 1509-1513, 1515-1521, 1701-1704
							16	*0121, 0605, 1216
				13				*05010101-050104, 0503, 0505-0508, 0510, 0513-0515, 0518-0522, 0524, 0525, 0741
				13				*0504
								*0511
				13				*0512
		11		13				*0516
								*0517, 1705
				13				*0523
								*0768
								HLA-Cw allele
9	10	11	12	13	14	15	16	Well No.
								B*1533
								B*5802
							16	B*6702
9	10	11	12	13	14	15	16	Well No.

⁴Primer mix 6: Specific PCR fragment of 270 bp in the Cw*0806 allele. Specific PCR fragment of 310 bp in the Cw*0823 allele.

Primer mix 10: Specific PCR fragment of 110 bp in the Cw*0809 allele. Specific PCR fragment of 140 bp in the Cw*0817 allele.

Primer mix 11: Specific PCR fragment of 280 bp in the Cw*0812 and in the Cw*0516 allele. Specific PCR fragment of 465 bp in the Cw*0820 allele.

Primer mix 14: Specific PCR fragment of 170 bp in the Cw*0818 allele. Specific PCR fragment of 280 bp in the Cw*0808 allele.

Primer mix 15: Specific PCR fragment of 260 bp in the Cw*0813 and *0816 alleles. Specific PCR fragment of 490 bp in the Cw*0819 allele.

Primer mix 16: Specific PCR fragment of 100 bp in the Cw*0814 and Cw*0121, 0605, 1216 and in the B*6702 allele. Specific PCR fragment of 540 bp in the Cw*0822 allele.

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CELL LINE VALIDATION SHEET																				
HLA-Cw*08 SSP primer set																				
				Well																
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	
				Prod. No.:	200629001	200629002	200958703	200958704	200842805	200958706	200958707	200629008	200958709	200958710	200958711	200629012	200629013	200958714	200958715	200958716
	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	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

Lot No.: **79F**

Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP[®] HLA-Cw*08 SSP

Product number: 101.623-12u – without *Taq* polymerase
Lot number: 79F
Expiry date: 2011-May-01
Number of tests: 12
Number of wells per test: 16

Well specifications:

Well No.	Production No.	Well No.	Production No.
1	2006-290-01	9	2009-587-09
2	2006-290-02	10	2009-587-10
3	2009-587-03	11	2009-587-11
4	2009-587-04	12	2006-290-12
5	2008-428-05	13	2006-290-13
6	2009-587-06	14	2009-587-14
7	2009-587-07	15	2009-587-15
8	2006-290-08	16	2009-587-16

The specificity of each primer solution of the HLA-Cw*08 primer set has been tested against 48 well characterized cell line DNAs.

No DNAs carrying the alleles to be amplified by primer solutions 4 to 11 and 14 to 16 were available. The specificity of the primers in primer solutions 5, 7, 8, 9, 11, 14, 15 and 16 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer solutions 4, 6 and 10 it was only possible to test the 5'-primer, the 3'-primer was not possible to test. In primer solution 11 and 14, one 5'-primer was not possible to test.

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

Date of approval: 2009-June-08

Approved by:

Quality Control, Supervisor

Lot No.: **79F**

Lot-specific information

Declaration of Conformity

Product name: *Olerup* SSP® HLA-Cw*08
Product number: 101.623-12u
Lot number: 79F

Intended use: HLA-Cw*08 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-June-08

Olle Olerup
Managing Director

Lot No.: **79F**

Lot-specific information

Lot No.: **79F**

Lot-specific information

Lot No.: **79F**

Lot-specific information

Lot No.: **79F**

Lot-specific information

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