

Lot No.: **54E**

Lot-specific Information

## **Olerup SSP<sup>®</sup> HLA-Cw\*05**

Product number: 101.613-12u – without *Taq* polymerase  
Lot number: 54E  
Expiry date: 2010-April-01  
Number of tests: 12  
Number of wells per test: 15  
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. 54E.**

### **CHANGES COMPARED TO THE PREVIOUS *OLERUP SSP<sup>®</sup>* HLA-Cw\*05 LOT**

The HLA-Cw\*05 specificity and interpretation tables have been updated for the HLA-Cw alleles described since the previous *Olerup SSP<sup>®</sup>* HLA-Cw\*05 lot was made (**Lot No. X61**).

One well has been removed from the HLA-Cw\*05 kit,  
well **11**.

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

Well	5'-primer	3'-primer	rationale
4	-	Modified	Increased specificity of specific primer pair.
8	-	Modified	Increased specificity of specific primer pair.
11	Removed	Removed	Primer not necessary when the Cw*0502 allele has been deleted from the allele database.

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## PRODUCT DESCRIPTION

### HLA-Cw\*05 SSP subtyping

#### CONTENT

The primer set contains 5'- and 3'-primers for identifying the Cw\*0501 to Cw\*0517 alleles.

#### PLATE LAYOUT

Each test consists of 16 PCR reactions in a 16 well PCR plate. Well 16 is empty.

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

The 16 well cut PCR plate is marked with 'Cw\*05'.

Well No. 1 is marked with the Lot No. '54E'.

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\*05 SSP subtypings will be influenced by the Cw\*0113, Cw\*0605, six Cw\*07, the Cw\*08 and the Cw\*1221 alleles when present on the other haplotype. In addition, the A\*2910 allele will be amplified by primer mix 6 and the B\*1533 allele will be amplified by primer mixes 3 and 10.

#### UNIQUELY IDENTIFIED ALLELES

All the HLA-C\*05 alleles, i.e. **Cw\*0501 to Cw\*0517**, recognized by the HLA Nomenclature Committee in January 2008<sup>1</sup> will give rise to unique amplification patterns by the primers in the HLA-Cw\*05 subtyping kit.

The HLA-Cw\*05 subtyping kit cannot distinguish the Cw\*050101 to Cw\*050104 alleles.

<sup>1</sup>HLA-Cw alleles listed on the IMGT/HLA web page 2008-January-11, release 2.20.0, [www.ebi.ac.uk/imgt/hla](http://www.ebi.ac.uk/imgt/hla).

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**RESOLUTION IN HOMO- AND HETEROZYGOTES**

The 16 HLA-Cw\*05 alleles can be combined in 136 homozygous and heterozygous combinations. Seventy-one of these genotypes do not give rise to unique amplification patterns.

+++----+ - - - - + - - -	0501,0517 = 0509,0511 = 0511,0517
+++--++- - - - - - - -	0503,0505 = 0503,0516
+++--+-+ - - - - + - - -	0503,0512 = 0503,0515
+++--+-+ - - - - - - - -	0501,0503 = 0503,0503
+++--+++ - - - - - - - -	0504,0505 = 0504,0516
+++--+-+ - - - - + - - -	0504,0512 = 0504,0515
+++--+-+ - - - - - - - -	0501,0504 = 0504,0504
+++--+++ - - - - - - - -	0505,0506 = 0506,0516
+++--+-+ + - - - - - - -	0505,0507N = 0507N,0516
+++--+-+ - + - - - - - -	0505,0508 = 0508,0516
+++--+-+ - - + - - - - -	0505,0510 = 0510,0516
+++--+-+ - - - + - - - -	0505,0511 = 0511,0516
+++--+-+ - - - - + - - -	0505,0512 = 0505,0515 = 0512,0516 = 0515,0516
+++--+-+ - - - - - + - -	0505,0513 = 0513,0516
+++--+-+ - - - - - - + -	0505,0514 = 0514,0516
+++--+-+ - - - - - - - -	0501,0505 = 0501,0516 = 0505,0516 = 0516,0516
+++--++- - - - - + - -	0506,0512 = 0506,0515
+++--++- - - - - - - -	0501,0506 = 0506,0506
+++--+-+ + - - - + - - -	0507N,0512 = 0507N,0515
+++--+-+ + - - - - - - -	0501,0507N = 0507N,0507N
+++--+-+ - + - - + - - -	0508,0512 = 0508,0515
+++--+-+ - + - - - - - -	0501,0508 = 0508,0508
+++--+-+ - - + - + - - -	0510,0512 = 0510,0515
+++--+-+ - - + - - - - -	0501,0510 = 0510,0510
+++--+-+ - - - + + - - -	0511,0512 = 0511,0515
+++--+-+ - - - + - - - -	0501,0511 = 0511,0511
+++--+-+ - - - - + + - -	0512,0513 = 0513,0515
+++--+-+ - - - - + - + -	0512,0514 = 0514,0515
+++--+-+ - - - - + - - -	0501,0512 = 0501,0515 = 0512,0515 = 0515,0515
+++--+-+ - - - - - + - -	0501,0513 = 0513,0513
+++--+-+ - - - - - - + -	0501,0514 = 0514,0514
-++-- - - - - + - - -	0509,0517 = 0517,0517

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## SPECIFICITY TABLE

### HLA-Cw\*05 SSP subtyping

Specificities and sizes of the PCR products of the 15 primer mixes used for HLA-Cw\*05 SSP subtyping

Primer Mix	Size of spec. PCR product <sup>1</sup>	Size of control band <sup>2</sup>	Amplified HLA-Cw*05 alleles	Other amplified HLA Class I alleles <sup>3,4</sup>
1	155 bp	<b>800 bp</b>	050101-050104, 0503-0508, 0510, 0511, 0513-0516	0741, 0802, 0804, 0805, 0807, 0812, 0813
2	165 bp	1070 bp	050101-050104, 0503-0517	0605, 0810, 1221
3	155 bp	1070 bp	0509, 0517	0113, 0815, <b>B*1533</b>
4 <sup>5</sup>	120 bp	<b>800 bp</b>	0503	0752
5	225 bp	1070 bp	0504	0809, 0811
6	270 bp	1070 bp	0505, 0516	0812, <b>A*2910</b>
7	265 bp	1070 bp	050101-050104, 0503, 0504, 0506-0508, 0510-0516	070401-070402, 0711, 0712, 0741, 080101-0814
8 <sup>5</sup>	85 bp	<b>800 bp</b>	0506	
9	285 bp	1070 bp	0507N	
10 <sup>5</sup>	95 bp	1070 bp	0508	<b>B*1533</b>
11	285 bp	1070 bp	0510	
12 <sup>5</sup>	95 bp	1070 bp	0511, 0517	0804, 0813
13 <sup>5</sup>	120 bp	1070 bp	0512, 0515	
14	240 bp	1070 bp	0513	
15	195 bp	1070 bp	0514	

<sup>1</sup>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\*05 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 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

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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.

<sup>2</sup>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\*05 subtyping.

In addition, wells number 4 and 8 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.

<sup>3</sup>Due to the sharing of sequence motifs between HLA-Cw alleles non-HLA-Cw\*05 alleles will be amplified by primer mixes 1, 2, 3, 5, 7 and 12.

<sup>4</sup>Due to the sharing of sequence motifs between HLA class I genes, the A\*2910 allele by primer mix 6 and the B\*1533 allele will be amplified by primer mixes 3, 10.

<sup>5</sup>Specific PCR fragments shorter than 125 base pairs have a lower intensity than longer PCR bands.

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<b>INTERPRETATION TABLE</b>								
<b>HLA-Cw*05 subtyping</b>								
<b>Amplification patterns of the Cw*0501 to 0517 alleles</b>								
	<b>Well</b>							
	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>7</b>	<b>8</b>
<b>Length of spec.</b>	<b>155</b>	<b>165</b>	<b>155</b>	<b>120</b>	<b>225</b>	<b>270</b>	<b>265</b>	<b>85</b>
<b>PCR product</b>								
<b>Length of int.</b>	<b>800</b>	<b>1070</b>	<b>1070</b>	<b>800</b>	<b>1070</b>	<b>1070</b>	<b>1070</b>	<b>800</b>
<b>pos. control<sup>1</sup></b>								
<b>5'-primer(s)<sup>2</sup></b>	<b>485</b>	<b>176</b>	<b>485</b>	<b>3<sup>rd</sup> I</b>	<b>419</b>	<b>379</b>	<b>379</b>	<b>176</b>
	5'-CAA <sup>3'</sup>	5'-gCA <sup>3'</sup>	5'-CAA <sup>3'</sup>	5'-TgT <sup>3'</sup>	5'-gTC <sup>3'</sup>	5'-ACg <sup>3'</sup>	5'-ACC <sup>3'</sup>	5'-gCA <sup>3'</sup>
						<b>361</b>		
						5'-AgT <sup>3'</sup>		
<b>3'-primer(s)<sup>3</sup></b>	<b>601</b>	<b>302</b>	<b>601</b>	<b>668</b>	<b>601</b>	<b>601</b>	<b>601</b>	<b>221</b>
	5'-CTT <sup>3'</sup>	5'-ggT <sup>3'</sup>	5'-CTC <sup>3'</sup>	5'-TgA <sup>3'</sup>	5'-CTT <sup>3'</sup>	5'-CTC <sup>3'</sup>	5'-CTC <sup>3'</sup>	5'-ACC <sup>3'</sup>
<b>Well No.</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>7</b>	<b>8</b>
<b>HLA-Cw allele<sup>4</sup></b>								
<b>*050101-050104</b>	<b>1</b>	<b>2</b>					<b>7</b>	
<b>*0503</b>	<b>1</b>	<b>2</b>		<b>4</b>			<b>7</b>	
<b>*0504</b>	<b>1</b>	<b>2</b>			<b>5</b>		<b>7</b>	
<b>*0505</b>	<b>1</b>	<b>2</b>				<b>6</b>		
<b>*0506</b>	<b>1</b>	<b>2</b>					<b>7</b>	<b>8</b>
<b>*0507N</b>	<b>1</b>	<b>2</b>					<b>7</b>	
<b>*0508</b>	<b>1</b>	<b>2</b>					<b>7</b>	
<b>*0509</b>		<b>2</b>	<b>3</b>					
<b>*0510</b>	<b>1</b>	<b>2</b>					<b>7</b>	
<b>*0511</b>	<b>1</b>	<b>2</b>					<b>7</b>	
<b>*0512</b>		<b>2</b>					<b>7</b>	
<b>*0513</b>	<b>1</b>	<b>2</b>					<b>7</b>	
<b>*0514</b>	<b>1</b>	<b>2</b>					<b>7</b>	
<b>*0515</b>	<b>1</b>	<b>2</b>					<b>7</b>	
<b>*0516</b>	<b>1</b>	<b>2</b>				<b>6</b>	<b>7</b>	
<b>*0517</b>		<b>2</b>	<b>3</b>					
<b>*0113, 0815</b>			<b>3</b>					
<b>*0605, 1221</b>		<b>2</b>						
<b>*070401-070402, 0711, 0712, 080101-080102, 0803, 0806, 0808, 0814</b>							<b>7</b>	
<b>*0741, 0802, 0805, 0807</b>	<b>1</b>						<b>7</b>	
<b>Well No.</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>7</b>	<b>8</b>

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<b>INTERPRETATION TABLE</b>							
<b>HLA-Cw*05 subtyping</b>							
<b>Amplification patterns of the Cw*0501 to 0517 alleles</b>							
<b>Well</b>							
<b>9</b>	<b>10</b>	<b>11</b>	<b>12</b>	<b>13</b>	<b>14</b>	<b>15</b>	
<b>285</b>	<b>95</b>	<b>285</b>	<b>95</b>	<b>120</b>	<b>240</b>	<b>195</b>	<b>Length of spec. PCR product</b>
<b>1070</b>	<b>1070</b>	<b>1070</b>	<b>1070</b>	<b>1070</b>	<b>1070</b>	<b>1070</b>	<b>Length of int. pos. control<sup>1</sup></b>
<b>355</b>	<b>485</b>	<b>355</b>	<b>485</b>	<b>176</b>	<b>115</b>	<b>446</b>	<b>5'-primer(s)<sup>2</sup></b>
5'-CC <sup>3'</sup>	5'-CAA <sup>3'</sup>	5'-TCA <sup>3'</sup>	5'-CAA <sup>3'</sup>	5'-gCA <sup>3'</sup>	5'-ggA <sup>3'</sup>	5'-CgT <sup>3'</sup>	
				<b>453</b>			
				5'-AAT <sup>3'</sup>			
<b>601</b>	<b>538</b>	<b>601</b>	<b>539</b>	<b>256</b>	<b>312</b>	<b>601</b>	<b>3'-primer(s)<sup>3</sup></b>
5'-CTT <sup>3'</sup>	5'-CCA <sup>3'</sup>	5'-CTT <sup>3'</sup>	5'-TCA <sup>3'</sup>	5'-CCA <sup>3'</sup>	5'-AgT <sup>3'</sup>	5'-CTT <sup>3'</sup>	
				<b>527</b>			
				5'-CCA <sup>3'</sup>			
<b>9</b>	<b>10</b>	<b>11</b>	<b>12</b>	<b>13</b>	<b>14</b>	<b>15</b>	<b>Well No.</b>
							<b>HLA-Cw allele<sup>4</sup></b>
							<b>*050101-050104</b>
							<b>*0503</b>
							<b>*0504</b>
							<b>*0505</b>
							<b>*0506</b>
<b>9</b>							<b>*0507N</b>
	<b>10</b>						<b>*0508</b>
							<b>*0509</b>
		<b>11</b>					<b>*0510</b>
			<b>12</b>				<b>*0511</b>
				<b>13</b>			<b>*0512</b>
					<b>14</b>		<b>*0513</b>
						<b>15</b>	<b>*0514</b>
				<b>13</b>			<b>*0515</b>
							<b>*0516</b>
			<b>12</b>				<b>*0517</b>
							<b>*0113, 0815</b>
							<b>*0605, 1221</b>
							<b>*070401-070402, 0711, 0712, 080101-080102, 0803, 0806, 0808, 0814</b>
							<b>*0741, 0802, 0805, 0807</b>
<b>9</b>	<b>10</b>	<b>11</b>	<b>12</b>	<b>13</b>	<b>14</b>	<b>15</b>	<b>Well No.</b>

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<b>Length of spec.</b>	<b>155</b>	<b>165</b>	<b>155</b>	<b>120</b>	<b>225</b>	<b>270</b>	<b>265</b>	<b>85</b>
<b>PCR product</b>								
<b>Well No.</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>7</b>	<b>8</b>
<b>*0752</b>				<b>4</b>				
<b>*0804, 0813</b>	<b>1</b>						<b>7</b>	
<b>*0809, 0811</b>					<b>5</b>		<b>7</b>	
<b>*0810</b>		<b>2</b>					<b>7</b>	
<b>*0812</b>	<b>1</b>					<b>6</b>	<b>7</b>	
<b>HLA-Cw allele<sup>4</sup></b>								
<b>Well No.</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>7</b>	<b>8</b>
<b>A*2910</b>						<b>6</b>		
<b>B*1533</b>			<b>3</b>					
<b>Well No.</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>7</b>	<b>8</b>

<sup>1</sup>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\*05 subtyping. In addition, wells number 4 and 8 contain the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to allow kit identification.



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285	95	285	95	120	240	195	Length of spec. PCR product
9	10	11	12	13	14	15	Well No.
							*0752
			12				*0804, 0813
							*0809, 0811
							*0810
							*0812
							HLA-Cw allele <sup>4</sup>
9	10	11	12	13	14	15	Well No.
							A*2910
	10						B*1533
9	10	11	12	13	14	15	Well No.

<sup>2</sup>The nucleotide position, in the 2<sup>nd</sup> or 3<sup>rd</sup> exon or the 3<sup>rd</sup> intron, matching the specificity-determining 3'-end of the primer is given. Nucleotide numbering as on the [www.ebi.ac.uk/imgt/hla](http://www.ebi.ac.uk/imgt/hla) web site. The sequence of the 3 terminal nucleotides of the primer is given.

<sup>3</sup>The nucleotide position, in the 2<sup>nd</sup>, 3<sup>rd</sup> or 4<sup>th</sup> 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](http://www.ebi.ac.uk/imgt/hla) web site. The sequence of the 3 terminal nucleotides of the primer is given.

<sup>4</sup>The HLA-Cw\*0502 nucleotide sequence has been deleted as it is identical to Cw\*0509.

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CELL LINE VALIDATION SHEET																				
HLA-Cw*05 SSP subtyping kit																				
				Well																
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15		
				Prod. No.:																
				200732201	200732202	200732203	200845804	200732205	200732206	200732207	200845808	200732209	200732210	200732212	200732213	200732214	200732215	200732216		
	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	HFKB	*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.: **54E**

Lot-specific Information

## CERTIFICATE OF ANALYSIS

### **Olerup SSP<sup>®</sup> HLA-Cw\*05 SSP**

**Product number:** 101.613-12u – without *Taq* polymerase  
**Lot number:** 54E  
**Expiry date:** 2010-April-01  
**Number of tests:** 12  
**Number of wells per test:** 15

#### **Well specifications:**

Well No.	Production No.	Well No.	Production No.
1	2007-322-01	9	2007-322-09
2	2007-322-02	10	2007-322-10
3	2007-322-03	12	2007-322-12
4	2008-458-04	13	2007-322-13
5	2007-322-05	14	2007-322-14
6	2007-322-06	15	2007-322-15
7	2007-322-07	16	2007-322-16
8	2008-458-08		

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

No DNAs carrying the alleles to be amplified by primer solutions 3, 4, 5, 6, 8, 9, 10, 11, 13, 14 and 15 were available. The specificities of the primers in primer solutions 3, 5, 6, 10, 11 and 13 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer solutions 4 and 8 it was only possible to test the 5'-primers, the 3'-primers were not possible to test. In primer solutions 9, 14 and 15 it was only possible to test the 3'-primer, the 5'-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.: **54E**

Lot-specific Information

## Declaration of Conformity

**Product name:** *Olerup* SSP® HLA-Cw\*05  
**Product number:** 101.613-12u  
**Lot number:** 54E

**Intended use:** HLA-Cw\*05 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-11

Olle Olerup  
Managing Director



Lot No.: **54E**

Lot-specific Information

Lot No.: **54E**

Lot-specific Information

Lot No.: **54E**

Lot-specific Information

Lot No.: **54E**

Lot-specific Information

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