

101.427-06 – including *Taq* pol., IFU-01 Rev. No. 03
 101.427-06u – without *Taq* polymerase, IFU-02 Rev. No. 03

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 “Instructions for Use” (IFU)

Lot No.: **09R**

Lot-specific information

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Olerup SSP[®] HLA-A*66

Product number: 101.427-06 – including *Taq* pol.
 101.427-06u – without *Taq* pol.

Lot number: 09R

Expiry date: 2015-February-01

Number of tests: 6

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. 09R.

CHANGES COMPARED TO THE PREVIOUS OLERUP SSP[®] HLA-A*66 LOT (08L)

The HLA-A*66 kit is updated for new alleles to enable separation of:

- Confirmed¹ alleles as listed in the IMGT/HLA database
- Polymorphisms in exons outside of the region encoding the peptide binding domain
- Null and Alternatively expressed alleles

One well has been added to the HLA-A*66 kit, well **15**.

The Lot-specific information for HLA-A*66 including and without *Taq* polymerase is now described in one common Product Insert.

¹As described in section Uniquely Identified Alleles.

The HLA-A*66 specificity and interpretation tables have been updated for the HLA-A alleles described since the previous *Olerup SSP[®]* HLA-A*66 lot was made (**Lot No. 08L**).

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

Well	5'-primer	3'-primer	rationale
15	New	New	New primer pair for the A*66:16 allele.

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Lot No.: **09R**

Lot-specific information

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Change in revision R01 compared to R00:

1. Primer mix 6 does not amplify the A*66:15 allele. This has been corrected in the Specificity and Interpretation tables.

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 101.427-06u – without *Taq* polymerase, IFU-02 Rev. No. 03

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Lot No.: **09R**

Lot-specific information

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PRODUCT DESCRIPTION

HLA-A*66 SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for identifying the HLA-A*66:01 to A*66:16 alleles.

PLATE LAYOUT

Each test consists of 15 PCR reactions in a 16 well cut 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 'HLA-A*66' in silver/gray ink.

Well No. 1 is marked with the Lot No. '09R'.

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 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-A*66 SSP subtypings will be influenced by the A*01, several A*02 alleles, four A*03 alleles, the A*11, three A*24 alleles, the A*25, the A*26, two A*31 allele, nine A*33 alleles, the A*34, the A*36, the A*43:01 allele, most A*68 alleles, the A*69:01, the A*74:10 and the A*80 alleles when present on the other haplotype.

UNIQUELY IDENTIFIED ALLELES

All the HLA-A*66 alleles, i.e. **A*66:01 to A*66:16 alleles**, recognized by the HLA Nomenclature Committee in April 2012¹ will give rise to unique amplification patterns by the primers in the HLA-A*66 subtyping kit.

The HLA-A*66 kit enables separation of the confirmed HLA-A*66 alleles as listed in the IMGT/HLA database. An HLA allele is listed as confirmed by IMGT/HLA if it has been sequenced by more than a single laboratory or from multiple sources. Current allele confirmation status for HLA-A*66 alleles is listed below.

The HLA-A*66 kit also enables identification of polymorphisms in exons outside of the region encoding the peptide binding domain and of null and alternatively expressed alleles

¹HLA-A alleles listed on the IMGT/HLA web page 2012-April-12, release 3.8.0, www.ebi.ac.uk/imgt/hla.

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 101.427-06u – without *Taq* polymerase, IFU-02 Rev. No. 03

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Lot No.: **09R**

Lot-specific information

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ALLELE CONFIRMATION STATUS

Allele	Status ¹	Allele	Status ¹
A*66:01	Confirmed	A*66:11	Confirmed
A*66:02	Confirmed	A*66:12	Confirmed
A*66:03	Confirmed	A*66:13	Confirmed
A*66:04	Unconfirmed	A*66:14	Unconfirmed
A*66:05	Unconfirmed	A*66:15	Unconfirmed
A*66:06	Unconfirmed	A*66:16	Unconfirmed
A*66:07	Unconfirmed		
A*66:08	Unconfirmed		
A*66:09	Confirmed		
A*66:10	Unconfirmed		

¹Allele status “confirmed” or “unconfirmed” as listed on the IMGT/HLA web page 2012-April-12, release 3.8.0, www.ebi.ac.uk/imgt/hla.

RESOLUTION IN HOMO- AND HETEROZYGOTES

A total of 17 alleles generate 16 amplification patterns that can be combined in 136 homozygous and heterozygous combinations. 66 of these genotypes do not give rise to unique amplification patterns. The different lengths of the specific PCR products were not considered in these calculations.

```

-+---- -+---- *66:02, *66:16 = *66:16, *66:16
+-+---- -+---- *66:05, *66:15 = *66:15, *66:15
+-+---- -+---- *66:05, *66:12 = *66:12, *66:15
+++---- -+---- *66:01, *66:11 = *66:01, *66:13 = *66:11, *66:13 = *66:13, *66:13
+++---- -+---- *66:01, *66:08 = *66:08, *66:08
+++---- -+---- *66:01, *66:10 = *66:10, *66:10
+++---- -+---- *66:01, *66:09 = *66:09, *66:09
+++---- -+---- *66:01, *66:06 = *66:06, *66:06
+++---- -+---- *66:01, *66:05 = *66:01, *66:15
+++---- -+---- *66:01, *66:04 = *66:04, *66:04
+++---- -+---- *66:02, *66:05 = *66:02, *66:15
+++---- -+---- *66:08, *66:11 = *66:08, *66:13
+++---- -+---- *66:10, *66:11 = *66:10, *66:13
+++---- -+---- *66:09, *66:11 = *66:09, *66:13
+++---- -+---- *66:06, *66:11 = *66:06, *66:13
+++---- -+---- *66:01, *66:14 = *66:06, *66:10 = *66:06, *66:14 = *66:10, *66:14 =
*66:14, *66:14
+++---- -+---- *66:05, *66:11 = *66:05, *66:13 = *66:11, *66:15 = *66:13, *66:15
+++---- -+---- *66:05, *66:08 = *66:08, *66:15
+++---- -+---- *66:05, *66:10 = *66:10, *66:15
+++---- -+---- *66:05, *66:09 = *66:09, *66:15
+++---- -+---- *66:05, *66:06 = *66:06, *66:15
+++---- -+---- *66:04, *66:11 = *66:04, *66:13
+++---- -+---- *66:01, *66:07 = *66:04, *66:05 = *66:04, *66:07 = *66:04, *66:15 =
*66:05, *66:07 = *66:07, *66:07 = *66:07, *66:15
+-+---- -+---- *66:05, *66:16 = *66:15, *66:16
+++---- -+---- *66:11, *66:14 = *66:13, *66:14
+++---- -+---- *66:05, *66:14 = *66:14, *66:15
+++---- -+---- *66:07, *66:11 = *66:07, *66:13

```

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Lot No.: **09R**

Lot-specific information

www.olerup-ssp.com**SPECIFICITY TABLE****HLA-A*66 SSP subtyping**

Specificities and sizes of the PCR products of the 15 primer mixes used for
 HLA-A*66 SSP subtyping

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified HLA-A*66 alleles ³	Other amplified HLA-A alleles ⁴
1⁶	175 bp	800 bp	*66:01, 66:04-66:15	*02:135, 25:01:01-25:05, 25:07-25:16, 26:01:01-26:01:20, 26:01:22-26:03:02, 26:05-26:08, 26:10-26:33, 26:35- 26:43:02, 26:45-26:72, 26:74, 43:01
2⁵	100 bp	1070 bp	*66:01, 66:04, 66:06- 66:11, 66:13- 66:14	*01:13, 01:17, 03:63, 03:88, 11:01:01- 11:11, 11:13-11:16, 11:20-11:27, 11:29-11:39, 11:41-11:52Q, 11:54- 11:95, 11:97, 11:99N-11:105, 11:107- 11:120, 11:122, 25:02, 26:13, 26:19, 26:33, 34:01:01-34:06, 34:08
3	430 bp	1070 bp	*66:01-66:02, 66:04, 66:06- 66:16	*02:11:01-02:11:04, 02:34-02:35:03, 02:56:01-02:56:02, 02:62, 02:69, 02:78, 02:103, 02:128, 02:297-02:298, 02:308, 24:19, 26:13, 26:19, 34:01:01- 34:09, 68:01:01:01-68:02:05, 68:04, 68:06-68:14, 68:16-68:19, 68:21:01- 68:30, 68:32-68:35, 68:37-68:56, 68:58-68:88, 69:01
4	175 bp	1070 bp	*66:02-66:03, 66:16	
5^{5,7}	70 bp, 100 bp	800 bp	*66:04, 66:07	*02:55, 26:03:01-26:03:02, 26:06, 26:21, 26:30, 33:24, 68:05, 68:15, 68:20
6⁵	80 bp	800 bp	*66:01, 66:04-66:10, 66:13-66:14	*01:13, 01:28, 02:346, 03:63, 03:88, 11:01:01-11:11, 11:13-11:16, 11:19- 11:27, 11:29-11:39, 11:41-11:44, 11:46-11:52Q, 11:54-11:110, 11:112- 11:122, 24:19, 24:44, 26:03:01- 26:03:02, 26:06, 26:21, 31:03, 34:01:01-34:08, 80:02
7	560 bp	1070 bp	*66:03	*02:16, 02:131
8⁵	95bp	1070 bp	*66:05, 66:07, 66:15	*01:01:01:01-01:01:27, 01:01:29- 01:04N, 01:06, 01:08-01:12, 01:14- 01:16N, 01:18N-01:33, 01:35-01:70, 01:72-01:99, 01:101-01:104, 01:106- 01:109, 02:346, 03:41, 11:17, 11:19, 11:40, 11:98, 11:121, 24:44 ^w , 24:109 ^w ,

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 101.427-06u – without *Taq* polymerase, IFU-02 Rev. No. 03

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Lot No.: 09R		Lot-specific information		www.olerup-ssp.com
				25:01:01-25:01:07, 25:03-25:12N, 25:14, 25:16, 26:01:01-26:01:21, 26:01:23-26:12, 26:14-26:18, 26:20- 26:29, 26:31-26:32, 26:34-26:43:02, 26:45-26:63, 26:66-26:74, 31:03, 33:13, 36:01-36:05, 43:01, 74:10, 80:01-80:02
9⁸	155 bp, 235 bp	1070 bp	*66:06, 66:14	*02:309, 03:01:19, 26:43:01-26:43:02, 31:03-31:04, 34:02:01-34:04, 34:06- 34:09
10	205 bp	1070 bp	*66:09	*02:03:01-02:03:04, 02:25, 02:38, 02:117, 02:148, 02:171:01-02:171:02, 02:230, 02:253, 02:258, 02:264, 02:267, 02:280-02:281, 02:315, 02:345, 02:355, 26:22
11⁹	190 bp, 235 bp	1070 bp	*66:10, 66:14	*26:29, 26:49
12	220 bp	1070 bp	*66:08	*02:294, 33:03:10, 33:32:02, 33:55- 33:59, 34:01:01 [?] -34:01:02 [?] , 34:05 [?]
13¹⁰	305 bp, 440 bp	1070 bp	*66:11, 66:13	
14	360 bp	1070 bp	*66:02-66:03, 66:12, 66:16	*02:135, 02:309, 03:01:19, 25:13, 26:30, 26:65, 31:04, 34:09
15	140 bp	1070 bp	*66:16	

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-A*66 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 more than 20 base pairs. Size differences of 20 base pairs or less 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-A*66 subtyping.

In addition, wells number 5 and 6 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.

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101.427-06u – without **Taq** polymerase, IFU-02 Rev. No. 03

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“Instructions for Use” (IFU)

Lot No.: 09R**Lot-specific information****www.olerup-ssp.com**

³For several HLA-A alleles 1st or 4th exon nucleotide sequences are not available. In these instances it is not known whether some of the primers of the SSP sets are completely matched with the target sequences or not. We assume that unknown sequences in these regions are conserved within allelic groups.

⁴Due to the sharing of sequence motifs between HLA-A alleles non-HLA-A*66 alleles will be amplified by primer mixes 1 to 3, 5 to 12 and 14.

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

⁶Primer mix 1 may give rise to a PCR fragment approx. 500 bp in size. This band should be disregarded in the interpretation of HLA-A*66 subtypings.

⁷Primer mix 5: Specific PCR fragment of 70 bp in the A*02:55, 26:03:01-26:03:02, 26:06, 26:21, 26:30, 33:24, 68:05, 68:15 and 68:20 alleles. Specific PCR fragment of 100 bp in the A*66:04 and A*66:07 alleles.

⁸Primer mix 9: Specific PCR fragment of 155 bp in the A*66:06 and in the A*02:309, 03:01:19, 26:43:01-26:43:02, 31:03-31:04, 34:02:01-34:04 and 34:06-34:09 alleles. Specific PCR fragment of 235 bp in the A*66:14 allele.

⁹Primer mix 11: Specific PCR fragment of 190 bp in the A*66:10 and in the A*26:29 and 26:49 alleles. Specific PCR fragment of 235 bp in the A*66:14 allele.

¹⁰Primer mix 13: Specific PCR fragment of 305 bp in the A*66:13 allele. Specific PCR fragment of 440 bp in the A*66:11 allele.

‘w’, might be weakly amplified.

‘?’, nucleotide sequence of the primer matching sequence is not known.

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 101.427-06u – without *Taq* polymerase, IFU-02 Rev. No. 03

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Lot No.: **09R**

Lot-specific information

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INTERPRETATION TABLE								
HLA-A*66 SSP subtyping								
Amplification patterns of the HLA-A*66:01 to 66:16 alleles								
	Well ⁵							
	1	2	3	4	5	6	7	8
Length of spec.	175	100	430	175	70	80	560	95
PCR product(s)					100			
Length of int.	800	1070	1070	1070	800	800	1070	1070
pos. control ¹								
5'-primer(s) ²	418	282	28	423	261	302	282	282
	5'-AgA 3'	5'-CAg 3'	5'-TCg 3'	5'-gCT 3'	5'-AAC 3'	5'-ggA 3'	5'-CAC 3'	5'-CAC 3'
	423				517			517
	5'-gCT 3'				5'-AgA 3'			5'-AgA 3'
3'-primer(s) ³	559	341	282	559	292	341	559	341
	5'-CCg 3'	5'-CgT 3'	5'-gAC 3'	5'-CTC 3'	5'-gTg 3'	5'-CgT 3'	5'-CTC 3'	5'-CgT 3'
	559		290		566			566
	5'-CCg 3'		5'-CAA 3'		5'-CCg 3'			5'-CCg 3'
					583			
					5'-gTg 3'			
Well No.	1	2	3	4	5	6	7	8
HLA-A allele ⁴								
*66:01	1	2	3			6		
*66:02			3	4				
*66:03				4			7	
*66:04	1	2	3		5	6		
*66:05	1					6		8
*66:06	1	2	3			6		
*66:07	1	2	3		5	6		8
*66:08	1	2	3			6		
*66:09	1	2	3			6		
*66:10	1	2	3			6		
*66:11	1	2	3					
*66:12	1		3					
*66:13	1	2	3			6		
*66:14	1	2	3			6		
*66:15	1		3					8
*66:16			3	4				
Well No.	1	2	3	4	5	6	7	8

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 101.427-06u – without *Taq* polymerase, IFU-02 Rev. No. 03

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 “Instructions for Use” (IFU)

Lot No.: **09R**

Lot-specific information

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INTERPRETATION TABLE							
HLA-A*66 SSP subtyping							
Amplification patterns of the HLA-A*66:01 to 66:16 alleles							
Well ⁵							
9	10	11	12	13	14	15	
155	205	190	220	305	360	140	Length of spec. PCR product(s)
235		235		440			
1070	1070	1070	1070	1070	1070	1070	
423	355	423	652	28	341	423	5'-primer(s) ²
^{5'} -gCT ^{3'}	^{5'} -CCg ^{3'}	^{5'} -gCT ^{3'}	^{5'} -CTg ^{3'}	^{5'} -TCg ^{3'}	^{5'} -ggC ^{3'}	^{5'} -gCT ^{3'}	
539	517	570	829	164	418	521	3'-primer(s) ³
^{5'} -TCA ^{3'}	^{5'} -CgT ^{3'}	^{5'} -CCg ^{3'}	^{5'} -CTC ^{3'}	^{5'} -gCA ^{3'}	^{5'} -gTC ^{3'}	^{5'} -ggA ^{3'}	
616		616		299			
^{5'} -CgC ^{3'}		^{5'} -CgC ^{3'}		^{5'} -CCg ^{3'}			
9	10	11	12	13	14	15	Well No.
							HLA-A allele ⁴
							*66:01
					14		*66:02
					14		*66:03
							*66:04
							*66:05
9							*66:06
							*66:07
			12				*66:08
	10						*66:09
		11					*66:10
				13			*66:11
					14		*66:12
				13			*66:13
9		11					*66:14
							*66:15
					14	15	*66:16
9	10	11	12	13	14	15	Well No.

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 101.427-06u – without *Taq* polymerase, IFU-02 Rev. No. 03

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Lot No.: **09R**

Lot-specific information

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Length of spec. PCR product(s)	175	100	430	175	70	80	560	95
					100			
Well No.	1	2	3	4	5	6	7	8
*01:01:01:01-01:01:27, 01:01:29-01:04N, 01:06, 01:08- 01:12, 01:14-01:16N, 01:18N- 01:27N, 01:29-01:33, 01:35- 01:70, 01:72-01:99, 01:101- 01:104, 01:106-01:109, 03:41, 11:17, 11:40, 25:06, 26:01:21, 26:04, 26:09, 26:34, 26:73, 33:13, 36:01-36:05, 74:10, 80:01								8
*01:13, 03:63, 03:88, 11:01:01- 11:11, 11:13-11:16, 11:20- 11:27, 11:29-11:39, 11:41- 11:44, 11:46-11:52Q, 11:54- 11:95, 11:97, 11:99N-11:105, 11:107-11:110, 11:112-11:120, 11:122		2				6		
*01:17, 11:45, 11:111		2						
*01:28, 02:346, 11:19, 11:98, 11:121, 80:02						6		8
*02:03:01-02:03:04, 02:25, 02:38, 02:117, 02:148, 02:171:01-02:171:02, 02:230, 02:253, 02:258, 02:264, 02:267, 02:280-02:281, 02:315, 02:345, 02:355								
*02:11:01-02:11:04, 02:34- 02:35:03, 02:56:01-02:56:02, 02:62, 02:69, 02:78, 02:103, 02:128, 02:297-02:298, 02:308, 68:01:01:01-68:02:05, 68:04, 68:06-68:14, 68:16-68:19, 68:21:01-68:30, 68:32-68:35, 68:37-68:56, 68:58-68:88, 69:01			3					
*02:16, 02:131							7	
*02:55, 33:24, 68:05, 68:15, 68:20					5			
*02:135, 25:13, 26:65	1							
Well No.	1	2	3	4	5	6	7	8

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 101.427-06u – without *Taq* polymerase, IFU-02 Rev. No. 03

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Lot No.: **09R**

Lot-specific information

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155	205	190	220	305	360	140	Length of spec. PCR product(s)
235		235		440			
9	10	11	12	13	14	15	Well No.
							*01:01:01:01-01:01:27, 01:01:29-01:04N, 01:06, 01:08- 01:12, 01:14-01:16N, 01:18N- 01:27N, 01:29-01:33, 01:35- 01:70, 01:72-01:99, 01:101- 01:104, 01:106-01:109, 03:41, 11:17, 11:40, 25:06, 26:01:21, 26:04, 26:09, 26:34, 26:73, 33:13, 36:01-36:05, 74:10, 80:01
							*01:13, 03:63, 03:88, 11:01:01- 11:11, 11:13-11:16, 11:20- 11:27, 11:29-11:39, 11:41- 11:44, 11:46-11:52Q, 11:54- 11:95, 11:97, 11:99N-11:105, 11:107-11:110, 11:112-11:120, 11:122
							*01:17, 11:45, 11:111
							*01:28, 02:346, 11:19, 11:98, 11:121, 80:02
	10						*02:03:01-02:03:04, 02:25, 02:38, 02:117, 02:148, 02:171:01-02:171:02, 02:230, 02:253, 02:258, 02:264, 02:267, 02:280-02:281, 02:315, 02:345, 02:355
							*02:11:01-02:11:04, 02:34- 02:35:03, 02:56:01-02:56:02, 02:62, 02:69, 02:78, 02:103, 02:128, 02:297-02:298, 02:308, 68:01:01:01-68:02:05, 68:04, 68:06-68:14, 68:16-68:19, 68:21:01-68:30, 68:32-68:35, 68:37-68:56, 68:58-68:88, 69:01
							*02:16, 02:131
							*02:55, 33:24, 68:05, 68:15, 68:20
					14		*02:135, 25:13, 26:65
9	10	11	12	13	14	15	Well No.

101.427-06 – including *Taq* pol., IFU-01 Rev. No. 03
 101.427-06u – without *Taq* polymerase, IFU-02 Rev. No. 03

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Lot No.: 09R	Lot-specific information				www.olerup-ssp.com			
	175	100	430	175	70	80	560	95
Length of spec. PCR product(s)					100			
Well No.	1	2	3	4	5	6	7	8
*02:294, 33:03:10, 33:32:02, 33:55-33:59								
*02:16, 02:131							7	
*02:55, 33:24, 68:05, 68:15, 68:20					5			
*02:135, 25:13, 26:65	1							
*02:294, 33:03:10, 33:32:02, 33:55-33:59								
*02:309, 03:01:19, 31:04								
*11:96, 11:106						6		
*24:19			3			6		
*24:44						6		w
*24:109								w
*25:01:01-25:01:07, 25:03- 25:05, 25:07-25:12N, 25:14, 25:16, 26:01:01-26:01:20, 26:01:23-26:02, 26:05, 26:07:01-26:08, 26:10-26:12, 26:14-26:18, 26:20, 26:23- 26:28, 26:31-26:32, 26:35- 26:42, 26:45-26:48, 26:50- 26:63, 26:66-26:72, 26:74, 43:01	1							8
*25:02, 26:33	1	2						
*25:15, 26:01:22, 26:64	1							
*26:03:01-26:03:02, 26:06, 26:21	1				5	6		8
*26:13, 26:19	1	2	3					
*26:22	1							8
*26:29, 26:49	1							8
*26:30	1				5			
*26:43:01-26:43:02	1							8
*31:03						6		8
*34:01:01-34:01:02, 34:05		2	3			6		
*34:02:01-34:04, 34:06, 34:08		2	3			6		
*34:07			3			6		
*34:09			3					
HLA-A allele								
Well No.	1	2	3	4	5	6	7	8

101.427-06 – including *Taq* pol., IFU-01 Rev. No. 03
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Lot No.: **09R**

Lot-specific information

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155	205	190	220	305	360	140	Length of spec. PCR product(s)
235		235		440			
9	10	11	12	13	14		Well No.
			12				*02:294, 33:03:10, 33:32:02, 33:55-33:59
							*02:16, 02:131
							*02:55, 33:24, 68:05, 68:15, 68:20
					14		*02:135, 25:13, 26:65
			12				*02:294, 33:03:10, 33:32:02, 33:55-33:59
9					14		*02:309, 03:01:19, 31:04
							*11:96, 11:106
							*24:19
							*24:44
							*24:109
							*25:01:01-25:01:07, 25:03- 25:05, 25:07-25:12N, 25:14, 25:16, 26:01:01-26:01:20, 26:01:23-26:02, 26:05, 26:07:01-26:08, 26:10-26:12, 26:14-26:18, 26:20, 26:23- 26:28, 26:31-26:32, 26:35- 26:42, 26:45-26:48, 26:50- 26:63, 26:66-26:72, 26:74, 43:01
							*25:02, 26:33
							*25:15, 26:01:22, 26:64
							*26:03:01-26:03:02, 26:06, 26:21
							*26:13, 26:19
	10						*26:22
		11					*26:29, 26:49
					14		*26:30
9							*26:43:01-26:43:02
9							*31:03
			?				*34:01:01-34:01:02, 34:05
9							*34:02:01-34:04, 34:06, 34:08
9							*34:07
9					14		*34:09
							HLA-A allele
9	10	11	12	13	14	15	Well No.

101.427-06 – including *Taq* pol., IFU-01 Rev. No. 03
101.427-06u – without *Taq* polymerase, IFU-02 Rev. No. 03

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Lot No.: 09R**Lot-specific information****www.olerup-ssp.com**

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-A*66 subtyping. .

In addition, wells number 5 and 6 contain the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to allow kit identification.

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

⁴HLA-A*66 alleles in bold lettering are listed as confirmed alleles on the on the IMGT/HLA web page www.ebi.ac.uk/imgt/hla, release 3.8.0, April 2012.

⁵Primer mix 5: Specific PCR fragment of 70 bp in the A*02:55, 26:03:01-26:03:02, 26:06, 26:21, 26:30, 33:24, 68:05, 68:15 and 68:20 alleles. Specific PCR fragment of 100 bp in the A*66:04 and A*66:07 alleles.

Primer mix 9: Specific PCR fragment of 155 bp in the A*66:06 and in the A*02:309, 03:01:19, 26:43:01-26:43:02, 31:03-31:04, 34:02:01-34:04 and 34:06-34:09 alleles. Specific PCR fragment of 235 bp in the A*66:14 allele.

Primer mix 11: Specific PCR fragment of 190 bp in the A*66:10 and in the A*26:29 and 26:49 alleles. Specific PCR fragment of 235 bp in the A*66:14 allele.

Primer mix 13: Specific PCR fragment of 305 bp in the A*66:13 allele. Specific PCR fragment of 440 bp in the A*66:11 allele.

'w', might be weakly amplified.

'?', nucleotide sequence of the primer matching sequence is not known.

101.427-06 – including **Taq** pol., IFU-01 Rev. No. 03
 101.427-06u – without **Taq** polymerase, IFU-02 Rev. No. 03

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Lot No.: **09R**

Lot-specific information

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CELL LINE VALIDATION SHEET																			
HLA-A*66 SSP subtyping kit																			
				Lot No.:	Well														
					1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
					200964201	200853102	201182503	200964204	200853105	200853106	200853107	200853108	201182509	200964210	201182511	200964212	201182513	201182514	201205015
	IHWC cell line	A*	A*																
1	9001 SA	*24:02			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2	9280 LK707	*02:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3	9011 E4181324	*01:01			-	-	-	-	-	-	-	+	-	-	-	-	-	-	-
4	9275 GU373	*30:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
5	9009 KAS011	*01:01			-	-	-	-	-	-	-	+	-	-	-	-	-	-	-
6	9353 SM	*02:01	*26:03		+	-	-	-	+	+	-	+	-	-	-	-	-	-	-
7	9020 QBL	*26:01			+	-	-	-	-	-	-	+	-	-	-	-	-	-	-
8	9025 DEU	*31:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
9	9026 YAR	*26:01			+	-	-	-	-	-	-	+	-	-	-	-	-	-	-
10	9107 LKT3	*24:02			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
11	9051 PITOUT	*29:02			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
12	9052 DBB	*02:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
13	9004 JESTHOM	*02:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
14	9071 OLGA	*31:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
15	9075 DKB	*24:02			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
16	9037 SWEIG007	*29:02			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
17	9282 CTM3953540	*03:01	*80:01		-	-	-	-	-	-	-	+	-	-	-	-	-	-	-
18	9257 32367	*33:03	*74:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
19	9038 BM16	*02:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
20	9059 SLE005	*02:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
21	9064 AMALA	*02:17			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
22	9056 KOSE	*02:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
23	9124 IHL	*02:01	*34:01		-	+	+	-	-	+	-	-	-	-	-	+	-	-	-
24	9035 JBUSH	*32:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
25	9049 IBW9	*33:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
26	9285 WT49	*02:05			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
27	9191 CH1007	*24:10	*29:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
28	9320 BEL5GB	*02:01	*29:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
29	9050 MOU	*29:02			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
30	9021 RSH	*30:01	*68:02		-	-	+	-	-	-	-	-	-	-	-	-	-	-	-
31	9019 DUCAF	*30:02			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
32	9297 HAG	*02:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
33	9098 MT14B	*31:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
34	9104 DHIF	*31:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
35	9302 SSTO	*32:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
36	9024 KT17	*02:06	*11:01		-	+	-	-	-	+	-	-	-	-	-	-	-	-	-
37	9065 HHKB	*03:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
38	9099 LZL	*02:17			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
39	9315 CML	*01:01	*03:01		-	-	-	-	-	-	-	+	-	-	-	-	-	-	-
40	9134 WHONP199	*02:07	*30:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
41	9055 H0301	*03:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
42	9066 TAB089	*02:07			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
43	9076 T7526	*02:06	*02:07		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
44	9057 TEM	*66:01			+	+	+	-	-	+	-	-	-	-	-	-	-	-	-
45	9239 SHJO	*23:01	*24:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
46	9013 SCHU	*03:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
47	9045 TUBO	*02:16	*03:01		-	-	-	-	-	-	-	+	-	-	-	-	-	-	-
48	9303 TER-ND	*02:01	*11:01		-	+	-	-	-	+	-	-	-	-	-	-	-	-	-

101.427-06 – including *Taq* pol., IFU-01 Rev. No. 03
 101.427-06u – without *Taq* polymerase, IFU-02 Rev. No. 03

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Lot No.: **09R**

Lot-specific information

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CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-A*66 SSP

Product number: 101.427-06 – including *Taq* pol.
 101.427-06u – without *Taq* pol.
Lot number: 09R
Expiry date: 2015-February-01
Number of tests: 6
Number of wells per test: 15

Well specifications:

Well No.	Production No.	Well No.	Production No.
1	2009-642-01	9	2011-825-09
2	2008-531-02	10	2009-642-10
3	2011-825-03	11	2011-825-11
4	2009-642-04	12	2009-642-12
5	2008-531-05	13	2011-825-13
6	2008-531-06	14	2011-825-14
7	2008-531-07	15	2012-050-15
8	2008-531-08		

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

No DNAs carrying the alleles to be amplified by primer solutions 11 to 13 and 15 were available. The specificities of the primers in primer solution 11 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer solutions 12, 13 and 15 it was only possible to test the 5'-primer, the 3'-primers were not possible to test. One of the 3'-primers in primer solutions 5, 8, 9 and 11 was not possible to test. The specificities of additional primers in primer solution 5 and 8 were tested by separately adding one additional 5'-primer, and/or one additional 3'-primer

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

Date of approval: 2012-August-20

Approved by:

Production Quality Control

101.427-06 – including **Taq pol.**, IFU-01 Rev. No. 03
101.427-06u – without **Taq polymerase**, IFU-02 Rev. No. 03

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Lot No.: **09R**

Lot-specific information

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Declaration of Conformity

Product name: Olerup SSP® HLA-A*66
Product number: 101.427-06/06u
Lot number: 09R

Intended use: HLA-A*66 high resolution histocompatibility testing

Manufacturer: Olerup SSP AB
Franzengatan 5
SE-112 51 Stockholm, 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 II List B, conformity assessed using Annex IV, as transposed into the national laws of the Member States of the European Union.

The Technical Documentation File is maintained at Olerup SSP AB, Franzengatan 5, SE-112 51 Stockholm, Sweden.

Notified Body: Lloyd's Register Quality Assurance Limited, Hiramford, Middlemarch Office Village, Siskin Drive, Coventry CV3 4FJ, United Kingdom. (Notified Body number: 0088.)

Stockholm, Sweden
2012-August-20

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs

101.427-06 – including *Taq* pol., IFU-01 Rev. No. 03
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