

101.433-06 – including *Taq* polymerase, IFU-01 Rev. No. 03
101.433-06u – without *Taq* polymerase, IFU-02 Rev. No. 03

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“Instructions for Use” (IFU)

Lot No.: **69N**

Lot-specific information
Olerup SSP[®] HLA-A*74

Product number:	101.433-06 – including <i>Taq</i> polymerase 101.433-06u –without <i>Taq</i> polymerase
Lot number:	69N
Expiry date:	2014-October-01
Number of tests:	6
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. 69N.

**CHANGES COMPARED TO THE PREVIOUS OLERUP SSP[®]
HLA-A*74 LOT (87K)**

The HLA-A*74 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*74 kit, well **16**.

The Lot-specific information for HLA-A*74 including and without *Taq* polymerase is now described in one common Product Insert.

¹As described in section Uniquely Identified Alleles.

The HLA-A*74 specificity and interpretation tables have been updated for the HLA-A alleles described since the previous *Olerup SSP[®]* HLA-A*74 lot was made (Lot No. 87K).

101.433-06 – including *Taq* polymerase, IFU-01 Rev. No. 03
101.433-06u – without *Taq* polymerase, IFU-02 Rev. No. 03

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Lot No.: 69N**Lot-specific information**

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

Well	5'-primer	3'-primer	rationale
12	-	-	Exchanged positive control primer pair.
16	New	New	New primer pair for the A*74:15 allele.

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 101.433-06u – without *Taq* polymerase, IFU-02 Rev. No. 03

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 “Instructions for Use” (IFU)

Lot No.: **69N**

Lot-specific information

PRODUCT DESCRIPTION

HLA-A*74 SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for identifying the A*74:01 to A*74:15 alleles.

PLATE LAYOUT

Each 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 cut PCR plate is marked with 'HLA-A*74' in silver/gray ink.

Well No. 1 is marked with the Lot No. '69N'.

A faint row of numbers is seen between wells 1 and 2 or wells 7 and 8 of the PCR trays. These stem from the manufacture of the trays, and should be disregarded.

The PCR plates are covered with a PCR-compatible foil.

Please note: When removing each 16 well PCR plate, make sure that the remaining plates stay covered. Use a scalpel or a similar instrument to carefully cut the foil between the plates.

INTERPRETATION

The interpretation of HLA-A*74 SSP subtypings will be influenced by six A*02, two A*03, A*26:07:02, the A*29, the A*32, three A*33 and the A*68:30 alleles when present on the other haplotype. In addition, primer mix 11 will amplify the C*06:02:15 allele.

UNIQUELY IDENTIFIED ALLELES

All the HLA-A*74 alleles, i.e. **A*74:01 to A*74:15 alleles**, recognized by the HLA Nomenclature Committee in January 2012¹ will be amplified by the primers in the HLA-A*74 subtyping kit.

The HLA-A*74 kit enables separation of the confirmed HLA-A*74 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*74 alleles is listed below.

The HLA-A*74 kit also enables identification of polymorphisms in exons outside of the region encoding the peptide binding domain and of null and alternatively expressed alleles.

The HLA-A*74 subtyping kit cannot distinguish the silent mutations in the A*74:02:01:01-74:02:01:02 alleles.

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 101.433-06u – without *Taq* polymerase, IFU-02 Rev. No. 03

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 “Instructions for Use” (IFU)

Lot No.: **69N**

Lot-specific information

¹HLA-A alleles listed on the IMGT/HLA web page 2012-January-12, release 3.7.0, www.ebi.ac.uk/imgt/hla.

ALLELE CONFIRMATION STATUS

Allele	Status ¹	Allele	Status ¹
A*74:01	Confirmed	A*74:10	Unconfirmed
A*74:02:01:01	Confirmed	A*74:11	Confirmed
A*74:02:01:02	Unconfirmed	A*74:12N	Unconfirmed
A*74:03	Confirmed	A*74:13	Confirmed
A*74:04	Unconfirmed	A*74:14N	Unconfirmed
A*74:05	Confirmed	A*74:15	Unconfirmed
A*74:06	Confirmed		
A*74:07	Confirmed		
A*74:08	Confirmed		
A*74:09	Confirmed		

¹Allele status “confirmed” or “unconfirmed” as listed on the IMGT/HLA web page 2012-January-12, release 3.7.0, www.ebi.ac.uk/imgt/hla.

RESOLUTION IN HOMO- AND HETEROZYGOTES

A total of 16 alleles generate 15 amplification patterns that can be combined in 120 homozygous and heterozygous combinations. 10 of these genotypes do not give rise to unique amplification patterns.

+-+----+- ----- *74:02:01:01, *74:07 = *74:07, *74:07
 ++----- -----+-- *74:01, *74:13 = *74:13, *74:13
 ++----- ----+---- *74:01, *74:11 = *74:11, *74:11
 ++----- +----- *74:01, *74:03 = *74:03, *74:03
 ++----- +-----+ - *74:01, *74:14N = *74:03, *74:14N

*74:02:01:01 = *74:02:01:01-74:02:01:02

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 101.433-06u – without *Taq* polymerase, IFU-02 Rev. No. 03

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Lot No.: **69N**

Lot-specific information
SPECIFICITY TABLE

HLA-A*74 SSP subtyping

Specificities and sizes of the PCR products of the 16 primer mixes used for HLA-A*74 SSP subtyping

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified HLA-A*74 alleles ³	Other amplified HLA-A alleles ⁴
1	160 bp	800 bp	*74:01-74:09, 74:11-74:15	*29:19
2	285 bp	1070 bp	*74:01, 74:03, 74:04 [?] -74:06 [?] , 74:08 [?] -74:10 [?] , 74:11, 74:12N [?] , 74:13, 74:14N [?] -74:15 [?]	
3	285 bp	1070 bp	*74:02:01:01-74:02:01:02, 74:04 [?] -74:06 [?] , 74:07, 74:08 [?] -74:10 [?] , 74:12N [?] , 74:14N [?] -74:15 [?]	*29:01:01:01-29:03, 29:04 [?] -29:10 [?] , 29:11, 29:12 [?] -29:32 [?] , 32:01:01-32:02, 32:03 [?] , 32:05, 32:06 [?] -32:16 [?] , 32:17, 32:18 [?] , 32:19N, 32:20 [?] -32:37 [?]
4	135 bp	1070 bp	*74:04	*02:01:09, 02:05:05, 02:06:07, 02:11:02, 02:35:03, 02:76:02, 03:01:03 ^w , 03:23:01, 26:07:02, 33:01:02, 33:08-33:09, 68:30
5	230 bp	1070 bp	*74:05	
6	155 bp	1070 bp	*74:06	*29:19
7	150 bp	800 bp	*74:07	
8⁵	115 bp	1070 bp	*74:08	
9	170 bp	800 bp	*74:03, 74:14N	
10	225 bp	1070 bp	*74:09	
11	200 bp	800 bp	*74:10	C*06:02:15
12	130 bp	800 bp	*74:11	
13	215 bp	1070 bp	*74:12N	
14	145 bp	1070 bp	*74:13	
15⁵	85 bp	1070 bp	*74:14N	
16	185 bp	1070 bp	*74:15	

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101.433-06u – without *Taq* polymerase, IFU-02 Rev. No. 03

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Lot No.: 69N**Lot-specific information**

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*74 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 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*74 subtyping.

In addition, wells number 7, 9, 11 and 12 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.

³For several HLA-A alleles 1st 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 the 1st exon are conserved within allelic groups.

⁴Due to the sharing of sequence motifs between HLA-A alleles a non-HLA-A*74 allele will be amplified by primer mixes 1, 3, 4 and 6. In addition, primer mix 11 will amplify the C*06:02:15 allele.

⁵Short specific PCR fragments are less intense and not as sharp as longer specific bands.

‘?’; nucleotide sequence information not available for the primer matching sequence.

‘w’, may be weakly amplified.

101.433-06 – including *Taq* polymerase, IFU-01 Rev. No. 03101.433-06u – without *Taq* polymerase, IFU-02 Rev. No. 03Visit www.olerup-ssp.com for

“Instructions for Use” (IFU)

Lot No.: **69N**

Lot-specific information

INTERPRETATION TABLE								
HLA-A*74 SSP subtyping								
Amplification patterns of the A*74:01 to 74:15 alleles								
	Well							
	1	2	3	4	5	6	7	8
Length of spec.	160	285	285	135	230	155	150	115
PCR product								
Length of int.	800	1070	1070	1070	1070	1070	800	1070
pos. control ¹								
5'-primer ²	180	67	67	144	98	180	180	448
	5' -TTT 3'	5' -CCA 3'	5' -CCT 3'	5' -gCC 3'	5' -CTT 3'	5' -TTT 3'	5' -TTT 3'	5' -CCT 3'
3'-primer(s) ³	299	180	180	240	289	292	290	523
	5' -CCA 3'	5' -TCA 3'	5' -TCA 3'	5' -ggA 3'	5' -AgC 3'	5' -gTg 3'	5' -CAA 3'	5' -ACT 3'
	299							
	5' -CCA 3'							
Well No.	1	2	3	4	5	6	7	8
HLA-A allele ⁴								
*74:01	1	2						
*74:02:01:01-74:02:01:02	1		3					
*74:03	1	2						
*74:04	1	?	?	4				
*74:05	1	?	?		5			
*74:06	1	?	?			6		
*74:07	1		3				7	
*74:08	1	?	?					8
*74:09	1	?	?					
*74:10		?	?					
*74:11	1	2						
*74:12N	1	?	?					
*74:13	1	2						
*74:14N	1	?	?					
*74:15	1	?	?					
*02:01:09, 02:05:05, 02:06:07, 02:11:02, 02:35:03, 02:76:02, 03:23:01, 26:07:02, 33:01:02, 33:08-33:09, 68:30				4				
*03:01:03				w				
*29:01:01:01-29:03, 29:11, 32:01:01- 32:02, 32:05, 32:17, 32:19N			3					
*29:04-29:10, 29:12-29:18, 29:20-29:32, 32:03, 32:06-32:16, 32:18, 32:20-32:37			?					
*29:19	1		?			6		
C*06:02:15								
HLA-A allele								
Well No.	1	2	3	4	5	6	7	8

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 101.433-06u – without *Taq* polymerase, IFU-02 Rev. No. 03

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 "Instructions for Use" (IFU)

Lot No.: **69N**

Lot-specific information

INTERPRETATION TABLE								
HLA-A*74 SSP subtyping								
Amplification patterns of the A*74:01 to 74:15 alleles								
Well								
9	10	11	12	13	14	15	16	
170	225	200	130	215	145	85	185	Length of spec. PCR product
800	1070	800	800	1070	1070	1070	1070	Length of int. pos. control ¹
180	113	180	211	364	180	180	448	5'-primer ²
5'-TTT 3'	5'-CCC 3'	5'-TTT 3'	5'-AgT 3'	5'-gA 3'	5'-TTT 3'	5'-TTT 3'	5'-CCT 3'	
308	299	341	299	538	282	225	594	3'-primer(s) ³
5'-TCg 3'	5'-CCA 3'	5'-CgT 3'	5'-CCA 3'	5'-CAA 3'	5'-gAC 3'	5'-ATT 3'	5'-CCC 3'	
9	10	11	12	13	14	15	16	Well No. HLA-A allele ⁴
								*74:01
								*74:02:01:01-74:02:01:02
9								*74:03
								*74:04
								*74:05
								*74:06
								*74:07
								*74:08
	10							*74:09
		11						*74:10
			12					*74:11
				13				*74:12N
					14			*74:13
9						15		*74:14N
							16	*74:15
								*02:01:09, 02:05:05, 02:06:07, 02:11:02, 02:35:03, 02:76:02, 03:23:01, 26:07:02, 33:01:02, 33:08-33:09, 68:30
								*03:01:03
								*29:01:01:01-29:03, 29:11, 32:01:01- 32:02, 32:05, 32:17, 32:19N
								*29:04-29:10, 29:12-29:18, 29:20-29:32, 32:03, 32:06-32:16, 32:18, 32:20-32:37
								*29:19
		11						C*06:02:15
9	10	11	12	13	14	15	16	HLA-A allele Well No.

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Lot No.: 69N**Lot-specific information**

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In addition, wells number 7, 9, 11 and 12 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 or 3rd 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 or 3rd 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*74 alleles in bold lettering are listed as confirmed alleles on the on the IMGT/HLA web page www.ebi.ac.uk/imgt/hla, release 3.7.0, January 2012.

'?', nucleotide sequence information not available for the primer matching sequence.

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 101.433-06u – without *Taq* polymerase, IFU-02 Rev. No. 03

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 “Instructions for Use” (IFU)

Lot No.: **69N**

Lot-specific information

CELL LINE VALIDATION SHEET																			
HLA-A*74 SSP subtyping kit																			
				Well															
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
			Lot No.:	200963601	200963602	200963603	200963604	200963605	200963606	200963607	200963608	200963609	200963610	200963611	201200812	200963613	200963614	200963615	201200816
	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	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

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 101.433-06u – without *Taq* polymerase, IFU-02 Rev. No. 03

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CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-A*74 SSP

Product number: 101.433-06 – including *Taq* polymerase
 101.433-06u –without *Taq* polymerase
Lot number: 69N
Expiry date: 2014-October-01
Number of tests: 6
Number of wells per test: 16

Well specifications:

Well No.	Production No.	Well No.	Production No.
1	2009-636-01	9	2009-636-09
2	2009-636-02	10	2009-636-10
3	2009-636-03	11	2009-636-11
4	2009-636-04	12	2012-008-12
5	2009-636-05	13	2009-636-13
6	2009-636-06	14	2009-636-14
7	2009-636-07	15	2009-636-15
8	2009-636-08	16	2012-008-16

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 4 to 8, 10 to 13, 15 and 16 were available. The specificities of the primers in primer solutions 4, 6, 7 and 11 were tested by separately adding one 5'-primer, respectively one 3'-primer. In primer solutions 5, 8, 15 and 16 it was only possible to test the 5'-primer, the 3'-primer was not possible to test. In primer solutions 10, 12 and 13 it was only possible to test the 3'-primer, the 5'-primer was not possible to test. In primer solution 1, one 3'-primer was not possible to test.

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

Date of approval: 2012-May-07

Approved by:

Production Quality Control

101.433-06 – including *Taq* polymerase, IFU-01 Rev. No. 03
101.433-06u – without *Taq* polymerase, IFU-02 Rev. No. 03

Visit www.olerup-ssp.com for
“Instructions for Use” (IFU)

Lot No.: **69N**

Lot-specific information

Declaration of Conformity

Product name: *Olerup* SSP® HLA-A*74

Product number: 101.433-06/06u

Lot number: 69N

Intended use: HLA-A*74 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.

The Authorized Representative located within the Community is: *Olerup* SSP AB.

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-May-07

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs

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For information on *Olerup* SSP distributors worldwide, contact **Olerup GmbH**.