

101.331.24/06 – including *Taq* pol., IFU-01
101.331.24u/06u – without *Taq* pol., IFU-02

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

Lot No.: **71S**

Lot-specific information
Olerup SSP[®] DPA1

Product number: 101.331-24/06 – including *Taq* pol.
101.331-24u/06u – without *Taq* pol.
Lot number: 71S
Expiry date: 2016-February-01
Number of tests: 24 test – Product No. 101.331-24/24u
6 tests – Product No. 101.331-06/06u
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. 71S.

CHANGES COMPARED TO THE PREVIOUS OLERUP SSP[®] DPA1 Lot (40R)

The DPA1 specificity and interpretation tables have been updated for the DPA1 alleles described since the previous *Olerup SSP[®] DPA1* lot was made (**Lot No. 40R**).

The Lot-specific information for DPA1 including and without *Taq* polymerase is described in one common Product Insert.

The primers of the wells detailed below have been added, exchanged or modified.

Well	5'-primer	3'-primer	rationale
1	Modified	-	Modified 5'-primer for decreased tendencies of primer oligomer formation.
10	-	Modified	Modified 3'-primer for increased yield of HLA-specific PCR product.
14	-	-	Exchanged positive control primer pair.
16	Exchanged	Exchanged	Exchanged primer pair, for decreased tendencies of primer oligomer formation.

101.331.24/06 – including *Taq* pol., IFU-01
101.331.24u/06u – without *Taq* pol., IFU-02

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

Lot No.: **71S**

Lot-specific information

PRODUCT DESCRIPTION

DPA1 SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for identifying the DPA1*01:03 to DPA1*04:01 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 'DPA1' in silver/gray ink.

Well No. 1 is marked with the Lot No. '71S'.

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

Only DPA1 alleles will be amplified by the DPA1 typing kit. Thus, the interpretation of DPA1 typings is not influenced by the DPA2 gene.

UNIQUELY IDENTIFIED ALLELES

All the phenotypically different DPA1 alleles, i.e. **DPA1*01:03 to DPA1*01:12**, **DPA1*02:01 to DPA1*02:05**, **DPA1*03:01 to DPA1*03:03** and **DPA1*04:01**, recognized by the HLA Nomenclature Committee in July 2013¹ will give rise to unique amplification patterns by the primers in the DPA1 typing kit.

The DPA1 typing kit cannot distinguish the following silent mutations: DPA1*01:03:01:01, DPA1*01:03:02 and DPA1*01:03:04, the DPA1*01:06:01 and DPA1*01:06:02, the DPA1*02:01:01 to DPA1*02:01:07 and the DPA1*02:02:01 to DPA1*02:02:05 alleles.

¹DPA1 alleles listed on the IMGT/HLA web page 2013-July-25, release 3.13.1, www.ebi.ac.uk/imgt/hla.

101.331.24/06 – including *Taq* pol., IFU-01
 101.331.24u/06u – without *Taq* pol., IFU-02

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

Lot No.: **71S**

Lot-specific information

RESOLUTION IN HOMO- AND HETEROZYGOTES

A total of 37 alleles generate 20 amplification patterns that can be combined in 210 homozygous and heterozygous combinations. 46 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.

+----+----	----+-----	*01:05, *04:01 = *04:01, *04:01
----+---+	+-----+--	*02:02:01, *02:05 = *02:05, *02:05
----+--+	+-----	*02:02:01, *02:04 = *02:04, *02:04
++-+-----	-----+--	*01:04, *01:08 = *01:08, *01:08
+++-----	-----+	*01:03:01:01, *01:09 = *01:09, *01:09
+++-----	-----+--	*01:03:01:01, *01:11 = *01:11, *01:11
+++-----	-----+--	*01:03:01:01, *01:07 = *01:07, *01:07
+++-----	---+-----	*01:03:01:01, *01:12 = *01:12, *01:12
+++--+-	-----	*01:03:01:01, *01:10 = *01:10, *01:10
+++--+-	-----	*01:03:01:01, *01:06:01 = *01:06:01, *01:10
++++-----	-----+--	*01:03:01:01, *01:08 = *01:04, *01:11 = *01:08, *01:11
+++-----	-++-----	*01:03:01:01, *03:01 = *01:03:03, *01:12 = *01:12, *03:01
+++-----	-----	*01:05, *01:06:01 = *01:10, *02:01:01
-++-++++	+-----	*01:06:01, *02:02:01 = *01:06:01, *02:04
+-+-----	+-----+--	*01:04, *02:05 = *01:08, *02:02:01 = *01:08, *02:05
+++-----	+-----+--	*01:03:01:01, *02:05 = *01:11, *02:02:01 = *01:11, *02:05
+++-----	+-----	*01:03:01:01, *02:04 = *01:10, *02:02:01 = *01:10, *02:04
++++-----	-++-----	*01:03:01:01, *03:03 = *01:04, *03:01 = *01:12, *03:03
+++-----	+-----+--	*01:10, *02:05 = *01:11, *02:04
++++-----	-++-----	*01:08, *03:01 = *01:11, *03:03

*01:03:01:01 = *01:03:01:01-01:03:02 and 01:03:04

*01:06:01 = *01:06:01-01:06:02

*02:01:01 = *02:01:01-02:01:07

*02:02:01 = *02:02:01-02:02:05

101.331.24/06 – including *Taq* pol., IFU-01
 101.331.24u/06u – without *Taq* pol., IFU-02

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

Lot No.: **71S**

Lot-specific information
SPECIFICITY TABLE

DPA1 SSP typing

Specificities and sizes of the PCR products of the 16 primer mixes used for DPA1 SSP typing

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified DPA1 ³ alleles
1⁴	85 bp	515 bp	*01:03:01:01-01:03:02, 01:03:04-01:05, 01:07-01:12, 04:01
2	255 bp	515 bp	*01:03:01:01-01:04, 01:06:01-01:12
3	205 bp	430 bp	*01:03:01:01-01:03:04, 01:06:01-01:07, 01:09-01:12, 03:01-03:02
4^{4,5}	115 bp	430 bp	*01:04, 01:08, 03:03
5⁴	105 bp	430 bp	*01:05, 02:01:01-02:05, 04:01
6^{8,9}	160 bp, 195 bp	515 bp	*01:06:01-01:06:02, 01:10, 02:04
7⁴	100 bp	430 bp	*01:06:01-01:06:02, 02:01:01-02:01:07
8⁴	100 bp	430 bp	*02:02:01-02:02:05, 02:04-02:05
9	205 bp	430 bp	*02:02:01-02:02:05, 02:04-02:05, 03:02
10⁴	85 bp	515 bp	*01:03:03, 02:03, 03:01-03:03
11^{4,6,7}	90 bp	515 bp	*01:12, 03:01, 03:03
12	205 bp	430 bp	*04:01
13	135 bp	430 bp	*01:07
14	130 bp	515 bp	*01:08, 01:11, 02:05
15⁷	245 bp	430 bp	*01:03:03, 03:01-03:03
16⁴	100 bp	430 bp	*01:09

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 DPA1 SSP typings.

When the primers in a primer mix can give rise to HLA-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 HLA-specific PCR product(s) are given for the alleles amplified by these primer mixes.

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

101.331.24/06 – including *Taq* pol., IFU-01
101.331.24u/06u – without *Taq* pol., IFU-02

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

Lot No.: 71S**Lot-specific information**

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 430 base pairs, for most wells, or a band of 515 base pairs, for some wells.

Well number 1 contains the primer pair giving rise to the longer, 515 bp, internal positive control band in order to help in the correct orientation of the DPA1 typing.

In addition, wells number 2, 6, 10, 11 and 14 contain the primer pair giving rise to the longer, 515 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 DPA1 alleles 1st and/or 3rd exon(s) and beyond, as well as intron 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.

⁴HLA-specific PCR products shorter than 125 base pairs have a lower intensity and are less sharp than longer PCR products.

⁵Primer mix 4 may faintly amplify the DPA1*04:01 allele.

⁶Primer mix 11 may have tendencies of unspecific amplifications.

⁷Primer mixes 11 and 15 may give rise to a lower yield of HLA-specific PCR product than the other DPA1 primer mixes.

⁸Primer mix 6 may give rise to a lower yield of HLA-specific PCR product than the other DPA1 primer mixes in the DPA1*01:06:01-01:06:02 and 02:04 alleles.

⁹Primer mix 6: Specific PCR fragment of 160 bp in the DPA1*01:10 and 02:04 alleles. Specific PCR fragment of 195 bp in the DPA1*01:06:01-01:06:02 alleles.

101.331.24/06 – including *Taq* pol., IFU-01
 101.331.24u/06u – without *Taq* pol., IFU-02

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

Lot No.: **71S**

Lot-specific information

INTERPRETATION TABLE								
DPA1 SSP typing								
Amplification patterns of the DPA1 alleles								
	Well⁵							
	1	2	3	4	5	6	7	8
Length of spec.	85	255	205	115	105	160	100	100
PCR product(s)						195		
Length of int.	515	515	430	430	430	515	430	430
pos. control¹								
5'-primer(s)²	15 (138) 5'-ACg 3'	11 (125) 5'-CgC 3'	28 (177) 5'-gAA 3'	3 (103) 5'-Cgg 3'	84 (345) 5'-AAT 3'	31 (185) 5'-gCA 3'	11 (125) 5'-CgC 3'	11 (125) 5'-CAT 3'
						43 (222) 5'-TgT 3'		
3'-primer(s)³	30 (184) 5'-CAT 3'	82 (340) 5'-ggT 3'	82 (340) 5'-ggT 3'	28 (177) 5'-TCg 3'	2nd I 5'-ggC 3'	68 (298) 5'-gTC 3'	30 (184) 5'-CTg 3'	30 (184) 5'-CTg 3'
						82 (340) 5'-ggT 3'		
Well No.	1	2	3	4	5	6	7	8
DPA1 allele⁴								
*01:03:01:01:01:03:02, 01:03:04	1	2	3					
*01:03:03		2	3					
*01:04	1	2		4				
*01:05	1				5			
*01:06:01:01:06:02		2	3			6	7	
*01:07	1	2	3					
*01:08	1	2		4				
*01:09	1	2	3					
*01:10	1	2	3			6		
*01:11	1	2	3					
*01:12	1	2	3					
*02:01:01:02:01:07					5		7	
*02:02:01:02:02:05					5			8
*02:03					5			
*02:04					5	6		8
*02:05					5			8
*03:01			3					
*03:02			3					
*03:03				4				
*04:01	1				5			
DPA1 allele⁴								
Well No.	1	2	3	4	5	6	7	8

101.331.24/06 – including *Taq* pol., IFU-01
 101.331.24u/06u – without *Taq* pol., IFU-02

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

Lot No.: **71S**

Lot-specific information

INTERPRETATION TABLE							
DPA1 SSP typing							
Amplification patterns of the DPA1 alleles							
Well ⁵							
9	10	11	12	13	14	15	16
205	85	90	205	135	130	245	100
Length of spec. PCR product(s)							
430	515	515	430	430	515	430	430
Length of int. pos. control ¹							
11 (125)	15 (138)	66 (290)	17 (145)	50 (244)	50 (242)	15 (138)	3 (103)
5'-CAT 3'	5'-ACC 3'	5'-ATC 3'	5'-gAA 3'	5'-AAA 3'	5'-CCg 3'	5'-ACC 3'	5'-Cgg 3'
5'-primer(s) ²							
66 (290)	30 (184)	82 (340)	72 (310)	82 (340)	76 (320)	82 (340)	23 (161)
5'-TCA 3'	5'-CAT 3'	5'-ggT 3'	5'-AgC 3'	5'-ggT 3'	5'-AAT 3'	5'-ggT 3'	5'-ACg 3'
3'-primer(s) ³							
					82 (340)		
					5'-ggT 3'		
9	10	11	12	13	14	15	16
Well No.							
DPA1 allele ⁴							
							*01:03:01-01:03:02, 01:03:04
	10					15	*01:03:03
							*01:04
							*01:05
							*01:06:01-01:06:02
				13			*01:07
					14		*01:08
						16	*01:09
							*01:10
					14		*01:11
		11					*01:12
							*02:01:01-02:01:07
9							*02:02:01-02:02:05
	10						*02:03
9							*02:04
9					14		*02:05
	10	11				15	*03:01
9	10					15	*03:02
	10	11				15	*03:03
			12				*04:01
9	10	11	12	13	14	15	16
DPA1 allele ⁴							
Well No.							

101.331.24/06 – including *Taq* pol., IFU-01
101.331.24u/06u – without *Taq* pol., IFU-02

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

Lot No.: 71S**Lot-specific information**

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 430 base pairs, for most wells, or a band of 515 base pairs, for some wells.

Well number 1 contains the primer pair giving rise to the longer, 515 bp, internal positive control band in order to help in the correct orientation of the DPA1 typing.

In addition, wells number 2, 6, 10, 11 and 14 contain the primer pair giving rise to the longer, 515 bp, internal positive control band in order to allow kit identification.

²The codon, and in parenthesis the nucleotide, in the 2nd exon, matching the specificity-determining 3'-end of the primer is given. Codon and 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 codon, and in parenthesis the nucleotide, in the 2nd exon and in the 2nd intron, matching the specificity-determining 3'-end of the primer is given in the anti-sense direction. Codon and 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.

⁴The sequence of the DPA1*0101 allele has been shown to be identical to DPA1*01:03:01.

The sequence of the DPA1*0102 allele has been shown to be identical to DPA1*01:03:01.

⁵Primer mix 6: Specific PCR fragment of 160 bp in the DPA1*01:10 and 02:04 alleles. Specific PCR fragment of 195 bp in the DPA1*01:06:01-01:06:02 alleles.

101.331.24/06 – including *Taq* pol., IFU-01
 101.331.24u/06u – without *Taq* pol., IFU-02

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

Lot No.: **71S**

Lot-specific information

CELL LINE VALIDATION SHEET																				
DPA1 SSP kit																				
					Well															
					1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
				Lot No.:	201323201	201323202	201323203	201323204	201323205	201323206	201323207	201323208	201323209	201323210	201323211	201323212	201323213	201323214	201323215	201323216
	IHCW cell line		DPA1																	
1	9001	SA	*01:03		+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-
2	9280	LK707	*01:03		+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-
3	9011	E4181324	*01:03		+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-
4	9275	GU373	*02:01	*04:01	+	-	-	-	+	-	+	-	-	-	-	+	-	-	-	-
5	9009	KAS011	*01:03	*02:01	+	+	+	-	+	-	+	-	-	-	-	-	-	-	-	-
6	9353	SM	*02:02		-	-	-	-	+	-	-	+	+	-	-	-	-	-	-	-
7	9020	QBL	*01:03		+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-
8	9025	DEJ	*01		+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-
9	9026	YAR	*01:03		+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-
10	9107	LKT3	*02:02		-	-	-	-	+	-	-	+	+	-	-	-	-	-	-	-
11	9051	PITOUT	*01:03		+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-
12	9052	DBB	*01:03		+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-
13	9004	JESTHOM	*01:03		+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-
14	9071	OLGA	*01:03		+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-
15	9075	DKB	*01:03		+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-
16	9037	SWEIG007	*01:03		+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-
17	9282	CTM3953540	*01:03	*02:01	+	+	+	-	+	-	+	-	-	-	-	-	-	-	-	-
18	9257	32367	*01:03	*03:01	+	+	+	-	-	-	-	-	-	+	+	-	-	-	+	-
19	9038	BM16	*01:03		+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-
20	9059	SLE005	*01:03		+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-
21	9064	AMALA	*01:03		+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-
22	9056	KOSE	*01:03	*02:01	+	+	+	-	+	-	+	-	-	-	-	-	-	-	-	-
23	9124	IHL	*01:03		+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-
24	9035	JBUSH	*01:03		+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-
25	9049	IBW9	*02:01		-	-	-	-	+	-	+	-	-	-	-	-	-	-	-	-
26	9285	WT49	*01:03		+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-
27	9191	CH1007	*01:03	*04:01	+	+	+	-	+	-	-	-	-	-	-	+	-	-	-	-
28	9320	BEL5GB	*01:03		+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-
29	9050	MOU	*01:03		+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-
30	9021	RSH	*02:02	*03:01	-	-	+	-	+	-	-	+	+	+	+	-	-	-	+	-
31	9019	DUCAF	*01:03		+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-
32	9297	HAG	*01:03		+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-
33	9098	MT14B	*01:03		+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-
34	9104	DHIF	*01:03		+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-
35	9302	SSTO	*01:03		+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-
36	9024	KT17	*02:02		-	-	-	-	+	-	-	+	+	-	-	-	-	-	-	-
37	9065	HHKB	*01:03		+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-
38	9099	LZL	*01:03		+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-
39	9315	CML	*01:03	*02:01	+	+	+	-	+	-	+	-	-	-	-	-	-	-	-	-
40	9134	WHONP199	*02:02		-	-	-	-	+	-	-	+	+	-	-	-	-	-	-	-
41	9055	H0301	*02:01		-	-	-	-	+	-	+	-	-	-	-	-	-	-	-	-
42	9066	TAB089	*02:02		-	-	-	-	+	-	-	+	+	-	-	-	-	-	-	-
43	9076	T7526	*04:01		+	-	-	-	+	-	-	-	-	-	-	+	-	-	-	-
44	9057	TEM	*01:03		+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-
45	9239	SHJO	*01:03	*03:01	+	+	+	-	-	-	-	-	-	+	+	-	-	-	+	-
46	9013	SCHU	*01:03		+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-
47	9045	TUBO	*01:03		+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-
48	9303	TER-ND	*01:03		+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-

101.331.24/06 – including *Taq* pol., IFU-01
101.331.24u/06u – without *Taq* pol., IFU-02

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

Lot No.: **71S**

Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP® DPA1 SSP

Product number: 101.331-24/06 – including *Taq* pol.
101.331-24u/06u – without *Taq* pol.
Lot number: 71S
Expiry date: 2016-February-01
Number of tests: 24 test – Product No. 101.331-24/24u
6 tests – Product No. 101.331-06/06u
Number of wells per test: 16

Well specifications:

Well No.	Production No.	Well No.	Production No.
1	2013-232-01	9	2013-232-09
2	2013-232-02	10	2013-232-10
3	2013-232-03	11	2013-232-11
4	2013-232-04	12	2013-232-12
5	2013-232-05	13	2013-232-13
6	2013-232-06	14	2013-232-14
7	2013-232-07	15	2013-232-15
8	2013-232-08	16	2013-232-16

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

No DNAs carrying the allele to be amplified by primer solutions 6, 13, 14 and 16 were available. The specificities of the primers in primer solutions 6 and 14 were tested by separately adding one additional 5'-primer and one additional 3'-primer, respectively. In primer solution 13 it was only possible to test the 3'-primer, the 5'-primer was not possible to test. In primer solution 16 it was only possible to test the 5'-primer, the 3'-primer was not possible to test. In primer solution 6 one 5'-primer was not possible to test, and in primer solutions 6 and 14 one 3'-primer was not possible to test.

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

Date of approval: 2013-September-05

Approved by:

Production Quality Control

101.331.24/06 – including *Taq* pol., IFU-01
101.331.24u/06u – without *Taq* pol., IFU-02

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

Lot No.: **71S**

Lot-specific information

Declaration of Conformity

Product name: *Olerup* SSP[®] DPA1
Product number: 101.331-24/24u, -06/06u
Lot number: 71S

Intended use: HLA-DPA1 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 13485:2012, 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, Franzengatan 5, SE-112 51 Stockholm, Sweden.

Stockholm, Sweden
2013-September-05

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs

101.331.24/06 – including *Taq* pol., IFU-01
101.331.24u/06u – without *Taq* pol., IFU-02

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

Lot No.: **71S**

Lot-specific information

ADDRESSES:

Manufacturer:

Olerup SSP AB, Franzengatan 5, SE-112 51 Stockholm, Sweden.

Tel: +46-8-717 88 27

Fax: +46-8-717 88 18

E-mail: info-ssp@olerup.com

Web page: <http://www.olerup-ssp.com>

Distributed by:

Olerup GmbH, Löwengasse 47 / 6, AT-1030 Vienna, Austria.

Tel: +43-1-710 15 00

Fax: +43-1-710 15 00 10

E-mail: support-at@olerup.com

Web page: <http://www.olerup.com>

Olerup Inc., 901 S. Bolmar St., Suite R, West Chester, PA 19382

Tel: 1-877-OLERUP1

Fax: 610-344-7989

E-mail: info.us@olerup.com

Web page: <http://www.olerup.com>

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