

Olerup SSP[®] HLA-A*29

Product number:	101.428-12 – including <i>Taq</i> polymerase
Lot number:	19K
Expiry date:	2012-June-01
Number of tests:	12
Number of wells per test:	16
Storage - pre-aliquoted primers:	dark at -20°C
- PCR Master Mix:	-20°C
- Adhesive PCR seals	RT
- Product Insert	RT

This Product Description is only valid for Lot No. 19K.

CHANGES COMPARED TO THE PREVIOUS *OLERUP SSP*[®] HLA-A*29 LOT

The HLA-A*29 specificity and interpretation tables have been updated for the HLA-A alleles described since the previous *Olerup SSP*[®] HLA-A*29 lot was made (Lot No. 77F).

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

Well	5'-primer	3'-primer	rationale
5	Added	Added	Primer pair added for the A*29:22 allele, exchanged positive control primer pair.
6	-	Added	Primer added for the A*29:20 allele.
8	Added	Added	Primer pair from well 14, exchanged positive control primer pair.
11	Added	Added	Primer pair from well 15, exchanged positive control primer pair.
12	Added, modified	Added, modified	Primer pair for the A*29:22 allele, exchanged positive control primer pair, increased yield of specific PCR product
14	New	New	Resolution of the A*29:18 and the A*32 and A*74 alleles.
15	New	New	Resolution of the A*29:18 and A*29:02:04 alleles.
16	Added	-	Primer added for the A*29:21 allele.

PRODUCT DESCRIPTION

HLA-A*29 SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for identifying the A*29:01 to A*29:22 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*29' in silver/gray ink.

Well No. 1 is marked with the Lot No. '19K'.

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*29 SSP subtypings will be influenced by the A*02:149, the A*03:27, the A*23:03:01, three A*24, the A*26:22, six A*31, the A*32, three A*33, the A*66*09 and the A*74 alleles when present on the other haplotype. In addition, the B*08:01:07 allele will be amplified by primer mix 7.

UNIQUELY IDENTIFIED ALLELES

All the HLA-A*29 alleles, i.e. **A*29:01 to A*29:22 alleles**, recognized by the HLA Nomenclature Committee in April 2010¹ will give rise to unique amplification patterns by the primers in the HLA-A*29 subtyping kit.

The HLA-A*29 subtyping kit cannot distinguish the A*29:01:01:01 and 29:01:02 alleles or the A*29:02:01-29:02:03 and 29:02:05 alleles.

¹HLA-A alleles listed on the IMGT/HLA web page 2010-April-01, release 3.0.0, www.ebi.ac.uk/imgt/hla.

RESOLUTION IN HOMO- AND HETEROZYGOTES

The 24 different amplification patterns generated by the 22 HLA-A*29 alleles can be combined in 300 homozygous and heterozygous combinations. 196 of these genotypes do not give rise to unique amplification patterns. The different sizes of the specific PCR products generated by primer mixes 5 to 13 and 16 were not considered in these calculations.

+++-----+ -----+- 29:01:01:02N,29:07 = 29:01:01:02N,29:13
+++----- --+-----+ 29:01:01:02N,29:10 = 29:01:01:02N,29:14
++----- ---+----- 29:01:01:02N,29:02:04 = 29:01:01:02N,29:18
++----- -----+- 29:01:01,29:01:01:02N = 29:01:01:02N,29:01:01:02N
+-+-----+ -----+- 29:01:01,29:19 = 29:06,29:20 = 29:19,29:20
+-+-----+ -----+- 29:07,29:20 = 29:13,29:20
+-+-----+ +-----+- 29:05,29:16 = 29:08N,29:20
+-+-----+ -+-----+- 29:05,29:17 = 29:09,29:20
+-+-----+ --+-----+- 29:10,29:20 = 29:14,29:20
+-+-----+ -----+- 29:05,29:12 = 29:11,29:20
+-+-----+ -----++ 29:05,29:15 = 29:20,29:21
+-+-----+ -----+- 29:01:01,29:05 = 29:02,29:20 = 29:05,29:20
++-----+ +-----+- 29:07,29:16 = 29:13,29:16
++-----+ -+-----+- 29:07,29:17 = 29:13,29:17
++-----+ -----+- 29:07,29:12 = 29:12,29:13
++-----+ -----++ 29:07,29:15 = 29:13,29:15
+-+-----+ -----+- 29:01:01,29:07 = 29:01:01,29:13
+-+-----+ ++-----+- 29:08N,29:17 = 29:09,29:16
+-+-----+ +-+-----+- 29:10,29:16 = 29:14,29:16
+-+-----+ +-----+- 29:08N,29:12 = 29:11,29:16
++-----+ +-----++ 29:08N,29:15 = 29:16,29:21
++-----+ +-----+- 29:01:01,29:08N = 29:02,29:16 = 29:08N,29:16
++-----+ -+-----+- 29:10,29:17 = 29:14,29:17
++-----+ -+-----+- 29:09,29:12 = 29:11,29:17
++-----+ -+-----++ 29:09,29:15 = 29:17,29:21
+-+-----+ -+-----+- 29:01:01,29:09 = 29:02,29:17 = 29:09,29:17
+-+-----+ --+-----+- 29:10,29:12 = 29:12,29:14
+-+-----+ --+-----++ 29:10,29:15 = 29:14,29:15
+-+-----+ --+-----+- 29:01:01,29:10 = 29:01:01,29:14
++-----+ -----++ 29:11,29:15 = 29:12,29:21
++-----+ -----++ 29:01:01,29:11 = 29:02,29:12 = 29:11,29:12
++-----+ -----++ 29:01:01,29:21 = 29:02,29:15 = 29:15,29:21
+-----+- ---+----- 29:02:04,29:20 = 29:18,29:20
+-----+- -----+- 29:01:01,29:20 = 29:20,29:20
+-----+- +-----+- 29:02:04,29:16 = 29:16,29:18
+-----+- +-----+- 29:01:01,29:16 = 29:16,29:16
+-----+- -+-----+- 29:02:04,29:17 = 29:17,29:18
+-----+- -+-----+- 29:01:01,29:17 = 29:17,29:17
+-----+- ---+----- 29:02:04,29:12 = 29:12,29:18
+-----+- ---+----- 29:02:04,29:15 = 29:15,29:18
+-----+- ---+----- 29:01:01,29:02:04 = 29:01:01,29:18
+-----+- -----+- 29:01:01,29:12 = 29:12,29:12
+-----+- -----++ 29:01:01,29:15 = 29:15,29:15
--++-----+ -----+- 29:03,29:07 = 29:03,29:13
--++-----+ --+-----+- 29:03,29:10 = 29:03,29:14
--++-----+ -----+- 29:02:04,29:03 = 29:03,29:18
--++-----+ -----+- 29:02,29:03 = 29:03,29:03
--++-----+ ---+----- 29:07,29:22 = 29:13,29:22
--++-----+ -----+- 29:04,29:07 = 29:04,29:13
--++-----+ --+-----+- 29:10,29:22 = 29:14,29:22

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Lot-specific information

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--+---- -+----+ 29:04,29:10 = 29:04,29:14
--+---- -+----+ 29:02,29:22 = 29:02:04,29:04 = 29:02:04,29:22 =
29:04,29:18 = 29:04,29:22 = 29:18,29:22 = 29:22,29:22
--+---- -+----+ 29:02,29:04 = 29:04,29:04
--+---- -+----+ 29:10,29:19 = 29:14,29:19
--+---- -+----+ 29:02:04,29:19 = 29:18,29:19
--+---- -+----+ 29:02,29:19 = 29:05,29:06 = 29:05,29:19 = 29:06,29:19
--+---- -+----+ 29:05,29:07 = 29:05,29:13
--+---- -+----+ 29:05,29:10 = 29:05,29:14
--+---- -+----+ 29:02:04,29:05 = 29:05,29:18
--+---- -+----+ 29:02,29:05 = 29:05,29:05
--+---- -+----+ 29:06,29:07 = 29:06,29:13
--+---- -+----+ 29:06,29:10 = 29:06,29:14
--+---- -+----+ 29:02:04,29:06 = 29:06,29:18
--+---- -+----+ 29:02,29:06 = 29:06,29:06
--+---- +----+ 29:07,29:08N = 29:08N,29:13
--+---- -+----+ 29:07,29:09 = 29:09,29:13
--+---- -+----+ 29:07,29:10 = 29:07,29:14 = 29:10,29:13 = 29:13,29:14
--+---- -+----+ 29:02:04,29:07 = 29:02:04,29:13 = 29:07,29:18 =
29:13,29:18
--+---- -+----+ 29:07,29:11 = 29:11,29:13
--+---- -+----+ 29:07,29:21 = 29:13,29:21
--+---- -+----+ 29:02,29:07 = 29:02,29:13 = 29:07,29:07 = 29:07,29:13
--+---- +----+ 29:08N,29:10 = 29:08N,29:14
--+---- +----+ 29:02:04,29:08N = 29:08N,29:18
--+---- +----+ 29:02,29:08N = 29:08N,29:08N
--+---- -+----+ 29:09,29:10 = 29:09,29:14
--+---- -+----+ 29:02:04,29:09 = 29:09,29:18
--+---- -+----+ 29:02,29:09 = 29:09,29:09
--+---- -+----+ 29:02:04,29:10 = 29:02:04,29:14 = 29:10,29:18
--+---- -+----+ 29:10,29:11 = 29:11,29:14
--+---- -+----+ 29:10,29:21 = 29:14,29:21
--+---- -+----+ 29:02,29:10 = 29:02,29:14 = 29:10,29:10 = 29:10,29:14
--+---- -+----+ 29:02:04,29:11 = 29:11,29:18
--+---- -+----+ 29:02:04,29:21 = 29:18,29:21
--+---- -+----+ 29:02,29:02:04 = 29:02,29:18
--+---- -+----+ 29:02,29:11 = 29:11,29:11
--+---- -+----+ 29:02,29:21 = 29:21,29:21
----- -+----+ 29:02:04,29:02:04 = 29:02:04,29:18

29:01 = 29:01:01:01 and 29:01:02
29:02 = 29:02:01-29:02:03 and 29:02:05

SPECIFICITY TABLE

HLA-A*29 SSP subtyping

Specificities and sizes of the PCR products of the 16 primer mixes used for HLA-A*29 SSP subtyping

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified HLA-A*29 alleles	Other amplified HLA-A alleles ³
1	480 bp	800 bp	*29:01:01:01-29:01:02, 29:12, 29:15-29:17, 29:20	
2⁴	130 bp	1070 bp	*29:01:01:02N	
3	440 bp	800 bp	*29:02:01-29:02:03, 29:02:05-29:11, 29:13-29:14, 29:19, 29:21-29:22	
4	165 bp	800 bp	*29:03	*23:03:01, 31:05, 32:13, 33:10
5^{4,6,7}	130 bp, 185 bp	800 bp	*29:04, 29:22	*02:149, 26:22, 33:22, 66:09
6^{4,8}	105 bp, 130 bp	800 bp	*29:05, 29:19-29:20	*31:24, 32:02, 32:22
7^{4,5,9}	105 bp, 210 bp	1070 bp	*29:06, 29:19	*32:12, B*08:01:07
8^{4,6,10}	85 bp, 260 bp	800 bp	*29:07, 29:13	*24:17, 24:41, 24:82, 31:07-31:08, 31:10
9^{4,5,11}	80 bp, 170 bp	1070 bp	*29:08N, 29:16	*03:27
10^{4,12}	95 bp, 170 bp	800 bp	*29:09, 29:17	*31:24
11^{4,13}	100 bp, 195 bp	800 bp	*29:10, 29:14	
12^{4,5,6,14}	80 bp, 185 bp	800 bp	*29:02:04, 29:18, 29:22	*02:149, 26:22, 32:01:01-32:03, 32:05-32:22, 33:22, 66:09, 74:01-74:13
13^{4,5,15}	85 bp, 165 bp	1070 bp	*29:11-29:12	*31:16
14	200 bp	1070 bp	*29:01:01:01-29:13, 29:15-29:17, 29:19-29:22	
15	240 bp	1070 bp	*29:01:01:01-29:12, 29:14-29:18, 29:20-29:22	*33:13
16^{4,16}	95 bp, 165 bp	1070 bp	*29:15, 29:21	

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Lot-specific information

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¹ 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-A*29 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.

² 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-A*29 subtyping.

In addition, wells number 3 to 6, 8 and 10 to 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.

³ Due to the sharing of sequence motifs between HLA-A alleles a few non-HLA-A*29 alleles will be amplified by primer mixes 4 to 10, 12, 13 and 15. In addition, the B*08:01:07 allele will be amplified by primer mix 7.

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

⁵ Primer mixes 7, 9, 12 and 13 may give rise to nonspecific amplifications.

⁶ Primer mixes 5, 8 and 12 may give rise to a long unspecific amplification product of approximately 600 bp. This should be disregarded when interpreting the A*29 typings.

⁷ Primer mix 5: Specific PCR fragment of 130 bp in the A*29:04 allele. Specific PCR fragment of 185 bp in the A*29:22 and the A*02:149, 26:22, 33:22 and 66:09 alleles.

⁸ Primer mix 6: Specific PCR fragment of 105 bp in the A*29:19 and 29:20 alleles. Specific PCR fragment of 130 bp in the A*29:05 and the 31:24, 32:02 and 32:22 alleles.

⁹ Primer mix 7: Specific PCR fragment of 105 bp in the A*29:19 allele. Specific PCR fragment of 210 bp in the A*29:06 and in the in the A*32:12 and B*08:01:07 alleles.

¹⁰ Primer mix 8: Specific PCR fragment of 85 bp in the A*29:07 and in the A*24:17 and 24:41 alleles. Specific PCR fragment of 260 bp in the A*29:13 and in the A*24:82, 31:07-31:08 and 31:10 alleles.

¹¹ Primer mix 9: Specific PCR fragment of 80 bp in the A*29:16 and in the A*03:27 alleles. Specific PCR fragment of 170 bp in the A*29:08N allele.

¹² Primer mix 10: Specific PCR fragment of 95 bp in the A*29:09 and in the A*31:24 alleles. Specific PCR fragment of 170 bp in the A*29:17 allele.

¹³ Primer mix 11: Specific PCR fragment of 100 bp in the A*29:14 allele. Specific PCR fragment of 195 bp in the A*29:10 allele.

¹⁴ Primer mix 12: Specific PCR fragment of 80 bp in the A*29:02:04 and 29:18 and in the A*32:01:01-32:03, 32:05-32:22 and 74:01-74:13 alleles. Specific PCR fragment of 185 bp in the A*29:22 and in the A*02:149, 26:22, 33:22 and 66:09 alleles.

¹⁵ Primer mix 13: Specific PCR fragment of 85 bp in the A*29:11 allele. Specific PCR fragment of 165 bp in the A*29:12 and in the A*31:16 alleles.

¹⁶ Primer mix 16: Specific PCR fragment of 95 bp in the A*29:15 allele. Specific PCR fragment of 165 bp in the A*29:21 allele.

INTERPRETATION TABLE								
HLA-A*29 SSP subtyping								
Amplification patterns of the A*29:01 to 29:22 alleles								
	Well ⁴							
	1	2	3	4	5	6	7	8
Length of spec.	480	130	440	165	130	105	105	85
PCR product(s)					185	130	210	260
Length of int.	800	1070	800	800	800	800	1070	800
pos. control ¹								
5'-primer(s) ²	180	808	219	448	180	219	219	98
	5' -TTT 3' 5' -CgT 3' 5' -gCA 3' 5' -CCT 3'				5' -TTT 3' 5' -gCA 3' 5' -gCA 3' 5' -CAC 3'			
					355	448	448	368
					5' -CCg 3' 5' -CCT 3' 5' -CCT 3' 5' -gTT 3'			
3'-primer(s) ³	376	895	376	570	268	282	282	317
	5' -gTg 3' 5' -CTC 3' 5' -gTC 3' 5' -CCg 3'				5' -ATg 3' 5' -gAg 3' 5' -gAg 3' 5' -ggA 3'			
					497	282	616	413
					5' -TgA 3' 5' -gAg 3' 5' -CgC 3' 5' -gCC 3'			
					539			
					5' -TCT 3'			
Well No.	1	2	3	4	5	6	7	8
HLA-A allele								
*29:01:01:01, 29:01:02	1							
*29:01:01:02N	1	2						
*29:02:01-29:02:03, 29:02:05			3					
*29:02:04								
*29:03			3	4				
*29:04			3		5			
*29:05			3			6		
*29:06			3				7	
*29:07			3					8
*29:08N			3					
*29:09			3					
*29:10			3					
*29:11			3					
*29:12	1							
*29:13			3					8
*29:14			3					
*29:15	1							
*29:16	1							
Well No.	1	2	3	4	5	6	7	8

INTERPRETATION TABLE								
HLA-A*29 SSP subtyping								
Amplification patterns of the A*29:01 to 29:22 alleles								
Well⁴								
9	10	11	12	13	14	15	16	
80	95	100	80	85	200	240	95	Length of spec.
170	170	195	185	165			165	PCR product(s)
1070	800	800	800	1070	1070	1070	1070	Length of int.
								pos. control ¹
97	130	180	180	97	98	98	134	5'-primer(s) ²
5' -TCA 3' 5' -AgA 3' 5' -TTT 3' 5' -TTT 3' 5' -TCA 3' 5' -CAC 3' 5' -CAC 3' 5' -CCT 3'								
413	448	448	355	448			484	
5' -CCg 3' 5' -CCT 3' 5' -CCT 3' 5' -CCg 3' 5' -CCT 3'							5' -ACg 3'	
224	257	238	218	221	257	299	257	3'-primer(s) ³
5' -TCT 3' 5' -gCA 3' 5' -CCT 3' 5' -gCg 3' 5' -ACA 3' 5' -gCA 3' 5' -TCg 3' 5' -gCA 3'								
454	502	601	497	494			538	
5' -CTg 3' 5' -CTT 3' 5' -CTT 3' 5' -TgA 3' 5' -TCg 3'							5' -CAA 3'	
9	10	11	12	13	14	15	16	Well No.
								HLA-A allele
					14	15		*29:01:01:01, 29:01:02
					14	15		*29:01:01:02N
					14	15		*29:02:01-29:02:03, 29:02:05
			12		14	15		*29:02:04
					14	15		*29:03
					14	15		*29:04
					14	15		*29:05
					14	15		*29:06
					14	15		*29:07
9					14	15		*29:08N
	10				14	15		*29:09
		11			14	15		*29:10
				13	14	15		*29:11
				13	14	15		*29:12
					14			*29:13
		11				15		*29:14
					14	15	16	*29:15
9					14	15		*29:16
9	10	11	12	13	14	15	16	Well No.

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Length of spec.	480	130	440	165	130	105	105	85
PCR product(s)					185	130	210	260
Well No.	1	2	3	4	5	6	7	8
*29:17	1							
*29:18								
*29:19			3			6	7	
*29:20	1					6		
*29:21			3					
*29:22			3		5			
*02:149, 26:22, 33:22, 66:09					5			
*03:27								
*23:03:01, 31:05, 33:10				4				
*24:17, 24:41, 24:82, 31:07-31:08, 31:10								8
*31:16								
*31:24						6		
*32:01:01-32:01:05, 32:03, 32:05-32:11Q, 32:14-32:21, 74:01- 74:13								
*32:02, 32:22						6		
*32:12							7	
*32:13				4				
*33:13								
B*08:01:07							7	
HLA-A allele								
Well No.	1	2	3	4	5	6	7	8

¹The internal positive control primer pairs amplify segments of the human growth hormone gene. The two different control primer pairs give rise to either an internal positive control band of 1070 base pairs, for most wells, or a band of 800 base pairs, for some wells.

Well number 1 contains the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to help in the correct orientation of the HLA-A*29 subtyping. .

In addition, wells number 3 to 6, 8 and 10 to 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 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.

⁴Primer mix 5: Specific PCR fragment of 130 bp in the A*29:04 allele. Specific PCR fragment of 185 bp in the A*29:22 and the A*02:149, 26:22, 33:22 and 66:09 alleles.

Primer mix 6: Specific PCR fragment of 105 bp in the A*29:19 and 29:20 alleles. Specific PCR fragment of 130 bp in the A*29:05 and the 31:24, 32:02 and 32:22 alleles.

Lot No.: **19K**

Lot-specific information

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80	95	100	80	85	200	240	95	Length of spec. PCR product(s)
170	170	195	185	165			165	Well No.
9	10	11	12	13	14	15	16	
	10				14	15		*29:17
			12			15		*29:18
					14			*29:19
					14	15		*29:20
					14	15	16	*29:21
			12		14	15		*29:22
			12					*02:149, 26:22, 33:22, 66:09
9								*03:27
								*23:03:01, 31:05, 33:10
								*24:17, 24:41, 24:82, 31:07-31:08, 31:10
				13				*31:16
	10							*31:24
			12					*32:01:01-32:01:05, 32:03, 32:05-32:11Q, 32:14-32:21, 74:01- 74:13
			12					*32:02, 32:22
			12					*32:12
			12					*32:13
						15		*33:13
								<i>B</i> *08:01:07
								HLA-A allele
9	10	11	12	13	14	15	16	Well No.

Primer mix 7: Specific PCR fragment of 105 bp in the A*29:19 allele. Specific PCR fragment of 210 bp in the A*29:06 and in the in the A*32:12 and B*08:01:07 alleles.

Primer mix 8: Specific PCR fragment of 85 bp in the A*29:07 and in the A*24:17 and 24:41 alleles. Specific PCR fragment of 260 bp in the A*29:13 and in the A*24:82, 31:07-31:08 and 31:10 alleles.

Primer mix 9: Specific PCR fragment of 80 bp in the A*29:16 and in the A*03:27 alleles. Specific PCR fragment of 170 bp in the A*29:08N allele.

Primer mix 10: Specific PCR fragment of 95 bp in the A*29:09 and in the A*31:24 alleles. Specific PCR fragment of 170 bp in the A*29:17 allele.

Primer mix 11: Specific PCR fragment of 100 bp in the A*29:14 allele. Specific PCR fragment of 195 bp in the A*29:10 allele.

Primer mix 12: Specific PCR fragment of 80 bp in the A*29:02:04 and 29:18 and in the A*32:01:01-32:03, 32:05-32:22 and 74:01-74:13 alleles. Specific PCR fragment of 185 bp in the A*29:22 and in the A*02:149, 26:22, 33:22 and 66:09 alleles.

Primer mix 13: Specific PCR fragment of 85 bp in the A*29:11 allele. Specific PCR fragment of 165 bp in the A*29:12 and in the A*31:16 alleles.

Primer mix 16: Specific PCR fragment of 95 bp in the A*29:15 allele. Specific PCR fragment of 165 bp in the A*29:21 allele.

CELL LINE VALIDATION SHEET																				
HLA-A*29 SSP subtyping kit																				
				Lot No.:	Well															
					1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
					200958401	200958402	200958403	200958404	201071405	201071406	200958407	201071408	200958409	200958410	201071411	201071412	200958413	201071414	201071415	201071416
	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	9007 DEM	*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		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-A*29 SSP

Product number: 101.428-12 – including *Taq* polymerase
Lot number: 19K
Expiry date: 2012-June-01
Number of tests: 12
Number of wells per test: 16

Well specifications:

Well No.	Production No.	Well No.	Production No.
1	2009-584-01	9	2009-584-09
2	2009-584-02	10	2009-584-10
3	2009-584-03	11	2010-714-11
4	2009-584-04	12	2010-714-12
5	2010-714-05	13	2009-584-13
6	2010-714-06	14	2010-714-14
7	2009-584-07	15	2010-714-15
8	2010-714-08	16	2010-714-16

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 2, 4 to 7, 9 to 11 and 13 and 16 were available. The specificities of the primers in primer solutions 4 to 7, 10 and 11 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer solutions 2, 9 and 13 it was only possible to test the 5'-primer, the 3'-primer was not possible to test. In primer solution 16 it was only possible to the 3'-primer, the 5'-primer was not possible to test. In primer solution 5, 6 and 7 one of the 3'-primers was not possible to test, and in primer solution 10 one of the 5'-primers was not possible to test. Additional primer pairs in primer solutions 8 and 12 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer.

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

Date of approval: 2010-June-17

Approved by:

Quality Control, Supervisor

Lot No.: **19K**

Lot-specific information

www.olerup-ssp.com

Declaration of Conformity

Product name: *Olerup* SSP® HLA-A*29
Product number: 101.428-12
Lot number: 19K

Intended use: HLA-A*29 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 9001:2008 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, Hasselstigen 1, SE-133 33 Saltsjöbaden, 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.)

Saltsjöbaden, Sweden
2010-June-17

Olle Olerup
Managing Director

Lot No.: **19K**

Lot-specific information

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