Olerup SSP® HLA-A*31

Product number:	**101.430-12u – without *Taq* polymerase**
Lot number:	**19M**
Expiry date:	**2013-November-01**
Number of tests:	**12**
Number of wells per test:	**32**
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. 19M.

CHANGES COMPARED TO THE PREVIOUS *OLERUP* SSP® HLA-A*31 LOT

The HLA-A*31 specificity and interpretation tables have been updated for the HLA-A alleles described since the previous *Olerup* SSP® HLA-A*31 lot was made **(Lot No. 84G)**.

Eight well has been added to the HLA-A*31 kit,
wells **25 to 32**.

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

Well	5'-primer	3'-primer	rationale
1	-	Added	Primer added for the A*31:01:07 allele.
4	Modified	-	Modified 5'-primer for improved specificity.
25	New	New	New primer pair for the A*31:29 allele.
26	New	New	New primer pair for the A*31:30 allele.
27	New	New	New primer pair for the A*31:31 allele.
28	New	New	New primer pair for the A*31:32 allele.
29	New	New	New primer pair for the A*31:36 allele.
30	New	New	New primer pairs for the A*31:33 and A*31:34 alleles.
31	New	New	New primer pair for the A*31:35 allele.
32	New	New	New primer pair for the A*31:37 allele.

Change in revision R01 compared to R00:

1. Primer mixes 4 and 7 may weakly amplify the A*34:01 allele.

PRODUCT DESCRIPTION

HLA-A*31 SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for identifying the A*31:01 to A*31:37 alleles.

PLATE LAYOUT

Each test consists of 32 PCR reactions in a 32 well cut PCR plate.

1	**2**	**3**	**4**	**5**	**6**	**7**	**8**
9	**10**	**11**	**12**	**13**	**14**	**15**	**16**
17	**18**	**19**	**20**	**21**	**22**	**23**	**24**
25	**26**	**27**	**28**	**29**	**30**	**31**	**32**

The 32 well cut PCR plate is marked with 'HLA-A*31' in silver/gray ink.
Well No. 1 is marked with the Lot Number '19M'.
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 32 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*31 SSP subtypings will be influenced by two A*01, twelve A*02, four A*03, six A*11, most A*23, six A*24, two A*26, most A*29, three A*30, the A*32, the A*33, most A*34, the A*66:06, three A*68, the A*74 and the A*80 alleles when present on the other haplotype. In addition, primer mix 1 will amplify the B*15:82 allele.

UNIQUELY IDENTIFIED ALLELES

All the HLA-A*31 alleles, i.e. **A*31:01 to A*31:37 alleles**, recognized by the HLA Nomenclature Committee in January 2010[1] will give rise to unique amplification patterns by the primers in the HLA-A*31 subtyping kit.
The HLA-A*31 subtyping kit cannot separate the A*31:01:02-31:01:09 alleles.

[1]HLA-A alleles listed on the IMGT/HLA web page 2010-July-16, release 3.1.0, www.ebi.ac.uk/imgt/hla.

RESOLUTION IN HOMO- AND HETEROZYGOTES

A total of 58 alleles generate 37 amplification patterns that can be combined in 703 homozygous and heterozygous combinations. 212 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.

+++++-+- +--+---- -------- --------	*31:03, *31:07 = *31:03, *31:08
+++++-+- +--+---- -------- --------	*31:04, *31:07 = *31:04, *31:08
++-+--+- +--+---- -------- --------	*31:06, *31:07 = *31:06, *31:08
++--+-+- +-++---- -------- --------	*31:07, *31:26 = *31:08, *31:26
++---++- +--+---- -------- --------	*31:05, *31:07 = *31:05, *31:08
++-----++ +--+-+-- -------- --------	*31:07, *31:24 = *31:08, *31:24
++-----++ +--+---- -----+-- --------	*31:07, *31:27 = *31:08, *31:27
++-----++ +--+---- -------- --------	*31:07, *31:09 = *31:08, *31:09
++-----+- ++-+---- -------- --------	*31:07, *31:11 = *31:08, *31:11
++-----+- +-++---- -------- --------	*31:07, *31:12 = *31:08, *31:12
++-----+- +--++--- -------- --------	*31:07, *31:13 = *31:08, *31:13
++-----+- +--+-+-- -------- --------	*31:07, *31:14N = *31:08, *31:14N
++-----+- +--+--+- +------- --------	*31:07, *31:25 = *31:08, *31:25
++-----+- +--+--+- -------- --------	*31:07, *31:15 = *31:08, *31:15
++-----+- +--+---+ -------- --------	*31:07, *31:16 = *31:08, *31:16
++-----+- +--+---- +------- --------	*31:07, *31:17 = *31:08, *31:17
++-----+- +--+---- -+------ --------	*31:07, *31:18 = *31:08, *31:18
++-----+- +--+---- --+----- --------	*31:07, *31:19 = *31:08, *31:19
++-----+- +--+---- ---+---- --------	*31:07, *31:20 = *31:08, *31:20
++-----+- +--+---- -----+-- --------	*31:07, *31:22 = *31:08, *31:22
++-----+- +--+---- ------+- --------	*31:07, *31:23 = *31:08, *31:23
++-----+- +--+---- -------+ --------	*31:07, *31:28 = *31:08, *31:28
++-----+- +--+---- -------- +-------	*31:07, *31:29 = *31:08, *31:29
++-----+- +--+---- -------- -+------	*31:07, *31:30 = *31:08, *31:30
++-----+- +--+---- -------- --+-----	*31:07, *31:31 = *31:08, *31:31
++-----+- +--+---- -------- ---+----	*31:07, *31:32 = *31:08, *31:32
++-----+- +--+---- -------- ----+---	*31:07, *31:36 = *31:08, *31:36
++-----+- +--+---- -------- -----+--	*31:07, *31:34 = *31:08, *31:34
++-----+- +--+---- -------- ------+-	*31:07, *31:35 = *31:08, *31:35
++-----+- +--+---- -------- -------+	*31:07, *31:37 = *31:08, *31:37
++-----+- +--+---- -------- --------	*31:01:02, *31:07 = *31:01:02, *31:08 = *31:02, *31:07 = *31:02, *31:08 = *31:02, *31:10
++-----+- +------- ----+--- --------	*31:07, *31:21 = *31:08, *31:21
++-----+- +------- -------- -----+--	*31:07, *31:33 = *31:08, *31:33
++-----+- +------- -------- --------	*31:07, *31:07 = *31:07, *31:08 = *31:07, *31:10 = *31:08, *31:10
++------ +--+---- -------- -----+--	*31:02, *31:33 = *31:02, *31:34
++------ +--+---- -------- --------	*31:01:02, *31:02 = *31:02, *31:02
+-+++--- +-++---- -------- --------	*31:03, *31:12 = *31:03, *31:26 = *31:04, *31:26
+-+++--- +--+---- -------- -----+--	*31:03, *31:33 = *31:03, *31:34
+-+++--- ---+---- -------- --------	*31:03, *31:03 = *31:03, *31:04 = *31:03, *31:06
+-++---- +--+---- -------- -----+--	*31:04, *31:33 = *31:04, *31:34
+-++---- ---+---- -------- --------	*31:04, *31:04 = *31:04, *31:06
+--+---- +--+---- -------- -----+--	*31:06, *31:33 = *31:06, *31:34
+---+--- +-++---- -------- -----+--	*31:26, *31:33 = *31:26, *31:34
+---+--- +-++---- -------- --------	*31:01:02, *31:26 = *31:12, *31:26 = *31:26, *31:26
+----+-- +--+---- -------- -----+--	*31:05, *31:33 = *31:05, *31:34
+----+-- +--+---- -------- --------	*31:01:02, *31:05 = *31:05, *31:05
+------+ +--+-+-- -----+-- --------	*31:14N, *31:27 = *31:22, *31:24 = *31:24, *31:27
+------+ +--+-+-- -------- -----+--	*31:24, *31:33 = *31:24, *31:34
+------+ +--+-+-- -------- --------	*31:01:02, *31:24 = *31:09, *31:14N = *31:09, *31:24 =

			*31:14N, *31:24 = *31:24, *31:24
+------+	+--+----	-----+--	-----+--	*31:27, *31:33 = *31:27, *31:34
+------+	+--+----	-----+--	--------	*31:01:02, *31:27 = *31:09, *31:22 = *31:09, *31:27 = *31:22, *31:27 = *31:27, *31:27
+------+	+--+----	--------	-----+--	*31:09, *31:33 = *31:09, *31:34
+------+	+--+----	--------	--------	*31:01:02, *31:09 = *31:09, *31:09
+-------	++-+----	--------	-----+--	*31:11, *31:33 = *31:11, *31:34
+-------	++-+----	--------	--------	*31:01:02, *31:11 = *31:11, *31:11
+-------	+-++----	--------	-----+--	*31:12, *31:33 = *31:12, *31:34
+-------	+-++----	--------	--------	*31:01:02, *31:12 = *31:12, *31:12
+-------	+--+----	--------	-----+--	*31:13, *31:33 = *31:13, *31:34
+-------	+--+----	--------	--------	*31:01:02, *31:13 = *31:13, *31:13
+-------	+--+-+--	--------	-----+--	*31:14N, *31:33 = *31:14N, *31:34
+-------	+--+-+--	--------	--------	*31:01:02, *31:14N = *31:14N, *31:14N
+-------	+--+--+-	+-------	-----+--	*31:25, *31:33 = *31:25, *31:34
+-------	+--+--+-	+-------	--------	*31:01:02, *31:25 = *31:15, *31:17 = *31:15, *31:25 = *31:17, *31:25 = *31:25, *31:25
+-------	+--+--+-	--------	-----+--	*31:15, *31:33 = *31:15, *31:34
+-------	+--+--+-	--------	--------	*31:01:02, *31:15 = *31:15, *31:15
+-------	+--+---+	--------	-----+--	*31:16, *31:33 = *31:16, *31:34
+-------	+--+---+	--------	--------	*31:01:02, *31:16 = *31:16, *31:16
+-------	+--+----	+-------	-----+--	*31:17, *31:33 = *31:17, *31:34
+-------	+--+----	+-------	--------	*31:01:02, *31:17 = *31:17, *31:17
+-------	+--+----	-+------	-----+--	*31:18, *31:33 = *31:18, *31:34
+-------	+--+----	-+------	--------	*31:01:02, *31:18 = *31:18, *31:18
+-------	+--+----	--+-----	-----+--	*31:19, *31:33 = *31:19, *31:34
+-------	+--+----	--+-----	--------	*31:01:02, *31:19 = *31:19, *31:19
+-------	+--+----	---+----	-----+--	*31:20, *31:33 = *31:20, *31:34
+-------	+--+----	---+----	--------	*31:01:02, *31:20 = *31:20, *31:20
+-------	+--+----	-----+--	-----+--	*31:22, *31:33 = *31:22, *31:34
+-------	+--+----	-----+--	--------	*31:01:02, *31:22 = *31:22, *31:22
+-------	+--+----	------+-	-----+--	*31:23, *31:33 = *31:23, *31:34
+-------	+--+----	------+-	--------	*31:01:02, *31:23 = *31:23, *31:23
+-------	+--+----	-------+	-----+--	*31:28, *31:33 = *31:28, *31:34
+-------	+--+----	-------+	--------	*31:01:02, *31:28 = *31:28, *31:28
+-------	+--+----	--------	+----+--	*31:29, *31:33 = *31:29, *31:34
+-------	+--+----	--------	+-------	*31:01:02, *31:29 = *31:29, *31:29
+-------	+--+----	--------	-+---+--	*31:30, *31:33 = *31:30, *31:34
+-------	+--+----	--------	-+------	*31:01:02, *31:30 = *31:30, *31:30
+-------	+--+----	--------	--+--+--	*31:31, *31:33 = *31:31, *31:34
+-------	+--+----	--------	--+-----	*31:01:02, *31:31 = *31:31, *31:31
+-------	+--+----	--------	---+-+--	*31:32, *31:33 = *31:32, *31:34
+-------	+--+----	--------	---+----	*31:01:02, *31:32 = *31:32, *31:32
+-------	+--+----	--------	----+--	*31:33, *31:36 = *31:34, *31:36
+-------	+--+----	--------	----+---	*31:01:02, *31:36 = *31:36, *31:36
+-------	+--+----	--------	-----++-	*31:33, *31:35 = *31:34, *31:35
+-------	+--+----	--------	-----+-+	*31:33, *31:37 = *31:34, *31:37
+-------	+--+----	--------	-----+--	*31:01:02, *31:33 = *31:01:02, *31:34 = *31:33, *31:34 = *31:34, *31:34
+-------	+--+----	--------	------+-	*31:01:02, *31:35 = *31:35, *31:35
+-------	+--+----	--------	-------+	*31:01:02, *31:37 = *31:37, *31:37

*31:01:02 = *31:01:02-31:01:09

SPECIFICITY TABLE

HLA-A*31 SSP subtyping

Specificities and sizes of the PCR products of the 32 primer mixes used for HLA-A*31 SSP subtyping

Primer Mix	Size of spec. PCR product[1]	Size of control band[2]	Amplified HLA-A*31 alleles	Other amplified HLA-A alleles[3]
1	155 bp	**800 bp**	*31:01:02-31:07, 31:09-31:37	*01:07, 02:185, 23:21, 24:124, 26:19, 29:14, 30:12, 30:18, 34:04, **B*15:82**
2	215 bp	**800 bp**	*31:02, 31:07-31:08	*02:243, 24:82, 33:08
3	155 bp	**800 bp**	*31:03-31:04	*03:01:19, 26:43:01, 34:02:01-34:04, 34:06-34:08, 66:06
4[7]	165 bp	1070 bp	*31:03-31:04, 31:06	*01:06, 02:114, 02:246, 03:05, 03:42, 11:24:01-11:25, 11:31, 11:35, 29:01:01:01-29:04, 29:06-29:22, 30:26, 33:18, 34:02:01-34:04, 34:07-34:08, 68:08:01-68:08:02, 80:01-80:02
5[8]	135 bp, 285 bp	1070 bp	*31:03, 31:26	*11:43, 33:13
6	165 bp	**800 bp**	*31:05	*23:03:01, 29:03, 32:13, 33:10
7[7]	505 bp	1070 bp	*31:07-31:08, 31:10	*02:81, 02:87, 02:112, 02:124, 02:129, 23:01:01-23:01:02, 23:03:01-23:13, 23:15-23:26, 24:13:01, 24:18, 24:24, 24:94, 29:13, 32:01:01-32:01:05, 32:03-32:09, 32:11Q-32:21, 32:23-32:25
8[9]	155 bp, 220 bp	1070 bp	*31:09, 31:24, 31:27	
9[4,5]	75 bp	1070 bp	*31:01:02-31:02, 31:05, 31:07-31:37	*02:65, 02:152, 23:03:01, 32:01:01-32:03, 32:05-32:25, 33:01:01-33:01:03, 33:03:01-33:17, 33:20-33:31, 74:01-74:14N

10	160 bp	1070 bp	*31:11	
11[10]	135 bp, 215 bp	1070 bp	*31:12, 31:26	
12	245 bp	1070 bp	*31:01:02-31:06, 31:09, 31:11-31:20, 31:22-31:32, 31:34-31:37	*02:243, 11:43, 29:19, 33:01:01-33:01:03, 33:03:01-33:12, 33:14-33:16, 33:18-33:31, 68:29
13[4]	85 bp	1070 bp	*31:13	*02:251
14[11]	150 bp, 470 bp	**800 bp**	*31:14N, 31:24	
15[12]	150 bp, 225 bp	1070 bp	*31:15, 31:25	
16	165 bp	1070 bp	*31:16	*29:12
17[13]	150 bp, 235 bp	1070 bp	*31:17, 31:25	
18	200 bp	1070 bp	*31:18	
19[4]	110 bp	1070 bp	*31:19	*03:52
20	325 bp	1070 bp	*31:20	
21	180 bp	1070 bp	*31:21	*01:07, 02:185
22[14]	155 bp, 190 bp	1070 bp	*31:22, 31:27	
23	200 bp	1070 bp	*31:23	
24[6]	220 bp	1070 bp	*31:28	
25	135 bp	**800 bp**	*31:29	*23:03:01, 29:07
26[4]	130 bp	1070 bp	*31:30	*32:10
27[4]	95 bp	1070 bp	*31:31	
28	175 bp	1070 bp	*31:32	
29	275 bp	1070 bp	*31:36	
30[6,15]	160 bp, 245 bp	**800 bp**	*31:33-31:34	
31[4]	75 bp	1070 bp	*31:35	*01:07
32[4]	75 bp	1070 bp	*31:37	

[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*31 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 inherit 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*31 subtyping.
In addition, wells number 2, 3, 6, 14, 25 and 30 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 non-HLA-A*31 alleles will be amplified by primer mixes 1 to 7, 9, 12, 13, 16, 19, 21, 25, 26 and 31. In addition, primer mix 1 will amplify the B*15:82 allele.
[4]Short specific PCR fragments are less intense and not as sharp as longer specific bands.
[5]Primer mix 9 may give a lower yield of specific PCR product than the other HLA-A*31 primer mixes.
[6]Primer mix 24 and 30 may give rise to nonspecific amplifications.
[7]Primer mixes 4 and 7 may weakly amplify the A*34:01 allele.
[8]Primer mix 5: Specific PCR product of 135 bp in the A*31:26 allele. Specific PCR product of 285 bp in the A*31:03 and in the A*11:43 and A*33:13 alleles.
[9]Primer mix 8: Specific PCR product of 155 bp in the A*31:24 and A*31:27 alleles. Specific PCR product of 220bp in the A*31:09 allele.
[10]Primer mix 11: Specific PCR product of 135 bp in the A*31:26 allele. Specific PCR product of 215 bp in the A*31:12 allele.
[11]Primer mix 14: Specific PCR product of 150 bp in the A*31:24 allele. Specific PCR product of 470bp in the A*31:14N allele.
[12]Primer mix 15: Specific PCR product of 150 bp in the A*31:25 allele. Specific PCR product of 225 bp in the A*31:15 allele.
[13]Primer mix 17: Specific PCR product of 150 bp in the A*31:25 allele. Specific PCR product of 235 bp in the A*31:17 allele.
[14]Primer mix 22: Specific PCR product of 155 bp in the A*31:27 allele. Specific PCR product of 190 bp in the A*31:22 allele.
[15]Primer mix 30: Specific PCR product of 160 bp in the A*31:34 allele. Specific PCR product of 245 bp in the A*31:33 allele.

INTERPRETATION TABLE

HLA-A*31 SSP subtyping

Amplification patterns of the A*31:01 to A*31:37 alleles

	Well[5]															
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**
Length of spec.	155	215	155	165	135	165	505	155	75	160	135	245	85	150	150	165
PCR product(s)					285			220			215			470	225	
Length of int.	800	800	800	1070	1070	800	1070	1070	1070	1070	1070	1070	1070	800	1070	1070
pos. control[1]																
5'-primer[2]	127	97	423	413	97	448	317	97	413	448	362	97	413	448	98	98
	5'-ggg 3'	5'-TCA 3'	5'-gCT 3'	5'-CCg 3'	5'-TCA 3'	5'-CCT 3'	5'-gCT 3'	5'-TCA 3'	5'-CCA 3'	5'-CCT 3'	5'-gAA 3'	5'-TCA 3'	5'-CCA 3'	5'-CCT 3'	5'-CAC 3'	5'-CAC 3'
					445			448			445			3rd l	448	
					5'-TCC 3'			5'-CCT 3'			5'-TCC 3'			5'-ATA 3'	5'-CCT 3'	
3'-primer[3]	238	270	538	539	341	570	538	214	448	565	538	299	456	559	281	221
	5'-CCT 3'	5'-ACT 3'	5'-CAA 3'	5'-TCA 3'	5'-CgT 3'	5'-CCg 3'	5'-CAA 3'	5'-CCA 3'	5'-CAA 3'	5'-CAg 3'	5'-CAA 3'	5'-CCA 3'	5'-TCg 3'	5'-CCg 3'	5'-AgC 3'	5'-ACA 3'
	238				538			278						621	559	
	5'-CCT 3'				5'-CAA 3'			5'-ggC 3'						5'-ggg 3'	5'-CCT 3'	
	245							559								
	5'-ACg 3'							5'-CCg 3'								
Well No.	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**
HLA-A allele[4]																
***31:01:02-31:01:09**	1								9			12				
***31:02**	1	2							9			12				
***31:03**	1		3	4	5							12				
***31:04**	1		3	4								12				
***31:05**	1					6			9			12				
***31:06**	1			4								12				
***31:07**	1	2					7		9							
***31:08**		2					7		9							
***31:09**	1							8	9			12				
***31:10**	1						7		9							
***31:11**	1								9	10		12				
***31:12**	1								9		11	12				
***31:13**	1								9			12	13			
Well No.	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**

INTERPRETATION TABLE

HLA-A*31 SSP subtyping

Amplification patterns of the A*31:01 to A*31:37 alleles

Well[5]																
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	
150	200	110	325	180	155	200	220	135	130	95	175	275	160	75	75	Length of spec.
235					190								245			PCR product(s)
1070	1070	1070	1070	1070	1070	1070	1070	800	1070	1070	1070	1070	800	1070	1070	Length of int.
																pos. control[1]
98	413	488	302	98	98	652	97	355	448	235	406	97	97	203	448	5'-primer[2]
5' -CAC 3'	5' -CCA 3'	5' -ggT 3'	5' -ggA 3'	5' -CTT 3'	5' -CAC 3'	5' -CTg 3'	5' -TCA 3'	5' -CCC 3'	5' -CCT 3'	5' -AgA 3'	5' -gCT 3'	5' -TCA 3'	5' -TCA 3'	5' -gAA 3'	5' -CCT 3'	
448													448			
5' -CCT 3'													5' -CCT 3'			
292	571	559	346	238	214	811	277	448	539	290	538	331	299	238	482	3'-primer[3]
5' -gTT 3'	5' -CCT 3'	5' -CgT 3'	5' -AgC 3'	5' -CCT 3'	5' -CCA 3'	5' -CAT 3'	5' -ggT 3'	5' -CAA 3'	5' -TCC 3'	5' -CAA 3'	5' -CAA 3'	5' -CTC 3'	5' -CCC 3'	5' -CCT 3'	5' -TgC 3'	
559					245								568			
5' -CCT 3'					5' -ACg 3'								5' -CTg 3'			
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Well No.
																HLA-A allele[4]
																*31:01:02-31:01:09
																*31:02
																*31:03
																*31:04
																*31:05
																*31:06
																*31:07
																*31:08
																*31:09
																*31:10
																*31:11
																*31:12
																*31:13
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Well No.

Length of spec.	**155**	**215**	**155**	**165**	**135**	**165**	**505**	**155**	**75**	**160**	**135**	**245**	**85**	**150**	**150**	**165**
PCR product(s)					**285**			**220**			**215**			**470**	**225**	
Well No.	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**
***31:14N**	**1**								**9**			**12**		**14**		
***31:15**	**1**								**9**			**12**			**15**	
***31:16**	**1**								**9**			**12**				**16**
***31:17**	**1**								**9**			**12**				
***31:18**	**1**								**9**			**12**				
***31:19**	**1**								**9**			**12**				
***31:20**	**1**								**9**			**12**				
***31:21**	**1**								**9**							
***31:22**	**1**								**9**			**12**				
***31:23**	**1**								**9**			**12**				
***31:24**	**1**							**8**	**9**			**12**		**14**		
***31:25**	**1**								**9**			**12**			**15**	
***31:26**	**1**				**5**				**9**		**11**	**12**				
***31:27**	**1**							**8**	**9**			**12**				
***31:28**	**1**								**9**			**12**				
***31:29**	**1**								**9**			**12**				
***31:30**	**1**								**9**			**12**				
***31:31**	**1**								**9**			**12**				
***31:32**	**1**								**9**			**12**				
***31:33**	**1**								**9**							
***31:34**	**1**								**9**			**12**				
***31:35**	**1**								**9**			**12**				
***31:36**	**1**								**9**			**12**				
***31:37**	**1**								**9**			**12**				
***01:06, 02:114, 02:246, 03:05, 03:42, 11:24:01-11:25, 11:31, 11:35, 29:01:01:01-29:02:05, 29:04, 29:06, 29:08N-29:11, 29:15-29:18, 29:20-29:22, 30:26, 68:08:01-68:08:02, 80:01-80:02**				**4**												
***01:07**	**1**															
***02:65, 02:152, 32:02, 32:22, 33:17, 74:01-74:14N**									**9**							
Well No.	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**

150	200	110	325	180	155	200	220	135	130	95	175	275	160	75	75	Length of spec.
235					190								245			PCR product(s)
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Well No.
																*31:14N
																*31:15
																*31:16
17																*31:17
	18															*31:18
		19														*31:19
			20													*31:20
				21												*31:21
					22											*31:22
						23										*31:23
																*31:24
17																*31:25
																*31:26
					22											*31:27
							24									*31:28
								25								*31:29
									26							*31:30
										27						*31:31
											28					*31:32
													30			*31:33
													30			*31:34
														31		*31:35
												29				*31:36
															32	*31:37
																*01:06, 02:114, 02:246, 03:05, 03:42, 11:24:01-11:25, 11:31, 11:35, 29:01:01:01-29:02:05, 29:04, 29:06, 29:08N-29:11, 29:15-29:18, 29:20-29:22, 30:26, 68:08:01-68:08:02, 80:01-80:02
				21										31		*01:07
																*02:65, 02:152, 32:02, 32:22, 33:17, 74:01-74:14N
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Well No.

Length of spec.	**155**	**215**	**155**	**165**	**135**	**165**	**505**	**155**	**75**	**160**	**135**	**245**	**85**	**150**	**150**	**165**
PCR product(s)					**285**			**220**			**215**			**470**	**225**	
Well No.	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**
***02:81, 02:87, 02:112, 02:124, 02:129, 23:01:01-23:01:02, 23:03:02-23:13, 23:15-23:20, 23:22-23:26, 24:13:01, 24:18, 24:24, 24:94, 32:04**							**7**									
***02:185**	**1**															
***02:243**		**2**										**12**				
***02:251**													**13**			
***03:01:19, 26:43:01, 34:06, 66:06**			**3**													
***03:52**																
***11:43**					**5**							**12**				
***23:03:01**						**6**	**7**		**9**							
***23:21**	**1**						**7**									
***24:82**		**2**														
24:124, 26:19, 30:12, 30:18, *B*15:82	**1**															
***29:03**				**4**		**6**										
***29:07**				**4**												
***29:12**				**4**												**16**
***29:13**				**4**			**7**									
***29:14**	**1**			**4**												
***29:19, 33:18**				**4**								**12**				
***32:01:01-32:01:05, 32:03, 32:05-32:09, 32:11Q-32:12, 32:14-32:21, 32:23-32:25**							**7**		**9**							
***32:10**									**9**							
***32:13**						**6**	**7**		**9**							
***33:01:01-33:01:03, 33:03:01-33:07, 33:09, 33:11-33:12, 33:14-33:16, 33:20-33:31**									**9**			**12**				
***33:08**		**2**							**9**			**12**				
Well No.	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**

150	200	110	325	180	155	200	220	135	130	95	175	275	160	75	75	Length of spec.
235					190								245			PCR product(s)
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Well No.
																*02:81, 02:87, 02:112, 02:124, 02:129, 23:01:01-23:01:02, 23:03:02-23:13, 23:15-23:20, 23:22-23:26, 24:13:01, 24:18, 24:24, 24:94, 32:04
				21												*02:185
																*02:243
																*02:251
																*03:01:19, 26:43:01, 34:06, 66:06
		19														*03:52
																*11:43
								25								*23:03:01
																*23:21
																*24:82
																*24:124, 26:19, 30:12, 30:18, *B*15:82*
																*29:03
								25								*29:07
																*29:12
																*29:13
																*29:14
																*29:19, 33:18
																*32:01:01-32:01:05, 32:03, 32:05-32:09, 32:11Q-32:12, 32:14-32:21, 32:23-32:25
									26							*32:10
																*32:13
																*33:01:01-33:01:03, 33:03:01-33:07, 33:09, 33:11-33:12, 33:14-33:16, 33:20-33:31
																*33:08
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Well No.

Length of spec.	**155**	**215**	**155**	**165**	**135**	**165**	**505**	**155**	**75**	**160**	**135**	**245**	**85**	**150**	**150**	**165**
PCR product(s)					**285**			**220**			**215**			**470**	**225**	
Well No.	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**
***33:10**						**6**			**9**			**12**				
***33:13**					**5**				**9**							
***33:19, 68:29**												**12**				
***34:02:01-34:03, 34:07-34:08**			**3**	**4**												
***34:04**	**1**		**3**	**4**												
HLA-A allele[4]																
Well No.	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**

[1]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*31 subtyping.
In addition, wells number 2, 3, 6, 14, 25 and 30 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.
[2]The nucleotide position, in the 2nd, 3rd or 4th exons or the 3rd intron, 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.
[3]The 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.

150	200	110	325	180	155	200	220	135	130	95	175	275	160	75	75	Length of spec.
235					190								245			PCR product(s)
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Well No.
																*33:10
																*33:13
																*33:19, 68:29
																*34:02:01-34:03, 34:07-34:08
																*34:04
																HLA-A allele[4]
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Well No.

[4]The sequence of the A*31011 allele has been shown to be identical to A*31:01:02.
[5]Primer mix 5: Specific PCR product of 135 bp in the A*31:26 allele. Specific PCR product of 285 bp in the A*31:03 and in the A*11:43 and A*33:13 alleles.
Primer mix 8: Specific PCR product of 155 bp in the A*31:24 and A*31:27 alleles. Specific PCR product of 220bp in the A*31:09 allele.
Primer mix 11: Specific PCR product of 135 bp in the A*31:26 allele. Specific PCR product of 215 bp in the A*31:12 allele.
Primer mix 14: Specific PCR product of 150 bp in the A*31:24 allele. Specific PCR product of 470bp in the A*31:14N allele.
Primer mix 15: Specific PCR product of 150 bp in the A*31:25 allele. Specific PCR product of 225 bp in the A*31:15 allele.
Primer mix 17: Specific PCR product of 150 bp in the A*31:25 allele. Specific PCR product of 235 bp in the A*31:17 allele.
Primer mix 22: Specific PCR product of 155 bp in the A*31:27 allele. Specific PCR product of 190 bp in the A*31:22 allele.
Primer mix 30: Specific PCR product of 160 bp in the A*31:34 allele. Specific PCR product of 245 bp in the A*31:33 allele.

CELL LINE VALIDATION SHEET

HLA-A*31 SSP subtyping kit

					Well													
					1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
				Lot No.:	201186101	201186102	200969703	201186104	200969705	200969706	200969707	200969708	200969709	200969710	200969711	200969712	200969713	200969714	200969715	201186116
	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	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

CELL LINE VALIDATION SHEET

HLA-A*31 SSP subtyping kit

					Well															
					17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32
				Prod. No.:	200969717	200969718	200969719	200969720	200969721	201186122	200969723	200969724	201186125	201186126	201186127	201186128	201186129	201186130	201186131	201186132
	IHWC cell line		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	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-A*31 SSP

Product number: **101.430-12u – without *Taq* polymerase**
Lot number: **19M**
Expiry date: **2013-November-01**
Number of tests: **12**
Number of wells per test: **32**

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2011-861-01	13	2009-697-13	25	2011-861-25
2	2011-861-02	14	2009-697-14	26	2011-861-26
3	2009-697-03	15	2009-697-15	27	2011-861-27
4	2011-861-04	16	2011-861-16	28	2011-861-28
5	2009-697-05	17	2009-697-17	29	2011-861-29
6	2009-697-06	18	2009-697-18	30	2011-861-30
7	2009-697-07	19	2009-697-19	31	2011-861-31
8	2009-697-08	20	2009-697-20	32	2011-861-32
9	2009-697-09	21	2009-697-21		
10	2009-697-10	22	2011-861-22		
11	2009-697-11	23	2009-697-23		
12	2009-697-12	24	2009-697-24		

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, 5, 6, 8, 10, 11 and 13 to 32 were available. The specificities of the primers in primer solutions 2, 5, 6, 8, 14, 21, 25, 26 and 31 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer solutions 10, 13, 15 to 18, 20, 22, 22 to 24, 29, 30 and 32 it was only possible to test the 5'-primer, the 3'-primer was not possible to test. In primer solutions 11, 19, 27 and 28 it was only possible to test the 3'-primer, the 5'-primer was not possible to test. In primer solution 5, one 5'-primer was not possible to test, and in primer solutions 1, 8 and 14 one or two 3'-primers were not possible to test.

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

Date of approval: 2011-May-27

Approved by:

Quality Control, Supervisor

Declaration of Conformity

Product name: *Olerup* SSP® HLA-A*31
Product number: 101.430-12u
Lot number: 19M

Intended use: HLA-A*31 high resolution histocompatibility testing

Manufacturer: *Olerup* SSP AB
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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-November-20

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs

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