Olerup SSP® HLA-A*33

Product number:	**101.432-12 – including *Taq* polymerase**
Lot number:	**81K**
Expiry date:	**2013-May-01**
Number of tests:	**12**
Number of wells per test:	**24**
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. 81K.

CHANGES COMPARED TO THE PREVIOUS *OLERUP* SSP® HLA-A*33 LOT

The HLA-A*33 specificity and interpretation tables have been updated for the HLA-A alleles described since the previous *Olerup* SSP® HLA-A*33 lot was made **(Lot No. 32G)**.

Eight wells have been added to the HLA-A*33 kit, wells **17 to 24**.

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

Well	5'-primer	3'-primer	rationale
7	Moved	Moved	Primer pair moved to well 17, exchanged positive control primer pair.
17	New, added	New, added	Primer pair from primer pair 7, new primer pair for the A*33:26 allele.
18	New	New	New primer pair for the A*33:27 allele.
19	New	New	New primer pair for the A*33:28 allele.
20	New	New	New primer pair for the A*33:29 allele.
21	New	New	New primer pair for the A*33:30 allele.
22	New	New	New primer pair for the A*33:31 allele.
23	New	New	New primer pair for the A*33:32 allele.
24	New	New	New primer pair for the A*33:34 allele.

PRODUCT DESCRIPTION

HLA-A*33 SSP subtyping

CONTENT
The primer set contains 5'- and 3'-primers for identifying the A*33:01 to A*33:34 alleles.

PLATE LAYOUT
Each test consists of 24 PCR reactions in a 24 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**

The 24 well cut PCR plate is marked with 'HLA-A*33' in silver/gray ink.
Well No. 1 is marked with the Lot No. '81K'.
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 24 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*33 SSP subtypings will be influenced by two A*01, several A*02, six A*03, the A*11:43, the A*23:03:01, nine A*24, the A*25, the A*26, the A*29, most A*31, the A*32, four A*34, the A*43:01, the A*66, the A*68:29 and the A*74 alleles when present on the other haplotype. In addition, the C*02:02:15 allele will be amplified by primer mix 19.

UNIQUELY IDENTIFIED ALLELES
All the HLA-A*33 alleles, i.e. **A*33:01 to A*33:34 alleles**, recognized by the HLA Nomenclature Committee in October 2010[1] will give rise to unique amplification patterns by the primers in the HLA-A*33 subtyping kit[2].
The A*33 subtyping kit cannot distinguish the A*33:01:01-33:01:05 or the A*33:03:01-33:03:06 alleles.

[1]HLA-A alleles listed on the IMGT/HLA web page 2010-October-15, release 3.2.0, www.ebi.ac.uk/imgt/hla.
[2]The A*33:08, A*26:22 and A*66:09 give rise to identical amplification patterns with the HLA-A*33 subtyping kit. These three alleles can be distinguished by e.g. the HLA-A low resolution kit and/or the HLA-A*26 and HLA-A*66 subtyping kits.

RESOLUTION IN HOMO- AND HETEROZYGOTES

A total of 42 alleles generate 33 amplification patterns that can be combined in 561 homozygous and heterozygous combinations. 306 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.

++++-+-+ -------- --------	*33:05, *33:24 = *33:07, *33:20
++++-+-- ++------- --------	*33:05, *33:08 = *33:05, *33:22
++++-+-- +-------- --------	*33:05, *33:09 = *33:05, *33:14
++++-+-- ------+- --------	*33:05, *33:23 = *33:16, *33:20
++++-+-- -------+ --------	*33:05, *33:17 = *33:05, *33:21
++++-+-- -------- --------	*33:01:01, *33:20 = *33:03:01, *33:05 = *33:05, *33:20
+++++--+ ++------- --------	*33:07, *33:08 = *33:07, *33:22
+++++--+ +-------- --------	*33:07, *33:09 = *33:07, *33:14
+++++--+ ------+- --------	*33:07, *33:23 = *33:16, *33:24
+++++--+ -------+ --------	*33:07, *33:17 = *33:07, *33:21
+++++--+ -------- --------	*33:01:01, *33:24 = *33:03:01, *33:07 = *33:07, *33:24
++++++-- ++-----+- --------	*33:08, *33:16 = *33:16, *33:22
++++++-- ++------- -+-------	*33:08, *33:27 = *33:22, *33:27
++++++-- ++------- ------+-	*33:08, *33:32 = *33:22, *33:32
++++++-- ++------- -------+	*33:08, *33:34 = *33:22, *33:34
++++++-- ++------- --------	*33:01:01, *33:08 = *33:01:01, *33:22
++++++-- +-----+- --------	*33:09, *33:16 = *33:14, *33:16
++++++-- +------- -+-------	*33:09, *33:27 = *33:14, *33:27
++++++-- +------- ------+-	*33:09, *33:32 = *33:14, *33:32
++++++-- +------- -------+	*33:09, *33:34 = *33:14, *33:34
++++++-- +------- --------	*33:01:01, *33:09 = *33:01:01, *33:14
++++++-- ------++ --------	*33:16, *33:17 = *33:16, *33:21
++++++-- ------+- --------	*33:01:01, *33:23 = *33:03:01, *33:16 = *33:16, *33:23
++++++-- -------+ -+-------	*33:17, *33:27 = *33:21, *33:27
++++++-- -------+ ------+-	*33:17, *33:32 = *33:21, *33:32
++++++-- -------+ -------+	*33:17, *33:34 = *33:21, *33:34
++++++-- -------+ --------	*33:01:01, *33:17 = *33:01:01, *33:21
+++-+-- -------- --------	*33:01:01, *33:05 = *33:05, *33:05
+++---+ -------- --------	*33:01:01, *33:07 = *33:07, *33:07
+++---- ------+- --------	*33:01:01, *33:16 = *33:16, *33:16
+++---- -------- -+-------	*33:01:01, *33:27 = *33:27, *33:27
+++---- -------- ------+-	*33:01:01, *33:32 = *33:32, *33:32
+++---- -------- -------+	*33:01:01, *33:34 = *33:34, *33:34
++-++--- ++------- --------	*33:04, *33:08 = *33:04, *33:22
++-++--- +------- --------	*33:04, *33:09 = *33:04, *33:14
++-++--- -------+ --------	*33:04, *33:17 = *33:04, *33:21
++-++--- -------- --------	*33:03:01, *33:04 = *33:04, *33:33
+--++--- ++------- --------	*33:08, *33:33 = *33:22, *33:33
+--++--- +------- --------	*33:09, *33:33 = *33:14, *33:33
+--++--- -----+-- --------	*33:15, *33:33 = *33:19, *33:33
+--++--- -------+ --------	*33:17, *33:33 = *33:21, *33:33
+--++--- -------- +-------	*33:18, *33:33 = *33:26, *33:33
+--++--- -------- --------	*33:03:01, *33:33 = *33:33, *33:33
+--+-+-- ++------- --------	*33:08, *33:20 = *33:20, *33:22
+--+-+-- +------- --------	*33:09, *33:20 = *33:14, *33:20
+--+-+-- -----+-- --------	*33:15, *33:20 = *33:19, *33:20
+--+-+-- -------+ --------	*33:17, *33:20 = *33:20, *33:21
+--+-+-- -------- +-------	*33:18, *33:20 = *33:20, *33:26
+--+-+-- -------- --------	*33:03:01, *33:20 = *33:20, *33:20
+--+--+- ++------- --------	*33:06, *33:08 = *33:06, *33:22
+--+--+- +------- --------	*33:06, *33:09 = *33:06, *33:14

+--+--+- -----+-- --------	*33:06, *33:15 = *33:06, *33:19
+--+--+- -------+ --------	*33:06, *33:17 = *33:06, *33:21
+--+--+- -------- +-------	*33:06, *33:18 = *33:06, *33:26
+--+--+- -------- --------	*33:03:01, *33:06 = *33:06, *33:06
+--+---+ ++------ --------	*33:08, *33:24 = *33:22, *33:24
+--+---+ +------- --------	*33:09, *33:24 = *33:14, *33:24
+--+---+ -----+-- --------	*33:15, *33:24 = *33:19, *33:24
+--+---+ -------+ --------	*33:17, *33:24 = *33:21, *33:24
+--+---+ -------- +-------	*33:18, *33:24 = *33:24, *33:26
+--+---+ -------- --------	*33:03:01, *33:24 = *33:24, *33:24
+--+---- +++-+--- --------	*33:08, *33:25 = *33:22, *33:25
+--+---- ++----- --------	*33:08, *33:10 = *33:10, *33:22
+--+---- ++-+---- --------	*33:08, *33:11 = *33:11, *33:22
+--+---- ++--+--- --------	*33:08, *33:12 = *33:12, *33:22
+--+---- ++---+-- --------	*33:08, *33:15 = *33:08, *33:19 = *33:15, *33:22 = *33:19, *33:22
+--+---- ++----+- --------	*33:08, *33:23 = *33:22, *33:23
+--+---- ++-----+ --------	*33:08, *33:17 = *33:17, *33:22 = *33:21, *33:22
+--+---- ++------ +-------	*33:08, *33:18 = *33:08, *33:26 = *33:18, *33:22 = *33:22, *33:26
+--+---- ++------ --+-----	*33:08, *33:28 = *33:22, *33:28
+--+---- ++------ ---+----	*33:08, *33:29 = *33:22, *33:29
+--+---- ++------ ----+---	*33:08, *33:30 = *33:22, *33:30
+--+---- ++------ -----+--	*33:08, *33:31 = *33:22, *33:31
+--+---- ++------ --------	*33:03:01, *33:08 = *33:03:01, *33:22 = *33:08, *33:13 = *33:08, *33:14 = *33:08, *33:22 = *33:09, *33:13 = *33:09, *33:22 = *33:13, *33:14 = *33:13, *33:22 = *33:14, *33:22 = *33:22, *33:22
+--+---- +-+-+--- --------	*33:09, *33:25 = *33:14, *33:25
+--+---- +-+----- --------	*33:09, *33:10 = *33:10, *33:14
+--+---- +--+---- --------	*33:09, *33:11 = *33:11, *33:14
+--+---- +---+--- --------	*33:09, *33:12 = *33:12, *33:14
+--+---- +----+-- --------	*33:09, *33:15 = *33:09, *33:19 = *33:14, *33:15 = *33:14, *33:19
+--+---- +-----+- --------	*33:09, *33:23 = *33:14, *33:23
+--+---- +------+ --------	*33:09, *33:17 = *33:14, *33:17 = *33:14, *33:21
+--+---- +------- +-------	*33:09, *33:18 = *33:09, *33:26 = *33:14, *33:18 = *33:14, *33:26
+--+---- +------- --+-----	*33:09, *33:28 = *33:14, *33:28
+--+---- +------- ---+----	*33:09, *33:29 = *33:14, *33:29
+--+---- +------- ----+---	*33:09, *33:30 = *33:14, *33:30
+--+---- +------- -----+--	*33:09, *33:31 = *33:14, *33:31
+--+---- +------- --------	*33:03:01, *33:09 = *33:03:01, *33:14 = *33:09, *33:14 = *33:14, *33:14
+--+---- -+---+-- --------	*33:13, *33:15 = *33:13, *33:19
+--+---- -+-----+ --------	*33:13, *33:17 = *33:13, *33:21
+--+---- -+------ +-------	*33:13, *33:18 = *33:13, *33:26
+--+---- -+------ --------	*33:03:01, *33:13 = *33:13, *33:13
+--+---- --+-+-- --------	*33:15, *33:25 = *33:19, *33:25
+--+---- --+-+--+ --------	*33:17, *33:25 = *33:21, *33:25
+--+---- --+-+--- +-------	*33:18, *33:25 = *33:25, *33:26
+--+---- --+-+--- --------	*33:03:01, *33:25 = *33:10, *33:12 = *33:10, *33:25 = *33:12, *33:25 = *33:25, *33:25
+--+---- --+--+-- --------	*33:10, *33:15 = *33:10, *33:19
+--+---- --+-----+ --------	*33:10, *33:17 = *33:10, *33:21
+--+---- --+------ +-------	*33:10, *33:18 = *33:10, *33:26
+--+---- --+------ --------	*33:03:01, *33:10 = *33:10, *33:10
+--+---- ---+-+-- --------	*33:11, *33:15 = *33:11, *33:19

+--+---- ---+---+ --------	*33:11, *33:17 = *33:11, *33:21
+--+---- ---+---- +-------	*33:11, *33:18 = *33:11, *33:26
+--+---- ---+---- --------	*33:03:01, *33:11 = *33:11, *33:11
+--+---- ----+-- --------	*33:12, *33:15 = *33:12, *33:19
+--+---- ----+--+ --------	*33:12, *33:17 = *33:12, *33:21
+--+---- ----+--- +-------	*33:12, *33:18 = *33:12, *33:26
+--+---- ----+--- --------	*33:03:01, *33:12 = *33:12, *33:12
+--+---- -----++- --------	*33:15, *33:23 = *33:19, *33:23
+--+---- -----+-+ --------	*33:15, *33:17 = *33:15, *33:21 = *33:17, *33:19 = *33:19, *33:21
+--+---- -----+-- +-------	*33:15, *33:18 = *33:15, *33:26 = *33:19, *33:26
+--+---- -----+-- --+-----	*33:15, *33:28 = *33:19, *33:28
+--+---- -----+-- ---+----	*33:15, *33:29 = *33:19, *33:29
+--+---- -----+-- ----+---	*33:15, *33:30 = *33:19, *33:30
+--+---- -----+-- -----+--	*33:15, *33:31 = *33:19, *33:31
+--+---- -----+-- --------	*33:03:01, *33:15 = *33:03:01, *33:19 = *33:15, *33:15 = *33:15, *33:19
+--+---- ------++ --------	*33:17, *33:23 = *33:21, *33:23
+--+---- ------+- +-------	*33:18, *33:23 = *33:23, *33:26
+--+---- ------+- --------	*33:03:01, *33:23 = *33:23, *33:23
+--+---- -------+ +-------	*33:17, *33:18 = *33:17, *33:26 = *33:18, *33:21 = *33:21, *33:26
+--+---- -------+ --+-----	*33:17, *33:28 = *33:21, *33:28
+--+---- -------+ ---+----	*33:17, *33:29 = *33:21, *33:29
+--+---- -------+ ----+---	*33:17, *33:30 = *33:21, *33:30
+--+---- -------+ -----+--	*33:17, *33:31 = *33:21, *33:31
+--+---- -------+ --------	*33:03:01, *33:17 = *33:03:01, *33:21 = *33:17, *33:17 = *33:17, *33:21
+--+---- -------- +-+-----	*33:18, *33:28 = *33:26, *33:28
+--+---- -------- +--+----	*33:18, *33:29 = *33:26, *33:29
+--+---- -------- +---+---	*33:18, *33:30 = *33:26, *33:30
+--+---- -------- +----+--	*33:18, *33:31 = *33:26, *33:31
+--+---- -------- +-------	*33:03:01, *33:18 = *33:03:01, *33:26 = *33:18, *33:26 = *33:26, *33:26
+--+---- -------- --+-----	*33:03:01, *33:28 = *33:28, *33:28
+--+---- -------- ---+----	*33:03:01, *33:29 = *33:29, *33:29
+--+---- -------- ----+---	*33:03:01, *33:30 = *33:30, *33:30
+--+---- -------- -----+--	*33:03:01, *33:31 = *33:31, *33:31
---+---- ++------ --------	*33:08, *33:08 = *33:08, *33:09

33:01:01 = 33:01:01-33:01:05
33:03:01= 33:03:01-33:03:06

SPECIFICITY TABLE

HLA-A*33 SSP subtyping

Specificities and sizes of the PCR products of the 24 primer mixes used for HLA-A*33 SSP subtyping

Primer Mix	Size of spec. PCR product[1]	Size of control band[2]	Amplified HLA-A*33 alleles	Other amplified HLA-A alleles[3]
1	205 bp	**800 bp**	*33:01:01-33:01:05, 33:03:01-33:07, 33:10-33:20, 33:22-33:34	*68:29
2	205 bp	**800 bp**	*33:01:01-33:01:05, 33:04-33:05, 33:07, 33:16, 33:27, 33:32, 33:34	*03:104, 66:04
3	155 bp	1070 bp	*33:01:01-33:01:05, 33:05, 33:07, 33:16, 33:27, 33:32, 33:34	*03:104, 66:04
4	210 bp	1070 bp	*33:03:01-33:03:06, 33:06, 33:08-33:15, 33:17, 33:20-33:26, 33:28-33:31, 33:33	*02:41, 02:65, 02:80, 02:117, 02:135, 02:152, 03:103, 24:62, 25:01:01-25:13, 26:01:01-26:39, 26:41-26:43:02, 26:45-26:56, 31:01:02-31:02, 31:05, 31:07-31:46, 32:01:01-32:03, 32:05-32:29, 34:01:01-34:01:02, 34:05-34:06, 43:01, 66:01-66:03, 66:05-66:15, 74:01-74:14N
5[4]	90 bp	**800 bp**	*33:04, 33:33	
6[4,7]	105 bp, 175 bp	1070 bp	*33:05, 33:20	
7[4]	105 bp	1070 bp	*33:06	
8[4,8]	125 bp, 235 bp	1070 bp	*33:07, 33:24	*02:243, 29:19
9[9]	150 bp, 185 bp	**800 bp**	*33:08-33:09, 33:14, 33:22	*01:20, 01:66, 02:24, 02:137, 02:243, 03:95, 26:22, 66:09

10[10]	140 bp, 215 bp, 285 bp	**800 bp**	*33:08, 33:13, 33:22	*01:20, 01:66, 02:24, 02:137, 02:243, 03:95, 11:43, 24:82, 26:22, 66:09
11[5]	165 bp	1070 bp	*33:10, 33:25	*23:03:01, 29:03, 31:05, 32:13
12	235 bp	1070 bp	*33:11	*11:43, 68:29
13[4,5,11]	95 bp,165 bp	1070 bp	*33:12, 33:25	
14[4,12]	115 bp, 335 bp	1070 bp	*33:15, 33:19	*02:10, 02:17:01-02:17:02, 02:39, 02:108, 02:110, 02:140, 02:148, 02:242, 02:244, 02:268, 03:15, 03:19, 24:04, 24:19, 24:28, 24:44, 24:89, 24:109, 24:129, 29:07, 31:29
15[6]	140 bp	1070 bp	*33:16, 33:23	
16[13]	210 bp, 245 bp	1070 bp	*33:17, 33:21	
17[4,14]	75 bp, 140 bp	1070 bp	*33:18, 33:26	*03:01:18, 29:01:01:01-29:01:01:02N, 29:01:03-29:27, 31:06, 32:30
18[4]	100 bp	1070 bp	*33:27	
19[4]	120 bp	1070 bp	*33:28	*03:01:18, 32:10, **C*02:02:15**
20[4]	90 bp	1070 bp	*33:29	
21[4]	115 bp	1070 bp	*33:30	
22[4]	115 bp	1070 bp	*33:31	*02:241, 26:24
23	170 bp	1070 bp	*33:32	
24[4]	95 bp	1070 bp	*33:34	*03:01:18, 29:09, 31:24

[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*33 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*33 subtyping.
In addition, wells number 2, 5, 9 and 10 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*33 alleles will be amplified by primer mixes 1 to 4, 7 to 12, 14, 17, 19, 22 and 24. In addition, the C*02:02:15 allele will be amplified by primer mix 19. The A*33:08, A*26:22 and A*66:09 give rise to identical amplification patterns with the HLA-A*33 subtyping kit. These three alleles can be distinguished by e.g. the HLA-A low resolution kit and/or the HLA-A*26 and HLA-A*66 subtyping kits.
[4]Short specific PCR fragments are less intense and not as sharp as longer specific bands.
[5]Primer mixes 11 and 13 may give to non-specific amplifications.
[6]Primer mix 15 may have tendencies of giving rise to primer dimers.
[7]Primer mix 6: Specific PCR fragment of 105 bp in the A*33:20 allele. Specific PCR fragment of 175 bp in the A*33:05 allele.
[8]Primer mix 8: Specific PCR fragment of 125 bp in the A*33:07 allele. Specific PCR fragment of 235 bp in the A*33:24 and the A*02:243 and 29:19 alleles.
[9]Primer mix 9: Specific PCR fragment of 150 bp in the A*33:14, 33:22, 01:20, 01:66, 02:24, 02:137, 03:95, 26:22 and 66:09 alleles. Specific PCR fragment of 185 bp in the A*33:08 and 33:09 and the A*02:243 alleles.
[10]Primer mix 10: Specific PCR fragment of 140 bp in the A*33:22 and the A*01:20, 01:66, 02:24, 02:137, 03:95, 26:22 and 66:09 alleles. Specific PCR fragment of 215 bp in the A*33:08 and the A*02:243 and 24:82 alleles. Specific PCR fragment of 285 bp in the A*33:13 and the A*11:43 alleles.
[11]Primer mix 13: Specific PCR fragment of 95 bp in the A*33:12 allele. Specific PCR fragment of 165 bp in the A*33:25 allele.
[12]Primer mix 14: Specific PCR fragment of 115 bp in the A*33:15 and A*02:140 alleles. Specific PCR fragment of 335 bp in the A*33:19 and A*02:10, 02:17:01-02:17:02, 02:39, 02:108, 02:110, 02:148, 02:242, 02:244, 02:268, 03:15, 03:19, 24:04, 24:19, 24:28, 24:44, 24:89, 24:109, 24:129, 29:07, 31:29 alleles.
[13]Primer mix 16: Specific PCR fragment of 210 bp in the A*33:21 allele. Specific PCR fragment of 245 bp in the A*33:17 allele.
[14]Primer mix 17: Specific PCR fragment of 75 bp in the A*33:18 and the A*03:01:18, 29:01:01:01-29:01:01:02N, 29:01:03-29:27, 31:06 and 32:30 alleles. Specific PCR fragment of 140 bp in the A*33:26 allele.

INTERPRETATION TABLE

HLA-A*33 SSP subtyping

Amplification patterns of the A*33:01 to A*33:34 alleles

	Well[6]											
	1	2	3	4	5	6	7	8	9	10	11	12
Length of spec.	205	205	155	210	90	105	105	125	150	140	165	235
PCR product(s)						175		235	185	215		
										285		
Length of int.	800	800	1070	1070	800	1070	1070	1070	800	800	1070	1070
pos. control[1]												
5'-primer[2]	97	418	468	414	414	97	228	97	97	97	448	97
	5'-TCA 3'	5'-Agg 3'	5'-TCT 3'	5'-CAg 3'	5'-CAg 3'	5'-TCA 3'	5'-ATg 3'	5'-TCA 3'	5'-TCA 3'	5'-TCA 3'	5'-CCT 3'	5'-TCA 3'
						413		448	355	355	652	
						5'-CCA 3'		5'-CCT 3'	5'-CCg 3'	5'-CCg 3'	5'-CTg 3'	
3'-primer(s)[3]	259	583	583	583	463	233	290	292	218	270	570	290
	5'-gTT 3'	5'-gTg 3'	5'-gTg 3'	5'-gTA 3'	5'-gCT 3'	5'-CCC 3'	5'-CAA 3'	5'-gTg 3'	5'-gCC 3'	5'-ACT 3'	5'-CCg 3'	5'-CAg 3'
						475		530	240	341	778	
						5'-Cgg 3'		5'-CCT 3'	5'-ggA 3'	5'-CgT 3'	5'-TgT 3'	
									453	453		
									5'-TCg 3'	5'-TCg 3'		
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
HLA-A allele[4]												
***33:01:01-33:01:05**	1	2	3									
***33:03:01-33:03:06**	1			4								
***33:04**	1	2			5							
***33:05**	1	2	3			6						
***33:06**	1			4			7					
***33:07**	1	2	3					8				
***33:08, 26:22, 66:09[5]**				4					9	10		
***33:09**				4					9			
***33:10**	1			4							11	
***33:11**	1			4								12
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

INTERPRETATION TABLE

HLA-A*33 SSP subtyping

Amplification patterns of the A*33:01 to A*33:34 alleles

Well[6]												
13	14	15	16	17	18	19	20	21	22	23	24	
95	115	140	210	75	100	120	90	115	115	170	95	Length of spec.
165	335		245	140								PCR product(s)
1070	1070	1070	1070	1070	1070	1070	1070	1070	1070	1070	1070	Length of int.
												pos. control[1]
395	317	158	97	161	390	448	397	463	652	453	448	5'-primer[2]
5' -gCC 3'	5' -gCg 3'	5' -ggg 3'	5' -TCA 3'	5' -CgC 3'	5' -gAg 3'	5' -CCT 3'	5' -gCg 3'	5' -TgT 3'	5' -CTg 3'	5' -AAA 3'	5' -CCT 3'	
652	652	482		413								
5' -CTg 3'	5' -CTg 3'	5' -ggC 3'		5' -CCg 3'								
448	368	259	265	259	448	527	448	538	728	583	502	3'-primer(s)[3]
5' -CAA 3'	5' -CAA 3'	5' -gTT 3'	5' -CCC 3'	5' -gTT 3'	5' -CAA 3'	5' -CCT 3'	5' -CAA 3'	5' -CAA 3'	5' -CCT 3'	5' -gTg 3'	5' -CTT 3'	
778	727	583	299	448								
5' -TgT 3'	5' -CCA 3'	5' -gTg 3'	5' -CCg 3'	5' -CAA 3'								
13	14	15	16	17	18	19	20	21	22	23	24	Well No.
												HLA-A allele[4]
												*33:01:01-33:01:05
												*33:03:01-33:03:06
												*33:04
												*33:05
												*33:06
												*33:07
												*33:08, 26:22, 66:09[5]
												*33:09
												*33:10
												*33:11
13	14	15	16	17	18	19	20	21	22	23	24	Well No.

Length of spec.	**205**	**205**	**155**	**210**	**90**	**105**	**105**	**125**	**150**	**140**	**165**	**235**
PCR product(s)						**175**		**235**	**185**	**215**		
										285		
Well No.	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**
***33:12**	**1**			**4**								
***33:13**	**1**			**4**						**10**		
***33:14**	**1**			**4**					**9**			
***33:15**	**1**			**4**								
***33:16**	**1**	**2**	**3**									
***33:17**	**1**			**4**								
***33:18**	**1**											
***33:19**	**1**											
***33:20**	**1**			**4**		**6**						
***33:21**				**4**								
***33:22**	**1**			**4**					**9**	**10**		
***33:23**	**1**			**4**								
***33:24**	**1**			**4**				**8**				
***33:25**	**1**			**4**							**11**	
***33:26**	**1**			**4**								
***33:27**	**1**	**2**	**3**									
***33:28**	**1**			**4**								
***33:29**	**1**			**4**								
***33:30**	**1**			**4**								
***33:31**	**1**			**4**								
***33:32**	**1**	**2**	**3**									
***33:33**	**1**			**4**	**5**							
***33:34**	**1**	**2**	**3**									
***01:20, 01:66, 02:24, 02:137, 03:95**									**9**	**10**		
***02:10, 02:17:01-02:17:02, 02:39, 02:108, 02:110, 02:140, 02:148, 02:242, 02:244, 02:268, 03:15, 03:19, 24:04, 24:19, 24:28, 24:44, 24:89, 24:109, 24:129**												
Well No.	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**

95	115	140	210	75	100	120	90	115	115	170	95	Length of spec.
165	335		245	140								PCR product(s)
13	14	15	16	17	18	19	20	21	22	23	24	Well No.
13												*33:12
												*33:13
												*33:14
	14											*33:15
		15										*33:16
			16									*33:17
				17								*33:18
	14											*33:19
												*33:20
			16									*33:21
												*33:22
		15										*33:23
												*33:24
13												*33:25
				17								*33:26
					18							*33:27
						19						*33:28
							20					*33:29
								21				*33:30
									22			*33:31
										23		*33:32
												*33:33
											24	*33:34
												*01:20, 01:66, 02:24, 02:137, 03:95
	14											*02:10, 02:17:01-02:17:02, 02:39, 02:108, 02:110, 02:140, 02:148, 02:242, 02:244, 02:268, 03:15, 03:19, 24:04, 24:19, 24:28, 24:44, 24:89, 24:109, 24:129
13	14	15	16	17	18	19	20	21	22	23	24	Well No.

Length of spec.	205	205	155	210	90	105	105	125	150	140	165	235
PCR product(s)						175		235	185	215		
										285		
Well No.	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**
*02:41, 02:65, 02:80, 02:117, 02:135, 02:152, 03:103, 24:62, 25:01:01-25:13, 26:01:01-26:21, 26:23, 26:25N-26:39, 26:41-26:43:02, 26:45-26:56, 31:01:02-31:02, 31:07-31:23, 31:25-31:28, 31:30-31:46, 32:01:01-32:03, 32:05-32:09, 32:11Q-32:12, 32:14-32:29, 34:01:01-34:01:02, 34:05-34:06, 43:01, 66:01-66:03, 66:05-66:08, 66:10-66:15, 74:01-74:14N				4								
*02:241												
*02:243								8	9	10		
*03:01:18												
*03:104, 66:04		2	3									
*11:43										10		12
*23:03:01											11	
*24:82										10		
*26:24				4								
*29:01:01:01-29:01:01:02N, 29:01:03-29:02:07, 29:04-29:06, 29:08N, 29:10-29:18, 29:20-29:27, 31:06, 32:30												
*29:03											11	
*29:07												
*29:09												
*29:19								8				
*31:05, 32:13				4							11	
*31:24				4								
*31:29				4								
*32:10				4								
*68:29	1											12
*C*02:02:15*												
HLA-A allele[4]												
Well No.	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**

95	115	140	210	75	100	120	90	115	115	170	95	Length of spec.
165	335		245	140								PCR product(s)
13	14	15	16	17	18	19	20	21	22	23	24	Well No.
												*02:41, 02:65, 02:80, 02:117, 02:135, 02:152, 03:103, 24:62, 25:01:01-25:13, 26:01:01-26:21, 26:23, 26:25N-26:39, 26:41-26:43:02, 26:45-26:56, 31:01:02-31:02, 31:07-31:23, 31:25-31:28, 31:30-31:46, 32:01:01-32:03, 32:05-32:09, 32:11Q-32:12, 32:14-32:29, 34:01:01-34:01:02, 34:05-34:06, 43:01, 66:01-66:03, 66:05-66:08, 66:10-66:15, 74:01-74:14N
									22			*02:241
												*02:243
				17		19					24	*03:01:18
												*03:104, 66:04
												*11:43
												*23:03:01
												*24:82
									22			*26:24
				17								*29:01:01:01-29:01:01:02N, 29:01:03-29:02:07, 29:04-29:06, 29:08N, 29:10-29:18, 29:20-29:27, 31:06, 32:30
				17								*29:03
	14			17								*29:07
				17							24	*29:09
				17								*29:19
												*31:05, 32:13
											24	*31:24
	14											*31:29
						19						*32:10
												*68:29
						19						*C*02:02:15*
												HLA-A allele[4]
13	14	15	16	17	18	19	20	21	22	23	24	Well No.

[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*33 subtyping. .
In addition, wells number 2, 5, 9 and 10 contain the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to allow kit identification.
[2]The nucleotide position, in the 2nd, 3rd or 4th exon, 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 exon, 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.
[4]The sequence of the A*3302 allele has been shown to be identical to A*33:03:01.
[5]Primer mix 6: Specific PCR fragment of 105 bp in the A*33:20 allele. Specific PCR fragment of 175 bp in the A*33:05 allele.
Primer mix 8: Specific PCR fragment of 125 bp in the A*33:07 allele. Specific PCR fragment of 235 bp in the A*33:24 and the A*02:243 and 29:19 alleles.
Primer mix 9: Specific PCR fragment of 150 bp in the A*33:14, 33:22, 01:20, 01:66, 02:24, 02:137, 03:95, 26:22 and 66:09 alleles. Specific PCR fragment of 185 bp in the A*33:08 and 33:09 and the A*02:243 alleles.
Primer mix 10: Specific PCR fragment of 140 bp in the A*33:22 and the A*01:20, 01:66, 02:24, 02:137, 03:95, 26:22 and 66:09 alleles. Specific PCR fragment of 215 bp in the A*33:08 and the A*02:243 and 24:82 alleles. Specific PCR fragment of 285 bp in the A*33:13 and the A*11:43 alleles.
Primer mix 13: Specific PCR fragment of 95 bp in the A*33:12 allele. Specific PCR fragment of 165 bp in the A*33:25 allele.
Primer mix 14: Specific PCR fragment of 115 bp in the A*33:15 and A*02:140 alleles. Specific PCR fragment of 335 bp in the A*33:19 and A*02:10, 02:17:01-02:17:02, 02:39, 02:108, 02:110, 02:148, 02:242, 02:244, 02:268, 03:15, 03:19, 24:04, 24:19, 24:28, 24:44, 24:89, 24:109, 24:129, 29:07, 31:29 alleles.
Primer mix 16: Specific PCR fragment of 210 bp in the A*33:21 allele. Specific PCR fragment of 245 bp in the A*33:17 allele.
Primer mix 17: Specific PCR fragment of 75 bp in the A*33:18 and the A*03:01:18, 29:01:01:01-29:01:01:02N, 29:01:03-29:27, 31:06 and 32:30 alleles. Specific PCR fragment of 140 bp in the A*33:26 allele.
[6]The A*33:08, A*26:22 and A*66:09 give rise to identical amplification patterns with the HLA-A*33 subtyping kit. These three alleles can be distinguished by e.g. the HLA-A low resolution kit and/or the HLA-A*26 and HLA-A*66 subtyping kits.

CELL LINE VALIDATION SHEET

HLA-A*33 SSP subtyping kit

					Well														
					1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
				Lot No.:	200964001	200964002	200964003	200964004	200964005	200964006	201080407	200964008	200964009	200964010	200964011	200964012	200964013	200964014	200964015	200964016
	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*33 SSP subtyping kit

					Well							
					17	18	19	20	21	22	23	24
				Lot No.:	201080417	201080418	201080419	201080420	201080421	201080422	201080423	201080424
	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	-	-	-	-	-	-	-	-

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-A*33 SSP

Product number: **101.432-12 – including *Taq* polymerase**
Lot number: **81K**
Expiry date: **2013-May-01**
Number of tests: **12**
Number of wells per test: **24**

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2009-640-01	9	2009-640-09	17	2010-804-17
2	2009-640-02	10	2009-640-10	18	2010-804-18
3	2009-640-03	11	2009-640-11	19	2010-804-19
4	2009-640-04	12	2009-640-12	20	2010-804-20
5	2009-640-05	13	2009-640-13	21	2010-804-21
6	2009-640-06	14	2009-640-14	22	2010-804-22
7	2010-804-07	15	2009-640-15	23	2010-804-23
8	2009-640-08	16	2009-640-16	24	2010-804-24

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 5, 7 to 13, 15, 16 and 18 to 24 were available. The specificities of the primers in primer solutions 5, 8 to 13, 19, 23 and 24 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer solutions 16 and 22 it was only possible to test the 5'-primers, the 3'-primers were not possible to test. In primer solution 7, 15, 18, 20 and 21 it was only possible to test the 3'-primers, the 5'-primers were not possible to test. Additional primers in primer solutions 6,14 and 17 were tested by separately adding one additional 5'-primer and/or one additional 3'-primer. In primer solutions 13 and 17, one 5'-primer was not possible to test, and in primer solutions 6, 8, 9, 11, 13 and 14 one 3'-primer was not possible to test.

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

Date of approval: 2010-December-10

Approved by:

Quality Control, Supervisor

Declaration of Conformity

Product name: *Olerup* SSP® HLA-A*33
Product number: 101.432-12
Lot number: 81K

Intended use: HLA-A*33 high resolution histocompatibility testing

Manufacturer: *Olerup* SSP AB
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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-December-10

Olle Olerup

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