

## **Olerup SSP™ HLA-A\*11**

**Product number:** 101.416-12/04 – licensed for PCR  
 101.416-12u/04u – not licensed for PCR

**Lot number:** Y15

**Expiry date:** 2009-August-01

**Number of tests:** 12 tests – Product No. 101.416-12/12u  
 4 tests – Product No. 101.416-04/04u

**Number of tubes per test:** 32

**Storage - pre-aliquoted primers:** dark at -20°C  
 - PCR Master Mix: -20°C

**This Product Description is only valid for Lot No. Y15.**

### **CHANGES COMPARED TO THE PREVIOUS OLERUP SSP™ HLA-A\*11 LOT**

The HLA-A\*11 specificity and interpretation tables have been updated for the HLA-A alleles described since the previous *Olerup SSP™* HLA-A\*11 lot was made (**Lot No. V73**).

Three tubes has been added to the HLA-A\*11 kit,  
 wells **29 to 32**.

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

Tube	5'-primer	3'-primer	rationale
4	Modified	-	Increased specificity of specific primer pair
6	Added	Removed	Primers for the A*1122 allele moved from vials 9 and 16 to vial 6 to decrease primer dimer formation tendency.
7	Modified	-	Increased specificity of specific primer pair
9	Removed	Removed	Primers for the A*1122 allele moved to vial 6.
14	Modified	-	Increased specificity of specific primer pair
15	Modified	-	Increased specificity of specific primer pair
16	Removed	Removed	Primers for the A*1122 allele moved to vial 6.
14	-	Modified	Increased specificity of specific primer pair
28	-	Modified	Increased specificity of specific primer pair
30	New	New	Primer pair for the A*1129 allele.
31	New	New	Primer pair for the A*1130 allele.
32	New	New	Primer pair for the A*1131 and 1132 alleles.

Change in revision R01 compared to R00:

1. The A\*3004, A\*3006 and A\*3017 alleles may be weakly amplified by primer mix 32.

## PRODUCT DESCRIPTION

### HLA-A\*11 SSP subtyping

#### CONTENT

The primer set contains 5'- and 3'-primers for identifying the HLA-A\*1101 to A\*1132 alleles.

The primer solutions are pre-aliquoted into 0.2 ml PCR tubes. Each tube in the set contains a dried primer solution consisting of a specific primer mix, i.e. allele- and group-specific primers as well as a **control primer pair** matching non-allelic sequences.

**PCR Master Mix complete with Taq**, Taq polymerase, nucleotides, buffer, glycerol and cresol red, as well as PCR lids are included in the licensed kit.

**PCR Master Mix without Taq**, nucleotides, buffer, glycerol and cresol red, as well as PCR lids are included in the unlicensed kit.

29 PCR reactions with a reaction volume of 10 µl are performed per sample.

**Note:** The pellets in the tubes may vary in form and colour. This does not affect the performance of the product.

#### PLATE LAYOUT

Each test consists of 32 PCR reactions in a 32 well 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 'A\*11 Y15'.

Well No. 1 is marked with '1'.

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\*11 SSP subtypings will be influenced by most A\*01 alleles, several A\*02 alleles, all A\*03, two A\*23, several A\*24, all A\*25, most A\*26, all A\*29, all A\*30, most A\*31, most A\*32, the A\*33, the A\*34, the A\*36, the A\*4301, all A\*66, all A\*68, the A\*6901, all A\*74 and the A\*8001 alleles when present on the other haplotype. In addition, the B\*0818 and B\*7301 alleles will be amplified by primer mix 10.

### UNIQUELY IDENTIFIED ALLELES

All the HLA-A\*11 alleles, i.e. A\*1101 to A\*1132, recognized by the HLA Nomenclature Committee in October 2007<sup>1</sup> will give rise to unique amplification patterns by the primers in the HLA-A\*11 subtyping kit. alleles.

The HLA-A\*11 subtyping kit cannot distinguish the A\*110101 to A\*110103, A\*110105 to A\*110108 alleles and the A\*110201 and A\*110202 alleles.

<sup>1</sup>*Nomenclature for factors of the HLA system, 1998. Tissue Antigens 1999; 53: 407-446.*  
HLA-A alleles listed on the IMGT/HLA web page 2007-October-05, release 2.19.0, www.ebi.ac.uk/imgt/hla.

### RESOLUTION IN HOMO- AND HETEROZYGOTES

The 31 HLA-A\*11 alleles will give rise to 32 different amplification patterns that can be combined in 528 homozygous and heterozygous combinations. 186 of these genotypes do not give rise to unique amplification patterns. (The different sizes of the specific PCR products generated by the primers in tubes 6, 19 and 32 have not been considered in these calculations.)

++-----	--+++-	+-----+	-----	1114,1120 = 1114,1125
++-----	--+++-	+-----	-----+	1114,1131 = 1114,1132
++-----	--+++-	--+-----	-----	1116,1120 = 1116,1125
++-----	--+++-	--+-----	-----+	1116,1131 = 1116,1132
++-----	--+++-	--+-----	-----	1101,1116 = 1102,1123 = 1116,1123
++-----	--+++-	-----+	-----	1102,1120 = 1102,1125
++-----	--+++-	-----	-----+	1102,1131 = 1102,1132
+--+-----	--+++-	-----+	-----	1103,1106 = 1103,1118
+--+-----	--+++-	-----+	-----+	1103,1131 = 1103,1132
+--+-----	--+++-	-----+	-----	1101,1103 = 1103,1103 = 1103,1120 = 1103,1125
+--+-----	--+++-	-----+	--+-----	1106,1127 = 1118,1127
+--+-----	--+++-	-----+	-----	1104,1106 = 1104,1118
+--+-----	--+++-	-----+	--+-----	1120,1127 = 1125,1127
+--+-----	--+++-	-----+	-----	1104,1120 = 1104,1125
+--+-----	--+++-	-----	--+-----+	1127,1131 = 1127,1132
+--+-----	--+++-	-----	-----+	1104,1131 = 1104,1132
+--+-----	--+++-	-----	--+-----	1104,1127 = 1127,1127
+--+-----	--+++-	-----+	-----	1105,1106 = 1105,1118
+--+-----	--+++-	-----+	-----	1105,1120 = 1105,1125
+--+-----	--+++-	-----	-----+	1105,1131 = 1105,1132
+--+-----	--+++-	-----	-----	1101,1105 = 1105,1105
+-----+	--+++-	-----+	-----	1106,1108 = 1108,1118
+-----+	--+++-	-----+	-----	1106,1109 = 1109,1118
+-----+	+-----+	-----+	-----	1106,1107 = 1107,1118
+-----+	+-----+	-----+	-----+	1106,1110 = 1110,1118
+-----+	+-----+	-----+	-----	1106,1111 = 1111,1118
+-----+	+-----+	-----+	-----	1106,1113 = 1113,1118
+-----+	+-----+	+-----+	-----	1106,111501 = 111501,1118
+-----+	+-----+	+-----+	-----	1106,1123 = 1118,1123
+-----+	+-----+	-----+	-----	1106,1120 = 1106,1125 = 1118,1120 = 1118,1125
+-----+	+-----+	-----+	-----	1106,1121N = 1118,1121N

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+-----+-- --++-+-- -----+-- +-----	1106,1124 = 1118,1124
+-----+-- --++-+-- -----+-- -+-----	1106,1126 = 1118,1126
+-----+-- --++-+-- -----+-- ---+-----	1106,111502 = 111502,1118
+-----+-- --++-+-- -----+-- -----+--	1106,1129 = 1118,1129
+-----+-- --++-+-- -----+-- -----+--	1106,1130 = 1118,1130
+-----+-- --++-+-- -----+-- -----+--	1106,1131 = 1106,1132 =
	1118,1131 = 1118,1132
+-----+-- --++-+-- -----+-- -----	1101,1106 = 1101,1118 =
	1106,1106 = 1106,1118 =
	1106,1122 = 1118,1122
+-----+-- --++-+-- -----+-- -----	1120,1122 = 1122,1125
+-----+-- --++-+-- -----+-- -----+--	1122,1131 = 1122,1132
+-----+-- --++-+-- -----+-- -----	1101,1122 = 1122,1122
+-----+-- --++-+-- -----+-- -----	1101,1108 = 1108,1120
+-----+-- --++-+-- -----+-- -----	1108,1108 = 1108,1125
+-----+-- --++-+-- -----+-- -----	1109,1120 = 1109,1125
+-----+-- --++-+-- -----+-- -----+--	1109,1131 = 1109,1132
+-----+-- --++-+-- -----+-- -----	1101,1109 = 1109,1109
+-----+-- --++-+-- -----+-- -----	1107,1120 = 1107,1125
+-----+-- --++-+-- -----+-- -----+--	1107,1131 = 1107,1132
+-----+-- --++-+-- -----+-- -----	1101,1107 = 1107,1107
+-----+-- --++-+-- -----+-- -----+--	1110,1120 = 1110,1125
+-----+-- --++-+-- -----+-- -----+--	1110,1131 = 1110,1132
+-----+-- --++-+-- -----+-- -----+--	1101,1110 = 1110,1110
+-----+-- --++-+-- -----+-- -----	1111,1120 = 1111,1125
+-----+-- --++-+-- -----+-- -----+--	1111,1131 = 1111,1132
+-----+-- --++-+-- -----+-- -----	1101,1111 = 1111,1111
+-----+-- --++-+-- -----+-- -----	1112,1120 = 1112,1125
+-----+-- --++-+-- -----+-- -----+--	1112,1131 = 1112,1132
+-----+-- --++-+-- -----+-- -----	1113,1120 = 1113,1125
+-----+-- --++-+-- -----+-- -----+--	1113,1131 = 1113,1132
+-----+-- --++-+-- -----+-- -----	1101,1113 = 1113,1113
+-----+-- --++-+-- -+-----+-- -----	111501,1120 = 111501,1125
+-----+-- --++-+-- -+-----+-- -----+--	111501,1131 = 111501,1132
+-----+-- --++-+-- -+-----+-- -----	1101,111501 = 111501,111501
+-----+-- --++-+-- ---++-+-- -----	1117,1120 = 1117,1125
+-----+-- --++-+-- ---++-+-- -----+--	1117,1131 = 1117,1132
+-----+-- --++-+-- ---++-+-- -----	1119,1120 = 1119,1125
+-----+-- --++-+-- ---++-+-- -----+--	1119,1131 = 1119,1132
+-----+-- --++-+-- -----+-- -----	1120,1121N = 1121N,1125
+-----+-- --++-+-- -----+-- -----+--	111502,1120 = 111502,1125
+-----+-- --++-+-- -----+-- -----+--	1120,1129 = 1125,1129
+-----+-- --++-+-- -----+-- -----+--	1120,1130 = 1125,1130
+-----+-- --++-+-- -----+-- -----+--	1120,1131 = 1120,1132 =
	1125,1132
+-----+-- --++-+-- -----+-- -----	1101,1120 = 1101,1125 =
	1120,1120 = 1120,1125
+-----+-- --++-+-- -----+-- -----+--	1121N,1131 = 1121N,1132
+-----+-- --++-+-- -----+-- -----	1101,1121N = 1121N,1121N
+-----+-- --++-+-- -----+-- -----+--	111502,1131 = 111502,1132
+-----+-- --++-+-- -----+-- -----	1101,111502 = 111502,111502
+-----+-- --++-+-- -----+-- -----+--	1129,1131 = 1129,1132
+-----+-- --++-+-- -----+-- -----+--	1101,1129 = 1129,1129

HLA-A\*11  
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+-----	--++--	-----	-----++	1130,1131 = 1130,1132
+-----	--++--	-----	-----+-	1101,1130 = 1130,1130
+-----	--++--	-----	-----+	1101,1131 = 1101,1132 =
				1131,1132 = 1132,1132
-+-----	--++--	+-----	-----	1102,1114 = 1114,1114
-+-----	--++--	--+-----	-----	1102,1116 = 1116,1116
-----	--++--	----+-----	-----	1117,1117 = 1117,1119

## LICENSES

### 101.416-12/04 – licensed for PCR.

#### Notice to purchaser: Limited License.

The purchase price of this product includes limited, non-transferable rights under U.S. Patents 4,683,202, 4,683,195 and 4,965,188 and their foreign counterparts, owned by Roche Molecular Systems, Inc. and F. Hoffman-La Roche Ltd (“Roche”), to use only this amount of the product to practice the Polymerase Chain Reaction (“PCR”) Process described in said patents solely for the HLA Typing applications of the purchaser solely for organ or tissue or bone marrow transplantation, and explicitly excludes analysis of forensic evidence or parentage determination. The rights to use this product to perform and to offer commercial service for HLA Typing for organ or tissue transplantation using PCR, including reporting the results of the purchaser’s activities for a fee or other commercial consideration, is also hereby granted. Further information on purchasing licenses to practice PCR may be obtained by contacting in the United States, the Director of Licensing at Roche Molecular Systems, inc., 1145 Atlantic Avenue, Alameda, California 94501, and outside the United States, the PCR Licensing Manager, F. Hoffmann-La Roche Ltd, Grenzacherstr. 124, CH-4070 Basel, Switzerland.

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### 101.416-12/04 and 101.416-12u/04u

These products use ARMS™ technology and is sold under license from Zeneca Limited. ARMS is the subject of European Patent No. 0332435, US Patent No. 5595890 and corresponding world-wide patents. ARMS is a trademark of Zeneca Limited.

## GUARANTEE

Olerup SSP AB guarantees that the primers in the HLA-A\*11 subtyping kit have the specificities given in the Specificity and Interpretation Tables of the product insert and in the GenoVision version of the HELMBERG-SCORE™ software. When stored at –20°C, the dried primers are stable for 22 months from the date of manufacture.

When stored at –20°C, the PCR Master Mix complete with *Taq* and the PCR Master Mix without *Taq* are stable for 24 months from the date of manufacture. The kit is shipped at ambient temperature.

## PROTOCOL

### DNA EXTRACTION

Extracted, highly pure DNA is needed for SSP typings. We recommend isolation of DNA using GenoPrep B200 or GenoPrep B350 cartridges on the GenoM™-6 robotic workstation (GenoVision Europe Tel: +43 1 710 15 00 or GenoVision Inc. USA Tel: +1 610 430 88 41; <http://www.genovision.com>). Using GenoM™-6-extracted DNA ACD, EDTA and heparinised blood can be used as starting material. Because of its high purity, GenoM™-6-extracted DNA can be diluted when used in combination with Olerup SSP™ products. The recommended DNA concentration is 15 ng/μl.

Alternatively – BUT DO NOT USE HEPARINISED BLOOD WITH THESE METHODS - the DNA can be extracted using trimethylammoniumbromide salts (DTAB/CTAB) or by salting out. Dissolve the extracted DNA in dH<sub>2</sub>O.

### IMPORTANT:

Optimal DNA concentration using: GenoM™-6-extracted DNA, 15 ng/μl.

DNA extracted by other methods, 30 ng/μl.

Concentration exceeding 50 ng/μl will increase the risk for nonspecific amplifications and weak extra bands, especially for HLA Class I high resolution SSP typings.

### PCR AMPLIFICATION

#### 101.416-12/04 – licensed for PCR

For one HLA-A\*11 subtyping, add at room temperature in a 0.5 ml tube:

38 x 2 μl = 76 μl DNA (30 ng/μl)

38 x 3 μl = 114 μl PCR Master Mix complete with *Taq* – mix well before taking your aliquot

38 x 5 μl = 190 μl dH<sub>2</sub>O

Mix well, dispense 10 μl of the DNA-PCR Master Mix-H<sub>2</sub>O mixture into each of the 32 wells of an HLA-A\*11 subtyping. **Well No. 1 of the 32 well PCR strip is marked with '1'**. Close the 32 well PCR strip with the provided lids.

#### 101.416-12u/04u – not licensed for PCR

For one HLA-A\*11 subtyping, add at room temperature in a 0.5 ml tube:

38 x 2 μl = 76 μl DNA (30 ng/μl)

38 x 3 μl = 114 μl PCR Master Mix without *Taq* – mix well before taking your aliquot

3.0 μl *Taq* polymerase (5 units/μl)

38 x 5 μl – 3.0 μl = 187 μl dH<sub>2</sub>O

Mix well, dispense 10 μl of the DNA-PCR Master Mix-*Taq*-H<sub>2</sub>O mixture into each of the 32 wells of an HLA-A\*11 subtyping. **Well No. 1 of the 32 well PCR plate is marked with '1'**. Close the 32 well PCR plate with the provided lids.

Use a 96 well thermal cycler with a heated lid. The temperature gradient across the heating block should be < 1°C.

**PCR cycling parameters:**

1. 1 cycle	94°C	2 min	denaturation
2. 10 cycles	94°C	10 sec.	denaturation
	65°C	60 sec.	annealing and extension
3. 20 cycles	94°C	10 sec.	denaturation
	61°C	50 sec.	annealing
	72°C	30 sec.	extension

**The same PCR cycling parameters are used for all the *Olerup* SSP kits.**

**AGAROSE GEL ELECTROPHORESIS**

Prepare a 2% (w/v) agarose gel in 0.5 x TBE buffer. Dissolve the agarose by boiling in a microwave oven. Let the gel solution cool to 60°C. Stain the gel prior to casting with ethidium bromide (10 mg/ml), 5 µl per 100 ml gel solution. For maximal ease of handling use our ethidium bromide dropper bottles (Product No. 103.301-10), 1 drop of ethidium bromide solution per 50-75 ml of gel. **Note:** **Ethidium bromide is a powerful carcinogen.**

Load the PCR products, preferably using an 8-channel pipette. Load a DNA size marker (100 base pair ladder, Product No. 103.201-100) in one well per row.

Run the gel in 0.5 x TBE buffer, without re-circulation of the buffer, for 15-20 minutes at 8-10 V/cm.

**DOCUMENTATION AND INTERPRETATION**

Put the gel on a UV transilluminator and document by photography.

Record the presence and absence of specific PCR products. The relative lengths of the specific PCR products are helpful in the interpretation of the results.

Record the presence and relative lengths of the internal positive control bands. The differently sized control bands will help in the correct orientation of the typing as well as in kit identification.

Lanes without either control band or specific PCR products should be repeated.

Interpret the typings with the ***lot-specific Interpretation and Specificity Tables***.

**INTERPRETATION SOFTWARE**

The interpretation software (Product No. 110.101), can be helpful in the interpretation of the typings.



## PCR MASTER MIXES

The PCR Master Mix complete with *Taq* contains:

<i>Taq</i> polymerase	0.4 unit per 10 $\mu$ l SSP reaction
nucleotides	final concentration of each dNTP is 200 $\mu$ M
PCR buffer	final concentrations: 50 mM KCl, 1.5 mM MgCl <sub>2</sub> , 10 mM Tris-HCl pH 8.3, 0.001% w/v gelatin
glycerol	final concentration of glycerol is 5%
cresol red	final concentration of cresol red is 100 $\mu$ g/ml

**The same PCR Master Mix complete with *Taq* is used for all the licensed *Olerup* SSP kits.**

The PCR Master Mix without *Taq* contains:

nucleotides	final concentration of each dNTP is 200 $\mu$ M
PCR buffer	final concentrations: 50 mM KCl, 1.5 mM MgCl <sub>2</sub> , 10 mM Tris-HCl pH 8.3, 0.001% w/v gelatin
glycerol	final concentration of glycerol is 5%
cresol red	final concentration of cresol red is 100 $\mu$ g/ml

**The same PCR Master Mix without *Taq* is used for all the unlicensed *Olerup* SSP kits.**

The PCR Master Mix complete with *Taq* and the PCR Master Mix without *Taq* can be shipped at ambient temperature.

When stored at  $-20^{\circ}\text{C}$ , the PCR Master Mix complete with *Taq* and the PCR Master Mix without *Taq* are stable for 24 months from the date of manufacture.

Vials with the PCR Master Mixes can be kept at  $+4^{\circ}\text{C}$  for 4 weeks, but the PCR Master Mixes are then no longer stable for 24 months.

## SPECIFICITY TABLE

### HLA-A\*11 SSP subtyping

Specificities and sizes of the PCR products of the 32 primer mixes used for HLA-A\*11 SSP subtyping

Primer Mix	Approx. Size of spec. PCR product <sup>1</sup>	Size of control band <sup>2</sup>	Amplified HLA-A*11 alleles <sup>3</sup>	Other amplified HLA-A alleles <sup>3</sup>
<b>1<sup>4</sup></b>	195 bp	<b>800 bp</b>	110101-110108, 1103-1113, 111501-111502, 1120-1127, 1129-1132	0113, 0117, 0234-023503, 0256, 0262, 0278, 9203, 03010101-0307, 0309-0331, 0333-0335, 0337, 0338, 2419, 2613, 2619, 2633, 29010101-2912, 2914-2917, 3018, 340101-3408, 6601, 6602, 6604, 6606, 680101-68020103, 6806-6814, 6816-6819, 6821-6830, 6832-6835, 6837-6841, 6901
<b>2</b>	270 bp	1070 bp	110201-110202, 1114, 1116	
<b>3</b>	200 bp	1070 bp	1103	
<b>4<sup>4</sup></b>	235 bp	1070 bp	1104, 1127	0112, 0114, 0119, 03010101-030105, 0302-0317, 0319-0338, 300101-3004, 3006-3013, 3015-3020, 3022-3024, 3103, 3104, 3204, 3402-3404, 3407, 3408, 3601, 3602
<b>5</b>	180 bp	<b>800 bp</b>	1105	
<b>6<sup>7,8</sup></b>	185, 550 bp	1070 bp	1106, 1118, 1122	0238, 9201, 2603, 2606, 2621, 2630
<b>7<sup>4,6</sup></b>	215 bp	1070 bp	1108	01010101-0102, 0104N, 0107-0111N, 0113-0118N, 0121-0124, 0126-0130,

				0318, 3004, 3006, 3017, 3601, 3602, 3604
<b>8<sup>5</sup></b>	105 bp	1070 bp	1109	
<b>9<sup>7</sup></b>	200 bp	<b>800 bp</b>	1107	
<b>10<sup>5</sup></b>	120 bp	1070 bp	1110	250101-2506, 260101-2606, 2608- 2618, 2620-2629, 2632-2635, 3313, 340101-3408, 6601, 6604-6606, <b>B*0818, B*7301</b>
<b>11</b>	215 bp	<b>800 bp</b>	110101-110103, 110104 <sup>weakly</sup> , 110105-1107, 1109-1122, 1127, 1129, 1130, 1132	0112, 0119, 0125, 0302, 0310, 0331, 0332
<b>12</b>	235 bp	1070 bp	110101-110103, 110104 <sup>weakly</sup> , 110105-1103, 1105-1125, 1129- 1132	01010101-0102, 0104N, 0106, 0107, 0109-0111N, 0113, 0116N-0118N, 0121- 0130, 0318, 3604
<b>13</b>	200 bp	1070 bp	1111	4301
<b>14<sup>5</sup></b>	100 bp	1070 bp	110101-1111, 1113-1116, 1120- 1127, 1129-1132	0113, 0117, 2502, 2613, 2619, 2633, 340101-340102 <sup>weakly</sup> , 3402-3404, 3405 <sup>weakly</sup> , 3406, 3408, 6601, 6604, 6606
<b>15<sup>5</sup></b>	100 bp	1070 bp	1112	0234-023503 <sup>weakly</sup> , 0256, 0262, 0278, 9203, 03010101- 0307, 0309-0322, 0323 <sup>weakly</sup> , 0324- 0328, 0331, 0333, 0335, 0337, 0338, 2424, 29010101- 2903, 2905-2917, 300101-300102, 3008, 301101- 301102, 3014L- 3020, 3023, 3024, 6602, 680101- 68020103, 6806- 6814, 6816-6819, 6821-6823, 6825-

				6830, 6832-6839, 6841, 6901
<b>16<sup>5,7</sup></b>	95 bp	1070 bp	1113	
<b>17</b>	200 bp	1070 bp	1114	0110, 300101-3003, 3007, 3008, 3010- 3016, 3018-3020, 3022, 3024, 8001
<b>18</b>	245 bp	1070 bp	111501	
<b>19<sup>9</sup></b>	175, 220 bp	1070 bp	1116, 1123	
<b>20</b>	235 bp	1070bp	1117	260101-2602, 2604, 260701-2615, 2617- 2619, 2622-2629, 2631-2634, 4301
<b>21<sup>5,6</sup></b>	100 bp	1070 bp	1117, 1119	01010101-0104N, 0106, 0108-0112, 0114-0116N, 0118N- 0130, 2444 <sup>weakly</sup> , 250101-250102, 2503-2506, 260101- 2612, 2614-2618, 2620-2629, 2631, 2632, 2634, 2635, 3103, 3313, 3601- 3604, 4301, 6605, 7410, 8001
<b>22</b>	230 bp	1070 bp	1106, 1118	0205-020604, 0208, 0210, 0214, 0221, 0228, 0241, 0244, 0251, 0254, 0257, 0261, 0272, 0279, 0284, 0291, 0299, 9206, 9208, 9222, 9226, 9227, 2603, 2606, 2621, 2630, 6815
<b>23<sup>5</sup></b>	80 bp	<b>800 bp</b>	1103, 1108, 1120, 1125	020301-020302 <sup>weakly</sup> , 0213, 0226, 0238, 9217 <sup>weakly</sup>
<b>24<sup>4</sup></b>	470 bp	1070 bp	1121N	0104N, 0321N, 2307N, 2411N
<b>25</b>	215 bp	1070 bp	1124	030102, 8001
<b>26</b>	305 bp	1070 bp	1126	0103, 2632, 3313, 3603, 7410
<b>27</b>	250 bp	1070 bp	1127	01010101-0102, 0104N, 0106-0119,

				0121-0130, 0318, 8001
<b>28</b>	245 bp	<b>800 bp</b>	111502	
<b>29<sup>5</sup></b>	80 bp	1070 bp	1110	0255, 0324, 2603, 2606, 2621, 2630, 3301, 330301-3307, 3310-3312, 340101, 3402-3408, 6601- 6606, 680101-6809, 6811N, 6812, 6815- 6829, 6831-6835, 6838-6841, 6901
<b>30</b>	265 bp	1070 bp	1129	
<b>31</b>	285 bp	1070 bp	1130	
<b>32<sup>10</sup></b>	205, 295	1070 bp	1131, 1132	0307, 3004 <sup>weakly</sup> , 3006 <sup>weakly</sup> , 3009, 3017 <sup>weakly</sup> , 3103, 3104

<sup>1</sup>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\*11 SSP subtypings. 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, e.g. the 5'-primer in primer solution 1.

PCR fragments longer than the control band may sometimes be observed. Such bands can be disregarded and do not influence the interpretation of the SSP typings.

<sup>2</sup>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 tubes, or a band of 800 base pairs, for some tubes.

Tube 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\*11 subtyping.

In addition, tubes number 5, 9, 11, 23 and 28 contain the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to allow kit identification.

**PLEASE NOTE:** All the SSP kits, except the B\*37, B\*41, B\*42, B\*46, B\*47, B\*48, B\*49, B\*50, B\*53, B\*67, B\*78, B\*81 and B\*82 kits and the Cw\*01, Cw\*02, Cw\*08, Cw\*12, Cw\*14, Cw\*15, Cw\*16, Cw\*17 and Cw\*18 kits, from *Olerup* SSP AB can be uniquely identified by the number of tubes and the kit-specific pattern of the two differently sized control bands.

In the presence of a specific amplification the intensity of the control band often decreases.

<sup>3</sup>Due to the sharing of sequence motifs between HLA-A alleles some non-HLA-A\*11 alleles will be amplified by primer mixes 1, 4, 6, 7 and 10 to 15, 17, 20 to 27, 29 and 32.

<sup>4</sup>Primer mixes 1, 4, 7 and 24 may give rise to nonspecific amplifications.

<sup>5</sup>Short specific PCR fragments are less intense and not as sharp as longer specific bands.

<sup>6</sup>The specific primer pair in primer mixes 7 and 21 may yield less specific PCR product than the other A\*11 primer mixes.

<sup>7</sup>Primer mixes 6, 9 and 16 have a tendency of giving rise to primer oligomer formation.

<sup>8</sup>Primer mix 6: Specific PCR product of 185 bp in the A\*1122 allele. Specific PCR product of 550 bp in the A\*1106, 1118 and A\*0238, 9201, 2603, 2606, 2621 and 2630 alleles.

<sup>9</sup>Primer mix 19: Specific PCR product of 175 bp in the A\*1116 allele. Specific PCR product of 220 bp in the A\*1123 allele.

<sup>10</sup>Primer mix 32: Specific PCR fragment of 205 bp in the A\*1131 and A\*0307, 3009, 3103 and 3104 alleles. Specific PCR fragment of 295 bp in the A\*1132 allele.

<b>INTERPRETATION TABLE</b>																
<b>HLA-A*11 SSP subtyping</b>																
<b>Amplification patterns of the A*1101 to A*1132 alleles</b>																
	<b>Tube<sup>5</sup></b>															
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
<b>Length of spec.</b>	195	270	200	235	180	185	215	105	200	120	215	235	200	100	100	95
<b>PCR product</b>						550										
<b>Length of int.</b>	800	1070	1070	1070	800	1070	1070	1070	800	1070	800	1070	1070	1070	1070	1070
<b>pos. control<sup>1</sup></b>																
<b>5'-primer(s)<sup>2</sup></b>	127	28	363	363	363	292	363	553	399	261	363	363	102	282	282	503
	5'-ggg <sup>3'</sup>	5'-TCC <sup>3'</sup>	5'-ATA <sup>3'</sup>	5'-ATA <sup>3'</sup>	5'-ATA <sup>3'</sup>	5'-CTC <sup>3'</sup>	5'-ATA <sup>3'</sup>	5'-TgC <sup>3'</sup>	5'-TTA <sup>3'</sup>	5'-AAC <sup>3'</sup>	5'-ATA <sup>3'</sup>	5'-ATA <sup>3'</sup>	5'-ACC <sup>3'</sup>	5'-Cag <sup>3'</sup>	5'-Cag <sup>3'</sup>	5'-Cag <sup>3'</sup>
						413										
						5'-CCC <sup>3'</sup>										
<b>3'-primer(s)<sup>3</sup></b>	282	127	524	559	502	559	539	616	559	341	539	559	257	341	341	559
	5'-gAC <sup>3'</sup>	5'-CTT <sup>3'</sup>	5'-CAC <sup>3'</sup>	5'-CgT <sup>3'</sup>	5'-CTC <sup>3'</sup>	5'-CCg <sup>3'</sup>	5'-TCC <sup>3'</sup>	5'-CgT <sup>3'</sup>	5'-CCg <sup>3'</sup>	5'-CgT <sup>3'</sup>	5'-TCT <sup>3'</sup>	5'-CCg <sup>3'</sup>	5'-gCA <sup>3'</sup>	5'-CgT <sup>3'</sup>	5'-Cgg <sup>3'</sup>	5'-CCg <sup>3'</sup>
<b>Tube No.</b>	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
<b>HLA-A allele<sup>4</sup></b>																
<b>*110101-110103, 110105-110108</b>	+										+	+		+		
<b>*110104</b>	+										W	W		+		
<b>*110201-110202</b>		+									+	+		+		
<b>*1103</b>	+		+								+	+		+		
<b>*1104</b>	+			+							+			+		
<b>*1105</b>	+				+						+	+		+		
<b>*1106</b>	+					+					+	+		+		
<b>*1107</b>	+								+		+	+		+		
<b>*1108</b>	+						+					+		+		
<b>*1109</b>	+							+			+	+		+		
<b>*1110</b>	+									+	+	+		+		
<b>*1111</b>	+										+	+	+	+		
<b>*1112</b>	+										+	+			+	
<b>*1113</b>	+										+	+		+		+
<b>*1114</b>		+									+	+		+		
<b>*111501</b>	+										+	+		+		
<b>*111502</b>	+										+	+		+		
<b>*1116</b>		+									+	+		+		
<b>*1117</b>											+	+				
<b>*1118</b>						+					+	+				
<b>*1119</b>											+	+				
<b>Tube No.</b>	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16

<b>INTERPRETATION TABLE</b>																
<b>HLA-A*11 SSP subtyping</b>																
<b>Amplification patterns of the A*1101 to A*1132 alleles</b>																
<b>Tube<sup>5</sup></b>																
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	
200	245	175	235	100	230	80	470	215	305	250	245	80	265	285	205	Length of spec.
		220													295	PCR product
1070	1070	1070	1070	1070	1070	800	1070	1070	1070	1070	800	1070	1070	1070	1070	Length of int. pos. control <sup>1</sup>
363	363	363	103	282	103	489	3rd I	363	341	363	363	261	363	363	363	5'-primer(s) <sup>2</sup>
5'-ATA <sup>3'</sup>	5'-ATA <sup>3'</sup>	5'-ATA <sup>3'</sup>	5'-CCT <sup>3'</sup>	5'-CAC <sup>3'</sup>	5'-CCT <sup>3'</sup>	5'-GCCA <sup>3'</sup>	5'-ATA <sup>3'</sup>	5'-ATA <sup>3'</sup>	5'-ggA <sup>3'</sup>	5'-ATA <sup>3'</sup>	5'-ATA <sup>3'</sup>	5'-AAC <sup>3'</sup>	5'-ATA <sup>3'</sup>	5'-ATA <sup>3'</sup>	5'-ATA <sup>3'</sup>	
526	565	497	299	341	292	527	621	538	362	570	565	299	587	605	527	3'-primer(s) <sup>3</sup>
5'-CCg <sup>3'</sup>	5'-CAg <sup>3'</sup>	5'-Tgg <sup>3'</sup>	5'-TCg <sup>3'</sup>	5'-CgT <sup>3'</sup>	5'-gTg <sup>3'</sup>	5'-CCT <sup>3'</sup>	5'-CCC <sup>3'</sup>	5'-CAg <sup>3'</sup>	5'-TCA <sup>3'</sup>	5'-CCg <sup>3'</sup>	5'-CAA <sup>3'</sup>	5'-CCA <sup>3'</sup>	5'-CCT <sup>3'</sup>	5'-gCA <sup>3'</sup>	5'-CAA <sup>3'</sup>	
526		542													616	
5'-CCA <sup>3'</sup>		5'-CTg <sup>3'</sup>													5'-CgC <sup>3'</sup>	
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Tube No.
																HLA-A allele <sup>4</sup>
																*110101-110103, 110105-110108
																*110104
																*110201-110202
																*1103
																*1104
																*1105
																*1106
																*1107
																*1108
																*1109
																*1110
																*1111
																*1112
																*1113
																*1114
																*111501
																*111502
																*1116
																*1117
																*1118
																*1119
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Tube No.

Length of spec.	195	270	200	235	180	185	215	105	200	120	215	235	200	100	100	95
PCR product						550										
Tube No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
*1120	+										+	+		+		
*1121N	+										+	+		+		
*1122	+					+					+	+		+		
*1123	+											+		+		
*1124	+											+		+		
*1125	+											+		+		
*1126	+													+		
*1127	+			+							+			+		
*1129	+										+	+		+		
*1130	+										+	+		+		
*1131	+											+		+		
*1132	+										+	+		+		
*01010101-0102, 0109, 0111N, 0116N, 0118N, 0121-0124, 0126-0130							+					+				
*0103, 3603, 7410																
*0104N							+					+				
*0106												+				
*0107							+					+				
*0108, 0115N							+									
*0110							+					+				
*0112, 0119				+							+					
*0113, 0117	+						+					+		+		
*0114				+			+									
*0120																
*0125											+	+				
*020301-020302, 9217																
*0205-020604, 0208, 0210, 0214, 0221, 0228, 0241, 0244, 0251, 0254, 0257, 0261, 0272, 0279, 0284, 0291, 0299, 9206, 9208, 9222, 9226, 9227																
*0213, 0226																
*0234-023503	+															W
Tube No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16



200	245	175	235	100	230	80	470	215	305	250	245	80	265	285	205	Length of spec. PCR product Tube No.
		220													295	
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	
						+										*1120
							+									*1121N
																*1122
		+														*1123
								+								*1124
						+										*1125
									+							*1126
										+						*1127
													+			*1129
														+		*1130
															+	*1131
															+	*1132
				+						+						*01010101-0102, 0109, 0111N, 0116N, 0118N, 0121-0124, 0126-0130
				+					+							*0103, 3603, 7410
				+			+			+						*0104N
				+						+						*0106
										+						*0107
				+						+						*0108, 0115N
+				+						+						*0110
				+						+						*0112, 0119
										+						*0113, 0117
				+						+						*0114
				+												*0120
				+						+						*0125
						W										*020301-020302, 9217
					+											*0205-020604, 0208, 0210, 0214, 0221, 0228, 0241, 0244, 0251, 0254, 0257, 0261, 0272, 0279, 0284, 0291, 0299, 9206, 9208, 9222, 9226, 9227
						+										*0213, 0226
																*0234-023503
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Tube No.

Length of spec.	195	270	200	235	180	185	215	105	200	120	215	235	200	100	100	95
PCR product						550										
Tube No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
*0238						+										
*0255, 3301, 330301-3307, 3310-3312, 6603, 680301-6805, 6820, 6831																
*0256, 0262, 0278, 9203, 030106, 29010101-2903, 2905-2912, 2914-2917, 6810, 6813, 6814, 6830, 6837	+														+	
*9201						+										
*03010101-03010103, 030103-030105, 0303N-0306, 0309, 0311N-0317, 0319, 0320, 0322, 0325-0328, 0333, 0335, 0337, 0338	+			+											+	
*030102	+			+											+	
*0302, 0310, 0331	+			+							+				+	
*0307	+			+											+	
*0308, 0336N, 3204				+												
*0318	+						+					+			+	
*0321N	+			+											+	
*0323	+			+											W	
*0324	+			+											+	
*0329, 0330, 0334	+			+												
*0332				+							+					
*2307N, 2411N																
*2419, 2904	+															
*2424, 2913, 6836															+	
*2444																
*250101-250102, 2503-2506, 2605, 2616, 2620, 2635										+						
*2502										+				+		
Tube No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16

HLA-A\*11  
 101.416-12/04 – licensed for PCR  
 101.416-12u/04u – not licensed for PCR  
 Lot No.: **Y15**

200	245	175	235	100	230	80	470	215	305	250	245	80	265	285	205	Length of spec.
		220													295	PCR product
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Tube No.
						+										*0238
												+				*0255, 3301, 330301-3307, 3310-3312, 6603, 680301-6805, 6820, 6831
																*0256, 0262, 0278, 9203, 030106, 29010101-2903, 2905-2912, 2914-2917, 6810, 6813, 6814, 6830, 6837
																*9201
																*03010101-03010103, 030103-030105, 0303N-0306, 0309, 0311N-0317, 0319, 0320, 0322, 0325-0328, 0333, 0335, 0337, 0338
								+								*030102
																*0302, 0310, 0331
															+	*0307
																*0308, 0336N, 3204
										+						*0318
							+									*0321N
																*0323
												+				*0324
																*0329, 0330, 0334
																*0332
							+									*2307N, 2411N
																*2419, 2904
																*2424, 2913, 6836
				W												*2444
				+												*250101-250102, 2503-2506, 2605, 2616, 2620, 2635
																*2502
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Tube No.

Length of spec.	195	270	200	235	180	185	215	105	200	120	215	235	200	100	100	95
PCR product						550										
Tube No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
*260101-2602, 2604, 2608-2612, 2614, 2615, 2617, 2618, 2622-2629, 2634										+						
*2603, 2606, 2621						+				+						
*260701-260702, 2631																
*2613, 2633	+									+				+		
*2619	+													+		
*2630						+										
*2632										+						
*300101-300102, 3008, 301101- 301102, 3015, 3016, 3019, 3020, 3024				+											+	
*300201-3003, 3007, 3010, 3012, 3013, 3022				+												
*3004, 3006				+			+									
*3009, 3104				+												
*3014L																+
*3017				+			+									+
*3018	+			+												+
*3023				+												+
*3103				+												
*3313										+						
*340101, 3405	+									+				W		
*340102	+									+				W		
*3402-3404, 3408	+			+						+				+		
*3406, 6601, 6604, 6606	+									+				+		
*3407	+			+						+						
*3601, 3602				+			+									
*3604							+					+				
*4301													+			
Tube No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16

200	245	175	235	100	230	80	470	215	305	250	245	80	265	285	205	Length of spec.
		220													295	PCR product
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Tube No.
			+	+												*260101-2602, 2604, 2608-2612, 2614, 2615, 2617, 2618, 2622-2629, 2634
				+	+							+				*2603, 2606, 2621
			+	+												*260701-260702, 2631
			+													*2613, 2633
			+													*2619
					+							+				*2630
			+	+					+							*2632
+																*300101-300102, 3008, 301101- 301102, 3015, 3016, 3019, 3020, 3024
+																*300201-3003, 3007, 3010, 3012, 3013, 3022
															W	*3004, 3006
															+	*3009, 3104
+																*3014L
															W	*3017
+																*3018
																*3023
				+											+	*3103
				+					+							*3313
												+				*340101, 3405
																*340102
												+				*3402-3404, 3408
												+				*3406, 6601, 6604, 6606
												+				*3407
				+												*3601, 3602
				+												*3604
			+	+												*4301
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Tube No.

Length of spec.	195	270	200	235	180	185	215	105	200	120	215	235	200	100	100	95
PCR product						550										
Tube No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
*6602, 680101- 68020103, 6806- 6809, 6811N, 6812, 6816-6819, 6821- 6823, 6825-6829, 6832-6835, 6838, 6839, 6841, 6901	+															+
*6605										+						
*6815																
*6824, 6840	+															
*8001																
HLA-A allele <sup>4</sup>																
Tube No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
B*0818, B*7301										+						
Tube No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16

<sup>1</sup>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 tubes, or a band of 800 base pairs, for some tubes. Tube 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\*11 subtyping. In addition, tubes number 5, 9, 11, 23 and 28 contain the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to allow kit identification.

**PLEASE NOTE:** All the SSP kits, except the B\*37, B\*41, B\*42, B\*46, B\*47, B\*48, B\*49, B\*50, B\*53, B\*67, B\*78, B\*81 and B\*82 kits and the Cw\*01, Cw\*02, Cw\*08, Cw\*12, Cw\*14, Cw\*15, Cw\*16, Cw\*17 and Cw\*18 kits, from *Olerup* SSP AB can be uniquely identified by the number of tubes and the kit-specific pattern of the two differently sized control bands.

<sup>2</sup>The nucleotide position, in the 1<sup>st</sup>, 2<sup>nd</sup> or 3<sup>rd</sup> exons, matching the specificity-determining 3'-end of the primer is given. Nucleotide numbering as in *Tissue Antigens* 1998, **51:II**, 417-466. The sequence of the 3 terminal nucleotides of the primer is given.

<sup>3</sup>The nucleotide position, in the 2<sup>nd</sup> or 3<sup>rd</sup> exons, matching the specificity-determining 3'-end of the primer is given in the anti-sense direction. Nucleotide numbering as in *Tissue Antigens* 1998, **51:II**, 417-466. The sequence of the 3 terminal nucleotides of the primer is given.

200	245	175	235	100	230	80	470	215	305	250	245	80	265	285	205	Length of spec.
		220													295	PCR product
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Tube No.
												+				*6602, 680101-68020103, 6806-6809, 6811N, 6812, 6816-6819, 6821-6823, 6825-6829, 6832-6835, 6838, 6839, 6841, 6901
				+								+				*6605
					+							+				*6815
												+				*6824, 6840
+				+				+		+						*8001
																HLA-A allele <sup>4</sup>
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Tube No.
																B*0818, B*7301
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Tube No.

<sup>4</sup>The A\*1128 allele has been renamed to A\*111502.

<sup>5</sup>Primer mix 6: Specific PCR product of 185 bp in the A\*1122 allele. Specific PCR product of 550 bp in the A\*1106, 1118 and A\*0238, 9201, 2603, 2606, 2621 and 2630 alleles.

<sup>5</sup>Primer mix 19: Specific PCR product of 175 bp in the A\*1116 allele. Specific PCR product of 220 bp in the A\*1123 allele.

<sup>5</sup>Primer mix 32: Specific PCR fragment of 205 bp in the A\*1131 and A\*0307, 3009, 3103 and 3104 alleles. Specific PCR fragment of 295 bp in the A\*1132 allele.

'w', may be weakly amplified.

CELL LINE VALIDATION SHEET				HLA-A*11 SSP subtyping kit																
				Tube																
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	
				Prod. No.:	200736801	200736802	200736803	200736804	200736805	200736806	200736807	200736808	200736809	200736810	200736811	200736812	200736813	200736814	200736815	200736816
cell line		A*																		
1	9001	SA	*2402	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2	9280	LK707	*0201	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3	9011	E4181324	*0101	-	-	-	-	-	-	-	+	-	-	-	+	-	-	-	-	-
4	9275	GU373	*3001	-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	+	-
5	9009	KAS011	*0101	-	-	-	-	-	-	-	+	-	-	-	+	-	-	-	-	-
6	9353	SM	*0201	*2603	-	-	-	-	-	+	-	-	-	+	-	-	-	-	-	-
7	9020	QBL	*2601	-	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-
8	9007	DEM	*0201	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
9	9026	YAR	*2601	-	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-
10	9107	LKT3	*2402	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
11	9051	PITOUT	*2902	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-
12	9052	DBB	*0201	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
13	9067	BTB	*0201	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
14	9071	OLGA	*3101	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
15	9075	DKB	*2402	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
16	9037	SWEIG007	*2902	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-
17	9008	WILJON	*2501	-	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-
18	9257	32367	*3303	*7401	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
19	9038	BM16	*0201	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
20	9059	SLE005	*0201	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
21	9064	AMALA	*0217	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
22	9056	KOSE	*0201	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
23	9124	IHL	*0201	*3401	+	-	-	-	-	-	-	-	-	+	-	-	-	+	-	-
24	9035	JBUSH	*3201	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
25	9049	IBW9	*3301	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
26	9285	WT49	*0205	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
27	9191	CH1007	*2410	*2901	+	-	-	-	-	-	-	-	-	-	-	+	-	+	-	-
28	9320	BEL5GB	*0201	*2902	+	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-
29	9050	MOU	*2902	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-
30	9021	RSH	*3001	*6802	+	-	-	+	-	-	-	-	-	-	-	-	-	-	+	-
31	9019	DUCAF	*3002	-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-
32	9297	HAG	*0201	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
33	9098	MT14B	*3101	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
34	9104	DHIF	*3101	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
35	9302	SSTO	*3201	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
36	9024	KT17	*0206	*1101	+	-	-	-	-	-	-	-	-	-	+	+	-	+	-	-
37	9065	HHKB	*0301	+	-	-	+	-	-	-	-	-	-	-	-	-	-	-	+	-
38	9099	LZL	*0217	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
39	9315	CML	*0101	*0301	+	-	-	+	-	-	+	-	-	-	+	-	-	+	-	-
40	9134	WHONP199	*0207	*3001	-	-	-	+	-	-	-	-	-	-	-	-	-	-	+	-
41	9055	H0301	*0301	+	-	-	+	-	-	-	-	-	-	-	-	-	-	-	+	-
42	9066	TAB089	*0207	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
43	9076	T7526	*0207	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
44	9057	TEM	*6601	+	-	-	-	-	-	-	-	-	-	+	-	-	-	+	-	-
45	9239	SHJO	*2301	*2402	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
46	9013	SCHU	*0301	+	-	-	+	-	-	-	-	-	-	-	-	-	-	-	+	-
47	9045	TUBO	*0216	*0301	+	-	-	+	-	-	-	-	-	-	-	-	-	-	+	-
48	9303	TER-ND	*0201	*1101	+	-	-	-	-	-	-	-	-	-	+	+	-	+	-	-



<b>CELL LINE VALIDATION SHEET</b>																				
<b>HLA-A*11 SSP subtyping kit</b>																				
			Prod. No.:	Tube																
				17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	
	cell line	A*		200736817	200736818	200736819	200736820	200736821	200736822	200736823	200736824	200736825	200736826	200736827	200736828	200736829	200736830	200736831	200736832	
1	9001 SA	*2402		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2	9280 LK707	*0201		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3	9011 E4181324	*0101		-	-	-	-	+	-	-	-	-	-	+	-	-	-	-	-	-
4	9275 GU373	*3001		+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
5	9009 KAS011	*0101		-	-	-	-	+	-	-	-	-	-	+	-	-	-	-	-	-
6	9353 SM	*0201	*2603	-	-	-	-	+	+	-	-	-	-	-	-	+	-	-	-	-
7	9020 QBL	*2601		-	-	-	+	+	-	-	-	-	-	-	-	-	-	-	-	-
8	9007 DEM	*0201		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
9	9026 YAR	*2601		-	-	-	+	+	-	-	-	-	-	-	-	-	-	-	-	-
10	9107 LKT3	*2402		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
11	9051 PITOUT	*2902		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
12	9052 DBB	*0201		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
13	9067 BTB	*0201		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
14	9071 OLGA	*3101		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
15	9075 DKB	*2402		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
16	9037 SWEIG007	*2902		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
17	9008 WILJON	*2501		-	-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-
18	9257 32367	*3303	*7401	-	-	-	-	-	-	-	-	-	-	-	-	+	-	-	-	-
19	9038 BM16	*0201		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
20	9059 SLE005	*0201		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
21	9064 AMALA	*0217		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
22	9056 KOSE	*0201		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
23	9124 IHL	*0201	*3401	-	-	-	-	-	-	-	-	-	-	-	-	+	-	-	-	-
24	9035 JBUSH	*3201		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
25	9049 IBW9	*3301		-	-	-	-	-	-	-	-	-	-	-	-	+	-	-	-	-
26	9285 WT49	*0205		-	-	-	-	-	+	-	-	-	-	-	-	-	-	-	-	-
27	9191 CH1007	*2410	*2901	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
28	9320 BEL5GB	*0201	*2902	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
29	9050 MOU	*2902		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
30	9021 RSH	*3001	*6802	+	-	-	-	-	-	-	-	-	-	-	-	+	-	-	-	-
31	9019 DUCAF	*3002		+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
32	9297 HAG	*0201		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
33	9098 MT14B	*3101		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
34	9104 DHIF	*3101		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
35	9302 SSTO	*3201		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
36	9024 KT17	*0206	*1101	-	-	-	-	-	+	-	-	-	-	-	-	-	-	-	-	-
37	9065 HHKB	*0301		-	-	-	-	-	-	+	-	-	-	-	-	-	-	-	-	-
38	9099 LZL	*0217		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
39	9315 CML	*0101	*0301	-	-	-	-	+	-	-	-	-	-	+	-	-	-	-	-	-
40	9134 WHONP199	*0207	*3001	+	-	-	-	-	+	-	-	-	-	-	-	-	-	-	-	-
41	9055 H0301	*0301		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
42	9066 TAB089	*0207		-	-	-	-	-	+	-	-	-	-	-	-	-	-	-	-	-
43	9076 T7526	*0206	*0207	-	-	-	-	-	+	+	-	-	-	-	-	-	-	-	-	-
44	9057 TEM	*6601		-	-	-	-	-	-	-	-	-	-	-	-	+	-	-	-	-
45	9239 SHJO	*2301	*2402	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
46	9013 SCHU	*0301		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
47	9045 TUBO	*0216	*0301	-	-	-	-	-	+	-	-	-	-	-	-	-	-	-	-	-
48	9303 TER-ND	*0201	*1101	-	-	-	-	-	+	-	-	-	-	-	-	-	-	-	-	-

## CERTIFICATE OF ANALYSIS

### Olerup SSP™ HLA-A\*11 SSP

Product number: 101.416-12/04 – licensed for PCR  
101.416-12u/04u – not licensed for PCR  
Lot number: Y15  
Expiry date: 2009-August-01  
Number of tests: 12 tests – Product No. 101.416-12/12u  
4 tests – Product No. 101.416-04/04U  
Number of tubes per test: 32

#### Tube specifications:

Tube No.	Production No.	Tube No.	Production No.	Tube No.	Production No.
1	2007-368-01	13	2007-368-13	25	2007-368-25
2	2007-368-02	14	2007-368-14	26	2007-368-26
3	2007-368-03	15	2007-368-15	27	2007-368-27
4	2007-368-04	16	2007-368-16	28	2007-368-28
5	2007-368-05	17	2007-368-17	29	2007-368-29
6	2007-368-06	18	2007-368-18	30	2007-368-30
7	2007-368-07	19	2007-368-19	31	2007-368-31
8	2007-368-08	20	2007-368-20	32	2007-368-32
9	2007-368-09	21	2007-368-21		
10	2007-368-10	22	2007-368-21		
11	2007-368-11	23	2007-368-23		
12	2007-368-12	24	2007-368-24		

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

No DNAs carrying the alleles to be amplified by primer solutions 2, 3, 8, 9, 13, 16, 18, 19, 26, 28, 30 to 32 were available. The specificities of the primers in primer solutions 3, 13, 26 and 32 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer solutions 2, 18, 19, 28, 30 and 31 it was only possible to test the 5'-primers, the 3'-primers were not possible to test. In primer solutions 8, 9 and 16 it was only possible to test the 3'-primers, the 5'-primers were not possible to test.

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

**Date of approval:** 2007-November-20

**Approved by:**

**Quality Control, Supervisor**

## Declaration of Conformity

**Product name:** Olerup SSP™ HLA-A\*11  
**Product number:** 101.416-12/04, 101.416-12u/04u  
**Lot number:** Y15

**Intended use:** HLA-A\*11 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 9001:2000 and ISO 13485:2003, following the provisions of the 98/79/EC Directive on *in vitro* diagnostic medical devices, Annex II List B, 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  
2007-November-20

Olle Olerup  
Managing Director

HLA-A\*11  
101.416-12/04 – licensed for PCR  
101.416-12u/04u – not licensed for PCR  
Lot No.: **Y15**

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Lot No.: **Y15**

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Lot No.: **Y15**

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## WARRANTY

*Olerup* SSP AB warrants its products to the original purchaser against defects in materials and workmanship under normal use and application. *Olerup* SSP AB's sole obligation under this warranty shall be to replace, at no charge, any product that does not meet the performance standards stated on the product specification sheet.

This warranty applies only to products that have been handled and stored in accordance with *Olerup* SSP AB's recommendations, and does not apply to products that have been the subject of alternation, misuse, or abuse.

All claims under this warranty must be directed to *Olerup* SSP AB in writing and must be accompanied by a copy of the purchaser's invoice. This warranty is in lieu of all other warranties, expressed or implied, including the warranties of merchantability and fitness for a particular purpose. In no case shall *Olerup* SSP AB be liable for incidental or consequential damages.

This product may not be reformulated, repacked or resold in any form without the written consent of *Olerup* SSP AB, Hasselstigen 1, SE-133 33 Saltsjöbaden, Sweden.

Handle all samples as if capable of transmitting disease. All work should be performed wearing gloves and appropriate protection.

*Olerup* SSP<sup>TM</sup> is a trademark of *Olerup* SSP AB.  
PCR<sup>TM</sup> is a trademark of F. Hoffmann-La Roche Ltd.  
ARMS<sup>TM</sup> is a trademark of Zeneca Ltd.

HLA-A\*11  
101.416-12/04 – licensed for PCR  
101.416-12u/04u – not licensed for PCR  
Lot No.: **Y15**

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[www.olerup.com](http://www.olerup.com)

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