

Olerup SSP™ DRB3

Product number: 101.121-24/04 – licensed for PCR
101.121-24u/04u – not licensed for PCR
Lot number: Y16
Expiry date: 2009-July-01
Number of tests: 24 tests – Product No. 101.121-24
4 tests – Product No. 101.121-04
Number of tubes per test: 24
Storage - pre-aliquoted primers: dark at -20°C
- PCR Master Mix: -20°C

This Product Description is only valid for Lot No. Y16.

CHANGES COMPARED TO THE PREVIOUS OLERUP SSP™ DRB3 LOT

The DRB3 primer set as well as the specificity and interpretation tables have been updated for the DRB alleles described since the previous *Olerup* SSP™ DRB3 lot (**Lot No. V61**) was made.

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

Tube	5'-primer	3'-primer	rationale
21	-	-	Changed to the 430 bp internal positive control primer pair to decrease primer dimer formation tendency.

Change in revision R01 compared to R00:

1. The length of the internal positive control band in primer mix 16 has been corrected to 515 bp in the Specificity and Interpretation Tables.

PRODUCT DESCRIPTION

DRB3 SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for identifying the DRB3*0101 to DRB3*0303 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.

24 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 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 'DRB3 Y16'.

Well No. 1 is marked with '1'.

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

Only alleles of the DRB3 locus will be amplified by the DRB3 subtyping kit, except that primer mixes 1, 2, 5, 8, 12 to 14, 16, 17, 19, 20 and 24 will amplify a few DRB1 alleles (1130, 1143, 1144, 1149, 1150, 1331, 1346, 1354, 1367, 1446, 1448, 1459, 0807, 0819, 0825, 1001). Thus, the interpretation of DRB3 subtypings is only marginally influenced by other DRB genes.

UNIQUELY IDENTIFIED ALLELES

All the DRB3 alleles, i.e. **DRB3*0101 to DRB3*0111, DRB3*0201 to DRB3*0222 and DRB3*0301 to DRB3*0303**, recognized by the HLA Nomenclature Committee in July 2007¹ will give rise to unique amplification patterns by the primers in the DRB3 subtyping kit.

The DRB3 subtyping kit cannot distinguish the DRB3*010101 to DRB3*010104 alleles or the DRB3*020201 to DRB3*020205 alleles or the DRB3*030101 and DRB3*030102 alleles.

¹**Nomenclature for factors of the HLA system, 1998.** *Tissue Antigens* 1999; **53**: 407-446.

DRB alleles listed on the IMGT/HLA web page 2007-July-09, release 2.18.0, www.ebi.ac.uk/imgt/hla.

RESOLUTION IN HOMO- AND HETEROZYGOTES

The 36 phenotypically different DRB3 alleles can be combined in 666 homozygous and heterozygous combinations. 231 of these genotypes do not give rise to unique amplification patterns. (The different sizes of the specific PCR products generated by primer mixes 1, 12, 15, 16, 19, 20, 21 and 22 were not considered in these calculations.)

++++----	+-----+	---+----	0102, 0107 = 0102, 0205
++++----	-----+	---+----	0101, 0102 = 0102, 0102
+++-+-	+-----+	---+----	0104, 0107 = 0104, 0205
+++-+-	-----+	---+----	0101, 0104 = 0104, 0104
+++-+-	+-----+	---+----	0105, 0107 = 0105, 0205
+++-+-	-----+	---+----	0101, 0105 = 0105, 0105
+++-----+	++-----	+-----+	0106, 0206 = 0108, 0202 = 0108, 0206
+++-----+	++-----	+-----+	0106, 0220 = 0108, 0220
+++-----+	+-----+	+-----+	0107, 0108 = 0108, 0205
+++-----+	+-----+	---+----	0106, 0107 = 0106, 0205
+++-----+	-----+	+-----+	0101, 0108 = 0106, 0108 = 0108, 0108
+++-----+	-----+	---+----	0101, 0106 = 0106, 0106
+++-----	++-----	---+----	0101, 0216 = 0110, 0216
+++-----	++-----	---+----	0101, 0211 = 0110, 0202 = 0110, 0211
+++-----	+-----+	---+----	0107, 0110 = 0110, 0205
+++-----	+-----+	---+----	0107, 0111 = 0111, 0205
+++-----	+-----+	---+----	0101, 0107 = 0101, 0205
+++-----	-+-----	---+----	0101, 0212 = 0111, 0210 = 0111, 0212
+++-----	-----+	---+----	0101, 0110 = 0110, 0110
+++-----	-----+	---+----	0101, 0111 = 0111, 0111
++-----	+++-----	---+----	0219, 0301 = 0222, 0301
++-----	+++-----	-+-----	0207, 0301 = 0221, 0301
++-----	+++-----	---+----	0208, 0301 = 0218, 0301
++-----	+++-----	---+----	0219, 0303 = 0222, 0303
++-----	+++-----	-+-----	0207, 0303 = 0221, 0303
++-----	+++-----	---+----	0208, 0303 = 0218, 0303
+-----	++-----	+-----	0107, 0206 = 0107, 0220
+-----	++-----	---+----	0107, 0208 = 0107, 0214
+-----	+-----+	-----	0107, 0107 = 0107, 0205
+-----	++++-----	-----	0204, 0205 = 0204, 0217
+-----	++++-----	-----	0201, 0205 = 0201, 0217
+-----	++-----	-----	0215, 0217 = 0217, 0222

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+----- ++-+++- +----- 0206,0217 = 0217,0220
+----- ++-+++- --+----- 0208,0217 = 0214,0217
+----- ++-+++- ----- 0202,0217 = 0205,0217 = 0217,0217
+----- ++-+++- +----- 0205,0206 = 0205,0220
+----- ++-+++- --+----- 0205,0208 = 0205,0214
----- ++++++++ --+----- 0201,0216 = 0204,0216
----- ++++++++ +-+----- 0109,0201 = 0109,0204
----- ++++++++ -----+ 0201,0219 = 0204,0219
----- ++++++++ ----- 0201,0215 = 0201,0222 = 0202,0204 =
                                0204,0215 = 0204,0222
----- +++++----- ----- 0201,0204 = 0204,0204
----- +++-+++++ --+-----+ 0215,0302 = 0219,0302 = 0222,0302
----- +++-+++++ +-+-----+ 0207,0302 = 0221,0302
----- +++-+++++ --+-----+ 0208,0302 = 0218,0302
----- ++-+++++ +-+----- 0206,0216 = 0216,0220
----- ++-+++++ +-+-----+ 0209,0216 = 0216,0221
----- ++-+++++ +-+----- 0109,0216 = 0207,0216
----- ++-+++++ --+++----- 0208,0216 = 0214,0216
----- ++-+++++ --+----- 0202,0216 = 0203,0216 = 0210,0216 =
                                0211,0216 = 0215,0216 = 0216,0216 =
                                0216,0222
----- ++-+++++ ----- 0203,0215 = 0203,0222
----- ++-+++++ +-+----- 0109,0206 = 0109,0220
----- ++-+++++ +-----+ 0206,0219 = 0219,0220
----- ++-+++++ +----- 0206,0215 = 0206,0222 = 0215,0220 =
                                0220,0222
----- ++-+++++ -+++----- 0109,0208 = 0109,0214
----- ++-+++++ +-+-----+ 0109,0219 = 0109,0221 = 0209,0215 =
                                0209,0219 = 0209,0222
----- ++-+++++ +-+----- 0109,0202 = 0109,0207 = 0109,0215 =
                                0109,0222
----- ++-+++++ +-+-----+ 0207,0219 = 0215,0221 = 0219,0221 =
                                0221,0222
----- ++-+++++ +-+----- 0207,0215 = 0207,0222
----- ++-+++++ --+-----+ 0208,0219 = 0214,0219 = 0215,0218 =
                                0218,0219 = 0218,0222
----- ++-+++++ --+----- 0208,0215 = 0208,0222 = 0214,0215 =
                                0214,0222
----- ++-+++++ ---+----- 0210,0215 = 0210,0222
----- ++-+++++ -----+ 0211,0215 = 0211,0222
----- ++-+++++ -----+ 0212,0215 = 0212,0222
----- ++-+++++ -----+ 0213,0215 = 0213,0222
----- ++-+++++ -----+ 0202,0219 = 0215,0219 = 0219,0219 =
                                0219,0222
----- ++-+++++ ----- 0202,0215 = 0202,0222 = 0215,0222 =
                                0222,0222
----- ++-+++++ +-+-----+ 0206,0209 = 0209,0220
----- ++-+++++ +-+-----+ 0206,0221 = 0220,0221
----- ++-+++++ +-+----- 0206,0207 = 0207,0220
----- ++-+++++ +-+-----+ 0206,0218 = 0218,0220
----- ++-+++++ +-+----- 0206,0208 = 0206,0214 = 0208,0220
----- ++-+++++ +-+----- 0206,0210 = 0210,0220
----- ++-+++++ +-+----- 0206,0211 = 0211,0220

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----- ++--++-- +----- 0206,0212 = 0212,0220
----- ++--++-- +----- 0206,0213 = 0213,0220
----- ++--++-- +----- 0202,0206 = 0202,0220 = 0206,0206 =
                          0206,0220
----- ++--++-- -++++--+ 0208,0209 = 0209,0214 = 0209,0218
----- ++--++-- -++++--+ 0207,0218 = 0208,0221 = 0214,0221 =
                          0218,0221
----- ++--++-- -++++--+ 0207,0208 = 0207,0214
----- ++--++-- -++++--+ 0202,0209 = 0207,0209 = 0209,0221 =
                          0210,0221
----- ++--++-- -++++--+ 0202,0221 = 0207,0221 = 0221,0221
----- ++--++-- -++++--+ 0202,0207 = 0207,0207
----- ++--++-- --++---- 0208,0210 = 0210,0214
----- ++--++-- --++---- 0208,0211 = 0211,0214
----- ++--++-- --++---- 0208,0212 = 0212,0214
----- ++--++-- --++---- 0208,0213 = 0213,0214
----- ++--++-- --++---- 0202,0218 = 0208,0218 = 0214,0218 =
                          0218,0218
----- ++--++-- --++---- 0202,0208 = 0202,0214 = 0208,0208 =
                          0208,0214
----- ++--++-- ----+--- 0202,0211 = 0211,0211
----- ++--++-- ----+--- 0202,0213 = 0213,0213
----- -+---++-+ -+---+ 0109,0109 = 0109,0210
----- -+---++-+ -+---+ 0209,0209 = 0209,0210

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LICENSES**101.121-24/04 – licensed for PCR.****Notice to purchaser: Limited License.**

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101.121-24/04 and 101.121-24u/04u

These products use ARMSTM 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 DRB3 subtyping kit have the specificities given in the Specificity and Interpretation Tables of the product insert and in the GenoVision version of the HELMBERG-SCORETM 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 dH₂O.

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

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For one DRB3 subtyping, add at room temperature in a 0.5 ml tube:

28 x 2 μl = 56 μl DNA (30 ng/μl)

28 x 3 μl = 84 μl PCR Master Mix complete with *Taq* – mix well
before taking your aliquot

28 x 5 μl = 140 μl dH₂O

Mix well, dispense 10 μl of the DNA-PCR Master Mix-H₂O mixture into each of the 24 wells of a DRB3 subtyping. **Well No. 1 of the 24 well PCR plate is marked with '1'.** Close the 24 well PCR plate with the provided lids.

101.121-24u/04u – not licensed for PCR

For one DRB3 subtyping, add at room temperature in a 0.5 ml tube:

28 x 2 μl = 56 μl DNA (30 ng/μl)

28 x 3 μl = 84 μl PCR Master Mix without *Taq* – mix well before
taking your aliquot

2.2 μl *Taq* polymerase (5 units/μl)

28 x 5 μl – 2.2 μl = 137.8 μl dH₂O

Mix well, dispense 10 μl of the DNA-PCR Master Mix-*Taq*-H₂O mixture into each of the 24 wells of a DRB3 subtyping. **Well No. 1 of the 24 well PCR plate is marked with '1'.** Close the 24 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 µl SSP reaction
nucleotides	final concentration of each dNTP is 200 µM
PCR buffer	final concentrations: 50 mM KCl, 1.5 mM MgCl ₂ , 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 µg/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 µM
PCR buffer	final concentrations: 50 mM KCl, 1.5 mM MgCl ₂ , 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 µg/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°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°C for 4 weeks, but the PCR Master Mixes are then no longer stable for 24 months.

SPECIFICITY TABLE

DRB3 SSP subtyping

Specificities and sizes of the PCR products of the 24 primer mixes used for DRB3 SSP subtyping

Primer Mix	Approx. size of spec. PCR product ¹	Size of control band ²	Amplified DRB3 alleles ³	Amplified DRB1 ⁴ alleles
1^{5,6,14}	100, 210 bp	515 bp	010101-0108, 0110, 0111, 0205, 0217, 030101-030102, 0303	1130 ^{weakly} , 1367, 1446
2⁵	125 bp	430 bp	010101-0106, 0108, 0110, 0111, 030101-030102, 0303	0807 ^{weakly} , 0819 ^{weakly} , 0825 ^{weakly} , 1331 ^{weakly} , 1346 ^{weakly} , 1354 ^{weakly} , 1448 ^{weakly}
3⁵	95 bp	515 bp	010101-0102, 0104-0108, 0110, 0111	
4⁵	85 bp	430 bp	0102	
5⁵	95 bp	430 bp	0103	1446
6	190 bp	430 bp	0104	
7⁵	90 bp	515 bp	0105	
8⁵	120 bp	430 bp	0106, 0108	1446
9	165 bp	430 bp	0107, 0201-0208, 0211, 0213-0222	
10	185 bp	430 bp	0109, 0201-0204, 0206-0214, 0216-0222, 0302	
11	270 bp	515 bp	0201, 0204, 030101- 0302	
12^{5,7}	90, 145 bp	515 bp	0201, 0204, 0217	1143, 1150, 1459
13	270 bp	515 bp	010101- 0111, 020201-0203, 0205-0213, 0215-0222, 0303	1130, 1367, 1446
14⁹	185 bp	515 bp	0107, 0109, 020201-020205, 0205-0213, 0215-0219, 0222	100101-100102 ^{weakly} , 1149 ^{weakly}
15^{5,8}	120, 180 bp	430 bp	0203, 0216, 030101-	

16 ^{5,9,10}	100, 155 bp	515 bp	0303 0109, 0204, 0215, 0216, 0219, 0222	1144 ^{weakly} , 1149 ^{weakly} , 1150 ^{weakly}
17 ⁵	120 bp	430 bp	0108, 0206, 0220	1367, 1446
18 ⁵	100 bp	430 bp	0109, 0207, 0209, 0221	
19 ¹¹	180, 270 bp	515 bp	0208, 0214, 0218	1130
20 ¹²	165, 180 bp	430 bp	010101-0106, 0108- 0111, 0209, 0210, 0216, 030101-0303	1130, 1367, 1446
21 ^{5,13,14}	125, 180, 210 bp	430 bp	0110, 0211, 0216	
22 ¹⁵	185, 245 bp	430 bp	0111, 0212	
23	195 bp	515 bp	0213	
24	185 bp	430 bp	0209, 0218, 0219, 0221, 030101-0303	1130

¹Alleles are assigned by the presence of specific PCR product(s). However, the sizes of the specific PCR products may be helpful in the interpretation of DRB3 SSP subtypings.

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 bp or more. Size differences shorter than 20 bp are not given. For high resolution SSP kits the length 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 band may sometimes be observed. Such bands can be disregarded and do not influence the interpretation of the SSP typings.

²The internal positive control primer pairs amplify segments of the human growth hormone gene. The two different control primer pairs give rise to either an internal positive control band of 430 base pairs, for most tubes, or a band of 515 base pairs, for some tubes.

Tube number 1 contains the primer pair giving rise to the longer, 515 bp, internal positive control band in order to help in the correct orientation of the DRB3 subtyping.

In addition, tubes number 3, 7, 11, 12, 13, 14, 16, 19 and 23 contain the primer pair giving rise to the longer, 515 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.

³For several DRB alleles only partial second exon nucleotide sequences are available. In these instances it is not known whether some of the primers of the SSP sets are completely matched with the target sequences or not. We assume that unknown sequences in the first hyperpolymorphic region of the second exon of DRB alleles are conserved within allelic groups and that unknown sequences of codons 87 to 92 are identical with the DRB1*0101 consensus sequence.

⁴Due to the sharing of sequence motifs between DRB3 and DRB1 alleles, primer mixes 1, 2, 5, 8, 12 to 14, 16, 17, 20 and 24 will amplify a few DRB1 alleles.

⁵Short specific PCR fragments are less intense and not as sharp as longer specific bands.

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⁶Primer mix 1: Specific PCR fragment of 100 bp in the DRB3*010101 to 0108, 0110, 0111, 0205, 030101-030102, 0303 and DRB1*1130, 1367 and 1146 alleles. Specific PCR fragment of 210 bp in the DRB3*0217 allele.

⁷Primer mix 12: Specific PCR fragment of 90 bp in the DRB3*0217 allele. Specific PCR fragment of 145 bp in the DRB3*0201, 0204 and DRB1*1143, 1150 and 1459 alleles.

⁸Primer mix 15: Specific PCR fragment of 120 bp DRB3*0203, 030101 to 0303 alleles. Specific PCR fragment of 180 bp in the DRB3*0216 allele.

⁹Primer mixes 14 and 16 has a tendency to giving rise to nonspecific amplifications.

¹⁰Primer mix 16: Specific PCR fragment of 100 bp in the DRB3*0216 allele. Specific PCR fragment of 155 bp in the DRB3*0109, 0204, 0215, 0219 and 0222 and DRB1*1144, 1149 and 1150 alleles.

¹¹Primer mix 19: Specific PCR fragment of 180 bp DRB3*0208, 0218 and DRB1*1130 alleles. Specific PCR fragment of 270 bp in the DRB3*0214 allele.

¹²Primer mix 20: Specific PCR fragment of 165 bp DRB3*010101 to 0106, 0108 to 0111, 0209, 0210, 030101 to 0303 and DRB1*1130, 1367 and 1446 alleles. Specific PCR fragment of 180 bp in the DRB3*0216 allele.

¹³Primer mix 21: Specific PCR fragment of 125 bp in the DRB3*0110. Specific PCR fragment of 180 bp in the DRB3*0216 allele. Specific PCR fragment of 210 bp in the DRB3*0211 allele.

¹⁴Primer mixes 1 and 21 may give rise to a primer oligomer formation.

¹⁵Primer mix 22: Specific PCR fragment of 185 bp in the DRB3*0111 allele. Specific PCR fragment of 245 bp in the DRB3*0212 allele.

DRB3

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INTERPRETATION TABLE												
DRB3 SSP subtyping												
Amplification patterns of the DRB3*0101 to *0303 alleles												
	Tube ⁴											
	1	2	3	4	5	6	7	8	9	10	11	12
Length of spec.	100	125	95	85	95	190	90	120	165	185	270	90
PCR product	210											145
Length of int.	515	430	515	430	430	430	515	430	430	430	515	515
pos. control ¹												
5'-primer(s) ²	10	30	11	11	11	8	11	11	10	30	10	51
	5'-g CT ^{3'}	5'-gA T ^{3'}	5'-g Cg ^{3'}	5'-Tg T ^{3'}	5'-g Cg ^{3'}	5'-C TC ^{3'}	5'-g Cg ^{3'}	5'-g Cg ^{3'}	5'-g CT ^{3'}	5'-gA C ^{3'}	5'-g CT ^{3'}	5'-g Ag ^{3'}
			11									
			5'-g Tg ^{3'}									
3'-primer(s) ³	30	57	28	26	28	57	28	38	51	77	86	67
	5'-gTA ^{3'}	5'-C gA ^{3'}	5'-CT g ^{3'}	5'-g gT ^{3'}	5'-CT C ^{3'}	5'-C gA ^{3'}	5'-gTT ^{3'}	5'-CAC ^{3'}	5'-C CC ^{3'}	5'-TA A ^{3'}	5'-C CA ^{3'}	5'-gAA ^{3'}
	30	57								77		86
	5'-gTA ^{3'}	5'-C AA ^{3'}								5'-A gT ^{3'}		5'-C CA ^{3'}
	67											
	5'-gAA ^{3'}											
Tube No.	1	2	3	4	5	6	7	8	9	10	11	12
DRB3 allele												
*010101-010104	+	+	+									
*0102	+	+	+	+								
*0103	+	+			+							
*0104	+	+	+			+						
*0105	+	+	+				+					
*0106	+	+	+					+				
*0107	+		+						+			
*0108	+	+	+					+				
*0109										+		
*0110	+	+	+									
*0111	+	+	+									
*0201									+	+	+	+
*020201-020205									+	+		
*0203									+	+		
*0204									+	+	+	+
*0205	+								+			
*0206									+	+		
*0207									+	+		
*0208									+	+		
*0209										+		
Tube No.	1	2	3	4	5	6	7	8	9	10	11	12

INTERPRETATION TABLE												
DRB3 SSP subtyping												
Amplification patterns of the DRB3*0101 to *0303 alleles												
Tube ⁴												
13	14	15	16	17	18	19	20	21	22	23	24	
270	185	120	100	120	100	180	165	125	185	195	185	Length of spec.
		180	155			270	180	180	245			PCR product
								210				
515	515	430	515	430	430	515	430	430	430	515	430	Length of int.
												pos. control ¹
10	38	11	38	10	38	10	10	10	9	26	11	5'-primer(s) ²
5'-g CT ^{3'}	5'-C gC ^{3'}	5'-g CT ^{3'}	5'-C gC ^{3'}	5'-g CT ^{3'}	5'-C gC ^{3'}	5'-g CT ^{3'}	5'-g CT ^{3'}	5'-g CT ^{3'}	5'-Tg C ^{3'}	5'-gg C ^{3'}	5'-g CT ^{3'}	
10	38								29			
5'-g CT ^{3'}	5'-C gC ^{3'}								5'-C AT ^{3'}			
86	86	37	57	37	57	57	51	39	77	77	58	3'-primer(s) ³
5'-C AC ^{3'}	5'-C AC ^{3'}	5'-C gg ^{3'}	5'-C Ag ^{3'}	5'-gTT ^{3'}	5'-C gA ^{3'}	5'-gCT ^{3'}	5'-CC g ^{3'}	5'-gCT ^{3'}	5'-TA A ^{3'}	5'-TA A ^{3'}	5'-C CT ^{3'}	
		37	74	37		58	57	57			60	
		5'-C gA ^{3'}	5'-C CC ^{3'}	5'-gTT ^{3'}		5'-C CT ^{3'}	5'-C Ag ^{3'}	5'-C Ag ^{3'}			5'-A gg ^{3'}	
		57	77			86		67				
		5'-C Ag ^{3'}	5'-A gg ^{3'}			5'-C Ag ^{3'}		5'-gAT ^{3'}				
13	14	15	16	17	18	19	20	21	22	23	24	Tube No.
												DRB3 allele
+							+					*010101-010104
+							+					*0102
+							+					*0103
+							+					*0104
+							+					*0105
+							+					*0106
+	+											*0107
+				+			+					*0108
+	+		+		+		+					*0109
+							+	+				*0110
+							+		+			*0111
												*0201
+	+											*020201-020205
+		+										*0203
			+									*0204
+	+											*0205
+	+			+								*0206
+	+				+							*0207
+	+					+						*0208
+	+				+		+				+	*0209
13	14	15	16	17	18	19	20	21	22	23	24	Tube No.

Length of spec.	100	125	95	85	95	190	90	120	165	185	270	90
PCR product	210											145
Tube No.	1	2	3	4	5	6	7	8	9	10	11	12
*0210										+		
*0211									+	+		
*0212										+		
*0213									+	+		
*0214									+	+		
*0215									+			
*0216									+	+		
*0217	+								+	+		+
*0218									+	+		
*0219									+	+		
*0220									+	+		
*0221									+	+		
*0222									+	+		
*030101-030102	+	+									+	
*0302										+	+	
*0303	+	+										
DRB3 allele												
Tube No.	1	2	3	4	5	6	7	8	9	10	11	12
DRB1*0807, 0819, 0825, 1331, 1346, 1354, 1448		W										
DRB1*100101-100102												
DRB1*1130	W											
DRB1*1143, 1459												+
DRB1*1144												
DRB1*1149												
DRB1*1150												+
DRB1*1367	+											
DRB1*1446	+				+			+				
Tube No.	1	2	3	4	5	6	7	8	9	10	11	12

270	185	120	100	120	100	180	165	125	185	195	185	Length of spec.
		180	155			270	180	180	245			PCR product
13	14	15	16	17	18	19	20	21	22	23	24	Tube No.
+	+						+					*0210
+	+							+				*0211
+	+								+			*0212
+	+									+		*0213
						+						*0214
+	+		+									*0215
+	+	+	+				+	+				*0216
+	+											*0217
+	+					+					+	*0218
+	+		+								+	*0219
+				+								*0220
+	+				+						+	*0221
+	+		+									*0222
		+					+				+	*030101-030102
		+					+				+	*0302
+		+					+				+	*0303
												DRB3 allele
13	14	15	16	17	18	19	20	21	22	23	24	Tube No.
												DRB1*0807, 0819, 0825, 1331, 1346, 1354, 1448
	W											DRB1*100101-100102
+						+	+				+	DRB1*1130
												DRB1*1143, 1459
			W									DRB1*1144
	W		W									DRB1*1149
			W									DRB1*1150
+				+			+					DRB1*1367
+				+			+					DRB1*1446
13	14	15	16	17	18	19	20	21	22	23	24	Tube No.

¹The internal positive control primer pairs amplify segments of the human growth hormone gene. The two different control primer pairs give rise to either an internal positive control band of 430 base pairs, for most tubes, or a band of 515 base pairs, for some tubes.

Tube number 1 contains the primer pair giving rise to the longer, 515 bp, internal positive control band in order to help in the correct orientation of the DRB3 subtyping.

In addition, tubes number 3, 7, 11, 12, 13, 14, 16, 19 and 23 contain the primer pair giving rise to the longer, 515 bp, internal positive control band in order to allow kit identification.

²The codon, in the 2nd exon, matching the specificity-determining 3'-end of the primer is given. Codon numbering as in *Tissue Antigens* 1998, **51:II**, 467-507. The sequence of the 3 terminal nucleotides of the primer is given. Empty spaces indicate codon boundaries.

³The codon, in the 2nd exon, matching the specificity-determining 3'-end of the primer is given in the anti-sense direction. Codon numbering as in *Tissue Antigens* 1998, **51:II**, 467-507. The sequence of the 3 terminal nucleotides of the primer is given. Empty spaces indicate codon boundaries.

⁴Primer mix 1: Specific PCR fragment of 100 bp in the DRB3*010101 to 0108, 0110, 0111, 0205, 030101-030102, 0303 and DRB1*1130, 1367 and 1146 alleles. Specific PCR fragment of 210 bp in the DRB3*0217 allele.

Primer mix 12: Specific PCR fragment of 90 bp in the DRB3*0217 allele. Specific PCR fragment of 145 bp in the DRB3*0201, 0204 and DRB1*1143, 1150 and 1459 alleles.

Primer mix 15: Specific PCR fragment of 120 bp DRB3*0203, 030101 to 0303 alleles. Specific PCR fragment of 180 bp in the DRB3*0216 allele.

Primer mix 16: Specific PCR fragment of 100 bp in the DRB3*0216 allele. Specific PCR fragment of 155 bp in the DRB3*0109, 0204, 0215, 0219 and 0222 and DRB1*1144, 1149 and 1150 alleles.

Primer mix 19: Specific PCR fragment of 180 bp DRB3*0208, 0218 and DRB1*1130 alleles. Specific PCR fragment of 270 bp in the DRB3*0214 allele.

Primer mix 20: Specific PCR fragment of 165 bp DRB3*010101 to 0106, 0108 to 0111, 0209, 0210, 030101 to 0303 and DRB1*1130, 1367 and 1446 alleles. Specific PCR fragment of 180 bp in the DRB3*0216 allele.

Primer mix 21: Specific PCR fragment of 125 bp in the DRB3*0110. Specific PCR fragment of 180 bp in the DRB3*0216 allele. Specific PCR fragment of 210 bp in the DRB3*0211 allele.

Primer mix 22: Specific PCR fragment of 185 bp in the DRB3*0111 allele. Specific PCR fragment of 245 bp in the DRB3*0212 allele.

'w', might be weakly amplified.

CELL LINE VALIDATION SHEET																				
DRB3 SSP subtyping kit																				
					Tube															
					1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
				Prod. No.	200622601	200622602	200622603	200622604	200622605	200622606	200622607	200622608	200622609	200622610	200622611	200622612	200622613	200622614	200622615	200736916
	cell line	DRB3																		
1	9001 SA				-	-	-	-	-	-	-	-		-	-	-	-	-	-	-
2	9280 LK707				-	-	-	-	-	-	-	-		-	-	-	-	-	-	-
3	9011 E4181324				-	-	-	-	-	-	-	-		-	-	-	-	-	-	-
4	9275 GU373	*0202			-	-	-	-	-	-	-	-	+	+	-	-	+	+	-	-
5	9009 KAS011				-	-	-	-	-	-	-	-		-	-	-	-	-	-	-
6	9353 SM				-	-	-	-	-	-	-	-		-	-	-	-	-	-	-
7	9020 QBL	*0202			-	-	-	-	-	-	-	-	+	+	-	-	+	+	-	-
8	9007 DEM				-	-	-	-	-	-	-	-		-	-	-	-	-	-	-
9	9026 YAR				-	-	-	-	-	-	-	-		-	-	-	-	-	-	-
10	9107 LKT3				-	-	-	-	-	-	-	-		-	-	-	-	-	-	-
11	9051 PITOUT				-	-	-	-	-	-	-	-		-	-	-	-	-	-	-
12	9052 DBB				-	-	-	-	-	-	-	-		-	-	-	-	-	-	-
13	9067 BTB				-	-	-	-	-	-	-	-		-	-	-	-	-	-	-
14	9071 OLGA				-	-	-	-	-	-	-	-		-	-	-	-	-	-	-
15	9075 DKB				-	-	-	-	-	-	-	-		-	-	-	-	-	-	-
16	9037 SWEIG007	*0202			-	-	-	-	-	-	-	-	+	+	-	-	+	+	-	-
17	9008 WILJON				-	-	-	-	-	-	-	-		-	-	-	-	-	-	-
18	9257 32367	*0202			-	-	-	-	-	-	-	-	+	+	-	-	+	+	-	-
19	9038 BM16	*0202			-	-	-	-	-	-	-	-	+	+	-	-	+	+	-	-
20	9059 SLE005	*0301			+	+	-	-	-	-	-	-		-	-	+	-	-	+	-
21	9064 AMALA	*0101			+	+	+	-	-	-	-	-		-	-	-	+	-	-	-
22	9056 KOSE	*0202	*0301		+	+	-	-	-	-	-	-	+	+	+	-	+	+	+	-
23	9124 IHL	*0202			-	-	-	-	-	-	-	-	+	+	-	-	+	+	-	-
24	9035 JBUSH	*0202			-	-	-	-	-	-	-	-	+	+	-	-	+	+	-	-
25	9049 IBW9				-	-	-	-	-	-	-	-		-	-	-	-	-	-	-
26	9285 WT49	*0202			-	-	-	-	-	-	-	-	+	+	-	-	+	+	-	-
27	9191 CH1007				-	-	-	-	-	-	-	-		-	-	-	-	-	-	-
28	9320 BEL5GB				-	-	-	-	-	-	-	-		-	-	-	-	-	-	-
29	9050 MOU				-	-	-	-	-	-	-	-		-	-	-	-	-	-	-
30	9021 RSH	*0101			+	+	+	-	-	-	-	-		-	-	-	+	-	-	-
31	9019 DUCAF	*0202			-	-	-	-	-	-	-	-	+	+	-	-	+	+	-	-
32	9297 HAG	*0101			+	+	+	-	-	-	-	-		-	-	-	+	-	-	-
33	9098 MT14B				-	-	-	-	-	-	-	-		-	-	-	-	-	-	-
34	9104 DHIF	*0202			-	-	-	-	-	-	-	-	+	+	-	-	+	+	-	-
35	9302 SSTO				-	-	-	-	-	-	-	-		-	-	-	-	-	-	-
36	9024 KT17				-	-	-	-	-	-	-	-		-	-	-	-	-	-	-
37	9065 HHKB	*0101			+	+	+	-	-	-	-	-		-	-	-	+	-	-	-
38	9099 LZL	*0101			+	+	+	-	-	-	-	-		-	-	-	+	-	-	-
39	9315 CML	*0101			+	+	+	-	-	-	-	-		-	-	-	+	-	-	-
40	9134 WHONP199				-	-	-	-	-	-	-	-		-	-	-	-	-	-	-
41	9055 H0301	*0301			+	+	-	-	-	-	-	-		-	-	+	-	-	+	-
42	9066 TAB089				-	-	-	-	-	-	-	-		-	-	-	-	-	-	-
43	9076 T7526				-	-	-	-	-	-	-	-		-	-	-	-	-	-	-
44	9057 TEM	*0201			-	-	-	-	-	-	-	-	+	+	+	+	-	-	-	-
45	9239 SHJO				-	-	-	-	-	-	-	-		-	-	-	-	-	-	-
46	9013 SCHU				-	-	-	-	-	-	-	-		-	-	-	-	-	-	-
47	9045 TUBO	*0202			-	-	-	-	-	-	-	-	+	+	-	-	+	+	-	-
48	9303 TER-ND				-	-	-	-	-	-	-	-		-	-	-	-	-	-	-

CELL LINE VALIDATION SHEET												
DRB3 SSP subtyping kit												
					Tube							
					17	18	19	20	21	22	23	24
				Prod. No.	200622617	200622618	200622619	200622620	200736921	200622622	200622623	200622624
	cell line		DRB3									
1	9001	SA			-	-	-	-	-	-	-	-
2	9280	LK707			-	-	-	-	-	-	-	-
3	9011	E4181324			-	-	-	-	-	-	-	-
4	9275	GU373	*0202		-	-	-	-	-	-	-	-
5	9009	KAS011			-	-	-	-	-	-	-	-
6	9353	SM			-	-	-	-	-	-	-	-
7	9020	QBL	*0202		-	-	-	-	-	-	-	-
8	9007	DEM			-	-	-	-	-	-	-	-
9	9026	YAR			-	-	-	-	-	-	-	-
10	9107	LKT3			-	-	-	-	-	-	-	-
11	9051	PITOUT			-	-	-	-	-	-	-	-
12	9052	DBB			-	-	-	-	-	-	-	-
13	9067	BTB			-	-	-	-	-	-	-	-
14	9071	OLGA			-	-	-	-	-	-	-	-
15	9075	DKB			-	-	-	-	-	-	-	-
16	9037	SWEIG007	*0202		-	-	-	-	-	-	-	-
17	9008	WILJON			-	-	-	-	-	-	-	-
18	9257	32367	*0202		-	-	-	-	-	-	-	-
19	9038	BM16	*0202		-	-	-	-	-	-	-	-
20	9059	SLE005	*0301		-	-	-	+	-	-	-	+
21	9064	AMALA	*0101		-	-	-	-	-	-	-	-
22	9056	KOSE	*0202	*0301	-	-	-	+	-	-	-	+
23	9124	IHL	*0202		-	-	-	-	-	-	-	-
24	9035	JBUSH	*0202		-	-	-	-	-	-	-	-
25	9049	IBW9			-	-	-	-	-	-	-	-
26	9285	WT49	*0202		-	-	-	-	-	-	-	-
27	9191	CH1007			-	-	-	-	-	-	-	-
28	9320	BEL5GB			-	-	-	-	-	-	-	-
29	9050	MOU			-	-	-	-	-	-	-	-
30	9021	RSH	*0101		-	-	-	+	-	-	-	-
31	9019	DUCAF	*0202		-	-	-	-	-	-	-	-
32	9297	HAG	*0101		-	-	-	+	-	-	-	-
33	9098	MT14B			-	-	-	-	-	-	-	-
34	9104	DHIF	*0202		-	-	-	-	-	-	-	-
35	9302	SSTO			-	-	-	-	-	-	-	-
36	9024	KT17			-	-	-	-	-	-	-	-
37	9065	HHKB	*0101		-	-	-	+	-	-	-	-
38	9099	LZL	*0101		-	-	-	+	-	-	-	-
39	9315	CML	*0101		-	-	-	+	-	-	-	-
40	9134	WHONP199			-	-	-	-	-	-	-	-
41	9055	H0301	*0301		-	-	-	+	-	-	-	+
42	9066	TAB089			-	-	-	-	-	-	-	-
43	9076	T7526			-	-	-	-	-	-	-	-
44	9057	TEM	*0201		-	-	-	-	-	-	-	-
45	9239	SHJO			-	-	-	-	-	-	-	-
46	9013	SCHU			-	-	-	-	-	-	-	-
47	9045	TUBO	*0202		-	-	-	-	-	-	-	-
48	9303	TER-ND			-	-	-	-	-	-	-	-

CERTIFICATE OF ANALYSIS

Olerup SSP™ DRB3 SSP

Product number: 101.121-24/04 – licensed for PCR
101.121-24u/04u – not licensed for PCR
Lot number: Y16
Expiry date: 2009-July-01
Number of tests: 24 tests – Product No. 101.121-24
4 tests – Product No. 101.121-04
Number of tubes per test: 24

Tube specifications:

Tube No.	Production No.	Tube No.	Production No.	Tube No.	Production No.
1	2006-226-01	9	2006-226-09	17	2006-226-17
2	2006-226-02	10	2006-226-10	18	2006-226-18
3	2006-226-03	11	2006-226-11	19	2006-226-19
4	2006-226-04	12	2006-226-12	20	2006-226-20
5	2006-226-05	13	2006-226-13	21	2007-369-21
6	2006-226-06	14	2006-226-14	22	2006-226-22
7	2006-226-07	15	2006-226-15	23	2006-226-23
8	2006-226-08	16	2007-369-16	24	2006-226-24

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 4 to 8, 16 to 19 and 21 to 23 were available. The specificities of the primers in primer solutions 5, 8, 16, 18 and 19 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer solutions 4, 6, 22 and 23 it was only possible to test the 3'-primer, the 5'-primer was not possible to test. In primer solutions 7, 17 and 21 it was only possible to test the 5'-primer, the 3'-primer was not possible to test. One of the 3'-primers in primer solutions 1, 2 and 12 were not possible to test. One of the 5'-primers in primer solution 3 was not possible to test.

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

Date of approval: 2007-September-25

Approved by:

Quality Control, Supervisor

Declaration of Conformity

Product name: Olerup SSP™ DRB3
Product number: 101.121-24/04, 101.121-24u/04u
Lot number: Y16

Intended use: DRB3 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, 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
2007-September-25

Olle Olerup
Managing Director

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.

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