

101.121-24/04 – including *Taq* pol., IFU-01
 101.121-24u/04u – without *Taq* pol., IFU-02

Visit www.olerup-ssp.com for
 “Instructions for Use” (IFU)

Lot No.: **94S**

Lot-specific information
Olerup SSP[®] DRB3

www.olerup-ssp.com

Product number: 101.121-24/04 – including *Taq* pol.
 101.121-24u/04u – without *Taq* pol.

Lot number: 94S

Expiry date: 2016-April-01

Number of tests: 24 tests – Product No. 101.121-24/24u
 4 tests – Product No. 101.121-04/04u

Number of wells per test: 32

Storage - pre-aliquoted primers: dark at -20°C

- PCR Master Mix: -20°C
- Adhesive PCR seals: RT
- Product Insert: RT

This Product Description is only valid for Lot No. 94S.

CHANGES COMPARED TO THE PREVIOUS *OLERUP SSP[®]* DRB3 LOT (52R)

The Lot-specific information for DRB3 including and without *Taq* polymerase is now described in one common Product Insert.

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. 52R**) was made.

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

Well	5'-primer	3'-primer	rationale
31	Added	Added	Primer added from well 32
32	Added, moved	Added, moved	Primer pair added for resolution of the DRB3*02:02:01:01-02:02:05 and DRB1*14:141 alleles, primer pair moved to well 31.

Change in revision R01 compared to R00:

1. The DRB3*02:15 and DRB3*02:27 and the DRB1*12:01:02-12:01:03, 12:02:02, 12:03:02, 12:16:01, 14:121, 15:03:01:01-15:03:02, 15:23, 15:54, 15:57, 15:78 and 15:94 alleles are weakly amplified by primer mix 10. This has been corrected in the specificity and interpretation tables.

101.121-24/04 – including *Taq* pol., IFU-01
 101.121-24u/04u – without *Taq* pol., IFU-02

Visit www.olerup-ssp.com for
 “Instructions for Use” (IFU)

Lot No.: **94S**

Lot-specific information

www.olerup-ssp.com

PRODUCT DESCRIPTION

DRB3 SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for identifying the DRB3*01:01 to DRB3*03:03 alleles.

PLATE LAYOUT

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

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

The 32 well cut PCR plate is marked with 'DRB3' in silver/gray ink.

Well No. 1 is marked with the Lot No. '94S'.

A faint row of numbers is seen between wells 1 and 2 or wells 7 and 8 of the PCR trays. These stem from the manufacture of the trays, and should be disregarded.

The PCR plates are covered with a PCR-compatible foil.

Please note: When removing each 32 well PCR plate, make sure that the remaining plates stay covered. Use a scalpel or a similar instrument to carefully cut the foil between the plates.

INTERPRETATION

The interpretation of DRB3 subtypings will be influenced by sixteen DRB1*03 alleles, two DRB1*04, five DRB1*08, the DRB1*10, eleven DRB1*11, three DRB1*12, several DRB1*13 alleles, several DRB1*14 and the DRB1*15:65 alleles. Thus, the interpretation of DRB3 subtypings is only marginally influenced by other DRB genes.

UNIQUELY IDENTIFIED ALLELES

All the DRB3 alleles, i.e. **DRB3*01:01 to DRB3*01:15, DRB3*02:01 to DRB3*02:29N and DRB3*03:01 to DRB3*03:03**, recognized by the HLA Nomenclature Committee in July 2013¹ will give rise to unique amplification patterns by the primers in the DRB3 subtyping kit.

The DRB3 subtyping kit cannot distinguish the silent mutations in the DRB3*01:01:02:01 to 01:01:05 alleles, the DRB3*02:02:01:01 to 02:02:05 alleles or the DRB3*03:01:01 to 03:01:03 alleles.

¹DRB alleles listed on the IMGT/HLA web page 2013-July-25, release 3.13.1, www.ebi.ac.uk/imgt/hla.

101.121-24/04 – including *Taq* pol., IFU-01
101.121-24u/04u – without *Taq* pol., IFU-02

Visit www.olerup-ssp.com for
“Instructions for Use” (IFU)

Lot No.: **94S**

Lot-specific information

www.olerup-ssp.com

RESOLUTION IN HOMO- AND HETEROZYGOTES

A total of 58 alleles generate 47 amplification patterns that can be combined in 1128 homozygous and heterozygous combinations. 299 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.

```

----- +-----+ ----- +-----+ *02:15, *02:27 = *02:27, *02:27
----- ++-----+ ----- +-----+ *02:02:01:01, *02:29N = *02:29N, *02:29N
----- ++-----+ ----- +-----+ *02:02:01:01, *02:28 = *02:28, *02:28
----- ++-----+ ----- +-----+ *02:02:01:01, *02:26 = *02:26, *02:26
----- ++-----+ ----- +-----+ *02:02:01:01, *02:13 = *02:13, *02:13
----- ++-----+ ----- +-----+ *02:02:01:01, *02:12 = *02:12, *02:12
----- ++-----+ ----- +-----+ *02:02:01:01, *02:11 = *02:11, *02:11
----- ++-----+ ----- +-----+ *02:02:01:01, *02:08 = *02:02:01:01, *02:14 = *02:08, *02:08 =
*02:08, *02:14
----- ++-----+ ----- +-----+ *02:02:01:01, *02:07 = *02:07, *02:07
----- ++-----+ ----- +-----+ *02:02:01:01, *02:06 = *02:02:01:01, *02:20 = *02:06, *02:06 =
*02:06, *02:20
----- ++-----+ ----- +-----+ *02:02:01:01, *02:22 = *02:22, *02:22
----- +++-----+ ----- +-----+ *02:01, *02:01 = *02:01, *02:24
----- +++-----+ ----- +-----+ *02:04, *02:04 = *02:04, *02:24
----- -++++-+ -++++-+ ----- *02:09, *02:09 = *02:09, *02:10
----- -++++-+ -++++-+ ----- *01:09, *01:09 = *01:09, *02:10
----- +-----+ ----- +-----+ *02:02:01:01, *02:25 = *02:25, *02:25 = *02:25, *02:29N
----- +-----+ ----- +-----+ *02:08, *02:29N = *02:14, *02:29N
----- +-----+ ----- +-----+ *02:08, *02:28 = *02:14, *02:28
----- +-----+ ----- +-----+ *02:08, *02:15 = *02:14, *02:15
----- +-----+ ----- +-----+ *02:08, *02:26 = *02:14, *02:26
----- +-----+ ----- +-----+ *02:02:01:01, *02:18 = *02:08, *02:18 = *02:14, *02:18 = *02:18,
*02:18
----- +-----+ ----- +-----+ *02:08, *02:13 = *02:13, *02:14
----- +-----+ ----- +-----+ *02:08, *02:12 = *02:12, *02:14
----- +-----+ ----- +-----+ *02:08, *02:11 = *02:11, *02:14
----- +-----+ ----- +-----+ *02:08, *02:10 = *02:10, *02:14
----- +-----+ ----- +-----+ *02:07, *02:08 = *02:07, *02:14
----- +-----+ ----- +-----+ *02:06, *02:29N = *02:20, *02:29N
----- +-----+ ----- +-----+ *02:06, *02:28 = *02:20, *02:28
----- +-----+ ----- +-----+ *02:06, *02:15 = *02:15, *02:20
----- +-----+ ----- +-----+ *02:06, *02:26 = *02:20, *02:26
----- +-----+ ----- +-----+ *02:06, *02:13 = *02:13, *02:20
----- +-----+ ----- +-----+ *02:06, *02:12 = *02:12, *02:20
----- +-----+ ----- +-----+ *02:06, *02:11 = *02:11, *02:20
----- +-----+ ----- +-----+ *02:06, *02:10 = *02:10, *02:20
----- +-----+ ----- +-----+ *02:02:01:01, *02:23 = *02:06, *02:08 = *02:06, *02:14 = *02:06,
*02:23 = *02:08, *02:20 = *02:08, *02:23 = *02:14, *02:23 = *02:20,
*02:23 = *02:23, *02:23
----- +-----+ ----- +-----+ *02:06, *02:07 = *02:07, *02:20
----- +-----+ ----- +-----+ *02:08, *02:22 = *02:14, *02:22
----- +-----+ ----- +-----+ *02:06, *02:22 = *02:20, *02:22
----- +-----+ ----- +-----+ *02:02:01:01, *02:17 = *02:03, *02:17 = *02:17, *02:17
+-----+ +-----+ -++++-+ ----- *02:05, *02:08 = *02:05, *02:14
+-----+ +-----+ -++++-+ ----- *02:05, *02:06 = *02:05, *02:20
+-----+ +-----+ -++++-+ ----- *01:07, *01:07 = *01:07, *02:05
+++-----+ ----- +-----+ *01:01:02:01, *01:12 = *01:12, *01:12
+++-----+ ----- +-----+ *01:01:02:01, *01:11 = *01:11, *01:11

```

101.121-24/04 – including *Taq* pol., IFU-01
101.121-24u/04u – without *Taq* pol., IFU-02

Visit www.olerup-ssp.com for
“Instructions for Use” (IFU)

Lot No.: 94S	Lot-specific information	www.olerup-ssp.com		
+++-----	-----+---	---+-----	-----	*01:01:02:01, *01:13 = *01:13, *01:13
+++-----+	-----+---	---+-----	-----	*01:01:02:01, *01:06 = *01:06, *01:06
+++-----+	-----+---	---+-----	-----	*01:01:02:01, *01:05 = *01:01:02:01, *01:15 = *01:05, *01:05 = *01:05, *01:15
+++-----+	-----+---	---+-----	-----	*01:01:02:01, *01:04 = *01:04, *01:04
+++-----+	-----+---	---+-----	-----	*01:01:02:01, *01:03 = *01:01:02:01, *01:10 = *01:03, *01:10 = *01:10, *01:10
++++-----	-----+---	---+-----	-----	*01:01:02:01, *01:02 = *01:02, *01:02
-----	++-----	---+-----	-----	*02:08, *02:27 = *02:14, *02:27
-----	++-----	---+-----	-----	*02:08, *02:25 = *02:14, *02:25 = *02:18, *02:25 = *02:18, *02:29N
-----	++-----	---+-----	-----	*02:02:01:01, *02:21 = *02:07, *02:21 = *02:07, *02:25 = *02:21, *02:21 = *02:21, *02:25 = *02:21, *02:29N
-----	++-----	---+-----	-----	*02:02:01:01, *02:09 = *02:07, *02:09
-----	++-----	---+-----	-----	*02:06, *02:27 = *02:20, *02:27
-----	++-----	---+-----	-----	*02:06, *02:25 = *02:20, *02:25
-----	++-----	---+-----	-----	*02:06, *02:18 = *02:18, *02:20 = *02:18, *02:23
-----	++-----	---+-----	-----	*02:02:01:01, *02:19 = *02:19, *02:19 = *02:19, *02:22 = *02:19, *02:25 = *02:19, *02:29N = *02:22, *02:25
-----	++-----	---+-----	-----	*01:09, *02:02:01:01 = *01:09, *02:07 = *01:09, *02:22
-----	++-----	---+-----	-----	*02:02:01:01, *02:16 = *02:03, *02:16 = *02:06, *02:16 = *02:10, *02:16 = *02:16, *02:16 = *02:16, *02:20
-----	++-----	---+-----	-----	*02:08, *02:17 = *02:14, *02:17
-----	++-----	---+-----	-----	*02:06, *02:17 = *02:17, *02:20
-----	++-----	---+-----	-----	*02:02:01:01, *02:04 = *02:04, *02:22 = *02:22, *02:24
+-+-----+	-----+---	---+-----	-----	*01:07, *01:15 = *01:15, *02:05
+++-----+	-----+---	---+-----	-----	*01:01:02:01, *01:08 = *01:06, *01:08 = *01:08, *01:08
+++-----+	-----+---	---+-----	-----	*01:05, *01:14 = *01:14, *01:15
+++-----+	-----+---	---+-----	-----	*01:05, *01:12 = *01:12, *01:15
+++-----+	-----+---	---+-----	-----	*01:05, *01:11 = *01:11, *01:15
+++-----+	-----+---	---+-----	-----	*01:05, *01:13 = *01:13, *01:15
+++-----+	-----+---	---+-----	-----	*01:05, *01:06 = *01:06, *01:15
+++-----+	-----+---	---+-----	-----	*01:04, *01:05 = *01:04, *01:15
+++-----+	-----+---	---+-----	-----	*01:03, *01:12 = *01:10, *01:12
+++-----+	-----+---	---+-----	-----	*01:03, *01:11 = *01:10, *01:11
+++-----+	-----+---	---+-----	-----	*01:03, *01:13 = *01:10, *01:13
+++-----+	-----+---	---+-----	-----	*01:03, *01:06 = *01:06, *01:10
+++-----+	-----+---	---+-----	-----	*01:03, *01:05 = *01:03, *01:15 = *01:05, *01:10 = *01:10, *01:15
+++-----+	-----+---	---+-----	-----	*01:03, *01:04 = *01:04, *01:10
+++-----+	-----+---	---+-----	-----	*01:02, *01:05 = *01:02, *01:15
++++-----	-----+---	---+-----	-----	*01:02, *01:03 = *01:02, *01:10
-----	++-----	---+-----	-----	*02:09, *02:21 = *02:09, *02:25 = *02:09, *02:29N = *02:10, *02:21
-----	++-----	---+-----	-----	*02:08, *02:21 = *02:14, *02:21 = *02:18, *02:21
-----	++-----	---+-----	-----	*02:08, *02:09 = *02:09, *02:14 = *02:09, *02:18
-----	++-----	---+-----	-----	*02:06, *02:21 = *02:20, *02:21
-----	++-----	---+-----	-----	*02:06, *02:09 = *02:09, *02:20
-----	++-----	---+-----	-----	*02:08, *02:19 = *02:14, *02:19 = *02:18, *02:19
-----	++-----	---+-----	-----	*02:07, *02:19 = *02:19, *02:21 = *02:21, *02:22
-----	++-----	---+-----	-----	*01:09, *02:08 = *01:09, *02:14
-----	++-----	---+-----	-----	*02:06, *02:19 = *02:19, *02:20
-----	++-----	---+-----	-----	*01:09, *02:06 = *01:09, *02:20
-----	++-----	---+-----	-----	*02:08, *02:16 = *02:14, *02:16 = *02:16, *02:23
+-+-----+	-----+---	---+-----	-----	*01:07, *02:10 = *01:15, *02:02:01:01
+-+-----+	-----+---	---+-----	-----	*01:07, *02:08 = *01:07, *02:14
+-+-----+	-----+---	---+-----	-----	*01:07, *02:06 = *01:07, *02:20
+++-----+	-----+---	---+-----	-----	*01:05, *03:03 = *01:15, *03:03
+++-----+	-----+---	---+-----	-----	*01:01:02:01, *01:07 = *01:05, *01:07 = *01:05, *02:05
+++-----+	-----+---	---+-----	-----	*01:05, *01:08 = *01:08, *01:15

101.121-24/04 – including *Taq* pol., IFU-01
101.121-24u/04u – without *Taq* pol., IFU-02

Visit www.olerup-ssp.com for
“Instructions for Use” (IFU)

Lot No.: 94S

Lot-specific information

www.olerup-ssp.com

+++--++-	-----	+-----	-----	*01:03, *01:08 = *01:08, *01:10
-----	+++--++-	-+-----	-----	*01:09, *02:19 = *01:09, *02:21 = *01:09, *02:25 = *02:09, *02:19
-----	+++--++-	-----	-----	*02:25, *03:02 = *02:29N, *03:02
-----	+++--++-	-+-----	-----	*02:08, *03:02 = *02:18, *03:02
-----	+++--++-	+-----	-----	*02:06, *03:02 = *02:16, *03:02
-----	++++++-	-----	-----	*02:04, *02:19 = *02:04, *02:25 = *02:19, *02:24
-----	++++++-	-+-----	-----	*01:09, *02:04 = *01:09, *02:24
+++-----	+++--++-	-----	+-----	*01:01:02:01, *02:26 = *01:12, *02:02:01:01 = *01:12, *02:26
+++-----	+++--++-	-----	-----	*01:01:02:01, *02:12 = *01:11, *02:02:01:01 = *01:11, *02:12
+++-----	+++--++-	-----	-----	*01:01:02:01, *02:11 = *01:13, *02:02:01:01 = *01:13, *02:11
+++-----+	+++--++-	+-----	-----	*01:06, *02:20 = *01:08, *02:20
+++-----+	-----	-+-----	-----	*01:05, *03:01:01 = *01:15, *03:01:01
+++--++-	+++--++-	-----	-----	*01:03, *01:07 = *01:07, *01:10
+-----+	+++--++-	+-----	-----	*01:07, *02:16 = *01:15, *02:16
+++-----	+++--++-	-----	-----	*02:25, *03:03 = *02:29N, *03:03
+++-----	+++--++-	-+-----	-----	*02:08, *03:03 = *02:18, *03:03
+++-----	+++--++-	+-----	-----	*02:06, *03:03 = *02:16, *03:03
+++-----	+++--++-	-----	+-----	*01:11, *02:26 = *01:12, *02:12
+++-----	+++--++-	-----	-----	*01:12, *02:11 = *01:13, *02:26
+++-----	+++--++-	-----	-----	*01:11, *02:11 = *01:13, *02:12
+++-----+	+++--++-	+-----	-----	*01:06, *02:06 = *01:08, *02:02:01:01 = *01:08, *02:06
+++-----	+++--++-	-----	-----	*02:25, *03:01:01 = *02:29N, *03:01:01
+++-----	+++--++-	-+-----	-----	*02:08, *03:01:01 = *02:18, *03:01:01
+++-----	+++--++-	+-----	-----	*02:06, *03:01:01 = *02:16, *03:01:01
+++-----+	+++--++-	+-----	-----	*01:06, *02:23 = *01:08, *02:08 = *01:08, *02:23
+++-----+	+++--++-	+-----	-----	*01:06, *02:16 = *01:08, *02:16

*01:01:02:01 = *01:01:02:01-01:01:05
*02:02:01 = *02:02:01-02:02:05
*03:01:01 = *03:01:01-03:01:03



101.121-24/04 – including *Taq* pol., IFU-01
 101.121-24u/04u – without *Taq* pol., IFU-02

Visit www.olerup-ssp.com for
 “Instructions for Use” (IFU)

Lot No.: **94S**

Lot-specific information

www.olerup-ssp.com

SPECIFICITY TABLE

DRB3 SSP subtyping

Specificities and sizes of the PCR products of the 32 primer mixes used for DRB3 SSP subtyping

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified DRB3 alleles ³	Amplified DRB1 ⁴ alleles
1⁵	100 bp	515 bp	*01:01:02:01-01:08, 01:10-01:13, 01:15, 02:05, 03:01:01-03:01:03, 03:03	03:42, 03:87, 11:30 ^w , 13:67, 14:46
2⁵	125 bp	430 bp	*01:01:02:01-01:06, 01:08, 01:10-01:14, 03:01:01-03:01:03, 03:03	03:38, 03:79, 04:82 ^w , 04:99 ^w , 08:07 ^w , 08:19 ^w , 08:25 ^w , 08:34 ^w , 08:52 ^w , 12:27 ^w , 13:31 ^w , 13:46 ^w , 13:54 ^w , 13:77 ^w , 13:100 ^w , 13:162 ^w , 14:48 ^w
3⁵	95 bp	430 bp	*01:01:02:01-01:02, 01:04-01:08, 01:10-01:13, 01:15	03:42
4	265 bp	430 bp	*01:02	
5^{5,9}	95 bp, 125 bp	430 bp	*01:03, 01:10	14:46
6	190 bp	430 bp	*01:04	
7^{5,10}	90 bp, 180 bp	515 bp	*01:05, 01:07, 01:15	03:42, 14:46
8⁵	120 bp	430 bp	*01:06, 01:08	03:42, 14:46
9⁶	165 bp	430 bp	*01:07, 02:01-02:08, 02:11-02:29N	14:141
10⁶	185 bp	515 bp	*01:09, 02:01-02:04, 02:06-02:14, 02:15 ^w , 02:16-02:26, 02:27 ^w , 02:28-02:29N, 03:02	08:32 ^w , 12:01:02 ^w -12:01:03 ^w , 12:02:02 ^w , 12:03:02 ^w , 12:16:01 ^w , 12:22 ^w , 14:121 ^w , 14:141, 15:03:01:01 ^w -15:03:02 ^w , 15:23 ^w , 15:54 ^w , 15:57 ^w , 15:78 ^w , 15:94 ^w
11⁷	270 bp	515 bp	*02:01, 02:04, 02:24, 03:01:01-03:02	03:42, 03:87
12^{5,11}	90 bp, 145 bp	515 bp	*02:01, 02:04, 02:17, 02:24	03:37, 03:80, 11:43, 11:50, 11:115, 12:34,

101.121-24/04 – including *Taq* pol., IFU-01
 101.121-24u/04u – without *Taq* pol., IFU-02

Visit www.olerup-ssp.com for
 “Instructions for Use” (IFU)

Lot No.: **94S**

Lot-specific information

www.olerup-ssp.com

				13:131, 13:150, 14:59, 14:86, 14:96, 15:65
13⁶	270 bp	515 bp	*01:01:02:01-01:13, 01:15, 02:02:01:01- 02:03, 02:05-02:13, 02:15-02:23, 02:25- 02:29N, 03:03	11:30, 13:67, 14:46, 14:141
14	185 bp	515 bp	*01:07, 01:09, 02:02:01:01- 02:02:05, 02:05- 02:13, 02:15-02:19, 02:21-02:23, 02:25- 02:29N	10:01:01 ^w -10:01:04 ^w , 10:03 ^w -10:06 ^w , 14:141
15^{5,12}	120 bp, 180 bp, 210 bp	430 bp	*02:03, 02:16-02:17, 03:01:01-03:03	
16	150 bp	430 bp	*01:09, 02:04, 02:19, 02:22	03:44
17^{5,13}	120 bp, 180 bp	430 bp	*01:08, 02:06, 02:16, 02:20, 02:23	03:42, 03:87, 13:67, 14:46
18⁵	100 bp	430 bp	*01:09, 02:07, 02:09, 02:21	
19^{7,14}	180 bp, 270 bp	515 bp	*02:08, 02:14, 02:18, 02:23	11:30
20⁷	170 bp	430 bp	*01:01:02:01-01:06, 01:08-01:13, 01:15, 02:09-02:10, 02:16, 03:01:01-03:03	03:42, 03:87, 11:30, 13:67, 14:46
21^{5,15}	120 bp, 210 bp	430 bp	*01:13, 02:11	
22¹⁶	185 bp, 245 bp	430 bp	*01:11, 02:12	
23	195 bp	430 bp	*02:13	
24	185 bp	430 bp	*02:09, 02:18-02:19, 02:21, 02:25, 03:01:01-03:03	11:30
25¹⁷	225 bp, 260 bp	430 bp	*01:12, 02:26	
26	235 bp	430 bp	*01:14	03:01:02, 03:02:02, 03:05:03, 03:13:02, 03:17, 03:24, 03:27, 03:35, 03:81, 11:27:01, 11:84:01, 11:124, 11:136, 11:138, 12:22, 13:33:02-13:33:03,

101.121-24/04 – including *Taq* pol., IFU-01
 101.121-24u/04u – without *Taq* pol., IFU-02

Visit www.olerup-ssp.com for
 “Instructions for Use” (IFU)

Lot No.: **94S**

Lot-specific information

www.olerup-ssp.com

				www.olerup-ssp.com
				13:61:01, 13:94:02, 13:96:02, 14:38, 14:47, 14:50, 14:98, 14:127:01
27⁵	90 bp	430 bp	*02:01	
28	235 bp	430 bp	*02:27	11:30, 13:67, 14:46
29⁸	160 bp	430 bp	*02:15, 02:27	10:01:01 ^w -10:06 ^w , 13:106
30	210 bp	430 bp	*02:28	
31⁵	80 bp	430 bp	*02:19, 02:21, 02:25, 02:29N	12:34
32⁸	240 bp	430 bp		11:13:01-11:13:02, 13:08, 14:01:01, 14:01:02 [?] -14:01:03 [?] , 14:04-14:05:01, 14:05:02 [?] -14:05:04 [?] , 14:07:01, 14:07:02 [?] - 14:09 [?] , 14:10-14:11, 14:12:01 [?] -14:12:02 [?] , 14:14, 14:15 [?] -14:20 [?] , 14:22 [?] -14:23:03 [?] , 14:24 [?] -14:32:02 [?] , 14:33 [?] -14:45 [?] , 14:47 [?] -14:53 [?] , 14:54:01-14:54:02, 14:55 [?] -14:56 [?] , 14:57, 14:58 [?] -14:65 [?] , 14:67 [?] -14:81 [?] , 14:82, 14:83 [?] -14:127:01 [?] , 14:128 [?] -14:131 [?] , 14:137N, 14:141

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 typings.

When the primers in a primer mix can give rise to HLA-specific PCR products of more than one length this is indicated if the size difference is more than 20 base pairs. Size differences of 20 base pairs or less are not given. For high resolution SSP kits the respective lengths of the HLA-specific PCR product(s) are given for the alleles amplified by these primer mixes.

Nonspecific amplifications, i.e. a ladder or a smear of bands, may sometimes be seen. GC-rich primers have a higher tendency of giving rise to nonspecific amplifications than other primers.

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

PCR fragments migrating faster than the control bands, but slower than a 400 bp fragment may be seen in some gel read-outs. Such bands can be disregarded and do not influence the interpretation of the SSP typings.

Some primers may give rise to primer oligomer artifacts. Sometimes this phenomenon is an inherent feature of the primer pair(s) of a primer mix. More often it is due to other factors such as too low amount of DNA in the PCR reactions, taking too long time in setting up the PCR reactions, working at elevated room temperature or using thermal cyclers that are not pre-heated.

101.121-24/04 – including *Taq* pol., IFU-01
101.121-24u/04u – without *Taq* pol., IFU-02

Visit www.olerup-ssp.com for
“Instructions for Use” (IFU)

Lot No.: 94S**Lot-specific information****www.olerup-ssp.com**

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 wells, or a band of 515 base pairs, for some wells.

Well 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, wells number 7, 10 to 14 and 19 contain the primer pair giving rise to the longer, 515 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.

³For several DRB alleles 1st and/or 3th exon(s) and above, as well as intron nucleotide sequences, are not 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 these regions 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 to 3, 5, 7 to 14, 16, 17, 19, 20, 24, 26, 28, 29 and 31 to 32 will amplify DRB1 alleles.

⁵HLA-specific PCR products shorter than 125 base pairs have a lower intensity and are less sharp than longer PCR products.

⁶Primer mixes 9, 10 and 13 may have tendencies of unspecific amplifications.

⁷Primer mix 11, 19 and 20 have a tendency to giving rise to primer oligomer formation.

⁸Primer mixes 29 and 32 may give rise to a lower yield of HLA-specific PCR product than the other DRB3 primer mixes.

⁹Primer mix 5: Specific PCR fragment of 95 bp in the DRB3*01:03 and the DRB1*14:46 alleles. Specific PCR fragment of 125 bp in the DRB3*01:10 allele.

¹⁰Primer mix 7: Specific PCR fragment of 90 bp in the DRB3*01:05 allele. Specific PCR fragment of 180 bp in the DRB3*01:07 and 01:15 and in the DRB1*03:42 and DRB1*14:46 alleles.

¹¹Primer mix 12: Specific PCR fragment of 90 bp in the DRB3*02:17 allele. Specific PCR fragment of 145 bp in the DRB3*02:01, 02:04 and 02:24 and in the DRB1*03:37, DRB1*03:80, DRB1*11:43, DRB1*11:50, DRB1*11:115, DRB1*12:34, DRB1*13:131, DRB1*13:150, DRB1*14:59, DRB1*14:86, DRB1*14:96 and DRB1*15:65 alleles.

¹²Primer mix 15: Specific PCR fragment of 120 bp DRB3*02:03 and 03:01:01-03:03 alleles. Specific PCR fragment of 180 bp in the DRB3*02:16 allele. Specific PCR fragment of 210 bp in the DRB3*02:17 allele.

¹³Primer mix 17: Specific PCR fragment of 120 bp in the DRB3*01:08, 02:06 and 02:20 and the DRB1*03:42, DRB1*03:87, DRB1*13:67 and DRB1*14:46 alleles. Specific PCR fragment of 180 bp in the DRB3*02:16 and 02:23 alleles.

¹⁴Primer mix 19: Specific PCR fragment of 180 bp in the DRB3*02:08, 02:18 and 02:23 and the DRB1*11:30 alleles. Specific PCR fragment of 270 bp in the DRB3*02:14 allele.

¹⁵Primer mix 21: Specific PCR fragment of 120 bp in the DRB3*01:13 allele. Specific PCR fragment of 210 bp in the DRB3*02:11 allele.

¹⁶Primer mix 22: Specific PCR fragment of 185 bp in the DRB3*01:11 allele. Specific PCR fragment of 245 bp in the DRB3*02:12 allele.

¹⁷Primer mix 25: Specific PCR fragment of 225 bp in the DRB3*02:26 allele. Specific PCR fragment of 260 bp in the DRB3*01:12 allele.

‘w’, might be weakly amplified.

101.121-24/04 – including *Taq* pol., IFU-01
 101.121-24u/04u – without *Taq* pol., IFU-02

Visit www.olerup-ssp.com for
 “Instructions for Use” (IFU)

Lot No.: 94S

Lot-specific information

www.olerup-ssp.com

INTERPRETATION TABLE																
DRB3 SSP subtyping																
Amplification patterns of the DRB3*01:01 to *03:03 alleles																
	Well ⁵															
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Length of spec. PCR product(s)	100	125	95	265	95	190	90	120	165	185	270	90	270	185	120	150
					125		180					145			180	
															210	
Length of int. pos. control ¹	515	430	430	430	430	430	515	430	430	515	515	515	515	515	430	430
5'-primer(s) ²	5'-gCT ³ 10(116)	5'-gAT ³ 29(175)	5'-gCG ³ 11(119)	5'-TgT ³ 10(118)	5'-gCg ³ 11(119)	5'-CTC ³ 8(110)	5'-gCg ³ 11(119)	5'-gCg ³ 11(119)	5'-gCT ³ 10(116)	5'-gAC ³ 29(175)	5'-gCT ³ 10(116)	5'-gAg ³ 51(239)	5'-gCT ³ 10(116)	5'-CgC ³ 38(200)	5'-gCT ³ 11(119)	5'-CgC ³ 38(200)
			5'-gTg ³ 11(119)						5'-gCT ³ 10(116)				5'-gCT ³ 10(116)	5'-CgC ³ 38(200)		
3'-primer(s) ³	5'-gTA ³ 29(175)	5'-CgA ³ 57(257)	5'-CTg ³ 28(171)	5'-CAC ³ 86(344)	5'-CTC ³ 28(171)	5'-CgA ³ 57(257)	5'-gTT ³ 27(169)	5'-CAC ³ 37(199)	5'-CCC ³ 51(239)	5'-AgT ³ 77(317)	5'-CCA ³ 86(344)	5'-gAA ³ 66(286)	5'-CAC ³ 86(344)	5'-CAC ³ 86(344)	5'-Cgg ³ 37(197)	5'-CCC ³ 74(308)
	5'-gTA ³ 29(175)	5'-CAA ³ 57(257)	5'-ATg ³ 28(171)		5'-gCT ³ 38(202)		5'-CAT ³ 57(257)			5'-TAA ³ 77(318)		5'-CCA ³ 86(344)			5'-CgA ³ 37(197)	
															5'-gAA ³ 66(286)	
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16

101.121-24/04 – including *Taq* pol., IFU-01
 101.121-24u/04u – without *Taq* pol., IFU-02

Visit www.olerup-ssp.com for
 “Instructions for Use” (IFU)

Lot No.: **94S**

Lot-specific information

www.olerup-ssp.com

Length of spec.	100	125	95	265	95	190	90	120	165	185	270	90	270	185	120	150
PCR product					125		180					145			180	
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
DRB3 allele ⁴																
*01:01:02:01-01:01:05	1	2	3										13			
*01:02	1	2	3	4									13			
*01:03	1	2			5								13			
*01:04	1	2	3			6							13			
*01:05	1	2	3				7						13			
*01:06	1	2	3					8					13			
*01:07	1		3				7		9				13	14		
*01:08	1	2	3					8					13			
*01:09										10			13	14		16
*01:10	1	2	3		5								13			
*01:11	1	2	3										13			
*01:12	1	2	3										13			
*01:13	1	2	3										13			
*01:14		2														
*01:15	1		3				7						13			
*02:01									9	10	11	12				
*02:02:01:01-02:02:05									9	10			13	14		
*02:03									9	10			13		15	
*02:04									9	10	11	12				16
*02:05	1								9				13	14		
*02:06									9	10			13	14		
*02:07									9	10			13	14		
*02:08									9	10			13	14		
*02:09										10			13	14		
*02:10										10			13	14		
*02:11									9	10			13	14		
*02:12									9	10			13	14		
*02:13									9	10			13	14		
*02:14									9	10						
*02:15									9	w			13	14		
*02:16									9	10			13	14	15	
*02:17									9	10		12	13	14	15	
*02:18									9	10			13	14		
*02:19									9	10			13	14		16
*02:20									9	10			13			
*02:21									9	10			13	14		
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16

101.121-24/04 – including *Taq* pol., IFU-01
 101.121-24u/04u – without *Taq* pol., IFU-02

Visit www.olerup-ssp.com for
 “Instructions for Use” (IFU)

Lot No.: **94S**

Lot-specific information

www.olerup-ssp.com

120	100	180	170	120	185	195	185	225	235	90	235	160	210	80	240	Length of spec. PCR product
180		270		210	245			260								
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Well No. DRB3 allele ⁴
			20													*01:01:02:01- 01:01:05
			20													*01:02
			20													*01:03
			20													*01:04
			20													*01:05
			20													*01:06
			20													*01:07
17			20													*01:08
	18		20													*01:09
			20													*01:10
			20		22											*01:11
			20					25								*01:12
			20	21												*01:13
			20						26							*01:14
			20													*01:15
										27						*02:01
																*02:02:01:01- 02:02:05
																*02:03
																*02:04
																*02:05
17																*02:06
	18															*02:07
		19														*02:08
	18		20				24									*02:09
			20													*02:10
				21												*02:11
					22											*02:12
						23										*02:13
		19														*02:14
												29				*02:15
17			20													*02:16
																*02:17
		19					24									*02:18
							24							31		*02:19
17																*02:20
	18						24							31		*02:21
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Well No.

101.121-24/04 – including *Taq* pol., IFU-01
 101.121-24u/04u – without *Taq* pol., IFU-02

Visit www.olerup-ssp.com for
 “Instructions for Use” (IFU)

Lot No.: **94S**

Lot-specific information

www.olerup-ssp.com

Length of spec.	100	125	95	265	95	190	90	120	165	185	270	90	270	185	120	150
PCR product					125		180					145			180	
															210	
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
*02:22									9	10			13	14		16
*02:23									9	10			13	14		
*02:24									9	10	11	12				
*02:25									9	10			13	14		
*02:26									9	10			13	14		
*02:27									9	w			13	14		
*02:28									9	10			13	14		
*02:29N									9	10			13	14		
*03:01:01- 03:01:03	1	2									11				15	
*03:02										10	11				15	
*03:03	1	2											13		15	
<i>DRB1</i> *03:01:02, <i>03:02:02</i> , <i>03:05:03</i> , <i>03:13:02</i> , <i>03:17</i> , <i>03:24</i> , <i>03:27</i> , <i>03:35</i> , <i>03:81</i> , <i>DRB1</i> *11:27:01, <i>11:84:01</i> , <i>11:124</i> , <i>11:136</i> , <i>11:138</i> , <i>DRB1</i> *13:33:02- <i>13:33:03</i> , <i>13:61:01</i> , <i>13:94:02</i> , <i>13:96:02</i>																
<i>DRB1</i> *03:37, <i>03:80</i> , <i>DRB1</i> *11:43, <i>11:50</i> , <i>11:115</i> , <i>DRB1</i> *13:131, <i>13:150</i> , <i>DRB1</i> *15:65												12				
<i>DRB1</i> *03:38, <i>03:79</i>		2														
<i>DRB1</i> *03:42	1		3				7	8			11					
<i>DRB1</i> *03:44																16
<i>DRB1</i> *03:87	1										11					
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16

101.121-24/04 – including *Taq* pol., IFU-01
 101.121-24u/04u – without *Taq* pol., IFU-02

Visit www.olerup-ssp.com for
 “Instructions for Use” (IFU)

Lot No.: **94S**

Lot-specific information

www.olerup-ssp.com

120	100	180	170	120	185	195	185	225	235	90	235	160	210	80	240	Length of spec. PCR product
180		270		210	245			260								
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Well No.
																*02:22
17		19														*02:23
																*02:24
							24							31		*02:25
								25								*02:26
										28	29					*02:27
													30			*02:28
														31		*02:29N
			20				24									*03:01:01- 03:01:03
			20				24									*03:02
			20				24									*03:03
										26						<i>DRB1*03:01:02,</i> <i>03:02:02,</i> <i>03:05:03,</i> <i>03:13:02, 03:17,</i> <i>03:24, 03:27,</i> <i>03:35, 03:81,</i> <i>DRB1*11:27:01,</i> <i>11:84:01, 11:124,</i> <i>11:136, 11:138,</i> <i>DRB1*13:33:02-</i> <i>13:33:03,</i> <i>13:61:01,</i> <i>13:94:02,</i> <i>13:96:02</i>
																<i>DRB1*03:37,</i> <i>03:80,</i> <i>DRB1*11:43,</i> <i>11:50, 11:115,</i> <i>DRB1*13:131,</i> <i>13:150,</i> <i>DRB1*15:65</i>
																<i>DRB1*03:38,</i> <i>03:79</i>
17			20													<i>DRB1*03:42</i>
																<i>DRB1*03:44</i>
17			20													<i>DRB1*03:87</i>
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Well No.

101.121-24/04 – including *Taq* pol., IFU-01
 101.121-24u/04u – without *Taq* pol., IFU-02

Visit www.olerup-ssp.com for
 “Instructions for Use” (IFU)

Lot No.: **94S**

Lot-specific information

www.olerup-ssp.com

Length of spec.	100	125	95	265	95	190	90	120	165	185	270	90	270	185	120	150
PCR product					125		180					145			180	
															210	
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
<i>DRB1*04:82, 04:99, DRB1*08:07, 08:19, 08:25, 08:34, 08:52, DRB1*12:27, DRB1*13:31, 13:46, 13:54, 13:77, 13:100, 13:162</i>		w														
<i>DRB1*08:32, DRB1*12:01:02-12:01:03, 12:02:02, 12:03:02, 12:16:01, DRB1*15:03:01:01-15:03:02, 15:23, 15:54, 15:57, 15:78, 15:94</i>										w						
<i>DRB1*10:01:01-10:01:04, 10:03-10:06</i>														w		
<i>DRB1*10:02</i>																
<i>DRB1*11:13:01-11:13:02, DRB1*13:08, DRB1*14:01:01, 14:04-14:05:01, 14:07:01, 14:10-14:11, 14:14, 14:54:01-14:54:02, 14:57, 14:82, 14:137N</i>																
<i>DRB1*11:30</i>	w												13			
<i>DRB1*12:22</i>										w						
<i>DRB1*12:34</i>												12				
<i>DRB1*13:67</i>	1												13			
<i>DRB1*13:106</i>																
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16

101.121-24/04 – including *Taq* pol., IFU-01
 101.121-24u/04u – without *Taq* pol., IFU-02

Visit www.olerup-ssp.com for
 “Instructions for Use” (IFU)

Lot No.: **94S**

Lot-specific information

www.olerup-ssp.com

120	100	180	170	120	185	195	185	225	235	90	235	160	210	80	240	Length of spec. PCR product
180		270		210	245			260								
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Well No.
																<i>DRB1*04:82,</i> <i>04:99,</i> <i>DRB1*08:07,</i> <i>08:19, 08:25,</i> <i>08:34, 08:52,</i> <i>DRB1*12:27,</i> <i>DRB1*13:31,</i> <i>13:46, 13:54,</i> <i>13:77, 13:100,</i> <i>13:162</i>
																<i>DRB1*08:32,</i> <i>DRB1*12:01:02-</i> <i>12:01:03,</i> <i>12:02:02,</i> <i>12:03:02,</i> <i>12:16:01,</i> <i>DRB1*15:03:01:0</i> <i>1-15:03:02, 15:23,</i> <i>15:54, 15:57,</i> <i>15:78, 15:94</i>
												w				<i>DRB1*10:01:01-</i> <i>10:01:04, 10:03-</i> <i>10:06</i>
												w				<i>DRB1*10:02</i>
															32	<i>DRB1*11:13:01-</i> <i>11:13:02,</i> <i>DRB1*13:08,</i> <i>DRB1*14:01:01,</i> <i>14:04-14:05:01,</i> <i>14:07:01, 14:10-</i> <i>14:11, 14:14,</i> <i>14:54:01-</i> <i>14:54:02, 14:57,</i> <i>14:82, 14:137N</i>
		19	20				24				28					<i>DRB1*11:30</i>
									26							<i>DRB1*12:22</i>
														31		<i>DRB1*12:34</i>
17			20								28					<i>DRB1*13:67</i>
												29				<i>DRB1*13:106</i>
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Well No.

101.121-24/04 – including *Taq* pol., IFU-01
 101.121-24u/04u – without *Taq* pol., IFU-02

Visit www.olerup-ssp.com for
 “Instructions for Use” (IFU)

Lot No.: **94S**

Lot-specific information

www.olerup-ssp.com

Length of spec.	100	125	95	265	95	190	90	120	165	185	270	90	270	185	120	150
PCR product					125		180					145			180	
															210	
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
DRB1*14:01:02-14:01:04, 14:05:02-14:05:04, 14:07:02-14:09, 14:12:01-14:12:02, 14:15-14:20, 14:22-14:37, 14:39-14:45, 14:49, 14:51-14:53, 14:55-14:56, 14:58, 14:60-14:65, 14:67-14:81, 14:83-14:85, 14:87-14:95, 14:97, 14:99-14:120, 14:122-14:126, 14:127:02-14:136, 14:138-14:140, 14:142																
DRB1*14:38, 14:47, 14:50, 14:98, 14:127:01																
DRB1*14:46	1				5		7	8					13			
DRB1*14:48		w														
DRB1*14:59, 14:86, 14:96												12				
DRB1*14:121										w						
DRB1*14:141									9	10			13	14		
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16

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 wells, or a band of 515 base pairs, for some wells.

Well 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, wells number wells number 7, 10 to 14 and 19 contain the primer pair giving rise to the longer, 515 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.

101.121-24/04 – including *Taq* pol., IFU-01
 101.121-24u/04u – without *Taq* pol., IFU-02

Visit www.olerup-ssp.com for
 “Instructions for Use” (IFU)

Lot No.: **94S**

Lot-specific information

www.olerup-ssp.com

120	100	180	170	120	185	195	185	225	235	90	235	160	210	80	240	Length of spec. PCR product
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Well No.
																<i>DRB1*14:01:02-14:01:04, 14:05:02-14:05:04, 14:07:02-14:09, 14:12:01-14:12:02, 14:15-14:20, 14:22-14:37, 14:39-14:45, 14:49, 14:51-14:53, 14:55-14:56, 14:58, 14:60-14:65, 14:67-14:81, 14:83-14:85, 14:87-14:95, 14:97, 14:99-14:120, 14:122-14:126, 14:127:02-14:136, 14:138-14:140, 14:142</i>
									26						?	<i>DRB1*14:38, 14:47, 14:50, 14:98, 14:127:01</i>
17			20								28					<i>DRB1*14:46</i>
															?	<i>DRB1*14:48</i>
															?	<i>DRB1*14:59, 14:86, 14:96</i>
															?	<i>DRB1*14:121</i>
															32	<i>DRB1*14:141</i>
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Well No.

²The codon, and in parenthesis the nucleotide, in the 2nd and 3rd exon, matching the specificity-determining 3'-end of the primer is given. Codon and nucleotide numbering as on the www.ebi.ac.uk/imgt/hla web site. The sequence of the 3 terminal nucleotides of the primer is given.

³The codon, and in parenthesis the nucleotide, in the 2nd and 3rd exon, matching the specificity-determining 3'-end of the primer is given in the anti-sense direction. Codon and 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.

⁴DRB3*010101 allele has been shown to be identical to DRB3*01:01:02:01

101.121-24/04 – including *Taq* pol., IFU-01
101.121-24u/04u – without *Taq* pol., IFU-02

Visit www.olerup-ssp.com for
“Instructions for Use” (IFU)

Lot No.: **94S**

Lot-specific information

www.olerup-ssp.com

⁵Primer mix 5: Specific PCR fragment of 95 bp in the DRB3*01:03 and the DRB1*14:46 alleles. Specific PCR fragment of 125 bp in the DRB3*01:10 allele.

Primer mix 7: Specific PCR fragment of 90 bp in the DRB3*01:05 allele. Specific PCR fragment of 180 bp in the DRB3*01:07 and 01:15 and in the DRB1*03:42 and DRB1*14:46 alleles.

Primer mix 12: Specific PCR fragment of 90 bp in the DRB3*02:17 allele. Specific PCR fragment of 145 bp in the DRB3*02:01, 02:04 and 02:24 and in the DRB1*03:37, DRB1*03:80, DRB1*11:43, DRB1*11:50, DRB1*11:115, DRB1*12:34, DRB1*13:131, DRB1*13:150, DRB1*14:59, DRB1*14:86, DRB1*14:96 and DRB1*15:65 alleles.

Primer mix 15: Specific PCR fragment of 120 bp DRB3*02:03 and 03:01:01-03:03 alleles. Specific PCR fragment of 180 bp in the DRB3*02:16 allele. Specific PCR fragment of 210 bp in the DRB3*02:17 allele.

Primer mix 17: Specific PCR fragment of 120 bp in the DRB3*01:08, 02:06 and 02:20 and the DRB1*03:42, DRB1*03:87, DRB1*13:67 and DRB1*14:46 alleles. Specific PCR fragment of 180 bp in the DRB3*02:16 and 02:23 alleles.

Primer mix 19: Specific PCR fragment of 180 bp in the DRB3*02:08, 02:18 and 02:23 and the DRB1*11:30 alleles. Specific PCR fragment of 270 bp in the DRB3*02:14 allele.

Primer mix 21: Specific PCR fragment of 120 bp in the DRB3*01:13 allele. Specific PCR fragment of 210 bp in the DRB3*02:11 allele.

Primer mix 22: Specific PCR fragment of 185 bp in the DRB3*01:11 allele. Specific PCR fragment of 245 bp in the DRB3*02:12 allele.

Primer mix 25: Specific PCR fragment of 225 bp in the DRB3*02:26 allele. Specific PCR fragment of 260 bp in the DRB3*01:12 allele.

'w', might be weakly amplified.

101.121-24/04 – including *Taq* pol., IFU-01
 101.121-24u/04u – without *Taq* pol., IFU-02

Visit www.olerup-ssp.com for
 “Instructions for Use” (IFU)

Lot No.: **94S**

Lot-specific information

www.olerup-ssp.com

CELL LINE VALIDATION SHEET																			
DRB3 SSP subtyping kit																			
			Prod. No.	Well															
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
	IHCW cell line	DRB3		201190801	201080502	201080503	201080504	201080505	201080506	201190807	201080508	201080509	201080510	201080511	201080512	201080513	201080514	201080515	201190816
1	9001 SA			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2	9280 LK707			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3	9011 E4181324			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4	9275 GU373	*02:02		-	-	-	-	-	-	-	-	+	+	-	-	+	+	-	-
5	9009 KAS011			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
6	9353 SM			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
7	9020 QBL	*02:02		-	-	-	-	-	-	-	-	+	+	-	-	+	+	-	-
8	9025 DEU			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
9	9026 YAR			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
10	9107 LKT3			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
11	9051 PITOUT			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
12	9052 DBB			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
13	9004 JESTHOM			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
14	9071 OLGA			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
15	9075 DKB			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
16	9037 SWEIG007	*02:02		-	-	-	-	-	-	-	-	+	+	-	-	+	+	-	-
17	9282 CTM3953540	*01:01		+	+	+	-	-	-	-	-	-	-	-	-	+	-	-	-
18	9257 32367	*02:02		-	-	-	-	-	-	-	-	+	+	-	-	+	+	-	-
19	9038 BM16	*02:02		-	-	-	-	-	-	-	-	+	+	-	-	+	+	-	-
20	9059 SLE005	*03:01		+	+	-	-	-	-	-	-	-	-	+	-	-	-	+	-
21	9064 AMALA	*01:01		+	+	+	-	-	-	-	-	-	-	-	-	+	-	-	-
22	9056 KOSE	*02:02	*03:01	+	+	-	-	-	-	-	-	+	+	+	-	+	+	+	-
23	9124 IHL	*02:02		-	-	-	-	-	-	-	-	+	+	-	-	+	+	-	-
24	9035 JBUSH	*02:02		-	-	-	-	-	-	-	-	+	+	-	-	+	+	-	-
25	9049 IBW9			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
26	9285 WT49	*02:02		-	-	-	-	-	-	-	-	+	+	-	-	+	+	-	-
27	9191 CH1007 ²			-	-	-	-	-	-	-	-	-	-	-	-	-	w	-	-
28	9320 BEL5GB			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
29	9050 MOU			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
30	9021 RSH	*01:01		+	+	+	-	-	-	-	-	-	-	-	-	+	-	-	-
31	9019 DUCAF	*02:02		-	-	-	-	-	-	-	-	+	+	-	-	+	+	-	-
32	9297 HAG	*01:01		+	+	+	-	-	-	-	-	-	-	-	-	+	-	-	-
33	9098 MT14B			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
34	9104 DHIF	*02:02		-	-	-	-	-	-	-	-	+	+	-	-	+	+	-	-
35	9302 SSTO			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
36	9024 KT17			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
37	9065 HHKB	*01:01		+	+	+	-	-	-	-	-	-	-	-	-	+	-	-	-
38	9099 LZL	*01:01		+	+	+	-	-	-	-	-	-	-	-	-	+	-	-	-
39	9315 CML	*01:01		+	+	+	-	-	-	-	-	-	-	-	-	+	-	-	-
40	9134 WHONP199			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
41	9055 H0301	*03:01		+	+	-	-	-	-	-	-	-	-	+	-	-	-	+	-
42	9066 TAB089			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
43	9076 T7526			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
44	9057 TEM ¹	*02:24		-	-	-	-	-	-	-	-	+	+	+	+	-	-	-	-
45	9239 SHJO			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
46	9013 SCHU			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
47	9045 TUBO	*02:02		-	-	-	-	-	-	-	-	+	+	-	-	+	+	-	-
48	9303 TER-ND			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

¹Cell line TEM, IHW 9057, is profiled as DRB3*02:01 by ECACC ((European Collection of Cell Cultures)). However, Olerup SSP AB has shown that this cell line includes the exon 3 polymorphism corresponding to DRB3*02:24.

²The DRB1*10:01 allele is weakly amplified by primer mix 14 in the CH1007 cell line.

101.121-24/04 – including *Taq* pol., IFU-01
 101.121-24u/04u – without *Taq* pol., IFU-02

Visit www.olerup-ssp.com for
 “Instructions for Use” (IFU)

Lot No.: **94S**

Lot-specific information

www.olerup-ssp.com

		CELL LINE VALIDATION SHEET																	
		DRB3 SSP subtyping kit																	
		Well ²																	
	IHWC cell line	DRB3	Prod. No.	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32
				201080517	201080518	201080519	201080520	201080521	201209822	201209823	201080524	201190825	201080526	201080527	201190828	201190829	201190830	201325531	201325532
1	9001 SA			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2	9280 LK707			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3	9011 E4181324			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4	9275 GU373	*02:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
5	9009 KAS011			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
6	9353 SM			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
7	9020 QBL	*02:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
8	9025 DEU			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
9	9026 YAR			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
10	9107 LKT3			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
11	9051 PITOUT			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
12	9052 DBB			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
13	9004 JESTHOM			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
14	9071 OLGA			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
15	9075 DKB			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
16	9037 SWEIG007	*02:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
17	9282 CTM3953540	*01:01		-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-
18	9257 32367	*02:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
19	9038 BM16	*02:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
20	9059 SLE005	*03:01		-	-	-	+	-	-	-	+	-	-	-	-	-	-	-	-
21	9064 AMALA	*01:01		-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-
22	9056 KOSE	*02:02	*03:01	-	-	-	+	-	-	-	+	-	-	-	-	-	-	-	+
23	9124 IHL	*02:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+
24	9035 JBUSH	*02:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
25	9049 IBW9			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
26	9285 WT49	*02:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
27	9191 CH1007			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
28	9320 BEL5GB			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
29	9050 MOU			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
30	9021 RSH	*01:01		-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-
31	9019 DUCAF	*02:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
32	9297 HAG	*01:01		-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-
33	9098 MT14B			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
34	9104 DHIF	*02:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
35	9302 SSTO			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
36	9024 KT17			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
37	9065 HHKB	*01:01		-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-
38	9099 LZL	*01:01		-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-
39	9315 CML	*01:01		-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-
40	9134 WHONP199			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
41	9055 H0301	*03:01		-	-	-	+	-	-	-	+	-	-	-	-	-	-	-	-
42	9066 TAB089			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
43	9076 T7526			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
44	9057 TEM ¹	*02:24		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+
45	9239 SHJO			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
46	9013 SCHU			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
47	9045 TUBO	*02:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
48	9303 TER-ND			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

¹Cell line TEM, IHW 9057, is profiled as DRB3*02:01 by ECACC ((European Collection of Cell Cultures)). However, Olerup SSP AB has shown that this cell line includes the exon 3 polymorphism corresponding to DRB3*02:24.

²Primer mix 32 amplifies DRB1*14 alleles in the KOSE, IHL and TEM cell lines.

101.121-24/04 – including *Taq* pol., IFU-01
 101.121-24u/04u – without *Taq* pol., IFU-02

Visit www.olerup-ssp.com for
 “Instructions for Use” (IFU)

Lot No.: **94S**

Lot-specific information

www.olerup-ssp.com

CERTIFICATE OF ANALYSIS

Olerup SSP® DRB3 SSP

Product number: 101.121-24/04 – including *Taq* pol.
 101.121-24u/04u – without *Taq* pol.

Lot number: 94S

Expiry date: 2016-April-01

Number of tests: 24 tests – Product No. 101.121-24/24u
 4 tests – Product No. 101.121-04/04u

Number of wells per test: 32

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2011-908-01	13	2010-805-13	25	2011-908-25
2	2010-805-02	14	2010-805-14	26	2010-805-26
3	2010-805-03	15	2010-805-15	27	2010-805-27
4	2010-805-04	16	2011-908-16	28	2011-908-28
5	2010-805-05	17	2010-805-17	29	2011-908-29
6	2010-805-06	18	2010-805-18	30	2011-908-30
7	2011-908-07	19	2010-805-19	31	2013-255-31
8	2010-805-08	20	2010-805-20	32	2013-255-32
9	2010-805-09	21	2010-805-21		
10	2010-805-10	22	2012-098-22		
11	2010-805-11	23	2012-098-23		
12	2010-805-12	24	2010-805-24		

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, 21 to 23 and 25 to 31 were available. The specificities of the primers in primer solutions 5, 7, 8, 16 to 19, 21, 22, 25, 26, 28, 29 and 31 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer solutions 4, 6, 23, 27 and 30 it was only possible to test the 3'-primer, the 5'-primer was not possible to test. One or two of the 3'-primers in primer solutions 1 to 3, 5, 7, 12, 15, 17, 19, 21, 25 and 31 were not possible to test. In primer solutions 2, 3 and 22 one of the 5'-primers was not possible to test. Additional 3'-primers in primer solutions 15, 20 and 24 were tested by separately adding one 5'-primer.

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

Date of approval: 2013- October-30

Approved by:

Production Quality Control

101.121-24/04 – including *Taq* pol., IFU-01
101.121-24u/04u – without *Taq* pol., IFU-02

Visit www.olerup-ssp.com for
“Instructions for Use” (IFU)

Lot No.: **94S**

Lot-specific information

www.olerup-ssp.com

Declaration of Conformity

Product name: *Olerup* SSP® DRB3
Product number: 101.121-24/24u, -04/04u
Lot number: 94S

Intended use: DRB3 high resolution histocompatibility testing

Manufacturer: *Olerup* SSP AB
Franzengatan 5
SE-112 51 Stockholm, Sweden
Phone: +46-8-717 88 27
Fax: +46-8-717 88 18

We, *Olerup* SSP AB, hereby declare that this product, to which this Declaration of Conformity relates is in conformity with the following Standard(s) and other normative document(s) ISO 9001:2008 and ISO 13485:2012, following the provisions of the 98/79/EC Directive on *in vitro* diagnostic medical devices, Annex II List B, conformity assessed using Annex IV, as transposed into the national laws of the Member States of the European Union.

The Technical Documentation File is maintained at *Olerup* SSP AB, Franzengatan 5, SE-112 51 Stockholm, Sweden.

Notified Body: Lloyd's Register Quality Assurance Limited, Hiramford, Middlemarch Office Village, Siskin Drive, Coventry CV3 4FJ, United Kingdom. (Notified Body number: 0088.)

Stockholm, Sweden
2013-October-30

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs

101.121-24/04 – including *Taq* pol., IFU-01
101.121-24u/04u – without *Taq* pol., IFU-02

Visit www.olerup-ssp.com for
“Instructions for Use” (IFU)

Lot No.: **94S**

Lot-specific information

www.olerup-ssp.com

101.121-24/04 – including *Taq* pol., IFU-01
101.121-24u/04u – without *Taq* pol., IFU-02

Visit www.olerup-ssp.com for
“Instructions for Use” (IFU)

Lot No.: **94S**

Lot-specific information

www.olerup-ssp.com

101.121-24/04 – including *Taq* pol., IFU-01
101.121-24u/04u – without *Taq* pol., IFU-02

Visit www.olerup-ssp.com for
“Instructions for Use” (IFU)

Lot No.: **94S**

Lot-specific information

www.olerup-ssp.com

101.121-24/04 – including *Taq* pol., IFU-01
101.121-24u/04u – without *Taq* pol., IFU-02

Visit www.olerup-ssp.com for
“Instructions for Use” (IFU)

Lot No.: **94S**

Lot-specific information

www.olerup-ssp.com

ADDRESSES:

Manufacturer:

Olerup SSP AB, Franzengatan 5, SE-112 51 Stockholm, Sweden.

Tel: +46-8-717 88 27

Fax: +46-8-717 88 18

E-mail: info-ssp@olerup.com

Web page: <http://www.olerup-ssp.com>

Distributed by:

Olerup GmbH, Löwengasse 47 / 6, AT-1030 Vienna, Austria.

Tel: +43-1-710 15 00

Fax: +43-1-710 15 00 10

E-mail: support-at@olerup.com

Web page: <http://www.olerup.com>

Olerup Inc., 901 S. Bolmar St., Suite R, West Chester, PA 19382

Tel: 1-877-OLERUP1

Fax: 610-344-7989

E-mail: info.us@olerup.com

Web page: <http://www.olerup.com>

For information on *Olerup* SSP distributors worldwide, contact **Olerup GmbH**.