

101.111-24/06 – including *Taq* pol., IFU-01
101.111-24u/06u – without *Taq* pol., IFU-02

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“Instructions for Use” (IFU)

Lot No.: **91R**

Lot-specific information

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Olerup SSP® DRB1*01

Product number:	101.111-24/06 – including <i>Taq</i> pol. 101.111-24u/06u – without <i>Taq</i> pol.
Lot number:	91R
Expiry date:	2015-August-01
Number of tests:	24 test – Product No. 101.111-24/24u 6 tests – Product No. 101.111-06/06u
Number of wells per test:	24
Storage - pre-aliquoted primers:	dark at -20°C
- PCR Master Mix:	-20°C
- Adhesive PCR seals	RT
- Product Insert	RT

This Product Description is only valid for Lot No. 91R.

CHANGES COMPARED TO THE PREVIOUS OLERUP SSP® DRB1*01 LOT (03R)

The DRB1*01 kit is updated for new alleles to enable separation of:

- Confirmed¹ alleles as listed in the IMGT/HLA database.
- Polymorphisms in exons outside of the region encoding the peptide binding domain.
- Null and Alternatively expressed alleles.

The Lot-specific information for DRB1*01 including and without *Taq* polymerase is now described in one common Product Insert.

¹As described in section Uniquely Identified Alleles.

The DRB1*01 specificity and interpretation tables have been updated for the DRB1 alleles described since the previous *Olerup SSP®* DRB1*01 lot was made (Lot No. 03R).

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

Well	5'-primer	3'-primer	rationale
8	Added	Added	New primer pair for the DRB1*01:50 allele.
10	-	Added	New 3'-primer for the DRB1*01:52N allele.
18	Added	Added	New primer pair for the DRB1*01:50 allele.
22		Added	New 3'-primer for the DRB1*01:52N allele.

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PRODUCT DESCRIPTION

DRB1*01 SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for identifying the DRB1*01:01 to DRB1*01:53 alleles.

PLATE LAYOUT

Each test consists of 24 PCR reactions in a 24 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

The 24 well PCR plate is marked with 'DRB1*01' in silver/gray ink.

Well No. 1 is marked with the Lot No. '91R'.

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

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

Please note: When removing each 24 well PCR plate, make sure that the remaining plates stay covered. Use a scalpel or a similar instrument to carefully cut the foil between the plates.

INTERPRETATION

Only the DRB1*01 alleles will be amplified by the DRB1*01 subtyping kit, except that the DRB1*14:112 will be amplified by primer mix 8. Thus, the interpretation of DRB1*01 subtypings is only marginally influenced by other groups of DRB1 alleles.

UNIQUELY IDENTIFIED ALLELES

All the DRB1*01 alleles, i.e. **DRB1*01:01 to DRB1*01:53**, recognized by the HLA Nomenclature Committee in October 2012¹ will be amplified by the primers in the DRB1*01 subtyping kit.

The DRB1*01 kit enables separation of the confirmed DRB1*01 alleles as listed in the IMGT/HLA database. An HLA allele is listed as confirmed by IMGT/HLA if it has been sequenced by more than a single laboratory or from multiple sources. Current allele confirmation status for DRB1*01 alleles is listed below.

The DRB1*01 kit also enables identification of polymorphisms in exons outside of the region encoding the peptide binding domain and of null and alternatively expressed alleles.

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The DRB1*01 primer set cannot distinguish the silent mutations in DRB1*01:01:01-01:01:23 alleles, the DRB1*01:02:01-01:02:05 and 01:02:07-01:02:08 alleles or the DRB1*01:24:01-01:24:02 alleles.

¹DRB1 alleles listed on the IMGT/HLA web page 2012-October-14, release 3.10.0, www.ebi.ac.uk/imgt/hla.

ALLELE CONFIRMATION STATUS

Allele	Status ¹	Allele	Status ¹	Allele	Status ¹
DRB1*01:01:01	Confirmed	DRB1*01:02:08	Unconfirmed	DRB1*01:31	Unconfirmed
DRB1*01:01:02	Unconfirmed	DRB1*01:03	Confirmed	DRB1*01:32	Confirmed
DRB1*01:01:03	Unconfirmed	DRB1*01:04	Confirmed	DRB1*01:33N	Unconfirmed
DRB1*01:01:04	Unconfirmed	DRB1*01:05	Unconfirmed	DRB1*01:34	Unconfirmed
DRB1*01:01:05	Unconfirmed	DRB1*01:06	Unconfirmed	DRB1*01:35	Confirmed
DRB1*01:01:06	Confirmed	DRB1*01:07	Confirmed	DRB1*01:36	Unconfirmed
DRB1*01:01:07	Confirmed	DRB1*01:08	Unconfirmed	DRB1*01:37	Unconfirmed
DRB1*01:01:08	Confirmed	DRB1*01:09	Unconfirmed	DRB1*01:38	Unconfirmed
DRB1*01:01:09	Unconfirmed	DRB1*01:10	Unconfirmed	DRB1*01:39N	Unconfirmed
DRB1*01:01:10	Confirmed	DRB1*01:11	Unconfirmed	DRB1*01:40N	Unconfirmed
DRB1*01:01:11	Unconfirmed	DRB1*01:12	Unconfirmed	DRB1*01:41	Unconfirmed
DRB1*01:01:12	Confirmed	DRB1*01:13	Unconfirmed	DRB1*01:42	Unconfirmed
DRB1*01:01:13	Unconfirmed	DRB1*01:14	Unconfirmed	DRB1*01:43	Unconfirmed
DRB1*01:01:14	Confirmed	DRB1*01:15	Confirmed	DRB1*01:44	Unconfirmed
DRB1*01:01:15	Unconfirmed	DRB1*01:16	Confirmed	DRB1*01:45	Unconfirmed
DRB1*01:01:16	Confirmed	DRB1*01:17	Unconfirmed	DRB1*01:46	Unconfirmed
DRB1*01:01:17	Confirmed	DRB1*01:18	Unconfirmed	DRB1*01:47	Unconfirmed
DRB1*01:01:18	Confirmed	DRB1*01:19	Confirmed	DRB1*01:48	Unconfirmed
DRB1*01:01:19	Confirmed	DRB1*01:20	Confirmed	DRB1*01:49	Unconfirmed
DRB1*01:01:20	Unconfirmed	DRB1*01:21	Unconfirmed	DRB1*01:50	Unconfirmed
DRB1*01:01:21	Unconfirmed	DRB1*01:22	Unconfirmed	DRB1*01:51	Unconfirmed
DRB1*01:01:22	Unconfirmed	DRB1*01:23	Confirmed	DRB1*01:52N	Unconfirmed
DRB1*01:01:23	Unconfirmed	DRB1*01:24:01	Confirmed	DRB1*01:53	Unconfirmed
DRB1*01:02:01	Confirmed	DRB1*01:24:02	Unconfirmed		
DRB1*01:02:02	Unconfirmed	DRB1*01:25	Unconfirmed		
DRB1*01:02:03	Unconfirmed	DRB1*01:26	Confirmed		
DRB1*01:02:04	Unconfirmed	DRB1*01:27	Confirmed		
DRB1*01:02:05	Unconfirmed	DRB1*01:28	Unconfirmed		
DRB1*01:02:06	Confirmed	DRB1*01:29	Confirmed		
DRB1*01:02:07	Unconfirmed	DRB1*01:30	Unconfirmed		

¹Allele status “confirmed” or “unconfirmed” as listed on the IMGT/HLA web page 2012-October-14, release 3.10.0, www.ebi.ac.uk/imgt/hla.

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RESOLUTION IN HOMO- AND HETEROZYGOTES

A total of 86 alleles generate 44 amplification patterns that can be combined in 990 homozygous and heterozygous combinations. 266 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.

--+-----	++-----	-----	*01:06, *01:06 = *01:06, *01:20
--+-----	-----	-----+	*01:02:06, *01:35 = *01:35, *01:35
--+-----	+-----	-----	*01:04, *01:04 = *01:04, *01:20
++-----	-----	-----+	*01:02:01, *01:02:01 = *01:02:01, *01:02:06
++-----	-----	-----+	*01:01:01, *01:40N = *01:40N, *01:40N
++-----	-----	-----+	*01:01:01, *01:36 = *01:36, *01:36
++-----	-----	-----+	*01:01:01, *01:32 = *01:32, *01:32
++-----	-----	-----+	*01:01:01, *01:30 = *01:30, *01:30
++-----	-----	-----+	*01:01:01, *01:25 = *01:25, *01:25
++-----	-----	-----+	*01:01:01, *01:22 = *01:22, *01:22
++-----	-----	-----+	*01:01:01, *01:19 = *01:19, *01:19
++-----	-----	-----+	*01:01:01, *01:16 = *01:16, *01:16
++-----	-----	-----+	*01:01:01, *01:14 = *01:14, *01:14
++-----	-----	-----+	*01:01:01, *01:13 = *01:13, *01:13
++-----	-----	-----+	*01:01:01, *01:12 = *01:12, *01:12
++-----	-----	-----+	*01:01:01, *01:18 = *01:18, *01:18
++-----	-----	-----+	*01:01:01, *01:09 = *01:09, *01:09
++-----	-----	-----+	*01:01:01, *01:08 = *01:01:01, *01:20 = *01:08, *01:08 = *01:08, *01:20
++-----	-----	-----+	*01:01:01, *01:07 = *01:07, *01:07
++-----	-----	-----+	*01:01:01, *01:17 = *01:17, *01:17
++-----	-----	-----+	*01:01:01, *01:05 = *01:05, *01:05
++-----	-----	-----+	*01:01:01, *01:11 = *01:11, *01:11
++-----	-----	-----+	*01:02:06, *01:04 = *01:04, *01:35 = *01:20, *01:35
++-----	-----	-----+	*01:02:01, *01:34 = *01:02:06, *01:34 = *01:34, *01:34
++-----	-----	-----+	*01:02:01, *01:26 = *01:02:06, *01:26 = *01:26, *01:26
++-----	-----	-----+	*01:02:01, *01:44 = *01:02:06, *01:44 = *01:44, *01:44
++-----	-----	-----+	*01:03, *01:39N = *01:39N, *01:39N
++-----	-----	-----+	*01:01:01, *01:21 = *01:16, *01:19 = *01:16, *01:21 = *01:19, *01:21 = *01:21, *01:21
++-----	-----	-----+	*01:01:01, *01:24:01 = *01:14, *01:19 = *01:14, *01:24:01 = *01:19, *01:24:01
++-----	-----	-----+	*01:01:01, *01:28 = *01:13, *01:16 = *01:13, *01:28 = *01:16, *01:28 = *01:28, *01:28
++-----	-----	-----+	*01:01:01, *01:51 = *01:13, *01:14 = *01:13, *01:51 = *01:14, *01:51
++-----	-----	-----+	*01:01:01, *01:52N = *01:09, *01:36 = *01:09, *01:52N = *01:36, *01:52N = *01:52N, *01:52N
++-----	-----	-----+	*01:08, *01:40N = *01:20, *01:40N
++-----	-----	-----+	*01:08, *01:36 = *01:20, *01:36
++-----	-----	-----+	*01:08, *01:32 = *01:20, *01:32
++-----	-----	-----+	*01:08, *01:30 = *01:20, *01:30
++-----	-----	-----+	*01:08, *01:25 = *01:20, *01:25
++-----	-----	-----+	*01:08, *01:22 = *01:20, *01:22
++-----	-----	-----+	*01:08, *01:19 = *01:19, *01:20
++-----	-----	-----+	*01:08, *01:16 = *01:16, *01:20
++-----	-----	-----+	*01:08, *01:14 = *01:14, *01:20
++-----	-----	-----+	*01:08, *01:13 = *01:13, *01:20
++-----	-----	-----+	*01:08, *01:12 = *01:12, *01:20
++-----	-----	-----+	*01:08, *01:18 = *01:18, *01:20

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+ - + - - - - + + - - - - - - - - - -			*01:01:01, *01:06 = *01:06, *01:08 = *01:06, *01:09 = *01:08, *01:09 = *01:09, *01:20
+ - + - - - - + - - - - - - - - + - - - - -			*01:01:01, *01:50 = *01:07, *01:25 = *01:07, *01:50 = *01:25, *01:50 = *01:50, *01:50
+ - + - - - - + - - - - - - - + - - - - -			*01:01:01, *01:27 = *01:07, *01:22 = *01:07, *01:27 = *01:22, *01:27 = *01:27, *01:27
+ - + - - - - + + - - - - - - - - - - -			*01:07, *01:08 = *01:07, *01:20
+ - + - - - - + - + - - - - - - - - - - -			*01:01:01, *01:15 = *01:09, *01:15 = *01:09, *01:17 = *01:15, *01:17
+ - + - - - - + + - - - - - - - - - - -			*01:08, *01:17 = *01:17, *01:20
+ - + - - - - + - - + - - - - - - - - - -			*01:01:01, *01:31 = *01:05, *01:12 = *01:05, *01:31 = *01:12, *01:31 = *01:31, *01:31
+ - + - - - - + - - - - - - - - - - -			*01:05, *01:08 = *01:05, *01:20
+ - + - - - - - - - - - - - - - - - + -			*01:01:01, *01:35 = *01:02:06, *01:11 = *01:11, *01:35
+ - + - - - - + - - - - - - - - - - -			*01:01:01, *01:04 = *01:04, *01:08 = *01:04, *01:11 = *01:08, *01:11 = *01:11, *01:20
+ - + - + + - - - - - - - - - - -			*01:01:01, *01:29 = *01:05, *01:11 = *01:05, *01:29 = *01:11, *01:29 = *01:29, *01:29
+ - + + - - - - - + - - - - - - - - - -			*01:01:01, *01:10 = *01:10, *01:10 = *01:10, *01:18
+ - + + - - - + - - - - - - - - - - -			*01:01:01, *01:03 = *01:03, *01:17
- + + - - - - - - - - + + - - - - - + -			*01:02:01, *01:23 = *01:02:06, *01:23
+ - + - - - - - - - - + + + - - - - - -			*01:14, *01:21 = *01:16, *01:24:01 = *01:21, *01:24:01
+ - + - - - - - - - - + + + - - - - - -			*01:13, *01:21 = *01:19, *01:28 = *01:21, *01:28
+ - + - - - - - - - - + + + - - - - - -			*01:13, *01:24:01 = *01:19, *01:51
+ - + - - - - - - - - + + + - - - - - -			*01:14, *01:28 = *01:16, *01:51 = *01:28, *01:51
+ - + - - - - - + - - - - + + - - - - -			*01:08, *01:21 = *01:20, *01:21
+ - + - - - - - + - - - - + + - - - - -			*01:08, *01:24:01 = *01:20, *01:24:01
+ - + - - - - - + - - - - + + - - - - -			*01:08, *01:28 = *01:20, *01:28
+ - + - - - - - + - - - - + + - - - - -			*01:08, *01:51 = *01:20, *01:51
+ - + - - - - - + + - - - - - - - - - + -			*01:06, *01:36 = *01:06, *01:52N = *01:08, *01:52N = *01:20, *01:52N
+ - + - - - - + - - - - - - - + + - - - -			*01:22, *01:50 = *01:25, *01:27 = *01:27, *01:50
+ - + - - - - + + - - - - - - - + - - - -			*01:08, *01:50 = *01:20, *01:50
+ - + - - - - + + - - - - - - - + - - - -			*01:08, *01:27 = *01:20, *01:27
+ - + - - - - + - + - - - - - - - - - + -			*01:15, *01:36 = *01:15, *01:52N = *01:17, *01:52N
+ - + - - - - + + - - - - - - - - - - -			*01:06, *01:15 = *01:06, *01:17 = *01:08, *01:15 = *01:15, *01:20
+ - + - - - - + - - + - - - - - - - - - -			*01:08, *01:31 = *01:20, *01:31
+ - + - + + - - + + - - - - - - - - - - -			*01:04, *01:09 = *01:06, *01:11
+ - + - + + - - - - - - - - - - - - - + -			*01:02:06, *01:29 = *01:05, *01:35 = *01:29, *01:35
+ - + - + + - - - - + - - - - - - - - - -			*01:11, *01:31 = *01:12, *01:29 = *01:29, *01:31
+ - + - + + - - + - - - - - - - - - - -			*01:04, *01:05 = *01:04, *01:29 = *01:08, *01:29 = *01:20, *01:29
+ - + + - - - - + - + - - - - - - - - - -			*01:08, *01:10 = *01:10, *01:20
+ - + + - - + - - - - - - - - - - - - - +			*01:01:01, *01:39N = *01:03, *01:40N = *01:17, *01:39N = *01:39N, *01:40N
+ - + + - - + - - - - - - - - - - - - - +			*01:01:01, *01:42 = *01:02:06, *01:03 = *01:17, *01:42
+ - + + - - + - - + - - - - - - - - - - -			*01:03, *01:10 = *01:03, *01:18 = *01:10, *01:17
+ - + + - - + - + - - - - - - - - - - -			*01:03, *01:08 = *01:03, *01:20
+ + + - - - - - - - - - - - - - + - + -			*01:01:01, *01:34 = *01:02:01, *01:32 = *01:32, *01:34
+ + + - - - - - - + - - - - - - - - - + -			*01:01:01, *01:26 = *01:02:01, *01:12 = *01:12, *01:26
+ + + - - - - - - + - - - - - - - - - + -			*01:01:01, *01:44 = *01:02:01, *01:18 = *01:18, *01:44
+ - + - - - - - - - - + + + + - - - - -			*01:21, *01:51 = *01:24:01, *01:28
+ - + + - - + - - - - - - - - - - - - - + +			*01:02:06, *01:39N = *01:40N, *01:42
+ - + + - - + - - + - - - - - - - - - - +			*01:10, *01:39N = *01:18, *01:39N
+ - + + - - + - - + - - - - - - - - - + -			*01:10, *01:42 = *01:18, *01:42
+ - + + - - + - + - - - - - - - - - - - +			*01:08, *01:39N = *01:20, *01:39N
+ - + + + - + - - - - - - - - - - - - - +			*01:03, *01:35 = *01:11, *01:42
+ + + - - - - - - - - + + - - - - - - - +			*01:01:01, *01:23 = *01:02:01, *01:51 = *01:13, *01:23 = *01:14, *01:23
+ + + - - - - - - + - - - - - - - - - + -			*01:12, *01:34 = *01:26, *01:32

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+++-----	---+-----	-----+-	*01:18, *01:34 = *01:32, *01:44
+++-----	---+-----	-----+-	*01:12, *01:44 = *01:18, *01:26
+++--+--	---+-----	-----+-	*01:02:01, *01:31 = *01:05, *01:26 = *01:26, *01:31
++++-----	---+-----	-----+-	*01:02:01, *01:10 = *01:10, *01:44
+++-----	-----+-	-----+-	*01:23, *01:32 = *01:34, *01:51
+++-----	-----+-	-----+-	*01:16, *01:23 = *01:23, *01:28
+++-----	-----+-	-----+-	*01:12, *01:23 = *01:26, *01:51
+++-----	---+-----	-----+-	*01:18, *01:23 = *01:44, *01:51

*01:01:01 = *01:01:01-01:01:23 and 01:38, 01:41, 01:45, 01:47-01:49 and 01:53

*01:02:01 = *01:02:01-01:02:05, 01:02:07-01:02:08 and 01:43 and 01:46

*01:12 = *01:12 and 01:37

*01:24:01= *01:24:01-01:24:02

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SPECIFICITY TABLE

DRB1*01 SSP subtyping

Specificities and sizes of the PCR products of the 24 primer mixes used for DRB1*01 SSP subtyping

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified DRB1*01 alleles ³	Other amplified DRB1 alleles ⁴
1⁶	255 bp	515 bp	*01:01:01-01:01:23, 01:03, 01:05, 01:07-01:19, 01:21, 01:22 ^w , 01:24:01-01:25, 01:27-01:32, 01:36-01:41, 01:45, 01:47-01:53	
2	235 bp	430 bp	*01:02:01-01:02:05, 01:02:07-01:02:08, 01:23, 01:26, 01:34, 01:43-01:44, 01:46	
3	200 bp	515 bp	*01:01:01-01:02:08, 01:04-01:14, 01:16-01:21, 01:22 ^w , 01:25-01:32, 01:34-01:38, 01:40N-01:41, 01:43-01:50, 01:52N-01:53	
4	210 bp	430 bp	*01:03, 01:10, 01:39N, 01:42	
5	220 bp	430 bp	*01:04, 01:11, 01:29, 01:35	
6⁷	135 bp, 210 bp	430 bp	*01:05, 01:29, 01:31	
7	210 bp	430 bp	*01:03, 01:15, 01:17, 01:39N, 01:42	
8^{5,8}	115 bp, 175 bp, 210 bp	430 bp	*01:07, 01:27, 01:50	*14:112
9^{5,9}	110 bp, 255 bp	430 bp	*01:04, 01:06, 01:08, 01:20	
10¹⁰	210 bp, 250 bp	430 bp	*01:06, 01:09, 01:15, 01:52N	
11¹¹	140 bp, 210 bp	430 bp	*01:10, 01:18, 01:44	
12¹²	140 bp, 180 bp, 215 bp	430 bp	*01:12, 01:26, 01:31, 01:37	
13^{5,13}	85 bp, 150 bp, 215 bp	430 bp	*01:13, 01:23, 01:28, 01:51	
14¹⁴	170 bp, 210 bp	430 bp	*01:14, 01:23-01:24:02, 01:51	
15¹⁵	150 bp, 220 bp	430 bp	*01:16, 01:21, 01:28	
16¹⁶	200 bp, 230 bp	430 bp	*01:19, 01:21, 01:24:01-01:24:02	

101.111-24/06 – including *Taq* pol., IFU-01
 101.111-24u/06u – without *Taq* pol., IFU-02

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17¹⁷	230 bp, 260 bp	430 bp	*01:22, 01:27
18^{5,18}	115 bp, 230 bp	430 bp	*01:25, 01:50
19⁵	125 bp	430 bp	*01:30
20	205 bp	430 bp	*01:33N
21^{5,19}	85 bp, 250 bp	430 bp	*01:32, 01:34
22²⁰	205 bp, 250 bp	430 bp	*01:36, 01:52N
23	255 bp	430 bp	*01:02:01-01:02:08, 01:23, 01:26, 01:34-01:35, 01:42- 01:44, 01:46
24	270 bp	430 bp	*01:39N-01:40N

¹ Alleles are assigned by the presence of specific PCR product(s). However, the sizes of the specific PCR products may be helpful in the interpretation of DRB*01 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 base pairs or more. Size differences shorter than 20 base pairs are not given. For high resolution SSP kits the respective lengths of the specific PCR product(s) of the alleles amplified by these primer mixes are given.

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

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

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

Some primers may give rise to primer oligomer artifacts. Sometimes this phenomenon is an 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.

² The internal positive control primer pairs amplify segments of the human growth hormone gene. The two different control primer pairs give rise to either an internal positive control band of 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 DRB1*01 subtyping.

In addition, well number 3 contains 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.

³ For several DRB1 alleles 1st and/or 3rd exon(s) and beyond, 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*01:01 consensus sequence.

⁴ Due to the sharing of sequence motifs between DRB1 alleles, primer mix 8 will amplify the DRB1*14:112 allele.

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

⁶ Primer mixes 1 has a tendency of giving rise to primer oligomer formation.

⁷ Primer mix 6: Specific PCR fragment of 130 bp in the DRB1*01:05 and DRB1*01:31 alleles. Specific PCR fragment of 210 bp in the DRB1*01:29 allele.

⁸ Primer mix 8: Specific PCR fragment of 115 bp in the DRB1*01:50. Specific PCR fragment of 175 bp in the DRB1*01:27 and 14:112 alleles. Specific PCR fragment of 210 bp in the DRB1*01:07 allele.

⁹ Primer mix 9: Specific PCR fragment of 110 bp in the DRB1*01:08 allele. Specific PCR fragment of 255 bp in the DRB1*01:04, 01:06 and 01:20 alleles.

101.111-24/06 – including *Taq* pol., IFU-01
101.111-24u/06u – without *Taq* pol., IFU-02

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¹⁰Primer mix 10: Specific PCR fragment of 210 bp in the DRB1*01:06, 01:09 and 01:15 alleles. Specific PCR fragment of 250 bp in the DRB1*01:52N allele.

¹¹Primer mix 11: Specific PCR fragment of 140 bp in the DRB1*01:18 and 01:44 alleles. Specific PCR fragment of 210 bp in the DRB1*01:10 allele.

¹²Primer mix 12: Specific PCR fragment of 140 bp in the DRB1*01:31 allele. Specific PCR fragment of 180 bp in the DRB1*01:26 and 01:37 alleles. Specific PCR fragment of 215 bp in the DRB1*01:12 allele.

¹³Primer mix 13: Specific PCR fragment of 85 bp in the DRB1*01:13 allele. Specific PCR fragment of 150 bp in the DRB1*01:28 allele. Specific PCR fragment of 215 bp in the DRB1*01:23 and *01:51 alleles.

¹⁴Primer mix 14: Specific PCR fragment of 170 bp in the DRB1*01:14 allele. Specific PCR fragment of 210 bp in the DRB1*01:24:01-01:24:02, *01:23 and *01:51 alleles.

¹⁵Primer mix 15: Specific PCR fragment of 150 bp in the DRB1*01:28 allele. Specific PCR fragment of 220 bp in the DRB1*01:16 and 01:21 alleles.

¹⁶Primer mix 16: Specific PCR fragment of 200 bp in the DRB1*01:24:01-01:24:02 alleles. Specific PCR fragment of 230 bp in the DRB1* 01:19 and 01:21 alleles.

¹⁷Primer mix 17: Specific PCR fragment of 230 bp in the DRB1*01:27 allele. Specific PCR fragment of 260 bp in the DRB1*01:22 allele.

¹⁸Primer mix 18: Specific PCR fragment of 115 bp in the DRB1*01:50 allele. Specific PCR fragment of 230 bp in the DRB1*01:25 allele.

¹⁹Primer mix 21: Specific PCR fragment of 85 bp in the DRB1*01:34 allele. Specific PCR fragment of 250 bp in the DRB1*01:32 allele.

²⁰Primer mix 22: Specific PCR fragment of 205 bp in the DRB1*01:36 allele. Specific PCR fragment of 250 bp in the DRB1*01:52N allele.

'w', might be weakly amplified.

101.111-24/06 – including *Taq* pol., IFU-01
 101.111-24u/06u – without *Taq* pol., IFU-02

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Lot-specific information

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INTERPRETATION TABLE												
DRB1*01 SSP subtyping												
Amplification patterns of the DRB1*01:01:01 to 01:52N alleles												
	Well⁵											
	1	2	3	4	5	6	7	8	9	10	11	12
Length of spec.	255	235	200	210	220	135	210	115	110	210	140	140
PCR product(s)						210		175	255	250	210	180
								210				215
Length of int.	515	430	515	430	430	430	430	430	430	430	430	430
pos. control¹												
5'-primer(s)²	14 (129)	14 (129)	14 (129)	14 (129)	14 (129)	14 (129)	14 (129)	9 (115)	14 (129)	14 (129)	14 (129)	14 (129)
	5'-gAA ³	5'-gAA ³	5'-gAA ³	5'-gAA ³	5'-gAA ³	5'-gAA ³	5'-gAA ³	5'-ggg ³	5'-gAA ³	5'-gAA ³	5'-gAA ³	5'-gAA ³
								22 (154)				
								5'-Agg ³				
								110 (417)				
								5'-CAC ³				
3'-primer(s)³	86 (344)	78 (321)	66 (286)	71 (299)	70 (296)	44 (220)	66 (286)	66 (286)	37 (197)	70 (298)	47 (227)	48 (230)
	5'-CAC ³	5'-CAA ³	5'-gAg ³	5'-gCT ³	5'-TCC ³	5'-CCT ³	5'-gAT ³	5'-gAg ³	5'-CgT ³	5'-CgC ³	5'-ggA ³	5'-CCT ³
			66 (286)		77 (317)	48 (230)	66 (286)	134 (490)	85 (341)	83 (336)	70 (298)	60 (266)
			5'-gAg ³		5'-AAT ³	5'-CCT ³	5'-gAT ³	5'-gCC ³	5'-CAA ³	5'-CCC ³	5'-CTT ³	5'-Agg ³
						70 (296)	74 (308)					72 (302)
						5'-TCC ³	5'-CCT ³					5'-CCA ³
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
DRB1 allele⁴												
*01:01:01-01:01:23, 01:38, 01:41, 01:45, 01:47-01:49, 01:53	1		3									
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

101.111-24/06 – including *Taq* pol., IFU-01
 101.111-24u/06u – without *Taq* pol., IFU-02

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Lot No.: **91R**

Lot-specific information

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INTERPRETATION TABLE												
DRB1*01 SSP subtyping												
Amplification patterns of the DRB1*01 to 01:52N alleles												
Well ⁵												
13	14	15	16	17	18	19	20	21	22	23	24	
85	170	150	200	230	115	125	205	85	205	255	270	Length of spec. PCR product(s)
150	210	220	230	260	230			250	250			
215												
430	430	430	430	430	430	430	430	430	430	430	430	Length of int. pos. control ¹
14 (129)	14 (129)	14 (129)	14 (129)	12 (123)	22 (154)	58 (262)	12 (124)	14 (129)	14 (129)	14 (129)	9 (114)	5'-primer(s) ²
5'-gAA 3'	5'-gAA 3'	5'-gAA 3'	5'-gAA 3'	5'-AAC 3'	5'-AgT 3'	5'-CCA 3'	5'-A.T 3'	5'-gAA 3'	5'-gAA 3'	5'-gAA 3'	5'-TgA 3'	
				22 (154)	110 (417)							
				5'-Agg 3'	5'-CAC 3'							
29 (175)	57 (257)	51 (239)	66 (286)	86 (344)	86 (344)	86 (344)	66 (286)	29 (173)	69 (293)	85 (341)	86 (344)	3'-primer(s) ³
5'-gAg 3'	5'-CAG 3'	5'-CCA 3'	5'-gAT 3'	5'-CAC 3'	5'-CAC 3'	5'-CAC 3'	5'-gAg 3'	5'-ATC 3'	5'-gCC 3'	5'-CAG 3'	5'-CAC 3'	
51 (239)	66 (286)	73 (305)	75 (313)		134 (490)			83 (337)	83 (336)			
5'-CCA 3'	5'-gAT 3'	5'-ggC 3'	5'-gTT 3'		5'-gCC 3'			5'-CCT 3'	5'-CCC 3'			
72 (303)	72 (303)	77 (319)	77 (319)									
5'-gCg 3'	5'-gCg 3'	5'-CAC 3'	5'-CAC 3'									
13	14	15	16	17	18	19	20	21	22	23	24	Well No.
												DRB1 allele ⁴
												*01:01:01-01:01:23, 01:38, 01:41, 01:45, 01:47-01:49, 01:53
13	14	15	16	17	18	19	20	21	22	23	24	Well No.

101.111-24/06 – including *Taq* pol., IFU-01
 101.111-24u/06u – without *Taq* pol., IFU-02

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Lot No.: **91R**

Lot-specific information

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Length of spec. PCR product(s)	255	235	200	210	220	135	210	115	110	210	140	140
						210		175	255	250	210	180
								210				215
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
*01:02:01-01:02:05, 01:02:07-01:02:08, 01:43, 01:46		2	3									
*01:02:06			3									
*01:03	1			4			7					
*01:04			3		5				9			
*01:05	1		3			6						
*01:06			3						9	10		
*01:07	1		3					8				
*01:08	1		3						9			
*01:09	1		3							10		
*01:10	1		3	4							11	
*01:11	1		3		5							
*01:12, 01:37	1		3									12
*01:13	1		3									
*01:14	1		3									
*01:15	1						7			10		
*01:16	1		3									
*01:17	1		3				7					
*01:18	1		3								11	
*01:19	1		3									
*01:20			3						9			
*01:21	1		3									
*01:22	w		w									
*01:23		2										
*01:24:01-01:24:02	1											
*01:25	1		3									
*01:26		2	3									12
*01:27	1		3					8				
*01:28	1		3									
*01:29	1		3		5	6						
*01:30	1		3									
*01:31	1		3			6						12
*01:32	1		3									
*01:33N												
*01:34		2	3									
*01:35			3		5							
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

101.111-24/06 – including *Taq* pol., IFU-01
 101.111-24u/06u – without *Taq* pol., IFU-02

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Lot No.: **91R**

Lot-specific information

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85	170	150	200	230	115	125	205	85	205	255	270	Length of spec. PCR product(s)
150	210	220	230	260	230			250	250			
215												
13	14	15	16	17	18	19	20	21	22	23	24	Well No.
										23		*01:02:01-01:02:05, 01:02:07-01:02:08, 01:43, 01:46
										23		*01:02:06
												*01:03
												*01:04
												*01:05
												*01:06
												*01:07
												*01:08
												*01:09
												*01:10
												*01:11
												*01:12, 01:37
13												*01:13
	14											*01:14
												*01:15
		15										*01:16
												*01:17
												*01:18
			16									*01:19
												*01:20
		15	16									*01:21
				17								*01:22
13	14									23		*01:23
	14		16									*01:24:01-01:24:02
					18							*01:25
										23		*01:26
				17								*01:27
13		15										*01:28
												*01:29
						19						*01:30
												*01:31
								21				*01:32
							20					*01:33N
								21		23		*01:34
										23		*01:35
13	14	15	16	17	18	19	20	21	22	23	24	Well No.

101.111-24/06 – including *Taq* pol., IFU-01
 101.111-24u/06u – without *Taq* pol., IFU-02

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Lot No.: **91R**

Lot-specific information

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Length of spec.	255	235	200	210	220	135	210	115	110	210	140	140
PCR product(s)						210		175	255	250	210	180
								210				215
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
*01:36	1		3									
*01:39N	1			4			7					
*01:40N	1		3									
*01:42				4			7					
*01:44		2	3								11	
*01:50	1		3					8				
*01:51	1											
*01:52N	1		3							10		
*14:112								8				
DRB1 allele⁴												
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

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 DRB1*01 subtyping.

In addition, well number 3 contains the primer pair giving rise to the longer, 515 bp, internal positive control band in order to allow kit identification.

²The codon, and in parenthesis the nucleotide, in the 2nd 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 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.

⁴DRB1*01 alleles in bold lettering are listed as confirmed alleles on the on the IMGT/HLA web page www.ebi.ac.uk/imgt/hla, release 3.10.0, October 2012.

101.111-24/06 – including *Taq* pol., IFU-01
101.111-24u/06u – without *Taq* pol., IFU-02

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Lot-specific information

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85	170	150	200	230	115	125	205	85	205	255	270	Length of spec. PCR product(s)
150	210	220	230	260	230			250	250			
215												
13	14	15	16	17	18	19	20	21	22	23	24	Well No.
									22			*01:36
											24	*01:39N
											24	*01:40N
										23		*01:42
										23		*01:44
					18							*01:50
13	14											*01:51
									22			*01:52N
												*14:112
												DRB1 allele ⁴
13	14	15	16	17	18	19	20	21	22	23	24	Well No.

⁵Primer mix 6: Specific PCR fragment of 130 bp in the DRB1*01:05 and DRB1*01:31 alleles. Specific PCR fragment of 210 bp in the DRB1*01:29 allele.

Primer mix 8: Specific PCR fragment of 115 bp in the DRB1*01:50. Specific PCR fragment of 175 bp in the DRB1*01:27 and 14:112 alleles. Specific PCR fragment of 210 bp in the DRB1*01:07 allele.

Primer mix 9: Specific PCR fragment of 110 bp in the DRB1*01:08 allele. Specific PCR fragment of 255 bp in the DRB1*01:04, 01:06 and 01:20 alleles.

Primer mix 10: Specific PCR fragment of 210 bp in the DRB1*01:06, 01:09 and 01:15 alleles. Specific PCR fragment of 250 bp in the DRB1*01:52N allele.

Primer mix 11: Specific PCR fragment of 140 bp in the DRB1*01:18 and 01:44 alleles. Specific PCR fragment of 210 bp in the DRB1*01:10 allele.

Primer mix 12: Specific PCR fragment of 140 bp in the DRB1*01:31 allele. Specific PCR fragment of 180 bp in the DRB1*01:26 and 01:37 alleles. Specific PCR fragment of 215 bp in the DRB1*01:12 allele.

Primer mix 13: Specific PCR fragment of 85 bp in the DRB1*01:13 allele. Specific PCR fragment of 150 bp in the DRB1*01:28 allele. Specific PCR fragment of 215 bp in the DRB1*01:23 and *01:51 alleles.

Primer mix 14: Specific PCR fragment of 170 bp in the DRB1*01:14 allele. Specific PCR fragment of 210 bp in the DRB1*01:24:01-01:24:02, *01:23 and *01:51 alleles.

Primer mix 15: Specific PCR fragment of 150 bp in the DRB1*01:28 allele. Specific PCR fragment of 220 bp in the DRB1*01:16 and 01:21 alleles.

Primer mix 16: Specific PCR fragment of 200 bp in the DRB1*01:24:01-01:24:02 alleles. Specific PCR fragment of 230 bp in the DRB1* 01:19 and 01:21 alleles.

Primer mix 17: Specific PCR fragment of 230 bp in the DRB1*01:27 allele. Specific PCR fragment of 260 bp in the DRB1*01:22 allele.

Primer mix 18: Specific PCR fragment of 115 bp in the DRB1*01:50 allele. Specific PCR fragment of 230 bp in the DRB1*01:25 allele.

Primer mix 21: Specific PCR fragment of 85 bp in the DRB1*01:34 allele. Specific PCR fragment of 250 bp in the DRB1*01:32 allele.

Primer mix 22: Specific PCR fragment of 205 bp in the DRB1*01:36 allele. Specific PCR fragment of 250 bp in the DRB1*01:52N allele.

'w', might be weakly amplified.

101.111-24/06 – including *Taq* pol., IFU-01
 101.111-24u/06u – without *Taq* pol., IFU-02

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Lot No.: **91R**

Lot-specific information

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CELL LINE VALIDATION SHEET																					
DRB1*01 SSP subtyping kit																					
					Well																
						1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
				Production No.		201314001	201314002	201314003	201314004	201314005	201314006	201314007	201314008	201314009	201314010	201314011	201314012	201314013	201314014	201314015	201314016
	IHWC cell line		DRB1																		
1	9001	SA	*01:01		+	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2	9280	LK707	*15:02	*04:05	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3	9011	E4181324	*15:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4	9275	GU373	*03:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
5	9009	KAS011	*16:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
6	9353	SM	*04:07	*08:03	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
7	9020	QBL	*03:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
8	9025	DEU	*04:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
9	9026	YAR	*04:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
10	9107	LKT3	*04:05		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
11	9051	PITOUT	*07:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
12	9052	DBB	*07:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
13	9004	JESTHOM	*01:01		+	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
14	9071	OLGA	*08:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
15	9075	DKB	*09:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
16	9037	SWEIG007	*11:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
17	9282	CTM3953540	*03:01	*13:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
18	9257	32367	*09:01	*11:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
19	9038	BM16	*12:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
20	9059	SLE005	*13:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
21	9064	AMALA	*14:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
22	9056	KOSE	*13:02	*14:54	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
23	9124	IHL	*08:03	*14:14	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
24	9035	JBUSH	*11:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
25	9049	IBW9	*07:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
26	9285	WT49	*03:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
27	9191	CH1007	*04:05	*10:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
28	9320	BEL5GB	*04:16	*07:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
29	9050	MOU	*07:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
30	9021	RSH	*03:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
31	9019	DUCAF	*03:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
32	9297	HAG	*13:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
33	9098	MT14B	*04:04		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
34	9104	DHIF	*11:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
35	9302	SSTO	*04:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
36	9024	KT17	*04:03	*04:06	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
37	9065	HHKB	*13:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
38	9099	LZL	*14:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
39	9315	CML	*03:01	*04:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
40	9134	WHONP199	*07:01	*09:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
41	9055	H0301	*13:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
42	9066	TAB089	*08:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
43	9076	T7526	*09:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
44	9057	TEM	*14:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
45	9239	SHJO	*07:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
46	9013	SCHU	*15:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
47	9045	TUBO	*11:04	*12:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
48	9303	TER-ND	*01:03		+	-	-	+	-	-	+	-	-	-	-	-	-	-	-	-	-

101.111-24/06 – including *Taq* pol., IFU-01
 101.111-24u/06u – without *Taq* pol., IFU-02

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Lot No.: **91R**

Lot-specific information

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CELL LINE VALIDATION SHEET												
DRB1*01 SSP subtyping kit												
					Well							
					17	18	19	20	21	22	23	24
				Production No.	201314017	201314018	201314019	201314020	201314021	201314022	201314023	201314024
	IHWC cell line		DRB1									
1	9001	SA	*01:01		-	-	-	-	-	-	-	-
2	9280	LK707	*15:02		*04:05	-	-	-	-	-	-	-
3	9011	E4181324	*15:02			-	-	-	-	-	-	-
4	9275	GU373	*03:01		-	-	-	-	-	-	-	-
5	9009	KAS011	*16:01		-	-	-	-	-	-	-	-
6	9353	SM	*04:07		*08:03	-	-	-	-	-	-	-
7	9020	QBL	*03:01			-	-	-	-	-	-	-
8	9025	DEU	*04:01		-	-	-	-	-	-	-	-
9	9026	YAR	*04:02		-	-	-	-	-	-	-	-
10	9107	LKT3	*04:05		-	-	-	-	-	-	-	-
11	9051	PITOUT	*07:01		-	-	-	-	-	-	-	-
12	9052	DBB	*07:01		-	-	-	-	-	-	-	-
13	9004	JESTHOM	*01:01		-	-	-	-	-	-	-	-
14	9071	OLGA	*08:02		-	-	-	-	-	-	-	-
15	9075	DKB	*09:01		-	-	-	-	-	-	-	-
16	9037	SWEIG007	*11:01		-	-	-	-	-	-	-	-
17	9282	CTM3953540	*03:01		*13:01	-	-	-	-	-	-	-
18	9257	32367	*09:01			*11:01	-	-	-	-	-	-
19	9038	BM16	*12:01		-		-	-	-	-	-	-
20	9059	SLE005	*13:02		-	-	-	-	-	-	-	-
21	9064	AMALA	*14:02		-	-	-	-	-	-	-	-
22	9056	KOSE	*13:02		*14:54	-	-	-	-	-	-	-
23	9124	IHL	*08:03			*14:14	-	-	-	-	-	-
24	9035	JBUSH	*11:01		-		-	-	-	-	-	-
25	9049	IBW9	*07:01		-	-	-	-	-	-	-	-
26	9285	WT49	*03:01		-	-	-	-	-	-	-	-
27	9191	CH1007	*04:05		*10:01	-	-	-	-	-	-	-
28	9320	BEL5GB	*04:16			*07:01	-	-	-	-	-	-
29	9050	MOU	*07:01		-		-	-	-	-	-	-
30	9021	RSH	*03:02		-	-	-	-	-	-	-	-
31	9019	DUCAF	*03:01		-	-	-	-	-	-	-	-
32	9297	HAG	*13:03		-	-	-	-	-	-	-	-
33	9098	MT14B	*04:04		-	-	-	-	-	-	-	-
34	9104	DHIF	*11:01		-	-	-	-	-	-	-	-
35	9302	SSTO	*04:03		-	-	-	-	-	-	-	-
36	9024	KT17	*04:03		*04:06	-	-	-	-	-	-	-
37	9065	HHKB	*13:01			-	-	-	-	-	-	-
38	9099	LZL	*14:02		-	-	-	-	-	-	-	-
39	9315	CML	*03:01		*04:01	-	-	-	-	-	-	-
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41	9055	H0301	*13:02		-		-	-	-	-	-	-
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46	9013	SCHU	*15:01		-	-	-	-	-	-	-	-
47	9045	TUBO	*11:04		*12:01	-	-	-	-	-	-	-
48	9303	TER-ND	*01:03			-	-	-	-	-	-	-

101.111-24/06 – including *Taq* pol., IFU-01
101.111-24u/06u – without *Taq* pol., IFU-02

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Lot No.: **91R**

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CERTIFICATE OF ANALYSIS

Olerup SSP® DRB1*01 SSP

Product number: 101.111-24/06 – including *Taq* pol.
101.111-24u/06u – without *Taq* pol.
Lot number: 91R
Expiry date: 2015-August-01
Number of tests: 24 test – Product No. 101.111-24/24u
6 tests – Product No. 101.111-06/06u
Number of wells per test: 24

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2013-140-01	9	2013-140-09	17	2013-140-17
2	2013-140-02	10	2013-140-10	18	2013-140-18
3	2013-140-03	11	2013-140-11	19	2013-140-19
4	2013-140-04	12	2013-140-12	20	2013-140-20
5	2013-140-05	13	2013-140-13	21	2013-140-21
6	2013-140-06	14	2013-140-14	22	2013-140-22
7	2013-140-07	15	2013-140-15	23	2013-140-23
8	2013-140-08	16	2013-140-16	24	2013-140-24

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

No DNAs carrying the alleles to be amplified by primer solutions 5, 6, 8 to 22 and 24 were available. The specificities of the primers in primer solutions 5, 6 and 9 to 16 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer solution 8, 17 to 20 and 24 it was only possible to test the 3'-primer, the 5'-primer was not possible to test. In primer solution 21 and 22 it was only possible to test the 5'-primer, the 3'-primer was not possible to test. In primer solutions 6, 10 and 12 to 16 one or two 3'-primers were not possible to test. Additional 3'-primers in primer solution 7 were tested by separately adding one additional 5'-primer.

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

Date of approval: 2013-March-20

Approved by:

Production Quality Control

101.111-24/06 – including *Taq* pol., IFU-01
101.111-24u/06u – without *Taq* pol., IFU-02

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Lot No.: **91R**

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Declaration of Conformity

Product name: *Olerup* SSP® DRB1*01
Product number: 101.111-24/24u, -06/06u
Lot number: 91R

Intended use: DRB1*01 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.

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.)

Stockholm, Sweden
2013-March-20

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs

101.111-24/06 – including *Taq* pol., IFU-01
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Lot No.: **91R**

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www.olerup-ssp.com

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

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