

101.128-12 – including *Taq* polymerase, IFU-01
101.128-12u – without *Taq* polymerase, IFU-02

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

Lot No.: **98N**

Lot-specific information
Olerup SSP[®] DRB1*12

Product number:	101.128-12 – including <i>Taq</i> polymerase 101.128-12u – without <i>Taq</i> polymerase
Lot number:	98N
Expiry date:	2015-February-01
Number of tests:	12
Number of wells per test:	24
Storage - pre-aliquoted primers:	dark at -20°C
- PCR Master Mix:	-20°C
- Adhesive PCR seals	RT
- Product Insert	RT

This Product Description is only valid for Lot No. 98N.

**CHANGES COMPARED TO THE PREVIOUS OLERUP SSP[®]
DRB1*12 LOT (83M)**

The DRB1*12 kit is updated to enable separation of:

- Confirmed DRB1*12 alleles as listed in the IMGT/HLA database¹
- Polymorphisms in exons outside of the region encoding the peptide binding domain
- Null and Alternatively expressed alleles

The Lot-specific information for DRB1*12 including and without *Taq* polymerase is now described in one common Product Insert.

¹As described in section Uniquely Identified Alleles.

The DRB1*12 specificity and interpretation tables have been updated for the DRB1 alleles described since the previous *Olerup SSP[®]* DRB1*12 lot was made (**Lot No. 83M**).

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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
16	Added	-	5'-primer added for the DRB1*12:31N allele.
21	-	Added	3'-primer added for the DRB1*12:01:04 allele.

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PRODUCT DESCRIPTION

DRB1*12 SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for identifying the DRB1*12:01 to DRB1*12:35 alleles.

PLATE LAYOUT

Each test consists of 24 PCR reactions in a 24 well cut PCR plate.

1	2	3	4	5	6	7	8
9	10	11	12	13	14	15	16
17	18	19	20	21	22	23	24

The 24 well cut PCR plate is marked with ‘DRB1*12’ in silver/gray ink.

Well No. 1 is marked with the Lot No. ‘98N’.

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

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

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

INTERPRETATION

The interpretation of DRB1*12 SSP subtypings will be influenced by the DRB1*01, most DRB1*08, three DRB1*11, five DRB1*13 and fifteen DRB1*14 alleles when present on the other haplotype. In addition, the DRB1*15 and DRB1*16 alleles will be weakly amplified by primer mix 14.

UNIQUELY IDENTIFIED ALLELES

All the phenotypically different DRB1*12 alleles, i.e. **DRB1*12:01 to DRB1*12:35**, recognized by the HLA Nomenclature Committee in April 2012¹ will be amplified by the primers in the DRB1*12 subtyping kit.

The DRB1*12 kit enables separation of the confirmed DRB1*12 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*12 alleles is listed below.

The DRB1*12 kit also enables identification of polymorphisms in exons outside of the region encoding the peptide binding domain and of null and alternatively expressed alleles.

The DRB1*12 subtyping kit cannot distinguish the following silent mutations: the DRB1*12:01:01 and 12:01:04 alleles, the 12:01:02-12:01:03 alleles or the DRB1*12:02:01 and 12:02:03-12:02:05 alleles.

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¹DRB1 alleles listed on the IMGT/HLA web page 2012-April-12, release 3.8.0, www.ebi.ac.uk/imgt/hla.

ALLELE CONFIRMATION STATUS

Allele	Status ¹	Allele	Status ¹	Allele	Status ¹
DRB1*12:01:01	Confirmed	DRB1*12:14	Unconfirmed	DRB1*12:34	Unconfirmed
DRB1*12:01:02	Unconfirmed	DRB1*12:15	Unconfirmed	DRB1*12:35	Unconfirmed
DRB1*12:01:03	Unconfirmed	DRB1*12:16:01	Unconfirmed		
DRB1*12:01:04	Unconfirmed	DRB1*12:17	Unconfirmed		
DRB1*12:02:01	Confirmed	DRB1*12:18	Unconfirmed		
DRB1*12:02:02	Confirmed	DRB1*12:19	Unconfirmed		
DRB1*12:02:03	Unconfirmed	DRB1*12:20	Confirmed		
DRB1*12:02:04	Unconfirmed	DRB1*12:21	Unconfirmed		
DRB1*12:02:05	Unconfirmed	DRB1*12:22	Unconfirmed		
DRB1*12:03:02	Unconfirmed	DRB1*12:23	Unconfirmed		
DRB1*12:04	Confirmed	DRB1*12:24N	Confirmed		
DRB1*12:05	Unconfirmed	DRB1*12:25	Unconfirmed		
DRB1*12:06	Unconfirmed	DRB1*12:26	Unconfirmed		
DRB1*12:07	Unconfirmed	DRB1*12:27	Confirmed		
DRB1*12:08	Confirmed	DRB1*12:28	Unconfirmed		
DRB1*12:09	Unconfirmed	DRB1*12:29	Unconfirmed		
DRB1*12:10	Unconfirmed	DRB1*12:30	Unconfirmed		
DRB1*12:11	Confirmed	DRB1*12:31N	Unconfirmed		
DRB1*12:12	Unconfirmed	DRB1*12:32	Unconfirmed		
DRB1*12:13	Unconfirmed	DRB1*12:33	Unconfirmed		

¹Allele status “confirmed” or “unconfirmed” as listed on the IMGT/HLA web page 2012-April-12, release 3.8.0, www.ebi.ac.uk/imgt/hla.

RESOLUTION IN HOMO- AND HETEROZYGOTES

A total of 44 alleles generate 32 amplification patterns that can be combined in 528 homozygous and heterozygous combinations. 361 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.

```

+++----- +----- +----- *12:05, *12:05 = *12:05, *12:14
+++----- -+----- +----- *12:05, *12:15 = *12:14, *12:15
+++----- ++----- +----- *12:18, *12:18 = *12:18, *12:33
+++----- ++----- +----- *12:02:01, *12:02:01 = *12:02:01, *12:02:02 = *12:02:01,
*12:33 = *12:02:02, *12:33
+++----- +----- +----- *12:01:02, *12:05 = *12:01:02, *12:14
+++----- +----- +----- *12:01:01, *12:01:01 = *12:01:01, *12:01:02 = *12:01:01,
*12:29 = *12:01:02, *12:29
+++----- +----- +----- *12:23, *12:23 = *12:23, *12:27
+++----- +----- +----- *12:02:01, *12:18 = *12:02:02, *12:18
+++----- +----- +----- *12:02:01, *12:16:01 = *12:02:01, *12:21 = *12:02:02,
*12:21 = *12:16:01, *12:21 = *12:16:01, *12:33 = *12:21,
*12:33
+++----- +----- +----- *12:02:01, *12:13 = *12:02:02, *12:13 = *12:13, *12:13 =
*12:13, *12:33
+++----- +----- +----- *12:02:01, *12:12 = *12:02:02, *12:12 = *12:12, *12:33

```

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++-++++-	++-----	-+-+----	*12:02:01, *12:26 = *12:02:02, *12:26 = *12:26, *12:26 = *12:26, *12:33
++-++++-	++-----+	----+----	*12:02:01, *12:27 = *12:02:01, *12:31N = *12:02:02, *12:27 = *12:02:02, *12:31N = *12:27, *12:31N = *12:27, *12:33 = *12:31N, *12:31N = *12:31N, *12:33
++-++++-	++-----+	----+----	*12:02:01, *12:07 = *12:02:02, *12:07 = *12:07, *12:33
++-++++-	++-----+	----+----	*12:02:01, *12:15 = *12:02:01, *12:20 = *12:02:02, *12:20 = *12:15, *12:20 = *12:15, *12:33 = *12:20, *12:20 = *12:20, *12:33
++-++++-	++-----	----+----	*12:02:01, *12:19 = *12:02:02, *12:19 = *12:19, *12:33
++-+++++	----+----	----+----	*12:05, *12:22 = *12:14, *12:22
++-+++++	--+-----	----+----	*12:03:02, *12:05 = *12:03:02, *12:14
++-+++++	-+-----	----+----	*12:01:02, *12:16:01 = *12:02:02, *12:22
++-+++++	-+-----	----+----	*12:01:02, *12:15 = *12:02:02, *12:05 = *12:02:02, *12:14
++-+++++	+-----	----+----	*12:01:01, *12:17 = *12:01:02, *12:17 = *12:17, *12:17 = *12:17, *12:29
++-+++++	+-----	----+----	*12:01:01, *12:22 = *12:22, *12:29
++-+++++	+-----	--+-----	*12:01:01, *12:12 = *12:01:02, *12:12 = *12:12, *12:29
++-+++++	+-----	-+-----	*12:01:01, *12:11 = *12:01:02, *12:11 = *12:11, *12:11 = *12:11, *12:29
++-+++++	+-----	+-----	*12:01:01, *12:10 = *12:01:02, *12:10 = *12:10, *12:10 = *12:10, *12:29
++-+++++	+-----+	----+----	*12:01:01, *12:08 = *12:01:02, *12:08 = *12:08, *12:29
++-+++++	+-----+	----+----	*12:01:01, *12:07 = *12:01:02, *12:07 = *12:07, *12:29
++-+++++	+-----+	----+----	*12:01:01, *12:06 = *12:01:02, *12:06 = *12:06, *12:06 = *12:06, *12:29
++-+++++	+-----	----+----	*12:01:01, *12:05 = *12:01:01, *12:14 = *12:01:01, *12:24N = *12:01:02, *12:24N = *12:05, *12:24N = *12:05, *12:29 = *12:14, *12:24N = *12:24N, *12:24N = *12:24N, *12:29
++-+++++	+-----	----+----	*12:01:01, *12:04 = *12:01:02, *12:04 = *12:04, *12:29
++-+++++	+-----	----+----	*12:01:01, *12:03:02 = *12:03:02, *12:29
++-+++++	++-----	----+----	*12:01:01, *12:02:01 = *12:01:01, *12:02:02 = *12:01:01, *12:33 = *12:01:02, *12:02:01 = *12:01:02, *12:33 = *12:02:01, *12:29 = *12:02:02, *12:29 = *12:29, *12:33
+++++++	+-----	----+----	*12:01:01, *12:09 = *12:01:02, *12:09 = *12:09, *12:29
++-+++++	++-----+	----+----	*12:08, *12:16:01 = *12:22, *12:27
++-+++++	++-----+	----+----	*12:03:02, *12:27 = *12:08, *12:19
++-+++++	++-----	----+----	*12:16:01, *12:18 = *12:18, *12:21
++-+++++	++-----	----+----	*12:13, *12:16:01 = *12:13, *12:21
++-+++++	++-----	--+-----	*12:12, *12:16:01 = *12:12, *12:21
++-+++++	++-----	-+-----	*12:16:01, *12:26 = *12:21, *12:26
++-+++++	++-----+	----+----	*12:18, *12:27 = *12:18, *12:31N
++-+++++	++-----+	----+----	*12:16:01, *12:31N = *12:21, *12:27 = *12:21, *12:31N
++-+++++	++-----+	----+----	*12:02:01, *12:23 = *12:02:02, *12:23 = *12:13, *12:23 = *12:13, *12:27 = *12:13, *12:31N = *12:23, *12:31N = *12:23, *12:33
++-++++-	++-----+	--+-----	*12:12, *12:27 = *12:12, *12:31N
++-++++-	++-----+	-+-----	*12:26, *12:27 = *12:26, *12:31N
++-++++-	++-----+	----+----	*12:07, *12:16:01 = *12:07, *12:21
++-++++-	++-----+	----+----	*12:07, *12:27 = *12:07, *12:31N
++-++++-	++-----+	----+----	*12:15, *12:18 = *12:18, *12:20
++-++++-	++-----	----+----	*12:15, *12:21 = *12:16:01, *12:20 = *12:20, *12:21
++-++++-	++-----	----+----	*12:13, *12:15 = *12:13, *12:20
++-++++-	++-----	--+-----	*12:12, *12:15 = *12:12, *12:20
++-++++-	++-----	-+-----	*12:15, *12:26 = *12:20, *12:26
++-++++-	++-----+	----+----	*12:15, *12:27 = *12:15, *12:31N = *12:20, *12:27 = *12:20, *12:31N



101.128-12 – including *Taq* polymerase, IFU-01
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++-+++++	++-++-+-	----+---	*12:07, *12:15 = *12:07, *12:20
++-+++++	+++-+---	----+---	*12:15, *12:19 = *12:19, *12:20
++-+++++	-+---+---	----+---	*12:05, *12:16:01 = *12:14, *12:16:01 = *12:15, *12:22
++-+++++	+-----+	+---+--+	*12:01:01, *12:25 = *12:01:02, *12:25 = *12:10, *12:17 = *12:10, *12:25 = *12:17, *12:25 = *12:25, *12:25 = *12:25, *12:29
++-+++++	+---+---	----+--+	*12:05, *12:17 = *12:14, *12:17 = *12:17, *12:24N
++-+++++	+---+---	--+--+	*12:05, *12:12 = *12:12, *12:14 = *12:12, *12:24N
++-+++++	+---+---	-+---+---	*12:05, *12:11 = *12:11, *12:14 = *12:11, *12:24N
++-+++++	+---+---	+---+---	*12:05, *12:10 = *12:10, *12:14 = *12:10, *12:24N
++-+++++	+---+--+	----+---	*12:05, *12:08 = *12:08, *12:14 = *12:08, *12:24N
++-+++++	+---+--+	----+---	*12:05, *12:07 = *12:07, *12:14 = *12:07, *12:24N
++-+++++	+---+--+	----+---	*12:05, *12:06 = *12:06, *12:14 = *12:06, *12:24N
++-+++++	+---+--+	----+---	*12:04, *12:05 = *12:04, *12:14 = *12:04, *12:24N
++-+++++	++-----	----+--+	*12:01:01, *12:18 = *12:01:02, *12:18 = *12:18, *12:29
++-+++++	++-----	----+--+	*12:02:01, *12:17 = *12:02:02, *12:17 = *12:17, *12:33
++-+++++	++-----	----+--+	*12:01:01, *12:16:01 = *12:01:01, *12:21 = *12:01:02, *12:21 = *12:02:01, *12:22 = *12:16:01, *12:29 = *12:21, *12:22 = *12:21, *12:29 = *12:22, *12:33
++-+++++	++-----	----+--+	*12:01:01, *12:13 = *12:01:02, *12:13 = *12:13, *12:29
++-+++++	++-----	-+---+---	*12:01:01, *12:26 = *12:01:02, *12:26 = *12:02:01, *12:11 = *12:02:02, *12:11 = *12:11, *12:26 = *12:11, *12:33 = *12:26, *12:29
++-+++++	++-----	+---+---	*12:02:01, *12:10 = *12:02:02, *12:10 = *12:10, *12:33
++-+++++	++-----+	----+---	*12:01:01, *12:27 = *12:01:01, *12:31N = *12:01:02, *12:27 = *12:01:02, *12:31N = *12:02:01, *12:08 = *12:02:02, *12:08 = *12:08, *12:31N = *12:08, *12:33 = *12:27, *12:29 = *12:29, *12:31N
++-+++++	++-----+	----+---	*12:02:01, *12:06 = *12:02:02, *12:06 = *12:06, *12:33
++-+++++	++-----+	----+---	*12:01:01, *12:15 = *12:01:01, *12:20 = *12:01:02, *12:20 = *12:02:01, *12:05 = *12:02:01, *12:14 = *12:02:01, *12:24N = *12:02:02, *12:24N = *12:05, *12:20 = *12:05, *12:33 = *12:14, *12:20 = *12:14, *12:33 = *12:15, *12:24N = *12:15, *12:29 = *12:20, *12:24N = *12:20, *12:29 = *12:24N, *12:33
++-+++++	++-+-----	----+---	*12:02:01, *12:04 = *12:02:02, *12:04
++-+++++	+++-----	----+---	*12:01:01, *12:19 = *12:01:02, *12:19 = *12:02:01, *12:03:02 = *12:03:02, *12:33 = *12:19, *12:29
+++++++	+---+---	----+---	*12:05, *12:09 = *12:09, *12:14 = *12:09, *12:24N
+++++++	++-----	----+---	*12:02:01, *12:09 = *12:02:02, *12:09
++-+++++	++-+-----	----+---	*12:15, *12:23 = *12:20, *12:23
++-+++++	+---+---	+---+--+	*12:05, *12:25 = *12:14, *12:25 = *12:24N, *12:25
++-+++++	++-----	----+--+	*12:16:01, *12:17 = *12:17, *12:21
++-+++++	++-----	-+---+---	*12:11, *12:16:01 = *12:11, *12:21 = *12:22, *12:26
++-+++++	++-----	+---+--+	*12:02:01, *12:25 = *12:02:02, *12:25 = *12:25, *12:33
++-+++++	++-----	+---+--+	*12:10, *12:16:01 = *12:10, *12:21
++-+++++	++-----+	----+--+	*12:17, *12:27 = *12:17, *12:31N
++-+++++	++-----+	----+--+	*12:08, *12:21 = *12:22, *12:31N
++-+++++	++-----+	----+--+	*12:01:01, *12:23 = *12:01:02, *12:23 = *12:08, *12:13 = *12:23, *12:29
++-+++++	++-----+	-+---+---	*12:08, *12:26 = *12:11, *12:27 = *12:11, *12:31N
++-+++++	++-----+	+---+---	*12:10, *12:27 = *12:10, *12:31N
++-+++++	++-----+	----+--+	*12:06, *12:16:01 = *12:06, *12:21
++-+++++	++-----+	----+--+	*12:06, *12:27 = *12:06, *12:31N
++-+++++	++-+-----	----+--+	*12:05, *12:18 = *12:14, *12:18 = *12:18, *12:24N
++-+++++	++-+-----	----+--+	*12:15, *12:17 = *12:17, *12:20
++-+++++	++-+-----	----+--+	*12:05, *12:21 = *12:14, *12:21 = *12:16:01, *12:24N =

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			*12:20, *12:22 = *12:21, *12:24N
+++++	++-+---	---+---	*12:05, *12:13 = *12:13, *12:14 = *12:13, *12:24N
+++++	++-+---	-+---+---	*12:05, *12:26 = *12:11, *12:15 = *12:11, *12:20 = *12:14, *12:26 = *12:24N, *12:26
+++++	++-+---	+---+---	*12:10, *12:15 = *12:10, *12:20
+++++	++-+---	----+---	*12:05, *12:27 = *12:05, *12:31N = *12:08, *12:15 = *12:08, *12:20 = *12:14, *12:27 = *12:14, *12:31N = *12:24N, *12:27 = *12:24N, *12:31N
+++++	++-+---	----+---	*12:06, *12:15 = *12:06, *12:20
+++++	++-+---	----+---	*12:04, *12:16:01 = *12:04, *12:21
+++++	++-+---	----+---	*12:04, *12:27 = *12:04, *12:31N
+++++	++-+---	----+---	*12:04, *12:15 = *12:04, *12:20
+++++	+++-----	-+---+---	*12:03:02, *12:26 = *12:11, *12:19
+++++	+++-----	----+---	*12:03:02, *12:20 = *12:05, *12:19 = *12:14, *12:19 = *12:19, *12:24N
+++++	+++-----	----+---	*12:09, *12:16:01 = *12:09, *12:21
+++++	+++-----	----+---	*12:09, *12:27 = *12:09, *12:31N
+++++	+++-----	----+---	*12:09, *12:15 = *12:09, *12:20
+++++	+++-----	+---+---	*12:16:01, *12:25 = *12:21, *12:25
+++++	+++-----	+---+---	*12:25, *12:27 = *12:25, *12:31N
+++++	+++-----	+---+---	*12:15, *12:25 = *12:20, *12:25
+++++	+++-----	----+---	*12:05, *12:23 = *12:14, *12:23 = *12:23, *12:24N

*12:01:01 = *12:01:01, 12:01:04 and 12:28, 12:30 and 12:34-12:35

*12:01:02 = *12:01:02-12:01:03

*12:02:01 = *12:02:01, 12:02:03-12:02:05 and 12:32

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Lot-specific information
SPECIFICITY TABLE

DRB1*12 SSP subtyping

Specificities and sizes of the PCR products of the 24 primer mixes used for
 DRB1*12 SSP subtyping

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified DRB1*12 alleles ³	Other amplified DRB1 alleles ⁴
1	135 bp	515 bp	*12:01:01-12:20, 12:22-12:35	*08:17, 08:28, 08:37, 08:45, 11:67, 13:17
2	215 bp	430 bp	*12:01:01-12:21, 12:23-12:35	*08:05, 08:18, 08:24-08:25, 08:31, 08:40-08:41, 08:47, 13:17, 13:116, 14:31, 14:52
3	165 bp	430 bp	*12:09	*08:02:01-08:02:04, 08:04:01-08:04:05, 08:04:07, 08:09, 08:13, 08:21, 08:24, 08:28, 08:30:01, 08:30:03, 08:42, 08:44-08:45, 13:17, 13:116, 14:15, 14:52
4⁵	105 bp	430 bp	*12:01:01-12:04, 12:06-12:13, 12:16:01-12:35	*08:32
5	165 bp	515 bp	*12:01:01-12:03:02, 12:05-12:08, 12:10- 12:17, 12:19-12:23, 12:24N ^w , 12:25- 12:32, 12:34-12:35	*08:19, 08:25, 08:34
6	250 bp	430 bp	*12:01:01-12:02:05, 12:04-12:15, 12:17- 12:18, 12:20-12:21, 12:23-12:35	*08:12, 08:22, 14:28
7	215 bp	430 bp	*12:01:01-12:02:05, 12:04-12:07, 12:09- 12:12, 12:13 ^w , 12:14- 12:15, 12:17-12:18, 12:20-12:21, 12:24N- 12:26, 12:28-12:35	
8	195 bp	430 bp	*12:01:01-12:01:04, 12:03:02-12:06, 12:08-12:11, 12:14, 12:17, 12:22, 12:24N- 12:25, 12:28-12:30, 12:34-12:35	*08:03:02-08:03:03, 08:10, 08:12, 08:14-08:15, 08:18- 08:19, 08:23, 08:25, 08:27, 08:29-08:30:03, 08:32- 08:38, 08:40, 08:45-08:47, 08:49

101.128-12 – including *Taq* polymerase, IFU-01
 101.128-12u – without *Taq* polymerase, IFU-02

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Lot No.: **98N**

Lot-specific information

9	165 bp	430 bp	*12:01:01, 12:01:04-12:02:01, 12:02:03-12:02:05, 12:04, 12:06-12:13, 12:17-12:21, 12:23-12:35	
10	195 bp	430 bp	*12:02:01-12:02:05, 12:13, 12:15-12:16:01, 12:18-12:21, 12:23, 12:26-12:27, 12:31N-12:33	*08:01:01-08:02:04, 08:04:01-08:09, 08:11, 08:16-08:17, 08:21-08:22, 08:24, 08:26, 08:28, 08:31, 08:39, 08:41-08:44, 11:67, 14:15, 14:73
11	250 bp	430 bp	*12:03:02, 12:19	*08:04:01, 08:04:02 ^w -08:04:03 ^w , 08:04:04-08:04:07, 08:06, 08:10, 08:28, 08:31, 11:67, 13:17, 13:116, 14:04, 14:11, 14:15, 14:31, 14:50, 14:52, 14:73, 14:76, 14:79, 14:107, 14:120
12⁶	170 bp	430 bp	*12:04	*08:31, 08:41, 11:67, 14:11
13^{5,8}	115 bp, 185 bp, 255 bp	515 bp	*12:05, 12:14-12:15, 12:20, 12:24N	
14	135 bp	515 bp	*12:06	*15:01:01:01 ^w -15:01:16 ^w , 15:01:18 ^w -15:71 ^w , 16:01:01 ^w -16:05:02 ^w , 16:07 ^w -16:19 ^w
15	200 bp	515 bp	*12:07	
16^{5,7,9}	75 bp, 115 bp	430 bp	*12:08, 12:23, 12:27, 12:31N	*11:76, 11:114, 13:34, 13:64, 13:136, 14:41, 14:77, 14:110
17^{5,7}	90 bp	430 bp	*12:10, 12:25	
18^{5,10}	90 bp, 135 bp	515 bp	*12:11, 12:26	
19	195 bp	430 bp	*12:12	*08:13, 08:48
20	220 bp	430 bp	*12:13, 12:23	
21⁵	115 bp	430 bp	*12:01:01-12:13, 12:15-12:28, 12:30-12:35	*08:32
22^{5,11}	105 bp, 220 bp	430 bp	*12:16:01, 12:21-12:22	*08:32
23^{5,6}	110 bp	430 bp	*12:17, 12:25	*01:01:01-01:45
24	170 bp	430 bp	*12:18	

101.128-12 – including *Taq* polymerase, IFU-01
101.128-12u – without *Taq* polymerase, IFU-02

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Lot-specific information

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 DRB1*12 SSP typings.

When the primers in a primer mix can give rise to specific PCR products of more than one length this is indicated if the size difference is 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 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.

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 DRB1*12 subtyping.

In addition, wells number 5, 13 to 15 and 18 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 only partial second exon and third 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*01:01 consensus sequence.

⁴Due to the sharing of sequence motifs, non-DRB1*12 alleles will be amplified by primer mixes 1 to 6, 8, 10 to 12, 16, 19 and 21 to 23. In addition, the DRB1*15 and DRB1*16 alleles will be weakly amplified by primer mix 14.

⁵Short specific PCR fragments have a lower intensity than longer PCR bands.

⁶Primer mixes 12 and 23 may give rise to a primer dimer artefact.

⁷Primer mixes 16 and 17 may have tendencies of giving rise to unspecific amplifications.

⁸Primer mix 13: Specific PCR fragment of 115 bp in the DRB1*12:24N allele. Specific PCR fragment of 185 bp in the DRB1*12:05, 12:14 and 12:15 alleles. Specific PCR fragment of 255 bp in the DRB1*12:20 allele.

⁹Primer mix 16: Specific PCR fragment of 75 bp in the DRB1*12:08, 12:23 and 12:27 and the DRB1*11:76, 11:114, 13:34, 13:64, 13:136, 14:41, 14:77 and 14:110 alleles. Specific PCR fragment of 115 bp in the DRB1*12:31N allele.

¹⁰Primer mix 18: Specific PCR fragment of 90 bp in the DRB1*12:26 allele. Specific PCR fragment of 135 bp in the DRB1*12:11 allele.

¹¹Primer mix 22: Specific PCR fragment of 105 bp in the DRB1*12:21 allele. Specific PCR fragment of 220 bp in the DRB1*12:16:01 and the DRB1*12:22 alleles. Specific PCR fragment of 105 and 220 bp in the DRB1*08:32 allele.

‘w’, may be weakly amplified.

101.128-12 – including *Taq* polymerase, IFU-01
 101.128-12u – without *Taq* polymerase, IFU-02

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Lot No.: **98N**

Lot-specific information

INTERPRETATION TABLE												
DRB1*12 SSP subtyping												
Amplification patterns of the DRB1*12:01 to 12:35 alleles												
	Well ⁶											
	1	2	3	4	5	6	7	8	9	10	11	12
Length of spec.	135	215	165	105	165	250	215	195	165	195	250	170
PCR product(s)												
Length of int.	515	430	430	430	515	430	430	430	430	430	430	430
pos. control ¹												
5'-primer ²	15 (133)	15 (133)	15 (133)	15 (133)	15 (133)	15 (133)	26 (165)	15 (133)	36 (196)	15 (133)	15 (133)	15 (133)
	5'-gTT ³	5'-gTT ³	5'-gTT ³	5'-gTT ³	5'-gTT ³	5'-gTT ³	5'-TTA ³	5'-gTT ³	5'-AgC ³	5'-gTT ³	5'-gTT ³	5'-gTT ³
3'-primer ³	47 (227)	73 (307)	57 (257)	36 (196)	57 (257)	85 (341)	85 (341)	66 (286)	78 (321)	66 (286)	85 (341)	58 (260)
	5'-ggA ³	5'-CgC ³	5'-CAT ³	5'-gAg ³	5'-CgA ³	5'-CAG ³	5'-CAG ³	5'-gAT ³	5'-CAA ³	5'-gAA ³	5'-CAA ³	5'-CCT ³
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
DRB1 allele ^{4,5}												
*12:01:01, 12:01:04, 12:28, 12:30, 12:34-12:35	1	2		4	5	6	7	8	9			
*12:01:02-12:01:03	1	2		4	5	6	7	8				
*12:02:01, 12:02:03-12:02:05, 12:32	1	2		4	5	6	7		9	10		
*12:02:02	1	2		4	5	6	7			10		
*12:03:02	1	2		4	5			8			11	
*12:04	1	2		4		6	7	8	9			12
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

101.128-12 – including *Taq* polymerase, IFU-01
 101.128-12u – without *Taq* polymerase, IFU-02

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Lot No.: **98N**

Lot-specific information

INTERPRETATION TABLE												
DRB1*12 SSP subtyping												
Amplification patterns of the DRB1*12:01 to 12:35 alleles												
Well⁶												
13	14	15	16	17	18	19	20	21	22	23	24	
115	135	200	75	90	90	195	220	115	105	110	170	Length of spec. PCR product(s)
185			115		135				220			
255												
515	515	515	430	430	515	430	430	430	430	430	430	Length of int. pos. control ¹
13 (125)	149 (534)	15 (133)	13 (127)	-16 (40)	15 (133)	15 (133)	24 (160)	15 (133)	26 (165)	64 (280)	15 (133)	5'-primer ²
5'-gTg ^{3'}	5'-Cag ^{3'}	5'-gTT ^{3'}	5'-gTT ^{3'}	5'-CAA ^{3'}	5'-gTT ^{3'}	5'-gTT ^{3'}	5'-TgT ^{3'}	5'-gTT ^{3'}	5'-TTA ^{3'}	5'-AgC ^{3'}	5'-gTT ^{3'}	
37 (197)			24 (160)	64 (280)			25 (161)			152 (543)		
5'-gTT ^{3'}			5'-TgT ^{3'}	5'-AgC ^{3'}			5'-gCT ^{3'}			5'-gAT ^{3'}		
61 (269)			26 (165)									
5'-CTA ^{3'}			5'-TTC ^{3'}									
85 (341)	181 (630)	69 (293)	37 (199)	-3 (79)	32 (182)	66 (286)	85 (341)	37 (199)	47 (227)	85 (341)	58 (262)	3'-primer ³
5'-Cag ^{3'}	5'-CTT ^{3'}	5'-CTC ^{3'}	5'-Cag ^{3'}	5'-AgC ^{3'}	5'-TAC ^{3'}	5'-gAg ^{3'}	5'-Cag ^{3'}	5'-Cag ^{3'}	5'-ggT ^{3'}	5'-Cag ^{3'}	5'-CTg ^{3'}	
				85 (341)	46 (226)			42 (213)	86 (344)	179 (624)		
				5'-Cag ^{3'}	5'-gAg ^{3'}			5'-TCA ^{3'}	5'-CAC ^{3'}	5'-ACA ^{3'}		
13	14	15	16	17	18	19	20	21	22	23	24	Well No.
												DRB1 allele ^{4,5}
								21				*12:01:01, 12:01:04, 12:28, 12:30, 12:34-12:35
								21				*12:01:02-12:01:03
								21				*12:02:01, 12:02:03-12:02:05, 12:32
								21				*12:02:02
								21				*12:03:02
								21				*12:04
13	14	15	16	17	18	19	20	21	22	23	24	Well No.

101.128-12 – including *Taq* polymerase, IFU-01
 101.128-12u – without *Taq* polymerase, IFU-02

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Lot No.: **98N**

Lot-specific information

Length of spec. PCR product(s)	135	215	165	105	165	250	215	195	165	195	250	170
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
*12:05	1	2			5	6	7	8				
*12:06	1	2		4	5	6	7	8	9			
*12:07	1	2		4	5	6	7		9			
*12:08	1	2		4	5	6		8	9			
*12:09	1	2	3	4		6	7	8	9			
*12:10	1	2		4	5	6	7	8	9			
*12:11	1	2		4	5	6	7	8	9			
*12:12	1	2		4	5	6	7		9			
*12:13	1	2		4	5	6	w		9	10		
*12:14	1	2			5	6	7	8				
*12:15	1	2			5	6	7			10		
*12:16:01	1	2		4	5					10		
*12:17	1	2		4	5	6	7	8	9			
*12:18	1	2		4		6	7		9	10		
*12:19	1	2		4	5				9	10	11	
*12:20	1	2		4	5	6	7		9	10		
*12:21		2		4	5	6	7		9	10		
*12:22	1			4	5			8				
*12:23	1	2		4	5	6			9	10		
*12:24N	1	2		4	w	6	7	8	9			
*12:25	1	2		4	5	6	7	8	9			
*12:26	1	2		4	5	6	7		9	10		
*12:27	1	2		4	5	6			9	10		
*12:29	1	2		4	5	6	7	8	9			
*12:31N	1	2		4	5	6	7		9	10		
*12:33	1	2		4		6	7		9	10		
*01:01:01-01:45												
*08:01:01-08:01:05, 08:07-08:08, 08:11, 08:16, 08:26, 08:39, 08:43										10		
*08:02:01-08:02:04, 08:09, 08:21, 08:42, 08:44			3							10		
*08:03:02-08:03:03, 08:14-08:15, 08:23, 08:27, 08:29, 08:30:02, 08:33, 08:35-08:36:01, 08:38, 08:46, 08:49								8				
*08:04:01, 08:04:04-08:04:05, 08:04:07, 14:15			3							10	11	
*08:04:02-08:04:03			3							10	w	
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

101.128-12 – including *Taq* polymerase, IFU-01
 101.128-12u – without *Taq* polymerase, IFU-02

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Lot No.: **98N**

Lot-specific information

115	135	200	75	90	90	195	220	115	105	110	170	Length of spec. PCR product(s)
185			115		135				220			
255												
13	14	15	16	17	18	19	20	21	22	23	24	Well No.
13								21				*12:05
	14							21				*12:06
		15						21				*12:07
			16					21				*12:08
								21				*12:09
				17				21				*12:10
					18			21				*12:11
						19		21				*12:12
							20	21				*12:13
13												*12:14
13								21				*12:15
								21	22			*12:16:01
								21		23		*12:17
								21			24	*12:18
								21				*12:19
13								21				*12:20
								21	22			*12:21
								21	22			*12:22
			16				20	21				*12:23
13								21				*12:24N
				17				21		23		*12:25
					18			21				*12:26
			16					21				*12:27
												*12:29
			16					21				*12:31N
								21				*12:33
										23		*01:01:01-01:45
												*08:01:01-08:01:05, 08:07-08:08, 08:11, 08:16, 08:26, 08:39, 08:43
												*08:02:01-08:02:04, 08:09, 08:21, 08:42, 08:44
												*08:03:02-08:03:03, 08:14-08:15, 08:23, 08:27, 08:29, 08:30:02, 08:33, 08:35-08:36:01, 08:38, 08:46, 08:49
												*08:04:01, 08:04:04-08:04:05, 08:04:07, 14:15
												*08:04:02-08:04:03
13	14	15	16	17	18	19	20	21	22	23	24	Well No.

101.128-12 – including *Taq* polymerase, IFU-01
 101.128-12u – without *Taq* polymerase, IFU-02

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Lot No.: **98N**

Lot-specific information

Length of spec. PCR product(s)	135	215	165	105	165	250	215	195	165	195	250	170
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
*08:04:06, 08:06, 14:73										10	11	
*08:05		2								10		
*08:10								8			11	
*08:12						6		8				
*08:13			3									
*08:17	1									10		
*08:18, 08:40, 08:47		2						8				
*08:19, 08:34					5			8				
*08:22						6				10		
*08:24		2	3							10		
*08:25		2			5			8				
*08:28	1		3							10	11	
*08:30:01, 08:30:03			3					8				
*08:31		2								10	11	12
*08:32				4				8				
*08:37	1							8				
*08:41		2								10		12
*08:45	1		3					8				
*08:48												
*11:67	1									10	11	12
*11:76, 11:114, 13:34, 13:64, 13:136, 14:41, 14:77, 14:110												
*13:17	1	2	3								11	
*13:116, 14:52		2	3								11	
*14:04, 14:50, 14:76, 14:79, 14:107, 14:120											11	
*14:11											11	12
*14:28						6						
*14:31		2									11	
*15:01:01:01-15:01:16, 15:01:18- 15:71, 16:01:01-16:05:02, 16:07- 16:19												
DRB1 allele^{4,5}												
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

101.128-12 – including *Taq* polymerase, IFU-01
 101.128-12u – without *Taq* polymerase, IFU-02

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Lot No.: **98N**

Lot-specific information

115	135	200	75	90	90	195	220	115	105	110	170	Length of spec. PCR product(s)
185			115		135				220			
255												
13	14	15	16	17	18	19	20	21	22	23	24	Well No.
												*08:04:06, 08:06, 14:73
												*08:05
												*08:10
												*08:12
						19						*08:13
												*08:17
												*08:18, 08:40, 08:47
												*08:19, 08:34
												*08:22
												*08:24
												*08:25
												*08:28
												*08:30:01, 08:30:03
												*08:31
								21	22			*08:32
												*08:37
												*08:41
												*08:45
						19						*08:48
												*11:67
			16									*11:76, 11:114, 13:34, 13:64, 13:136, 14:41, 14:77, 14:110
												*13:17
												*13:116, 14:52
												*14:04, 14:50, 14:76, 14:79, 14:107, 14:120
												*14:11
												*14:28
												*14:31
	w											*15:01:01:01-15:01:16, 15:01:18- 15:71, 16:01:01-16:05:02, 16:07- 16:19
												DRB1 allele^{4,5}
13	14	15	16	17	18	19	20	21	22	23	24	Well No.

101.128-12 – including *Taq* polymerase, IFU-01
101.128-12u – without *Taq* polymerase, IFU-02

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Lot No.: 98N**Lot-specific information**

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*12 subtyping.

In addition, wells number 5, 13 to 15 and 18 contain 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 1st, 2nd or 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 1st, 2nd or 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.

⁴The sequence of the DRB1*12031 allele has been shown to be identical to DRB1*12:01:01.

⁵DRB1*12 alleles in bold lettering are listed as confirmed alleles on the on the IMGT/HLA web page www.ebi.ac.uk/imgt/hla, release 3.8.0, April 2012.

⁶Primer mix 13: Specific PCR fragment of 115 bp in the DRB1*12:24N allele. Specific PCR fragment of 185 bp in the DRB1*12:05, 12:14 and 12:15 alleles. Specific PCR fragment of 255 bp in the DRB1*12:20 allele.

Primer mix 16: Specific PCR fragment of 75 bp in the DRB1*12:08, 12:23 and 12:27 and the DRB1*11:76, 11:114, 13:34, 13:64, 13:136, 14:41, 14:77 and 14:110 alleles. Specific PCR fragment of 115 bp in the DRB1*12:31N allele.

Primer mix 18: Specific PCR fragment of 90 bp in the DRB1*12:26 allele. Specific PCR fragment of 135 bp in the DRB1*12:11 allele.

Primer mix 22: Specific PCR fragment of 105 bp in the DRB1*12:21 allele. Specific PCR fragment of 220 bp in the DRB1*12:16:01 and the DRB1*12:22 alleles. Specific PCR fragment of 105 and 220 bp in the DRB1*08:32 allele.

'w', may be weakly amplified.

101.128-12 – including *Taq* polymerase, IFU-01
 101.128-12u – without *Taq* polymerase, IFU-02

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 “Instructions for Use” (IFU)

Lot No.: **98N**

Lot-specific information

CELL LINE VALIDATION SHEET																				
DRB1*12 SSP subtyping kit																				
				Well																
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	
				Prod. No.:	201203901	201203902	201203903	201203904	201203905	201203906	201203907	201203908	201203909	201203910	201203911	201203912	201203913	201203914	201203915	201203916
IHCW 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		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

101.128-12 – including *Taq* polymerase, IFU-01
 101.128-12u – without *Taq* polymerase, IFU-02

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 “Instructions for Use” (IFU)

Lot No.: **98N**

Lot-specific information

CELL LINE VALIDATION SHEET													
DRB1*12 SSP subtyping kit													
					Well								
					17	18	19	20	21	22	23	24	
					Prod. No.:	201203917	201203918	201203919	201203920	201203921	201203922	201203923	201203924
IHCW 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		-	-	-	-	-	-	+	-	

101.128-12 – including *Taq* polymerase, IFU-01
 101.128-12u – without *Taq* polymerase, IFU-02

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Lot No.: **98N**

Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP® DRB1*12 SSP

Product number: 101.128-12 – including *Taq* polymerase
 101.128-12u – without *Taq* polymerase
Lot number: 98N
Expiry date: 2015-February-01
Number of tests: 12
Number of wells per test: 24

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2012-039-01	9	2012-039-09	17	2012-039-17
2	2012-039-02	10	2012-039-10	18	2012-039-18
3	2012-039-03	11	2012-039-11	19	2012-039-19
4	2012-039-04	12	2012-039-12	20	2012-039-20
5	2012-039-05	13	2012-039-13	21	2012-039-21
6	2012-039-06	14	2012-039-14	22	2012-039-22
7	2012-039-07	15	2012-039-15	23	2012-039-23
8	2012-039-08	16	2012-039-16	24	2012-039-24

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

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

Date of approval: 2012-August-27

Approved by:

Production Quality Control

101.128-12 – including *Taq* polymerase, IFU-01
101.128-12u – without *Taq* polymerase, IFU-02

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“Instructions for Use” (IFU)

Lot No.: **98N**

Lot-specific information

Declaration of Conformity

Product name: *Olerup* SSP® DRB1*12
Product number: 101.128-12/12u
Lot number: 98N

Intended use: DRB1*12 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 13485:2003, 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, 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
2012-August-27

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs

101.128-12 – including *Taq* polymerase, IFU-01
101.128-12u – without *Taq* polymerase, IFU-02

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Lot No.: **98N**

Lot-specific information

101.128-12 – including *Taq* polymerase, IFU-01
101.128-12u – without *Taq* polymerase, IFU-02

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Lot No.: **98N**

Lot-specific information

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Fax: +46-8-717 88 18

E-mail: info-ssp@olerup.com

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

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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**.