Lot No.: 18N **Lot-specific information**

Olerup SSP® DRB1*08

Product number:	**101.127-12/04 – including *Taq* pol.** **101.127-12u/04u – without *Taq* pol.**
Lot number:	**18N**
Expiry date:	**2014-August-01**
Number of tests:	**12 tests – Product No. 101.127-12/12u** **4 tests – Product No. 101.127-04/04u**
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. 18N.

CHANGES COMPARED TO THE PREVIOUS *OLERUP* SSP® DRB1*08 LOT

The DRB1*08 kit is updated to enable separation of:

- Confirmed DRB1*08 alleles as listed in the IMGT/HLA database[1]
- Polymorphisms in exons outside of the region encoding the peptide binding domain
- Null and Alternatively expressed alleles

The Lot-specific information for DRB1*08 including and without *Taq* polymerase is now described in one common Product Insert.

[1]As described in section Uniquely Identified Alleles.

The DRB1*08 specificity and interpretation tables have been updated for the DRB1 alleles described since the previous *Olerup* SSP® DRB1*08 lot was made **(Lot No. 66K)**.

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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
2	-	Modified, added	Primer added for the DRB1*08:04:06 allele, increased yield of specific PCR product.
12	-	Added	Primer added for the DRB1*08:44 allele.
15	-	Added	Primer added for the DRB1*08:49 allele.
19	-	Added	Primer added for the DRB1*08:49 allele.

101.127-12/04 – including *Taq* polymerase, IFU-01 Rev. No. 03
101.127-12u/04u – without *Taq* polymerase, IFU-02 Rev. No. 03

Visit www.olerup-ssp.com for **"Instructions for Use" (IFU)**

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PRODUCT DESCRIPTION

DRB1*08 SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for identifying the DRB1*08:01 to DRB1*08:49 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*08' in silver/gray ink.
Well No. 1 is marked with the Lot No. '18N'.
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*08 SSP subtypings will be influenced by the DRB1*03:12, eleven DRB1*04 alleles, the DRB1*07:12, seven DRB1*11, the DRB1*12, several DRB1*13, several DRB1*14 and two DRB1*15 allele when present on the other haplotype.

UNIQUELY IDENTIFIED ALLELES

All the phenotypically different DRB1*08 alleles, i.e. **DRB1*08:01 to DRB1*08:49**, recognized by the HLA Nomenclature Committee in January 2012[1] will be amplified by the primers in the DRB1*08 subtyping kit[2].

The DRB1*08 kit enables separation of the confirmed DRB1*08 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*08 alleles is listed below.
The DRB1*08 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*08 subtyping kit cannot distinguish the following silent mutations: DRB1*08:01:01-08:01:05, the DRB1*08:02:01-08:02:04, DRB1*08:03:02-08:03:03, the DRB1*08:04:01 and 08:04:04-08:04:07 alleles, the DRB1* 08:04:02-08:04:03 alleles or the DRB1*08:30:01-08:30:03 alleles.

[1]DRB1 alleles listed on the IMGT/HLA web page 2012-January-12, release 3.7.0, www.ebi.ac.uk/imgt/hla.
[2]The DRB1*08:20 and DRB1*14:12:01-14:12:02 give rise to identical amplification patterns with the DRB1*08 subtyping kit. These two alleles can be distinguished by e.g. the DR low resolution kit and/or the DRB1*14 subtyping kit.

ALLELE CONFIRMATION STATUS

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

[1]Allele status "confirmed" or "unconfirmed" as listed on the IMGT/HLA web page 2012-January-12, release 3.7.0, www.ebi.ac.uk/imgt/hla.

RESOLUTION IN HOMO- AND HETEROZYGOTES

A total of 65 alleles generate 46 amplification patterns that can be combined in 1081 homozygous and heterozygous combinations. 518 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.

```
+++++++- -------+ --------   *08:18, *08:44 = *08:24, *08:27
+++++++- --------+ --------   *08:02:01, *08:18 = *08:03:02, *08:24
++++++-++ ++------+ +--+----   *08:09, *08:12 = *08:12, *08:21
++++++-++ +-------+ +--+--+-   *08:09, *08:10 = *08:10, *08:21
++++++-++ ------+-+ +--+++-   *08:23, *08:28 = *08:28, *08:29
```

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	Lot-specific information
++++++-+ ------+- +---+-++	*08:14, *08:28 = *08:28, *08:36
++++++-+ ------+- +---+-+-	*08:03:02, *08:28 = *08:04:01, *08:37 = *08:28, *08:37
++++++-+ -------+ +---++--	*08:04:01, *08:23 = *08:04:01, *08:29
++++++-+ -------+ +---+++	*08:04:01, *08:14 = *08:04:01, *08:36
++++++-- +--+---+ --------	*08:09, *08:27 = *08:21, *08:27
++++++-- +---+--+ --------	*08:09, *08:33 = *08:21, *08:33
++++++-- +---+-+- ----+---	*08:09, *08:37 = *08:21, *08:37
++++++-- +---++-- --+-----	*08:09, *08:49 = *08:21, *08:49
++++++-- +------+ -+------	*08:09, *08:32 = *08:21, *08:32
++++++-- +------+ --+-----	*08:09, *08:38 = *08:21, *08:38
++++++-- +------+ -----+--	*08:09, *08:23 = *08:09, *08:29 = *08:21, *08:23
++++++-- +------+ -------+	*08:02:01, *08:35 = *08:09, *08:35 = *08:09, *08:36 = *08:21, *08:35 = *08:21, *08:36
+++++-+- +------+ --------	*08:03:02, *08:09 = *08:03:02, *08:21
+++++-+- ---+---+ -----+--	*08:23, *08:44 = *08:29, *08:44
+++++-+- ---+---+ --------	*08:02:01, *08:27 = *08:03:02, *08:44 = *08:27, *08:44
+++++-+- -----+-- ----+---	*08:01:01, *08:45 = *08:17, *08:30:01 = *08:17, *08:45 = *08:43, *08:45
+++++-+- -------+ -----+--	*08:02:01, *08:23 = *08:02:01, *08:29
+++++-+- -------- --------	*08:01:01, *08:30:01 = *08:30:01, *08:43
+++-+++- ---+---- --------	*08:05, *08:13 = *08:05, *08:44 = *08:24, *08:48
+++-+++- -------- --------	*08:01:01, *08:24 = *08:02:01, *08:05
+++-+-++ ++------ +--+----	*08:09, *08:22 = *08:21, *08:22
+++-+-++ +------- +--+--+-	*08:06, *08:09 = *08:06, *08:21
+++-+-++ -+-+---- +--+----	*08:13, *08:22 = *08:22, *08:44
+++-+-++ ---+---- +--+--+-	*08:06, *08:13 = *08:06, *08:44
+++-+-++ -----+-- +---+-+-	*08:01:01, *08:28 = *08:04:01, *08:17 = *08:17, *08:28 = *08:28, *08:43
+++-+-++ -------- +-----+-	*08:01:01, *08:04:01 = *08:04:01, *08:43
+++-+-+- +--+---- --------	*08:09, *08:48 = *08:21, *08:48
+++-+-+- +---+--- --------	*08:09, *08:39 = *08:21, *08:39
+++-+-+- +----+-- ----+---	*08:09, *08:17 = *08:17, *08:21
+++-+-+- +------- --+-----	*08:09, *08:16 = *08:16, *08:21
+++-+-+- +------- -------+	*08:09, *08:26 = *08:21, *08:26
+++-+-+- +------- --------	*08:01:01, *08:09 = *08:01:01, *08:21 = *08:09, *08:43
+++-+-+- ---+--- --------	*08:13, *08:39 = *08:39, *08:44
+++-+-+- ---+-+- ----+---	*08:13, *08:17 = *08:17, *08:44
+++-+-+- ---+---- --+-----	*08:13, *08:16 = *08:16, *08:44
+++-+-+- ---+---- -------+	*08:13, *08:26 = *08:26, *08:44
+++-+-+- ---+---- --------	*08:01:01, *08:13 = *08:01:01, *08:44 = *08:02:01, *08:48 = *08:13, *08:43 = *08:43, *08:44 = *08:44, *08:48
+++-+-+- -------- --------	*08:01:01, *08:02:01 = *08:02:01, *08:43
+++--++- -------- --------	*08:05, *08:24 = *08:24, *08:43
++-++-+- ---+-+-+ ----+---	*08:13, *08:37 = *08:27, *08:45
++-++-+- ---+---+ -----+--	*08:13, *08:23 = *08:13, *08:29
++-++-+- ---+---+ --------	*08:03:02, *08:13 = *08:13, *08:27 = *08:27, *08:30:01
++-++-+- ------+-+ ----++--	*08:23, *08:45 = *08:29, *08:45
++-++-+- ------+-+ ----+---	*08:03:02, *08:45 = *08:30:01, *08:37 = *08:37, *08:45
++-++-+- -------+ -----+--	*08:23, *08:30:01 = *08:29, *08:30:01
+-++++++ -+-----+ +--+----	*08:05, *08:12 = *08:18, *08:22 = *08:22, *08:40
+-++++++ -------+ +--+--+-	*08:05, *08:10 = *08:06, *08:18
+-++++-- -+--+--+ --------	*08:11, *08:40 = *08:39, *08:40
+-++++-- -+-----+ --+-----	*08:07, *08:40 = *08:16, *08:40
+-++++-- --+----+ --------	*08:03:02, *08:41 = *08:08, *08:18
+-++++-- -----+--+ --------	*08:05, *08:33 = *08:11, *08:18 = *08:18, *08:39
+-++++-- ------+-+ ----+---	*08:05, *08:37 = *08:17, *08:18
+-++++-- ------+- --------	*08:01:01, *08:25 = *08:05, *08:34
+-++++-- -------+ --+-----	*08:05, *08:38 = *08:07, *08:18 = *08:16, *08:18
+-++++-- -------+ -------+	*08:05, *08:36 = *08:18, *08:26
+-++++-- -------+ --------	*08:01:01, *08:18 = *08:03:02, *08:05
+-+++-++ -+--+--+ +--+----	*08:11, *08:12 = *08:12, *08:39 = *08:22, *08:33
+-+++-++ -+----+-+ +--++---	*08:12, *08:17 = *08:22, *08:37
+-+++-++ -+-----+ +-++----	*08:07, *08:12 = *08:12, *08:16 = *08:22, *08:38

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+-++++-++ -+------+ +--+-+--	*08:22, *08:23 = *08:22, *08:29
+-++++-++ -+------+ +--+---+	*08:12, *08:26 = *08:14, *08:22 = *08:22, *08:36
+-++++-++ -+------+ +--+----	*08:01:01, *08:12 = *08:03:02, *08:22 = *08:12, *08:43
+-++++-++ ------+-+ +--+--+-	*08:06, *08:33 = *08:10, *08:11 = *08:10, *08:39
+-++++-++ ------+-+ +--++-+-	*08:06, *08:37 = *08:10, *08:17
+-++++-++ -------+ +-++--+-	*08:06, *08:38 = *08:07, *08:10 = *08:10, *08:16
+-++++-++ -------+ +--+-++-	*08:06, *08:23 = *08:06, *08:29
+-++++-++ -------+ +--+--++	*08:06, *08:14 = *08:06, *08:36 = *08:10, *08:26
+-++++-++ -------+ +--+--+-	*08:01:01, *08:10 = *08:03:02, *08:06 = *08:10, *08:43
+-++++-+- +---+--+ -------+	*08:11, *08:35 = *08:35, *08:39
+-++++-+- +------+ --+----+	*08:07, *08:35 = *08:16, *08:35
+-++++-+- +------+ -------+	*08:01:01, *08:35 = *08:26, *08:35 = *08:35, *08:43
+-++++-+- --+----+ -----+--	*08:08, *08:23 = *08:08, *08:29
+-++++-+- --+----- --------	*08:01:01, *08:15 = *08:15, *08:43
+-++++-+- ---++--+ --------	*08:11, *08:27 = *08:27, *08:39
+-++++-+- ---+---+ --+-----	*08:07, *08:27 = *08:16, *08:27
+-++++-+- ---+---+ --------	*08:01:01, *08:27 = *08:27, *08:43
+-++++-+- ----++-+ ----+---	*08:11, *08:37 = *08:17, *08:33 = *08:37, *08:39
+-++++-+- ----+-++ --+-----	*08:11, *08:49 = *08:39, *08:49
+-++++-+- ----+--+ +------+	*08:11, *08:14 = *08:14, *08:39
+-++++-+- ----+--+ -+------	*08:11, *08:32 = *08:32, *08:39
+-++++-+- ----+--+ --+-----	*08:07, *08:33 = *08:11, *08:38 = *08:16, *08:33 = *08:38, *08:39
+-++++-+- ----+--+ -----+--	*08:11, *08:23 = *08:11, *08:29 = *08:23, *08:39 = *08:29, *08:39
+-++++-+- ----+--+ -------+	*08:11, *08:36 = *08:26, *08:33 = *08:36, *08:39
+-++++-+- ----+--+ --------	*08:01:01, *08:33 = *08:03:02, *08:11 = *08:03:02, *08:39 = *08:11, *08:33 = *08:33, *08:39 = *08:33, *08:43
+-++++-+- -----+-+ --+-+---	*08:07, *08:37 = *08:16, *08:37 = *08:17, *08:38
+-++++-+- -----+-+ ----+---	*08:17, *08:23 = *08:17, *08:29
+-++++-+- -----+-+ ----+--+	*08:17, *08:36 = *08:26, *08:37
+-++++-+- -----+-+ ----+---	*08:01:01, *08:37 = *08:03:02, *08:17 = *08:17, *08:37 = *08:37, *08:43
+-++++-+- ------++ --+-----	*08:01:01, *08:49 = *08:07, *08:49 = *08:16, *08:49 = *08:43, *08:49
+-++++-+- ------++ -----+--	*08:01:01, *08:19 = *08:19, *08:43
+-++++-+- ------+- --------	*08:01:01, *08:34 = *08:34, *08:43
+-++++-+- -------+ +-+----+	*08:07, *08:14 = *08:14, *08:16
+-++++-+- -------+ +------+	*08:01:01, *08:14 = *08:14, *08:26
+-++++-+- -------+ -+------	*08:07, *08:32 = *08:16, *08:32
+-++++-+- -------+ -+------	*08:01:01, *08:32 = *08:32, *08:43
+-++++-+- -------+ --+--+--	*08:07, *08:23 = *08:07, *08:29 = *08:16, *08:23 = *08:16, *08:29
+-++++-+- -------+ --+----+	*08:07, *08:36 = *08:16, *08:36 = *08:26, *08:38
+-++++-+- -------+ --+-----	*08:01:01, *08:38 = *08:03:02, *08:07 = *08:03:02, *08:16 = *08:07, *08:38 = *08:16, *08:38 = *08:38, *08:43
+-++++-+- -------+ -----+-+	*08:23, *08:26 = *08:26, *08:29
+-++++-+- -------+ -----+--	*08:01:01, *08:23 = *08:01:01, *08:29 = *08:23, *08:43
+-++++-+- -------+ -------+	*08:01:01, *08:36 = *08:03:02, *08:26 = *08:26, *08:36 = *08:36, *08:43
+-++++-+- -------+ --------	*08:01:01, *08:03:02 = *08:03:02, *08:43
+-++++--+ -+------+ +--+--+-	*08:06, *08:12 = *08:10, *08:22
+-++-++- -+------+ --------	*08:05, *08:40 = *08:40, *08:43
+-++-++- ------+- --------	*08:05, *08:25 = *08:25, *08:43
+-++-++- -------+ --------	*08:05, *08:18 = *08:18, *08:43
+-+-+++- --+----- --------	*08:01:01, *08:41 = *08:05, *08:08
+-+-+++- ----+--- --------	*08:05, *08:11 = *08:05, *08:39
+-+-+++- -------- --+-----	*08:05, *08:07 = *08:05, *08:16
+-+-+-++ -+--+--- +--+----	*08:11, *08:22 = *08:22, *08:39
+-+-+-++ -+------ +-++----	*08:07, *08:22 = *08:16, *08:22
+-+-+-++ -+------ +--+----	*08:01:01, *08:22 = *08:22, *08:43
+-+-+-++ ----+--- +--+--+-	*08:06, *08:11 = *08:06, *08:39
+-+-+-++ -------- +-++--+-	*08:06, *08:07 = *08:06, *08:16
+-+-+-++ -------- +--+--+-	*08:01:01, *08:06 = *08:06, *08:43
+-+-+-+- --+----- --------	*08:01:01, *08:08 = *08:08, *08:43
+-+-+-+- ---++--- --------	*08:11, *08:48 = *08:39, *08:48
+-+-+-+- ---+---- --+-----	*08:07, *08:48 = *08:16, *08:48

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+-+-+-+- ---+---- --------	*08:01:01, *08:48 = *08:43, *08:48
+-+-+-+- ----+-- ----+---	*08:11, *08:17 = *08:17, *08:39
+-+-+-+- ----+--- --+-----	*08:07, *08:39 = *08:11, *08:16 = *08:16, *08:39
+-+-+-+- ----+--- -------+	*08:11, *08:26 = *08:26, *08:39
+-+-+-+- ----+--- --------	*08:01:01, *08:11 = *08:01:01, *08:39 = *08:11, *08:39 = *08:11, *08:43 = *08:39, *08:39 = *08:39, *08:43
+-+-+-+- -----+-- --+-+---	*08:07, *08:17 = *08:16, *08:17
+-+-+-+- -----+-- ----+---	*08:01:01, *08:17 = *08:17, *08:17 = *08:17, *08:43
+-+-+-+- -------- ++------	*08:01:01, *08:20 = *08:20, *08:43
+-+-+-+- -------- --+----+	*08:07, *08:26 = *08:16, *08:26
+-+-+-+- -------- --+-----	*08:01:01, *08:07 = *08:01:01, *08:16 = *08:07, *08:16 = *08:07, *08:43 = *08:16, *08:16 = *08:16, *08:43
+-+-+-+- -------- -------+	*08:01:01, *08:26 = *08:26, *08:26 = *08:26, *08:43
+-+-+-+- -------- --------	*08:01:01, *08:01:01 = *08:01:01, *08:43
+-+--+++ --+----- ------+-	*08:05, *08:31 = *08:31, *08:43
+-+--++- --+----- --------	*08:05, *08:41 = *08:41, *08:43
+-+--++- -------- --------	*08:05, *08:05 = *08:05, *08:43
+--+++++ -+-----+ +--+----	*08:12, *08:18 = *08:12, *08:40
+--++++- -+-+---+ --------	*08:27, *08:40 = *08:40, *08:48
+--++++- ---+---+ --------	*08:18, *08:27 = *08:18, *08:48
+--++++- ------++ --+-----	*08:18, *08:49 = *08:25, *08:38 = *08:25, *08:49
+--++++- ------++ -----+--	*08:18, *08:19 = *08:23, *08:25
+--++++- ------++ --------	*08:03:02, *08:25 = *08:18, *08:34
+--+++++ -+-+---+ +--+----	*08:12, *08:27 = *08:12, *08:48
+--+++++ -+-----+ +--+-+--	*08:12, *08:23 = *08:12, *08:29
+--+++++ -+-----+ +--+---+	*08:12, *08:14 = *08:12, *08:36
+--+++++ ---+---+ +--+--+-	*08:10, *08:27 = *08:10, *08:48
+--+++++ -------+ +--+-++-	*08:10, *08:23 = *08:10, *08:29
+--+++++ -------+ +--+--++	*08:10, *08:14 = *08:10, *08:36
+--+++-+ +--+---+ -------+	*08:27, *08:35 = *08:35, *08:48
+--+++-+ +------+ -----+-+	*08:23, *08:35 = *08:29, *08:35
+--+++-+ +------+ -------+	*08:03:02, *08:35 = *08:35, *08:35 = *08:35, *08:36
+--+++-+ --+----- -----+--	*08:15, *08:23 = *08:15, *08:29
+--+++-+ ---+--- --------	*08:27, *08:33 = *08:33, *08:48
+--+++-+ ---+-+- ----+---	*08:27, *08:37 = *08:37, *08:48
+--+++-+ ---+--+ --+-----	*08:27, *08:49 = *08:48, *08:49
+--+++-+ ---+--+ -----+--	*08:19, *08:27 = *08:19, *08:48
+--+++-+ ---+---+ +------+	*08:14, *08:27 = *08:14, *08:48
+--+++-+ ---+---+ -+------	*08:27, *08:32 = *08:32, *08:48
+--+++-+ ---+---+ --+-----	*08:27, *08:38 = *08:38, *08:48
+--+++-+ ---+---+ -----+--	*08:23, *08:27 = *08:23, *08:48 = *08:27, *08:29 = *08:29, *08:48
+--+++-+ ---+---+ -------+	*08:27, *08:36 = *08:36, *08:48
+--+++-+ ---+---+ --------	*08:03:02, *08:27 = *08:03:02, *08:48 = *08:27, *08:27 = *08:27, *08:48
+--+++-+ ----+--+ -----+--	*08:23, *08:33 = *08:29, *08:33
+--+++-+ ----+--+ --------	*08:03:02, *08:33 = *08:33, *08:33
+--+++-+ -----+-+ ----+--	*08:23, *08:37 = *08:29, *08:37
+--+++-+ -----+-+ ----+---	*08:03:02, *08:37 = *08:37, *08:37
+--+++-+ ------++ --+--+--	*08:19, *08:38 = *08:19, *08:49 = *08:23, *08:49 = *08:29, *08:49
+--+++-+ ------++ --+-----	*08:03:02, *08:49 = *08:34, *08:38 = *08:34, *08:49 = *08:38, *08:49 = *08:49, *08:49
+--+++-+ ------++ -----+--	*08:03:02, *08:19 = *08:19, *08:23 = *08:19, *08:29 = *08:23, *08:34 = *08:29, *08:34
+--+++-+ -------+ ++---+--	*08:20, *08:23 = *08:20, *08:29
+--+++-+ -------+ ++-----+	*08:14, *08:20 = *08:14, *08:32 = *08:20, *08:36
+--+++-+ -------+ ++------	*08:03:02, *08:20 = *08:20, *08:32
+--+++-+ -------+ +------+	*08:03:02, *08:14 = *08:14, *08:36
+--+++-+ -------+ -+---+--	*08:23, *08:32 = *08:29, *08:32
+--+++-+ -------+ -+------	*08:03:02, *08:32 = *08:32, *08:32
+--+++-+ -------+ --+--+--	*08:23, *08:38 = *08:29, *08:38
+--+++-+ -------+ --+-----	*08:03:02, *08:38 = *08:38, *08:38
+--+++-+ -------+ -----+-+	*08:23, *08:36 = *08:29, *08:36
+--+++-+ -------+ -----+--	*08:03:02, *08:23 = *08:03:02, *08:29 = *08:23, *08:23 = *08:23,

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	Lot-specific information
	*08:29
+--++-+- -------+ -------+	*08:03:02, *08:36 = *08:36, *08:36
+--+-++- -+------+ --------	*08:18, *08:40 = *08:40, *08:40
-++++++- --+----- --------	*08:15, *08:24 = *08:30:01, *08:41
-++++++- ------+- --------	*08:02:01, *08:25 = *08:24, *08:34
-+++++++ ------+- +---+-+-	*08:04:01, *08:45 = *08:28, *08:30:01 = *08:28, *08:45
-+++++-+- +-+----- --------	*08:09, *08:15 = *08:15, *08:21
-+++++-+- +-----+- ----+---	*08:09, *08:45 = *08:21, *08:45
-+++++-+- +------++ -----+--	*08:09, *08:19 = *08:19, *08:21
-+++++-+- +------+- --------	*08:09, *08:34 = *08:21, *08:34
-+++++-+- +------- --------	*08:09, *08:30:01 = *08:21, *08:30:01
-+++++-+- --+----- --------	*08:02:01, *08:15 = *08:08, *08:30:01
-++-++++ --++---- ------+-	*08:13, *08:31 = *08:31, *08:44
-++-+++- --++---- --------	*08:13, *08:41 = *08:41, *08:44
-++-+++- --+----- --------	*08:02:01, *08:41 = *08:08, *08:24
-++-+++- ---+---- --------	*08:13, *08:24 = *08:24, *08:44
-++-+-++ +----+-- +---+-+-	*08:09, *08:28 = *08:21, *08:28
-++-+-++ +------- +-----+-	*08:04:01, *08:09 = *08:04:01, *08:21
-++-+-++ ---+-+-- +---+-+-	*08:13, *08:28 = *08:28, *08:44
-++-+-++ ---+---- +-----+-	*08:04:01, *08:13 = *08:04:01, *08:44
-++-+-+- +-+----- --------	*08:08, *08:09 = *08:08, *08:21
-++-+-+- +--+---- --------	*08:09, *08:13 = *08:09, *08:44 = *08:13, *08:21 = *08:21, *08:44
-++-+-+- +---+--- --------	*08:09, *08:11 = *08:11, *08:21
-++-+-+- +------- ++------	*08:09, *08:20 = *08:20, *08:21
-++-+-+- +------- --+-----	*08:07, *08:09 = *08:07, *08:21
-++-+-+- +------- --------	*08:02:01, *08:09 = *08:02:01, *08:21 = *08:09, *08:09 = *08:09, *08:21
-++-+-+- --++---- --------	*08:08, *08:13 = *08:08, *08:44
-++-+-+- ---+---- --------	*08:11, *08:13 = *08:11, *08:44
-++-+-+- ---+---- --+-----	*08:07, *08:13 = *08:07, *08:44
-++-+-+- ---+---- --------	*08:02:01, *08:13 = *08:02:01, *08:44 = *08:13, *08:44 = *08:44, *08:44
-++-+--+ ------+- +---+-+-	*08:04:01, *08:28 = *08:28, *08:28
-+-++-+- ------+- ----+---	*08:30:01, *08:45 = *08:45, *08:45
--++++- --+----+- --------	*08:08, *08:25 = *08:34, *08:41
---++-+- -------+ -----+--	*08:19, *08:19 = *08:19, *08:34

*08:01:01 = *08:01:01-08:01:05
*08:02:01 = *08:02:01-08:02:04 and 08:42
*08:03:02 = *08:03:02-08:03:03 and 08:46
*08:04:01 = *08:04:01-08:04:07
*08:30:01 = *08:30:01-08:30:03
*08:18 = *08:18 and 08:47

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SPECIFICITY TABLE

DRB1*08 SSP subtyping

Specificities and sizes of the PCR products of the 24 primer mixes used for DRB1*08 SSP subtyping

Primer Mix	Size of spec. PCR product[1]	Size of control band[2]	Amplified DRB1*08 alleles[3]	Other amplified DRB1 alleles[4]
1	165 bp	**515 bp**	*08:01:01-08:01:05, 08:03:02-08:03:03, 08:05-08:06, 08:10, 08:12, 08:14, 08:16-08:18, 08:22-08:23, 08:26-08:27, 08:29, 08:32-08:33, 08:35-08:40, 08:43, 08:46-08:49	
2[6]	165 bp	430 bp	*08:02:01-08:02:04, 08:04:01-08:04:07, 08:09, 08:13, 08:21, 08:24, 08:28, 08:30:01-08:30:03, 08:42, 08:44-08:45	*12:09, 13:17, 13:116, 14:15, 14:52
3	195 bp	430 bp	*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, 12:02:01-12:02:05, 12:13, 12:15-12:16, 12:18-12:21, 12:23, 12:26-12:27, 12:31N-12:33, 14:15, 14:73
4	195 bp	430 bp	*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	*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, 13:17, 13:116
5[6]	225 bp	**515 bp**	*08:01:01-08:04:07, 08:06-08:13, 08:15-08:17, 08:19-08:20, 08:22-08:23, 08:26-08:28, 08:30:01-08:30:03, 08:32-08:39, 08:42, 08:44-08:46, 08:48-08:49	*11:23, 11:25, 11:45, 11:55, 11:64, 11:67, 11:119, 13:13, 13:18, 13:47, 13:55, 13:119, 14:03:01-14:03:02, 14:12:01-14:12:02, 14:15, 14:27, 14:40, 14:55, 14:63, 14:67, 14:77-14:78, 14:84-14:85, 14:89, 14:102, 14:115-14:116

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6	215 bp	430 bp	*08:05, 08:18, 08:24-08:25, 08:31, 08:40-08:41, 08:47	*12:01:01-12:21, 12:23-12:35, 13:17, 13:116, 14:31, 14:52
7	250 bp	430 bp	*08:01:01-08:03:03, 08:05, 08:07-08:09, 08:11, 08:13-08:19, 08:21, 08:23-08:27, 08:29-08:30:03, 08:32-08:49	*12:16, 12:22, 14:68, 14:93
8	250 bp	430 bp	*08:04:01-08:04:07, 08:06, 08:10, 08:12, 08:22, 08:28, 08:31	*11:67, 12:01:01-12:15, 12:17-12:21, 12:23-12:35, 13:17, 13:116, 14:04, 14:11, 14:15, 14:28, 14:31, 14:50, 14:52, 14:71, 14:73, 14:76, 14:79, 14:107, 14:120
9	150 bp	430 bp	*08:09, 08:21, 08:35	*14:15, 14:40, 14:55, 14:77, 14:84
10[7]	205 bp, 250 bp	**515 bp**	*08:12, 08:22, 08:40	*12:01:01-12:02:05, 12:04-12:15, 12:17-12:18, 12:20-12:21, 12:23-12:35, 13:17, 13:116, 14:28
11	170 bp	**515 bp**	*08:08, 08:15, 08:31, 08:41	*11:67, 12:04, 14:04, 14:11, 14:28, 14:31, 14:50, 14:68, 14:71, 14:73, 14:76, 14:79, 14:93, 14:107, 14:120
12[5,8]	95 bp, 145 bp, 195 bp	430 bp	*08:13, 08:27, 08:44, 08:48	*12:12
13[9]	135 bp, 165 bp, 260 bp	430 bp	*08:11, 08:33, 08:39	
14	135 bp	430 bp	*08:17, 08:28, 08:37, 08:45	*11:67, 12:01:01-12:20, 12:22-12:35, 13:17
15	175 bp	430 bp	*08:19, 08:25, 08:34, 08:49	*12:01:01-12:03:02, 12:05-12:08, 12:10-12:17, 12:19-12:32, 12:34-12:35
16[5]	70 bp	430 bp	*08:03:02-08:03:03, 08:10, 08:12, 08:14, 08:18-08:19, 08:23, 08:27, 08:29, 08:32-08:33, 08:35-08:38, 08:40, 08:46-08:47, 08:49	*04:12, 04:86, 04:106, 07:12, 13:03:01-13:04, 13:12:01-13:13, 13:30, 13:32-13:33:03, 13:38, 13:48, 13:58, 13:65-13:66:02, 13:81, 13:89, 13:93-13:95, 13:101, 13:115, 13:118, 13:120, 13:122, 14:63, 14:78

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17[5,10]	75 bp, 175 bp	430 bp	*08:04:01, 08:04:02[W]-08:04:03[W], 08:04:04-08:04:07, 08:06, 08:10, 08:12, 08:14, 08:20, 08:22, 08:28	*04:12, 04:18, 04:25, 04:58, 11:25, 11:67, 11:119, 13:18, 14:12:01-14:12:02, 14:15, 14:78, 14:84, 15:21
18[11]	150 bp, 225 bp	430 bp	*08:20, 08:32	*11:23, 11:25, 11:45, 11:55, 11:64, 11:119, 13:13, 13:18, 13:47, 13:55, 13:119, 14:03:01-14:03:02, 14:12:01-14:12:02, 14:27, 14:40, 14:55, 14:63, 14:67, 14:77-14:78, 14:84-14:85, 14:89, 14:102, 14:115-14:116
19[5,12]	100 bp, 165 bp, 180 bp	**515 bp**	*08:07, 08:16, 08:38, 08:49	
20[5]	125 bp	**515 bp**	*08:06, 08:10, 08:12, 08:22	*03:12, 04:10:01-04:12, 04:67, 04:91, 13:04, 13:32, 13:48, 13:58, 13:75, 13:81, 13:89, 13:93-13:94, 13:108, 14:65, 14:78, 15:12
21[5]	120 bp	**515 bp**	*08:17, 08:28, 08:37, 08:45	*11:23, 11:25, 11:45, 11:55, 11:64, 11:67, 11:119, 13:18, 13:119, 15:21
22[13]	130 bp, 165 bp, 215 bp	430 bp	*08:19, 08:23, 08:29	*14:04, 14:11, 14:28, 14:68, 14:71, 14:73, 14:93, 14:120
23	250 bp	430 bp	*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, 12:03:02, 12:19, 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
24[5,14]	125 bp, 175 bp	430 bp	*08:14, 08:26, 08:35-08:36	*03:12, 13:32, 13:65, 13:93, 13:120, 14:13, 14:63, 14:65, 14:78, 14:85

[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 DRB1*08SSP 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.

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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 inherit 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*08 subtyping.

In addition, wells number 5, 10, 11 and 19 to 21 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.

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

[4]Due to the sharing of sequence motifs within the DR52 group of DRB1 alleles, non-DRB1*08 alleles are amplified by primer mixes 2 to 12, 14 to 18 and 20 to 24.

The DRB1*08:20 and DRB1*14:12:01-14:12:02 give rise to identical amplification patterns with the DRB1*08 subtyping kit. These alleles can be distinguished by e.g. the DR low resolution kit and/or the DRB1*14 subtyping kit.

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

[6]Primer mixes 2 and 5 may give rise to nonspecific amplifications.

[7]Primer mix 10: Specific PCR fragment of 205 bp in the DRB1*08:40 and in the DRB1*13:17 and 13:116 alleles. Specific PCR fragment of 250 bp in the DRB1*08:12 and 08:22 and in the DRB1*12:01:01-12:02:05, 12:04-12:15, 12:17-12:18, 12:20-12:21, 12:23-12:35 and 14:28 alleles.

[8]Primer mix 12: Specific PCR fragment of 95 bp in the DRB1*08:27 allele. Specific PCR fragment of 145 bp in the DRB1 *08:44 allele. Specific PCR fragment of 195 bp in the DRB1 08:13 and 08:48 and in the DRB1*12:12 alleles.

[9]Primer mix 13: Specific PCR fragment of 135 bp in the DRB1*08:33 allele. Specific PCR fragment of 165 bp in the DRB1*08:11 allele. Specific PCR fragment of 260 bp in the DRB1*08:39 allele.

[10]Primer mix 17: Specific PCR fragment of 75 bp in the DRB1*08:04:01, 08:04:02w-08:04:03w, 08:04:04-08:04:07, 08:06, 08:10, 08:12, 08:20, 08:22 and 08:28 and in the DRB1*04:12, 04:18, 04:25, 04:58, 11:25, 11:67, 11:119, 13:18, 14:12:01-14:12:02, 14:15, 14:78, 14:84 and 15:21 alleles. Specific PCR fragment of 175 bp in the DRB1*08:14 allele.

[11]Primer mix 18: Specific PCR fragment of 150 bp in the DRB1*08:32 allele. Specific PCR fragment of 225 bp in the DRB1*08:20 and in the DRB1*11:23, 11:25, 11:45, 11:55, 11:64, 11:119, 13:13, 13:18, 13:47, 13:55, 13:119, 14:03:01-14:03:02, 14:12:01-14:12:02, 14:27, 14:40, 14:55, 14:63, 14:67, 14:77-14:78, 14:84-14:85, 14:89, 14:102 and 14:115-14:116 alleles.

[12]Primer mix 19: Specific PCR fragment of 100 bp in the DRB1*08:16 and 08:38 alleles. Specific PCR fragment of 165 bp in the DRB1*08:07 allele. Specific PCR fragment of 180 bp in the DRB1*08:49 allele.

[13]Primer mix 22: Specific PCR fragment of 130 bp in the DRB1*08:23 allele. Specific PCR fragment of 165 bp in the DRB1*08:19 allele. Specific PCR fragment of 215 bp in the DRB1*08:29 and in the DRB1*14:04, 14:11, 14:28, 14:68, 14:71, 14:73, 14:93 and 14:120 alleles.

[14]Primer mix 24: Specific PCR fragment of 125 bp in the DRB1*08:26, 08:35 and 08:36 and in the DRB1*03:12, 13:32, 13:65, 13:93, 13:120, 14:13, 14:63, 14:65, 14:78 and 14:85 alleles. Specific PCR fragment of 175 bp in the DRB1*08:14 allele.

'w', may be weakly amplified.

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INTERPRETATION TABLE

DRB1*08 SSP subtyping

Amplification patterns of the DRB1*08:01 to 08:49 alleles

	Well[7]											
	1	2	3	4	5	6	7	8	9	10	11	12
Length of spec.	165	165	195	195	225	215	250	250	150	205	170	95
PCR product(s)										250		145
												195
Length of int.	515	430	430	430	515	430	430	430	430	515	515	430
pos. control[1]												
5'-primer(s)[2]	16(133) 5' -gTT 3'	16(133) 5' -gTT 3'	16(133) 5' -gTT 3'	16(133) 5' -gTT 3'	12(122) 5' -TAC 3'	16(133) 5' -gTT 3'	16(133) 5' -gTT 3'	16(133) 5' -gTT 3'	37(197) 5' -gTT 3'	16(133) 5' -gTT 3'	16(133) 5' -gTT 3'	16(133) 5' -gTT 3'
3'-primer(s)[3]	57(256) 5' -gCT 3'	57(257) 5' -CAT 3'	67(286) 5' -gAA 3'	67(286) 5' -gAT 3'	74(307) 5' -CAg 3'	74(307) 5' -CgC 3'	86(344) 5' -CAC 3'	86(344) 5' -CCA 3'	74(307) 5' -CAg 3'	71(299) 5' -gCT 3'	58(261) 5' -TCC 3'	34(188) 5' -CTC 3'
		57(257) 5' -CAT 3'		67(286) 5' -gAT 3'				86(344) 5' -CAA 3'		85(341) 5' -CAg 3'	58(261) 5' -TCC 3'	51(239) 5' -CCA 3'
		58(261) 5' -TCA 3'										67(286) 5' -gAg 3'
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

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INTERPRETATION TABLE

DRB1*08 SSP subtyping

Amplification patterns of the DRB1*08:01 to 08:49 alleles

Well[7]												
13	14	15	16	17	18	19	20	21	22	23	24	
135	135	175	70	75	150	100	125	120	130	250	125	Length of spec.
165				175	225	165			165		175	PCR product(s)
260						180			215			
430	430	430	430	430	430	515	515	515	430	430	430	Length of int.
												pos. control[1]
5'-gTT 3' 16(133)	5'-gTT 3' 16(133)	5'-gTT 3' 16(133)	5'-AgC 3' 57(258)	5'-TAg 3' 12(122)	5'-gTC 3' 13(125)	5'-gTT 3' 16(133)	5'-AgC 3' 57(258)	5'-gTT 3' 47(227)	5'-gTT 3' 16(133)	5'-gTT 3' 16(133)	5'-TAg 3' 12(122)	5'-primer(s)[2]
				5'-CCT 3' 74(308)	5'-AgC 3' 37(196)						5'-gCT 3' 25(161)	
											5'-TCC 3' 32(181)	
5'-CCA 3' 48(229)	5'-ggA 3' 47(227)	5'-CgA 3' 57(257)	5'-gAT 3' 67(286)	5'-gCT 3' 57(256)	5'-CAg 3' 74(307)	5'-gTg 3' 33(184)	5'-CCA 3' 86(344)	5'-CAg 3' 74(307)	5'-CCT 3' 45(220)	5'-CAA 3' 85(341)	5'-gCT 3' 57(256)	3'-primer(s)[3]
5'-CAg 3' 57(257)		5'-TTg 3' 61(270)	5'-gAT 3' 67(286)	5'-CCA 3' 86(344)		5'-gTC 3' 37(196)			5'-gAT 3' 57(256)			
5'-AgT 3' 88(350)						5'-CAA 3' 57(257)			5'-CCT 3' 74(308)			
						5'-TTg 3' 61(270)						
13	14	15	16	17	18	19	20	21	22	23	24	Well No.

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For *In Vitro* Diagnostic Use.

Lot No.: 18N **Lot-specific information**

Length of spec.	**165**	**165**	**195**	**195**	**225**	**215**	**250**	**250**	**150**	**205**	**170**	**95**
PCR product(s)										**250**		**145**
												195
Well No.	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**
DRB1 allele[4,5]												
***08:01:01**-08:01:05	**1**		**3**		**5**		**7**					
***08:02:01**-08:02:04, 08:42		**2**	**3**		**5**		**7**					
***08:03:02**-08:03:03, 08:46	**1**			**4**	**5**		**7**					
***08:04:01**, 08:04:04-08:04:07		**2**	**3**		**5**			**8**				
***08:04:02**-08:04:03		**2**	**3**		**5**			**8**				
***08:05**	**1**		**3**			**6**	**7**					
***08:06**	**1**		**3**		**5**			**8**				
***08:07**			**3**		**5**		**7**					
***08:08**			**3**		**5**		**7**				**11**	
***08:09**		**2**	**3**		**5**		**7**		**9**			
***08:10**	**1**			**4**	**5**			**8**				
***08:11**			**3**		**5**		**7**					
***08:12**	**1**			**4**	**5**			**8**		**10**		
***08:13**		**2**			**5**		**7**					**12**
***08:14**	**1**			**4**			**7**					
***08:15**				**4**	**5**		**7**				**11**	
***08:16**	**1**		**3**		**5**		**7**					
***08:17**	**1**		**3**		**5**		**7**					
***08:18**, 08:47	**1**			**4**		**6**	**7**					
***08:19**				**4**	**5**		**7**					
*08:20, 14:12:01-14:12:02[6]					**5**							
*08:21		**2**	**3**				**7**		**9**			
***08:22**	**1**		**3**		**5**			**8**		**10**		
*08:23	**1**			**4**	**5**		**7**					
*08:24		**2**	**3**			**6**	**7**					
*08:25				**4**		**6**	**7**					
*08:26	**1**		**3**		**5**		**7**					
*08:27	**1**			**4**	**5**		**7**					**12**
*08:28		**2**	**3**		**5**			**8**				
*08:29	**1**			**4**			**7**					
*08:30:01-08:30:03		**2**		**4**	**5**		**7**					
*08:31			**3**			**6**		**8**			**11**	
***08:32**	**1**			**4**	**5**		**7**					
*08:33	**1**			**4**	**5**		**7**					
*08:34				**4**	**5**		**7**					
***08:35**	**1**			**4**	**5**		**7**		**9**			
*08:36	**1**			**4**	**5**		**7**					
Well No.	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**

101.127-12/04 – including *Taq* polymerase, IFU-01 Rev. No. 03
101.127-12u/04u – without *Taq* polymerase, IFU-02 Rev. No. 03

Visit www.olerup-ssp.com for **"Instructions for Use" (IFU)**

Lot No.: 18N **Lot-specific information**

135	135	175	70	75	150	100	125	120	130	250	125	**Length of spec.**
165				175	225	165			165		175	**PCR product(s)**
260						180			215			
13	14	15	16	17	18	19	20	21	22	23	24	**Well No.**
												DRB1 allele[4,5]
												***08:01:01**-08:01:05
												***08:02:01**-08:02:04, 08:42
			16									***08:03:02**-08:03:03, 08:46
				17						23		***08:04:01**, 08:04:04-08:04:07
				w						w		***08:04:02**-08:04:03
												***08:05**
				17			20			23		***08:06**
						19						***08:07**
												***08:08**
												***08:09**
			16	17			20			23		***08:10**
13												***08:11**
			16	17			20					***08:12**
												***08:13**
			16	17							24	***08:14**
												***08:15**
						19						***08:16**
	14							21				***08:17**
			16									***08:18**, 08:47
		15	16						22			***08:19**
				17	18							*08:20, 14:12:01-14:12:02[6]
												*08:21
				17			20					***08:22**
			16						22			*08:23
												*08:24
		15										*08:25
											24	*08:26
			16									*08:27
	14			17				21		23		*08:28
			16						22			*08:29
												*08:30:01-08:30:03
										23		*08:31
			16		18							***08:32**
13			16									*08:33
		15										*08:34
			16								24	***08:35**
			16								24	*08:36
13	14	15	16	17	18	19	20	21	22	23	24	**Well No.**

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101.127-12/04 – including *Taq* polymerase, IFU-01 Rev. No. 03
101.127-12u/04u – without *Taq* polymerase, IFU-02 Rev. No. 03

Visit www.olerup-ssp.com for **"Instructions for Use" (IFU)**

Lot No.: 18N **Lot-specific information**

Length of spec.	**165**	**165**	**195**	**195**	**225**	**215**	**250**	**250**	**150**	**205**	**170**	**95**
PCR product(s)										**250**		**145**
												195
Well No.	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**
*08:37	**1**			**4**	**5**		**7**					
*08:38	**1**			**4**	**5**		**7**					
*08:39	**1**		**3**		**5**		**7**					
*08:40	**1**			**4**		**6**	**7**			**10**		
*08:41			**3**			**6**	**7**				**11**	
*08:43	**1**		**3**				**7**					
***08:44**		**2**	**3**		**5**		**7**					**12**
***08:45**		**2**		**4**	**5**		**7**					
*08:48	**1**				**5**		**7**					**12**
***08:49**	**1**			**4**	**5**		**7**					
*03:12, 14:65												
*04:10:01-04:11, 04:67, 04:91, 13:75, 13:108, 15:12												
*04:12												
*04:18, 04:25, 04:58												
*04:86, 04:106, 07:12, 13:03:01-13:03:06, 13:12:01-13:12:02, 13:30, 13:33:01-13:33:03, 13:38, 13:66:01-13:66:02, 13:95, 13:101, 13:115, 13:118, 13:122												
*11:23, 11:45, 11:55, 11:64, 13:119					**5**							
*11:25, 11:119, 13:18					**5**							
*11:67			**3**		**5**			**8**			**11**	
*12:01:01-12:01:04, 12:05-12:06, 12:08, 12:10-12:11, 12:14, 12:17, 12:24N-12:25, 12:28-12:30, 12:34-12:35				**4**		**6**		**8**		**10**		
*12:02:01-12:02:05, 12:13, 12:15, 12:20, 12:23, 12:26-12:27, 12:31N-12:32			**3**			**6**		**8**		**10**		
*12:03:02				**4**		**6**		**8**				
*12:04				**4**		**6**		**8**		**10**	**11**	
*12:07						**6**		**8**		**10**		
*12:09		**2**		**4**		**6**		**8**		**10**		
*12:12						**6**		**8**		**10**		**12**
*12:16			**3**			**6**	**7**					
*12:18, 12:33			**3**			**6**		**8**		**10**		
*12:19			**3**			**6**		**8**				
*12:21			**3**			**6**		**8**		**10**		
Well No.	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**

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For *In Vitro* Diagnostic Use.

101.127-12/04 – including *Taq* polymerase, IFU-01 Rev. No. 03
101.127-12u/04u – without *Taq* polymerase, IFU-02 Rev. No. 03

Visit www.olerup-ssp.com for **"Instructions for Use" (IFU)**

Lot No.: 18N **Lot-specific information**

135	**135**	**175**	**70**	**75**	**150**	**100**	**125**	**120**	**130**	**250**	**125**	**Length of spec.**
165				**175**	**225**	**165**			**165**		**175**	**PCR product(s)**
260						**180**			**215**			
13	**14**	**15**	**16**	**17**	**18**	**19**	**20**	**21**	**22**	**23**	**24**	**Well No.**
	14		**16**					**21**				*08:37
			16			**19**						*08:38
13												*08:39
			16									*08:40
												*08:41
												*08:43
												***08:44**
	14							**21**				***08:45**
												*08:48
		15	**16**			**19**						***08:49**
							20				**24**	*03:12, 14:65
							20					*04:10:01-04:11, 04:67, 04:91, 13:75, 13:108, 15:12
			16	**17**			**20**					*04:12
				17								*04:18, 04:25, 04:58
			16									*04:86, 04:106, 07:12, 13:03:01-13:03:06, 13:12:01-13:12:02, 13:30, 13:33:01-13:33:03, 13:38, 13:66:01-13:66:02, 13:95, 13:101, 13:115, 13:118, 13:122
					18			**21**				*11:23, 11:45, 11:55, 11:64, 13:119
				17	**18**			**21**				*11:25, 11:119, 13:18
	14			**17**				**21**		**23**		*11:67
	14	**15**										*12:01:01-12:01:04, 12:05-12:06, 12:08, 12:10-12:11, 12:14, 12:17, 12:24N-12:25, 12:28-12:30, 12:34-12:35
	14	**15**										*12:02:01-12:02:05, 12:13, 12:15, 12:20, 12:23, 12:26-12:27, 12:31N-12:32
	14	**15**								**23**		*12:03:02
	14											*12:04
	14	**15**										*12:07
	14											*12:09
	14	**15**										*12:12
	14	**15**										*12:16
	14											*12:18, 12:33
	14	**15**								**23**		*12:19
		15										*12:21
13	**14**	**15**	**16**	**17**	**18**	**19**	**20**	**21**	**22**	**23**	**24**	**Well No.**

101.127-12/04 – including *Taq* polymerase, IFU-01 Rev. No. 03
101.127-12u/04u – without *Taq* polymerase, IFU-02 Rev. No. 03

Visit www.olerup-ssp.com for **"Instructions for Use" (IFU)**

Lot No.: 18N **Lot-specific information**

Length of spec.	**165**	**165**	**195**	**195**	**225**	**215**	**250**	**250**	**150**	**205**	**170**	**95**
PCR product(s)										**250**		**145**
												195
Well No.	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**
*12:22				**4**			**7**					
*13:04, 13:48, 13:58, 13:81, 13:89, 13:94												
*13:13					**5**							
*13:17		**2**		**4**		**6**		**8**		**10**		
*13:32, 13:93												
*13:47, 13:55, 14:03:01-14:03:02, 14:27, 14:67, 14:89, 14:102, 14:115-14:116					**5**							
*13:65, 13:120												
*13:116		**2**		**4**		**6**		**8**		**10**		
*14:04, 14:11, 14:120								**8**			**11**	
*14:13												
*14:15		**2**	**3**		**5**			**8**	**9**			
*14:28								**8**		**10**	**11**	
*14:31						**6**		**8**			**11**	
*14:40, 14:55, 14:77					**5**				**9**			
*14:50, 14:76, 14:79, 14:107								**8**			**11**	
*14:52		**2**				**6**		**8**				
*14:63					**5**							
*14:68, 14:93							**7**				**11**	
*14:71								**8**			**11**	
*14:73			**3**					**8**			**11**	
*14:78					**5**							
*14:84					**5**				**9**			
*14:85					**5**							
*15:21												
Well No.	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**

[1]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*08 subtyping.
In addition, wells number 5, 10, 11 and 19 to 21 contain the primer pair giving rise to the longer, 515 bp, internal positive control band in order to allow kit identification.
[2]The 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.

Lot No.: 18N **Lot-specific information**

135	135	175	70	75	150	100	125	120	130	250	125	**Length of spec.**
165				175	225	165			165		175	**PCR product(s)**
260						180			215			
13	**14**	**15**	**16**	**17**	**18**	**19**	**20**	**21**	**22**	**23**	**24**	**Well No.**
	14	**15**										*12:22
			16				**20**					*13:04, 13:48, 13:58, 13:81, 13:89, 13:94
			16		**18**							*13:13
	14									**23**		*13:17
			16				**20**				**24**	*13:32, 13:93
					18							*13:47, 13:55, 14:03:01-14:03:02, 14:27, 14:67, 14:89, 14:102, 14:115-14:116
			16								**24**	*13:65, 13:120
										23		*13:116
									22	**23**		*14:04, 14:11, 14:120
											24	*14:13
				17						**23**		*14:15
									22			*14:28
										23		*14:31
					18							*14:40, 14:55, 14:77
										23		*14:50, 14:76, 14:79, 14:107
										23		*14:52
			16		**18**						**24**	*14:63
									22			*14:68, 14:93
									22			*14:71
									22	**23**		*14:73
			16	**17**	**18**		**20**				**24**	*14:78
				17	**18**							*14:84
					18						**24**	*14:85
				17				**21**				*15:21
13	**14**	**15**	**16**	**17**	**18**	**19**	**20**	**21**	**22**	**23**	**24**	**Well No.**

[3]The 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.
[4]The sequence of the DRB1*080301 allele has been shown to be identical to DRB1*08:03:02.
[5]DRB1*08 alleles in bold lettering are listed as confirmed alleles on the on the IMGT/HLA web page www.ebi.ac.uk/imgt/hla, release 3.7.0, January 2012.
[6]The DRB1*08:20 and DRB1*14:12:01-14:12:02 give rise to identical amplification patterns with the DRB1*08 subtyping kit. These two alleles can be distinguished by the DR low resolution kit and/or the DRB1*14 subtyping kit.

101.127-12/04 – including *Taq* polymerase, IFU-01 Rev. No. 03 Visit www.olerup-ssp.com for
101.127-12u/04u – without *Taq* polymerase, IFU-02 Rev. No. 03 **"Instructions for Use" (IFU)**

Lot No.: 18N **Lot-specific information**

[7]Primer mix 10: Specific PCR fragment of 205 bp in the DRB1*08:40 and in the DRB1*13:17 and 13:116 alleles. Specific PCR fragment of 250 bp in the DRB1*08:12 and 08:22 and in the DRB1*12:01:01-12:02:05, 12:04-12:15, 12:17-12:18, 12:20-12:21, 12:23-12:35 and 14:28 alleles.
Primer mix 12: Specific PCR fragment of 95 bp in the DRB1*08:27 allele. Specific PCR fragment of 145 bp in the DRB1 *08:44 allele. Specific PCR fragment of 195 bp in the DRB1 08:13 and 08:48 and in the DRB1*12:12 alleles.
Primer mix 13: Specific PCR fragment of 135 bp in the DRB1*08:33 allele. Specific PCR fragment of 165 bp in the DRB1*08:11 allele. Specific PCR fragment of 260 bp in the DRB1*08:39 allele.
Primer mix 17: Specific PCR fragment of 75 bp in the DRB1*08:04:01, 08:04:02w-08:04:03w, 08:04:04-08:04:07, 08:06, 08:10, 08:12, 08:20, 08:22 and 08:28 and in the DRB1*04:12, 04:18, 04:25, 04:58, 11:25, 11:67, 11:119, 13:18, 14:12:01-14:12:02, 14:15, 14:78, 14:84 and 15:21 alleles. Specific PCR fragment of 175 bp in the DRB1*08:14 allele.
Primer mix 18: Specific PCR fragment of 150 bp in the DRB1*08:32 allele. Specific PCR fragment of 225 bp in the DRB1*08:20 and in the DRB1*11:23, 11:25, 11:45, 11:55, 11:64, 11:119, 13:13, 13:18, 13:47, 13:55, 13:119, 14:03:01-14:03:02, 14:12:01-14:12:02, 14:27, 14:40, 14:55, 14:63, 14:67, 14:77-14:78, 14:84-14:85, 14:89, 14:102 and 14:115-14:116 alleles.
Primer mix 19: Specific PCR fragment of 100 bp in the DRB1*08:16 and 08:38 alleles. Specific PCR fragment of 165 bp in the DRB1*08:07 allele. Specific PCR fragment of 180 bp in the DRB1*08:49 allele.
Primer mix 22: Specific PCR fragment of 130 bp in the DRB1*08:23 allele. Specific PCR fragment of 165 bp in the DRB1*08:19 allele. Specific PCR fragment of 215 bp in the DRB1*08:29 and in the DRB1*14:04, 14:11, 14:28, 14:68, 14:71, 14:73, 14:93 and 14:120 alleles.
Primer mix 24: Specific PCR fragment of 125 bp in the DRB1*08:26, 08:35 and 08:36 and in the DRB1*03:12, 13:32, 13:65, 13:93, 13:120, 14:13, 14:63, 14:65, 14:78 and 14:85 alleles. Specific PCR fragment of 175 bp in the DRB1*08:14 allele.
'w', may be weakly amplified.

101.127-12/04 – including *Taq* polymerase, IFU-01 Rev. No. 03
101.127-12u/04u – without *Taq* polymerase, IFU-02 Rev. No. 03

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Lot No.: 18N **Lot-specific information**

CELL LINE VALIDATION SHEET

DRB1*08 SSP subtyping kit

					Well															
					1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
				Prod. No.:	201079101	201295602	201079103	201079104	201079105	201079106	201079107	201079108	201079109	201079110	201079111	201295612	201079113	201079114	201295615	201079116
	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		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

101.127-12/04 – including *Taq* polymerase, IFU-01 Rev. No. 03
101.127-12u/04u – without *Taq* polymerase, IFU-02 Rev. No. 03

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Lot No.: 18N **Lot-specific information**

CELL LINE VALIDATION SHEET

DRB1*08 SSP subtyping kit

					Well							
					17	18	19	20	21	22	23	24
				Prod. No.:	201079117	201079118	201295619	201079120	201079121	201079122	201079123	201079124
	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		-	-	-	-	-	-	-	-

Lot No.: 18N **Lot-specific information**

CERTIFICATE OF ANALYSIS

Olerup SSP® DRB1*08 SSP

Product number: **101.127-12/04 – including *Taq* pol.**
101.127-12u/04u – without *Taq* pol.
Lot number: **18N**
Expiry date: **2014-August-01**
Number of tests: **12 tests – Product No. 101.127-12/12u**
4 tests – Product No. 101.127-04/04u
Number of wells per test: **24**

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2010-791-01	9	2010-791-09	17	2010-791-17
2	2012-956-02	10	2010-791-10	18	2010-791-18
3	2010-791-03	11	2010-791-11	19	2012-956-19
4	2010-791-04	12	2012-956-12	20	2010-791-20
5	2010-791-05	13	2010-791-13	21	2010-791-21
6	2010-791-06	14	2010-791-14	22	2010-791-22
7	2010-791-07	15	2012-956-15	23	2010-791-23
8	2010-791-08	16	2010-791-16	24	2010-791-24

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 No. 9, 12, 21 and 24 were available. The specificities of the primers in primer solutions 9, 21 and 24 were tested by separately adding one additional 5'-primer, respectively, one additional 3'-primer. In primer solution 12 it was only possible to test the 5'-primer, the 3'-primers were not possible to test. In primer solutions 2, 8, 13, 15, 19 and 22 one or two 3'-primers were not possible to test, and in primer solution 17 and 24 one or two 5'-primers were not possible to test. Additional primers in primer solutions 2, 10, 11 and 17 to 19 were tested by separately adding one additional 5'-primer or 3'-primer.

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

Date of approval: 2012-February-10

Approved by:

Production Quality Control

Lot No.: 18N **Lot-specific information**

Declaration of Conformity

Product name: *Olerup* SSP® DRB1*08
Product number: 101.127-12/04, -12u/04u
Lot number: 18N

Intended use: DRB1*08 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-February-10

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs

101.127-12/04 – including *Taq* polymerase, IFU-01 Rev. No. 03
101.127-12u/04u – without *Taq* polymerase, IFU-02 Rev. No. 03

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Lot No.: 18N **Lot-specific information**

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