

101.126-12 – including *Taq* polymerase, IFU-01  
101.126-12u – without *Taq* polymerase, IFU-02

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“Instructions for Use” (IFU)

Lot No.: **84R**

Lot-specific information  
**Olerup SSP<sup>®</sup> DRB1\*16**

Product number:	101.126-12 – including <i>Taq</i> polymerase 101.126-12u – without <i>Taq</i> polymerase
Lot number:	84R
Expiry date:	2015-July-01
Number of tests:	12
Number of wells per test:	16
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. 84R.**

**CHANGES COMPARED TO THE PREVIOUS OLERUP SSP<sup>®</sup>  
DRB1\*16 LOT (65N)**

The DRB1\*16 kit is updated for new alleles to enable separation of:

- Confirmed<sup>1</sup> alleles as listed in the IMGT/HLA database
- Polymorphisms in exons outside of the region encoding the peptide binding domain
- Null and Alternatively expressed alleles

The Lot-specific information for DRB1\*16 including and without *Taq* polymerase is now described in one common Product Insert.

<sup>1</sup>As described in section Uniquely Identified Alleles.

The DRB1\*16 specificity and interpretation tables have been updated for the DRB1 alleles described since the previous *Olerup SSP<sup>®</sup>* DRB1\*16 lot was made (Lot No. 65N).

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

The DRB1\*16 primer set is unchanged compared to previous lot.

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## PRODUCT DESCRIPTION

### DRB1\*16 SSP subtyping

#### CONTENT

The primer set contains 5'- and 3'-primers for identifying the DRB1\*16:01 to DRB1\*16:19 alleles.

#### PLATE LAYOUT

Each test consists of 16 PCR reactions in a 16 well cut PCR plate.

1	2	3	4	5	6	7	8
9	10	11	12	13	14	15	16

The 16 well cut PCR plate is marked with 'DRB1\*16' in silver/gray ink.

Well No. 1 is marked with the Lot No. '84R'.

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 16 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\*16 PCR-SSP subtypings will be influenced by the DRB1\*01:23, two DRB1\*04, five DRB1\*11, most DRB1\*12, two DRB1\*13 and the DRB1\*15, when present on the other haplotype. In addition, primer mix 16 will amplify the DRB5\*01:13 allele.

#### UNIQUELY IDENTIFIED ALLELES

All the DRB1\*16 alleles, i.e. **DRB1\*16:01 to DRB1\*16:19**, recognized by the HLA Nomenclature Committee in October 2012<sup>1</sup> will be amplified by the primers in the DRB1\*16 subtyping kit<sup>2</sup>.

The DRB1\*16 kit enables separation of the confirmed DRB1\*16 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\*16 alleles is listed below.

The DRB1\*16 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\*16 subtyping kit cannot distinguish the following silent mutations: the DRB1\*16:01:01-16:01:02, DRB1\*16:02:01-16:02:02 or the DRB1\*16:05:01-16:05:02 alleles.

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<sup>1</sup>DRB1 alleles listed on the IMGT/HLA web page 2012-October-14, release 3.10.0, [www.ebi.ac.uk/imgt/hla](http://www.ebi.ac.uk/imgt/hla).

### ALLELE CONFIRMATION STATUS

Allele	Status	Allele	Status
<b>DRB1*16:01:01</b>	<b>Confirmed</b>	DRB1*16:11	Unconfirmed
DRB1*16:01:02	Unconfirmed	<b>DRB1*16:12</b>	<b>Confirmed</b>
<b>DRB1*16:02:01</b>	<b>Confirmed</b>	DRB1*16:13N	Unconfirmed
DRB1*16:02:02	Unconfirmed	<b>DRB1*16:14</b>	<b>Confirmed</b>
DRB1*16:03	Unconfirmed	<b>DRB1*16:15</b>	<b>Confirmed</b>
<b>DRB1*16:04</b>	<b>Confirmed</b>	DRB1*16:16	Unconfirmed
<b>DRB1*16:05:01</b>	<b>Confirmed</b>	DRB1*16:17	Unconfirmed
<b>DRB1*16:05:02</b>	<b>Confirmed</b>	DRB1*16:18	Unconfirmed
DRB1*16:07	Unconfirmed	DRB1*16:19	Unconfirmed
<b>DRB1*16:08</b>	<b>Confirmed</b>		
<b>DRB1*16:09</b>	<b>Confirmed</b>		
<b>DRB1*16:10</b>	<b>Confirmed</b>		

<sup>1</sup>Allele status “confirmed” or “unconfirmed” as listed on the IMGT/HLA web page 2012-October-14, release 3.10.0, [www.ebi.ac.uk/imgt/hla](http://www.ebi.ac.uk/imgt/hla).

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### RESOLUTION IN HOMO- AND HETEROZYGOTES

A total of 21 alleles generate 18 amplification patterns that can be combined in 171 homozygous and heterozygous combinations. 55 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.

+-----+-	-----	*16:05:01, *16:07 = *16:07, *16:07
+-------	----+---	*16:01:01, *16:13N = *16:13N, *16:13N
+--+-----	-----	*16:01:01, *16:08 = *16:08, *16:08
+--+-----	-----	*16:01:01, *16:04 = *16:04, *16:04
+--+-----	-----	*16:01:01, *16:03 = *16:03, *16:03
++-----	-----+	*16:02:01, *16:16 = *16:16, *16:16
++-----	-----+--	*16:02:01, *16:14 = *16:14, *16:14
++-----	-----+---	*16:02:01, *16:19 = *16:19, *16:19
++-----	----+----	*16:02:01, *16:12 = *16:02:01, *16:17 = *16:12, *16:17 = *16:17, *16:17
++-----	--+-----	*16:02:01, *16:11 = *16:11, *16:11
++-+-----	-----	*16:02:01, *16:18 = *16:18, *16:18
+--+-----	++-----	*16:01:01, *16:09 = *16:09, *16:09
++-----	---+----+	*16:12, *16:16 = *16:16, *16:17
++-----	---+--+	*16:12, *16:14 = *16:14, *16:17
++-----	---++---	*16:12, *16:19 = *16:17, *16:19
++-----	--++-----	*16:11, *16:12 = *16:11, *16:17
++-----	++-----	*16:02:01, *16:10 = *16:10, *16:10
++-+-----	---+-----	*16:12, *16:18 = *16:17, *16:18
+++-----	----+---	*16:01:01, *16:19 = *16:02:01, *16:13N = *16:13N, *16:19
+++-----	-----	*16:01:01, *16:18 = *16:02:01, *16:04 = *16:04, *16:18
+++-----	++-----	*16:10, *16:12 = *16:10, *16:17
+++-----	++-----	*16:01:01, *16:10 = *16:02:01, *16:09 = *16:09, *16:10
+++-----	-----+---	*16:04, *16:19 = *16:13N, *16:18
+++-----	++-----+---	*16:09, *16:19 = *16:10, *16:13N
+++-----	++-----	*16:04, *16:10 = *16:09, *16:18

\*16:01:01 = \*16:01:01-16:01:02

\*16:02:01 = \*16:02:01-16:02:02

\*16:05:01 = \*16:05:01-16:05:02

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Lot-specific information  
**SPECIFICITY TABLE**

**DRB1\*16 SSP subtyping**

Specificities and sizes of the PCR products of the 16 primer mixes used for DRB1\*16 SSP subtyping

Primer Mix	Size of spec. PCR product <sup>1</sup>	Size of control band <sup>2</sup>	Amplified DRB1*16 alleles <sup>3</sup>	Other amplified DRB1 alleles <sup>4</sup>
<b>1</b>	260 bp	<b>515 bp</b>	*16:01:01- 16:05:02, 16:07- 16:11, 16:13N- 16:14, 16:16- 16:19	*15:02:01-15:02:09, 15:08, 15:11, 15:14-15:15, 15:19, 15:26-15:27, 15:29-15:31, 15:34, 15:38-15:39, 15:44, 15:47, 15:58, 15:60, 15:63, 15:68, 15:78, 15:80N
<b>2</b>	200 bp	<b>515 bp</b>	*16:02:01- 16:02:02, 16:10- 16:11, 16:14, 16:16-16:19	
<b>3<sup>6</sup></b>	200 bp	430 bp	*16:01:01- 16:01:02, 16:03- 16:04, 16:08- 16:09, 16:13N, 16:15	
<b>4</b>	215 bp	430 bp	*16:03	
<b>5</b>	220 bp	430 bp	*16:04, 16:18	*15:21
<b>6</b>	200 bp	430 bp	*16:05:01- 16:05:02, 16:07	*15:10, 15:21
<b>7</b>	160 bp	<b>515 bp</b>	*16:07	
<b>8<sup>5</sup></b>	110 bp	430 bp	*16:08	
<b>9</b>	140 bp	430 bp	*16:09-16:10	*15:01:01:01-15:06:02, 15:08, 15:10, 15:12-15:27, 15:29- 15:33, 15:35-15:47, 15:49- 15:58, 15:60-15:68, 15:70- 15:81
<b>10<sup>5</sup></b>	115 bp	430 bp	*16:09-16:10	*11:01:03, 11:01:10-11:01:11, 11:04:07, 11:19:02, 12:01:01, 12:01:03-12:02:03, 12:02:05- 12:10, 12:12-12:15, 12:17- 12:20, 12:23-12:37, 13:02:02, 13:77, 15:50N, 15:80N
<b>11</b>	215 bp	430 bp	*16:11	
<b>12</b>	215 bp	<b>515 bp</b>	*16:12, 16:17	
<b>13<sup>5,7</sup></b>	120 bp, 155 bp	430 bp	*16:13N, 16:19	

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<b>14</b>	175 bp	430 bp	*16:14	
<b>15<sup>5</sup></b>	80 bp	430 bp	*16:15	*01:23, 04:53, 04:99, 11:04:07, 12:01:01, 12:01:03- 12:02:03, 12:02:05-12:06, 12:08-12:15, 12:17-12:21, 12:23-12:37, 13:77
<b>16<sup>5</sup></b>	85 bp	430 bp	*16:16	*11:01:03, 11:01:10-11:01:11, 11:04:07, 11:19:02, 12:04, <b>DRB5*01:13</b>

<sup>1</sup>Alleles are assigned by the presence of specific PCR product(s). However, the sizes of the specific PCR products may be helpful in the interpretation of DRB\*16 SSP subtypings.

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

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

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

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

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

<sup>2</sup>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\*16 subtyping.

In addition, wells number 2, 7 and 12 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.

<sup>3</sup>For several DRB1 alleles 1<sup>st</sup> and/or 3<sup>rd</sup> exon(s) and beyond, as well as intron nucleotide sequences, are not available. In these instances it is not known whether some of the primers of the SSP sets are completely matched with the target sequences or not. We assume that unknown sequences in these regions are conserved within allelic groups.

<sup>4</sup>Due to the sharing of sequence motifs between DRB1 alleles, primer mixes 1, 5, 6, 9, 10, 15 and 16 will amplify other DRB1 alleles. In addition, primer mix 16 will amplify the DRB5\*01:13 allele.

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

<sup>6</sup>Primer mix 3 has a tendency to giving rise to primer oligomer formation.

<sup>7</sup>Primer mix 13: Specific PCR fragment of 120 bp in the DRB1\*16:19 allele. Specific PCR fragment of 155 bp in the DRB1\*16:13N allele.

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<b>INTERPRETATION TABLE</b>								
<b>DRB1*16 SSP subtyping</b>								
<b>Amplification patterns of the DRB1*16:01 to 16:19 alleles</b>								
	Well <sup>6</sup>							
	1	2	3	4	5	6	7	8
Length of spec.	260	200	200	215	220	200	160	110
PCR product(s)								
Length of int.	515	515	430	430	430	430	515	430
pos. control <sup>1</sup>								
5'-primer <sup>2</sup>	13(126)	13(126)	13(126)	13(126)	13(126)	13(126)	27(167)	13(126)
	5'-Agg 3'	5'-Agg 3'	5'-Agg 3'	5'-Agg 3'	5'-Agg 3'	5'-Agg 3'	5'-CCC 3'	5'-Agg 3'
3'-primer(s) <sup>3</sup>	86(344)	66(286)	66(286)	71(301)	73(307)	66(286)	66(286)	37(197)
	5'-CAC 3'	5'-gAg 3'	5'-gAA 3'	5'-ggC 3'	5'-CAg 3'	5'-gAT 3'	5'-gAT 3'	5'-CgT 3'
			66(286)			66(286)	66(286)	
			5'-gAA 3'			5'-gAT 3'	5'-gAT 3'	
Well No.	1	2	3	4	5	6	7	8
DRB1 allele <sup>4,5</sup>								
*16:01:01-16:01:02	1		3					
*16:02:01-16:02:02	1	2						
*16:03	1		3	4				
*16:04	1		3		5			
*16:05:01-16:05:02	1					6		
*16:07	1					6	7	
*16:08	1		3					8
*16:09	1		3					
*16:10	1	2						
*16:11	1	2						
*16:12								
*16:13N	1		3					
*16:14	1	2						
*16:15			3					
*16:16	1	2						
*16:17	1	2						
*16:18	1	2			5			
*16:19	1	2						
*01:23, 04:53, 04:99, 12:11, 12:21								
Well No.	1	2	3	4	5	6	7	8



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INTERPRETATION TABLE								
DRB1*16 SSP subtyping								
Amplification patterns of the DRB1*16:01 to 16:19 alleles								
Well <sup>6</sup>								
9	10	11	12	13	14	15	16	
140	115	215	215	120	175	80	85	Length of spec. PCR product(s)
				155				Length of int. pos. control <sup>1</sup>
430	430	430	515	430	430	430	430	
13(126)	47(227)	13(127)	13(126)	13(126)	13(126)	72(303)	58(261)	5'-primer <sup>2</sup>
5'-Agg 3'	5'-gTT 3'	5'-ggA 3'	5'-AAg 3'	5'-Agg 3'	5'-Agg 3'	5'-CgC 3'	5'-gAg 3'	
			15(133)					
			5'-gTA 3'					
47(227)	72(303)	72(303)	72(303)	39(203)	57(258)	86(344)	72(303)	3'-primer(s) <sup>3</sup>
5'-ggA 3'	5'-gCg 3'	5'-gCg 3'	5'-gCg 3'	5'-AgT 3'	5'-gCT 3'	5'-CCA 3'	5'-gCg 3'	
				51(241)				
				5'-CTA 3'				
9	10	11	12	13	14	15	16	Well No. DRB1 allele <sup>4,5</sup>
								*16:01:01-16:01:02
								*16:02:01-16:02:02
								*16:03
								*16:04
								*16:05:01-16:05:02
								*16:07
								*16:08
9	10							*16:09
9	10							*16:10
		11						*16:11
			12					*16:12
				13				*16:13N
					14			*16:14
						15		*16:15
							16	*16:16
			12					*16:17
								*16:18
				13				*16:19
						15		*01:23, 04:53, 04:99, 12:11, 12:21
9	10	11	12	13	14	15	16	Well No.

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Length of spec. PCR product(s)	260	200	200	215	220	200	160	110
	1	2	3	4	5	6	7	8
*11:01:03, 11:01:10- 11:01:11, 11:19:02								
*11:04:07, 12:04								
*12:01:01, 12:01:03- 12:02:03, 12:02:05- 12:03:03, 12:05-12:06, 12:08-12:10, 12:12- 12:15, 12:17-12:20, 12:23-12:37, 13:77								
*12:07, 13:02:02								
*15:01:01:01-15:01:21, 15:03:01:01-15:06:02, 15:12-15:13, 15:16- 15:18, 15:20, 15:22- 15:25, 15:32-15:33, 15:35-15:37:02, 15:40- 15:43, 15:45-15:46, 15:49, 15:51-15:57, 15:61-15:62, 15:64- 15:67, 15:70-15:77, 15:79, 15:81								
*15:02:01-15:02:09, 15:08, 15:14-15:15, 15:19, 15:26-15:27, 15:29-15:31, 15:38- 15:39, 15:44, 15:47, 15:58, 15:60, 15:63, 15:68, 15:78	1							
*15:10						6		
*15:11, 15:34	1							
*15:21					5	6		
*15:50N								
*15:80N	1							
<i>DRB5*01:13</i>								
<b>DRB1 allele<sup>4,5</sup></b>								
<b>Well No.</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>7</b>	<b>8</b>

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140	115	215	215	120	175	80	85	Length of spec. PCR product(s)
				155				
9	10	11	12	13	14	15	16	Well No.
	10						16	*11:01:03, 11:01:10- 11:01:11, 11:19:02
	10					15	16	*11:04:07, 12:04
	10					15		*12:01:01, 12:01:03- 12:02:03, 12:02:05- 12:03:03, 12:05-12:06, 12:08-12:10, 12:12- 12:15, 12:17-12:20, 12:23-12:37, 13:77
	10							*12:07, 13:02:02
9								*15:01:01:01-15:01:21, 15:03:01:01-15:06:02, 15:12-15:13, 15:16- 15:18, 15:20, 15:22- 15:25, 15:32-15:33, 15:35-15:37:02, 15:40- 15:43, 15:45-15:46, 15:49, 15:51-15:57, 15:61-15:62, 15:64- 15:67, 15:70-15:77, 15:79, 15:81
9								*15:02:01-15:02:09, 15:08, 15:14-15:15, 15:19, 15:26-15:27, 15:29-15:31, 15:38- 15:39, 15:44, 15:47, 15:58, 15:60, 15:63, 15:68, 15:78
9								*15:10
								*15:11, 15:34
9								*15:21
9	10							*15:50N
9	10							*15:80N
							16	<i>DRB5*01:13</i>
								<b>DRB1 allele<sup>4,5</sup></b>
9	10	11	12	13	14	15	16	Well No.

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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\*16 subtyping.

In addition, wells number 2, 7 and 12 contain the primer pair giving rise to the longer, 515 bp, internal positive control band in order to allow kit identification.

<sup>2</sup>The codon, and in parenthesis the nucleotide, in the 2<sup>nd</sup> 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](http://www.ebi.ac.uk/imgt/hla) web site. The sequence of the 3 terminal nucleotides of the primer is given.

<sup>3</sup>The codon, and in parenthesis the nucleotide, in the 2<sup>nd</sup> 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](http://www.ebi.ac.uk/imgt/hla) web site. The sequence of the 3 terminal nucleotides of the primer is given.

<sup>4</sup>The DRB1\*1606 allele has been shown to be identical to DRB1\*16:05:01.

<sup>5</sup>DRB1\*16 alleles in bold lettering are listed as confirmed alleles on the IMGT/HLA web page [www.ebi.ac.uk/imgt/hla](http://www.ebi.ac.uk/imgt/hla), release 3.10.0, October 2012.

<sup>6</sup>Primer mix 13: Specific PCR fragment of 120 bp in the DRB1\*16:19 allele. Specific PCR fragment of 155 bp in the DRB1\*16:13N allele.

101.126-12 – including *Taq* polymerase, IFU-01  
 101.126-12u – without *Taq* polymerase, IFU-02

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Lot No.: **84R**

Lot-specific information

CELL LINE VALIDATION SHEET																				
DRB1*16 SSP subtyping kit																				
				Well																
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	
				Prod. No.:	201184301	201184302	201184303	201184304	201184305	201184306	201184307	201184308	201184309	201184310	201184311	201184312	201200413	201184314	201213115	201184316
IHC 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	*14:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
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		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

101.126-12 – including *Taq* polymerase, IFU-01  
 101.126-12u – without *Taq* polymerase, IFU-02

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Lot No.: **84R**

Lot-specific information

## CERTIFICATE OF ANALYSIS

### Olerup SSP® DRB1\*16 SSP

**Product number:** 101.126-12 – including *Taq* polymerase  
 101.126-12u – without *Taq* polymerase  
**Lot number:** 84R  
**Expiry date:** 2015-July-01  
**Number of tests:** 12  
**Number of wells per test:** 16

#### Well specifications:

Well No.	Production No.	Well No.	Production No.
1	2011-843-01	9	2011-843-09
2	2011-843-02	10	2011-843-10
3	2011-843-03	11	2011-843-11
4	2011-843-04	12	2011-843-12
5	2011-843-05	13	2012-004-13
6	2011-843-06	14	2011-843-14
7	2011-843-07	15	2012-131-15
8	2011-843-08	16	2011-843-16

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 4, 6 to 8, 11 to 14 and 16 were available. The specificities of the primers in primer solutions 6, 8 and 16 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer solutions 4, 13 and 14 it was only possible to test the 5'-primers, the 3'-primers were not possible to test. In primer solution 7, 11 and 12 it was only possible to test the 3'-primers, the 5'-primers were not possible to test. In primer solution 3, one 3'-primer was not possible to test.

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

**Date of approval:** 2013-February-15

**Approved by:**

#### Production Quality Control

101.126-12 – including *Taq* polymerase, IFU-01  
101.126-12u – without *Taq* polymerase, IFU-02

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Lot No.: **84R**

Lot-specific information

## Declaration of Conformity

**Product name:** *Olerup* SSP® DRB1\*16  
**Product number:** 101.126-12  
**Lot number:** 84R

**Intended use:** DRB1\*16 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  
2013-February-15

Ann-Cathrin Jareman  
Head of QA and Regulatory Affairs

101.126-12 – including *Taq* polymerase, IFU-01  
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Lot No.: **84R**

Lot-specific information

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