

101.101.48/12 – including *Taq* pol., IFU-01 Rev. No. 03
 101.101.48u/12u – without *Taq* pol., IFU-02 Rev. No. 03

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

Lot No.: **01N**

Lot-specific information

Olerup SSP[®] DR low resolution

Product number:	101.101-48/12 – including <i>Taq</i> pol. 101.101-48u/12u – without <i>Taq</i> pol.
Lot number:	01N
Expiry date:	2014-April-01
Number of tests:	48 tests – Product No. 101.101-48/48u 12 tests – Product No. 101.101-12/12u
Number of wells per test:	31 + 1
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. 01N.

CHANGES COMPARED TO THE PREVIOUS OLERUP SSP[®] DR LOW RESOLUTION LOT

The DR low resolution specificity and interpretation tables have been updated for the HLA-DRB1 alleles described since the previous Olerup SSP[®] DR low resolution lot was made (**Lot No. 59M**).

Eight wells have been added to the DR low kit, wells **25 to 32**.

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

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

Well	5'-primer	3'-primer	rationale
9	Removed	Removed, added	Improved resolution of DRB1*07 alleles.
15	-	Modified	Improved allelic resolution.
21	Moved, new	Moved, new	Primer pair moved to well 29, improved resolution of DRB1*08 and DRB1*12 alleles.
22	Moved, new	Moved, new	Primer pair moved to well 30, improved resolution of DRB1*08 and DRB1*13 alleles.

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23	Moved, new	Moved, new	Primer pair moved to well 31, improved resolution of DRB1*12 alleles.
24	Moved, new	Moved, new	Negative control moved to well 32, improved resolution of DRB1*13 alleles.
25	New	New	Improved resolution of DRB1*13 alleles.
26	New	New	Improved resolution of DRB1*13 and DRB1*14 alleles.
27	New	New	Improved resolution of DRB1*14 alleles.
28	New	New	Improved resolution of DRB1*14 alleles.
29	Moved	Moved	Primer pair from well 21.
30	Moved	Moved	Primer pair from well 22.
31	Moved	Moved	Primer pair from well 23.
32	Moved	Moved	Negative control moved from well 24.

Change in revision R01 compared to R00:

1. Primer mix 4 may have a tendency of giving rise to nonspecific amplifications.

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Well **32** contains Negative Control primer pairs, that will amplify more than 95% of the *Olerup SSP*[®] HLA Class I, DRB, DQB1 and DPB1 amplicons as well as the amplicons generated by control primer pairs.

PCR product sizes range from 75 to 430 base pairs.

The PCR product generated by the control primer pair is 430 base pairs.

Length of PCR product	105	200	105	80	75	80
5'-primer¹	164	340	440	45	45	43
	5'-CAC ^{3'}	5'-Agg ^{3'}	5'-TTA ^{3'}	5'-Tgg ^{3'}	5'-Tgg ^{3'}	5'-Tgg ^{3'}
3'-primer²	231	2nd I	507	59	58	57
	5'-TgC ^{3'}	5'-AAA ^{3'}	5'-TTg ^{3'}	5'-CTC ^{3'}	5'-ggC ^{3'}	5'-CTC ^{3'}
A*	+	+	+			
B*	+	+	+			
C*	+	+	+			
DRB1				+	+	
DRB3				+	+	
DRB5				+		
DQB1					+	
DPB1						+

¹The nucleotide position for HLA class I genes and the codon for HLA class II genes, in the 2nd or 3rd exon, matching the specificity-determining 3'-end of the primer is given. Nucleotide and codon numbering as on the www.ebi.ac.uk/imgt/hla web site. The sequence of the 3 terminal nucleotides of the primer is given.

²The nucleotide position for HLA class I genes and the codon for HLA class II genes, in the 2nd or 3rd exon or the 2nd intron, matching the specificity-determining 3'-end of the primer is given in the anti-sense direction. Nucleotide and codon numbering as on the www.ebi.ac.uk/imgt/hla web site. The sequence of the 3 terminal nucleotides of the primer is given.

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PRODUCT DESCRIPTION

DR low resolution

CONTENT

The primer set contains 5'- and 3'-primers for grouping the DRB1*01:01 to DRB1*10:03 alleles into the corresponding serological groups DR1 to DR18 as well as primer pairs for recognizing the DRB3, DRB4 and DRB5 groups of alleles.

PLATE LAYOUT

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

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

Wells 1 to 31 – DR low resolution primers.

Well 32 – Negative Control.

The 32 well cut PCR plate is marked with ‘DR low’ in silver/gray ink.

Well No. 1 is marked with the Lot No. ‘01N’.

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

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

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

INTERPRETATION

Only HLA-DRB alleles will be amplified by the 31 wells of the DR low resolution primer set, **wells 1 to 31**. Thus, the interpretation of DR low resolution typings is not influenced by other HLA class II genes.

UNIQUELY IDENTIFIED ALLELES

All the HLA-DRB1, -DRB3, -DRB4¹ and -DRB5 alleles, i.e. **DRB1*01:01 to 10:03, DRB3*01:01 to DRB3*03:03, DRB4*01:01 to DRB4*01:08, DRB5*01:01 to DRB5*02:05**, recognized by the HLA Nomenclature Committee in July 2011² will be amplified by the primers in the DR low resolution SSP kit. The HLA-DRB alleles will be grouped into their corresponding serological specificities.

¹The DRB4*02:01N and DRB4*03:01N null alleles will not be amplified by the DR low resolution primer set.

²DRB alleles listed on the IMGT/HLA web page 2011-July-14, release 3.5.0, www.ebi.ac.uk/imgt/hla.

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Lot-specific information
SPECIFICITY TABLE

DR low resolution primer set

Specificities and sizes of the PCR products of the 31+1 primer mixes of the DR low resolution primer set

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	DR serology ³	Amplified HLA-DRB ⁴ alleles
1⁶	205 bp, 255 bp	515 bp	1	*01:01:01-01:02:05, 01:04-01:37
2	200 bp	430 bp	1/103	*01:03
3⁶	200 bp, 215 bp	430 bp	2, 15	*15:01:01:01-15:58
4⁹	210 bp	430 bp	16	*16:01:01-16:05:02, 16:07-16:18
5^{5-7,12}	120 bp, 220 bp	430 bp	3, 11, 17, 18	*03:01:01:01-03:65, 11:07, 11:53, 11:103, 11:105, 11:107, 15:25
6^{5,6,12}	80 bp, 210 bp	430 bp	3, 6, 11, 13, 14, 17	*03:01:01:01-03:01:14, 03:04:01-03:06, 03:08-03:16, 03:18-03:20, 03:22-03:23, 03:25-03:26, 03:28, 03:30-03:31, 03:33-03:34, 03:36-03:37, 03:43-03:48, 03:50-03:52, 03:54-03:65, 08:40, 11:02:01-11:03, 11:11:01- 11:11:02, 11:14:01-11:14:02, 11:16, 11:20- 11:21, 11:36, 11:40-11:41, 11:48, 11:59, 11:63, 11:65:01-11:65:02, 11:68, 11:70, 11:73, 11:76, 11:79-11:80, 11:83, 11:85- 11:87, 11:93, 13:01:01-13:04, 13:08, 13:10, 13:15-13:17, 13:19-13:20, 13:22-13:24, 13:27-13:29, 13:31-13:41, 13:43, 13:45, 13:48, 13:51-13:54, 13:57, 13:59, 13:61:01- 13:61:02, 13:63-13:66:02, 13:68-13:76, 13:78- 13:81, 13:83-13:85, 13:87-13:99, 13:101- 13:102, 13:104-13:107, 13:109, 13:111- 13:117, 14:16, 14:19, 14:21, 14:82, 14:95, 14:109
7^{5,6}	85 bp, 210 bp	430 bp	3, 6, 11, 13, 14, 1403, 18	*03:02:01-03:03, 03:27, 03:29, 03:38, 03:53, 11:13:01 ^w -11:13:02 ^w , 11:26, 11:34, 13:15, 13:19, 13:26, 13:44, 13:53, 13:57, 13:85- 13:86, 13:104, 14:02-14:03:02, 14:06:01- 14:06:02, 14:09, 14:12:01-14:13, 14:17-14:21, 14:24, 14:27, 14:29-14:30, 14:32:01 ^w - 14:32:02 ^w , 14:33, 14:40-14:41, 14:47-14:49, 14:51, 14:63, 14:65 ^w , 14:67, 14:77-14:78, 14:80-14:81, 14:83, 14:85, 14:89, 14:94, 14:98, 14:102, 14:106, 14:108-14:109, 14:115

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8^{5,6}	100 bp, 175 bp	430 bp	3, 4	*04:01:01-04:102
9	235 bp	430 bp	7	*07:01:01:01-07:01:04, 07:03-07:21
10⁶	170 bp, 215 bp, 250 bp	515 bp	8, 11, 12, 14	*08:01:01-08:19, 08:21-08:48, 11:67, 12:04, 12:16, 12:22, 14:11, 14:15, 14:68, 14:93
11^{5,6}	85 bp, 135 bp, 180 bp	430 bp	3, 9, 11	*03:08, 03:65, 09:01:02-09:16, 11:07, 11:53, 11:103, 11:105, 11:107
12	205 bp	430 bp	10	*10:01:01-10:03
13^{5,6}	100 bp, 170 bp	430 bp	3, 8, 11, 13, 14	*03:08, 03:65, 08:31, 08:41, 11:01:01-11:70, 11:72-11:113
14^{5,6}	85 bp, 105 bp	430 bp	12	*08:32, 12:01:01-12:34
15¹¹	215 bp	430 bp	6, 8, 11, 13, 14, 1403	*08:20-08:21, 11:01:01-11:04:08, 11:06:01- 11:06:02, 11:08:01-11:12:02, 11:14:01-11:16, 11:18-11:21, 11:23-11:25, 11:27:01-11:33, 11:35-11:51, 11:54:01-11:54:02, 11:56-11:66, 11:68, 11:70, 11:72-11:81, 11:83-11:88, 11:90-11:97, 11:99-11:102, 11:106, 11:108- 11:113, 13:01:01-13:08, 13:10-13:16, 13:18- 13:43, 13:45-13:85, 13:87-13:115, 13:117- 13:119, 14:03:01-14:03:02, 14:12:01- 14:12:02, 14:16, 14:19, 14:21-14:22, 14:25, 14:27, 14:40, 14:53, 14:63, 14:67, 14:69, 14:74, 14:77-14:78, 14:84-14:85, 14:98, 14:102, 14:105, 14:109, 14:115-14:116
16⁶	195 bp, 215 bp	430 bp	6, 8, 11, 12, 13, 14	*08:01:01-08:02:04, 08:04:01-08:09, 08:11, 08:16-08:17, 08:20-08:22, 08:24, 08:26, 08:28, 08:31, 08:39, 08:41-08:44, 11:01:01- 11:06:02, 11:09-11:12:02, 11:14:01-11:16, 11:20-11:21, 11:23-11:25, 11:27:01-11:30, 11:32-11:33, 11:35-11:41, 11:43-11:44, 11:46:01-11:51, 11:54:01-11:56, 11:58:01- 11:63, 11:65:01-11:70, 11:72, 11:74:01-11:78, 11:80-11:88, 11:90-11:97, 11:99-11:102, 11:106, 11:108-11:113, 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, 13:01:01- 13:02:01, 13:02:03-13:02:05, 13:04-13:05:02, 13:07:01-13:09, 13:11:01-13:11:02, 13:14:01- 13:24, 13:26-13:29, 13:31-13:32, 13:34-13:36, 13:38-13:43, 13:45-13:55, 13:57, 13:59, 13:61:01-13:65, 13:67-13:76, 13:78-13:80, 13:83-13:84, 13:87, 13:91-13:93, 13:96:01- 13:100, 13:102-13:109, 13:111-13:114,

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17 ¹²	175 bp 430 bp	3, 6, 11, 13, 14, 1403, 17, 18		*03:01:01:01-03:07, 03:09, 03:11:01-03:41, 03:43-03:45, 03:47-03:63, 08:20, 13:01:01-13:16, 13:18-13:42, 13:44, 13:46-13:66:02, 13:68-13:102, 13:104-13:115, 13:117-13:119, 14:02-14:03:02, 14:05:01-14:06:02, 14:09, 14:12:01-14:14, 14:17-14:21, 14:23:01, 14:23:03-14:24, 14:27, 14:29-14:30, 14:33, 14:36-14:37, 14:40-14:45, 14:47-14:48, 14:51, 14:56, 14:59, 14:63-14:65, 14:67, 14:77-14:78, 14:80-14:81, 14:83-14:85, 14:89, 14:91, 14:94-14:96, 14:98, 14:100, 14:102-14:103, 14:106, 14:108-14:109, 14:115-14:116
18 ^{5,7,10,11}	100 bp, 140 bp, 155 bp	430 bp	4, 6, 8,13, 14, 1404	*04:62, 04:69, 04:73, 08:08, 11:69, 11:82, 13:45, 14:01:01-14:01:02, 14:04, 14:07:01-14:07:02, 14:10, 14:16, 14:22, 14:25-14:26, 14:28, 14:31-14:32:02, 14:35, 14:37-14:39, 14:49-14:50, 14:53-14:55, 14:57-14:58, 14:60-14:62, 14:68-14:71, 14:73-14:76, 14:79, 14:82, 14:86-14:88, 14:90, 14:93, 14:99, 14:101, 14:104-14:105, 14:107, 14:110-14:114, 14:117, DRB4*01:03:01:02N
19 ^{5,6,8}	110 bp, 140 bp, 170 bp	430 bp	3, 4, 6, 9, 11, 13, 14, 1404	*03:10, 09:01:02-09:01:05, 09:01:07-09:02:02, 09:04-09:16, 11:13:01-11:13:02, 11:17, 11:52, 13:43, 14:01:01-14:02, 14:04-14:11, 14:13-14:14, 14:16-14:18, 14:19 ^w , 14:20, 14:21 ^w , 14:22-14:23:03, 14:26, 14:28-14:36, 14:38-14:39, 14:41, 14:43-14:52, 14:54-14:57, 14:59-14:62, 14:64-14:65, 14:68, 14:70-14:76, 14:79-14:83, 14:86-14:88, 14:90-14:97, 14:99-14:101, 14:103-14:108, 14:109 ^w , 14:110-14:114, 14:117, 15:27, 15:34
20 ^{5,6}	110 bp, 175 bp, 225 bp	430 bp	2 ^w , 3, 4, 6, 8, 11, 13, 14, 1403, 1404, 16 ^w	*03:10, 08:09, 08:20-08:21, 08:32, 08:35, 11:13:01-11:13:02, 11:17, 11:23, 11:25, 11:31, 11:45, 11:52, 11:55, 11:64, 11:89, 11:96, 13:13, 13:18, 13:43, 13:45, 13:47, 13:55, 13:119, 14:01:01-14:01:03, 14:03:01-14:05:03, 14:07:01-14:08, 14:10-14:12:02, 14:14-14:16, 14:18, 14:22-14:23:03, 14:25-14:28, 14:31-14:32:02, 14:34-14:36, 14:38-14:40, 14:42-14:45, 14:49-14:50, 14:53-14:65, 14:67-14:79, 14:81-14:82, 14:84-14:93, 14:95-14:97, 14:99-14:105, 14:107, 14:110-14:117, 15:21 ^w , 16:04 ^w , 16:18 ^w

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21	165 bp	430 bp	8, 12, 13, 14	*08:01:01-08:04:05, 08:04:07-08:06, 08:09-08:10, 08:12-08:14, 08:16-08:18, 08:21-08:24, 08:26-08:30:03, 08:32-08:33, 08:35-08:40, 08:42-08:48, 12:09, 13:17, 13:116, 14:15, 14:52
22 ⁵	75 bp, 175 bp	430 bp	2, 4, 8, 11, 13, 14	*04:12, 04:18, 04:25, 04:58, 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, 11:25, 11:67, 13:18, 14:12:01-14:12:02, 14:15, 14:78, 14:84, 15:21
23	135 bp	430 bp	8, 12, 13	*08:17, 08:28, 08:37, 08:45, 11:67, 12:01:01-12:20, 12:22-12:34, 13:17
24	170 bp	430 bp	3, 6, 11, 13, 14	*03:12, 13:03:01-13:04, 13:12:01-13:13, 13:21:01-13:21:02, 13:30, 13:32-13:33:03, 13:38, 13:48-13:49, 13:55, 13:58, 13:65-13:66:02, 13:75, 13:81, 13:88-13:90, 13:93-13:95, 13:101, 13:108, 13:115, 13:118, 14:13, 14:63, 14:65, 14:78, 14:85
25	150 bp	430 bp	2, 4, 6, 11, 13	*11:16, 11:20, 11:40, 11:59, 13:01:01-13:02:01, 13:02:03-13:02:05, 13:08, 13:15-13:16, 13:19-13:20, 13:27-13:29, 13:31-13:32, 13:34-13:36, 13:39-13:41, 13:43, 13:51-13:53, 13:57, 13:59, 13:61:01-13:61:02, 13:63-13:65, 13:67-13:69, 13:71-13:74, 13:76, 13:78-13:80, 13:83-13:84, 13:87, 13:91-13:93, 13:96:01-13:99, 13:102-13:107, 13:109, 13:111-13:114, 13:117, 14:16, 14:57, 15:10
26	145 bp	430 bp	3, 6, 11, 13, 14, 17	*03:01:01:01-03:01:14, 03:04:01-03:05:03, 03:07-03:16, 03:18-03:25, 03:28-03:30, 03:32-03:34, 03:36-03:37, 03:39-03:40, 03:43-03:52, 03:54-03:59, 03:61-03:65, 11:01:01-11:01:06, 11:01:08-11:04:08, 11:06:01-11:16, 11:18-11:21, 11:23-11:29, 11:31-11:36, 11:38-11:40, 11:42-11:47, 11:49:01-11:49:02, 11:51, 11:53-11:55, 11:57-11:66, 11:68-11:70, 11:72-11:82, 11:84-11:87, 11:89-11:103, 11:105-11:106, 11:108-11:113, 13:01:01-13:01:08, 13:02:01-13:02:05, 13:04-13:06, 13:09-13:11:02, 13:14:01-13:16, 13:18, 13:20-13:25, 13:27-13:31, 13:34, 13:39, 13:41-13:46, 13:50:01-13:52, 13:54, 13:56-13:57, 13:59, 13:61:01-13:64, 13:66:01-13:66:02, 13:68-13:69, 13:71, 13:73-13:75, 13:77-13:80, 13:82-13:83, 13:86-13:87, 13:91-13:93, 13:96:01-13:100, 13:102, 13:104-13:107, 13:109-13:114, 13:117,

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				13:119, 14:17, 14:21, 14:30, 14:33, 14:35, 14:42, 14:53, 14:64-14:65, 14:72, 14:95
27	145 bp, 215 bp	430 bp	6, 8, 11, 13, 14, 1403, 1404	*08:09, 08:20-08:21, 08:35, 11:13:01-11:13:02, 11:17, 11:23, 11:25, 11:45, 11:52, 11:55, 11:64, 11:89, 13:13, 13:18, 13:47, 13:55, 13:119, 14:01:01-14:01:03, 14:03:01-14:05:03, 14:07:01-14:08, 14:10-14:12:02, 14:14-14:15, 14:18, 14:23:01-14:23:03, 14:26-14:28, 14:31-14:32:02, 14:34-14:36, 14:38-14:40, 14:42-14:45, 14:50, 14:54-14:56, 14:58-14:65, 14:67-14:68, 14:70-14:72, 14:75, 14:77-14:78, 14:81-14:82, 14:84-14:93, 14:95-14:97, 14:99-14:103, 14:110, 14:112-14:117
28	140 bp	430 bp	6, 13, 14	*13:10, 13:85, 14:02, 14:06:01-14:06:02, 14:09, 14:13, 14:17, 14:19, 14:21, 14:29-14:30, 14:33, 14:46-14:48, 14:51-14:52, 14:80, 14:83, 14:106, 14:108-14:109
29 ^{6,11,12}	160 bp, 240 bp	430 bp	52	DRB3*01:01:02:01-01:15, DRB3*02:01-02:28, DRB3*03:01:01-03:03
30 ^{7,10}	215 bp	430 bp	53	DRB4*01:01:01:01-01:08
31	175 bp	430 bp	51	DRB5*01:01:01-01:14, DRB5*02:02-02:05
32 ^{7,13}	-	-		Negative control

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 DR low resolution SSP subtypings.

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

Nonspecific amplifications, i.e. a ladder or a smear of bands, may sometimes be seen. GC-rich primers have a higher tendency of giving rise to nonspecific amplifications than other primers, e.g. the primers in wells 3, 18, 19 and 20.

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 DR low resolution typing.

In addition, well number 10 contains the primer pair giving rise to the longer, 515 bp, internal positive control band in order to allow kit identification.

In the presence of a specific amplification the intensity of the control band often decreases.

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³The serological reactivity of all DRB alleles is not known. In this table we use the information in the HLA Dictionary 2004 on the www.ebi.ac.uk/imgt/hla web site and the expert-assigned serological grouping in Tissue Antigens (2009) 73:95-170.

⁴For several DRB alleles only partial second exon nucleotide sequences are available. In these instances it is not known whether some of the primers of the SSP set 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.

⁵Specific PCR fragments shorter than 125 base pairs have a lower intensity and are less sharp than longer PCR bands.

⁶Individual alleles can give rise to two differently sized specific PCR fragments in primer mix 1, 3, 5 to 8, 10, 11, 13, 14, 16, 19, 20 and 29.

⁷Primer mixes 5, 18, 30 and 32 may have tendencies of primer oligomer formation.

⁸Primer mix 19 has a tendency of primer oligomer formation and also has an intense primer cloud due to the high number of primers present in the primer mix.

⁹Primer mix 4 may have tendencies of unspecific amplifications.

¹⁰The DRB4*01:03:01:02N allele is amplified by the primer pairs in wells 18 and 30, whereas the DRB4*02:01N and DRB4*03:01N null alleles are not amplified by these primer pairs.

¹¹Due to sharing of sequence motifs, DRB3*02:27 is amplified by the primer pairs in well 15 in addition to primer mix 29.

¹²Due to sharing of sequence motifs in codon 38, DRB3*01:14 will also be amplified in primer mixes 5, 6 and 17 in addition to primer mix 29.

¹³Primer mix 32 contains a negative control, which will amplify more than 95% of HLA amplicons as well as the amplicons generated by control primer pairs. PCR product sizes range from 75 to 200 base pairs. The PCR product generated by the control primer pair is 430 base pairs.

‘w’, might be weakly amplified.

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		INTERPRETATION TABLE															
		DR low resolution SSP typing															
		Amplification patterns of the DRB1*01:01 to DRB1*10:03 alleles															
		Well⁴															
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Length of spec.		205	200	200	210	120	80	85	100	235	170	85	205	100	85	215	195
PCR product(s)		255		215		220	210	210	175		215	135		170	105		215
											250	180					
Length of int. pos. control ¹		515	430	430	430	430	430	430	430	430	515	430	430	430	430	430	430
Well No.	DR	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
DRB1 allele ²	ser ³																
*01:01:01-01:02:05, 01:04-01:37	DR1, Null, –	1															
*01:03	DR1/103		2														
*03:01:01-01:03:01:14, 03:04:01-03:05:03, 03:09, 03:11:01-03:11:02, 03:13:01-03:16, 03:18-03:20, 03:22-03:23, 03:25, 03:28, 03:30, 03:33-03:34, 03:36-03:37, 03:43-03:45, 03:47-03:48, 03:50-03:52, 03:54-03:59, 03:61-03:63	DR3, DR17, –					5	6										
*03:02:01-03:03, 03:27, 03:38, 03:53	DR3, DR18, –					5		7									
*03:06, 03:26, 03:31, 03:60	DR3, –					5	6										
*03:07, 03:21, 03:24, 03:32, 03:39-03:40, 03:49	DR3, –					5											
*03:08, 03:65	DR3, –					5	6					11		13			
*03:10	DR3					5	6										
*03:12	DR3					5	6										
*03:17, 03:35, 03:41	DR3, –					5											
*03:29	DR3					5		7									
*03:42	–					5											
*03:46, 03:64	–					5	6										
*04:01:01-04:11, 04:13-04:17:02, 04:19-04:24, 04:26-04:57, 04:59-04:61, 04:63-04:68, 04:70-04:72:02, 04:74-04:102	DR3, DR4, Null, –																
*04:12, 04:18, 04:25, 04:58	DR4																
*04:62, 04:69, 04:73	DR4, –																
Well No.	DR	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16

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Well No.	DR	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
DRB1 allele²	ser³																
*07:01:01:01-07:01:04, 07:03-07:21	DR7, Null, –									9							
*08:01:01-08:02:04, 08:05, 08:16, 08:24, 08:26, 08:39, 08:42-08:44	DR8, –										10						16
*08:03:02, 08:13, 08:18, 08:23, 08:27, 08:29-08:30:03, 08:33, 08:36, 08:38, 08:46-08:48	DR8, –										10						
*08:04:01, 08:04:04-08:04:05, 08:04:07, 08:06, 08:22	DR8, –										10						16
*08:04:02-08:04:03	DR8										10						16
*08:04:06	–										10						16
*08:07, 08:11	DR8										10						16
*08:08	DR8										10						16
*08:09	DR8										10						16
*08:10, 08:12, 08:14	DR8										10						
*08:15, 08:19, 08:25, 08:34	DR8, –										10						
*08:17	DR8										10						16
*08:20	–															15	16
*08:21	DR8										10					15	16
*08:28	DR8										10						16
*08:31, 08:41	DR8, DR11, –										10			13			16
*08:32	–										10			14			
*08:35	–										10						
*08:37, 08:45	–										10						
*08:40	–						6				10						
*09:01:02-09:01:05, 09:01:07-09:02:02, 09:04-09:16	DR9, –											11					
*09:01:06, 09:03	DR9											11					
*10:01:01-10:03	DR10, –												12				
Well No.	DR	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16

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17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	DR	Well No.
																ser ³	DRB1 allele ²
																DR7, Null, –	*07:01:01-01-07:01:04, 07:03-07:21
				21												DR8, –	*08:01:01-08:02:04, 08:05, 08:16, 08:24, 08:26, 08:39, 08:42-08:44
				21												DR8, –	*08:03:02, 08:13, 08:18, 08:23, 08:27, 08:29-08:30:03, 08:33, 08:36, 08:38, 08:46-08:48
				21	22											DR8, –	*08:04:01, 08:04:04-08:04:05, 08:04:07, 08:06, 08:22
				21	w											DR8	*08:04:02-08:04:03
					22											–	*08:04:06
																DR8	*08:07, 08:11
18																DR8	*08:08
			20	21						27						DR8	*08:09
				21	22											DR8	*08:10, 08:12, 08:14
																DR8, –	*08:15, 08:19, 08:25, 08:34
				21		23										DR8	*08:17
17			20		22					27						–	*08:20
			20	21						27						DR8	*08:21
				21	22	23										DR8	*08:28
																DR8, DR11, –	*08:31, 08:41
			20	21												–	*08:32
			20	21						27						–	*08:35
				21		23										–	*08:37, 08:45
				21												–	*08:40
		19														DR9, –	*09:01:02-09:01:05, 09:01:07-09:02:02, 09:04-09:16
																DR9	*09:01:06, 09:03
																DR10, –	*10:01:01-10:03
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	DR	Well No.

Neg. Control

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Lot-specific information

Well No.	DR	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
DRB1 allele²	ser³																
*11:01:01-11:01:06, 11:01:08-11:01:15, 11:04:01-11:04:08, 11:06:01-11:06:02, 11:09-11:10:02, 11:12:01-11:12:02, 11:15, 11:24, 11:27:01-11:29, 11:32-11:33, 11:35, 11:38-11:39, 11:43-11:44, 11:46:01-11:47, 11:49:01-11:49:02, 11:51, 11:54:01-11:54:02, 11:58:01-11:58:02, 11:60-11:62, 11:66, 11:72, 11:74:01-11:75, 11:77-11:78, 11:81, 11:84, 11:90-11:92, 11:94-11:95, 11:97, 11:99-11:102, 11:106, 11:108-11:113	DR11, –													13		15	16
*11:01:07, 11:30, 11:37, 11:50, 11:56, 11:88	DR11, –													13		15	16
*11:02:01-11:03, 11:11:01-11:11:02, 11:14:01-11:14:02, 11:21, 11:36, 11:63, 11:65:01-11:65:02, 11:68, 11:70, 11:76, 11:80, 11:85-11:87, 11:93	DR11, –						6							13		15	16
*11:05	DR11													13			16
*11:07, 11:53, 11:103, 11:105	DR11, –					5						11		13			
*11:08:01-11:08:02, 11:18-11:19:03, 11:42, 11:57	DR11, –													13		15	
*11:13:01-11:13:02	DR11							w						13			
*11:16, 11:20, 11:40, 11:59	DR11, DR13						6							13		15	16
*11:17, 11:52	DR11, DR14													13			
*11:22, 11:104	–													13			
*11:23	DR11													13		15	16
*11:25	DR11													13		15	16
*11:26, 11:34	DR11							7						13			
*11:31	DR11													13		15	
*11:41, 11:48, 11:83	DR11, –						6							13		15	16
*11:45, 11:64	DR11, –													13		15	
*11:55	DR11													13			16
*11:67	–											10		13			16
*11:69, 11:82	–													13			16
*11:73, 11:79	–						6							13		15	
*11:89	–													13			
Well No.	DR	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16

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17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	DR	Well No.
																ser ³	DRB1 allele ²
									26							DR11, –	*11:01:01-11:01:06, 11:01:08-11:01:15, 11:04:01-11:04:08, 11:06:01-11:06:02, 11:09-11:10:02, 11:12:01-11:12:02, 11:15, 11:24, 11:27:01-11:29, 11:32-11:33, 11:35, 11:38-11:39, 11:43-11:44, 11:46:01-11:47, 11:49:01-11:49:02, 11:51, 11:54:01-11:54:02, 11:58:01-11:58:02, 11:60-11:62, 11:66, 11:72, 11:74:01-11:75, 11:77-11:78, 11:81, 11:84, 11:90-11:92, 11:94-11:95, 11:97, 11:99-11:102, 11:106, 11:108-11:113
																DR11, –	*11:01:07, 11:30, 11:37, 11:50, 11:56, 11:88
									26							DR11, –	*11:02:01-11:03, 11:11:01-11:11:02, 11:14:01-11:14:02, 11:21, 11:36, 11:63, 11:65:01-11:65:02, 11:68, 11:70, 11:76, 11:80, 11:85-11:87, 11:93
									26							DR11	*11:05
									26							DR11, –	*11:07, 11:53, 11:103, 11:105
									26							DR11, –	*11:08:01-11:08:02, 11:18-11:19:03, 11:42, 11:57
		19	20						26	27						DR11	*11:13:01-11:13:02
								25	26							DR11, DR13	*11:16, 11:20, 11:40, 11:59
		19	20							27						DR11, DR14	*11:17, 11:52
																–	*11:22, 11:104
			20						26	27						DR11	*11:23
			20	22					26	27						DR11	*11:25
									26							DR11	*11:26, 11:34
			20						26							DR11	*11:31
																DR11, –	*11:41, 11:48, 11:83
			20						26	27						DR11, –	*11:45, 11:64
			20						26	27						DR11	*11:55
				22	23											–	*11:67
	18								26							–	*11:69, 11:82
									26							–	*11:73, 11:79
			20						26	27						–	*11:89
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	DR	Well No.

Neg. Control

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Lot-specific information

Well No.	DR	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
DRB1 allele ²	ser ³																
*11:96	–													13		15	16
*11:98	–													13			
*11:107	–					5						11		13			
*12:01:01-12:01:04, 12:03:02, 12:05-12:08, 12:10-12:12, 12:14, 12:17, 12:24N-12:25, 12:28-12:30, 12:34	DR12, Null, –														14		
*12:02:01-12:02:05, 12:13, 12:15, 12:18-12:20, 12:23, 12:26-12:27, 12:31N-12:33	DR12, Null, –														14		16
*12:04, 12:22	DR12, –										10				14		
*12:09	DR12														14		
*12:16	–										10				14		16
*12:21	–														14		16
*13:01:01-13:01:08, 13:02:01, 13:02:03-13:02:05, 13:16, 13:20, 13:27-13:29, 13:31, 13:34, 13:39, 13:41, 13:51- 13:52, 13:59, 13:61:01- 13:61:02, 13:63-13:64, 13:68- 13:69, 13:71, 13:73-13:74, 13:78-13:80, 13:83, 13:87, 13:91-13:92, 13:96:01-13:99, 13:102, 13:105-13:107, 13:109, 13:111-13:114, 13:117	DR13, Null, –						6									15	16
*13:01:09, 13:08, 13:35-13:36, 13:40, 13:72, 13:76, 13:84	DR13, –						6										15 16
*13:02:02	DR13						6										15
*13:03:01-13:03:06, 13:33:01- 13:33:03, 13:81, 13:88-13:90, 13:94-13:95, 13:101, 13:115	DR13, –						6										15
*13:04, 13:75	DR13, –						6										15 16
*13:05:01-13:05:02, 13:11:01- 13:11:02, 13:14:01-13:14:03, 13:42, 13:46, 13:50:01- 13:50:02, 13:62, 13:100	DR6, DR11, DR13, –																15 16
*13:06, 13:25, 13:56, 13:77, 13:82, 13:110	DR6, DR11, DR13, –																15
*13:07:01-13:07:02	DR13																15 16
*13:09	DR13																16
*13:10	DR13						6										15
Well No.	DR	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16

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17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	DR	Well No.
																ser ³	DRB1 allele ²
			20						26							-	*11:96
									26							-	*11:98
																-	*11:107
						23										DR12, Null, -	*12:01:01-12:01:04, 12:03:02, 12:05-12:08, 12:10-12:12, 12:14, 12:17, 12:24N-12:25, 12:28-12:30, 12:34
						23										DR12, Null, -	*12:02:01-12:02:05, 12:13, 12:15, 12:18-12:20, 12:23, 12:26-12:27, 12:31N-12:33
						23										DR12, -	*12:04, 12:22
				21		23										DR12	*12:09
						23										-	*12:16
																-	*12:21
17								25	26							DR13, Null, -	*13:01:01-13:01:08, 13:02:01, 13:02:03-13:02:05, 13:16, 13:20, 13:27-13:29, 13:31, 13:34, 13:39, 13:41, 13:51- 13:52, 13:59, 13:61:01- 13:61:02, 13:63-13:64, 13:68- 13:69, 13:71, 13:73-13:74, 13:78-13:80, 13:83, 13:87, 13:91-13:92, 13:96:01-13:99, 13:102, 13:105-13:107, 13:109, 13:111-13:114, 13:117
17								25								DR13, -	*13:01:09, 13:08, 13:35-13:36, 13:40, 13:72, 13:76, 13:84
17									26							DR13	*13:02:02
17							24									DR13, -	*13:03:01-13:03:06, 13:33:01- 13:33:03, 13:81, 13:88-13:90, 13:94-13:95, 13:101, 13:115
17							24		26							DR13, -	*13:04, 13:75
17									26							DR6, DR11, DR13, -	*13:05:01-13:05:02, 13:11:01- 13:11:02, 13:14:01-13:14:03, 13:42, 13:46, 13:50:01- 13:50:02, 13:62, 13:100
17									26							DR6, DR11, DR13, -	*13:06, 13:25, 13:56, 13:77, 13:82, 13:110
17																DR13	*13:07:01-13:07:02
17									26							DR13	*13:09
17									26		28					DR13	*13:10
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	DR	Well No.

Neg. Control

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 101.101.48u/12u – without *Taq* pol., IFU-02 Rev. No. 03

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Lot-specific information

Well No.	DR	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
DRB1 allele ²	ser ³																
*13:12:01-13:12:02, 13:58, 13:118	DR13, –															15	
*13:13	DR13															15	
*13:15, 13:57, 13:104	DR13, –						6	7								15	16
*13:17	DR13						6										16
*13:18	DR13															15	16
*13:19, 13:53	DR13						6	7								15	16
*13:21:01-13:21:02	DR13, DR11															15	16
*13:22-13:24, 13:54	DR11, DR13, DR14, –						6									15	16
*13:26	DR14							7								15	16
*13:30	–															15	
*13:32, 13:65	DR13						6									15	16
*13:37	DR13						6									15	
*13:38, 13:48	DR13						6									15	16
*13:43	DR13						6									15	16
*13:44, 13:86	–							7									
*13:45	DR13						6									15	16
*13:47	–															15	16
*13:49, 13:108	DR6, –															15	16
*13:55	–															15	16
*13:60	DR6															15	
*13:66:01-13:66:02	DR13, –						6									15	
*13:67, 13:103	DR13, –															15	16
*13:70	DR13						6									15	16
*13:85	–						6	7								15	
*13:93	–						6									15	16
*13:116	–						6										16
*13:119	–															15	
*14:01:01-14:01:02, 14:04, 14:07:01-14:07:02, 14:10, 14:26, 14:28, 14:31, 14:38-14:39, 14:50, 14:54-14:55, 14:60-14:62, 14:70-14:71, 14:75, 14:86-14:88, 14:90, 14:99, 14:101, 14:110, 14:112-14:114, 14:117	DR14, DR1404, –																
*14:01:03, 14:08, 14:23:02, 14:34, 14:92N, 14:97	DR14, Null, –																
Well No.	DR	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16

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 101.101.48u/12u – without *Taq* pol., IFU-02 Rev. No. 03

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Lot No.: **01N**

Lot-specific information

17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	DR	Well No.
																ser ³	DRB1 allele ²
17							24									DR13, –	*13:12:01-13:12:02, 13:58, 13:118
17			20				24			27						DR13	*13:13
17								25	26							DR13, –	*13:15, 13:57, 13:104
				21		23										DR13	*13:17
17			20		22			26	27							DR13	*13:18
17								25								DR13	*13:19, 13:53
17							24	26								DR13, DR11	*13:21:01-13:21:02
17								26								DR11, DR13, DR14, –	*13:22-13:24, 13:54
17																DR14	*13:26
17							24	26								–	*13:30
17							24	25								DR13	*13:32, 13:65
17																DR13	*13:37
17							24									DR13	*13:38, 13:48
		19	20					25	26							DR13	*13:43
17								26								–	*13:44, 13:86
	18		20					26								DR13	*13:45
17			20							27						–	*13:47
17							24									DR6, –	*13:49, 13:108
17			20				24			27						–	*13:55
17																DR6	*13:60
17							24	26								DR13, –	*13:66:01-13:66:02
								25								DR13, –	*13:67, 13:103
17																DR13	*13:70
17											28					–	*13:85
17							24	25	26							–	*13:93
				21												–	*13:116
17			20					26	27							–	*13:119
	18	19	20							27						DR14, DR1404, –	*14:01:01-14:01:02, 14:04, 14:07:01-14:07:02, 14:10, 14:26, 14:28, 14:31, 14:38-14:39, 14:50, 14:54-14:55, 14:60-14:62, 14:70-14:71, 14:75, 14:86-14:88, 14:90, 14:99, 14:101, 14:110, 14:112-14:114, 14:117
		19	20							27						DR14, Null, –	*14:01:03, 14:08, 14:23:02, 14:34, 14:92N, 14:97
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	DR	Well No.

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 101.101.48u/12u – without *Taq* pol., IFU-02 Rev. No. 03

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Lot No.: **01N**

Lot-specific information

Well No.	DR	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
DRB1 allele ²	ser ³																
*14:02, 14:06:01-14:06:02, 14:09, 14:29, 14:47-14:48, 14:51, 14:80, 14:83, 14:106, 14:108	DR14, –							7									
*14:03:01-14:03:02, 14:40, 14:67, 14:77, 14:102, 14:115	DR6, DR14, DR1403, –							7								15	
*14:05:01-14:05:03, 14:14, 14:23:01, 14:23:03, 14:36, 14:43-14:45, 14:56, 14:59, 14:91, 14:96, 14:100, 14:103	DR14, –																
*14:11	DR14										10						
*14:12:01-14:12:02	DR14, –							7								15	
*14:13	DR14							7									
*14:15	DR8										10						16
*14:16	DR6						6									15	16
*14:17, 14:30, 14:33	DR6							7									
*14:18, 14:81	DR14, –							7									
*14:19, 14:109	DR14, –						6	7								15	
*14:20, 14:41, 14:94	DR14, –							7									
*14:21	DR14						6	7								15	
*14:22, 14:105	DR14, –															15	16
*14:24	DR14							7									16
*14:25	DR6															15	16
*14:27	DR14							7								15	16
*14:32:01-14:32:02	DR14							w									
*14:35	DR14																
*14:37	DR14																16
*14:42	–																
*14:46	DR14																
*14:49	DR14							7									
*14:52	DR14																
*14:53	DR13, 14															15	16
*14:57	DR4, DR6																
*14:58	DR14																
*14:63, 14:85	DR6, –							7								15	
*14:64	DR14																
*14:65	DR6							w									
*14:68, 14:93	DR14, –										10						
*14:69	–															15	
*14:72	–																
Well No.	DR	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16

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Lot No.: **01N**

Lot-specific information

17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	DR	Well No.
																ser ³	DRB1 allele ²
17		19									28					DR14, –	*14:02, 14:06:01-14:06:02, 14:09, 14:29, 14:47-14:48, 14:51, 14:80, 14:83, 14:106, 14:108
17			20								27					DR6, DR14, DR1403, –	*14:03:01-14:03:02, 14:40, 14:67, 14:77, 14:102, 14:115
17		19	20								27					DR14, –	*14:05:01-14:05:03, 14:14, 14:23:01, 14:23:03, 14:36, 14:43-14:45, 14:56, 14:59, 14:91, 14:96, 14:100, 14:103
		19	20								27					DR14	*14:11
17			20		22						27					DR14, –	*14:12:01-14:12:02
17		19					24				28					DR14	*14:13
			20	21	22						27					DR8	*14:15
	18	19	20					25								DR6	*14:16
17		19							26		28					DR6	*14:17, 14:30, 14:33
17		19	20								27					DR14, –	*14:18, 14:81
17		w									28					DR14, –	*14:19, 14:109
17		19														DR14, –	*14:20, 14:41, 14:94
17		w							26		28					DR14	*14:21
	18	19	20													DR14, –	*14:22, 14:105
17																DR14	*14:24
	18		20													DR6	*14:25
17			20								27					DR14	*14:27
	18	19	20								27					DR14	*14:32:01-14:32:02
	18	19	20						26	27						DR14	*14:35
17	18															DR14	*14:37
17			20						26	27						–	*14:42
		19									28					DR14	*14:46
	18	19	20													DR14	*14:49
		19		21							28					DR14	*14:52
	18		20						26							DR13, 14	*14:53
	18	19	20					25								DR4, DR6	*14:57
	18		20								27					DR14	*14:58
17			20				24				27					DR6, –	*14:63, 14:85
17		19	20						26	27						DR14	*14:64
17		19	20				24		26	27						DR6	*14:65
	18	19	20								27					DR14, –	*14:68, 14:93
	18		20													–	*14:69
		19	20						26	27						–	*14:72
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	DR	Well No.

Neg. Control

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Lot No.: **01N**

Lot-specific information

Well No.	DR	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
DRB1 allele²	ser³																
*14:73	–																16
*14:74	–																15
*14:76, 14:79, 14:104, 14:107, 14:111	–																
*14:78	–							7									15
*14:82	–						6										
*14:84	–																15
*14:89	–							7									
*14:95	–						6										
*14:98	–							7									15
*14:116	–																15
*15:01:01:01-15:09, 15:11- 15:20, 15:22-15:24, 15:26, 15:28-15:33, 15:35-15:58	DR2, DR15, Null, –			3													
*15:10	DR2			3													
*15:21	DR2			3													
*15:25	–			3		5											
*15:27, 15:34	–			3													
*16:01:01-16:03, 16:05:01- 16:05:02, 16:07-16:17	DR16, Null, –				4												
*16:04, 16:18	DR16, –				4												
<i>DRB3*01:01:02:01-01:15,</i> <i>DRB3*02:01-02:26,</i> <i>DRB3*02:28, DRB3*03:01:01- 03:03</i>	DR52, –																
<i>DRB3*02:27</i>	–																15
<i>DRB4*01:01:01:01-01:03:01:01,</i> <i>DRB4*01:03:01:03-01:08</i>	DR53, –																
<i>DRB4*01:03:01:02N</i>	Null																
<i>DRB5*01:01:01-01:14,</i> <i>DRB5*02:02-02:05</i>	DR51, Null, –																
Well No.		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16

¹The internal positive control primer pairs amplify segments of the human growth hormone gene. The two different control primer pairs give rise to either an internal positive control band of 430 base pairs, for most wells, or a band of 515 base pairs, for some wells.

Well number 1 contains the primer pair giving rise to the longer, 515 bp, internal positive control band in order to help in the correct orientation of the DR low resolution typing.

In addition, well number 10 contains the primer pair giving rise to the longer, 515 bp, internal positive control band in order to allow kit identification.

²The sequence of the DRB1*0702 allele has been shown to be identical to DRB1*07:01:01:01.

The sequence of the DRB1*08031 allele has been shown to be identical to DRB1*08:03:02.

The sequence of the DRB1*09011 allele has been shown to be identical to DRB1*09:01:02.

The sequence of the DRB1*1171 allele has been shown to be identical to DRB1*11:02:01.

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

The DRB1*1466 allele has been renamed DRB1*14:32:02.

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Lot No.: **01N**

Lot-specific information

17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	DR	Well No.
																ser ³	DRB1 allele ²
	18	19	20													-	*14:73
	18	19	20													-	*14:74
	18	19	20													-	*14:76, 14:79, 14:104, 14:107, 14:111
17			20		22		24			27						-	*14:78
	18	19	20							27						-	*14:82
17			20		22					27						-	*14:84
17			20							27						-	*14:89
17		19	20							26	27					-	*14:95
17																-	*14:98
17			20							27						-	*14:116
																DR2, DR15, Null, -	*15:01:01:01-15:09, 15:11- 15:20, 15:22-15:24, 15:26, 15:28-15:33, 15:35-15:58
								25								DR2	*15:10
			w		22											DR2	*15:21
																-	*15:25
	19															-	*15:27, 15:34
																DR16, Null, -	*16:01:01-16:03, 16:05:01- 16:05:02, 16:07-16:17
			w													DR16, -	*16:04, 16:18
												29				DR52, -	<i>DRB3*01:01:02:01-01:15,</i> <i>DRB3*02:01-02:26,</i> <i>DRB3*02:28, DRB3*03:01:01- 03:03</i>
												29				-	<i>DRB3*02:27</i>
													30			DR53, -	<i>DRB4*01:01:01:01-01:03:01:01,</i> <i>DRB4*01:03:01:03-01:08</i>
	18												30			Null	<i>DRB4*01:03:01:02N</i>
														31		DR51, Null, -	<i>DRB5*01:01:01-01:14,</i> <i>DRB5*02:02-02:05</i>
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32		Well No.

The sequence of the DRB1*1606 allele has been shown to be identical to DRB1*16:05:01.

The sequence of the DRB3*010101 allele has been shown to be identical to DRB3*01:01:02:01.

The DRB4*0101102N allele has been shown to be identical to DRB4*01:03:10:02N.

The sequence of the DRB5*0201 allele has been shown to be identical to DRB5*02:02.

Due to sharing of sequence motifs in codon 38, DRB3*01:14 will also be amplified in primer mixes 5, 6 and 17 in addition to primer mix 29.

³The serological reactivity of all DRB alleles is not known. In this table we use the information in the HLA Dictionary 2004 on the www.ebi.ac.uk/imgt/hla web site and the expert-assigned serological grouping in Tissue Antigens (2009) 73:95-170.

⁴Primer mix 32 contains a negative control, which will amplify more than 95% of HLA amplicons as well as the amplicons generated by control primer pairs. PCR product sizes range from 75 to 200 base pairs. The PCR product generated by the control primer pair is 430 base pairs.

‘ser’, serological HLA specificity. ‘w’, may be weakly amplified.

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Lot No.: **01N**

Lot-specific information

Primers

Well No.	1	2	3	4	5	6	7	8
Length of spec.	205	200	200	210	120	80	85	100
PCR product(s)	255		215		220	210	210	175
Length of int.	515	430	430	430	430	430	430	430
pos. control ¹								
5'-primer(s) ²	13(124) 5' -A.T 3'	14(129) 5' -gAA 3'	13(126) 5' -Agg 3'	13(126) 5' -Agg 3'	13(125) 5' -gTC 3'	13(125) 5' -gTC 3'	13(125) 5' -gTC 3'	13(125) 5' -ACA 3'
			13(126) 5' -AAg 3'	13(126) 5' -AAg 3'	47(227) 5' -gTT 3'	16(133) 5' -gTT 3'		13(125) 5' -ACC 3'
								13(125) 5' -ATA 3'
								13(125) 5' -gTC 3'
3'-primer(s) ³	67(286) 5' -gAg 3'	67(286) 5' -gAT 3'	67(286) 5' -gAT 3'	67(286) 5' -gAA 3'	73(305) 5' -ggC 3'	26(164) 5' -ggT 3'	28(171) 5' -CTC 3'	33(184) 5' -gTg 3'
	67(286) 5' -gAg 3'		70(295) 5' -CTg 3'	67(286) 5' -gAg 3'	73(305) 5' -ggC 3'	71(299) 5' -gCT 3'	70(295) 5' -CTg 3'	58(260) 5' -Cgg 3'
	67(286) 5' -gAT 3'		70(295) 5' -Tg 3'	70(297) 5' -CTg 3'	74(308) 5' -CCC 3'			
	71(299) 5' -gCg 3'		71(298) 5' -CgC 3'	72(301) 5' -ggC 3'				
	86(344) 5' -CCA 3'		71(299) 5' -gCT 3'					
			73(305) 5' -ggC 3'					
Well No.	1	2	3	4	5	6	7	8

Well No.	9	10	11	12	13	14	15	16
Length of spec.	235	170	85	205	100	85	215	195
PCR product(s)		215	135		170	105		215
Length of int.	430	515	430	430	430	430	430	430
pos. control ¹								
5'-primer(s) ²	14(127) 5' -ATA 3'	16(133) 5' -gTT 3'	26(165) 5' -TAT 3'	31(178) 5' -gCg 3'	13(125) 5' -gTC 3'	16(133) 5' -gTT 3'	10(116) 5' -gCT 3'	10(116) 5' -gCT 3'
	14(127) 5' -ATA 3'	16(133) 5' -gTT 3'	58(261) 5' -gAg 3'		16(133) 5' -gTC 3'		12(122) 5' -TAT 3'	12(122) 5' -TAT 3'
					38(200) 5' -CgT 3'		13(125) 5' -gTC 3'	13(125) 5' -gTC 3'
								16(133) 5' -gTT 3'
								16(133) 5' -gTC 3'
	78(319) 5' -CAC 3'	58(260) 5' -CCT 3'	57(257) 5' -CgA 3'	86(344) 5' -CAC 3'				
3'-primer(s) ³	78(319) 5' -gTA 3'	74(307) 5' -CAg 3'	73(305) 5' -ggC 3'	86(344) 5' -CCA 3'	58(260) 5' -CCT 3'	30(175) 5' -gTg 3'	70(295) 5' -gTC 3'	67(286) 5' -gAA 3'
		86(344) 5' -CAC 3'	78(319) 5' -CAC 3'		58(260) 5' -CCT 3'	38(199) 5' -CAg 3'	71(299) 5' -gCT 3'	71(298) 5' -CgC 3'
					58(260) 5' -CCT 3'			71(298) 5' -CTC 3'
Well No.	9	10	11	12	13	14	15	16

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Lot No.: **01N**

Lot-specific information

Well No.	17	18	19	20	21	22	23	24
Length of spec.	175	100	110	110	165	75	135	170
PCR product(s)		140	140	175		175		
		155	170	225				
Length of int.	430	430	430	430	430	430	430	430
pos. control ¹								
5'-primer(s) ²	13(125) 5'-gTC 3'	1st I 5'-CAA 3'	26(164) 5'-gTA 3'	13(125) 5'-gTC 3'	16(133) 5'-gTT 3'	12(122) 5'-TAg 3'	16(133) 5'-gTT 3'	13(125) 5'-gTC 3'
		37(197) 5'-gTT 3'	34(189) 5'-CAg 3'	34(189) 5'-CAg 3'		74(308) 5'-CCT 3'		
		37(197) 5'-gTA 3'						
3'-primer(s) ³								
	58(260) 5'-Cgg 3'	42(213) 5'-TCA 3'	57(257) 5'-CAg 3'	57(257) 5'-CAg 3'	57(256) 5'-gCT 3'	57(256) 5'-gCT 3'	47(227) 5'-ggA 3'	57(256) 5'-gCT 3'
	58(260) 5'-CAg 3'	57(257) 5'-CAg 3'	70(295) 5'-CTg 3'	60(265) 5'-gTg 3'	57(257) 5'-CAT 3'	86(344) 5'-CCA 3'		
		71(298) 5'-CgC 3'	70(296) 5'-TCC 3'	70(296) 5'-TCC 3'	57(257) 5'-CAT 3'			
				74(307) 5'-CAg 3'				
Well No.	17	18	19	20	21	22	23	24

Well No.	25	26	27	28	29	30	31
Length of spec.	150	145	145	140	160	215	175
PCR product(s)			215		240		
Length of int.	430	430	430	430	430	430	430
pos. control ¹							
5'-primer(s) ¹	34(189) 5'-CAg 3'	13(125) 5'-gTC 3'	13(125) 5'-gTC 3'	37(196) 5'-AgA 3'	10(116) 5'-gCT 3'	28(170) 5'-gAT 3'	13(125) 5'-gTA 3'
	34(189) 5'-CAg 3'		37(197) 5'-gTT 3'		10(116) 5'-gCT 3'		
					38(199) 5'-TCC 3'		
3'-primer(s) ²	71(298) 5'-CTC 3'	47(227) 5'-ggA 3'	70(296) 5'-TCC 3'	70(295) 5'-CTg 3'	51(239) 5'-CCC 3'	87(346) 5'-CTC 3'	57(258) 5'-gCg 3'
		48(229) 5'-CCA 3'	74(307) 5'-CAg 3'	71(298) 5'-CTT 3'	77(317) 5'-AAT 3'	87(346) 5'-CTT 3'	58(260) 5'-CCT 3'
			368 5'-CAT 3'				
Well No.	25	26	27	28	29	30	31

¹The codon, and in parenthesis the nucleotide, in the 2nd exon or the 1st intron, 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.

²The 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.

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Lot No.: **01N**

Lot-specific information

CELL LINE VALIDATION SHEET																				
DR low resolution primer set																				
				Prod. No.:	Well															
					1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
					201191601	201191602	201191603	201191604	201191605	201191606	201191607	201191608	201191609	201191610	201191611	201191612	201191613	201191614	201191615	201191616
	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			-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-

101.101.48/12 – including *Taq* pol., IFU-01 Rev. No. 03
 101.101.48u/12u – without *Taq* pol., IFU-02 Rev. No. 03

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Lot No.: **01N**

Lot-specific information

CELL LINE VALIDATION SHEET																		
DR low resolution primer set																		
			Prod. No.:	Well ¹														
				17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
	IHWC cell line	DRB1		201191617	201191618	201191619	201191620	201191621	201191622	201191623	201191624	201191625	201191626	201191627	201191628	201191629	201191630	201191631
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		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

¹The DRB4*01:03:01:02N allele is amplified by primer mix 18 in the 9052 (DBB) cell line.

101.101.48/12 – including *Taq* pol., IFU-01 Rev. No. 03
 101.101.48u/12u – without *Taq* pol., IFU-02 Rev. No. 03

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 “Instructions for Use” (IFU)

Lot No.: **01N**

Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP® DR low resolution

Product number: 101.101-48/12 – including *Taq* pol.
 101.101-48u/12u – without *Taq* pol.
Lot number: 01N
Expiry date: 2014-April-01
Number of tests: 48 tests – Product No. 101.101-48/48u
 12 tests – Product No. 101.101-12/12u
Number of wells per test: 31 + 1

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2011-916-01	13	2011-916-13	25	2011-916-25
2	2011-916-02	14	2011-916-14	26	2011-916-26
3	2011-916-03	15	2011-916-15	27	2011-916-27
4	2011-916-04	16	2011-916-16	28	2011-916-28
5	2011-916-05	17	2011-916-17	29	2011-916-29
6	2011-916-06	18	2011-916-18	30	2011-916-30
7	2011-916-07	19	2011-916-19	31	2011-916-31
8	2011-916-08	20	2011-916-20		
9	2011-916-09	21	2011-916-21		
10	2011-916-10	22	2011-916-22		
11	2011-916-11	23	2011-916-23		
12	2011-916-12	24	2011-916-24		

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

The reactivities of additional 3'-primers in primer solutions 1, 3, 4, 9 to 12, 18, 20, 22 and 27 were tested by separately adding one or more additional 5'-primers. Additional 5'-primers in primer solutions 6, 11, 15, 16, 18 and 27 were tested by separately adding another 3'-primer.

One or more of the 5'-primers in primer solutions 1, 3, 4, 8 to 10, 13, 15, 16 and 22 and one or two of the 3'-primers in primer solutions 1, 3, 4, 13, 21, 26 and 30 were not possible to test.

The negative control primer pairs, **Production No. 2011-917-01**, can detect contamination with PCR products diluted 10^{-7} .

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

Date of approval: 2012-February-10

Approved by:

Production Quality Control

101.101.48/12 – including *Taq* pol., IFU-01 Rev. No. 03
101.101.48u/12u – without *Taq* pol., IFU-02 Rev. No. 03

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“Instructions for Use” (IFU)

Lot No.: **01N**

Lot-specific information

Declaration of Conformity

Product name: *Olerup* SSP® DR low resolution
Product number: 101.101-48/48u, -12/12u
Lot number: 01N

Intended use: DRB1 low 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

101.101.48/12 – including *Taq* pol., IFU-01 Rev. No. 03
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“Instructions for Use” (IFU)

Lot No.: **01N**

Lot-specific information

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