

101.103.48/12 – including *Taq* pol., IFU-01 Rev. No. 03
101.103.48u/12u – without *Taq* pol., IFU-02 Rev. No. 03

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“Instructions for Use” (IFU)

Lot No.: **67N**

Lot-specific information

Olerup SSP[®] DR low resolution screening

Product number:	101.103-48/12 – including <i>Taq</i> pol. 101.103-48u/12u – without <i>Taq</i> pol.
Lot number:	67N
Expiry date:	2014-October-01
Number of tests:	48 tests – Product No. 101.401-48/48u 12 tests – Product No. 101.401-12/12u
Number of wells per test:	23 + 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. 67N.

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

Change in revision R01 compared to R01:

1. One missing page has been inserted in the interpretation table.

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Well **24** 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 screening

CONTENT

The primer set contains 5'- and 3'-primers for grouping the DRB1*01:01 to DRB1*10:04 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 24 PCR reactions in a 24 well cut PCR plate.

1	2	3	4	5	6	7	8
9	1	1	1	1	1	1	1
	0	1	2	3	4	5	6
1	1	1	2	2	2	2	2
7	8	9	0	1	2	3	4

Wells 1 to 23 – DR low resolution screening primers.

Well 24 – Negative Control.

The 24 well cut PCR plate is marked with 'DR low screening' in silver/gray ink.

Well No. 1 is marked with the Lot No. '67N'.

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

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

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

INTERPRETATION

Only HLA-DRB alleles will be amplified by the 23 wells of the DR low resolution screening primer set, **wells 1 to 23**. Thus, the interpretation of DR low resolution screening 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 10:04, 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 January 2012² will be amplified by the primers in the DR low resolution screening SSP kit. The HLA-DRB alleles will be grouped into their corresponding serological specificities.

¹The DRB4*02:67N and DRB4*03:67N null alleles will not be amplified by the DR low resolution screening primer set.

²DRB alleles listed on the IMGT/HLA web page 2012-January-12, release 3.7.0, www.ebi.ac.uk/imgt/hla.

³The DRB1*08:09 and the DRB1*14:15 alleles yield identical amplification patterns with the DR low resolution screening primer set. These alleles can be separated by the respective high resolution primer sets.

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The DRB1*08:20 and the DRB1*13:18, 13:47 and 13:55 alleles yield identical amplification patterns with the DR low resolution screening primer set. These alleles can be separated by the respective high resolution primer sets.

The DRB1*08:31, 08:41 and DRB1*11:67 alleles yield identical amplification patterns with the DR low resolution screening primer set. These alleles can be separated by the respective high resolution primer sets.

The DRB1*13:13 and 13:119 and the DRB1*14:84 and 14:116 alleles yield identical amplification patterns with the DR low resolution screening primer set. These alleles can be separated by the respective high resolution primer sets.

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SPECIFICITY TABLE

DR low resolution screening primer set

Specificities and sizes of the PCR products of the 23+1 primer mixes of the DR low resolution screening primer set

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	DR serology ³	Amplified HLA-DRB ⁴ alleles
1^{6,7}	200 bp, 255 bp	515 bp	1	*01:01:01-01:02:08, 01:04-01:38, 01:40N-01:45
2	200 bp	430 bp	1/103	*01:03, 01:39N, 01:42
3⁶	200 bp, 215 bp	430 bp	2, 15	*15:01:01:01-15:69
4	210 bp	430 bp	16	*16:01:01-16:05:02, 16:07-16:19
5^{5,6,11}	120 bp, 220 bp	430 bp	3, 11, 17, 18	*03:01:01:01-03:75, 03:77, 11:07, 11:53, 11:103, 11:105, 11:107, 15:25
6^{5,6,8,11}	80 bp, 210 bp	430 bp	3, 6, 11, 13, 14, 17	*03:01:01:01-03:01:19, 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, 03:54-03:68N, 03:70-03:73, 03:75-03:77, 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, 11:118, 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, 13:120-13:131, 13:133, 13:135, 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, 03:74, 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,

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				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, 14:119, 14:121
8^{5,7}	100 bp, 175 bp	430 bp	3, 4	*04:01:01-04:107
9⁶	210 bp, 230 bp	430 bp	7, 13, 14	*07:01:01:01-07:01:04, 07:03-07:22, 12:22, 13:17, 13:116, 14:50
10⁶	170 bp, 215 bp, 250 bp	515 bp	8, 11, 12, 14	*08:01:01-08:19, 08:21-08:49, 11:67, 12:04, 12:16, 12:22, 14:11, 14:15, 14:68, 14:93
11^{5,6}	90 bp, 135 bp, 180 bp	430 bp	3, 9, 11	*03:08, 03:65, 09:01:02-09:17, 11:07, 11:53, 11:103, 11:105, 11:107
12	175 bp	430 bp	10	*03:76, 10:01:01-10:04, 11:59, 11:80, 11:83, 11:87, 13:27, 13:41, 13:71, 13:129
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, 11:72-11:121
14^{5,6}	85 bp, 105 bp	430 bp	12	*08:32, 12:01:01-12:35
15^{7,12}	215 bp	430 bp	6, 11, 13, 14, 1403	*03:76, 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, 11:99-11:102:02, 11:106, 11:108-11:121, 13:01:01-13:08, 13:10-13:16, 13:18-13:43, 13:45-13:85, 13:87-13:115, 13:117-13:128, 13:130-13:135, 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, DRB3*02:27
16^{6,7}	195 bp, 225 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,

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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, 11:99-11:102:02, 11:106, 11:108-11:118, 11:120-11:121, 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, 13:116-13:117, 13:121, 13:123-13:132, 13:135, 14:15-14:16, 14:22, 14:24-14:25, 14:27, 14:37, 14:53, 14:73, 14:105				
17¹¹	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, 03:66-03:68N, 03:70-03:77, 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, 13:117-13:121, 13:123-13:135, 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, 14:121
18^{5,6,9,10}	100 bp, 140 bp, 155 bp	430 bp	4, 6, 8,13, 14, 1404	*04:62, 04:69, 04:73, 04:105, 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,

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				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, 14:117-14:120, 14:122, DRB4*01:03:01:02N
19 ^{5,6,9}	110 bp, 135 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, 09:04-09:17, 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, 14:117-14:122, 15:27, 15:34, 15:66
20 ⁵⁻⁷	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, 11:119, 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, 14:110-14:120, 14:122, 15:21 ^w , 16:04 ^w , 16:18 ^w
21 ^{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
22 ^{5,7,10}	215 bp	430 bp	53	DRB4*01:01-01:08
23	175 bp	430 bp	51	DRB5*01:01-01:01:14, DRB5*02:02-02:05
24 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 screening 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.

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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 screening 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.

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 11, 13, 14, 16 and 18 to 21.

⁷Primer mixes 1, 8, 15, 16, 20 and 22 may have tendencies of primer oligomer formation.

⁸Primer mix 6 may give a lower yield of HLA-specific PCR product than the other DR low primer mixes.

⁹Primer 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.

¹⁰The DRB4*01:03:01:02N allele is amplified by the primer pairs in wells 18 and 22, whereas the DRB4*02:01N and DRB4*03:01N null alleles are not amplified by these primer pairs.

¹¹Due 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 21.

¹²Due to sharing of sequence motifs, DRB3*02:27 is amplified by the primer pairs in well 15 in addition to primer mix 21.

¹³Primer mix 24 contains a negative control, which will amplify more than 95% of HLA amplicons as well as amplicons generated by a control primer pair. 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 screening SSP typing												
Amplification patterns of the DRB1*01:01 to DRB1*10:04 alleles												
Well ⁶												
13	14	15	16	17	18	19	20	21	22	23	24	
100	85	215	195	175	100	110	110	160	215	175	Neg. Control	Length of spec. PCR product(s)
170	105		225		140	135	175	240				
					155	170	225					
430	430	430	430	430	430	430	430	430	430	430	Neg. Control	Length of int. pos. control ¹
13 (125)	16 (133)	10 (116)	10 (116)	13 (125)	1 st I (164)	26 (164)	13 (125)	10 (116)	28 (170)	13 (125)		
5'-gTC ³	5'-gTT ³	5'-gCT ³	5'-gCT ³	5'-gTC ³	5'-CAA ³	5'-gTA ³	5'-gTC ³	5'-gCT ³	5'-gAT ³	5'-gTA ³		
16 (133)		12 (122)	12 (122)		37 (197)	34 (189)	34 (189)	10 (116)			Negative Control	5'-primer(s) ²
5'-gTC ³		5'-TAT ³	5'-TAT ³		5'-gTT ³	5'-CAG ³	5'-CAG ³	5'-gCT ³				
38 (200)		13 (125)	13 (125)		37 (197)			38 (199)				
5'-CgT ³		5'-gTC ³	5'-gTC ³		5'-gTA ³			5'-TCC ³			Negative Control	3'-primer(s) ³
			16 (133)									
			5'-gTT ³									
			16 (133)								Negative Control	3'-primer(s) ³
			5'-gTC ³									
58 (260)	30 (175)	70 (295)	67 (286)	58 (260)	42 (213)	57 (257)	57 (257)	51 (239)	87 (346)	57 (258)	Negative Control	3'-primer(s) ³
5'-CCT ³	5'-gTg ³	5'-gTC ³	5'-gAA ³	5'-Cgg ³	5'-TCA ³	5'-CAG ³	5'-CAG ³	5'-CCC ³	5'-CTC ³	5'-gCg ³		
58 (260)	38 (199)	71 (299)	71 (298)	58 (260)	57 (257)	70 (295)	60 (265)	77 (317)	87 (346)	58 (260)		
5'-CCT ³	5'-CAG ³	5'-gCT ³	5'-CgC ³	5'-CAG ³	5'-CAG ³	5'-CTg ³	5'-gTg ³	5'-AAT ³	5'-CTT ³	5'-CCT ³	Negative Control	3'-primer(s) ³
58 (260)			71 (298)		71 (298)	70 (296)	70 (296)					
5'-CCT ³			5'-CTC ³		5'-CgC ³	5'-TCC ³	5'-TCC ³					
							74 (307)				Negative Control	3'-primer(s) ³
							5'-CAG ³					
13	14	15	16	17	18	19	20	21	22	23	24	DR
												Well No.

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Lot-specific information

Well No.	DR	1	2	3	4	5	6	7	8	9	10	11	12
DRB1 allele⁴	ser⁵												
*01:01:01-01:02:08, 01:04-01:38, 01:40N-01:41, 01:43-01:45	1, Null, -	1											
*01:03, 01:39N	103, Null		2										
*01:42	-	1	2										
*03:01:01-01:03:01:19, 03:04:01-03:06, 03:09, 03:11:01-03:16, 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, 03:43-03:45, 03:47-03:48, 03:50-03:52, 03:54-03:63, 03:66-03:68N, 03:70-03:73, 03:75, 03:77	3, 17(3), Null, -					5	6						
*03:02:01-03:03, 03:27, 03:29, 03:38, 03:53, 03:74	18(3), -					5		7					
*03:07, 03:17, 03:21, 03:24, 03:32, 03:35, 03:39-03:41, 03:49	3, -					5							
*03:08, 03:65	-					5	6					11	
*03:10	17(3)					5	6						
*03:42, 03:69	-					5							
*03:46, 03:64	-					5	6						
*03:76	-						6						12
*04:01:01-04:61, 04:63-04:68, 04:70-04:72:02, 04:74-04:104, 04:106-04:107	4, Null, -								8				
*04:62, 04:69, 04:73, 04:105	-								8				
*07:01:01-07:01:04, 07:03-07:22	7, Null, -									9			
*08:01:01-08:02:04, 08:04:01-08:07, 08:11, 08:16-08:17, 08:22, 08:24, 08:26, 08:28, 08:39, 08:42-08:44	8, -										10		
*08:03:02-08:03:03, 08:10, 08:12-08:15, 08:18-08:19, 08:23, 08:25, 08:27, 08:29-08:30:03, 08:33-08:34, 08:36-08:38, 08:45-08:49	8, -										10		
*08:08	-										10		
*08:09, 14:15 ⁷	8										10		
*08:20, 13:18, 13:47, 13:55 ⁸	13(6), -												
Well No.	DR	1	2	3	4	5	6	7	8	9	10	11	12

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13	14	15	16	17	18	19	20	21	22	23	24	DR	Well No.
												ser ⁵	DRB1 allele ⁴
												1, Null, -	*01:01:01-01:02:08, 01:04-01:38, 01:40N-01:41, 01:43-01:45
												103, Null	*01:03, 01:39N
												-	*01:42
				17								3, 17(3), Null, -	*03:01:01-01:03:01:19, 03:04:01-03:06, 03:09, 03:11:01-03:16, 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, 03:43-03:45, 03:47-03:48, 03:50-03:52, 03:54-03:63, 03:66-03:68N, 03:70-03:73, 03:75, 03:77
				17								18(3), -	*03:02:01-03:03, 03:27, 03:29, 03:38, 03:53, 03:74
				17								3, -	*03:07, 03:17, 03:21, 03:24, 03:32, 03:35, 03:39-03:41, 03:49
13												-	*03:08, 03:65
						19	20					17(3)	*03:10
												-	*03:42, 03:69
												-	*03:46, 03:64
		15		17								-	*03:76
												4, Null, -	*04:01:01-04:61, 04:63-04:68, 04:70-04:72:02, 04:74-04:104, 04:106-04:107
					18							-	*04:62, 04:69, 04:73, 04:105
												7, Null, -	*07:01:01-01:07:01:04, 07:03-07:22
			16									8, -	*08:01:01-08:02:04, 08:04:01-08:07, 08:11, 08:16-08:17, 08:22, 08:24, 08:26, 08:28, 08:39, 08:42-08:44
												8, -	*08:03:02-08:03:03, 08:10, 08:12-08:15, 08:18-08:19, 08:23, 08:25, 08:27, 08:29-08:30:03, 08:33-08:34, 08:36-08:38, 08:45-08:49
			16		18							-	*08:08
			16				20					8	*08:09, 14:15 ⁷
		15	16	17			20					13(6), -	*08:20, 13:18, 13:47, 13:55 ⁸
13	14	15	16	17	18	19	20	21	22	23	24	DR	Well No.

Negative Control

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Well No.	DR	1	2	3	4	5	6	7	8	9	10	11	12
*08:21	-										10		
*08:31, 08:41, 11:67 ⁹	11(5), -										10		
*08:32	-										10		
*08:35	-										10		
*08:40	-						6				10		
*09:01:02-09:01:05, 09:01:07-09:02:02, 09:04-09:17	9, -											11	
*09:01:06, 09:03	9, -											11	
*10:01:01-10:04	10, -												12
*11:01:01-11:01:16, 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, 11:27:01-11:30, 11:32-11:33, 11:35, 11:37:01-11:39, 11:43-11:44, 11:46:01-11:47, 11:49:01-11:51, 11:54:01-11:54:02, 11:56, 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, 11:88, 11:90-11:92, 11:94-11:95, 11:97, 11:99-11:102:02, 11:106, 11:108-11:117, 11:120-11:121	11(5), -												
*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, 11:63, 11:65:01-11:65:02, 11:68, 11:70, 11:76, 11:85-11:86, 11:93, 11:118	11(5), 13 (6), -						6						
*11:05	11(5)												
*11:07, 11:53, 11:103, 11:105, 11:107	11(5), -					5						11	
*11:08:01-11:08:02, 11:18-11:19:03, 11:42, 11:57	11(5), -												
*11:13:01-11:13:02	11(5)							w					
*11:17, 11:52	11(5), -												
*11:22, 11:98, 11:104	-												
*11:23, 11:25, 11:96	11(5), -												
*11:26, 11:34	11(5), -							7					
*11:31, 11:45, 11:64, 11:119	-												
*11:55	-												
*11:59, 11:80, 11:83, 11:87	-						6						12
Well No.	DR	1	2	3	4	5	6	7	8	9	10	11	12

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13	14	15	16	17	18	19	20	21	22	23	24	DR	Well No.
		15	16				20					-	*08:21
13			16									11(5), -	*08:31, 08:41, 11:67 ⁹
	14						20					-	*08:32
							20					-	*08:35
												-	*08:40
						19						9, -	*09:01:02-09:01:05, 09:01:07-09:02:02, 09:04-09:17
												9, -	*09:01:06, 09:03
												10, -	*10:01:01-10:04
13		15	16									11(5), -	*11:01:01-11:01:16, 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, 11:27:01-11:30, 11:32-11:33, 11:35, 11:37:01-11:39, 11:43-11:44, 11:46:01-11:47, 11:49:01-11:51, 11:54:01-11:54:02, 11:56, 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, 11:88, 11:90-11:92, 11:94-11:95, 11:97, 11:99-11:102:02, 11:106, 11:108-11:117, 11:120-11:121
13		15	16									11(5), 13 (6), -	*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, 11:63, 11:65:01-11:65:02, 11:68, 11:70, 11:76, 11:85-11:86, 11:93, 11:118
13			16									11(5)	*11:05
13												11(5), -	*11:07, 11:53, 11:103, 11:105, 11:107
13		15										11(5), -	*11:08:01-11:08:02, 11:18-11:19:03, 11:42, 11:57
13						19	20					11(5)	*11:13:01-11:13:02
13						19	20					11(5), -	*11:17, 11:52
13												-	*11:22, 11:98, 11:104
13		15	16				20					11(5), -	*11:23, 11:25, 11:96
13												11(5), -	*11:26, 11:34
13		15					20					-	*11:31, 11:45, 11:64, 11:119
13			16				20					-	*11:55
13		15	16									-	*11:59, 11:80, 11:83, 11:87
13	14	15	16	17	18	19	20	21	22	23	24	DR	Well No.

Negative Control

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Well No.	DR	1	2	3	4	5	6	7	8	9	10	11	12
*11:69, 11:82	-												
*11:73, 11:79	-						6						
*11:89	-												
*12:01:01-12:01:04, 12:03, 12:05-12:12, 12:14, 12:17, 12:24N-12:25, 12:28-12:30, 12:34-12:35	12(5), Null, -												
*12:02:01-12:02:05, 12:13, 12:15, 12:18-12:21, 12:23, 12:26-12:27, 12:31N-12:33	12(5), Null, -												
*12:04	-										10		
*12:16	-										10		
*12:22	-									9	10		
*13:01:01-13:02:01, 13:02:03- 13:02:05, 13:04, 13:08, 13:16, 13:20, 13:22-13:24, 13:28- 13:29, 13:31-13:32, 13:34- 13:36, 13:38-13:40, 13:48, 13:51-13:52, 13:54, 13:59, 13:61:01-13:61:02, 13:63- 13:65, 13:68-13:70, 13:72- 13:76, 13:78-13:80, 13:83- 13:84, 13:87, 13:91-13:93, 13:96:01-13:99, 13:102, 13:105-13:107, 13:109, 13:111-13:114, 13:117, 13:121, 13:123-13:128, 13:130-13:131, 13:135	13(6), 14(6), Null, -						6						
*13:02:02, 13:03:01-13:03:06, 13:10, 13:33:01-13:33:03, 13:37, 13:66:01-13:66:02, 13:81, 13:88-13:90, 13:94- 13:95, 13:101, 13:115, 13:120, 13:133	13(6), -						6						
*13:05:01-13:05:02, 13:07:01- 13:07:02, 13:11:01-13:11:02, 13:14:01-13:14:03, 13:21:01- 13:21:02, 13:42, 13:46, 13:49- 13:50:02, 13:62, 13:100, 13:108, 13:132	13(6), -												
*13:06, 13:12:01-13:12:02, 13:25, 13:30, 13:56, 13:58, 13:60, 13:77, 13:82, 13:110, 13:118, 13:134	13(6), -												
*13:09	-												
Well No.	DR	1	2	3	4	5	6	7	8	9	10	11	12

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13	14	15	16	17	18	19	20	21	22	23	24	DR	Well No.
13			16		18							-	*11:69, 11:82
13		15										-	*11:73, 11:79
13							20					-	*11:89
	14											12(5), Null, -	*12:01:01-12:01:04, 12:03, 12:05-12:12, 12:14, 12:17, 12:24N-12:25, 12:28-12:30, 12:34-12:35
	14		16									12(5), Null, -	*12:02:01-12:02:05, 12:13, 12:15, 12:18-12:21, 12:23, 12:26-12:27, 12:31N-12:33
	14											-	*12:04
	14		16									-	*12:16
	14											-	*12:22
		15	16	17								13(6), 14(6), Null, -	*13:01:01-13:02:01, 13:02:03- 13:02:05, 13:04, 13:08, 13:16, 13:20, 13:22-13:24, 13:28- 13:29, 13:31-13:32, 13:34- 13:36, 13:38-13:40, 13:48, 13:51-13:52, 13:54, 13:59, 13:61:01-13:61:02, 13:63- 13:65, 13:68-13:70, 13:72- 13:76, 13:78-13:80, 13:83- 13:84, 13:87, 13:91-13:93, 13:96:01-13:99, 13:102, 13:105-13:107, 13:109, 13:111-13:114, 13:117, 13:121, 13:123-13:128, 13:130-13:131, 13:135
		15		17								13(6), -	*13:02:02, 13:03:01-13:03:06, 13:10, 13:33:01-13:33:03, 13:37, 13:66:01-13:66:02, 13:81, 13:88-13:90, 13:94- 13:95, 13:101, 13:115, 13:120, 13:133
		15	16	17								13(6), -	*13:05:01-13:05:02, 13:07:01- 13:07:02, 13:11:01-13:11:02, 13:14:01-13:14:03, 13:21:01- 13:21:02, 13:42, 13:46, 13:49- 13:50:02, 13:62, 13:100, 13:108, 13:132
		15		17								13(6), -	*13:06, 13:12:01-13:12:02, 13:25, 13:30, 13:56, 13:58, 13:60, 13:77, 13:82, 13:110, 13:118, 13:134
			16	17								-	*13:09
13	14	15	16	17	18	19	20	21	22	23	24	DR	Well No.

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Well No.	DR	1	2	3	4	5	6	7	8	9	10	11	12
*13:13, 13:119, 14:84, 14:116 ¹⁰	13(6), -												
*13:15, 13:19, 13:53, 13:57, 13:104	13(6), -						6	7					
*13:17, 13:116	13(6), -						6			9			
*13:26	-							7					
*13:27, 13:41, 13:71	13(6), -						6						12
*13:43	-						6						
*13:44, 13:86	-							7					
*13:45	-						6						
*13:67, 13:103	-												
*13:85	-						6	7					
*13:122	-						6						
*13:129	-						6						12
*14:01:01-14:01:02, 14:04, 14:07:01-14:07:02, 14:10, 14:26, 14:28, 14:31, 14:35, 14:38-14:39, 14:54-14:55, 14:57, 14:60-14:62, 14:70- 14:71, 14:75-14:76, 14:79, 14:86-14:88, 14:90, 14:99, 14:101, 14:104, 14:107, 14:110-14:114, 14:117- 14:118, 14:120, 14:122	14(6), 1404, -												
*14:01:03, 14:08, 14:23:02, 14:34, 14:72, 14:92N, 14:97	14(6), Null, -												
*14:02, 14:06:01-14:06:02, 14:09, 14:13, 14:17, 14:20, 14:29-14:30, 14:33, 14:41, 14:47-14:48, 14:51, 14:80, 14:83, 14:94, 14:106, 14:108, 14:121	14(6), 6, -							7					
*14:03:01-14:03:02, 14:12:01- 14:12:02, 14:40, 14:63, 14:67, 14:77-14:78, 14:85, 14:102, 14:115	1403, 14(6), -							7					
*14:05:01-14:05:03, 14:14, 14:23:01, 14:23:03, 14:36, 14:43-14:45, 14:56, 14:59, 14:64, 14:91, 14:96, 14:100, 14:103	14(6), -												
*14:11	14(6)									10			
*14:16	6						6						
*14:18, 14:81	6, -							7					
*14:19, 14:21, 14:109	14(6), -						6	7					
Well No.	DR	1	2	3	4	5	6	7	8	9	10	11	12

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13	14	15	16	17	18	19	20	21	22	23	24	DR	Well No.
		15		17			20					13(6), -	*13:13, 13:119, 14:84, 14:116 ¹⁰
		15	16	17								13(6), -	*13:15, 13:19, 13:53, 13:57, 13:104
			16									13(6), -	*13:17, 13:116
		15	16	17								-	*13:26
		15	16	17								13(6), -	*13:27, 13:41, 13:71
		15	16			19	20					-	*13:43
				17								-	*13:44, 13:86
		15	16		18		20					-	*13:45
		15	16									-	*13:67, 13:103
		15		17								-	*13:85
		15										-	*13:122
			16	17								-	*13:129
												Negative Control	*14:01:01-14:01:02, 14:04, 14:07:01-14:07:02, 14:10, 14:26, 14:28, 14:31, 14:35, 14:38-14:39, 14:54-14:55, 14:57, 14:60-14:62, 14:70- 14:71, 14:75-14:76, 14:79, 14:86-14:88, 14:90, 14:99, 14:101, 14:104, 14:107, 14:110-14:114, 14:117- 14:118, 14:120, 14:122
					18	19	20						14(6), 1404, -
						19	20						*14:01:03, 14:08, 14:23:02, 14:34, 14:72, 14:92N, 14:97
				17		19							*14:02, 14:06:01-14:06:02, 14:09, 14:13, 14:17, 14:20, 14:29-14:30, 14:33, 14:41, 14:47-14:48, 14:51, 14:80, 14:83, 14:94, 14:106, 14:108, 14:121
		15		17			20						*14:03:01-14:03:02, 14:12:01- 14:12:02, 14:40, 14:63, 14:67, 14:77-14:78, 14:85, 14:102, 14:115
				17		19	20						*14:05:01-14:05:03, 14:14, 14:23:01, 14:23:03, 14:36, 14:43-14:45, 14:56, 14:59, 14:64, 14:91, 14:96, 14:100, 14:103
						19	20						14(6)
		15	16		18	19	20						6
				17		19	20						6, -
		15		17		w							14(6), -
13	14	15	16	17	18	19	20	21	22	23	24	DR	Well No.

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*14:22, 14:105	14(6), -												
*14:24	-							7					
*14:25, 14:53	13(6), -												
*14:27	14(6)							7					
*14:32:01-14:32:02	-							w					
*14:37	-												
*14:42	-												
*14:46, 14:52	-												
*14:49, 14:119	14(6), -							7					
*14:50	14(6)									9			
*14:58	-												
*14:65	-							w					
*14:68, 14:93	-									10			
*14:69	-												
*14:73	-												
*14:74	-												
*14:82	-						6						
*14:89	-							7					
*14:95	-						6						
*14:98	-							7					
*15:01:01:01-15:20, 15:22-15:24, 15:26, 15:28-15:33, 15:35-15:65, 15:67-15:69	15(2), 2, Null, -			3									
*15:21	-			3									
*15:25	-			3		5							
*15:27, 15:34, 15:66	-			3									
*16:01:01-16:03, 16:05:01-16:05:02, 16:07-16:17, 16:19	16(2), 2, Null, -				4								
*16:04, 16:18	16(2), -				4								
DRB3*01:01:02:01-01:15, DRB3*02:01-02:26, DRB3*02:28, DRB3*03:01:01-03:03	52, -												
DRB3*02:27	-												
DRB4*01:01-01:03:01:01, DRB4*01:03:01:03-01:08	53, -												
DRB4*01:03:01:02N	Null												
DRB5*01:01:01-01:14, DRB5*02:02-02:05	51, Null, -												
Well No.	ser ⁵	1	2	3	4	5	6	7	8	9	10	11	12

101.103.48/12 – including *Taq* pol., IFU-01 Rev. No. 03
 101.103.48u/12u – without *Taq* pol., IFU-02 Rev. No. 03

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Lot No.: **67N**

Lot-specific information

13	14	15	16	17	18	19	20	21	22	23	24	DR	Well No.
		15	16		18	19	20					14(6), -	*14:22, 14:105
			16	17								-	*14:24
		15	16		18		20					13(6), -	*14:25, 14:53
		15	16	17			20					14(6)	*14:27
					18	19	20					-	*14:32:01-14:32:02
			16	17	18							-	*14:37
				17			20					-	*14:42
						19						-	*14:46, 14:52
					18	19	20					14(6), -	*14:49, 14:119
					18	19	20					14(6)	*14:50
					18		20					-	*14:58
				17		19	20					-	*14:65
					18	19	20					-	*14:68, 14:93
		15			18		20					-	*14:69
			16		18	19	20					-	*14:73
		15			18	19	20					-	*14:74
					18	19	20					-	*14:82
				17			20					-	*14:89
				17		19	20					-	*14:95
		15		17								-	*14:98
												15(2),	*15:01:01:01-15:20, 15:22-
												2, Null,	15:24, 15:26, 15:28-15:33,
							w					-	15:35-15:65, 15:67-15:69
												-	*15:21
												-	*15:25
						19						-	*15:27, 15:34, 15:66
												16(2),	*16:01:01-16:03, 16:05:01-
												2, Null,	16:05:02, 16:07-16:17, 16:19
							w					-	
												16(2), -	*16:04, 16:18
								21				52, -	DRB3*01:01:02:01-01:15,
													DRB3*02:01-02:26,
													DRB3*02:28,
													DRB3*03:01:01-03:03
		15						21				-	DRB3*02:27
									22			53, -	DRB4*01:01-01:03:01:01,
										22			DRB4*01:03:01:03-01:08
					18							Null	DRB4*01:03:01:02N
											23	51,	DRB5*01:01:01-01:14,
												Null, -	DRB5*02:02-02:05
13	14	15	16	17	18	19	20	21	22	23	24	ser ⁵	Well No.

Negative Control

101.103.48/12 – including **Taq pol.**, IFU-01 Rev. No. 03
101.103.48u/12u – without **Taq pol.**, IFU-02 Rev. No. 03

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Lot No.: 67N**Lot-specific information**

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

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

³The codon, and in parenthesis the nucleotide, in the 2nd exon, matching the specificity-determining 3'-end of the primer is given in the anti-sense direction. Codon and nucleotide numbering as on the www.ebi.ac.uk/imgt/hla web site. The sequence of the 3 terminal nucleotides of the primer is given.

⁴The 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.

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 21.

⁵The 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, the information available at the www.worldmarrow.org web site and the expert-assigned serological grouping in Tissue Antigens (2009) 73:95-170.

⁶Primer mix 24 contains a negative control, which will amplify more than 95% of HLA amplicons as well as an amplicon generated by a positive control primer pair. HLA-specific PCR product sizes range from 75 to 200 base pairs. The PCR product generated by the positive control primer pair is 430 base pairs.

⁷The DRB1*08:09 and the DRB1*14:15 alleles yield identical amplification patterns with the DR low resolution screening primer set. These alleles can be separated by the respective high resolution primer sets.

⁸The DRB1*08:20 and the DRB1*13:18, 13:47 and 13:55 alleles yield identical amplification patterns with the DR low resolution screening primer set. These alleles can be separated by the respective high resolution primer sets.

⁹The DRB1*08:31, 08:41 and DRB1*11:67 alleles yield identical amplification patterns with the DR low resolution screening primer set. These alleles can be separated by the respective high resolution primer sets.

¹⁰The DRB1*13:13 and 13:119 and the DRB1*14:84 and 14:116 alleles yield identical amplification patterns with the DR low resolution screening primer set. These alleles can be separated by the respective high resolution primer sets.

'ser', serological HLA specificity.

'w', may be weakly amplified.

101.103.48/12 – including **Taq** pol., IFU-01 Rev. No. 03
 101.103.48u/12u – without **Taq** pol., IFU-02 Rev. No. 03

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Lot No.: **67N**

Lot-specific information

CELL LINE VALIDATION SHEET																					
DR low resolution primer set																					
					Well																
						1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
				Prod. No.:		201297201	201297202	201297203	201297204	201297205	201297206	201297207	201297208	201297209	201297210	201297211	201297212	201297213	201297214	201297215	201297216
	IHCW cell line		DRB1																		
1	9001	SA	*01:01		+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2	9280	LK707	*15:02	*04:05	-	-	+	-	-	-	-	-	+	-	-	-	-	-	-	-	-
3	9011	E4181324	*15:02		-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4	9275	GU373	*03:01		-	-	-	-	+	+	-	-	-	-	-	-	-	-	-	-	-
5	9009	KAS011	*16:01		-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-
6	9353	SM	*04:07	*08:03	-	-	-	-	-	-	-	-	+	-	+	-	-	-	-	-	-
7	9020	QBL	*03:01		-	-	-	-	+	+	-	-	-	-	-	-	-	-	-	-	-
8	9025	DEJ	*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		-	-	-	-	-	-	+	-	-	-	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		-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

101.103.48/12 – including *Taq* pol., IFU-01 Rev. No. 03
 101.103.48u/12u – without *Taq* pol., IFU-02 Rev. No. 03

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Lot No.: **67N**

Lot-specific information

CELL LINE VALIDATION SHEET												
DR low resolution primer set												
					Prod. No.:	Well ¹						
						17	18	19	20	21	22	23
						201297217	201200618	201200619	201297220	201297229	201297230	201297231
	IHCW cell line		DRB1									
1	9001	SA	*01:01		-	-	-	-	-	-	-	-
2	9280	LK707	*15:02	*04:05	-	-	-	-	-	+	+	+
3	9011	E4181324	*15:02		-	-	-	-	-	-	-	+
4	9275	GU373	*03:01		+	-	-	-	+	-	-	-
5	9009	KAS011	*16:01		-	-	-	-	-	-	-	+
6	9353	SM	*04:07	*08:03	-	-	-	-	-	+	-	-
7	9020	QBL	*03:01		+	-	-	-	+	-	-	-
8	9025	DEU	*04:01		-	-	-	-	-	+	-	-
9	9026	YAR	*04:02		-	-	-	-	-	+	-	-
10	9107	LKT3	*04:05		-	-	-	-	-	+	-	-
11	9051	PITOUT	*07:01		-	-	-	-	-	+	-	-
12	9052	DBB	*07:01		-	-	-	-	-	+	-	-
13	9004	JESTHOM	*01:01		-	-	-	-	-	-	-	-
14	9071	OLGA	*08:02		-	-	-	-	-	-	-	-
15	9075	DKB	*09:01		-	-	+	-	-	+	-	-
16	9037	SWEIG007	*11:01		-	-	-	-	+	-	-	-
17	9282	CTM3953540	*03:01	*13:01	+	-	-	-	+	-	-	-
18	9257	32367	*09:01	*11:01	-	-	+	-	+	+	-	-
19	9038	BM16	*12:01		-	-	-	-	+	-	-	-
20	9059	SLE005	*13:02		+	-	-	-	+	-	-	-
21	9064	AMALA	*14:02		+	-	+	-	+	-	-	-
22	9056	KOSE	*13:02	*14:54	+	+	+	+	+	-	-	-
23	9124	IHL	*08:03	*14:14	+	-	+	+	+	-	-	-
24	9035	JBUSH	*11:01		-	-	-	-	+	-	-	-
25	9049	IBW9	*07:01		-	-	-	-	-	+	-	-
26	9285	WT49	*03:01		+	-	-	-	+	-	-	-
27	9191	CH1007	*04:05	*10:01	-	-	-	-	-	+	-	-
28	9320	BEL5GB	*04:16	*07:01	-	-	-	-	-	+	-	-
29	9050	MOU	*07:01		-	-	-	-	-	+	-	-
30	9021	RSH	*03:02		+	-	-	-	+	-	-	-
31	9019	DUCAF	*03:01		+	-	-	-	+	-	-	-
32	9297	HAG	*13:03		+	-	-	-	-	+	-	-
33	9098	MT14B	*04:04		-	-	-	-	-	+	-	-
34	9104	DHIF	*11:01		-	-	-	-	+	-	-	-
35	9302	SSTO	*04:03		-	-	-	-	-	+	-	-
36	9024	KT17	*04:03	*04:06	-	-	-	-	-	+	-	-
37	9065	HHKB	*13:01		+	-	-	-	+	-	-	-
38	9099	LZL	*14:02		+	-	+	-	+	-	-	-
39	9315	CML	*03:01	*04:01	+	-	-	-	+	+	-	-
40	9134	WHONP199	*07:01	*09:01	-	-	+	-	-	+	-	-
41	9055	H0301	*13:02		+	-	-	-	+	-	-	-
42	9066	TAB089	*08:03		-	-	-	-	-	-	-	-
43	9076	T7526	*09:01		-	-	+	-	-	+	-	-
44	9057	TEM	*14:01		-	+	+	+	+	-	-	-
45	9239	SHJO	*07:01		-	-	-	-	-	+	-	-
46	9013	SCHU	*15:01		-	-	-	-	-	-	-	+
47	9045	TUBO	*11:04	*12:01	-	-	-	-	+	-	-	-
48	9303	TER-ND	*01:03		-	-	-	-	-	-	-	-

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

101.103.48/12 – including *Taq* pol., IFU-01 Rev. No. 03
101.103.48u/12u – without *Taq* pol., IFU-02 Rev. No. 03

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Lot No.: **67N**

Lot-specific information

CERTIFICATE OF ANALYSIS

Product number: 101.103-48/12 – including *Taq* pol.
101.103-48u/12u – without *Taq* pol.
Lot number: 67N
Expiry date: 2014-October-01
Number of tests: 48 tests – Product No. 101.401-48/48u
12 tests – Product No. 101.401-12/12u
Number of wells per test: 23 + 1

Well specifications:

Well No.	Production No.	Well No.	Production No.
1	2012-972-01	13	2012-972-13
2	2012-972-02	14	2012-972-14
3	2012-972-03	15	2012-972-15
4	2012-972-04	16	2012-972-16
5	2012-972-05	17	2012-972-17
6	2012-972-06	18	2012-006-18
7	2012-972-07	19	2012-006-19
8	2012-972-08	20	2012-972-20
9	2012-972-09	21	2012-972-29
10	2012-972-10	22	2012-972-30
11	2012-972-11	23	2012-972-31
12	2012-972-12		

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

One or more additional 3'-primers in primer solution 1, 3, 4, 9, 10, 11, 18 and 20 were tested by separately adding additional 5'-primers.

One 5'-primer in primer solutions 6, 9, 11, 12, 15, 16 and 18 was tested by separately adding additional 3'-primers.

In primer solutions 1, 3, 4, 13 and 22 one or more 3'-primers were not possible to test, and in primer solutions 1, 3, 4, 8, 9, 10, 13, 15 and 16 one or more 5'-primers were not possible to test.

The negative control primer pairs, **Production No. 2012-002-01**, can detect contamination with PCR products diluted 10^{-7} .

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

Date of approval: 2012-April-25

Approved by:

Production Quality Control

101.103.48/12 – including **Taq** pol., IFU-01 Rev. No. 03
101.103.48u/12u – without **Taq** pol., IFU-02 Rev. No. 03

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Lot No.: **67N**

Lot-specific information

Declaration of Conformity

Product name: Olerup SSP® DR low resolution screening
Product number: 101.103-48/48u, -12/12u
Lot number: 67N

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-April-25

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs

101.103.48/12 – including *Taq* pol., IFU-01 Rev. No. 03
101.103.48u/12u – without *Taq* pol., IFU-02 Rev. No. 03

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

Lot No.: **67N**

Lot-specific information

101.103.48/12 – including **Taq** pol., IFU-01 Rev. No. 03
101.103.48u/12u – without **Taq** pol., IFU-02 Rev. No. 03

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“Instructions for Use” (IFU)

Lot No.: **67N**

Lot-specific information

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