

101.704-48/12 – including *Taq* pol., IFU-01 Rev. No. 03
101.704-48u/12u – without *Taq* pol., IFU-02 Rev. No. 03

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“Instructions for Use” (IFU)

Lot No.: **34N**

Lot-specific information

Olerup SSP® DQ-DR SSP Combi Tray

Product number:	101.704-48/12 – including <i>Taq</i> pol. 101.704-48u/12u – without <i>Taq</i> pol.
Lot number:	34N
Expiry date:	2014-September-01
Number of tests:	48 tests – Product No. 101.704-48/48u 12 tests – Product No. 101.704-12/12u
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. 34N.

CHANGES COMPARED TO THE PREVIOUS OLERUP SSP® DQ-DR SSP COMBI TRAY LOT (11M)

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

The DQ low resolution specificity and interpretation tables have been updated for the HLA-DQB1 alleles described since the previous *Olerup SSP®* DQ-DR Combi Tray lot was made (**Lot No. 11M**).

The DQ low primer set is unchanged compared to the previous lot.

The DR low resolution specificity and interpretation tables have been updated for the HLA-DRB1 alleles described since the previous *Olerup SSP®* DQ-DR Combi Tray lot was made (**Lot No. 11M**).

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

Well	5'-primer	3'-primer	rationale
17	Added	-	Primer added for the DRB1*07:22 allele.
20	Added	Exchanged	Improved allelic resolution of DRB1*03 and DRB1*13 alleles.
23	-	Modified	Improved allelic resolution.

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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 an amplicon generated by a control primer pair.

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'-Tg g ^{3'}	5'-Tg g ^{3'}	5'-Tg g ^{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

DQ-DR SSP Combi Tray

CONTENT

The primer set contains 5'- and 3'-primers for grouping the DQB1 alleles in to the serological groups DQ2 to DQ9.

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.

Please note that DQB1 amplifications usually are somewhat less pronounced than e.g. DRB and DQA1 amplifications even when using the same DNA preparation and exactly the same experimental procedures.

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 8 – DQ low resolution primers.

Wells 9 to 31 – DR low resolution primers.

Well 32 – Negative Control.

The 32 well cut PCR plate is marked with 'DQ-DR'.

Well No. 1 is marked with the Lot No. '34N' in silver/gray ink.

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 the DQB1 alleles will be amplified by the 8 wells of the DQ low resolution primer set, **wells 1 to 8**. Thus, the interpretation of DQ low resolution typings is not influenced the DQB2 and DQB3 genes.

Only HLA-DRB alleles will be amplified by the 23 wells of the DR low resolution primer set, **wells 9 to 31**. Thus, the interpretation of DR low resolution typings is not influenced by other HLA class II genes.

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UNIQUELY IDENTIFIED ALLELES

All the DQB1 alleles, i.e. **DQB1*05:01 to 05:14, DQB1*06:01 to 06:47, DQB1*02:01 to 02:06, DQB1*03:01 to 03:39 and DQB1*04:01 to 04:08**, recognized by the HLA Nomenclature Committee in January 2012¹ will be amplified by the primers in the DQ low resolution SSP primer set, **wells 1 to 8**. The DQB1 alleles will be grouped into their corresponding serological specificities², i.e.:

DQ5(1) =	DQB1*05:01:01-05:05
DQ6(1) =	DQB1*06:01:01-06:44
DQ2 =	DQB1*02:01:01-02:05
DQ3 =	DQB1*03:06, 03:10, 03:14
DQ7(3) =	DQB1*03:01:01-03:01:06, 03:04, 03:09, 03:13, 03:16, 03:19
DQ8(3) =	DQB1*03:02:01-03:02:05, 03:05:01-03:05:04, 03:07-03:08, 03:11, 03:18
DQ9(3) =	DQB1*03:03:02:01-03:03:04, 03:12, 03:15, 03:17, 03:20
DQ4 =	DQB1*04:01-04:02

¹DQB1 alleles listed on the IMGT/HLA web page 2012-January-12, release 3.7.0, www.ebi.ac.uk/imgt/hla.

²The serological split of the DQB1*05:05 to 05:14 alleles, the DQB1*06:06 to 06:07, 06:10, 06:13, 06:15-06:24 and 06:27 to 06:47 alleles, the DQB1*02:04-02:06 alleles, the DQB1*03:07-03:09 and 03:11- 03:39 alleles and the DQB1:04:0301-04:08 alleles is not known. In this table we have used the expert-assigned serological grouping in Tissue Antigens (2009) 73:95-170, and also inferred the serological grouping from the naming of the sequence-defined allele.

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 and 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 SSP kit. The HLA-DRB alleles will be grouped into their corresponding serological specificities^{3,4}.

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 2012-January-12, release 3.7.0, www.ebi.ac.uk/imgt/hla.

³The serological split of all DRB1 alleles is not known. In this table we use the expert-assigned serological grouping in Tissue Antigens (2009) 73:95-170 and the serological grouping of the sequence-defined allele.

⁴The DRB1*08:09 and the DRB1*14:15 alleles yield identical amplification patterns with the DR low resolution primer set. These alleles can be separated by the respective high resolution primer sets.

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

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SPECIFICITY TABLE

DQ low resolution primer set

Specificities and sizes of the PCR products of the 8 primer mixes of the DQ low resolution primer set

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	DQ serology ³	Amplified DQB1 alleles ⁴
1	225 bp	515 bp	5	*05:01:01:01-05:14
2	220 bp, 270 bp	430 bp	1, 5, 6, null	*06:01:01-06:44, 06:47
3	210 bp	430 bp	2	*02:01:01-02:06
4	220 bp	515 bp	3, 7	*03:01:01:01-03:01:06, 03:04, 03:09-03:10, 03:13-03:14, 03:16, 03:19, 03:21-03:22, 03:24, 03:27-03:29, 03:35-03:36
5⁶	130 bp	515 bp	6, 8	*03:02:01-03:02:05, 03:05:01-03:05:04, 03:07-03:08, 03:11, 03:18, 03:32, 03:37, 06:29
6^{6,7}	135 bp	515 bp	2, 3, 4, 9	*02:03, 03:03:02:01-03:03:04, 03:06, 03:12, 03:15, 03:20, 03:25-03:26, 03:30-03:31, 03:33-03:34, 03:38-03:39, 04:03:01-04:03:02
7^{5,6}	145 bp, 185 bp	515 bp	3, 7, 8, 9	*03:01:01:01-03:39
8⁶	210 bp, 245 bp	430 bp	4	*04:01:01-04:08

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 DQ 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.

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

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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 DQ low resolution typing.

In addition, wells number 4, 5, 6 and 7 contain the primer pair giving rise to the longer, 515 bp, internal positive control band in order to allow kit identification.

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

³The serological reactivity of all DQ alleles is not known. In this table we use the expert-assigned serological grouping in Tissue Antigens (2009) 73:95-170 and the serological grouping of the sequence-defined allele. The DQB1*03:10 allele has been assigned type DQ7 by NMDP.

⁴For several DQB1 alleles only partial second exon nucleotide sequences are available. In these instances it is not known whether some of the primers of the SSP sets are completely matched with the target sequences or not. We assume that unknown sequences in the 5'- and 3'-ends of the second exon of the DQB1 gene are conserved within allelic groups.

⁵Primer mix 7 may give rise to nonspecific amplifications.

⁶Primer mixes 5, 6, 7 and 8 may yield somewhat less intense HLA-specific PCR fragments than the other DQ low resolution primer mixes.

⁷Primer mix 6 may have tendencies of primer oligomer formation.

‘w’, may be weakly amplified.

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SPECIFICITY TABLE

DR low resolution primer set

Specificities and sizes of the PCR products of the 23+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 alleles ⁴
9^{6,8}	200 bp, 255 bp	515 bp	1	*01:01:01-01:02:08, 01:04-01:38, 01:40N-01:45
10	200 bp	430 bp	103	*01:03, 01:39N, 01:42
11⁶	200 bp, 215 bp	430 bp	2, 15	*15:01:01:01-15:69
12	210 bp	430 bp	16	*16:01:01-16:05:02, 16:07-16:19
13^{5,6,7}	120 bp, 220 bp	430 bp	3, 17, 18, 11	*03:01:01:01-03:75, 03:77, 11:07, 11:53, 11:103, 11:105, 11:107, 15:25
14^{5,6,7}	80 bp, 210 bp	430 bp	3, 6, 17, 11, 13, 14	*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
15^{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, 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,

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				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
16^{5,6,8}	100 bp, 175 bp	430 bp	4	*04:01:01-04:107
17⁶	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
18⁶	170 bp, 215 bp, 250 bp	515 bp	8, 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
19^{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
20	175 bp	430 bp	10, 11, 13	*03:76, 10:01:01-10:04, 11:59, 11:80, 11:83, 11:87, 13:27, 13:41, 13:71, 13:129
21^{5,6}	100 bp, 170 bp	430 bp	3, 8, 11, 14	*03:08, 03:65, 08:31, 08:41, 11:01:01-11:70, 11:72-11:121
22^{5,6}	85 bp, 105 bp	430 bp	12	*08:32, 12:01:01-12:35
23⁸	215 bp	430 bp	6, 8, 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
24^{6,8}	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,

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				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
25⁷	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
26^{5,6}	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, 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

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27^{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
28^{5,6,8}	110 bp, 175 bp, 225 bp	430 bp	2, 3, 4, 6, 8, 11,13, 14, 1403, 1404, 16	*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
29^{5,6,7}	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^{8,10}	215 bp	430 bp	53	DRB4*01:01:01:01-01:08
31	175 bp	430 bp	51	DRB5*01:01:01:01-01:14, DRB5*02:02-02:05
32¹¹	-	-		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 11, 26, 27 and 28.

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.

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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 9 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 18 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 split of all DRB1 alleles is not known. In this table we use the expert-assigned serological grouping in Tissue Antigens (2009) 73:95-170 and the serological grouping of the sequence-defined allele.

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.

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

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

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

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 mixes 9, 11, 13 to 19, 21, 22, 24 and 26 to 29.

⁷Due to sharing of sequence motifs in codon 38, DRB3*01:14 will also be amplified in primer mixes 13, 14 and 25 in addition to primer mix 29.

⁸Primer mixes 9, 16, 23, 24, 28 and 30 may give rise to primer oligomer formation.

⁹Primer mix 27 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 primer mix 30, whereas the DRB4*02:01N and DRB4*03:01N null alleles are not amplified by this primer pair.

¹¹Primer 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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Lot No.: **34N**

Lot-specific information

INTERPRETATION TABLE

DQ low resolution SSP typing

Amplification patterns of the DQB1*05:01 to DQB1*04:08 alleles

		Well							
		1	2	3	4	5	6	7	8
Length of spec.		225	220	210	220	130	135	145	210
PCR product(s)			270					185	245
Length of int.		515	430	430	515	515	515	515	430
pos. control ¹									
5'-primer(s) ²		26 (173)	9 (122)	30 (185)	26 (173)	28 (179)	26 (173)	38 (210)	9 (122)
		5' -ggg 3'	5' -gTT 3'	5' -AAg 3'	5' -TTA 3'	5' -gAC 3'	5' -TCT 3'	5' -gCA 3'	5' -gTT 3'
			26 (173)			28 (179)		48 (240)	21 (159)
			5' -TTA 3'			5' -gAC 3'		5' -CgC 3'	5' -ACC 3'
			26 (173)					55 (260)	
			5' -TCT 3'					5' -gCC 3'	
								55 (260)	
								5' -gCA 3'	
3'-primer(s) ³		87 (356)	86 (353)	86 (353)	86 (353)	57 (266)	57 (266)	86 (353)	77 (327)
		5' -ggT 3'	5' -ACg 3'	5' -gCT 3'	5' -gCT 3'	5' -Cgg 3'	5' -CgT 3'	5' -gCT 3'	5' -ACg 3'
			86 (353)						
			5' -ACC 3'						
Well No.		1	2	3	4	5	6	7	8
DQB1 allele ⁴	ser. ⁵								
*05:01:01:01-05:14	5, –	1							
*06:01:01-06:28, 06:30-06:44, 06:47	1, 5, 6, Null, –		2						
*06:29	6		2			5			
*02:01:01-02:02, 02:04-02:06	2, –			3					
*02:03	2			3			6		
Well No.		1	2	3	4	5	6	7	8

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Lot-specific information

Well No.		1	2	3	4	5	6	7	8
DQB1 allele⁴	ser.⁵								
*03:01:01:03:01:06, 03:04, 03:09-03:10, 03:13-03:14, 03:16, 03:19, 03:21-03:22, 03:24, 03:27- 03:29, 03:35-03:36	3, 7, –				4			7	
*03:02:01-03:02:05, 03:05:01- 03:05:04, 03:07-03:08, 03:11, 03:18, 03:32, 03:37	8, –					5		7	
*03:03:02:01-03:03:04, 03:06, 03:12, 03:15, 03:20, 03:25-03:26, 03:30-03:31, 03:33-03:34, 03:38- 03:39	3, 9, –						6	7	
*03:17, 03:23	9, –							7	
*04:01:01-04:02:02, 04:04-04:08	4, –								8
*04:03:01-04:03:02	–						6		8
DQB1 allele⁴	ser.⁵								
Well No.		1	2	3	4	5	6	7	8

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 DQ low resolution typing.

In addition, wells number 4, 5, 6 and 7 contain the primer pair giving rise to the longer, 515 bp, internal positive control band in order to allow kit identification.

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

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

⁴The sequence of the DQB1*030301 allele has been shown to be identical to DQB1*03:03:02.

⁵The serological reactivity of all DQ alleles is not known. In this table we use the expert-assigned serological grouping in Tissue Antigens (2009) 73:95-170 and the serological grouping of the sequence-defined allele. The DQB1*03:10 allele has been assigned type DQ7 by NMDP.

‘w’, may be weakly amplified.

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Lot No.: **34N**

Lot-specific information

INTERPRETATION TABLE													
DR low resolution SSP typing													
Amplification patterns of the DRB1*01:01 to DRB1*10:04 alleles													
		Well ⁶											
		9	10	11	12	13	14	15	16	17	18	19	20
Length of spec.		205	200	200	210	120	80	85	100	210	170	90	175
PCR product(s)		255		215		220	210	210	175	235	215	135	
											250	180	
Length of int.		515	430	430	430	430	430	430	430	430	515	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'	14 (127) 5'-ATA 3'	16 (133) 5'-gTT 3'	26 (165) 5'-TAT 3'	26 (164) 5'-gTA 3'
		14 (129) 5'-gAA 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'	14 (127) 5'-ATA 3'	16 (133) 5'-gTT 3'	58 (261) 5'-gAg 3'	31 (178) 5'-gCg 3'
									13 (125) 5'-ATA 3'	14 (127) 5'-gTA 3'			
									13 (125) 5'-gTC 3'	16 (133) 5'-gTT 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'	71 (298) 5'-CTC 3'	58 (260) 5'-CCT 3'	57 (257) 5'-CgA 3'	74 (307) 5'-CgC 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'	73 (305) 5'-ggC 3'	74 (307) 5'-CAg 3'	73 (305) 5'-ggC 3'	
		67 (286) 5'-gAT 3'		70 (295) 5'-Tg 3'	70 (297) 5'-CTg 3'	74 (308) 5'-CCC 3'				77 (317) 5'-AAT 3'	86 (344) 5'-CAC 3'	78 (319) 5'-CAC 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.	DR	9	10	11	12	13	14	15	16	17	18	19	20
DRB1 allele ⁴	ser ⁵												
*01:01:01-01:02:08, 01:04-01:38, 01:40N- 01:41, 01:43-01:45	DR1, Null, –	9											
*01:03, 01:39N	DR103, DR1, Null		10										
*01:42	–	9	10										
Well No.	DR	9	10	11	12	13	14	15	16	17	18	19	20

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Lot-specific information

INTERPRETATION TABLE													
DR low resolution SSP typing													
Amplification patterns of the DRB1*01:01 to DRB1*10:04 alleles													
Well ⁶											Negative control		
21	22	23	24	25	26	27	28	29	30	31			
100	85	215	195	175	100	110	110	160	215	175			
170	105		225		140	135	175	240					
					155	170	225						
430	430	430	430	430	430	430	430	430	430	430			
13 (125)	16 (133)	10 (116)	10 (116)	13 (125)	1 st I -CAA	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'-gTA 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)					
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'					
			16 (133)										
			5'-gTT 3'										
			16 (133)										
			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		
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'			
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)						
							5'-CAG 3'						
21	22	23	24	25	26	27	28	29	30	31	Negative control		
21	22	23	24	25	26	27	28	29	30	31	32	DR	Well No.
												ser ⁵	DRB1 allele ⁴
												DR1, Null, –	*01:01:01-01:02:08, 01:04-01:38, 01:40N- 01:41, 01:43-01:45
												DR103, DR1, Null	*01:03, 01:39N
												–	*01:42
21	22	23	24	25	26	27	28	29	30	31	32	DR	Well No.

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Lot No.: **34N**

Lot-specific information

Well No.	DR	9	10	11	12	13	14	15	16	17	18	19	20
DRB1 allele ⁴	ser ⁵												
*03:01:01:03:01:19, 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	DR17, DR3, Null, –					13	14						
*03:02:01:03:03, 03:27, 03:29, 03:38, 03:53, 03:74	DR18, DR3, –					13		15					
*03:07, 03:17, 03:21, 03:24, 03:32, 03:35, 03:39-03:41, 03:49	DR3, –					13							
*03:08, 03:65	DR3, –					13	14					19	
*03:10	DR3					13	14						
*03:42, 03:69	–					13							
*03:46, 03:64	–					13	14						
*03:76	–						14						20
*04:01:01:04:61, 04:63- 04:68, 04:70-04:72:02, 04:74-04:104, 04:106- 04:107	DR4, DR3, Null, –								16				
*04:62, 04:69, 04:73, 04:105	DR4, –								16				
*07:01:01:07:01:04, 07:03-07:22	DR7, Null, –									17			
*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	DR8, –										18		
*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	DR8, –										18		
*08:08	DR8										18		
*08:09, 14:15 ⁷	DR8										18		
*08:20, 13:18, 13:47, 13:55 ⁸	DR13, –												
*08:21	DR8										18		
Well No.	DR	9	10	11	12	13	14	15	16	17	18	19	20

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Lot No.: **34N**

Lot-specific information

21	22	23	24	25	26	27	28	29	30	31	32	DR	Well No.
												ser ⁵	DRB1 allele ⁴
				25								DR17, DR3, Null, –	*03:01:01-03:01:19, 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
				25								DR18, DR3, –	*03:02:01-03:03, 03:27, 03:29, 03:38, 03:53, 03:74
				25								DR3, –	*03:07, 03:17, 03:21, 03:24, 03:32, 03:35, 03:39-03:41, 03:49
21												DR3, –	*03:08, 03:65
						27	28					DR3	*03:10
												–	*03:42, 03:69
												–	*03:46, 03:64
		23		25								–	*03:76
												DR4, DR3, Null, –	*04:01:01-04:61, 04:63- 04:68, 04:70-04:72:02, 04:74-04:104, 04:106- 04:107
					26							DR4, –	*04:62, 04:69, 04:73, 04:105
												DR7, Null, –	*07:01:01-07:01:04, 07:03-07:22
			24									DR8, –	*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
												DR8, –	*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
			24		26							DR8	*08:08
			24				28					DR8	*08:09, 14:15 ⁷
		23	24	25			28					DR13, –	*08:20, 13:18, 13:47, 13:55 ⁸
		23	24				28					DR8	*08:21
21	22	23	24	25	26	27	28	29	30	31	32	DR	Well No.

Negative control

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Lot No.: **34N**

Lot-specific information

Well No.	DR	9	10	11	12	13	14	15	16	17	18	19	20
DRB1 allele ⁴	ser ⁵												
*08:31, 08:41, 11:67 ⁹	DR8, DR11, –										18		
*08:32	–										18		
*08:35	–										18		
*08:40	–						14				18		
*09:01:02-09:01:05, 09:01:07-09:02:02, 09:04-09:17	DR9, –											19	
*09:01:06, 09:03	DR9											19	
*10:01:01-10:04	DR10, –												20
*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	DR11, –												
*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	DR11, DR13, –						14						
*11:05	DR11												
*11:07, 11:53, 11:103, 11:105, 11:107	DR11, –					13						19	
*11:08:01-11:08:02, 11:18-11:19:03, 11:42, 11:57	DR11, –												
*11:13:01-11:13:02	DR11							w					
Well No.	DR	9	10	11	12	13	14	15	16	17	18	19	20

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Lot-specific information

21	22	23	24	25	26	27	28	29	30	31	32	DR	Well No.
												ser ⁵	DRB1 allele ⁴
21			24									DR8, DR11, –	*08:31, 08:41, 11:67 ⁹
	22						28					–	*08:32
							28					–	*08:35
												–	*08:40
						27						DR9, –	*09:01:02-09:01:05, 09:01:07-09:02:02, 09:04-09:17
												DR9	*09:01:06, 09:03
												DR10, –	*10:01:01-10:04
21		23	24									DR11, –	*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
21		23	24									DR11, DR13, –	*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
21			24									DR11	*11:05
21												DR11, –	*11:07, 11:53, 11:103, 11:105, 11:107
21		23										DR11, –	*11:08:01-11:08:02, 11:18-11:19:03, 11:42, 11:57
21						27	28					DR11	*11:13:01-11:13:02
21	22	23	24	25	26	27	28	29	30	31	32	DR	Well No.

Negative control

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Lot No.: **34N**

Lot-specific information

Well No.	DR	9	10	11	12	13	14	15	16	17	18	19	20
DRB1 allele ⁴	ser ⁵												
*11:17, 11:52	DR14, DR11												
*11:22, 11:98, 11:104	–												
*11:23, 11:25, 11:96	DR11, –												
*11:26, 11:34	DR11							15					
*11:31, 11:45, 11:64, 11:119	DR11, –												
*11:55	DR11												
*11:59, 11:80, 11:83, 11:87	DR11, –						14						20
*11:69, 11:82	–												
*11:73, 11:79	–						14						
*11:89	–												
*12:01:01-12:01:04, 12:03:02, 12:05-12:12, 12:14, 12:17, 12:24N- 12:25, 12:28-12:30, 12:34-12:35	DR12, 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	DR12, Null, –												
*12:04	DR12										18		
*12:16	–										18		
*12:22	–									17	18		
*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	DR13, DR11, DR14, Null, –						14						
Well No.	DR	9	10	11	12	13	14	15	16	17	18	19	20

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Lot-specific information

21	22	23	24	25	26	27	28	29	30	31	32	DR	Well No.
												ser ⁵	DRB1 allele ⁴
21						27	28					DR14, DR11	*11:17, 11:52
21												–	*11:22, 11:98, 11:104
21		23	24				28					DR11, –	*11:23, 11:25, 11:96
21												DR11	*11:26, 11:34
21		23					28					DR11, –	*11:31, 11:45, 11:64, 11:119
21			24				28					DR11	*11:55
21		23	24									DR11, –	*11:59, 11:80, 11:83, 11:87
21			24		26							–	*11:69, 11:82
21		23										–	*11:73, 11:79
21							28					–	*11:89
	22											DR12, Null, –	*12:01:01-12:01:04, 12:03:02, 12:05-12:12, 12:14, 12:17, 12:24N- 12:25, 12:28-12:30, 12:34-12:35
	22		24									DR12, 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
	22											DR12	*12:04
	22		24									–	*12:16
	22											–	*12:22
		23	24	25								DR13, DR11, DR14, 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
21	22	23	24	25	26	27	28	29	30	31	32	DR	Well No.

Negative control

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 101. 704-48u/12u – without *Taq* pol., IFU-02 Rev. No. 03

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Lot No.: **34N**

Lot-specific information

Well No.	DR	9	10	11	12	13	14	15	16	17	18	19	20
DRB1 allele ⁴	ser ⁵												
*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	DR13, –						14						
*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	DR13, DR11, DR6, –												
*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	DR13, DR11, DR6, –												
*13:09	DR13												
*13:13, 13:119, 14:84, 14:116 ¹⁰	DR13, –												
*13:15, 13:19, 13:53, 13:57, 13:104	DR13, –						14	15					
*13:17, 13:116	DR13, –						14			17			
*13:26	DR14							15					
*13:27, 13:41, 13:71	DR13						14						20
*13:43	DR13						14						
*13:44, 13:86	–							15					
*13:45	DR13						14						
*13:67, 13:103	DR13, –												
*13:85	–						14	15					
*13:122	–						14						
*13:129	–						14						20
Well No.	DR	9	10	11	12	13	14	15	16	17	18	19	20

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Lot No.: **34N**

Lot-specific information

21	22	23	24	25	26	27	28	29	30	31	32	DR	Well No.
												ser ⁵	DRB1 allele ⁴
		23		25								DR13, –	*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
		23	24	25								DR13, DR11, DR6, –	*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
		23		25								DR13, DR11, DR6, –	*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
			24	25								DR13	*13:09
		23		25			28					DR13, –	*13:13, 13:119, 14:84, 14:116 ¹⁰
		23	24	25								DR13, –	*13:15, 13:19, 13:53, 13:57, 13:104
			24									DR13, –	*13:17, 13:116
		23	24	25								DR14	*13:26
		23	24	25								DR13	*13:27, 13:41, 13:71
		23	24			27	28					DR13	*13:43
				25								–	*13:44, 13:86
		23	24		26		28					DR13	*13:45
		23	24									DR13, –	*13:67, 13:103
		23		25								–	*13:85
		23										–	*13:122
			24	25								–	*13:129
21	22	23	24	25	26	27	28	29	30	31	32	DR	Well No.

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Lot No.: **34N**

Lot-specific information

Well No.	DR	9	10	11	12	13	14	15	16	17	18	19	20
DRB1 allele ⁴	ser ⁵												
*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	DR14, DR 1404, DR4, DR6, –												
*14:01:03, 14:08, 14:23:02, 14:34, 14:72, 14:92N, 14:97	DR14, 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	DR14, DR6, –							15					
*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	DR 1403, DR14, DR6, –							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, 14:64, 14:91, 14:96, 14:100, 14:103	DR14, –												
*14:11	DR14										18		
*14:16	DR6						14						
*14:18, 14:81	DR14, –							15					
*14:19, 14:21, 14:109	DR14, –						14	15					
*14:22, 14:105	DR14, –												
*14:24	DR14							15					
*14:25, 14:53	DR6, DR13, 14												
*14:27	DR14							15					
*14:32:01-14:32:02	DR14							w					
*14:37	DR14												
*14:42	–												
Well No.	DR	9	10	11	12	13	14	15	16	17	18	19	20

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Lot-specific information

21	22	23	24	25	26	27	28	29	30	31	32	DR	Well No.
												ser ⁵	DRB1 allele ⁴
					26	27	28					DR14, DR 1404, DR4, DR6, –	*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
						27	28					DR14, Null, –	*14:01:03, 14:08, 14:23:02, 14:34, 14:72, 14:92N, 14:97
				25		27						DR14, DR6, –	*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
		23		25			28					DR 1403, DR14, DR6, –	*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
				25		27	28					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, 14:64, 14:91, 14:96, 14:100, 14:103
						27	28					DR14	*14:11
		23	24		26	27	28					DR6	*14:16
				25		27	28					DR14, –	*14:18, 14:81
		23		25		w						DR14, –	*14:19, 14:21, 14:109
		23	24		26	27	28					DR14, –	*14:22, 14:105
			24	25								DR14	*14:24
		23	24		26		28					DR6, DR13, 14	*14:25, 14:53
		23	24	25			28					DR14	*14:27
					26	27	28					DR14	*14:32:01-14:32:02
			24	25	26							DR14	*14:37
				25			28					–	*14:42
21	22	23	24	25	26	27	28	29	30	31	32	DR	Well No.

Negative control

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Lot-specific information

Well No.	DR	9	10	11	12	13	14	15	16	17	18	19	20
DRB1 allele ⁴	ser ⁵												
*14:46, 14:52	DR14												
*14:49, 14:119	DR14, –							15					
*14:50	DR14									17			
*14:58	DR14												
*14:65	DR6							w					
*14:68, 14:93	DR14, –										18		
*14:69	–												
*14:73	–												
*14:74	–												
*14:82	–						14						
*14:89	–							15					
*14:95	–						14						
*14:98	–							15					
*15:01:01:01-15:20, 15:22-15:24, 15:26, 15:28-15:33, 15:35- 15:65, 15:67-15:69	DR15, DR2, Null, –			11									
*15:21	DR2			11									
*15:25	–			11		13							
*15:27, 15:34, 15:66	–			11									
*16:01:01-16:03, 16:05:01-16:05:02, 16:07-16:17, 16:19	DR16, Null, –				12								
*16:04, 16:18	DR16, –				12								
DRB3*01:01:02:01- 01:15, DRB3*02:01- 02:26, DRB3*02:28, DRB3*03:01:01-03:03	DR52, –												
DRB3*02:27	–												
DRB4*01:01:01:01- 01:03:01:01, 01:03:01:03-01:08	DR53, –												
DRB4*01:03:01:02N	Null												
DRB5*01:01:01-01:14, DRB5*02:02:02-05	DR51, Null, –												
DRB1 allele ⁴	ser ⁵												
Well No.	DR	9	10	11	12	13	14	15	16	17	18	19	20

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Lot-specific information

21	22	23	24	25	26	27	28	29	30	31	32	DR	Well No.
												ser ⁵	DRB1 allele ⁴
						27						DR14	*14:46, 14:52
					26	27	28					DR14, –	*14:49, 14:119
					26	27	28					DR14	*14:50
					26		28					DR14	*14:58
				25		27	28					DR6	*14:65
					26	27	28					DR14, –	*14:68, 14:93
		23			26		28					–	*14:69
			24		26	27	28					–	*14:73
		23			26	27	28					–	*14:74
					26	27	28					–	*14:82
				25			28					–	*14:89
				25		27	28					–	*14:95
		23		25								–	*14:98
												DR15, DR2, Null, –	*15:01:01:01-15:20, 15:22-15:24, 15:26, 15:28-15:33, 15:35- 15:65, 15:67-15:69
							w					DR2	*15:21
												–	*15:25
						27						–	*15:27, 15:34, 15:66
												DR16, Null, –	*16:01:01-16:03, 16:05:01-16:05:02, 16:07-16:17, 16:19
							w					DR16, –	*16:04, 16:18
								29				DR52, –	DRB3*01:01:02:01- 01:15, DRB3*02:01- 02:26, DRB3*02:28, DRB3*03:01:01-03:03
		23						29				–	DRB3*02:27
									30			DR53, –	DRB4*01:01:01:01- 01:03:01:01, 01:03:01:03-01:08
					26				30			Null	DRB4*01:03:01:02N
										31		DR51, Null, –	DRB5*01:01:01-01:14, DRB5*02:02-02:05
21	22	23	24	25	26	27	28	29	30	31	32	ser ⁵	DRB1 allele ⁴
												DR	Well No.

Negative control

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Lot No.: 34N**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 9 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 18 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 renamed 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 13, 14 and 25 in addition to primer mix 29.

⁵The serological reactivity of all DRB alleles is not known. In this table we use the expert-assigned serological grouping in Tissue Antigens (2009) 73:95-170 and the serological grouping of the sequence-defined allele.

⁶Primer 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.

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

‘ser’, serological HLA specificity.

‘w’, may be weakly amplified.

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Lot No.: **34N**

Lot-specific information

CELL LINE VALIDATION SHEET													
DQ low resolution primer set													
					Well								
						1	2	3	4	5	6	7	8
				Production No.		201194801	201194802	201194803	201194804	201194805	201194806	201194807	201194808
	IHWC cell line		DQB1										
1	9001	SA	*05:01			+	-	-	-	-	-	-	-
2	9280	LK707	*06:01	*02:02		-	+	+	-	-	-	-	-
3	9011	E4181324	*06:01			-	+	-	-	-	-	-	-
4	9275	GU373	*02:01			-	-	+	-	-	-	-	-
5	9009	KAS011	*05:02			+	-	-	-	-	-	-	-
6	9353	SM	*03:02	*06:01		-	+	-	-	+	-	+	-
7	9020	QBL	*02:01			-	-	+	-	-	-	-	-
8	9025	DEU	*03:01			-	-	-	+	-	-	+	-
9	9026	YAR	*03:02			-	-	-	-	+	-	+	-
10	9107	LKT3	*04:01			-	-	-	-	-	-	-	+
11	9051	PITOUT	*02:02			-	-	+	-	-	-	-	-
12	9052	DBB	*03:03			-	-	-	-	-	+	+	-
13	9004	JESTHOM	*05:01			+	-	-	-	-	-	-	-
14	9071	OLGA	*04:02			-	-	-	-	-	-	-	+
15	9075	DKB	*03:03			-	-	-	-	-	+	+	-
16	9037	SWEIG007	*03:01			-	-	-	+	-	-	+	-
17	9282	CTM 3953540	*02:01	*06:03		-	+	+	-	-	-	-	-
18	9257	32367	*06:02	*02:02		-	+	+	-	-	-	-	-
19	9038	BM16	*03:01			-	-	-	+	-	-	+	-
20	9059	SLE005	*06:04			-	+	-	-	-	-	-	-
21	9064	AMALA	*03:01			-	-	-	+	-	-	+	-
22	9056	KOSE	*05:03	*06:04		+	+	-	-	-	-	-	-
23	9124	IHL	*05:03	*06:01		+	+	-	-	-	-	-	-
24	9035	JBUSH	*03:01			-	-	-	+	-	-	+	-
25	9049	IBW9	*02:02			-	-	+	-	-	-	-	-
26	9285	WT49	*02:01			-	-	+	-	-	-	-	-
27	9191	CH1007	*04:01	*05:01		+	-	-	-	-	-	-	+
28	9320	BEL5GB	*02:02	*03:01		-	-	+	+	-	-	+	-
29	9050	MOU	*02:02			-	-	+	-	-	-	-	-
30	9021	RSH	*04:02			-	-	-	-	-	-	-	+
31	9019	DUCAF	*02:01			-	-	+	-	-	-	-	-
32	9297	HAG	*03:01			-	-	-	+	-	-	+	-
33	9098	MT14B	*03:02			-	-	-	-	+	-	+	-
34	9104	DHIF	*03:01			-	-	-	+	-	-	+	-
35	9302	SSTO	*03:05			-	-	-	-	+	-	+	-
36	9024	KT17	*03:02			-	-	-	-	+	-	+	-
37	9065	HHKB	*06:03			-	+	-	-	-	-	-	-
38	9099	LZL	*03:01			-	-	-	+	-	-	+	-
39	9315	CML	*02:01	*03:01		-	-	+	+	-	-	+	-
40	9134	WHONP199	*02:02	*03:03		-	-	+	-	-	+	+	-
41	9055	H0301	*06:09			-	+	-	-	-	-	-	-
42	9066	TAB089	*06:01			-	+	-	-	-	-	-	-
43	9076	T7526	*03:03			-	-	-	-	-	+	+	-
44	9057	TEM	*05:03			+	-	-	-	-	-	-	-
45	9239	SHJO	*02:02			-	-	+	-	-	-	-	-
46	9013	SCHU	*06:02			-	+	-	-	-	-	-	-
47	9045	TUBO	*03:01			-	-	-	+	+	-	+	-
48	9303	TER-ND	*05:01			+	-	-	-	-	-	-	-

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Lot-specific information

[illegible]

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Lot No.: **34N**

Lot-specific information

CELL LINE VALIDATION SHEET												
DR low resolution primer set												
					Well							
					25	26	27	28	29	30	31	
					201297217	201297218	201297219	201297220	201297221	201297222	201297223	
				Prod. No.:								
	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		-	-	-	-	-	-	-	

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Lot No.: **34N**

Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP® DQ-DR SSP Combi Tray

Product number: 101.704-48/12 – including *Taq* pol.
 101.704-48u/12u – without *Taq* pol.
Lot number: 34N
Expiry date: 2014-September-01
Number of tests: 48 tests – Product No. 101.704-48/48u
 12 tests – Product No. 101.704-12/12u
Number of wells per test: 31 + 1

Well specifications:

Well No.	Production No.
1	2011-948-01
2	2011-948-02
3	2011-948-03
4	2011-948-04
5	2011-948-05
6	2011-948-06
7	2011-948-07
8	2011-948-08

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
9	2012-972-01	17	2012-972-09	25	2012-972-17
10	2012-972-02	18	2012-972-10	26	2012-972-18
11	2012-972-03	19	2012-972-11	27	2012-972-19
12	2012-972-04	20	2012-972-12	28	2012-972-20
13	2012-972-05	21	2012-972-13	29	2012-972-21
14	2012-972-06	22	2012-972-14	30	2012-972-22
15	2012-972-07	23	2012-972-15	31	2012-972-23
16	2012-972-08	24	2012-972-16		

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

One 5'-primer and one or more 3'-primers in primer solution 17, 19 and 26 were tested by separately adding additional 5'-primers or 3'-primers.

One or more additional 3'-primers in primer solution 9, 11, 12, 18 and 28 were tested by separately adding another 5'-primer.

One 5'-primer in primer solutions 2, 8, 14, 20, 23 and 24 was tested by separately adding additional 3'-primers.

In primer solutions 9, 11, 12, 21 and 30 one or more 3'-primers were not possible to test, and in primer solutions 9, 11, 12, 16 to 18, 21, 23 and 24 one or more 5'-primers were not possible to test.

The negative control primer pairs, **Production No. 2011-928-01**, can detect contamination with PCR products diluted 10^{-7} .

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Lot No.: **34N**

Lot-specific information

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

Date of approval: 2012-April-05

Approved by:

Production Quality Control

101.704-48/12 – including *Taq* pol., IFU-01 Rev. No. 03
101. 704-48u/12u – without *Taq* pol., IFU-02 Rev. No. 03

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Lot No.: **34N**

Lot-specific information

Declaration of Conformity

Product name: *Olerup* SSP® DQ-DR SSP Combi Tray
Product number: 101.704-48/48u, -12/12u
Lot number: 34N

Intended use: DQB1 and 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-05

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs

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Lot No.: **34N**

Lot-specific information

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