

101.214-24/06 – including *Taq* polymerase, IFU-01
 101.214-24u/06u – without *Taq* polymerase, IFU-02

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

Lot No.: **16N**

Lot-specific information
Olerup SSP[®] DQB1*03

Product number:	101.214-24/06 – including <i>Taq</i> pol. 101.214-24u/06u – without <i>Taq</i> pol.
Lot number:	16N
Expiry date:	2014-August-01
Number of tests:	24 test – Product No. 101.214-24/24u 6 tests – Product No. 101.214-06/06u
Number of wells per test:	31
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. 16N.

**CHANGES COMPARED TO THE PREVIOUS OLERUP SSP[®]
 DQB1*03 LOT**

The DQB1*03 specificity and interpretation tables have been updated for the HLA-DQB1 alleles described since the previous *Olerup SSP[®]* DQB1*03 lot was made (Lot No. 56K).

Seven wells have been added to the DQB1*03 kit, wells **25 to 31**.

The Lot-specific information for DQB1*03 including and without *Taq* polymerase is now described in one common Product Insert.

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

Well	5'-primer	3'-primer	rationale
14	Added	-	Improved yield of specific PCR product.
25	New	New	New primer pairs for the DQB1*03:29 and 03:34 alleles.
26	New	New	New primer pair for the DQB1*03:30 allele.
27	New	New	New primer pairs for the DQB1*03:31 and 03:32 alleles.
28	New	New	New primer pairs for the DQB1*03:37 and 03:38 alleles.

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29	New	New	New primer pairs for the DQB1*03:33 and 03:35 alleles.
30	New	New	New primer pair for the DQB1*03:36 allele.
31	New	New	New primer pair for the DQB1*03:28 allele.

Change in revision R01 compared to R00:

1. Primer mix 19 may give a lower yield of specific PCR product than the other DQB1*03 primer mixes.

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PRODUCT DESCRIPTION

DQB1*03 SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for identifying the DQB1*03:01 to DQB1*03:38 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 31 PCR reactions in a 32 well PCR plate. Well 32 is empty.

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	empty

The 32 well cut PCR plate is marked with ‘DQB1*03’ in silver/gray ink.

Well No. 1 is marked with the Lot No. ‘16N’.

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

The interpretation of DQB1*03 SSP subtypings will be influenced by the DQB1*02, the DQB1*04 and by many DQB1*06 alleles, when present on the other haplotype. The interpretation of DQB1*03 subtypings is not influenced by the DQB2 and DQB3 genes.

UNIQUELY IDENTIFIED ALLELES

All the DQB1*03 alleles, i.e. **DQB1*03:01 to DQB1*03:38**, recognized by the HLA Nomenclature Committee in October 2011¹ will give rise to unique amplification patterns by the primers in the DQB1*03 subtyping kit.

The DQB1*03 subtyping kit cannot distinguish the following silent mutations: the DQB1*03:01:01:01-03:01:02 and 03:01:04-03:01:06, DQB1*03:02:01 to DQB1*03:02:05, DQB1*03:03:02:01-03:03:04 and the DQB1*03:05:01 to DQB1*03:05:04 alleles.

¹HLA-DQB1 alleles listed on the IMGT/HLA web page 2011-October-10, release 3.6.0, www.ebi.ac.uk/imgt/hla.

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RESOLUTION IN HOMO- AND HETEROZYGOTES

A total of 57 alleles generate 39 amplification patterns that can be combined in 780 homozygous and heterozygous combinations. 142 of these genotypes do not give rise to unique amplification patterns. The different lengths of the specific PCR products were not considered in these calculations.

++++-----	-+-+-++	-----	-----	*03:01:01:01, *03:11 = *03:09, *03:11
+++-+---	-----+	-----	-----	*03:01:01:01, *03:20 = *03:01:03, *03:20
+++-+---	-----+	-----	-----	*03:01:01:01, *03:06 = *03:01:03, *03:06
+++-+---	-----+	-----	-----	*03:01:01:01, *03:15 = *03:01:03, *03:15
+++-+---	-----+	-----	-----	*03:01:01:01, *03:26 = *03:01:03, *03:26 = *03:09, *03:26
++-+-----	-----+	-----	-----	*03:01:01:01, *03:12 = *03:01:03, *03:12
++-+-----	-----+	-----	-----	*03:01:01:01, *03:30 = *03:01:03, *03:30
++-+-----	-----+	-----	-----	*03:01:01:01, *03:31 = *03:01:03, *03:31
++-+-----	-----+	-----	-----	*03:01:01:01, *03:38 = *03:01:03, *03:38
++-+-----	-----+	-----	-----	*03:01:01:01, *03:03:02:01 = *03:01:03, *03:03:02:01
++-+-----	-----+	-----	-----	*03:01:01:01, *03:23 = *03:01:03, *03:23
++-+-----	-----+	-----	-----	*03:01:01:01, *03:34 = *03:01:03, *03:34 = *03:29, *03:34
++-+-----	-----+	-----	-----	*03:01:01:01, *03:33 = *03:01:03, *03:33
++-+-----	-----+	-----	-----	*03:01:01:01, *03:14 = *03:04, *03:10
++-+-----	-----+	-----	-----	*03:01:03, *03:14 = *03:04, *03:14
++-+-----	-----+	-----	-----	*03:01:03, *03:04 = *03:04, *03:04
++-+-----	-----+	-----	-----	*03:01:01:01, *03:17 = *03:01:03, *03:17
++-+-----	-----+	-----	-----	*03:01:01:01, *03:16 = *03:01:03, *03:16
++-+-----	-----+	-----	-----	*03:01:01:01, *03:09 = *03:01:03, *03:09 = *03:09, *03:09
++-+-----	-----+	-----	-----	*03:01:01:01, *03:10 = *03:01:03, *03:10
++-+-----	-----+	-----	-----	*03:01:01:01, *03:13 = *03:01:03, *03:13
++-+-----	-----+	-----	-----	*03:01:01:01, *03:19 = *03:01:03, *03:19
++-+-----	-----+	-----	-----	*03:01:01:01, *03:21 = *03:01:03, *03:21 = *03:21, *03:21
++-+-----	-----+	-----	-----	*03:01:01:01, *03:22 = *03:01:03, *03:22 = *03:22, *03:22
++-+-----	-----+	-----	-----	*03:01:01:01, *03:24 = *03:01:03, *03:24 = *03:24, *03:24
++-+-----	-----+	-----	-----	*03:01:01:01, *03:27 = *03:01:03, *03:27 = *03:27, *03:27
++-+-----	-----+	-----	-----	*03:01:01:01, *03:29 = *03:01:03, *03:29 = *03:29, *03:29
++-+-----	-----+	-----	-----	*03:01:01:01, *03:35 = *03:01:03, *03:35 = *03:35, *03:35
++-+-----	-----+	-----	-----	*03:01:01:01, *03:36 = *03:01:03, *03:36 = *03:36, *03:36
++-+-----	-----+	-----	-----	*03:01:01:01, *03:28 = *03:01:03, *03:28 = *03:28, *03:28
++-+-----	-----+	-----	-----	*03:01:01:01, *03:01:01:01 = *03:01:01:01, *03:01:03
--+--+---	-----+	-----	-----	*03:07, *03:17 = *03:07, *03:20
--+--+---	-----+	-----	-----	*03:08, *03:17 = *03:08, *03:20
--+--+---	-----+	-----	-----	*03:11, *03:17 = *03:11, *03:20
--+--+---	-----+	-----	-----	*03:17, *03:18 = *03:18, *03:20
--+--+---	-----+	-----	-----	*03:02:01, *03:17 = *03:02:01, *03:20
--+--+---	-----+	-----	-----	*03:17, *03:32 = *03:20, *03:32

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--++-+--	-----++	-+-----	----+---	*03:17, *03:37 = *03:20, *03:37
--++-----	-+-----++	-+-----	-----	*03:07, *03:26 = *03:11, *03:15
--++-----	-----++	-+-----	-----	*03:02:01, *03:15 = *03:03:02:01, *03:07
--++-----	-----++	-+-----	----+---	*03:07, *03:31 = *03:15, *03:32
--++-----	-+-----++	-+-----	-----	*03:02:01, *03:26 = *03:03:02:01, *03:11
--++-----	-+-----++	-+-----	----+---	*03:11, *03:31 = *03:26, *03:32
--++-----	-----++	-+-----	----+---	*03:31, *03:37 = *03:32, *03:38
--++-----	-----++	-+-----	----+---	*03:02:01, *03:31 = *03:03:02:01, *03:32 = *03:31, *03:32
--++-----	-----++	-+-----	----+---	*03:02:01, *03:38 = *03:03:02:01, *03:37
--++-----	-----+-	-+-----	----+---	*03:02:01, *03:32 = *03:32, *03:32
--+-+--+	-----++	-+-----	-----	*03:17, *03:25 = *03:20, *03:25
--+-+--+	-----++	-+-----	-----	*03:06, *03:17 = *03:06, *03:20
--+-+--+	-----++	-+-----	-----	*03:15, *03:17 = *03:15, *03:20
--+-+--	-+-----++	-+-----	-----	*03:17, *03:26 = *03:20, *03:26
--+-+--	--++-----	-+-----	-----	*03:12, *03:17 = *03:12, *03:20
--+-+--	-----++	-+-----	-----	*03:03:02:01, *03:05:01 = *03:03:02:01, *03:17 = *03:03:02:01, *03:20 = *03:05:01, *03:20
--+-+--	-----++	-+-----	----+---	*03:17, *03:30 = *03:20, *03:30
--+-+--	-----++	-+-----	----+---	*03:17, *03:31 = *03:20, *03:31
--+-+--	-----++	-+-----	----+---	*03:17, *03:38 = *03:20, *03:38
--+-+--	-----++	-+-----	-----	*03:17, *03:23 = *03:20, *03:23
--+-+--	-----++	-+-----	+-----	*03:17, *03:34 = *03:20, *03:34
--+-+--	-----++	-+-----	----+---	*03:17, *03:33 = *03:20, *03:33
--+-+--	-----++	-+-----	-----	*03:17, *03:20 = *03:20, *03:20
--+-+--	-----++	-+-----	-----	*03:03:02:01, *03:06 = *03:03:02:01, *03:25
--+-+--	-----++	-+-----	----+---	*03:03:02:01, *03:30 = *03:30, *03:30
--+-+--	-----++	-+-----	----+---	*03:03:02:01, *03:31 = *03:31, *03:31
--+-+--	-----++	-+-----	----+---	*03:03:02:01, *03:38 = *03:38, *03:38

*03:01:01 = *03:01:01:01-03:01:02, 03:01:04-03:01:06
 *03:02:01 = *03:02:01-03:02:05
 *03:03:02 = *03:03:02:01-03:03:04
 *03:05:01 = *03:05:01-03:05:04



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SPECIFICITY TABLE

DQB1*03 SSP subtyping

Specificities and sizes of the PCR products of the 31 primer mixes used for
 DQB1*03 SSP subtyping

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified DQB1*03 alleles ³	Other amplified DQB1 alleles ⁴
1	165 bp	515 bp	*03:01:01:01-03:01:06, 03:04, 03:09, 03:13, 03:16, 03:19, 03:21-03:22, 03:24, 03:27-03:29, 03:35-03:36	
2	220 bp	515 bp	*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	
3	135 bp	515 bp	*03:02:01-03:02:05, 03:07-03:08, 03:11, 03:18, 03:32, 03:37	*02:01:01-02:02, 02:04-02:06, 06:29
4	220 bp	515 bp	*03:02:01-03:03:04, 03:06-03:08, 03:11-03:12, 03:15, 03:18, 03:20, 03:23, 03:25-03:26, 03:30-03:34, 03:37-03:38	*02:01:01-02:06, 04:03:01-04:03:02
5	135 bp	430 bp	*03:04, 03:14	
6^{5,9}	95 bp, 130 bp	430 bp	*03:05:01-03:05:04, 03:17, 03:20	
7⁵	115 bp	430 bp	*03:06, 03:25	
8^{5,10}	110 bp, 140 bp	430 bp	*03:07, 03:15-03:16	
9	135 bp	430 bp	*03:08	*06:02:02, 06:03:02
10¹¹	135 bp, 260 bp	430 bp	*03:09, 03:11, 03:26	
11⁷	135 bp	430 bp	*03:10, 03:12, 03:14	*06:01:01-06:01:06, 06:43
12	260 bp	515 bp	*03:01:01:01-03:01:06, 03:04, 03:09-03:10, 03:12-03:14, 03:16, 03:19, 03:21-03:22, 03:24, 03:27-03:29, 03:35-03:36	
13	165 bp	430 bp	*03:13	

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14^{5,7}	130 bp	515 bp	*03:01:01:01-03:01:06, 03:04, 03:09-03:10, 03:13-03:14, 03:19, 03:21-03:22, 03:24, 03:27-03:29, 03:35-03:36	
15	135 bp	515 bp	*03:01:01:01-03:15, 03:17- 03:22, 03:24, 03:26-03:38	
16^{5,7}	130 bp	430 bp	*03:01:01:01-03:01:02, 03:01:04-03:01:06, 03:03:02:01-03:03:04, 03:06, 03:09-03:10, 03:12-03:13, 03:15-03:17, 03:19-03:24, 03:26-03:31, 03:33-03:36, 03:38	*02:03
17	220 bp	430 bp	*03:18	
18	175 bp	515 bp	*03:02:01-03:03:04, 03:05:01- 03:05:04, 03:06 [?] -03:08 [?] , 03:11 [?] -03:18 [?] , 03:19, 03:20 [?] , 03:23 [?] , 03:25, 03:26 [?] , 03:30- 03:32, 03:33 [?] -03:34 [?] , 03:37 [?] , 03:38	*04:01:01-04:08
19⁸	175 bp	515 bp	*03:01:01:01-03:01:06, 03:04, 03:06 [?] -03:08 [?] , 03:09-03:10, 03:11 [?] -03:18 [?] , 03:20 [?] , 03:21- 03:22, 03:23 [?] , 03:24, 03:26 [?] , 03:27-03:29, 03:33 [?] -03:34 [?] , 03:35-03:36, 03:37 [?]	
20	150 bp	430 bp	*03:21	
21	160 bp	515 bp	*03:22	
22	160 bp	515 bp	*03:23	*06:03:01-06:03:02, 06:04:02, 06:07:01, 06:08:01, 06:11:01- 06:11:02, 06:26N, 06:28, 06:30-06:32, 06:40-06:41, 06:44
23^{5,6}	130 bp	430 bp	*03:24	
24	210 bp	430 bp	*03:27	
25¹²	170 bp, 240 bp	430 bp	*03:29, 03:34	
26	180 bp	430 bp	*03:30	*06:29
27^{8,13}	175 bp, 250 bp	430 bp	*03:31-03:32	
28	200 bp	430 bp	*03:37-03:38	

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29 ^{5,6,14}	110 bp, 165 bp	515 bp	*03:33, 03:35
30	135 bp	430 bp	*03:36
31	195 bp	430 bp	*03:28

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 DQB1*03 SSP typings.

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 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 DQB1*03 subtyping.

In addition, wells number 2 to 4, 12, 14, 15, 18, 19, 21, 22 and 29 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.

³For several DQB1 alleles only 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 of DQB1 alleles are conserved within allelic groups.

⁴Due to the sharing of sequence motifs, non-DQB1*03 alleles will be amplified by primer mixes 3, 4, 9, 11, 16, 18, 22 and 26.

⁵Short specific PCR fragments have a lower intensity and are less sharp as longer specific bands.

⁶Primer mixes 23 and 29 may give rise to primer oligomer formation.

⁷Primer mixes 11, 14 and 16 may give rise to nonspecific amplifications.

⁸Primer mixes 19 and 27 may give a lower yield of specific PCR product than the other DQB1*03 primer mixes.

⁹Primer mix 6: Specific PCR fragment of 95 bp in the DQB1*03:20 allele. Specific PCR fragment of 130 bp in the DQB1*03:05:01-03:05:04 and 03:17 alleles.

¹⁰Primer mix 8: Specific PCR fragment of 110 bp in the DQB1*03:15 allele. Specific PCR fragment of 140 bp in the DQB1*03:07 and 03:16 alleles.

¹¹Primer mix 10: Specific PCR fragment of 135 bp in the DQB1*03:09 allele. Specific PCR fragment of 260 bp in the DQB1*03:11 and 03:26 alleles.

¹²Primer mix 25: Specific PCR fragment of 170 bp in the DQB1*03:29 allele. Specific PCR fragment of 240 bp in the DQB1*03:34 allele.

¹³Primer mix 27: Specific PCR fragment of 175 bp in the DQB1*03:32 allele. Specific PCR fragment of 250 bp in the DQB1*03:31 allele.

¹⁴Primer mix 29: Specific PCR fragment of 110 bp in the DQB1*03:33 allele. Specific PCR fragment of 165 bp in the DQB1*03:35 allele.

‘?’, nucleotide sequence information not available for the primer matching region.

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INTERPRETATION TABLE																
DQB1*03 SSP subtyping																
Amplification patterns of the DQB1*03:01 to DQB1*03:38 alleles																
	Well ⁵															
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Length of spec. PCR product(s)	165	220	135	220	135	95	115	110	135	135	135	260	165	130	135	130
Length of int. pos. control ¹	515	515	515	515	430	430	430	430	430	430	430	515	430	515	515	430
5'-primer(s) ²	45(230)	26(173)	26(173)	26(173)	26(173)	26(173)	38(210)	49(242)	38(210)	14(136)	13(134)	13(134)	26(173)	26(173)	55(260)	57(266)
	5'-ggA ^{3'}	5'-TTA ^{3'}	5'-TCT ^{3'}	5'-TCT ^{3'}	5'-TTA ^{3'}	5'-ggg ^{3'}	5'-gCA ^{3'}	5'-ggT ^{3'}	5'-gCA ^{3'}	5'-gCC ^{3'}	5'-ggC ^{3'}	5'-ggC ^{3'}	5'-TTA ^{3'}	5'-TTA ^{3'}	5'-gCC ^{3'}	5'-TgA ^{3'}
						38(208)		55(260)		135(500)						
						5'-ACA ^{3'}		5'-gCA ^{3'}		5'-TgA ^{3'}						
								63(285)								
								5'-Agg ^{3'}								
3'-primer(s) ³	86(353)	86(353)	57(266)	86(353)	57(266)	55(260)	62(282)	86(353)	70(304)	86(353)	45(230)	86(353)	67(296)	55(260)	86(353)	86(353)
	5'-gCT ^{3'}	5'-gCT ^{3'}	5'-Cgg ^{3'}	5'-gCT ^{3'}	5'-Cgg ^{3'}	5'-gCg ^{3'}	5'-CTA ^{3'}	5'-gCT ^{3'}	5'-CCC ^{3'}	5'-gCT ^{3'}	5'-CCC ^{3'}	5'-gCT ^{3'}	5'-ggT ^{3'}	5'-gCg ^{3'}	5'-gCT ^{3'}	5'-gCT ^{3'}
										167(596)						
										5'-CAT ^{3'}						
														55(260)		
														5'-ggg ^{3'}		
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16



101.214-24/06 – including *Taq* polymerase, IFU-01
 101.214-24u/06u – without *Taq* polymerase, IFU-02

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

Lot No.: **16N**

Lot-specific information

Length of spec.	165	220	135	220	135	95	115	110	135	135	135	260	165	130	135	130
PCR product(s)						130		140		260						
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
DQB1 allele ⁴																
*03:01:01:01-03:01:02, 03:01:04-03:01:06	1	2										12		14	15	16
*03:01:03	1	2										12		14	15	
*03:02:01-03:02:05			3	4											15	
*03:03:02:01-03:03:04				4											15	16
*03:04	1	2			5							12		14	15	
*03:05:01-03:05:04						6									15	
*03:06				4			7								15	16
*03:07			3	4				8							15	
*03:08			3	4					9						15	
*03:09	1	2								10		12		14	15	16
*03:10		2									11	12		14	15	16
*03:11			3	4						10					15	
*03:12				4							11	12			15	16
*03:13	1	2										12	13	14	15	16
*03:14		2			5						11	12		14	15	
*03:15				4				8							15	16
*03:16	1	2						8				12				16
*03:17						6									15	16
*03:18			3	4											15	
*03:19	1	2										12		14	15	16
*03:20				4		6									15	16
*03:21	1	2										12		14	15	16
*03:22	1	2										12		14	15	16
*03:23				4												16
*03:24	1	2										12		14	15	16
*03:25				4			7									
*03:26				4						10					15	16
*03:27	1	2										12		14	15	16
*03:28	1	2										12		14	15	16
*03:29	1	2										12		14	15	16
*03:30				4											15	16
*03:31				4											15	16
*03:32			3	4											15	
*03:33				4											15	16
*03:34				4											15	16
*03:35	1	2										12		14	15	16
*03:36	1	2										12		14	15	16
*03:37			3	4											15	
*03:38				4											15	16
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16



101.214-24/06 – including *Taq* polymerase, IFU-01
 101.214-24u/06u – without *Taq* polymerase, IFU-02

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

Lot No.: **16N**

Lot-specific information

220	175	175	150	160	160	130	210	170	180	175	200	110	135	195	Length of spec. PCR product(s)
17	18	19	20	21	22	23	24	240	250			165			Well No.
															DQB1 allele ⁴
		19													*03:01:01-03:01:02, 03:01:04-03:01:06
		19													*03:01:03
	18														*03:02:01-03:02:05
	18														*03:03:02:01-03:03:04
		19													*03:04
	18														*03:05:01-03:05:04
	?	?													*03:06
	?	?													*03:07
	?	?													*03:08
		19													*03:09
		19													*03:10
	?	?													*03:11
	?	?													*03:12
	?	?													*03:13
	?	?													*03:14
	?	?													*03:15
	?	?													*03:16
	?	?													*03:17
17	?	?													*03:18
	18														*03:19
	?	?													*03:20
		19	20												*03:21
		19		21											*03:22
	?	?			22										*03:23
		19				23									*03:24
	18														*03:25
	?	?													*03:26
		19					24								*03:27
		19												31	*03:28
		19						25							*03:29
	18								26						*03:30
	18									27					*03:31
	18									27					*03:32
	?	?										29			*03:33
	?	?						25							*03:34
		19										29			*03:35
		19											30		*03:36
	?	?									28				*03:37
	18										28				*03:38
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	Well No.



101.214-24/06 – including *Taq* polymerase, IFU-01
 101.214-24u/06u – without *Taq* polymerase, IFU-02

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 “Instructions for Use” (IFU)

Lot No.: **16N**

Lot-specific information

Length of spec. PCR product(s)	165	220	135	220	135	95	115	110	135	135	135	260	165	130	135	130
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
*02:01:01-02:02, 02:04-02:06			3	4												
*02:03				4												16
*04:01:01-04:02:02, 04:04-04:08																
*04:03:01-04:03:02				4												
*06:01:01-06:01:06, 06:43											11					
*06:02:02									9							
*06:03:01, 06:04:02, 06:07:01, 06:08:01, 06:11:01-06:11:02, 06:26N, 06:28, 06:30-06:32, 06:40-06:41, 06:44																
*06:03:02									9							
*06:29			3													
DQB1 allele ⁴																
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16

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

Well number 1 contains the primer pair giving rise to the longer, 515 bp, internal positive control band in order to help in the correct orientation of the DQB1*03 subtyping.

In addition, wells number 2 to 4, 12, 14, 15, 18, 19, 21, 22 and 29 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 or 3rd 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 or 3rd 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.

101.214-24/06 – including *Taq* polymerase, IFU-01
 101.214-24u/06u – without *Taq* polymerase, IFU-02

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 “Instructions for Use” (IFU)

Lot No.: **16N**

Lot-specific information

220	175	175	150	160	160	130	210	170	180	175	200	110	135	195	Length of spec. PCR product(s)
17	18	19	20	21	22	23	24	240	250			165			Well No.
															*02:01:01-02:02, 02:04-02:06
															*02:03
	18														*04:01:01-04:02:02, 04:04-04:08
	18														*04:03:01-04:03:02
															*06:01:01-06:01:06, 06:43
															*06:02:02
					22										*06:03:01, 06:04:02, 06:07:01, 06:08:01, 06:11:01-06:11:02, 06:26N, 06:28, 06:30-06:32, 06:40-06:41, 06:44
					22										*06:03:02
									26						*06:29
															DQB1 allele ⁴
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	Well No.

⁴The sequence of the DQB1*03031 allele has been shown to be identical to DQB1*03:03:02.

⁵Primer mix 6: Specific PCR fragment of 95 bp in the DQB1*03:20 allele. Specific PCR fragment of 130 bp in the DQB1*03:05:01-03:05:04 and 03:17 alleles.

Primer mix 8: Specific PCR fragment of 110 bp in the DQB1*03:15 allele. Specific PCR fragment of 140 bp in the DQB1*03:07 and 03:16 alleles.

Primer mix 10: Specific PCR fragment of 135 bp in the DQB1*03:09 allele. Specific PCR fragment of 260 bp in the DQB1*03:11 and 03:26 alleles.

Primer mix 25: Specific PCR fragment of 170 bp in the DQB1*03:29 allele. Specific PCR fragment of 240 bp in the DQB1*03:34 allele.

Primer mix 27: Specific PCR fragment of 175 bp in the DQB1*03:32 allele. Specific PCR fragment of 250 bp in the DQB1*03:31 allele.

Primer mix 29: Specific PCR fragment of 110 bp in the DQB1*03:33 allele. Specific PCR fragment of 165 bp in the DQB1*03:35 allele.

‘?’, nucleotide sequence information not available for the primer matching region.

101.214-24/06 – including *Taq* polymerase, IFU-01
 101.214-24u/06u – without *Taq* polymerase, IFU-02

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

Lot No.: **16N**

Lot-specific information

CELL LINE VALIDATION SHEET																			
DQB1*03 SSP subtyping kit																			
				Well															
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
				200963001	200963002	200963003	200963004	200963005	200963006	200963007	200963008	200963009	200963010	200963011	200963012	200963013	201295314	200963015	200963016
IHCW 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	CTM3953540	*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		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-



101.214-24/06 – including *Taq* polymerase, IFU-01
 101.214-24u/06u – without *Taq* polymerase, IFU-02

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 “Instructions for Use” (IFU)

Lot No.: **16N**

Lot-specific information

CELL LINE VALIDATION SHEET																		
DQB1*03 SSP subtyping kit																		
				Well														
				17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
				200963017	200963018	200963019	201295320	200963021	200963022	200963023	201295324	201295325	201295326	201295327	201295328	201295329	201295330	201295331
	IHWC cell line	DQB1		Production No.														
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 CTM3953540	*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			-	-	-	-	-	-	-	-	-	-	-	-	-	-



101.214-24/06 – including *Taq* polymerase, IFU-01
 101.214-24u/06u – without *Taq* polymerase, IFU-02

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

Lot No.: **16N**

Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP® DQB1*03 SSP

Product number: 101.214-24/06 – including *Taq* pol.
 101.214-24u/06u – without *Taq* pol.

Lot number: 16N

Expiry date: 2014-August-01

Number of tests: 24 test – Product No. 101.214-24/24u
 6 tests – Product No. 101.214-06/06u

Number of wells per test: 31

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2009-630-01	13	2009-630-13	25	2012-953-25
2	2009-630-02	14	2012-953-14	26	2012-953-26
3	2009-630-03	15	2009-630-15	27	2012-953-27
4	2009-630-04	16	2009-630-16	28	2012-953-28
5	2009-630-05	17	2009-630-17	29	2012-953-29
6	2009-630-06	18	2009-630-18	30	2012-953-30
7	2009-630-07	19	2009-630-19	31	2012-953-31
8	2009-630-08	20	2012-953-20		
9	2009-630-09	21	2009-630-21		
10	2009-630-10	22	2009-630-22		
11	2009-630-11	23	2009-630-23		
12	2009-630-12	24	2012-953-24		

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

No DNAs carrying the alleles to be amplified by primer solutions 7 to 10, 13, 17, 20, 21, and 23 to 31 were available. The specificities of the primers in primer solutions 7, 9, 10 and 25 to 28 were tested by separately adding additional 5'-primers respectively 3'-primers. In primer solutions 8, 17, 20, 21, 29 and 30 it was only possible to test the 3'-primer, the 5'-primers were not possible to test. In primer solutions 13, 23, 24 and 31 it was only possible to test the 5'-primers, the 3'-primers were not possible to test. In primer solutions 10 and 14 one of the 3'-primers was not possible to test, and in primer solution 6, 25, 27 and 28 one of the 5'-primers was not possible to test.

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

Date of approval: 2012-February-15

Approved by:

Production Quality Control

101.214-24/06 – including *Taq* polymerase, IFU-01
101.214-24u/06u – without *Taq* polymerase, IFU-02

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

Lot No.: **16N**

Lot-specific information

Declaration of Conformity

Product name: *Olerup* SSP® DQB1*03
Product number: 101.214-24/06, -24u/06u
Lot number: 16N

Intended use: DQB1*03 high resolution histocompatibility testing

Manufacturer: *Olerup* SSP AB
Franzengatan 5
SE-112 51 Stockholm, Sweden
Phone: +46-8-717 88 27
Fax: +46-8-717 88 18

We, *Olerup* SSP AB, hereby declare that this product, to which this Declaration of Conformity relates is in conformity with the following Standard(s) and other normative document(s) ISO 9001:2008 and ISO 13485:2003, following the provisions of the 98/79/EC Directive on *in vitro* diagnostic medical devices, Annex III, 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.

Stockholm, Sweden
2012-February-15

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs

101.214-24/06 – including *Taq* polymerase, IFU-01
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Lot-specific information

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