

101.213.24 – including *Taq* pol., IFU-01.101.213.24u – without *Taq* pol., IFU-02.Visit www.olerup-ssp.com for

“Instructions for Use” (IFU)

Lot No.: **08S**

Lot-specific information

Olerup SSP® DQB1*02

Product number:	101.213-24 – including <i>Taq</i> polymerase 101.213-24u – without <i>Taq</i> polymerase
Lot number:	08S
Expiry date:	2015-October-01
Number of tests:	24
Number of wells per test:	12
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. 08S.

**CHANGES COMPARED TO THE PREVIOUS OLERUP SSP®
DQB1*02 Lot (63N)**

The DQB1*02 specificity and interpretation tables have been updated with the DQB1 alleles described since the previous *Olerup SSP®* DQB1*02 lot (Lot No. **63N**) was made.

Five wells has been added to the DQB1*02 kit, wells **8 to 12**.

The Lot-specific information for DQB1*02 including and without *Taq* polymerase is now described in one common Product Insert.

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

Well	5'-primer	3'-primer	rationale
6	Exchanged	-	Decrease tendencies of primer oligomer formation.
8	New	New	New primer pair for the DQB1*02:10 allele.
9	New	New	New primer pair for the DQB1*02:07 allele.
10	New	New	New primer pair for the DQB1*02:08 allele.
11	New	New	New primer pair for the DQB1*02:09 allele.
12	New	New	New primer pair for the DQB1*02:11 allele.

101.213.24 – including *Taq* pol., IFU-01.
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Change in revision R01 compared to R00:

1. Primer mix 2 may have a tendency of unspecific amplifications. A footnote has been added in the Specificity Table.

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PRODUCT DESCRIPTION

DQB1*02 SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for identifying the DQB1*02:01 to DQB1*02:11 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 12 PCR reactions in an 16 well PCR plate. Wells 13 to 16 are empty.

1	2	3	4	5	6	7	8
9	10	11	12	empty	empty	empty	empty

The 8 well PCR plate is marked with 'DQ2' in silver/gray ink.

Well No. 1 is marked with the Lot No. '08S'.

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 heat-sealed with a PCR-compatible foil.

Please note: When removing each 16 well PCR plate, make sure that the remaining plates stay covered. Use a scalpel or a similar instrument to carefully cut the foil between the plates.

INTERPRETATION

The interpretation of DQB1*02 SSP subtypings will be influenced by the DQB1*03, the DQB1*04, most DQB1*05 and most DQB1*06 alleles, when present on the other haplotype. The interpretation of DQB1*02 subtypings is not influenced by the DQB2 and DQB3 genes.

UNIQUELY IDENTIFIED ALLELES

All the DQB1*02 alleles, i.e. **DQB1*02:01 to DQB1*02:11**, recognized by the HLA Nomenclature Committee in January 2013¹ will give rise to unique amplification patterns by the primers in the DQB1*02 subtyping kit.

The DQB1*02 kit cannot distinguish the silent mutation in the DQB1*02:01:01-02:01:06 and DQB1*02:01:08 or the DQB1*02:02:01-02:02:02 alleles.

¹HLA-DQB1 alleles listed on the IMGT/HLA web page 2013-January-11, release 3.11.0, www.ebi.ac.uk/imgt/hla.

The DQB1*02:01:07 and the DQB1*03:01:01:01-03:23, 03:25-03:47, 04:01:01-04:09, 05:01:01:01-05:13, 05:15-05:18, 06:01:01-06:37 and 06:39-06:52 alleles give rise to identical amplification patterns with the DQB1*02 primer set. These alleles can be distinguished by the DQ low resolution kit and/or respective DQB1 high resolution kit.

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RESOLUTION IN HOMO- AND HETEROZYGOTES

A total of 19 alleles generate 12 amplification patterns that can be combined in 78 homozygous and heterozygous combinations. 31 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.

+ - + - - - - - - - - -	*02:01:01, *02:01:01 = *02:01:01, *02:01:07
+ - - + - - - - - - - +	*02:02:01, *02:11 = *02:11, *02:11
+ - - + - - - - - - - +	*02:02:01, *02:10 = *02:10, *02:10
+ - - + - - - - - - - +	*02:02:01, *02:06 = *02:06, *02:06
+ - + - - - - - - - - +	*02:01:01, *02:09 = *02:01:07, *02:09 = *02:09, *02:09
+ - + - - - - - - - - +	*02:01:01, *02:08 = *02:01:07, *02:08 = *02:08, *02:08
+ - + - - - - - - - - +	*02:01:01, *02:07 = *02:01:07, *02:07 = *02:07, *02:07
+ - + - - - - - - - - +	*02:01:01, *02:05 = *02:01:07, *02:05 = *02:05, *02:05
+ - + - - - - - - - - +	*02:01:01, *02:04 = *02:01:07, *02:04 = *02:04, *02:04
+ - + - - - - - - - - +	*02:01:01, *02:02:01 = *02:01:07, *02:02:01
+ - + - - - - - - - - +	*02:01:01, *02:11 = *02:01:07, *02:11
+ - + - - - - - - - - +	*02:01:01, *02:10 = *02:01:07, *02:10
+ - + - - - - - - - - +	*02:01:01, *02:06 = *02:01:07, *02:06

*02:01:01 = *02:01:01-02:01:06 and 02:01:08

*02:02:01 = *02:02:01-02:02:02

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Lot-specific information
SPECIFICITY TABLE

DQB1*02 SSP subtyping

Specificities and sizes of the PCR products of the 12 primer mixes used for DQB1*02 SSP subtyping

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified DQB1*02 alleles ³	Other amplified DQB1 alleles ⁴
1⁵	120 bp	515 bp	*02:01:01-02:01:06, 02:01:08-02:02:02, 02:04-02:11	
2^{5,6}	85 bp	430 bp	*02:03	
3⁶	145 bp	515 bp	*02:01:01-02:01:08, 02:04-02:05, 02:07-02:09	*03:01:01:01-03:23, 03:25-03:47, 04:01:01-04:09, 05:01:01:01-05:13, 05:15-05:18, 06:01:01-06:37, 06:39-06:52
4	140 bp	430 bp	*02:02:01-02:03, 02:06, 02:10-02:11	
5	145 bp	430 bp	*02:04	
6	210 bp	430 bp	*02:05	
7	245 bp	430 bp	*02:06	*03:24
8	160 bp	430 bp	*02:10	
9	195 bp	430 bp	*02:07	
10	180 bp	430 bp	*02:08	
11	270 bp	430 bp	*02:09	
12⁵	115 bp	430 bp	*02:11	

¹ Alleles are assigned by the presence of specific PCR product(s). However, the sizes of the specific PCR products may be helpful in the interpretation of DQB1*02 SSP typings.

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

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

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

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

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

²The internal positive control primer pairs amplify segments of the human growth hormone gene.

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Lot No.: 08S**Lot-specific information**

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*02 subtyping.

In addition, well number 3 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.

³For several DQB1 alleles 1st and/or 3rd exon(s) and beyond, as well as intron nucleotide sequences, are not available. In these instances it is not known whether some of the primers of the SSP sets are completely matched with the target sequences or not. We assume that unknown sequences in these regions are conserved within allelic groups.

⁴Due to the sharing of sequence motifs, non-DQB1*02 alleles will be amplified by primer mixes 3 and 7.

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

⁶Primer mixes 2 and 3 may have a tendency of unspecific amplifications.

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Lot-specific information

INTERPRETATION TABLE												
DQB1*02 SSP subtyping												
Amplification patterns of the 02:01 to 02:11 alleles												
	Well											
	1	2	3	4	5	6	7	8	9	10	11	12
Length of spec. PCR product	120	85	145	140	145	210	245	160	195	180	270	115
Length of int. pos. control ¹	515	430	515	430	430	430	430	430	430	430	430	430
5'-primer ²	30(185) 5'-AAG 3'	57(266) 5'-TgA 3'	135(500) 5'-TgA 3'	101(400) 5'-TCT 3'	135(502) 5'-ACg 3'	21(159) 5'-ACA 3'	101(400) 5'-TCT 3'	101(400) 5'-TCT 3'	30(185) 5'-AAG 3'	30(185) 5'-AAG 3'	101(400) 5'-TCT 3'	32(193) 5'-ATg 3'
3'-primer ³	57(266) 5'-Cgg 3'	71(309) 5'-CgT 3'	169(604) 5'-gAC 3'	135(500) 5'-ggC 3'	169(604) 5'-gAC 3'	77(326) 5'-CCg 3'	169(604) 5'-gAT 3'	141(520) 5'-AAT 3'	81(338) 5'-Tgg 3'	77(326) 5'-CCT 3'	178(631) 5'-gCg 3'	57(266) 5'-Cgg 3'
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
DQB1 allele												
*02:01:01-02:01:06, 02:01:08	1		3									
*02:01:07, 03:01:01-01-03:23, 03:25-03:47, 04:01:01-04:09, 05:01:01-05:13, 05:15-05:18, 06:01:01-06:37, 06:39-06:52 ⁴			3									
*02:02:01-02:02:02	1			4								
*02:03		2		4								
*02:04	1		3		5							
*02:05	1		3			6						
*02:06	1			4			7					
*02:07	1		3						9			
*02:08	1		3							10		
*02:09	1		3								11	
*02:10	1			4				8				
*02:11	1			4								12
*03:24							7					
DQB1 allele												
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

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*02 subtyping.

In addition, well number 3 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 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.

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⁴The DQB1*02:01:07 and the DQB1*03:01:01:01-03:23, 03:25-03:47, 04:01:01-04:09, 05:01:01:01-05:13, 05:15-05:18, 06:01:01-06:37 and 06:39-06:52 alleles give rise to identical amplification patterns with the DQB1*02 primer set. These alleles can be distinguished by the DQ low resolution kit and/or respective DQB1 high resolution kit.

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CELL LINE VALIDATION SHEET																	
DQB1*02 SSP subtyping kit																	
						Well											
						1	2	3	4	5	6	7	8	9	10	11	12
					Production No.	200961701	200961702	200961703	200961704	200961705	201315806	201200107	201315808	201315809	201315810	201315811	201315812
	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			-	-	+	-	-	-	-	-	-	-	-	-

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CERTIFICATE OF ANALYSIS**Olerup SSP® DQB1*02 SSP**

Product number:

101.213-24 – including *Taq* polymerase101.213-24u – without *Taq* polymerase

Lot number:

08S

Expiry date:

2015-October-01

Number of tests:

24

Number of wells per test:

12**Well specifications:**

Well No.	Production No.	Well No.	Production No.
1	2009-617-01	9	2013-158-09
2	2009-617-02	10	2013-158-10
3	2009-617-03	11	2013-158-11
4	2009-617-04	12	2013-158-12
5	2009-617-05		
6	2013-158-06		
7	2012-001-07		
8	2013-158-08		

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

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

Date of approval: 2013-May-23

Approved by:

Production Quality Control

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Lot-specific information

Declaration of Conformity

Product name: Olerup SSP® DQB1*02**Product number:** 101.213-24/24u**Lot number:** 08S**Intended use:** DQB1*02 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 13485:2012, 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
2015-September-01

Daniel Malica
Head of QA and Regulatory Affairs

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Lot-specific information

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