

101.201-48/12– including *Taq* pol., IFU-01 Rev. No. 03
101.201-48u/12u– without *Taq* pol., IFU-02 Rev. No. 03

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

Lot No.: **87N**

Lot-specific information

Olerup SSP[®] DQ low resolution

Product number:	101.201-48/12 - including <i>Taq</i> pol. 101.201-48u/12u - without <i>Taq</i> pol.
Lot number:	87N
Expiry date:	2014-November-01
Number of tests:	48 tests – Product No. 101.201-48/48u 12 tests – Product No. 101.201-12/48u
Number of wells per test:	8
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. 87N.

CHANGES COMPARED TO THE PREVIOUS OLERUP SSP[®] DQ LOW RESOLUTION LOT (39M)

The DQ low resolution specificity and interpretation tables have been updated for the HLA-DQB1 alleles described since the previous *Olerup SSP[®]* DQ low resolution lot was made (**Lot No. 39M**).

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

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

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PRODUCT DESCRIPTION

DQ low resolution SSP typing

CONTENT

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

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.

STRIP LAYOUT

Each test consists of 8 PCR reactions in an 8 well PCR plate.

1	2	3	4	5	6	7	8
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The 8 well cut PCR plate is marked with ‘DQ low’ in silver/gray ink.

Well No. 1 is marked with the Lot No. ‘87N’.

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 8 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 DQ low resolution typing kit. Thus, the interpretation of DQ low resolution typings is not influenced the DQB2 and DQB3 genes.

UNIQUELY IDENTIFIED ALLELES

All the DQB1 alleles, i.e. **DQB1*05:01 to 05:14, DQB1*06:01 to 06:49, DQB1*02:01 to 02:06, DQB1*03:01 to 03:40 and DQB1*04*01 to 04:08**, recognized by the HLA Nomenclature Committee in April 2012¹ will be amplified by the primers in the DQ low resolution SSP kit. The DQB1 alleles will be grouped into their corresponding serological specificities, i.e.:

DQ5(1) =	DQB1*05:01 -05:05 ²
DQ6(1) =	DQB1*06:01-06:33 ²
DQ2 =	DQB1*02:01-02:05
DQ3 =	DQB1*03:01-03:20 ²
DQ4 =	DQB1*04:01-04:02 ²

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The DQ3 alleles may be further subdivided into the DQ3, DQ7, DQ8 and DQ9 based upon serology and expert assignment³. Thus;

DQ3	=	DQB1*03:06, 03:10, 03:14
DQ7	=	DQB1*03:01:01-03:01:03, 03:04, 03:09, 03:13, 03:16, 03:19
DQ8	=	DQB1*03:02:01, 03:05:01, 03:07, 03:08, 03:11, 03:18
DQ9	=	DQB1*03:03:02, 03:12, 03:15, 03:17, 03:20

¹HLA-DQB1 alleles listed on the IMGT/HLA web page 2012-April-12, release 3.8.0, www.ebi.ac.uk/imgt/hla.

²The serological split of the DQB1*05:05 to 05:14, DQB1*06:06 to 06:07, 06:10, 06:13, 06:15 to 06:24 and 06:27 to 06:49, the DQB1*03:02:02-03:02:04, 03:03:03, 03:05:02, 03:07 to 03:09 and 03:11 to 03:40 and the DQB1*04:03 and 04:08 alleles is not known. The grouping of not serologically defined alleles is taken from the expert-assigned serological grouping in Tissue Antigens (2009) 73:95-170.

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Lot-specific information
SPECIFICITY TABLE

DQ low resolution SSP typing

Specificities and sizes of the PCR products of the 8 primer mixes used for DQ low resolution SSP typing

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
2⁸	220 bp, 270 bp	430 bp	1, 5, 6	*06:01:01-06:49
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, 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, 03:38-03:40, 04:03:01-04:03:02
7^{5,6,8}	145 bp, 185 bp	515 bp	3, 7, 8, 9	*03:01:01:01-03:40
8^{6,8}	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 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

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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 to 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 split of the DQB1*05:05 to 05:14, DQB1*06:06 to 06:07, 06:10, 06:13, 06:15 to 06:24 and 06:27 to 06:49, the DQB1*03:02:02-03:02:04, 03:03:03, 03:05:02, 03:07 to 03:09 and 03:11 to 03:40 and the DQB1*04:03 and 04:08 alleles is not known. The grouping of not serologically defined alleles is taken from the expert-assigned serological grouping in Tissue Antigens (2009) 73:95-170.

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 give a lower yield of HLA-specific PCR products than the other DQ low resolution primer mixes.

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

⁸The primer pairs in wells 2, 7 and 8 will in some samples give rise to two HLA-specific PCR fragments.

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INTERPRETATION TABLE									
DQ low resolution SSP typing									
Amplification patterns of the DQB1*05:01 to DQB1*04:08 alleles									
		Well⁶							
		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. control¹									
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 allele⁴	ser.⁵								
*02:01:01-02:02, 02:04-02:06	DQ2, –			3					
*02:03	DQ2			3			6		
*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	DQ3, DQ7, –				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	DQ8, –					5		7	
Well No.		1	2	3	4	5	6	7	8

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Length of spec.		225	220	210	220	130	135	145	210
PCR product(s)			270					185	245
Well No.		1	2	3	4	5	6	7	8
*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- 03:40	DQ3, DQ9, –						6	7	
*03:17, 03:23	DQ9, –							7	
*04:01:01-04:02:02, 04:04-04:08	DQ4, –								8
*04:03:01-04:03:02	–						6		8
*05:01:01:01-05:14	DQ5, –	1							
*06:01:01-06:28, 06:30- 06:49	DQ1, DQ5, DQ6, Null, –		2						
*06:29	DQ6		2			5			
DQB1 allele ⁴	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 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 DQB1*03031 allele has been shown to be identical to DQB1*03:03:02.

⁵The serological split of the DQB1*05:05 to 05:14, DQB1*06:06 to 06:07, 06:10, 06:13, 06:15 to 06:24 and 06:27 to 06:49, the DQB1*03:02:02-03:02:04, 03:03:03, 03:05:02, 03:07 to 03:09 and 03:11 to 03:40 and the DQB1*04:03 and 04:08 alleles is not known. The grouping of not serologically defined alleles is taken from the expert-assigned serological grouping in Tissue Antigens (2009) 73:95-170.

⁶The primer pairs in wells 2, 7 and 8 will in some samples give rise to two HLA-specific PCR fragments.

'ser', serological HLA specificity.

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CELL LINE VALIDATION SHEET												
DQ low resolution primer set												
				Well								
				1	2	3	4	5	6	7	8	
				201194801	201194802	201194803	201194804	201194805	201194806	201194807	201194808	
				Production No.								
				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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CERTIFICATE OF ANALYSIS

Olerup SSP[®] DQ low resolution SSP

Product number: 101.201-48/12 - including *Taq* pol.
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Lot number: 87N

Expiry date: 2014-November-01

Number of tests: 48 tests – Product No. 101.201-48/48u
 12 tests – Product No. 101.201-12/48u

Number of wells per test: 8

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

The specificity of each primer solution of the kit has been tested against 48 well characterized IHWC cell line DNAs.
 Additional 5'-primers in primer solutions 2 and 8 were tested by separately adding another 3'-primer.

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

Date of approval: 2012-May-25

Approved by:

Production Quality Control

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Declaration of Conformity

Product name: *Olerup* SSP® DQ low resolution
Product number: 101.201-48/48u, -12/12u
Lot number: 87N

Intended use: DQB1 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 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.

The Authorized Representative located within the Community is: *Olerup* SSP AB.

Stockholm, Sweden
2012-May-25

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs

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