

## Olerup SSP<sup>®</sup> 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:	41E
Expiry date:	2010-May-01
Number of tests:	48 tests – Product No. 101.201-48 12 tests – Product No. 101.201-12
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. 41E.**

### CHANGES COMPARED TO THE PREVIOUS OLERUP SSP<sup>®</sup> DQ LOW RESOLUTION LOT

The DQ low resolution specificity and interpretation tables have been updated for the HLA-DQB1 alleles described since the previous *Olerup SSP<sup>®</sup>* DQ low resolution lot was made (**Lot No. X48**).

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

Well	5'-primer	3'-primer	rationale
7	Modified	-	Increased yield of specific PCR product
8	Exchanged	-	Primer exchanged to amplify the DQB1*0403 allele.

## 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'.

Well No. 1 is marked with the Lot No. '41E'.

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\*050101 to 0505**, **DQB1\*060101 to 0634**, **DQB1\*020101 to 0205**, **DQB1\*030101 to 0321** and **DQB1\*0401 to 0403**, recognized by the HLA Nomenclature Committee in April 2008<sup>1</sup> 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\*050101-0505<sup>2</sup>  
DQ6(1) = DQB1\*060101-0634<sup>2</sup>  
DQ2 = DQB1\*020101-0205  
DQ3 = DQB1\*030101-0321<sup>2</sup>  
DQ7(3) = DQB1\*030101-030103, DQB1\*0304  
DQ8(3) = DQB1\*030201, DQB1\*030501, DQB1\*0310  
DQ9(3) = DQB1\*030302  
DQ4 = DQB1\*0401-0403<sup>2</sup>

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Lot-specific information

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<sup>1</sup>HLA-DQB1 alleles listed on the IMGT/HLA web page 2008-April-08, release 2.21.0, [www.ebi.ac.uk/imgt/hla](http://www.ebi.ac.uk/imgt/hla).

<sup>2</sup>The serological split of the DQB1\*0505, DQB1\*0606 to 0608 alleles, the DQB1\*0610 to 0634, the DQB1\*030202-030204, DQB1\*030303, DQB1\*030502 to 0321 and the DQB1\*0403 alleles is not known. In this table we have inferred the serological grouping from the naming of the sequence-defined allele.

## 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 <sup>1</sup>	Size of control band <sup>2</sup>	DQ serology <sup>3</sup>	Amplified DQB1 alleles <sup>4</sup>
<b>1</b>	220 bp	<b>515 bp</b>	5	050101-0505
<b>2</b>	220, 270 bp	430 bp	6	060101-0630
<b>3</b>	205 bp	430 bp	2	020101-0205
<b>4<sup>5</sup></b>	130, 145 bp	<b>515 bp</b>	2, 3, 6, 8	020101-0202, 0204, 0205, 030201-030204, 030501, 030503, 0307, 0308, 0311, 0318, 0629
<b>5<sup>5</sup></b>	220 bp	<b>515 bp</b>	3, 7, 8	030101-030104, 0304, 0309, 0310, 0313, 0314, 0316, 0319, 0321
<b>6<sup>5</sup></b>	220 bp	<b>515 bp</b>	2, 3, 4, 8, 9	020101-0205, 030201-030204, 030302-030303, 0306-0308, 0311, 0312, 0315, 0318, 0320, 0403
<b>7<sup>5,6</sup></b>	135 bp	<b>515 bp</b>	3, 7, 8, 9	030101-030204, 030302-0321
<b>8<sup>5</sup></b>	210 bp	430 bp	4	040-0403

<sup>1</sup>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 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 length 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.

<sup>2</sup>The 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,

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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.

<sup>3</sup>The serological reactivity of the DQB1\*0505, DQB1\*0606 to 0608 alleles, the DQB1\*0610 to 0633, the DQB1\*030202-030204, DQB1\*030303, DQB1\*030502 to 0321 and the DQB1\*0403 alleles is not known. In this table we have inferred the serological grouping from the naming of the sequence-defined allele.

<sup>4</sup>For 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.

<sup>5</sup>These primer mixes may yield somewhat less intense specific PCR fragments than the other DQ low resolution primer mixes.

<sup>6</sup>This primer mix may give rise to nonspecific amplifications.

<b>INTERPRETATION TABLE</b>									
<b>DQ low resolution SSP typing</b>									
<b>Amplification patterns of the DQB1*0501 to DQB1*0402 alleles</b>									
		<b>Well</b>							
		<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>7</b>	<b>8</b>
<b>Length of spec.</b>		<b>220</b>	<b>220</b>	<b>205</b>	<b>130</b>	<b>220</b>	<b>220</b>	<b>135</b>	<b>210</b>
<b>PCR product(s)</b>			<b>270</b>		<b>145</b>				
<b>Length of int.</b>		<b>515</b>	<b>430</b>	<b>430</b>	<b>515</b>	<b>515</b>	<b>515</b>	<b>515</b>	<b>430</b>
<b>pos. control<sup>1</sup></b>									
<b>5'-primer(s)<sup>2</sup></b>		<b>26</b>	<b>9</b>	<b>30</b>	<b>21</b>	<b>26</b>	<b>26</b>	<b>55</b>	<b>21</b>
		<sup>5'</sup> -g gg <sup>3'</sup>	<sup>5'</sup> -g TT <sup>3'</sup>	<sup>5'</sup> -A Ag <sup>3'</sup>	<sup>5'</sup> -ACC <sup>3'</sup>	<sup>5'</sup> -T TA <sup>3'</sup>	<sup>5'</sup> -T CT <sup>3'</sup>	<sup>5'</sup> -g CC <sup>3'</sup>	<sup>5'</sup> -ACC <sup>3'</sup>
			<b>26</b>		<b>26</b>			<b>55</b>	
			<sup>5'</sup> -T TA <sup>3'</sup>		<sup>5'</sup> -T CT <sup>3'</sup>			<sup>5'</sup> -g CA <sup>3'</sup>	
			<b>26</b>						
			<sup>5'</sup> -T CT <sup>3'</sup>						
<b>3'-primer(s)<sup>3</sup></b>		<b>87</b>	<b>86</b>	<b>86</b>	<b>57</b>	<b>86</b>	<b>86</b>	<b>86</b>	<b>77</b>
		<sup>5'</sup> -g gT <sup>3'</sup>	<sup>5'</sup> -A Cg <sup>3'</sup>	<sup>5'</sup> -g CT <sup>3'</sup>	<sup>5'</sup> -C gg <sup>3'</sup>	<sup>5'</sup> -g CT <sup>3'</sup>	<sup>5'</sup> -g CT <sup>3'</sup>	<sup>5'</sup> -g CT <sup>3'</sup>	<sup>5'</sup> -AC g <sup>3'</sup>
			<b>86</b>						
			<sup>5'</sup> -A CC <sup>3'</sup>						
<b>Well No.</b>		<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>7</b>	<b>8</b>
<b>DQB1 allele<sup>4</sup></b>	<b>ser.<sup>5</sup></b>								
<b>*050101-0505</b>	<b>5</b>	<b>1</b>							
<b>*060101-0628, 0630-0634</b>	<b>6</b>		<b>2</b>						
<b>*0629</b>	<b>6</b>		<b>2</b>		<b>4</b>				
<b>*020101-0202, 0204, 0205</b>	<b>2</b>			<b>3</b>	<b>4</b>		<b>6</b>		
<b>*0203</b>	<b>2</b>			<b>3</b>			<b>6</b>		
<b>*030101-030104, 0304, 0309, 0310, 0313, 0314, 0316, 0319, 0321</b>	<b>3, 7, 8</b>					<b>5</b>		<b>7</b>	
<b>*030201-030204, 0307, 0308, 0311, 0318</b>	<b>3, 8</b>				<b>4</b>		<b>6</b>	<b>7</b>	
<b>*030302-030303, 0306, 0312, 0315, 0320</b>	<b>3, 9</b>						<b>6</b>	<b>7</b>	
<b>*030501, 030503</b>	<b>3, 8</b>				<b>4</b>			<b>7</b>	
<b>*030502, 030504, 0317</b>								<b>7</b>	
<b>*0401, 0402</b>	<b>4</b>								<b>8</b>
<b>*0403</b>	<b>4</b>						<b>6</b>		<b>8</b>
<b>DQB1 allele<sup>4</sup></b>	<b>ser.<sup>5</sup></b>								
<b>Well No.</b>		<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>7</b>	<b>8</b>

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Lot-specific information

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<sup>1</sup>The 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.

<sup>2</sup>The codon, in the 2<sup>nd</sup> exon, matching the specificity-determining 3'-end of the primer is given. Codon numbering as on the [www.ebi.ac.uk/imgt/hla](http://www.ebi.ac.uk/imgt/hla) web site. The sequence of the 3 terminal nucleotides of the primer is given. Empty spaces indicate codon boundaries.

<sup>3</sup>The codon, in the 2<sup>nd</sup> exon, matching the specificity-determining 3'-end of the primer is given in the anti-sense direction. Codon numbering as on the [www.ebi.ac.uk/imgt/hla](http://www.ebi.ac.uk/imgt/hla) web site. The sequence of the 3 terminal nucleotides of the primer is given. Empty spaces indicate codon boundaries.

<sup>4</sup>The sequence of the DQB1\*030301 allele has been shown to be identical to DQB1\*030302.

<sup>5</sup>The serological reactivity of the DQB1\*0505, DQB1\*0606 to 0608 alleles, the DQB1\*0610 to 0634, the DQB1\*030202-030204, DQB1\*030303, DQB1\*030502 to 0321 and the DQB1\*0403 alleles is not known. In this table we have inferred the serological grouping from the naming of the sequence-defined allele.

CELL LINE VALIDATION SHEET											
DQ low resolution primer set											
				Well							
				1	2	3	4	5	6	7	8
				200844601	200844602	200844603	200844604	200844605	200844606	200844607	200847108
			Production No.								
	IHWC cell line		DQB1								
1	9001 SA		*0501		+	-	-	-	-	-	-
2	9280 LK707		*0601	*0202	-	+	+	+	-	+	-
3	9011 E4181324		*0601		-	+	-	-	-	-	-
4	9275 GU373		*0201		-	-	+	+	-	+	-
5	9009 KAS011		*0502		+	-	-	-	-	-	-
6	9353 SM		*0302	*0601	-	+	-	+	-	+	+
7	9020 QBL		*0201		-	-	+	+	-	+	-
8	9007 DEM		*0302	*0502	+	-	-	+	-	+	+
9	9026 YAR		*0302		-	-	-	+	-	+	-
10	9107 LKT3		*0401		-	-	-	-	-	-	+
11	9051 PITOUT		*0202		-	-	+	+	-	+	-
12	9052 DBB		*0303		-	-	-	-	-	+	+
13	9067 BTB		*0402		-	-	-	-	-	-	+
14	9071 OLGA		*0402		-	-	-	-	-	-	+
15	9075 DKB		*0303		-	-	-	-	-	+	+
16	9037 SWEIG007		*0301		-	-	-	-	+	-	+
17	9008 WILJON		*0602	*0603	-	+	-	-	-	-	-
18	9257 32367		*0602	*0202	-	+	+	+	-	+	-
19	9038 BM16		*0301		-	-	-	-	+	-	+
20	9059 SLE005		*0604		-	+	-	-	-	-	-
21	9064 AMALA		*0301		-	-	-	-	+	-	+
22	9056 KOSE		*0503	*0604	+	+	-	-	-	-	-
23	9124 IHL		*0503	*0601	+	+	-	-	-	-	-
24	9035 JBUSH		*0301		-	-	-	-	+	-	+
25	9049 IBW9		*0202		-	-	+	+	-	+	-
26	9285 WT49		*0201		-	-	+	+	-	+	-
27	9191 CH1007		*0401	*0501	+	-	-	-	-	-	+
28	9320 BEL5GB		*0202	*0301	-	-	+	+	+	+	-
29	9050 MOU		*0202		-	-	+	+	-	+	-
30	9021 RSH		*0402		-	-	-	-	-	-	+
31	9019 DUCAF		*0201		-	-	+	+	-	+	-
32	9297 HAG		*0301		-	-	-	-	+	-	+
33	9098 MT14B		*0302		-	-	-	+	-	+	+
34	9104 DHIF		*0301		-	-	-	-	+	-	+
35	9302 SSTO		*0305		-	-	-	+	-	-	+
36	9024 KT17		*0302		-	-	-	+	-	+	+
37	9065 HHKB		*0603		-	+	-	-	-	-	-
38	9099 LZL		*0301		-	-	-	-	+	-	+
39	9315 CML		*0201	*0301	-	-	+	+	+	+	+
40	9134 WHONP199		*0202	*0303	-	-	+	+	-	+	+
41	9055 H0301		*0609		-	+	-	-	-	-	-
42	9066 TAB089		*0601		-	+	-	-	-	-	-
43	9076 T7526		*0303		-	-	-	-	-	+	+
44	9057 TEM		*0503		+	-	-	-	-	-	-
45	9239 SHJO		*0202		-	-	+	+	-	+	-
46	9013 SCHU		*0602		-	+	-	-	-	-	-
47	9045 TUBO		*0301		-	-	-	-	+	-	+
48	9303 TER-ND		*0501		+	-	-	-	-	-	-





## CERTIFICATE OF ANALYSIS

### **Olerup SSP<sup>®</sup> DQ low resolution SSP**

**Product number:** 101.201-48/12 – including *Taq* pol.  
101.201-48u/12u – without *Taq* pol.  
**Lot number:** 41E  
**Expiry date:** 2010-May-01  
**Number of tests:** 48 tests – Product No. 101.201-48  
12 tests – Product No. 101.201-12  
**Number of wells per test:** 8

#### **Well specifications:**

Well No.	Production No.
1	2008-446-01
2	2008-446-02
3	2008-446-03
4	2008-446-04
5	2008-446-05
6	2008-446-06
7	2008-446-07
8	2008-471-08

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

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

**Date of approval:** 2008-May-09

**Approved by:**

**Quality Control, Supervisor**

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Lot-specific information

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## Declaration of Conformity

**Product name:** *Olerup* SSP® DQ low resolution  
**Product number:** 101.201-48/12, 101.201-48u/12u  
**Lot number:** 41E

**Intended use:** DQB1 low resolution histocompatibility testing

**Manufacturer:** *Olerup* SSP AB  
Hasselstigen 1  
SE-133 33 Saltsjöbaden, Sweden  
**Phone:** +46-8-717 88 27  
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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 9001:2000 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, Hasselstigen 1, SE-133 33 Saltsjöbaden, Sweden.

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

Saltsjöbaden, Sweden  
2008-May-09

Olle Olerup  
Managing Director

DQ low resolution  
101.201-48/12 – including *Taq* polymerase  
101.201-48u/12u – without *Taq* polymerase

Product Insert

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DQ low resolution  
101.201-48/12 – including *Taq* polymerase  
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Product Insert

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Lot-specific information

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