

## **Olerup SSP® DRB5\*0108N**

Product number: 101.812-12 – including *Taq* polymerase  
Lot number: 42G  
Expiry date: 2011-October-01  
Number of tests: 12  
Number of wells per test: 2  
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. 42G.**

The DRB5\*0108N specificity and interpretation tables have been updated compared the previous *Olerup SSP®* DRB5\*0108N lot (Lot No. 75E).

The plate layout of the DRB5\*0108N kit has been changed to 2 wells in an 8-well plate.

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

Well	5'-primer	3'-primer	rationale
2	-	Exchange	Primer exchanged to avoid co-amplification of the DRB1*0907 allele.

## PRODUCT DESCRIPTION

### DRB5\*0108N SSP subtyping

#### CONTENT

The primer set contains 5'- and 3'-primers for identifying the DRB5\*0108N allele.

#### PLATE LAYOUT

Each test consists of 2 PCR reactions in an 8 well cut PCR plate. Wells 3 to 8 are empty.

1	2	empty	empty	empty	empty	empty	empty
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The 8 well cut PCR plate is marked with the Lot No. '42G'.

Well No. 1 is marked with the Lot No. '42G'.

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 8 well PCR plate, make sure that the remaining plates stay sealed. Use a scalpel or a similar instrument to carefully cut the foil between the plates.

#### INTERPRETATION

The interpretation of DRB5\*0108N SSP subtypings will be influenced by the other DRB5 alleles.

#### UNIQUELY IDENTIFIED ALLELES

The DRB5\*0108N allele will give rise to a unique amplification pattern by the primers in the DRB5\*0108N kit<sup>1</sup>.

<sup>1</sup>DRB5 alleles listed on the IMGT/HLA web page 2009-July-17, release 2.26.0, [www.ebi.ac.uk/imgt/hla](http://www.ebi.ac.uk/imgt/hla).

## SPECIFICITY TABLE

### DRB5\*0108N SSP subtyping

Specificities and sizes of the PCR products of the 2 primer mixes used for DRB5\*0108N SSP subtyping

Primer Mix	Size of spec. PCR product <sup>1</sup>	Size of control band <sup>2</sup>	Amplified DRB5 alleles
1	195 bp	515 bp	0108N
2	175 bp	430 bp	010101-0113, 0202-0205

<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 DRB5\*0108N SSP typings.

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 shorter, 515 bp, internal positive control band in order to help in the correct orientation of the DRB5\*0108N subtyping.

<b>INTERPRETATION TABLE</b>		
<b>DRB5*0108N SSP typing</b>		
	<b>Well</b>	
	<b>1</b>	<b>2</b>
<b>Length of spec.</b>	<b>195</b>	<b>175</b>
<b>PCR product</b>		
<b>Length of int.</b>	<b>515</b>	<b>430</b>
<b>pos. control<sup>1</sup></b>		
<b>5'-primer(s)<sup>2</sup></b>	<b>108(409)</b>	<b>13(125)</b>
	5' -A gA 3'	5' -gTA 3'
<b>3'-primer(s)<sup>3</sup></b>	<b>160(565)</b>	<b>57(258)</b>
	5' -CAT 3'	5' -gCg 3'
		<b>58(260)</b>
		5' -CCT 3'
<b>Well No.</b>	<b>1</b>	<b>2</b>
<b>DRB5 allele</b>		
<b>*0108N</b>	<b>1</b>	<b>2</b>
<b>*010101-0107, 0109-0113, 0202-0205</b>		<b>2</b>
<b>DRB5 allele</b>		
<b>Well No.</b>	<b>1</b>	<b>2</b>

<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 DRB5 subtyping.

<sup>2</sup>The codon, and in parenthesis the nucleotide, in the 2<sup>nd</sup> or 3<sup>rd</sup> 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](http://www.ebi.ac.uk/imgt/hla) web site. The sequence of the 3 terminal nucleotides of the primer is given.

<sup>3</sup>The codon, and in parenthesis the nucleotide, in the 2<sup>nd</sup> or 3<sup>rd</sup> 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](http://www.ebi.ac.uk/imgt/hla) web site. The sequence of the 3 terminal nucleotides of the primer is given.

CELL LINE VALIDATION SHEET					
DRB5*0108N SSP kit					
					Well
					1 2
					200847901 200964902
					Lot No.:
IHC cell line		DRB5			
1	9001 SA			-	-
2	9280 LK707	*0102		-	+
3	9011 E4181324	*0102		-	+
4	9275 GU373			-	-
5	9009 KAS011	*0202		-	+
6	9353 SM			-	-
7	9020 QBL			-	-
8	9025 DEU			-	-
9	9026 YAR			-	-
10	9107 LKT3			-	-
11	9051 PITOUT			-	-
12	9052 DBB			-	-
13	9004 JESTHOM			-	-
14	9071 OLGA			-	-
15	9075 DKB			-	-
16	9037 SWEIG007			-	-
17	9282 CTM3953540			-	-
18	9257 32367			-	-
19	9038 BM16			-	-
20	9059 SLE005			-	-
21	9064 AMALA			-	-
22	9056 KOSE			-	-
23	9124 IHL			-	-
24	9035 JBUSH			-	-
25	9049 IBW9			-	-
26	9285 WT49			-	-
27	9191 CH1007			-	-
28	9320 BEL5GB			-	-
29	9050 MOU			-	-
30	9021 RSH			-	-
31	9019 DUCAF			-	-
32	9297 HAG			-	-
33	9098 MT14B			-	-
34	9104 DHIF			-	-
35	9302 SSTO			-	-
36	9024 KT17			-	-
37	9065 HHKB			-	-
38	9099 LZL			-	-
39	9315 CML			-	-
40	9134 WHONP199			-	-
41	9055 H0301			-	-
42	9066 TAB089			-	-
43	9076 T7526			-	-
44	9057 TEM			-	-
45	9239 SHJO			-	-
46	9013 SCHU	*0101		-	+
47	9045 TUBO			-	-
48	9303 TER-ND			-	-

## CERTIFICATE OF ANALYSIS

### **Olerup SSP® DRB5\*0108N SSP**

Product number: 101.812-12 – including *Taq* polymerase  
Lot number: 42G  
Expiry date: 2011-October-01  
Number of tests: 12  
Number of wells per test: 2

#### **Well specifications:**

Well No.	Production No.
1	2008-479-01
2	2009-649-02

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:** 2009-October-19

**Approved by:**

Quality Control, Supervisor

## Declaration of Conformity

**Product name:** *Olerup* SSP® DRB5\*0108N  
**Product number:** 101.812-12  
**Lot number:** 42G

**Intended use:** DRB5\*0108N histocompatibility testing

**Manufacturer:** *Olerup* SSP AB  
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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 9001:2008 and ISO 13485:2003, following the provisions of the 98/79/EC Directive on *in vitro* diagnostic medical devices, Annex II List B, 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.

Notified Body: Lloyd's Register Quality Assurance Limited, Hiramford, Middlemarch Office Village, Siskin Drive, Coventry CV3 4FJ, United Kingdom. (Notified Body number: 0088.)

Saltsjöbaden, Sweden  
2009-October-19

Olle Olerup  
Managing Director

Lot No.: **42G**

Lot-specific information

[www.olerup.com](http://www.olerup.com)

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