Lot No.: 42G **Lot-specific information**

Olerup SSP® DRB5*0108N

Product number:	**101.812-12u – without *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.

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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**

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[1].

[1]DRB5 alleles listed on the IMGT/HLA web page 2009-July-17, release 2.26.0, www.ebi.ac.uk/imgt/hla.

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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[1]	Size of control band[2]	Amplified DRB5 alleles
1	195 bp	**515 bp**	0108N
2	175 bp	430 bp	010101-0113, 0202-0205

[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 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 inherit 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.
[2]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.

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

[1]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.
[2]The 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.
[3]The 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.

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CELL LINE VALIDATION SHEET

DRB5*0108N SSP kit

					Well	
					1	2
				Lot No.:	200847901	200964902
	IHWC 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			-	-

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CERTIFICATE OF ANALYSIS

Olerup SSP® DRB5*0108N SSP

Product number: **101.812-12u – without *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

Lot No.: 42G **Lot-specific information**

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
Hasselstigen 1
SE-133 33 Saltsjöbaden, 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 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**

ADDRESSES:

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