Lot No.: 52F **Lot-specific information**

Olerup SSP® DRA

Product number:	**101.131-24u – without *Taq* polymerase**
Lot number:	**52F**
Expiry date:	**2011-February-01**
Number of tests:	**24**
Number of wells per test:	**2**
Storage - pre-aliquoted primers:	**dark at -20°C**
- PCR Master Mix:	**-20°C**

This Product Description is only valid for Lot No. 52F.

CHANGES COMPARED TO THE PREVIOUS *OLERUP* SSP® DRA LOT

The DRA primer set as well as the specificity and interpretation tables are unchanged compared to the previous *Olerup* SSP® DRA lot **(Lot No. Y51)**.

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PRODUCT DESCRIPTION

DRA SSP typing

CONTENT
The primer set contains 5'- and 3'-primers for identifying the DRA*0101 to DRA*0102 alleles.

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

1	**2**	**empty**	**empty**	**empty**	**empty**	**empty**	**empty**

The 8 well PCR plate is marked with 'DRA' in silver/gray ink.
Well No. 1 is marked with the Lot No. '52F'.
The PCR plates are covered with a PCR-compatible foil.
Please note: When removing each two-well typing, make sure that the remaining plates/wells stay covered. Use a scalpel or a similar instrument to carefully cut the foil between the plates/wells.

INTERPRETATION
Only the DRA alleles will be amplified by the DRA typing kit. Thus, the interpretation of DRA typings is not influenced by the other HLA class II genes.

UNIQUELY IDENTIFIED ALLELES
All the DRA alleles, i.e. **DRA*0101 to DRA*0102**, recognized by the HLA Nomenclature Committee in February 2009[1] will give rise to unique amplification patterns by the primers in the DRA typing kit.
The DRA kit cannot distinguish the DRA*010201 and DRA*010202 alleles.

[1]DRA alleles listed on the IMGT/HLA web page 2009-January-16, release 2.24.0, www.ebi.ac.uk/imgt/hla.

RESOLUTION IN HOMO- AND HETEROZYGOTES
The 2 DRA alleles can be combined in 3 homozygous and heterozygous combinations. These 3 genotypes give rise to unique amplification patterns.

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SPECIFICITY TABLE

DRA SSP typing

Specificities and sizes of the PCR products of the 2 primer mixes used for DRA SSP typing

Primer Mix	Size of spec. PCR product[1]	Size of control band[2]	Amplified DRA alleles
1[3]	65	**515 bp**	0101
2[3]	100	430 bp	010201-010202

[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 DRA SSP subtypings.
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 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 longer, 515 bp, internal positive control band in order to help in the correct orientation of the DRA typing.
In the presence of a specific amplification the intensity of the control band often decreases.
[3]Specific PCR fragments shorter than 125 base pairs are less intense and not as sharp as longer specific bands.

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INTERPRETATION TABLE			
DRA SSP typing			
Amplification patterns of the DRA alleles			
	well		
	1	2	
Length of spec.	65	100	Length of spec.
PCR product			PCR product
Length of int.	515	430	Length of int.
pos. control			pos. control
5'-primer[2]	217	197	5'-primer[2]
	5'-gA g3'	5'-CC C3'	
3'-primer[3]	224	217	3'-primer[3]
	5'-g TT3'	5'-CAA3'	
Well No.	1	2	Well No.
DRA allele			DRA allele
*0101	1		*0101
*010201-010202		2	*010201-010202
DRA allele			DRA allele
Well No.	1	2	Well No.

[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 DRA typing.
[2]The codon, in the 4th exon, matching the specificity-determining 3'-end of the primer is given. Codon numbering as on the 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.
[3]The codon, in the 4th 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 web site. The sequence of the 3 terminal nucleotides of the primer is given. Empty spaces indicate codon boundaries.

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CELL LINE VALIDATION SHEET						
DRA SSP typing kit						
					Well	
					1	2
				Production No.	200855701	200855702
	IHWC cell line		DRA			
1	9001	SA	*0101		+	-
2	9280	LK707	*0101		+	-
3	9011	E4181324	*0101		+	-
4	9275	GU373	*0101		+	-
5	9009	KAS011	*0101		+	-
6	9359	SM	*0102		-	+
7	9020	QBL	*0101		+	-
8	9007	DEM	*0102		-	+
9	9026	YAR	*0101		+	-
10	9107	LKT3	*0101		+	-
11	9051	PITOUT	*0101		+	-
12	9052	DBB	*0101		+	-
13	9067	BTB	*0102		-	+
14	9071	OLGA	*0102		-	+
15	9075	DKB	*0101	*0102	+	+
16	9037	SWEIG007	*0101		+	-
17	9008	WILJON	*0102		-	+
18	9257	32367	*0102		-	+
19	9038	BM16	*0101		+	-
20	9059	SLE005	*0101		+	-
21	9064	AMALA	*0101		+	-
22	9056	KOSE	*0102		-	+
23	9124	IHL	*0101	*0102	+	+
24	9035	JBUSH	*0101		+	-
25	9049	IBW9	*0101		+	-
26	9285	WT49	*0101	*0102	+	+
27	9191	CH1007	*0102		-	+
28	9320	BEL5GB	*0101		+	-
29	9050	MOU	*0101		+	-
30	9021	RSH	*0101	*0102	+	+
31	9019	DUCAF	*0101		+	-
32	9297	HAG	*0101		+	-
33	9098	MT14B	*0101		+	-
34	9104	DHIF	*0101		+	-
35	9302	SSTO	*0101		+	-
36	9024	KT17	*0101		+	-
37	9065	HHKB	*0102		-	+
38	9099	LZL	*0102		-	+
39	9315	CML	*0101		+	-
40	9062	WDV	*0101		+	-
41	9055	H0301	*0102		-	+
42	9066	TAB089	*0101	*0102	+	+
43	9076	T7526	*0102		-	+
44	9057	TEM	*0102		-	+
45	9239	SHJO	*0102		-	+
46	9013	SCHU	*0101	*0102	+	+
47	9045	TUBO	*0102		-	+
48	9303	TER-ND	*0101		+	-

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CERTIFICATE OF ANALYSIS

Olerup SSP® DRA SSP

Product number: **101.131-24u – without Taq polymerase**
Lot number: **52F**
Expiry date: **2011-February-01**
Number of tests: **24**
Number of wells per test: **2**

Well specifications:

Well No.	Production No.
1	2008-557-01
2	2008-557-02

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-May-25

Approved by:

Quality Control, Supervisor

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Declaration of Conformity

Product name: *Olerup* SSP® DRA
Product number: 101.131-24u
Lot number: 52F

Intended use: DRA high resolution 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 9001:2000 and ISO 13485:2003, following the provisions of the 98/79/EC Directive on *in vitro* diagnostic medical devices, Annex II List B, conformity assessed using Annex IV, 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-May-25

Olle Olerup
Managing Director

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