

101.813-12 – including *Taq* polymerase, IFU-01 Rev. No. 03
101. 813-12u – without *Taq* polymerase, IFU-02 Rev. No. 03

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“Instructions for Use” (IFU)

Lot No.: **45N**

Lot-specific information

Olerup SSP[®] DRB1*14:01/14:54

Product number:	101.813-12– including <i>Taq</i> pol. 101.813-12u– without <i>Taq</i> pol.
Lot number:	45N
Expiry date:	2014-August-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. 45N.

The DRB1*14:01/14:54 specificity and interpretation tables have been updated compared to the previous *Olerup SSP[®]* DRB1*14:01/14:54 lot (Lot No. **12L**).

The Lot-specific information for DRB1*14:01/14:54 including and without *Taq* polymerase is now described in one common Product Insert.

The DRB1*14:01/14:54 primer set is unchanged compared to the previous lot.

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PRODUCT DESCRIPTION

DRB1*14:01/14:54 SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for separating the DRB1*14:01 and DRB1*14:54 alleles.

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 '45N' in silver/gray ink.

Well No. 1 is marked with the Lot No. '45N'.

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

The interpretation of DRB1*14:01/14:54 PCR-SSP subtypings will be influenced by five DRB1*11 alleles as well as by many DRB1*14 alleles.

UNIQUELY IDENTIFIED ALLELES

The DRB1*14:01 and DRB1*14:54 alleles give different patterns in the DRB1*14:01/14:54 subtyping kit.

The DRB1*14:01/14:54 subtyping kit cannot distinguish the following silent mutations: the DRB1*14:01:01-14:01:03 alleles.

¹DRB alleles listed on the IMGT/HLA web page 2012-January-12, release 3.7.0, www.ebi.ac.uk/imgt/hla.

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SPECIFICITY TABLE

DRB1*14:01/14:54 SSP subtyping

Specificities and sizes of the PCR products of the 2 primer mixes used for DRB1*14:01/14:54 SSP subtyping

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified DRB1*14:01/14:54 alleles	Other amplified DRB alleles ^{3,4}
1	250 bp	515 bp	*14:01:01-14:01:03	
2	210 bp	430 bp	*14:54	*11:13:01-11:13:02, 11:17, 11:52, 11:89, 14:01:01-14:01:03, 14:05:01-14:05:03, 14:07:01-14:08, 14:14, 14:18, 14:23:01-14:23:03, 14:26, 14:32:01-14:32:02, 14:34-14:36, 14:38-14:39, 14:42-14:45, 14:55 ^w , 14:56, 14:58-14:60, 14:62, 14:64-14:65, 14:70, 14:72, 14:75, 14:81-14:82, 14:86-14:88, 14:90-14:92N, 14:95-14:97, 14:99-14:101, 14:103, 14:110, 14:112-14:114, 14:117-14:118, 14:122

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 DRB1*14 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 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 two different control primer pairs give rise to an internal positive control band of either 430 or 515 base pairs.

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 DRB1*14:01/14:54 subtyping.

In the presence of a specific amplification the intensity of the control band often decreases.

³Due to the sharing of sequence motifs five DRB1*11 alleles as well as many DRB1*14 alleles are amplified by the DRB1*14:01/14:54 primer mixes.

⁴For several DRB alleles only partial nucleotide sequences from the second exon are available. In these instances it is not known whether some of the primers of the SSP set are completely matched with the target sequences or not. We assume that unknown sequences in the first hyperpolymorphic region of the second exon of DRB alleles are conserved within allelic groups and that unknown sequences of codons 87 to 92 are identical with the DRB1*01:01 consensus sequence.

'w', might be weakly amplified.

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INTERPRETATION TABLE		
DRB1*14:01/14:54 SSP typing		
	Well	
	1	2
Length of spec.	250	210
PCR product		
Length of int.	515	430
pos. control¹		
5'-primer(s)²	112(421)	13(125)
	5' -ACT 3'	5' -gTC 3'
3'-primer(s)³	181(630)	70(296)
	5' -CTT 3'	5' -TCC 3'
Well No.	1	2
DRB1 allele⁴		
*14:01:01-14:01:03	1	2
*14:54		2
*11:13:01-11:13:02, 11:17, 11:52, 11:89, 14:05:01-14:05:03, 14:07:01-14:08, 14:14, 14:18, 14:23:01-14:23:03, 14:26, 14:32:01-14:32:02, 14:34-14:36, 14:38-14:39, 14:42-14:45, 14:56, 14:58-14:60, 14:62, 14:64-14:65, 14:70, 14:72, 14:75, 14:81-14:82, 14:86-14:88, 14:90-14:92N, 14:95-14:97, 14:99-14:101, 14:103, 14:110, 14:112-14:114, 14:117-14:118, 14:122		2
*14:55		w
DRB1 allele		
Well No.	1	2

¹The internal positive control primer pairs amplify segments of the human growth hormone gene. The two different control primer pairs give rise to an internal positive control band of either 430 or 515 base pairs.

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 DRB1*14:01/14:54 subtyping.

²The codon, and in parenthesis the nucleotide, in the 2nd and 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.

³The codon, and in parenthesis the nucleotide, in the 2nd and 3rd 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 DRB1*1466 allele has been renamed to DRB1*14:32:02

'w', might be weakly amplified.

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CELL LINE VALIDATION SHEET						
DRB1*14:01/14:54 SSP subtyping kit						
						Well
						1 2
						Prod. No.:
						201182901
						201182902
IHWC cell line			DRB1			
1	9001	SA	*01:01		-	-
2	9280	LK707	*15:02	*04:05	-	-
3	9011	E4181324	*15:02		-	-
4	9275	GU373	*03:01		-	-
5	9009	KAS011	*16:01		-	-
6	9353	SM	*04:07	*08:03	-	-
7	9020	QBL	*03:01		-	-
8	9025	DEU	*04:01		-	-
9	9026	YAR	*04:02		-	-
10	9107	LKT3	*04:05		-	-
11	9051	PITOUT	*07:01		-	-
12	9052	DBB	*07:01		-	-
13	9004	JESTHOM	*01:01		-	-
14	9071	OLGA	*08:02		-	-
15	9075	DKB	*09:01		-	-
16	9037	SWEIG007	*11:01		-	-
17	9282	CTM3953540	*03:01	*13:01	-	-
18	9257	32367	*09:01	*11:01	-	-
19	9038	BM16	*12:01		-	-
20	9059	SLE005	*13:02		-	-
21	9064	AMALA	*14:02		-	-
22	9056	KOSE	*13:02	*14:54	-	+
23	9124	IHL	*08:03	*14:14	-	+
24	9035	JBUSH	*11:01		-	-
25	9049	IBW9	*07:01		-	-
26	9285	WT49	*03:01		-	-
27	9191	CH1007	*04:05	*10:01	-	-
28	9320	BEL5GB	*04:16	*07:01	-	-
29	9050	MOU	*07:01		-	-
30	9021	RSH	*03:02		-	-
31	9019	DUCAF	*03:01		-	-
32	9297	HAG	*13:03		-	-
33	9098	MT14B	*04:04		-	-
34	9104	DHIF	*11:01		-	-
35	9302	SSTO	*04:03		-	-
36	9024	KT17	*04:03	*04:06	-	-
37	9065	HHKB	*13:01		-	-
38	9099	LZL	*14:02		-	-
39	9315	CML	*03:01	*04:01	-	-
40	9134	WHONP199	*07:01	*09:01	-	-
41	9055	H0301	*13:02		-	-
42	9066	TAB089	*08:03		-	-
43	9076	T7526	*09:01		-	-
44	9057	TEM	*14:01		+	+
45	9239	SHJO	*07:01		-	-
46	9013	SCHU	*15:01		-	-
47	9045	TUBO	*11:04	*12:01	-	-
48	9303	TER-ND	*01:03		-	-

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CERTIFICATE OF ANALYSIS

Olerup SSP® DRB1*14:01/14:54 SSP

Product number: 101.813-12– including *Taq* pol.
101.813-12u– without *Taq* pol.
Lot number: 45N
Expiry date: 2014-August-01
Number of tests: 12
Number of wells per test: 2

Well specifications:

Well No.	Production No.
1	2011-829-01
2	2011-829-02

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: 2012-March-09

Approved by:

Production Quality Control

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Lot-specific information

Declaration of Conformity

Product name: *Olerup* SSP® DRB1*14:01/14:54
Product number: 101.813-12
Lot number: 45N

Intended use: DRB1*14:01/14:54 high resolution histocompatibility testing

Manufacturer: *Olerup* SSP AB
Franzengatan 5
SE-112 51 Stockholm, Sweden
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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, 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, Franzengatan 5, SE-112 51 Stockholm, Sweden.

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

Stockholm, Sweden
2012-March-09

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs

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