

101.811-12 – including *Taq* polymerase, IFU-01 Rev. No. 03101.811-12u – without *Taq* polymerase, IFU-02 Rev. No. 03Visit www.olerup-ssp.com for

“Instructions for Use” (IFU)

Lot No.: **43N**

Lot-specific information

Olerup SSP[®] DRB4*01:03:01:02N

Product number:	101.811-12 – including <i>Taq</i> polymerase 101.811-12u – without <i>Taq</i> polymerase
Lot number:	43N
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. 43N.

The DRB4*01:03:01:02N specificity and interpretation tables have been updated compared the previous *Olerup SSP[®]* DRB4*01:03:01:02N lot (**Lot No. 93K**).

The Lot-specific information for DRB4*01:03:01:02N including and without *Taq* polymerase is now described in one common Product Insert.

The DRB4*01:03:01:02N primer set is unchanged compared to the previous lot.

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PRODUCT DESCRIPTION

DRB4*01:03:01:02N SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for identifying the DRB4*01:03:01:02N 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. '43N' in silver/gray ink.

Well No. 1 is marked with the Lot No. '43N'.

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 DRB4*01:03:01:02N SSP subtypings will be influenced by most other DRB4 alleles.

UNIQUELY IDENTIFIED ALLELES

The DRB4*01:03:01:02N allele will give rise to a unique amplification pattern by the primers in the DRB4*01:03:01:02N kit¹.

¹DRB4 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**DRB4*01:03:01:02N SSP subtyping**

Specificities and sizes of the PCR products of the 2 primer mixes used for DRB4*01:03:01:02N SSP subtyping

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified DRB4 alleles ³
1	155 bp	515 bp	*01:03:01:02N
2	245 bp	430 bp	*01:01:01:01-01:03:01:01, 01:03:01:03-01:04, 01:05 [?] , 01:06-01:08, 02:01N

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 DRB4*01:03:01:02N 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.

²The 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 DRB4*01:03:01:02N subtyping.

³For 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.

‘?’, the nucleotide sequence of the primer matching region is not known.

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INTERPRETATION TABLE		
DRB4*01:03:01:02N SSP typing		
	Well	
	1	2
Length of spec.	155	245
PCR product		
Length of int.	515	430
pos. control¹		
5'-primer(s)²	1st I⁴	1st I⁵
	5' -CAA 3'	5' -ggg 3'
3'-primer(s)³	42(213)	5⁶
	5' -TCA 3'	5' -TgC 3'
Well No.	1	2
DRB4 allele		
*01:03:01:02N	1	
*01:01:01:01-01:03:01:01, 01:03:01:03-01:04, 01:06-01:08, 02:01N		2
*01:05		?
DRB4 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 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 DRB4 subtyping.

²The codon, and in parenthesis the nucleotide, in the 2nd exon or 1st intron, 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 exon or 1st intron, 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.

⁴Matching the sequence of the 3'-end of the 1st intron.

⁵Matching sequences within the 1st intron.

⁶Matching sequences from the 3'-end of the 1st intron into the 5'-end of the 2nd exon.

‘?’, the nucleotide sequence of the primer matching region is not known.

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Lot-specific information

CELL LINE VALIDATION SHEET					
DRB4*01:03:01:02N SSP kit					
					Well
					1 2
					200847701 200847702
IHC cell line		DRB4			
1	9001 SA			-	-
2	9280 LK707	*01:03		-	+
3	9011 E4181324			-	-
4	9275 GU373			-	-
5	9009 KAS011			-	-
6	9353 SM	*01:03		-	+
7	9020 QBL			-	-
8	9025 DEU	*01:01		-	+
9	9026 YAR	*01:03		-	+
10	9107 LKT3	*01:03		-	+
11	9051 PITOUT	*01:01		-	+
12	9052 DBB	*01:03N		+	-
13	9004 JESTHOM			-	-
14	9071 OLGA			-	-
15	9075 DKB	*01:03		-	+
16	9037 SWEIG007			-	-
17	9282 CTM3953540			-	-
18	9257 32367	*01:01		-	+
19	9038 BM16			-	-
20	9059 SLE005			-	-
21	9064 AMALA			-	-
22	9056 KOSE			-	-
23	9124 IHL			-	-
24	9035 JBUSH			-	-
25	9049 IBW9	*01:01		-	+
26	9285 WT49			-	-
27	9191 CH1007	*01:03		-	+
28	9320 BEL5GB	*01:01		-	+
29	9050 MOU	*01:01		-	+
30	9021 RSH			-	-
31	9019 DUCAF			-	-
32	9297 HAG			-	-
33	9098 MT14B	*01:03		-	+
34	9104 DHIF			-	-
35	9302 SСТО	*01:03		-	+
36	9024 KT17	*01:03		-	+
37	9065 HHKB			-	-
38	9099 LZL			-	-
39	9315 CML	*01:02		-	+
40	9134 WHONP199	*01:03		-	+
41	9055 H0301			-	-
42	9066 TAB089			-	-
43	9076 T7526	*01:03		-	+
44	9057 TEM			-	-
45	9239 SHJO	*01:01	*01:03	-	+
46	9013 SCHU			-	-
47	9045 TUBO			-	-
48	9303 TER-ND			-	-

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CERTIFICATE OF ANALYSIS

Olerup SSP® DRB4*01:03:01:02N SSP

Product number: 101.811-12 – including *Taq* polymerase
101.811-12u – without *Taq* polymerase
Lot number: 43N
Expiry date: 2014-August-01
Number of tests: 12
Number of wells per test: 2

Well specifications:

Well No.	Production No.
1	2008-477-01
2	2008-477-02

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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Declaration of Conformity

Product name: Olerup SSP® DRB4*01:03:01:02N
Product number: 101.811-12
Lot number: 43N

Intended use: DRB4*01:03:01:02N histocompatibility testing

Manufacturer: Olerup SSP AB
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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, 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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