

101.123-24/06 – including *Taq* polymerase, IFU-01 Rev. No. 03
101.123-24u/06u – without *Taq* polymerase, IFU-02 Rev. No. 03

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“Instructions for Use” (IFU)

Lot No.: **35N**

Lot-specific information
Olerup SSP[®] DRB5

Product number:	101.123-24/06 – including <i>Taq</i> pol. 101.123-24u/06u – without <i>Taq</i> pol.
Lot number:	35N
Expiry date:	2014-August-01
Number of tests:	24 test – Product No. 101.123-24/24u 6 tests – Product No. 101.123-06/06u
Number of wells per test:	16
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. 35N.

CHANGES COMPARED TO THE PREVIOUS OLERUP SSP[®] DRB5 LOT

The DRB5 specificity and interpretation tables have been updated for the HLA-DRB alleles described since the previous *Olerup SSP[®] DRB5* lot was made (**Lot No. 14M**).

The Lot-specific information for DRB5 including and without *Taq* polymerase is now described in one common Product Insert.

The DRB5 primer set is unchanged compared to the previous lot.

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PRODUCT DESCRIPTION

DRB5 SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for identifying the DRB5*01:01 to DRB5*01:14 and the DRB5*02:02 to DRB5*02:05 alleles.

PLATE LAYOUT

Each test consists of 16 PCR reactions in a 16 well cut PCR plate.

1	2	3	4	5	6	7	8
9	10	11	12	13	14	15	16

The 16 well cut PCR plate is marked with 'DRB5' in silver/gray ink.

Well No. 1 is marked with the Lot No. '35N'.

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 16 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

Only alleles of the DRB5 locus will be amplified by the DRB5 subtyping kit, except that the DRB1*09:07 allele will be amplified by primer mixes 1, 2, 3 and 15.

UNIQUELY IDENTIFIED ALLELES

All the DRB5 alleles, i.e. **DRB5*01:01 to DRB5*01:14 and DRB5*02:02 to DRB5*02:05**, recognized by the HLA Nomenclature Committee in January 2012¹ will give rise to unique amplification patterns by the primers in the DRB5 subtyping kit.

¹DRB5 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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RESOLUTION IN HOMO- AND HETEROZYGOTES

A total of 19 alleles generate 19 amplification patterns that can be combined in 190 homozygous and heterozygous combinations. 67 of these genotypes do not give rise to unique amplification patterns. The different lengths of the specific PCR products were not considered in these calculations.

++++++--	----	*01:05, *01:06 = *01:05, *01:11
++++++--	----	*01:01:01, *01:05 = *01:01:02, *01:05
++++++--	----	*01:06, *01:13 = *01:11, *01:13
++++++--	----	*01:06, *01:07 = *01:07, *01:11 = *01:07, *02:03
++++++--	----	*01:06, *01:09 = *01:09, *01:11 = *01:09, *02:03
++++++--	----	*01:01:01, *01:06 = *01:01:01, *01:11 = *01:01:01, *02:03
++++++--	----	*01:04, *01:07 = *01:07, *01:13
++++++--	----	*01:04, *01:09 = *01:09, *01:13
++++++--	----	*01:01:01, *01:04 = *01:01:01, *01:13 = *01:01:02, *01:13 = *01:04, *01:13
++++++--	----	*01:07, *01:09 = *01:07, *01:14
++++++--	----	*01:01:01, *01:12 = *01:07, *01:12
++++++--	----	*01:01:01, *01:07 = *01:01:02, *01:07 = *01:07, *01:07
++++++--	----	*01:01:01, *01:09 = *01:01:01, *01:14 = *01:01:02, *01:09 = *01:09, *01:09 = *01:09, *01:14
++++++--	----	*01:01:01, *01:01:01 = *01:01:01, *01:01:02
++++++--	----	*01:06, *01:08N = *01:08N, *01:11
++++++--	----	*01:06, *01:10N = *01:10N, *01:11
++++++--	----	*01:02, *01:06 = *01:02, *01:11
++++++--	----	*01:04, *01:06 = *01:04, *01:11 = *01:04, *02:03
++++++--	----	*01:06, *01:12 = *01:11, *01:12
++++++--	----	*01:06, *01:14 = *01:11, *01:14
++++++--	----	*01:01:02, *01:06 = *01:01:02, *01:11 = *01:01:02, *02:03
++++++--	----	*01:01:02, *01:04 = *01:04, *01:04
++++++--	----	*01:02, *01:12 = *01:10N, *01:12
++++++--	----	*01:02, *01:08N = *01:08N, *01:08N
++++++--	----	*01:02, *01:10N = *01:10N, *01:10N
++++++--	----	*01:03, *01:06 = *01:03, *01:11
++++++--	----	*01:06, *01:11 = *01:06, *02:03 = *01:11, *01:11 = *01:11, *02:03

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Lot-specific information

SPECIFICITY TABLE

DRB5 SSP subtyping

Specificities and sizes of the PCR products of the 16 primer mixes used for DRB5 SSP subtyping

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified DRB5 ³ alleles	Other amplified DRB alleles ⁴
1	255 bp	515 bp	*01:01:01-01:05, 01:07-01:14, 02:03	DRB1*09:07
2	210 bp	515 bp	*01:01:01-01:05, 01:07-01:10N, 01:12-01:14, 02:04	DRB1*09:07
3⁶	225 bp	430 bp	*01:01:01-01:02, 01:04-01:05, 01:07-01:10N, 01:12-01:14, 02:05	DRB1*09:07
4⁵	100 bp	430 bp	*01:01:01-01:01:02, 01:04, 01:06-01:07, 01:09, 01:11	
5	150 bp	515 bp	*01:01:01, 01:05, 01:07, 01:09, 01:13	
6	145 bp	430 bp	*01:02-01:03, 01:05, 01:08N, 01:10N	
7	150 bp	430 bp	*01:02-01:03, 01:08N, 01:10N	
8	215 bp	430 bp	*01:03, 01:06, 01:11, 02:02-02:04	
9⁷	175 bp, 225 bp	430 bp	*01:04, 01:13	
10⁸	130 bp, 160 bp	430 bp	*01:07, 01:12	
11	200 bp	430 bp	*01:06, 01:11, 02:02-02:03	
12	185 bp	515 bp	*02:02, 02:04-02:05	
13	195 bp	430 bp	*01:08N	
14^{5,9}	110 bp, 210 bp	430 bp	*01:09, 01:14	
15	240 bp	430 bp	*01:10N, 01:12	DRB1*09:07
16	140 bp	430 bp	*02:05	

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Lot No.: 35N**Lot-specific information**

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 DRB5 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 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 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.

In addition, wells number 2, 5 and 12 contain the primer pair giving rise to the longer, 515 bp, internal positive control band in order to allow kit identification.

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

³For several DRB alleles only second exon nucleotide sequences are available. In these instances it is not known whether some of the primers of the SSP sets 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.

⁴Due to the sharing of sequence motifs between DRB alleles the DRB1*09:07 allele will be amplified by primer mixes 1, 2, 3 and 15.

⁵Specific PCR fragments shorter than 125 base pairs are less intense and not as sharp as longer specific bands.

⁶Primer mix 3 frequently gives rise to an extra band longer than the control band. This band should be disregarded in the interpretation of DRB5 SSP typings.

⁷Primer mix 9: Specific PCR fragment of 175 bp in the DRB5*01:13 allele. Specific PCR fragment of 225 bp in the DRB5*01:04 allele.

⁸Primer mix 10: Specific PCR fragment of 130 bp in the DRB5*01:07 allele. Specific PCR fragment of 160 bp in the DRB5*01:12 allele.

⁹Primer mix 14: Specific PCR fragment of 110 bp in the DRB5*01:14 allele. Specific PCR fragment of 210 bp in the DRB5*01:09 allele.

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Lot-specific information

INTERPRETATION TABLE								
DRB5 SSP subtyping								
Amplification patterns of DRB5*01:01 to 02:05 alleles								
	Well⁵							
	1	2	3	4	5	6	7	8
Length of spec. PCR product(s)	255	210	225	100	150	145	150	215
Length of int.	515	515	430	430	515	430	430	430
pos. control¹								
5'-primer(s)²	13(125)	13(125)	13(125)	38(199)	37(196)	38(199)	37(196)	13(125)
	5' -gTA 3'	5' -gTA 3'	5' -gTA 3'	5' -ACT 3'	5' -Agg 3'	5' -ACg 3'	5' -AgA 3'	5' -gTA 3'
						38(199)		
						5' -ACg 3'		
3'-primer(s)³	85(341)	67(286)	71(299)	57(258)	72(303)	72(303)	72(303)	71(299)
	5' -CAA 3'	5' -gAA 3'	5' -gCC 3'	5' -gCg 3'	5' -gCg 3'	5' -gCg 3'	5' -gCg 3'	5' -gCg 3'
		67(286)	74(307)					71(299)
		5' -gAA 3'	5' -CAg 3'					5' -gCg 3'
		70(296)	78(319)					
		5' -TCC 3'	5' -CAC 3'					
		72(303)						
		5' -gCg 3'						
Well No.	1	2	3	4	5	6	7	8
DRB5 allele⁴								
*01:01:01	1	2	3	4	5			
*01:01:02	1	2	3	4				
*01:02	1	2	3			6	7	
*01:03	1	2				6	7	8
*01:04	1	2	3	4				
*01:05	1	2	3		5	6		
*01:06				4				8
*01:07	1	2	3	4	5			
*01:08N	1	2	3			6	7	
*01:09	1	2	3	4	5			
*01:10N	1	2	3			6	7	
*01:11	1			4				8
*01:12	1	2	3					
*01:13	1	2	3		5			
*01:14	1	2	3					
Well No.	1	2	3	4	5	6	7	8

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INTERPRETATION TABLE								
DRB5 SSP subtyping								
Amplification patterns of DRB5*01:01 to 02:05 alleles								
Well⁵								
9	10	11	12	13	14	15	16	
175	130	200	185	195	110	240	140	Length of spec.
225	160				210			PCR product(s)
430	430	430	515	430	430	430	430	Length of int.
								pos. control¹
13(125)	38(199)	13(125)	37(196)	108(409)	13(125)	13(125)	37(196)	5'-primer(s)²
5' -gTA 3'	5' -ACT 3'	5' -gTA 3'	5' -AgA 3'	5' -AgA 3'	5' -gTA 3'	5' -gTA 3'	5' -AgA 3'	
58(260)	67(286)	67(286)	85(341)	160(565)	37(196)	78(319)	70(295)	3'-primer(s)³
5' -CCT 3'	5' -gAT 3'	5' -gAT 3'	5' -CAg 3'	5' -CAT 3'	5' -gTA 3'	5' -CAC 3'	5' -CTg 3'	
74(307)	78(319)				70(295)	79(323)		
5' -CAg 3'	5' -CAC 3'				5' -gTT 3'	5' -TgC 3'		
9	10	11	12	13	14	15	16	Well No.
								DRB5 allele⁴
								*01:01:01
								*01:01:02
								*01:02
								*01:03
9								*01:04
								*01:05
		11						*01:06
	10							*01:07
				13				*01:08N
					14			*01:09
						15		*01:10N
		11						*01:11
	10					15		*01:12
9								*01:13
					14			*01:14
9	10	11	12	13	14	15	16	Well No.

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Length of spec.	255	210	225	100	150	145	150	215
PCR product(s)								
Well No.	1	2	3	4	5	6	7	8
*02:02								8
*02:03	1							8
*02:04		2						8
*02:05			3					
DRB1*09:07	1	2	3					
Well No.	1	2	3	4	5	6	7	8

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 DRB5 subtyping.

In addition, wells number 2, 5 and 12 contain the primer pair giving rise to the longer, 515 bp, internal positive control band in order to allow kit identification.

²The 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.

³The codon, and in parenthesis the nucleotide, in the 2nd or 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.

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175	130	200	185	195	110	240	140	Length of spec.
225	160				210			PCR product(s)
9	10	11	12	13	14	15	16	Well No.
		11	12					*02:02
		11						*02:03
			12					*02:04
			12				16	*02:05
						15		<i>DRB1*09:07</i>
9	10	11	12	13	14	15	16	Well No.

⁴The DRB5*0201 allele has been shown to be identical to DRB5*02:02.

⁵Primer mix 9: Specific PCR fragment of 175 bp in the DRB5*01:13 allele. Specific PCR fragment of 225 bp in the DRB5*01:04 allele.

Primer mix 10: Specific PCR fragment of 130 bp in the DRB5*01:07 allele. Specific PCR fragment of 160 bp in the DRB5*01:12 allele.

Primer mix 14: Specific PCR fragment of 110 bp in the DRB5*01:14 allele. Specific PCR fragment of 210 bp in the DRB5*01:09 allele.

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CELL LINE VALIDATION SHEET			
DRB5 SSP subtyping kit			
			Well
			1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16
		Prod. No.:	201297401 201297402 201297403 201297404 201297405 201297406 201297407 201297408 201297409 201297410 201297411 201297412 201297413 201297414 201297415 201297416
	IHWC cell line	DRB5	
1	9001 SA		- - - - - - - - - - - - - - - -
2	9280 LK707	*01:02	+ + + - - + + - - - - - - - -
3	9011 E4181324	*01:02	+ + + - - + + - - - - - - - -
4	9275 GU373		- - - - - - - - - - - - - - - -
5	9009 KAS011	*02:02	- - - - - - - - + - - + + - - - -
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	*01:01	+ + + + + - - - - - - - - - -
47	9045 TUBO		- - - - - - - - - - - - - - - -
48	9303 TER-ND		- - - - - - - - - - - - - - - -

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Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP® DRB5 SSP

Product number: 101.123-24/06 – including *Taq* pol.
101.123-24u/06u – without *Taq* pol.
Lot number: 35N
Expiry date: 2014-August-01
Number of tests: 24 test – Product No. 101.123-24/24u
6 tests – Product No. 101.123-06/06u
Number of wells per test: 16

Well specifications:

Well No.	Production No.	Well No.	Production No.
1	2012-974-01	9	2012-974-09
2	2012-974-02	10	2012-974-10
3	2012-974-03	11	2012-974-11
4	2012-974-04	12	2012-974-12
5	2012-974-05	13	2012-974-13
6	2012-974-06	14	2012-974-14
7	2012-974-07	15	2012-974-15
8	2012-974-08	16	2012-974-16

The specificity of each primer solution of the kit has been tested against 48 well characterized IHWC cell line DNAs.

No DNAs carrying the alleles to be amplified by primer solutions 9, 10 and 14 to 16 were available. The specificities of the primers in primer solutions 9, 10 and 14 to 16 were tested by separately adding one additional 5'-primer, respectively one or two additional 3'-primer(s). In primer solutions 2, 14 and 15 one 3'-primer was not possible to test. Additional 3'-primers in primer solutions 2 and 3 were tested by separately adding additional 5'-primers.

Results: No false positive or false negative amplifications were obtained.

Date of approval: 2012-February-10

Approved by:

Production Quality Control

101.123-24/06 – including *Taq* polymerase, IFU-01 Rev. No. 03
101.123-24u/06u – without *Taq* polymerase, IFU-02 Rev. No. 03

Visit www.olerup-ssp.com for
“Instructions for Use” (IFU)

Lot No.: **35N**

Lot-specific information

Declaration of Conformity

Product name: *Olerup* SSP® DRB5
Product number: 101.123-24/06, -24u/06u
Lot number: 35N

Intended use: DRB5 high resolution histocompatibility testing

Manufacturer: *Olerup* SSP AB
Franzengatan 5
SE-112 51 Stockholm, 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, 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-February-10

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs

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For information on *Olerup* SSP distributors worldwide, contact **Olerup GmbH**.