101.123-24/06 – including *Taq* polymerase, IFU-01
101.123-24u/06u – without *Taq* polymerase, IFU-02

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Lot No.: 49R

Lot-specific information

Olerup SSP® DRB5

Product number:	**101.123-24/06 – including *Taq* pol.** **101.123-24u/06u – without *Taq* pol.**
Lot number:	**49R**
Expiry date:	**2015-May-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. 49R.

CHANGES COMPARED TO THE PREVIOUS *OLERUP* SSP® DRB5 LOT(35N)

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. 35N)**.

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

The primers of the wells detailed below have been exchanged, added or modified compared to the previous lot.

Well	5'-primer	3'-primer	rationale
4	Added	Added	Primer pair added for the DRB5*02:06 allele.

101.123-24/06 – including *Taq* polymerase, IFU-01
101.123-24u/06u – without *Taq* polymerase, IFU-02

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Lot No.: 49R **Lot-specific information**

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*02:06 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. '49R'.
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*02:06**, recognized by the HLA Nomenclature Committee in July 2012[1] will give rise to unique amplification patterns by the primers in the DRB5 subtyping kit.

[1]DRB5 alleles listed on the IMGT/HLA web page 2012-July-12, release 3.9.0, www.ebi.ac.uk/imgt/hla.

Lot No.: 49R **Lot-specific information**

RESOLUTION IN HOMO- AND HETEROZYGOTES

A total of 20 alleles generate 20 amplification patterns that can be combined in 210 homozygous and heterozygous combinations. 88 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.

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

101.123-24/06 – including *Taq* polymerase, IFU-01
101.123-24u/06u – without *Taq* polymerase, IFU-02

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Lot No.: 49R

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**
3[6]	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**
4[5,7,8]	100 bp, 150 bp	430 bp	*01:01:01-01:01:02, 01:04, 01:06-01:07, 01:09, 01:11, 02:06	
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, 02:06	
9[9]	175 bp, 225 bp	430 bp	*01:04, 01:13	
10[10]	130 bp, 160 bp	430 bp	*01:07, 01:12	
11	200 bp	430 bp	*01:06, 01:11, 02:02-02:03, 02:06	
12	185 bp	**515 bp**	*02:02, 02:04-02:06	
13	195 bp	430 bp	*01:08N	
14[5,11]	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	

101.123-24/06 – including *Taq* polymerase, IFU-01
101.123-24u/06u – without *Taq* polymerase, IFU-02

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Lot No.: 49R **Lot-specific information**

[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 SSP subtypings.
When the primers in a primer mix can give rise to HLA-specific PCR products of more than one length this is indicated if the size difference is more than 20 base pairs. Size differences of 20 base pairs or less are not given. For high resolution SSP kits the respective lengths of the HLA-specific PCR product(s) are given for the alleles amplified by these primer mixes.
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 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.
[3]For several DRB alleles 1st and/or 3rd exon(s) and above, as well as intron nucleotide sequences, are not 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 these regions are conserved within allelic groups and that unknown sequences of codons 87 to 92 are identical with the DRB1*01:01 consensus sequence.
[4]Due 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.
[5]HLA-specific PCR products shorter than 125 base pairs have a lower intensity and are less sharp than longer PCR products.
[6]Primer 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.
[7]Primer mix 4 has a tendency to giving rise to primer oligomer formation.
[8]Primer mix 4: Specific PCR fragment of 100 bp in the DRB5*01:01:01-01:01:02, 01:04, 01:06-01:07, 01:09 and 01:11 alleles. Specific PCR fragment of 150 bp in the DRB5*02:06 allele.
[9]Primer 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.
[10]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.
[11]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.

101.123-24/06 – including *Taq* polymerase, IFU-01
101.123-24u/06u – without *Taq* polymerase, IFU-02

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Lot No.: 49R **Lot-specific information**

INTERPRETATION TABLE

DRB5 SSP subtyping

Amplification patterns of DRB5*01:01 to 02:06 alleles

	Well[5]							
	1	2	3	4	5	6	7	8
Length of spec.	255	210	225	100	150	145	150	215
PCR product(s)				150				
Length of int.	515	515	430	430	515	430	430	430
pos. control[1]								
5'-primer(s)[2]	13(125)	13(125)	13(125)	37(199)	36(196)	37(199)	36(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'
				97(379)		37(199)		
				5' -CTg 3'		5' -ACg 3'		
3'-primer(s)[3]	85(341)	66(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'
		66(286)	73(307)	134(490)				71(299)
		5' -gAA 3'	5' -CAg 3'	5' -gCC 3'				5' -gCg 3'
		70(296)	77(319)					
		5' -TCC 3'	5' -CAC 3'					
		72(303)						
		5' -gCg 3'						
Well No.	1	2	3	4	5	6	7	8
DRB5 allele[4]								
*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

101.123-24/06 – including *Taq* polymerase, IFU-01
101.123-24u/06u – without *Taq* polymerase, IFU-02

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Lot No.: 49R **Lot-specific information**

INTERPRETATION TABLE

DRB5 SSP subtyping

Amplification patterns of DRB5*01:01 to 02:06 alleles

Well[5]								
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. control[1]
13(125)	37(199)	13(125)	36(196)	107(409)	13(125)	13(125)	36(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)	66(286)	66(286)	85(341)	159(565)	36(196)	77(319)	69(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'	
73(307)	77(319)				69(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 allele[4]
								*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.

101.123-24/06 – including *Taq* polymerase, IFU-01
101.123-24u/06u – without *Taq* polymerase, IFU-02

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Lot No.: 49R **Lot-specific information**

Length of spec.	**255**	**210**	**225**	**100**	**150**	**145**	**150**	**215**
PCR product(s)				**150**				
Well No.	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**
***02:02**								**8**
***02:03**	**1**							**8**
***02:04**		**2**						**8**
***02:05**			**3**					
***02:06**				**4**				**8**
DRB1*09:07	**1**	**2**	**3**					
Well No.	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**

[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.
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.
[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 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.

Lot No.: 49R **Lot-specific information**

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
		11	12					*02:06
						15		*DRB1*09:07*
9	10	11	12	13	14	15	16	Well No.

[4]The DRB5*0201 allele has been shown to be identical to DRB5*02:02.
[5]Primer mix 4: Specific PCR fragment of 100 bp in the DRB5*01:01:01-01:01:02, 01:04, 01:06-01:07, 01:09 and 01:11 alleles. Specific PCR fragment of 150 bp in the DRB5*02:06 allele.
Primer 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.

101.123-24/06 – including *Taq* polymerase, IFU-01
101.123-24u/06u – without *Taq* polymerase, IFU-02

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Lot No.: 49R **Lot-specific information**

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	201209604	201297405	201297406	201297407	201297408	201297409	201297410	201297411	201297412	201297413	201297414	201297415	201209616
	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		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

Lot No.: 49R **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: **49R**
Expiry date: **2015-May-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	2012-096-04	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	2012-096-16

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 solution 4 one 5'-primer was not possible to test, and in primer solutions 2, 14 and 15 one 3'-primer was not possible to test. Additional 3'-primers in primer solutions 2, 3 and 4 were tested by separately adding additional 5'-primers.

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

Date of approval: 2012-November-15

Approved by:

Production Quality Control

Lot No.: 49R **Lot-specific information**

Declaration of Conformity

Product name: *Olerup* SSP® DRB5
Product number: 101.123-24/06, -24u/06u
Lot number: 49R

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-November-15

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs

101.123-24/06 – including *Taq* polymerase, IFU-01
101.123-24u/06u – without *Taq* polymerase, IFU-02

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

Lot No.: 49R **Lot-specific information**

101.123-24/06 – including *Taq* polymerase, IFU-01
101.123-24u/06u – without *Taq* polymerase, IFU-02

Visit www.olerup-ssp.com for
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101.123-24/06 – including *Taq* polymerase, IFU-01
101.123-24u/06u – without *Taq* polymerase, IFU-02

Visit www.olerup-ssp.com for
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Lot No.: 49R **Lot-specific information**

Lot No.: 49R **Lot-specific information**

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