101.903-24 – including *Taq* polymerase, IFU-01
101. 903-24u – without *Taq* polymerase, IFU-02

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Lot No.: 59N **Lot-specific information**

Olerup SSP® DQA1*02,05;DQB1*02,03:02

Product number:	**101.903-24 – including *Taq* polymerase** **101.903-24u – without *Taq* polymerase**
Lot number:	**59N**
Expiry date:	**2014-September-01**
Number of tests:	**24**
Number of wells per test:	**15 + 1**
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. 59N.

CHANGES COMPARED TO THE PREVIOUS *OLERUP* SSP®
DQA1*02,05;DQB1*02,03:02 LOT (34M)

The Lot-specific information for DQA1*02,05;DQB1*02,03:02 including and without *Taq* polymerase is now described in one common Product Insert.

The specificity and interpretation tables have been updated for the DQA1 and DQB1 alleles described since the previous *Olerup* SSP® DQA1*02,05;DQB1*02,03:02 lot **(Lot No. 34M)** was made.

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

Well	5'-primer	3'-primer	rationale
6	-	Exchanged	Exchanged 3'-primer for improved resolution of the DQB1*03:02 and DQB1*03:04 alleles.

Change in revision R01 compared to R00:
1. The control primer pair for the Negative Control, well 16, has been corrected in the Specificity and Interpretation tables.

Change in revision R02 compared to R01:
1. Primer mix 9 may have tendencies of unspecific amplifications. A footnote has been added in the Specificity Table.

Lot No.: 59N **Lot-specific information**

Well **16** contains Negative Control primer pairs, that will amplify more than 95% of the *Olerup* SSP® HLA Class I, DRB, DQB1 and DPB1 amplicons as well as amplicons generated by a control primer pair.

PCR product sizes range from 75 to 430 base pairs.
The PCR product generated by the control primer pair is 430 base pairs.

Length of PCR product	**105**	**200**	**105**	**80**	**75**	**80**
5'-primer[1]	**164**	**340**	**440**	**45**	**45**	**43**
	5'-CAC3'	**5'-Agg3'**	**5'-TTA3'**	**5'-Tgg3'**	**5'-Tgg3'**	**5'-Tgg3'**
3'-primer[2]	**231**	**2nd I**	**507**	**59**	**58**	**57**
	5'-TgC3'	**5'-AAA3'**	**5'-TTg3'**	**5'-CTC3'**	**5'-ggC3'**	**5'-CTC3'**
A*	**+**	**+**	**+**			
B*	**+**	**+**	**+**			
C*	**+**	**+**	**+**			
DRB1				**+**	**+**	
DRB3				**+**	**+**	
DRB5				**+**		
DQB1					**+**	
DPB1						**+**

[1]The nucleotide position for HLA class I genes and the codon for HLA class II genes, in the 2nd or 3rd exon, matching the specificity-determining 3'-end of the primer is given. Nucleotide and 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.

[2]The nucleotide position for HLA class I genes and the codon for HLA class II genes, in the 2nd or 3rd exon or the 2nd intron, matching the specificity-determining 3'-end of the primer is given in the anti-sense direction. Nucleotide and 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.

101.903-24 – including *Taq* polymerase, IFU-01
101. 903-24u – without *Taq* polymerase, IFU-02

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Lot No.: 59N **Lot-specific information**

PRODUCT DESCRIPTION

DQA1*02,05;DQB1*02,03:02 SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for identifying the DQA1*02, DQA1*05, DQB1*02 and DQB1*03:02 alleles.

Please note that DQB1 amplifications usually are somewhat less pronounced than e.g. DRB and DQA1 amplifications even when using the same DNA preparation and exactly the same experimental procedures.

PLATE LAYOUT

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

1 DQA1	**2 DQA1**	**3 DQB1**	**4 DQB1**	**5 DQB1**	**6 DQB1**	**7 DQB1**	**8 DQB1**
9 DQB1	**10 DQB1**	**11 DQB1**	**12 DQA1**	**13 DQA1**	**14 DQA1**	**15 DQA1**	**16 Neg ctrl**

The 16 well cut PCR plate is marked with '59N' in silver/gray ink.
Well No. 1 is marked with the Lot No '59N'.
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.
Wells 1, 2, 12 to 15: DQA1 primers.
Wells 3 to 11: DQB1 primers.
Well 16: Negative control primers.
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.

UNIQUELY IDENTIFIED ALLELES

All the DQA1*02 and DQA1*05 alleles as well as all the DQB1*02 and DQB1*03 alleles, i.e. **DQA1*02:01, DQA1*05:01 to 05:11, DQB1*02:01 to 02:06 and DQB1*03:01 to 03:39**, recognized by the HLA Nomenclature Committee in April 2011[1] have been considered in the specificity and interpretation tables of the DQA1*02,05;DQB1*02,03:02 kit.

[1]DQA1 and DQB1 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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101. 903-24u – without *Taq* polymerase, IFU-02

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Lot No.: 59N **Lot-specific information**

SPECIFICITY TABLE

DQA1*02,05;DQB1*02,03:02 SSP subtyping

Specificities and sizes of the PCR products of the 15+1 primer mixes used for DQA1*02,05;DQB1*02,03:02 SSP typing

Primer Mix	Size of spec. PCR product[1]	Size of control band[2]	Amplified DQA1 alleles[3]	Amplified DQB1 alleles[3]
1	175 bp	**430 bp**	*02:01	
2	165 bp	515 bp	*05:01:01:01-05:09, 05:11	
3[6]	210 bp	515 bp		*02:01:01-02:06
4[4]	80 bp	515 bp		*03:01:01:01-03:01:06, 03:03:02:01-03:03:04, 03:09-03:10, 03:12-03:13, 03:15-03:17, 03:19-03:24, 03:26-03:31, 03:33-03:36, 03:38-03:39, *06:01:01^{W}-06:01:06^{W}, 06:07:01^{W}-06:07:02^{W}, 06:15^{W}, 06:32^{W}, 06:35^{W}, 06:37^{W}
5[5,6]	135 bp	**430 bp**		*02:01:01-02:02, 02:04-02:06, 1*03:02:01-03:02:05, 03:07-03:08, 03:11, 03:18, 03:32, 03:37, *06:29
6[4]	110 bp	515 bp		*03:02:01-03:03:04, 03:06, 03:08, 03:11-03:12, 03:15, 03:18, 03:20, 03:25-03:26, 03:30-03:34, 03:37-03:39, *04:03:01-04:03:02, *06:19
7[4,6]	115 bp	515 bp		*03:06, 03:25
8[6,7]	150 bp, 190 bp, 220 bp	515 bp		*03:07, 03:18, 03:37
9[8]	135 bp, 175 bp	515 bp		*03:08, 03:32, *06:02:02, 06:03:02
10[9]	135 bp, 260 bp	515 bp		*03:09, 03:11, 03:26
11[6,10]	145 bp, 185 bp	515 bp		*03:01:01:01-03:39
12[4,12]	90 bp	515 bp	*05:02	
13	200 bp	**430 bp**	*05:01:01:01-05:01:02, 05:02$^{?}$, 05:04$^{?}$, 05:05:01:01-05:05:01:03, 05:08-05:11	
14	200 bp	515 bp	*05:02$^{?}$, 05:03, 05:04$^{?}$, 05:06-05:07	

Lot No.: 59N **Lot-specific information**

15	205 bp	515 bp	*05:01:01:01-05:03, 05:05:01:01-05:09, 05:11
16[11]	-	-	**Negative control**

[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 DQA1 and DQB1 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 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 515 base pairs, for most wells, or a band of 430 base pairs, for some wells.
Well number 1 contains the primer pair giving rise to the shorter, 430 bp, internal positive control band in order to help in the correct orientation of the DQA1*02,05;DQB1*02,03:02 typing.
In addition, wells number 5 and 13 contain the primer pair giving rise to the shorter, 430 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 DQA1 and DQB1 alleles only partial second exon nucleotide sequences are available or nucleotide sequence information is not available for the 1st and 3rd exons. 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 of DQA1 and DQB1 alleles are conserved within allelic groups.
[4]Specific PCR fragments shorter than 125 base pairs are less intense and not as sharp as longer specific bands.
[5]Primer mix 5 may yield less specific PCR products than the other DQB1 primer mixes.
[6]Primer mixes 3, 5, 7, 8 and 11 have a tendency of primer oligomer formation.
[7]Primer mix 8: Specific PCR fragment of 150 bp in the DQB1*03:07 allele. Specific PCR fragment of 190 bp in the DQB1*03:37 allele. Specific PCR fragment of 220 bp in the DQB1*03:18 allele.
[8]Primer mix 9: Specific PCR fragment of 135 bp in the DQB1*03:08 and the DQB1*06:02:02 and 06:03:02 alleles. Specific PCR fragment of 175 bp in the DQB1*03:32 alleles.
[9]Primer mix 10: Specific PCR fragment of 135 bp in the DQB1*03:09 allele. Specific PCR fragment of 260 bp in the DQB1*03:11 and 03:26 alleles.
[10]Primer mix 11: Specific PCR fragment of 145 bp in the DQB1*03:01:02, 03:02:03, 03:03:03, 03:05:01-03:05:02, 03:20, 03:23 and 03:37 alleles. Specific PCR fragment of 185 bp in the DQB1*03:25 allele. Specific PCR fragment of 145 and 185 bp in the DQB1*03:01:01:01-03:01:01:03, 03:01:03-03:02:02, 03:02:04-03:03:02:03, 03:04, 03:05:03-03:19, 03:21-03:22, 03:24, 03:26-03:36 and 03:38-03:39 alleles. Both bands may not always be visible.
[11]Primer mix 16 contains a negative control, which will amplify more than 95% of HLA amplicons as well as the amplicons generated by a control primer pair. PCR product sizes range from 75 to 200 base pairs. The PCR product generated by the control primer pair is 430 base pairs.
[12]Primer mix 9 may have tendencies of unspecific amplifications.
'w', might be weakly amplified.
'?', nucleotide sequence information not available for the primer matching sequence.

101.903-24 – including *Taq* polymerase, IFU-01
101. 903-24u – without *Taq* polymerase, IFU-02

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Lot No.: 59N **Lot-specific information**

INTERPRETATION TABLE

DQA1*02,05;DQB1*02,03:02 typing

Amplification patterns of the DQA1*02 and 05 and DQB1*02 and 03 alleles

	Well[5]							
	1	2	3	4	5	6	7	8
Length of spec.	175	165	210	80	135	110	115	150
PCR product(s)								190
								220
Length of int.	430	515	515	515	430	515	515	515
pos. control[1]								
5'-primer(s)[2]	7 (90)	33 (169)	30 (185)	57 (266)	26 (173)	26 (173)	38 (210)	27 (175)
	5' -CAC 3'	5' -AgC 3'	5' -AAg 3'	5' -TgA 3'	5' -TCT 3'	5' -TCT 3'	5' -gCA 3'	5' -TTC 3'
								36 (204)
								5' -gAC 3'
								49 (242)
								5' -ggT 3'
3'-primer(s)[3]	52 (224)	75 (293)	86 (353)	69 (304)	57 (266)	47 (237)	62 (282)	86 (353)
	5' -TgT 3'	5' -gAC 3'	5' -gCT 3'	5' -CCT 3'	5' -Cgg 3'	5' -CgA 3'	5' -CTA 3'	5' -gCT 3'
						48 (240)		
						5' -gCg 3'		
Well No.	1	2	3	4	5	6	7	8
DQA1 or DQB1 allele[4]								
DQA1*02:01	1							
DQA1*05:01:01:01-05:01:02, 05:05:01:01-05:05:01:03, 05:08-05:09, 05:11		2						
DQA1*05:02		2						
DQA1*05:03, 05:06-05:07		2						
DQA1*05:04		2						
Well No.	1	2	3	4	5	6	7	8

101.903-24 – including *Taq* polymerase, IFU-01
101. 903-24u – without *Taq* polymerase, IFU-02

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Lot No.: 59N **Lot-specific information**

INTERPRETATION TABLE

DQA1*02,05;DQB1*02,03:02 typing

Amplification patterns of the DQA1*02 and 05 and DQB1*02 and 03 alleles

Well[5]								
9	10	11	12	13	14	15	16	
135	135	145	90	200	200	205	Neg kontr.	Length of spec.
175	260	185						PCR product(s)
515	515	515	515	430	515	515		Length of int.
								pos. control[1]
38 (210) 5' -gCA 3'	13 (136) 5' -gCC 3'	38 (210) 5' -gCA 3'	59 (245) 5' -CCg 3'	107 (389) 5' -CAT 3'	107 (389) 5' -CAT 3'	21 (131) 5' -TCC 3'	Negative Control	5'-primer(s)[2]
140 (517) 5' -CTA 3'	135 (500) 5' -TgA 3'	48 (240) 5' -CgC 3'						
		55 (260) 5' -gCC 3'						
		55 (260) 5' -gCA 3'						
69 (304) 5' -CCC 3'	86 (353) 5' -gCT 3'	86 (353) 5' -gCT 3'	75 (293) 5' -gAC 3'	159 (547) 5' -AgC 3'	159 (547) 5' -AgA 3'	75 (293) 5' -gAC 3'		3'-primer(s)[3]
185 (650) 5' -CgA 3'	167 (596) 5' -CAT 3'							
9	10	11	12	13	14	15	16	Well No.
								DQA1 or DQB1 allele[4]
							Neg. Ctrl.	DQA1*02:01
				13		15		DQA1*05:01:01:01-05:01:02, 05:05:01:01-05:05:01:03, 05:08-05:09, 05:11
			12	?	?	15		DQA1*05:02
					14	15		DQA1*05:03, 05:06-05:07
				?	?			DQA1*05:04
9	10	11	12	13	14	15	16	Well No.

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Length of spec.	**175**	**165**	**210**	**80**	**135**	**110**	**115**	**150**
PCR product(s)								**190**
								220
Well No.	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**
DQA1 or DQB1 allele[4]								
DQA1*05:10								
DQB1*02:01:01-02:02, 02:04-02:06			**3**		**5**			
DQB1*02:03			**3**					
DQB1*03:01:01:01-03:01:06, 03:10, 03:13, 03:16-03:17, 03:19, 03:21-03:24, 03:27-03:29, 03:35-03:36				**4**				
DQB1*03:02:01-03:02:05					**5**	**6**		
DQB1*03:03:02:01-03:03:04, 03:12, 03:15, 03:20, 03:30-03:31, 03:33-03:34, 03:38-03:39				**4**		**6**		
DQB1*03:04-03:05:04, 03:14								
DQB1*03:06, 03:25						**6**	**7**	
DQB1*03:07					**5**			**8**
DQB1*03:08, 03:32					**5**	**6**		
DQB1*03:09				**4**				
DQB1*03:11					**5**	**6**		
DQB1*03:18, 03:37					**5**	**6**		**8**
DQB1*03:26				**4**		**6**		
DQB1*04:03:01-04:03:02, DQB1*06:19						**6**		
DQB1*06:01:01-06:01:06, 06:07:01-06:07:02, 06:15, 06:32, 06:35, 06:37				**w**				
DQB1*06:02:02, 06:03:02								
DQB1*06:29					**5**			
DQA1 or DQB1 allele[4]								
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 515 base pairs, for most wells, or a band of 430 base pairs, for some wells.
Well number 1 contains the primer pair giving rise to the shorter, 430 bp, internal positive control band in order to help in the correct orientation of the DQA1*02,05;DQB1*02,03:02 typing.
In addition, wells number 5 and 13 contain the primer pair giving rise to the shorter, 430 bp, internal positive control band in order to allow kit identification.
[2]The codon, and in parenthesis the nucleotide, in the 1st, 2nd or 3rd exon, matching the specificity-determining 3'-end of the primer is given. Codon and nucleotide numbering as in www.ebi.ac.uk/imgt/hla.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.
[4]DQA1*05013 has been renamed to DQA1*05:05.
The sequence of the DQB1*03031 allele has been shown to be identical to DQB1*03:03:02.
[5]Primer mix 8: Specific PCR fragment of 150 bp in the DQB1*03:07 allele. Specific PCR fragment of 190 bp in the DQB1*03:37 allele. Specific PCR fragment of 220 bp in the DQB1*03:18 allele.

101.903-24 – including *Taq* polymerase, IFU-01
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135	135	145	90	200	200	205		**Length of spec.**
175	260	185						**PCR product(s)**
9	10	11	12	13	14	15	16	**Well No.**
								DQA1 or DQB1 allele[4]
				13				**DQA1*05:10**
								DQB1*02:01:01-02:02, 02:04-02:06
								DQB1*02:03
		11						**DQB1*03:01:01:01-03:01:06, 03:10, 03:13, 03:16-03:17, 03:19, 03:21-03:24, 03:27-03:29, 03:35-03:36**
		11						**DQB1*03:02:01-03:02:05**
		11						**DQB1*03:03:02:01-03:03:04, 03:12, 03:15, 03:20, 03:30-03:31, 03:33-03:34, 03:38-03:39**
		11						**DQB1*03:04-03:05:04, 03:14**
		11						**DQB1*03:06, 03:25**
		11						**DQB1*03:07**
9		11						**DQB1*03:08, 03:32**
	10	11						**DQB1*03:09**
	10	11						**DQB1*03:11**
		11						**DQB1*03:18, 03:37**
	10	11						**DQB1*03:26**
								DQB1*04:03:01-04:03:02, DQB1*06:19
								DQB1*06:01:01-06:01:06, 06:07:01-06:07:02, 06:15, 06:32, 06:35, 06:37
9								**DQB1*06:02:02, 06:03:02**
								DQB1*06:29
								DQA1 or DQB1 allele[4]
9	10	11	12	13	14	15	16	**Well No.**

Primer mix 9: Specific PCR fragment of 135 bp in the DQB1*03:08 and the DQB1*06:02:02 and 06:03:02 alleles. Specific PCR fragment of 175 bp in the DQB1*03:32 alleles.
Primer mix 10: Specific PCR fragment of 135 bp in the DQB1*03:09 allele. Specific PCR fragment of 260 bp in the DQB1*03:11 and 03:26 alleles.
Primer mix 11: Specific PCR fragment of 145 bp in the DQB1*03:01:02, 03:02:03, 03:03:03, 03:05:01-03:05:02, 03:20, 03:23 and 03:37 alleles. Specific PCR fragment of 185 bp in the DQB1*03:25 allele. Specific PCR fragment of 145 and 185 bp in the DQB1*03:01:01:01-03:01:01:03, 03:01:03-03:02:02, 03:02:04-03:03:02:03, 03:04, 03:05:03-03:19, 03:21-03:22, 03:24, 03:26-03:36 and 03:38-03:39 alleles. Both bands may not always be visible.
Primer mix 16 contains a negative control, which will amplify more than 95% of HLA amplicons as well as the amplicons generated by control primer pairs. PCR product sizes range from 75 to 200 base pairs. The PCR product generated by the control primer pair is 430 base pairs.
'w', might be weakly amplified.
'?', nucleotide sequence information not available for the primer matching sequence.

101.903-24 – including *Taq* polymerase, IFU-01
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Lot No.: 59N **Lot-specific information**

CELL LINE VALIDATION SHEET

DQA1*02,05;DQB1*02,03:02 typing kit

					Well					
					1	2	12	13	14	15
				Prod. No.:	201076701	201076702	201076713	201076714	201076715	201076716
	IHWC cell line		DQA1*							
1	9001	SA	*01:01		-	-	-	-	-	-
2	9280	LK707	*01:03	*03:03	-	-	-	-	-	-
3	9011	E4181324	*01:03		-	-	-	-	-	-
4	9275	GU373	*05:01		-	+	-	+	-	+
5	9009	KAS011	*01:02		-	-	-	-	-	-
6	9353	SM	*01:03	*03:01	-	-	-	-	-	-
7	9020	QBL	*05:01		-	+	-	+	-	+
8	9025	DEU	*03		-	-	-	-	-	-
9	9026	YAR	*03:01		-	-	-	-	-	-
10	9107	LKT3	*03:03		-	-	-	-	-	-
11	9051	PITOUT	*02:01		+	-	-	-	-	-
12	9052	DBB	*02:01		+	-	-	-	-	-
13	9004	JESTHOM	*01:01		-	-	-	-	-	-
14	9071	OLGA	*04:01		-	-	-	-	-	-
15	9075	DKB	*03:02		-	-	-	-	-	-
16	9037	SWEIG007	*05:05		-	+	-	+	-	+
17	9282	CTM3953540	*01:03	*05:01	-	+	-	+	-	+
18	9257	32367	*01:02	*03:03	-	-	-	-	-	-
19	9038	BM16	*05:05		-	+	-	+	-	+
20	9059	SLE005	*01:02		-	-	-	-	-	-
21	9064	AMALA	*05:03		-	+	-	-	+	+
22	9056	KOSE	*01:02	*01:04	-	-	-	-	-	-
23	9124	IHL	*01:03	*01:04	-	-	-	-	-	-
24	9035	JBUSH	*05:05		-	+	-	+	-	+
25	9049	IBW9	*02:01		+	-	-	-	-	-
26	9285	WT49	*05:01		-	+	-	+	-	+
27	9191	CH1007	*03:03	*01:05	-	-	-	-	-	-
28	9320	BEL5GB	*02:01	*03:03	+	-	-	-	-	-
29	9050	MOU	*02:01		+	-	-	-	-	-
30	9021	RSH	*04:01		-	-	-	-	-	-
31	9019	DUCAF	*05:01		-	+	-	+	-	+
32	9297	HAG	*05:05		-	+	-	+	-	+
33	9098	MT14B	*03:01		-	-	-	-	-	-
34	9104	DHIF	*05:05		-	+	-	+	-	+
35	9302	SSTO	*03:01		-	-	-	-	-	-
36	9024	KT17	*03:01		-	-	-	-	-	-
37	9065	HHKB	*01:03		-	-	-	-	-	-
38	9099	LZL	*05:03		-	+	-	-	+	+
39	9315	CML	*03:03	*05:01	-	+	-	+	-	+
40	9134	WHONP199	*02:01	*03:02	+	-	-	-	-	-
41	9055	H0301	*01:02		-	-	-	-	-	-
42	9066	TAB089	*01:03		-	-	-	-	-	-
43	9076	T7526	*03:02		-	-	-	-	-	-
44	9057	TEM	*01:04		-	-	-	-	-	-
45	9239	SHJO	*02:01	*03:03	+	-	-	-	-	-
46	9013	SCHU	*01:02		-	-	-	-	-	-
47	9045	TUBO	*05:05		-	+	-	+	-	+
48	9303	TER-ND	*01:01		-	-	-	-	-	-

101.903-24 – including *Taq* polymerase, IFU-01
101. 903-24u – without *Taq* polymerase, IFU-02

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Lot No.: 59N **Lot-specific information**

CELL LINE VALIDATION SHEET

DQA1*02,05;DQB1*02,03:02 typing kit

					Well								
					3	4	5	6	7	8	9	10	11
				Production No.	201076703	201076704	201076705	201299606	201076707	201187608	201187609	201076710	201076711
	IHWC cell line		DQB1										
1	9001	SA	*05:01		-	-	-	-	-	-	-	-	-
2	9280	LK707	*06:01	*02:02	+	w	+	-	-	-	-	-	-
3	9011	E4181324	*06:01		-	w	-	-	-	-	-	-	-
4	9275	GU373	*02:01		+	-	+	-	-	-	-	-	-
5	9009	KAS011	*05:02		-	-	-	-	-	-	-	-	-
6	9353	SM	*03:02	*06:01	-	+	+	+	-	-	-	-	+
7	9020	QBL	*02:01		+	-	+	-	-	-	-	-	-
8	9025	DEU	*03:01		-	+	-	-	-	-	-	-	+
9	9026	YAR	*03:02		-	-	+	+	-	-	-	-	+
10	9107	LKT3	*04:01		-	-	-	-	-	-	-	-	-
11	9051	PITOUT	*02:02		+	-	+	-	-	-	-	-	-
12	9052	DBB	*03:03		-	+	-	+	-	-	-	-	+
13	9004	JESTHOM	*05:01		-	-	-	-	-	-	-	-	-
14	9071	OLGA	*04:02		-	-	-	-	-	-	-	-	-
15	9075	DKB	*03:03		-	+	-	+	-	-	-	-	+
16	9037	SWEIG007	*03:01		-	+	-	-	-	-	-	-	+
17	9282	CTM3953540	*02:01	*0603	+	-	+	-	-	-	-	-	-
18	9257	32367	*06:02	*02:02	+	-	+	-	-	-	-	-	-
19	9038	BM16	*03:01		-	+	-	-	-	-	-	-	+
20	9059	SLE005	*06:04		-	-	-	-	-	-	-	-	-
21	9064	AMALA	*03:01		-	+	-	-	-	-	-	-	+
22	9056	KOSE	*05:03	*06:04	-	-	-	-	-	-	-	-	-
23	9124	IHL	*05:03	*06:01	-	w	-	-	-	-	-	-	-
24	9035	JBUSH	*03:01		-	+	-	-	-	-	-	-	+
25	9049	IBW9	*02:02		+	-	+	-	-	-	-	-	-
26	9285	WT49	*02:01		+	-	+	-	-	-	-	-	-
27	9191	CH1007	*04:01	*05:01	-	-	-	-	-	-	-	-	-
28	9320	BEL5GB	*02:02	*03:01	+	+	+	-	-	-	-	-	+
29	9050	MOU	*02:02		+	-	+	-	-	-	-	-	-
30	9021	RSH	*04:02		-	-	-	-	-	-	-	-	-
31	9019	DUCAF	*02:01		+	-	+	-	-	-	-	-	-
32	9297	HAG	*03:01		-	+	-	-	-	-	-	-	+
33	9098	MT14B	*03:02		-	-	+	+	-	-	-	-	+
34	9104	DHIF	*03:01		-	+	-	-	-	-	-	-	+
35	9302	SSTO	*03:05		-	-	-	-	-	-	-	-	+
36	9024	KT17	*03:02		-	-	+	+	-	-	-	-	+
37	9065	HHKB	*06:03		-	-	-	-	-	-	-	-	-
38	9099	LZL	*03:01		-	+	-	-	-	-	-	-	+
39	9315	CML	*02:01	*03:01	+	+	+	-	-	-	-	-	+
40	9134	WHONP199	*02:02	*03:03	+	+	+	+	-	-	-	-	+
41	9055	H0301	*06:09		-	-	-	-	-	-	-	-	-
42	9066	TAB089	*06:01		-	w	-	-	-	-	-	-	-
43	9076	T7526	*03:03		-	+	-	+	-	-	-	-	+
44	9057	TEM	*05:03		-	-	-	-	-	-	-	-	-
45	9239	SHJO	*02:02		+	-	+	-	-	-	-	-	-
46	9013	SCHU	*06:02		-	-	-	-	-	-	-	-	-
47	9045	TUBO	*03:01		-	+	-	-	-	-	-	-	+
48	9303	TER-ND	*05:01		-	-	-	-	-	-	-	-	-

Lot No.: 59N **Lot-specific information**

CERTIFICATE OF ANALYSIS

Olerup SSP® DQA1*02,05;DQB1*02,03:02 SSP

Product number: **101.903-24 – including *Taq* polymerase**
101.903-24u – without *Taq* polymerase
Lot number: **59N**
Expiry date: **2014-September-01**
Number of tests: **24**
Number of wells per test: **15 + 1**

Well specifications:

Well No.	Production No.	Well No.	Production No.
1	2010-767-01	9	2011-876-09
2	2010-767-02	10	2010-767-10
3	2010-767-03	11	2010-767-11
4	2010-767-04	12	2010-767-12
5	2010-767-05	13	2010-767-13
6	2012-996-06	14	2010-767-14
7	2010-767-07	15	2010-767-15
8	2011-876-08		

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 7 to 10 and 12 were available. The specificities of the primers in primer solutions 7, 9 and 10 were tested by separately adding one additional 5'-primers, respectively one additional 3'-primer. In primer solutions 8 and 12 it was only possible to test the 3'-primers, the 5'-primers were not possible to test. In primer solution 9 one of the 5'-primers was not possible to test, and in primer solutions 6 and 10 one of the 3'-primers was not possible to test.

The negative control primer pairs, **Production No. 2011-928-01**, can detect contamination with PCR products diluted 10^{-7}.

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

Date of approval: 2012-April-27

Approved by:

Production Quality Control

Lot No.: 59N **Lot-specific information**

Declaration of Conformity

Product name: *Olerup* SSP® DQA1*02,05;DQB1*02,03:02
Product number: 101.903-24/24u
Lot number: 59N

Intended use: DQA1*02, DQA1*05, DQB1*02 and DQB1*03 medium 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 III, 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.

The Authorized Representative located within the Community is: *Olerup* SSP AB.

Stockholm, Sweden
2012-April-27

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs

101.903-24 – including *Taq* polymerase, IFU-01
101. 903-24u – without *Taq* polymerase, IFU-02

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Lot No.: 59N **Lot-specific information**

101.903-24 – including *Taq* polymerase, IFU-01
101. 903-24u – without *Taq* polymerase, IFU-02

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Lot No.: 59N **Lot-specific information**

Lot No.: 59N **Lot-specific information**

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