Olerup SSP® DQA1

Product number:	**101.231-24u/04u – without *Taq* pol.**
Lot number:	**58M**
Expiry date:	**2014-March-01**
Number of tests:	**24 tests – Product No. 101.231-24u**
	4 tests – Product No. 101.231-04u
Number of wells per test:	**32**
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. 58M.

CHANGES COMPARED TO THE PREVIOUS *OLERUP* SSP® DQA1 LOT

The DQA1 specificity and interpretation tables have been updated compared the previous *Olerup* SSP® DQA1 lot **(Lot No. 69K)**.

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

Well	5'-primer	3'-primer	rationale
30	Added	Added	Primer pair added for the DQA1*05:11 allele.

PRODUCT DESCRIPTION

DQA1 SSP typing

CONTENT

The primer set contains 5'- and 3'-primers for identifying the DQA1*01:01 to DQA1*06:02 alleles.

PLATE LAYOUT

Each test consists of 32 PCR reactions in a 32 well cut PCR plate.

1	**2**	**3**	**4**	**5**	**6**	**7**	**8**
9	**10**	**11**	**12**	**13**	**14**	**15**	**16**
17	**18**	**19**	**20**	**21**	**22**	**23**	**24**
25	**26**	**27**	**28**	**29**	**30**	**31**	**32**

The 32 well cut PCR plate is marked with 'DQA1', in silver/gray ink.
Well No. 1 is marked with the Lot No. '58M'.
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 32 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

Only DQA1 alleles will be amplified by the DQA1 typing kit. Thus, the interpretation of DQA1 typings is not influenced by the DQA2 gene.

UNIQUELY IDENTIFIED ALLELES

All the DQA1 alleles, i.e. **DQA1*01:01 to 01:07, DQA1*02:01, DQA1*03:01 to 03:03, DQA1*04:01 to DQA1*04:04, DQA1*05:01 to 05:11 and DQA1*06:01 to DQA1*06:02**, recognized by the HLA Nomenclature Committee in July 2011[1] will give rise to unique amplification patterns by the primers in the DQA1 typing kit.
The DQA1 typing kit cannot distinguish the DQA1*01:01:01-01:01:02 alleles, the DQA1*01:02:01:01-01:02:03 alleles, the DQA1*01:03:01:01-01:03:01:02 alleles, the DQA1*01:04:01:01-01:04:02 alleles, the DQA1*05:01:01:01-05:01:02 alleles, the DQA1*05:05:01:01-05:05:01:03 alleles and the DQA1*06:01:01-06:01:02 alleles.

[1]DQA1 alleles listed on the IMGT/HLA web page 2011-July-14, release 3.5.0, www.ebi.ac.uk/imgt/hla.

RESOLUTION IN HOMO- AND HETEROZYGOTES

A total of 44 alleles generate 30 amplification patterns that can be combined in 465 homozygous and heterozygous combinations. 128 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.

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

*01:01:01 = *01:01:01-01:01:02, *01:02:01 = *01:02:01-01:02:03, *01:03:01:01= *01:03:01:01-01:03:01:02, *01:04:01 = *01:04:01-01:04:02, *05:01:01:01 = *05:01:01:01-05:01:02, *05:05:01:01= *05:05:01:01-05:05:01:03, *06:01:01 = *06:01:01-06:01:02

SPECIFICITY TABLE

DQA1 SSP typing

Specificities and sizes of the PCR products of the 32 primer mixes used for DQA1 SSP typing

Primer Mix	Size of spec. PCR product[1]	Size of control band[2]	Amplified DQA1 alleles[3]
1	145 bp	**515 bp**	*01:01:01-01:01:02, 01:04:01:01-01:05, 01:07
2[5]	170 bp	**515 bp**	*01:01:01-01:02:04, 01:04:01:01-01:07
3	145 bp	430 bp	*01:02:01:01-01:03:01:02, 01:06
4	170 bp	430 bp	*01:03:01:01-01:03:01:02
5	220 bp	430 bp	*01:04:01:01-01:05, 01:06[?], 01:07
6[4]	100 bp	430 bp	*01:04:01:01-01:04:02, 01:06[?], 01:07
7[4,5]	95 bp	430 bp	*01:06
8[4]	65 bp	430 bp	*01:01:01-01:02:03, 01:03:01:01-01:03:01:02, 01:06[?], 02:01, 03:01:01-03:03, 04:01:01-04:04, 05:01:01:01-05:11, 06:01:01-06:02
9	175 bp	430 bp	*02:01
10	185 bp	430 bp	*03:01:01-03:03
11	215 bp	430 bp	*03:02
12	225 bp	**515 bp**	*03:02-03:03
13	225 bp	**515 bp**	*01:01:01-01:07, 02:01, 03:01:01, 04:01:01, 04:02-04:04, 05:01:01:01-05:11, 06:01:01-06:02
14[4,5]	125 bp	430 bp	*04:01:01-04:02, 04:04, 05:01:01:01-05:11
15	165 bp	430 bp	*05:01:01:01-05:09, 05:11
16[4]	90 bp	430 bp	*05:02
17	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
18	200 bp	430 bp	*05:02[?], 05:03, 05:04[?], 05:06-05:07
19	205 bp	430 bp	*05:01:01:01-05:03, 05:05:01:01-05:09, 05:11
20	135 bp	430 bp	*05:04
21[4,6]	100 bp	430 bp	*05:02[?], 05:04[?], 05:05:01:01-05:05:01:03, 05:08-05:09, 05:10[?], 05:11
22[4]	120 bp	**515 bp**	*06:01:01-06:02
23[4]	85 bp	430 bp	*04:01:01-04:04, 06:01:01-06:02
24	220 bp	430 bp	*01:01:01-01:07, 02:01[w], 03:01:01-03:03, 04:01:01-04:04, 05:01:01:01-05:01:02, 05:02[?], 05:03, 05:04[?], 05:06-05:07, 05:10[?], 06:01:01-06:02

25[4,8]	80 bp, 175 bp	430 bp	*01:07, 05:09
26	160 bp	430 bp	*04:02, 05:10
27[4,7]	90 bp	430 bp	*04:03N
28[4]	105 bp	430 bp	*04:04
29	160 bp	430 bp	*06:02
30[4,9]	115 bp, 215 bp	430 bp	*05:06, 05:11
31[4]	100 bp	430 bp	*05:07
32	135 bp	430 bp	*05:08

[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 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, e.g. the primers in wells 11, 12, 17, 18, 21, 23 and 27.
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 DQA1 typing.
In addition, wells number 2, 12, 13 and 22 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 DQA1 alleles only partial 1st, 2nd, 3rd and 4th 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 are conserved within allelic groups.
[4]Short specific PCR fragments are less intense and not as sharp as longer specific bands.
[5]Primer mixes 2, 7 and 14 may have tendencies of giving rise to primer dimer artifacts.
[6]Primer mixes 21 may give a lower yield of HLA-specific PCR product than the other DQA1 primer mixes.
[7]Primer mix 27 may give rise to nonspecific amplifications.
[8]Primer mix 25: Specific PCR product of 80 bp in the DQA1*05:09 allele. Specific PCR product of 175 bp in the DQA1*01:07 allele.
[9]Primer mix 30: Specific PCR product of 115 bp in the DQA1*05:11 allele. Specific PCR product of 215 bp in the DQA1*05:06 allele.
'w', may be weakly amplified.
'?', nucleotide sequence information not available for the primer matching sequence.

INTERPRETATION TABLE

DQA1 SSP typing

Amplification patterns of the DQA1*01:01 to *06:02 alleles

	Well[5]															
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Length of spec.	145	170	145	170	220	100	95	65	175	185	215	225	225	125	165	90
PCR product(s)																
Length of int.	515	515	430	430	430	430	430	430	430	430	430	515	515	430	430	430
pos. control[1]																
5'-primer(s)[2]	34(169)	25(143)	34(169)	25(143)	-7(49)	199(664)	25(143)	-7(49)	7(90)	7(90)	-6(53)	99(366)	99(366)	25(143)	34(169)	59(245)
	5'-Agg 3'	5'-gTA 3'	5'-AgC 3'	5'-gTT 3'	5'-CCA 3'	5'-gCA 3'	5'-gTA 3'	5'-CCg 3'	5'-CAC 3'	5'-CAT 3'	5'-gAC 3'	5'-CCC 3'	5'-CCC 3'	5'-gTA 3'	5'-AgC 3'	5'-CCg 3'
3'-primer(s)[3]	69(274)	69(274)	69(274)	69(274)	1st I	218(722)	44(199)	2(74)	52(224)	55(232)	1st I	160(548)	160(548)	53(226)	75(293)	75(293)
	5'-TgC 3'	5'-TgC 3'	5'-TgC 3'	5'-TgC 3'	5'-TTT 3'	5'-CTT 3'	5'-AgC 3'	5'-TgT 3'	5'-TgT 3'	5'-TCT 3'	5'-TTT 3'	5'-CAT 3'	5'-CAg 3'	5'-TTg 3'	5'-gAC 3'	5'-gAC 3'
													160(548)			
													5'-CAg 3'			
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
DQA1 allele[4]																
*01:01:01-01:01:02	1	2						8					13			
*01:02:01:01-01:02:03		2	3					8					13			
*01:02:04		2	3										13			
*01:03:01:01-01:03:01:02			3	4				8					13			
*01:04:01:01-01:04:02	1	2			5	6							13			
*01:05	1	2			5								13			
*01:06		2	3		?	?	7	?					13			
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16

INTERPRETATION TABLE

DQA1 SSP typing

Amplification patterns of the DQA1*01:01 to *06:02 alleles

Well[5]																
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	
200	200	205	135	100	120	85	220	80	160	90	105	160	115	100	135	Length of spec.
								175					215			PCR product(s)
430	430	430	430	430	515	430	430	430	430	430	430	430	430	430	430	Length of int.
																pos. control[1]
107(389)	107(389)	21(131)	21(131)	-13(31)	25(143)	32(165)	up[6]	-13(31)	34(169)	53(226)	153(526)	99(366)	102(373)	189(634)	107(389)	5'-primer(s)[2]
5'-CAT 3'	5'-CAT 3'	5'-TCC 3'	5'-TCT 3'	5'-ggA 3'	5'-gTT 3'	5'-gAC 3'	5'-ACT 3'	5'-ggA 3'	5'-AgC 3'	5'-gAT 3'	5'-gTC 3'	5'-CCC 3'	5'-CAg 3'	5'-CTA 3'	5'-CAT 3'	
								34(169)	101(372)				194(650)			
								5'-Agg 3'	5'-ACg 3'				5'-Agg 3'			
160(547)	160(547)	75(293)	52(223)	1st I	52(223)	47(208)	-13(31)	1(70)	77(298)	69(274)	174(591)	139(484)	160(547)	208(691)	139(485)	3'-primer(s)[3]
5'-AgC 3'	5'-AgA 3'	5'-gAC 3'	5'-TCT 3'	5'-TgC 3'	5'-TCT 3'	5'-ACA 3'	5'-ggC 3'	5'-TTT 3'	5'-AAC 3'	5'-TgT 3'	5'-TCg 3'	5'-gCg 3'	5'-AgA 3'	5'-gCA 3'	5'-AgA 3'	
								79(304)	138(482)				218(722)			
								5'-gCA 3'	5'-TgA 3'				5'-CTC 3'			
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Well No.
																DQA1 allele[4]
							24									*01:01:01-01:01:02
							24									*01:02:01:01-01:02:03
							24									*01:02:04
							24									*01:03:01:01-01:03:01:02
							24									*01:04:01:01-01:04:02
							24									*01:05
							24									*01:06
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Well No.

Length of spec.	**145**	**170**	**145**	**170**	**220**	**100**	**95**	**65**	**175**	**185**	**215**	**225**	**225**	**125**	**165**	**90**
PCR product(s)																
Well No.	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**
***01:07**	**1**	**2**			**5**	**6**							**13**			
***02:01**								**8**	**9**				**13**			
***03:01:01**								**8**		**10**			**13**			
***03:02**								**8**		**10**	**11**	**12**				
***03:03**								**8**		**10**		**12**				
***04:01:01**								**8**					**13**	**14**		
***04:01:02**								**8**						**14**		
***04:02**								**8**					**13**	**14**		
***04:03N**								**8**					**13**			
***04:04**								**8**					**13**	**14**		
***05:01:01:01-05:01:02**								**8**					**13**	**14**	**15**	
***05:02**								**8**					**13**	**14**	**15**	**16**
***05:03**								**8**					**13**	**14**	**15**	
***05:04**								**8**					**13**	**14**	**15**	
***05:05:01:01-05:05:01:03**								**8**					**13**	**14**	**15**	
***05:06**								**8**					**13**	**14**	**15**	
***05:07**								**8**					**13**	**14**	**15**	
***05:08**								**8**					**13**	**14**	**15**	
***05:09**								**8**					**13**	**14**	**15**	
***05:10**								**8**					**13**	**14**		
***05:11**								**8**					**13**	**14**	**15**	
***06:01:01-06:01:02**								**8**					**13**			
***06:02**								**8**					**13**			
DQA1 allele[4]																
Well No.	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**

[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 DQA1 typing.
In addition, wells number 2, 12, 13 and 22 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 1st, 2nd, 3rd or 4th 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 1st, 2nd, 3rd or 4th exon or the 1st intron, 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.

200	200	205	135	100	120	85	220	80	160	90	105	160	115	100	135	Length of spec.
								175					215			PCR product(s)
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Well No.
							24	25								*01:07
							w									*02:01
							24									*03:01:01
							24									*03:02
							24									*03:03
						23	24									*04:01:01
						23	24									*04:01:02
						23	24		26							*04:02
						23	24			27						*04:03N
						23	24				28					*04:04
17		19					24									*05:01:01:01-05:01:02
?	?	19		?			?									*05:02
	18	19					24									*05:03
?	?		20	?			?									*05:04
17		19		21												*05:05:01:01-05:05:01:03
	18	19					24						30			*05:06
	18	19					24							31		*05:07
17		19		21											32	*05:08
17		19		21				25								*05:09
17				?			?		26							*05:10
17		19		21									30			*05:11
					22	23	24									*06:01:01-06:01:02
					22	23	24					29				*06:02
																DQA1 allele[4]
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Well No.

[4]The sequence of the DQA1*0301 allele has been shown to be identical to DQA1*03:02.
DQA1*0501 has been renamed to DQA1*05:05.
[5]Primer mix 25: Specific PCR product of 80 bp in the DQA1*05:09 allele. Specific PCR product of 175 bp in the DQA1*01:07 allele.
Primer mix 30: Specific PCR product of 115 bp in the DQA1*05:11 allele. Specific PCR product of 215 bp in the DQA1*05:06 allele.
[6]Primer located upstream of the 1st exon.
'w', may be weakly amplified.
'?', nucleotide sequence information not available for the primer matching sequence.

CELL LINE VALIDATION SHEET

DQA1 SSP typing kit

					Well															
					1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
				Prod. No.:	200960901	200960902	200960903	200960904	200960905	200960906	200960907	200960908	200960909	200960910	200960911	200960912	200960913	200960914	200960915	200960916
	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		+	+	-	-	-	-	-	+	-	-	-	-	+	-	-	-

CELL LINE VALIDATION SHEET

DQA1 SSP typing kit

					Well													
					17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32
				Prod. No.:	200960917	200960918	200960919	200960920	200960921	201189122	200960923	200960924	200960925	201189126	200960927	200960928	200960929	201189130	200960931	200960932
	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		-	-	-	-	-	-	-	w	-	-	-	-	-	-	-	-
12	9052	DBB	*02:01		-	-	-	-	-	-	-	w	-	-	-	-	-	-	-	-
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		-	-	-	-	-	-	-	w	-	-	-	-	-	-	-	-
26	9285	WT49	*05:01		+	-	+	-	-	-	-	+	-	-	-	-	-	-	-	-
27	9191	CH1007	*03:03	*01:05	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-
28	9320	BEL5GB	*02:01	*03:03	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-
29	9050	MOU	*02:01		-	-	-	-	-	-	-	w	-	-	-	-	-	-	-	-
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		-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-

CERTIFICATE OF ANALYSIS

Olerup SSP® DQA1 SSP

Product number: **101.231-24u/04u – without *Taq* pol.**
Lot number: **58M**
Expiry date: **2014-March-01**
Number of tests: **24 tests – Product No. 101.231-24u**
4 tests – Product No. 101.231-04u
Number of wells per test: **32**

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2009-609-01	13	2009-609-13	25	2009-609-25
2	2009-609-02	14	2009-609-14	26	2011-891-26
3	2009-609-03	15	2009-609-15	27	2009-609-27
4	2009-609-04	16	2009-609-16	28	2009-609-28
5	2009-609-05	17	2009-609-17	29	2009-609-29
6	2009-609-06	18	2009-609-18	30	2011-891-30
7	2009-609-07	19	2009-609-19	31	2009-609-31
8	2009-609-08	20	2009-609-20	32	2009-609-32
9	2009-609-09	21	2009-609-21		
10	2009-609-10	22	2011-891-22		
11	2009-609-11	23	2009-609-23		
12	2009-609-12	24	2009-609-24		

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, 16, 20, 26 to 29 and 31 were available. In primer solutions 7, 26, 29 and 31 the 5'-primers were tested by adding one additional 3'-primer, the 3'-primers were not possible to test. In primer solutions 16, 20, 27 and 28 the 3'-primers were tested by adding one additional 5'-primer, the 5'-primers were not possible to test. In primer solution 25, one 3'-primer was not possible to test, and one additional 5'-primer was tested by separately adding one 3'-primer. In primer solution 30, one 5'-primer was not possible to test, and one additional 3'-primer was tested by separately adding one 5'-primer.

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

Date of approval: 2011-October-06

Approved by:

Quality Control, Supervisor

Declaration of Conformity

Product name: *Olerup* SSP® DQA1
Product number: 101.231-24u/04u
Lot number: 58M

Intended use: HLA-DQA1 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 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.

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
2011-October-06

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs

ADDRESSES:

Manufacturer:
***Olerup* SSP AB**, Franzengatan 5, SE-112 51 Stockholm, Sweden.
Tel: +46-8-717 88 27
Fax: +46-8-717 88 18
E-mail: info-ssp@olerup.com
Web page: http://www.olerup-ssp.com

Distributed by:
Olerup GmbH, Löwengasse 47 / 6, AT-1030 Vienna, Austria.
Tel: +43-1-710 15 00
Fax: +43-1-710 15 00 10
E-mail: support-at@olerup.com
Web page: http://www.olerup.com

Olerup Inc., 901 S. Bolmar St., Suite R, West Chester, PA 19382
Tel: 1-877-OLERUP1
Fax: 610-344-7989
E-mail: info.us@olerup.com
Web page: http://www.olerup.com

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