Olerup SSP® HLA-A*23

Product number:	**101.421-06 – including *Taq* polymerase**
Lot number:	**31G**
Expiry date:	**2011-October-01**
Number of tests:	**6**
Number of wells per test:	**24**
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. 31G.

CHANGES COMPARED TO THE PREVIOUS *OLERUP* SSP® HLA-A*23 LOT

The HLA-A*23 specificity and interpretation tables have been updated for the HLA-A alleles described since the previous *Olerup* SSP® HLA-A*23 lot was made **(Lot No. 33F)**.

Two wells have been added to the HLA-A*23kit,
wells **23 and 24**.

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

Well	5'-primer	3'-primer	rationale
23	New	New	New primer pair for the A*2320 allele.
24	New	New	New primer pair for the A*2321 allele.

PRODUCT DESCRIPTION

HLA-A*23 SSP subtyping

CONTENT
The primer set contains 5'- and 3'-primers for identifying the A*2301 to A*2321 alleles.

PLATE LAYOUT
Each test consists of 24 PCR reactions in a 24 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**

The 24 well cut PCR plate is marked with 'HLA-A*23' in silver/gray ink.
Well No. 1 is marked with the Lot Number '31G'.
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 24 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
The interpretation of HLA-A*23 SSP subtypings will be influenced three A*01, twelve A*02, the A*0321N, the A*1121N, most A*24, the A*2616, the A*2907, several A*30, the A*3208, the A*3319 and two A*68 alleles when present on the other haplotype. In addition, the B*1827 allele will be amplified by primer mixes 1, 3, 14 and 15.

UNIQUELY IDENTIFIED ALLELES
All the HLA-A*23 alleles, i.e. **A*2301 to A*2321 alleles**, recognized by the HLA Nomenclature Committee in July 2009[1] will give rise to unique amplification patterns by the primers in the HLA-A*23 subtyping kit.
The HLA-A*23 subtyping kit cannot distinguish the A*230301 and A*230302 alleles.

[1]HLA-A alleles listed on the IMGT/HLA web page 2009-July-17, release 2.26.0, www.ebi.ac.uk/imgt/hla.

RESOLUTION IN HOMO- AND HETEROZYGOTES

The 21 HLA-A*23 alleles can be combined in 231 homozygous and heterozygous combinations. Fifty-six of these genotypes do not give rise to unique amplification patterns. (The different sizes of the specific PCR products generated by primer mix 16 were not considered in these calculations.)

```
++++----- -------- -+--+---  230101,2303 = 2303,2317
++-+---- -------- -+--+---  230101,2318 = 2317,2318 = 2318,2318
++--+--- -------- -+--+---  230101,2306 = 2306,2306 = 2306,2317
++---+-- -------- -+--+---  230101,2307N = 2307N,2307N =
                            2307N,2317
++----+- -------- -+--+---  230101,2308N = 2308N,2308N =
                            2308N,2317
++-----+ -------- -+--+---  230101,2309 = 2309,2309 = 2309,2317
++------ +------- -+--+---  230101,2305 = 2305,2305 = 2305,2317
++------ -+------ -+--+---  230101,2310 = 2310,2310 = 2310,2317
++------ --+----- -+--+---  230101,2311N = 2311N,2311N =
                            2311N,2317
++------ ---+---- -+--+---  230101,2312 = 2312,2312 = 2312,2317
++------ ----+--- -+--+---  230101,2302 = 2302,2317
++------ -----+-- -+--+---  230101,2304 = 2304,2317
++------ ------++ -+--+---  230101,2314 = 2314,2314 = 2314,2317
++------ -------- ++--+---  230101,2313 = 2313,2313 = 2313,2317
++------ -------- -++-+---  230101,2315 = 2315,2315 = 2315,2317
++------ -------- -+-++---  230101,2316 = 2316,2316 = 2316,2317
++------ -------- -+--++--  230101,2319Q = 2317,2319Q =
                            2319Q,2319Q
++------ -------- -+--+-+-  230101,2320 = 2317,2320 = 2320,2320
++------ -------- -+--+--+  230101,2321 = 2317,2321 = 2321,2321
++------ -------- -+--+---  230101,230101 = 230101,2317

2303 = 230301 and 230302
```

SPECIFICITY TABLE

HLA-A*23 SSP subtyping

Specificities and sizes of the PCR products of the 24 primer mixes used for HLA-A*23 SSP subtyping

Primer Mix	Size of spec. PCR product[1]	Size of control band[2]	Amplified HLA-A*23 alleles	Other amplified HLA Class I alleles[3]
1[4]	210 bp	**800 bp**	*230101, 230301-2321	*021701, 021702, 9208, 9210, 241301, 241302, 2418, 2424, 2494, 2907, **B*1827**
2	160 bp	1070 bp	*230101, 2302, 2305-2321	*0219, 0236, 0237, 0254, 24020101-240217, 240220, 2404-2409N, 2411N, 241301-2415, 2417, 2419, 2420, 2424-2432, 2434-2464, 2466-2474, 2476-2493, 2495-2499, 3319, 6826
3[5]	125 bp	**800 bp**	*230301, 230302	*2421, 2907, **B*1827**
4[5]	90 bp	1070 bp	*2318	
5	230 bp	**800 bp**	*2306	
6	470 bp	1070 bp	*2307N	*0104N, 0321N, 1121N, 2411N
7[5]	95 bp	**800 bp**	*2308N	*0282N
8[6]	215 bp	1070 bp	*2309	*0102, 0120
9	235 bp	1070 bp	*2305	*2425
10	230 bp	**800 bp**	*2310	*2410[W], 2446
11	200 bp	**800 bp**	*2311N	
12	190 bp	1070 bp	*2312	*2430, 2442, 3208
13	210 bp	**800 bp**	*2302	*2406, 2487
14	245 bp	1070 bp	*2304	*021701, 021702, 9208, 9210, 240301, 240302, 2410, 2418, 2422, 2433, 2494, 2907, **B*1827**
15	210 bp	1070 bp	*2314	*241302, **B*1827**
16[7]	175 bp, 205 bp	**800 bp**	*2314	*021701[W], 021702[W], 24020101-240217, 240220-2411N, 241301, 241302, 2417-2450, 2454-2456, 2458-2463, 2466-2491, 2493, 2495-2499, 2616, 3319, 6845

17	225 bp	1070 bp	*2313	*2407, 2419, 2424, 300101, 300102, 301101, 301102, 3014L-3020, 3023-3026, 6845
18[5]	110 bp	1070 bp	*230101, 2302[w], 2304-2313, 2314[w], 2315-2321	*0240, 0251, 9230, 2424
19[5]	120 bp	**800 bp**	*2315	
20	230 bp	**800 bp**	*2316	
21[5]	90 bp	**800 bp**	*230101-2316, 2318-2321	
22	290 bp	1070 bp	*2319Q	
23[6]	170 bp	1070 bp	*2320	
24	180 bp	**800 bp**	*2321	

[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 HLA-A*23 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 1070 base pairs, for most wells, or a band of 800 base pairs, for some wells.
Well number 1 contains the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to help in the correct orientation of the HLA-A*23 subtyping.
In addition, wells number 3, 5, 7, 10, 11, 13, 16, 19 to 21 and 24 contain the primer pair giving rise to the shorter, 800 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]Due to the sharing of sequence motifs between HLA-A alleles non-HLA-A*23 alleles will be amplified by primer mixes 1 to 3, 6 to 10 and 12 to 18. In addition, the B*1827 allele will be amplified by primer mixes 1, 3, 14 and 15.
[4]Primer mix 1 may yield somewhat less PCR product than the other A*23 primer mixes.
[5]Short specific PCR fragments are less intense and not as sharp as longer specific bands.
[6]Primer mix 8 and 23 may give rise to nonspecific amplifications.
[7]Primer mix 16: Specific PCR fragment of 175 bp in the A*2314 and A*240216, 2406, 241301-241302, 2418, 2422, 2454, 2487 and 2491 alleles. Specific PCR fragment of 205 bp in the A*2405, 2424, 2616 and A*6845 alleles. Specific PCR fragment of 175 and 205 bp in the A*24020101-240215, 240217, 240220-2404, 2407-2411N, 2417, 2419-2421, 2423, 2425-2450, 2455, 2456, 2458-2463, 2466-2486N, 2488-2490N, 2493, 2495-2499 and A*3319 alleles.
'w', may be weakly amplified.

INTERPRETATION TABLE

HLA-A*23 SSP subtyping

Amplification patterns of the A*2301 to A*2321 alleles

	Well[4]											
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**
Length of spec. PCR product	**210**	**160**	**125**	**90**	**230**	**470**	**95**	**215**	**235**	**230**	**200**	**190**
Length of int. pos. control[1]	**800**	**1070**	**800**	**1070**	**800**	**1070**	**800**	**1070**	**1070**	**800**	**800**	**1070**
5'-primer(s)[2]	**368**	**453**	**368**	**678**	**144**	**3rd I**	**564**	**98**	**28**	**368**	**160**	**144**
	5' -gTT 3'	5' -AAA 3'	5' -gTT 3'	5' -AgA 3'	5' -gCC 3'	5' -ATA 3'	5' -TgA 3'	5' -CTC 3'	5' -TCg 3'	5' -gTT 3'	5' -ACg 3'	5' -gCC 3'
3'-primer(s)[3]	**539**	**570**	**453**	**728**	**331**	**621**	**616**	**271**	**92**	**559**	**317**	**292**
	5' -TCA 3'	5' -CCg 3'	5' -TCg 3'	5' -CCT 3'	5' -CTC 3'	5' -ggg 3'	5' -CgT 3'	5' -CAT 3'	5' -AAC 3'	5' -CCg 3'	5' -ggA 3'	5' -gTg 3'
Well No.	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**
HLA-A allele												
***230101**	**1**	**2**										
***2302**		**2**										
***230301, 230302**	**1**		**3**									
***2304**	**1**											
***2305**	**1**	**2**							**9**			
***2306**	**1**	**2**			**5**							
***2307N**	**1**	**2**				**6**						
***2308N**	**1**	**2**					**7**					
***2309**	**1**	**2**						**8**				
***2310**	**1**	**2**								**10**		
***2311N**	**1**	**2**									**11**	
***2312**	**1**	**2**										**12**
***2313**	**1**	**2**										
***2314**	**1**	**2**										
***2315**	**1**	**2**										
***2316**	**1**	**2**										
***2317**	**1**	**2**										
***2318**	**1**	**2**		**4**								
***2319Q**	**1**	**2**										
***2320**	**1**	**2**										
Well No.	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**

INTERPRETATION TABLE

HLA-A*23 SSP subtyping

Amplification patterns of the A*2301 to A*2321 alleles

Well[4]												
13	14	15	16	17	18	19	20	21	22	23	24	
210	245	210	175	225	110	120	230	90	290	170	180	Length of spec.
			205									PCR product
800	1070	1070	800	1070	1070	800	800	800	1070	1070	800	Length of int.
												pos. control[1]
368	368	368	98	98	453	493	379	920	368	678	98	5'-primer(s)[2]
5' -gTT 3'	5' -gTT 3'	5' -gTT 3'	5' -CTC 3'	5' -CTC 3'	5' -AAA 3'	5' -CTg 3'	5' -ACA 3'	5' -CCA 3'	5' -gTT 3'	5' -AgA 3'	5' -CTC 3'	
			368									
			5' -gTT 3'									
539	570	538	259	282	524	570	570	971	619	806	238	3'-primer(s)[3]
5' -TCC 3'	5' -CAC 3'	5' -CAg 3'	5' -gTT 3'	5' -gAC 3'	5' -CAC 3'	5' -CCg 3'	5' -CCg 3'	5' -CAg 3'	5' -gTT 3'	5' -CTA 3'	5' -CCT 3'	
			502	282								
			5' -CTT 3'	5' -gAC 3'								
			539									
			5' -TCT 3'									
13	14	15	16	17	18	19	20	21	22	23	24	Well No.
												HLA-A allele
					18			21				*230101
13					w			21				*2302
								21				*230301, 230302
	14				18			21				*2304
					18			21				*2305
					18			21				*2306
					18			21				*2307N
					18			21				*2308N
					18			21				*2309
					18			21				*2310
					18			21				*2311N
					18			21				*2312
				17	18			21				*2313
		15	16		w			21				*2314
					18	19		21				*2315
					18		20	21				*2316
					18							*2317
					18			21				*2318
					18			21	22			*2319Q
					18			21		23		*2320
13	14	15	16	17	18	19	20	21	22	23	24	Well No.

Length of spec.	**210**	**160**	**125**	**90**	**230**	**470**	**95**	**215**	**235**	**230**	**200**	**190**
PCR product												
Well No.	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**
***2321**	**1**	**2**										
***0102, 0120**								**8**				
***0104N, 0321N, 1121N**						**6**						
***021701, 021702**	**1**											
***0219, 0236, 0237, 0254, 2414, 2415, 2451-2453, 2457, 2464, 2492, 6826**		**2**										
***0240, 0251, 9230**												
***0282N**							**7**					
***24020101-240217, 240220, 2404, 2405, 2408, 2409N, 2417, 2420, 2426-2429, 2431, 2432, 2434-2441, 2443-2445N, 2447-2450, 2454-2456, 2458-2463, 2466-2474, 2476-2486N, 2488-2491, 2493, 2495-2499, 3319**		**2**										
***240301, 240302, 2422, 2433**												
***2406, 2487**		**2**										
***2407, 2419**		**2**										
***2410**										**w**		
***2411N**		**2**				**6**						
***241301**	**1**	**2**										
***241302**	**1**	**2**										
***2418**	**1**											
***2421**			**3**									
***2423, 2475, 2616**												
***2424**	**1**	**2**										
***2425**		**2**							**9**			
***2430, 2442**		**2**										**12**
***2446**		**2**								**10**		
***2494, 9208, 9210**	**1**											
***2907**	**1**		**3**									
***300101, 300102, 301101, 301102, 3014L-3020, 3023-3026**												
***3208**												**12**
***6845**												
B*1827	**1**		**3**									
Well No.	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**

210	245	210	175	225	110	120	230	90	290	170	180	Length of spec.
			205									PCR product
13	14	15	16	17	18	19	20	21	22	23	24	Well No.
					18			21			24	*2321
												*0102, 0120
												*0104N, 0321N, 1121N
	14		w									*021701, 021702
												*0219, 0236, 0237, 0254, 2414, 2415, 2451-2453, 2457, 2464, 2492, 6826
					18							*0240, 0251, 9230
												*0282N
			16									*24020101-240217, 240220, 2404, 2405, 2408, 2409N, 2417, 2420, 2426-2429, 2431, 2432, 2434-2441, 2443-2445N, 2447-2450, 2454-2456, 2458-2463, 2466-2474, 2476-2486N, 2488-2491, 2493, 2495-2499, 3319
	14		16									*240301, 240302, 2422, 2433
13			16									*2406, 2487
			16	17								*2407, 2419
	14		16									*2410
			16									*2411N
			16									*241301
		15	16									*241302
	14		16									*2418
			16									*2421
			16									*2423, 2475, 2616
			16	17	18							*2424
			16									*2425
			16									*2430, 2442
			16									*2446
	14											*2494, 9208, 9210
	14											*2907
				17								*300101, 300102, 301101, 301102, 3014L-3020, 3023-3026
												*3208
			16	17								*6845
	14	15										*B*1827*
13	14	15	16	17	18	19	20	21	22	23	24	Well No.

[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 1070 base pairs, for most Wells, or a band of 800 base pairs, for some Wells.
Well number 1 contains the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to help in the correct orientation of the HLA-A*23 subtyping. .
In addition, wells number 3, 5, 7, 10, 11, 13, 16 and 19 to 21 contain the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to allow kit identification.
[2]The nucleotide position, in the 1st, 2nd, 3rd or 4th exons or 3rd intron matching the specificity-determining 3'-end of the primer is given. 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 nucleotide position, in the 2nd, 3rd or 4th exons, matching the specificity-determining 3'-end of the primer is given in the anti-sense direction. 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]Primer mix 16: Specific PCR fragment of 175 bp in the A*2314 and A*240216, 2406, 241301-241302, 2418, 2422, 2454, 2487 and 2491 alleles. Specific PCR fragment of 205 bp in the A*2405, 2424, 2616 and A*6845 alleles. Specific PCR fragment of 175 and 205 bp in the A*24020101-240215, 240217, 240220-2404, 2407-2411N, 2417, 2419-2421, 2423, 2425-2450, 2455, 2456, 2458-2463, 2466-2486N, 2488-2490N, 2493, 2495-2499 and A*3319 alleles.
'w', may be weakly amplified.

CELL LINE VALIDATION SHEET

HLA-A*23 SSP subtyping kit

					Well														
					1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
				Lot No.:	200853601	200853602	200853603	200853623	200853605	200853606	200853607	200853608	200853609	200853610	200853611	200853612	200853613	200853614	200853615	200853616
	IHWC cell line		A*	A*																
1	9001	SA	*2402		-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	+
2	9280	LK707	*0201		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3	9011	E4181324	*0101		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4	9275	GU373	*3001		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
5	9009	KAS011	*0101		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
6	9353	SM	*0201	*2603	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
7	9020	QBL	*2601		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
8	9025	DEU	*3101		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
9	9026	YAR	*2601		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
10	9107	LKT3	*2402		-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	+
11	9051	PITOUT	*2902		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
12	9052	DBB	*0201		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
13	9004	JESTHOM	*0201		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
14	9071	OLGA	*3101		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
15	9075	DKB	*2402		-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	+
16	9037	SWEIG007	*2902		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
17	9282	CTM3953540	*0301	*8001	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
18	9257	32367	*3303	*7401	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
19	9038	BM16	*0201		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
20	9059	SLE005	*0201		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
21	9064	AMALA	*0217		+	-	-	-	-	-	-	-	-	-	-	-	-	+	-	W
22	9056	KOSE	*0201		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
23	9124	IHL	*0201	*3401	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
24	9035	JBUSH	*3201		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
25	9049	IBW9	*3301		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
26	9285	WT49	*0205		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
27	9191	CH1007	*2410	*2901	-	-	-	-	-	-	-	-	-	W	-	-	-	+	-	+
28	9320	BEL5GB	*0201	*2902	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
29	9050	MOU	*2902		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
30	9021	RSH	*3001	*6802	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
31	9019	DUCAF	*3002		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
32	9297	HAG	*0201		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
33	9098	MT14B	*3101		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
34	9104	DHIF	*3101		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
35	9302	SSTO	*3201		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
36	9024	KT17	*0206	*1101	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
37	9065	HHKB	*0301		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
38	9099	LZL	*0217		+	-	-	-	-	-	-	-	-	-	-	-	-	+	-	W
39	9315	CML	*0101	*0301	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
40	9134	WHONP199	*0207	*3001	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
41	9055	H0301	*0301		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
42	9066	TAB089	*0207		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
43	9076	T7526	*0207		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
44	9057	TEM	*6601		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
45	9239	SHJO	*2301	*2402	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-	+
46	9013	SCHU	*0301		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
47	9045	TUBO	*0216	*0301	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
48	9303	TER-ND	*0201	*1101	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

CELL LINE VALIDATION SHEET

HLA-A*23 SSP subtyping kit

					Well							
					17	18	19	20	21	22	23	24
				Lot No.:	200853617	200853618	200853619	200853620	200853621	200853622	200967723	200963924
	IHWC cell line		A*	A*								
1	9001	SA	*2402		-	-	-	-	-	-	-	-
2	9280	LK707	*0201		-	-	-	-	-	-	-	-
3	9011	E4181324	*0101		-	-	-	-	-	-	-	-
4	9275	GU373	*3001		+	-	-	-	-	-	-	-
5	9009	KAS011	*0101		-	-	-	-	-	-	-	-
6	9353	SM	*0201	*2603	-	-	-	-	-	-	-	-
7	9020	QBL	*2601		-	-	-	-	-	-	-	-
8	9025	DEU	*3101		-	-	-	-	-	-	-	-
9	9026	YAR	*2601		-	-	-	-	-	-	-	-
10	9107	LKT3	*2402		-	-	-	-	-	-	-	-
11	9051	PITOUT	*2902		-	-	-	-	-	-	-	-
12	9052	DBB	*0201		-	-	-	-	-	-	-	-
13	9004	JESTHOM	*0201		-	-	-	-	-	-	-	-
14	9071	OLGA	*3101		-	-	-	-	-	-	-	-
15	9075	DKB	*2402		-	-	-	-	-	-	-	-
16	9037	SWEIG007	*2902		-	-	-	-	-	-	-	-
17	9282	CTM3953540	*0301	*8001	-	-	-	-	-	-	-	-
18	9257	32367	*3303	*7401	-	-	-	-	-	-	-	-
19	9038	BM16	*0201		-	-	-	-	-	-	-	-
20	9059	SLE005	*0201		-	-	-	-	-	-	-	-
21	9064	AMALA	*0217		-	-	-	-	-	-	-	-
22	9056	KOSE	*0201		-	-	-	-	-	-	-	-
23	9124	IHL	*0201	*3401	-	-	-	-	-	-	-	-
24	9035	JBUSH	*3201		-	-	-	-	-	-	-	-
25	9049	IBW9	*3301		-	-	-	-	-	-	-	-
26	9285	WT49	*0205		-	-	-	-	-	-	-	-
27	9191	CH1007	*2410	*2901	-	-	-	-	-	-	-	-
28	9320	BEL5GB	*0201	*2902	-	-	-	-	-	-	-	-
29	9050	MOU	*2902		-	-	-	-	-	-	-	-
30	9021	RSH	*3001	*6802	+	-	-	-	-	-	-	-
31	9019	DUCAF	*3002		-	-	-	-	-	-	-	-
32	9297	HAG	*0201		-	-	-	-	-	-	-	-
33	9098	MT14B	*3101		-	-	-	-	-	-	-	-
34	9104	DHIF	*3101		-	-	-	-	-	-	-	-
35	9302	SSTO	*3201		-	-	-	-	-	-	-	-
36	9024	KT17	*0206	*1101	-	-	-	-	-	-	-	-
37	9065	HHKB	*0301		-	-	-	-	-	-	-	-
38	9099	LZL	*0217		-	-	-	-	-	-	-	-
39	9315	CML	*0101	*0301	-	-	-	-	-	-	-	-
40	9134	WHONP199	*0207	*3001	+	-	-	-	-	-	-	-
41	9055	H0301	*0301		-	-	-	-	-	-	-	-
42	9066	TAB089	*0207		-	-	-	-	-	-	-	-
43	9076	T7526	*0207		-	-	-	-	-	-	-	-
44	9057	TEM	*6601		-	-	-	-	-	-	-	-
45	9239	SHJO	*2301	*2402	-	+	-	-	+	-	-	-
46	9013	SCHU	*0301		-	-	-	-	-	-	-	-
47	9045	TUBO	*0216	*0301	-	-	-	-	-	-	-	-
48	9303	TER-ND	*0201	*1101	-	-	-	-	-	-	-	-

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-A*23 SSP

Product number: **101.421-06 – including *Taq* polymerase**
Lot number: **31G**
Expiry date: **2011-October-01**
Number of tests: **6**
Number of wells per test: **24**

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2008-536-01	9	2008-536-09	17	2008-536-17
2	2008-536-02	10	2008-536-10	18	2008-536-18
3	2008-536-03	11	2008-536-11	19	2008-536-19
4	2008-536-23	12	2008-536-12	20	2008-536-20
5	2008-536-05	13	2008-536-13	21	2008-536-21
6	2008-536-06	14	2008-536-14	22	2008-536-22
7	2008-536-07	15	2008-536-15	23	2009-677-23
8	2008-536-08	16	2008-536-16	24	2009-639-24

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 3 to 5, 9, 11, 13, 15, 19, 20 and 22 to 24 were available. The specificities of the primers in primer solutions 3, 13 and 15 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer solutions 4, 5, 9 and 22 to 24 it was only possible to test the 5'-primers, the 3'-primers were not possible to test. In primer solutions 11, 19 and 20 it was only possible to test the 3'-primers, the 5'-primers was not possible to test. Additional primers in primer solution 16 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer.

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

Date of approval: 2009-November-17

Approved by:

Quality Control, Supervisor

Declaration of Conformity

Product name: *Olerup* SSP® HLA-A*23
Product number: 101.421-06
Lot number: 31G

Intended use: HLA-A*23 high resolution histocompatibility testing

Manufacturer: *Olerup* SSP AB
Hasselstigen 1
SE-133 33 Saltsjöbaden, 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, Hasselstigen 1, SE-133 33 Saltsjöbaden, Sweden.

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

Notified Body: Lloyd's Register Quality Assurance Limited, Hiramford, Middlemarch Office Village, Siskin Drive, Coventry CV3 4FJ, United Kingdom. (Notified Body number: 0088.)

Saltsjöbaden, Sweden
2009- November-17

Olle Olerup
Managing Director

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