

Lot No.: **33F**

Lot-specific information

Olerup SSP[®] HLA-A*23

Product number: 101.421-06u – without *Taq* polymerase
Lot number: 33F
Expiry date: 2010-November-01
Number of tests: 6
Number of Wells per test: 22
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. 33F.

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. 27E).

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	New	New	New primer pair for the A*2318 allele.
5	-	-	Exchanged control primer pair.
8	-	Exchanged	Exchanged 3'-primer for increased specificity.
16	-	-	Exchanged control primer pair.
18	Modified	-	Increased yield of specific PCR product.
21	-	Modified	Increased yield of specific PCR product.

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PRODUCT DESCRIPTION

HLA-A*23 SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for identifying the A*2301 to A*2319Q alleles.

PLATE LAYOUT

Each test consists of 22 PCR reactions in a 24 well cut PCR plate. Wells 23 to 24 are empty.

1	2	3	4	5	6	7	8
9	10	11	12	13	14	15	16
17	18	19	20	21	22	empty	empty

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 '33F'.

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*3319 and the A*6826 when present on the other haplotype. In addition, the B*1827 allele will be amplified by primer mixes 1 and 15.

UNIQUELY IDENTIFIED ALLELES

All the HLA-A*23 alleles, i.e. **A*2301 to A*2319Q alleles**, recognized by the HLA Nomenclature Committee in October 2008¹ 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.

¹HLA-A alleles listed on the IMGT/HLA web page 2008-October-10, release 2.23.0, www.ebi.ac.uk/imgt/hla.

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RESOLUTION IN HOMO- AND HETEROZYGOTES

The 19 HLA-A*23 alleles can be combined in 190 homozygous and heterozygous combinations. Fifty of these genotypes do not give rise to unique amplification patterns.

+++-----	-----	-+---+	2301,2303 = 2303,2317
++-+-----	-----	-+---+	2301,2318 = 2317,2318 = 2318,2318
+++--+---	-----	-+---+	2301,2306 = 2306,2306 = 2306,2317
++----+--	-----	-+---+	2301,2307N = 2307N,2307N = 2307N,2317
++-----+	-----	-+---+	2301,2308N = 2308N,2308N = 2308N,2317
+++-----	-----	-+---+	2301,2309 = 2309,2309 = 2309,2317
+++-----	+-----	-+---+	2301,2305 = 2305,2305 = 2305,2317
+++-----	-+-----	-+---+	2301,2310 = 2310,2310 = 2310,2317
+++-----	--+-----	-+---+	2301,2311N = 2311N,2311N = 2311N,2317
+++-----	---+-----	-+---+	2301,2312 = 2312,2312 = 2312,2317
+++-----	-----+---	-+---+	2301,2302 = 2302,2317
+++-----	-----+--	-+---+	2301,2304 = 2304,2317
+++-----	-----++	-+---+	2301,2314 = 2314,2314 = 2314,2317
+++-----	-----	++---+	2301,2313 = 2313,2313 = 2313,2317
+++-----	-----	-+---+	2301,2315 = 2315,2315 = 2315,2317
+++-----	-----	-+---+	2301,2316 = 2316,2316 = 2316,2317
+++-----	-----	-+---+	2301,2319Q = 2317,2319Q = 2319Q,2319Q
+++-----	-----	-+---+	2301,2301 = 2301,2317

2303 = 230301 and 230302

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SPECIFICITY TABLE

HLA-A*23 SSP subtyping

Specificities and sizes of the PCR products of the 22 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
1⁴	210 bp	800 bp	2301, 230301-2319Q	021701-021702, 9208, 9210, 241301-241302, 2418, 2424, 2494, 2907, B*1827
2	160 bp	1070 bp	2301, 2302, 2305-2319Q	0219, 0236, 0237, 0254, 24020101-240216, 2404-2409N, 2411N, 241301-2415, 2417, 2419, 2420, 2424-2432, 2434-2464, 2466-2474, 2476-2493, 3319, 6826
3⁵	125 bp	800 bp	230301-230302	2421, 2907
4⁵	90 bp	1070 bp	2318	
5	230 bp	1070 bp	2306	
6	470 bp	1070 bp	2307N	0104N, 0321N, 1121N, 2411N
7⁵	95 bp	800 bp	2308N	0282N
8	215 bp	1070 bp	2309	0102, 0120
9	235 bp	1070 bp	2305	2425
10	230 bp	800 bp	2310	2410 ^{weakly} , 2446
11	200 bp	800 bp	2311N	
12	190 bp	1070 bp	2312	2430, 2442
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
15	210 bp	1070 bp	2314	241302, B*1827
16⁶	175, 205 bp	800 bp	2314	021701-021702 ^{weakly} , 24020101-2411N, 241301-241302, 2417-2450, 2454-2456, 2458-2463, 2466-2491,

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			2493, 2616, 3319
17	225 bp		2407, 2419, 2424, 300101-300102, 301101-301102, 3014L-3020, 3023- 3026
		1070 bp	
18⁵	110 bp		0240, 0251, 9230, 2424
		1070 bp	
			2301, 2302 ^{weakly} , 2304-2313, 2314 ^{weakly} , 2315- 2319Q
19⁵	120 bp	800 bp	2315
20	230 bp	800 bp	2316
21⁵	90 bp	800 bp	2301-2316, 2318, 2319Q
22	290 bp	1070 bp	2319Q

¹Alleles are assigned by the presence of specific PCR product(s). However, the sizes of the specific PCR products may be helpful in the interpretation of 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 length of the specific PCR product(s) of the alleles amplified by these primer mixes are given.

Nonspecific amplifications, i.e. a ladder or a smear of bands, may sometimes be seen. GC-rich primers have a higher tendency of giving rise to nonspecific amplifications than other primers.

PCR fragments longer than the control bands may sometimes be observed. Such bands should be disregarded and do not influence the interpretation of the SSP typings.

PCR fragments migrating faster than the control bands, but slower than a 400 bp fragment may be seen in some gel read-outs. Such bands can be disregarded and do not influence the interpretation of the SSP typings.

Some primers may give rise to primer oligomer artifacts. Sometimes this phenomenon is an inherent feature of the primer pair(s) of a primer mix. More often it is due to other factors such as too low amount of DNA in the PCR reactions, taking too long time in setting up the PCR reactions, working at elevated room temperature or using thermal cyclers that are not pre-heated.

²The internal positive control primer pairs amplify segments of the human growth hormone gene. The two different control primer pairs give rise to either an internal positive control band of 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.

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

³Due 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, 12 to 18. In addition, the B*1827 allele will be amplified by primer mixes 1 and 15.

⁴Primer mixes 1 may yield somewhat less PCR product than the other A*23 primer mixes.

⁵Short specific PCR fragments are less intense and not as sharp as longer specific bands.

⁶Primer mix 16: Specific PCR fragment of 175 bp in the A*2314 and A*021701-021712^{weakly}, 240216, 2406, 241301-241302, 2418, 2422, 2454, 2487 and 2491 alleles. Specific PCR fragment of 205 bp in the A*2405, 2424 and A*2616 alleles. Specific PCR fragment of 175 and 205 bp in the A*24020101-240215, 240301-2404, 2407-2411N, 2417, 2419-2421, 2423, 2425-2450, 2455, 2456, 2458-2463, 2466-2486N, 2488-2490N, 2493 and A*3319 alleles.

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INTERPRETATION TABLE												
HLA-A*23 SSP subtyping												
Amplification patterns of the A*2301 to A*2319Q alleles												
	Well⁴											
	1	2	3	4	5	6	7	8	9	10	11	12
Length of spec.	210	160	125	90	230	470	95	215	235	230	200	190
PCR product												
Length of int.	800	1070	800	1070	800	1070	800	1070	1070	800	800	1070
pos. control¹												
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	270	92	559	317	292
	5'-TCA ^{3'}	5'-CCg ^{3'}	5'-TCg ^{3'}	5'-CCT ^{3'}	5'-CTC ^{3'}	5'-CCC ^{3'}	5'-CgT ^{3'}	5'-ATA ^{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												
*2301	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										
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

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INTERPRETATION TABLE										
HLA-A*23 SSP subtyping										
Amplification patterns of the A*2301 to A*2319Q alleles										
Well⁴										
13	14	15	16	17	18	19	20	21	22	
210	245	210	175	225	110	120	230	90	290	Length of spec.
			205							PCR product
800	1070	1070	800	1070	1070	800	800	800	1070	Length of int.
										pos. control ¹
368	368	368	98	98	453	493	379	920	368	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'}	
			368							
			5'-gTT ^{3'}							
539	570	538	259	282	524	570	570	971	619	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'-ggT ^{3'}	
			502							
			5'-CTT ^{3'}							
			539							
			5'-TCT ^{3'}							
13	14	15	16	17	18	19	20	21	22	Well No.
										HLA-A allele
					18			21		*2301
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		18			21		*2314
					18	19		21		*2315
					18		20	21		*2316
					18					*2317
					w			21		*2318
					18			21	22	*2319Q
13	14	15	16	17	18	19	20	21	22	Well No.

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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	
*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								
*2494, 9208, 9210	1												
*24020101-240216, 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, 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				
*2907	1	3											
*300101-300102, 301101- 301102, 3014L-3020, 3023- 3026													
HLA-A allele													
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	
B*1827	1												
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	

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210	245	210	175	225	110	120	230	90	290	Length of spec.
			205							PCR product
13	14	15	16	17	18	19	20	21	22	Well No.
										*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
	14									*2494, 9208, 9210
			16							*24020101-240216, 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, 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									*2907
				17						*300101-300102, 301101- 301102, 3014L-3020, 3023 3026
										HLA-A allele
13	14	15	16	17	18	19	20	21	22	Well No.
		15								B*1827
13	14	15	16	17	18	19	20	21	22	Well No.

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¹The internal positive control primer pairs amplify segments of the human growth hormone gene. The two different control primer pairs give rise to either an internal positive control band of 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.

²The 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.

³The 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.

⁴Primer mix 16: Specific PCR fragment of 175 bp in the A*2314 and A*021701-021712^{weakly}, 240216, 2406, 241301-241302, 2418, 2422, 2454, 2487 and 2491 alleles. Specific PCR fragment of 205 bp in the A*2405, 2424 and A*2616 alleles. Specific PCR fragment of 175 and 205 bp in the A*24020101-240215, 240301-2404, 2407-2411N, 2417, 2419-2421, 2423, 2425-2450, 2455, 2456, 2458-2463, 2466-2486N, 2488-2490N, 2493 and A*3319 alleles.

'w', may be weakly amplified.

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CELL LINE VALIDATION SHEET																					
HLA-A*23 SSP subtyping kit																					
				Lot No.:	Well																
					1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	
	IHWC cell line	A*	A*		200853601	200853602	200853603	200853623	200853605	200853606	200853607	200853608	200853609	200853610	200853611	200853612	200853613	200853614	200853615	200853616	
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	9007 DEM	*0201			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
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		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

Lot No.: **33F**

Lot-specific information

CELL LINE VALIDATION SHEET										
HLA-A*23 SSP subtyping kit										
					Well					
					17	18	19	20	21	22
				Lot No.:	200853617	200853618	200853619	200853620	200853621	200853622
	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	9007 DEM	*0201			-	-	-	-	-	-
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		-	-	-	-	-	-

Lot No.: **33F**

Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP[®] HLA-A*23 SSP

Product number: 101.421-06u – without *Taq* polymerase
Lot number: 33F
Expiry date: 2010-November-01
Number of tests: 6
Number of Wells per test: 22

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		
8	2008-536-08	16	2008-536-16		

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 3 to 5, 9, 11, 13, 15, 19, 20 and 22 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 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-May-25

Approved by:

Quality Control, Supervisor

Lot No.: **33F**

Lot-specific information

Declaration of Conformity

Product name: *Olerup* SSP® HLA-A*23
Product number: 101.421-06u
Lot number: 33F

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 9001:2000 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-May-25

Olle Olerup
Managing Director

Lot No.: **33F**

Lot-specific information

Lot No.: **33F**

Lot-specific information

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