

Olerup SSP[®] HLA-A*23

Product number:	101.421-06 – including <i>Taq</i> polymerase 101.421-06u – without <i>Taq</i> polymerase
Lot number:	27E
Expiry date:	2010-February-01
Number of tests:	6
Number of Wells per test:	22
Storage - pre-aliquoted primers:	dark at -20°C
- PCR Master Mix:	-20°C

This Product Description is only valid for Lot No. 27E.

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. X44).

Four wells have been added to the HLA-A*23 kit,
wells **19 and 22**.

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

Well	5'-primer	3'-primer	rationale
19	New	New	New primer pair for the A*2315 allele.
20	New	New	New primer pair for the A*2316 allele.
21	New	New	New primer pair for the A*2317 allele.
22	New	New	New primer pair for the A*2319Q allele.

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 'A*23'.

Well No. 1 is marked with '27E'.

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, thirteen A*02, the A*0321N, the A*1121N, most A*24, the A*2616, most A*29, several A*30, most A*31, most A*32, most A*33, the A*6826 and the A*74 alleles 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 alleles¹, i.e. **A*2301 to A*2319Q alleles**, recognized by the HLA Nomenclature Committee in January 2008⁸ will give rise to unique amplification patterns by the primers in the HLA-A*23 subtyping kit.

¹The nucleotide sequence of the A*2318 allele is not yet retrievable.

²HLA-A alleles listed on the IMGT/HLA web page 2008-January-11, release 2.20.0, www.ebi.ac.uk/imgt/hla.

RESOLUTION IN HOMO- AND HETEROZYGOTES

The 18 HLA-A*23 alleles give rise to 19 different amplification patterns that can be combined in 190 homozygous and heterozygous combinations. Fifty-one of these genotypes do not give rise to unique amplification patterns.

++++-----	-----	-+----	2301,230301 = 230301,2317
+++-----	-----	-+----	2301,230302 = 230302,2317
+++-----	-----	-+----	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
++-----	-----	----+	230301,230301 = 230301,230302

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 ³	Other amplified HLA Class I alleles ⁴
1 ⁵	210 bp	800 bp	2301, 230301-2317, 2319Q	021701-021702, 9208, 9210, 241301-241302, 2418, 2424, 2907, B*1827
2	160 bp	1070 bp	2301, 2302, 2305-2317, 2319Q	0219, 0236, 0237, 0254, 24020101-240215, 2404-2409N, 2411N, 241301-2415, 2417, 2419, 2420, 2424-2432, 2434-2474, 2476-2484N, 6826
3 ⁶	125 bp	800 bp	230301-230302	2421, 2907
4 ^{5,6}	130 bp	800 bp	230301	0265, 29010101-2904, 2906-2917, 310102, 310103, 3102, 3105-3121, 320101-320103, 3203, 3205-3209, 3211Q-3215, 3301, 330301-3313, 7401-7412N
5	230 bp	1070 bp	2306	
6	470bp	1070 bp	2307N	0104N, 0321N, 1121N, 2411N
7 ⁶	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
14	245 bp	1070 bp	2304	021701-021702, 9208, 9210, 240301-240302, 2410, 2418, 2422, 2433, 2907
15	245 bp	1070 bp	2314	241302, B*1827

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16⁷	175, 205 bp	1070 bp	2314	021701-021702 ^{weakly} , 24020101-2411N, 241301-241302, 2417- 2450, 2454-2456, 2458-2463, 2466- 2484N, 2616
17	225 bp	1070 bp	2313	2407, 2419, 2424, 300101-300102, 301101-301102, 3014L-3020, 3023, 3024
18⁶	110 bp	1070 bp	2301, 2302 ^{weakly} , 2304-2317, 2319Q	0240, 0251, 9230, 2424
19⁶	120 bp	800 bp	2315	
20	230 bp	800 bp	2316	
21⁶	90 bp	800 bp	2301-2316, 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, 4, 7, 10, 11, 13 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.

³The nucleotide sequence of the A*2318 allele is not yet retrievable.

⁴Due to the sharing of sequence motifs between HLA-A alleles non-HLA-A*23 alleles will be amplified by primer mixes 1 to 4, 6 to 10, 12 to 18. In addition, the B*1827 allele will be amplified by primer mixes 1 and 15.

⁵Primer mixes 1 and 4 may yield somewhat less PCR product than the other A*23 primer mixes.

⁶Short specific PCR fragments are less intense and not as sharp as longer specific bands.

⁷Primer mix 16: Specific PCR fragment of 175 bp in A*2314 and A*021701-027102, 24020101-2411N, 241301-241302, 2417-2423, 2425-2450, 2454-2456, 2458-2463, 2466-2484N alleles. Specific PCR fragment of 205 bp in the A*2424 and A*2616 alleles.

INTERPRETATION TABLE												
HLA-A*23 SSP subtyping												
Amplification patterns of the A*2301 to A*2319Q alleles												
	Well ⁵											
	1	2	3	4	5	6	7	8	9	10	11	12
Length of spec.	210	160	125	130	230	470	95	215	235	230	200	190
PCR product												
Length of int.	800	1070	800	800	1070	1070	800	1070	1070	800	800	1070
pos. control ¹												
5'-primer(s) ²	368	453	368	448	144	3 rd	564	98	28	368	160	144
	5'-gTT ^{3'}	5'-AAA ^{3'}	5'-gTT ^{3'}	5'-CCT ^{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	539	331	621	616	270	92	559	317	292
	5'-TCA ^{3'}	5'-CCg ^{3'}	5'-TCg ^{3'}	5'-TCA ^{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 ⁴												
*2301	1	2										
*2302		2										
*230301	1		3	4								
*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										
*2319Q	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*2319Q alleles										
Well⁵										
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	1070	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 ⁴
					18			21		*2301
13					w			21		*2302
								21		*230301
								21		*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
					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	130	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, 6826		2										
*0240, 0251, 9230												
*0265, 29010101-2904, 2906, 2908N-2917, 310102- 3102, 3105-3121, 320101- 320103, 3203, 3205-3209, 3211Q-3215, 3301, 330301- 3313, 7401-7412N				4								
*0282N							7					
*9208, 9210	1											
*24020101-240215, 2404, 2405, 2408, 2409N, 2417, 2420, 2426-2429, 2431, 2432, 2434-2441, 2443- 2445N, 2447-2450, 2454- 2456, 2458-2463, 2466- 2474, 2476-2484N		2										
*240301-240302, 2422, 2433												
*2406		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	4								
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

Lot No.: **27E**

Lot-specific information

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210	245	210	175	225	110	120	230	90	290	Length of spec. PCR product	
13	14	15	16	17	18	19	20	21	22	Well No.	
			205							*0102, 0120	
										*0104N, 0321N, 1121N	
	14		w							*021701-021702	
										*0219, 0236, 0237, 0254, 2414, 2415, 2451-2453, 2457, 2464, 6826	
				18							*0240, 0251, 9230
										*0265, 29010101-2904, 2906, 2908N-2917, 310102 3102, 3105-3121, 320101- 320103, 3203, 3205-3209, 3211Q-3215, 3301, 330301 3313, 7401-7412N	
	14									*0282N	
										*9208, 9210	
			16							*24020101-240215, 2404, 2405, 2408, 2409N, 2417, 2420, 2426-2429, 2431, 2432, 2434-2441, 2443- 2445N, 2447-2450, 2454- 2456, 2458-2463, 2466- 2474, 2476-2484N	
	14		16							*240301-240302, 2422, 2433	
13			16							*2406	
			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	
13	14	15	16	17	18	19	20	21	22	Well No.	

Length of spec.	210	160	125	130	230	470	95	215	235	230	200	190
PCR product												
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
*300101-300102, 301101-301102, 3014L-3020, 3023, 3024												
HLA-A allele ⁴												
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

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, 4, 7, 10, 11, 13 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 in *Tissue Antigens* 1998, **51:II**, 417-466. 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 in *Tissue Antigens* 1998, **51:II**, 417-466. The sequence of the 3 terminal nucleotides of the primer is given.

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210	245	210	175	225	110	120	230	90	290	Length of spec. PCR product
			205							
13	14	15	16	17	18	19	20	21	22	Well No.
				17						*300101-300102, 301101-301102, 3014L-3020, 3023, 3024
										HLA-A allele ⁴
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.

⁴The nucleotide sequence of the A*2318 allele is not yet retrievable.

⁵Primer mix 16: Specific PCR fragment of 175 bp in A*2314 and A*021701-027102, 24020101-2411N, 241301-241302, 2417-2423, 2425-2450, 2454-2456, 2458-2463, 2466-2484N alleles. Specific PCR fragment of 205 bp in the A*2424 and A*2616 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
			Lot No.:	200730801	200730802	200730803	200730804	200730805	200730806	200730807	200730808	200730809	200730810	200730811	200730812	200730813	200730814	200730815	200730816
	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	9067 BTB	*0201		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
14	9071 OLGA	*3101		-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-
15	9075 DKB	*2402		-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	+
16	9037 SWEIG007	*2902		-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-
17	9008 WILJON	*2501		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
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
				Lot No.:	200730817	200730818	200843219	200843220	200843221	200843222
	IHC 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	9067 BTB	*0201			-	-	-	-	-	-
14	9071 OLGA	*3101			-	-	-	-	-	-
15	9075 DKB	*2402			-	-	-	-	-	-
16	9037 SWEIG007	*2902			-	-	-	-	-	-
17	9008 WILJON	*2501			-	-	-	-	-	-
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
101.421-06u – without *Taq* polymerase
Lot number: 27E
Expiry date: 2010-February-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	2007-308-01	9	2007-308-09	17	2007-308-17
2	2007-308-02	10	2007-308-10	18	2007-308-18
3	2007-308-03	11	2007-308-11	19	2008-432-19
4	2007-308-04	12	2007-308-12	20	2008-432-20
5	2007-308-05	13	2007-308-13	21	2008-432-21
6	2007-308-06	14	2007-308-14	22	2008-432-22
7	2007-308-07	15	2007-308-15		
8	2007-308-08	16	2007-308-16		

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, 5, 9, 11, 12, 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 5, 9, 12 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.

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

Date of approval: 2008-March-07

Approved by:

Quality Control, Supervisor

Lot No.: **27E**

Lot-specific information

www.olerup.com

Declaration of Conformity

Product name: *Olerup* SSP® HLA-A*23
Product number: 101.421-06, 101.421-06u
Lot number: V12

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
2008-March-07

Olle Olerup
Managing Director

101.421-06 – including *Taq* polymerase101.421-06u – without *Taq* polymeraseLot No.: **27E**

Lot-specific information

www.olerup.com**ADDRESSES:****Manufacturer:****Olerup SSP AB**, Hasselstigen 1, SE-133 33 Saltsjöbaden, Sweden.**Tel:** +46-8-717 88 27**Fax:** +46-8-717 88 18**E-mail:** info-ssp@olerup.com**Web page:** <http://www.olerup.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**.