

Lot No.: **70F**

Lot-specific Information
Olerup SSP[®] HLA-B*56

Product number:	101.571-06u – without <i>Taq</i> polymerase
Lot number:	70F
Expiry date:	2011-April-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. 70F.

**CHANGES COMPARED TO THE PREVIOUS *OLERUP SSP[®]*
HLA-B*56 LOT**

The HLA-B*56 specificity and interpretation tables have been updated for the HLA-B alleles described since the previous *Olerup SSP[®]* HLA-B*56 lot was made (Lot No. 08E).

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

Well	5'-primer	3'-primer	rationale
5	Modified	Removed	Decrease unspecific amplification, one 3'-primer removed.
10	-	-	Exchanged positive control primer pair.
13	Added	-	Primer added for the B*5622 allele
17	Exchanged	Exchanged	Changed to more specific primer pair.
20	Exchanged	Exchanged	Increase yield of specific PCR product.
23	Added	Added	New primer pair for the B*5624 allele.

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PRODUCT DESCRIPTION

HLA-B*56 SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for identifying the B*5601 to B*5624 alleles.

PLATE LAYOUT

Each test consists of 24 PCR reactions in a 24 well 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 PCR plate is marked with 'HLA-B*56' in silver/gray ink.

Well No. 1 is marked with the Lot No. '70F'.

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-B*56 SSP subtypings will be influenced by three B*07, four B*08, the B*13, the B*1407N, several B*15, most B*18, four B*27, most B*35, most B*37, six B*38, seven B*39, seven B*40, the B*4209, most B*44, the B*45, three B*46, the B*4802, the B*49, the B*50, the B*51, the B*52, the B*53, the B*54, the B*55, the B*57, the B*58, the B*59, the B*78, two B*81, the B*82 and the B*8301 alleles when present on the other haplotype. In addition, the Cw*0206 and Cw*1215 alleles will be amplified by primer mix 4, the C*0312 and Cw*0319 alleles weakly by primer mix 14 and the Cw*1509, Cw*1519 and Cw*1520 alleles by primer mix 22.

UNIQUELY IDENTIFIED ALLELES

All the HLA-B*56 alleles, i.e. **B*5601 to B*5624**, recognized by the HLA Nomenclature Committee in January 2009¹ will give rise to unique amplification patterns by the primers in the HLA-B*56 subtyping kit².

¹HLA-B alleles listed on the IMGT/HLA web page 2009-January-16, release 2.24.0, www.ebi.ac.uk/imgt/hla.

²The HLA-B56 primer set cannot separate the B*5609, B*3576 and B*3578 alleles. These alleles can be distinguished by the HLA-B low resolution and/or B*35 kits.

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RESOLUTION IN HOMO- AND HETEROZYGOTES

The 24 HLA-B*56 alleles give rise to 25 different amplification patterns. These can be combined in 325 homozygous and heterozygous combinations. 131 of these genotypes do not give rise to unique amplification patterns.

++++---+	--++----	-----	5608, 5610 = 5610, 5614
++++---+	--+-+---	-----	5604, 5608 = 5604, 5614
++++---+	--+-----	-----	5602, 5608 = 5602, 5614
++++----	-+-----	-----	5602, 5609 = 5602, 5612
++++----	--++----	-----+	5602, 5623 = 5610, 5617
++++----	--++----	-----+	5610, 5620 = 5610, 5624
++++----	--+-----	-----+	5602, 5620 = 5602, 5624
+++-+---	--+-----	+-----	5606, 5608 = 5606, 5614
+++-+---	--+-----	-----	5603, 5608 = 5603, 5614
+++--+++	--+-----	+-----	560501, 5608 = 560501, 5614
+++--+++	--+-----	+-----+	5608, 5621 = 5614, 5621
+++--+++	--+-----	+-----	560502, 5608 = 560502, 5614
+++-----	+-----	-----	5607, 5608 = 5607, 5614
+++-----	-++-+---	-----	5608, 5611 = 5611, 5614
+++-----	-++-+---	-----	5608, 5609 = 5608, 5612 = 5609, 5614 = 5612, 5614
+++-----	--++----	-----+	5608, 5623 = 5614, 5623
+++-----	--+-+---	-----	5608, 5622 = 5614, 5622
+++-----	--+-+---	-----	5608, 5613 = 5613, 5614
+++-----	--+-----	+-----	5608, 5615 = 5614, 5615
+++-----	--+-----	+-----	5608, 5616 = 5614, 5616
+++-----	--+-----	-+-----	5608, 5619N = 5614, 5619N
+++-----	--+-----	-----+	5608, 5617 = 5614, 5617
+++-----	--+-----	-----+	5608, 5618 = 5614, 5618
+++-----	--+-----	-----+	5608, 5620 = 5608, 5624 = 5614, 5620 = 5614, 5624
+++-----	--+-----	-----	5601, 5608 = 5601, 5614 = 5608, 5608 = 5608, 5614
+++-----	+++-----	-----	5607, 5609 = 5607, 5612
+++-----	+-----	-----+	5607, 5620 = 5607, 5624
+++-----	+-----	-----	5601, 5607 = 5607, 5607
+++-----	-++-+---	-----+	5611, 5620 = 5611, 5624
+++-----	-++-+---	-----	5609, 5613 = 5612, 5613
+++-----	-++-+---	+-----	5609, 5616 = 5612, 5616
+++-----	-++-+---	-+-----	5609, 5619N = 5612, 5619N
+++-----	-++-+---	-----+	5609, 5617 = 5612, 5617
+++-----	-++-+---	-----+	5609, 5620 = 5609, 5624 = 5612, 5624
+++-----	-++-+---	-----	5601, 5609 = 5601, 5612
+++-----	--++----	-----+	5620, 5623 = 5623, 5624
+++-----	--++----	-----+	5601, 5623 = 5617, 5623
+++-----	--+-+---	-----+	5620, 5622 = 5622, 5624
+++-----	--+-+---	-----+	5613, 5620 = 5613, 5624
+++-----	--+-+---	-----	5601, 5613 = 5613, 5613
+++-----	--+-----	+-----+	5615, 5620 = 5615, 5624
+++-----	--+-----	+-----+	5616, 5620 = 5616, 5624
+++-----	--+-----	+-----	5601, 5616 = 5616, 5616
+++-----	--+-----	-+-----	5619N, 5620 = 5619N, 5624
+++-----	--+-----	-+-----	5601, 5619N = 5619N, 5619N

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+++-----	--+-----	-----+-+	5617, 5620 = 5617, 5624
+++-----	--+-----	-----+--	5601, 5617 = 5617, 5617
+++-----	--+-----	-----+-	5601, 5620 = 5601, 5624 = 5620, 5624 =
			5624, 5624
++-+-----	-+-+-----	-----	5609, 5610 = 5610, 5612
++-----	-+++-----	-----+--	5609, 5623 = 5612, 5623
++-----	-+-+-----	-----	5609, 5611 = 5609, 5622 = 5611, 5611 =
			5611, 5612 = 5611, 5622 = 5612, 5622
++-----	-+-----	+-----	5609, 5615 = 5612, 5615
++-----	-+-----	-----	5609, 5609 = 5609, 5612
-+---+++-	-----	+-----	5603, 560501 = 560501, 5606
-+---+--+	-----	+-----+	5603, 5621 = 5606, 5621
-+---+--+	-----	+-----	5603, 560502 = 5603, 5606 = 560502, 5606
			= 5606, 5606
-+---++-	-----	+-----	560501, 560501 = 560501, 560502
-+---+--+	-----	+-----+	560502, 5621 = 5621, 5621

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Lot-specific Information
SPECIFICITY TABLE

HLA-B*56 SSP subtyping

Specificities and sizes of the PCR products of the 24 primer mixes used for HLA-B*56 SSP subtyping

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified HLA-B*56 alleles ³	Other amplified HLA Class I alleles ⁴
1⁵	125 bp	800 bp	5601, 5602, 5607-5611, 5613-5617, 5619N, 5622-5624	1301-1304, 1306-1309, 1311-1320, 1322, 1323, 1516, 1520, 1534, 1542, 1562, 1567, 1585, 1586, 1595, 9537, 1822, 2714, 350101-350803, 3510, 3511, 3513-3515, 3519-3521, 3523-3530, 3533-3538, 3540N-3542, 3545-3550, 3552, 3554-3558, 3560, 3562, 3563, 3565Q, 3566, 356801-3572, 3574-3578, 3580-3585, 3589-3594, 4028, 4410, 4415, 4418, 4448, 4501-4509, 4611, 4618, 4802, 490101-4905, 5001, 5002, 5115, 5156, 530101-5306, 5308-5316, 5401-5405, 5407, 5408N, 5410, 5412-5417, 550101-5503, 5505, 5507, 5509-5513, 5515, 5516, 5518, 5519, 5521-5534, 5705, 580101-5802, 5804-5807, 5809, 5811-5819, 5901, 5903, 5904, 8201, 8202
2	400 bp	1070 bp	5601-5613, 5615-5624	0765, 3576, 3578, 5401-5406, 5408N-5417, 550101-5505, 5507-5517, 5519-5533, 8101, 8104N, 8201, 8202, 8301
3	180 bp	1070 bp	5601, 5602, 5604, 5607, 5608, 5613, 5614, 5616, 5617, 5619N, 5620, 5624	1303, 1573, 4071, 4410, 4415, 4418, 4501, 4504-4507, 4611, 490101-4903, 5001, 5002, 5004, 5115, 5162, 5403, 5904, 8201, 8202
4⁵	105 bp	800 bp	5602, 5604, 5610	1311, 1573, 1586, 3917, 4048, 4071, 5162, 8201, 8202, Cw*0206, Cw*1215
5	290 bp	1070 bp	5603, 5606	

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6⁵	105 bp	1070 bp	560501	
7^{5,6}	120 bp	800 bp	560501-5606, 5621	510101-510103, 510105- 510203, 5103, 5105, 5107- 510902, 5111N, 5112, 511302, 5114, 5116-5123, 5126-5137, 5139-5141N, 5143, 5144N, 5148-5155, 5157, 5158, 5160, 5161, 5163, 520101-5213, 550104, 5808, 7801-7806
8	400 bp	1070 bp	5608, 5614	
9	145 bp	1070 bp	5607	0802, 9515, 2701, 380201- 3804, 3808, 3815, 4440, 4444
10	150 bp	800 bp	5609, 5611, 5612	1301, 1306, 1307N, 1312, 1313, 1317, 1320, 1322, 1323, 1502, 1513, 1520, 1521, 1525, 1536, 1544, 1562, 1577, 1580, 1585, 1588, 1589, 9506, 9512, 9521, 9539, 9544, 1822, 2719, 2730, 350101-350403, 3506- 350803, 3510-3517, 3519- 3521, 3523-3530, 3533-3536, 3538-3542, 3545-3550, 3552, 3554-3557, 3559, 3561-3563, 3565Q, 3569-3571, 3574, 3576-3578, 3580-3585, 3590- 3594, 370101-370104, 3703N- 3706, 3708, 3710, 3711, 3713, 3714, 3942, 4028, 44020101- 4414, 4416, 4417, 4419N, 4421-4430, 4432-4440, 4442- 4446, 4448-4452N, 4455- 446402, 4802, 5104, 5142, 5146, 5156, 530101-5306, 5308-5313, 5315, 5316, 5514, 570101-5710, 5712, 5714- 5719, 580101-580102, 5804, 5805, 5809-5815, 5817N, 5819, 8301
11⁵	105 bp	800 bp	5601, 5607, 5608, 5613, 5614, 5616, 5617, 5619N, 5620, 5623, 5624	130201-1303, 1308Q, 1309, 1314-1316, 1318, 1319, 1542, 3560, 4415, 4418, 4501, 4503- 4508, 4611, 4618, 490101- 4903, 5001, 5002, 5004, 5115, 5401-5403, 5405N, 5407, 5408N, 5410, 5412, 5413, 5416, 5417, 550101-5503, 5505, 5507, 5509-5512, 5515,

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				5516, 5518, 5519, 5521, 5522, 5524-5526, 5529-5531, 5533, 5534, 5901, 5904
12	180 bp	800 bp	5610, 5623	1306, 1542, 1586, 3560, 3917 ^{weakly} , 4508 ^{weakly} , 4618, 5401, 5402, 5405N, 5407, 5408N, 5410, 5412, 5413, 5416, 5417, 550101-5503, 5505, 5507, 5510-5512, 5515, 5516, 5518, 5519, 5521, 5525, 5526, 5529-5531, 5533, 5534, 5901
13⁷	180 bp	1070 bp	5611, 5622	1558, 9533, 3503, 3506, 3513, 3536, 3538, 3555, 3556, 3559, 3570, 3574, 3575, 3584, 3585, 3932, 3933, 511301-511302, 5214, 5304
14⁵	80 bp	1070 bp	5604	1573, 3917, 4048, 4071, 5004, 5162 Cw*0312^{weakly}, Cw*0319^{weakly}
15	160 bp	1070 bp	5613	4415, 4418, 4501, 4504-4508, 8201, 8202
16	160 bp	1070 bp		44020101-440205, 4406, 4408, 4409, 4411, 4412, 4416, 4419N-4424, 4427, 4433, 4434, 4441, 4444, 4448, 4449, 4452N, 4453, 4455, 4459, 4463, 8301
17⁷	180 bp	800 bp	560501-5606, 5615, 5621	0821, 0825, 1509, 1530, 1548, 9550, 350201-350203, 350401-350403, 350901-350902, 3512, 3518, 3522, 3544, 3581, 3583, 4005, 4026, 4028, 4063, 4092, 4462, 510101-510902, 5111N, 5112, 5118-5120, 5122-512402, 5126-5130, 5132, 5133, 5135, 5138-5141N, 5143, 5144N, 5146, 5148-5161, 520101-5207, 5209-5211, 5213, 5508, 5702-570302, 5707, 5709, 5712, 5717, 5808, 7801-7806
18⁶	300 bp	800 bp	5616	5510, 8201, 8202
19	185 bp	800 bp	5619N	1407N, 3940N
20	215 bp	1070 bp		150104, 370104, 5401-5417
21^{5,7}	110 bp	1070 bp	5617, 5623	0737
22	180 bp	1070 bp	5618	0837, 1550, 1569, 1593,

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				180101-1809, 1811-1815, 1817N-1819, 1822-1825, 1827- 1832, 3535, 3593, 3907, 3943, 4209, 4603, 5409, 5414, 5514, 5523, 5805 Cw*1509, Cw*1519, Cw*1520
23^{5,8}	85, 345 bp	1070 bp	5620, 5624	4048
24⁵	70 bp	1070 bp	5621	0736, 5412

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 DR low resolution 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 1 070 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-B*56 subtyping.

In addition, wells number 4, 7, 10, 11, 12, 17 to 19 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 HLA-B56 primer set cannot separate the B*5609, B*3576 and B*3578 alleles. These alleles can be distinguished by the HLA-B low resolution and/or B*35 kits.

⁴Due to the sharing of sequence motifs between HLA-B alleles non-HLA-B*56 alleles will be amplified by primer mixes 1 to 4, 7 and 9 to 24. In addition, the Cw*0206 and Cw*1215 alleles will be amplified by primer mix 4, the C*0312 and Cw*0319 alleles weakly by primer mix 14 and the Cw*1509, Cw*1519 and Cw*1520 alleles by primer mix 22.

⁵Specific PCR fragments shorter than 125 base pairs have a lower intensity than longer PCR bands.

⁶Primer mix 7 and 18 may give rise to less specific PCR products than the other HLA-B*56 primer mixes.

⁷Primer mixes 13, 17 and 21 may give rise to unspecific amplification products.

⁸Primer mix 23: Specific PCR fragment of 85 bp in the B*5620 and in the B*4048 alleles. Specific PCR fragment of 345 bp in the B*5624 allele.

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INTERPRETATION TABLE												
HLA-B*56 SSP subtyping												
Amplification patterns of the B*5601 to B*5624 alleles												
	Well⁴											
	1	2	3	4	5	6	7	8	9	10	11	12
Length of spec.	125	400	180	105	290	105	120	400	145	150	105	180
PCR product												
Length of int.	800	1070	1070	800	1070	1070	800	1070	1070	800	800	800
pos. control¹												
5'-primer²	379	41	420	355	48	141	357	41	206	355	357	420
	5'-ACC3'	5'-CTg3'	5'-TTA3'	5'-CCC3'	5'-gCC3'	5'-ATT3'	5'-Tgg3'	5'-CTg3'	5'-AgA3'	5'-TCA3'	5'-Tgg3'	5'-TTA3'
3'-primer(s)³	463	272	559	420	165	204	435	269	309	463	420	559
	5'-gCT3'	5'-TgT3'	5'-CAG3'	5'-gCT3'	5'-Tgg3'	5'-TCT3'	5'-TCT3'	5'-ACT3'	5'-gTg3'	5'-gCT3'	5'-gCT3'	5'-CgT3'
		277	564									
		5'-ggC3'	5'-ACT3'									
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
HLA-B allele												
*5601	1	2	3								11	
*5602	1	2	3	4								
*5603		2			5							
*5604		2	3	4								
*560501		2				6	7					
*560502		2					7					
*5606		2			5		7					
*5607	1	2	3						9		11	
*5608	1	2	3					8			11	
*5609, 3576, 3578⁵	1	2							10			
*5610	1	2		4								12
*5611	1	2							10			
*5612		2								10		
*5613	1	2	3								11	
*5614	1		3					8			11	
*5615	1	2										
*5616	1	2	3								11	
*5617	1	2	3								11	
*5618		2										
*5619N	1	2	3								11	
*5620		2	3								11	
*5621		2					7					
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

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INTERPRETATION TABLE												
HLA-B*56 SSP subtyping												
Amplification patterns of the B*5601 to B*5624 alleles												
Well ⁴												
13	14	15	16	17	18	19	20	21	22	23	24	
180	80	160	160	180	300	185	215	110	180	85	70	Length of spec.
										345		PCR product
1070	1070	1070	1070	800	800	800	1070	1070	1070	1070	1070	Length of int.
												pos. control ¹
420	379	420	418	419	15	419	1st I	206	419	420	272	5'-primer ²
5'-TTC ^{3'}	5'-ACg ^{3'}	5'-TTA ^{3'}	5'-Agg ^{3'}	5'-gTA ^{3'}	5'-gCA ^{3'}	5'-gTT ^{3'}	5'-CAg ^{3'}	5'-AgA ^{3'}	5'-gTC ^{3'}	5'-TTA ^{3'}	5'-CTA ^{3'}	
										701		
										5'-CCT ^{3'}		
559	420	538	538	559	142	564	175	277	559	463	302	3'-primer(s) ³
5'-CAg ^{3'}	5'-gCT ^{3'}	5'-gTC ^{3'}	5'-gTC ^{3'}	5'-CAg ^{3'}	5'-TgA ^{3'}	5'-ACT ^{3'}	5'-CCg ^{3'}	5'-ggC ^{3'}	5'-CgT ^{3'}	5'-gCg ^{3'}	5'-ggT ^{3'}	
										916		
										5'-gAT ^{3'}		
13	14	15	16	17	18	19	20	21	22	23	24	Well No.
												HLA-B allele
												*5601
												*5602
												*5603
14												*5604
				17								*560501
				17								*560502
				17								*5606
												*5607
												*5608
												*5609, 3576, 3578 ⁵
												*5610
13												*5611
												*5612
	15											*5613
												*5614
				17								*5615
					18							*5616
								21				*5617
									22			*5618
						19						*5619N
										23		*5620
				17							24	*5621
13	14	15	16	17	18	19	20	21	22	23	24	Well No.

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Well No.	1	2	3	4	5	6	7	8	9	10	11	12
*5622	1	2										
*5623	1	2									11	12
*5624	1	2	3								11	
*0736												
*0737												
*0765, 5504, 5517, 5520, 8101, 8104N		2										
*0802, 9515, 2701, 380201- 3804, 3808, 3815									9			
*0821, 0825, 1509, 1530, 1548, 9550, 350901- 350902, 3518, 3522, 3544, 4005, 4026, 4063, 4092, 510104, 510204, 5106, 512401-512402, 5138, 5159												
*0837, 1550, 1569, 1593, 180101-1809, 1811-1815, 1817N-1819, 1823N-1825, 1827-1832, 3907, 3943, 4209, 4603												
*1301, 1307N, 1312, 1313, 1317, 1320, 1322, 1323, 1520, 1562, 1585, 350101- 350107, 3507-350803, 3510, 3511, 351401-3515, 3519-3521, 3523-3530, 3533, 3534, 3540N-3542, 3545-3550, 3552, 3554, 3557, 3562, 3563, 3565Q, 3569, 3571, 3577, 3580, 3582, 3590-3592, 3594, 4802, 530101-5303, 5305, 5306, 5308-5313, 5315, 5316, 5705, 580101- 580102, 5804, 5809, 5811- 5815, 5817N, 5819	1									10		
*130201-130204, 1308Q, 1309, 1314-1316, 1318, 1319, 4503	1										11	
*1303, 4611, 490101-4903, 5001, 5002, 5115, 5904	1		3								11	
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

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13	14	15	16	17	18	19	20	21	22	23	24	Well No.
13												*5622
								21				*5623
										23		*5624
											24	*0736
								21				*0737
												*0765, 5504, 5517, 5520, 8101, 8104N
												*0802, 9515, 2701, 380201- 3804, 3808, 3815
				17								*0821, 0825, 1509, 1530, 1548, 9550, 350901- 350902, 3518, 3522, 3544, 4005, 4026, 4063, 4092, 510104, 510204, 5106, 512401-512402, 5138, 5159
									22			*0837, 1550, 1569, 1593, 180101-1809, 1811-1815, 1817N-1819, 1823N-1825, 1827-1832, 3907, 3943, 4209, 4603
												*1301, 1307N, 1312, 1313, 1317, 1320, 1322, 1323, 1520, 1562, 1585, 350101- 350107, 3507-350803, 3510, 3511, 351401-3515, 3519-3521, 3523-3530, 3533, 3534, 3540N-3542, 3545-3550, 3552, 3554, 3557, 3562, 3563, 3565Q, 3569, 3571, 3577, 3580, 3582, 3590-3592, 3594, 4802, 530101-5303, 5305, 5306, 5308-5313, 5315, 5316, 5705, 580101- 580102, 5804, 5809, 5811- 5815, 5817N, 5819
												*130201-130204, 1308Q, 1309, 1314-1316, 1318, 1319, 4503
												*1303, 4611, 490101-4903, 5001, 5002, 5115, 5904
13	14	15	16	17	18	19	20	21	22	23	24	Well No.

Lot No.: **70F**

Lot-specific Information

Well No.	1	2	3	4	5	6	7	8	9	10	11	12
*1304, 1516, 1534, 1567, 1595, 9537, 2714, 3505, 3537, 3558, 3566, 356801- 356802, 3572, 3589, 4502, 4904, 4905, 5314, 5802, 5806, 5807, 5816, 5818, 5903	1											
*1306	1									10		12
*1311	1			4								
*1407N, 3940N												
*150104												
*1502, 1513, 1521, 1525, 1536, 1544, 1577, 1580, 1588, 1589, 9506, 9512, 9521, 9539, 9544, 2719, 2730, 3516, 3517, 3539, 3561, 370101-370103, 3703N-3706, 3708, 3710, 3711, 3713, 3714, 3942, 440301-4405, 4407, 4413, 4414, 4417, 4425, 4426, 442801-4430, 4432, 4435- 4439, 4442, 4443, 4445, 4446, 4450, 4451, 4456N- 4458N, 4460, 4461N, 446401-446402, 5142, 570101-570103, 5704, 5706, 5708, 5710, 5714- 5716, 5718, 5719, 5810N										10		
*1542, 3560, 4618, 5518, 5534, 5901	1										11	12
*1558, 9533, 3932, 3933, 511301, 5214												
*1573, 4071, 5162			3	4								
*1586	1			4								12
*1822, 3535, 3593, 5805	1									10		
*350201-350203, 350401- 350403, 3581, 3583, 4028, 5156	1									10		
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

Lot No.: **70F**

Lot-specific Information

13	14	15	16	17	18	19	20	21	22	23	24	Well No.
												*1304, 1516, 1534, 1567, 1595, 9537, 2714, 3505, 3537, 3558, 3566, 356801- 356802, 3572, 3589, 4502, 4904, 4905, 5314, 5802, 5806, 5807, 5816, 5818, 5903
												*1306
												*1311
						19						*1407N, 3940N
							20					*150104
												*1502, 1513, 1521, 1525, 1536, 1544, 1577, 1580, 1588, 1589, 9506, 9512, 9521, 9539, 9544, 2719, 2730, 3516, 3517, 3539, 3561, 370101-370103, 3703N-3706, 3708, 3710, 3711, 3713, 3714, 3942, 440301-4405, 4407, 4413, 4414, 4417, 4425, 4426, 442801-4430, 4432, 4435- 4439, 4442, 4443, 4445, 4446, 4450, 4451, 4456N- 4458N, 4460, 4461N, 446401-446402, 5142, 570101-570103, 5704, 5706, 5708, 5710, 5714- 5716, 5718, 5719, 5810N
												*1542, 3560, 4618, 5518, 5534, 5901
13												*1558, 9533, 3932, 3933, 511301, 5214
	14											*1573, 4071, 5162
												*1586
									22			*1822, 3535, 3593, 5805
				17								*350201-350203, 350401- 350403, 3581, 3583, 4028, 5156
13	14	15	16	17	18	19	20	21	22	23	24	Well No.

Lot No.: **70F**

Lot-specific Information

Well No.	1	2	3	4	5	6	7	8	9	10	11	12
*3503, 3506, 3513, 3536, 3538, 3555, 3556, 3570, 3574, 3584, 3585, 5304	1									10		
*3512, 4462, 5104, 5146, 5702-570302, 5707, 5709, 5712, 5717										10		
*3559										10		
*3575	1											
*370104										10		
*3917				4								W
*4048				4								
*44020101-440205, 4406, 4408, 4409, 4411, 4412, 4416, 4419N, 4421-4424, 4427, 4433, 4434, 4449, 4452N, 4455, 4459, 4463										10		
*4410	1		3							10		
*4415, 4418, 4501, 4504- 4507	1		3								11	
*4420, 4441, 4453												
*4440									9	10		
*4444									9	10		
*4448	1									10		
*4508	1										11	W
*5004			3								11	
*510101-510103, 510105- 510203, 5103, 5105, 5107- 510902, 5111N, 5112, 5118- 5120, 5122, 5123, 5126- 5130, 5132, 5133, 5135, 5139-5141N, 5143, 5144N, 5148-5155, 5157, 5158, 5160, 5161, 520101-5207, 5209-5211, 5213, 5808, 7801-7806							7					
*511302							7					
* 5114, 5116, 5117, 5121, 5131, 5134, 5136, 5137, 5163, 5208, 5212							7					
*5401, 5402, 5405N, 5408N, 5410, 5413, 5416, 5417	1	2									11	12
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

Lot No.: **70F**

Lot-specific Information

13	14	15	16	17	18	19	20	21	22	23	24	Well No.
13												*3503, 3506, 3513, 3536, 3538, 3555, 3556, 3570, 3574, 3584, 3585, 5304
				17								*3512, 4462, 5104, 5146, 5702-570302, 5707, 5709, 5712, 5717
13												*3559
13												*3575
							20					*370104
	14											*3917
	14									23		*4048
			16									*44020101-440205, 4406, 4408, 4409, 4411, 4412, 4416, 4419N, 4421-4424, 4427, 4433, 4434, 4449, 4452N, 4455, 4459, 4463
												*4410
		15										*4415, 4418, 4501, 4504- 4507
			16									*4420, 4441, 4453
												*4440
			16									*4444
			16									*4448
		15										*4508
	14											*5004
				17								*510101-510103, 510105- 510203, 5103, 5105, 5107- 510902, 5111N, 5112, 5118- 5120, 5122, 5123, 5126- 5130, 5132, 5133, 5135, 5139-5141N, 5143, 5144N, 5148-5155, 5157, 5158, 5160, 5161, 520101-5207, 5209-5211, 5213, 5808, 7801-7806
13												*511302
												* 5114, 5116, 5117, 5121, 5131, 5134, 5136, 5137, 5163, 5208, 5212
							20					*5401, 5402, 5405N, 5408N, 5410, 5413, 5416, 5417
13	14	15	16	17	18	19	20	21	22	23	24	Well No.

Lot No.: **70F**

Lot-specific Information

Well No.	1	2	3	4	5	6	7	8	9	10	11	12
*5403	1	2	3								11	
*5404, 5415	1	2										
*5406, 5411		2										
*5407	1										11	12
*5409		2										
*5412	1	2									11	12
*5414	1	2										
*550101-550103, 550201-5503, 5505, 5507, 5511, 5512, 5515, 5516, 5519, 5521, 5525, 5526, 5529-5531, 5533	1	2									11	12
*550104	1	2					7				11	12
*5508		2										
*5509, 5522, 5524	1	2									11	
*5510	1	2									11	12
*5513, 5527, 5528, 5532	1	2										
*5514		2								10		
*5523	1	2										
*8201, 8202	1	2	3	4								
*8301		2								10		
HLA-B allele												
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
Cw*0206, 1215				4								
Cw*0312, 0319												
Cw*1509, 1519, 1520												
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 1 070 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-B*56 subtyping.

In addition, wells number 4, 7, 10, 11, 12 and 17 to 19 contain the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to allow kit identification.

²The codon, in the 1st, 2nd or 3rd exon or in the 1st 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 codon, in the 2nd or 3rd exon, 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.

Lot No.: **70F**

Lot-specific Information

13	14	15	16	17	18	19	20	21	22	23	24	Well No.
							20					*5403
							20					*5404, 5415
							20					*5406, 5411
							20					*5407
							20		22			*5409
							20				24	*5412
							20		22			*5414
												*550101-550103, 550201-5503, 5505, 5507, 5511, 5512, 5515, 5516, 5519, 5521, 5525, 5526, 5529-5531, 5533
												*550104
				17								*5508
												*5509, 5522, 5524
				18								*5510
												*5513, 5527, 5528, 5532
									22			*5514
									22			*5523
		15		18								*8201, 8202
			16									*8301
												HLA-B allele
13	14	15	16	17	18	19	20	21	22	23	24	Well No.
												Cw*0206, 1215
	w											Cw*0312, 0319
									22			Cw*1509, 1519, 1520
13	14	15	16	17	18	19	20	21	22	23	24	Well No.

⁴Primer mix 23: Specific PCR fragment of 85 bp in the B*5620 and in the B*4048 alleles. Specific PCR fragment of 345 bp in the B*5624 allele.

⁵The HLA-B56 primer set cannot separate the B*5609, B*3576 and B*3578 alleles. These alleles can be distinguished by the HLA-B low resolution and/or B*35 kits.

'w', may be weakly amplified.

Lot No.: **70F**

Lot-specific Information

CELL LINE VALIDATION SHEET					Well															
HLA-B*56 SSP subtyping kit					1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
				Prod. No.:	200628702	200841102	200841103	200501004	200957705	200615006	200501007	200615008	200501009	200957710	200615011	200628712	200957713	200501014	200615015	200615016
	IHWC cell line	B*																		
1	9001 SA	*0702			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2	9280 LK707	*5201	*7301		-	-	-	-	-	-	+	-	-	-	-	-	-	-	-	-
3	9011 E4181324	*52011			-	-	-	-	-	-	+	-	-	-	-	-	-	-	-	-
4	9275 GU373	*1510	*5301		+	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-
5	9009 KAS011	*3701			-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-
6	9353 SM	*3901	*5101		-	-	-	-	-	-	+	-	-	-	-	-	-	-	-	-
7	9020 QBL	*1801			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
8	9007 DEM	*5701			+	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-
9	9026 YAR	*3801			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
10	9107 LKT3	*5401			+	+	-	-	-	-	-	-	-	-	+	+	-	-	-	-
11	9051 PITOUT	*4403			-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-
12	9052 DBB	*5701			-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-
13	9004 JESTHOM	*2705			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
14	9071 OLGA	*1501	*1520		+	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-
15	9075 DKB	*4001			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
16	9037 SWEIG007	*4002			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
17	9282 CTM3953540	*0801	*5501		+	+	-	-	-	-	-	-	-	-	+	+	-	-	-	-
18	9257 32367	*1401	*5601		+	+	+	-	-	-	-	-	-	-	+	-	-	-	-	-
19	9038 BM16	*1801			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
20	9059 SLE005	*4001			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
21	9064 AMALA	*1501			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
22	9056 KOSE	*3503			+	-	-	-	-	-	-	-	-	+	-	-	+	-	-	-
23	9124 IHL	*4002	*5602		W	+	+	+	-	-	-	-	-	-	-	-	-	-	-	-
24	9035 JBUSH	*3801			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
25	9049 IBW9	*1402			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
26	9285 WT49	*5801			+	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-
27	9191 CH1007	*0705	*5101		-	-	-	-	-	-	+	-	-	-	-	-	-	-	-	-
28	9320 BEL5GB	*4402	*4403		-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	+
29	9050 MOU	*4403			-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-
30	9021 RSH	*4201			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
31	9019 DUCAF	*1801			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
32	9297 HAG	*4102			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
33	9098 MT14B	*4001			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
34	9104 DHIF	*3801			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
35	9302 SSTO	*4402			-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	+
36	9024 KT17	*1501	*3501		+	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-
37	9065 HHKB	*0702			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
38	9099 LZL	*1501			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
39	9315 CML	*0801	*2705		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
40	9134 WHONP199	*1302	*4601		+	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-
41	9055 H0301	*1402			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
42	9066 TAB089	*4601			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
43	9076 T7526	*4601			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
44	9057 TEM	*3801			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
45	9239 SHJO	*4201	*5001		+	-	+	-	-	-	-	-	-	-	+	-	-	-	-	-
46	9013 SCHU	*0702			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
47	9045 TUBO	*5101			-	-	-	-	-	-	+	-	-	-	-	-	-	-	-	-
48	9303 TER-ND	*3501	*4403		+	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-

Lot No.: **70F**

Lot-specific Information

CELL LINE VALIDATION SHEET													
HLA-B*56 SSP subtyping kit													
					Prod. No.:	Well							
						17	18	19	20	21	22	23	24
						200957717	200957718	200841119	200957720	200628721	200628722	200957723	200841124
	IHWC cell line		B*										
1	9001	SA	*0702			-	-	-	-	-	-	-	-
2	9280	LK707	*5201	*7301		+	-	-	-	-	-	-	-
3	9011	E4181324	*52011			+	-	-	-	-	-	-	-
4	9275	GU373	*1510	*5301		-	-	-	-	-	-	-	-
5	9009	KAS011	*3701			-	-	-	-	-	-	-	-
6	9353	SM	*3901	*5101		+	-	-	-	-	-	-	-
7	9020	QBL	*1801			-	-	-	-	-	+	-	-
8	9007	DEM	*5701			-	-	-	-	-	-	-	-
9	9026	YAR	*3801			-	-	-	-	-	-	-	-
10	9107	LKT3	*5401			-	-	-	+	-	-	-	-
11	9051	PITOUT	*4403			-	-	-	-	-	-	-	-
12	9052	DBB	*5701			-	-	-	-	-	-	-	-
13	9004	JESTHOM	*2705			-	-	-	-	-	-	-	-
14	9071	OLGA	*1501	*1520		-	-	-	-	-	-	-	-
15	9075	DKB	*4001			-	-	-	-	-	-	-	-
16	9037	SWEIG007	*4002			-	-	-	-	-	-	-	-
17	9282	CTM3953540	*0801	*5501		-	-	-	-	-	+	-	-
18	9257	32367	*1401	*5601		-	-	-	-	-	-	-	-
19	9038	BM16	*1801			-	-	-	-	-	+	-	-
20	9059	SLE005	*4001			-	-	-	-	-	-	-	-
21	9064	AMALA	*1501			-	-	-	-	-	-	-	-
22	9056	KOSE	*3503			-	-	-	-	-	-	-	-
23	9124	IHL	*4002	*5602		-	-	-	-	-	-	-	-
24	9035	JBUSH	*3801			-	-	-	-	-	-	-	-
25	9049	IBW9	*1402			-	-	-	-	-	-	-	-
26	9285	WT49	*5801			-	-	-	-	-	-	-	-
27	9191	CH1007	*0705	*5101		+	-	-	-	-	-	-	-
28	9320	BEL5GB	*4402	*4403		-	-	-	-	-	-	-	-
29	9050	MOU	*4403			-	-	-	-	-	-	-	-
30	9021	RSH	*4201			-	-	-	-	-	-	-	-
31	9019	DUCAF	*1801			-	-	-	-	-	+	-	-
32	9297	HAG	*4102			-	-	-	-	-	-	-	-
33	9098	MT14B	*4001			-	-	-	-	-	-	-	-
34	9104	DHIF	*3801			-	-	-	-	-	-	-	-
35	9302	SSTO	*4402			-	-	-	-	-	-	-	-
36	9024	KT17	*1501	*3501		-	-	-	-	-	-	-	-
37	9065	HHKB	*0702			-	-	-	-	-	-	-	-
38	9099	LZL	*1501			-	-	-	-	-	-	-	-
39	9315	CML	*0801	*2705		-	-	-	-	-	-	-	-
40	9134	WHONP199	*1302	*4601		-	-	-	-	-	-	-	-
41	9055	H0301	*1402			-	-	-	-	-	-	-	-
42	9066	TAB089	*4601			-	-	-	-	-	-	-	-
43	9076	T7526	*4601			-	-	-	-	-	-	-	-
44	9057	TEM	*3801			-	-	-	-	-	-	-	-
45	9239	SHJO	*4201	*5001		-	-	-	-	-	-	-	-
46	9013	SCHU	*0702			-	-	-	-	-	-	-	-
47	9045	TUBO	*5101			+	-	-	-	-	-	-	-
48	9303	TER-ND	*3501	*4403		-	-	-	-	-	-	-	-

Lot No.: **70F**

Lot-specific Information

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-B*56 SSP

Product number: 101.571-06u – without *Taq* polymerase
Lot number: 70F
Expiry date: 2011-April-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	2006-287-02	9	2005-010-09	17	2009-577-17
2	2008-411-02	10	2009-577-10	18	2009-577-18
3	2008-411-03	11	2006-150-11	19	2008-411-19
4	2005-010-04	12	2006-287-12	20	2009-577-20
5	2009-577-05	13	2009-577-13	21	2006-287-21
6	2006-150-06	14	2005-010-14	22	2006-287-22
7	2005-010-07	15	2006-150-15	23	2009-577-23
8	2006-150-08	16	2006-150-16	24	2008-411-24

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 6, 8, 14, 19, 21, 23 and 24 were available. The specificities of the primers in primer solutions 6, 8, 14, 23 and 24 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer solutions 19 and 21, it was only possible to test the 5'-primer, the 3'-primer was not possible to test. In primer solutions 2 and 3, one or two 3'-primers were not possible to test, and in primer solution 23, one 5'-primer was not possible to test.

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

Date of approval: 2009-May-27

Approved by:

Quality Control, Supervisor

Lot No.: **70F**

Lot-specific Information

Declaration of Conformity

Product name: Olerup SSP® HLA-B*56
Product number: 101.571-06u
Lot number: 70F

Intended use: HLA-B*56 high resolution histocompatibility testing

Manufacturer: Olerup SSP AB
Hasselstigen 1
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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-27

Olle Olerup
Managing Director

Lot No.: **70F**

Lot-specific Information

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Lot-specific Information

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