

101.403.48/12 – including *Taq* pol., IFU-01
101.403.48u/12u – without *Taq* pol., IFU-02

Visit www.olerup-ssp.com for
“Instructions for Use” (IFU)

Lot No.: **71N**

Lot-specific information

Olerup SSP[®] HLA-A low resolution screening

Product number:	101.403-48/12 – including <i>Taq</i> polymerase 101.403-48u/12u – without <i>Taq</i> polymerase
Lot number:	71N
Expiry date:	2014-October-01
Number of tests:	48 tests – Product No. 101.403-48/48u 12 tests – Product No. 101.403-12/12u
Number of wells per test:	23 +1
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. 71N.

The Lot-specific Information for HLA-A low resolution screening including and without *Taq* polymerase is described in one common Product Insert.

Change in revision R01 compared to R00:

1. The HLA-A*03:01:03, 03:09, 03:23:01, 03:89, 03:108, 11:06, 11:18, 24:28, 24:89, 26:03:01-26:03:02, 26:06, 26:07:02, 26:21, 26:30, 30:13, 30:16, 30:44, 30:46, 68:05, 68:15, 68:20 and 68:30 alleles are weakly amplified by primer mix 2. This has been corrected in the Specificity and Interpretation Tables.

Change in revision R02 compared to R01:

1. In primer mix 5, the specific PCR product of 535 base pairs may be difficult to distinguish from the internal control band. A foot note has been added to the Specificity Table.

101.403.48/12 – including *Taq* pol., IFU-01
 101.403.48u/12u – without *Taq* pol., IFU-02

Visit www.olerup-ssp.com for
 “Instructions for Use” (IFU)

Lot No.: **71N**

Lot-specific information

Well **24** contains Negative Control primer pairs, that will amplify more than 95% of the *Olerup* SSP® HLA Class I, DRB, DQB1 and DPB1 amplicons as well as an amplicon generated by a positive control primer pair.

PCR product sizes range from 75 to 430 base pairs.
 The PCR product generated by the control primer pair is 430 base pairs.

Length of PCR product	105	200	105	80	75	80
5'-primer¹	164	340	440	45	45	43
	5'-CAC ^{3'}	5'-Agg ^{3'}	5'-TTA ^{3'}	5'-Tgg ^{3'}	5'-Tgg ^{3'}	5'-Tgg ^{3'}
3'-primer²	231	2nd I	507	59	58	57
	5'-TgC ^{3'}	5'-AAA ^{3'}	5'-TTg ^{3'}	5'-CTC ^{3'}	5'-ggC ^{3'}	5'-CTC ^{3'}
A*	+	+	+			
B*	+	+	+			
C*	+	+	+			
DRB1				+	+	
DRB3				+	+	
DRB5				+		
DQB1					+	
DPB1						+

¹The nucleotide position for HLA class I genes and the codon for HLA class II genes, in the 2nd or 3rd exon, matching the specificity-determining 3'-end of the primer is given. Nucleotide and codon numbering as on the www.ebi.ac.uk/imgt/hla web site. The sequence of the 3 terminal nucleotides of the primer is given.

²The nucleotide position for HLA class I genes and the codon for HLA class II genes, in the 2nd or 3rd exon or the 2nd intron, matching the specificity-determining 3'-end of the primer is given in the anti-sense direction. Nucleotide and codon numbering as on the www.ebi.ac.uk/imgt/hla web site. The sequence of the 3 terminal nucleotides of the primer is given.

101.403.48/12 – including *Taq* pol., IFU-01
 101.403.48u/12u – without *Taq* pol., IFU-02

Visit www.olerup-ssp.com for
 “Instructions for Use” (IFU)

Lot No.: **71N**

Lot-specific information

PRODUCT DESCRIPTION

HLA-A low resolution screening

CONTENT

The primer set contains 5'- and 3'-primers for grouping the HLA-A*01:01 to A*80:02 alleles into the corresponding serological groups A1 to A80.

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

Wells 1 to 23 – HLA-A low resolution screening primers.

Well 24 – Negative Control.

The 24 well PCR plate is marked with ‘HLA-A low screening’ in silver/gray ink.

Well No. 1 is marked with the Lot No. ‘71N’.

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

Only HLA-A alleles will be amplified by the 24 wells of the HLA-A low resolution screening primer set except that primer mix 6 will amplify the B*18:27 allele. Thus, the interpretation of HLA-A low resolution screening is only influenced by this HLA-B allele and not by other HLA Class I genes.

UNIQUELY IDENTIFIED ALLELES

All the HLA-A alleles, i.e. **A*01:01 to A*80:02**, recognized by the HLA Nomenclature Committee in January 2012¹ will be amplified by the primers in the HLA-A low resolution screening primer set. The HLA-A alleles will be grouped into their corresponding serological specificities².

¹HLA-A, HLA-B and HLA-C alleles listed on the IMGT/HLA web page 2012-January-12, release 3.7.0, www.ebi.ac.uk/imgt/hla.

²The A*23:14 and the A*24:05, 24:13:02 and 24:24 alleles will give rise to identical amplification patterns. These four alleles can be separated by the respective high resolution SSP primer sets.

101.403.48/12 – including *Taq* pol., IFU-01
 101.403.48u/12u – without *Taq* pol., IFU-02

Visit www.olerup-ssp.com for
 “Instructions for Use” (IFU)

Lot No.: **71N**

Lot-specific information

SPECIFICITY TABLE

HLA-A low resolution screening primer set

Specificities and sizes of the PCR products of the 23+1 primer mixes used for HLA-A low resolution screening SSP typing

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	HLA-A serology ³	Amplified HLA-A alleles ^{4,5}
1^{6,7}	120 bp, 145 bp, 225 bp	800 bp	A1, A36	*01:01:01:01-01:04N, 01:06-01:33, 01:35-01:104, 03:18, 03:135, 11:94, 11:112, 36:01-36:05
2⁷	210 bp, 255 bp, 365 bp, 415 bp	800 bp	A2,A19, A28, A203, A210, A3, A11, A9, A26, A30, A68	*02:01:01:01-02:01:15, 02:01:17-02:01:19, 02:01:21-02:22:02, 02:24:01-02:35:01, 02:35:03-02:47, 02:49-02:77, 02:78 ^w , 02:79:01-02:97:02, 02:99, 02:101:01-02:128, 02:130-02:336, 03:01:03 ^w , 03:09 ^w , 03:23:01 ^w , 03:89 ^w , 03:108 ^w , 11:06 ^w , 11:18 ^w , 24:28 ^w , 24:89 ^w , 26:03:01-26:03:02 ^w , 26:06 ^w , 26:07:02 ^w , 26:21 ^w , 26:30 ^w , 30:13 ^w , 30:16 ^w , 30:44 ^w , 30:46 ^w , 68:05 ^w , 68:15 ^w , 68:20 ^w , 68:30 ^w
3⁸	205 bp, 235 bp	1070 bp	A1, A3, A11, A32, A34, A36	*01:12, 01:19, 01:21, 03:01:01:01-03:17, 03:19-03:74, 03:76-03:94, 03:96-03:133, 11:25, 11:60, 24:92, 32:04, 33:49 ^w , 34:02:01, 34:02:02 ^w , 34:03-34:04, 34:07-34:09, 36:02
4	190 bp	800 bp	A1, A2, A3, A11, A26, A30, A36	*01:01:01:01-01:01:22, 01:01:24-01:04N, 01:06-01:07, 01:09-01:11N, 01:13, 01:16N-01:18N, 01:20-01:29, 01:31N-01:33, 01:35-01:78, 01:80-01:98, 01:100-01:104, 02:78, 02:169, 03:12, 03:18, 03:88, 03:135 ^w , 11:01:01-11:27, 11:29-11:52Q, 11:54-11:112, 26:19, 26:72, 30:08, 36:04, 68:13, 68:66
5^{7,13}	160 bp, 535 bp	800 bp	A3,A9,A23, A24, A31, A32	*01:95, 03:30, 23:01:01-23:50, 24:02:01:01-24:11N, 24:13:01-24:15, 24:17-24:64, 24:66-24:88, 24:90N-24:128, 24:130-24:190, 31:08, 32:05, 32:13, 33:53
6¹⁰	135 bp, 175 bp, 210 bp	800 bp	A9,A23, A24, A29, A80	*23:01:01-23:50, 24:05, 24:13:02, 24:24, 29:07, 30:56, 31:29, 80:01-80:02, B*18:27
7⁷	175 bp, 205 bp	1070 bp	A2, A23, A24, A26, A33	*02:17:01 ^w -02:17:02 ^w , 23:14, 24:02:01:01-24:11N, 24:13:01-24:13:02, 24:17-24:50, 24:54-24:56, 24:58-24:63, 24:66-24:91,

101.403.48/12 – including *Taq* pol., IFU-01
 101.403.48u/12u – without *Taq* pol., IFU-02

Visit www.olerup-ssp.com for
 “Instructions for Use” (IFU)

Lot No.: **71N**

Lot-specific information

				24:93, 24:95-24:113, 24:115-24:137, 24:139-24:187, 24:189-24:190, 26:16, 33:19, 68:45
8⁷	165 bp, 200 bp	800 bp	A2, A3, A10, A11, A25, A26, A28,A32, A34, A66, A68, A69	*01:51, 02:55, 03:24, 03:50, 11:10, 25:01:01-25:16, 26:01:01-26:06, 26:08- 26:15, 26:17-26:18, 26:20-26:43:02, 26:45- 26:63, 26:65-26:71N, 29:28, 32:15, 33:51, 34:01:01-34:09, 66:01-66:16, 68:01:01:01- 68:85, 69:01
9⁶	75 bp	800 bp	A25, A32	*25:01:01-25:16, 32:01:01-32:02, 32:04, 32:06-32:37
10⁶	85 bp	1070 bp	A2, A10, A26, A33	*01:51, 01:83, 02:146, 26:01:01-26:02, 26:04, 26:07:01-26:18, 26:20, 26:22-26:29, 26:31-26:43:02, 26:45-26:71N, 33:13, 33:48, 68:84
11^{6,7}	80 bp, 175 bp, 500 bp	1070 bp	A1, A11, A24, A26, A31, A34, A66	*01:13, 01:28, 03:63, 03:88, 11:01:01-11:27, 11:29-11:52Q, 11:54-11:112, 24:19, 24:44, 26:03:01-26:03:02, 26:06, 26:21, 31:03, 34:01:01-34:08, 66:01, 66:04-66:11, 66:13- 66:15, 80:02
12⁶	125 bp, 185 bp	800 bp	A11, A25, A26, A31, A34, A43, A66	*02:309, 03:01:19, 11:11, 25:05-25:06, 26:09, 26:54, 31:03-31:04, 34:01:01-34:09, 43:01, 66:02-66:03, 66:16
13	175 bp, 225 bp	1070 bp	A1, A2, A3, A25, A26, A34, A43, A66, A74	*01:13, 02:34-02:35:03, 02:56:01-02:56:02, 02:62, 02:103, 02:135, 03:01:01:01- 03:01:22, 03:01:24-03:07, 03:09-03:11N, 03:13-03:31, 03:33-03:35, 03:37-03:40, 03:42-03:56, 03:58, 03:60-03:71, 03:73- 03:87, 03:90-03:106, 03:109-03:110, 03:112-03:133, 03:135, 25:01:01-25:05, 25:07-25:16, 26:01:01-26:01:20, 26:01:22, 26:02 ^w , 26:03:01-26:03:02, 26:05-26:08, 26:10-26:33, 26:35-26:43:02, 26:45-26:72, 30:55, 34:08, 43:01, 66:01, 66:04-66:15, 68:71, 74:13
14⁶	100 bp, 200 bp, 240 bp	1070 bp	A29, A33	*02:237, 02:309, 03:95, 26:19, 26:22, 29:01:01:01-29:32, 30:57, 31:03-31:04, 33:13, 33:48, 66:09
15^{6,7,9,11}	90 bp, 135 bp, 205 bp	1070 bp	A1, A30	*01:13, 01:28, 03:43, 03:82, 30:01:01- 30:04:02, 30:06-30:20, 30:22-30:58, 31:35
16	240 bp, 370 bp, 395 bp	1070 bp	A31, A32	*02:237, 03:95, 29:14, 31:01:02-31:56, 31:58-31:59, 32:05, 33:53

101.403.48/12 – including *Taq* pol., IFU-01
101.403.48u/12u – without *Taq* pol., IFU-02

Visit www.olerup-ssp.com for
“Instructions for Use” (IFU)

Lot No.: **71N**

Lot-specific information

17	140 bp, 180 bp	1070 bp	A29, A32	*01:95, 03:43, 03:82, 29:13, 31:35, 32:01:01-32:03, 32:05-32:37, 74:07
18	200 bp	1070 bp	A33, A68	*02:243, 33:01:01-33:01:06, 33:03:01-33:50, 33:52-33:54, 68:29
19	160 bp, 200 bp	800 bp	A74	*29:19, 74:01-74:15
20¹⁰	220 bp, 245 bp	800 bp	A2, A210, A25, A68	*02:34-02:35:03, 02:46, 02:48, 02:56:01- 02:56:02, 02:62, 02:70, 02:78, 02:103, 02:129, 25:05, 26:54, 68:01:01:01-68:85
21	240 bp, 375 bp	800 bp	A2, A24, A26, A68, A69	*02:55, 02:243, 24:82, 26:22, 33:22, 66:09, 68:29, 69:01
22^{6,12}	85 bp, 240 bp	800 bp	A2, A36	*02:34-02:35:03, 02:46, 02:48, 02:56:01- 02:56:02, 02:62, 02:70, 02:78, 02:103, 02:129, 36:01-36:05
23^{6,10}	75 bp, 160 bp, 240 bp, 495 bp	800 bp	A2, A26, A68, A80	*02:55, 03:41, 03:63, 03:75, 03:88, 24:18, 26:03:01-26:03:02, 26:05-26:06, 26:21, 26:30, 33:24, 36:02, 68:05, 68:15, 68:20, 80:01
24¹⁴	-	-	-	Negative control

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 low resolution screening 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 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 low resolution screening typing.

In addition, wells number 2, 4 to 6, 8, 9, 12 and 19 to 23 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 serological reactivity of all HLA-A alleles is not known. In this table we use the expert-assigned serological grouping in Tissue Antigens (2009) 73:95-170 and the serological grouping of the sequence-defined allele.

101.403.48/12 – including *Taq* pol., IFU-01
101.403.48u/12u – without *Taq* pol., IFU-02

Visit www.olerup-ssp.com for
“Instructions for Use” (IFU)

Lot No.: 71N**Lot-specific information**

⁴Nucleotide sequence information is available for only exons 2 and 3 of many HLA Class I alleles and for only exon 2 of many HLA Class II alleles and not for other exons or for the introns of these alleles. We assume that unknown sequences outside exons 2 and 3 and in the introns are conserved within loci and within allelic groups.

⁵Primer mix 6 will amplify the B*18:27 allele.

⁶Specific PCR fragments shorter than 125 base pairs have a lower intensity and are less sharp than longer PCR bands.

⁷The primer pairs in wells 1, 2, 5, 7, 8, 11 and 15 will in many samples give rise to two or three HLA-specific PCR fragments.

⁸Primer mix 3 may faintly amplify the A*30:04, 30:06, 30:17 and 30:29 alleles.

⁹Primer mix 15 may yield less specific PCR product than the other primer mixes.

¹⁰Primer mixes 6, 20 and 23 may have a tendency of primer dimer formation.

¹¹Primer mix 15 may have tendencies of unspecific amplifications.

¹²Primer mix 22 might faintly amplify most A*11 alleles.

¹³In primer mix 5, the specific PCR product of 535 base pairs may be difficult to distinguish from the internal control band. The alleles giving rise to a product of this size are the following:
A*01:95, 23:09, 24:02:06, 24:02:27, 24:08, 24:24, 24:29, 24:42, 24:67, 24:116, 24:137, 24:140, 24:145, 24:156, 24:171 and 32:13.

¹⁴Primer mix 24 contains a negative control, which will amplify more than 95% of HLA amplicons as well as the amplicons generated by control primer pairs. PCR product sizes range from 75 to 200 base pairs. The PCR product generated by the control primer pair is 430 base pairs.

‘w’, might be weakly amplified.

101.403.48/12 – including *Taq* pol., IFU-01
 101.403.48u/12u – without *Taq* pol., IFU-02

Visit www.olerup-ssp.com for
 “Instructions for Use” (IFU)

Lot No.: **71N**

Lot-specific information

Well No.		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
HLA-A allele ⁴	ser ⁵																								
*01:01:01:01-01:01:22, 01:01:24-01:04N, 01:06- 01:07, 01:09-01:11N, 01:16N-01:18N, 01:20, 01:22N-01:27N, 01:29, 01:31N-01:33, 01:35- 01:50, 01:52N-01:78, 01:80-01:82, 01:84-01:94, 01:96-01:98, 01:100- 01:104	A1, Null, -	1			4																				
*01:01:23, 01:08, 01:14- 01:15N, 01:30, 01:79, 01:99	A1, Null, -	1																							
*01:12, 01:19	A1, -	1		3																					
*01:13	-	1		4								11		13		15									
*01:21	-	1		3	4																				
*01:28	-	1		4								11				15									
*01:51	-	1		4					8		10														
*01:83	-	1		4							10														
*01:95	-	1		4	5													17							
*02:01:01:01-02:01:15, 02:01:17-02:01:19, 02:01:21-02:16, 02:18- 02:22:02, 02:24:01-02:33, 02:36-02:45, 02:47, 02:49- 02:54, 02:57-02:61, 02:63- 02:69, 02:71-02:77, 02:79:01-02:97:02, 02:99, 02:101:01-02:102, 02:104- 02:128, 02:130-02:134, 02:136-02:145, 02:147- 02:168, 02:170-02:236, 02:238-02:242, 02:244- 02:308, 02:310-02:336	A2, A19, Low A2, A203, A210, Null, -			2																					
*02:17:01-02:17:02	A2		2					w																	
*02:34-02:35:01, 02:35:03, 02:56:01- 02:56:02, 02:62, 02:103	A2, -		2											13							20		22		
*02:35:02	A2													13							20		22		
*02:46, 02:70	A2		2																		20		22		
*02:48, 02:129	-																				20		22		
*02:55	-		2						8														21		23
*02:78	A2		w		4																20		22		
*02:135	-		2											13											
Well No.		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24

Negative control



101.403.48/12 – including *Taq* pol., IFU-01
 101.403.48u/12u – without *Taq* pol., IFU-02

Visit www.olerup-ssp.com for
 “Instructions for Use” (IFU)

Lot No.: **71N**

Lot-specific information

Well No.		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
HLA-A allele ⁴	ser ⁵																								
*02:146	-		2								10														
*02:169	-		2	4																					
*02:237	-		2											14	16										
*02:243	-		2															18			21				
*02:309	-		2									12	14												
*03:01:01:01-03:01:02, 03:01:04-03:01:18, 03:01:20-03:01:22, 03:01:24-03:07, 03:10- 03:11N, 03:13-03:17, 03:19-03:22:02, 03:23:02, 03:25-03:29, 03:31, 03:33- 03:35, 03:37-03:40, 03:42, 03:44-03:49, 03:51- 03:56, 03:58, 03:60- 03:62, 03:64-03:71, 03:73- 03:74, 03:76-03:81, 03:83- 03:87, 03:90-03:94, 03:96- 03:106, 03:109-03:110,	A3, Null, -			3										13											
*03:01:03, 03:09, 03:23:01	A3, -		w	3										13											
*03:01:19	-			3								12	13												
*03:01:23, 03:08, 03:32, 03:36N, 03:57, 03:59, 03:72, 03:107, 03:111	Null, -			3																					
*03:12	-			3	4																				
*03:18	-	1			4									13											
*03:24, 03:50	A3, -			3					8					13											
*03:30	-			3	5									13											
*03:41	-			3																				23	
*03:43, 03:82	-			3										13	15	17									
*03:63	-			3								11		13										23	
*03:75	-													13										23	
*03:88	-			3	4							11												23	
*03:89, 03:108	-		w	3																					
*03:95	-													13	14	16									
*03:135	-	1			w									13											
*11:01:01-11:05, 11:07- 11:09, 11:12-11:17, 11:19- 11:24:02, 11:26-11:27, 11:29-11:52Q, 11:54- 11:59, 11:61-11:93, 11:95- 11:111	A11, Null, -				4								11												
*11:06, 11:18	A11, -		w		4								11												
Well No.		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24

Negative Control

101.403.48/12 – including *Taq* pol., IFU-01
 101.403.48u/12u – without *Taq* pol., IFU-02

Visit www.olerup-ssp.com for
 “Instructions for Use” (IFU)

Lot No.: 71N

Lot-specific information

Well No.		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
HLA-A allele ⁴	ser ⁵																								
*11:10	A11				4				8			11													
*11:11	-				4							11	12												
*11:25, 11:60	A11, -			3	4							11													
*11:94, 11:112	-	1			4							11													
*23:01:01-23:13, 23:15-23:50	A23(9), Null, -					5	6																		
*23:14, 24:05, 24:13:02, 24:24 ⁷	A9, A24(9), -					5	6	7																	
*24:02:01:01-24:04, 24:06-24:11N, 24:13:01, 24:17, 24:20-24:23, 24:25-24:27, 24:29-24:43, 24:45N-24:50, 24:54-24:56, 24:58-24:63, 24:66-24:81, 24:83N-24:88, 24:90N-24:91, 24:93, 24:95-24:113, 24:115-24:128, 24:130-24:137, 24:139-24:187, 24:189-24:190	A24(9), Low A24(9), A2403, A9, Null, -					5		7																	
*24:14-24:15, 24:51-24:53, 24:57, 24:64, 24:94, 24:114, 24:138, 24:188	A24(9), -					5																			
*24:18	A24(9), A3					5		7																23	
*24:19, 24:44	A9, -					5		7				11													
*24:28	A9		w			5		7																	
*24:82	-					5		7														21			
*24:89	-		w					7																	
*24:92	-			3		5																			
*24:129	-							7																	
*25:01:01-25:04, 25:07-25:16	A25(10) , Null, -								8	9				13											
*25:05	-								8	9		12	13								20				
*25:06	-								8	9		12													
*26:01:01-26:01:20, 26:01:22, 26:08, 26:10-26:15, 26:17-26:18, 26:20, 26:23-26:29, 26:31-26:33, 26:35-26:43:02, 26:45-26:53, 26:55-26:63, 26:65-26:71N	A26(10) , A10, Null, -								8		10		13												
*26:01:21, 26:04, 26:34	A26(10) , -								8		10														
*26:02	A26(10)								8		10		w												
Well No.		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24

Negative Control

101.403.48/12 – including *Taq* pol., IFU-01
 101.403.48u/12u – without *Taq* pol., IFU-02

Visit www.olerup-ssp.com for
 “Instructions for Use” (IFU)

Lot No.: **71N**

Lot-specific information

Well No.		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
HLA-A allele⁴	ser⁵																								
*26:03:01-26:03:02, 26:06, 26:21	A26(10) , -		w						8			11		13											23
*26:05	A26(10)								8					13											23
*26:07:01, 26:64	A26(10) , -											10		13											
*26:07:02	A26(10) , -		w									10		13											
*26:09	A26(10)								8		10		12												
*26:16	-							7			10			13											
*26:19	-				4									13	14										
*26:22	A26(10)								8		10			13	14							21			
*26:30	-		w						8					13											23
*26:54	-								8		10		12	13							20				
*26:72	-				4									13											
*29:01:01:01-29:06, 29:08N-29:12, 29:15- 29:18, 29:20-29:27, 29:29- 29:32	A29(19) , Null, -														14										
*29:07	-						6							14											
*29:13	-													14			17								
*29:14	-													14		16									
*29:19	-													14						19					
*29:28	-								8					14											
*30:01:01-30:04:02, 30:06- 30:07, 30:09-30:12, 30:14- 30:15, 30:17-30:20, 30:22-	A30(19) , Null, -															15									
*30:08	-				4											15									
*30:13, 30:16,30:44, 30:46	A30(19) , -															15									
*30:55	-													13		15									
*30:56	-						6									15									
*30:57	-														14	15									
*31:01:02-31:02, 31:05- 31:07, 31:09-31:28, 31:30- 31:34, 31:36-31:56, 31:58- 31:59	A31(19) , Null, -																16								
*31:03	-											11	12		14	16									
*31:04	A31(19)												12		14	16									
*31:08	-					5										16									
*31:29	-						6									16									
*31:35	-															15	16	17							
*32:01:01-32:02, 32:06- 32:12, 32:14, 32:16-32:37	A32(19) , Null, -									9								17							
*32:03	-																	17							
*32:04	-				3					9															
Well No.		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24

Negative Control



101.403.48/12 – including *Taq* pol., IFU-01
 101.403.48u/12u – without *Taq* pol., IFU-02

Visit www.olerup-ssp.com for
 “Instructions for Use” (IFU)

Lot No.: 71N

Lot-specific information

Well No.		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
HLA-A allele ⁴	ser ⁵																								
*32:05	-					5											16	17							
*32:13	-					5				9								17							
*32:15	-								8	9								17							
*33:01:01-33:01:06, 33:03:01-33:12, 33:14- 33:18, 33:20-33:21, 33:23, 33:25-33:47, 33:50, 33:52, 33:54	A33(19) , A19, -																		18						
*33:13, 33:48	-										10				14			18							
*33:19	-							7										18							
*33:22	-																	18			21				
*33:24	-																	18						23	
*33:49	-			w														18							
*33:51	-								8																
*33:53	-					5											16	18							
*34:01:01-34:01:02, 34:05- 34:06	A34(10) , -								8			11	12												
*34:02:01, 34:03-34:04, 34:07	A34(10) , -			3					8			11	12												
*34:02:02	-			w					8			11	12												
*34:08	-			3					8			11	12	13											
*34:09	-			3					8				12												
*36:01, 36:03, 36:05	A36, -	1																						22	
*36:02	-	1	3																					22	23
*36:04	A36	1		4																				22	
*43:01	A43												12	13											
*66:01, 66:04-66:08, 66:10-66:11, 66:13-66:15	A66(10) , -								8			11		13											
*66:02-66:03, 66:16	A66(10) , A10, -								8				12												
*66:09	-								8			11		13	14								21		
*66:12	-								8					13											
*68:01:01:01-68:04, 68:06- 68:12, 68:14, 68:16- 68:19, 68:21:01-68:28, 68:31-68:44, 68:46-68:65, 68:67-68:70, 68:72-68:83, 68:85	A68(28) , A28, Null, -								8													20			
*68:05, 68:15, 68:20	A68(28) , -		w						8													20			23
*68:13, 68:66	-			4					8													20			
*68:29	-								8									18			20	21			
*68:30	A68(28)		w						8													20			
*68:45	-							7	8													20			
Well No.		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24

Negative Control

101.403.48/12 – including *Taq* pol., IFU-01
101.403.48u/12u – without *Taq* pol., IFU-02

Visit www.olerup-ssp.com for
“Instructions for Use” (IFU)

Lot No.: **71N**

Lot-specific information

Well No.		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	
HLA-A allele ⁴	ser ⁵																									
*68:71	-								8						13							20				
*68:84	-								8			10										20				
*69:01	A69(28)								8														21			
*74:01-74:06, 74:08-74:12N, 74:14N-74:15	A74(19), Null, -																					19				
*74:07	A74(19)																	17			19					
*74:13	-													13							19					
*80:01	A80							6																	23	
*80:02	-							6				11														
<i>B*18:27</i>								6																		
Well No.		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	

Neg. Control

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 low resolution screening SSP typing.

In addition, wells number 2, 4 to 6, 8, 9, 12 and 19 to 23 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 or 3rd exon or in the 2nd 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 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.

⁴The sequence of the A*0105N has been shown to be identical to A*01:04N.

The A*01:34N allele has been renamed to A*01:01:38L.

The A*020116 allele has been renamed to A*02:134.

The A*020120 allele has been renamed to A*02:01:18.

The sequence of the A*0223 allele has been shown to be identical to A*02:22:01.

The sequence of the A*0298 allele has been shown to be identical to A*02:96.

The A*02:100 allele has never been assigned.

The A*1128 allele has been renamed to A*11:15:02.

The A*11:53 allele has been shown to be identical to corrected sequence of A*11:02:01.

The sequence of the A*2401 allele has been shown to be in error.

The sequence of the A*2412 allele has been shown to be identical to A*24:08.

The A*2416 allele has been renamed to A*31:08.

The A*2465 allele has been renamed to A*24:13:02.

The A*26:44 allele has been renamed to A*26:43:02.

The sequence of the A*3005 allele has been shown to be identical to A*30:04.

The A*3021 allele has been renamed to A*30:11:02.

The sequence of the A*31011 allele has been shown to be identical to A*31:01:02.

The sequence of the A*3302 allele has been shown to be identical to A*33:03:01.

⁵The serological reactivity of all HLA-A alleles is not known. In this table we use the expert-assigned serological grouping in Tissue Antigens (2009) 73:95-170 and the serological grouping of the sequence-defined allele.

⁶The primer pairs in wells 1, 2, 5, 7, 8, 11 and 15 will in many samples give rise to two or three HLA-specific PCR fragments.

⁷The A*23:14 and the A*24:05, 24:13:02 and 24:24 alleles will give rise to identical amplification patterns. These four alleles can be separated by the respective high resolution SSP primer sets.

⁸Primer mix 24 contains a negative control, which will amplify more than 95% of HLA amplicons as well as the amplicons generated by control primer pairs. PCR product sizes range from 75 to 200 base pairs. The PCR product generated by the control primer pair is 430 base pairs.

'w', may be weakly amplified.

101.403.48/12 – including *Taq* pol., IFU-01
 101.403.48u/12u – without *Taq* pol., IFU-02

Visit www.olerup-ssp.com for
 “Instructions for Use” (IFU)

Lot No.: **71N**

Lot-specific information

				CELL LINE VALIDATION SHEET																
				HLA-A low resolution screening primer set																
				Well																
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	
				Lot No.:	201193101	201191802	201193103	201191804	201191805	201191806	201191807	201191808	201191809	201191810	201191811	201191812	201191813	201191814	201193115	201191816
	IHWC cell line	A*	A*																	
1	9001 SA	*24:02		-	-	-	-	+	-	+	-	-	-	-	-	-	-	-	-	
2	9280 LK707	*02:01		-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
3	9011 E4181324	*01:01		+	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	
4	9275 GU373	*30:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-	
5	9009 KAS011	*01:01		+	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	
6	9353 SM	*02:01	*26:03	-	+	-	-	-	-	-	-	+	-	-	+	-	+	-	-	
7	9020 QBL	*26:01		-	-	-	-	-	-	-	-	+	-	+	-	+	-	-	-	
8	9025 DEU	*31:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	
9	9026 YAR	*26:01		-	-	-	-	-	-	-	-	+	-	+	-	-	+	-	-	
10	9107 LKT3	*24:02		-	-	-	-	+	-	+	-	-	-	-	-	-	-	-	-	
11	9051 PITOUT	*29:02		-	-	-	-	-	-	-	-	-	-	-	-	-	+	-	-	
12	9052 DBB	*02:01		-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
13	9004 JESTHOM	*02:01		-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
14	9071 OLGA	*31:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	
15	9075 DKB	*24:02		-	-	-	-	+	-	+	-	-	-	-	-	-	-	-	-	
16	9037 SWEIG007	*29:02		-	-	-	-	-	-	-	-	-	-	-	-	-	+	-	-	
17	9282 CTM3953540	*03:01	*80:01	-	-	+	-	-	+	-	-	-	-	-	-	+	-	-	-	
18	9257 32367	*33:03	*74:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
19	9038 BM16	*02:01		-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
20	9059 SLE005	*02:01		-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
21	9064 AMALA	*02:17		-	+	-	-	-	-	-	W	-	-	-	-	-	-	-	-	
22	9056 KOSE	*02:01		-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
23	9124 IHL	*02:01	*34:01	-	+	-	-	-	-	-	+	-	-	+	+	-	-	-	-	
24	9035 JBUSH	*32:01		-	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	
25	9049 IBW9	*33:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
26	9285 WT49	*02:05		-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
27	9191 CH1007	*24:10	*29:01	-	-	-	-	+	-	+	-	-	-	-	-	-	+	-	-	
28	9320 BEL5GB	*02:01	*29:02	-	+	-	-	-	-	-	-	-	-	-	-	-	+	-	-	
29	9050 MOU	*29:02		-	-	-	-	-	-	-	-	-	-	-	-	-	+	-	-	
30	9021 RSH	*30:01	*68:02	-	-	-	-	-	-	-	+	-	-	-	-	-	-	+	-	
31	9019 DUCAF	*30:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-	
32	9297 HAG	*02:01		-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
33	9098 MT14B	*31:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	
34	9104 DHIF	*31:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	
35	9302 SSTO	*32:01		-	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	
36	9024 KT17	*02:06	*11:01	-	+	-	+	-	-	-	-	-	-	+	-	-	-	-	-	
37	9065 HHKB	*03:01		-	-	+	-	-	-	-	-	-	-	-	-	+	-	-	-	
38	9099 LZL	*02:17		-	+	-	-	-	-	W	-	-	-	-	-	-	-	-	-	
39	9315 CML	*01:01	*03:01	+	-	+	+	-	-	-	-	-	-	-	-	+	-	-	-	
40	9134 WHONP199	*02:07	*30:01	-	+	-	-	-	-	-	-	-	-	-	-	-	-	+	-	
41	9055 H0301	*03:01		-	-	+	-	-	-	-	-	-	-	-	-	+	-	-	-	
42	9066 TAB089	*02:07		-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
43	9076 T7526	*02:06	*02:07	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
44	9057 TEM	*66:01		-	-	-	-	-	-	-	+	-	-	+	-	+	-	-	-	
45	9239 SHJO	*23:01	*24:02	-	-	-	-	+	+	+	-	-	-	-	-	-	-	-	-	
46	9013 SCHU	*03:01		-	-	+	-	-	-	-	-	-	-	-	-	+	-	-	-	
47	9045 TUBO	*02:16	*03:01	-	+	+	-	-	-	-	-	-	-	-	-	+	-	-	-	
48	9303 TER-ND	*02:01	*11:01	-	+	-	+	-	-	-	-	-	-	+	-	-	-	-	-	

101.403.48/12 – including *Taq* pol., IFU-01
 101.403.48u/12u – without *Taq* pol., IFU-02

Visit www.olerup-ssp.com for
 “Instructions for Use” (IFU)

Lot No.: **71N**

Lot-specific information

CELL LINE VALIDATION SHEET											
HLA-A low resolution screening primer set											
				Well							
				17	18	19	20	21	22	23	
				Lot No.:	201191817	201191818	201194019	201191820	201191821	201191822	201191823
	IHWC cell line	A*	A*								
1	9001 SA	*24:02			-	-	-	-	-	-	-
2	9280 LK707	*02:01			-	-	-	-	-	-	-
3	9011 E4181324	*01:01			-	-	-	-	-	-	-
4	9275 GU373	*30:01			-	-	-	-	-	-	-
5	9009 KAS011	*01:01			-	-	-	-	-	-	-
6	9353 SM	*02:01	*26:03		-	-	-	-	-	-	+
7	9020 QBL	*26:01			-	-	-	-	-	-	-
8	9025 DEU	*31:01			-	-	-	-	-	-	-
9	9026 YAR	*26:01			-	-	-	-	-	-	-
10	9107 LKT3	*24:02			-	-	-	-	-	-	-
11	9051 PITOUT	*29:02			-	-	-	-	-	-	-
12	9052 DBB	*02:01			-	-	-	-	-	-	-
13	9004 JESTHOM	*02:01			-	-	-	-	-	-	-
14	9071 OLGA	*31:01			-	-	-	-	-	-	-
15	9075 DKB	*24:02			-	-	-	-	-	-	-
16	9037 SWEIG007	*29:02			-	-	-	-	-	-	-
17	9282 CTM3953540	*03:01	*80:01		-	-	-	-	-	-	+
18	9257 32367	*33:03	*74:01		-	+	+	-	-	-	-
19	9038 BM16	*02:01			-	-	-	-	-	-	-
20	9059 SLE005	*02:01			-	-	-	-	-	-	-
21	9064 AMALA	*02:17			-	-	-	-	-	-	-
22	9056 KOSE	*02:01			-	-	-	-	-	-	-
23	9124 IHL	*02:01	*34:01		-	-	-	-	-	-	-
24	9035 JBUSH	*32:01			+	-	-	-	-	-	-
25	9049 IBW9	*33:01			-	+	-	-	-	-	-
26	9285 WT49	*02:05			-	-	-	-	-	-	-
27	9191 CH1007	*24:10	*29:01		-	-	-	-	-	-	-
28	9320 BEL5GB	*02:01	*29:02		-	-	-	-	-	-	-
29	9050 MOU	*29:02			-	-	-	-	-	-	-
30	9021 RSH	*30:01	*68:02		-	-	-	+	-	-	-
31	9019 DUCAF	*30:02			-	-	-	-	-	-	-
32	9297 HAG	*02:01			-	-	-	-	-	-	-
33	9098 MT14B	*31:01			-	-	-	-	-	-	-
34	9104 DHIF	*31:01			-	-	-	-	-	-	-
35	9302 SSTO	*32:01			+	-	-	-	-	-	-
36	9024 KT17	*02:06	*11:01		-	-	-	-	-	-	-
37	9065 HHKB	*03:01			-	-	-	-	-	-	-
38	9099 LZL	*02:17			-	-	-	-	-	-	-
39	9315 CML	*01:01	*03:01		-	-	-	-	-	-	-
40	9134 WHONP199	*02:07	*30:01		-	-	-	-	-	-	-
41	9055 H0301	*03:01			-	-	-	-	-	-	-
42	9066 TAB089	*02:07			-	-	-	-	-	-	-
43	9076 T7526	*02:06	*02:07		-	-	-	-	-	-	-
44	9057 TEM	*66:01			-	-	-	-	-	-	-
45	9239 SHJO	*23:01	*24:02		-	-	-	-	-	-	-
46	9013 SCHU	*03:01			-	-	-	-	-	-	-
47	9045 TUBO	*02:16	*03:01		-	-	-	-	-	-	-
48	9303 TER-ND	*02:01	*11:01		-	-	-	-	-	-	-

101.403.48/12 – including *Taq* pol., IFU-01
 101.403.48u/12u – without *Taq* pol., IFU-02

Visit www.olerup-ssp.com for
 “Instructions for Use” (IFU)

Lot No.: **71N**

Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-A low resolution screening

Product number: 101.403-48/12 – including *Taq* polymerase
 101.403-48u/12u – without *Taq* polymerase
Lot number: 71N
Expiry date: 2014-October-01
Number of tests: 48 tests – Product No. 101.403-48/48u
 12 tests – Product No. 101.403-12/12u
Number of wells per test: 23 +1

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2011-931-01	9	2011-918-09	17	2011-918-17
2	2011-918-02	10	2011-918-10	18	2011-918-18
3	2011-931-03	11	2011-918-11	19	2011-940-19
4	2011-918-04	12	2011-918-12	20	2011-918-20
5	2011-918-05	13	2011-918-13	21	2011-918-21
6	2011-918-06	14	2011-918-14	22	2011-918-22
7	2011-918-07	15	2011-931-15	23	2011-918-23
8	2011-918-08	16	2011-918-16		

The specificity of each primer solution of the kit has been tested against 48 well characterized IHWC cell line DNAs.

Additional 5'-primers in primer solutions 1, 4, 5, 7, 8, 10, 12, 14 to 17 and 20 to 23 was tested by separately adding one 3'-primer. Additional 3'-primers in primer solutions 3 to 8, 12 and 14 to 23 were tested by separately adding one 5'-primer. One or two of the 5'-primers in primer solutions 2, 9 to 11 and 15 were not possible to test, and in primer solutions 3, 8, 18 and 19 one 3'-primer was not possible to test.

The negative control primer pairs, **Production No. 2012-002-01**, can detect contamination with PCR products diluted 10^{-7} .

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

Date of approval: 2012-April-27

Approved by:

Production Quality Control

101.403.48/12 – including *Taq* pol., IFU-01
101.403.48u/12u – without *Taq* pol., IFU-02

Visit www.olerup-ssp.com for
“Instructions for Use” (IFU)

Lot No.: **71N**

Lot-specific information

Declaration of Conformity

Product name: *Olerup* SSP® HLA-A low resolution screening
Product number: 101.403-48/48u, -12/12u
Lot number: 71N

Intended use: HLA-A low resolution screening histocompatibility testing

Manufacturer: *Olerup* SSP AB
Franzengatan 5
SE-112 51 Stockholm, Sweden
Phone: +46-8-717 88 27
Fax: +46-8-717 88 18

We, *Olerup* SSP AB, hereby declare that this product, to which this Declaration of Conformity relates is in conformity with the following Standard(s) and other normative document(s) ISO 9001:2008 and ISO 13485:2003, following the provisions of the 98/79/EC Directive on *in vitro* diagnostic medical devices, Annex 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, Franzengatan 5, SE-112 51 Stockholm, Sweden.

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

Stockholm, Sweden
2012-April-27

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs

101.403.48/12 – including *Taq* pol., IFU-01
101.403.48u/12u – without *Taq* pol., IFU-02

Visit www.olerup-ssp.com for
“Instructions for Use” (IFU)

Lot No.: **71N**

Lot-specific information

101.403.48/12 – including *Taq* pol., IFU-01
101.403.48u/12u – without *Taq* pol., IFU-02

Visit www.olerup-ssp.com for
“Instructions for Use” (IFU)

Lot No.: **71N**

Lot-specific information

ADDRESSES:

Manufacturer:

Olerup SSP AB, Franzengatan 5, SE-112 51 Stockholm, Sweden.

Tel: +46-8-717 88 27

Fax: +46-8-717 88 18

E-mail: info-ssp@olerup.com

Web page: <http://www.olerup-ssp.com>

Distributed by:

Olerup GmbH, Löwengasse 47 / 6, AT-1030 Vienna, Austria.

Tel: +43-1-710 15 00

Fax: +43-1-710 15 00 10

E-mail: support-at@olerup.com

Web page: <http://www.olerup.com>

Olerup Inc., 901 S. Bolmar St., Suite R, West Chester, PA 19382

Tel: 1-877-OLERUP1

Fax: 610-344-7989

E-mail: info.us@olerup.com

Web page: <http://www.olerup.com>

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