

101.401.48/12 – including *Taq* pol., IFU-01
 101.401.48u/12u – without *Taq* pol., IFU-02

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

Lot No.: **71R**

Lot-specific information

Olerup SSP[®] HLA-A low resolution

Product number:	101.401-48/12 – including <i>Taq</i> polymerase 101.401-48u/12u – without <i>Taq</i> polymerase
Lot number:	71R
Expiry date:	2015-October-01
Number of tests:	48 tests – Product No. 101.401-48/48u 12 tests – Product No. 101.401-12/12u
Number of wells per test:	31 +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. 71R.

CHANGES COMPARED TO THE PREVIOUS OLERUP SSP[®] HLA-A LOW RESOLUTION LOT (02N)

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

The **HLA-A low resolution** specificity and interpretation tables have been updated for the HLA-A alleles described since the previous *Olerup SSP[®]* HLA-A low resolution lot was made (**Lot No. 02N**).

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

Well	5'-primer	3'-primer	rationale
2	Exchanged	-	5'-primer exchanged for improved specificity of primer pair.
6	-	Exchanged	3'-primers exchanged for resolution of the A*23:14:02 and A*23:34 alleles.
9	Exchanged	-	Exchanged 5'-primer for the A*25:17 allele.
10	Exchanged, added	-	5'-primer added for the A*26:72 allele, exchanged positive control primer pair.
12	Added	-	5'-primer added for the A*34:10N allele.
13	-	Added	3'-primer added for the A*25:18 allele.
14	Added	-	5'-primer added for the A*29:37 allele.

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16	-	Added	3'-primer added for the A*31:01:07 allele.
25	-	Modified	Primer modified for improved specificity of primer pair
27	-	Added	3'-primer added for the A*03:05:02 allele.

Changes in revision R01 compared to R00:

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.
2. Primer mix 6 does not amplify the A*24:05 and A*24:199 alleles. This has been corrected in the Specificity and Interpretation Tables.

Change in revision R02 compared to R01:

1. Primer mix 30 amplifies the A*32:26 allele. This has been corrected in the Specificity and Interpretation Tables.

Change in revision R03 compared to R02:

1. Primer mix 11 does not amplify the A*31:03 and A*66:15 alleles. This has been corrected in the Specificity and Interpretation tables.

Change in revision R04 compared to R03:

1. Primer mix 25 does not amplify the A*32:04 allele. This has been corrected in the Specificity and Interpretation tables.

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Well **32** 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.

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PRODUCT DESCRIPTION

HLA-A low resolution

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 32 PCR reactions in a 32 well PCR plate. This lot is manufactured using white plastic trays.

1	2	3	4	5	6	7	8
9	10	11	12	13	14	15	16
17	18	19	20	21	22	23	24
25	26	27	28	29	30	31	32

Wells 1 to 31 – HLA-A low resolution primers.

Well 32 – Negative Control.

The 32 well PCR plate is marked with ‘HLA-A low’ in silver/gray ink.

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

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 32 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 32 wells of the HLA-A low resolution primer set except that primer mix 4 will amplify the C*03:174 and C*08:69 alleles, primer mix 6 will amplify the B*18:27 allele and primer mix 9 will amplify B*07:81, B*08:52, B*18:67, B*38:41, B*53:05 and B*53:16 alleles. Thus, the interpretation of HLA-A low resolution is only influenced by these alleles 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 October 2012¹ will be amplified by the primers in the HLA-A low resolution 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-October-14, release 3.10.0, www.ebi.ac.uk/imgt/hla.

²The A*23:14:01-23:14:02 and the A*24:71 alleles will give rise to identical amplification patterns. These alleles can be separated by the respective high resolution SSP primer sets.

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Lot-specific information
SPECIFICITY TABLE

HLA-A low resolution primer set

Specificities and sizes of the PCR products of the 31+1 primer mixes used for HLA-A low resolution SSP typing

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	HLA-A serology ³	Amplified HLA-A alleles ^{4,5,6}
1⁷	120 bp, 145 bp	800 bp	A1, A36	*01:01:01:01-01:01:31, 01:01:33-01:04N, 01:06-01:33, 01:35-01:68, 01:70-01:122, 36:01-36:05
2⁸	175 bp, 215 bp, 255 bp, 365 bp, 415 bp	800 bp	A2,A19, A28, A203, A210	*02:01:01:01-02:01:15, 02:01:17- 02:01:19, 02:01:21-02:01:81, 02:01:83- 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, 02:130-02:392
3	235 bp	1070 bp	A3,A32/A3, A36	*03:01:01:01-03:01:29, 03:01:31- 03:01:34, 03:01:36-03:04:03, 03:06- 03:09, 03:11N-03:17:02, 03:19-03:39, 03:41, 03:43-03:74, 03:76-03:94, 03:96- 03:97, 03:99-03:104, 03:106-03:121, 03:123-03:134, 03:136-03:161N, 11:130, 32:04, 36:02
4	190 bp	800 bp	A1,A3,A11, A30, A36, A68	*01:01:01:01-01:01:22, 01:01:24- 01:01:47, 01:01:49-01:04N, 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, 01:80-01:83:01, 01:83:02 ^w , 01:84-01:98, 01:100-01:122, 02:78, 02:169, 03:12, 03:18, 03:88, 03:135, 11:01:01-11:27, 11:29-11:52Q, 11:54-11:132, 26:19, 26:72, 30:08, 36:04, 68:13:01, 68:66, C*03:174, C*08:69
5^{8,15}	160 bp, 535 bp	800 bp	A3, A9, A23, A24, A2403, A31, A32	*01:95, 03:30, 03:152, 23:01:01-23:55, 24:02:01:01-24:11N, 24:13:01-24:15, 24:17-24:64, 24:66-24:88, 24:90N- 24:128, 24:130-24:210, 24:212-24:214, 24:216-24:222N, 31:08, 32:05, 32:13, 33:53
6¹³	135 bp, 195 bp, 205 bp	800 bp	A9,A23, A24, A29, A80	*23:01:01-23:55, 24:24, 24:71, 29:07, 30:56, 31:29, 80:01:01:01-80:02, B*18:27

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7⁸	175 bp, 205 bp	1070 bp	A2, A9, A23, A24, A2403, A26, A33	*02:17:01 ^w -02:17:02 ^w , 23:14:01-23:14:02, 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, 24:93, 24:95-24:113, 24:115-24:137, 24:139- 24:187, 24:189-24:210, 24:212-24:214, 24:216-24:221, 26:16, 33:19, 68:45
8⁸	165 bp, 200 bp	800 bp	A2/A28, A3, A10, A11, A25, A26, A32, A34, A66, A68, A69	*01:51, 02:55, 03:24, 03:50, 11:10, 25:01:01-25:16, 25:18-25:22, 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, 26:73-26:80, 29:28, 32:15, 33:51, 34:01:01-34:10N, 66:01-66:19, 68:01:01:01-68:96, 69:01
9^{7,14}	75 bp	800 bp	A25, A32	*25:01:01-25:22, 32:01:01-32:01:13, 32:02, 32:04, 32:06-32:37, 32:39-32:55, B*07:81, B*08:52, B*18:67, B*38:41, B*53:05, B*53:16
10⁷	80 bp, 240 bp	800 bp	A10, A26, A33	*01:43, 01:51, 11:17, 11:40, 26:01:01- 26:02, 26:04, 26:07:01-26:20, 26:22- 26:29, 26:31-26:43:02, 26:45-26:77, 26:79-26:80, 33:13, 33:48, 43:01, 68:84
11^{7,8}	80 bp, 175 bp, 500 bp	1070 bp	A1, A9, A11, A26, A31, A34, A66	*01:13, 01:28, 03:63, 03:88, 11:01:01- 11:27, 11:29-11:52Q, 11:54-11:132, 24:19, 24:44, 26:03:01-26:03:02, 26:06, 26:21, 26:78, 34:01:01-34:08, 34:10N, 66:01, 66:04-66:11, 66:13-66:14, 66:17- 66:19, 80:02
12⁷	125 bp, 185 bp	800 bp	A3, A10, 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- 34:10N, 43:01, 66:02-66:03, 66:16
13	175 bp, 225 bp	1070 bp	A1, A2, A3, A10, A25, A26, A34, A43, A66	*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, 03:112-03:141, 03:143- 03:151, 03:153-03:161N, 25:01:01-25:05, 25:07-25:22, 26:01:01-26:01:20, 26:01:22-26:01:27, 26:02 ^w , 26:03:01- 26:03:02, 26:05-26:08, 26:10-26:28, 26:29 ^w , 26:30-26:33, 26:35-26:43:02, 26:45-26:48, 26:49 ^w , 26:50-26:72, 26:74- 26:77, 26:79-26:80, 30:55, 34:08, 43:01,

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				66:01, 66:04-66:09, 66:10 ^W , 66:11-66:15, 66:17-66:19, 68:71, 74:13
14⁷	80 bp, 115 bp, 200 bp, 240 bp	1070 bp	A26, A29, A31, A34	*02:237, 02:309, 03:95, 26:19, 26:22, 29:01:01:01-29:45, 30:57, 33:13, 33:48, 66:09
15⁷⁻¹⁰	90 bp, 135 bp, 205 bp	1070 bp	A1, A30	*01:13, 01:28, 03:43, 03:82, 11:113, 30:01:01-30:04:02, 30:06-30:20, 30:22- 30:70N, 31:35
16	240 bp, 370 bp, 395 bp	1070 bp	A31, A32	*02:237, 03:95, 29:14, 31:01:02-31:70, 32:05, 33:53
17	140 bp, 180 bp	1070 bp	A32, A36, A74	*01:95, 03:43, 03:82, 29:13, 29:39, 31:35, 32:01:01-32:03, 32:05-32:55, 74:07
18	200 bp	1070 bp	A33, A68	*02:243, 33:01:01-33:01:07, 33:03:01- 33:37, 33:39-33:50, 33:52-33:64, 68:29
19	160 bp, 200 bp	800 bp	A74	*29:19, 29:39, 74:01-74:17
20	220 bp, 245 bp	800 bp	A2, A25, A28, 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, 68:01:01:01-68:96
21	240 bp, 375 bp	800 bp	A2/A28, A26, A68, A69	*02:55, 02:243, 24:82, 26:22, 33:22, 66:09, 68:29, 69:01
22^{7,11}	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, 31:62, 36:01-36:05
23⁷	70 bp, 160 bp, 240 bp, 495 bp	800 bp	A2/A28, A24/A3, A26, A36, A68, A80	*02:55, 03:41, 03:63, 03:75, 03:88, 11:130, 24:18, 24:204, 24:213, 26:03:01- 26:03:02, 26:05-26:06, 26:21, 26:30, 26:78, 33:24, 36:02, 68:05, 68:15, 68:20, 80:01:01:01-80:01:01:02
24	360 bp		A3, A10, A26, A31, A66	*02:135, 02:309, 03:01:19, 25:13, 26:30, 26:65, 31:04, 34:09, 66:02-66:03, 66:12, 66:16
25	190 bp, 400 bp	1070 bp	A1, A29, A30, A31, A32, A33, A74	*29:01:01:01-29:29, 29:31-29:45, 30:01:01-30:04:02, 30:06-30:11:02, 30:13-30:17, 30:19-30:20, 30:22-30:30, 30:32-30:40, 30:42-30:54, 30:56-30:59N, 30:61-30:70N, 31:01:02-31:08, 31:10- 31:27, 31:29-31:70, 32:01:01-32:03, 32:05-32:23, 32:25-32:48N, 32:50-32:55, 33:01:01-33:01:07, 33:03:01-33:37, 33:39-33:64, 74:01-74:17

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26	195 bp, 225 bp	800 bp	A1, A36, A43	*01:01:01:01-01:02, 01:04N, 01:07- 01:11N, 01:13, 01:16N-01:18N, 01:21- 01:33, 01:35-01:52N, 01:54-01:62, 01:64, 01:67-01:72, 01:74-01:97, 01:99-01:122, 03:18, 03:135, 11:11, 11:94, 11:112, 36:04, 43:01
27⁹	205 bp	1070 bp	A1, A3, A11, A30, A31, A32, A34	*01:12, 01:19, 01:21, 02:156, 02:338, 03:01:01:01-03:01:05, 03:01:07-03:01:13, 03:01:15-03:17:02, 03:19-03:49, 03:51- 03:53, 03:55-03:63, 03:67-03:74, 03:76- 03:94, 03:96-03:126, 03:128-03:134, 03:136-03:139, 03:141-03:152, 03:154- 03:161N, 11:25, 11:31, 11:35, 11:60, 24:92, 30:04:01-30:04:02, 30:06, 30:09, 30:17, 30:29, 30:46, 31:03-31:04, 32:04, 33:49, 34:02:01-34:04, 34:07-34:10N
28^{7,9}	100 bp	1070 bp	A2, A3, A9, A11, A23, A24, A28, A29, A30, A66, A68, A69	*02:34-02:35:03, 02:56:01-02:56:02, 02:62, 02:78, 02:103, 03:01:01:01-03:07, 03:09-03:28, 03:30-03:31, 03:33, 03:35, 03:37-03:40, 03:42-03:61, 03:64-03:87, 03:90-03:106, 03:109-03:151, 03:153- 03:161N, 11:12, 23:13, 24:07, 24:24, 24:108, 24:112, 24:131, 29:01:01:01- 29:18, 29:21-29:29, 29:31-29:33, 29:35- 29:45, 30:01:01-30:01:07, 30:08, 30:11:01-30:11:02, 30:14L-30:20, 30:23- 30:26, 30:30, 30:35-30:43, 30:48-30:49, 30:52-30:56, 30:58-30:60, 30:62-30:63, 30:65, 32:17, 34:09, 66:02, 66:12, 66:16, 68:01:01:01-68:02:05, 68:06-68:14, 68:16-68:19, 68:21:01-68:30, 68:32- 68:39, 68:41-68:71, 68:73-68:84, 68:86- 68:89, 68:91-68:92, 68:94N-68:96, 69:01, 74:13
29¹⁰	260 bp	800 bp	A3, A11, A26, A30, A68, A74	*03:09, 03:108, 11:06, 11:18, 26:03:01- 26:03:02, 26:06, 26:21, 26:30, 26:78, 29:19, 30:13, 30:16, 30:44, 30:46, 33:24, 68:05, 68:15, 68:20, 74:06
30¹²	180 bp	1070 bp	A25, A10, A26, A43, A66	*02:135, 25:01:01-25:05, 25:07-25:17, 25:19-25:22, 26:01:01-26:01:20, 26:01:22-26:03:02, 26:05-26:08, 26:10- 26:33, 26:35-26:43:02, 26:45-26:72, 26:74-26:77, 26:79-26:80, 32:26, 43:01, 66:01, 66:04-66:15, 66:17-66:19
31⁷	110 bp, 195 bp	1070 bp	A34	*34:01:01-34:02:03, 34:04-34:05, 34:07- 34:10N
32¹⁶	-	-	-	Negative control

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¹ Alleles are assigned by the presence of specific PCR product(s). However, the sizes of the specific PCR products may be helpful in the interpretation of HLA-A low resolution SSP typings.

When the primers in a primer mix can give rise to HLA-specific PCR products of more than one length this is indicated if the size difference is more than 20 base pairs. Size differences of 20 base pairs or less are not given. For high resolution SSP kits the respective lengths of the HLA-specific PCR product(s) are given for the alleles amplified by these primer mixes.

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.

² The internal positive control primer pairs amplify segments of the human growth hormone gene. The two different control primer pairs give rise to either an internal positive control band of 1070 base pairs, for most wells, or a band of 800 base pairs, for some wells.

Well number 1 contains the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to help in the correct orientation of the HLA-A low resolution typing.

In addition, wells number 2, 4 to 6, 8 to 10, 12, 19 to 23, 26 and 29 contain the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to allow kit identification.

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

³ The 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.

⁴ For several HLA Class I alleles 1st and/or 4th exon(s) and beyond, as well as intron nucleotide sequences, are not available. In these instances it is not known whether some of the primers of the SSP sets are completely matched with the target sequences or not. We assume that unknown sequences in these regions are conserved within allelic groups.

⁵ The A*23:14:01-23:14:02 and the A*24:05, 24:71 and 24:199 alleles will give rise to identical amplification patterns. These three alleles can be separated by the respective high resolution SSP primer sets.

⁶ Due to sharing of sequence motifs, primer mix 4 will amplify C*03:174 and C*08:69, primer mix 6 will amplify the B*18:27 allele, primer mix 9 will amplify B*07:81, B*08:52, B*18:67, B*38:41, B*53:05 and B*53:16 alleles.

⁷ HLA-specific PCR products shorter than 125 base pairs have a lower intensity and are less sharp than longer PCR products.

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

⁹ Primer mixes 15, 27 and 28 may give rise to a lower yield of HLA-specific PCR product than the other HLA-A low primer mixes.

¹⁰ Primer mixes 15 and 29 may have tendencies of unspecific amplifications.

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

¹² Primer mix 30 may generate a false positive band of about 500 base pairs. This band should be disregarded when interpreting HLA-A low resolution typings.

¹³ Primer mix 6 may give rise to a lower yield of A*23 alleles than the other A low primer mixes.

¹⁴ Primer mix 9 may faintly amplify A*34 alleles.

¹⁵ In 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, 23:51, 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, 24:191, 24:192 and 32:13.

¹⁶ Primer mix 32 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.

101.401.48/12 – including *Taq* pol., IFU-01
 101.401.48u/12u – without *Taq* pol., IFU-02

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

Lot No.: **71R**

Lot-specific information

Well No.		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
HLA-A allele⁴	ser⁵																
*01:01:01:01-01:01:22, 01:01:24-01:01:31, 01:01:33- 01:01:47, 01:01:49-01:02, 01:04N, 01:07, 01:09- 01:11N, 01:16N-01:18N, 01:22N-01:27N, 01:29, 01:31N-01:33, 01:35-01:42, 01:44-01:50, 01:52N, 01:54- 01:62, 01:64, 01:67-01:68, 01:70-01:72, 01:74-01:78, 01:80-01:83:01, 01:84-01:94, 01:96-01:97, 01:100-01:122	A1, Null, -				4												
*01:01:23, 01:01:48, 01:08, 01:30, 01:79, 01:99	A1, -	1															
*01:01:32, 01:69:01-01:69:02	-				4												
*01:03, 01:06, 01:20, 01:53N, 01:63, 01:65-01:66, 01:73, 01:98	A1, Null, -	1			4												
*01:12, 01:19	A1, -	1															
*01:13	-	1			4							11		13		15	
*01:14-01:15N	Null, -	1															
*01:21	-	1			4												
*01:28	-	1			4							11				15	
*01:43	-	1			4						10						
*01:51	-	1			4				8		10						
*01:83:02	-	1			w												
*01:95	-	1			4	5											
*02:01:01:01-02:01:15, 02:01:17-02:01:19, 02:01:21- 02:01:81, 02:01:83-02:16, 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, 02:136-02:155, 02:157- 02:168, 02:170-02:236, 02:238-02:242, 02:244- 02:308, 02:310-02:337, 02:339-02:392	A2, Low A2,, A203, A210, A2, 19, 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			
*02:35:02	A2													13			
*02:46, 02:70	A2		2														
Well No.		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16

101.401.48/12 – including *Taq* pol., IFU-01
 101.401.48u/12u – without *Taq* pol., IFU-02

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

Lot No.: **71R**

Lot-specific information

17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32		Well No.
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32		Well No.
																ser ⁵	HLA-A allele ⁴
									26							A1, Null, -	*01:01:01:01:01:01:22, 01:01:24-01:01:31, 01:01:33-01:01:47, 01:01:49-01:02, 01:04N, 01:07, 01:09-01:11N, 01:16N-01:18N, 01:22N-01:27N, 01:29, 01:31N-01:33, 01:35-01:42, 01:44-01:50, 01:52N, 01:54-01:62, 01:64, 01:67-01:68, 01:70-01:72, 01:74-01:78, 01:80-01:83:01, 01:84-01:94, 01:96-01:97, 01:100-01:122
									26							A1, -	*01:01:23, 01:01:48, 01:08, 01:30, 01:79, 01:99
									26							-	*01:01:32, 01:69:01-01:69:02
																A1, Null, -	*01:03, 01:06, 01:20, 01:53N, 01:63, 01:65-01:66, 01:73, 01:98
										27						A1, -	*01:12, 01:19
									26							-	*01:13
									26	27						Null, -	*01:14-01:15N
									26							-	*01:21
									26							-	*01:28
									26							-	*01:43
									26							-	*01:51
									26							-	*01:83:02
17									26							-	*01:95
																A2, Low A2,, A203, A210, A2, 19, Null, -	*02:01:01:01:02:01:15, 02:01:17-02:01:19, 02:01:21-02:01:81, 02:01:83-02:16, 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, 02:136-02:155, 02:157-02:168, 02:170-02:236, 02:238-02:242, 02:244-02:308, 02:310-02:337, 02:339-02:392
																A2	*02:17:01-02:17:02
			20		22						28					A2, -	*02:34-02:35:01, 02:35:03, 02:56:01-02:56:02, 02:62, 02:103
			20		22						28					A2	*02:35:02
			20		22											A2	*02:46, 02:70
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32		Well No.

Negative Control



101.401.48/12 – including *Taq* pol., IFU-01
 101.401.48u/12u – without *Taq* pol., IFU-02

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 “Instructions for Use” (IFU)

Lot No.: **71R**

Lot-specific information

Well No.		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
HLA-A allele ⁴	ser ⁵																
*02:48, 02:129	-																
*02:55	-		2						8								
*02:78	A2		w		4												
*02:135	-		2											13			
*02:156, 02:338	-		2														
*02:169	-		2		4												
*02:237	-		2												14		16
*02:243	-		2														
*02:309	-		2										12		14		
*03:01:01:01-03:01:05, 03:01:07-03:01:13, 03:01:15- 03:01:18, 03:01:20-03:01:22, 03:01:24-03:01:29, 03:01:31- 03:01:34, 03:01:36-03:04:03, 03:06-03:07, 03:11N, 03:13- 03:17:02, 03:19-03:23:02, 03:25-03:28, 03:31, 03:33, 03:35, 03:37-03:39, 03:44- 03:49, 03:51-03:53, 03:55- 03:56, 03:58, 03:60-03:61, 03:67-03:71, 03:73-03:74, 03:76-03:81, 03:83-03:87, 03:90-03:94, 03:96-03:97, 03:99-03:104, 03:106, 03:109- 03:110, 03:112-03:121, 03:123-03:126, 03:128- 03:134, 03:136-03:139, 03:141, 03:143-03:151, 03:154-03:161N	A3, Null, -				3									13			
*03:01:06, 03:01:14, 03:54, 03:64-03:66, 03:127, 03:140, 03:153	A3, -				3									13			
*03:01:19	-				3								12	13			
*03:01:23, 03:57, 03:59, 03:72, 03:111, 03:142	-				3												
*03:01:30, 03:01:35, 03:05:01-03:05:02, 03:10, 03:40, 03:42, 03:98, 03:105, 03:122	A3, -													13			
*03:08, 03:32, 03:36N, 03:89, 03:107	Null, -				3												
*03:09	-				3									13			
*03:12	-				3		4										
*03:18, 03:135	-				4									13			
*03:24	A3				3				8					13			
*03:29, 03:34, 03:62	-				3									13			
*03:30	-				3		5							13			
*03:41	-				3												
*03:43, 03:82	-				3									13		15	
Well No.		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16

101.401.48/12 – including *Taq* pol., IFU-01
 101.401.48u/12u – without *Taq* pol., IFU-02

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 “Instructions for Use” (IFU)

Lot No.: **71R**

Lot-specific information

17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Well No.
																ser ⁵
			20		22											HLA-A allele ⁴
				21		23										- *02:48, 02:129
			20		22						28					- *02:55
							24						30			A2 *02:78
										27						- *02:135
																- *02:156, 02:338
																- *02:169
																- *02:237
18				21												- *02:243
							24									- *02:309
											27	28				A3, - *03:01:01:01-03:01:05, Null, - 03:01:07-03:01:13, 03:01:15- 03:01:18, 03:01:20-03:01:22, 03:01:24-03:01:29, 03:01:31- 03:01:34, 03:01:36-03:04:03, 03:06-03:07, 03:11N, 03:13- 03:17:02, 03:19-03:23:02, 03:25-03:28, 03:31, 03:33, 03:35, 03:37-03:39, 03:44- 03:49, 03:51-03:53, 03:55- 03:56, 03:58, 03:60-03:61, 03:67-03:71, 03:73-03:74, 03:76-03:81, 03:83-03:87, 03:90-03:94, 03:96-03:97, 03:99-03:104, 03:106, 03:109 03:110, 03:112-03:121, 03:123-03:126, 03:128- 03:134, 03:136-03:139, 03:141, 03:143-03:151, 03:154-03:161N
												28				A3, - *03:01:06, 03:01:14, 03:54, 03:64-03:66, 03:127, 03:140, 03:153
							24				27	28				- *03:01:19
											27	28				- *03:01:23, 03:57, 03:59, 03:72, 03:111, 03:142
											27	28				A3, - *03:01:30, 03:01:35, 03:05:01-03:05:02, 03:10, 03:40, 03:42, 03:98, 03:105, 03:122
											27					Null, - *03:08, 03:32, 03:36N, 03:89, 03:107
											27	28	29			- *03:09
											27	28				- *03:12
									26		28					- *03:18, 03:135
											27	28				A3 *03:24
											27					- *03:29, 03:34, 03:62
											27	28				- *03:30
						23					27					- *03:41
17											27	28				- *03:43, 03:82
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Well No.

Negative Control

101.401.48/12 – including *Taq* pol., IFU-01
 101.401.48u/12u – without *Taq* pol., IFU-02

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

Lot No.: **71R**

Lot-specific information

Well No.		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
HLA-A allele ⁴	ser ⁵																
*03:50	-			3					8					13			
*03:63	-			3								11		13			
*03:75	-													13			
*03:88	-			3	4							11					
*03:95	-													13	14		16
*03:108	-			3													
*03:152	-			3		5											
*11:01:01-11:05, 11:07-11:09, 11:13-11:16, 11:19-11:24:02, 11:26-11:27, 11:29-11:30, 11:32-11:34, 11:36-11:39, 11:41-11:52Q, 11:54-11:59, 11:61-11:93, 11:95-11:111, 11:114-11:129, 11:131-11:132	A11, Null, -				4							11					
*11:06, 11:18	-				4							11					
*11:10	A11				4				8			11					
*11:11	-				4							11	12				
*11:12	A11				4							11					
*11:17, 11:40	-				4						10	11					
*11:25, 11:31, 11:35, 11:60	A11, -				4							11					
*11:94, 11:112	-				4							11					
*11:113	-				4							11				15	
*11:130	-			3	4							11					
*23:01:01-23:12, 23:15-23:55	A23, Null, -					5	6										
*23:13	-					5	6										
*23:14:01-23:14:02, 24:71 ⁷	A9, -					5	6	7									
*24:02:01:01-24:06, 24:08-24:11N, 24:13:01-24:13:02, 24:17, 24:20-24:23, 24:25-24:43, 24:45N-24:50, 24:54-24:56, 24:58-24:63, 24:66-24:70, 24:72-24:81, 24:83N-24:88, 24:90N-24:91, 24:93, 24:95-24:107, 24:109-24:111, 24:113, 24:115-24:128, 24:130, 24:132N-24:137, 24:139-24:187, 24:189-24:203, 24:205-24:210, 24:212, 24:214, 24:216-24:221	A24, Low A24, A240 3, A9, Null, -					5		7									
*24:07, 24:108, 24:112, 24:131	A24, -					5		7									
*24:14-24:15, 24:51-24:53, 24:57, 24:64, 24:94, 24:114, 24:138, 24:188, 24:222N	A24, Null, -					5											
Well No.		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16

101.401.48/12 – including *Taq* pol., IFU-01
 101.401.48u/12u – without *Taq* pol., IFU-02

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 “Instructions for Use” (IFU)

Lot No.: **71R**

Lot-specific information

17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32		Well No.
																ser ⁵	HLA-A allele ⁴
											28					-	*03:50
						23				27						-	*03:63
						23					28					-	*03:75
						23				27						-	*03:88
											28					-	*03:95
										27		29				-	*03:108
										27						-	*03:152
																A11, Null, -	*11:01:01-11:05, 11:07-11:09, 11:13-11:16, 11:19-11:24:02, 11:26-11:27, 11:29-11:30, 11:32-11:34, 11:36-11:39, 11:41-11:52Q, 11:54-11:59, 11:61-11:93, 11:95-11:111, 11:114-11:129, 11:131-11:132
												29				-	*11:06, 11:18
																A11	*11:10
									26							-	*11:11
											28					A11	*11:12
																-	*11:17, 11:40
										27						A11, -	*11:25, 11:31, 11:35, 11:60
									26							-	*11:94, 11:112
																-	*11:113
						23										-	*11:130
																A23, Null, -	*23:01:01-23:12, 23:15-23:55
											28					-	*23:13
																A9, -	*23:14:01-23:14:02, 24:71 ⁷
																A24, Low A24, A240 3, A9, Null, -	*24:02:01:01-24:06, 24:08-24:11N, 24:13:01-24:13:02, 24:17, 24:20-24:23, 24:25-24:43, 24:45N-24:50, 24:54-24:56, 24:58-24:63, 24:66-24:70, 24:72-24:81, 24:83N-24:88, 24:90N-24:91, 24:93, 24:95-24:107, 24:109-24:111, 24:113, 24:115-24:128, 24:130, 24:132N-24:137, 24:139-24:187, 24:189-24:203, 24:205-24:210, 24:212, 24:214, 24:216-24:221
											28					A24, -	*24:07, 24:108, 24:112, 24:131
																A24, Null, -	*24:14-24:15, 24:51-24:53, 24:57, 24:64, 24:94, 24:114, 24:138, 24:188, 24:222N
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32		Well No.

Negative Control

101.401.48/12 – including *Taq* pol., IFU-01
 101.401.48u/12u – without *Taq* pol., IFU-02

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 “Instructions for Use” (IFU)

Lot No.: 71R

Lot-specific information

Well No.		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
HLA-A allele ⁴	ser ⁵																
*24:18, 24:204, 24:213	A24, A3, -					5		7									
*24:19, 24:44	A9, -					5		7				11					
*24:24	-					5	6	7									
*24:82	-					5		7									
*24:89, 24:129	-							7									
*24:92	-					5											
*25:01:01-25:04, 25:07- 25:12N, 25:14-25:16, 25:19- 25:22	A25, Null, -								8	9				13			
*25:05	-								8	9			12	13			
*25:06	-								8	9			12				
*25:13	-								8	9				13			
*25:17	-									9				13			
*25:18	-								8	9				13			
*26:01:01-26:01:20, 26:01:22- 26:01:27, 26:08, 26:10-26:15, 26:17-26:18, 26:20, 26:23- 26:28, 26:31-26:33, 26:35- 26:43:02, 26:45-26:48, 26:50- 26:53, 26:55-26:63, 26:66- 26:71N, 26:74-26:77, 26:79- 26:80	A26, A10, Null, -								8		10			13			
*26:01:21, 26:04, 26:34, 26:73	A26, -								8		10						
*26:02, 26:29, 26:49	A26, -								8		10			w			
*26:03:01-26:03:02, 26:06, 26:21	A26, -								8			11		13			
*26:05	A26								8					13			
*26:07:01-26:07:02, 26:64	A26, -										10			13			
*26:09	A26								8		10		12				
*26:16	-							7			10			13			
*26:19	-				4						10			13	14		
*26:22	A26								8		10			13	14		
*26:30	-								8					13			
*26:54	-								8		10		12	13			
*26:65	-								8		10			13			
*26:72	-				4						10			13			
*26:78	-								8			11					
*29:01:01:01-29:06, 29:08N- 29:12, 29:15-29:18, 29:21- 29:27, 29:29, 29:31-29:33, 29:35-29:38, 29:40-29:45	A29, Null, -														14		
*29:07	-							6							14		
*29:13	-														14		
*29:14	-														14	16	
*29:19	-														14		
*29:20, 29:34	-														14		
*29:28	-								8						14		
Well No.		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16

101.401.48/12 – including *Taq* pol., IFU-01
 101.401.48u/12u – without *Taq* pol., IFU-02

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 “Instructions for Use” (IFU)

Lot No.: **71R**

Lot-specific information

17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32		Well No.
																ser ⁵	HLA-A allele ⁴
						23										A24, A3, - A9, -	*24:18, 24:204, 24:213 *24:19, 24:44
											28					-	*24:24
				21												-	*24:82
											27					-	*24:89, 24:129 *24:92
													30			A25, Null, -	*25:01:01-25:04, 25:07- 25:12N, 25:14-25:16, 25:19- 25:22
			20										30			-	*25:05
																-	*25:06
							24						30			-	*25:13
													30			-	*25:17
																-	*25:18
														30		A26, A10, Null, -	*26:01:01-26:01:20, 26:01:22 26:01:27, 26:08, 26:10-26:15, 26:17-26:18, 26:20, 26:23- 26:28, 26:31-26:33, 26:35- 26:43:02, 26:45-26:48, 26:50- 26:53, 26:55-26:63, 26:66- 26:71N, 26:74-26:77, 26:79- 26:80
														30		A26, -	*26:01:21, 26:04, 26:34, 26:73
														30		A26, -	*26:02, 26:29, 26:49
														29	30	A26, -	*26:03:01-26:03:02, 26:06, 26:21
						23										A26	*26:05
						23										A26, -	*26:07:01-26:07:02, 26:64
																A26	*26:09
																-	*26:16
																-	*26:19
				21												A26	*26:22
						23	24					29	30			-	*26:30
			20													-	*26:54
							24									-	*26:65
																-	*26:72
						23						29				-	*26:78
								25			28					A29, Null, -	*29:01:01:01-29:06, 29:08N- 29:12, 29:15-29:18, 29:21- 29:27, 29:29, 29:31-29:33, 29:35-29:38, 29:40-29:45
								25			28					-	*29:07
17								25			28					-	*29:13
								25			28					-	*29:14
		19						25				29				-	*29:19
								25								-	*29:20, 29:34
								25			28					-	*29:28
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32		Well No.

Negative Control

101.401.48/12 – including *Taq* pol., IFU-01
 101.401.48u/12u – without *Taq* pol., IFU-02

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

Lot No.: **71R**

Lot-specific information

Well No.		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
HLA-A allele ⁴	ser ⁵																
*29:30	-														14		
*29:39	-														14		
*30:01:01-30:01:07, 30:11:01-30:11:02, 30:14L-30:15, 30:19-30:20, 30:23-30:26, 30:30, 30:35-30:40, 30:42-30:43, 30:48-30:49, 30:52-30:54, 30:58-30:59N, 30:62-30:63, 30:65	A30, Null, -															15	
*30:02:01-30:03, 30:07, 30:10, 30:22, 30:27N-30:28, 30:32-30:34, 30:45, 30:47, 30:50-30:51, 30:61, 30:64, 30:66-30:70N	A30, Null, -															15	
*30:04:01-30:04:02, 30:06, 30:09, 30:29	A30, -															15	
*30:08	-				4											15	
*30:12, 30:31	-															15	
*30:13, 30:44	-															15	
*30:16	-															15	
*30:17	A30															15	
*30:18, 30:41, 30:60	A30, -															15	
*30:46	-															15	
*30:55	-													13		15	
*30:56	-						6									15	
*30:57	-														14	15	
*31:01:02-31:02, 31:05-31:07, 31:10-31:27, 31:30-31:34, 31:36-31:61, 31:63-31:70	A31, Null, -																16
*31:03	-												12				16
*31:04	A31												12				16
*31:08	-					5											16
*31:09, 31:28	-																16
*31:29	-						6										16
*31:35	-															15	16
*31:62	-																16
*32:01:01-32:01:13, 32:02, 32:06-32:12, 32:14, 32:16, 32:18-32:23, 32:25, 32:27-32:37, 32:39-32:48N, 32:50-32:55	A32, Null, -										9						
*32:01:14, 32:03, 32:38	-																
*32:04	-			3							9						
*32:05	-					5											16
*32:13	-					5					9						
*32:15	-								8		9						
*32:17	-										9						
*32:24, 32:49	-										9						
*32:26	-										9						
Well No.		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16

101.401.48/12 – including *Taq* pol., IFU-01
 101.401.48u/12u – without *Taq* pol., IFU-02

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

Lot No.: **71R**

Lot-specific information

17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	ser ⁵	Well No. HLA-A allele ⁴
																-	*29:30
17		19						25			28					-	*29:39
								25			28					A30, Null, -	*30:01:01-30:01:07, 30:11:01- 30:11:02, 30:14L-30:15, 30:19-30:20, 30:23-30:26, 30:30, 30:35-30:40, 30:42- 30:43, 30:48-30:49, 30:52- 30:54, 30:58-30:59N, 30:62- 30:63, 30:65
								25								A30, Null, -	*30:02:01-30:03, 30:07, 30:10, 30:22, 30:27N-30:28, 30:32-30:34, 30:45, 30:47, 30:50-30:51, 30:61, 30:64, 30:66-30:70N
								25		27						A30, -	*30:04:01-30:04:02, 30:06, 30:09, 30:29
								25			28					-	*30:08
								25				29				-	*30:12, 30:31
								25			28	29				-	*30:13, 30:44
								25		27	28					-	*30:16
								25			28					A30	*30:17
								25		27		29				A30, -	*30:18, 30:41, 30:60
								25			28					-	*30:46
								25			28					-	*30:55
								25			28					-	*30:56
								25								-	*30:57
								25								A31, Null, -	*31:01:02-31:02, 31:05- 31:07, 31:10-31:27, 31:30- 31:34, 31:36-31:61, 31:63- 31:70
								25		27						-	*31:03
							24	25		27						A31	*31:04
								25								-	*31:08
								25								-	*31:09, 31:28
								25								-	*31:29
17								25								-	*31:35
					22			25								-	*31:62
17								25								A32, Null, -	*32:01:01-32:01:13, 32:02, 32:06-32:12, 32:14, 32:16, 32:18-32:23, 32:25, 32:27- 32:37, 32:39-32:48N, 32:50- 32:55
17								25								-	*32:01:14, 32:03, 32:38
										27						-	*32:04
17								25								-	*32:05
17								25								-	*32:13
17								25								-	*32:15
17								25			28					-	*32:17
17																-	*32:24, 32:49
17								25					30			-	*32:26
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32		Well No.

Negative Control

101.401.48/12 – including *Taq* pol., IFU-01
 101.401.48u/12u – without *Taq* pol., IFU-02

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

Lot No.: 71R

Lot-specific information

Well No.		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
HLA-A allele ⁴	ser ⁵																
*33:01:01-33:01:07, 33:03:01-33:12, 33:14-33:18:02, 33:20-33:21, 33:23, 33:25-33:37, 33:39-33:47, 33:50, 33:52, 33:54-33:64	A33, A19, -																
*33:13, 33:48	-										10				14		
*33:19	-							7									
*33:22	-																
*33:24	-																
*33:49	-																
*33:51	-								8								
*33:53	-					5											16
*34:01:01-34:01:02, 34:05	A34, -								8			11	12				
*34:02:01-34:02:03, 34:04, 34:07, 34:10N	A34, Null, -								8			11	12				
*34:03	-								8			11	12				
*34:06	-								8			11	12				
*34:08	-								8			11	12	13			
*34:09	-								8				12				
*36:01, 36:03, 36:05	A36, -	1															
*36:02	-	1		3													
*36:04	A36	1			4												
*43:01	A43										10		12	13			
*66:01, 66:04-66:08, 66:11, 66:13-66:14, 66:17-66:19	A66, -								8			11		13			
*66:02, 66:16	A66, -								8				12				
*66:03	A10								8				12				
*66:09	-								8			11		13	14		
*66:10	-								8			11		w			
*66:12	-								8					13			
*66:15	-								8					13			
*68:01:01:01-68:02:05, 68:06-68:12, 68:13:02-68:14, 68:16-68:19, 68:21:01-68:28, 68:30, 68:32-68:39, 68:41-68:44, 68:46-68:65, 68:67-68:70, 68:73-68:83, 68:86-68:89, 68:91-68:92, 68:94N-68:96	A68, A28, Null, -								8								
*68:03:01-68:04, 68:31, 68:40, 68:72, 68:85, 68:90, 68:93	A68, -								8								
*68:05, 68:15, 68:20	A68, -								8								
*68:13:01, 68:66	-				4				8								
*68:29	-								8								
*68:45	-							7	8								
*68:71	-								8					13			
*68:84	-								8		10						
Well No.		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16

101.401.48/12 – including *Taq* pol., IFU-01
 101.401.48u/12u – without *Taq* pol., IFU-02

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 “Instructions for Use” (IFU)

Lot No.: **71R**

Lot-specific information

17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Well No.
																ser ⁵
																HLA-A allele ⁴
	18							25								A33, A19, - *33:01:01-33:01:07, 33:03:01 33:12, 33:14-33:18:02, 33:20 33:21, 33:23, 33:25-33:37, 33:39-33:47, 33:50, 33:52, 33:54-33:64
	18							25								- *33:13, 33:48
	18							25								- *33:19
	18			21				25								- *33:22
	18					23		25				29				- *33:24
	18							25		27						- *33:49
								25								- *33:51
	18							25								- *33:53
														31		A34, - *34:01:01-34:01:02, 34:05
										27				31		A34, Null, - *34:02:01-34:02:03, 34:04, 34:07, 34:10N
										27						- *34:03
										27						- *34:06
										27				31		- *34:08
							24			27	28			31		- *34:09
					22											A36, - *36:01, 36:03, 36:05
					22	23										- *36:02
					22			26								A36 *36:04
								26						30		A43 *43:01
														30		A66, - *66:01, 66:04-66:08, 66:11, 66:13-66:15, 66:17-66:19
							24			28						A66, - *66:02, 66:16
							24									A10 *66:03
				21										30		- *66:09
														30		- *66:10
							24			28				30		- *66:12
														30		- *66:15
			20								28					A68, A28, Null, - *68:01:01:01-68:02:05, 68:06 68:12, 68:13:02-68:14, 68:16 68:19, 68:21:01-68:28, 68:30, 68:32-68:39, 68:41-68:44, 68:46-68:65, 68:67-68:70, 68:73-68:83, 68:86-68:89, 68:91-68:92, 68:94N-68:96
			20													A68, - *68:03:01-68:04, 68:31, 68:40, 68:72, 68:85, 68:90, 68:93
			20			23						29				A68, - *68:05, 68:15, 68:20
			20								28					- *68:13:01, 68:66
	18		20	21							28					- *68:29
			20								28					- *68:45
			20								28					- *68:71
			20								28					- *68:84
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Well No.

Negative Control



101.401.48/12 – including *Taq* pol., IFU-01
 101.401.48u/12u – without *Taq* pol., IFU-02

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 “Instructions for Use” (IFU)

Lot No.: **71R**

Lot-specific information

Well No.		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
HLA-A allele ⁴	ser ⁵																
*69:01	A69								8								
*74:01-74:05, 74:08-74:12N, 74:14N-74:17	A74, Null, -																
*74:06	A74																
*74:07	A74																
*74:13	-													13			
*80:01:01:01-80:01:01:02	A80, -						6										
*80:02	-						6				11						
B*07:81, B*08:52, B*18:67, B*38:41, B*53:05, B*53:16	-									9							
B*18:27	-						6										
C*03:174, C*08:69	-				4												
Well No.		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16

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 SSP typing.

In addition, wells number 2, 4 to 6, 8 to 10, 12, 19 to 23, 26 and 29 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 A*01:01:38L.

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

The A*020120 allele has been shown to be identical to A*02:01:18.

The A*02:01:82 allele has been shown to be identical to A*02:01:84.

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 the 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 sequence of the A*24:211 allele has been shown to be identical to A*24:135:02.

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.

The sequence of the A*33:38 allele has been shown to be identical to A*33:44.

101.401.48/12 – including *Taq* pol., IFU-01
101.401.48u/12u – without *Taq* pol., IFU-02

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“Instructions for Use” (IFU)

Lot No.: **71R**

Lot-specific information

17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32		Well No.
																	ser ⁵
																	HLA-A allele ⁴
				21							28						A69
																	*69:01
		19						25									A74, -
																	*74:01-74:05, 74:08-74:12N, 74:14N-74:17
		19						25				29					A74
																	*74:06
17		19						25									A74
																	*74:07
		19						25			28						-
																	*74:13
						23											A80, -
																	*80:01:01:01-80:01:01:02
																	-
																	*80:02
																	-
																	<i>B*07:81, B*08:52, B*18:67, B*38:41, B*53:05, B*53:16</i>
																	-
																	<i>B*18:27</i>
																	-
																	<i>C*03:174, C*08:69</i>
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32		Well No.

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

⁷The A*23:14:01-23:14:02 and the A*24:71 alleles will give rise to identical amplification patterns. These alleles can be separated by the respective high resolution SSP primer sets.

⁸Primer mix 32 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.

101.401.48/12 – including *Taq* pol., IFU-01
 101.401.48u/12u – without *Taq* pol., IFU-02

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 “Instructions for Use” (IFU)

Lot No.: **71R**

Lot-specific information

CELL LINE VALIDATION SHEET																				
HLA-A low resolution primer set																				
				Well																
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	
				Lot No.:	201211701	201211702	201211703	201211704	201211705	201211706	201211707	201211708	201211709	201211710	201211711	201211712	201211713	201211714	201211715	201211716
	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	-	+	-	+	-	-	-	-	-	-	-	+	-	-	-	-	-

101.401.48/12 – including *Taq* pol., IFU-01
 101.401.48u/12u – without *Taq* pol., IFU-02

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 “Instructions for Use” (IFU)

Lot No.: **71R**

Lot-specific information

CELL LINE VALIDATION SHEET				Well															
HLA-A low resolution primer set																			
				Lot No.:	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
					201211717	201211718	201211719	201211720	201211721	201211722	201211723	201211724	201211725	201191826	201211727	201211728	201211729	201211730	201191831
	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 CTV3953540	*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	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

101.401.48/12 – including *Taq* pol., IFU-01
 101.401.48u/12u – without *Taq* pol., IFU-02

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Lot No.: **71R**

Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-A low resolution

Product number: 101.401-48/12 – including *Taq* polymerase
 101.401-48u/12u – without *Taq* polymerase
Lot number: 71R
Expiry date: 2015-October-01
Number of tests: 48 tests – Product No. 101.401-48/48u
 12 tests – Product No. 101.401-12/12u
Number of wells per test: 31 + 1

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2012-117-01	13	2012-117-13	25	2012-117-25
2	2012-117-02	14	2012-117-14	26	2011-918-26
3	2012-117-03	15	2012-117-15	27	2012-117-27
4	2012-117-04	16	2012-117-16	28	2012-117-28
5	2012-117-05	17	2012-117-17	29	2012-117-29
6	2012-117-06	18	2012-117-18	30	2012-117-30
7	2012-117-07	19	2012-117-19	31	2011-918-31
8	2012-117-08	20	2012-117-20		
9	2012-117-09	21	2012-117-21		
10	2012-117-10	22	2012-117-22		
11	2012-117-11	23	2012-117-23		
12	2012-117-12	24	2012-117-24		

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

Additional 5'- and 3'-primers in primer solutions 4, 5, 7, 8, 12, 14 to 17, 20 to 23 and 26 were tested by separately adding 3'-primers, respectively 5'-primers. One additional 5'-primer in primer solution 1 were tested by separately adding one 3'-primer. Additional 3'-primers in primer solutions 18, 19 and 27 were tested by separately adding one 5'-primer. One or two of the 5'-primers in primer solutions 2, 11, 12, 15 and 29 were not possible to test, and in primer solutions 3, 6, 8, 13, 16, 18 and 19 one 3'-primer was not possible to test.

The negative control primer pairs, **Production No. 2013-165-01**, can detect contamination with PCR products diluted 10^{-7} .

101.401.48/12 – including *Taq* pol., IFU-01
101.401.48u/12u – without *Taq* pol., IFU-02

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Lot No.: **71R**

Lot-specific information

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

Date of approval: 2013-July-17

Approved by:

Production Quality Control

101.401.48/12 – including *Taq* pol., IFU-01
101.401.48u/12u – without *Taq* pol., IFU-02

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Lot No.: **71R**

Lot-specific information

Declaration of Conformity

Product name: *Olerup* SSP® HLA-A low resolution
Product number: 101.401-48/48u, -12/12u
Lot number: 71R

Intended use: HLA-A low resolution 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 13485:2012, 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
2014-September-02

Daniel Malica
Head of QA and Regulatory Affairs

101.401.48/12 – including *Taq* pol., IFU-01
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Lot No.: **71R**

Lot-specific information

101.401.48/12 – including *Taq* pol., IFU-01
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Lot No.: **71R**

Lot-specific information

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