HLA-C low resolution Product Insert Page 1 of 28 101.601-24/12 – including *Taq* polymerase General "Instructions for Use"

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Lot No.: 89K Lot-specific information www.olerup-ssp.com

# Olerup SSP® HLA-C low resolution

Product number: 101.601-24/12 – including *Taq* pol.

Lot number: 89K

Expiry date: 2013-August-01

Number of tests: 24 tests – Product No. 101.601-24

12 tests - Product No. 101.601-12

Number of wells per test: 23 + 1

Storage - pre-aliquoted primers: dark at -20°C

PCR Master Mix: -20°C
 Adhesive PCR seals
 Product Insert
 RT

This Product Description is only valid for Lot No. 89K.

# CHANGES COMPARED TO THE PREVIOUS OLERUP SSP® HLA-C LOW RESOLUTION LOT

The HLA-C low resolution specificity and interpretation tables have been updated for the HLA-C alleles described since the previous *Olerup* SSP<sup>®</sup> HLA-C low resolution lot was made (Lot No. 60G).

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

Well	5'-primer	3'-primer	rationale
2	Added	Added	Primer pairs added for the C*01:43,
			C*02:43 and C*07:101 alleles.
3	Added	Added	Primers added for the C*02:33 allele,
			increased yield of specific PCR product.
4	Exchanged	-	Increased resolution.
6	-	Added	Primer added for the C*04:01:23 and
			C*07:125 alleles.
11	-	Added	Primer added for the C*02:02:12 allele.
12	-	Added	Exchanged positive control primer pair,
			primer added for the C*05:46 allele.
13	Added	-	Primer added for the C*04:01:23 allele.
15	-	Added	Primer added for the C*03:99 allele.
16	Removed	Removed	Increased resolution.
18	-	Added	Primers added for the C*04:52, C*04:55
			and C*16:22 alleles.

CE

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19	Added	Added,	Improved specificity, primer pair added
		removed	for the C*15:25 allele.
20	-	Added,	Improved specificity, primer added for
		modified	improved resolution of the C*06.31 allele.
23	Added	Added	Primer added for the C*06:44 and
			C*06:02:06 alleles.

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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 the amplicons generated by control primer pairs.

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	105	200	105	80	75	80
product						
5'-primer <sup>1</sup>	164	340	440	45	45	43
	<sup>5'</sup> -CAC <sup>3'</sup>	<sup>5'</sup> -Agg <sup>3'</sup>	<sup>5'</sup> -TTA <sup>3'</sup>	<sup>5'</sup> -Tgg <sup>3'</sup>	<sup>5'</sup> -Tgg <sup>3'</sup>	<sup>5'</sup> -Tgg <sup>3'</sup>
3'-primer <sup>2</sup>	231	2 <sup>nd</sup> I	507	59	58	57
	<sup>5'</sup> -TgC <sup>3'</sup>	<sup>5'</sup> -AAA <sup>3'</sup>	<sup>5'</sup> -TTg <sup>3'</sup>	<sup>5'</sup> -CTC <sup>3'</sup>	<sup>5'</sup> -ggC <sup>3'</sup>	<sup>5'</sup> -CTC <sup>3'</sup>
<b>A</b> *	+	+	+			
B*	+	+	+			
C*	+	+	+			
DRB1				+	+	
DRB3				+	+	
DRB5				+		
DQB1					+	
DPB1						+

<sup>&</sup>lt;sup>1</sup>The nucleotide position for HLA class I genes and the codon for HLA class II genes, in the 2<sup>nd</sup> or 3<sup>rd</sup> exon or the 2<sup>nd</sup> intron, matching the specificity-determining 3'-end of the primer is given. Nucleotide numbering as on the <a href="https://www.ebi.ac.uk/imgt/hla">www.ebi.ac.uk/imgt/hla</a> web site. The sequence of the 3 terminal nucleotides of the primer is given.

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<sup>&</sup>lt;sup>2</sup>The nucleotide position for HLA class I genes and the codon for HLA class II genes, in the 2<sup>nd</sup> or 3<sup>rd</sup> exon, matching the specificity-determining 3'-end of the primer is given in the anti-sense direction. Nucleotide numbering as on the <a href="https://www.ebi.ac.uk/imgt/hla">www.ebi.ac.uk/imgt/hla</a> web site. The sequence of the 3 terminal nucleotides of the primer is given.

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#### PRODUCT DESCRIPTION

### **HLA-C-low resolution SSP subtyping**

#### **CONTENT**

The primer set contains 5'- and 3'-primers for grouping the HLA-C\*01:02 to C\*18:04 alleles into the groups C\*01:xx to C\*18:xx.

#### PLATE LAYOUT

Each test consists of 24 PCR reactions in a 24 well cut 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-C low resolution primers.

Well 24 – Negative Control.

The 24 well cut PCR plate is marked with 'HLA-C low' in silver/gray ink.

Well No. 1 is marked with the Lot No. '89K'.

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 sealed. Use a scalpel or a similar instrument to carefully cut the foil between the plates.

#### INTERPRETATION

Only HLA-C alleles will be amplified by the HLA-C low resolution typing kit, except that primer mix 1 will amplify the B\*54:18 allele, primer mix 13 will amplify the B\*67:02 allele, primer mix 20 will amplify the B\*14:03 allele and primer mix 23 will amplify the A\*24:106 and B\*46:25 alleles. Thus, the interpretation of HLA-C low resolution typings is only influenced by these five alleles and not by other HLA class I genes.

#### **UNIQUELY IDENTIFIED ALLELES**

All the HLA-C alleles, i.e. **C\*01:02 to C\*18:04**, recognized by the HLA Nomenclature Committee in October 2010<sup>1</sup> will be amplified by the primers in the HLA-C low resolution SSP kit. The HLA-C alleles will be grouped into the C\*01xx to C\*18xx groups.

<sup>1</sup>HLA-C alleles listed on the IMGT/HLA web page 2010-October-15, release 3.2.0, www.ebi.ac.uk/imgt/hla.

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## **SPECIFICITY TABLE**

# **HLA-C low resolution SSP typing**

Specificities and sizes of the PCR products of the 24 primer mixes used for HLA-C low resolution SSP typing

Primer Mix	Size of spec. PCR product <sup>1</sup>	Size of control band <sup>2</sup>	Amplified HLA class I alleles <sup>3,4</sup>
1	155 bp	800 bp	*01:02:01-01:45, <b>B*54:18</b>
<b>2</b> <sup>5</sup>	130 bp, 200 bp, 270 bp, 300 bp	800 bp	*01:10, 01:43, 02:02:01-02:02:03, 02:02:05-02:40, 02:42-02:46, 04:32, 04:77, 06:08, 07:101, 07:148, 08:31, 14:25, 15:42, 16:29, 17:01:01:01-17:06, 17:08, 18:03
<b>3</b> <sup>13</sup>	280 bp	800 bp	*02:02:01-02:02:03, 02:02:05-02:03, 02:04 <sup>w</sup> , 02:05-02:13, 02:14 <sup>w</sup> , 02:15-02:25Q, 02:26:02-02:40, 02:42-02:46, 03:02:01-03:02:06, 03:04:01:01-03:10, 03:14-03:17, 03:19, 03:23-03:29, 03:32-03:38:02, 03:40-03:42, 03:44-03:48, 03:51, 03:54, 03:57, 03:60, 03:63-03:65, 03:70-03:74, 03:77-03:78, 03:80, 03:82, 03:84, 03:87, 03:89-03:95, 03:98, 03:100-03:101, 04:03, 04:06, 04:16, 04:80, 06:03, 07:96, 15:02:01-15:09, 15:10:02-15:11, 15:13, 15:15-15:22, 15:24-15:35, 15:37-15:45
<b>4</b> <sup>6</sup>	170 bp, 275 bp	1070 bp	*03:02:01-03:04:06, 03:04:08-03:15, 03:17-03:40, 03:42-03:57, 03:59-03:79, 03:81-03:85, 03:87-03:93, 03:95-03:98, 03:100-03:102
5	280 bp	800 bp	*03:03:01-03:03:13, 03:11:01-03:13, 03:20N-03:22Q, 03:30-03:31, 03:43:01-03:43:02, 03:49-03:50, 03:52-03:53, 03:55-03:56, 03:58-03:59, 03:61-03:62, 03:66, 03:67 <sup>w</sup> , 03:68-03:69, 03:75-03:76, 03:79, 03:81, 03:83, 03:85-03:86, 03:88, 03:96-03:97, 03:102, 15:12
<b>6</b> <sup>12</sup>	130 bp, 335 bp	800 bp	*02:02:01-02:02:03, 02:02:05-02:02:12, 02:02:14-02:20, 02:22-02:25Q, 02:27:01-02:38N, 02:40, 02:42-02:44, 02:46, 04:01:01-04:01:26, 04:03-04:15:02, 04:17-04:20, 04:23-04:41, 04:43-04:81, 05:26, 07:02:09, 07:125, 15:11, 15:36
7	390 bp	1070 bp	*05:01:01:01-05:01:15, 05:03-05:51Q, 08:10
8 <sup>11</sup>	130 bp, 355 bp	800 bp	*02:06, 06:02:01:01-06:02:01:02, 06:02:03-06:16N, 06:18-06:31, 06:33-06:55, 12:03:09, 12:15, 15:02:01-15:03, 15:07-15:08, 15:10:01-15:13, 15:15-15:18, 15:21, 15:26, 15:28, 15:31-15:35, 15:37-15:39, 15:41-15:45

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<b>9</b> <sup>7</sup>	245 bp, 425 bp	800 bp	*07:01:01-07:33N, 07:35-0	07:160
108,10,13	115 bp, 165 bp, 265 bp, 390 bp	800 bp	*01:43, 07:101, 07:148, 08	3:01:01-08:44
11	340 bp	1070 bp	*01:14, 02:02:01-02:02:03 02:26:02, 02:28-02:40, 02 03:45, 04:01:01:01-04:01: 04:20, 04:23-04:28, 04:30 04:56-04:81, 05:01:01:01-06:02:01:01-06:02:01:02, 06:51, 06:53-06:55, 07:07 08:10, 12:04:01-12:05, 12 14:04, 14:12, 15:02:01-15 15:15-15:20, 15:22-15:24, 15:45, 16:02:01-16:02:05, 16:25, 17:01:01:01-17:08,	:42-02:46, 03:07, 03:15, 26, 04:03-04:10, 04:12-04:35, 04:37-04:54, 05:01:15, 05:03-05:51Q, 06:02:03-06:10, 06:12-07:09, 07:49, 07:76, 109, 12:21, 12:33, 12:41, 15:26-15:42, 15:44-16:09, 16:12, 16:19,
12 <sup>10,11</sup>	100 bp, 160 bp, 220 bp	800 bp	*01:04, 01:21, 05:42, 05:4 08:21, 12:02:01-12:03:01: 12:03:09-12:03:14, 12:04: 12:13, 12:14:02-12:25, 12 16:15:02, 17:05	6, 07:101, 07:148, 08:05, 02, 12:03:03-12:03:07, 02-12:08, 12:10:01-
13 <sup>9,12,13</sup>	120 bp, 250 bp	800 bp	*01:21, 02:12, 04:01:01:01:01:01:01:01:01:01:01:01:01:01:	23-04:35, 04:37-04:54, , 07:02:09, 07:125, 2:01-12:03:03, 12:03:05- 14, 12:04:02, 12:06- :22-12:32, 12:34-12:48, 5, 16:01:01-16:02:05,
14 <sup>14</sup>	160 bp, 220 bp	800 bp	*01:04, 01:09, 02:05, 02:1 06:02:01:02, 06:02:03-06: 06:34, 06:36-06:39, 06:41 12:03:01:01-12:07, 12:11-12:23, 12:25-12:26, 12:28 12:37-12:39N, 12:42Q-12: 14:16, 16:04:01, 16:29	03, 06:07-06:13, 06:15- -06:55, 07:125, 12:13, 12:15, 12:19, -12:29, 12:31-12:35,
15 <sup>13</sup>	130 bp, 255 bp, 555 bp	1070 bp	*02:02:01 <sup>w</sup> , 02:02:02-02:0 02:15-02:26:02, 02:28-02: 03:10, 03:15, 03:29, 03:45 03:99, 04:03, 04:06, 04:16 05:01:01:01-05:01:15, 05: 05:44-05:51Q, 06:03, 08:1 12:09, 12:21, 12:33, 12:41 15:08-15:13, 15:15-15:22, 15:37-15:42, 15:44-15:45,	40, 02:42-02:46, 03:07, 5, 03:58, 03:86, 03:94, 6, 04:37, 04:80, 03-05:19, 05:21-05:42, 10, 12:04:01-12:05, 1, 15:02:01-15:06:03, 15:24, 15:26-15:35,

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			16:09, 16:12, 16:18-16:19, 16:25, 17:01:01:01- 17:08
16 <sup>12,13</sup>	255 bp	1070 bp	*04:11, 04:29, 04:36, 04:55, 07:64, 14:02:01-14:11, 14:13-14:25
<b>17</b> <sup>9,10,13</sup>	110 bp, 325 bp	1070 bp	*02:06, 03:81, 05:36, 07:123, 12:08, 12:15, 15:02:01-15:13, 15:15-15:24, 15:26-15:45, 16:20
18 <sup>12</sup>	180 bp, 210 bp, 240 bp	1070 bp	*02:13, 02:18, 02:33, 04:01:01-04:01:22, 04:01:24-04:01:26, 04:03-04:10, 04:12-04:20, 04:23-04:32, 04:34-04:81, 05:17, 05:25, 05:42, 06:05, 06:31, 07:02:09, 07:31, 08:01:01-08:01:03, 08:03:01-08:03:02, 08:06, 08:08-08:11, 08:14, 08:16, 08:20-08:22, 08:24, 08:26N, 08:28, 08:36N, 08:38, 08:40-08:42, 08:44, 12:14:01-12:14:02, 12:28, 14:10, 14:15, 15:12, 15:25, 16:01:01-16:02:05, 16:04:01, 16:06-16:32
19 <sup>11,15</sup>	225 bp, 250 bp	800 bp	*04:58, 05:23, 08:07, 12:14:01-12:14:02, 14:17, 15:25, 17:01:01:01-17:08
20	215 bp, 425 bp	800 bp	*01:02:01-01:03, 01:06-01:08, 01:10-01:20, 01:23-01:34, 01:37N-01:45, 03:58, 03:86, 03:94, 03:99, 04:37, 05:16, 06:05-06:06, 06:17, 06:31, 07:07, 07:09, 07:49, 07:76, 08:12, 12:09, 12:24, 14:02:01-14:05, 14:07N, 14:10-14:14, 14:17-14:25, 16:04:01, 16:29, 18:01-18:04, <b>B*14:03</b>
21	325 bp, 380 bp	1070 bp	*01:03, 01:24, 01:34, 02:22, 03:03:01-03:04:19, 03:06-03:12, 03:14, 03:18-03:24, 03:26, 03:28-03:32, 03:34, 03:37-03:59, 03:61-03:70, 03:72-03:83, 03:85, 03:87-03:88, 03:90-03:93, 03:96, 03:98, 03:100-03:102, 04:01:01-04:01:15, 04:01:17-04:01:26, 04:03-04:20, 04:24-04:53, 04:55-04:71, 04:73-04:81, 05:01:01:01-05:01:15, 05:03, 05:05-05:21, 05:23-05:51Q, 06:09, 06:14, 06:35, 07:10, 07:28, 07:41, 07:43, 08:01:01-08:08, 08:10, 08:12-08:44, 12:31, 12:44, 15:02:01-15:13, 15:15-15:21, 15:23-15:36, 15:38-15:45, 17:01:01:01-17:08, 18:01-18:04
<b>22</b> <sup>12</sup>	135 bp	1070 bp	*03:02:01-03:17, 03:19-03:38:02, 03:40-03:66, 03:67 <sup>w</sup> , 03:68-03:98, 03:100-03:102, 04:32, 04:77, 06:03, 07:96, 14:25, 15:43, 18:03
23	160 bp, 235 bp	1070 bp	*04:42, 06:02:01:01-06:02:01:02, 06:02:03-06:02:11, 06:04-06:55, 07:01:01-07:02:07, 07:02:09-07:25, 07:27:01-07:32N, 07:35-07:38, 07:41-07:63, 07:65-07:91, 07:93-07:95, 07:97-07:138, 07:140-07:151, 07:153-07:155, 07:157-07:160, 12:16, 16:01:01-16:02:05, 16:06-16:28, 16:30N-16:32, 18:01-18:04, <b>A*24:106, B*46:25</b>
24 <sup>16</sup>	-	-	Negative Control
			<b>G</b>

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<sup>1</sup>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-C low resolution SSP typings.

When the primers in a primer mix can give rise to specific PCR products of more than one

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 inherit 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.

<sup>2</sup>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-C low resolution typing.

In addition, wells number 2, 3, 5, 6, 8, 9, 10, 12, 13, 14, 19 and 20 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.

<sup>3</sup>For several HLA-C alleles only partial 1<sup>st</sup> and 4<sup>th</sup> exon and 1<sup>st</sup>, 2<sup>nd</sup> and 3<sup>rd</sup> intron nucleotide sequences are available. In these instances it is not known whether some of the primers of the HLA-C low resolution SSP sets are completely matched with the target sequences or not. We assume that unknown sequences are conserved within allelic groups.

<sup>4</sup>Due to sharing of sequence motifs primer mix 1 will amplify the B\*54:18 allele, primer mix 13 will amplify the B\*67:02 allele, primer mix 20 will amplify the B\*14:03 allele and primer mix 23 will amplify the A\*24:106 and B\*46:25 alleles.

<sup>5</sup>Primer mix 2 will for most C\*02 alleles give rise to two specific PCR fragments.

<sup>6</sup>Primer mix 4 will for most C\*03 alleles give rise to two specific PCR fragments.

<sup>7</sup>Primer mix 9 will for most C\*07 alleles give rise to two specific PCR fragments.

<sup>8</sup>Primer mix 10 will for most C\*08 alleles give rise to multiple specific PCR fragments.

<sup>9</sup>Primer mix 17 will for most C\*15 alleles give rise to two specific PCR fragments.

<sup>10</sup>Specific PCR fragments shorter than 125 base pairs have a lower intensity and are less sharp than longer PCR bands.

<sup>11</sup>Primer mixes 8, 12 and 19 may give rise to unspecific amplification.

<sup>12</sup>Primer mixes 6, 13, 16, 18 and 22 have a tendency of giving rise to primer oligomer artifacts.

<sup>13</sup>Primer mixes 3, 10, 13, 15, 16 and 17 yield somewhat less intense specific PCR fragments than the other HLA-C low resolution primer mixes.

<sup>14</sup>Primer mix 14 might faintly amplify most C\*01 and the C\*14 alleles.

<sup>15</sup>Primer mix 19 might generate a false band of about 500 base pairs. This band should be disregarded when interpreting HLA-C low resolution typings.

<sup>16</sup>Primer 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.

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	INTERP											
	HLA-C low											
Amplif	ication patterr	ns of t	the C	*01:02	2 to C			les				
							ell <sup>5</sup>		ı			
	1	2	3	4	5	6	7	8	9	10	11	12
Length of spec.	155	130	280	170	280	130	390	130	245	115	340	100
PCR product(s)		200 270		275		335		355	425	165 265		160 220
		300								390		220
Length of int.	800	800	800	1070	800	800	1070	800	800	800	1070	800
pos. control <sup>1</sup>		000	000	1070	000	000	10.0	000	000	000	10.0	000
5'-primer(s) <sup>2</sup>	89	47	105	355	105	47	1 <sup>st</sup> I	28	47	1 <sup>st</sup> I	1 <sup>st</sup> I	176
5 -primer(s)					%							
	5g AA 3.	<sup>5′</sup> -Agg ³′	-gCT ³	-TCA ³'	-9СТ	-Agg ³'	-CgA 3.	-TCA 3.	-Agg ³′	5' -CgA 3'	5' -CgA 3'	<sup>5'</sup> -gСА <sup>3'</sup>
	منا		, 0	ŗ,	2.	52	in	ĵ,	52		ic	
		89 **		459		112		2 <sup>nd</sup> I	648	176		361
		-gAA ³		-gAT ³′		° cc⊤		° -ccA ³	5' -CAC 3'	-gCA ³		<sup>5'</sup> -АgТ <sup>3'</sup>
		5		26		ŗ,		٠.	20	ΐο		
		2 <sup>nd</sup> I				118				527		419
		-CCA 3.				-ccA ³				5' -TAC 3'		5' -gTC 3'
		Ÿ				Ÿ				۶۲.		
		703										
		-CTA ³′										
		5-										
o. · / \3	201	176	343	589	343	201	302	213	302	175	302	289
3'-primer(s) <sup>3</sup>		'n								že.		
	·cTc ³	-ACT	ို	⁵ -СТТ ³′	-L 3,	-CTT 3.	-ggT ³'	-Cgg <sub>3.</sub>	-ggC <sup>3,</sup>	ရိဘ္ -	-ggT ³'	5 -AgC 3
	ñ	ù	O	ož.	2.	io.	io I	io.	is oi	ù	ù	
	201	559	343			218		420	853	302	304	289
	CTT 3	CTC 3.	G			gCT ³		gCT ³	CAT 3'	-ggC 3.	-CAA 3.	-AgC 3"
	۶.	.s	io			r, O		ر. ق	2.		i <sub>o</sub>	is -
		861								601		474
		-TCg ³'								·CTT ³'		5' -gCA 3'
		۶۲								ှ		 ģ
												477
												5' -gCA 3'
												gC
												538
												.ε <b>Δ</b>
												5' -gCA 3'
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Well No.	1	2	3	4	5	6	7	8	9	10	11	12

	Lot	No.: ₹	<u> </u>			18.15				<u>iforma</u>		
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				Am			patte	rns o	f the	C*01:	02 to	C*18:04 alleles
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13	14	15	16 255	17	18	19 225	20 215	21 325	22 135	23	24	Langth of an a
120 250	160 220	130 255	255	110 325	180 210	<b>225 250</b>	425	380	135	160 235		Length of spec. PCR product(s)
230	220	555		323	240	230	423	300		233		PCK product(s)
		000										
800	800	1070	1070	1070	1070	800	800	1070	1070	1070		Length of int.
												pos. control <sup>1</sup>
201	97	98	98	201	201	2 <sup>nd</sup> I	47	355	105	97		5'-primer(s) <sup>2</sup>
۶ -ccA ³	-TCg 3'	-CTA 3.	-CTC ³′	-ccA 3.	-ccA 3'	-CCA 3	-Agg ³'	-TCA 3"	-gCT ³	<sup>5′</sup> -TCg <sup>3′</sup>		
ن ن	Ļ.	is O	is is	ن	ن ن	ن ن	۶ ک	<sub>-5</sub>	, D	- ·s		
218	361	368		409	2 <sup>nd</sup> I		361	412	459	97		
۶ -ggA ³′	-AgT ³'	-gTg ³'		-ggC 3.	-ccA ³′		-AgT ³'	5 -ATA 3'	-gAT ³'	-TTg ³'		
	رة -	in in		ر. -	io.		رة 4-	5A	r, G	ù		
2 <sup>nd</sup> I					361					418		
° -ccA ³					-AgT ³'					<sup>5'</sup> -Agg <sup>3'</sup>		
٠,					2/							
										419		
										-gTC ³	<u></u>	
										is	ont	
289	218	312	311	270	341	512	302	3 <sup>rd</sup> I	201	213	Negative Control	3'-primer(s) <sup>3</sup>
ာ့	 H	. <sub></sub>	-ggT ³'	. <sub>.</sub> 6	<u> </u>	, <sub>e</sub> ¥	. <sub>.</sub> –	့်	-cTC ³	 6	ativ	. , ,
۶' -AgC ³'	°-gCT	5' -AgT 3'	-96	۶ -TAg	° -cgT	e -ccA	5' -ggT	5' -CTC 3'	်ု	<sup>5'</sup> -Cgg <sup>3'</sup>	leg	
289	538	361		3 <sup>rd</sup> I	343	538	527		559	289	_	
AgC 3'	CCA 3.	CCA 3.		CTC 3′	. <b>.</b> -	-gTC ³′	CCg 3.		CTC ³′	-AgC ³′		
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539	538	459			343		538			289		
5' -ТСТ 3'	-gCA ³'	-AgA ³'			ران ب		-CCg 3.			-AgC ³′		
Ļ5	ŗ. Ď	¥			į,		ن			.sA		
					527					539		
					-ccg 3.					-TCT ³'		
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					5' -CCA 3'							
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*01:04	1											12
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B*54:18	1											
*01:09	1											
*01:10	1	2										
*01:14	1										11	
*01:21	1											12
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07:149-07:151, 07:153-07:155,												
07:157-07:160												
*07:02:08, 07:26, 07:33N, 07:39-												
07:40, 07:92, 07:139, 07:152N,									9			
07:156												
*07:02:09						6			9			
*07:07, 07:09, 07:49, 07:76									9		11	
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
		_										

February 2011 Rev. No.: 00 For In Vitro Diagnostic Use.

HLA-C low resolution Product Insert 101.601-24/12 – including *Taq* polymerase

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IFU-01 Rev. No. 02 can be downloaded from

	Lo	t No.:	89K				Lot-sp	ecific	inform	nation		www.olerup-ssp.com
13	14	15	16	17	18	19	20	21	22	23	24	Well No.
												HLA-C allele⁴
												*05:01:01:01-05:01:15, 05:03,
												05:05-05:15, 05:18-05:19, 05:21,
		15						21				05:24, 05:27-05:35, 05:37-05:41,
												05:44-05:45, 05:47-05:51Q
		15										*05:04, 05:22
		15					20	21				*05:16
		15			18			21				*05:17, 05:25
								21				*05:20, 05:43
		15				19		21				*05:23
		15				10		21				*05:26
		15		17				21				*05:36
13		15		17	18			21				*05:42
13		15			10			21				*05:46
13		13						21				*06:02:01:01-06:02:01:02,
												06:02:03-06:02:11, 06:07, 06:10,
	14									23		06:12-06:13, 06:15-06:16N, 06:18-
	14									23		06:30, 06:33-06:34, 06:36-06:39,
												06:41-06:51, 06:53-06:55
	14	15							22			*06:03
	14	10							22	23	_	*06:04, 06:40
					18		20			23	Negative Control	•
					10		20			23	Ö	*06:05
	14						20			23	e e	*06:06 *06:08
	14							21		23	aţį	*06:09
	14							21		23	eg	
	14							21		23	Z	*06:11, 06:52 *06:14, 06:35
	4.4						20	21				•
	14 14				10		20			23		*06:17
	14				18		20			23 23		*06:31
	14									23		*06:32
												*07:01:01-07:02:07, 07:02:10-
												07:06, 07:08, 07:11-07:25,
												07:27:01-07:27:02, 07:29-07:30,
												07:32N, 07:35-07:38, 07:42, 07:44-
										23		07:48, 07:50-07:63, 07:65-07:75,
												07:77-07:91, 07:93-07:95, 07:97-
												07:100, 07:102-07:122, 07:124,
												07:126-07:138, 07:140-07:147,
												07:149-07:151, 07:153-07:155,
												07:157-07:160
												*07:02:08, 07:26, 07:33N, 07:39-
												07:40, 07:92, 07:139, 07:152N,
												07:156
13					18					23		*07:02:09
	_		_			_	20			23		*07:07, 07:09, 07:49, 07:76
13	14	15	16	17	18	19	20	21	22	23	24	Well No.

CE

February 2011 Rev. No.: 00 HLA-C low resolution Product Insert 101.601-24/12 – including *Taq* polymerase

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IFU-01 Rev. No. 02 can be downloaded from

Lot No.: **89K** 

February 2011 Rev. No.: 00 Lot-specific information

www.olerup-ssp.com

					ı							
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
HLA-C allele <sup>4</sup>												
*07:10, 07:28, 07:41, 07:43									9			
*07:31									9			
*07:64									9			
*07:96			3						9			
*07:101, 07:148		2							9	10		12
*07:123									9			
*07:125						6			9			
*08:01:01-08:01:03, 08:03:01- 08:03:02, 08:06, 08:08, 08:14, 08:16, 08:20, 08:22, 08:24, 08:26N, 08:28, 08:36N, 08:38, 08:40-08:42, 08:44										10		
*08:02:01-08:02:05, 08:04, 08:13, 08:15, 08:17-08:19, 08:23, 08:27, 08:29-08:30, 08:32-08:35, 08:37, 08:39, 08:43										10		
*08:05										10		12
*08:07										10		
*08:09, 08:11										10		
*08:10							7			10	11	
*08:12										10		
*08:21										10		12
*08:25										10		
*08:31		2								10		
*12:02:01-12:02:06, 12:10:01- 12:10:02, 12:17-12:18, 12:20, 12:22, 12:27, 12:30, 12:36, 12:40												12
*12:03:01:01-12:03:01:02, 12:03:03, 12:03:05-12:03:07, 12:03:10-12:03:14, 12:06-12:07, 12:11-12:13, 12:19, 12:23, 12:25, 12:29, 12:32, 12:34-12:35, 12:37-												12
12:39N, 12:42Q-12:43, 12:45- 12:48, 12:50 *12:03:02, 12:03:08, 12:26												
*12:03:04												12
*12:03:09								8				12
*12:03:09								0			11	12
*12:04:01, 12:33											11	12
*12:04:02											11	12
											11	12
*12:08 *12:09											11	12
*12:14:01											11	
	4	2	2	А		6	7	0	0	40	44	40
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

**(E** 

Lot No.: 89K Lot-specific information www.olerup-ssp.com

												<u> </u>
13	14	15	16	17	18	19	20	21	22	23	24	Well No.
												HLA-C allele <sup>4</sup>
								21		23		*07:10, 07:28, 07:41, 07:43
					18					23		*07:31
			16									*07:64
									22			*07:96
										23		*07:101, 07:148
				17						23		*07:123
13	14									23		*07:125
												*08:01:01-08:01:03, 08:03:01-
												08:03:02, 08:06, 08:08, 08:14,
					18			21				08:16, 08:20, 08:22, 08:24,
												08:26N, 08:28, 08:36N, 08:38,
												08:40-08:42, 08:44
												*08:02:01-08:02:05, 08:04, 08:13,
								21				08:15, 08:17-08:19, 08:23, 08:27,
												08:29-08:30, 08:32-08:35, 08:37,
												08:39, 08:43
13								21				*08:05
						19		21				*08:07
		4.5			18						<u>0</u>	*08:09, 08:11
		15			18			21			할	*08:10
40					40		20	21			Negative Control	*08:12
13					18			21			<u>8</u>	*08:21
13								21			gat	*08:25
								21			Š	*42-02-04 42-02-05 42-42-04
42												*12:02:01-12:02:06, 12:10:01-
13												12:10:02, 12:17-12:18, 12:20, 12:22, 12:27, 12:30, 12:36, 12:40
												*12:03:01:01-12:03:01:02,
												12:03:03, 12:03:05-12:03:07,
												12:03:10-12:03:14, 12:06-12:07,
13	14											12:11-12:13, 12:19, 12:23, 12:25,
13	14											12:29, 12:32, 12:34-12:35, 12:37-
												12:39N, 12:42Q-12:43, 12:45-
												12:48, 12:50
13	14											*12:03:02, 12:03:08, 12:26
13	14											*12:03:04
	14											*12:03:09
	14	15										*12:04:01, 12:33
13	14	15										*12:04:02
	14	15										*12:05
13				17								*12:08
		15					20					*12:09
13					18	19						*12:14:01
13	14	15	16	17	18	19	20	21	22	23	24	Well No.
			. •									1.0.1101

**(E** 

LOT NO.: 0310					mation	<u> </u>				ssp.cc		
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
HLA-C allele <sup>4</sup>												
*12:14:02												12
*12:15								8				12
*12:16												12
*12:21											11	12
*12:24												12
*12:28												12
*12:31												12
*12:41											11	12
*12:44												12
*12:49												12
*14:02:01-14:03, 14:05, 14:07N,												
14:11, 14:13-14:14, 14:18-14:24												
*14:04											11	
*14:06, 14:08-14:09												
*14:10												
*14:12											11	
*14:15												
*14:16												
*14:17												
*14:25		2										
*15:02:01-15:02:07, 15:08,												
15:10:02, 15:13, 15:15, 15:17-			2								44	
15:18, 15:26, 15:28, 15:31-15:35,			3					8			11	
15:38-15:39, 15:41, 15:44-15:45												
*15:03, 15:16			3					8			11	
*15:04-15:06:03, 15:09, 15:19-												
15:20, 15:24, 15:27, 15:29-15:30,			3								11	
15:40												
*15:07			3					8				
*15:10:01								8			11	
*15:11			3			6		8			11	
*15:12					5			8			11	
*15:21			3					8				
*15:22			3								11	
*15:23											11	
*15:25			3									
*15:36						6					11	
*15:37			3					8			11	
*15:42		2	3					8			11	
*15:43			3					8				
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	Well No.
												HLA-C allele <sup>4</sup>
13					18	19						*12:14:02
13	14			17								*12:15
13										23		*12:16
		15										*12:21
13							20					*12:24
13	14				18							*12:28
13	14							21				*12:31
13		15										*12:41
13								21				*12:44
												*12:49
			16				20					*14:02:01-14:03, 14:05, 14:07N,
			10				20					14:11, 14:13-14:14, 14:18-14:24
			16				20					*14:04
			16									*14:06, 14:08-14:09
			16		18		20					*14:10
							20					*14:12
			16		18							*14:15
	14		16								2	*14:16
			16			19	20				ont	*14:17
			16				20		22		Negative Control	*14:25
											<u>i</u>	*15:02:01-15:02:07, 15:08,
		15		17				21			ga	15:10:02, 15:13, 15:15, 15:17-
		13		''				~ '			Š	15:18, 15:26, 15:28, 15:31-15:35,
												15:38-15:39, 15:41, 15:44-15:45
13		15		17				21				*15:03, 15:16
												*15:04-15:06:03, 15:09, 15:19-
		15		17				21				15:20, 15:24, 15:27, 15:29-15:30,
												15:40
				17				21				*15:07
		15		17				21				*15:10:01
		15		17				21				*15:11
		15		17	18			21				*15:12
		15		17				21				*15:21
		15		17								*15:22
				17				21				*15:23
13					18	19		21				*15:25
				17				21				*15:36
		15		17								*15:37
		15		17				21				*15:42
				17				21	22			*15:43
13	14	15	16	17	18	19	20	21	22	23	24	Well No.

Lot No.: 89K **Lot-specific information** www.olerup-ssp.com

Well No.	1	2	3	4	5	6	7	8	9	10	11	12
HLA-C allele⁴												
*16:01:01-16:01:05, 16:06-16:08,												
16:10-16:11, 16:13-16:15:01,												
16:16Q-16:17, 16:21-16:24, 16:26-												
16:28, 16:30N-16:32												
*16:02:01-16:02:05, 16:09, 16:12,											11	
16:19, 16:25											11	
*16:04:01												
*16:15:02												12
*16:18												
*16:20												
*16:29		2										
*17:01:01:01-17:01:03, 17:01:05-		2									11	
17:04, 17:06, 17:08												
*17:01:04		2									11	
*17:05		2									11	12
*17:07											11	
*18:01-18:02, 18:04											11	
*18:03		2									11	
A*24:106, B*46:25												
B*14:03												
B*67:02												
HLA-C allele <sup>4</sup>												
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

<sup>&</sup>lt;sup>1</sup>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-C low resolution SSP typing.

In addition, wells number 2, 3, 5, 6, 8, 9, 10, 13, 14, 19 and 20 contain the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to allow kit identification.

<sup>2</sup>The nucleotide position, in the 1<sup>st</sup>, 2<sup>nd</sup>, 3<sup>rd</sup> or 4<sup>th</sup> exon or the 1<sup>st</sup> or 2<sup>nd</sup> intron, matching the specificity-determining 3'-end of the primer is given. Nucleotide numbering as on the <a href="https://www.ebi.ac.uk/imgt/hla">www.ebi.ac.uk/imgt/hla</a> web site. The sequence of the 3 terminal nucleotides of the primer is given.

<sup>3</sup>The nucleotide position, in the 1<sup>st</sup>, 2<sup>nd</sup>, 3<sup>rd</sup> or 4<sup>th</sup> exon or the 3<sup>rd</sup> intron, matching the specificitydetermining 3'-end of the primer is given in the anti-sense direction. Nucleotide numbering as on the www.ebi.ac.uk/imqt/hla web site. The sequence of the 3 terminal nucleotides of the primer is given.

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13	14	15	16	17	18	19	20	21	22	23	24	Well No.
												HLA-C allele <sup>4</sup>
												*16:01:01-16:01:05, 16:06-16:08,
13					18					23		16:10-16:11, 16:13-16:15:01,
13					10					23		16:16Q-16:17, 16:21-16:24, 16:26-
												16:28, 16:30N-16:32
13		15			18					23		*16:02:01-16:02:05, 16:09, 16:12,
13		13			10					23		16:19, 16:25
	14				18		20					*16:04:01
13					18					23	_	*16:15:02
13		15			18					23	) tr	*16:18
13				17	18					23	Negative Control	*16:20
	14				18		20				ě	*16:29
		15				19		21			aţi	*17:01:01:01-17:01:03, 17:01:05-
		13				13		21			<u>e</u>	17:04, 17:06, 17:08
13		15				19		21			Z	*17:01:04
		15				19		21				*17:05
		15				19		21				*17:07
							20	21		23		*18:01-18:02, 18:04
							20	21	22	23		*18:03
										23		A*24:106, B*46:25
							20					B*14:03
13												B*67:02
												HLA-C allele <sup>4</sup>
13	14	15	16	17	18	19	20	21	22	23	24	Well No.

<sup>4</sup>The sequence of the Cw\*0101 allele has been shown to be identical to C\*01:02.

The sequence of the Cw\*0201 allele has been shown to be identical to C\*02:02:02.

The sequence of the Cw\*020204 allele has been shown to be identical to C\*02:10.

The sequence of the Cw\*021603 allele has been shown to be identical to C\*02:16:02.

The sequence of the Cw\*0301 allele has been shown to be identical to C\*03:04:01.

The sequence of the Cw\*0402 allele has been shown to be identical to C\*04:01:01.

The sequence of the Cw\*0421 allele has been shown to be identical to C\*04:15:02.

The sequence of the Cw\*0422 allele has been shown to be identical to C\*04:21.

The sequence of the Cw\*0502 allele has been shown to be identical to C\*05:09.

The sequence of the Cw\*0601 allele has been shown to be identical to C\*06:02:01.

The sequence of the Cw\*060202 allele has been renamed C\*06:17.

The sequence of the Cw\*0734 allele has been renamed C\*07:27:02.

The sequence of the Cw\*1101 allele has been shown to be in error.

The sequence of the Cw\*1201 allele has been shown to be identical to C\*12:02:02.

The sequence of the Cw\*1301 allele has been shown to be in error.

The sequence of the Cw\*1401 allele has been shown to be identical to C\*14:02:01.

The sequence of the Cw\*1501 allele has been shown to be identical to C\*15:02:01.

The sequence of the Cw\*1514 allele has been renamed C\*15:10:02.

The sequence of the Cw\*1603 allele has been shown to be identical to C\*14:03.

The sequence of the Cw\*16042 allele has been shown to be identical to C\*16:04:01.

The sequence of the Cw\*1605 allele has been shown to be identical to C\*16:04:01. 'w', might be weakly amplified.

Lot No.: 89K Lot-specific information www.olerup-ssp.com

	CELL LINE VALIDATION SHEET																			
HLA-C low resolution SSP primer set																				
		П	LA-C IC	ow res	DIU	ITIC	n ;	<u> </u>	P	orii	me									
					_	_	_		_	_	-	W		40	4.4	40	40		4.5	40
					1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
				::	2	05	03	4	05	90	07	80	60	10	7	7	13	4	15	16
				ž	931	811	735	31	931	31	531	931	931	931	31	811	31	931	811	811
				Prod. No.:	200963101	201181102	201073503	201181104	200963105	201181106	200963107	200963108	200963109	200963110	201181111	201181112	201181113	200963114	201181115	201181116
					20	8	8	×	8	×	2	×	20	2	×	8	×	8	8	20
		VC cell line		<u>;*</u>																
1	9001		*07:02	*45.05	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-
2		LK707 E4181324	*07:01 *12:02	*15:05	-	-	+	-	-	-	-	-	+	-	+	-	-	-	+	-
3 4		GU373	*03:04	*04:01	-	÷	+	+	-	+	-	-	-	-	+	+	+	-	-	-
5		KAS011	*06:02	04.01	-		Ξ	Ξ.	-	Ξ.	-	+	-	-	+	-	Ξ.	+		-
6	9353		*03:04	*07:02	-	-	+	+	-	-	-	-	+	-	-	-	-	-	-	-
7	9020		*05:01	57.02	-	-		-	-	-	+	-	-	-	+	-	-	-	+	-
8	9025		*04:01		-	-	-	-	-	+		-	-	-	+	-	+	-	÷	-
9	9026		*12:03		-	-	-	-	-	÷	-	-	-	-		+	+	+	-	-
10	9107		*01:02		+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
11	9051	PITOUT	*16:01		-	-	-	-	-	-	-	-	-	-	-	-	+	-	-	-
12	9052		*06:02		-	-	-	-	-	-	-	+	-	-	+	-	-	+	-	-
13	9004	JESTHOM	*01:02		+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
14		OLGA	*01:02	*03:04	+	-	+	+	-	-	-	-	-	-	-	-	-	-	-	-
15	9075		*03:04		-	-	+	+	-	-	-	-	-	-	-	-	-	-	-	-
16		SWEIG007	*02:02		-	+	+	-	-	+	-	-	-	-	+	-	-	-	+	-
17		CTM3953540	*03:03	*07:01	-	-	-	+	+	-	-	-	+	-	-	-	-	-	-	-
18		32367	*01:02	*07:05	+	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-
19		BM16	*07:01		-	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-
20		SLE005 AMALA	*03:04		-	-	+	+	-	-	-	-	-	-	-	-	-	-	-	-
22		KOSE	*03:03 *12:03		-		÷	+	+	-	-	-	-	-	-	+	+	+	-	-
23	9124		*01:02	*15:02	+		+	-	-	-	-	+	-	-	+	-		-	+	_
24		JBUSH	*12:03	10.02	-	-	÷	-	-	-	-	÷	-	-	÷	+	+	+	-	-
25		IBW9	*08:02		-	-	-	-	-	-	-	-	-	+	-		÷		-	-
26		WT49	*07:01		-	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-
27		CH1007	*07:04	*15:05	-	-	+	-	-	-	-	-	+	-	+	-	-	-	+	-
28	9320	BEL5GB	*05:01	*16:01	-	-	-	-	-	-	+	-	-	-	+	-	+	-	+	-
29	9050	MOU	*16:01		-	-	-	-	-	-	-	-	-	-	-	-	+	-	-	-
30	9021	RSH	*17:01		-	+	-	-	-	-	-	-	•	-	+	-	-	-	+	-
31	9019	DUCAF	*05:01		-	-	-	-	-	-	+	-	-	-	+	_	-	-	+	-
32	9297		*17:01	*17:03	-	+	-	-	-	-	-	-	-	-	+	-	-	-	+	-
33		MT14B	*03:04		-	-	+	+	-	-	-	-	-	-	-	-	-	-	-	-
34	9104		*12:03		-	-	-	-	-	-	-	-	-	-	-	+	+	+	-	-
35		SSTO	*05:01	*0.4.0.1	-	-	-	-	-	-	+	-	-	-	+	-	-	-	+	-
36		KT17	*03:03	*04:01	-	-	-	+	+	+	-	-	-	-	+	-	+	-	-	-
37		HHKB	*07:02		-	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-
38 39	9099 9315		*03:03	*07:01	-	-	-	+	+	-	-	-	-	-	-	-	-	-	-	-
40		WHONP199	*01:02	*06:02	+	+	+	-	-	+	-	+	+	-	+	-	-	+	+	-
41		H0301	*08:02	00.02	H-	-	i	-	-	-	-	<u> </u>	÷	+	-	-	-	-	-	_
42		TAB089	*01:02		+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
43		T7526	*01:02	*08:01	+	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-
44	9057		*12:03	33.01	-	-	-	-	-	-	-	-	-	-	-	+	+	+	-	-
45		SHJO	*06:02	*17:01	-	+	-	-	-	-	-	+	-	-	+		÷	+	+	-
46		SCHU	*07:02		-	Ė	-	-	-	-	-	÷	+	-	Ė	-	-	÷	÷	-
47		TUBO	*07:04	*15:02	-	-	+	-	-	-	-	+	+	-	+	-	-	-	+	-
48		TER-ND	*04:01	*16:01	-	-	-	-	-	+	-	-	-	-	+	-	+	-	-	-

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		ELL LINE									
	H	LA-C low re	<u>esolutio</u>	on SSP	, bi	rim	er	se	t		
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					963	8	8	8	963	963	8
				Prod. No.:	200963117	201181118	201181119	201181120	200963121	200963122	201181123
$\vdash$		VO II II			2	7	7	7	7	7	7
1	9001	VC cell line	*07:02	C*	-					_	$\overline{}$
2		LK707	*07:02	*15:05	+	-	-	-	+	-	+
3		E4181324	*12:02	15.05	Ι.	-	-	-	_	-	-
4		GU373	*03:04	*04:01	-	+	-	-	+	+	-
5		KAS011	*06:02	04.01	-	-	-	-	÷	÷	+
6	9353		*03:04	*07:02	-	-	-	-	+	+	+
7	9020		*05:01	002	-	-	-	-	+		-
8	9025		*04:01		-	+	-	-	+	-	-
9		YAR	*12:03		-	÷	-	-	-	-	-
10		LKT3	*01:02		-	-	-	+	-	-	-
11		PITOUT	*16:01		-	+	-	-	-	-	+
12	9052	DBB	*06:02		-	-	-	-	-	-	+
13	9004	JESTHOM	*01:02		-	-	-	+	-	-	-
14	9071	OLGA	*01:02	*03:04	-	-	-	+	+	+	-
15	9075		*03:04		-	-	-	-	+	+	-
16	9037	SWEIG007	*02:02		-	-	-	-	-	-	-
17		CTM3953540	*03:03	*07:01	-	-	-	-	+	+	+
18		32367	*01:02	*07:05	-	-	-	+	-	-	+
19		BM16	*07:01		-	-	-	-	-	-	+
20		SLE005	*03:04		-	-	-	-	+	+	
21		AMALA	*03:03		-	-	-	-	+	+	-
22		KOSE	*12:03	**= 00	-	-	-	-	-	-	-
23	9124		*01:02	*15:02	+	-	-	+	+	-	-
24		JBUSH	*12:03		-	-	-	-	-	-	-
25 26		IBW9 WT49	*08:02 *07:01		-	-	-	-	+	-	-
27		CH1007	*07:01	*15:05	+				+		+
28		BEL5GB	*05:01	*16:01	Ξ	+	÷		+	÷	+
29		MOU	*16:01	10.01	-	+	-	-	-	-	+
30	9021		*17:01		-	÷	+	-	+	-	-
31	2010	DUCAF	*05:01		-	-	÷	-	+	-	-
32		HAG	*17:01	*17:03	-	-	+	-	+	-	-
33		MT14B	*03:04	11.00	-	-	-	-	+	+	-
34	9104		*12:03		-	-	-	-	-	-	-
35		SSTO	*05:01		-	-	-	-	+	-	-
36		KT17	*03:03	*04:01	-	+	-	-	+	+	-
37	9065	HHKB	*07:02		-	-	-	-	-	-	+
38	9099	LZL	*03:03		-	-	-	-	+	+	-
39	9315	CML	*02:02	*07:01	-	-	-	-	-	-	+
40	9134	WHONP199	*01:02	*06:02	-	-	Ŀ	+	_	Ŀ	+
41		H0301	*08:02		-	-	-	-	+	-	-
42		TAB089	*01:02		-	-	-	+	-	-	-
43		T7526	*01:02	*08:01	-	+	-	+	+	-	-
44	9057		*12:03		-	-	-	-	-	-	-
45		SHJO	*06:02	*17:01	-	-	+	-	+	-	+
46		SCHU	*07:02	***	-	-	-	-	-	-	+
47		TUBO	*07:04	*15:02	+	-	-	-	+	-	+
48	9303	TER-ND	*04:01	*16:01	-	+	-	-	+		+

HLA-C low resolution Product Insert Page 26 of 28 101.601-24/12 – including *Taq* polymerase General "Instructions for Use"

IFU-01 Rev. No. 02 can be downloaded from

Lot No.: 89K Lot-specific information www.olerup-ssp.com

#### **CERTIFICATE OF ANALYSIS**

Olerup SSP® HLA-C low resolution SSP

Product number: 101.601-24/12 – including *Taq* pol.

Lot number: 89K

Expiry date: 2013-August-01

Number of tests: 24 tests – Product No. 101.601-24

12 tests - Product No. 101.601-12

Number of wells per test: 23 + 1

#### Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2009-631-01	9	2009-631-09	17	2009-631-17
2	2011-811-02	10	2009-631-10	18	2011-811-18
3	2010-735-03	11	2011-811-11	19	2011-811-19
4	2011-811-04	12	2011-811-12	20	2011-811-20
5	2009-631-05	13	2011-811-13	21	2009-631-21
6	2011-811-06	14	2009-631-14	22	2009-631-22
7	2009-631-07	15	2011-811-15	23	2011-811-23
8	2009-631-08	16	2011-811-16		

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 solution 2, 6, 12 to 15, 22 and 23 were tested by separately adding one 3'-primer. Additional 3'-primers in primer solutions 2, 10, 12, 14, 15, 18, 19 and 22, were tested by separately adding one 5'-primer. In primer solutions 3, 11, 12, 14 and 18, one or two 3'-primers were not possible to test, and in primer solution 23, one 5'-primer was not possible to test.

The negative control primer pairs, **Production No. 2010-760-01**, can detect contamination with PCR products diluted 10<sup>-7</sup>.

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

Date of approval: 2011-February-16

Approved by:

**Quality Control, Supervisor** 

HLA-C low resolution Product Insert Page 27 of 28 101.601-24/12 – including *Taq* polymerase General "Instructions for Use"

IFU-01 Rev. No. 02 can be downloaded from

Lot No.: 89K Lot-specific information www.olerup-ssp.com

# **Declaration of Conformity**

**Product name:** Olerup SSP® HLA-C low resolution

**Product number:** 101.601-24/12

Lot number: 89K

**Intended use:** HLA-C low resolution histocompatibility testing

Manufacturer: Olerup SSP AB

Hasselstigen 1

SE-133 33 Saltsjöbaden, Sweden

**Phone:** +46-8-717 88 27 **Fax:** +46-8-717 88 18

We, *Olerup* SSP AB, hereby declare that this product, to which this Declaration of Conformity relates is in conformity with the following Standard(s) and other normative document(s) ISO 9001:2008 and ISO 13485:2004, following the provisions of the 98/79/EC Directive on *in vitro* diagnostic medical devices, Annex III, as transposed into the national laws of the Member States of the European Union.

The Technical Construction File is maintained at *Olerup* SSP AB, Hasselstigen 1, SE-133 33 Saltsjöbaden, Sweden.

The Authorized Representative located within the Community is: *Olerup* SSP AB.

Saltsjöbaden, Sweden 2011-February-16

Olle Olerup Managing Director HLA-C low resolution Product Insert Page 28 of 28 101.601-24/12 – including *Taq* polymerase General "Instructions for Use"

IFU-01 Rev. No. 02 can be downloaded from

Lot No.: 89K Lot-specific information www.olerup-ssp.com

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*E-mail:* info-ssp@olerup.com

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**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: <a href="http://www.olerup.com">http://www.olerup.com</a>

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