

101.601.24/12 – including *Taq* pol., IFU-01 Rev. No. 03  
 101.601.24u/12u – without *Taq* pol., IFU-02 Rev. No. 03

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 “Instructions for Use” (IFU)

Lot No.: **64N**

Lot-specific information

## **Olerup SSP<sup>®</sup> HLA-C low resolution**

<b>Product number:</b>	<b>101.601-24/12 – including <i>Taq</i> pol. 101.601-24u/12u – without <i>Taq</i> pol.</b>
<b>Lot number:</b>	<b>64N</b>
<b>Expiry date:</b>	<b>2014-October-01</b>
<b>Number of tests:</b>	<b>24 tests – Product No. 101.601-24/24u 12 tests – Product No. 101.601-12/12u</b>
<b>Number of wells per test:</b>	<b>31 + 1</b>
<b>Storage - pre-aliquoted primers:</b>	<b>dark at -20°C</b>
- PCR Master Mix:	-20°C
- Adhesive PCR seals	RT
- Product Insert	RT

**This Product Description is only valid for Lot No. 64N.**

### **CHANGES COMPARED TO THE PREVIOUS *OLERUP SSP<sup>®</sup>* HLA-C LOW RESOLUTION LOT (89K)**

Eight wells have been added to the HLA-C low kit, wells **25 to 32**.

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

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. 89K**).

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

Well	5'-primer	3'-primer	rationale
8	Modified	Modified	Improved specificity of primer pair.
12	Moved	Moved	Primer pair moved to well 26, to decrease tendencies of primer oligomer formation.
13	Modified	Modified	Improved specificity of primer pair.
15	Moved	Moved	Primer pair moved to well 28 for improved specificity, exchanged positive control primer pair.

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17	-	-	Exchanged positive control primer pair.
23	Moved	Moved	Primer pair moved to well 30 for improved specificity of amplification.
24	Moved, new	Moved, new	Negative control moved to well 32, new primer pair for improved resolution of C*02 alleles.
25	New	New	Improved resolution of C*04 alleles.
26	New, added	New, added	Improved resolution of C*01 and C*12 alleles, primer pair from well 12.
27	New	New	Improved resolution of C*12 and C*16 alleles.
28	New, added	New, added	Improved resolution of C*14 alleles, primer pair from well 15.
29	New	New	Improved resolution of C*15 alleles.
30	New, added	New, added	Primer added for the C*06:44 and C*06:02:06 alleles, primer pair from well 23.
31	New	New	Improved resolution of C*05, C*08 and C*12 alleles.
32	New	New	Negative control primer pair from well 24.

Change in revision R01 compared to R00:

1. Correction of the product number in the Declaration of Conformity.

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

<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 [www.ebi.ac.uk/imgt/hla](http://www.ebi.ac.uk/imgt/hla) web site. The sequence of the 3 terminal nucleotides of the primer is given.

<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 [www.ebi.ac.uk/imgt/hla](http://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-C-low resolution SSP subtyping

#### CONTENT

The primer set contains 5'- and 3'-primers for grouping the HLA-C\*01:02 to C\*18:05 alleles into the groups C\*01:xx to C\*18:xx.

#### PLATE LAYOUT

Each test consists of 32 PCR reactions in a 32 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
25	26	27	28	29	30	31	32

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

Well 32 – Negative Control.

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

Well No. 1 is marked with the Lot No. ‘64N’.

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 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 mixes 20 and 26 will amplify the B\*14:03 allele, primer mix 27 will amplify the B\*35:08:02, B\*35:08:05 and B\*67:02 alleles and primer mix 30 will amplify the A\*24:106, A\*24:174 and B\*46:25 alleles. Thus, the interpretation of HLA-C low resolution typings is only influenced by these eight alleles and not by other HLA class I genes.

#### UNIQUELY IDENTIFIED ALLELES

All the HLA-C alleles, i.e. **C\*01:02 to C\*18:05**, recognized by the HLA Nomenclature Committee in January 2012<sup>1</sup> will be amplified by the primers in the HLA-C low resolution SSP kit<sup>2</sup>. 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 2012-January-12, release 3.7.0, [www.ebi.ac.uk/imgt/hla](http://www.ebi.ac.uk/imgt/hla).

<sup>2</sup>The C\*01:05, 01:22 and 01:35-01:36 and the B\*54:18 alleles give rise to identical amplification patterns with the HLA-C low resolution primer set. These alleles are separated by the HLA-B low primer set.

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Lot-specific information  
**SPECIFICITY TABLE**

**HLA-C low resolution SSP typing**

Specificities and sizes of the PCR products of the 31+1 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>
<b>1</b>	155 bp	<b>800 bp</b>	*01:02:01-01:61, <b>B*54:18</b>
<b>2<sup>5</sup></b>	130 bp, 200 bp, 270 bp, 300 bp	<b>800 bp</b>	*01:10, 01:43, 02:02:01-02:02:03, 02:02:05-02:40, 02:42-02:55, 04:32, 04:77, 06:08, 07:101, 07:148, 07:161, 08:31, 14:25, 15:42, 16:29, 17:01:01:01-17:06, 17:08-17:11, 18:03
<b>3<sup>13</sup></b>	280 bp	<b>800 bp</b>	*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, 02:26-02:40, 02:42-02:55, 03:02:01-03:02:08, 03:04:01:01-03:10, 03:14-03:17, 03:19, 03:23-03:29, 03:32-03:38:02, 03:40:01-03:42, 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, 03:104-03:111, 03:113-03:115, 03:117-03:118, 03:121N, 03:123, 03:125, 03:128-03:131, 03:134-03:136, 03:138-03:139, 04:03, 04:06, 04:16, 04:80, 04:107, 05:58:01, 06:03, 07:96, 15:02:01-15:09, 15:10:02-15:11, 15:13, 15:15-15:22, 15:24-15:35, 15:37-15:56, 16:34
<b>4<sup>6</sup></b>	170 bp, 275 bp	1070 bp	*03:02:01-03:04:06, 03:04:08-03:15, 03:17-03:40:02, 03:42-03:57, 03:59-03:79, 03:81-03:85, 03:87-03:93, 03:95-03:98, 03:100-03:109, 03:111-03:112, 03:114-03:139
<b>5</b>	280 bp	<b>800 bp</b>	*03:03:01-03:03:18, 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, 03:102-03:103, 03:112, 03:116, 03:119-03:120, 03:122, 03:124, 03:126-03:127, 03:132-03:133, 15:12
<b>6<sup>13</sup></b>	130 bp, 330 bp	<b>800 bp</b>	*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, 02:46-02:55, 04:01:01:01-04:01:27, 04:01:29-04:01:36, 04:03-04:15:03, 04:17-04:20, 04:23-04:41, 04:43-04:102, 04:104-04:107, 05:26, 07:02:09, 07:125, 15:11, 15:36, 16:34
<b>7</b>	390 bp, 445 bp	1070 bp	*05:01:01:01-05:01:18, 05:03-05:72, 08:10, 16:40

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<b>8</b>	130 bp, 355 bp	<b>800 bp</b>	*02:06, 02:47, 06:02:01:01-06:02:01:02, 06:02:03-06:16N, 06:18-06:31, 06:33-06:69, 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, 15:47-15:53, 15:56
<b>9<sup>7</sup></b>	245 bp, 425 bp	<b>800 bp</b>	*07:01:01-07:33N, 07:35-07:220
<b>10<sup>8,10,13</sup></b>	115 bp, 165 bp, 265 bp, 390 bp	<b>800 bp</b>	*01:43, 07:101, 07:148, 07:161, 08:01:01-08:56
<b>11</b>	340 bp	1070 bp	*01:14, 01:59, 02:02:01-02:02:03, 02:02:05-02:11, 02:13- 02:26:03, 02:28-02:40, 02:42-02:55, 03:07, 03:15, 03:45, 03:130, 04:01:01:01-04:01:36, 04:03-04:10, 04:12-04:20, 04:23-04:28, 04:30-04:35, 04:37-04:54, 04:56-04:107, 05:01:01:01-05:01:18, 05:03-05:72, 06:02:01:01- 06:02:01:02, 06:02:03-06:02:11, 06:02:13-06:10, 06:12- 06:51, 06:53-06:69, 07:07, 07:09, 07:49, 07:76, 07:210, 08:10, 12:04:01-12:05, 12:09, 12:21, 12:33, 12:41, 12:54, 12:60, 14:04, 14:12, 15:02:01-15:06:03, 15:08-15:13, 15:15-15:20, 15:22-15:24, 15:26-15:42, 15:44-15:56, 16:02:01-16:02:09, 16:09, 16:12, 16:19, 16:25, 17:01:01:01-17:11, 18:01-18:05
<b>12<sup>10,11</sup></b>	100 bp, 160 bp, 220 bp	<b>800 bp</b>	*01:04, 01:21, 12:02:01-12:03:01:02, 12:03:03-12:03:07, 12:03:09-12:03:15, 12:03:17-12:03:19, 12:04:02-12:08, 12:10:01-12:13, 12:14:02-12:25, 12:27-12:32, 12:34- 12:58, 12:60-12:68, 14:02:08, 16:15:02
<b>13<sup>9,10</sup></b>	110 bp, 250 bp	<b>800 bp</b>	*01:21, 02:12, 02:49, 02:55, 04:01:01:01-04:01:36, 04:03- 04:09N, 04:12-04:20, 04:23-04:35, 04:37-04:54, 04:56- 04:107, 05:42, 05:46, 07:02:09, 07:125, 08:05, 08:21, 08:25, 12:02:01-12:03:03, 12:03:05-12:03:08, 12:03:10- 12:03:12, 12:03:13 <sup>w</sup> , 12:03:14-12:03:20, 12:04:02, 12:06- 12:08, 12:10:01-12:20, 12:22-12:32, 12:34-12:48, 12:50- 12:68, 15:03, 15:16, 15:25, 16:01:01-16:02:09, 16:06- 16:28, 16:30N-16:32, 16:34, 16:36-16:39, 16:41, 16:43- 16:44, 17:01:04, <b>B*67:02</b>
<b>14<sup>14</sup></b>	160 bp, 220 bp	<b>800 bp</b>	*01:04, 01:09, 02:05, 02:17, 04:42, 06:02:01:01- 06:02:01:02, 06:02:03-06:02:15, 06:02:17-06:03, 06:07- 06:13, 06:15-06:34, 06:36-06:39, 06:41-06:69, 07:125, 12:03:01:01-12:07, 12:11-12:13, 12:15, 12:19, 12:23, 12:25-12:26, 12:28-12:29, 12:31-12:35, 12:37-12:39N, 12:42Q-12:43, 12:45-12:48, 12:50-12:55, 12:57-12:63, 12:65-12:66, 14:16, 16:04, 16:29, 16:33, 16:42
<b>15<sup>13</sup></b>	130 bp, 255 bp	<b>800 bp</b>	*02:02:01 <sup>w</sup> , 02:02:02-02:02:03, 02:02:05-02:13, 02:15- 02:26:03, 02:28-02:40, 02:42-02:55, 03:07, 03:10, 03:15, 03:29, 03:45, 04:03, 04:06, 04:16, 04:37, 04:80, 04:103,

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			04:107, 05:01:01:01-05:01:18, 05:03-05:19, 05:21-05:42, 05:44-05:72, 06:03, 08:10, 12:04:01-12:05, 12:09, 12:21, 12:33, 12:41, 12:60, 15:02:01-15:06:03, 15:08-15:13, 15:15-15:22, 15:24, 15:26-15:35, 15:37-15:42, 15:44-15:56, 16:02:01-16:02:09, 16:09, 16:12, 16:19, 16:25, 16:37, 17:01:01:01-17:11
<b>16<sup>12</sup></b>	255 bp, 445 bp	1070 bp	*04:11, 04:29, 04:36, 04:55, 07:64, 12:55, 14:02:01-14:11, 14:13-14:34, 16:40
<b>17<sup>9,10</sup></b>	110 bp, 325 bp	<b>800 bp</b>	*02:06, 03:81, 05:36, 07:123, 07:173, 12:08, 12:15, 15:02:01-15:13, 15:15-15:24, 15:26-15:56, 16:20
<b>18<sup>12</sup></b>	180 bp, 210 bp, 240 bp	1070 bp	*02:13, 02:18, 02:33, 02:49, 04:01:01:01-04:01:22, 04:01:24-04:01:36, 04:03-04:10, 04:12-04:20, 04:23-04:32, 04:34-04:106, 05:17, 05:25, 05:42, 05:55, 05:68, 06:05, 06:31, 07:02:09, 07:31, 07:177, 08:01:01-08:01:05, 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, 08:46, 08:50, 08:56, 12:14:01-12:14:02, 12:28, 12:58, 14:10, 14:15, 15:12, 15:25, 16:01:01-16:02:09, 16:04, 16:06-16:39, 16:41-16:42, 16:44
<b>19<sup>11,15</sup></b>	225 bp, 250 bp	<b>800 bp</b>	*01:60, 04:58, 05:23, 05:62, 08:07, 08:47, 12:14:01-12:14:02, 14:17, 15:25, 17:01:01:01-17:11
<b>20</b>	215 bp, 425 bp	<b>800 bp</b>	*01:02:01-01:03, 01:06-01:08, 01:10-01:20, 01:23-01:34, 01:37N-01:48, 01:51-01:54, 01:56N-01:61, 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, 07:210, 08:12, 12:09, 12:24, 14:02:01-14:05, 14:07N, 14:10-14:14, 14:17-14:27, 14:29-14:34, 16:04, 16:29, 16:33, 16:42, 18:01-18:05, <b>B*14:03</b>
<b>21</b>	325 bp, 380 bp	1070 bp	*01:03, 01:24, 01:34, 01:49-01:50, 01:55, 02:22, 03:03:01-03:04:25, 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, 03:100-03:107, 03:109, 03:111-03:120, 03:122-03:131, 03:133-03:134, 03:136-03:138, 04:01:01:01-04:01:15, 04:01:17-04:01:36, 04:03-04:20, 04:24-04:53, 04:55-04:71, 04:73-04:107, 05:01:01:01-05:01:18, 05:03, 05:05-05:21, 05:23-05:72, 06:09, 06:14, 06:35, 07:10, 07:28, 07:41, 07:43, 07:184, 07:196, 08:01:01-08:08, 08:10, 08:12-08:47, 08:49-08:56, 12:31, 12:44, 15:02:01-15:13, 15:15-15:21, 15:23-15:36, 15:38-15:54, 15:56, 17:01:01:01-17:11, 18:01-18:05
<b>22<sup>12,15</sup></b>	135 bp	1070 bp	*03:02:01-03:04:24, 03:05-03:17, 03:19-03:38:02, 03:40:01-03:66, 03:67 <sup>w</sup> , 03:68-03:98, 03:100-03:136, 03:138-03:139, 04:32, 04:77, 06:03, 07:96, 14:25, 15:43, 18:03

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<b>23</b>	155 bp, 235 bp	1070 bp	*04:42, 06:02:01:01-06:02:01:02, 06:02:03-06:02:19, 06:04-06:69, 07:01:01-07:02:07, 07:02:09-07:02:28, 07:03-07:25, 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, 07:157-07:176, 07:178-07:209, 07:211- 07:220, 12:16, 18:01-18:05
<b>24</b> <sup>10,13</sup>	95 bp	<b>800 bp</b>	*02:02:01-02:02:03, 02:02:06-02:02:12, 02:02:15- 02:02:22, 02:04, 02:07-02:09, 02:11, 02:13, 02:15, 02:19- 02:27:01, 02:28-02:31, 02:34-02:40, 02:42-02:50, 02:52N- 02:55, 12:03:17
<b>25</b>	260 bp, 360 bp	1070 bp	*04:01:01:01-04:01:36, 04:03-04:20, 04:23-04:107, 16:34
<b>26</b>	155 bp, 220 bp	1070 bp	*01:02:01-01:03, 01:06-01:08, 01:10-01:20, 01:23-01:34, 01:37N-01:48, 01:51-01:54, 01:56N-01:61, 03:58, 03:86, 03:94, 03:99, 04:37, 05:16, 05:42, 05:46, 06:05-06:06, 06:67, 07:101, 07:148, 07:161, 08:05, 08:12, 08:21, 12:09, 12:24, 14:02:01-14:05, 14:07N, 14:10-14:14, 14:17-14:27, 14:29-14:34, 17:05, <b>B*14:03</b>
<b>27</b>	140 bp	1070 bp	*01:21, 02:12w, 02:27:01-02:27:02, 03:04:25, 04:11, 04:29, 04:36, 04:55, 07:02:09, 08:01:01-08:09, 08:11- 08:56, 12:02:01-12:03:03, 12:03:05-12:03:08, 12:03:10- 12:03:20, 12:06-12:08, 12:10:01-12:20, 12:22-12:26, 12:28-12:32, 12:34-12:40, 12:42Q-12:53, 12:55-12:59, 12:61-12:68, 14:02:03, 14:03, 14:08, 14:10, 14:22, 15:07, 15:21w, 15:25, 16:01:01, 16:01:03-16:01:07, 16:04, 16:06- 16:08, 16:10-16:11, 16:13-16:18, 16:20-16:24, 16:26- 16:36, 16:37w, 16:38-16:44, <b>B*35:08:02, B*35:08:05, B*67:02</b>
<b>28</b>	210 bp, 555 bp	1070 bp	*03:58, 03:86, 03:94, 03:99, 14:02:01-14:04, 14:07N, 14:10-14:14, 14:17-14:27, 14:29-14:34, 15:37, 16:18
<b>29</b>	175 bp	1070 bp	*03:08, 03:29, 03:31, 07:20, 07:96, 15:02:01-15:09, 15:12- 15:13, 15:15, 15:18-15:19, 15:21-15:24, 15:26, 15:28- 15:42, 15:44-15:56
<b>30</b>	160 bp	1070 bp	*07:53, 07:216, 16:01:01-16:02:09, 16:06-16:28, 16:30N- 16:32, 16:34, 16:36-16:39, 16:41, 16:43-16:44, <b>A*24:106, A*24:174, B*46:25</b>
<b>31</b>	520 bp	1070 bp	*01:14, 02:02:01-02:02:03, 02:02:05-02:02:22, 02:04- 02:15, 02:17, 02:19-02:26:03, 02:28-02:40, 02:42-02:55, 04:01:01:01-04:01:36, 04:03, 04:05, 04:07-04:10, 04:12, 04:15:01-04:20, 04:23-04:28, 04:30-04:33, 04:35, 04:37- 04:54, 04:56-04:57, 04:59Q-04:67, 04:69-04:107, 05:01:01:01-05:01:18, 05:03-05:10, 05:12-05:16, 05:18:01-05:19, 05:21-05:26, 05:28-05:31, 05:33-05:50, 05:52-05:61, 05:63-05:67, 05:69, 05:71-05:72,



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Lot No.: **64N**

Lot-specific information

	06:02:01:01-06:02:01:02, 06:02:03-06:03, 06:05-06:10, 06:12-06:39, 06:41-06:51, 06:53-06:69, 12:04:01-12:05, 12:09, 12:21, 12:33, 12:41, 12:60, 14:12, 15:08, 18:01- 18:05
<b>32<sup>16</sup></b>	<b>Negative Control</b>

<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 length this is indicated if the size difference is 20 base pairs or more. Size differences shorter than 20 base pairs are not given. For high resolution SSP kits the respective lengths of the specific PCR product(s) of the alleles amplified by these primer mixes are given.

Nonspecific amplifications, i.e. a ladder or a smear of bands, may sometimes be seen. GC-rich primers have a higher tendency of giving rise to nonspecific amplifications than other primers.

PCR fragments longer than the control bands may sometimes be observed. Such bands should be disregarded and do not influence the interpretation of the SSP typings.

PCR fragments migrating faster than the control bands, but slower than a 400 bp fragment may be seen in some gel read-outs. Such bands can be disregarded and do not influence the interpretation of the SSP typings.

Some primers may give rise to primer oligomer artifacts. Sometimes this phenomenon is an inherent feature of the primer pair(s) of a primer mix. More often it is due to other factors such as too low amount of DNA in the PCR reactions, taking too long time in setting up the PCR reactions, working at elevated room temperature or using thermal cyclers that are not pre-heated.

<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 to 10, 12 to 15, 17, 19, 20 and 24 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 mixes 20 and 26 will amplify the B\*14:03 allele, primer mix 27 will amplify the B\*35:08:02, B\*35:08:05 and B\*67:02 alleles and primer mix 30 will amplify the A\*24:106, A\*24:174 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 12 and 19 may give rise to unspecific amplification.

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

<sup>13</sup>Primer mixes 3, 6, 10, 15 and 24 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 mixes 19 and 22 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 32 contains a negative control, which will amplify more than 95% of HLA amplicons as well as the amplicon generated by a control primer pair. 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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Lot No.: **64N**

Lot-specific information

Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
<b>HLA-C allele<sup>4</sup></b>																
*01:02:01-01:02:14, 01:06-01:08, 01:11-01:13, 01:15-01:20, 01:23, 01:25-01:33, 01:37N-01:42, 01:44- 01:48, 01:51-01:54, 01:56N-01:58, 01:61	1															
*01:03, 01:24, 01:34	1															
*01:04	1											12		14		
*01:05, 01:22, 01:35-01:36, <i>B*54:18</i> <sup>5</sup>	1															
*01:09	1													14		
*01:10	1	2														
*01:14	1											11				
*01:21	1											12	13			
*01:43	1	2								10						
*01:49-01:50, 01:55	1															
*01:59	1											11				
*01:60	1															
*02:02:01		2	3			6						11				w
*02:02:02-02:02:03, 02:02:06- 02:02:12, 02:02:15-02:02:22, 02:07- 02:09, 02:11, 02:15, 02:19-02:20, 02:23-02:25Q, 02:28-02:31, 02:34- 02:38N, 02:40, 02:42-02:44, 02:46, 02:48, 02:50, 02:52N-02:54		2	3			6						11				15
*02:02:05, 02:02:14, 02:10, 02:32, 02:51		2	3			6						11				15
*02:02:13		2	3									11				15
*02:03, 02:16:01-02:16:02		2	3			6						11				15
*02:04		2	w			6						11				15
*02:05, 02:17		2	3			6						11		14	15	
*02:06		2	3			6		8				11				15
*02:12		2	3			6							13			15
*02:13		2	3			6						11				15
*02:14		2	w			6						11				
*02:18		2	3			6						11				15
*02:21, 02:26:02-02:26:03, 02:39, 02:45		2	3									11				15
*02:22		2	3			6						11				15
*02:26:01		2										11				15
*02:27:01		2	3			6										
*02:27:02		2	3			6										
*02:33		2	3			6						11				15
*02:47		2	3			6		8				11				15
*02:49		2	3			6						11		13		15
*02:55		2	3			6						11		13		15
<b>Well No.</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>7</b>	<b>8</b>	<b>9</b>	<b>10</b>	<b>11</b>	<b>12</b>	<b>13</b>	<b>14</b>	<b>15</b>	<b>16</b>

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Lot No.: **64N**

Lot-specific information

17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Well No.
																HLA-C allele <sup>4</sup>
			20						26							*01:02:01-01:02:14, 01:06-01:08, 01:11-01:13, 01:15-01:20, 01:23, 01:25-01:33, 01:37N-01:42, 01:44- 01:48, 01:51-01:54, 01:56N-01:58, 01:61
			20	21					26							*01:03, 01:24, 01:34
																*01:04
																*01:05, 01:22, 01:35-01:36, <i>B*54:18</i> <sup>5</sup>
																*01:09
			20						26							*01:10
			20						26					31		*01:14
										27						*01:21
			20						26							*01:43
				21												*01:49-01:50, 01:55
			20						26							*01:59
		19	20						26							*01:60
							24								31	*02:02:01
							24								31	*02:02:02-02:02:03, 02:02:06- 02:02:12, 02:02:15-02:02:22, 02:07- 02:09, 02:11, 02:15, 02:19-02:20, 02:23-02:25Q, 02:28-02:31, 02:34- 02:38N, 02:40, 02:42-02:44, 02:46, 02:48, 02:50, 02:52N-02:54
															31	*02:02:05, 02:02:14, 02:10, 02:32, 02:51
															31	*02:02:13
																*02:03, 02:16:01-02:16:02
							24								31	*02:04
															31	*02:05, 02:17
17															31	*02:06
										w					31	*02:12
	18						24								31	*02:13
															31	*02:14
	18															*02:18
							24								31	*02:21, 02:26:02-02:26:03, 02:39, 02:45
				21			24								31	*02:22
							24								31	*02:26:01
							24			27						*02:27:01
										27						*02:27:02
	18														31	*02:33
							24								31	*02:47
	18						24								31	*02:49
							24								31	*02:55
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Well No.

Negative Control



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Lot No.: **64N**

Lot-specific information

Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
<b>HLA-C allele<sup>4</sup></b>																
*03:02:01-03:02:08, 03:05, 03:17, 03:25, 03:27, 03:33, 03:35-03:36, 03:60, 03:71, 03:84, 03:89, 03:95, 03:108, 03:121N, 03:135, 03:139			3	4												
*03:03:01-03:03:18, 03:11:01-03:12, 03:20N-03:22Q, 03:30, 03:43:01- 03:43:02, 03:49-03:50, 03:52-03:53, 03:55-03:56, 03:59, 03:61-03:62, 03:66, 03:68-03:69, 03:75-03:76, 03:79, 03:83, 03:85, 03:88, 03:96, 03:102-03:103, 03:112, 03:116, 03:119-03:120, 03:122, 03:124, 03:126-03:127, 03:133				4	5											
*03:04:01:01-03:04:06, 03:04:08- 03:04:24, 03:06, 03:09, 03:14, 03:19, 03:23-03:24, 03:26, 03:28, 03:32, 03:34, 03:37-03:38:02, 03:40:01- 03:40:02, 03:42, 03:44, 03:46-03:48, 03:51, 03:54, 03:57, 03:63-03:65, 03:70, 03:72-03:74, 03:77-03:78, 03:82, 03:87, 03:90-03:93, 03:98, 03:100-03:101, 03:104-03:107, 03:109, 03:111, 03:114-03:115, 03:117-03:118, 03:123, 03:125, 03:128-03:129, 03:131, 03:134, 03:136, 03:138			3	4												
*03:04:07, 03:41, 03:80, 03:113			3													
*03:04:25			3	4												
*03:07, 03:45			3	4							11				15	
*03:08			3	4												
*03:10			3	4												15
*03:13, 03:97, 03:132				4	5											
*03:15			3	4							11					15
*03:16, 03:110			3													
*03:18, 03:39, 03:137				4												
*03:29			3	4												15
*03:31				4	5											
*03:58					5											
*03:67				4	w											
*03:81				4	5											
*03:86					5											
*03:94			3													
*03:99																
*03:130			3	4							11					
<b>Well No.</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>7</b>	<b>8</b>	<b>9</b>	<b>10</b>	<b>11</b>	<b>12</b>	<b>13</b>	<b>14</b>	<b>15</b>	<b>16</b>

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17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Well No.
																HLA-C allele <sup>4</sup>
					22											*03:02:01-03:02:08, 03:05, 03:17, 03:25, 03:27, 03:33, 03:35-03:36, 03:60, 03:71, 03:84, 03:89, 03:95, 03:108, 03:121N, 03:135, 03:139
				21	22											*03:03:01-03:03:18, 03:11:01-03:12, 03:20N-03:22Q, 03:30, 03:43:01-03:43:02, 03:49-03:50, 03:52-03:53, 03:55-03:56, 03:59, 03:61-03:62, 03:66, 03:68-03:69, 03:75-03:76, 03:79, 03:83, 03:85, 03:88, 03:96, 03:102-03:103, 03:112, 03:116, 03:119-03:120, 03:122, 03:124, 03:126-03:127, 03:133
				21	22											*03:04:01:01-03:04:06, 03:04:08-03:04:24, 03:06, 03:09, 03:14, 03:19, 03:23-03:24, 03:26, 03:28, 03:32, 03:34, 03:37-03:38:02, 03:40:01-03:40:02, 03:42, 03:44, 03:46-03:48, 03:51, 03:54, 03:57, 03:63-03:65, 03:70, 03:72-03:74, 03:77-03:78, 03:82, 03:87, 03:90-03:93, 03:98, 03:100-03:101, 03:104-03:107, 03:109, 03:111, 03:114-03:115, 03:117-03:118, 03:123, 03:125, 03:128-03:129, 03:131, 03:134, 03:136, 03:138
				21	22											*03:04:07, 03:41, 03:80, 03:113
				21						27						*03:04:25
				21	22											*03:07, 03:45
				21	22							29				*03:08
				21	22											*03:10
					22											*03:13, 03:97, 03:132
					22											*03:15
					22											*03:16, 03:110
				21												*03:18, 03:39, 03:137
				21	22							29				*03:29
				21	22							29				*03:31
			20	21	22				26		28					*03:58
				21	w											*03:67
17				21	22											*03:81
			20		22				26		28					*03:86
			20		22				26		28					*03:94
			20						26		28					*03:99
				21	22											*03:130
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Well No.

Negative Control



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 101.601.24u/12u – without *Taq* pol., IFU-02 Rev. No. 03

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Lot No.: **64N**

Lot-specific information

Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
HLA-C allele <sup>4</sup>																
*04:01:01:01-04:01:15, 04:01:17-04:01:22, 04:01:24-04:01:27, 04:01:29-04:01:36, 04:05, 04:07-04:09N, 04:12, 04:15:01-04:15:03, 04:17-04:20, 04:24-04:28, 04:30-04:31, 04:35, 04:38-04:41, 04:43-04:53, 04:56-04:57, 04:59Q-04:67, 04:69-04:71, 04:73-04:76, 04:78-04:79, 04:81-04:102, 04:104-04:106						6					11		13			
*04:01:16, 04:23, 04:54, 04:72						6					11		13			
*04:01:23, 04:33						6					11		13			
*04:01:28											11		13			
*04:03, 04:80			3			6					11		13		15	
*04:04:01-04:04:02, 04:13-04:14, 04:34, 04:68						6					11		13			
*04:06			3			6					11		13		15	
*04:10						6					11					
*04:11						6										16
*04:16			3								11		13		15	
*04:29						6							13			16
*04:32, 04:77		2				6					11		13			
*04:36, 04:55						6										16
*04:37						6					11		13		15	
*04:42											11		13	14		
*04:58						6					11		13			
*04:103											11		13		15	
*04:107			3			6					11		13		15	
*05:01:01:01-05:01:18, 05:03, 05:05-05:10, 05:12-05:15, 05:18:01-05:19, 05:21, 05:24, 05:28-05:31, 05:33-05:35, 05:37-05:41, 05:44-05:45, 05:47-05:50, 05:52-05:54, 05:56-05:57, 05:58:02-05:61, 05:63-05:67, 05:69, 05:71-05:72							7				11				15	
*05:04, 05:22:01-05:22:02							7				11				15	
*05:11, 05:27, 05:32, 05:51Q, 05:70							7				11				15	
*05:16							7				11				15	
*05:17, 05:68							7				11				15	
*05:20							7				11					
*05:23							7				11				15	
*05:25, 05:55							7				11				15	
*05:26						6	7				11				15	
*05:36							7				11				15	
*05:42							7				11		13		15	
*05:43							7				11					
*05:46							7				11		13		15	
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16



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Lot-specific information

17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Well No.
																HLA-C allele <sup>4</sup>
	18			21				25						31		*04:01:01:01-04:01:15, 04:01:17-04:01:22, 04:01:24-04:01:27, 04:01:29-04:01:36, 04:05, 04:07-04:09N, 04:12, 04:15:01-04:15:03, 04:17-04:20, 04:24-04:28, 04:30-04:31, 04:35, 04:38-04:41, 04:43-04:53, 04:56-04:57, 04:59Q-04:67, 04:69-04:71, 04:73-04:76, 04:78-04:79, 04:81-04:102, 04:104-04:106
	18							25						31		*04:01:16, 04:23, 04:54, 04:72
				21				25						31		*04:01:23, 04:33
	18			21				25						31		*04:01:28
	18			21				25						31		*04:03, 04:80
	18			21				25								*04:04:01-04:04:02, 04:13-04:14, 04:34, 04:68
	18			21				25								*04:06
	18			21				25						31		*04:10
				21				25		27						*04:11
	18			21				25						31		*04:16
	18			21				25		27						*04:29
	18			21	22			25						31		*04:32, 04:77
	18			21				25		27						*04:36, 04:55
	18		20	21				25	26					31		*04:37
	18			21		23		25						31		*04:42
	18	19		21				25								*04:58
	18			21				25						31		*04:103
				21				25						31		*04:107
				21										31		*05:01:01:01-05:01:18, 05:03, 05:05-05:10, 05:12-05:15, 05:18:01-05:19, 05:21, 05:24, 05:28-05:31, 05:33-05:35, 05:37-05:41, 05:44-05:45, 05:47-05:50, 05:52-05:54, 05:56-05:57, 05:58:02-05:61, 05:63-05:67, 05:69, 05:71-05:72
														31		*05:04, 05:22:01-05:22:02
			20	21					26					31		*05:11, 05:27, 05:32, 05:51Q, 05:70
	18			21												*05:16
				21												*05:17, 05:68
				21												*05:20
		19		21										31		*05:23
	18			21										31		*05:25, 05:55
				21										31		*05:26
17				21										31		*05:36
	18			21					26					31		*05:42
				21										31		*05:43
				21					26					31		*05:46
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Well No.

Negative Control



101.601.24/12 – including *Taq* pol., IFU-01 Rev. No. 03  
 101.601.24u/12u – without *Taq* pol., IFU-02 Rev. No. 03

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 “Instructions for Use” (IFU)

Lot No.: **64N**

Lot-specific information

Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
HLA-C allele <sup>4</sup>																
*05:58:01			3				7				11				15	
*05:62							7				11				15	
*06:02:01:01-06:02:01:02, 06:02:03-06:02:11, 06:02:13-06:02:15, 06:02:17-06:02:19, 06:07, 06:10, 06:12-06:13, 06:15-06:16N, 06:18-06:30, 06:33-06:34, 06:36-06:39, 06:41-06:51, 06:53-06:66, 06:68-06:69								8			11			14		
*06:02:12								8						14		
*06:02:16								8			11					
*06:03			3					8			11			14	15	
*06:04, 06:40								8			11					
*06:05								8			11					
*06:06								8			11					
*06:08		2						8			11			14		
*06:09								8			11			14		
*06:11, 06:52								8						14		
*06:14, 06:35								8			11					
*06:17											11			14		
*06:31								8			11			14		
*06:32											11			14		
*06:67								8			11			14		
*07:01:01-07:02:07, 07:02:10-07:02:28, 07:03-07:06, 07:08, 07:11-07:19, 07:21-07:25, 07:27:01-07:27:02, 07:29-07:30, 07:32N, 07:35-07:38, 07:42, 07:44-07:48, 07:50-07:52, 07:54-07:63, 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, 07:162-07:172, 07:174-07:176, 07:178-07:183, 07:185-07:195, 07:197-07:209, 07:211-07:215, 07:217-07:220									9							
*07:02:08, 07:02:29, 07:26, 07:33N, 07:39-07:40, 07:92, 07:139, 07:152N, 07:156									9							
*07:02:09						6			9				13			
*07:07, 07:09, 07:49, 07:76									9		11					
*07:10, 07:28, 07:41, 07:43, 07:184, 07:196									9							
*07:20									9							
*07:31									9							
*07:53, 07:216									9							
*07:64									9							16
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16

101.601.24/12 – including *Taq* pol., IFU-01 Rev. No. 03  
 101.601.24u/12u – without *Taq* pol., IFU-02 Rev. No. 03

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 “Instructions for Use” (IFU)

Lot No.: **64N**

Lot-specific information

17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Well No.
																HLA-C allele <sup>4</sup>
				21										31		*05:58:01
		19		21												*05:62
						23								31		*06:02:01:01-06:02:01:02, 06:02:03-06:02:11, 06:02:13-06:02:15, 06:02:17-06:02:19, 06:07, 06:10, 06:12-06:13, 06:15-06:16N, 06:18-06:30, 06:33-06:34, 06:36-06:39, 06:41-06:51, 06:53-06:66, 06:68-06:69
						23								31		*06:02:12
						23								31		*06:02:16
					22									31		*06:03
						23										*06:04, 06:40
	18		20			23			26					31		*06:05
			20			23			26					31		*06:06
						23								31		*06:08
				21		23								31		*06:09
						23										*06:11, 06:52
				21		23								31		*06:14, 06:35
			20			23								31		*06:17
	18		20			23								31		*06:31
						23								31		*06:32
						23			26					31		*06:67
						23										*07:01:01-07:02:07, 07:02:10-07:02:28, 07:03-07:06, 07:08, 07:11-07:19, 07:21-07:25, 07:27:01-07:27:02, 07:29-07:30, 07:32N, 07:35-07:38, 07:42, 07:44-07:48, 07:50-07:52, 07:54-07:63, 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, 07:162-07:172, 07:174-07:176, 07:178-07:183, 07:185-07:195, 07:197-07:209, 07:211-07:215, 07:217-07:220
																*07:02:08, 07:02:29, 07:26, 07:33N, 07:39-07:40, 07:92, 07:139, 07:152N, 07:156
	18					23				27						*07:02:09
			20			23										*07:07, 07:09, 07:49, 07:76
				21		23										*07:10, 07:28, 07:41, 07:43, 07:184, 07:196
						23						29				*07:20
	18					23										*07:31
						23								30		*07:53, 07:216
																*07:64
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Well No.

Negative Control



101.601.24/12 – including *Taq* pol., IFU-01 Rev. No. 03  
 101.601.24u/12u – without *Taq* pol., IFU-02 Rev. No. 03

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 “Instructions for Use” (IFU)

Lot No.: **64N**

Lot-specific information

Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
HLA-C allele <sup>4</sup>																
*07:96			3						9							
*07:101, 07:148, 07:161		2							9	10						
*07:123, 07:173									9							
*07:125						6			9				13	14		
*07:177									9							
*07:210									9		11					
*08:01:01-08:01:05, 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, 08:46, 08:50, 08:56										10						
*08:02:01-08:02:07, 08:04, 08:13, 08:15:01-08:15:02, 08:17-08:19, 08:23, 08:27, 08:29-08:30, 08:32-08:35, 08:37, 08:39, 08:43, 08:45, 08:49, 08:51-08:55N										10						
*08:05										10			13			
*08:07, 08:47										10						
*08:09, 08:11										10						
*08:10							7			10	11				15	
*08:12										10						
*08:21										10			13			
*08:25										10			13			
*08:31		2								10						
*08:48										10						
*12:02:01-12:02:07, 12:10:01-12:10:02, 12:17-12:18, 12:20, 12:22, 12:30, 12:36, 12:40, 12:56, 12:64, 12:67-12:68												12	13			
*12:03:01:01-12:03:01:02, 12:03:03, 12:03:05-12:03:07, 12:03:10-12:03:12, 12:03:14-12:03:15, 12:03:18-12:03:19, 12:06-12:07, 12:11-12:13, 12:19, 12:23, 12:25, 12:29, 12:32, 12:34-12:35, 12:37-12:39N, 12:42Q-12:43, 12:45-12:48, 12:50-12:53, 12:57, 12:61-12:63, 12:65-12:66												12	13	14		
*12:03:02, 12:03:08, 12:03:16, 12:03:20, 12:26, 12:59													13	14		
*12:03:04												12		14		
*12:03:09								8				12		14		
*12:03:13												12	w	14		
*12:03:17												12	13	14		
*12:04:01, 12:33											11			14	15	
*12:04:02, 12:60											11	12	13	14	15	
*12:05											11	12		14	15	
*12:08												12	13			
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16

101.601.24/12 – including *Taq* pol., IFU-01 Rev. No. 03  
 101.601.24u/12u – without *Taq* pol., IFU-02 Rev. No. 03

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Lot No.: **64N**

Lot-specific information

17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Well No.
																HLA-C allele <sup>4</sup>
					22							29				*07:96
						23			26							*07:101, 07:148, 07:161
17						23										*07:123, 07:173
						23										*07:125
	18															*07:177
			20													*07:210
	18			21						27						*08:01:01-08:01:05, 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, 08:46, 08:50, 08:56
				21						27						*08:02:01-08:02:07, 08:04, 08:13, 08:15:01-08:15:02, 08:17-08:19, 08:23, 08:27, 08:29-08:30, 08:32-08:35, 08:37, 08:39, 08:43, 08:45, 08:49, 08:51-08:55N
				21				26	27							*08:05
		19		21						27						*08:07, 08:47
	18									27						*08:09, 08:11
	18			21												*08:10
			20	21				26	27							*08:12
	18			21				26	27							*08:21
				21						27						*08:25
				21						27						*08:31
										27						*08:48
										27						*12:02:01-12:02:07, 12:10:01-12:10:02, 12:17-12:18, 12:20, 12:22, 12:30, 12:36, 12:40, 12:56, 12:64, 12:67-12:68
										27						*12:03:01:01-12:03:01:02, 12:03:03, 12:03:05-12:03:07, 12:03:10-12:03:12, 12:03:14-12:03:15, 12:03:18-12:03:19, 12:06-12:07, 12:11-12:13, 12:19, 12:23, 12:25, 12:29, 12:32, 12:34-12:35, 12:37-12:39N, 12:42Q-12:43, 12:45-12:48, 12:50-12:53, 12:57, 12:61-12:63, 12:65-12:66
										27						*12:03:02, 12:03:08, 12:03:16, 12:03:20, 12:26, 12:59
																*12:03:04
																*12:03:09
										27						*12:03:13
							24			27						*12:03:17
														31		*12:04:01, 12:33
														31		*12:04:02, 12:60
														31		*12:05
17										27						*12:08
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Well No.

Negative Control



101.601.24/12 – including *Taq* pol., IFU-01 Rev. No. 03  
 101.601.24u/12u – without *Taq* pol., IFU-02 Rev. No. 03

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 “Instructions for Use” (IFU)

Lot No.: **64N**

Lot-specific information

Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
HLA-C allele <sup>4</sup>																
*12:09											11				15	
*12:14:01													13			
*12:14:02												12	13			
*12:15								8				12	13	14		
*12:16												12	13			
*12:21											11	12			15	
*12:24												12	13			
*12:27												12	13			
*12:28, 12:58												12	13	14		
*12:31												12	13	14		
*12:41											11	12	13		15	
*12:44												12	13			
*12:49												12				
*12:54											11	12	13	14		
*12:55												12	13	14		16
*14:02:01-14:02:02, 14:02:04- 14:02:07, 14:02:09, 14:07N, 14:11, 14:13-14:14, 14:18-14:21N, 14:23- 14:24, 14:26-14:27, 14:29-14:34																16
*14:02:03, 14:03, 14:22																16
*14:02:08												12				16
*14:04											11					16
*14:05																16
*14:06, 14:09, 14:28																16
*14:08																16
*14:10																16
*14:12											11					16
*14:15																16
*14:16														14		16
*14:17																16
*14:25		2														16
*15:02:01-15:02:07, 15:13, 15:15, 15:18, 15:26, 15:28, 15:31-15:35, 15:38-15:39, 15:41, 15:44-15:45, 15:47-15:53, 15:56			3					8			11				15	
*15:03			3					8			11		13		15	
*15:04-15:06:03, 15:09, 15:19, 15:24, 15:29-15:30, 15:40, 15:46, 15:54			3								11				15	
*15:07			3					8								
*15:08			3					8			11				15	
*15:10:01								8			11				15	
*15:10:02, 15:17			3					8			11				15	
*15:11			3			6		8			11				15	
*15:12					5			8			11				15	
*15:16			3					8			11		13		15	
*15:20, 15:27			3								11				15	
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16

101.601.24/12 – including *Taq* pol., IFU-01 Rev. No. 03  
 101.601.24u/12u – without *Taq* pol., IFU-02 Rev. No. 03

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Lot No.: **64N**

Lot-specific information

17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Well No.
																HLA-C allele <sup>4</sup>
			20						26					31		*12:09
	18	19								27						*12:14:01
	18	19								27						*12:14:02
17										27						*12:15
						23				27						*12:16
														31		*12:21
			20						26	27						*12:24
																*12:27
	18									27						*12:28, 12:58
				21						27						*12:31
														31		*12:41
				21						27						*12:44
										27						*12:49
																*12:54
										27						*12:55
			20						26		28					*14:02:01-14:02:02, 14:02:04-14:02:07, 14:02:09, 14:07N, 14:11, 14:13-14:14, 14:18-14:21N, 14:23-14:24, 14:26-14:27, 14:29-14:34
			20						26	27	28					*14:02:03, 14:03, 14:22
			20						26		28					*14:02:08
			20						26		28					*14:04
			20						26							*14:05
																*14:06, 14:09, 14:28
										27						*14:08
	18		20						26	27	28					*14:10
			20						26		28			31		*14:12
	18															*14:15
																*14:16
		19	20						26		28					*14:17
			20		22				26		28					*14:25
17				21								29				*15:02:01-15:02:07, 15:13, 15:15, 15:18, 15:26, 15:28, 15:31-15:35, 15:38-15:39, 15:41, 15:44-15:45, 15:47-15:53, 15:56
17				21								29				*15:03
17				21								29				*15:04-15:06:03, 15:09, 15:19, 15:24, 15:29-15:30, 15:40, 15:46, 15:54
17				21						27		29				*15:07
17				21								29		31		*15:08
17				21												*15:10:01
17				21												*15:10:02, 15:17
17				21												*15:11
17	18			21								29				*15:12
17				21												*15:16
17				21												*15:20, 15:27
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Well No.

Negative Control



101.601.24/12 – including *Taq* pol., IFU-01 Rev. No. 03  
 101.601.24u/12u – without *Taq* pol., IFU-02 Rev. No. 03

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 “Instructions for Use” (IFU)

Lot No.: **64N**

Lot-specific information

Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
HLA-C allele <sup>4</sup>																
*15:21			3					8								15
*15:22, 15:55			3								11					15
*15:23											11					
*15:25			3										13			
*15:36						6					11					
*15:37			3					8			11					15
*15:42		2	3					8			11					15
*15:43			3					8								
*16:01:01, 16:01:03-16:01:07, 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, 16:36, 16:38-16:39, 16:41, 16:44													13			
*16:01:02													13			
*16:02:01-16:02:09, 16:09, 16:12, 16:19, 16:25											11		13		15	
*16:04, 16:33, 16:42														14		
*16:15:02												12	13			
*16:18													13			
*16:20													13			
*16:29		2												14		
*16:34			3			6							13			
*16:35																
*16:37													13		15	
*16:40							7									16
*16:43													13			
*17:01:01:01-17:01:03, 17:01:05-17:04, 17:06, 17:08-17:11		2									11					15
*17:01:04		2									11		13		15	
*17:05		2									11				15	
*17:07											11				15	
*18:01-18:02, 18:04-18:05											11					
*18:03		2									11					
A*24:106, A*24:174, B*46:25																
B*14:03																
B*35:08:02, B*35:08:05																
B*67:02													13			
HLA-C allele <sup>4</sup>																
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16



101.601.24/12 – including *Taq* pol., IFU-01 Rev. No. 03  
 101.601.24u/12u – without *Taq* pol., IFU-02 Rev. No. 03

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 “Instructions for Use” (IFU)

Lot No.: **64N**

Lot-specific information

17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Well No.
																HLA-C allele <sup>4</sup>
17				21						w		29				*15:21
17												29				*15:22, 15:55
17				21								29				*15:23
	18	19		21						27						*15:25
17				21								29				*15:36
17											28	29				*15:37
17				21								29				*15:42
17				21	22											*15:43
	18									27			30			*16:01:01, 16:01:03-16:01:07, 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, 16:36, 16:38-16:39, 16:41, 16:44
	18												30			*16:01:02
	18												30			*16:02:01-16:02:09, 16:09, 16:12, 16:19, 16:25
	18		20							27						*16:04, 16:33, 16:42
	18									27			30			*16:15:02
	18									27	28		30			*16:18
17	18									27			30			*16:20
	18		20							27						*16:29
	18							25		27			30			*16:34
	18									27						*16:35
	18									w			30			*16:37
										27						*16:40
										27			30			*16:43
		19		21												*17:01:01:01-17:01:03, 17:01:05-17:04, 17:06, 17:08-17:11
		19		21												*17:01:04
		19		21				26								*17:05
		19		21												*17:07
			20	21		23								31		*18:01-18:02, 18:04-18:05
			20	21	22	23								31		*18:03
													30			A*24:106, A*24:174, B*46:25
			20						26							B*14:03
										27						B*35:08:02, B*35:08:05
										27						B*67:02
																HLA-C allele <sup>4</sup>
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Well No.

Negative Control



101.601.24/12 – including *Taq* pol., IFU-01 Rev. No. 03  
101.601.24u/12u – without *Taq* pol., IFU-02 Rev. No. 03

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**Lot No.: 64N****Lot-specific information**

<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 to 10, 12 to 15, 17, 19, 20 and 24 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 [www.ebi.ac.uk/imgt/hla](http://www.ebi.ac.uk/imgt/hla) web site. The sequence of the 3 terminal nucleotides of the primer is given.

<sup>3</sup>The nucleotide position, in the 2<sup>nd</sup>, 3<sup>rd</sup> or 4<sup>th</sup> exon or the 3<sup>rd</sup> intron, 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](http://www.ebi.ac.uk/imgt/hla) web site. The sequence of the 3 terminal nucleotides of the primer is given.

<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.

<sup>5</sup>The C\*01:05, 01:22 and 01:35-01:36 and the B\*54:18 alleles give rise to identical amplification patterns with the HLA-C low resolution primer set. These alleles are separated by the HLA-B low primer set.

<sup>6</sup>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.

101.601.24/12 – including *Taq* pol., IFU-01 Rev. No. 03  
 101.601.24u/12u – without *Taq* pol., IFU-02 Rev. No. 03

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Lot No.: **64N**

Lot-specific information

				<b>CELL LINE VALIDATION SHEET</b>																
				<b>HLA-C low resolution SSP primer set</b>																
				<b>Well</b>																
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	
				Prod. No.:	201188801	201188802	201188803	201188804	201188805	201200306	201200307	201200308	201188809	201188810	201188811	201200312	201200313	201188814	201200315	201200316
<b>IHWC cell line</b>		<b>C*</b>																		
1	9001 SA	*07:02		-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-
2	9280 LK707	*07:01	*15:05	-	-	+	-	-	-	-	-	-	+	-	+	-	-	-	+	-
3	9011 E4181324	*12:02		-	-	-	-	-	-	-	-	-	-	-	-	+	+	-	-	-
4	9275 GU373	*03:04	*04:01	-	-	+	+	-	+	-	-	-	-	-	+	-	+	-	-	-
5	9009 KAS011	*06:02		-	-	-	-	-	-	-	-	+	-	-	+	-	-	+	-	-
6	9353 SM	*03:04	*07:02	-	-	+	+	-	-	-	-	-	+	-	-	-	-	-	-	-
7	9020 QBL	*05:01		-	-	-	-	-	-	-	+	-	-	-	+	-	-	-	+	-
8	9025 DEU	*04:01		-	-	-	-	-	-	+	-	-	-	-	+	-	+	-	-	-
9	9026 YAR	*12:03		-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	-	-
10	9107 LKT3	*01:02		+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
11	9051 PITOUT	*16:01		-	-	-	-	-	-	-	-	-	-	-	-	-	+	-	-	-
12	9052 DBB	*06:02		-	-	-	-	-	-	-	-	+	-	-	+	-	-	+	-	-
13	9004 JESTHOM	*01:02		+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
14	9071 OLGA	*01:02	*03:04	+	-	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-
15	9075 DKB	*03:04		-	-	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-
16	9037 SWEIG007	*02:02		-	+	+	-	-	+	-	-	-	-	-	+	-	-	-	+	-
17	9282 CTM3953540	*03:03	*07:01	-	-	-	+	+	-	-	-	-	+	-	-	-	-	-	-	-
18	9257 32367	*01:02	*07:05	+	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-
19	9038 BM16	*07:01		-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-
20	9059 SLE005	*03:04		-	-	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-
21	9064 AMALA	*03:03		-	-	-	+	+	-	-	-	-	-	-	-	-	-	-	-	-
22	9056 KOSE	*12:03		-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	-	-
23	9124 IHL	*01:02	*15:02	+	-	+	-	-	-	-	+	-	-	-	+	-	-	-	+	-
24	9035 JBUSH	*12:03		-	-	-	-	-	-	-	-	-	-	-	+	+	+	-	-	-
25	9049 IBW9	*08:02		-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-
26	9285 WT49	*07:01		-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-
27	9191 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 HAG	*17:01	*17:03	-	+	-	-	-	-	-	-	-	-	-	+	-	-	-	+	-
33	9098 MT14B	*03:04		-	-	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-
34	9104 DHIF	*12:03		-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	-	-
35	9302 SSTO	*05:01		-	-	-	-	-	-	-	+	-	-	-	+	-	-	-	+	-
36	9024 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	+	-	-	-	-	-	-	-	+	-	-	+	-	-	+	-	-
41	9055 H0301	*08:02		-	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-
42	9066 TAB089	*01:02		+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
43	9076 T7526	*01:02	*08:01	+	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-
44	9057 TEM	*12:03		-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	-	-
45	9239 SHJO	*06:02	*17:01	-	+	-	-	-	-	-	-	+	-	-	+	-	-	+	+	-
46	9013 SCHU	*07:02		-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-
47	9045 TUBO	*07:04	*15:02	-	-	+	-	-	-	-	-	+	-	-	+	-	-	-	+	-
48	9303 TER-ND	*04:01	*16:01	-	-	-	-	-	-	+	-	-	-	-	+	-	+	-	-	-



101.601.24/12 – including *Taq* pol., IFU-01 Rev. No. 03  
 101.601.24u/12u – without *Taq* pol., IFU-02 Rev. No. 03

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Lot No.: **64N**

Lot-specific information

				Well															
				17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	
				Prod. No.:	201200317	201188818	201188819	201188820	201188821	201188822	201200323	201200324	201200325	201200326	201200327	201200328	201200329	201200330	201200331
IHWC cell line		C*																	
1	9001 SA	*07:02		-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	
2	9280 LK707	*07:01	*15:05	+	-	-	-	+	-	+	-	-	-	-	-	+	-	-	
3	9011 E4181324	*12:02		-	-	-	-	-	-	-	-	-	-	+	-	-	-	-	
4	9275 GU373	*03:04	*04:01	-	+	-	-	+	+	-	-	+	-	-	-	-	-	+	
5	9009 KAS011	*06:02		-	-	-	-	-	-	-	+	-	-	-	-	-	-	+	
6	9353 SM	*03:04	*07:02	-	-	-	-	+	+	+	-	-	-	-	-	-	-	-	
7	9020 QBL	*05:01		-	-	-	-	+	-	-	-	-	-	-	-	-	-	+	
8	9025 DEU	*04:01		-	+	-	-	+	-	-	-	+	-	-	-	-	-	+	
9	9026 YAR	*12:03		-	-	-	-	-	-	-	-	-	-	+	-	-	-	-	
10	9107 LKT3	*01:02		-	-	-	+	-	-	-	-	-	+	-	-	-	-	-	
11	9051 PITOUT	*16:01		-	+	-	-	-	-	-	-	-	-	-	+	-	-	+	
12	9052 DBB	*06:02		-	-	-	-	-	-	-	+	-	-	-	-	-	-	+	
13	9004 JESTHOM	*01:02		-	-	-	+	-	-	-	-	-	+	-	-	-	-	-	
14	9071 OLGA	*01:02	*03:04	-	-	-	+	+	+	-	-	-	+	-	-	-	-	-	
15	9075 DKB	*03:04		-	-	-	-	+	+	-	-	-	-	-	-	-	-	-	
16	9037 SWEIG007	*02:02		-	-	-	-	-	-	-	-	+	-	-	-	-	-	+	
17	9282 CTM3953540	*03:03	*07:01	-	-	-	-	+	+	+	-	-	-	-	-	-	-	-	
18	9257 32367	*01:02	*07:05	-	-	-	+	-	-	+	-	-	+	-	-	-	-	-	
19	9038 BM16	*07:01		-	-	-	-	-	-	+	-	-	-	-	-	-	-	-	
20	9059 SLE005	*03:04		-	-	-	-	+	+	-	-	-	-	-	-	-	-	-	
21	9064 AMALA	*03:03		-	-	-	-	+	+	-	-	-	-	-	-	-	-	-	
22	9056 KOSE	*12:03		-	-	-	-	-	-	-	-	-	-	+	-	-	-	-	
23	9124 IHL	*01:02	*15:02	+	-	-	+	+	-	-	-	-	+	-	-	+	-	-	
24	9035 JBUSH	*12:03		-	-	-	-	-	-	-	-	-	-	+	-	-	-	-	
25	9049 IBW9	*08:02		-	-	-	-	+	-	-	-	-	-	+	-	-	-	-	
26	9285 WT49	*07:01		-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	
27	9191 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 HAG	*17:01	*17:03	-	-	+	-	+	-	-	-	-	-	-	-	-	-	-	
33	9098 MT14B	*03:04		-	-	-	-	+	-	-	-	-	-	-	-	-	-	-	
34	9104 DHIF	*12:03		-	-	-	-	-	-	-	-	-	-	+	-	-	-	-	
35	9302 SSTO	*05:01		-	-	-	-	+	-	-	-	-	-	-	-	-	-	+	
36	9024 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	-	-	-	+	-	-	+	-	-	+	-	-	-	-	+	
41	9055 H0301	*08:02		-	-	-	-	+	-	-	-	-	-	+	-	-	-	-	
42	9066 TAB089	*01:02		-	-	-	+	-	-	-	-	-	+	-	-	-	-	-	
43	9076 T7526	*01:02	*08:01	-	+	-	+	+	-	-	-	-	+	+	-	-	-	-	
44	9057 TEM	*12:03		-	-	-	-	-	-	-	-	-	-	+	-	-	-	-	
45	9239 SHJO	*06:02	*17:01	-	-	+	-	+	-	+	-	-	-	-	-	-	-	+	
46	9013 SCHU	*07:02		-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	
47	9045 TUBO	*07:04	*15:02	+	-	-	-	+	-	+	-	-	-	-	-	-	+	-	
48	9303 TER-ND	*04:01	*16:01	-	+	-	-	+	-	-	-	+	-	+	-	-	+	+	



101.601.24/12 – including *Taq* pol., IFU-01 Rev. No. 03  
 101.601.24u/12u – without *Taq* pol., IFU-02 Rev. No. 03

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Lot No.: **64N**

Lot-specific information

## CERTIFICATE OF ANALYSIS

### Olerup SSP® HLA-C low resolution SSP

**Product number:** 101.601-24/12 – including *Taq* pol.  
 101.601-24u/12u – without *Taq* pol.  
**Lot number:** 64N  
**Expiry date:** 2014-October-01  
**Number of tests:** 24 tests – Product No. 101.601-24/24u  
 12 tests – Product No. 101.601-12/12u  
**Number of wells per test:** 31 + 1

#### Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2011-888-01	13	2012-003-13	25	2012-003-25
2	2011-888-02	14	2011-888-14	26	2012-003-26
3	2011-888-03	15	2012-003-15	27	2012-003-27
4	2011-888-04	16	2012-003-16	28	2012-003-28
5	2011-888-05	17	2012-003-17	29	2012-003-29
6	2012-003-06	18	2011-888-18	30	2012-003-30
7	2012-003-07	19	2011-888-19	31	2012-003-31
8	2012-003-08	20	2011-888-20		
9	2011-888-09	21	2011-888-21		
10	2011-888-10	22	2011-888-22		
11	2011-888-11	23	2012-003-23		
12	2012-003-12	24	2012-003-24		

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, 7, 13 to 16, 22, 26, 28 and 30 were tested by separately adding one 3'-primer. Additional 3'-primers in primer solutions 2, 7, 10, 14 to 16, 18, 19, 22, 26 and 28 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. 2010-928-01**, can detect contamination with PCR products diluted  $10^{-7}$ .

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

**Date of approval:** 2012-April-20

**Approved by:**

#### Production Quality Control

101.601.24/12 – including **Taq pol.**, IFU-01 Rev. No. 03  
101.601.24u/12u – without **Taq pol.**, IFU-02 Rev. No. 03

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“Instructions for Use” (IFU)

Lot No.: **64N**

Lot-specific information

## Declaration of Conformity

**Product name:** Olerup SSP® HLA-C low resolution  
**Product number:** 101.601-24/24u, -12/12u  
**Lot number:** 64N

**Intended use:** HLA-C 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 13485:2004, 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 Documentation File is maintained at Olerup SSP AB, Franzengatan 5, SE-112 51 Stockholm, Sweden.

Stockholm, Sweden  
2012-May-23

Ann-Cathrin Jareman  
Head of QA and Regulatory Affairs

101.601.24/12 – including *Taq* pol., IFU-01 Rev. No. 03  
101.601.24u/12u – without *Taq* pol., IFU-02 Rev. No. 03

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101.601.24/12 – including *Taq pol.*, IFU-01 Rev. No. 03  
101.601.24u/12u – without *Taq pol.*, IFU-02 Rev. No. 03

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