

101.612-12 – including *Taq* pol., IFU-01
101.612-12u – without *Taq* pol., IFU-02

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“Instructions for Use” (IFU)

Lot No.: **60R**

Lot-specific information
Olerup SSP[®] HLA-C*04

Product number:	101.612-12 – including <i>Taq</i> polymerase 101.612-12u – without <i>Taq</i> polymerase
Lot number:	60R
Expiry date:	2015-June-01
Number of tests:	12
Number of wells per test:	48
Storage - pre-aliquoted primers:	dark at -20°C
- PCR Master Mix:	-20°C
- Adhesive PCR seals	RT
- Product Insert	RT

This Product Description is only valid for Lot No. 60R.

**CHANGES COMPARED TO THE PREVIOUS OLERUP SSP[®]
HLA-C*04 LOT (79N)**

The HLA-C*04 specificity and interpretation tables have been updated for the HLA-C alleles described since the previous *Olerup SSP[®]* HLA-C*04 lot was made (Lot No. 79N).

The HLA-C*04 kit is updated for new alleles to enable separation of:

- Confirmed¹ alleles as listed in the IMGT/HLA database
- Polymorphisms in exons outside of the region encoding the peptide binding domain
- Null and Alternatively expressed alleles

One new well has been added to the HLA-C*04 kit, well **48**.

The Lot-specific information for HLA-C*04 including and without *Taq* polymerase is described in one common Product Insert.

¹As described in section Uniquely Identified Alleles.

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

Well	5'-primer	3'-primer	rationale
9	-	-	Exchanged positive control primer pair.
14	-	Removed	3'-primer removed for improved specificity of amplification and decreased tendencies of primer oligomer formation.
16	Added	-	5'-primer added for the C*04:123N allele.
27	-	Added	3'-primer added for the C*04:120 allele.
29	Added	Added	Primer pair added for the C*04:82 allele.
34	-	Added	3'-primer added for the C*04:120 allele.
35	-	Added	3'-primer added for the C*04:115N allele.
38	Added	-	5'-primer added for the C*04:123N allele.
40	-	Added	3'-primer added for the C*04:64:02 allele.
42	Exchanged	Exchanged	Exchanged primer pair for the C*04:82 allele.
43	-	Added	3'-primer added for the C*04:115N allele.
44	Added	-	5'-primer added for the C*04:108 allele.
47	Moved, added	Moved, added	Primer pairs moved to well 48, new primer pair for the C*04:114 allele.
48	New	New	Primer pair from well 47.

Change in revision R01 compared to R00:

1. Primer mix 1 may amplify the C*04:110 allele. This has been corrected in the Specificity and Interpretation Tables.

Change in revision R02 compared to R01:

1. The HLA-C*04:15:02 and 04:17 and the C*03:13:01, 03:35, 08:01:07, 08:02:07 and 08:33:02 alleles are amplified by primer mix 16. This has been corrected in the Specificity and Interpretation Tables.

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PRODUCT DESCRIPTION

HLA-C*04 SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for identifying the HLA-C*04:01 to HLA-C*04:127 alleles.

PLATE LAYOUT

Each test consists of 48 PCR reactions in a 48 well PCR plate.

1	2	3	4	5	6	7	8
9	10	11	12	13	14	15	16
17	18	19	20	21	22	23	24
25	26	27	28	29	30	31	32
33	34	35	36	37	38	39	40
41	42	43	44	45	46	47	48

The 48 well cut PCR plate is marked with 'HLA-C*04' in silver/gray ink.

Well No. 1 is marked with the Lot No. '60R'.

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 heat-sealed with a PCR-compatible foil.

Please note: When removing each 48 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

The interpretation of HLA-C*04 SSP subtypings will be influenced by other HLA-C alleles, as primer mixes 1, 2, 4, 5, 7, 8, 10 to 12, 15 to 20, 24, 25, 27, 30, 33, 34, 39, 41, 42, 44, 47 and 48 amplify non-HLA-C*04 alleles. In addition, the A*24:96 and A*24:146 alleles will be amplified by primer mix 15, the A*33:52 allele will be amplified by primer mix 20, the A*68:46 allele will be amplified by primer mix 47, the B*07:90 allele will be amplified by primer mix 30, the B*15:27:01-15:27:03 and 15:109 alleles will be amplified by primer mixes 18 and 25, the B*15:78:03 allele will be amplified by primer mixes 16 and 44, the B*40:100 allele will be amplified by primer mixes 32 and 33 and the B*58:02 allele will be amplified by primer mixes 5 and 8.

UNIQUELY IDENTIFIED ALLELES

All the HLA-C*04 alleles, i.e. **C*04:01 to C*04:127**, recognized by the HLA Nomenclature Committee in July 2012¹ will be amplified by the primers in the HLA-C*04 kit².

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The HLA-C*04 kit enables separation of the confirmed HLA-C*04 alleles as listed in the IMGT/HLA database. An HLA allele is listed as confirmed by IMGT/HLA if it has been sequenced by more than a single laboratory or from multiple sources. Current allele confirmation status for HLA-C*04 alleles is listed below.

The HLA-C*04 kit also enables identification of polymorphisms in exons outside of the region encoding the peptide binding domain and of null and alternatively expressed alleles.

The HLA-C*04 primer set cannot distinguish the following silent mutations: the C*04:01:01:01-04:01:09, 04:01:11-04:01:22, 04:01:24-04:01:27 and 04:01:29-04:01:41 alleles, the C*04:01:10 and 04:01:23 alleles, the C*04:04:01-04:04:02 alleles, the C*04:15:01 and 04:15:03 alleles, the C*04:64:01-04:64:02 alleles and the C*04:94:01-04:94:02 alleles.

The C*04:44 and C*04:47 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 20.

The C*04:23, C*04:38 and C*04:39 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 21.

The C*04:25, C*04:40 and C*04:41 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 23.

The C*04:44 and C*04:47 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 20.

The C*04:46 and C*04:50 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 27.

The C*04:48 and C*04:75 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 28.

The C*04:54 and C*04:105N alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 41.

The C*04:56 and C*04:64:01-04:64:02 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 40.

The C*04:59Q and C*04:78 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 32.

The C*04:61 and C*04:96 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 34.

The C*04:62 and C*04:76 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 35.

The C*04:65 and C*04:72 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 33.

The C*04:67 and C*04:93N alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 46.

The C*04:81 and C*04:88N alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 43.

The C*04:84 and C*04:106 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 48.

¹HLA-C alleles listed on the IMGT/HLA web page 2012-July-12, release 3.9.0, www.ebi.ac.uk/imgt/hla.

²The HLA-C*04 primer set cannot separate the C*04:03 and 02:49 alleles or the C*04:107 and the C*02:12 and 02:55 alleles. These alleles can be distinguished by the HLA-C low resolution kit and/or the HLA-C*02 high resolution kit.

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ALLELE CONFIRMATION STATUS

Allele	Status ¹	Allele	Status ¹	Allele	Status ¹	Allele	Status ¹
C*04:01:01:01	Confirmed	C*04:07	Confirmed	C*04:57	Unconfirmed	C*04:105N	Unconfirmed
C*04:01:01:02	Unconfirmed	C*04:08	Confirmed	C*04:58	Confirmed	C*04:106	Unconfirmed
C*04:01:01:03	Unconfirmed	C*04:09N	Confirmed	C*04:59Q	Confirmed	C*04:107	Unconfirmed
C*04:01:01:04	Unconfirmed	C*04:10	Confirmed	C*04:60	Unconfirmed	C*04:108	Confirmed
C*04:01:01:05	Unconfirmed	C*04:11	Unconfirmed	C*04:61	Confirmed	C*04:109	Unconfirmed
C*04:01:02	Unconfirmed	C*04:12	Unconfirmed	C*04:62	Confirmed	C*04:110	Unconfirmed
C*04:01:03	Unconfirmed	C*04:13	Confirmed	C*04:63	Confirmed	C*04:111	Unconfirmed
C*04:01:04	Confirmed	C*04:14	Confirmed	C*04:64:01	Unconfirmed	C*04:112	Unconfirmed
C*04:01:05	Unconfirmed	C*04:15:01	Unconfirmed	C*04:64:02	Unconfirmed	C*04:113	Unconfirmed
C*04:01:06	Unconfirmed	C*04:15:02	Confirmed	C*04:65	Confirmed	C*04:114	Confirmed
C*04:01:07	Unconfirmed	C*04:15:03	Unconfirmed	C*04:66	Unconfirmed	C*04:115N	Unconfirmed
C*04:01:08	Confirmed	C*04:16	Confirmed	C*04:67	Unconfirmed	C*04:116	Unconfirmed
C*04:01:09	Confirmed	C*04:17	Unconfirmed	C*04:68	Confirmed	C*04:117	Unconfirmed
C*04:01:10	Confirmed	C*04:18	Unconfirmed	C*04:69	Confirmed	C*04:118	Unconfirmed
C*04:01:11	Confirmed	C*04:19	Unconfirmed	C*04:70	Unconfirmed	C*04:119	Unconfirmed
C*04:01:12	Confirmed	C*04:20	Unconfirmed	C*04:71	Unconfirmed	C*04:120	Confirmed
C*04:01:13	Confirmed	C*04:23	Unconfirmed	C*04:72	Unconfirmed	C*04:121	Unconfirmed
C*04:01:14	Confirmed	C*04:24	Unconfirmed	C*04:73	Unconfirmed	C*04:122	Unconfirmed
C*04:01:15	Confirmed	C*04:25	Unconfirmed	C*04:74	Confirmed	C*04:123N	Unconfirmed
C*04:01:16	Confirmed	C*04:26	Confirmed	C*04:75	Unconfirmed	C*04:124	Unconfirmed
C*04:01:17	Unconfirmed	C*04:27	Confirmed	C*04:76	Unconfirmed	C*04:125	Unconfirmed
C*04:01:18	Unconfirmed	C*04:28	Unconfirmed	C*04:77	Confirmed	C*04:126	Unconfirmed
C*04:01:19	Unconfirmed	C*04:29	Confirmed	C*04:78	Unconfirmed	C*04:127	Unconfirmed
C*04:01:20	Unconfirmed	C*04:30	Unconfirmed	C*04:79	Unconfirmed		
C*04:01:21	Confirmed	C*04:31	Unconfirmed	C*04:80	Unconfirmed		
C*04:01:22	Unconfirmed	C*04:32	Confirmed	C*04:81	Confirmed		
C*04:01:23	Unconfirmed	C*04:33	Confirmed	C*04:82	Unconfirmed		
C*04:01:24	Unconfirmed	C*04:34	Unconfirmed	C*04:83	Confirmed		
C*04:01:25	Unconfirmed	C*04:35	Unconfirmed	C*04:84	Unconfirmed		
C*04:01:26	Unconfirmed	C*04:36	Confirmed	C*04:85	Unconfirmed		
C*04:01:27	Unconfirmed	C*04:37	Confirmed	C*04:86	Unconfirmed		
C*04:01:28	Confirmed	C*04:38	Confirmed	C*04:87	Unconfirmed		
C*04:01:29	Unconfirmed	C*04:39	Confirmed	C*04:88N	Unconfirmed		
C*04:01:30	Confirmed	C*04:40	Confirmed	C*04:89	Unconfirmed		
C*04:01:31	Unconfirmed	C*04:41	Unconfirmed	C*04:90	Unconfirmed		
C*04:01:32	Unconfirmed	C*04:42	Unconfirmed	C*04:91	Unconfirmed		
C*04:01:33	Confirmed	C*04:43	Confirmed	C*04:92	Unconfirmed		
C*04:01:34	Unconfirmed	C*04:44	Unconfirmed	C*04:93N	Unconfirmed		
C*04:01:35	Unconfirmed	C*04:45	Confirmed	C*04:94:01	Confirmed		
C*04:01:36	Unconfirmed	C*04:46	Unconfirmed	C*04:94:02	Unconfirmed		
C*04:01:37	Unconfirmed	C*04:47	Confirmed	C*04:95N	Unconfirmed		
C*04:01:38	Unconfirmed	C*04:48	Confirmed	C*04:96	Confirmed		
C*04:01:39	Unconfirmed	C*04:49	Unconfirmed	C*04:97	Unconfirmed		
C*04:01:40	Unconfirmed	C*04:50	Unconfirmed	C*04:98	Unconfirmed		
C*04:01:41	Unconfirmed	C*04:51	Unconfirmed	C*04:99	Unconfirmed		
C*04:03	Confirmed	C*04:52	Confirmed	C*04:100	Unconfirmed		
C*04:04:01	Confirmed	C*04:53	Unconfirmed	C*04:101	Unconfirmed		
C*04:04:02	Unconfirmed	C*04:54	Confirmed	C*04:102	Unconfirmed		
C*04:05	Unconfirmed	C*04:55	Unconfirmed	C*04:103	Confirmed		
C*04:06	Confirmed	C*04:56	Confirmed	C*04:104	Unconfirmed		

¹Allele status “confirmed” or “unconfirmed” as listed on the IMGT/HLA web page 2012-July-12, release 3.9.0, www.ebi.ac.uk/imgt/hla.

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RESOLUTION IN HOMO- AND HETEROZYGOTES

A total of 178 alleles generate 82 amplification patterns that can be combined in 3403 homozygous and heterozygous combinations. 1863 of these genotypes do not give rise to unique amplification patterns. The different lengths of the specific PCR products were not considered in these calculations.

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SPECIFICITY TABLE

HLA-C*04 SSP subtyping

Specificities and sizes of the PCR products of the 48 primer mixes used for HLA-C*04 SSP subtyping

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified HLA-C*04 alleles ³	Other amplified HLA Class I alleles ⁴
1⁷	250 bp	800 bp	*04:01:01:01-04:01:41, 04:03, 04:05, 04:07-04:12, 04:15:01-04:18, 04:19 ^w , 04:20, 04:23-04:33, 04:35-04:57, 04:59Q-04:67, 04:69-04:94:02, 04:95N ^w , 04:96-04:109, 04:110 ² , 04:112-04:121, 04:123N-04:127	*01:02:01-01:21, 01:23-01:34, 01:36-01:73, 02:02:01-02:02:03, 02:02:05-02:02:24, 02:04-02:15, 02:17, 02:19-02:40, 02:42-02:63, 05:01:01:01-05:01:21, 05:03-05:10, 05:12-05:16, 05:18:01-05:26, 05:28-05:50, 05:52-05:61, 05:63-05:67, 05:69, 05:71-05:78, 05:80-05:81, 06:02:01:01-06:02:01:02, 06:02:03-06:03:02, 06:05-06:39, 06:41-06:78, 06:80-06:87, 08:02:01-08:02:07, 08:05, 08:07, 08:12, 08:15:01-08:15:02, 08:17-08:19, 08:23, 08:25, 08:27-08:35, 08:37, 08:43, 08:45, 08:47-08:49, 08:51-08:53, 08:55N, 08:62-08:63, 08:33:03, 12:02:01-12:13, 12:15-12:17, 12:21-12:82, 14:02:01-14:05, 14:07N-14:14, 14:16-14:43, 15:08, 16:04:01, 16:29, 16:33, 16:42, 18:01-18:05
2	220 bp	1070 bp	*04:01:01:01-04:01:27, 04:01:29-04:01:41, 04:04:01-04:05, 04:07-04:09N, 04:12 ^w , 04:13-04:15:03, 04:17-04:20, 04:23-04:35, 04:37-04:41, 04:43-04:54, 04:56-04:70, 04:72-04:79, 04:81-04:102, 04:104-04:106, 04:108-04:127	*07:64
3	145 bp	1070 bp	*04:01:01:01-04:01:41, 04:04:01-04:05, 04:08-04:15:03, 04:17-04:20, 04:23-04:26, 04:28-	

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		04:41, 04:43-04:79, 04:81-04:86, 04:88N, 04:90-04:102, 04:104- 04:106, 04:108-04:127	
4⁷	210 bp	1070 bp	*04:03, 04:06, 04:80, 04:107
5⁷	250 bp	1070 bp	*04:04:01-04:04:02, 04:06, 04:13, 04:34, 04:58, 04:122
			*02:12, 02:49, 02:55
			*01:22, 01:35, 02:03, 02:16:01- 02:16:02, 02:18, 05:11, 05:17, 05:27, 05:68, 05:79, 06:04, 08:01:01-08:01:08, 08:03:01- 08:04:02, 08:06, 08:08-08:11, 08:13-08:14, 08:16:01-08:16:02, 08:20-08:22, 08:24, 08:26N, 08:36N, 08:38-08:42, 08:44, 08:46, 08:50, 08:54, 08:56-08:61, 12:14:01-12:14:02, 12:18:01- 12:18:02, 12:20, 14:06, 14:15, 15:02:01-15:07, 15:09-15:13, 15:15- 15:19, 15:21-15:24, 15:26-15:50, 15:52-15:61, 16:35, 16:40, 16:48, 17:01:01:01-17:13, B*58:02
6⁵	95 bp	1070 bp	*04:05
7⁶	145 bp	1070 bp	*04:07, 04:27, 04:32, 04:77, 04:89
8	270 bp	1070 bp	*04:08, 04:34
			*03:34, 03:142, 05:78, 07:64, 14:25, 15:36, 18:03
			*01:35, 02:58, 05:27, 05:39, 08:41, 14:20, 15:15, 17:07, B*58:02
9^{5,10}	110 bp, 180 bp, 220 bp	800 bp	*04:09N, 04:30, 04:35
10¹¹	195 bp, 220 bp	1070 bp	*04:10-04:11, 04:31, 04:36, 04:55
11⁷	180 bp	1070 bp	*04:01:01:01-04:01:09, 04:01:11-04:01:22, 04:01:24-04:01:41, 04:03-04:10, 04:12- 04:20, 04:23-04:26, 04:28-04:32, 04:34- 04:51, 04:53-04:54, 04:56-04:106, 04:108- 04:115N, 04:117- 04:127
			*05:78, 15:36
			*02:49, 05:25, 05:42, 06:05, 06:76:02, 07:02:09, 08:28, 12:28, 15:25, 16:26, 16:46
12^{5,12}	125 bp, 165 bp	1070 bp	*04:11, 04:29, 04:33, 04:36, 04:55
13¹³	225 bp, 270 bp	1070 bp	*04:12, 04:52, 04:55
			*07:125

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14 ^{6,14}	155 bp, 185 bp	1070 bp	*04:16, 04:18	
15	180 bp	1070 bp	*04:14, 04:28, 04:68	*16:45, A*24:96, A*24:146
16 ^{5,15}	85 bp, 130 bp	1070 bp	*04:15:01-04:15:03, 04:17, 04:37, 04:123N	*03:05, 03:13:01, 03:25, 03:27, 03:35, 03:135, 08:01:07, 08:02:07, 08:33:02, 14:09, B*15:78:03
17	320 bp	1070 bp	*04:17, 04:80, 04:100	*01:50
18 ^{5,16}	125 bp, 220 bp	1070 bp	*04:19, 04:70, 04:94:01- 04:94:02	*12:10:01-12:10:02, 18:03, B*15:27:01-15:27:03, B*15:109
19 ^{5,17}	120 bp, 155 bp	1070 bp	*04:20, 04:35, 04:37	*03:135
20 ¹⁸	165 bp, 250 bp, 545 bp	1070 bp	*04:15:02, 04:17, 04:44, 04:47, 04:100	*05:78, 15:36, A*33:52
21 ^{5,6,19}	85 bp, 145 bp, 240 bp	1070 bp	*04:23, 04:38-04:39, 04:108	
22	130 bp	1070 bp	*04:24	
23 ^{5,8,20}	85 bp, 145 bp, 215 bp	1070 bp	*04:25, 04:40-04:41	
24 ⁶	170 bp	1070 bp	*04:26, 04:30, 04:42	*07:125
25	200 bp	1070 bp	*04:43, 04:94:01- 04:94:02	*12:10:01-12:10:02, 18:03, B*15:27:01-15:27:03, B*15:109
26 ⁷	215 bp	800 bp	*04:45	
27 ^{5,21}	125 bp, 280 bp	800 bp	*04:46, 04:50, 04:120	*05:64, 08:19
28 ^{5,8,22}	120 bp, 215 bp	1070 bp	*04:48, 04:75	
29 ^{5,23}	105 bp, 185 bp	1070 bp	*04:49, 04:82	
30 ⁵	75 bp	1070 bp	*04:53	*05:49, B*07:90
31 ²⁴	130 bp, 180 bp	1070 bp	*04:51, 04:95N	
32 ^{5,25}	105 bp, 235 bp, 275 bp	1070 bp	*04:59Q, 04:77-04:78	B*40:100
33 ^{5,26}	80 bp, 180 bp	1070 bp	*04:58, 04:65, 04:72	*07:08, 07:108, B*40:100
34 ^{5,27}	75 bp, 200 bp, 275 bp	1070 bp	*04:13, 04:58, 04:61, 04:68, 04:96, 04:120	*05:64, 07:08, 07:108, 08:19
35 ^{5,28}	85 bp, 145 bp, 175 bp	1070 bp	*04:62, 04:76, 04:115N	

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36 ⁵	115 bp	1070 bp	*04:57, 04:63	
37 ^{5,8,29}	110 bp, 135 bp	1070 bp	*04:63, 04:73-04:74	
38 ^{5,30}	95 bp, 135 bp	1070 bp	*04:74, 04:83, 04:123N	
39 ³¹	135 bp, 330 bp	1070 bp	*04:71, 04:79, 04:95N	*01:21
40 ³²	140 bp, 270 bp	800 bp	*04:56, 04:64:01- 04:64:02	
41 ^{6,33}	135 bp, 280 bp	1070 bp	*04:54, 04:105N	*01:04, 01:54, 14:02:01-14:24:01, 14:25, 14:27-14:43
42 ⁵	100 bp	1070 bp	*04:69, 04:82	*16:12
43 ^{7,34}	145 bp, 170 bp, 260 bp	1070 bp	*04:81, 04:88N, 04:115N	
44 ^{5,35}	90 bp, 135 bp	1070 bp	*04:60, 04:108	*03:81, B*15:78:03
45 ³⁶	135 bp, 160 bp	1070 bp	*04:16, 04:66, 04:103	
46 ^{5,37}	125 bp, 300 bp	1070 bp	*04:67, 04:93N	
47 ^{5,7}	50 bp	800 bp	*04:114	*01:59, 03:130, 03:140, 05:20, 06:82, 07:49, 07:210, 07:238, 07:247, 12:54, 14:04, A*68:46
48 ^{9,38}	155 bp, 240 bp	1070 bp	*04:84, 04:106	*07:167

¹Alleles are assigned by the presence of specific PCR product(s). However, the sizes of the specific PCR products may be helpful in the interpretation of HLA-C*04 SSP typings.

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

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

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

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

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

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

Well number 1 contains the primer pair giving rise to the shorter, 800 bp, internal positive control

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band in order to help in the correct orientation of the HLA-C*04 subtyping.

In addition, wells number 9, 26, 27, 40 and 47 contains 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.

³For several HLA Class I alleles 1st and/or 4th exon(s) and beyond, as well as intron nucleotide sequences, are not available. In these instances it is not known whether some of the primers of the SSP sets are completely matched with the target sequences or not. We assume that unknown sequences in these regions are conserved within allelic groups.

⁴Due to the sharing of sequence motifs between HLA-C alleles non-HLA-C*04 alleles will be amplified by primer mixes 1, 2, 4, 5, 7, 8, 10 to 12, 15 to 20, 24, 25, 27, 30, 33, 34, 39, 41, 42, 44, 47 and 48. In addition, the A*24:96 and A*24:146 alleles will be amplified by primer mix 15, the A*33:52 allele will be amplified by primer mix 20, the A*68:46 allele will be amplified by primer mix 47, the B*07:90 allele will be amplified by primer mix 30, the B*15:27:01-15:27:03 and 15:109 alleles will be amplified by primer mixes 18 and 25, the B*15:78:03 allele will be amplified by primer mixes 16 and 44, the B*40:100 allele will be amplified by primer mixes 32 and 33 and the B*58:02 allele will be amplified by primer mixes 5 and 8.

⁵HLA-specific PCR products shorter than 125 base pairs have a lower intensity and are less sharp than longer PCR products.

⁶Primer mixes 7, 21, 24, 41 have a tendency to giving rise to primer oligomer formation.

⁷Primer mixes 1, 4, 5, 11, 26, 43 and 47 may have tendencies of unspecific amplification.

⁸Primer mixes 23, 28 and 37 may give rise to a long unspecific amplification product of approximately 500 bp. This should be disregarded when interpreting the C*04 typings.

⁹Primer mix 48 has a pronounced tendency of giving rise to primer oligomer formation, and may furthermore give rise to a lower yield of HLA-specific PCR product than the other C*04 primer mixes for the C*04:106 allele.

¹⁰Primer mix 9: Specific PCR fragment of 110 bp in the C*04:35 allele. Specific PCR fragment of 180 bp in the C*04:30 allele. Specific PCR fragment of 220 bp in the C*04:09N allele.

¹¹Primer mix 10: Specific PCR fragment of 195 bp in the C*04:31 allele. Specific PCR fragment of 220 bp in the C*04:10-04:11, 04:36 and 04:55 and the C*05:78 and 15:36 alleles.

¹²Primer mix 12: Specific PCR fragment of 125 bp in the C*04:29, 04:36 and 04:55 and the C*07:125 alleles. Specific PCR fragment of 165 bp in the C*04:33 allele. Specific PCR fragment of 125 and 165 bp in the C*04:11 allele.

¹³Primer mix 13: Specific PCR fragment of 225 bp in the C*04:12 allele. Specific PCR fragment of 270 bp in the C*04:52 and 04:55 alleles.

¹⁴Primer mix 14: Specific PCR fragment of 155 bp in the C*04:16 allele. Specific PCR fragment of 185 bp in the C*04:18 allele.

¹⁵Primer mix 16: Specific PCR fragment of 85 bp in the C*04:123N allele. Specific PCR fragment of 130 bp in the C*04:15:01-04:15:03, 04:17 and 04:37 and the C*03:05, 03:13:01, 03:25, 03:27, 03:35, 03:135, 08:01:07, 08:02:07, 08:33:02 and 14:09 and the B*15:78:03 alleles.

¹⁶Primer mix 18: Specific PCR fragment of 125 bp in the C*04:70 allele. Specific PCR fragment of 220 bp in the C*04:19 and 04:94:01-04:94:02 and the C*12:10:01-12:10:02 and 18:03 and in the B*15:27:01-15:27:03 and B*15:109 alleles.

¹⁷Primer mix 19: Specific PCR fragment of 120 bp in the C*04:35 and 04:37 alleles. Specific PCR fragment of 155 bp in the C*04:20 and the C*03:135 alleles.

¹⁸Primer mix 20: Specific PCR fragment of 165 bp in the C*04:44 allele. Specific PCR fragment of 250 bp in the C*04:47 allele. Specific PCR fragment of 545 bp in the C*04:15:02, 04:17 and 04:100 and in the C*05:78 and 15:36 and the A*33:52 alleles.

¹⁹Primer mix 21: Specific PCR fragment of 85 bp in the C*04:23 and 04:108 alleles. Specific PCR fragment of 145 bp in the C*04:38 allele. Specific PCR fragment of 240 bp in the C*04:39 allele.

²⁰Primer mix 23: Specific PCR fragment of 85 bp in the C*04:25 allele. Specific PCR fragment of 145 bp in the C*04:40 allele. Specific PCR fragment of 215 bp in the C*04:41 allele.

²¹Primer mix 27: Specific PCR fragment of 125 bp in the C*04:50 allele. Specific PCR fragment of 280 bp in the C*04:46 and 04:120 and the C*05:64 and 08:19 alleles.

²²Primer mix 28: Specific PCR fragment of 120 bp in the C*04:75 allele. Specific PCR fragment of 215 bp in the C*04:48 allele.

²³Primer mix 29: Specific PCR fragment of 105 bp in the C*04:82 allele. Specific PCR fragment of 185 bp in the C*04:49 allele.

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²⁴Primer mix 31: Specific PCR fragment of 130 bp in the C*04:95N allele. Specific PCR fragment of 180 bp in the C*04:51 allele.

²⁵Primer mix 32: Specific PCR fragment of 105 bp in the C*04:78 allele. Specific PCR fragment of 235 bp in the C*04:59Q allele. Specific PCR fragment of 275 bp in the C*04:77 and in the B*40:100 alleles.

²⁶Primer mix 33: Specific PCR fragment of 80 bp in the C*04:72 allele. Specific PCR fragment of 180 bp in the C*04:58 and 04:65 and the C*07:08 and 07:108 and in the B*40:100 alleles.

²⁷Primer mix 34: Specific PCR fragment of 75 bp in the C*04:96 allele. Specific PCR fragment of 200 bp in the C*04:13, 04:58, 04:61 and 04:68 and the C*07:08 and 07:108 alleles. Specific PCR fragment of 275 bp in the C*04:120 and the C*05:64 and 08:19 alleles.

²⁸Primer mix 35: Specific PCR fragment of 85 bp in the C*04:62 allele. Specific PCR fragment of 145 bp in the C*04:115N allele. Specific PCR fragment of 175 bp in the C*04:76 allele.

²⁹Primer mix 37: Specific PCR fragment of 110 bp in the C*04:63 and 04:73 alleles. Specific PCR fragment of 135 bp in the C*04:74 allele.

³⁰Primer mix 38: Specific PCR fragment of 95 bp in the C*04:83 and 04:123N alleles. Specific PCR fragment of 135 bp in the C*04:74 allele.

³¹Primer mix 39: Specific PCR fragment of 135 bp in the C*04:71 and 04:95N and the C*01:21 alleles. Specific PCR fragment of 330 bp in the C*04:79 allele.

³²Primer mix 40: Specific PCR fragment of 140 bp in the C*04:56 allele. Specific PCR fragment of 270 bp in the C*04:64:01-04:64:02 alleles.

³³Primer mix 41: Specific PCR fragment of 135 bp in the C*04:105N allele. Specific PCR fragment of 280 bp in the C*04:54 and the 01:04, 01:54, 14:02:01-14:24:01, 14:25 and 14:27-14:43 alleles.

³⁴Primer mix 43: Specific PCR fragment of 145 bp in the C*04:115N allele. Specific PCR fragment of 170 bp in the C*04:81 allele. Specific PCR fragment of 260 bp in the C*04:88N allele.

³⁵Primer mix 44: Specific PCR fragment of 90 bp in the C*04:108 and in the C*03:81 and the B*15:78:03 alleles. Specific PCR fragment of 135 bp in the C*04:60 allele.

³⁶Primer mix 45: Specific PCR fragment of 135 bp in the C*04:66 allele. Specific PCR fragment of 160 bp in the C*04:16 and 04:103 alleles.

³⁷Primer mix 46: Specific PCR fragment of 125 bp in the C*04:93N allele. Specific PCR fragment of 300 bp in the C*04:67 allele.

³⁸Primer mix 48: Specific PCR fragment of 155 bp in the C*04:84 and the C*07:167 alleles. Specific PCR fragment of 240 bp in the C*04:106 allele.

‘w’, may be weakly amplified.

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Length of spec.	250	220	145	210	250	95	145	270	110	195	180	125	225	155	180	85	320	125	120	165	85	130	85	170
PCR product(s)									220	180	110	125	270	185	155	130	320	220	155	250	145	130	145	170
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
HLA-C allele ^{4,5}																								
*04:01:01:01-04:01:09, 04:01:11-04:01:22, 04:01:24- 04:01:27, 04:01:29- 04:01:41, 04:85-04:86, 04:90-04:92, 04:97-04:99, 04:101-04:102, 04:104, 04:109, 04:112- 04:113, 04:117-04:119, 04:121, 04:124-04:127	1	2	3								11													
*04:01:10, 04:01:23, 04:116	1	2	3																					
*04:01:28	1		3								11													
*04:03, 02:49⁶	1			4							11													
*04:04:01-04:04:02, 04:122		2	3		5						11													
*04:05	1	2	3			6					11													
*04:06				4	5						11													
*04:07, 04:89	1	2					7				11													
*04:08	1	2	3					8			11													
*04:09N	1	2	3						9		11													
*04:10	1		3							10	11													
*04:11	1		3							10		12												
*04:12	1	w	3								11		13											
*04:13		2	3		5						11													
*04:14		2	3								11				15									
*04:15:01, 04:15:03	1	2	3								11					16								
*04:15:02	1	2	3								11					16				20				
*04:16	1										11		14											
*04:17	1	2	3								11					16	17			20				
*04:18	1	2	3								11		14											
*04:19	w	2	3								11							18						
*04:20	1	2	3								11								19					
*04:23, 04:38, 04:39⁹	1	2	3								11										21			
*04:24	1	2	3								11											22		
*04:25, 04:40, 04:41¹⁰	1	2	3								11												23	
*04:26	1	2	3								11													24
*04:27	1	2				7																		
*04:28	1	2	3								11				15									
*04:29	1	2	3								11	12												
*04:30	1	2	3						9		11													24
*04:31	1	2	3							10	11													
*04:32	1	2	3			7					11													
*04:33	1	2	3									12												
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

101.612-12 – including *Taq* pol., IFU-01
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200	215	280	215	185	75	180	235	105	80	75	85	115	110	95	135	140	135	100	145	90	135	135	125	50	155	Length of spec. PCR product(s)	
25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	Well No. HLA-C allele ^{4,5}			
																											*04:01:01-01-04:01:09, 04:01:11-04:01:22, 04:01:24- 04:01:27, 04:01:29- 04:01:41, 04:85-04:86, 04:90-04:92, 04:97-04:99, 04:101-04:102, 04:104, 04:109, 04:112- 04:113, 04:117-04:119, 04:121, 04:124-04:127
																											*04:01:10, 04:01:23, 04:116
																											*04:01:28
																											*04:03, 02:49 ⁶
																											*04:04:01-04:04:02, 04:122
																											*04:05
																											*04:06
																											*04:07, 04:89
																											*04:08
																											*04:09N
																											*04:10
																											*04:11
																											*04:12
									34																		*04:13
																											*04:14
																											*04:15:01, 04:15:03
																											*04:15:02
																						45					*04:16
																											*04:17
																											*04:18
																											*04:19
																											*04:20
																											*04:23, 04:38, 04:39 ⁹
																											*04:24
																											*04:25, 04:40, 04:41 ¹⁰
																											*04:26
																											*04:27
																											*04:28
																											*04:29
																											*04:30
																											*04:31
																											*04:32
																											*04:33
25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	Well No.			



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Lot-specific information

Length of spec.	250	220	145	210	250	95	145	270	110	195	180	125	225	155	180	85	320	125	120	165	85	130	85	170
PCR product(s)									220	180	220	165	270	185		130		220	155	250	145		215	
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
*04:34		2	3		5			8			11													
*04:35	1	2	3						9		11								19					
*04:36	1		3							10	11	12												
*04:37	1	2	3								11				16				19					
*04:42	1										11													24
*04:43	1	2	3								11													
*04:44, 04:47 ^B	1	2	3								11									20				
*04:45	1	2	3								11													
*04:46, 04:50 ¹¹	1	2	3								11													
*04:48, 04:75 ¹²	1	2	3								11													
*04:49	1	2	3								11													
*04:51	1	2	3								11													
*04:52	1	2	3										13											
*04:53	1	2	3								11													
*04:54, 04:105N ¹³	1	2	3								11													
*04:55	1		3							10		12	13											
*04:56, 04:64:01-04:64:02 ¹⁴	1	2	3								11													
*04:57	1	2	3								11													
*04:58		2	3		5						11													
*04:59Q, 04:78 ¹⁵	1	2	3								11													
*04:60	1	2	3								11													
*04:61, 04:96 ¹⁶	1	2	3								11													
*04:62, 04:76 ¹⁷	1	2	3								11													
*04:63	1	2	3								11													
*04:65, 04:72 ¹⁸	1	2	3								11													
*04:66	1	2	3								11													
*04:67, 04:93N ¹⁹	1	2	3								11													
*04:68		2	3								11			15										
*04:69	1	2	3								11													
*04:70	1	2	3								11							18						
*04:71	1		3								11													
*04:73	1	2	3								11													
*04:74	1	2	3								11													
*04:77	1	2	3				7				11													
*04:79	1	2	3								11													
*04:80	1			4							11						17							
*04:81, 04:88N ²⁰	1	2	3								11													
*04:82	1	2	3								11													
*04:83	1	2	3								11													
*04:84, 04:106 ²¹	1	2	3								11													
*04:87	1	2									11													
*04:94:01-04:94:02	1	2	3								11						18							
*04:95N	w	2	3								11													
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24

101.612-12 – including *Taq* pol., IFU-01
 101.612-12u – without *Taq* pol., IFU-02

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Lot-specific information

Lot-specific information																				Length of spec.				
200	215	280	215	185	75	180	235	180	200	175	115	135	135	330	270	280	100	170	135	160	300	50	155	PCR product(s)
25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	Well No.
																								*04:34
																								*04:35
																								*04:36
																								*04:37
																								*04:42
25																								*04:43
																								* 04:44, 04:47⁸
	26																							*04:45
		27																						*04:46, 04:50 ¹¹
			28																					*04:48 , 04:75 ¹²
				29																				*04:49
						31																		*04:51
					30																			*04:52
																								*04:53
																41								*04:54 , 04:105N ¹³
																								*04:55
															40									*04:56 , 04:64:01-04:64:02 ¹⁴
											36													*04:57
								33	34															*04:58
							32																	*04:59Q , 04:78 ¹⁵
																			44					*04:60
										34														*04:61 , 04:96¹⁶
											35													*04:62 , 04:76 ¹⁷
											36	37												*04:63
								33																*04:65 , 04:72 ¹⁸
																				45				*04:66
										34											46			*04:67, 04:93N ¹⁹
																								*04:68
																								*04:69
																								*04:70
																								*04:71
																								*04:73
																								*04:74
																								*04:77
							32																	*04:79
																								*04:80
																								*04:81 , 04:88N ²⁰
					29																			*04:82
														38										*04:83
																							48	*04:84, 04:106 ²¹
																								*04:87
25																								*04:94:01-04:94:02
							31								39									*04:95N
25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	Well No.



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 101.612-12u – without *Taq* pol., IFU-02

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Lot No.: **60R**

Lot-specific information

Length of spec.	250	220	145	210	250	95	145	270	110	195	180	125	225	155	180	85	320	125	120	165	85	130	85	170
PCR product(s)									220	180	220	165	270	185		130		220	155	250	240		215	
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
*04:100	1	2	3								11						17			20				
*04:103	1										11													
*04:107, 02:12, 02:55 ⁷	1			4																				
*04:108	1	2	3								11										21			
*04:110	?	2	3								11													
*04:111		2	3								11													
*04:114	1	2	3								11													
*04:115N	1	2	3								11													
*04:120	1	2	3								11													
*04:123N	1	2	3								11					16								
*01:02:01-01:03, 01:05-01:20, 01:23-01:34, 01:36-01:49, 01:51-01:53, 01:55-01:58, 01:60-01:73, 02:02:01-02:02:03, 02:02:05-02:02:24, 02:04-02:11, 02:13-02:15, 02:17, 02:19-02:40, 02:42-02:48, 02:50-02:54, 02:56-02:57, 02:59-02:63, 05:01:01:01-05:01:21, 05:03-05:10, 05:12-05:16, 05:18:01-05:19, 05:21-05:24, 05:26, 05:28-05:38, 05:40-05:41, 05:43-05:48N, 05:50, 05:52-05:61, 05:63, 05:65-05:67, 05:69, 05:71-05:77, 05:80-05:81, 06:02:01:01-06:02:01:02, 06:02:03-06:03:02, 06:06-06:39, 06:41-06:76:01, 06:77-06:78, 06:80-06:81, 06:83-06:87, 08:02:01-08:02:06, 08:05, 08:07, 08:12, 08:15:01-08:15:02, 08:17-08:18, 08:23, 08:25, 08:27, 08:29-08:33:01, 08:34-08:35, 08:37, 08:43, 08:45, 08:47-08:49, 08:51-08:53, 08:55N, 08:62-08:63, 08:33:03, 12:02:01-12:09, 12:11-12:13, 12:15-12:17, 12:21-12:27, 12:29-12:53, 12:55-12:82, 14:24:02, 14:26, 15:08, 16:04:01, 16:29, 16:33, 16:42, 18:01-18:02, 18:04-18:05	1																							
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



101.612-12 – including *Taq* pol., IFU-01
 101.612-12u – without *Taq* pol., IFU-02

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Lot No.: **60R**

Lot-specific information

Length of spec.	250	220	145	210	250	95	145	270	110	195	180	125	225	155	180	85	320	125	120	165	85	130	85	170
PCR product(s)									180	220		165	270	185		130		220	155	250	240		145	
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
*01:04, 01:54, 14:02:01-14:03, 14:05, 14:07N-14:08, 14:10-14:14, 14:16-14:19, 14:21N-14:24:01, 14:27-14:43	1																							
*01:21	1																							
*01:22, 02:03, 02:16:01-02:16:02, 02:18, 05:11, 05:17, 05:68, 05:79, 06:04, 08:01:01-08:01:06, 08:01:08, 08:03:01-08:04:02, 08:06, 08:08-08:11, 08:13-08:14, 08:16:01-08:16:02, 08:20-08:22, 08:24, 08:26N, 08:36N, 08:38-08:40, 08:42, 08:44, 08:46, 08:50, 08:54, 08:56-08:61, 12:14:01-12:14:02, 12:18:01-12:18:02, 12:20, 15:02:01-15:07, 15:09-15:13, 15:16-15:19, 15:21-15:24, 15:26-15:35, 15:37-15:50, 15:52-15:61, 16:35, 16:40, 16:48, 17:01:01:01-17:06, 17:08-17:13					5																			
*01:35, 05:27, 08:41, 15:15, 17:07, B*58:02					5			8																
*01:50	1																17							
*01:59, 05:20, 06:82, 12:54	1																							
*02:58, 05:39	1							8																
*03:05, 03:13:01, 03:25, 03:27, 03:35																16								
*03:34, 03:142							7																	
*03:81																								
*03:130, 03:140, 07:49, 07:210, 07:238, 07:247, A*68:46																								
*03:135																16		19						
*05:25, 05:42, 06:05, 06:76:02, 08:28, 12:28	1										11													
*05:49	1																							
*05:64, 08:19	1																							
*05:78	1						7			10										20				
*07:02:09, 15:25, 16:26, 16:46											11													
*07:08, 07:108																								
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



101.612-12 – including *Taq* pol., IFU-01101.612-12u – without *Taq* pol., IFU-02Visit www.olerup-ssp.com for

“Instructions for Use” (IFU)

Lot No.: **60R**

Lot-specific information

Length of spec.	250	220	145	210	250	95	145	270	110	180	195	180	125	225	155	180	85	320	125	120	165	85	130	85	170	
PCR product(s)									220	180	110			270	185		130		220	125	155	250	145		215	145
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		
*07:64		2					7																			
*07:125												12													24	
*07:167																										
*08:01:07					5											16										
*08:02:07, 08:33:02	1															16										
*12:10:01-12:10:02	1																	18								
*14:04	1																									
*14:06, 14:15					5																					
*14:09	1															16										
*14:20	1							8																		
*14:25	1						7																			
*15:36					5		7			10											20					
*16:12																										
*16:45, A*24:96, A*24:146																15										
*18:03	1						7											18								
A*33:52																					20					
B*07:90																										
B*15:27:01-15:27:03, B*15:109																		18								
B*15:78:03																16										
B*40:100																										
HLA-C allele ^{4,5}																										
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		

¹The internal positive control primer pairs amplify segments of the human growth hormone gene. The two different control primer pairs give rise to either an internal positive control band of 1070 base pairs, for most wells, or a band of 800 base pairs, for some wells.

Well number 1 contains the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to help in the correct orientation of the HLA-C*04 subtyping. .

In addition, wells number 9, 26, 27, 40 and 47 contain the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to allow kit identification.

²The nucleotide position, in the 2nd, 3rd, 4th, 5th or 6th, exon or in the 2nd and 3rd intron, matching the specificity-determining 3'-end of the primer is given. Nucleotide numbering as on the www.ebi.ac.uk/imgt/hla web site. The sequence of the 3 terminal nucleotides of the primer is given.

³The nucleotide position, in the 2nd, 3rd, 4th, 5th or 7th exon or in the 3rd 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 web site. The sequence of the 3 terminal nucleotides of the primer is given.

⁴The nucleotide sequence of the Cw*0402 allele has been shown to be identical to C*04:01:01:01. The nucleotide sequence of the Cw*0421 allele has been renamed C*04:15:02.

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

⁵HLA-C*04 alleles in bold lettering are listed as confirmed alleles on the IMGT/HLA web page www.ebi.ac.uk/imgt/hla, release 3.9.0, July 2012.

⁶The HLA-C*04 primer set cannot separate the C*04:03 and 02:49 alleles. These alleles can be distinguished by the HLA-C low resolution kit and/or the HLA-C*02 high resolution kit.

101.612-12 – including *Taq pol.*, IFU-01
101.612-12u – without *Taq pol.*, IFU-02

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Lot No.: 60R**Lot-specific information**

¹⁸The C*04:65 and C*04:72 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 33.

¹⁹The C*04:67 and C*04:93N alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 46.

²⁰The C*04:81 and C*04:88N alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 43.

²¹The C*04:84 and C*04:106 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 48.

²²Primer mix 9: Specific PCR fragment of 110 bp in the C*04:35 allele. Specific PCR fragment of 180 bp in the C*04:30 allele. Specific PCR fragment of 220 bp in the C*04:09N allele.

Primer mix 10: Specific PCR fragment of 195 bp in the C*04:31 allele. Specific PCR fragment of 220 bp in the C*04:10-04:11, 04:36 and 04:55 and the C*05:78 and 15:36 alleles.

Primer mix 12: Specific PCR fragment of 125 bp in the C*04:29, 04:36 and 04:55 and the C*07:125 alleles. Specific PCR fragment of 165 bp in the C*04:33 allele. Specific PCR fragment of 125 and 165 bp in the C*04:11 allele.

Primer mix 13: Specific PCR fragment of 225 bp in the C*04:12 allele. Specific PCR fragment of 270 bp in the C*04:52 and 04:55 alleles.

Primer mix 14: Specific PCR fragment of 155 bp in the C*04:16 allele. Specific PCR fragment of 185 bp in the C*04:18 allele.

Primer mix 16: Specific PCR fragment of 85 bp in the C*04:123N allele. Specific PCR fragment of 130 bp in the C*04:15:01-04:15:03, 04:17 and 04:37 and the C*03:05, 03:13:01, 03:25, 03:27, 03:35, 03:135, 08:01:07, 08:02:07, 08:33:02 and 14:09 and the B*15:78:03 alleles.

Primer mix 18: Specific PCR fragment of 125 bp in the C*04:70 allele. Specific PCR fragment of 220 bp in the C*04:19 and 04:94:01-04:94:02 and the C*12:10:01-12:10:02 and 18:03 and in the B*15:27:01-15:27:03 and B*15:109 alleles.

Primer mix 19: Specific PCR fragment of 120 bp in the C*04:35 and 04:37 alleles. Specific PCR fragment of 155 bp in the C*04:20 and the C*03:135 alleles.

Primer mix 20: Specific PCR fragment of 165 bp in the C*04:44 allele. Specific PCR fragment of 250 bp in the C*04:47 allele. Specific PCR fragment of 545 bp in the C*04:15:02, 04:17 and 04:100 and in the C*05:78 and 15:36 and the A*33:52 alleles.

Primer mix 21: Specific PCR fragment of 85 bp in the C*04:23 and 04:108 alleles. Specific PCR fragment of 145 bp in the C*04:38 allele. Specific PCR fragment of 240 bp in the C*04:39 allele.

Primer mix 23: Specific PCR fragment of 85 bp in the C*04:25 allele. Specific PCR fragment of 145 bp in the C*04:40 allele. Specific PCR fragment of 215 bp in the C*04:41 allele.

Primer mix 27: Specific PCR fragment of 125 bp in the C*04:50 allele. Specific PCR fragment of 280 bp in the C*04:46 and 04:120 and the C*05:64 and 08:19 alleles.

Primer mix 28: Specific PCR fragment of 120 bp in the C*04:75 allele. Specific PCR fragment of 215 bp in the C*04:48 allele.

Primer mix 29: Specific PCR fragment of 105 bp in the C*04:82 allele. Specific PCR fragment of 185 bp in the C*04:49 allele.

Primer mix 31: Specific PCR fragment of 130 bp in the C*04:95N allele. Specific PCR fragment of 180 bp in the C*04:51 allele.

Primer mix 32: Specific PCR fragment of 105 bp in the C*04:78 allele. Specific PCR fragment of 235 bp in the C*04:59Q allele. Specific PCR fragment of 275 bp in the C*04:77 and in the B*40:100 alleles.

Primer mix 33: Specific PCR fragment of 80 bp in the C*04:72 allele. Specific PCR fragment of 180 bp in the C*04:58 and 04:65 and the C*07:08 and 07:108 and in the B*40:100 alleles.

Primer mix 34: Specific PCR fragment of 75 bp in the C*04:96 allele. Specific PCR fragment of 200 bp in the C*04:13, 04:58, 04:61 and 04:68 and the C*07:08 and 07:108 alleles. Specific PCR fragment of 275 bp in the C*04:120 and the C*05:64 and 08:19 alleles.

Primer mix 35: Specific PCR fragment of 85 bp in the C*04:62 allele. Specific PCR fragment of 145 bp in the C*04:115N allele. Specific PCR fragment of 175 bp in the C*04:76 allele.

Primer mix 37: Specific PCR fragment of 110 bp in the C*04:63 and 04:73 alleles. Specific PCR fragment of 135 bp in the C*04:74 allele.

Primer mix 38: Specific PCR fragment of 95 bp in the C*04:83 and 04:123N alleles. Specific PCR fragment of 135 bp in the C*04:74 allele.

101.612-12 – including *Taq* pol., IFU-01
101.612-12u – without *Taq* pol., IFU-02

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Lot No.: 60R**Lot-specific information**

Primer mix 39: Specific PCR fragment of 135 bp in the C*04:71 and 04:95N and the C*01:21 alleles. Specific PCR fragment of 330 bp in the C*04:79 allele.

Primer mix 40: Specific PCR fragment of 140 bp in the C*04:56 allele. Specific PCR fragment of 270 bp in the C*04:64:01-04:64:02 alleles.

Primer mix 41: Specific PCR fragment of 135 bp in the C*04:105N allele. Specific PCR fragment of 280 bp in the C*04:54 and the 01:04, 01:54, 14:02:01-14:24:01, 14:25 and 14:27-14:43 alleles.

Primer mix 43: Specific PCR fragment of 145 bp in the C*04:115N allele. Specific PCR fragment of 170 bp in the C*04:81 allele. Specific PCR fragment of 260 bp in the C*04:88N allele.

Primer mix 44: Specific PCR fragment of 90 bp in the C*04:108 and in the C*03:81 and the B*15:78:03 alleles. Specific PCR fragment of 135 bp in the C*04:60 allele.

Primer mix 45: Specific PCR fragment of 135 bp in the C*04:66 allele. Specific PCR fragment of 160 bp in the C*04:16 and 04:103 alleles.

Primer mix 46: Specific PCR fragment of 125 bp in the C*04:93N allele. Specific PCR fragment of 300 bp in the C*04:67 allele.

Primer mix 48: Specific PCR fragment of 155 bp in the C*04:84 and the C*07:167 alleles. Specific PCR fragment of 240 bp in the C*04:106 allele.

‘w’, may be weakly amplified.

101.612-12 – including *Taq* pol., IFU-01
 101.612-12u – without *Taq* pol., IFU-02

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Lot No.: **60R**

Lot-specific information

CELL LINE VALIDATION SHEET																				
HLA-C*04 SSP subtyping kit																				
				Well																
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	
				Prod. No.:	201070201	201070202	201070203	201201804	201070205	201070206	201070207	201070208	201210609	201201810	201210611	201070212	201070213	201210614	201070215	201210616
IHCW 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	+	+	+	-	-	-	-	-	-	-	+	-	-	-	-	-	-



101.612-12 – including *Taq* pol., IFU-01
 101.612-12u – without *Taq* pol., IFU-02

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 “Instructions for Use” (IFU)

Lot No.: **60R**

Lot-specific information

CELL LINE VALIDATION SHEET																				
HLA-C*04 SSP subtyping kit																				
				Well																
				17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	
				Prod. No.:	201185317	201201818	201070219	201070220	201070221	201070222	201070223	201070224	201201825	201070226	201210627	201185328	201210629	201070230	201201831	201210632
	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	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-



101.612-12 – including *Taq* pol., IFU-01
 101.612-12u – without *Taq* pol., IFU-02

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 “Instructions for Use” (IFU)

Lot No.: **60R**

Lot-specific information

CELL LINE VALIDATION SHEET																				
HLA-C*04 SSP subtyping kit																				
				Well																
				33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	
				Prod. No.:	201185333	201210634	201210635	201185336	201210637	201210638	201201839	201210640	201201841	201210642	201210643	201210644	201201845	201210646	201210647	201201847
IHCW 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	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-



101.612-12 – including *Taq* pol., IFU-01
 101.612-12u – without *Taq* pol., IFU-02

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 “Instructions for Use” (IFU)

Lot No.: **60R**

Lot-specific information
CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-C*04 SSP

Product number: 101.612-12 – including *Taq* polymerase
 101.612-12u – without *Taq* polymerase
 Lot number: 60R
 Expiry date: 2015-June-01
 Number of tests: 12
 Number of wells per test: 48

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2010-702-01	17	2011-853-17	33	2011-853-33
2	2010-702-02	18	2012-018-18	34	2012-106-34
3	2010-702-03	19	2010-702-19	35	2012-106-35
4	2012-018-04	20	2010-702-20	36	2011-853-36
5	2010-702-05	21	2010-702-21	37	2012-106-37
6	2010-702-06	22	2010-702-22	38	2012-106-38
7	2010-702-07	23	2010-702-23	39	2012-018-39
8	2010-702-08	24	2010-702-24	40	2012-106-40
9	2012-106-09	25	2012-018-25	41	2012-018-41
10	2012-018-10	26	2010-702-26	42	2012-106-42
11	2012-106-11	27	2012-106-27	43	2012-106-43
12	2010-702-12	28	2011-853-28	44	2012-106-44
13	2010-702-13	29	2012-106-29	45	2012-018-45
14	2012-106-14	30	2010-702-30	46	2012-106-46
15	2010-702-15	31	2012-018-31	47	2012-106-47
16	2012-106-16	32	2012-106-32	48	2012-018-47

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

No DNAs carrying the alleles to be amplified by primer solutions 6, 8, 10, 12 to 15, 17, 19 to 24, 26 to 40 and 42 to 48 were available. The specificity of the primers in primer solutions 8, 10, 12 to 15, 17, 19 to 21, 24, 27, 28, 31 to 34, 39, 42, 44, 45, 47 and 48 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer solutions 3, 6, 26, 29, 35, 40 and 43 it was only possible to test the 5'-primers, the 3'-primers were not possible to test. In primer solutions 22, 23, 30, 36 to 38 and 46 it was only possible to test the 3'-primers, the 5'-primers were not possible to test. In primer solutions 9, 15, 16, 18, 19, 24, 28, 31, 41, 44 and 45 one or two of the 5'-primers were not possible to test, and in primer solutions 9, 10, 13, 14, 18, 20, 21, 24, 25, 27, 28, 31 to 34, 39, 42 and 48 one or two of the 3'-primers were not possible to test. Additional primers in primer solutions 7, 9, 16, 18 and 41 were tested by separately adding one 5'-primer and/or one 3'-primer.

101.612-12 – including *Taq* pol., IFU-01
101.612-12u – without *Taq* pol., IFU-02

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Lot No.: **60R**

Lot-specific information

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

Date of approval: 2013-January-11

Approved by:

Production Quality Control

101.612-12 – including *Taq* pol., IFU-01
101.612-12u – without *Taq* pol., IFU-02

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Lot No.: **60R**

Lot-specific information
Declaration of Conformity

Product name: *Olerup* SSP® HLA-C*04
Product number: 101.612-12/12u
Lot number: 60R

Intended use: HLA-C*04 high 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 13485:2003, 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.

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

Stockholm, Sweden

Daniel Malica
Head of QA and Regulatory Affairs

101.612-12 – including *Taq* pol., IFU-01
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Lot No.: **60R**

Lot-specific information

101.612-12 – including *Taq* pol., IFU-01
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Lot No.: **60R**

Lot-specific information

101.612-12 – including *Taq* pol., IFU-01
101.612-12u – without *Taq* pol., IFU-02

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Lot No.: **60R**

Lot-specific information

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E-mail: info-ssp@olerup.com

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