• LERUPSSP® HLA-C*15

Product Insert

101.626-12 – including *Taq* polymerase, IFU-01 101.626-12u – without *Taq* polymerase, IFU-02 Page 1 of 16 Visit <u>www.olerup-ssp.com</u> for "Instructions for Use" (IFU)

Lot No.: 23V Lot-specific information

Olerup SSP® HLA-C*15

Product number: 101.626-12 – including *Taq* polymerase

101.626-12u – without *Taq* polymerase

Lot number: 23V

Expiry date: 2016-July-01

Number of tests: 12 Number of wells per test: 30+1

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

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

This Product Description is only valid for Lot No. 23V.

Complete product documentation consists of generic Instructions for Use (IFU), lot specific Product Insert, Worksheet and Certificate.

CHANGES COMPARED TO THE PREVIOUS OLERUP SSP® HLA-C*15 Lot (05S)

The HLA-C*15 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

A well containing Negative Control primer pairs has been added.

The format of the Product Insert and Worksheet have been changed.

Four wells have been added to HLA-C*15, wells **28 to 31**.

The HLA-C*15 specificity and interpretation tables have been updated for the HLA-C alleles described since the previous *Olerup* SSP® HLA-C*15 lot was made (Lot No. 05S).

As of lot series V, the Specificity Table is included in the lot-specific Product Insert, and the Interpretation Table is included in the Worksheet.

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¹As described in section Uniquely Identified Alleles.

Lot No.: 23V **Lot-specific information**

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

Well	5'-primer	3'-primer	rationale
3	Exchanged	-	5'-primer exchanged for improved resolution of the C*15:02 and C*15:03 alleles.
18	Moved	Moved	Primer pair moved to well 28, for improved specificity.
21	Modified		5'-primer modified for increased yield of specific PCR product. Exchanged positive control primer pair
28	Added	Added	Primer pair added from well 18.
29	New	New	New primer pair for the C*15:81 allele.
30	New	New	New primer pair for the C*15:82 allele.
31			Negative Control

Change in revision R01 compared to R00:

1. The listing of alleles according to amplicon length has been corrected for primer mix 12 in the Specificity Table.

HLA-C*15 Product Insert

101.626-12 – including *Taq* **polymerase**, IFU-01 **101.626-12u – without** *Taq* **polymerase**, IFU-02

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Lot No.: 23V

Lot-specific information

PRODUCT DESCRIPTION

HLA-C*15 SSP typing

CONTENT

The primer set contains 5'- and 3'-primers for identifying the C*15:02 to C*15:82 alleles.

PLATE LAYOUT

Each HLA-C*15 test consists of 31 PCR reactions in a 32 well cut PCR plate.

Well 32 is empty.

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	NC	empty

The 32 well PCR plate is marked with 'HLA-C*15' in silver/gray ink.

Well No. 1 is marked with the Lot No. '23V'.

Wells 1 to 30 – HLA-C*15 high resolution primers.

Well 31 - Negative Control (NC).

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 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

Due to the sharing of sequence motifs between HLA-C alleles, non-HLA-C*15 alleles will be amplified by primer mixes 1 to 5, 7 to 15, 17, 18, 21, 23, 24 and 27. In addition, a few HLA-B alleles will be amplified by primer mixes 5, 7, 8, 12, 14, 16, 18, 25 and 26.

For further details see Specificity Table.

UNIQUELY IDENTIFIED ALLELES

All the HLA-C*15 alleles, i.e. **C*15:02 to C*15:82**, recognized by the HLA Nomenclature Committee in October 2013^{1,2} will be amplified by the primers in the HLA-C*15 SSP kit.

The HLA-C*15 kit enables separation of the confirmed HLA-C*15 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*15 alleles is listed below.

The HLA-C*15 kit also enables identification of polymorphisms in exons outside of the region encoding the peptide binding domain and of null and alternatively expressed alleles OLERUPSSP® HLA-C*15

Product Insert

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101.626-12 – including *Taq* **polymerase**, IFU-01 **101.626-12u – without** *Taq* **polymerase**, IFU-02

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Lot No.: 23V Lot-specific information

The following HLA-C*15 alleles can be distinguished by the different sizes of the HLA-specific PCR product:

Alleles	Primer mix
C*15:32Q, 15:41	24
C*15:34, 15:39	17
C*15:35, 15:47	21
C*15:44, 15:45	20

The HLA-C*15 subtyping kit cannot distinguish the following silent mutations: C*15:02:01 to C*15:02:17 and C*15:02:19 alleles, the C*15:05:01 to C*15:05:09 alleles, the C*15:06:01 to C*15:06:03 alleles or the C*15:10:01 and C*15:10:03 alleles.

ALLELE CONEIDMATION STATUS

ALLE	LE CONFIRI	MATION 31	AIUS				
Allele	Status ¹	Allele	Status ¹	Allele	Status ¹	Allele	Status ¹
C*15:02:01	Confirmed	C*15:06:01	Confirmed	C*15:34	Unconfirmed	C*15:64	Unconfirmed
C*15:02:02	Unconfirmed	C*15:06:02	Confirmed	C*15:35	Unconfirmed	C*15:65	Unconfirmed
C*15:02:03	Confirmed	C*15:06:03	Confirmed	C*15:36	Confirmed	C*15:66	Unconfirmed
C*15:02:04	Confirmed	C*15:07	Confirmed	C*15:37	Unconfirmed	C*15:67	Unconfirmed
C*15:02:05	Confirmed	C*15:08	Unconfirmed	C*15:38	Unconfirmed	C*15:68	Unconfirmed
C*15:02:06	Unconfirmed	C*15:09	Confirmed	C*15:39	Confirmed	C*15:69	Unconfirmed
C*15:02:07	Confirmed	C*15:10:01	Unconfirmed	C*15:40	Confirmed	C*15:70	Unconfirmed
C*15:02:08	Confirmed	C*15:10:02	Confirmed	C*15:41	Unconfirmed	C*15:71	Unconfirmed
C*15:02:09	Unconfirmed	C*15:10:03	Unconfirmed	C*15:42	Confirmed	C*15:72	Unconfirmed
C*15:02:10	Unconfirmed	C*15:11	Confirmed	C*15:43	Unconfirmed	C*15:73	Unconfirmed
C*15:02:11	Unconfirmed	C*15:12	Unconfirmed	C*15:44	Confirmed	C*15:74	Unconfirmed
C*15:02:12	Unconfirmed	C*15:13	Confirmed	C*15:45	Unconfirmed	C*15:75	Unconfirmed
C*15:02:13	Unconfirmed	C*15:15	Unconfirmed	C*15:46	Unconfirmed	C*15:76	Unconfirmed
C*15:02:14	Unconfirmed	C*15:16	Unconfirmed	C*15:47	Unconfirmed	C*15:77	Unconfirmed
C*15:02:15	Confirmed	C*15:17	Confirmed	C*15:48	Unconfirmed	C*15:78	Unconfirmed
C*15:02:16	Unconfirmed	C*15:18	Confirmed	C*15:49	Unconfirmed	C*15:79	Unconfirmed
C*15:02:17	Unconfirmed	C*15:19	Confirmed	C*15:50	Unconfirmed	C*15:80	Unconfirmed
C*15:02:18	Unconfirmed	C*15:21	Unconfirmed	C*15:51	Unconfirmed	C*15:81	Unconfirmed
C*15:02:19	Unconfirmed	C*15:22	Confirmed	C*15:52	Confirmed	C*15:82	Unconfirmed
C*15:03	Unconfirmed	C*15:23	Confirmed	C*15:53	Unconfirmed		
C*15:04	Confirmed	C*15:24	Confirmed	C*15:54	Unconfirmed		
C*15:05:01	Unconfirmed	C*15:25	Unconfirmed	C*15:55	Unconfirmed		
C*15:05:02	Confirmed	C*15:26	Confirmed	C*15:56	Confirmed		
C*15:05:03	Unconfirmed	C*15:27	Confirmed	C*15:57	Unconfirmed		
C*15:05:04	Unconfirmed	C*15:28	Confirmed	C*15:58	Unconfirmed		
C*15:05:05	Unconfirmed	C*15:29	Unconfirmed	C*15:59	Unconfirmed		
C*15:05:06	Confirmed	C*15:30	Confirmed	C*15:60	Unconfirmed		
C*15:05:07	Unconfirmed	C*15:31	Confirmed	C*15:61	Unconfirmed		
C*15:05:08	Unconfirmed	C*15:32Q	Confirmed	C*15:62	Unconfirmed		
C*15:05:09	Unconfirmed	C*15:33	Confirmed	C*15:63	Unconfirmed		0.000

¹Allele status "confirmed" or "unconfirmed" as listed on the IMGT/HLA web page 2013-October-11, release 3.14.0, www.ebi.ac.uk/imgt/hla.

RESOLUTION IN HOMO- AND HETEROZYGOTES

Results file with resolution in HLA-C*15 homo- and heterozygotes is available upon request.

¹HLA-C alleles listed on the IMGT/HLA web page 2013-October-11, release 3.14.0,

www.ebi.ac.uk/imgt/hla.

Alleles that have been deleted from or renamed in the official WHO HLA Nomenclature up to and including the last IMGT/HLA database release can be retrieved from web page http://hla.alleles.org/alleles/deleted.html

⊙LERUPSSP® HLA-C*15

Product Insert 101.626-12 – including *Taq* **polymerase**, IFU-01 **101.626-12u – without** *Taq* polymerase, IFU-02

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Lot No.: 23V

Lot-specific information SPECIFICITY TABLE

HLA-C*15 SSP subtyping

Specificities and sizes of the PCR products of the 30+1 primer mixes used for HLA-C*15 SSP subtyping

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified HLA-C*15 alleles ³	Other amplified HLA Class I alleles ⁴
1	325 bp	800 bp	*15:02:01-15:02:17, 15:02:19-15:03, 15:05:01-15:13, 15:15- 15:19, 15:21-15:24, 15:26-15:29, 15:31- 15:39, 15:41-15:63, 15:67-15:75, 15:78- 15:82	*02:06, 02:23, 02:36, 02:68, 03:81, 03:175, 03:199, 04:108, 06:89, 07:123, 07:173, 07:294, 12:15, 16:20
2	175 bp	1070 bp	*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, 15:44-15:62, 15:64- 15:82	*03:08, 03:29, 03:31, 07:20, 07:96:01- 07:96:02, 07:263
3 ⁵	85 bp 210 bp	1070 bp	*15:28 *15:03, 15:16, 15:25 ^w	*03:15, 03:27 ^w , 03:38:01 ^w -03:38:02 ^w , 03:69 ^w , 03:130, 03:136 ^w , 03:163, 04:16, 06:03:01, 07:02:10 ^w , 07:96:01 ^w -07:96:02 ^w , 07:127 ^w , 07:246 ^w , 07:263 ^w , 12:03:23 ^w
4	315 bp	1070 bp	*15:04, 15:09, 15:19, 15:27, 15:30, 15:61, 15:65, 15:77	*01:04, 01:21, 01:54, 02:02:01-02:02:03, 02:02:05-02:05:02, 02:08-02:18, 02:20-02:21, 02:24-02:40, 02:42-02:46, 02:48-02:67Q, 02:70-02:72, 03:02:01-03:02:11, 03:14-03:16, 03:33, 03:36, 03:40:01-03:40:03, 03:42-03:43:02, 03:60, 03:71, 03:84, 03:89, 03:95, 03:108, 03:110, 03:119, 03:121N, 03:132, 03:139, 03:146, 03:169Q, 03:175, 03:190, 03:194, 03:197-03:201N, 03:216, 04:54, 05:04:01-05:04:02, 06:02:01:01-06:02:01:03, 06:02:03-06:08, 06:10-06:33, 06:35-06:37, 06:39-06:102, 06:104-06:106:02, 06:108-06:117, 07:01:01:01-07:03, 07:05-07:10, 07:14-07:27:02, 07:30-07:33N, 07:35-07:40, 07:42-07:44, 07:46-07:62, 07:64-07:100, 07:102-07:138, 07:140-07:141:02, 07:143-07:176, 07:178-07:180, 07:182-07:183, 07:185-07:198N, 07:200-07:218, 07:220-07:230, 07:232-07:247, 07:249-07:271, 07:273-07:288, 07:291-07:294,

• LERUPSSP® HLA-C*15 **Product Insert 101.626-12 – including** *Taq* **polymerase**, IFU-01 **101.626-12u – without** *Taq* **polymerase**, IFU-02

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Lot No.:	234	LU	t-specific information	
				07:296-07:322, 07:325-07:327, 07:330-07:335, 07:337, 08:09, 08:11, 08:59, 12:02:01-12:14:02, 12:16-12:30, 12:32-12:111, 14:02:01-14:25, 14:27-14:53, 14:56-14:58, 16:01:01-16:02:11, 16:04:01, 16:06-16:09, 16:11-16:44, 16:46-16:60
5 ^{5,6}	100 bp	1070 bp	*15:05:01-15:05:09, 15:22-15:23, 15:29, 15:36, 15:46, 15:54, 15:59, 15:69-15:70	*04:108, B*35:03:11, B*35:205
6	305 bp 345 bp 370 bp	1070 bp	*15:06:01-15:06:03, 15:40, 15:55 *15:26, 15:69 *15:22, 15:37, 15:55, 15:58, 15:65, 15:72	
7	140 bp	800 bp	*15:07, 15:21, 15:25	*01:21, 02:12, 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, 08:11-08:63, 08:65-08:88N, 08:90-08:94, 12:02:01-12:03:03, 12:03:05-12:03:08, 12:03:10-12:03:23, 12:03:24 ^w , 12:03:25-12:03:28, 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, 12:61-12:111, 14:02:03, 14:03, 14:08, 14:10, 14:22, 14:35N, 14:38, 14:41, 14:53-14:54, 16:01:01, 16:01:03-16:01:15, 16:04:01, 16:06-16:08, 16:10-16:11, 16:13-16:18, 16:20-16:24, 16:26-16:45, 16:49-16:56, 16:58-16:59, B*35:08:02, B*35:08:05, B*67:02
8	160 bp	1070 bp	*15:08, 15:74	*02:06, 02:47, 12:15, B*07:78 ^w , B*13:18 ^w , B*13:31 ^w , B*13:41 ^w , B*15:73 ^w , B*54:10 ^w , B*55:09 ^w , B*55:21 ^w , B*55:37 ^w , B*55:52 ^w , B*56:43 ^w
	185 bp		*15:19	
9	135 bp 305 bp	1070 bp	*15:11, 15:23, 15:63 *15:18	*02:02:01-02:02:03, 02:02:05- 02:02:12, 02:02:14-02:02:25, 02:03- 02:20, 02:22-02:25Q, 02:27:01- 02:38N, 02:40, 02:42-02:44, 02:46- 02:68, 02:70-02:72, 04:03:01- 04:03:02, 04:06, 04:42, 04:80, 04:107, 04:147, 04:160, 05:26, 05:43, 06:05, 07:02:09, 08:37, 12:16, 16:21, 16:34
10	170 bp	1070 bp	*15:10:01-15:10:03	*01:64, 02:08, 03:18, 03:64:01- 03:64:02, 04:01:01-04:01:02, 04:01:04-04:01:54, 04:04:01-04:05, 04:07-04:15:03, 04:17-04:20, 04:23- 04:79, 04:81-04:106, 04:108-04:132, 04:134-04:139, 04:141-04:146, 04:148-04:159, 05:01:01:01-05:01:21,

• LERUPSSP® HLA-C*15 **Product Insert 101.626-12 – including** *Taq* **polymerase**, IFU-01 **101.626-12u – without** *Taq* **polymerase**, IFU-02

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Lot No.: 23V	Lot-specific information

Lot No.: 4	23 V	LO	-specific information	
				05:01:23-05:01:27, 05:03-05:57, 05:59-05:97, 06:28, 06:76:01-06:76:02, 07:64, 07:73, 07:92, 07:172, 08:01:01-08:13, 08:15:01-08:57, 08:59-08:63, 08:65-08:79, 08:81-08:88N, 08:90-08:94, 12:02:01-12:15, 12:17-12:70, 12:72-12:111, 14:02:01-14:02:09, 14:02:11-14:02:15, 14:04-14:09, 14:11-14:17, 14:19-14:21N, 14:23-14:34, 14:36-14:37, 14:39-14:40, 14:42-14:52, 14:55-14:58, 16:01:01-16:02:11, 16:04:01, 16:06-16:33, 16:35-16:60, 17:01:01-01-17:01:07, 17:01:09-17:22, 18:04
11	315 bp	800 bp	*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, 15:56-15:58, 15:60, 15:62-15:63, 15:67-15:68, 15:71-15:75, 15:78-15:82	*02:06, 02:47, 03:19, 03:102, 07:289, 12:15
12 ⁵	100 bp 240 bp	1070 bp	*15:28 *15:07, 15:21, 15:25, 15:43	*02:12, 02:27:01-02:27:02, 03:02:01-03:02:09, 03:02:11-03:03:14, 03:03:15 ^w , 03:03:16-03:03:20, 03:03:22-03:04:16, 03:04:18-03:04:25, 03:04:27-03:06, 03:08-03:11:02, 03:13:01-03:14, 03:16-03:17, 03:19-03:38:02, 03:40:01-03:44, 03:46-03:64:01, 03:65-03:66, 03:68-03:98, 03:100-03:114, 03:116:01-03:129, 03:131-03:133, 03:135-03:136, 03:138-03:139, 03:141-03:143, 03:145-03:155, 03:157-03:162, 03:164-03:165, 03:167-03:169Q, 03:171-03:181, 03:183-03:194, 03:196-03:218, 03:220, 07:96:01-07:96:02, 12:03:23, 16:34, B*40:164
13 ⁵	125 bp 185 bp	1070 bp	*15:24 *15:12	*04:89, 04:135, 05:47 *04:52, 04:55, 05:55, 12:58, 14:10
14	130 bp 440 bp	800 bp	*15:13, *15:11,15:16-15:17, 15:43	*02:06, 02:47, 03:19, 03:102, 07:289, 12:15, B*46:11, B*46:18 , B*56:08 , B*56:14
15⁵	85 bp	1070 bp	*15:02:01-15:06:03, 15:08-15:10:03, 15:12- 15:13, 15:15, 15:18- 15:19, 15:21-15:24, 15:26, 15:28-15:42, 15:44-15:47, 15:49- 15:82	*03:29, 04:112, 05:36, 06:44, 07:07, 07:09, 18:05

Product Insert

HLA-C*15 101.626-12 - including *Taq* polymerase, IFU-01 **101.626-12u – without** *Taq* **polymerase**, IFU-02

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Lot No.: 23V Lot-specific information

LOT NO	<u> </u>	LU	-specific information	
16 ⁵	90 bp 165 bp 345 bp	1070 bp	*15:27 *15:15, 15:77 *15:26, 15:69	B*35:222
17 ⁷	140 bp 215 bp 295 bp	1070 bp	*15:34 *15:36 *15:39	*04:112 *01:30, 08:51, 12:87
18 ^{5,7}	160 bp	1070 bp	*15:31	*07:123, 07:173, 07:294, B*15:200 , B*39:82 , B*51:115 , B*58:05
19	165 bp 355 bp	1070 bp	*15:42 *15:46	
20 ⁵	120 bp 235 bp	1070 bp	*15:44 *15:45	
21	170 bp 445 bp	800 bp	*15:47 *15:35	*02:35, 05:21
22	225 bp	800 bp	*15:38	
23 ⁶	175 bp 545 bp	1070 bp	*15:48 *15:29	*08:22, 08:56
24	175 bp 380 bp	1070 bp	*15:32Q *15:41	*06:74Q
25	225 bp	1070 bp	*15:52	B*18:91
26	225 bp 205 bp	1070 bp 1070 bp	*15:56	B*35:132
27	330 bp	1070 bp	*15:30	*07:174, 07:298
28 ⁵	85 bp	1070 bp	*15:33	3 1, 37.233
29	255 bp	1070 bp	*15:81	
30 ⁵	90 bp	1070 bp	*15:82	
31 ⁸			Negative Control	

¹Alleles are assigned by the presence of specific PCR product(s). However, the sizes of the specific PCR products may be helpful in the interpretation of C*15 high resolution SSP typings. When the primers in a primer mix can give rise to HLA-specific PCR products of more than one length this is indicated if the size difference is more than 20 base pairs. Size differences of 20 base pairs or less are not given. For high resolution SSP kits, the alleles listed are specified according to amplicon length.

Nonspecific amplifications, i.e. a ladder or a smear of bands, may sometimes be seen. GC-rich primers have a higher tendency of giving rise to nonspecific amplifications than other primers. PCR fragments longer than the control bands may sometimes be observed. Such bands should be disregarded and do not influence the interpretation of the SSP typings.

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

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

²The internal positive control primer pairs amplify segments of the human growth hormone gene. The internal positive control bands are 1070 or 800 base pairs respectively, well distribution as outlined in the table. Well number 1 contains the shorter, 800 bp, internal positive control band. The well distribution of the internal controls can help in orientation of the kit on gel photo, as well as allow for kit identification. In the presence of a specific amplification the intensity of the control **◆LERUPSSP®** HLA-C*15

Product Insert

101.626-12 – including *Taq* **polymerase**, IFU-01 **101.626-12u – without** *Taq* **polymerase**, IFU-02

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Lot No.: 23V

Lot-specific information

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. Assumption is made 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*15 alleles will be amplified by primer mixes 1 to 5, 7 to 15, 17, 18, 21, 23, 24 and 27. In addition, a few HLA-B alleles will be amplified by primer mixes 5, 7, 8, 12, 14, 16, 18, 25 and 26.

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

⁶Primer mixes 5 and 23 may give rise to a lower yield of HLA-specific PCR product than the other C*15 primer mixes.

⁷Primer mixes 17 and 18 may have tendencies of unspecific amplifications.

⁸Primer mix 31 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.

CE

OLERUPSSP® HLA-C*15

Product Insert

101.626-12 – including *Taq* polymerase, IFU-01 101.626-12u – without *Taq* polymerase, IFU-02

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Lot No.: 23V Lot-specific information

PRIMER SPECIFICATION

Well No.	1	2	3	4	5	6	7	8	9	10	11	12
Length of spec.	325	175	85	315	100	305	140	160	135	170	315	100
PCR product			210			345		185	305			240
						370						
Length of int.	800	1070	1070	1070	1070	1070	800	1070	1070	1070	800	1070
pos. control 1												
5'-primer(s) ²	409	134	118	419	420	355	201	125	97	1 st I	420	105
,	^{5'} -ggC ^{3'}	5' -CCA 3'	^{5'} -CCg ^{3'}	^{5'} -gTC ^{3'}	5' -TTC 3'	5' -CCC 3'	5' -CCA 3'	^{5'} -CgA ^{3'}	^{5'} -TCg ^{3'}	^{5'} -CgA ^{3'}	^{5'} -TTA ^{3'}	^{5'} -gCT ^{3'}
						379		420	118		420	
						^{5'} -ACg ^{3'}		^{5'} -TTA ^{3'}	5' -CCA 3'		^{5'} -TTA ^{3'}	
						419			430			
						^{5'} -gTA ^{3'}			^{5'} -ACC ^{3'}			
3'-primer(s) ³	3 rd I	270	164	3 rd I	477	3 rd I	302	270	201	134	3 rd I	164
,	5' -CTC 3'	^{5'} -TAg ^{3'}	^{5'} -gCA ^{3'}	5' -CTC 3'	^{5'} -gCg ^{3'}	^{5'} -ggA ^{3'}	^{5'} -ggC ^{3'}	^{5'} -TAg ^{3'}	5' -CTT 3'	^{5'} -AgC ^{3'}	5' -CTC 3'	^{5'} -gCA ^{3'}
			289				302	539	3 rd I			302
			^{5'} -AgC ^{3'}				^{5'} -ggC ^{3'}	5' -TCC 3'	5' -CTC 3'			^{5'} -ggC ^{3'}
												302
												^{5'} -ggC ^{3'}
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

Well No.	13	14	15	16	17	18	19	20	21	22	23	24
Length of spec.	125	130	85	90	140	160	165	120	170	225	175	175
PCR product	185	440		165	215		355	235	445		545	380
				345	295							
Length of int.	1070	800	1070	1070	1070	1070	1070	1070	800	800	1070	1070
pos. control 1												
5'-primer(s) ²	201	270	270	261	98	409	368	105	322	128	134	356
	5' -CCA 3'	^{5'} -AAg ^{3'}	^{5'} -AAC ^{3'}	5' -AAC 3'	5' -CTC 3'	^{5'} -ggC ^{3'}	^{5'} -gTC ^{3'}	^{5'} -gCT ^{3'}	^{5'} -gCC ^{3'}	^{5'} -AgT ^{3'}	5' -CCA 3'	^{5'} -CAA ³
	2 nd I	757		379	2 nd I		560		715		972	562
	5' -CCA 3'	5' -CCC 3'		^{5'} -ACg ^{3'}	5' -CCA 3'		^{5'} -CgA ^{3'}		^{5'} -CAg ^{3'}		5' -CTA 3'	^{5'} -Cgg ³
				560								
				5' -CCT 3'								
3'-primer(s) ³	343	420	312	312	270	527	3 rd I	186	477	312	266	3 rd I
. ,	^{5'} -T ^{3'}	^{5'} -gCT ^{3'}	^{5'} -AgT ^{3'}	^{5'} -AgT ^{3'}	^{5'} -TAg ^{3'}	^{5'} -CCg ^{3'}	^{5'} -ggA ^{3'}	5' -TCC 3'	^{5'} -gCg ^{3'}	^{5'} -AgT ^{3'}	^{5'} -TCA ^{3'}	^{5'} -CTC ³
	412	846		3 rd I	427			299	846		1034	
	^{5'} -gTT ^{3'}	5' -CAC 3'		^{5'} -ggA ^{3'}	^{5'} -gTT ^{3'}			5' -TCT 3'	5' -CAC 3'		^{5'} -AgT ^{3'}	
					583							
					^{5'} -gTg ^{3'}							
Well No.	13	14	15	16	17	18	19	20	21	22	23	24

January 2015 Rev. No.: 01

Product Insert

HLA-C*15 **101.626-12 – including** *Taq* **polymerase**, IFU-01 **101.626-12u – without** *Taq* **polymerase**, IFU-02

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Well No.	25	26	27	28	29	30
Length of spec.	225	205	330	85	255	90
PCR product						
Length of int.	1070	1070	1070	1070	1070	1070
pos. control ¹						
5'-primer(s) ²	409	409	404	409	631	797
	^{5'} -ggC ^{3'}	^{5'} -ggC ^{3'}	^{5'} -CCA ^{3'}	^{5'} -ggC ^{3'}	^{5'} -Agg ^{3'}	^{5'} -CCg ^{3'}
21 mailing a #(a) ³	595	575	3 rd I	455	846	846
3'-primer(s) ³					5' -CAC 3'	
	^{5'} -CCg ^{3'}					
Well No.	25	26	27	28	29	30

¹The internal positive control primer pairs amplify segments of the human growth hormone gene. The internal positive control bands are 1070 or 800 base pairs respectively, well distribution as outlined in the table. Well number 1 contains the shorter, 800 bp, internal positive control band. The well distribution of the internal controls can help in orientation of the kit on gel photo, as well as allow for kit identification. In the presence of a specific amplification the intensity of the control band often decreases.

²The nucleotide position 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 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.

101.626-12 – including *Taq* **polymerase**, IFU-01 **101.626-12u – without** *Taq* **polymerase**, IFU-02

CELL LINE VALIDATION SHEET																				
HLA-C*15 SSP primer set ²																				
			Well																	
					1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
				Prod. No.:	201329001	201329002	201329003	201329004	201329005	201329006	201329007	201329008	201329009	201329010	201329011	201329012	201329013	201329014	201329015	201329016
IHWC cell line ¹			C*	· `	.,	.,	.,	.,	.,	.,	.,	.,	.,	.,	.,	.,	.,	.,	.,	
1	9001		*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		*05:01		-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-
8	9025		*04:01		-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-
9	9026		*12:03		-	-	-	+	-	-	+	-	-	+	-	-	-	-	-	-
10	9107		*01:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
11		PITOUT	*16:01		-	-	-	+	-	-	+	-	-	+	-	-	-	-	-	-
12	9052		*06:02		-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-
13		JESTHOM	*01:02	400.04	-	-	-	·	-	-	-	-	-	-	-	-	-	-	-	-
14		OLGA	*01:02	*03:04	-	-	•	·	-	-	-	-	-	-	-	+	-	•	-	-
15	9075		*03:04		-	•	•	·	-	•	-	-	-	-	•	+	-	•	-	•
16		SWEIG007	*02:02	*07.04	-	-	-	+	-	-	-	-	+	-	-	-	-	-	-	-
17		CTM3953540	*03:03	*07:01	-	-	-	+	-	-	-	-	-	-	-	+	-	-	-	-
18		32367	*01:02	*07:05	-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-
19 20		BM16 SLE005	*07:01 *03:04		-	-	-	+	-	-	-	-	-	-	-	÷	-	-	-	-
21		AMALA	*03:03		H	-	-	-	H	-	-	-	Ë	-	-	+	-	-	-	-
22		KOSE	*12:03		-	-		+	-	-	+	-	-	+	-	-	-	-	-	
23	9124		*01:02	*15:02	+	+	-	Η.	-	-	-	_	-	-	+		-	-	+	-
24		JBUSH	*12:03	13.02	-	-	-	+	-	-	+	-	-	+	-		-	-	-	-
25	9049		*08:02		-	-	-	÷	-	-	+	-	-	+	-	-	-	-	-	-
26		WT49	*07:01		-	-	-	+	-	-	Ė	-	-	Ė	-	-	-	-	-	-
27		CH1007	*07:04	*15:29	+	+	-	÷	+	-	-	-	-	-	-	-	-	-	+	-
28		BEL5GB	*05:01	*16:01	Ė	÷	-	+		-	+	-	-	+	-	-	-	-	÷	-
29	9050		*16:01	10.01	-	-	-	+	-	-	+	-	-	+	-	-	-	-	-	-
30	9021		*17:01		-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-
31	0040	DUCAF	*05:01		-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-
32	9297		*17:01	*17:03	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-
33		MT14B	*03:04		-	-	-	-	-	-	-	-	-	-	-	+	-	-	-	-
34	9104		*12:03		-	-	-	+	-	-	+	-	-	+	-	-	-	-	-	-
35	9302	SSTO	*05:01		-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-
36	9024		*03:03	*04:01	-	-	-	-	-	-	-	-	-	+	-	+	-	-	-	-
37		HHKB	*07:02		-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-
38	9099		*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		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	-	-	-	+	-	-	+	-	-	+	-	-	-	-	-	-

CELL LINE VALIDATION SHEET																		
HLA-C*15 SSP primer set ²																		
	Well															_		
					17	18	19	20	21			24	25	26	27	28	29	30
				.: 9	201329017	201329018	201329019	201329020	201329021	201329022	201329023	201329024	201329025	201329026	201329027	201329028	201329029	201329030
				Prod. No.:	326	326	326	326	326	326	326	326	326	328	326	326	326	326
				٥٥	201	201	201	201	201	201	201	201	201	201	201	201	201	201
	IHV	/C cell line ¹		C*	Ť	<u> </u>					``	``	Ť	``				
1	9001		*07:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-
2	9280	LK707	*07:01	*15:05	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3	9011	E4181324	*12:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-
4	9275	GU373	*03:04	*04:01	-	-	-	-	-	-	-	-	•	-	-	-	-	-
5		KAS011	*06:02		-	-	-	-	-	-	-	-	-	-	Ŀ	Ŀ	-	-
6	9353		*03:04	*07:02	ļ-	-	-	-	-	-	-	-	-	-	-	-	-	-
7	9020		*05:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-
8	9025		*04:01		ļ-	-	-	-	-	-	-	-	-	-	-	-	-	-
9	9026		*12:03		μ-	-	-	-	-	-	-	-	-	-	-	-	-	-
10 11		PITOUT	*01:02 *16:01	-	H	=	-	=	=	-	-	÷	-	-	-	-	-	-
12	9051				H	-	-	-	-	-	-	-		-	÷	÷	-	-
13		JESTHOM	*06:02 *01:02		H	-	-	-			-		-	-	÷	÷	-	
14		OLGA	*01:02	*03:04	-	-	-	-	-	-	-		-	-			-	-
15	9075		*03:04	00.04	-	-	-	-	-	-	-	-	-	-	-	-	-	-
16		SWEIG007	*02:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-
17		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		JBUSH	*12:03		-	-	-	-	-	-	-	•	-	-	Ŀ	Ŀ	-	-
25		IBW9	*08:02		-	-	•	-	-	-	-	•	-	-	Ŀ	Ŀ	-	-
26		WT49	*07:01	***	-	-	-	-	-	-	-	-	-	-	-	-	-	-
27		CH1007	*07:04	*15:29	-	-	•	•	-	-	+	•	-	•	Ŀ	Ŀ	-	-
28		BEL5GB	*05:01	*16:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-
29	9050		*16:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-
30	9021	DUCAF	*17:01 *05:01		H	-	-	-	-	-	-	-	-	-	-	-	-	-
32	9297		*17:01	*17:03	H	-	-	-	-		-	÷	-	-	Ë	Ë	Ë	H
33		MT14B	*03:04	17.03	∺	-	-	-	-		-	÷	-	-	÷	÷	-	-
34	9104		*12:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-
35		SSTO	*05:01		۱.	-	-	-	-	-	-	-	-	-	-	-	-	-
36		KT17	*03:03	*04:01	۱-	-	-	-	-	-	-	-	-	-	-	-	-	-
37		HHKB	*07:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-
38	9099		*03:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-
39	9315	CML	*02:02	*07:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-
40	9134	WHONP199	*01:02	*06:02	-	-	-	-	-	-	-	-	·	-	-	-	-	-
41		H0301	*08:02		-	-	-	-	-	-	-	-	١	-	Ē	Ξ	-	-
42		TAB089	*01:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-
43		T7526	*01:02	*08:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-
44	9057		*12:03		<u> -</u>	-	-	-	-	-	-	-	-	-	-	-	-	-
45		SHJO	*06:02	*17:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-
46		SCHU	*07:02	***	⊢-	-	-	-	-	-	-	-	-	-	-	-	-	-
47		TUBO	*07:04	*15:02	ļ-	-	-	-	-	-	-	-	-	-	-	-	-	-
48	9303	TER-ND	*04:01	*16:01	<u> </u>	-	-	-	-	-	-	-		-	-	-	-	-

¹The provided cell line HLA specificities are retrieved from the http://www.ihwg.org/hla web site. The specificity of an individual cell line may thus be subject to change.

Product Insert

HLA-C*15 **101.626-12 – including** *Taq* **polymerase**, IFU-01 **101.626-12u – without** *Taq* **polymerase**, IFU-02

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Lot No.: 23V

Lot-specific information

²The specificity of each primer solution in the kit has been tested against 48 well characterized cell line DNAs and where applicable, additional cell line DNAs.

No DNAs carrying the alleles to be amplified by primer solutions 3, 6, 8, 13, 14, 16 to 22 and 24 to 30 were available. The specificity of the primers in primer solutions 3, 6, 8, 13, 14 and 16 to 19 were tested by separately adding one 5'-primer, respectively one 3'-primer.

In primer solutions 20, 25, 26 and 28 it was only possible to test the 5'-primer, the 3'-primers were not possible to test. In primer solutions 21, 22, 24, 27, 29 and 30 it was only possible to test the 3'-primers, the 5'primers were not possible to test.

In primer mixes 8, 9, 11 and 14 one of the 5'-primers could not be tested, and in primer mixes 3, 7, 12, 17, 18 and 23 one or two of the 3'-primers could not be tested. Additional primers in primer solutions 9 and 23 were tested by separately adding either one 5'-primer or one 3'-primer.

• LERUPSSP® HLA-C*15 **Product Insert 101.626-12 – including** *Taq* **polymerase**, IFU-01 **101.626-12u – without** *Taq* **polymerase**, IFU-02

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•LERUPSSP® HLA-C*15

Product Insert

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101.626-12 – including *Taq* **polymerase**, IFU-01 **101.626-12u – without** *Taq* **polymerase**, IFU-02

"Instructions for Use" (IFU)

Lot No.: 23V Lot-specific information

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