

Lot No.: 5L1

Lot-specific information

Olerup SSP® HLA-B*46

Product number:	101.544-06 – including Taq polymerase 101.544-06u – without Taq polymerase
Lot number:	5L1
Expiry date:	2024-10-01
Number of tests:	6
Number of wells per test:	23+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. 5L1.

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-B*46 LOT (2K1)**

- The product documentation has been updated for new alleles of IMGT 3.40.0
- The kit resolution focuses on common and well documented (CWD) alleles¹.

¹As described in section Uniquely Identified Alleles.

The HLA-B*46 specificity and interpretation tables have been updated for the HLA-B alleles described since the previous *Olerup SSP®* HLA-B*46 lot was made (**Lot No. 2K1**).

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

Well	5'-primer	3'-primer	rationale
22	Added	-	5'-primer added for the B*46:77 allele.

¹S. J. Mack, P. Cano, J. A. Hollenbach et al.
Common and well-documented HLA alleles: 2012 update to the CWD catalogue. *Tissue Antigens*, 2013, 81, 194–203

Lot No.: **5L1**

Lot-specific information

Well **24** contains Negative Control primer pairs, that will amplify a majority of the *Olerup* SSP[®] HLA Class I, DRB, DQB1, DPB1 and DQA1 amplicons as well as all the amplicons generated by the control primer pairs matching the human growth hormone gene.

HLA-specific PCR product sizes range from 75 to 200 base pairs.

The PCR product generated by the positive control primer pair is 200 base pairs.

Length of PCR product	105	200	105	80	75	80	85
5'-primer¹	164	340	440	45	45	43	36
	5'-CAC ^{3'}	5'-Agg ^{3'}	5'-TTA ^{3'}	5'-Tgg ^{3'}	5'-Tgg ^{3'}	5'-Tgg ^{3'}	5'-TAC ^{3'}
							36
							5'-TAT ^{3'}
3'-primer²	231	2nd I	507	59	58	57	47
	5'-TgC ^{3'}	5'-AAA ^{3'}	5'-TTg ^{3'}	5'-CTC ^{3'}	5'-ggC ^{3'}	5'-CTC ^{3'}	5'-ACA ^{3'}
							48
							5'-gCA ^{3'}
							48
							5'-gCC ^{3'}
							52
							5'-TgT ^{3'}
A*	+	+	+				
B*	+	+	+				
C*	+	+	+				
DRB1				+	+		
DRB3				+	+		
DRB5				+			
DQB1					+		
DPB1						+	
DQA1							+

¹The nucleotide position for HLA class I genes and the codon for HLA class II genes, in the 2nd or 3rd exon, matching the specificity-determining 3'-end of the primer is given. Nucleotide and codon numbering as on the www.ebi.ac.uk/imgt/hla web site. The sequence of the 3 terminal nucleotides of the primer is given.

²The nucleotide position for HLA class I genes and the codon for HLA class II genes, in the 2nd or 3rd exon or the 2nd intron, matching the specificity-determining 3'-end of the primer is given in the anti-sense direction. Nucleotide and codon numbering as on the www.ebi.ac.uk/imgt/hla web site. The sequence of the 3 terminal nucleotides of the primer is given.

Lot No.: **5L1**

Lot-specific information

PRODUCT DESCRIPTION

HLA-B*46 SSP typing

CONTENT

The primer set contains 5'- and 3'-primers for identifying the B*46:01 to B*46:81 alleles.

PLATE LAYOUT

Each HLA-B*46 test consists of 24 PCR reactions in a 24 well cut PCR plate.

1	2	3	4	5	6	7	8
9	10	11	12	13	14	15	16
17	18	19	20	21	22	23	NC

The 24 well PCR plate is marked with 'HLA-B*46' in silver/gray ink.

Well No. 1 is marked with the Lot Number '5L1'.

Wells 1 to 23 – HLA-B*46 high resolution primers.

Well 24 – 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 24 well PCR plate, make sure that the remaining plates stay sealed. Use a scalpel or a similar instrument to carefully cut the foil between the plates.

INTERPRETATION

Due to the sharing of sequence motifs between HLA-B alleles, non-HLA-B*46 alleles will be amplified by some primer mixes. For further details see Specificity Table.

UNIQUELY IDENTIFIED ALLELES

All the HLA-B*46, i.e. **B*46:01 to B*46:81**, recognized by the HLA Nomenclature Committee in April 2020^{1,2} will be amplified by the primers in the HLA-B*46 SSP kit³.

The HLA-B*46 kit enables separation of the confirmed HLA-B*46 alleles as listed in the IMGT/HLA database 3.31.0. 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-B*46 alleles is listed below.

The HLA-B*46 kit also enables identification of many null and alternatively expressed alleles.

Lot No.: **5L1**

Lot-specific information

The following HLA-B*46 alleles can be distinguished by the different sizes of the HLA-specific PCR product:

Alleles	Primer mix
B*46:23, 46:57	18
B*46:28, 46:34	20

¹HLA-B alleles listed on the IMGT/HLA web page 2020-April-20, release 3.40.0, www.ebi.ac.uk/imgt/hla.

²Alleles 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>.

³The following alleles give rise to identical amplification patterns with the HLA-B*46 high resolution kit. These alleles can be distinguished by the HLA-B low resolution and/or the respective high resolution kits.

Alleles

B*46:01:26, 46:31, 46:47, 46:49, 46:79N, 15:318

B*46:77, 15:401, 54:06

Lot No.: **5L1**

Lot-specific information

ALLELE CONFIRMATION STATUS

Allele	Status ¹	Allele	Status ¹	Allele	Status ¹	Allele	Status ¹
B*46:01:01	Confirmed	B*46:09	Unconfirmed	B*46:36	Unconfirmed	B*46:65	Unconfirmed
B*46:01:02	Unconfirmed	B*46:10	Unconfirmed	B*46:37	Unconfirmed	B*46:66	Unconfirmed
B*46:01:03	Unconfirmed	B*46:11	Confirmed	B*46:38	Unconfirmed	B*46:67	Unconfirmed
B*46:01:04	Unconfirmed	B*46:12	Unconfirmed	B*46:39	Unconfirmed	B*46:68	Unconfirmed
B*46:01:05	Unconfirmed	B*46:13:01	Unconfirmed	B*46:40:01	Confirmed	B*46:69	Unconfirmed
B*46:01:06	Unconfirmed	B*46:13:02	Unconfirmed	B*46:40:02	Unconfirmed	B*46:70	Unconfirmed
B*46:01:07	Unconfirmed	B*46:13:03	Unconfirmed	B*46:41N	Unconfirmed	B*46:71	Unconfirmed
B*46:01:08	Unconfirmed	B*46:14	Unconfirmed	B*46:42	Unconfirmed	B*46:72	Unconfirmed
B*46:01:09	Unconfirmed	B*46:15N	Unconfirmed	B*46:43	Unconfirmed	B*46:73	Unconfirmed
B*46:01:10	Confirmed	B*46:16	Unconfirmed	B*46:44	Unconfirmed		
B*46:01:11	Unconfirmed	B*46:17	Unconfirmed	B*46:45	Unconfirmed		
B*46:01:12	Unconfirmed	B*46:18	Unconfirmed	B*46:46	Unconfirmed		
B*46:01:13	Unconfirmed	B*46:19	Unconfirmed	B*46:47	Unconfirmed		
B*46:01:14	Unconfirmed	B*46:20	Unconfirmed	B*46:48	Unconfirmed		
B*46:01:15	Unconfirmed	B*46:21:01	Confirmed	B*46:49	Unconfirmed		
B*46:01:16	Unconfirmed	B*46:21:02	Unconfirmed	B*46:50	Unconfirmed		
B*46:01:17	Unconfirmed	B*46:22	Confirmed	B*46:51Q	Unconfirmed		
B*46:01:18	Unconfirmed	B*46:23	Unconfirmed	B*46:52	Unconfirmed		
B*46:01:19	Unconfirmed	B*46:24	Unconfirmed	B*46:53	Unconfirmed		
B*46:01:20	Unconfirmed	B*46:25	Unconfirmed	B*46:54	Unconfirmed		
B*46:01:21	Unconfirmed	B*46:26	Unconfirmed	B*46:55N	Unconfirmed		
B*46:01:22	Unconfirmed	B*46:27	Confirmed	B*46:56	Unconfirmed		
B*46:01:23	Unconfirmed	B*46:28	Unconfirmed	B*46:57	Unconfirmed		
B*46:02	Unconfirmed	B*46:29	Unconfirmed	B*46:58	Unconfirmed		
B*46:03	Unconfirmed	B*46:30	Confirmed	B*46:59	Unconfirmed		
B*46:04	Unconfirmed	B*46:31	Unconfirmed	B*46:60	Unconfirmed		
B*46:05	Unconfirmed	B*46:32	Confirmed	B*46:61	Unconfirmed		
B*46:06	Unconfirmed	B*46:33	Unconfirmed	B*46:62	Unconfirmed		
B*46:07N	Unconfirmed	B*46:34	Unconfirmed	B*46:63	Unconfirmed		
B*46:08	Unconfirmed	B*46:35	Unconfirmed	B*46:64	Unconfirmed		

¹Allele status “confirmed” or “unconfirmed” as listed on the IMGT/HLA web page 2018-January-19, release 3.31.0, www.ebi.ac.uk/imgt/hla.

RESOLUTION IN HOMO- AND HETEROZYGOTES

Results file with resolution in HLA-B*46 homo- and heterozygotes is available upon request.

Lot No.: 5L1

Lot-specific information
SPECIFICITY TABLE

HLA-B*46 SSP subtyping

Specificities and sizes of the PCR products of the 23+1 primer mixes used for HLA-B*46 SSP subtyping

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified HLA-B*46 alleles ³	Other amplified HLA Class I alleles
1 ⁴	100 bp	800 bp	*46:01:01:01-46:01:25, 46:01:27-46:03, 46:05-46:15N, 46:17-46:21:02, 46:23-46:30, 46:32-46:39, 46:42-46:46, 46:48, 46:50-46:76, 46:78, 46:80-46:81	C*01:73
2 ⁴	115 bp	1070 bp	*46:02, 46:16	
3	395 bp	1070 bp	*46:03, 46:18, 46:21:01-46:21:02, 46:29	*15:42, 15:44, 15:50, 15:69, 15:86, 15:93, 15:121, 15:186, 15:188, 15:199, 15:224, 15:252, 15:265, 15:323, 15:348, 15:368, 15:449, 15:485, 15:494, 15:497
4	130 bp 245 bp	1070 bp	*46:04, 46:40:01-46:40:02 *46:14	*18:06, 18:142 ^w , 35:74, 35:186, 35:356 *18:06, 18:142 ^w , 27:202, 40:73, 73:01:01:01 ^w -73:02 ^w , C*03:278, C*03:504, C*07:714, C*07:724, C*16:86
5	235 bp	1070 bp	*46:01:01:01-46:04, 46:06-46:71, 46:73-46:76, 46:78-46:81	*08:15, 15:57 ^w , 15:289, 15:318, 15:397, 15:526, 35:74, 35:186, 35:356, 40:73, 55:03, 55:49, 55:69, C*07:441:01-07:441:02, C*16:86, C*16:147
6 ⁴	120 bp 225 bp	800 bp	*46:20 *46:06	*35:392, 35:425, 55:19 *07:09:01-07:09:02, 07:11, 07:17, 07:162, 07:237, 07:255, 07:287, 15:138, 15:241, 15:297, 18:35, 18:110, 35:66, 40:38, 40:52, 40:59-40:60, 40:158, 40:222, 40:352, 40:422, 48:14, 48:23, C*07:38:01-07:38:02
7 ^{4,5}	105 bp 140 bp	1070 bp	*46:16 *46:07N	*14:07N, 35:461N, 39:40:01N-39:40:02N, 56:19N
8	180 bp 190 bp 380 bp	800 bp	*46:56 *46:39 *46:06, 46:08, 46:11, 46:13:01-46:13:03, 46:18-46:19, 46:21:01-46:21:02, 46:25, 46:33, 46:43	*35:298 *15:02:01:01-15:03:11, 15:05:01-15:06, 15:09:01-15:10:05, 15:13:01-15:13:02, 15:16:01:01-15:18:07, 15:21:01:01-15:21:01:02, 15:23, 15:25:01:01-15:25:04, 15:29:01:01-15:29:01:02, 15:31:01:01-15:31:01:03, 15:36-15:37, 15:39:01:01-15:40:02, 15:42, 15:44, 15:48, 15:52, 15:55, 15:61-15:62, 15:64:01-15:64:02, 15:67, 15:69, 15:72, 15:74, 15:80, 15:86, 15:88-15:91, 15:93, 15:95, 15:98, 15:103, 15:106-15:108, 15:112, 15:114-15:115, 15:119, 15:121, 15:123-15:124,

Lot No.: **5L1**

Lot-specific information

				15:127, 15:131-15:134, 15:136, 15:138-15:139, 15:151, 15:153, 15:155-15:156, 15:158, 15:161-15:162, 15:168, 15:170, 15:173, 15:176-15:177, 15:185-15:186, 15:188, 15:194-15:198, 15:200, 15:204, 15:208, 15:210, 15:213-15:214, 15:216, 15:219-15:220:02, 15:222-15:224, 15:226N, 15:229-15:230, 15:235, 15:238, 15:240, 15:242:01-15:243, 15:249-15:250, 15:252-15:255, 15:263, 15:265-15:266, 15:268, 15:271, 15:273-15:275:02, 15:281-15:283, 15:288-15:294N, 15:297, 15:301-15:302N, 15:306-15:308, 15:310-15:314, 15:319, 15:323, 15:325, 15:328-15:330, 15:332, 15:335, 15:337-15:339, 15:341, 15:345, 15:348, 15:351, 15:354, 15:356-15:358, 15:360-15:361, 15:364, 15:366, 15:369, 15:376, 15:378, 15:380N, 15:382-15:384, 15:388-15:389, 15:393-15:397, 15:399, 15:402-15:404, 15:407-15:408, 15:411, 15:414, 15:418, 15:420-15:421, 15:423-15:427, 15:433-15:439, 15:444-15:449, 15:451, 15:454N-15:455, 15:458, 15:460, 15:462-15:463N, 15:468, 15:475, 15:485, 15:487N, 15:491, 15:494-15:495, 15:497, 15:500, 15:502-15:506, 15:508-15:509, 15:511, 15:516-15:517, 15:523, 15:526-15:527, 15:530, 15:532, 15:537, 15:539, 15:543-15:544N, 15:546Q, 15:548, 15:550, 15:552-15:553, 15:555, 15:557, 15:560
g⁴	115 bp	1070 bp	*46:01:01:01-46:02, 46:04-46:05, 46:07N, 46:09-46:10, 46:12, 46:14-46:17, 46:20, 46:22-46:24, 46:26-46:32, 46:34-46:42, 46:44, 46:46-46:53, 46:55N-46:57, 46:60-46:61, 46:63-46:81	*07:100, 13:31, 13:41, 13:131, 15:01:01:01-15:01:04, 15:01:06-15:01:16, 15:01:18-15:01:30, 15:01:32-15:01:62, 15:04:01:01-15:04:04, 15:07:01:01-15:08:02, 15:11:01-15:12:03, 15:14-15:15:01:02, 15:19, 15:24:01-15:24:02, 15:26N-15:28, 15:30:01:01-15:30:01:03, 15:32:01-15:32:02, 15:34-15:35, 15:38:01-15:38:02, 15:43, 15:45-15:46, 15:50, 15:53-15:54, 15:56-15:58, 15:60, 15:63, 15:66, 15:68, 15:70-15:71, 15:73:01:01-15:73:01:02, 15:75-15:77, 15:79N, 15:81-15:82, 15:85, 15:87, 15:92, 15:94N, 15:96-15:97, 15:101-15:102, 15:104-15:105, 15:109-15:111N, 15:113, 15:117-15:118, 15:120, 15:122, 15:125:01-15:126, 15:128-15:129, 15:135, 15:137, 15:140, 15:142-15:149N, 15:152, 15:154, 15:157, 15:159-15:160:01:02, 15:163-15:167, 15:169, 15:171-15:172, 15:174-15:175, 15:178, 15:180-15:184, 15:187, 15:189-15:193, 15:201-15:203, 15:205-15:207, 15:209N, 15:211-15:212, 15:215, 15:217, 15:225, 15:227-15:228, 15:231-15:234, 15:236, 15:239, 15:241, 15:244-15:247, 15:251:01-15:251:03, 15:256-15:262N, 15:264, 15:267, 15:269-15:270, 15:272N, 15:276-15:280, 15:284-15:286, 15:296, 15:298-15:299, 15:303-15:305, 15:309, 15:315-15:318, 15:320-15:321Q,

Lot No.: **5L1**

Lot-specific information

				15:324, 15:326-15:327, 15:331, 15:333-15:334, 15:336, 15:340, 15:342-15:344, 15:346-15:347, 15:349:01-15:350, 15:353, 15:355, 15:359, 15:363:01-15:363:02, 15:365, 15:367-15:368, 15:370-15:373, 15:375N, 15:377Q, 15:381, 15:385-15:387, 15:390-15:392, 15:398, 15:400N-15:401, 15:405-15:406, 15:409-15:410, 15:412-15:413, 15:415-15:417, 15:419, 15:422, 15:428-15:432, 15:440-15:443, 15:450, 15:452-15:453, 15:456-15:457, 15:459, 15:461, 15:464-15:467, 15:469-15:474, 15:476-15:484, 15:486, 15:488-15:490, 15:492-15:493, 15:496N, 15:498-15:499, 15:501, 15:507, 15:510, 15:512-15:515, 15:520Q-15:522, 15:525, 15:528N-15:529, 15:531, 15:533-15:536, 15:538, 15:540N-15:542, 15:545, 15:547, 15:549N, 15:551, 15:554, 15:556, 15:558-15:559, 15:561-15:562N, 18:19, 18:164, 27:25, 27:115, 27:161, 35:14:01-35:14:03, 35:43:01, 35:43:03-35:44, 35:62, 35:67, 35:79, 35:86, 35:102, 35:117, 35:135, 35:163, 35:185, 35:213, 35:265, 35:343, 35:390N, 35:413, 35:475-35:476, 37:66, 39:36, 44:146, 44:275, 44:299, 50:47, 51:61:01-51:61:02, 51:220, 52:21:01-52:21:02, 54:06, 54:33, 54:40, 55:21, 56:03, 56:43, 58:78, A*25:66, A*26:68, A*26:100, A*26:200, A*68:56, C*02:56, C*06:20, C*12:50
10^{4,5}	100 bp	800 bp	*46:05	*07:204, 07:210, 07:383, 13:124, 14:02:13, 15:125:01, 35:54, 37:85, 51:140, C*05:01:28, C*07:02:30, C*08:16:02
	160 bp		*46:38	*18:135:01:01-18:135:01:02
	315 bp		*46:15N	
11	150 bp	1070 bp	*46:09	*15:415, 15:499, 15:507, 35:62, C*02:28, C*12:180
12⁴	100 bp	1070 bp	*46:40:01-46:40:02	*35:186
	170 bp		*46:10	C*02:167, C*03:504, C*05:205, C*06:284, C*07:828
	305 bp		*46:55N	
	380 bp		*46:19	*15:48, 15:108, 15:136, 15:235, 15:249
13^{4,5}	105 bp	1070 bp	*46:11, 46:18	*07:78, 13:02:01:01-13:02:14, 13:02:16-13:03, 13:08-13:09, 13:14-13:16, 13:18-13:19, 13:27, 13:30-13:34, 13:37-13:38, 13:40-13:42, 13:44-13:45, 13:48-13:49N, 13:53-13:56:02N, 13:58, 13:65-13:70, 13:74-13:75, 13:81-13:82, 13:84-13:85, 13:88-13:89, 13:91, 13:93-13:94, 13:96-13:105, 13:111-13:121, 13:123Q-13:126, 13:128, 13:130-13:134, 13:136-13:137N, 13:139N, 14:37, 15:42, 15:303, 15:485, 15:552, 35:60, 44:15:01:01-44:15:01:02, 44:18, 44:339, 45:01:01:01-45:01:09, 45:03-45:08, 45:10-45:25, 49:01:01:01-49:03, 49:06-49:14, 49:16-49:17, 49:19N-49:46, 49:48-49:49, 49:51-49:60N, 49:62-49:67, 50:01:01:01-50:02:01:02, 50:04-50:08, 50:10-50:11, 50:13, 50:15, 50:18-50:19, 50:31-50:32, 50:34-50:40, 50:43-50:50,

Lot No.: **5L1**

Lot-specific information

	220 bp		*46:22, 46:32	50:52-50:69, 51:15, 51:106:02, 51:157, 51:225, 51:300, 52:25:01, 54:01:01:01-54:03, 54:05N, 54:07-54:08N, 54:10, 54:12-54:13, 54:16-54:30, 54:32-54:37, 54:39-54:41, 55:01:01:01-55:01:03, 55:01:05-55:01:06, 55:01:08-55:02:10, 55:02:12-55:03, 55:05, 55:07, 55:09-55:12, 55:15-55:16, 55:18-55:19, 55:21-55:22, 55:24-55:26, 55:29-55:31, 55:33-55:38, 55:40-55:41, 55:43, 55:45-55:48, 55:50, 55:52, 55:54-55:57, 55:59-55:60, 55:62-55:67, 55:69-55:80, 55:82-55:85, 55:87-55:93, 55:95-55:107, 56:01:01:01-56:01:15, 56:07-56:08, 56:13-56:14, 56:16-56:17, 56:19N-56:20:02, 56:23-56:30, 56:33-56:49, 56:52-56:55:01:02, 56:58-56:59, 56:61-56:62, 56:64-56:65, 56:67-56:73, 59:01:01:01-59:01:01:02, 59:04-59:10N *13:31, 13:41, 13:131, 15:04:01:01-15:04:04, 15:137, 15:303, 15:499, 15:531, 35:265, 50:47, 51:61:01-51:61:02, 52:21:01-52:21:02, 54:33, 54:40, 55:21, 56:43, C*12:183
14⁵	215 bp	1070 bp	*46:12	*07:55, 07:100, 08:70, 15:07:01:01-15:07:03, 15:45, 15:68, 15:126, 15:207, 15:324, 15:331, 15:405, 15:431, 15:450, 15:524, 48:19, C*02:60, C*06:264
15	305 bp 330 bp	1070 bp	*46:55N *46:01:03, 46:01:16, 46:01:24, 46:11, 46:13:01-46:13:02, 46:18, 46:21:02, 46:33	*15:01:44, 15:02:09, 15:03:02, 15:03:04, 15:05:02, 15:07:03, 15:13:02, 15:18:06, 15:27:03, 15:38:02, 15:39:02, 15:42, 15:48, 15:78:04, 15:86, 15:179:01, 15:188, 15:224, 15:269, 15:275:01, 15:383, 15:393, 15:407, 15:435, 15:485, 15:552
16⁵	205 bp	1070 bp	*46:17, 46:22	*15:14, 15:91, 15:131, 15:161, 15:518, 15:551, 18:56, 18:169, 35:45, 35:71, 44:17, 44:43:01-44:43:02, 44:144, 44:230, 44:256, 44:308, 45:09, 53:22, 57:93, 57:119, 58:07, C*02:82, C*06:165, C*14:61
17	365 bp	800 bp	*46:06, 46:11, 46:13:01-46:13:03, 46:18, 46:21:01- 46:21:02, 46:25, 46:33, 46:43	*15:05:01-15:05:03, 15:31:01:01-15:31:01:03, 15:52, 15:55, 15:84 ^w , 15:86, 15:91, 15:107, 15:114, 15:123-15:124, 15:151, 15:155, 15:185, 15:188, 15:222, 15:224, 15:237 ^w , 15:275:01-15:275:02, 15:283, 15:332, 15:348, 15:383, 15:393, 15:396, 15:407, 15:421, 15:485, 15:539, 15:552
18⁴	95 bp 265 bp	1070 bp	*46:23 *46:57	
19	160 bp 230 bp	800 bp	*46:38 *46:24	*18:135:01:01-18:135:01:02 *15:19, 15:304N
20⁴	225 bp 340 bp	1070 bp	*46:34 *46:28	*15:340
21	235 bp 270 bp	1070 bp	*46:51Q *46:26	
22	180 bp 215 bp	1070 bp	*46:56 *46:27	*15:292, 15:401, 35:113, 44:98, 52:31:01-52:31:02, A*02:376, C*03:125, C*03:176
	245 bp		*46:41N	

Lot No.: **5L1**

Lot-specific information

	325 bp		*46:77	*07:13, 07:247, 07:270, 08:188, 15:434, 27:198, 39:121, 54:01:01:01-54:01:06, 54:01:08-54:41, 55:07, 59:06
23	400 bp	1070 bp	*46:06, 46:25, 46:30, 46:51Q	*15:40:01-15:40:02, 15:47:01-15:47:02, 15:49, 15:52, 15:114, 15:117, 15:124, 15:138, 15:238, 15:241, 15:389, 15:421, 15:519, 15:532
24⁶	-	-	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 HLA-B*46 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 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 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.

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.

⁴HLA-specific PCR products shorter than 125 base pairs have a lower intensity and are less sharp than longer PCR products.

⁵Primer mixes 7, 10, 13, 14 and 16 may have tendencies of unspecific amplifications.

⁶Primer mix 24 contains a negative control, which will amplify the majority of HLA amplicons as well as the amplicons generated by the control primer pairs matching the human growth hormone gene. HLA-specific PCR product sizes range from 75 to 200 base pairs and the PCR product generated by the HGH positive control primer pair is 200 base pairs.

Abbreviations

'w', might be weakly amplified.

Lot No.: 5L1

Lot-specific information
PRIMER SPECIFICATION

Well No.	1	2	3	4	5	6	7	8	9	10	11	12
Length of spec.	100	115	395	130	235	120	105	190	115	100	150	100
PCR product				245		225	140	380		160		170
							180			315		305
												380
Length of int. pos. control ¹	800	1070	1070	1070	1070	800	1070	800	1070	800	1070	1070
5'-primer(s) ²	209	209	2 nd I	97	106	106	209	2 nd I	463	106	419	142
	5'-ggC 3'	5'-ggC 3'	5'-CAA 3'	5'-TCC 3'	5'-CCA 3'	5'-CCA 3'	5'-ggC 3'	5'-CAA 3'	5'-TgA 3'	5'-CCg 3'	5'-gTC 3'	5'-TCA 3'
				209		419	463	625		736		209
				5'-ggg 3'		5'-gTC 3'	5'-TgA 3'	5'-CCA 3'		5'-gCT 3'		5'-ggA 3'
				209			3 rd I			890		2 nd I
				5'-ggA 3'			5'-Agg 3'			5'-gAA 3'		5'-CAA 3'
3'-primer(s) ³	269	272	559	299	299	187	272	538	538	165	527	269
	5'-ACT 3'	5'-TgA 3'	5'-CgT 3'	5'-TCA 3'	5'-TCA 3'	5'-gTT 3'	5'-TgA 3'	5'-CAg 3'	5'-CCA 3'	5'-Tgg 3'	5'-CCA 3'	5'-ACT 3'
		293				605	564	544		916		470
		5'-ggC 3'				5'-gCT 3'	5'-ACT 3'	5'-ggT 3'		5'-gAT 3'		5'-TCT 3'
						707	774					544
						5'-TCA 3'	5'-ggT 3'					5'-ggT 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	
Length of spec.	105	215	305	205	365	95	160	225	235	180	400	
PCR product	220		330				265	230	340	270	215	
										245		
										325		
Length of int. pos. control ¹	1070	1070	1070	1070	800	1070	800	1070	1070	1070	1070	
5'-primer(s) ²	106	363	2 nd I	106	2 nd I	419	821	45	369	206	2 nd I	
	5'-CCA 3'	5'-AgC 3'	5'-CAA 3'	5'-CCA 3'	5'-CAA 3'	5'-gTC 3'	5'-gCT 3'	5'-ggA 3'	5'-TAC 3'	5'-Agg 3'	5'-CAA 3'	
	357		419			3 rd I	890	668		289		
	5'-Tgg 3'		5'-gTC 3'			5'-Agg 3'	5'-gAA 3'	5'-ggC 3'		5'-gA 3'		
										385		
										5'-ggT 3'		
										3 rd I		
										5'-Agg 3'		
3'-primer(s) ³	281	538	470	281	527	472	916	214	564	2 nd I	559	
	5'-CCC 3'	5'-CCA 3'	5'-TCT 3'	5'-CCC 3'	5'-CCA 3'	5'-ggA 3'	5'-gAT 3'	5'-CCA 3'	5'-ACC 3'	5'-TCg 3'	5'-CTC 3'	
	420		486	572		791		853	599	559	564	
	5'-gCT 3'		5'-gCg 3'	5'-gCg 3'		5'-AgT 3'		5'-TAg 3'	5'-CCC 3'	5'-CAg 3'	5'-ACC 3'	
	538		498							707		
	5'-CCA 3'		5'-gTA 3'							5'-TCA 3'		
Well No.	13	14	15	16	17	18	19	20	21	22	23	

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.

Lot No.: **5L1**

Lot-specific information

CELL LINE VALIDATION SHEET																				
HLA-B*46 SSP primer set²																				
				Well																
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	
				Prod. No.:	201776601	201776602	201776603	201776604	201776605	201893806	201776607	201776608	201776609	201776610	201776611	201776612	201776613	201776614	201776615	201776616
IHC cell line ¹		B*																		
1	9001 SA	*07:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2	9280 LK707	*52:01	*73:01	-	-	-	w	-	-	-	-	-	-	-	-	-	-	-	-	-
3	9011 E4181324	*52:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4	9275 GU373	*15:10	*53:01	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-
5	9009 KAS011	*37:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
6	9353 SM	*39:01	*51:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
7	9020 QBL	*18:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
8	9025 DEU	*35:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
9	9026 YAR	*38:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
10	9107 LKT3	*54:01		-	-	-	-	-	-	-	-	-	-	-	-	-	+	-	-	-
11	9051 PITOUT	*44:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
12	9052 DBB	*57:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
13	9025 JESTHOM	*27:05		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
14	9071 OLGA	*15:01	*15:20	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-
15	9075 DKB	*40:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
16	9037 SWEIG007	*40:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
17	9282 CTM8953540	*08:01	*55:01	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-	-	-
18	9257 32367	*14:01	*56:01	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-	-	-
19	9038 BM16	*18:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
20	9059 SLE005	*40:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
21	9064 AMALA	*15:01		-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-
22	9056 KOSE	*35:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
23	9124 IHL	*40:02	*56:02	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
24	9035 JBUSH	*38:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
25	9049 IBW9	*14:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
26	9285 WT49	*58:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
27	9191 CH1007	*07:05	*51:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
28	9320 BEL5GB	*44:02	*44:03	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
29	9050 MOU	*44:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
30	9021 RSH	*42:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
31	9019 DUCAF	*18:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
32	9297 HAG	*41:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
33	9098 MT14B	*40:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
34	9104 DHIF	*38:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
35	9302 SSTO	*44:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
36	9024 KT17	*15:01	*35:01	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-
37	9065 HHKB	*07:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
38	9099 LZL	*15:01		-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-
39	9315 CML	*08:01	*27:05	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
40	9134 WHONP199	*13:02	*46:01	+	-	-	-	+	-	-	-	+	-	-	-	+	-	-	-	-
41	9055 H0301	*14:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
42	9066 TAB089	*46:01		+	-	-	-	+	-	-	-	+	-	-	-	-	-	-	-	-
43	9076 T7526	*46:01		+	-	-	-	+	-	-	-	+	-	-	-	-	-	-	-	-
44	9057 TEM	*38:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
45	9239 SHJO	*42:01	*50:01	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-	-	-
46	9013 SCHU	*07:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
47	9045 TUBO	*51:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
48	9303 TER-ND	*35:01	*44:03	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

Lot No.: **5L1**

Lot-specific information

CELL LINE VALIDATION SHEET											
HLA-B*46 SSP primer set ²											
				Well							
				17	18	19	20	21	22	23	
				Prod. No.:	201776617	201776618	201909319	201893820	201776621	202023822	201776623
IHWC cell line ¹		B*									
1	9001 SA	*07:02		-	-	-	-	-	-	-	
2	9280 LK707	*52:01	*73:01	-	-	-	-	-	-	-	
3	9011 E4181324	*52:01		-	-	-	-	-	-	-	
4	9275 GU373	*15:10	*53:01	-	-	-	-	-	-	-	
5	9009 KAS011	*37:01		-	-	-	-	-	-	-	
6	9353 SM	*39:01	*51:01	-	-	-	-	-	-	-	
7	9020 QBL	*18:01		-	-	-	-	-	-	-	
8	9025 DEU	*35:01		-	-	-	-	-	-	-	
9	9026 YAR	*38:01		-	-	-	-	-	-	-	
10	9107 LKT3	*54:01		-	-	-	-	-	+	-	
11	9051 PITOUT	*44:03		-	-	-	-	-	-	-	
12	9052 DBB	*57:01		-	-	-	-	-	-	-	
13	9025 JESTHOM	*27:05		-	-	-	-	-	-	-	
14	9071 OLGA	*15:01	*15:20	-	-	-	-	-	-	-	
15	9075 DKB	*40:01		-	-	-	-	-	-	-	
16	9037 SWEIG007	*40:02		-	-	-	-	-	-	-	
17	9282 CTM3953540	*08:01	*55:01	-	-	-	-	-	-	-	
18	9257 32367	*14:01	*56:01	-	-	-	-	-	-	-	
19	9038 BM16	*18:01		-	-	-	-	-	-	-	
20	9059 SLE005	*40:01		-	-	-	-	-	-	-	
21	9064 AMALA	*15:01		-	-	-	-	-	-	-	
22	9056 KOSE	*35:03		-	-	-	-	-	-	-	
23	9124 IHL	*40:02	*56:02	-	-	-	-	-	-	-	
24	9035 JBUSH	*38:01		-	-	-	-	-	-	-	
25	9049 IBW9	*14:02		-	-	-	-	-	-	-	
26	9285 WT49	*58:01		-	-	-	-	-	-	-	
27	9191 CH1007	*07:05	*51:01	-	-	-	-	-	-	-	
28	9320 BEL5GB	*44:02	*44:03	-	-	-	-	-	-	-	
29	9050 MOU	*44:03		-	-	-	-	-	-	-	
30	9021 RSH	*42:01		-	-	-	-	-	-	-	
31	9019 DUCAF	*18:01		-	-	-	-	-	-	-	
32	9297 HAG	*41:02		-	-	-	-	-	-	-	
33	9098 MT14B	*40:01		-	-	-	-	-	-	-	
34	9104 DHIF	*38:01		-	-	-	-	-	-	-	
35	9302 SSTO	*44:02		-	-	-	-	-	-	-	
36	9024 KT17	*15:01	*35:01	-	-	-	-	-	-	-	
37	9065 HHKB	*07:02		-	-	-	-	-	-	-	
38	9099 LZL	*15:01		-	-	-	-	-	-	-	
39	9315 CML	*08:01	*27:05	-	-	-	-	-	-	-	
40	9134 WHONP199	*13:02	*46:01	-	-	-	-	-	-	-	
41	9055 H0301	*14:02		-	-	-	-	-	-	-	
42	9066 TAB089	*46:01		-	-	-	-	-	-	-	
43	9076 T7526	*46:01		-	-	-	-	-	-	-	
44	9057 TEM	*38:01		-	-	-	-	-	-	-	
45	9239 SHJO	*42:01	*50:01	-	-	-	-	-	-	-	
46	9013 SCHU	*07:02		-	-	-	-	-	-	-	
47	9045 TUBO	*51:01		-	-	-	-	-	-	-	
48	9303 TER-ND	*35:01	*44:03	-	-	-	-	-	-	-	

Lot No.: 5L1

Lot-specific information

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.

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 2, 3, 6, 7, 10 to 12, 15, 17, 18 and 20 to 21 were available.

The specificities of the primers in primer solutions 3, 6, 10 to 12, 15 and 17 were tested by separately adding one or two additional 5'-primers, respectively one or two additional 3'-primers.

In primer solutions 2, 7, 18, 20 and 21 it was only possible to test the 5'-primers, the 3'-primers were not possible to test.

In primer solutions 4, 8, 10, 19 and 22 one or two of the 5'-primers were not possible to test, and in primer solutions 6, 8, 12, 13, 15, 16, 22 and 23 one or two of the 3'-primers were not possible to test. In addition, one or more 3'- and/or 5'-primers in primer solutions 4, 8, 13, 16 and 22 were tested by separately adding one 5'-primer and/or one 3'-primer respectively.

Lot No.: **5L1**

Lot-specific information

ADDRESSES:

Manufacturer:

CareDx AB, Franzengatan 5, SE-112 51 Stockholm, Sweden.

Tel: +46-8-508 939 00

Fax: +46-8-717 88 18

E-mail: orders-se@caredx.com

Web page: <https://labproducts.caredx.com/>

Distributed by:

CareDx GmbH, Löwengasse 47 / 6, AT-1030 Vienna, Austria.

Tel: +43-1-710 15 00

Fax: +43-1-710 15 00 10

E-mail: orders-at@caredx.com

Web page: <https://labproducts.caredx.com/>

CareDx Lab Solutions Inc., 901 S. Bolmar St., Suite R, West Chester, PA 19382

Tel: 1-877-653-78171

Fax: 610-344-7989

E-mail: orders-us@caredx.com

Web page: <https://labproducts.caredx.com/>

For information on CareDx distributors worldwide, contact **CareDx GmbH**.