101.544-06 – including *Taq* pol., IFU-01
101.544-06u – without *Taq* pol., IFU-02

Visit www.olerup-ssp.com for
"Instructions for Use" (IFU)

Lot No.: 58Y

Lot-specific information

Olerup SSP® HLA-B*46

Product number:	**101.544-06– including *Taq* polymerase** **101.544-06u – without *Taq* polymerase**
Lot number:	**58Y**
Expiry date:	**2018-February-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. 58Y.

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 (97S)

The HLA-B*46 kit is updated for new alleles to enable separation of:

- Confirmed[1] 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.

[1]As described in section Uniquely Identified Alleles.

The HLA-B*46 primer set, 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. 97S)**. The kit design is based on IMGT/HLA database 3.20.0.

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.

101.544-06 – including *Taq* pol., IFU-01
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Lot No.: 58Y **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
4	Added	-	5'-primer added for the B*46:40 allele.
7	Added	Added	Primer pair added for the B*46:56 allele.
12	Added	Added	5'-primer added for the B*46:40 allele, 3'-primer added for the B*46:55N allele.
13	-	Added	3'-primer added for the B*46:32 allele.
15	-	Added	3'-primer added for the B*46:55N allele.
18	Added	Added	Primer pair added for the B*46:57 allele.
20	Added	Added	Primer pair added from well 23.
21	-	Added	3'-primer added for the B*46:51Q allele.
22	Added	Added	Primer pair added for the B*46:56 allele.
23	Moved, added	Moved, added	Primer pair moved to well 20, primer pair added from well 24, 3'-primer added for the B*46:51Q allele.
24	Moved	Moved	Primer pair moved to well 23, negative control.

Lot No.: 58Y **Lot-specific information**

Well **24** contains Negative Control primer pairs, that will amplify more than 95% 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 430 base pairs.

Length of PCR product	**105**	**200**	**105**	**80**	**75**	**80**	**85**
5'-primer[1]	**164**	**340**	**440**	**45**	**45**	**43**	**36**
	5'-CAC3'	**5'-Agg3'**	**5'-TTA3'**	**5'-Tgg3'**	**5'-Tgg3'**	**5'-Tgg3'**	**5'-TAC3'**
							36
							5'-TAT3'
3'-primer[2]	**231**	**2nd I**	**507**	**59**	**58**	**57**	**47**
	5'-TgC3'	**5'-AAA3'**	**5'-TTg3'**	**5'-CTC3'**	**5'-ggC3'**	**5'-CTC3'**	**5'-ACA3'**
							48
							5'-gCA3'
							48
							5'-gCC3'
							52
							5'-TgT3'
A*	**+**	**+**	**+**				
B*	**+**	**+**	**+**				
C*	**+**	**+**	**+**				
DRB1				**+**	**+**		
DRB3				**+**	**+**		
DRB5				**+**			
DQB1					**+**		
DPB1						**+**	
DQA1							**+**

[1]The 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 codonnumbering as on the www.ebi.ac.uk/imgt/hla web site. The sequence of the 3 terminal nucleotides of the primer is given.
[2]The 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.

101.544-06 – including *Taq* pol., IFU-01
101.544-06u – without *Taq* pol., IFU-02

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"Instructions for Use" (IFU)

Lot No.: 58Y **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*46:63 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**	**24**

The 24 well PCR plate is marked with 'HLA-B*46' in silver/gray ink.
Well No. 1 is marked with the Lot Number '58Y'.
Wells 1 to 23 – HLA-*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 primer 1, 3 to 17, 19, 20 and 22 to 23. In addition, a few HLA-A and HLA-C alleles will be amplified by primer mixes 1, 4, 6, 9 to 11, 14, 16 and 22.
For further details see Specificity Table.

UNIQUELY IDENTIFIED ALLELES

All the HLA-B*46, i.e. **B*46:01 to B*46:63**, recognized by the HLA Nomenclature Committee in April 2015[1,2] will be amplified by the primers in the HLA-B*46 SSP kit[3].

The HLA-B*46 kit enables separation of the confirmed HLA-B*46 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-B*46 alleles is listed below.

The HLA-B*46 kit also enables identification of polymorphisms in exons outside of the region encoding the peptide binding domain and of null and alternatively expressed alleles.

101.544-06 – including *Taq* pol., IFU-01
101.544-06u – without *Taq* pol., IFU-02

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Lot No.: 58Y **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*46:20, 46:41N	6
B*46:23, 46:57	18
B*46:28, 46:34	20

The HLA-B*46 subtyping kit cannot distinguish the silent mutations in the B*46:01:01-46:01:02, 46:01:04-46:01:15 and 46:01:17-46:01:18 alleles, the B*46:01:03 and 46:01:16 alleles or the B*46:13:01-46:13:02 alleles.

[1]HLA-B alleles listed on the IMGT/HLA web page 2015-April-17, release 3.20.0, www.ebi.ac.uk/imgt/hla.
[2]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.
[3]The HLA-B*46 primer set cannot separate the B*46:08 from B*15:289 alleles. These alleles can be distinguished by the HLA-C low resolution kit.

ALLELE CONFIRMATION STATUS

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

101.544-06 – including *Taq* pol., IFU-01
101.544-06u – without *Taq* pol., IFU-02

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Lot No.: 58Y **Lot-specific information**

[1]Allele status "confirmed" or "unconfirmed" as listed on the IMGT/HLA web page 2015-April-17, release 3.20.0, 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.

101.544-06 – including *Taq* pol., IFU-01
101.544-06u – without *Taq* pol., IFU-02

Visit www.olerup-ssp.com for
"Instructions for Use" (IFU)

Lot No.: 58Y **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[4]
1	130 bp	**800 bp**	*46:01:01-46:03, 46:05-46:39, 46:41N-46:46, 46:48-46:63	*15:57[W], 15:289, 15:318, **C*01:73**
2[5]	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
4	130 bp 200 bp 245 bp	1070 bp	*46:04 *46:40 *46:14	*18:06, 40:73, 73:01[W]-73:02[W], **C*03:278**
5	235 bp	1070 bp	*46:01:01-46:04, 46:06-46:63	*08:15, 15:57[W], 15:289, 15:318, 35:74, 35:186, 40:73, 55:03, 55:49, 55:69
6[5]	120 bp 215 bp	**800 bp**	*46:20 *46:06, 46:41N	*55:19 *07:09, 07:11, 07:17, 07:162, 07:237, 07:255, 15:138, 15:241, 15:297, 18:35, 35:66, 40:38, 40:52, 40:59-40:60, 40:158, 40:222, 48:14, 48:23, **C*07:38:01-07:38:02**
7[5,6]	105 bp 140 bp 180 bp	1070 bp	*46:16 *46:07N *46:56	*14:07N, 39:40:01N-39:40:02N, 56:19N
8	190 bp 380 bp	**800 bp**	*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	*15:02:01-15:03:05, 15:05:01-15:06, 15:09-15:10:04, 15:13:01-15:13:02, 15:16:01-15:18:06, 15:21, 15:23, 15:25:01-15:25:03, 15:29, 15:31, 15:36-15:37, 15:39:01-15:40, 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, 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, 15:222-15:224, 15:226N, 15:229-15:230, 15:235, 15:238, 15:240, 15:242-15:243, 15:249-15:250, 15:252-15:255, 15:263, 15:265-15:266, 15:268, 15:271, 15:273-15:275, 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, 15:354

9[5]	115 bp	1070 bp	*46:01:01-46:02, 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	*07:100, 13:31, 13:41, 15:01:01:01-15:01:04, 15:01:06-15:01:16, 15:01:18-15:01:30, 15:01:32-15:01:39, 15:04:01-15:04:02, 15:07:01-15:08:02, 15:11:01-15:12, 15:14-15:15, 15:19, 15:24:01-15:24:02, 15:26N-15:28, 15:30, 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, 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, 15:125-15:126, 15:128-15:129, 15:135, 15:137, 15:140, 15:142-15:149N, 15:152, 15:154, 15:157, 15:159-15:160, 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, 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, 15:324, 15:326-15:327, 15:331, 15:333-15:334, 15:336, 15:340, 15:342-15:344, 15:346-15:347, 15:353, 15:355, 18:19, 27:25, 27:115, 35:14:01-35:14:02, 35:43:01-35:44, 35:62, 35:67, 35:79, 35:86, 35:102, 35:117, 35:135, 35:163, 35:185, 35:213, 35:265, 39:36, 44:146, 51:61:01-51:61:02, 52:21, 54:06, 54:33, 55:21, 56:03, 56:43, **A*26:68, A*26:100, A*68:56, C*02:56, C*06:20, C*12:50**
10[5,6,7]	100 bp 160 bp 315 bp	**800 bp**	*46:05 *46:38 *46:15N	*07:204, 07:210, 14:02:13, 15:125, 35:54, 51:140, **C*05:01:28, C*07:02:30, C*08:16:02**
11	150 bp	1070 bp	*46:09	*35:62, **C*02:28**
12	170 bp 305 bp 380 bp	1070 bp	*46:10, 46:40 *46:55N *46:19	 *15:48, 15:108, 15:136, 15:235, 15:249

Lot No.: 58Y **Lot-specific information**

13[5,6]	105 bp	1070 bp	*46:11, 46:18	*07:78, 13:02:01-13:02:14, 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, 14:37, 15:42, 15:303, 35:60, 44:15, 44:18, 45:01:01-45:01:02, 45:03-45:08, 45:10-45:15, 49:01:01-49:03, 49:06-49:14, 49:16-49:17, 49:19N-49:37, 50:01:01-50:02, 50:04-50:08, 50:10-50:11, 50:13, 50:15, 50:18-50:19, 50:31-50:32, 50:34-50:40, 51:15, 51:157, 52:25, 54:01:01-54:03, 54:05N, 54:07-54:08N, 54:10, 54:12-54:13, 54:16-54:30, 54:32-54:34, 55:01:01-55:01:03, 55:01:05-55:01:06, 55:01:08-55:03, 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, 55:69-55:71, 55:73, 56:01:01:01-56:01:08, 56:07-56:08, 56:13-56:14, 56:16-56:17, 56:19N-56:20:02, 56:23-56:30, 56:33-56:47, 59:01:01:01-59:01:01:02, 59:04-59:09
	220 bp		*46:22, 46:32	*13:31, 13:41, 15:04:01-15:04:02, 15:137, 15:303, 35:265, 51:61:01-51:61:02, 52:21, 54:33, 55:21, 56:43
14[6]	215 bp	1070 bp	*46:12	*07:55, 07:100, 08:70, 15:07:01-15:07:03, 15:45, 15:68, 15:126, 15:207, 15:324, 15:331, 48:19, **C*02:60**
15	305 bp 330 bp	1070 bp	*46:55N *46:01:03, 46:01:16, 46:11, 46:13:01-46:13:02, 46:18, 46:21:02, 46:33	*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, 15:86, 15:179:01, 15:188, 15:224, 15:269, 15:275
16[6]	205 bp	1070 bp	*46:17, 46:22	*15:14, 15:91, 15:131, 15:161, 18:56, 35:45, 35:71, 44:17, 44:43:01-44:43:02, 44:144, 45:09, 53:22, 58:07, **C*02:82, 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	*15:05:01-15:05:02, 15:31, 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, 15:283, 15:332
18[5]	95 bp 265 bp	1070 bp	*46:23 *46:57	
19	160 bp 230 bp	1070 bp	*46:38 *46:24	*15:19, 15:304N
20[5]	50 bp 225 bp	1070 bp	*46:28 *46:34	*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, 35:113, 44:98, 52:31:01-52:31:02, **A*02:376, C*03:125, C*03:176**
23[5]	395 bp	1070 bp	*46:06, 46:25, 46:30, 46:51Q	*15:40, 15:47:01-15:47:02, 15:49, 15:52, 15:114, 15:117, 15:124, 15:138, 15:238, 15:241
24[8]	-	-	**Negative Control**	

101.544-06 – including *Taq* pol., IFU-01
101.544-06u – without *Taq* pol., IFU-02

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Lot No.: 58Y **Lot-specific information**

[1]Alleles are assigned by the presence of specific PCR product(s). However, the sizes of the specific PCR products may be helpful in the interpretation of HLA-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 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.

[2]The 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.

[3]For 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.

[4]Due to the sharing of sequence motifs between HLA-B alleles, non-HLA-B*46 alleles will be amplified by primer 1, 3 to 17, 19, 20 and 22 to 23. In addition, a few HLA-A and HLA-C alleles will be amplified by primer mixes 1, 4, 6, 9 to 11, 14, 16 and 22.

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

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

[7]Primer mix 10 has a tendency to giving rise to primer oligomer formation.

[8]Primer mix 24 contains a negative control, which will amplify more than 95% 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 430 base pairs.

'w', might be weakly amplified.

101.544-06 – including *Taq* pol., IFU-01
101.544-06u – without *Taq* pol., IFU-02

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Lot No.: 58Y

Lot-specific information

PRIMER SPECIFICATION

Well No.	1	2	3	4	5	6	7	8	9	10	11	12
Length of spec.	130	115	395	130	235	120	105	190	115	100	150	170
PCR product				200		215	140	380		160		305
				245			180			315		380
Length of int.	800	1070	1070	1070	1070	800	1070	800	1070	800	1070	1070
pos. control[1]												
5'-primer(s)[2]	209	209	2nd I	97	106	106	209	2nd I	463	106	419	141
	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' -ATT 3'
				141		419	463	625		736		142
				5' -ATT 3'		5' -gTC 3'	5' -TgA 3'	5' -CCA 3'		5' -gCT 3'		5' -TCA 3'
				209			3rd I			890		2nd I
				5' -ggg 3'			5' -Agg 3'			5' -gAA 3'		5' -CAA 3'
3'-primer(s)[3]	299	272	559	299	299	187	272	538	538	165	527	269
	5' -TCA 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				271	564	544		916		470
		5' -ggC 3'				5' -gTA 3'	5' -ACT 3'	5' -ggT 3'		5' -gAT 3'		5' -TCT 3'
						605	707	774				544
						5' -gCT 3'	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	50	235	180	395
PCR product	220		330			265	230	225	270	215	
Length of int.	1070	1070	1070	1070	800	1070	1070	1070	1070	1070	1070
pos. control[1]											
5'-primer(s)[2]	106	363	2nd I	106	2nd I	419	821	209	369	385	2nd I
	5' -CCA 3'	5' -AgC 3'	5' -CAA 3'	5' -CCA 3'	5' -CAA 3'	5' -gTC 3'	5' -gCT 3'	5' -ggC 3'	5' -TAC 3'	5' -ggT 3'	5' -CAA 3'
	357			419		3rd I	890	668		3rd I	
	5' -Tgg 3'			5' -gTC 3'		5' -Agg 3'	5' -gAA 3'	5' -ggC 3'		5' -Agg 3'	
3'-primer(s)[3]	281	538	470	281	527	472	916	214	564	559	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' -CAg 3'	5' -CTC 3'
	420		486	572		791		853	599	707	564
	5' -gCT 3'		5' -gCg 3'	5' -gCg 3'		5' -AgT 3'		5' -TAg 3'	5' -CCC 3'	5' -TCA 3'	5' -ACC 3'
	538		498								
	5' -CCA 3'		5' -gTA 3'								
Well No.	13	14	15	16	17	18	19	20	21	22	23

[1]The 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.

[2]The 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.

[3]The 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.

101.544-06 – including *Taq* pol., IFU-01
101.544-06u – without *Taq* pol., IFU-02

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Lot No.: 58Y **Lot-specific information**

CELL LINE VALIDATION SHEET

HLA-B*46 SSP primer set[2]

					Well															
					1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
				Prod. No.:	201193601	201193602	201193603	201554004	201193605	201193606	201554007	201325808	201193609	201325810	201193611	201554012	201554013	201193614	201554015	201193616
	IHWC 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	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	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

101.544-06 – including *Taq* pol., IFU-01
101.544-06u – without *Taq* pol., IFU-02

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Lot No.: 58Y **Lot-specific information**

CELL LINE VALIDATION SHEET

HLA-B*46 SSP primer set[2]

					Well						
					17	18	19	20	21	22	23
				Prod. No.:	201554017	201554018	201325819	201554020	201554021	201554022	201554024
	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	-	-	-	-	-	-	-

101.544-06 – including *Taq* pol., IFU-01
101.544-06u – without *Taq* pol., IFU-02

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Lot No.: 58Y **Lot-specific information**

[1]The 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.

[2]The 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 22 were available.

The specificities of the primers in primer solutions 3, 6, 10 to 12, 15, 17 and 22 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'-primer, the 3'-primer was 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 of the 3'-primers was not possible to test.

Additional primers in primer solutions 4, 8, 13 and 16 were tested by separately adding one 5'-primer and/or one 3'-primer.

101.544-06 – including *Taq* pol., IFU-01
101.544-06u – without *Taq* pol., IFU-02

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Lot No.: 58Y **Lot-specific information**

Lot No.: 58Y **Lot-specific information**

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