101.524-12 – including *Taq* polymerase, IFU-01
101.524-12u – without *Taq* polymerase, IFU-02

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Lot No.: 6K2 **Lot-specific information**

Olerup SSP® HLA-B*14

Product number:	**101.524-12 – including *Taq* polymerase** **101.524-12u – without *Taq* polymerase**
Lot number:	**6K2**
Expiry date:	**2023-12-01**
Number of tests:	**12**
Number of wells per test:	**21+1**
Storage - pre-aliquoted primers:	**dark at -20ºC**
- PCR Master Mix:	**-20ºC**
- Adhesive PCR seals	**RT**
- Product Insert	**RT**

This Product Description is only valid for Lot No. 6K2.

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*14 LOT (7G2)

- The product documentation has been updated for new alleles of IMGT 3.37.0
- The kit resolution focuses on common and well documented (CWD) alleles[1].

[1]As described in section Uniquely Identified Alleles.

The HLA-B*14 specificity and interpretation tables have been updated for the HLA-B alleles described since the previous *Olerup* SSP® HLA-B*14 lot was made **(Lot No. 7G2)**.

The HLA-B*14 primer set is unchanged compared to the previous *Olerup* SSP® HLA-B*14 **(Lot No. 7G2)**.

101.524-12 – including *Taq* polymerase, IFU-01
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Lot No.: 6K2 **Lot-specific information**

Well **22** 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'-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 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.
[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.

101.524-12 – including *Taq* polymerase, IFU-01
101.524-12u – without *Taq* polymerase, IFU-02

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Lot No.: 6K2

Lot-specific information

PRODUCT DESCRIPTION

HLA-B*14 SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for identifying the HLA-B*14:01 to B*14:82 alleles.

PLATE LAYOUT

Each test consists of 22 PCR reactions in a 24 well PCR plate. Wells 23 and 24 are empty.

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

The 24 well cut PCR plate is marked with 'HLA-B*14' in silver/gray ink.
Well No. 1 is marked with the Lot No. '6K2'.
Wells 1 to 21 – HLA-B*14 high resolution primers.
Well 22 – 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 covered with a PCR-compatible foil.
Please note: When removing each 24 well PCR plate, make sure that the remaining plates stay covered. 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 some non-HLA-B*14 alleles will be amplified by some primer mixes. For further details see Specificity Table.

UNIQUELY IDENTIFIED ALLELES

All the HLA-B*14 alleles, i.e. **B*14:01 to B*14:82**, recognized by the HLA Nomenclature Committee in July 2019[1,2] will be amplified by the primers in the HLA-B*14 subtyping kit.

The HLA-B*14 kit enables separation of the confirmed HLA-B*14 alleles as listed in the IMGT/HLA database 3.27.0. 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*14 alleles is listed below.

The HLA-B*14 kit also enables identification of many null and alternatively expressed alleles.

101.524-12 – including *Taq* polymerase, IFU-01
101.524-12u – without *Taq* polymerase, IFU-02

Visit https://labproducts.caredx.com for **"Instructions for Use" (IFU)**

Lot No.: 6K2 **Lot-specific information**

The following alleles will give rise to identical amplification patterns with the HLA-B*14 subtyping kit. These alleles can be distinguished by the HLA-B low resolution kit and/or the respective high resolution subtyping kits:

Alleles
B*14:08:01-14:08:02, 39:43
B*14:62, 15:44, 39:129, 59:08

The following HLA-B*14 alleles can be distinguished by the different sizes of the HLA-specific PCR product:

Alleles	Primer mix
B*14:16, 14:23	16

[1]HLA-B alleles listed on the IMGT/HLA web page 2019-July-10, release 3.37.0, 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.

ALLELE CONFIRMATION STATUS

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

[1]Allele status "confirmed" or "unconfirmed" as listed on the IMGT/HLA web page 2017-January-20, release 3.27.0, www.ebi.ac.uk/imgt/hla.

RESOLUTION IN HOMO- AND HETEROZYGOTES

Results file with resolution in HLA-B*14 homo- and heterozygotes is available upon request.

101.524-12 – including *Taq* polymerase, IFU-01
101.524-12u – without *Taq* polymerase, IFU-02

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Lot No.: 6K2 **Lot-specific information**

SPECIFICITY TABLE

HLA-B*14 SSP subtyping

Specificities and sizes of the PCR products of the 21+1 primer mixes used for HLA-B*14 SSP subtyping

Primer Mix	Size of spec. PCR product[1]	Size of control band[2]	Amplified HLA-B*14 alleles[3]	Other amplified HLA Class I alleles
1	265 bp	**800 bp**	*14:01:01:01-14:04, 14:07N, 14:09, 14:11-14:12, 14:14-14:19, 14:21-14:36, 14:38-14:45, 14:47-14:52, 14:54, 14:57-14:61, 14:63-14:82	*18:44:01-18:44:02, **C*01:30, C*06:207, C*12:87, C*14:76**
2	185 bp	1070 bp	*14:01:01:01-14:01:09, 14:07N-14:08:02, 14:10, 14:12, 14:14, 14:19, 14:26, 14:32, 14:40, 14:46-14:47, 14:49, 14:53-14:55, 14:65, 14:71, 14:77-14:78N, 14:80-14:82	*07:02:32, 07:85:02, 18:01:37, 27:07:04, 38:01:01:01-38:01:07, 38:01:09-38:02:02:02, 38:02:04-38:03, 38:07-38:24, 38:26-38:32, 38:34N-38:83N, 38:84[w], 38:85-38:86, 38:156-38:162, 39:01:01:01-39:01:01:09, 39:01:03:01-39:01:08, 39:01:10-39:01:25, 39:01:27-39:02:01, 39:03:01:01-39:03:01:02, 39:05:01:01-39:06:02:04, 39:06:04-39:09:03, 39:11, 39:14:01:01-39:15, 39:18, 39:19:02, 39:22, 39:24:01-39:39:01, 39:40:01N-39:44, 39:46-39:48, 39:50-39:62, 39:64-39:71, 39:73-39:75, 39:77, 39:79-39:82, 39:84-39:88, 39:90-39:91, 39:93-39:95N, 39:97N-39:98, 39:100, 39:102-39:104, 39:106-39:109, 39:111-39:125, 39:127-39:128, 39:130, 39:132, 39:134-39:142N, 39:144, 39:146N-39:155, 67:01:01, 67:03-67:04, 67:06-67:07
3	210 bp	**800 bp**	*14:02:01:01-14:03, 14:04[w], 14:05-14:06:02, 14:09, 14:11, 14:13, 14:15-14:18, 14:20, 14:22-14:25, 14:27, 14:29-14:31, 14:33-14:39, 14:41N, 14:43-14:45, 14:48, 14:50-14:52, 14:56, 14:58-14:64, 14:66-14:70Q, 14:72N, 14:74-14:76N, 14:79N	*15:09:01-15:10:04, 15:18:01:01-15:18:07, 15:21:01:01-15:21:01:02, 15:23, 15:37, 15:44, 15:51-15:52, 15:66, 15:72, 15:80, 15:90, 15:93, 15:99, 15:108, 15:114-15:115, 15:119, 15:124, 15:133-15:134, 15:153, 15:161, 15:176, 15:186, 15:189, 15:197:01-15:198, 15:200, 15:221, 15:226N, 15:229, 15:238, 15:243, 15:252, 15:263, 15:275:01-15:275:02, 15:290, 15:292-15:294N, 15:306-15:307, 15:311-15:314, 15:323, 15:329, 15:335, 15:337-15:338, 15:351, 15:354, 15:376, 15:380N, 15:382[w], 15:388, 15:394, 15:404, 15:414, 15:420, 15:427, 15:433-15:436, 15:439, 15:445, 15:451, 15:455, 15:487N, 15:498, 15:503-15:504, 15:506, 15:526, 15:530, 35:26, 35:82, 35:85, 35:135, 35:294, 38:05, 38:33, 39:04,

101.524-12 – including *Taq* polymerase, IFU-01
101.524-12u – without *Taq* polymerase, IFU-02

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				39:129, 44:263, 51:22, 56:33, 59:08, 78:03
4[4,6]	85 bp	1070 bp	*14:03	*07:218, 07:220, 18:13, 18:30, 51:29, 51:82, 51:217, 51:279, 52:24, **C*01:30, C*05:216, C*08:51, C*08:114, C*14:76**
	270 bp		*14:20	
5	135 bp 220 bp	1070 bp	*14:07N *14:04	*39:40:01N-39:40:02N
6[4]	100 bp	1070 bp	*14:05, 14:29	*07:115, 07:246, 07:327, 08:69, 08:200, 35:440, 38:19, 39:03:01:01-39:03:01:02, 39:24:01-39:24:02, 39:37, 39:76, 39:120, 39:144, 39:152, 40:314, 41:18, 42:06, 42:20, 48:07, **C*08:08:01-08:08:02**
	175 bp 530 bp		*14:17 *14:29	
7	260 bp	1070 bp	*14:06:01-14:06:02, 14:08:01-14:08:02, 14:55-14:56	*15:37-15:38:02, 15:185, 15:323, 15:335, 15:364, 15:368, 15:435, 18:01:01:01-18:01:15, 18:01:17-18:01:39, 18:03:01-18:09, 18:12:01-18:13, 18:15, 18:17N-18:20, 18:23N-18:26, 18:28-18:34, 18:36-18:38, 18:40-18:43, 18:45-18:55, 18:57:01-18:57:02, 18:59-18:68, 18:70-18:100, 18:102-18:104, 18:106-18:109, 18:111-18:148, 18:151-18:163, 18:166-18:167, 18:169, 18:171-18:178, 18:180-18:185, 39:32, 39:43, 39:48, 40:51, 40:113, 40:163, 51:06:01-51:06:04, 51:45, 51:62, 51:135, 51:194, 51:293, 56:31, 67:06, **C*02:142, C*05:216, C*07:516, C*07:521:01-07:521:02, C*08:51, C*08:114**
8	250 bp	1070 bp	*14:01:01:01-14:01:09, 14:07N-14:08:02, 14:10, 14:12, 14:14, 14:19, 14:26, 14:32, 14:40, 14:46-14:47, 14:49, 14:53-14:55, 14:65, 14:71, 14:77-14:78N, 14:80-14:82	*07:02:01:01-07:02:15, 07:02:17-07:02:77, 07:02:79-07:05:04, 07:05:06-07:26, 07:28, 07:30-07:35, 07:37:01-07:37:02, 07:39-07:64, 07:66-07:69, 07:73-07:78, 07:80, 07:82-07:85:02, 07:87-07:110, 07:112-07:148, 07:150-07:178, 07:181N-07:183, 07:185, 07:186[w], 07:187-07:191, 07:193-07:194, 07:196-07:203, 07:205-07:209, 07:212-07:218, 07:220-07:235, 07:237-07:243, 07:245-07:272N, 07:274-07:296, 07:298-07:312, 07:313[w], 07:314-07:351N, 07:353-07:382, 07:384-07:385, 08:94, 08:190[w], 08:226, 15:68, 15:71, 15:175, 15:381, 18:01:01:01-18:01:12, 18:01:14-18:03:02, 18:05:01:01-18:08, 18:10-18:15, 18:17N-18:24, 18:26-18:53, 18:55-18:66, 18:69, 18:71-18:83, 18:85-18:94N, 18:96-18:106, 18:108-18:124, 18:126-18:135:01:02, 18:137-18:146, 18:148-18:178, 18:180-18:185, 27:08, 27:12:01:01-27:12:01:02, 27:18, 27:26, 27:33, 27:40, 27:42, 27:44, 27:89, 27:153, 27:204, 35:03:21, 35:08:12, 35:50, 35:84, 35:162, 35:197, 35:231, 35:267, 35:269, 35:411, 35:423,

				37:05, 37:11, 37:37, 37:67, 38:156-38:159, 39:01:01:01-39:01:01:09, 39:01:03:01-39:01:14, 39:01:16-39:03:01:02, 39:05:01:01-39:11, 39:13:01-39:20, 39:22-39:62, 39:64-39:71, 39:73-39:75, 39:77-39:98, 39:99[w], 39:100-39:103, 39:105-39:128, 39:130-39:155, 40:02:01:01-40:02:14, 40:02:16-40:06:14, 40:06:16-40:06:20, 40:06:22, 40:08-40:09, 40:11:01-40:11:02, 40:18, 40:20:01:01-40:20:01:02, 40:24, 40:26-40:29, 40:35:01-40:35:02, 40:37, 40:39-40:40, 40:44, 40:50, 40:56, 40:64:01:01-40:64:02, 40:68, 40:70:01-40:71, 40:74-40:75, 40:78, 40:82-40:83, 40:85-40:86, 40:89-40:91, 40:93-40:95, 40:97-40:99, 40:103-40:105, 40:107, 40:111, 40:115, 40:119-40:120, 40:122, 40:127, 40:131, 40:133Q, 40:142N-40:145, 40:148-40:149, 40:159, 40:161-40:162, 40:165, 40:167, 40:169, 40:173-40:174, 40:176-40:177, 40:180-40:181, 40:184, 40:189, 40:200, 40:202-40:203, 40:205-40:206, 40:209-40:211, 40:214, 40:220, 40:224-40:226, 40:229-40:230, 40:232, 40:243-40:244, 40:248, 40:254-40:256N, 40:266-40:271, 40:274-40:276, 40:283-40:284, 40:287, 40:290-40:291N, 40:293-40:297, 40:302-40:307, 40:309, 40:311, 40:313-40:314, 40:317, 40:320, 40:322, 40:330-40:331, 40:334, 40:337N, 40:341, 40:343, 40:345N, 40:347-40:351, 40:354, 40:356, 40:359, 40:361N-40:364, 40:366, 40:369, 40:371, 40:373-40:376, 40:378, 40:384, 40:387-40:390, 40:399N, 40:405, 40:408-40:415, 40:425, 40:427, 40:429, 40:434-40:435, 40:437-40:438N, 40:440-40:442, 42:01:01-42:02:01:02, 42:04-42:21, 42:23-42:27, 44:131, 48:01:01:01-48:17, 48:19-48:21, 48:23-48:50, 50:43, 54:02, 55:10, 55:82, 56:35, 67:01:01-67:07, 73:01-73:02, 81:01:01-81:08, **C*03:03:51, C*03:137, C*03:182, C*03:459, C*07:102[w], C*07:351, C*08:02:22, C*12:82, C*16:116**
9	160 bp 280 bp	1070 bp	*14:09 *14:32	**C*05:16, C*05:85, C*05:107, C*06:129, C*07:364, C*08:12**
10[4,5]	110 bp 180 bp	1070 bp	*14:29 *14:11, 14:28	*08:01:24, 15:189, 35:03:17, 35:26, 38:33, 39:04, 49:26, 51:01:68
11	135 bp	1070 bp	*14:01:01:01-14:18, 14:20-14:26, 14:28-14:43, 14:45, 14:47-14:82	*07:02:15, 07:19, 07:31, 07:34, 07:43, 08:01:01:01-08:05, 08:07-08:10, 08:12:01-08:20:02, 08:22-08:24, 08:26:01-08:39, 08:41-08:78, 08:80-

				08:124, 08:126-08:155, 08:157-08:164, 08:166-08:170, 08:172-08:174, 08:176-08:185, 08:187-08:191, 08:193-08:204, 08:206-08:209, 08:211-08:245, 13:06, 13:46, 13:53, 13:131, 15:42, 15:44, 15:50, 15:69, 15:83, 15:86, 15:93, 15:121, 15:186, 15:188, 15:199, 15:218Q, 15:224, 15:252, 15:265, 15:323, 15:348, 15:368, 15:449, 15:485, 15:494, 15:497, 18:01:01:01-18:09, 18:11-18:15, 18:17N-18:20, 18:22-18:34, 18:37:01-18:49, 18:51-18:55, 18:59-18:85, 18:87-18:100, 18:102-18:152, 18:154N-18:163, 18:166-18:168, 18:170-18:185, 27:15, 27:28, 27:62, 27:71, 35:35, 35:60, 35:87, 35:93, 35:96, 35:157, 35:188, 35:190, 35:213, 35:262, 35:276-35:277, 35:343, 35:350, 37:01:01:01-37:01:04, 37:01:06-37:01:20, 37:03N-37:06:02, 37:08-37:25, 37:27-37:38, 37:40-37:47, 37:49-37:87, 37:89-37:90, 38:01:01:01-38:07, 38:09-38:21, 38:23-38:29, 38:31-38:62, 38:64, 38:66-38:86, 38:156-38:158, 38:160-38:162, 39:01:01:01-39:01:01:09, 39:01:03:01-39:20, 39:22-39:31:01:02, 39:34-39:46, 39:48-39:49, 39:51-39:73, 39:75-39:79, 39:81-39:101, 39:103-39:155, 40:39, 40:51, 40:163, 40:184, 40:199, 40:424, 41:01:01:01-41:16, 41:18, 41:20-41:61, 41:63, 42:01:01-42:02:01:02, 42:04-42:27, 44:03:28, 44:04, 44:56N, 44:132, 44:163:01-44:163:02, 44:166, 44:190, 44:268, 44:446, 45:08, 46:03, 46:18, 46:21:01-46:21:02, 46:29, 47:08, 48:37, 50:45, 50:49, 51:21, 51:36, 51:101, 51:143, 51:153, 51:157, 51:197, 51:280, 51:295, 51:300, 52:37, 52:71, 52:84, 54:01:01-54:02, 54:04-54:05N, 54:07-54:25, 54:27-54:32, 54:34-54:39, 54:41, 55:01:01:01-55:01:20, 55:01:22-55:05, 55:07, 55:10-55:21, 55:23, 55:25-55:50, 55:52-55:106, 56:10, 56:12, 56:18, 56:23, 56:31-56:32, 56:54, 56:66, 57:26, 58:05, 58:20, 58:35, 58:76, 58:84, 59:01:01:01-59:03, 59:05-59:08, 59:10N, 67:01:01-67:07, 78:07
12	230 bp	1070 bp	*14:12, 14:19, 14:27	*15:510, 44:440, 50:51, 57:11, 58:02:01-58:02:02, 58:06-58:07, 58:25, 58:38, 58:43, 58:46, 58:60, 58:104, **C*01:35, C*01:107, C*03:17:01-03:17:02, C*03:71, C*03:249, C*03:271, C*03:302, C*06:96, C*06:197, C*12:122, C*14:20, C*16:149**
13[6]	210 bp	1070 bp	*14:13, 14:53	*08:118, 13:15, 13:62, 15:435, 18:26, 18:61, 18:97, 27:153, 35:233, 39:32, 39:48, 40:28, 40:51, 40:113, 40:163, 40:174, 44:459, 51:01:01:01-51:01:18,

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14[6]	190 bp	1070 bp	*14:14, 14:18, 14:73	*07:16, 07:27, 07:37:01-07:38, 07:50, 07:75:01:01-07:75:01:02, 07:91, 07:180, 07:207, 07:219, 07:228:01-07:228:02, 07:306, 08:03, 08:23, 08:54:01-08:54:02, 08:110, 08:133, 08:139, 15:03:01:01-15:03:09, 15:09:01-15:10:04, 15:18:01:01-15:18:07, 15:23, 15:29, 15:37, 15:47:01-15:47:02, 15:49, 15:51-15:52, 15:54, 15:62, 15:64:01-15:64:02, 15:68-15:69, 15:72, 15:74, 15:80, 15:90-15:91, 15:93, 15:98-15:99, 15:103, 15:108, 15:114-15:115, 15:119, 15:123-15:124, 15:127, 15:131-15:134, 15:151, 15:153, 15:156, 15:158, 15:161, 15:173, 15:176, 15:186, 15:197:01-15:198, 15:200, 15:210, 15:220:01:01-15:221, 15:226N, 15:229, 15:235, 15:238, 15:242:01-15:243, 15:251:01-15:253, 15:263, 15:266, 15:274-15:275:02, 15:281-15:282, 15:290, 15:292-15:293, 15:306-15:307, 15:311-15:314, 15:323, 15:329, 15:335, 15:337-15:338, 15:351, 15:354, 15:369, 15:376, 15:379-15:380N, 15:382, 15:388-15:389, 15:414, 15:426-15:427, 15:429, 15:433-15:436, 15:439, 15:444-15:445, 15:447-15:448, 15:451, 15:455, 15:475, 15:487N, 15:498, 15:502-15:503, 15:506, 15:509, 15:517, 15:526-15:527, 15:530, 15:539, 15:545, 18:01:01:01-18:01:01:23, 18:01:03-18:01:22, 18:01:24-18:02:02,

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				18:05:01:01-18:15, 18:17N-18:28, 18:30-18:79, 18:81-18:93, 18:95-18:97, 18:99-18:101, 18:103-18:106, 18:108-18:124, 18:126-18:131:01:02, 18:133-18:141, 18:143-18:151, 18:153-18:170, 18:173, 18:175-18:185, 35:25, 35:124-35:125, 35:142, 35:162, 35:267, 35:320, 37:01:01:01-37:01:11, 37:01:13-37:21, 37:23-37:36, 37:38-37:59, 37:61-37:87, 37:89-37:90, 38:01:01:01-38:02:09, 38:04-38:12, 38:15, 38:17-38:25, 38:27, 38:29-38:40, 38:42-38:45, 38:47-38:86, 38:157, 38:159-38:162, 39:05:01:01-39:05:03, 39:07-39:08, 39:11, 39:13:01-39:13:02, 39:20, 39:37, 39:49, 39:55-39:56, 39:113, 39:118, 39:147N, 39:149, 40:12:01-40:12:02, 40:149, 41:22, 42:11, 44:130, 44:156, 44:221, 44:224, 44:258, 48:01:01:01-48:02:01, 48:02:03-48:47, 48:49-48:50, 49:25, 51:116, 51:176, 51:179, 51:218, 52:16, 52:27, 52:77, 53:43:01-53:43:02, 57:58, 57:80, 58:12, 81:08, **C*06:147**
15[4]	100 bp 270 bp	**800 bp**	*14:15 *14:10	*55:77 *18:22, 18:69, 18:105, 18:149-18:150, 35:21, 35:24:01-35:24:02, 35:81, 35:96, 35:109, 35:157, 35:188, 35:190, 35:233, 35:287, 37:04:01-37:04:02, 40:28, 44:190, 44:203:01-44:203:02, 44:275, 44:290, 51:04:01-51:04:02, 51:46, 51:56:01-51:56:03, 51:139, 51:227, 51:281, 52:88, 53:02, 53:06, 53:28, 57:14:01-57:14:02, 58:09, 58:76, **C*03:384, C*15:39, C*15:130**
16[4]	90 bp 175 bp 280 bp	1070 bp	*14:23 *14:16 *14:32	***07:239, C*01:101, C*01:113, C*15:55 C*05:16, C*05:85, C*05:107, C*06:129, C*07:364, C*08:12**
17	245 bp	1070 bp	*14:22, 14:37, 14:55	*13:15, 18:22, 18:52, 18:105, 35:21, 35:24:01-35:24:02, 35:81, 35:96, 35:109, 35:157, 35:188, 35:190, 35:287, 40:28, 49:09, 50:58, 51:56:01-51:56:03, 51:158:02, 51:225, 53:02, 53:06, 53:28, 56:34, 58:09, 58:76, **A*33:40:01, C*01:30, C*02:142, C*05:216, C*06:207, C*07:516, C*07:521:01-07:521:02, C*08:51, C*08:114, C*12:87, C*14:76, C*15:39, C*15:130**
18	165 bp	1070 bp	*14:34	*46:48
19	200 bp	1070 bp	*14:41N	
20[4]	115 bp	1070 bp	*14:02:17, 14:33	*35:12:04, 35:16-35:17:03, 35:32:01, 35:61:02, 35:98, 35:125, 35:346, 44:140, 46:01:07, 50:04, 58:59:01, **C*03:102, 03:263:01-03:263:03**

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21	240 bp	1070 bp	*14:46	*07:239, 40:243, **C*01:10, C*02:05:01-02:05:03, C*02:17, C*06:08, C*12:119, C*14:25, C*16:29, C*16:50, C*17:21**
22[7]	-	-	**Negative Control**	

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

[5]Primer mixes 10 may give rise to a lower yield of HLA-specific PCR product than the other B*14 primer mixes.

[6]Primer mix 4, 13 and 14 may have tendencies of unspecific amplifications.

[7]Primer mix 22 contains a negative control, which will amplify a 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

101.524-12 – including *Taq* polymerase, IFU-01
101.524-12u – without *Taq* polymerase, IFU-02

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Lot No.: 6K2

Lot-specific information

PRIMER SPECIFICATION

Well No.	1	2	3	4	5	6	7	8	9	10	11	12
Length of spec.	265	185	210	85	135	100	260	250	160	110	135	230
PCR product				270	220	175			280	180		
						530						
Length of int.	800	1070	800	1070	1070	1070	1070	1070	1070	1070	1070	1070
pos. control[1]												
5'-primer(s)[2]	361	102	103	353	91	113	363	102	361	106	558	361
	5' -AgT 3'	5' -ACT 3'	5' -CCg 3'	5' -CAA 3'	5' -ggC 3'	5' -CCA 3'	5' -Agg 3'	5' -ACT 3'	5' -AgT 3'	5' -CCA 3'	5' -ggT 3'	5' -AgT 3'
	361	103		539	564	176		103		176	560	
	5' -AgT 3'	5' -CCT 3'		5' -gCg 3'	5' -TgA 3'	5' -gAT 3'		5' -CCT 3'		5' -gAT 3'	5' -CAC 3'	
		103				363		103				
		5' -CCT 3'				5' -AgC 3'		5' -CCT 3'				
3'-primer(s)[3]	583	246	272	583	269	246	583	310	479	246	3rd I	541
	5' -gTg 3'	5' -TAT 3'	5' -TgC 3'	5' -gTg 3'	5' -AgT 3'	5' -TAT 3'	5' -gTg 3'	5' -gTT 3'	5' -CCC 3'	5' -TAT 3'	5' -TAT 3'	5' -TCC 3'
		246			3rd I	419			601			559
		5' -TAT 3'			5' -TAT 3'	5' -CgA 3'			5' -CTT 3'			5' -CAg 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
	210	190	100	90	245	165	200	115	240
			270	175					
				280					
	1070	1070	800	1070	1070	1070	1070	1070	1070
pos. control[1]									
5'-primer(s)[2]	412	142	103	361	379	103	361	387	361
	5' -ATA 3'	5' -TCT 3'	5' -CCg 3'	5' -AgT 3'	5' -ACC 3'	5' -CCg 3'	5' -AgT 3'	5' -CCC 3'	5' -AgT 3'
			355						
			5' -TCA 3'						
3'-primer(s)[3]	583	292	164	409	583	227	522	463	559
	5' -gTg 3'	5' -gTA 3'	5' -gCA 3'	5' -ATg 3'	5' -gTg 3'	5' -CTg 3'	5' -C.g 3'	5' -gCT 3'	5' -CTC 3'
		292	583	494					
		5' -gTA 3'	5' -gTg 3'	5' -TCC 3'					
		292		601					
		5' -gTA 3'		5' -CTT 3'					
Well No.	13	14	15	16	17	18	19	20	21

[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.

101.524-12 – including *Taq* polymerase, IFU-01
101.524-12u – without *Taq* polymerase, IFU-02

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Lot No.: 6K2 **Lot-specific information**

CELL LINE VALIDATION SHEET

HLA-B*14 SSP subtyping kit[2]

					Well															
					1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
				Prod. No.:	201561801	201561802	201561803	201561804	201561805	201561806	201561807	201561808	201561809	201561810	201788411	201561812	201561813	201561814	201561815	201561816
	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	9004	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	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

101.524-12 – including *Taq* polymerase, IFU-01
101.524-12u – without *Taq* polymerase, IFU-02

Visit https://labproducts.caredx.com for **"Instructions for Use" (IFU)**

Lot No.: 6K2 **Lot-specific information**

CELL LINE VALIDATION SHEET

HLA-B*14 SSP subtyping kit[2]

					Well				
					17	18	19	20	21
				Prod. No.:	201561817	201561818	201561819	201561820	201561821
	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	9004	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	-	-	-	-	-

101.524-12 – including *Taq* polymerase, IFU-01 Visit https://labproducts.caredx.com for
101.524-12u – without *Taq* polymerase, IFU-02 **"Instructions for Use" (IFU)**

Lot No.: 6K2 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 4 to 6, 9, 15 to 19 and 21 were available. The specificities of the primers in primer solutions 4 to 6, 9, 15 to 17 and 21 were tested by separately adding additional 5'-primers respectively 3'-primers. In primer solutions 18 and 19 it was only possible to test the 5'-primer, the 3'-primer was not possible to test. In primer solutions 1, 4 to 6, 10 and 11 one or two 5'-primers were not possible to test, and in primer solutions 5, 9, 12, 15 and 16 one 3'-primer was not possible to test.
In addition, one 5'-primer in primer solutions 2 and 8 was tested by separately adding one 3'-primer.

Lot No.: 6K2 **Lot-specific information**

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