

101.542-06 – including Taq polymerase
101.542-06u – without Taq polymerase

Visit www.caredx.com for
 “Instructions for Use” (IFU)

Lot No.: 8R8

Lot-specific information

Olerup SSP® HLA-B*41

Product number:	101.542-06 – including Taq polymerase 101.542-06u – without Taq polymerase
Lot number:	8R8
Expiry date:	2027-05-01
Number of tests:	6
Number of wells per test:	23+1
Storage - pre-aliquoted primers:	dark, between -15°C and -25°C
- PCR Master Mix:	between -15°C and -25°C
- Adhesive PCR seals	RT

This Product Description is only valid for Lot No. 8R8.

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*41 LOT (0R3).**

- The product documentation has been updated for new alleles of IMGT 3.51.0.
- The kit resolution focuses on common and well documented (CWD) alleles¹.

¹As described in section Uniquely Identified Alleles.

The HLA-B*41 primer set, specificity and interpretation tables have been updated for the HLA-B alleles described since the previous *Olerup SSP*® HLA-B*41 lot was made (**Lot No. 0R3**).

The primers of the wells detailed below have been exchanged, added or modified compared to the previous lot (**Lot No. 0R3**).

Well	5'-primer	3'-primer	rationale
16	-	Added	3'-primer added for the B*41:18 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



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Well **24** contains Negative Control primer pairs, that will amplify the 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.



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For *In Vitro* Diagnostic Use
 MA123 v02 SSP PI Template
 Date: June 2023, Rev. No: 00

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Lot No.: **8R8**

Lot-specific information

PRODUCT DESCRIPTION

HLA-B*41 SSP typing

CONTENT

The primer set contains 5'- and 3'-primers for identifying the B*41:01 to B*41:79 alleles.

PLATE LAYOUT

Each HLA-B*41 test consists of 24 PCR reactions in a 24 well cut PCR plate.

Note: This lot was manufactured using white plastic trays.

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*41’ in silver/gray ink.

Well No. 1 with the Lot No. ‘8R8’.

Wells 1 to 23 – HLA-B*41 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*41 alleles will be amplified by some primer mixes. For further details see Specificity Table.

UNIQUELY IDENTIFIED ALLELES

All the HLA-B*41, i.e. **B*41:01 to B*41:79** recognized by the HLA Nomenclature Committee in January 2023^{1,2} will be amplified by the primers in the HLA-B*41 SSP kit³.

The HLA-B*41 kit enables separation of the confirmed HLA-B*41 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*41 alleles is listed below.

The HLA-B*41 kit also enables identification of many null and alternatively expressed alleles.



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Lot-specific information

The following HLA-B*41 alleles can be distinguished by the different sizes of the HLA-specific PCR product:

Alleles	Primer mix
B*41:04, 41:36	4
B*41:10, 41:45N	3

¹HLA-B alleles listed on the IMGT/HLA web page 2023-January-12, release 3.51.0, 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*41 high resolution kit. These alleles can be distinguished by the HLA-B low resolution and/or the respective high resolution kits.

Alleles

B*41:08, B*40:136, 40:231, 40:279
B*41:23, B*42:27
B*41:46-41:47, B*44:166
B*41:62, B*40:02:20

ALLELE CONFIRMATION STATUS

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

¹Allele 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*41 homo- and heterozygotes is available upon request.



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Lot-specific information
SPECIFICITY TABLE

HLA-B*41 SSP subtyping

Specificities and sizes of the PCR products of the 23+1 primer mixes used for
HLA-B*41 SSP subtyping

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified HLA-B*41 alleles ³	Other amplified HLA Class I alleles
1	285 bp	800 bp	*41:01:01:01-41:01:08, 41:05, 41:07, 41:12, 41:14, 41:16-41:17, 41:20-41:22, 41:25-41:26, 41:28, 41:30, 41:33-41:35, 41:37, 41:44, 41:50, 41:53-41:54, 41:56Q-41:57, 41:59-41:61, 41:64, 41:66-41:67, 41:70, 41:73, 41:75-41:79	*08:09, 08:84, 08:254, 42:04, 55:20
2	165 bp	1070 bp	*41:02:01:01-41:02:11, 41:04, 41:10-41:11, 41:13, 41:15, 41:18-41:19, 41:23, 41:27, 41:31, 41:36, 41:38-41:43, 41:45N-41:47, 41:49, 41:51-41:52, 41:55, 41:58, 41:62, 41:65, 41:68-41:69, 41:71-41:72, 41:74	*07:02:13, 07:02:35, 07:04:02, 07:05:10, 07:22:02, 07:68:02, 07:151:02, 07:209, 07:262:01, 07:424, 08:01:01:01-08:01:01:67, 08:01:03-08:01:27, 08:01:29-08:01:32, 08:01:34-08:05, 08:07-08:08N, 08:10-08:11, 08:13-08:15, 08:17-08:48, 08:50-08:53:01, 08:54:01-08:59:02, 08:61-08:78, 08:79:02-08:83, 08:85-08:88, 08:90-08:106, 08:108-08:128, 08:130-08:155, 08:157-08:180, 08:182-08:183, 08:185-08:212, 08:213:02-08:223, 08:225-08:231, 08:233-08:253, 08:256-08:290, 08:292-08:295, 08:297-08:306, 13:108, 14:05, 14:13, 14:53, 15:07:03, 15:383, 18:14, 35:05:01:01-35:05:06, 35:22:01:01-35:22:01:02, 35:51:01-35:51:02, 35:58, 35:66, 35:72, 35:87, 35:89, 35:97, 35:199, 35:232, 35:368, 35:389, 35:416, 35:427N, 35:440, 35:459N, 35:472, 35:481, 35:498-35:499, 35:509, 35:519, 35:541, 35:572, 37:09, 38:19, 39:03:01:01-39:03:02, 39:14:01:01-39:14:01:03, 39:24:01-39:24:03, 39:29, 39:37:01:01-39:37:01:02, 39:76, 39:120, 39:144, 39:152, 39:182, 39:184-39:185, 40:02:20, 40:35:03, 40:71, 42:01:01:01-42:01:01:03, 42:01:03-42:02:02, 42:05:01-42:12, 42:14-42:16:01, 42:17-42:33, 44:54, 44:106, 44:135, 44:158, 44:166, 44:184, 44:213, 48:12, 51:64, 51:148, 53:14, 53:67, 55:04, 55:49, 55:51, 55:86, 55:110, 58:18, C*03:296:01, C*07:294, C*07:526:01, C*07:530:01, C*07:681
	215 bp		*41:02:01:01-41:02:11, 41:04, 41:10-41:11, 41:13, 41:15, 41:18-41:19, 41:23-41:24,	*07:04:01-07:04:02, 07:19, 07:25, 07:146, 07:349, 08:01:01:01-08:05, 08:07-08:08N, 08:10-08:11, 08:14-08:15, 08:17-08:19N, 08:21-08:24, 08:26:01-08:39, 08:41-08:48,

- tog bort:** ³
- formaterade:** PI tabell Char, Teckenfärg: Auto, Språkkontrollera text, Inte Upphöjd/ Nedsänkt
- tog bort:** ¹
- tog bort:** ²
- formaterade:** PI tabell Char, Teckenfärg: Auto, Språkkontrollera text, Inte Upphöjd/ Nedsänkt
- formaterade:** PI tabell Char, Teckenfärg: Auto, Språkkontrollera text, Inte Upphöjd/ Nedsänkt

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3	75 bp	1070 bp	*41:03:01, 41:10, 41:22	*07:143, 07:335, 08:62, 08:226, 08:242, 15:210, 15:426, 15:571, 18:01:01:01-18:01:12, 18:01:12- 18:03:02, 18:05:01:01-18:15, 18:17N-18:24, 18:26-18:28, 18:30-18:42, 18:44:01-18:79, 18:81-18:97, 18:99-18:101, 18:103-18:106Q, 18:108-18:111, 18:113-18:119, 18:121-18:124, 18:126-18:226, 27:75, 35:162, 37:01:01:01- 37:21, 37:23-37:40, 37:42N-37:54, 37:56-37:61, 37:63-37:84, 37:86N-37:94, 37:96-37:106, 39:31:01:01-39:31:01:02, 39:101, 39:128, 40:01:51, 40:149, 42:02:01:01-42:02:02, 42:09, 42:17-42:18, 42:26, 48:22, 48:30, 50:01:22, 50:77, 51:116, 51:354, C*06:77, C*07:714, C*07:724 *40:528
4	225 bp 90 bp	800 bp	*41:45N *41:12, 41:36	*15:46, 15:106, 35:47, 35:154, 35:450, 40:10:01:01-40:10:02, 40:248, 40:282, 40:325, 40:351, 40:364, 40:526, 44:34:02, 44:245:01- 44:245:02, 44:269, 49:48, 53:30, 56:67, 57:45, 58:111
5	265 bp 230 bp	1070 bp	*41:04, 41:07 *41:23, 41:27	*08:96:01, 08:107, 35:530, 53:15, 55:20 *07:143, 08:62, 08:226, 08:242, 18:03:01:01- 18:03:02, 18:152, 18:171, 18:198, 18:203, 27:04:01-27:04:06, 27:06:01:01-27:06:02, 27:08, 27:11-27:12:01:03, 27:15, 27:20-27:21:02, 27:24-27:26, 27:31, 27:33, 27:36, 27:40, 27:61, 27:63, 27:66N, 27:68-27:69, 27:79, 27:86, 27:89 ^w , 27:91, 27:100, 27:103, 27:105-27:109, 27:112-27:115, 27:120, 27:125, 27:138, 27:147, 27:149, 27:153-27:154, 27:165, 27:168, 27:173, 27:183, 27:192, 27:202, 27:204:01:01- 27:204:01:02, 27:208, 27:210-27:211, 27:214, 27:222, 27:226, 27:229, 27:240, 27:242, 27:247, 37:37, 39:31:01:01-39:31:01:02, 39:101, 39:128, 40:43, 40:50:01:01-40:50:01:02, 40:166, 40:513, 42:02:01:01-42:02:02, 42:09, 42:17-42:18, 42:26-42:27, 45:06, 46:14 ^w , 49:67, 50:52, 54:02, 55:16, 56:35, C*03:278^w, C*03:504^w, C*07:714^w, C*07:724^w, C*16:86^w *27:05:59
	255 bp		*41:05	

tog bort: 4

formaterade: PI tabell Char, Språkkontrollera text, Inte Upphöjd/ Nedsänkt

tog bort: 4

formaterade: PI tabell Char, Språkkontrollera text, Inte Upphöjd/ Nedsänkt



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6	220 bp	1070 bp	*41:01:01:01-41:01:08, 41:05-41:07, 41:09, 41:12, 41:14, 41:16- 41:17, 41:20-41:22, 41:25-41:26, 41:28- 41:30, 41:32-41:35, 41:37, 41:44, 41:50, 41:53-41:54, 41:56Q- 41:57, 41:59-41:61, 41:64, 41:66-41:67, 41:70, 41:73, 41:75- 41:79	*08:09, 08:84, 08:254, 13:46, 13:154, 15:83:01:01-15:83:01:02, 42:04, 44:15:01:01- 44:15:01:02, 44:18:01:01-44:18:01:02, 44:20, 44:100, 44:355, 45:01:01:01-45:25, 45:27-45:30, 51:08:01:01-51:08:06, 51:20, 51:36, 51:44N, 51:97, 51:141, 51:153:01-51:153:02, 51:263, 51:274-51:275, 51:342, 51:354, 51:362, 51:371, 52:19, 55:20, 55:56, 56:13
7	295 bp	1070 bp	*41:06, 41:09	*13:02:01:01-13:02:23, 13:02:25-13:04, 13:08- 13:09, 13:14-13:16, 13:18-13:19, 13:27, 13:30- 13:35, 13:37-13:38, 13:40-13:42, 13:44-13:49N, 13:53-13:56:02N, 13:58-13:59, 13:62, 13:65- 13:70, 13:72, 13:74-13:75, 13:81, 13:84-13:85, 13:88-13:89, 13:91, 13:93-13:94, 13:96-13:105, 13:111-13:121, 13:123Q-13:128, 13:130-13:134, 13:136-13:137N, 13:139N-13:140, 13:143, 13:145, 13:147, 13:149-13:160, 13:164-13:167, 13:169, 13:172, 13:175-13:176, 14:37, 15:04:01:01-15:04:04, 15:16:01:01-15:16:05, 15:42, 15:67, 15:83:01:01-15:83:01:02, 15:95, 15:137, 15:155, 15:222, 15:254, 15:293, 15:303, 15:310, 15:362, 15:408, 15:485, 15:499, 15:517, 15:531, 15:550, 15:552, 15:602, 15:609, 15:613, 27:14, 27:81, 27:130, 27:153, 35:37, 35:60, 35:235, 35:265, 35:273, 35:276, 35:534, 39:06:01:01-39:06:08, 39:33-39:34, 39:50, 39:57, 39:62, 39:64, 39:83:01-39:83:03, 39:102, 39:109, 39:127, 39:129, 39:132, 39:140-39:141, 39:154, 39:178, 39:186-39:187, 40:06:01:01- 40:06:31, 40:44, 40:53, 40:70:01-40:70:02, 40:75, 40:83, 40:86, 40:93, 40:95-40:96, 40:103, 40:109-40:110, 40:127, 40:131, 40:148, 40:159, 40:161-40:162, 40:165, 40:167, 40:177, 40:190, 40:230, 40:244, 40:256N, 40:268-40:270, 40:275, 40:294-40:295, 40:306-40:307, 40:311, 40:313, 40:317-40:318, 40:330, 40:340-40:342, 40:348-40:350, 40:354, 40:361N-40:364, 40:366, 40:373-40:374, 40:376, 40:387-40:389, 40:408, 40:411, 40:423, 40:425, 40:427, 40:434, 40:445, 40:449, 40:451, 40:453-40:454, 40:459- 40:460, 40:464, 40:468, 40:471, 40:473, 40:476, 40:478, 40:482, 40:484, 40:487N-40:488N, 40:492, 40:494, 40:519-40:520, 40:526, 44:15:01:01-44:15:01:02, 44:18:01:01- 44:18:01:02, 44:20, 44:47, 44:100, 44:197, 44:339, 44:355, 44:459, 45:01:01:01-45:04, 45:06-45:25, 45:27-45:30, 46:11, 46:18, 46:32:01-46:32:02, 49:01:01:01-49:01:11, 49:01:13-49:01:21, 49:01:23-49:14, 49:16-49:46, 49:48-49:60N, 49:62-49:78, 50:01:01:01- 50:02:01:02, 50:04:01-50:10, 50:13-50:16, 50:18-50:22, 50:31-50:50, 50:52-50:79,



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				40:43, 40:46-40:47, 40:49, 40:51, 40:54-40:55, 40:61-40:63, 40:65-40:67, 40:69, 40:72:01-40:74, 40:76, 40:79, 40:81, 40:84, 40:87:01-40:87:02, 40:92, 40:100-40:102, 40:106, 40:108, 40:112-40:114:02, 40:116-40:118N, 40:121, 40:123, 40:125:01-40:125:03, 40:128, 40:130:01-40:130:02, 40:132, 40:134-40:136, 40:138, 40:140-40:141, 40:146-40:147, 40:149-40:156, 40:163, 40:166, 40:168, 40:170-40:172, 40:175, 40:178-40:179, 40:182-40:183, 40:185-40:188, 40:191-40:199, 40:204, 40:207-40:208, 40:210, 40:212-40:213, 40:215-40:218, 40:221, 40:223, 40:227-40:228, 40:231, 40:234-40:239, 40:241-40:242, 40:245:01-40:245:02, 40:247, 40:249-40:253, 40:257-40:265N, 40:272-40:273, 40:277-40:279, 40:281-40:282, 40:285-40:286N, 40:288, 40:299-40:301, 40:308, 40:310, 40:312, 40:315, 40:319, 40:321, 40:323:01-40:329, 40:332-40:333, 40:336, 40:338N-40:339, 40:344, 40:346, 40:351, 40:353:01:01-40:353:02, 40:355, 40:357-40:358, 40:360, 40:365, 40:367, 40:370, 40:372N, 40:379:01:01-40:379:01:02, 40:380-40:383, 40:385-40:386, 40:391-40:398, 40:400-40:402, 40:404, 40:406-40:407, 40:416-40:419, 40:421Q, 40:424, 40:426N, 40:428N, 40:430-40:431, 40:433, 40:436, 40:439, 40:443, 40:446-40:448, 40:450, 40:452, 40:456, 40:461-40:463, 40:466, 40:474-40:475:02, 40:477, 40:479-40:480, 40:483N, 40:485-40:486, 40:490-40:491, 40:495, 40:497, 40:499, 40:501, 40:503, 40:506N-40:510N, 40:512-40:513, 40:516-40:517, 40:523-40:525, 40:528, 44:31, 46:74, 48:03:01:01-48:03:02, 48:40, 48:57, 51:06:01:01-51:06:04, 51:59, 51:194, 51:293, 51:341, 51:352, 55:08, 57:82, C*04:89, C*04:127, C*04:135, C*04:210, C*04:237, C*04:379, C*05:47, C*05:84, C*05:139, C*05:180N, C*05:182, C*05:193, C*05:236, C*05:240, C*05:256, C*07:775, C*08:208N
21	90 bp	1070 bp	*41:01:01:01-41:01:08, 41:05-41:07, 41:09, 41:12, 41:14, 41:16-41:17, 41:20, 41:22, 41:25-41:26, 41:28-41:30, 41:32-41:35, 41:37, 41:44, 41:50, 41:53-41:54, 41:56Q-41:57, 41:59-41:61, 41:64, 41:67, 41:70, 41:73, 41:75-41:79	*08:254, 40:366, 45:14, 51:372
22	155 bp	1070 bp	*41:01:01:01-41:02:03, 41:02:05-41:11, 41:13-41:22, 41:24-41:70, 41:72-41:79	*13:167, 15:53, 15:212, 15:336, 15:347, 15:559, 15:588, 18:102, 18:107, 27:18, 27:29, 27:119, 35:63, 35:317, 38:22, 40:01:01-40:01:38, 40:01:40-40:02:02, 40:02:05-40:06:31, 40:09, 40:11:01:01-40:11:02, 40:13-40:16:01:02,

tog bort: ⁴
 formaterade: PI tabell Char, Språkkontrollera text, Inte Upphöjd/ Nedsänkt

101.542-06 – including *Taq* polymerase
 101.542-06u – without *Taq* polymerase

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 “Instructions for Use” (IFU)

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Lot-specific information

				40:18-40:20:01:02, 40:22N-40:27:01, 40:27:03-40:40, 40:42-40:60, 40:62-40:67, 40:69-40:74, 40:76-40:82, 40:84-40:93, 40:95-40:102, 40:104-40:105, 40:107-40:136, 40:138-40:161, 40:163-40:165, 40:167-40:169, 40:171-40:184, 40:186:01-40:199, 40:201-40:208, 40:210-40:214, 40:216N-40:219, 40:221-40:225:02, 40:227-40:231, 40:233-40:247, 40:249-40:251, 40:253-40:309, 40:311-40:321, 40:323:01-40:361N, 40:363, 40:366-40:387, 40:389-40:396, 40:398-40:427, 40:429, 40:431-40:456, 40:458-40:461, 40:463-40:480, 40:482-40:491, 40:493-40:512, 40:514N-40:516, 40:518-40:528, 44:02:01:01-44:02:01:73, 44:02:03-44:02:04, 44:02:06-44:02:47, 44:02:49:01-44:03:37, 44:03:39-44:03:62, 44:03:64-44:05:06, 44:07-44:59:02, 44:61N-44:82, 44:85:01-44:89, 44:91-44:92, 44:94-44:96, 44:98-44:136, 44:138Q, 44:140-44:155, 44:157-44:193, 44:195N-44:204:02, 44:206-44:224, 44:226-44:231, 44:233-44:234, 44:236, 44:238, 44:240-44:241, 44:243-44:245:02, 44:247-44:262, 44:264-44:268, 44:270:01-44:355, 44:357-44:365, 44:437-44:444, 44:446-44:452:02, 44:454-44:524, 44:526-44:528, 44:530-44:537, 44:539-44:546, 45:01:01:01-45:05, 45:07-45:25, 45:27-45:30, 47:01:01:02-47:12, 49:01:01:01-49:02, 49:04:01-49:14, 49:16-49:66, 49:68, 49:70-49:76, 49:78, 50:01:01:01-50:01:09, 50:01:11-50:02:01:02, 50:04:01-50:22, 50:31-50:76, 50:78-50:79, 51:103, 51:203, 51:276, 52:106, 53:30, 57:51, 57:69, C*16:85
23	260 bp	800 bp	*41:43	*08:01:44, 14:01:01:01-14:07N, 14:08:01 [?] -14:09 [?] , 14:10, 14:11 [?] , 14:12, 14:13 [?] -14:30 [?] , 14:31, 14:32 [?] , 14:33-14:34, 14:35 [?] -14:40 [?] , 14:41N, 14:42:01 [?] , 14:42:02, 14:43 [?] -14:45 [?] , 14:46, 14:47 [?] -14:48 [?] , 14:49, 14:50 [?] -14:52 [?] , 14:53-14:54, 14:55 [?] , 14:57 [?] -14:58 [?] , 14:59, 14:60 [?] , 14:61-14:116, 15:04:04, 15:09:02, 18:168, 35:01:25, 35:35, 35:471, 38:01:01:01-38:02:11, 38:03 [?] -38:04 [?] , 38:05-38:06, 38:07 [?] -38:08 [?] , 38:09, 38:10 [?] , 38:11-38:12, 38:13 [?] , 38:14, 38:15 [?] -38:16 [?] , 38:17-38:18, 38:19 [?] -38:20:01 [?] , 38:20:02, 38:21 [?] -38:23 [?] , 38:24, 38:25 [?] -38:27 [?] , 38:28, 38:29 [?] , 38:30, 38:31 [?] -38:34N [?] , 38:35, 38:36 [?] -38:45 [?] , 38:46-38:50, 38:51 [?] -38:54 [?] , 38:55Q, 38:56 [?] -38:57 [?] , 38:58, 38:59 [?] , 38:60, 38:61 [?] -38:66 [?] , 38:67-38:104, 38:160-38:173Q, 39:01:01:01-39:01:01:29, 39:01:03:01-39:15, 39:16 [?] -39:18 [?] , 39:19:01, 39:19:02 [?] , 39:20, 39:22-39:26, 39:27 [?] , 39:28, 39:29 [?] -39:30 [?] , 39:31:01:01-39:31:01:02, 39:32 [?] , 39:33-39:34, 39:35 [?] , 39:36-39:39:01, 39:39:02 [?] , 39:40:01N-39:42, 39:44-39:47, 39:48 [?] , 39:49-39:50, 39:51 [?] -39:57 [?] , 39:58-39:60, 39:61 [?] , 39:62-39:64, 39:65 [?] -39:76 [?] , 39:77,



101.542-06 – including Taq polymerase
101.542-06u – without Taq polymerase

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Lot-specific information

	39:78 [?] -39:83:01 [?] , 39:83:02-39:88, 39:89 [?] -39:91 [?] , 39:92, 39:93 [?] -39:96 [?] , 39:97N-39:98, 39:99 [?] -39:102 [?] , 39:103-39:104, 39:105 [?] -39:115 [?] , 39:116N, 39:117 [?] -39:118 [?] , 39:119, 39:120 [?] , 39:121-39:123, 39:124 [?] -39:128 [?] , 39:129-39:132, 39:133N [?] , 39:134-39:178, 39:180-39:194Q, 40:01:42, 40:06:03, 44:05:05, 58:20, 67:01:01-67:04, 67:06-67:07
24 ⁶	- - Negative Control

tog bort: ⁶

formaterade: PI tabell Char, Språkkontrollera text, Inte Upphöjd/ Nedsänkt

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*41 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 9 and 20 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.

?: nucleotide sequence information not available for the primer matching sequence.



0197

For *In Vitro* Diagnostic Use
MA123 v02 SSP PI Template
Date: June 2023, Rev. No: 00

101.542-06 – including *Taq* polymerase
 101.542-06u – without *Taq* polymerase

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Lot No.: 8R8

Lot-specific information

PRIMER SPECIFICATION

Well No.	1	2	3	4	5	6	7	8	9	10	11	12
Length of spec. PCR product	285	165	75	90	230	220	295	215	105	105	245	210
Length of int. pos. control ¹	800	1070	1070	800	1070	1070	1070	1070	1070	800	800	1070
5'-primer(s) ²	357 5'-Tgg 3'	363 5'-AgC 3'	97 5'-TCC 3'	144 5'-gCA 3'	97 5'-TCC 3'	357 5'-Tgg 3'	357 5'-Tgg 3'	97 5'-TCC 3'	540 5'-gAC 3'	540 5'-gAC 3'	357 5'-Tgg 3'	369 5'-TAC 3'
			363 5'-AgC 3'	379 5'-ACC 3'								
3'-primer(s) ³	603 5'-gTg 3'	486 5'-gCg 3'	126 5'-TCT 3'	193 5'-CgT 3'	278 5'-TgT 3'	538 5'-gTC 3'	610 5'-CTg 3'	272 5'-Tgg 3'	605 5'-gCT 3'	603 5'-gTg 3'	559 5'-CgT 3'	538 5'-gTC 3'
		538 5'-gTC 3'	142 5'-TgA 3'	603 5'-gTg 3'	292 5'-gTC 3'	280 5'-gTC 3'		280 5'-gTC 3'				
			279 5'-TTg 3'	312 5'-AgC 3'								
			407 5'-gCT 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. PCR product	285	115	115	95	85	140	130	90	90	155	260
Length of int. pos. control ¹	1070	1070	1070	1070	1070	1070	1070	1070	1070	1070	800
5'-primer(s) ²	357 5'-Tgg 3'	366 5'-ATT 3'	106 5'-CCA 3'	363 5'-AgC 3'	400 5'-TCT 3'	363 5'-AgC 3'	160 5'-ACT 3'	363 5'-Agg 3'	362 5'-gAg 3'	167 5'-gCT 3'	3 rd I 5'-Agg 3'
		400 5'-TCT 3'	540 5'-gAC 3'		560 5'-CgA 3'		185 5'-CAA 3'				
			463 5'-TgT 3'								
3'-primer(s) ³	603 5'-gTC 3'	538 5'-gTC 3'	322 5'-gTg 3'	419 5'-CgA 3'	603 5'-gTg 3'	463 5'-gCT 3'	272 5'-Tgg 3'	412 5'-gTT 3'	409 5'-ATg 3'	272 5'-Tgg 3'	786 5'-CTg 3'
			613 5'-gCC 3'	610 5'-CTg 3'						292 5'-gTA 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.



0197

For *In Vitro* Diagnostic Use
 MA123 v02 SSP PI Template
 Date: June 2023, Rev. No: 00

101.542-06 – including Taq polymerase
 101.542-06u – without Taq polymerase

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 “Instructions for Use” (IFU)

Lot No.: 8R8

Lot-specific information

CELL LINE VALIDATION SHEET																				
HLA-B*41 SSP primer set ²																				
				Well																
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	
				Prod. No.:	201893901	202016702	202240603	201893904	202016705	201893906	201893907	202240608	201893909	201893910	201893911	201893912	201893913	202240614	201910015	202350616
IHC 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 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	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-



101.542-06 – including Taq polymerase
 101.542-06u – without Taq polymerase

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Lot No.: 8R8

Lot-specific information

CELL LINE VALIDATION SHEET											
HLA-B*41 SSP primer set ²											
				Well							
				17	18	19	20	21	22	23	
				Prod. No.:	202240617	202240618	202016719	201910020	202240621	202350622	202240623
IHCW 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	-	-	-	-	-	+	-



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For *In Vitro* Diagnostic Use
 MA123 v02 SSP PI Template
 Date: June 2023, Rev. No: 00

101.542-06 – including *Taq* polymerase
101.542-06u – without *Taq* polymerase

Visit www.caredx.com for
“Instructions for Use” (IFU)

Lot No.: **8R8**

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 9, 14, 15, 17 and 19 were available.

The specificities of the primers in primer solutions 9 and 17 were tested by separately adding one 3'-primer, respectively one 5'-primer.

In primer solutions 14 and 19 it was only possible to test the 3'-primers, the 5'-primers were not possible to be tested.

In primer solution 15 it was only possible to test the 5'-primers, the 3'-primers were not possible to be tested.

In primer solutions 3, 5 and 8, two or three 3'-primers were not possible to be tested. In primer mix 17, one 5'-primer was not possible to test.

In addition, one or more 5-' and/or 3'-primers in primer solutions 2 to 4 and 16 were tested by separately adding one 3'-primers and/or 5'-primers respectively.



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Lot No.: **8R8**

Lot-specific information

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