

101.546-06 – including *Taq* polymerase
101.546-06u – without *Taq* polymerase

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

Lot No.: **6R0**

Lot-specific information

Olerup SSP[®] HLA-B*48

Product number:	101.546-06 – including <i>Taq</i> polymerase 101.546-06u – without <i>Taq</i> polymerase
Lot number:	6R0
Expiry date:	2027-01-01
Number of tests:	6
Number of wells per test:	19+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. 6R0.

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*48 LOT (3K3).

- The product documentation has been updated for new alleles of IMGT 3.50.0
- The kit resolution focuses on common and well documented (CWD) alleles¹.

¹As described in section Uniquely Identified Alleles.

The HLA-B*48 specificity and interpretation tables have been updated for the HLA-B alleles described since the previous *Olerup SSP[®] HLA-B*48* lot was made (**Lot No. 3K3**).

The HLA-B*48 primer set is unchanged compared to the previous *Olerup SSP[®] HLA-B*48* (**Lot No. 3K3**).

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

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

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

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

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

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



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PRODUCT DESCRIPTION

HLA-B*48 SSP typing

CONTENT

The primer set contains 5'- and 3'-primers for identifying the B*48:01 to B*48:55 alleles.

PLATE LAYOUT

Each HLA-B*48 test consists of 20 PCR reactions in a 24 well cut PCR plate. Wells 21 to 24 are empty.

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	NC	empty	empty	empty	empty

The 24 well PCR plate is marked with ‘HLA-B*48’ in silver/gray ink.

Well No. 1 is marked with the Lot No. ‘6R0’.

Wells 1 to 19 – HLA-B*48 high resolution primers.

Well 20 – 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*48 alleles will be amplified by some primer mixes. For further details see Specificity Table.

UNIQUELY IDENTIFIED ALLELES

All the HLA-B*48 alleles, i.e. **B*48:01 to B*48:55**, recognized by the HLA Nomenclature Committee in October 2022^{1,2} will be amplified by the primers in the HLA-B*48 SSP kit³.

The HLA-B*48 kit enables separation of the confirmed HLA-B*48 alleles as listed in the IMGT/HLA database 3.26.0. 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*48 alleles is listed below.

The HLA-B*48 kit also enables identification of many null and alternatively expressed alleles.



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The following HLA-B*48 alleles can be distinguished by the different sizes of the HLA-specific PCR product:

Alleles	Primer mix
B*48:09, 48:11	14
B*48:18, 48:29	15
B*48:19, 48:27	9

¹HLA-B alleles listed on the IMGT/HLA web page 2022-October-12, release 3.50.0, 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 will give rise to identical amplification patterns with the HLA-B*48 subtyping kit. These alleles can be distinguished by the HLA-B low resolution and/or the respective HLA-B kits.

Alleles

B*48:08, B*07:400, B*07:453

B*48:10, B*39:13:02, B*42:11

B*48:12, B*52:90

B*48:23, B*40:430

ALLELE CONFIRMATION STATUS

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

¹Allele status “confirmed” or “unconfirmed” as listed on the IMGT/HLA web page 2016-October-14, release 3.26.0, www.ebi.ac.uk/imgt/hla.

RESOLUTION IN HOMO- AND HETEROZYGOTES

Results file with resolution in HLA-B*48 homo- and heterozygotes is available upon request.



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SPECIFICITY TABLE

HLA-B*48 SSP subtyping

Specificities and sizes of the PCR products of the 19+1 primer mixes used for HLA-B*48 SSP subtyping

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified HLA-B*48 alleles ³	Other amplified HLA-B alleles
1	385 bp	800 bp	*48:01:01:01-48:05, 48:07-48:15, 48:17-48:38, 48:40-48:55	*07:400, 07:453, 08:17, 08:38:01-08:38:02, 08:54:01-08:54:02, 08:101, 08:228, 08:285, 15:68, 15:634, 38:03-38:04, 38:25, 39:02:01:01-39:02:03, 39:08, 39:13:01-39:13:02, 39:22-39:23, 39:49, 39:101, 39:105, 39:110, 39:162, 39:164, 39:184, 40:01:01-40:01:79, 40:06:16 [?] , 40:07, 40:09 [?] , 40:14:01 [?] -40:14:02 [?] , 40:14:03, 40:15 [?] , 40:16:01:01-40:16:01:02, 40:18 [?] , 40:21 [?] , 40:22N-40:23, 40:24 [?] , 40:27:02 [?] , 40:28 [?] -40:29 [?] , 40:30-40:33, 40:34 [?] -40:35:02 [?] , 40:36 [?] , 40:38, 40:42-40:43, 40:44 [?] -40:47 [?] , 40:48, 40:49 [?] , 40:51-40:52, 40:53 [?] , 40:54-40:55, 40:56 [?] -40:58 [?] , 40:59-40:60, 40:61 [?] -40:63 [?] , 40:65 [?] , 40:66, 40:67 [?] , 40:71 [?] , 40:72:01-40:74, 40:75 [?] , 40:76-40:77, 40:78 [?] , 40:79-40:80, 40:81 [?] -40:88 [?] , 40:91 [?] -40:93 [?] , 40:95 [?] -40:96 [?] , 40:98 [?] , 40:100 [?] -40:101 [?] , 40:102, 40:103 [?] -40:105 [?] , 40:107 [?] -40:109 [?] , 40:112 [?] , 40:113-40:114:01:02, 40:114:02 [?] -40:116 [?] , 40:117, 40:118N [?] , 40:121 [?] , 40:123 [?] , 40:124:01, 40:124:02 [?] -40:125:01 [?] , 40:125:02-40:126, 40:127 [?] , 40:128, 40:130:01 [?] , 40:130:02, 40:131 [?] -40:137 [?] , 40:138-40:140, 40:141 [?] , 40:145 [?] , 40:146-40:147, 40:148 [?] -40:149 [?] , 40:150, 40:151 [?] , 40:152-40:153, 40:154 [?] , 40:155:01N-40:155:02N, 40:156 [?] -40:159 [?] , 40:160:01, 40:160:02 [?] -40:165 [?] , 40:167 [?] , 40:168, 40:169 [?] , 40:170-40:172, 40:173 [?] -40:180 [?] , 40:182 [?] , 40:183, 40:184 [?] -40:185 [?] , 40:186:01, 40:186:02 [?] -40:190 [?] , 40:191, 40:192 [?] -40:201 [?] , 40:203 [?] -40:213 [?] , 40:215 [?] -40:225:01 [?] , 40:226 [?] -40:228 [?] , 40:230 [?] -40:231 [?] , 40:233 [?] -40:236 [?] , 40:237, 40:238 [?] -40:243 [?] , 40:245:01-40:245:02, 40:246 [?] -40:248 [?] , 40:249-40:253, 40:256N [?] -40:257 [?] , 40:258-40:265N, 40:272-40:273, 40:274 [?] -40:276 [?] , 40:277-40:278, 40:279 [?] -40:283 [?] , 40:285-40:286N, 40:287 [?] -40:289 [?] , 40:291N [?] -40:295 [?] , 40:297 [?] -40:300 [?] , 40:301, 40:306 [?] -40:308 [?] , 40:310, 40:311 [?] -40:312 [?] , 40:315 [?] , 40:316-40:317, 40:318 [?] -40:319 [?] , 40:321, 40:322 [?] , 40:323:01-40:323:02, 40:324 [?] -40:330 [?] , 40:332, 40:333 [?] , 40:335 [?] -40:344 [?] , 40:346, 40:348 [?] -40:352 [?] , 40:354 [?] , 40:355, 40:358 [?] -40:361N [?] , 40:363 [?] -40:364 [?] , 40:366 [?] , 40:367-40:368, 40:370, 40:372N, 40:374 [?] , 40:376 [?] , 40:377, 40:379:01:01-40:383, 40:385-40:386, 40:388 [?] , 40:391-40:395, 40:396 [?] , 40:397-40:398, 40:400 [?] ,



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2	145 bp	800 bp	*48:01:01:01-48:01:12, 48:03:01:01-48:03:02, 48:06-48:07, 48:09, 48:11, 48:15-48:23, 48:26-48:50, 48:52, 48:54-48:55	*07:174, 07:202, 07:222, 07:279, 27:36, 27:125, 38:63, 40:01:01-40:01:29, 40:01:31-40:01:45, 40:01:47-40:01:79, 40:07, 40:10:01:01-40:10:02, 40:12:01-40:12:02, 40:21-40:23, 40:25, 40:30-40:31, 40:33-40:34, 40:36, 40:38, 40:42-40:43, 40:45-40:49, 40:52, 40:54-40:55, 40:59-40:61, 40:63, 40:66-40:67, 40:69, 40:73-40:74, 40:76, 40:79-40:81, 40:84, 40:87:01-40:88, 40:100-40:102, 40:106, 40:112-40:114:02, 40:116-40:118N, 40:123-40:126, 40:128, 40:132, 40:134-40:135, 40:137-40:141, 40:146-40:147, 40:149-40:156, 40:160:01-40:160:02, 40:166, 40:168, 40:170-40:172, 40:175, 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, 40:233-40:236, 40:239-40:242, 40:245:01-40:245:02, 40:247, 40:249-40:253, 40:257-40:265N, 40:272-40:273, 40:277-40:282, 40:285-40:286N, 40:288, 40:298:01-40:301, 40:308, 40:310, 40:315-40:316, 40:319, 40:321, 40:323:01-40:325, 40:327-40:329, 40:332-40:333, 40:338N-40:339, 40:344, 40:346, 40:352-40:353:02, 40:355, 40:357-40:358, 40:360, 40:365, 40:367-40:368, 40:370, 40:372N, 40:377, 40:379:01:01-40:383, 40:385-40:386, 40:391-40:397, 40:400-40:404, 40:406-40:407, 40:416-40:419, 40:421Q-40:422, 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, 40:469, 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, 40:524-40:525, 44:31, 46:06, 81:01:01:01-81:10



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3	175 bp	800 bp	*48:01:01:01-48:01:11, 48:04:01:01-48:04:02, 48:06-48:07, 48:09, 48:11, 48:15-48:16, 48:18-48:20, 48:22, 48:24, 48:27-48:39, 48:41-48:55
			*07:174, 07:202, 07:222, 07:279, 08:213:01-08:213:02, 27:24, 40:31, 40:45, 40:80, 81:01:01:01-81:10
4	150 bp	800 bp	*48:02:01-48:02:03, 48:25
			*07:235, 07:359, 08:49, 08:255, 13:01:01:01-13:01:21, 13:06-13:07N, 13:12:01-13:13:02, 13:17, 13:20, 13:22:01-13:23, 13:25-13:26:02, 13:28-13:29, 13:36, 13:39, 13:43, 13:50-13:52, 13:57, 13:60-13:61, 13:63N, 13:73, 13:76N-13:80, 13:83, 13:86-13:87, 13:90, 13:92, 13:95, 13:106-13:107, 13:109-13:110, 13:122, 13:129, 13:135, 13:138, 13:141-13:142, 13:144, 13:146, 13:148, 13:161N-13:163, 13:168, 13:170-13:171, 13:173, 14:10, 14:102, 15:02:01:01-15:02:12, 15:13:01-15:13:03, 15:20-15:21:01:02, 15:25:01:01-15:25:04, 15:36, 15:44, 15:62, 15:77, 15:80, 15:85, 15:88-15:89:02, 15:106, 15:112, 15:121, 15:139, 15:144, 15:154, 15:165, 15:170, 15:194, 15:204, 15:213-15:214, 15:223, 15:240, 15:250, 15:265, 15:271, 15:283, 15:289, 15:291, 15:297, 15:301-15:302N, 15:308, 15:319, 15:325, 15:328, 15:330, 15:341, 15:345, 15:357-15:358, 15:366, 15:374, 15:378, 15:393-15:394, 15:399, 15:402, 15:404, 15:407, 15:418, 15:420, 15:425, 15:437-15:438, 15:454N, 15:458, 15:460, 15:463N, 15:468, 15:491, 15:495, 15:505, 15:537, 15:543-15:544N, 15:557, 15:564, 15:566-15:567, 15:569, 15:574, 15:584N, 15:587, 15:589, 15:592, 15:594, 15:596N, 15:599, 15:615, 15:623, 15:625, 15:627, 15:630, 15:645-15:646, 18:22, 18:69, 18:105, 18:149-18:150, 18:204, 27:19:01:01-27:19:01:02, 27:30, 27:127, 27:150, 35:01:01:01-35:01:54, 35:01:56-35:01:61, 35:01:63-35:04:03, 35:06-35:08:15, 35:10-35:17:04, 35:19-35:21, 35:23-35:30:01:02, 35:33-35:36, 35:38-35:42:02, 35:45-35:50, 35:52, 35:54-35:57, 35:59:01-35:59:02, 35:61:01-35:63, 35:65Q, 35:69-35:71, 35:74, 35:76-35:78, 35:80-35:85, 35:90-35:96, 35:98, 35:100-35:101:02, 35:103-35:113, 35:115-35:116, 35:120-35:126, 35:128-35:134N, 35:136-35:150:02, 35:152-35:173:02N, 35:175-35:184, 35:186-35:198, 35:200-35:204, 35:206-35:229, 35:231, 35:233, 35:236-35:250, 35:252-35:259, 35:261-35:264, 35:266-35:272, 35:274-35:275, 35:277-35:291, 35:293-35:320, 35:322-35:330, 35:332-35:366, 35:370-35:371, 35:373-35:388, 35:390N-35:408, 35:410-35:415, 35:417-35:426, 35:428Q-35:432, 35:434-35:439:01:02, 35:441-35:458, 35:460Q-35:470, 35:473-35:474, 35:477-35:480, 35:482-35:497, 35:500-35:508N, 35:510-35:518, 35:520, 35:522, 35:524-35:533, 35:536-35:538, 35:540, 35:542N-35:548, 35:550-35:568,



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

101.546-06 – including *Taq* polymerase

101.546-06u – without *Taq* polymerase

Lot No.: **6R0**

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For *In Vitro* Diagnostic Use

MA123 v02 SSP PI Template

Date: January 2023, Rev. No: 00

101.546-06 – including *Taq* polymerase
 101.546-06u – without *Taq* polymerase

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Lot No.: **6R0**

Lot-specific information

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	250 bp		*48:11	
15⁵	140 bp	1070 bp	*48:12, 48:14, 48:29	*07:68:01-07:68:03, 07:100, 07:237, 07:262:01-07:262:02, 07:424, 08:71, 08:274, 08:296, 13:108, 14:05, 14:13, 14:53, 15:07:01:01-15:07:03, 15:45, 15:55, 15:68, 15:126, 15:197:02, 15:207, 15:324, 15:329, 15:331, 15:360, 15:383, 15:405, 15:431, 15:450, 18:14, 27:32, 27:138, 27:180, 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, 35:89, 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, 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, 40:35:01-40:35:03, 40:71, 41:24, 42:10, 42:17, 44:54, 44:106, 44:135, 44:158, 44:184, 44:213, 46:12, 51:64, 53:14, 53:67, 55:110, 58:18
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For *In Vitro* Diagnostic Use
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101.546-06 – including *Taq* polymerase

101.546-06u – without *Taq* polymerase

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101.546-06 – including *Taq* polymerase

101.546-06u – without *Taq* polymerase

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Lot-specific information

PRIMER SPECIFICATION

Well No.	1	2	3	4	5	6	7	8	9	10	11	12
Length of spec. PCR product	385	145	175	150	230	90	385	85	75	290	150	110
					285	170		225	215			135
						285						
Length of int. pos. control ¹	800	800	800	800	1070	1070	1070	1070	800	800	800	1070
5'-primer(s) ²	44	499	363	355	363	144	44	260	363	363	165	97
	5'-ggC 3'	5'-TCT 3'	5'-AgC 3'	5'-TCA 3'	5'-Agg 3'	5'-TCC 3'	5'-ggC 3'	5'-ggT 3'	5'-AgC 3'	5'-AgC 3'	5'-ACC 3'	5'-TCC 3'
					363	225		419		363		419
					5'-Agg 3'	5'-TgC 3'		5'-gTT 3'		5'-AgC 3'		5'-gTC 3'
					418	363		419				
					5'-Agg 3'	5'-AAT 3'		5'-gTT 3'				
3'-primer(s) ³	259	605	499	463	605	272	259	302	398	610	272	165
	5'-CTC 3'	5'-gCT 3'	5'-ggA 3'	5'-gCT 3'	5'-gCT 3'	5'-Tgg 3'	5'-gTT 3'	5'-ggC 3'	5'-ggC 3'	5'-CTg 3'	5'-Tgg 3'	5'-Tgg 3'
						605	259	605	537			512
						5'-gCT 3'	5'-gTT 3'	5'-gCT 3'	5'-Agg 3'			5'-CCA 3'
									539			
									5'-TCC 3'			
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

Well No.	13	14	15	16	17	18	19
Length of spec. PCR product	135	100	140	130	75	60	150
		250	435				
Length of int. pos. control ¹	1070	1070	1070	1070	1070	1070	1070
5'-primer(s) ²	397	363	44	161	693	272	419
	5'-gCT 3'	5'-AgC 3'	5'-ggC 3'	5'-Cgg 3'	5'-ggT 3'	5'-CTT 3'	5'-gTC 3'
	412	693	363	527			
	5'-ATA 3'	5'-ggT 3'	5'-AgC 3'	5'-TgA 3'			
3'-primer(s) ³	499	419	309	259	728	292	527
	5'-ggT 3'	5'-Cgg 3'	5'-ATC 3'	5'-CTC 3'	5'-CCT 3'	5'-gTA 3'	5'-CCT 3'
		572	463	605			
		5'-gCA 3'	5'-gCT 3'	5'-gCT 3'			
		755					
		5'-CAA 3'					
Well No.	13	14	15	16	17	18	19

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.



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101.546-06 – including *Taq* polymerase

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Lot No.: **6R0**

Lot-specific information

CELL LINE VALIDATION SHEET																			
HLA-B*48 SSP primer set²																			
				Well															
				Prod. No.:															
				201907501	201907502	201907503	201907504	201907505	201907506	201907507	201907508	201907509	201907510	201907511	201907512	201907513	201907514	201907515	201907516
		IHWC cell line¹	B*	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
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	VHONP199	*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	-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-



0197

101.546-06 – including *Taq* polymerase

101.546-06u – without *Taq* polymerase

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

Lot No.: **6R0**

Lot-specific information

CELL LINE VALIDATION SHEET								
HLA-B*48 SSP primer set²								
					Well			
					17	18	19	
					Prod. No.:	201907517	201907518	201907519
IHWC cell line¹			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	-	+	-	



0197

101.546-06 – including *Taq* polymerase

101.546-06u – without *Taq* polymerase

Lot No.: **6R0**

Lot-specific information

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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 6, 8 and 17 were available. The specificities of the primers in primer solutions 6 and 8 were tested by separately adding additional 3'-primers, respectively additional 5'-primers. In primer solution 17 it was only possible to test the 5'-primer, the 3'-primer was not possible to test. In primer solutions 6 and 8, one or two 5'-primers were not possible to test, and in primer solutions 9 and 14 two 3'-primers were not possible to test. Additional primers in primer solutions 5, 12, 14 and 16 were tested by separately adding one 5'-primer and/or one 3'-primer.



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For *In Vitro* Diagnostic Use

MA123 v02 SSP PI Template

Date: January 2023, Rev. No: 00

101.546-06 – including *Taq* polymerase

101.546-06u – without *Taq* polymerase

Lot No.: **6R0**

Lot-specific information

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

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Web page: www.caredx.com

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



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For *In Vitro* Diagnostic Use

MA123 v02 SSP PI Template

Date: January 2023, Rev. No: 00