

101.411-24/06 – including *Taq* polymerase
101.411-24u/06u – without *Taq* polymerase

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

Lot No.: **3R6**

Lot-specific information

Olerup SSP® HLA-A*01

Product number:	101.411-24/06 – including <i>Taq</i> pol. 101.411-24u/06u – without <i>Taq</i> pol.
Lot number:	3R6
Expiry date:	2026-09-01
Number of tests:	24 tests – Product No. 101.411-24/24u 6 tests – Product No. 101.411-06/06u
Number of wells per test:	62+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. 3R6.

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-A*01 LOT (5K8)

- The product documentation has been updated for new alleles of IMGT 3.49.0.
- The kit resolution focuses on common and well documented (CWD) alleles¹.

- ¹As described in section Uniquely Identified Alleles.

The HLA-A*01 primer set, specificity and interpretation tables have been updated for the HLA-A alleles described since the previous *Olerup SSP®* HLA-A*01 lot was made (**Lot No. 5K8**). The kit design is based on IMGT/HLA database 3.49.0.

The HLA-A*01 primer set is unchanged compared to the previous lot.

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 **63** 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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PRODUCT DESCRIPTION

HLA-A*01 SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for identifying the A*01:01 to A*01:419 alleles.

PLATE LAYOUT

Each test consists of 63 PCR reactions in a 64 well cut PCR plate. Well 64 is empty.

1	2	3	4	5	6	7	8
9	10	11	12	13	14	15	16
17	18	19	20	21	22	23	24
25	26	27	28	29	30	31	32
33	34	35	36	37	38	39	40
41	42	43	44	45	46	47	48
49	50	51	52	53	54	55	56
57	58	59	60	61	62	NC	empty

The 64 well cut PCR plate is marked with ‘HLA-A*01’ in silver/gray ink.

Well No. 1 is marked with the Lot No. ‘3R6’.

Wells 1 to 62 – HLA-A*01 high resolution primers.

Well 63 – 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.

INTERPRETATION

Due to the sharing of sequence motifs between HLA-A alleles non-HLA-A*01 alleles will be amplified by some primer mixes. For further details see Specificity Table.

UNIQUELY IDENTIFIED ALLELES

All the HLA-A*01 alleles, i.e. **A*01:01 to A*01:419**, recognized by the HLA Nomenclature Committee in July 2022^{1,2} will be amplified by the primers in the HLA-A*01 subtyping kit³.

The HLA-A*01 kit enables separation of the confirmed HLA-A*01 alleles as listed in the IMGT/HLA database 3.24.0. 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-A*01 alleles is listed below.



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Lot-specific information

The HLA-A*01 kit also enables identification of many null and alternatively expressed alleles.

The following HLA-A*01 alleles can be distinguished by the different sizes of the HLA-specific PCR product:

Alleles	Primer mix	Alleles	Primer mix
A*01:31N, 01:173	25	A*01:53N-01:54	36
A*01:32, 01:104	26	A*01:65, 01:92	37
A*01:47, 01:49	35	A*01:87N, 01:141	27, 42
A*01:48, 01:123N	36	A*01:137, 01:150	10, 35
A*01:50, 01:62	38		

¹HLA-A alleles listed on the IMGT/HLA web page 2022-July-12, release 3.49.0, 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 A*01 primer set cannot separate the following alleles. These alleles can be distinguished by the HLA-A low resolution and/or HLA-A*25 kits.

Alleles

A*01:69:01-01:69:03, 25:59



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ALLELE CONFIRMATION STATUS

Allele	Status ¹	Allele	Status ¹	Allele	Status ¹	Allele	Status ¹
A*01:01:01:01	Confirmed	A*01:01:49	Unconfirmed	A*01:26	Confirmed	A*01:74	Unconfirmed
A*01:01:01:02N	Unconfirmed	A*01:01:50	Unconfirmed	A*01:27N	Unconfirmed	A*01:75	Unconfirmed
A*01:01:01:03	Unconfirmed	A*01:01:51	Unconfirmed	A*01:28	Unconfirmed	A*01:76	Unconfirmed
A*01:01:02	Unconfirmed	A*01:01:52	Unconfirmed	A*01:29	Confirmed	A*01:77	Confirmed
A*01:01:03	Confirmed	A*01:01:53	Unconfirmed	A*01:30	Unconfirmed	A*01:78	Unconfirmed
A*01:01:04	Unconfirmed	A*01:01:54	Unconfirmed	A*01:31N	Unconfirmed	A*01:79	Unconfirmed
A*01:01:05	Unconfirmed	A*01:01:55	Unconfirmed	A*01:32	Unconfirmed	A*01:80	Unconfirmed
A*01:01:06	Confirmed	A*01:01:56	Unconfirmed	A*01:33	Confirmed	A*01:81	Confirmed
A*01:01:07	Unconfirmed	A*01:01:57	Unconfirmed	A*01:35	Confirmed	A*01:82	Unconfirmed
A*01:01:08	Unconfirmed	A*01:01:58	Unconfirmed	A*01:36	Unconfirmed	A*01:83:01	Unconfirmed
A*01:01:09	Confirmed	A*01:01:59	Unconfirmed	A*01:37	Confirmed	A*01:83:02	Unconfirmed
A*01:01:10	Confirmed	A*01:01:60	Unconfirmed	A*01:38	Confirmed	A*01:84	Unconfirmed
A*01:01:11	Confirmed	A*01:01:61	Unconfirmed	A*01:39	Confirmed	A*01:85	Unconfirmed
A*01:01:12	Confirmed	A*01:01:62	Confirmed	A*01:40	Confirmed	A*01:86	Confirmed
A*01:01:13	Confirmed	A*01:01:63	Unconfirmed	A*01:41	Confirmed	A*01:87N	Unconfirmed
A*01:01:14	Unconfirmed	A*01:01:64	Unconfirmed	A*01:42	Unconfirmed	A*01:88	Unconfirmed
A*01:01:15	Confirmed	A*01:01:65	Confirmed	A*01:43	Confirmed	A*01:89	Unconfirmed
A*01:01:16	Confirmed	A*01:01:66	Confirmed	A*01:44	Confirmed	A*01:90	Unconfirmed
A*01:01:17	Confirmed	A*01:01:67	Unconfirmed	A*01:45	Unconfirmed	A*01:91	Unconfirmed
A*01:01:18	Confirmed	A*01:01:68	Unconfirmed	A*01:46	Unconfirmed	A*01:92	Confirmed
A*01:01:19	Confirmed	A*01:01:69	Confirmed	A*01:47	Unconfirmed	A*01:93	Unconfirmed
A*01:01:20	Unconfirmed	A*01:01:70	Unconfirmed	A*01:48	Confirmed	A*01:94	Unconfirmed
A*01:01:21	Unconfirmed	A*01:01:71	Confirmed	A*01:49	Confirmed	A*01:95	Confirmed
A*01:01:22	Confirmed	A*01:01:72	Unconfirmed	A*01:50	Unconfirmed	A*01:96	Unconfirmed
A*01:01:23	Unconfirmed	A*01:01:73	Unconfirmed	A*01:51	Confirmed	A*01:97	Unconfirmed
A*01:01:24	Unconfirmed	A*01:01:74	Unconfirmed	A*01:52:01N	Unconfirmed	A*01:98	Confirmed
A*01:01:25	Unconfirmed	A*01:01:75	Unconfirmed	A*01:52:02N	Unconfirmed	A*01:99	Unconfirmed
A*01:01:26	Confirmed	A*01:02	Confirmed	A*01:53N	Unconfirmed	A*01:100	Confirmed
A*01:01:27	Unconfirmed	A*01:03	Confirmed	A*01:54	Unconfirmed	A*01:101	Confirmed
A*01:01:28	Unconfirmed	A*01:04N	Confirmed	A*01:55	Unconfirmed	A*01:102	Unconfirmed
A*01:01:29	Confirmed	A*01:06	Confirmed	A*01:56N	Unconfirmed	A*01:103	Unconfirmed
A*01:01:30	Unconfirmed	A*01:07	Unconfirmed	A*01:57N	Confirmed	A*01:104	Confirmed
A*01:01:31	Unconfirmed	A*01:08	Unconfirmed	A*01:58	Unconfirmed	A*01:105	Unconfirmed
A*01:01:32	Unconfirmed	A*01:09	Unconfirmed	A*01:59	Unconfirmed	A*01:106	Confirmed
A*01:01:33	Confirmed	A*01:10	Unconfirmed	A*01:60	Unconfirmed	A*01:107	Unconfirmed
A*01:01:34	Confirmed	A*01:11N	Unconfirmed	A*01:61	Confirmed	A*01:108	Unconfirmed
A*01:01:35	Unconfirmed	A*01:12	Unconfirmed	A*01:62	Unconfirmed	A*01:109	Unconfirmed
A*01:01:36	Unconfirmed	A*01:13	Unconfirmed	A*01:63	Unconfirmed	A*01:110	Unconfirmed
A*01:01:37	Unconfirmed	A*01:14	Unconfirmed	A*01:64	Confirmed	A*01:111	Unconfirmed
A*01:01:38L	Confirmed	A*01:15N	Confirmed	A*01:65	Confirmed	A*01:112	Unconfirmed
A*01:01:39	Unconfirmed	A*01:16N	Unconfirmed	A*01:66	Confirmed	A*01:113	Confirmed
A*01:01:40	Unconfirmed	A*01:17	Confirmed	A*01:67:01	Unconfirmed	A*01:114	Unconfirmed
A*01:01:41	Unconfirmed	A*01:18N	Unconfirmed	A*01:67:02	Unconfirmed	A*01:115	Confirmed
A*01:01:42	Confirmed	A*01:19	Confirmed	A*01:68	Confirmed	A*01:116	Unconfirmed
A*01:01:43	Unconfirmed	A*01:20	Unconfirmed	A*01:69:01	Unconfirmed	A*01:117	Unconfirmed
A*01:01:44	Confirmed	A*01:21	Confirmed	A*01:69:02	Confirmed	A*01:118	Unconfirmed
A*01:01:45	Unconfirmed	A*01:22N	Unconfirmed	A*01:70	Unconfirmed	A*01:119	Unconfirmed
A*01:01:46	Unconfirmed	A*01:23	Confirmed	A*01:71	Confirmed	A*01:120	Unconfirmed
A*01:01:47	Confirmed	A*01:24	Confirmed	A*01:72	Confirmed	A*01:121	Unconfirmed
A*01:01:48	Unconfirmed	A*01:25	Confirmed	A*01:73	Unconfirmed	A*01:122	Unconfirmed



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A*01:123N	Unconfirmed	A*01:143	Confirmed	A*01:163	Unconfirmed	A*01:183	Unconfirmed
A*01:124	Unconfirmed	A*01:144	Confirmed	A*01:164	Confirmed	A*01:184	Unconfirmed
A*01:125	Unconfirmed	A*01:145	Unconfirmed	A*01:165	Unconfirmed	A*01:185	Unconfirmed
A*01:126	Unconfirmed	A*01:146	Unconfirmed	A*01:166	Unconfirmed	A*01:186N	Unconfirmed
A*01:127	Unconfirmed	A*01:147Q	Unconfirmed	A*01:167	Unconfirmed	A*01:187	Unconfirmed
A*01:128	Unconfirmed	A*01:148	Unconfirmed	A*01:168	Unconfirmed	A*01:188	Unconfirmed
A*01:129	Unconfirmed	A*01:149	Unconfirmed	A*01:169	Unconfirmed	A*01:189	Unconfirmed
A*01:130	Unconfirmed	A*01:150	Confirmed	A*01:170	Unconfirmed	A*01:190	Confirmed
A*01:131	Unconfirmed	A*01:151	Unconfirmed	A*01:171	Unconfirmed	A*01:191	Unconfirmed
A*01:132	Confirmed	A*01:152	Unconfirmed	A*01:172	Unconfirmed	A*01:192	Unconfirmed
A*01:133	Unconfirmed	A*01:153	Unconfirmed	A*01:173	Unconfirmed	A*01:193	Unconfirmed
A*01:134	Confirmed	A*01:154	Unconfirmed	A*01:174	Unconfirmed	A*01:194	Unconfirmed
A*01:135	Unconfirmed	A*01:155	Unconfirmed	A*01:175	Unconfirmed	A*01:195	Unconfirmed
A*01:136	Unconfirmed	A*01:156	Unconfirmed	A*01:176	Unconfirmed	A*01:196	Unconfirmed
A*01:137	Confirmed	A*01:157	Unconfirmed	A*01:177	Unconfirmed	A*01:197	Unconfirmed
A*01:138	Unconfirmed	A*01:158	Unconfirmed	A*01:178N	Unconfirmed	A*01:198	Unconfirmed
A*01:139	Unconfirmed	A*01:159	Unconfirmed	A*01:179N	Unconfirmed	A*01:199	Unconfirmed
A*01:140	Unconfirmed	A*01:160N	Unconfirmed	A*01:180	Unconfirmed	A*01:200	Unconfirmed
A*01:141	Unconfirmed	A*01:161	Unconfirmed	A*01:181	Unconfirmed	A*01:201	Unconfirmed
A*01:142	Unconfirmed	A*01:162N	Unconfirmed	A*01:182	Unconfirmed		

¹Allele status “confirmed” or “unconfirmed” as listed on the IMGT/HLA web page 2016-May-04, release 3.24.0, www.ebi.ac.uk/imgt/hla.

RESOLUTION IN HOMO- AND HETEROZYGOTES

Results file with resolution in HLA-A*01 homo- and heterozygotes is available upon request.



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SPECIFICITY TABLE

HLA-A*01 SSP subtyping

Specificities and sizes of the PCR products of the 62+1 primer mixes used for HLA-A*01 SSP subtyping

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified HLA-A*01 alleles ³	Other amplified HLA-A alleles
1	235 bp	800 bp	*01:01:01:01-01:01:22, 01:01:24-01:01:78, 01:01:80, 01:01:82- 01:01:121, 01:01:123- 01:02:02, 01:04:01:01N- 01:04:01:02N, 01:06-01:07, 01:09:01:01-01:11N, 01:13, 01:16N-01:18N, 01:21- 01:33, 01:35-01:40, 01:42- 01:62, 01:64-01:65, 01:67:01-01:72, 01:74- 01:88:03, 01:90-01:98, 01:100-01:129, 01:131- 01:146, 01:148, 01:150- 01:158, 01:160N-01:177, 01:179N-01:191, 01:193- 01:199, 01:201-01:204, 01:206-01:207, 01:209- 01:243, 01:245-01:254, 01:256-01:278, 01:280- 01:286, 01:288-01:300, 01:302-01:306, 01:308N- 01:313, 01:316-01:339, 01:341-01:349, 01:351- 01:354, 01:356-01:379N, 01:381-01:390, 01:392- 01:395, 01:397-01:402, 01:404-01:419	*03:18, 03:105, 03:135, 11:01:44, 11:38-11:39, 11:94, 11:236, 11:271, 11:326, 25:59
2	145 bp	1070 bp	*01:01:01:01-01:01:140, 01:03:01:01-01:04:01:02N, 01:06-01:17, 01:18N ^w , 01:19, 01:21-01:23:02, 01:24 ^w , 01:25-01:33, 01:35- 01:42, 01:44-01:68, 01:70- 01:142, 01:144-01:170, 01:172-01:187, 01:189, 01:191-01:219, 01:221- 01:306, 01:308N-01:341, 01:343-01:400N, 01:402- 01:411N, 01:413-01:419	*03:395, 32:156, 36:01:01:01-36:12
3 ⁴	120 bp	800 bp	*01:02:01:01-01:02:02, 01:20, 01:190, 01:412	



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4	305 bp	1070 bp	*01:03:01:01-01:03:03, 01:192, 01:287N, 01:307, 01:315, 01:350, 01:355N	*11:26, 11:118, 11:372, 26:32, 26:70, 26:176, 29:66, 31:164, 32:62, 33:13, 33:184, 36:03, 68:227, 74:10, 74:30, B*57:102, C*06:72
5^{6,7}	460 bp	1070 bp	*01:04:01:01N-01:04:01:02N	*03:21N, 11:21N, 23:07N, 24:11N, 30:132N
6⁴	125 bp 210 bp	1070 bp	*01:60 *01:09:01:01-01:09:02	*26:31, 34:24, C*06:71, C*07:581 C*07:274
7⁴	60 bp 115 bp	1070 bp	*01:06 *01:86	*02:576, 31:62, 34:22
8^{4,6}	110 bp	1070 bp	*01:07, 01:23:01-01:23:02, 01:51, 01:83:01-01:83:02, 01:191, 01:299, 01:405	*24:243, 26:120, 31:35, 32:156
	180 bp		*01:01:01:02N	
9⁶	235 bp	800 bp	*01:08, 01:27N	
10^{4,5}	120 bp 155 bp	800 bp	*01:150 *01:10	*03:231:01 ^w , 03:231:02, 11:14 ^w , 11:50Q, 11:290, 30:26, 68:293Q, 80:01:01:01 ^w -80:09N ^w
	240 bp 270 bp		*01:137 *01:29	
11	135 bp	800 bp	*01:13, 01:28, 01:176, 01:194, 01:229, 01:299	*03:395, 11:282, 31:35
	180 bp 275 bp		*01:106 *01:11N	
12^{4,7}	90 bp	800 bp		*02:576, 02:682, 03:187, 11:155, 11:226, 31:62, 34:22, 36:01:01:01- 36:12, 68:41, 68:230, B*07:439, B*35:491, B*40:359, B*55:96, B*57:65, C*04:31, C*06:137, C*07:569, C*07:990, C*07:994
	125 bp		*01:86, 01:115, 01:350	B*35:491, B*40:359, B*44:289, B*55:96
13⁷	205 bp	1070 bp	*01:12, 01:19, 01:21, 01:126, 01:200, 01:244, 01:360	*02:156 ^w , 02:338 ^w , 02:952 ^w , 03:02:01:01-03:02:06, 03:07:01:01 ^w -03:07:01:02 ^w , 03:07:02, 03:10, 03:31-03:32, 03:42 ^w , 03:73, 03:76, 03:82, 03:90, 03:106, 03:113, 03:133 ^w , 03:160, 03:171 ^w , 03:198, 03:218, 03:223, 03:236-03:237, 03:242, 03:244, 03:253, 03:274-03:275N, 03:281, 03:285, 03:309, 03:314, 03:318- 03:319, 03:332-03:333, 03:348, 03:356, 03:373, 03:385, 03:442, 11:31 ^w , 11:35 ^w , 11:60, 11:158 ^w , 11:183 ^w , 11:209, 11:366, 24:92, 24:458, 24:551, 24:557, 30:04:01:01 ^w -30:04:04 ^w , 30:06 ^w , 30:09:01:01 ^w -30:09:01:02 ^w , 30:17 ^w , 30:29 ^w , 30:46 ^w , 30:77 ^w , 30:90 ^w , 30:99, 30:103 ^w , 30:105 ^w , 30:117 ^w , 30:139 ^w , 30:150 ^w , 30:155 ^w ,



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				30:183 ^w , 31:03 ^w -31:04:02 ^w , 31:176 ^w , 31:179 ^w , 33:49 ^w , 33:144 ^w , 68:103:01 ^w -68:103:02 ^w , 74:23
14⁴	75 bp 120 bp	1070 bp	*01:59 *01:13, 01:17, 01:176, 01:194, 01:302	*03:395, 11:282
15	235 bp	800 bp	*01:01:48, 01:12, 01:14, 01:19, 01:200, 01:244, 01:391	*02:156, 02:338, 02:952, 03:01:01:01-03:01:05, 03:01:07- 03:01:29, 03:01:31-03:01:48, 03:01:51-03:01:89, 03:01:91- 03:17:02, 03:19-03:39, 03:41- 03:74, 03:76-03:94, 03:96-03:97, 03:99-03:104, 03:106-03:134, 03:136-03:176, 03:178N-03:193, 03:195-03:199, 03:201-03:203, 03:205-03:207, 03:209-03:214, 03:216-03:248, 03:250-03:259, 03:261-03:287, 03:289:01-03:321, 03:323N-03:325, 03:327-03:342N, 03:344-03:346, 03:348-03:376, 03:378-03:413, 03:415-03:448N, 11:04, 11:27, 11:35, 11:130, 11:209, 24:92, 24:458, 24:551, 24:557, 30:01:01:01-30:02:08, 30:02:10-30:04:04, 30:06-30:13, 30:15-30:20, 30:22-30:27N, 30:29- 30:42, 30:44-30:46, 30:48-30:51, 30:53-30:71, 30:73N-30:79, 30:81- 30:112, 30:114-30:116, 30:118- 30:130N, 30:132N-30:164, 30:166- 30:179, 30:181-30:201, 30:203, 31:03-31:04:02, 31:176, 31:179, 32:04, 33:49, 33:144, 34:02:01:01- 34:04, 34:07-34:10N, 34:13, 34:15, 34:20-34:22, 34:24-34:26N, 34:28- 34:30N, 36:01:01:01-36:02, 36:05- 36:12, 68:103:01-68:103:02, 74:23, 80:03
16⁶	180 bp 235 bp	1070 bp	*01:01:01:02N *01:15N	
17	180 bp 210 bp 285 bp	1070 bp	*01:106 *01:16N *01:101	*03:87, 11:30, 30:92
18	140 bp	1070 bp	*01:01:01:01-01:01:96, 01:01:98-01:01:110, 01:01:112-01:04:01:02N, 01:06, 01:08-01:12, 01:14- 01:27N, 01:29-01:33, 01:35- 01:68, 01:70-01:94, 01:96- 01:133, 01:135-01:175, 01:177-01:182, 01:184- 01:193, 01:195-01:215, 01:217-01:228Q, 01:230- 01:255, 01:257-01:288,	*26:120, 36:01:01:01-36:12



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Lot-specific information

			Lot-specific information	
			01:290N-01:297, 01:300-01:302, 01:304-01:354, 01:356-01:419	
19	150 bp 170 bp	1070 bp	*01:269N *01:18N, 01:30, 01:145, 01:236	*26:145N, 34:29N *02:262, 02:547, 02:700, 02:848, 02:910, 24:22, 24:160, 24:299, 24:478, 26:149, 31:200
20⁴	65 bp	800 bp	*01:10, 01:21, 01:26, 01:192	*02:848, 03:135, 11:94, 11:112, 11:211, 11:290, B*15:90, B*45:05
21⁴	125 bp 220 bp 255 bp	1070 bp	*01:44 *01:155 *01:20, 01:66, 01:130	*02:19, 02:36-02:37, 02:54, 02:255, 02:417, 02:723, 02:848, 02:883, 02:949, 24:14:01:01-24:14:01:04, 24:93, 24:324, 69:09
22⁶	590 bp	1070 bp	*01:22N, 01:107	
23	165 bp	1070 bp	*01:24, 01:30, 01:145, 01:236	*02:262, 02:547, 02:700, 02:848, 02:910, 24:22, 24:160, 24:299, 24:478, 26:149, 31:200
24	215 bp	1070 bp	*01:12, 01:19, 01:25, 01:127, 01:136, 01:360, 01:380:01:01-01:380:01:02	*03:02:01:01-03:02:06, 03:10, 03:31-03:32, 03:65, 03:69N, 03:73, 03:76, 03:82, 03:90, 03:106, 03:113, 03:160, 03:167, 03:198, 03:218, 03:223, 03:236-03:237, 03:242, 03:244, 03:253, 03:274-03:275N, 03:281, 03:285, 03:309, 03:314, 03:318-03:319, 03:333, 03:348, 03:356, 03:385, 11:01:01:01-11:01:03, 11:01:05-11:01:56, 11:01:58-11:01:71, 11:01:73-11:07:02, 11:09-11:22, 11:27, 11:29-11:30, 11:32:01-11:34, 11:36-11:43, 11:45-11:47, 11:49, 11:51-11:52Q, 11:54:01-11:93, 11:95-11:100, 11:102-11:117, 11:119:01-11:138, 11:140-11:142, 11:144-11:157, 11:159-11:182Q, 11:184-11:190, 11:192-11:210N, 11:212-11:225, 11:227-11:241, 11:243-11:268, 11:270, 11:272Q-11:287N, 11:289, 11:291-11:298, 11:300-11:325, 11:327-11:329, 11:331-11:345, 11:347N-11:371, 11:373-11:428, 24:92, 24:458, 24:551, 24:555, 24:557, 30:99, 30:164
25⁴	80 bp 425 bp	1070 bp	*01:31N, 01:51, 01:59 *01:19, 01:173	*26:120
26⁴	90 bp	1070 bp	*01:104, 01:134, 01:229, 01:405	*02:346, 02:427, 02:952, 11:06, 11:312, 25:11, 26:03:01:01-26:03:01:02, 26:06, 26:21, 26:36, 26:78, 26:92, 26:111, 26:146, 26:177, 26:193, 33:184, 80:01:01:01 ^w



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Lot-specific information

	460 bp		*01:32	
	545 bp		*01:45	*02:453, 02:557, 02:690, 03:78, 11:108, 23:92, 23:96, 24:271, 30:201, 33:151, 36:12, 66:17
27⁴	110 bp	1070 bp	*01:87N	
	170 bp		*01:33, 01:141	*02:679, 03:193
	195 bp		*01:109	*03:182, 11:100, 11:175, 30:200
28^{4,5,6}	95 bp	1070 bp	*01:01:38L	*03:01:96, 11:01:98, 24:02:03Q, 30:02:25
	135 bp		*01:132	*30:142
	195 bp		*01:109	*03:182, 11:100, 11:175, 30:200
29⁴	110 bp	800 bp	*01:69:01-01:69:03	*02:609, 02:1022, 03:107, 03:413, 11:17, 23:09, 24:129, 25:59, 26:62, 26:72, 32:24, 33:185
	155 bp		*01:35	*03:77, 11:144
	230 bp		*01:68	
	285 bp		*01:101	*03:87, 11:30, 30:92
30	135 bp	1070 bp	*01:95, 01:289	*24:243
	180 bp		*01:07, 01:100, 01:190, 01:194, 01:289, 01:298	*03:395, 24:243, 31:35, 32:156
	220 bp		*01:155	
	280 bp		*01:142	*24:150, 31:199
31⁵	240 bp	1070 bp	*01:38, 01:63	
32⁴	110 bp	1070 bp	*01:57N	*66:39N, B*08:252N, B*40:118N, B*40:291N, C*06:152N, C*07:191N, C*07:733N
	140 bp		*01:43	*11:282, 26:120
33⁴	85 bp	1070 bp	*01:61	*26:149, B*15:90, B*45:05
34	130 bp	800 bp	*01:60, 01:71, 01:115, 01:350	*26:31, 34:24, B*35:491, B*40:359, B*44:289, B*55:96, C*06:71, C*07:581
	150 bp		*01:269N	*26:145N, 34:29N
	215 bp		*01:58	
35⁴	110 bp	800 bp	*01:47, 01:150	
	180 bp		*01:07, 01:49, 01:100, 01:190, 01:194, 01:289, 01:298	*03:395, 11:229, 24:243, 31:35, 32:156
	240 bp		*01:137	
36⁴	90 bp	1070 bp	*01:54	*03:250
	140 bp		*01:48	*03:390:02
	175 bp		*01:53N	*11:397N
	235 bp		*01:123N	
37⁴	65 bp	1070 bp	*01:65	
	115 bp		*01:71, 01:247N	
	150 bp		*01:77, 01:92	
38⁴	100 bp	1070 bp	*01:50	
	180 bp		*01:62	*02:315, 02:1027, 03:85, C*01:209
	240 bp		*01:68, 01:72	*11:236, 30:45
39⁴	125 bp	800 bp	*01:77	B*07:241, C*04:251
	170 bp		*01:39, 01:113	
40	155 bp	1070 bp	*01:36, 01:113, 01:143	*31:35



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41 ⁴	95 bp	1070 bp	*01:55, 01:81	*03:26, 03:318, 03:370, 11:77, 11:126:01:01-11:126:01:02, 11:335:01-11:335:02, 11:348, 30:151
42 ⁴	110 bp 185 bp 255 bp	1070 bp	*01:87N *01:64, 01:141 *01:142	*03:232 *24:150
43	550 bp	1070 bp	*01:45, 01:56N	*02:453, 02:557, 02:690, 02:989N, 03:78, 11:69N, 11:108, 23:92, 23:96, 24:271, 30:201, 33:151, 36:12, 66:17
	590 bp		*01:107	
44 ⁴	65 bp 245 bp	1070 bp	*01:98, 01:391 *01:46	*24:87, 24:285, B*07:64
45 ^{4,6}	65 bp	1070 bp	*01:98, 01:391	*24:87, 24:285, B*07:64
46 ⁴	85 bp	1070 bp	*01:81	*03:26, 03:318, 03:370, 11:77, 11:126:01:01-11:126:01:02, 11:335:01-11:335:02, 11:348, 30:151
	155 bp 245 bp		*01:40 *01:72, 01:147Q	*11:160 *11:236, 30:45
47 ⁶	295 bp 325 bp 450 bp 550 bp	1070 bp	*01:41 *01:42 *01:48 *01:123N	*11:48
48	180 bp	1070 bp	*01:144	
49 ⁶	215 bp	1070 bp	*01:160N	
50	200 bp 230 bp	1070 bp	*01:250N *01:162N	
51 ⁵	210 bp	1070 bp	*01:164	*24:193
52	250 bp	1070 bp	*01:178N-01:179N	
53 ⁴	110 bp 215 bp	1070 bp	*01:247N *01:186N	
54 ⁴	70 bp 155 bp	1070 bp	*01:103 *01:132	*30:142
55	150 bp 190 bp	1070 bp	*01:52:02N *01:258N	
56 ⁴	60 bp	1070 bp	*01:25, 01:127	*11:155, 24:136, 24:229, 24:367
57	190 bp 240 bp	1070 bp	*01:258N *01:208Q	
58	330 bp	1070 bp	*01:228Q	
59	180 bp 200 bp	1070 bp	*01:240N *01:250N	
60	285 bp	1070 bp	*01:37:01:01-01:37:01:02	*03:360, 11:172, 30:156, 30:170
61	235 bp	1070 bp	*01:248Q	
62	150 bp	1070 bp	*01:52:01N	
63 ⁸	-	-	Negative Control	



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Lot-specific information

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-A*01 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 10, 28, 31 and 51 have a tendency of giving rise to primer oligomer formation.

⁶Primer mixes 5, 8, 9, 16, 22, 28, 45, 47 and 49 may have tendencies of unspecific amplifications.

⁷Primer mixes 5, 12 and 13 may give rise to a lower yield of HLA-specific PCR product than the other A*01 primer mixes.

⁸Primer mix 63 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.



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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	235	145	120	305	460	125	60	110	235	120	135	90
						210	115	180		155	180	125
										240	275	
										270		
Length of int. pos. control ¹	800	1070	800	1070	1070	1070	1070	1070	800	800	800	800
5'-primer(s) ²	363 5'-ATA 3'	98 5'-CTT 3'	123 5'-AgT 3'	341 5'-ggA 3'	3 rd I 5'-ATA 3'	171 5'-TTA 3'	521 5'-ggT 3'	203 5'-gAA 3'	363 5'-ATA 3'	113 5'-CCC 3'	203 5'-gAA 3'	521 5'-ggT 3'
	363 5'-ATA 3'	98 5'-CTT 3'				171 5'-TTg 3'				413 5'-CCg 3'	363 5'-ATA 3'	
						257 5'-CCC 3'						
3'-primer(s) ³	558 5'-Cgg 3'	203 5'-TCT 3'	203 5'-TCT 3'	362 5'-TCA 3'	621 5'-ggg 3'	341 5'-CgT 3'	538 5'-CAA 3'	271 5'-CAC 3'	553 5'-CTA 3'	341 5'-CgT 3'	299 5'-CCA 3'	570 5'-CAC 3'
	559 5'-CCT 3'	203 5'-TCT 3'					595 5'-CCg 3'	341 5'-CgT 3'	559 5'-CCA 3'	490 5'-AgA 3'	500 5'-TgC 3'	595 5'-CCg 3'
										527 5'-CCC 3'	597 5'-TTA 3'	616 5'-CgC 3'
										613 5'-gCC 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	24
Length of spec. PCR product	205	75	235	180	180	140	150	65	125	590	165	215
		120		235	210		170		220			
					285				255			
Length of int. pos. control ¹	1070	1070	800	1070	1070	1070	1070	800	1070	1070	1070	1070
5'-primer(s) ²	363 5'-ATA 3'	203 5'-gAA 3'	363 5'-ATA 3'	203 5'-gAA 3'	363 5'-ATA 3'	203 5'-gAA 3'	215 5'-gCC 3'	521 5'-ggC 3'	355 5'-CCg 3'	3 rd I 5'-ATA 3'	89 5'-gAA 3'	363 5'-ATA 3'
				363 5'-ATA 3'			232 5'-AgT 3'		484 5'-ACT 3'		413 5'-CCA 3'	
							413 5'-CCA 3'		627 5'-CCC 3'			
3'-primer(s) ³	527 5'-CCA 3'	237 5'-CCg 3'	559 5'-CgT 3'	341 5'-CgT 3'	500 5'-TgC 3'	299 5'-TCg 3'	341 5'-CgT 3'	545 5'-AgA 3'	570 5'-CCg 3'	750 5'-T.g 3'	203 5'-TCT 3'	539 5'-TCT 3'
		282 5'-gAC 3'	559 5'-CgT 3'	557 5'-gC 3'	531 5'-TCC 3'	300 5'-TTT 3'	545 5'-AgA 3'		805 5'-CgT 3'	750 5'-TCg 3'	545 5'-AgA 3'	
		282 5'-gAC 3'			605 5'-gCA 3'		545 5'-AgA 3'				545 5'-AgA 3'	
Well No.	13	14	15	16	17	18	19	20	21	22	23	24



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Well No.	25	26	27	28	29	30	31	32	33	34	35	36
Length of spec.	80	90	110	95	110	135	240	110	85	130	110	90
PCR product	425	460	170	135	155	180		140		150	180	140
		545	195	195	230	220				215	240	175
					285	280						235
Length of int. pos. control ¹	1070	1070	1070	1070	800	1070	1070	1070	1070	800	800	1070
5'-primer(s) ²	203	292	98	650	203	203	360	102	502	168	203	413
	5'-gAA 3'	5'-CTC 3'	5'-CTT 3'	5'-CCC 3'	5'-gAg 3'	5'-gAA 3'	5'-CAC 3'	5'-ACC 3'	5'-CCC 3'	5'-CAT 3'	5'-gAA 3'	5'-CCg 3'
		3 rd I	650		363	627	383	385		232	413	
		5'-ATA 3'	5'-CCC 3'		5'-ATA 3'	5'-CCC 3'	5'-ggA 3'	5'-ggC 3'		5'-AgT 3'	5'-CCg 3'	
										257		
										5'-CCC 3'		
										261		
										5'-gAC 3'		
										521		
										5'-ggT 3'		
3'-primer(s) ³	237	341	218	705	271	299	570	203	545	341	265	461
	5'-CCg 3'	5'-CgT 3'	5'-gCT 3'	5'-TCT 3'	5'-CAT 3'	5'-TCT 3'	5'-CCg 3'	5'-TCT 3'	5'-AgA 3'	5'-CgT 3'	5'-CCA 3'	5'-gCC 3'
	251	622	721	742	476	341		454		616	341	510
	5'-CCT 3'	5'-ggT 3'	5'-CA 3'	5'-CTT 3'	5'-CCA 3'	5'-Cgg 3'		5'-CTA 3'		5'-CgC 3'	5'-Cgg 3'	5'-CAg 3'
	259	704	791	806	554	805					490	549
	5'-gTT 3'	5'-CCA 3'	5'-AgT 3'	5'-CCA 3'	5'-CCg 3'	5'-CgT 3'					5'-AgA 3'	5'-AgT 3'
	346		806		605	866					556	608
	5'-AgC 3'		5'-CCA 3'		5'-gCA 3'	5'-gAA 3'					5'-gCT 3'	5'-CA 3'
											613	
											5'-gCC 3'	
Well No.	25	26	27	28	29	30	31	32	33	34	35	36

Well No.	37	38	39	40	41	42	43	44	45	46	47	48
Length of spec.	65	100	125	155	95	110	550	65	65	85	295	180
PCR product	115	180	170			185	590	245		155	325	
	150	240				255				245	450	
											550	
Length of int. pos. control ¹	1070	1070	800	1070	1070	1070	1070	1070	1070	1070	1070	1070
5'-primer(s) ²	230	102	82	82	349	102	3 rd I	364	545	363	341	203
	5'-Agg 3'	5'-ACA 3'	5'-ACC 3'	5'-ACC 3'	5'-CTg 3'	5'-ACA 3'	5'-ATA 3'	5'-TAg 3'	5'-AgC 3'	5'-ATA 3'	5'-ggA 3'	5'-gAA 3'
	261	363	404	97	831	650		545		831		
	5'-gAC 3'	5'-ATA 3'	5'-CCA 3'	5'-TCA 3'	5'-gAg 3'	5'-CCC 3'		5'-AgC 3'		5'-gAg 3'		
	270		454	428								
	5'-AAT 3'		5'-ACA 3'	5'-Cgg 3'								
	454											
	5'-ACA 3'											
	548											
	5'-CTg 3'											
3'-primer(s) ³	341	241	203	203	413	250	704	570	570	479	353	343
	5'-CgT 3'	5'-CgA 3'	5'-TCT 3'	5'-TCT 3'	5'-gCC 3'	5'-CCg 3'	5'-CCA 3'	5'-CCg 3'	5'-CCg 3'	5'-CCA 3'	5'-TgA 3'	5'-T 3'
	570	420	538	545	874	721	723			564	382	
	5'-CCg 3'	5'-gCT 3'	5'-CCg 3'	5'-AgA 3'	5'-CTC 3'	5'-CA 3'	5'-TgT 3'			5'-ACC 3'	5'-CCA 3'	
		554				791	750			570	510	
		5'-CCg 3'				5'-AgT 3'	5'-TCg 3'			5'-CAg 3'	5'-CAg 3'	
		570				866				874	608	
		5'-CAg 3'				5'-gAA 3'				5'-CTC 3'	5'-CA 3'	
Well No.	37	38	39	40	41	42	43	44	45	46	47	48



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Well No.	49	50	51	52	53	54	55	56	57	58	59	60
Length of spec. PCR product	215	200	210	250	110	70	150	60	190	330	180	285
		230			215	155	190		240		200	
Length of int. pos. control ¹	1070	1070	1070	1070	1070	1070	1070	1070	1070	1070	1070	1070
5'-primer(s) ²	363	98	401	363	166	627	363	521	363	341	98	755
	5'-ATA 3'	5'-CTT 3'	5'-CCC 3'	5'-ATA 3'	5'-CgT 3'	5'-CCC 3'	5'-ATA 3'	5'-ggT 3'	5'-ATA 3'	5'-ggA 3'	5'-CTT 3'	5'-CAT 3'
					270							
					5'-AAT 3'							
3'-primer(s) ³	535	258	570	564	341	658	471	539	513	387	235	899
	5'-CTA 3'	5'-TCC 3'	5'-CCg 3'	5'-ACT 3'	5'-CgT 3'	5'-gTg 3'	5'-gTT 3'	5'-TCT 3'	5'-TCT 3'	5'-...g 3'	5'-CTA 3'	5'-ACA 3'
		286		580		742	513		563		258	
		5'-CTA 3'		5'-TCA 3'		5'-CTT 3'	5'-TCT 3'		5'-CgT 3'		5'-TCC 3'	
Well No.	49	50	51	52	53	54	55	56	57	58	59	60

Well No.	61	62
Length of spec. PCR product	235	150
Length of int. pos. control ¹	1070	1070
5'-primer(s) ²	1036	363
	5'-ACA 3'	5'-ATA 3'
3'-primer(s) ³	1087	470
	5'-...C 3'	5'-TCT 3'
Well No.	61	62

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: September 2022, Rev. No: 00

101.411-24/06 – including *Taq* polymerase
 101.411-24u/06u – without *Taq* polymerase

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 “Instructions for Use” (IFU)

Lot No.: **3R6**

Lot-specific information

CELL LINE VALIDATION SHEET																			
HLA-A*01 SSP subtyping kit ²																			
			Prod. No.:	Well															
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
				202013101	202013102	202013103	202013104	202013105	202013106	202013107	202013108	202013109	202013110	202013111	202013112	202013113	202013114	202013115	202013116
	IHWC cell line ¹	A*																	
1	9001 SA	*24:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2	9280 LK707	*02:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3	9011 E4181324	*01:01		+	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4	9275 GU373	*30:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-
5	9009 KAS011	*01:01		+	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
6	9353 SM	*02:01	*26:03	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
7	9020 QBL	*26:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
8	9025 DEU	*31:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
9	9026 YAR	*26:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
10	9107 LKT3	*24:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
11	9051 PITOUT	*29:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
12	9052 DBB	*02:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
13	9004 JESTHOM	*02:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
14	9071 OLGA	*31:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
15	9075 DKB	*24:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
16	9037 SWEIG007	*29:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
17	9282 CTM3953540	*03:01	*80:01	-	-	-	-	-	-	-	-	-	W	-	-	-	-	+	-
18	9257 32367	*33:03	*74:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
19	9038 BM16	*02:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
20	9059 SLE005	*02:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
21	9064 AMALA	*02:17		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
22	9056 KOSE	*02:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
23	9124 IHL	*02:01	*34:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
24	9035 JBUSH	*32:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
25	9049 IBW9	*33:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
26	9285 WT49	*02:05		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
27	9191 CH1007	*24:10	*29:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
28	9320 BEL5GB	*02:01	*29:02	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
29	9050 MOU	*29:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
30	9021 RSH	*30:01	*68:02	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-
31	9019 DUCAF	*30:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-
32	9297 HAG	*02:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
33	9098 MT14B	*31:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
34	9104 DHIF	*31:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
35	9302 SSTO	*32:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
36	9024 KT17	*02:06	*11:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
37	9065 HHKB	*03:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-
38	9099 LZL	*02:17		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
39	9315 CML	*01:01	*03:01	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-	+
40	9134 WHONP199	*02:07	*30:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+
41	9055 H0301	*03:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-
42	9066 TAB089	*02:07		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
43	9076 T7526	*02:06	*02:07	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
44	9057 TEM	*66:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
45	9239 SHJO	*23:01	*24:02	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
46	9013 SCHU	*03:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-
47	9045 TUBO	*02:16	*03:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-
48	9303 TER-ND	*02:01	*11:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-



0197

101.411-24/06 – including *Taq* polymerase
101.411-24u/06u – without *Taq* polymerase

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Lot No.: **3R6**

Lot-specific information

CELL LINE VALIDATION SHEET				Well																
HLA-A*01 SSP subtyping kit ²																				
				Prod. No.:																
				202013117	202013118	202013119	202013120	202013121	202013122	202013123	202013124	202013125	202013126	202013127	202013128	202013129	202013130	202013131	202013132	
	IHC cell line ¹	A*																		
1	9001 SA	*24:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2	9280 LK707	*02:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3	9011 E4181324	*01:01		-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4	9275 GU373	*30:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
5	9009 KAS011	*01:01		-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
6	9353 SM	*02:01	*26:03	-	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-
7	9020 QBL	*26:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
8	9025 DEU	*31:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
9	9026 YAR	*26:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
10	9107 LKT3	*24:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
11	9051 PITOUT	*29:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
12	9052 DBB	*02:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
13	9004 JESTHOM	*02:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
14	9071 OLGA	*31:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
15	9075 DKB	*24:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
16	9037 SWEIG007	*29:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
17	9282 CTM3953540	*03:01	*80:01	-	-	-	-	-	-	-	-	-	-	W	-	-	-	-	-	-
18	9257 32367	*33:03	*74:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
19	9038 BM16	*02:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
20	9059 SLE005	*02:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
21	9064 AMALA	*02:17		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
22	9056 KOSE	*02:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
23	9124 IHL	*02:01	*34:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
24	9035 JBUSH	*32:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
25	9049 IBW9	*33:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
26	9285 WT49	*02:05		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
27	9191 CH1007	*24:10	*29:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
28	9320 BEL5GB	*02:01	*29:02	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
29	9050 MOU	*29:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
30	9021 RSH	*30:01	*68:02	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
31	9019 DUCAF	*30:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
32	9297 HAG	*02:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
33	9098 MT14B	*31:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
34	9104 DHIF	*31:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
35	9302 SSTO	*32:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
36	9024 KT17	*02:06	*11:01	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-
37	9065 HHKB	*03:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
38	9099 LZL	*02:17		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
39	9315 CML	*01:01	*03:01	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
40	9134 WHONP199	*02:07	*30:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
41	9055 H0301	*03:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
42	9066 TAB089	*02:07		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
43	9076 T7526	*02:06	*02:07	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
44	9057 TEM	*66:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
45	9239 SHJO	*23:01	*24:02	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
46	9013 SCHU	*03:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
47	9045 TUBO	*02:16	*03:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
48	9303 TER-ND	*02:01	*11:01	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-



101.411-24/06 – including *Taq* polymerase
 101.411-24u/06u – without *Taq* polymerase

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Lot No.: **3R6**

Lot-specific information

CELL LINE VALIDATION SHEET																				
HLA-A*01 SSP subtyping kit²																				
			Well																	
			Prod. No.:	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	
				202013133	202013134	202013135	202013136	202013137	202013138	202013139	202013140	202013141	202013142	202013143	202013144	202013145	202013146	202013147	202013148	
IHC cell line¹			A*																	
1	9001	SA	*24:02	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2	9280	LK707	*02:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3	9011	E4181324	*01:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4	9275	GU373	*30:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
5	9009	KAS011	*01:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
6	9353	SM	*02:01	*26:03	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
7	9020	QBL	*26:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
8	9025	DEU	*31:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
9	9026	YAR	*26:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
10	9107	LKT3	*24:02	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
11	9051	PITOUT	*29:02	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
12	9052	DBB	*02:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
13	9004	JESTHOM	*02:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
14	9071	OLGA	*31:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
15	9075	DKB	*24:02	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
16	9037	SWEIG007	*29:02	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
17	9282	CTM3953540	*03:01	*80:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
18	9257	32367	*33:03	*74:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
19	9038	BM16	*02:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
20	9059	SLE005	*02:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
21	9064	AMALA	*02:17	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
22	9056	KOSE	*02:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
23	9124	IHL	*02:01	*34:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
24	9035	JBUSH	*32:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
25	9049	IBW9	*33:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
26	9285	WT49	*02:05	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
27	9191	CH1007	*24:10	*29:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
28	9320	BEL5GB	*02:01	*29:02	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
29	9050	MOU	*29:02	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
30	9021	RSH	*30:01	*68:02	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
31	9019	DUCAF	*30:02	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
32	9297	HAG	*02:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
33	9098	MT14B	*31:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
34	9104	DHIF	*31:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
35	9302	SSTO	*32:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
36	9024	KT17	*02:06	*11:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
37	9065	HHKB	*03:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
38	9099	LZL	*02:17	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
39	9315	CML	*01:01	*03:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
40	9134	WHONP199	*02:07	*30:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
41	9055	H0301	*03:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
42	9066	TAB089	*02:07	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
43	9076	T7526	*02:06	*02:07	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
44	9057	TEM	*66:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
45	9239	SHJO	*23:01	*24:02	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
46	9013	SCHU	*03:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
47	9045	TUBO	*02:16	*03:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
48	9303	TER-ND	*02:01	*11:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-



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101.411-24/06 – including *Taq* polymerase
101.411-24u/06u – without *Taq* polymerase

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Lot No.: **3R6**

Lot-specific information

CELL LINE VALIDATION SHEET																		
HLA-A*01 SSP subtyping kit ²																		
				Well														
				49	50	51	52	53	54	55	56	57	58	59	60	61	62	
				Prod. No.:	202013149	202013150	202013151	202013152	202013153	202013154	202013155	202013156	202013157	202013158	202013159	202013160	202013161	202013162
IHC cell line ¹			A*															
1	9001	SA	*24:02	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
2	9280	LK707	*02:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
3	9011	E4181324	*01:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
4	9275	GU373	*30:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
5	9009	KAS011	*01:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
6	9353	SM	*02:01	*26:03	-	-	-	-	-	-	-	-	-	-	-	-	-	
7	9020	QBL	*26:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
8	9025	DEU	*31:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
9	9026	YAR	*26:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
10	9107	LKT3	*24:02	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
11	9051	PITOUT	*29:02	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
12	9052	DBB	*02:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
13	9004	JESTHOM	*02:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
14	9071	OLGA	*31:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
15	9075	DKB	*24:02	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
16	9037	SWEIG007	*29:02	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
17	9282	CTM3953540	*03:01	*80:01	-	-	-	-	-	-	-	-	-	-	-	-	-	
18	9257	32367	*33:03	*74:01	-	-	-	-	-	-	-	-	-	-	-	-	-	
19	9038	BM16	*02:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
20	9059	SLE005	*02:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
21	9064	AMALA	*02:17	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
22	9056	KOSE	*02:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
23	9124	IHL	*02:01	*34:01	-	-	-	-	-	-	-	-	-	-	-	-	-	
24	9035	JBUSH	*32:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
25	9049	IBW9	*33:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
26	9285	WT49	*02:05	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
27	9191	CH1007	*24:10	*29:01	-	-	-	-	-	-	-	-	-	-	-	-	-	
28	9320	BEL5GB	*02:01	*29:02	-	-	-	-	-	-	-	-	-	-	-	-	-	
29	9050	MOU	*29:02	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
30	9021	RSH	*30:01	*68:02	-	-	-	-	-	-	-	-	-	-	-	-	-	
31	9019	DUCAF	*30:02	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
32	9297	HAG	*02:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
33	9098	MT14B	*31:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
34	9104	DHIF	*31:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
35	9302	SSTO	*32:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
36	9024	KT17	*02:06	*11:01	-	-	-	-	-	-	-	-	-	-	-	-	-	
37	9065	HHKB	*03:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
38	9099	LZL	*02:17	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
39	9315	CML	*01:01	*03:01	-	-	-	-	-	-	-	-	-	-	-	-	-	
40	9134	WHONP199	*02:07	*30:01	-	-	-	-	-	-	-	-	-	-	-	-	-	
41	9055	H0301	*03:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
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Lot No.: 3R6

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 6 to 11, 14, 16, 19 to 23, 25, 27 to 59 and 61 to 62 were available. The specificities of primers in primer solutions 7, 8, 10, 11, 14, 19 to 21, 23, 25, 27 to 30, 32 to 35, 38, 40, 41, 44 to 46, 48 and 56 were tested by separately adding additional 5'-primers, respectively additional 3'-primers. In primer solutions 6, 31, 37, 39, 51 and 53 it was only possible to test the 3'-primer, the 5'-primers were not possible to test. In primer solutions 9, 16, 22, 36, 42, 43, 47, 49, 50, 52, 54, 55, 57 to 59 and 61 to 62 it was only possible to test the 5'-primers, the 3'-primers were not possible to test. In primer solutions 1, 7, 8, 10 to 12, 14, 17, 18, 21, 25 to 30, 32, 34, 35, 38 and 46 one or more of the 3'-primers were not possible to test, and in primer solutions 2, 10, 19, 21, 34, 40, 41 and 44 one, two or three of the 5'-primers were not possible to test. In addition, the primers in primer solutions 15 and 26 were tested by separately adding one 5'-primer or one 3'-primer.



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For *In Vitro* Diagnostic Use

MA123 v02 SSP PI Template

Date: September 2022, Rev. No: 00

101.411-24/06 – including *Taq* polymerase
101.411-24u/06u – without *Taq* polymerase

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

Lot No.: **3R6**

Lot-specific information

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Fax: +46-8-717 88 18

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Web page: www.caredx.com

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MA123 v02 SSP PI Template

Date: September 2022, Rev. No: 00