

101.501-48/12 – including *Taq* polymerase, IFU-01 Visit <https://labproducts.caredx.com> for
101.501-48u/12u – without *Taq* polymerase, IFU-02 “Instructions for Use” (IFU)

Lot No.: **1N1**

Lot-specific information

Olerup SSP® HLA-B low resolution

Product number: 101.501-48/12 – including *Taq* pol.
101.501-48u/12u – without *Taq* pol.
Lot number: 1N1
Expiry date: 2025-04-01
Number of tests: 48 tests – Product No. 101.501-48/48u
12 tests – Product No. 101.501-12/12u
Number of wells per test: 63 + 1
Storage - pre-aliquoted primers: dark at -20°C
- PCR Master Mix: -20°C
- Adhesive PCR seals RT
- Product Insert RT

This Product Description is only valid for Lot No. 1N1.

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 LOW RESOLUTION LOT (6L0)**

The HLA-B low resolution primer set, specificity and interpretation tables have been updated for the HLA-B alleles reported since the previous *Olerup SSP®* HLA-B low resolution lot was made (**Lot No. 6L0**). The kit design is based on IMGT/HLA database 3.43.0.

The primers of the wells detailed below have been exchanged, added or modified compared to the previous lot.

Well	5'-primer	3'-primer	rationale
5	-	Optimized	3'-primer optimized for improved yield.
21	Added	-	5'-primers added for the B*39:01:19 and B*39:25N alleles.
24	Modified	-	Modified 5'-primer for improving HLA-specific amplification.
37	Added	-	5'-primer added for the B*40:430 allele.
48	-	-	Exchanged positive control primer pair.



0197

For *In Vitro* Diagnostic Use
MA123 v01 SSP PI Template
Date: May 2021, Rev. No: 00

101.501-48/12 – including *Taq* polymerase, IFU-01
101.501-48u/12u – without *Taq* polymerase, IFU-02

Visit <https://labproducts.caredx.com> for
“Instructions for Use” (IFU)

Lot No.: **1N1**

Lot-specific information

Well **64** 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.



0197

For *In Vitro* Diagnostic Use
MA123 v01 SSP PI Template
Date: May 2021, Rev. No: 00

101.501-48/12 – including *Taq* polymerase, IFU-01
101.501-48u/12u – without *Taq* polymerase, IFU-02

Visit <https://labproducts.caredx.com> for
“Instructions for Use” (IFU)

Lot No.: **1N1**

Lot-specific information
PRODUCT DESCRIPTION

HLA-B low resolution SSP typing

CONTENT

The primer set contains 5'- and 3'-primers for grouping the B*07:02 to B*83:01 alleles into the corresponding serological groups B7 to B81 as well as primer pairs for recognizing the Bw4 and Bw6 sequence motifs.

PLATE LAYOUT

Each test consists of 64 PCR reactions in a 64 well cut PCR plate.

1	2	3	4	5	6	7	8
9	10	11	12	13	14	15	16
17	18	19	20	21	22	23	24
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	63	NC

The 64 well cut PCR plate is marked with ‘HLA-B low’ in silver/gray ink.

Well No. 1 is marked with the Lot No. ‘1N1’.

Wells 1 to 63 – HLA-B low resolution primers.

Well 64 – Negative Control.

A faint row of numbers is seen between wells 1 and 2 or wells 7 and 8 of the PCR trays. These stem from the manufacture of the trays, and should be disregarded. The PCR plates are covered with a PCR-compatible foil.

INTERPRETATION

Only HLA-B alleles will be amplified by the HLA-B low resolution typing kit, except that a few HLA-A and HLA-C alleles will be amplified by some primer mixes. For further details see Specificity Table.

UNIQUELY IDENTIFIED ALLELES

All the HLA-B alleles recognized by the HLA Nomenclature Committee in January 2021^{1,2} will be amplified by the primers in the HLA-B low resolution SSP kit. Most HLA-B alleles will also be grouped into their corresponding serological specificities^{3,4}.



0197

For *In Vitro* Diagnostic Use
MA123 v01 SSP PI Template
Date: May 2021, Rev. No: 00

101.501-48/12 – including *Taq* polymerase, IFU-01
101.501-48u/12u – without *Taq* polymerase, IFU-02

Visit <https://labproducts.caredx.com> for
“Instructions for Use” (IFU)

Lot No.: **1N1**

Lot-specific information

Notes on Bw assignment

The Bw4 and Bw6 status of HLA-B alleles is based their serological type:

	Serological Type
Bw4	B5, B5102, B5103, B13, B17, B27, B37, B38(16), B44(12), B47, B49(21), B51(5), B52(5), B53, B57(17), B58(17), B59, B63(15), B77(15)
Bw6	B7, B703, B8, B14, B18, B22, B2708, B35, B39(16), B3901, B3902, B40, B4005, B41, B42, B45(12), B46, B48, B50(21), B54(22), B55(22), B56(22), B60(40), B61(40), B62(15), B64(14), B65(14), B67, B70, B71(70), B72(70), B73, B75(15), B76(15), B78, B81, B82

However, according to the HLA Dictionary⁵ there are several exceptions to these associations. This product contains reactions specific to the sequences that code for the Bw4 and Bw6 epitopes. A small number of alleles classified as Bw4 or Bw6 in the HLA Dictionary are not amplified neither by the Bw4 nor the Bw6 primer mix:

Bw Reactivity	Allele
Bw6	B*15:377Q, B*35:01:39, B*35:02:09, B*39:01:15

¹HLA-B alleles listed on the IMGT/HLA web page 2021-January-18, release 3.43.0, 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>.

³It is not possible to identify all serological splits and combinations of the B15 group of alleles, as the serological reactivity of several of the B*15 alleles is not known.

The resolution has been updated to fulfill the NMDP medium resolution confirmatory typing requirements effective from February 1st 2001.

DNA-based HLA-B typing resolution required:

B*07:xx, B*08:xx, B*13:xx, B*14:xx, B*18:xx, B*27:xx, B*15:22, B*35:xx, B*37:xx, B*38:xx, B*39:xx, B*40:05, B*41:xx, B*42:xx, B*44:xx, B*45:xx, B*46:xx, B*47:xx, B*48:xx, B*49:xx, B*50:xx, B*51:xx, B*52:xx, B*53:xx, B*54:xx, B*55:xx, B*56:xx, B*57:xx, B*58:xx, B*59:xx, B*67:xx, B*73:xx, B*78:xx, B*81:xx, B*82:xx,

B*40EJD^a 40:01, 40:07, 40:10, 40:12, 40:14, 40:15, 40:16

B*40EJB^b 40:02, 40:03, 40:04, 40:06, 40:08, 40:09, 40:11, 40:13, 40:18, 40:19, 40:20

B*15EJA^c 15:01, 15:04, 15:05, 15:06, 15:07, 15:20, 15:24, 15:25, 15:26N, 15:27, 15:28, 15:30, 15:32, 15:33, 15:34, 15:35, 15:36, 15:38, 15:39, 15:40, 15:43, 15:45

B*15AHM^d 15:16, 15:17

B*15EHZ^e 15:03, 15:09, 15:10, 15:18, 15:23, 15:29, 15:37, 15:47

B*15CYP^f 15:02, 15:08, 15:11, 15:15, 15:21, 15:31, 15:44

B*15AND^g 15:12, 15:14, 15:19

B*1513^h



0197

For *In Vitro* Diagnostic Use
MA123 v01 SSP PI Template
Date: May 2021, Rev. No: 00

101.501-48/12 – including *Taq* polymerase, IFU-01
101.501-48u/12u – without *Taq* polymerase, IFU-02

Visit <https://labproducts.caredx.com> for
“Instructions for Use” (IFU)

Lot No.: **1N1**

Lot-specific information

- ^aB60 serologic equivalent cluster.
- ^bB61 serologic equivalent cluster.
- ^cB62 serologic equivalent cluster.
- ^dB63 serologic equivalent cluster.
- ^eB70 serologic equivalent cluster.
- ^fB75 serologic equivalent cluster.
- ^gB76 serologic equivalent cluster.
- ^hB77 serologic equivalent cluster.

⁴The following alleles give rise to identical amplification patterns with the HLA-B low resolution primer set. These alleles can be separated by the respective high resolution primer sets.

Alleles	Alleles
B*08:26:01-08:26:02, 08:50, 08:62, 08:85, 08:94, 08:242, 08:263, 08:265, B*42:26	B*57:67:01, B*58:36
B*38:156, B*39:136	B*57:128, B*58:100
B*38:159, B*39:01:19, 39:25N, 39:30, 39:33, 39:47, 39:50, 39:74, 39:82, 39:102, 39:107, 39:112, 39:128	

⁵Holdsworth, R Hurley, C K Marsh, S G E Lau, M Noreen, H J Kempenich, J H Setterholm, M Maiers, M: 'The HLA dictionary 2008 : a summary of HLA-A , -B , -C , -DRB1 / 3 / 4 / 5 , and -DQB1 alleles and their association with serologically defined HLA-A, -B, -C, -DR and -DQ antigens', Tissue Antigens, 2009, 73(2), pp. 95-170.



0197

For *In Vitro* Diagnostic Use
MA123 v01 SSP PI Template
Date: May 2021, Rev. No: 00

101.501-48/12 – including *Taq* polymerase, IFU-01
101.501-48u/12u – without *Taq* polymerase, IFU-02

Visit <https://labproducts.caredx.com> for
“Instructions for Use” (IFU)

Lot No.: **1N1**

Lot-specific information
SPECIFICITY TABLE

HLA-B low resolution SSP typing

Specificities and sizes of the PCR products of the 63+1 primer mixes used for
HLA-B low resolution SSP typing

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	HLA-B serol. ³	Amplified HLA-B alleles ⁴
1^{5,8}	110 bp	800 bp	7, 703, 40, 41, 42, 48, 61	*07:02:01:01-07:18:02, 07:20-07:32, 07:34-07:39, 07:41-07:47, 07:49N-07:52, 07:54-07:59, 07:61-07:99, 07:101-07:121, 07:123-07:138, 07:140-07:163, 07:166-07:208, 07:210-07:222, 07:224-07:225, 07:227-07:234, 07:236-07:300, 07:302-07:342, 07:344-07:345, 07:347-07:358, 07:360Q-07:362, 07:364-07:385, 07:387, 07:389-07:406, 07:408-07:410, 07:412-07:415N, 08:79, 08:156, 08:187, 15:138, 15:230, 15:241, 15:297, 35:66, 37:07, 40:15-40:16:01:02, 40:23, 40:32, 40:98, 40:128, 40:136, 40:158, 40:183, 40:198, 40:231, 40:279, 40:355, 40:466, 41:08, 42:05:01-42:05:02, 44:150, 46:87, 48:05, 48:08, 48:15, C*02:23, C*03:260, C*04:77
2	215 bp	1070 bp	8, 44	*08:01:01:01-08:05, 08:07-08:25, 08:27-08:49, 08:51-08:61, 08:63-08:64, 08:66-08:84, 08:86N-08:93, 08:95-08:122, 08:124-08:131, 08:133-08:225, 08:227, 08:229-08:238, 08:240-08:241, 08:243-08:262, 08:264, 08:266, 13:93, 15:142, 15:180, 15:429, 35:218, 35:256, 37:62, 40:328, 44:49, 44:156, 49:25, 51:68, 51:176, 52:77, C*06:147
3	140 bp, 235 bp	1070 bp	7, 8, 13, 15, 35, 4005, 44, 49, 61, 62, 77	*07:20, 07:24, 07:60, 07:100, 07:131, 07:220, 07:223, 07:358, 08:21, 08:25, 08:175, 13:01:01:01-13:04, 13:06-13:08, 13:10-13:23, 13:25-13:38, 13:40-13:57, 13:59-13:66, 13:68-13:96, 13:99-13:151, 15:07:01:01-15:07:03, 15:36 ^w , 15:45, 15:55, 15:68, 15:89:01 ^w , 15:126, 15:197:02, 15:207, 15:324, 15:329, 15:331, 15:360, 15:383, 15:405, 15:431, 15:450, 15:524, 35:05:01:01-35:05:05, 35:16-35:17:04, 35:22:01:01-35:22:01:02, 35:30:01:01-35:30:01:02, 35:51:01-35:51:02, 35:58, 35:72, 35:89, 35:97, 35:113-35:114, 35:125, 35:164, 35:199, 35:232, 35:242, 35:318, 35:346, 35:368, 35:389, 35:416, 35:427N, 35:440, 35:459N, 35:472, 35:481, 35:498-35:499, 40:05:01:01-40:05:01:03, 40:71, 40:174, 41:62, 44:08 ^w , 44:54, 44:57 ^w , 44:60, 44:106, 44:110, 44:135, 44:158, 44:184, 44:211, 44:213, 46:12, 51:64, 51:148, 53:14, 55:51, 58:18, C*03:05, C*03:25, C*03:27, C*03:143, C*03:167, C*03:296:01-03:296:02, C*03:335, C*03:346, C*03:407, C*03:482, C*03:494
4^{5,6,7,9}	105 bp, 140 bp, 260 bp	800 bp	12, 13, 14, 15, 17, 18, 21, 27, 35, 39, 40, 41, 44, 45, 47, 48, 49, 50, 57, 58, 60, 61, 62, 64, 65	*07:68:01-07:68:03, 07:100, 07:218, 07:220, 07:237, 07:262, 08:71, 08:118, 13:01:01:01-13:01:09, 13:01:11-13:04, 13:06-13:13:02, 13:15-13:23, 13:25-13:57, 13:59-13:82, 13:84-13:92, 13:94-13:96, 13:99-13:101, 13:102 ^w , 13:103N-13:105, 13:107-13:151, 14:01:01:01-14:02:08, 14:02:10-14:05, 14:07N, 14:09, 14:11-14:19, 14:21-14:36, 14:38-14:54, 14:57-14:95, 14:97-14:99, 15:07:01:01-15:07:03, 15:45-15:46, 15:53, 15:55, 15:68, 15:106, 15:126, 15:197:02, 15:207, 15:212, 15:324, 15:329, 15:331, 15:336, 15:347, 15:360, 15:383, 15:399, 15:405, 15:431, 15:450, 15:510, 15:559, 18:14, 18:44:01-18:44:02, 18:107, 27:32, 27:106, 27:138, 27:180,



0197

For *In Vitro* Diagnostic Use
MA123 v01 SSP PI Template
Date: May 2021, Rev. No: 00

101.501-48/12 – including *Taq* polymerase, IFU-01
101.501-48u/12u – without *Taq* polymerase, IFU-02

Visit <https://labproducts.caredx.com> for
“Instructions for Use” (IFU)

Lot No.: **1N1**

Lot-specific information

				27:224, 35:05:01:01-35:05:05, 35:22:01:01-35:22:01:02, 35:46-35:47, 35:51:01-35:51:02, 35:58, 35:63, 35:66, 35:72, 35:89, 35:97, 35:137, 35:147, 35:154, 35:182, 35:199, 35:207, 35:217, 35:232, 35:278, 35:317, 35:368, 35:389, 35:416, 35:427N, 35:440, 35:450, 35:459N, 35:472, 35:475, 35:481, 35:498-35:499, 38:19, 39:03:01:01-39:03:01:03, 39:14:01:01-39:14:01:03, 39:24:01-39:24:02, 39:29, 39:37:01:01-39:37:01:02, 39:76, 39:79, 39:120, 39:144, 39:152, 40:01:01-40:01:39, 40:01:41-40:01:70, 40:07, 40:10:01:01-40:10:02, 40:14:01-40:16:01:02, 40:22N-40:23, 40:25, 40:30-40:36, 40:38, 40:42-40:43, 40:45-40:49, 40:51-40:55, 40:58-40:63, 40:65-40:67, 40:69, 40:71-40:73, 40:76-40:77, 40:79-40:81, 40:84, 40:87:01-40:88, 40:92, 40:100-40:102, 40:106, 40:108, 40:110, 40:112-40:114:02, 40:116-40:118N, 40:121, 40:123-40:126, 40:128-40:130:02, 40:132, 40:134-40:136, 40:139-40:141, 40:146-40:147, 40:150-40:156, 40:158, 40:160:01-40:160:02, 40:163-40:164, 40:166, 40:168, 40:170-40:172, 40:174-40:175, 40:178-40:179, 40:182-40:183, 40:186:01-40:188, 40:191-40:199, 40:204, 40:207-40:208, 40:212-40:213, 40:215-40:219, 40:221-40:223, 40:227-40:228, 40:231, 40:233-40:242, 40:245:01-40:245:02, 40:247, 40:249-40:250, 40:252-40:253, 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, 40:312, 40:315-40:316, 40:319, 40:321, 40:323:01-40:327, 40:329, 40:332-40:333, 40:336, 40:338N-40:339, 40:342, 40:344, 40:346, 40:352-40:353:02, 40:355, 40:357-40:358, 40:360, 40:367-40:368, 40:370, 40:372N, 40:377, 40:379-40:383, 40:385-40:386, 40:391-40:392, 40:394-40:398, 40:400-40:404, 40:406-40:407, 40:416-40:422, 40:424, 40:426N, 40:428N, 40:431, 40:433, 40:436, 40:439, 40:443, 40:446-40:450, 40:452, 40:456, 40:461-40:463, 40:466, 40:469-40:470, 40:474-40:475, 41:01:01:01-41:58, 41:60-41:68, 42:10, 42:17, 44:02:01:01-44:02:31, 44:02:33-44:02:39, 44:02:41-44:02:56, 44:02:58-44:02:60, 44:02:61 ^w , 44:02:62-44:03:06, 44:03:08-44:03:18, 44:03:21-44:03:30, 44:03:32-44:05:04, 44:07-44:48, 44:50:01-44:82, 44:84:01-44:102, 44:104-44:129, 44:132-44:155, 44:157-44:193, 44:195N-44:211, 44:213-44:223, 44:226-44:230, 44:231 ^w , 44:232-44:245, 44:247-44:321, 44:322 ^w , 44:323-44:346, 44:437-44:444, 44:446-44:504, 45:01:01:01-45:25, 45:27, 46:12, 46:84, 47:01:01:02-47:10, 48:12, 48:14, 48:29, 49:01:01:01-49:02, 49:04:01-49:14, 49:16-49:24, 49:26-49:30, 49:32-49:67, 49:69-49:70, 50:01:01:01-50:02:01:02, 50:04-50:20, 50:31-50:33, 50:35-50:42, 50:44-50:70, 50:72N-50:74, 51:64, 51:203, 51:276, 53:14, 53:30, 54:38, 55:110, 56:67, 57:11, 57:45, 57:51, 57:69, 57:71, 57:88, 58:02:01:01-58:02:02, 58:06-58:07, 58:18, 58:25, 58:38, 58:43, 58:60, 58:104, 58:111, C*01:30, C*01:32:01-01:32:02, C*06:20, C*06:207, C*12:87, C*14:76, C*14:82, C*16:85, C*16:98, C*16:102, C*16:110
5'	185 bp, 235 bp	800 bp	7, 16, 17, 27, 2708, 37, 38, 39, 3901, 3902, 64, 67	*07:02:32, 07:85:02, 07:197, 14:01:01:01-14:01:05, 14:01:07-14:01:11, 14:07N-14:08:02, 14:10, 14:12, 14:14, 14:19, 14:26, 14:32, 14:40, 14:46-14:47, 14:49, 14:53-14:55, 14:65, 14:71, 14:77-14:78N, 14:80-14:83, 14:86-14:87, 14:95, 14:97, 18:01:37, 18:165, 27:01-27:05:15, 27:05:17-27:05:19, 27:05:21-27:05:37, 27:05:39-27:06:01:02, 27:07:04, 27:08-27:10, 27:12:01:01-27:13:02, 27:16-27:18, 27:20, 27:23, 27:26-27:27, 27:29, 27:31, 27:35-27:37, 27:39-27:42, 27:44-27:46, 27:48-27:61, 27:64N-27:69, 27:72-27:75,



0197

For *In Vitro* Diagnostic Use
MA123 v01 SSP PI Template
Date: May 2021, Rev. No: 00

101.501-48/12 – including *Taq* polymerase, IFU-01
101.501-48u/12u – without *Taq* polymerase, IFU-02

Visit <https://labproducts.caredx.com> for
“Instructions for Use” (IFU)

Lot No.: **1N1**

Lot-specific information

				27:77-27:80, 27:82-27:124, 27:126, 27:128-27:129, 27:131-27:137, 27:140-27:149, 27:151-27:152, 27:154-27:163, 27:165-27:179, 27:181-27:186, 27:188-27:212N, 27:214, 27:216-27:217, 27:220-27:232, 27:234-27:238, 37:02, 38:01:01:01-38:01:07, 38:01:09-38:02:02:02, 38:02:04-38:03, 38:07-38:24, 38:26-38:32, 38:34N-38:83N, 38:84 ^w , 38:85-38:86, 38:156-38:171, 39:01:01:01-39:01:01:17, 39:01:03:01-39:01:08, 39:01:10-39:01:25, 39:01:27-39:01:29, 39:01:31-39:02:01:02, 39:03:01:01-39:03:01:03, 39:05:01:01-39:06:02:07, 39:06:04-39:09:05, 39:11, 39:14:01:01-39:15, 39:18, 39:19:02, 39:22, 39:24:01-39:39:01, 39:40:01N-39:44, 39:46-39:48, 39:50-39:62, 39:64-39:71, 39:73-39:75, 39:77, 39:79-39:82, 39:83:02, 39:84-39:88, 39:90-39:91, 39:93-39:95N, 39:97N-39:98, 39:100, 39:102-39:104, 39:106-39:109, 39:111-39:125, 39:127-39:128, 39:130, 39:132, 39:134-39:142N, 39:144, 39:146N-39:161N, 39:163, 39:165-39:169, 40:225:02, 40:429, 40:469, 47:04-47:05, 48:21, 48:26, 67:01:01, 67:03-67:04, 67:06-67:07
6	190 bp	800 bp	14, 35, 38, 39, 65	*07:28, 08:87, 14:02:01:01-14:02:02, 14:02:04-14:02:05, 14:02:07-14:06:02, 14:09, 14:11, 14:13, 14:15-14:18, 14:20, 14:22-14:23, 14:25, 14:27, 14:29-14:31, 14:33-14:39, 14:41N, 14:43-14:45, 14:48, 14:50-14:52, 14:56-14:64, 14:67-14:70Q, 14:72N-14:76N, 14:79N, 14:84-14:85N, 14:88-14:94, 14:96, 14:98-14:99, 15:77, 15:189, 15:233, 18:166, 27:227, 35:01:64, 35:03:17, 35:26, 35:29:03, 38:05, 38:33, 39:04, 39:129, 40:414, 44:16, 44:37:01-44:37:02, 44:64:01-44:64:02, 44:91, 44:132, 44:150, 44:190, 44:268, 44:275, 44:290, 49:61, 51:01:68, 51:261, 51:274, 52:26, 57:04:01-57:04:03, 58:114, A*23:31, A*24:106, C*01:115, C*02:97, C*03:433, C*03:514, C*06:306, C*07:231, C*14:79, C*16:10
7	290 bp	1070 bp	15, 22, 46, 62, 63, 71, 72, 75, 76, 77	*15:01:01:01-15:01:03, 15:01:06-15:01:53, 15:01:55-15:02:12, 15:03:03, 15:04:01:01-15:08:02, 15:10:02, 15:11:01-15:11:03, 15:11:05-15:15:01:02, 15:17:01:01-15:17:07, 15:19-15:21:01:02, 15:24:01-15:28, 15:30:01:01-15:36, 15:38:01-15:40:02, 15:42-15:46, 15:48, 15:50, 15:55-15:58, 15:60, 15:63, 15:65-15:66, 15:70-15:71, 15:73:01:01-15:73:01:02, 15:75-15:79N, 15:81-15:89:02, 15:92, 15:94N, 15:96-15:97, 15:101-15:102, 15:104-15:107, 15:109-15:113, 15:116-15:118, 15:120-15:122, 15:125:01-15:126, 15:128-15:129, 15:135-15:150, 15:152, 15:154-15:155, 15:157, 15:159-15:160:01:02, 15:162-15:172, 15:174-15:175, 15:177-15:179:02, 15:181N-15:185, 15:187-15:196, 15:199, 15:201-15:209N, 15:211, 15:213-15:219, 15:223-15:225, 15:227-15:228, 15:230-15:234, 15:236-15:237, 15:239-15:241, 15:244-15:251:02, 15:256-15:262N, 15:264-15:265, 15:267-15:273, 15:276-15:280, 15:283-15:289, 15:291, 15:295-15:305, 15:308-15:310, 15:315-15:322, 15:324-15:328, 15:330-15:334, 15:339-15:346, 15:348-15:350, 15:352-15:353, 15:355-15:361, 15:363:01-15:368, 15:370-15:375N, 15:377Q-15:378, 15:381, 15:383-15:387, 15:390-15:396, 15:398-15:407, 15:409-15:413, 15:415-15:417, 15:419-15:425, 15:428-15:432, 15:437-15:438, 15:440-15:443, 15:446, 15:449-15:450, 15:452-15:454N, 15:456-15:474, 15:476-15:486, 15:488-15:497, 15:499-15:501, 15:505, 15:507-15:508, 15:510, 15:512-15:514, 15:516, 15:518-15:525, 15:528N-15:529, 15:531-15:538, 15:540N-15:545, 15:547, 15:549N, 15:551-15:552, 15:554-15:558, 15:561-15:562N, 15:564-15:569, 15:572, 15:574-15:581, 15:583-15:585,



0197

For *In Vitro* Diagnostic Use
MA123 v01 SSP PI Template
Date: May 2021, Rev. No: 00

101.501-48/12 – including *Taq* polymerase, IFU-01
101.501-48u/12u – without *Taq* polymerase, IFU-02

Visit <https://labproducts.caredx.com> for
“Instructions for Use” (IFU)

Lot No.: **1N1**

Lot-specific information

				46:01:01:01-46:70, 46:72-46:76, 46:78-46:87, C*01:73, C*03:02:23, C*05:01:28, C*07:02:30, C*08:16:02, C*14:02:27
8	165 bp, 225 bp, 285 bp, 330 bp	1070 bp	5, 8, 12, 21, 22, 37, 41, 42, 44, 45, 48, 51, 56, 57, 60, 62, 70, 71, 72, 82	*07:349, 08:01:01:01-08:01:22, 08:01:24-08:05, 08:08N-08:13, 08:15-08:27, 08:29-08:36, 08:38:01-08:48, 08:50-08:73, 08:75- 08:76, 08:78, 08:80-08:86N, 08:88, 08:90-08:106, 08:109-08:110, 08:112-08:155, 08:157-08:163, 08:165-08:199, 08:201-08:226, 08:228-08:244, 08:246-08:250, 08:252N-08:254, 08:256-08:263, 08:265-08:266, 13:46, 15:03:01:01-15:03:11, 15:09:01-15:10:07, 15:18:01:01-15:18:09, 15:23, 15:29:01:01-15:29:01:02, 15:37, 15:46-15:47:02, 15:49, 15:51-15:54, 15:61-15:62, 15:64:01- 15:64:02, 15:69, 15:72, 15:74, 15:80, 15:83:01:01-15:83:01:02, 15:90-15:91, 15:93, 15:98-15:99, 15:103, 15:106, 15:108, 15:114- 15:115, 15:119, 15:123-15:124, 15:127, 15:131-15:134, 15:143, 15:151, 15:153, 15:156, 15:158, 15:161, 15:173, 15:176, 15:186, 15:197:01-15:198, 15:200, 15:210, 15:212, 15:220:01:01-15:221, 15:226N, 15:229, 15:235, 15:238, 15:242:01-15:243, 15:252- 15:253, 15:255, 15:259, 15:263, 15:266, 15:274-15:275:02, 15:281- 15:282, 15:290, 15:292-15:294N, 15:306-15:307, 15:311-15:314, 15:323, 15:329, 15:335, 15:337-15:338, 15:351, 15:354, 15:369, 15:379-15:380N, 15:382, 15:388-15:389, 15:397, 15:414, 15:426- 15:427, 15:433, 15:435, 15:439, 15:444-15:445, 15:447-15:448, 15:451, 15:455, 15:475, 15:487N, 15:498, 15:502-15:504, 15:509, 15:511, 15:517, 15:525-15:527, 15:530, 15:539, 15:548, 15:553, 15:560, 15:563, 15:570-15:571, 15:582, 27:195, 35:87, 37:12, 37:84, 38:30, 39:156, 40:12:01-40:12:02, 40:26, 40:40, 40:136, 40:231, 40:279, 41:01:01:01-41:03:02, 41:05-41:09, 41:11-41:17, 41:19-41:48, 41:50, 41:53-41:61, 41:64-41:68, 42:01:01:01- 42:02:02, 42:04-42:08, 42:10-42:15, 42:17-42:19, 42:21-42:28, 44:02:68, 44:14-44:15:01:02, 44:18, 44:20, 44:62, 44:100, 44:166, 44:213, 45:01:01:01-45:25, 45:27, 51:08:01:01-51:08:04, 51:20, 51:36, 51:44N, 51:97, 51:141, 51:153, 51:263, 51:274-51:275, 52:19, 55:20, 55:56, 56:13, 57:09, 82:01:01:01-82:04, C*03:342, C*07:46, C*07:356, C*07:546, C*12:184, C*15:99, C*16:85
9	180 bp, 390 bp	1070 bp	63	*15:01:01:02N, 15:16:01:01-15:17:07, 15:67, 15:95, 15:162, 15:168, 15:177, 15:196, 15:208, 15:216, 15:222, 15:230, 15:254, 15:268, 15:273, 15:356, 15:361-15:362, 15:396, 15:403, 15:408, 15:411, 15:423-15:424, 15:446, 15:462, 15:500, 15:516, 15:523, 15:532, 15:550, 15:555, 15:575N
10	180 bp	800 bp	13, 22, 55, 60	*07:78, 13:01:01:01-13:02:32, 13:07N-13:09, 13:11, 13:14-13:20, 13:22:01-13:23, 13:25, 13:27-13:34, 13:36-13:45, 13:47, 13:49N- 13:50, 13:52, 13:54-13:58, 13:60-13:61, 13:63N-13:70, 13:73-13:78, 13:80-13:85, 13:87-13:107, 13:109-13:119, 13:121-13:126, 13:128- 13:130, 13:132-13:139N, 13:141-13:145, 13:147-13:151, 40:48, 40:377, 45:10, 49:07, 50:31, 54:26, 55:09, 55:22, 55:24, 56:60, 59:09
11⁵	100 bp, 195 bp	1070 bp	8, 12, 27, 38, 39, 3902, 44, 45, 48, 60, 70, 71, 72, 82	*07:27, 07:50, 07:219, 08:04:01-08:04:02, 08:17, 08:54:01- 08:54:02, 08:110, 13:97, 14:73, 15:03:01:01-15:03:09, 15:03:11, 15:47:01-15:47:02, 15:49, 15:54, 15:61-15:62, 15:64:01-15:64:02, 15:68-15:69, 15:91, 15:98, 15:103, 15:123, 15:127, 15:131-15:132, 15:151, 15:156, 15:158, 15:173, 15:210, 15:220:01:01-15:220:02, 15:235, 15:242:01-15:242:02, 15:253, 15:259, 15:266, 15:274,



0197

For *In Vitro* Diagnostic Use
MA123 v01 SSP PI Template
Date: May 2021, Rev. No: 00

101.501-48/12 – including *Taq* polymerase, IFU-01
101.501-48u/12u – without *Taq* polymerase, IFU-02

Visit <https://labproducts.caredx.com> for
“Instructions for Use” (IFU)

Lot No.: **1N1**

Lot-specific information

				15:281-15:282, 15:369, 15:379, 15:389, 15:397, 15:444, 15:448, 15:475, 15:502, 15:511, 15:517, 15:527, 15:539, 15:560, 15:571, 15:582, 18:37:01-18:37:02, 18:125, 27:18, 27:29, 35:361, 37:28, 38:03, 38:158, 39:02:01:01-39:02:03, 39:08, 39:13:01-39:13:02, 39:23, 39:39:01-39:39:02, 39:49, 39:88, 39:101, 39:105, 39:110, 39:162, 39:164, 40:12:01-40:12:02, 40:46, 40:93, 40:430, 42:11, 44:10, 44:15:01:01-44:15:01:02, 44:18, 44:40, 44:44, 44:117, 44:130, 44:140, 44:156, 44:210:01-44:210:02, 44:251, 44:339-44:340, 45:01:01:01-45:03, 45:05-45:07, 45:11-45:23, 45:25, 45:27, 48:01:01:01-48:05, 48:07-48:30, 48:32-48:40, 48:42-48:50, 49:20, 50:02:01:01-50:02:01:02, 50:56, 52:16, 55:18, 56:44, 56:74, 58:44, 82:01:01:01-82:03, C*04:345, C*05:102, C*05:184, C*08:93, C*15:25
12	280 bp	1070 bp	5, 7, 8, 13, 15, 16, 17, 18, 22, 35, 40, 42, 44, 46, 48, 49, 51, 53, 55, 56, 57, 58, 60, 61, 62, 63, 70, 71, 72, 75, 76, 77, 78	*07:09:01-07:09:02, 07:11, 07:17, 07:162, 07:235, 07:237, 07:255, 07:287, 08:28, 08:35, 08:37, 08:89, 08:107, 13:04, 13:10, 13:26:01-13:26:02, 13:72, 13:127, 14:56, 15:01:01:01-15:01:04, 15:01:06-15:02:11, 15:03:01:01-15:08:02, 15:11:01-15:16:04, 15:18:01:01-15:21:01:02, 15:23-15:29:01:02, 15:31:01:01-15:36, 15:38:01-15:40:02, 15:43-15:44, 15:46-15:47:02, 15:49-15:57, 15:60-15:62, 15:64:01-15:72, 15:74-15:76, 15:78:01:01-15:82, 15:84-15:85, 15:87-15:89:02, 15:91-15:98, 15:101-15:129, 15:131-15:132, 15:134-15:136, 15:138-15:149N, 15:151-15:161, 15:163-15:167, 15:169-15:176, 15:178-15:187, 15:189-15:195, 15:197:01-15:207, 15:209N-15:215, 15:217-15:223, 15:225-15:228, 15:231-15:232, 15:234-15:242:02, 15:244-15:247, 15:249-15:251:03, 15:254-15:268, 15:270-15:272N, 15:274-15:286, 15:288-15:302N, 15:304N-15:311, 15:314-15:322, 15:325-15:328, 15:330-15:333, 15:335-15:337, 15:340-15:341, 15:343-15:355, 15:357-15:360, 15:362-15:395, 15:397-15:399, 15:401-15:402, 15:404-15:410, 15:412-15:415, 15:417-15:419, 15:421-15:422, 15:425-15:426, 15:428-15:434, 15:436-15:438, 15:440-15:444, 15:447-15:454N, 15:456-15:459, 15:461, 15:463N-15:484, 15:487N, 15:489-15:499, 15:501-15:502, 15:504-15:505, 15:507-15:515, 15:517-15:522, 15:524-15:529, 15:531, 15:533-15:540N, 15:542-15:545, 15:547-15:551, 15:554, 15:556-15:562N, 15:564-15:574, 15:576-15:577, 15:579-15:584N, 18:01:01:01-18:15, 18:17N-18:25, 18:27-18:40, 18:42-18:60, 18:62-18:121, 18:123-18:147, 18:149-18:164, 18:167, 18:169-18:188, 18:190, 18:192-18:201, 27:41, 27:107, 35:01:01:01-35:01:66, 35:05:01:01-35:05:05, 35:07-35:08:14, 35:10-35:11:03, 35:14:01-35:17:04, 35:19-35:21, 35:23-35:30:01:02, 35:32:01-35:32:03, 35:35, 35:37, 35:40N-35:43:01, 35:43:03-35:43:04, 35:45-35:54, 35:57-35:58, 35:61:01-35:64:02, 35:66-35:69, 35:71-35:72, 35:76-35:80, 35:82, 35:86, 35:89-35:94, 35:97, 35:99-35:105, 35:107-35:108:02, 35:110-35:126, 35:130N-35:135, 35:137-35:148, 35:158-35:159, 35:161, 35:165N-35:166, 35:168, 35:170-35:171, 35:173:01N-35:178, 35:180, 35:185-35:192, 35:194, 35:196-35:197, 35:200, 35:202-35:203, 35:206-35:210, 35:212, 35:215:01-35:219, 35:222, 35:224-35:229, 35:232, 35:238-35:241, 35:244-35:245, 35:247-35:250, 35:252-35:255, 35:259-35:260, 35:262-35:265, 35:268-35:269, 35:271-35:272, 35:275, 35:277, 35:280, 35:283-35:284, 35:286-35:289, 35:293-35:295, 35:297, 35:299-35:308, 35:310, 35:313-35:315, 35:317-35:319, 35:322, 35:324-35:325, 35:327-35:328, 35:330-35:334, 35:336-35:338, 35:340-35:343,



0197

For In Vitro Diagnostic Use
MA123 v01 SSP PI Template
Date: May 2021, Rev. No: 00

101.501-48/12 – including *Taq* polymerase, IFU-01
101.501-48u/12u – without *Taq* polymerase, IFU-02

Visit <https://labproducts.caredx.com> for
“Instructions for Use” (IFU)

Lot No.: **1N1**

Lot-specific information

				35:346-35:348, 35:351-35:353, 35:356, 35:359, 35:363, 35:365, 35:368-35:370, 35:373, 35:376, 35:380:01:01-35:380:01:02, 35:382-35:383, 35:385-35:386, 35:388-35:390N, 35:392-35:393, 35:400-35:402, 35:404-35:406, 35:408-35:409, 35:411-35:412, 35:414, 35:416-35:418, 35:421, 35:426-35:430N, 35:433, 35:437, 35:439:01:01-35:439:01:02, 35:441, 35:444-35:445, 35:447-35:449, 35:453N-35:454, 35:456N, 35:458-35:459N, 35:461N-35:462, 35:464-35:467, 35:470, 35:472-35:473, 35:475-35:476, 35:479-35:481, 35:484-35:485, 35:488, 35:490-35:491, 35:493-35:495, 35:497-35:500, 35:502-35:504, 35:506, 37:35, 37:56, 37:94, 38:52, 39:07, 39:43, 39:91, 39:134, 39:169, 40:03:01:01-40:03:02, 40:20:01:01-40:20:01:02, 40:38, 40:52, 40:59-40:60, 40:105, 40:158-40:159, 40:222, 40:267, 40:284, 40:352, 40:422, 41:24, 41:30, 41:51, 42:09, 44:17, 44:43:01-44:43:02, 44:144, 44:230, 44:256, 44:276, 44:308, 45:09, 46:01:01:01-46:10, 46:12-46:17, 46:19-46:60, 46:62-46:69, 46:71-46:73, 46:75-46:80, 46:82-46:87, 48:02:01-48:02:03, 48:14, 48:23, 48:25, 49:04:01-49:05:02, 50:33, 51:37, 51:45, 51:63:01-51:63:02, 51:97, 51:216, 51:220, 51:251, 52:39, 52:97, 53:01:01:01-53:03, 53:05:01-53:06, 53:08:01-53:18, 53:20-53:30, 53:32, 53:34-53:35, 53:37-53:41, 53:43:01-53:61, 53:63, 54:06, 54:09, 54:14, 55:14, 55:23, 55:32, 55:68, 56:03, 56:09, 56:18, 56:31-56:32, 56:50, 57:01:01:01-57:01:32, 57:01:34-57:01:44, 57:06, 57:08, 57:10-57:11, 57:13-57:16, 57:18-57:27, 57:29-57:31:02, 57:33-57:38, 57:40-57:41, 57:43-57:45, 57:47-57:56, 57:58-57:62, 57:64-57:65, 57:67:01-57:69, 57:71-57:75, 57:77-57:79N, 57:81, 57:83, 57:85-57:93, 57:95, 57:97-57:100, 57:102-57:117, 57:119-57:123, 57:125-57:136, 57:138-57:141, 58:01:01:01-58:02:02, 58:04-58:07, 58:09-58:19, 58:21-58:26, 58:29, 58:31N-58:33, 58:35-58:64, 58:66-58:72N, 58:74-58:113, 58:115-58:123, 58:125-58:128N
13⁹	195 bp	1070 bp	27, 35, 37, 44, 58, 76	*07:27, 07:236, 07:240, 08:126, 08:131, 08:139, 15:12:01-15:12:03, 15:14, 15:19, 15:91, 15:131, 15:161, 15:270, 15:298, 15:304N, 15:518, 15:551, 18:54, 18:56, 18:108, 18:132, 18:169, 18:195, 35:45, 35:71, 37:01:01:01-37:01:11, 37:01:13-37:09, 37:12-37:13, 37:15-37:21, 37:23-37:28, 37:30N-37:33N, 37:35-37:36, 37:38-37:66, 37:68-37:94, 38:17, 44:17, 44:43:01-44:43:02, 44:144, 44:230, 44:256, 44:308, 45:09, 46:17, 53:22, 57:93, 57:119, 58:07, A*24:174, C*02:82, C*06:165, C*14:61
14⁵	105 bp, 395 bp, 435 bp	800 bp	5, 7, 15, 41, 42, 62, 63, 70, 71, 75, 77	*07:04:01-07:04:02, 07:25, 07:146, 07:349, 08:187, 15:09:01-15:10:07, 15:13:01-15:13:03, 15:16:01:01-15:18:09, 15:21:01:01-15:21:01:02, 15:23-15:24:02, 15:37, 15:44, 15:51-15:52, 15:66-15:67, 15:72, 15:76, 15:80, 15:87, 15:90, 15:93, 15:95, 15:99, 15:101, 15:108, 15:114-15:115, 15:119, 15:124, 15:133-15:134, 15:153, 15:157, 15:161-15:162, 15:168, 15:176-15:177, 15:186, 15:189, 15:196-15:198, 15:200, 15:208, 15:216, 15:221-15:222, 15:226N, 15:229-15:230, 15:238, 15:243, 15:252, 15:254-15:255, 15:263, 15:268, 15:273, 15:275:01-15:275:02, 15:290, 15:292-15:294N, 15:306-15:307, 15:311-15:314, 15:323, 15:329, 15:335, 15:337-15:338, 15:351, 15:354, 15:356, 15:361-15:362, 15:376, 15:380N, 15:382, 15:388, 15:394, 15:396, 15:403-15:404, 15:408, 15:411, 15:414, 15:418, 15:420, 15:423-15:424, 15:426-15:427, 15:433-15:436, 15:439, 15:442, 15:445-15:447, 15:451, 15:455,



0197

For *In Vitro* Diagnostic Use
MA123 v01 SSP PI Template
Date: May 2021, Rev. No: 00

101.501-48/12 – including *Taq* polymerase, IFU-01
101.501-48u/12u – without *Taq* polymerase, IFU-02

Visit <https://labproducts.caredx.com> for
“Instructions for Use” (IFU)

Lot No.: **1N1**

Lot-specific information

				15:462, 15:487N, 15:498, 15:500, 15:503-15:504, 15:509, 15:516, 15:523, 15:526, 15:530, 15:532, 15:548, 15:550, 15:555, 15:563, 15:570, 15:573, 15:575N, 40:136, 40:231, 40:279, 41:08, 42:05:01-42:05:02, A*25:01:20, C*03:542, C*07:335, C*14:62
15⁵	115 bp, 150 bp	1070 bp	18	*08:176, 15:545, 18:01:01:01-18:15, 18:17N-18:28, 18:30-18:71, 18:73-18:91, 18:93-18:101, 18:103-18:106Q, 18:108-18:174, 18:176-18:201, 35:289, 35:487, 44:445, 48:28
16⁵	80 bp	1070 bp	7, 27, 2708, 44, 60	*07:73, 08:88, 08:102, 27:01-27:05:22, 27:05:24-27:21:02, 27:23-27:51, 27:53-27:66N, 27:68-27:74, 27:76-27:139, 27:141-27:188, 27:190-27:197, 27:199-27:214, 27:216-27:235, 27:237-27:238, 38:22, 40:46, 40:93, 44:40, 44:44, 44:130, 44:210:01-44:210:02, 49:26
17⁵	100 bp, 150 bp	800 bp	12, 13, 17, 18, 22, 27, 35, 37, 39, 44, 45, 47, 48, 51, 53, 56, 57, 58, 62, 70, 75, 77, 78	*07:137, 07:235, 07:359, 08:49, 08:60, 08:76, 08:129, 08:181, 08:255, 13:01:01:01-13:01:17, 13:06-13:07N, 13:12:01-13:13:02, 13:17, 13:20-13:23, 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, 14:10, 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, 18:22, 18:69, 18:105, 18:149-18:150, 27:19:01:01-27:19:01:02, 27:30, 27:127, 27:150, 27:188, 35:01:01:01-35:01:54, 35:01:56-35:01:61, 35:01:63-35:04:03, 35:06-35:21, 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, 35:88, 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, 35:206-35:231, 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, 35:293-35:330, 35:332-35:366, 35:370-35:388, 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, 35:500-35:507, 37:01:01:01-37:01:07, 37:01:09, 37:01:11-37:01:26, 37:03N-37:06:02, 37:08, 37:10-37:43, 37:45-37:50, 37:52-37:80, 37:82N-37:95, 38:20:01-38:20:02, 39:42, 40:04:01-40:04:02, 40:28, 40:30, 40:34, 40:64:01:01-40:64:02, 40:68, 40:99, 40:129, 40:137, 40:160:01-40:160:02, 40:343, 40:458, 41:48, 42:13, 44:02:01:01-44:02:33, 44:02:35-44:02:57, 44:02:59-44:14, 44:16-44:17, 44:19N, 44:21-44:30, 44:32-44:40, 44:42-44:46:02, 44:48-44:52N, 44:55-44:64:02, 44:66-44:98, 44:101-44:105, 44:107-44:134, 44:136-44:137, 44:139-44:157,



0197

For *In Vitro* Diagnostic Use
MA123 v01 SSP PI Template
Date: May 2021, Rev. No: 00

101.501-48/12 – including *Taq* polymerase, IFU-01
101.501-48u/12u – without *Taq* polymerase, IFU-02

Visit <https://labproducts.caredx.com> for
“Instructions for Use” (IFU)

Lot No.: **1N1**

Lot-specific information

				44:159-44:165, 44:167-44:181, 44:183, 44:185-44:191, 44:194-44:196, 44:198N-44:212, 44:214-44:229, 44:231-44:235, 44:237N-44:245, 44:247-44:304, 44:306N-44:338, 44:340-44:342, 44:344-44:346, 44:437-44:439, 44:441-44:458, 44:460-44:490, 44:492-44:504, 46:33, 46:67, 48:02:01-48:02:03, 48:25, 49:61, 50:17, 51:04:01-51:04:02, 51:42, 51:46, 51:56:01-51:56:03, 51:139, 51:186, 51:227, 51:281, 51:310, 52:88, 53:01:01:01-53:13, 53:15-53:43:02, 53:45-53:46, 53:48N-53:63, 55:14, 56:09, 56:11-56:12, 56:60, 57:01:01:01-57:01:04, 57:01:06-57:10, 57:12, 57:14:01-57:20, 57:22-57:30, 57:32-57:46, 57:48-57:81, 57:84-57:117, 57:119-57:141, 58:01:01:01-58:01:02, 58:01:04-58:01:15, 58:01:17-58:01:37, 58:04-58:05, 58:09-58:15, 58:17N, 58:19, 58:21-58:24, 58:28:01-58:29, 58:31N-58:37, 58:39N-58:42, 58:44-58:45:02, 58:47-58:59:02, 58:62-58:103, 58:105-58:120, 58:123-58:126, 58:128N, 83:01, C*03:102, C*03:263:01-03:263:03, C*03:317, C*03:382, C*03:514, C*15:24, C*15:126
18⁹	140 bp	1070 bp	8, 18, 22, 35, 39, 78	*07:65, 07:134, 07:400, 08:32, 08:133, 08:180, 08:239, 15:202, 15:239, 15:308, 15:376, 18:01:01:01-18:03:01:03, 18:04:01-18:08, 18:10-18:15, 18:17N-18:36, 18:38-18:47, 18:49-18:53, 18:55-18:65, 18:68-18:106Q, 18:108-18:124, 18:126-18:135:01:02, 18:137-18:177, 18:179-18:193, 18:196-18:201, 35:01:01:01-35:02:08, 35:02:10-35:18, 35:20:01-35:24:02, 35:27-35:43:01, 35:43:03-35:45, 35:48, 35:50-35:62, 35:64:01-35:72, 35:74-35:153, 35:155-35:197, 35:199-35:206, 35:208:01-35:209, 35:211-35:216N, 35:218-35:253, 35:255-35:270, 35:272-35:273, 35:275-35:310, 35:312-35:316, 35:318-35:360, 35:362-35:449, 35:451-35:470, 35:472-35:507, 37:05, 37:11, 37:14, 37:29, 37:37, 37:67, 39:19:01-39:19:02, 40:185, 40:209, 40:308, 40:350, 40:365, 45:22, 46:40:01-46:40:02, 56:06, 56:45, 58:64, 78:01:01:02-78:10
19^{5,8}	55 bp, 245 bp, 390 bp, 415 bp	1070 bp	5, 15, 44, 48, 60, 62, 63, 70, 71, 72, 75, 76, 77, 82	*15:01:01:01-15:01:04, 15:01:06-15:21:01:02, 15:23-15:40:02, 15:42-15:58, 15:60-15:67, 15:69-15:99, 15:102-15:129, 15:131-15:179:02, 15:181N-15:235, 15:237-15:254, 15:256-15:505, 15:507-15:514, 15:516-15:545, 15:547-15:585, 40:12:01-40:12:02, 40:26, 40:40, 44:02:68, 46:50, 82:01:01:01-82:03, C*03:179, C*04:345, C*06:147, C*12:301, C*14:61, C*16:85
20⁸	210 bp	800 bp	27, 37	*07:27, 07:236, 07:273, 08:49, 08:126, 18:54, 18:195, 37:01:01:01-37:95, 38:17, C*07:302
21	170 bp	800 bp	16, 35, 38, 39, 3901, 3902, 67, 72	*08:55, 15:69, 15:186, 15:449, 15:494, 18:168, 35:35, 35:276, 35:468, 35:471, 38:01:01:01-38:09, 38:11-38:21, 38:23-38:29, 38:31-38:35, 38:38-38:44, 38:46-38:49, 38:51, 38:53-38:62, 38:64, 38:66-38:69, 38:71-38:86, 38:157-38:158, 38:160-38:167, 38:169, 38:171, 39:01:01:01-39:01:17, 39:01:03:01-39:20, 39:22-39:29, 39:31:01:01-39:31:01:02, 39:35, 39:37:01:01-39:42, 39:44-39:46, 39:48-39:49, 39:51-39:73, 39:75-39:81, 39:83:01-39:101, 39:103-39:106, 39:108-39:111, 39:113-39:127, 39:129-39:135, 39:137-39:155, 39:157N-39:168, 39:170, 40:184, 40:424, 50:49, 51:101, 52:71, 52:84, 58:20, 58:84, 67:01:01-67:07, C*15:51
22⁵	110 bp	1070 bp	38	*14:93, 27:07:04, 38:01:01:01-38:01:07, 38:01:09-38:01:14, 38:01:16-38:02:02:02, 38:02:04-38:03, 38:05, 38:08-38:24, 38:26-38:34N, 38:36-38:80N, 38:82-38:86, 38:160-38:171, 49:26, 51:01:68, 52:01:10, A*23:01:18, A*25:01:08



0197

For In Vitro Diagnostic Use
MA123 v01 SSP PI Template
Date: May 2021, Rev. No: 00

101.501-48/12 – including *Taq* polymerase, IFU-01
101.501-48u/12u – without *Taq* polymerase, IFU-02

Visit <https://labproducts.caredx.com> for
“Instructions for Use” (IFU)

Lot No.: **1N1**

Lot-specific information

23	395 bp	1070 bp	14, 16, 38, 39, 3901, 64, 65	*07:69, 07:85:01-07:85:02, 07:180, 07:306, 08:65, 08:226, 08:228, 14:01:01:01-14:01:07, 14:01:09-14:20, 14:22-14:41N, 14:43-14:48, 14:50-14:56, 14:58-14:72N, 14:74-14:99, 38:01:01:01-38:02:10, 38:04-38:05, 38:08-38:25, 38:27-38:53, 38:55Q-38:73, 38:75-38:86, 38:156-38:165N, 38:167-38:171, 39:01:01:01-39:01:01:17, 39:01:03:01-39:01:32, 39:03:01:01-39:07, 39:09:01:01-39:09:05, 39:11-39:12:01:02, 39:14:01:01-39:15, 39:18-39:19:02, 39:22, 39:24:01-39:38Q, 39:40:01N-39:48, 39:50-39:57, 39:59-39:62, 39:64-39:82, 39:84-39:87N, 39:90-39:95N, 39:97N-39:98, 39:100, 39:102-39:104, 39:106-39:109, 39:111-39:125, 39:127-39:130, 39:132-39:142N, 39:144, 39:146N-39:153, 39:155-39:161N, 39:163, 39:165-39:169, 40:75 [?] , 40:322 [?] , 49:26
24	160 bp, 425 bp	1070 bp	7, 703, 8, 14, 15, 16, 21, 39, 3901, 3902, 40, 41, 42, 45, 48, 50, 60, 61, 64, 65, 67, 70, 73, 81	*07:02:01:01-07:02:66, 07:02:68-07:02:77, 07:02:79-07:02:81, 07:02:83-07:26, 07:28-07:35, 07:37:01-07:37:02, 07:39-07:64, 07:66-07:80, 07:82-07:148, 07:150-07:178, 07:181N-07:191, 07:193-07:194, 07:196-07:218, 07:220-07:235, 07:237-07:256, 07:258-07:270, 07:272N, 07:274-07:415N, 08:01:01:01-08:01:03, 08:01:05-08:01:56, 08:04:01-08:05, 08:07-08:35, 08:37-08:51, 08:53:01-08:77, 08:79-08:116, 08:118-08:125, 08:127-08:130, 08:132-08:135, 08:137-08:138, 08:140-08:228, 08:230-08:254, 08:256-08:266, 14:01:01:01-14:01:04, 14:01:06-14:02:04, 14:02:06-14:02:07, 14:02:09-14:29, 14:31-14:76N, 14:78N-14:92, 14:94-14:99, 15:68, 15:180, 27:14, 27:81, 27:130, 38:156-38:159, 39:01:01:01-39:01:01:17, 39:01:03:01-39:06:04, 39:06:06-39:20, 39:22-39:24:01, 39:25N-39:103, 39:105-39:170, 40:01:01-40:01:04, 40:01:06-40:01:70, 40:06:01:01-40:06:04:03, 40:06:06-40:07, 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 [?] -40:25 [?] , 40:27:02 [?] , 40:28 [?] -40:29 [?] , 40:30-40:33, 40:34 [?] -40:36 [?] , 40:38 [?] , 40:42-40:44, 40:45 [?] -40:46 [?] , 40:48, 40:49 [?] , 40:51-40:54, 40:55 [?] -40:58 [?] , 40:59-40:60, 40:61 [?] -40:63 [?] , 40:65 [?] , 40:66, 40:67 [?] -40:69 [?] , 40:70:01-40:70:02, 40:71 [?] , 40:72:01-40:75, 40:77, 40:78 [?] , 40:79-40:80, 40:81 [?] -40:82 [?] , 40:83, 40:84 [?] -40:85 [?] , 40:86, 40:87:01 [?] -40:88 [?] , 40:91 [?] -40:92 [?] , 40:93, 40:95 [?] , 40:96, 40:98 [?] , 40:100 [?] -40:102 [?] , 40:103, 40:104 [?] -40:108 [?] , 40:109-40:110, 40:112 [?] , 40:113-40:114:01:02, 40:114:02 [?] -40:116 [?] , 40:118N [?] , 40:121 [?] , 40:123 [?] , 40:124:01, 40:124:02 [?] -40:125:01 [?] , 40:125:02-40:128, 40:130:01 [?] , 40:130:02-40:131, 40:132 [?] -40:134 [?] , 40:136 [?] -40:137 [?] , 40:138-40:140, 40:141 [?] , 40:145 [?] , 40:146-40:148, 40:149 [?] , 40:150, 40:151 [?] , 40:152-40:153, 40:154 [?] , 40:155:01N-40:155:02N, 40:156 [?] , 40:158 [?] , 40:159-40:160:01, 40:160:02 [?] , 40:161-40:162, 40:163 [?] -40:164 [?] , 40:165, 40:166 [?] , 40:167, 40:168 [?] -40:169 [?] , 40:170-40:172, 40:173 [?] -40:176 [?] , 40:177, 40:178 [?] -40:180 [?] , 40:182 [?] , 40:183, 40:184 [?] -40:185 [?] , 40:186:01, 40:186:02 [?] -40:187 [?] , 40:189 [?] , 40:190-40:191, 40:192 [?] -40:200 [?] , 40:203 [?] -40:213 [?] , 40:215 [?] -40:225:01 [?] , 40:226 [?] -40:228 [?] , 40:230, 40:231 [?] -40:236 [?] , 40:237, 40:238 [?] -40:243 [?] , 40:244-40:245:02, 40:246 [?] -40:248 [?] , 40:249-40:253, 40:256N, 40:257 [?] , 40:258-40:265N, 40:268-40:270, 40:272-40:273, 40:274 [?] , 40:275, 40:276 [?] , 40:277-40:278, 40:279 [?] -40:280 [?] , 40:282 [?] -40:283 [?] , 40:285-40:286N, 40:287 [?] -40:289 [?] , 40:291N [?] , 40:293 [?] , 40:294-40:295, 40:297 [?] , 40:298:01-40:298:02, 40:299 [?] -40:300 [?] , 40:301, 40:306-40:307, 40:308 [?] , 40:310-40:311, 40:312 [?] , 40:313, 40:315 [?] , 40:316-40:318, 40:319 [?] , 40:321, 40:322 [?] , 40:323:01-40:323:02,



0197

For *In Vitro* Diagnostic Use
MA123 v01 SSP PI Template
Date: May 2021, Rev. No: 00

101.501-48/12 – including *Taq* polymerase, IFU-01
101.501-48u/12u – without *Taq* polymerase, IFU-02

Visit <https://labproducts.caredx.com> for
“Instructions for Use” (IFU)

Lot No.: **1N1**

Lot-specific information

				40:324 [?] -40:329 [?] , 40:330, 40:332, 40:333 [?] , 40:336 [?] -40:339 [?] , 40:340-40:342, 40:343 [?] , 40:346, 40:348-40:350, 40:351 [?] -40:352 [?] , 40:354-40:355, 40:357 [?] -40:360 [?] , 40:361N-40:364, 40:366-40:368, 40:370, 40:372N-40:374, 40:376-40:377, 40:379-40:383, 40:385-40:389, 40:391-40:393, 40:395, 40:396 [?] , 40:397-40:398, 40:400 [?] , 40:401-40:404, 40:406-40:408, 40:411, 40:416-40:419, 40:421Q-40:428N, 40:430-40:431, 40:433-40:434, 40:436, 40:439, 40:443, 40:445-40:454, 40:456, 40:459-40:461, 40:463-40:464, 40:466, 40:468-40:469, 40:471, 40:473-40:475, 41:01:01:01-41:45N, 41:47-41:59, 41:62-41:68, 42:01:01:01-42:02:02, 42:04-42:21, 42:23-42:28, 45:01:01:01-45:01:09, 45:01:11-45:25, 45:27, 48:01:01:01-48:17, 48:19-48:50, 49:01:14, 50:01:01:01-50:02:01:02, 50:04-50:20, 50:31-50:74, 51:01:09, 51:01:21, 51:01:25, 51:10, 51:24:02-51:24:04, 51:197, 51:217, 51:279, 52:54, 54:11, 56:20:02, 56:68, 67:01:01-67:07, 73:01:01:01-73:03, 81:02:01-81:02:02, C*03:464, C*05:152, C*07:463, C*07:758, C*16:112
25¹⁰	180 bp	1070 bp	15, 40, 44, 48, 60	*15:116, 15:124, 15:352, 15:412, 15:507, 27:125, 35:230, 35:331, 38:63, 40:01:01-40:01:06, 40:01:08-40:01:17, 40:01:19-40:01:70, 40:07, 40:10:01:01-40:10:02, 40:12:01-40:12:02, 40:21-40:23, 40:25, 40:30, 40:33-40:34, 40:36, 40:38, 40:42-40:43, 40:46-40:49, 40:51-40:52, 40:54-40:55, 40:59-40:63, 40:65-40:67, 40:69, 40:73-40:74, 40:76, 40:79, 40:81, 40:84, 40:87:01-40:88, 40:92, 40:100-40:102, 40:106, 40:108, 40:112-40:114:02, 40:116-40:118N, 40:123-40:126, 40:128, 40:130:01-40:130:02, 40:132, 40:134-40:135, 40:137-40:141, 40:146-40:147, 40:149-40:156, 40:160:01-40:160:02, 40:163, 40:166, 40:168, 40:170-40:172, 40:175, 40:178-40:179, 40:182-40:183, 40:185-40:188, 40:191, 40:193-40:196, 40:198-40:199, 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, 40:234-40:236, 40:238-40:242, 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, 40:299-40:301, 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, 40:352-40:353:02, 40:355, 40:357-40:358, 40:360, 40:365, 40:367-40:368, 40:370, 40:372N, 40:377, 40:379, 40:381-40:383, 40:385-40:386, 40:391-40:398, 40:400-40:402, 40:404, 40:406-40:407, 40:416-40:419, 40:421Q-40:422, 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, 40:474-40:475, 44:31, 44:169, 44:182, 46:06, 46:43, 48:03:01:01-48:03:02, 48:17, 48:23, 48:40, 57:59, C*03:129, C*03:234, C*04:366, C*04:368, C*05:136, C*17:16:01-17:16:02



0197

For In Vitro Diagnostic Use
MA123 v01 SSP PI Template
Date: May 2021, Rev. No: 00

101.501-48/12 – including *Taq* polymerase, IFU-01
101.501-48u/12u – without *Taq* polymerase, IFU-02

Visit <https://labproducts.caredx.com> for
“Instructions for Use” (IFU)

Lot No.: **1N1**

Lot-specific information

26⁸	130 bp, 290 bp, 465 bp, 570 bp	1070 bp	13, 17, 18, 21, 35, 40, 4005, 41, 46, 47, 50, 57, 60, 61, 62, 63	*13:02:06, 13:26:01, 13:72, 13:127, 15:16:03, 15:20, 15:34:02, 15:85, 15:194, 15:393, 15:407, 18:22, 18:48, 18:52, 18:105, 27:107, 35:46, 35:50, 35:84, 35:207, 35:231, 40:02:01:01-40:06:25, 40:08- 40:09, 40:10:02 [?] , 40:11:01:01-40:11:02, 40:13, 40:14:01 [?] -40:14:02 [?] , 40:15 [?] , 40:18-40:20:01:02, 40:22N [?] , 40:24, 40:25 [?] , 40:26-40:29, 40:34 [?] , 40:35:01-40:35:02, 40:36 [?] , 40:37, 40:38 [?] , 40:39, 40:44, 40:45 [?] , 40:47 [?] , 40:49 [?] , 40:50:01:01-40:50:01:02, 40:53 [?] , 40:55 [?] , 40:56, 40:57 [?] -40:58 [?] , 40:61 [?] -40:63 [?] , 40:64:01:01-40:64:02, 40:65 [?] , 40:67 [?] , 40:68, 40:69 [?] , 40:70:01-40:71, 40:74-40:75, 40:76 [?] , 40:78, 40:81 [?] , 40:82, 40:84 [?] , 40:85-40:86, 40:87:01 [?] -40:88 [?] , 40:89-40:91, 40:92 [?] , 40:94-40:99, 40:100 [?] -40:102 [?] , 40:103-40:105, 40:106 [?] , 40:107, 40:108 [?] , 40:109, 40:111, 40:112 [?] , 40:114:02 [?] , 40:115, 40:116 [?] , 40:118N [?] , 40:119-40:120, 40:121 [?] , 40:122, 40:123 [?] , 40:124:02 [?] -40:125:01 [?] , 40:127, 40:129, 40:130:01 [?] , 40:131, 40:132 [?] , 40:133Q, 40:134 [?] -40:136 [?] , 40:141 [?] , 40:142N-40:145, 40:148-40:149, 40:151 [?] , 40:154 [?] , 40:156 [?] , 40:157, 40:158 [?] , 40:159, 40:160:02 [?] , 40:161-40:162, 40:163 [?] -40:164 [?] , 40:165, 40:166 [?] , 40:167, 40:168 [?] , 40:169, 40:173-40:174, 40:175 [?] , 40:176, 40:178 [?] - 40:179 [?] , 40:180-40:181, 40:182 [?] , 40:184, 40:186:02 [?] -40:188 [?] , 40:189-40:190, 40:192 [?] -40:199 [?] , 40:200-40:203, 40:204 [?] , 40:205- 40:206, 40:207 [?] -40:208 [?] , 40:210 [?] , 40:211, 40:212 [?] -40:213 [?] , 40:214, 40:215 [?] -40:219 [?] , 40:220, 40:221 [?] -40:223 [?] , 40:224-40:226, 40:227 [?] - 40:228 [?] , 40:229-40:230, 40:231 [?] , 40:232, 40:233 [?] -40:236 [?] , 40:238 [?] - 40:242 [?] , 40:243-40:244, 40:246, 40:247 [?] , 40:248, 40:254-40:256N, 40:257 [?] , 40:266-40:271, 40:274-40:276, 40:279 [?] -40:282 [?] , 40:283- 40:284, 40:287, 40:288 [?] , 40:289-40:293, 40:295-40:297, 40:298:01 [?] -40:300 [?] , 40:302-40:307, 40:308 [?] , 40:309, 40:311, 40:312 [?] , 40:313-40:314, 40:315 [?] , 40:317, 40:318 [?] -40:319 [?] , 40:320, 40:322, 40:324 [?] -40:329 [?] , 40:330-40:331, 40:333 [?] , 40:334-40:335, 40:336 [?] , 40:337N, 40:338N [?] -40:339 [?] , 40:340-40:341, 40:342 [?] , 40:343, 40:344 [?] , 40:345N, 40:347-40:351, 40:354, 40:356, 40:357 [?] - 40:358 [?] , 40:359, 40:360 [?] , 40:361N-40:364, 40:366, 40:369, 40:371, 40:374-40:376, 40:384, 40:387-40:390, 40:396 [?] , 40:399N, 40:400 [?] , 40:405, 40:408-40:415, 40:420, 40:423, 40:425, 40:427, 40:429, 40:432, 40:434-40:435, 40:437-40:438N, 40:440-40:442, 40:444- 40:445, 40:449, 40:451, 40:453-40:455, 40:458-40:460, 40:464- 40:465, 40:467-40:468, 40:470-40:473, 44:02:59, 44:103, 44:131, 44:139 [?] , 44:212, 46:01:07, 46:33, 47:01:01:02-47:01:02, 47:01:04- 47:03, 47:05-47:10, 57:05, 57:67:01, 58:36, C*01:73, C*03:504
27⁵	105 bp	1070 bp	7, 8, 22, 41, 42	*07:04:01-07:04:02, 07:25, 07:146, 07:349, 08:01:01:01-08:01:24, 08:01:26-08:05, 08:07-08:12:03, 08:14-08:19N, 08:21-08:24, 08:26:01-08:30N, 08:32-08:39, 08:41-08:54:02, 08:56:01-08:69, 08:71-08:78, 08:80-08:102, 08:104-08:112, 08:114-08:133, 08:135- 08:142, 08:144-08:155, 08:157-08:168, 08:170, 08:172-08:174, 08:176-08:204, 08:206-08:254, 08:256-08:266, 35:87, 40:136, 40:231, 40:279, 41:01:01:01-41:08, 41:10-41:28, 41:30-41:31, 41:33-41:61, 41:63-41:68, 42:01:01:01-42:02:02, 42:04-42:07, 42:09-42:18, 42:20-42:28, 44:166, 44:342, 55:20
28	325 bp	800 bp	7, 22, 27, 2708, 35, 42, 45, 46, 54, 55, 56,	*07:02:01:01-07:02:84, 07:04:01-07:07:03, 07:09:01-07:15, 07:17- 07:26, 07:28-07:31:02, 07:33:01-07:36, 07:39-07:46, 07:47 ^w , 07:48- 07:49N, 07:51-07:68:03, 07:70-07:84, 07:86-07:179, 07:181N- 07:206, 07:208-07:218, 07:220-07:227, 07:229:01-07:231N,



0197

For *In Vitro* Diagnostic Use
MA123 v01 SSP PI Template
Date: May 2021, Rev. No: 00

101.501-48/12 – including *Taq* polymerase, IFU-01
101.501-48u/12u – without *Taq* polymerase, IFU-02

Visit <https://labproducts.caredx.com> for
“Instructions for Use” (IFU)

Lot No.: **1N1**

Lot-specific information

			67, 73, 78, 81, 82	07:233-07:305, 07:307-07:399, 07:401-07:415N, 08:123, 08:132, 14:21, 14:57, 15:76, 15:101, 15:255, 15:509, 27:01-27:11, 27:13:01-27:15, 27:17, 27:19:01:01-27:21:02, 27:24-27:28, 27:30-27:38, 27:40-27:58, 27:60-27:76, 27:78-27:91, 27:93-27:118, 27:120-27:128, 27:130-27:136, 27:138-27:152, 27:154-27:203, 27:205-27:214, 27:216-27:238, 35:76, 35:186, 35:229, 35:368, 37:60, 38:26, 40:166, 42:01:01:01-42:02:02, 42:04-42:06, 42:08-42:10, 42:12-42:23, 42:25, 42:27-42:28, 44:90, 44:97, 45:06, 46:01:01:01-46:01:30, 46:02 ^w , 46:03-46:40:02, 46:42-46:48, 46:50-46:87, 54:01:01:01-54:29, 54:31-54:43, 55:01:01:01-55:05, 55:07-55:17, 55:19-55:77, 55:79-55:111, 56:01:01:01-56:16, 56:18-56:22, 56:24-56:32, 56:34-56:41, 56:43, 56:45-56:53, 56:55:01:02-56:66, 56:68-56:77N, 67:01:01-67:07, 73:01:01:01-73:03, 81:01:01:01-81:10, 82:01:01:01-82:04, 83:01
29⁵	80 bp, 115 bp, 160 bp, 195 bp, 225 bp, 260 bp	1070 bp	12, 35, 37, 44, 47, 57	*07:359, 08:49, 08:60, 08:76, 08:87, 08:129, 08:181, 08:213:01, 08:255, 15:578, 27:127, 35:38, 35:45, 35:71, 35:115, 35:169, 35:260, 35:309, 35:452, 37:01:01:01-37:01:07, 37:01:09, 37:01:11-37:01:26, 37:03N-37:06:02, 37:08, 37:10-37:38, 37:41-37:43, 37:45-37:50, 37:52-37:65, 37:67-37:82N, 37:84-37:93, 37:95, 40:132, 40:178, 40:231, 40:279, 40:458, 41:48, 42:13, 44:02:01:01-44:14, 44:16-44:17, 44:19N-44:36, 44:38-44:63, 44:65-44:134, 44:136-44:149N, 44:151-44:157, 44:159-44:165, 44:167-44:183, 44:185-44:212, 44:214-44:229, 44:231-44:235, 44:237N-44:245, 44:247-44:267N, 44:269-44:274, 44:277-44:289, 44:291-44:338, 44:340-44:346, 44:437-44:458, 44:460-44:504, 48:11, 51:42, 51:274, 53:22, 53:62, 57:07, 57:09, 57:24, 57:93, 57:119, 58:94N, 83:01, C*15:25
30	215 bp	800 bp	5, 8, 12, 17, 21, 22, 41, 42, 44, 45, 51, 5102, 5103, 52, 53, 56, 62	*08:09, 08:84, 08:254, 13:46, 15:83:01:01-15:83:01:02, 41:01:01:01-41:01:07, 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, 42:04, 44:06, 44:15:01:01-44:15:01:02, 44:18, 44:20, 44:100, 45:01:01:01-45:25, 45:27, 49:03, 51:01:01:01-51:01:01:70, 51:01:03-51:01:08, 51:01:10-51:01:39, 51:01:41-51:02:01:03, 51:02:03-51:04:02, 51:06:01-51:06:03, 51:07:01, 51:08:01:01-51:09:01, 51:09:03-51:14, 51:16-51:24:05, 51:26-51:46, 51:48-51:53, 51:55-51:77, 51:79-51:88, 51:90-51:92:02, 51:94-51:102, 51:104:01-51:115, 51:117-51:118N, 51:120-51:131, 51:133-51:143, 51:145-51:147, 51:149N-51:175, 51:177-51:178N, 51:181-51:217, 51:219-51:225, 51:227-51:332, 52:01:02:01-52:01:02:05, 52:01:04, 52:01:09, 52:01:40, 52:01:43, 52:01:47, 52:02:01, 52:03, 52:06:01-52:06:02, 52:09:01, 52:10:03, 52:19, 52:21:01, 52:31:02, 52:85, 52:97, 53:01:13, 53:06, 55:20, 55:56, 56:13, 57:01:20, 58:08:01, A*23:01:14
31⁹	130 bp, 280 bp	800 bp	7, 17, 18, 22, 35, 37, 40, 46, 51, 53, 60, 62, 78	*07:12, 07:14:01-07:14:02, 07:18:01-07:18:02, 07:137, 07:162-07:163, 07:199, 07:225, 07:227, 07:248, 07:350, 14:10, 15:57 ^w , 15:289, 15:297, 15:318, 15:579, 18:22, 18:69, 18:105, 18:149-18:150, 35:21, 35:24:01-35:24:02, 35:81, 35:96, 35:109, 35:157, 35:188, 35:190, 35:233, 35:287, 37:04:01-37:04:02, 40:28, 40:30, 40:34, 40:59, 40:137, 40:160:01-40:160:02, 44:150, 44:190, 44:203:01-44:203:02, 44:275, 44:290, 46:01:01:01-46:39, 46:41N-46:46, 46:48-46:71, 46:73-46:76, 46:78-46:85, 46:87, 48:17, 51:04:01-51:04:02, 51:46, 51:56:01-51:56:03, 51:139, 51:227,



0197

For *In Vitro* Diagnostic Use
MA123 v01 SSP PI Template
Date: May 2021, Rev. No: 00

101.501-48/12 – including *Taq* polymerase, IFU-01
101.501-48u/12u – without *Taq* polymerase, IFU-02

Visit <https://labproducts.caredx.com> for
“Instructions for Use” (IFU)

Lot No.: **1N1**

Lot-specific information

32⁵	90 bp, 410 bp	1070 bp	7, 15, 22, 27, 2708 35, 47, 54, 55, 56, 78, 81, 82	51:281, 51:310, 52:88, 53:02, 53:06, 53:28, 57:14:01-57:14:02, 58:09, 58:76, C*01:73, C*03:260, C*03:384, C*15:39, C*15:130, C*15:195
				*07:65, 07:209, 07:271, 27:01 ^w , 27:02:01:01-27:11, 27:13:01-27:15, 27:17, 27:19:01:01-27:21:02, 27:24-27:28, 27:30-27:38, 27:40- 27:58, 27:60-27:76, 27:78-27:91, 27:93-27:118, 27:120-27:128, 27:130-27:136, 27:138-27:152, 27:154-27:194, 27:196-27:203, 27:205-27:214, 27:216-27:238, 35:76, 35:186, 35:229, 35:368, 37:60, 44:90, 44:97, 47:01:01:02-47:03, 47:06-47:10, 54:01:01:01- 54:29, 54:31-54:43, 55:01:01:01-55:05, 55:07-55:17, 55:19-55:77, 55:79-55:111, 56:01:01:01-56:16, 56:18-56:22, 56:24-56:32, 56:34- 56:41, 56:43, 56:45-56:53, 56:55:01:02-56:66, 56:69-56:77N, 81:01:01:01-81:01:05, 81:05, 81:09-81:10, 82:01:01:01-82:04, 83:01, C*14:79
33⁵	90 bp, 175 bp	1070 bp	7, 15, 27, 2708, 35, 48, 60, 62, 75, 77, 81	*07:174, 07:202, 07:222, 07:279, 07:409 ^w , 08:213:01-08:213:02, 13:36, 15:02:01:01-15:02:12, 15:08:01-15:08:02, 15:11:01-15:11:07, 15:13:01-15:13:03, 15:15:01:01-15:15:01:02, 15:21:01:01- 15:21:01:02, 15:31:01:01-15:31:01:03, 15:44, 15:55, 15:76 ^w , 15:88- 15:89:02, 15:112, 15:121, 15:139, 15:144, 15:148, 15:170, 15:189, 15:191, 15:194, 15:209N, 15:213-15:215, 15:223, 15:265, 15:283- 15:284, 15:291, 15:297, 15:301-15:303, 15:305, 15:319, 15:325, 15:328, 15:330, 15:341, 15:345, 15:350, 15:357-15:358, 15:367, 15:374, 15:378, 15:384, 15:394, 15:399, 15:404, 15:418, 15:420, 15:425, 15:437-15:438, 15:454N, 15:460, 15:479, 15:486, 15:491, 15:495, 15:505, 15:508, 15:513, 15:537, 15:557, 15:567, 15:569, 15:574, 27:24, 35:46, 35:311, 40:31, 40:45, 40:80, 48:01:01:01- 48:01:10, 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, 48:41-48:50, 51:104:02, 56:39 ^w , 81:01:01:01-81:10
				*15:16:01:01-15:17:07, 15:24:01-15:24:02, 15:67, 15:87, 15:143, 15:152, 15:157, 15:162, 15:168, 15:177, 15:196, 15:208, 15:216, 15:222, 15:230, 15:254, 15:268, 15:273, 15:356, 15:361-15:362, 15:396, 15:403, 15:408, 15:411, 15:423-15:424, 15:442, 15:446, 15:500, 15:516, 15:523, 15:532, 15:546Q, 15:550, 15:555, 15:575N, 27:02:01:01-27:02:04, 27:02:06, 27:30, 27:53, 27:57, 27:62, 27:65N, 27:75, 27:77, 27:83, 27:95, 27:102, 27:119, 27:126, 27:134, 27:163, 27:171-27:172, 27:176N, 27:181, 27:188, 27:197, 27:203, 27:213, 27:232, 27:236, 37:34, 38:25, 40:13, 40:19, 40:61, 40:109, 40:117, 40:292, 40:340, 40:394, 41:46, 41:60, 44:18, 44:25, 44:50:01, 44:50:03, 44:95, 48:18, 49:01:01:01-49:01:18, 49:03- 49:14, 49:16-49:25, 49:27-49:69, 51:112, 51:231, 51:310, 52:01:01:01-52:01:28, 52:01:30-52:19, 52:21:01-52:72, 52:74- 52:101, 53:17:01-53:17:02, 53:28, 53:30, 53:39, 54:12, 55:103, 56:21, 56:42, 56:54, 56:65, 57:45, 57:51, 57:69, 57:128, 58:100, 58:111, 59:01:01:01-59:07, 59:09-59:12, A*24:309, A*32:39
34⁵	55 bp, 105 bp, 145 bp, 395 bp, 430 bp	1070 bp	15, 27, 44, 48, 49, 52, 59, 60, 61, 62, 63	*15:16:01:01-15:17:07, 15:24:01-15:24:02, 15:67, 15:87, 15:143, 15:152, 15:157, 15:162, 15:168, 15:177, 15:196, 15:208, 15:216, 15:222, 15:230, 15:254, 15:268, 15:273, 15:356, 15:361-15:362, 15:396, 15:403, 15:408, 15:411, 15:423-15:424, 15:442, 15:446, 15:500, 15:516, 15:523, 15:532, 15:546Q, 15:550, 15:555, 15:575N, 27:02:01:01-27:02:04, 27:02:06, 27:30, 27:53, 27:57, 27:62, 27:65N, 27:75, 27:77, 27:83, 27:95, 27:102, 27:119, 27:126, 27:134, 27:163, 27:171-27:172, 27:176N, 27:181, 27:188, 27:197, 27:203, 27:213, 27:232, 27:236, 37:34, 38:25, 40:13, 40:19, 40:61, 40:109, 40:117, 40:292, 40:340, 40:394, 41:46, 41:60, 44:18, 44:25, 44:50:01, 44:50:03, 44:95, 48:18, 49:01:01:01-49:01:18, 49:03- 49:14, 49:16-49:25, 49:27-49:69, 51:112, 51:231, 51:310, 52:01:01:01-52:01:28, 52:01:30-52:19, 52:21:01-52:72, 52:74- 52:101, 53:17:01-53:17:02, 53:28, 53:30, 53:39, 54:12, 55:103, 56:21, 56:42, 56:54, 56:65, 57:45, 57:51, 57:69, 57:128, 58:100, 58:111, 59:01:01:01-59:07, 59:09-59:12, A*24:309, A*32:39
				*07:78, 07:84, 13:16, 13:31 ^w , 13:48, 13:62, 13:128, 13:131 ^w , 13:145 ^w , 14:37, 15:04:01:01 ^w -15:04:04 ^w , 15:16:01:01-15:16:04, 15:42, 15:67, 15:95, 15:137 ^w , 15:254, 15:293, 15:303 ^w , 15:310, 15:362, 15:408, 15:517, 15:531 ^w , 15:550, 27:153, 35:265 ^w , 40:95, 40:148, 40:161, 44:459, 46:32:01 ^w -46:32:02 ^w , 49:01:01:01- 49:01:01:12, 49:01:03-49:10, 49:12-49:14, 49:16-49:44, 49:46,
35^{5,9}	120 bp, 210 bp	800 bp	5, 13, 15, 17, 22, 35, 45, 49, 50, 51, 5102, 5103, 52,	*07:78, 07:84, 13:16, 13:31 ^w , 13:48, 13:62, 13:128, 13:131 ^w , 13:145 ^w , 14:37, 15:04:01:01 ^w -15:04:04 ^w , 15:16:01:01-15:16:04, 15:42, 15:67, 15:95, 15:137 ^w , 15:254, 15:293, 15:303 ^w , 15:310, 15:362, 15:408, 15:517, 15:531 ^w , 15:550, 27:153, 35:265 ^w , 40:95, 40:148, 40:161, 44:459, 46:32:01 ^w -46:32:02 ^w , 49:01:01:01- 49:01:01:12, 49:01:03-49:10, 49:12-49:14, 49:16-49:44, 49:46,



0197

For *In Vitro* Diagnostic Use
MA123 v01 SSP PI Template
Date: May 2021, Rev. No: 00

101.501-48/12 – including *Taq* polymerase, IFU-01
101.501-48u/12u – without *Taq* polymerase, IFU-02

Visit <https://labproducts.caredx.com> for
“Instructions for Use” (IFU)

Lot No.: **1N1**

Lot-specific information

			55, 56, 62, 63, 78	49:48-49:60N, 49:62-49:70, 50:01:01:01-50:02:01:02, 50:04-50:11, 50:13-50:16, 50:18-50:20, 50:31-50:46, 50:47 ^w , 50:48, 50:50, 50:52- 50:65, 50:67-50:69, 50:71-50:74, 51:01:01:01-51:03, 51:05, 51:07:01-51:09:03, 51:11N-51:14, 51:16-51:24:05, 51:26-51:41N, 51:43-51:44N, 51:48-51:55, 51:57-51:58, 51:60-51:61:02, 51:63:01- 51:63:02, 51:65-51:80, 51:82-51:134, 51:136-51:138, 51:140- 51:147, 51:149N-51:156, 51:158:01-51:193, 51:195-51:212, 51:214- 51:219, 51:221-51:226, 51:228-51:280, 51:282-51:292, 51:294- 51:309, 51:311-51:318N, 51:320-51:332, 52:01:01:01-52:87, 52:89N-52:96N, 52:97 ^w , 52:98-52:101, 54:20, 54:33 ^w , 55:01:01:01- 55:01:06, 55:01:08-55:01:26, 55:02:11, 55:03, 55:05, 55:09, 55:11, 55:15, 55:17, 55:21 ^w , 55:24-55:25, 55:28:01-55:29, 55:31, 55:33, 55:36, 55:38, 55:40, 55:44-55:45, 55:52-55:55N, 55:58-55:60, 55:64, 55:66, 55:68, 55:73-55:76, 55:78-55:79, 55:84-55:85, 55:87, 55:90-55:95, 55:97N-55:106, 55:108-55:109, 55:111, 56:05:01- 56:06, 56:21, 56:25, 56:37, 58:08:01-58:08:02, 59:12, 78:01:01:02- 78:10, C*03:464, C*05:152, C*12:183^w, C*14:92
36	390 bp, 430 bp	1070 bp	5, 17, 27, 35, 44, 51, 5102, 5103, 52, 53, 57, 58, 61, 78	*15:506, 18:33, 18:67, 18:136, 18:194:01:01-18:194:01:02, 27:02:01:01-27:02:06, 27:12:01:01-27:12:01:03, 27:16, 27:30, 27:53, 27:57, 27:62, 27:65N, 27:75, 27:77, 27:83, 27:92, 27:95, 27:102, 27:119, 27:126, 27:134, 27:153, 27:157, 27:163, 27:171- 27:172, 27:176N, 27:181, 27:188, 27:197, 27:203, 27:213, 27:232, 27:236, 35:26, 35:82, 35:85, 35:135, 35:294, 35:471, 37:34, 37:57, 40:13, 40:19 [?] , 40:75 [?] , 40:109 [?] , 40:292 [?] , 40:322 [?] , 40:340 [?] , 44:06, 44:25, 44:50:01, 44:50:03, 44:95, 44:263, 49:62, 51:01:01:01- 51:01:39, 51:01:41-51:24:05, 51:26-51:46, 51:48-51:53, 51:55- 51:77, 51:79-51:332, 52:01:01:01-52:01:28, 52:01:30-52:19, 52:21:01-52:89N, 52:91-52:101, 53:01:01:01-53:01:17, 53:01:19- 53:02, 53:04-53:08:02, 53:10, 53:14-53:30, 53:32-53:35, 53:37, 53:39-53:54, 53:56-53:63, 57:01:01:01-57:04:02, 57:05-57:11, 57:13-57:141, 58:01:01:01-58:02:02, 58:04-58:16:02, 58:18-58:29, 58:31N-58:63, 58:65-58:107, 58:109-58:128N, 78:03
37	145 bp, 210 bp	1070 bp	12, 21, 35, 4005, 41, 45, 47, 50, 60, 61	*07:133, 07:177, 08:102, 08:122, 08:155, 13:09, 13:39, 13:67, 14:48, 15:46, 15:53, 15:106, 15:143, 15:183, 15:212, 15:336, 15:345, 15:511, 15:525, 15:559, 18:48, 18:80, 18:102, 18:107, 27:08, 27:12:01:01-27:12:01:03, 27:18, 27:26, 27:33, 27:40, 27:42, 27:44, 27:89, 27:153, 27:165 ^w , 27:204, 35:19, 35:47, 35:63, 35:84, 35:90, 35:150:01-35:150:02, 35:154, 35:184, 35:201, 35:217, 35:274, 35:317, 35:441, 35:450, 39:69, 40:01:01-40:11:02, 40:14:01-40:16:01:02, 40:18, 40:20:01:01-40:20:01:02, 40:22N- 40:40, 40:42-40:46, 40:48-40:75, 40:77-40:95, 40:97-40:108, 40:111-40:116, 40:118N-40:136, 40:138-40:156, 40:158-40:187, 40:189-40:200, 40:202-40:291N, 40:293-40:339, 40:341-40:364, 40:366-40:393, 40:395-40:399N, 40:401-40:475, 41:01:01:01-41:04, 41:06-41:25, 41:27-41:45N, 41:47-41:59, 41:61-41:68, 44:09, 44:46:01-44:46:02, 44:75, 44:90, 44:129, 44:131, 44:254, 44:277, 44:438N, 45:01:01:01-45:01:08, 45:01:10-45:15, 45:17-45:25, 45:27, 46:10, 47:02, 47:03 ^w , 48:41, 50:01:01:01-50:02:01:02, 50:04- 50:20, 50:31-50:74, 56:36, 56:67, 73:01:01:01-73:03, C*03:504, C*07:828
38^{9,15}	300 bp	1070 bp	7, 12, 13, 15, 17, 18,	*07:54, 07:123, 07:400, 08:17, 08:38:01-08:38:02, 08:54:01- 08:54:02, 08:101, 08:228, 13:01:01:01-13:01:14, 13:01:16-13:04,



0197

For *In Vitro* Diagnostic Use
MA123 v01 SSP PI Template
Date: May 2021, Rev. No: 00

101.501-48/12 – including *Taq* polymerase, IFU-01
101.501-48u/12u – without *Taq* polymerase, IFU-02

Visit <https://labproducts.caredx.com> for
“Instructions for Use” (IFU)

Lot No.: **1N1**

Lot-specific information

			21, 27, 2708, 35, 37, 38, 39, 3902, 40, 4005, 41, 44, 45, 47, 48, 49, 50, 52, 60, 61, 62, 70, 72, 76	13:06, 13:08-13:23, 13:25-13:35, 13:37-13:151, 15:01:01:01-15:01:04, 15:01:06-15:01:18, 15:01:20-15:01:67, 15:03:01:01-15:03:04, 15:03:06-15:07:03, 15:12:01-15:12:03, 15:14, 15:19-15:20, 15:24:01-15:27:04, 15:30:01:01-15:30:01:03, 15:32:01-15:36, 15:38:01-15:40:02, 15:42-15:43, 15:45-15:50, 15:53-15:54, 15:56-15:58, 15:60-15:63, 15:65-15:66, 15:68-15:71, 15:73:01:01-15:75, 15:77-15:79N, 15:81-15:87, 15:91-15:92, 15:94N, 15:96-15:98, 15:101-15:107, 15:109-15:111N, 15:113, 15:116-15:118, 15:122-15:123, 15:125:01-15:129, 15:131-15:132, 15:135-15:138, 15:140-15:142, 15:145-15:147, 15:150-15:152, 15:154-15:160:01:02, 15:163-15:167, 15:169, 15:171-15:175, 15:178-15:179:02, 15:181N-15:185, 15:187-15:188, 15:190N, 15:192-15:193, 15:195, 15:199, 15:201-15:207, 15:210-15:212, 15:217-15:220:02, 15:224-15:225, 15:227-15:228, 15:231-15:237, 15:239-15:245:02Q, 15:247-15:251:03, 15:253, 15:255-15:262N, 15:264, 15:266-15:267, 15:269-15:272N, 15:274, 15:276-15:282, 15:286-15:289, 15:295-15:296, 15:298-15:300, 15:304N, 15:309-15:310, 15:315-15:318, 15:320-15:322, 15:324, 15:326-15:327, 15:331-15:334, 15:336, 15:339-15:340, 15:342-15:344, 15:346-15:349:02, 15:352-15:353, 15:355, 15:359-15:360, 15:363:01-15:366, 15:368-15:373, 15:375N-15:377Q, 15:379, 15:381, 15:383, 15:385-15:387, 15:389-15:391, 15:393, 15:395, 15:397-15:398, 15:400N-15:402, 15:405-15:407, 15:409-15:410, 15:412-15:413, 15:415-15:417, 15:419, 15:421-15:422, 15:429-15:432, 15:440-15:444, 15:448-15:450, 15:452-15:453, 15:456-15:459, 15:461, 15:463N-15:478, 15:480-15:485, 15:488-15:490, 15:492-15:494, 15:496N-15:497, 15:499, 15:501-15:502, 15:507, 15:510-15:512, 15:514-15:515, 15:517-15:522, 15:524-15:525, 15:527-15:529, 15:531, 15:533-15:536, 15:538-15:545, 15:547, 15:549N, 15:551-15:552, 15:554, 15:556, 15:558-15:562N, 15:564-15:566, 15:568, 15:571-15:572, 15:576-15:585, 18:12:01-18:12:02, 18:178, 18:195, 27:01-27:21:02, 27:24-27:91, 27:93-27:108, 27:110-27:156, 27:158-27:214, 27:216-27:238, 35:10, 35:13, 35:16, 35:28:01:01-35:28:01:03, 35:63, 35:69, 35:80, 35:207, 35:226, 35:270, 35:317-35:318, 35:361, 35:477, 37:01:01:01-37:07, 37:09-37:66, 37:68-37:95, 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, 40:01:01-40:07, 40:09-40:16:01:02, 40:18-40:24, 40:26-40:40, 40:42-40:67, 40:70:01-40:105, 40:107-40:165, 40:167-40:231, 40:233-40:312, 40:314-40:356, 40:358-40:475, 41:01:01:01-41:68, 42:11, 44:02:01:01-44:02:21, 44:02:23-44:02:64, 44:02:66-44:03:35, 44:03:37-44:03:44, 44:03:46-44:05:04, 44:07-44:11, 44:13-44:170, 44:172-44:231, 44:233-44:245, 44:247-44:262, 44:264-44:346, 44:437-44:504, 45:01:01:01-45:21, 45:23-45:25, 45:27, 47:01:01:02-47:10, 48:01:01:01-48:05, 48:07-48:15, 48:17-48:38, 48:40-48:50, 49:01:01:01-49:14, 49:16-49:25, 49:27-49:62, 49:64-49:66, 49:68-49:70, 50:01:01:01-50:02:01:02, 50:04-50:14, 50:16-50:20, 50:31-50:74, 51:310, 52:01:01:01-52:72, 52:74-52:101, 53:17:01-53:17:02, 53:28, 53:38, 54:35, 55:18, 55:34, 55:40, 56:67, 78:05-78:06
39 ^{7,13}	160 bp, 370 bp	1070 bp	22, 44, 45, 47, 54	*08:87, 08:255, 15:578, 27:127, 41:55, 44:02:01:01-44:02:70, 44:06, 44:08-44:09, 44:11-44:12, 44:16, 44:19N-44:24, 44:27:01:01-44:27:03, 44:33-44:34:02, 44:41:01-44:41:02, 44:44, 44:48-44:49,



0197

For *In Vitro* Diagnostic Use
MA123 v01 SSP PI Template
Date: May 2021, Rev. No: 00

101.501-48/12 – including *Taq* polymerase, IFU-01
101.501-48u/12u – without *Taq* polymerase, IFU-02

Visit <https://labproducts.caredx.com> for
“Instructions for Use” (IFU)

Lot No.: **1N1**

Lot-specific information

				44:52N-44:53:02, 44:55, 44:59:01-44:59:02, 44:63, 44:66-44:68, 44:71-44:74, 44:80, 44:83-44:84:02, 44:86-44:87, 44:89-44:91, 44:93, 44:95, 44:97, 44:99-44:102, 44:104, 44:106, 44:112-44:113, 44:116, 44:118-44:119, 44:121, 44:126:01-44:127, 44:131-44:132, 44:137-44:138Q, 44:142, 44:145, 44:148-44:149N, 44:151-44:152, 44:162, 44:168-44:173, 44:176-44:177, 44:179, 44:185, 44:187, 44:190-44:191, 44:195N-44:196, 44:200-44:201, 44:206, 44:208, 44:211-44:212, 44:214, 44:216, 44:218-44:221, 44:225, 44:229, 44:235, 44:238, 44:240-44:244, 44:249, 44:253-44:255, 44:257, 44:260-44:262, 44:265, 44:267N, 44:269-44:270:02, 44:273-44:274, 44:279, 44:287, 44:289, 44:291-44:293, 44:296-44:297, 44:301, 44:303N, 44:306N, 44:311-44:315, 44:320-44:322, 44:326-44:327, 44:329, 44:331, 44:334N-44:335, 44:337-44:338, 44:341N-44:344, 44:437, 44:439, 44:441-44:442, 44:445-44:446, 44:448N-44:449N, 44:451-44:453, 44:455, 44:457, 44:461-44:464:01:02, 44:467-44:468, 44:470, 44:473, 44:477-44:480Q, 44:482, 44:484, 44:492, 44:494-44:495, 44:497-44:499, 44:502-44:503, 51:274, 54:01:01:01-54:43, 83:01
40	180 bp, 210 bp, 240 bp	1070 bp	8, 13, 15, 18, 22, 35, 39, 40, 42, 51, 54, 55, 56, 59, 62, 78	*07:65, 07:206, 08:09, 08:26:03, 08:56:03, 08:84, 08:181, 13:06, 13:46, 13:53, 13:131, 14:37, 15:32:02, 15:42, 15:83:01:01-15:83:01:02, 15:86, 15:224, 15:485, 18:04:01, 18:98:02, 18:125, 18:191, 35:03:27, 35:08:05, 35:42:02, 35:60, 35:185, 35:276, 39:06:01-39:06:06, 39:17, 39:34, 39:57, 39:62-39:64, 39:83:01-39:83:03, 39:90, 39:109, 39:127, 39:129, 39:132, 39:140-39:141, 39:154, 40:01:11, 40:58, 41:66, 42:04, 45:08, 46:18, 46:40:01, 50:45, 50:49, 51:21, 51:36, 51:101, 51:143, 51:153, 51:157, 51:197, 51:280, 51:295, 51:300, 52:37, 52:71, 52:84, 54:01:01:01-54:02, 54:04-54:05N, 54:07-54:08N, 54:10-54:25, 54:27-54:32, 54:34-54:39, 54:41-54:43, 55:01:01:01-55:03, 55:05, 55:07, 55:10-55:21, 55:23, 55:25-55:48, 55:50, 55:52-55:85, 55:87-55:109, 55:111, 56:05:01, 56:06, 56:10, 56:23, 56:54, 56:66, 57:26, 59:01:01:01-59:03, 59:05-59:08, 59:10N-59:11, 78:01:01:02-78:01:02, 78:02:02-78:03, 78:07-78:10, C*01:90, C*06:72, C*07:536, C*07:758, C*08:207, C*12:183, C*14:92, C*15:91, C*15:128
41	180 bp, 205 bp	1070 bp	7, 12, 15, 21, 22, 44, 45, 49, 50, 56, 61, 62, 82, C ^w 3	*07:29, 07:186, 07:383, 08:123, 08:132, 13:03, 13:48, 13:120, 13:146, 15:73:01:01-15:73:01:02, 15:303, 15:486, 15:552, 35:432, 35:446, 40:71, 44:10, 44:15:01:01-44:15:01:02, 44:18, 44:140, 44:339-44:340, 45:01:01:01-45:01:11, 45:04-45:07, 45:11-45:23, 45:24 ^w , 45:25, 45:27, 46:11, 49:01:01:01-49:01:07, 49:01:09-49:03, 49:06, 49:08-49:14, 49:16-49:17, 49:19N-49:49, 49:51-49:60N, 49:62-49:70, 50:01:01:01-50:02:01:02, 50:04-50:08, 50:10-50:13, 50:15-50:19, 50:32, 50:34-50:38, 50:40-50:44, 50:46-50:48, 50:50-50:74, 51:15, 51:62, 51:106:01-51:106:02, 51:223, 51:225, 52:25:01-52:25:02, 54:03, 54:33, 54:40, 56:01:01:01-56:01:04, 56:01:06-56:01:12, 56:01:14-56:02:03, 56:04:01:01-56:04:04, 56:07-56:08, 56:13-56:14, 56:16-56:17, 56:20:01-56:20:02, 56:24-56:30, 56:33-56:49, 56:51-56:53, 56:55:01:02-56:59, 56:61-56:65, 56:67-56:77N, 58:73, 59:04, 59:12, 82:01:01:01-82:04, C*03:19, C*03:102



0197

For *In Vitro* Diagnostic Use
MA123 v01 SSP PI Template
Date: May 2021, Rev. No: 00

101.501-48/12 – including *Taq* polymerase, IFU-01
101.501-48u/12u – without *Taq* polymerase, IFU-02

Visit <https://labproducts.caredx.com> for
“Instructions for Use” (IFU)

Lot No.: **1N1**

Lot-specific information

42^{5,9}	90 bp, 150 bp, 415 bp	800 bp	57	*15:462, 38:157, 57:01:01:01-57:01:22, 57:01:24-57:04:01, 57:04:03-57:35, 57:37-57:88, 57:90-57:108, 57:110-57:127, 57:129- 57:141, 58:36, C*06:140
43^{5,11}	90 bp	1070 bp	5, 13, 17, 35, 39, 49, 55, 56, 58, 60, 61, 62, 71, C ^w 2	*07:182N, 13:11, 13:58, 15:18:03, 15:73:01:01-15:73:01:02, 15:86, 15:224, 15:486, 18:191, 35:60, 35:291, 35:432, 35:446, 39:17, 40:48, 40:71, 40:377, 45:22, 49:03, 49:47:01-49:47:02, 50:51 ^w , 51:15, 51:62, 51:106:02, 51:157, 51:225, 51:300, 52:25:01, 56:02:01:01-56:02:03, 56:04:01:01-56:04:04, 56:10, 56:45, 56:51, 56:56-56:57, 56:63, 56:66, 57:120, 58:01:01:01-58:01:20, 58:01:21 ^w , 58:01:22-58:02:02, 58:04-58:29, 58:31N-58:35, 58:37- 58:43, 58:45:01-58:99, 58:101-58:110, 58:112-58:128N, 82:03, A*02:339, A*02:510, C*02:06:01-02:06:02, C*02:47, C*05:132, C*06:168^w, C*06:224^w, C*07:536, C*07:725, C*08:207, C*12:03:66^w, C*12:15^w, C*12:208, C*15:58^w, C*15:72, C*15:225
44⁵	95 bp	1070 bp	8, 18, 22, 35, 37, 38, 39, 44, 51, 5102, 5103, 53, 78	*07:65 ^w , 07:134 ^w , 08:32, 08:133, 08:180, 08:239, 15:308, 18:01:01:01-18:03:01:03, 18:04:01-18:11, 18:13-18:15, 18:17N- 18:36, 18:38-18:47, 18:49-18:65, 18:67-18:106Q, 18:108-18:124, 18:126-18:177, 18:179-18:194:01:02, 18:196-18:201, 35:01:01:01- 35:01:55, 35:01:57-35:08:04, 35:08:06-35:09:03, 35:11:01-35:12:04, 35:14:01-35:15:02, 35:17:01-35:18, 35:20:01-35:24:02, 35:27, 35:29:01-35:43:01, 35:43:03-35:45, 35:48, 35:50-35:62, 35:64:01- 35:68:02, 35:70-35:72, 35:74-35:75, 35:76 ^w , 35:77-35:79, 35:81- 35:153, 35:155-35:185, 35:187-35:190, 35:192-35:197, 35:199- 35:206, 35:208:01-35:209, 35:211-35:216N, 35:218-35:225, 35:227- 35:253, 35:255-35:269, 35:272-35:273, 35:275-35:310, 35:312- 35:316, 35:319-35:360, 35:362-35:449, 35:451-35:476, 35:478- 35:507, 37:08, 37:67, 38:06-38:07, 39:19:01-39:19:02, 44:06, 45:22, 51:01:01:01-51:24:05, 51:26-51:46, 51:48-51:103, 51:105-51:111, 51:113-51:117, 51:119-51:146, 51:148-51:230:01:03, 51:232:01- 51:266, 51:268-51:283, 51:285-51:309, 51:311-51:332, 53:01:01:01-53:16, 53:18-53:27, 53:29, 53:31-53:37, 53:40-53:63, 56:06 ^w , 56:45 ^w , 78:01:01:02-78:04, 78:07-78:10
45^{5,7,8}	115 bp, 150 bp	1070 bp	15, 18, 22, 27, 35, 39, 46, 55, 62, 72, 73, 75, 76	*07:100, 13:31, 13:41, 13:131, 13:145, 15:01:01:01-15:01:04, 15:01:06-15:01:16, 15:01:18-15:01:30, 15:01:32-15:01:67, 15:04:01:01-15:04:04, 15:07:01:01-15:08:02, 15:11:01-15:12:03, 15:14-15:15:01:02, 15:19, 15:24:01-15:24:02, 15:26N-15:28, 15:30:01:01-15:30:01:03, 15:32:01-15:32:02, 15:34:01-15:35, 15:38:01-15:38:02, 15:43, 15:45-15:46, 15:50, 15:53-15:54, 15:56- 15:58, 15:60, 15:63, 15:66, 15:68, 15:70-15:71, 15:73:01:01- 15:73:01:02, 15:75-15:77, 15:79N, 15:81-15:82, 15:85, 15:87, 15:92, 15:94N, 15:96-15:97, 15:101-15:102, 15:104-15:105, 15:109- 15:111N, 15:113, 15:117-15:118, 15:120, 15:122, 15:125:01- 15:126, 15:128-15:129, 15:135, 15:137, 15:140, 15:142-15:149N, 15:152, 15:154, 15:157, 15:159-15:160:01:02, 15:163-15:167, 15:169, 15:171-15:172, 15:174-15:175, 15:178, 15:180-15:184, 15:187, 15:189-15:193, 15:201-15:203, 15:205-15:207, 15:209N, 15:211-15:212, 15:215, 15:217, 15:225, 15:227-15:228, 15:231- 15:234, 15:236, 15:239, 15:241, 15:244-15:247, 15:251:01- 15:251:03, 15:256-15:262N, 15:264, 15:267, 15:269-15:270, 15:272N, 15:276-15:280, 15:284-15:286, 15:296, 15:298-15:299, 15:303-15:305, 15:309, 15:315-15:318, 15:320-15:321Q, 15:324, 15:326-15:327, 15:331, 15:333-15:334, 15:336, 15:340,



0197

For *In Vitro* Diagnostic Use
MA123 v01 SSP PI Template
Date: May 2021, Rev. No: 00

101.501-48/12 – including *Taq* polymerase, IFU-01
101.501-48u/12u – without *Taq* polymerase, IFU-02

Visit <https://labproducts.caredx.com> for
“Instructions for Use” (IFU)

Lot No.: **1N1**

Lot-specific information

				15:342-15:344, 15:346-15:347, 15:349:01-15:350, 15:353, 15:355, 15:359, 15:363:01-15:363:02, 15:365, 15:367-15:368, 15:370-15:373, 15:375N, 15:377Q, 15:381, 15:385-15:387, 15:390-15:392, 15:398, 15:400N-15:401, 15:405-15:406, 15:409-15:410, 15:412-15:413, 15:415-15:417, 15:419, 15:422, 15:428-15:432, 15:440-15:443, 15:450, 15:452-15:453, 15:456-15:457, 15:459, 15:461, 15:464-15:467, 15:469-15:474, 15:476-15:484, 15:486, 15:488-15:490, 15:492-15:493, 15:496N, 15:498-15:499, 15:501, 15:507, 15:510, 15:512-15:515, 15:520Q-15:522, 15:525, 15:528N-15:529, 15:531, 15:533-15:536, 15:538, 15:540N-15:542, 15:545, 15:547, 15:549N, 15:551, 15:554, 15:556, 15:558-15:559, 15:561-15:562N, 15:565, 15:568, 15:572, 15:576, 15:579-15:581, 15:583, 15:585, 18:19, 18:164, 27:25, 27:75, 27:115, 27:161, 35:14:01-35:14:03, 35:43:01, 35:43:03-35:44, 35:62, 35:67, 35:79, 35:86, 35:102, 35:117, 35:135, 35:163, 35:185, 35:213, 35:265, 35:343, 35:390N, 35:413, 35:475-35:476, 37:60, 37:66, 39:18, 39:36, 44:146, 44:275, 44:299, 46:01:01:01-46:02, 46:04-46:05, 46:07N, 46:09-46:10, 46:12, 46:14-46:17, 46:20, 46:22-46:24, 46:26-46:32:02, 46:34-46:42, 46:44, 46:46-46:53, 46:55N-46:57, 46:60-46:61, 46:63-46:82, 46:84-46:87, 50:47, 51:61:01-51:61:02, 51:220, 52:21:01-52:21:02, 52:97, 54:06, 54:33, 54:40, 55:21, 56:03, 56:43, 58:78, 73:01:01:01-73:03, A*25:66, A*26:68, A*26:100, A*26:200, A*68:56, C*02:56, C*06:20, C*12:50
46^{9,12}	360 bp	1070 bp	Bw4	*07:27, 07:36, 07:38, 07:81, 07:149, 07:180, 07:219, 07:236, 07:273, 08:02-08:03, 08:52, 08:78, 08:117, 08:126, 08:255, 13:01:01:01-13:04, 13:06-13:08, 13:10-13:23, 13:25-13:38, 13:40-13:66, 13:68-13:151, 14:93, 15:13:01-15:13:03, 15:16:01:01-15:17:07, 15:23-15:24:02, 15:36, 15:43, 15:67, 15:87, 15:89:01-15:89:02, 15:95, 15:115, 15:157, 15:162, 15:168, 15:177, 15:196, 15:208, 15:216, 15:222, 15:230, 15:254, 15:256, 15:268, 15:273, 15:339, 15:356, 15:361-15:362, 15:396, 15:403, 15:408, 15:411, 15:418, 15:423-15:424, 15:442, 15:446, 15:462, 15:500, 15:505, 15:516, 15:523, 15:532, 15:546Q, 15:550, 15:555, 15:575N, 18:09, 18:54, 18:67, 18:136, 18:194:01:01-18:195, 27:01-27:05:36, 27:05:38-27:07:06, 27:09-27:11, 27:13:01-27:17, 27:19:01:01-27:21:02, 27:23-27:25, 27:27-27:32, 27:34-27:39, 27:41, 27:43, 27:45-27:88, 27:90:01-27:152, 27:154-27:168, 27:170-27:203, 27:205-27:214, 27:216-27:238, 35:36, 35:329, 35:471, 37:01:01:01-37:04:02, 37:06:01-37:10, 37:12-37:36, 37:38-37:66, 37:68-37:95, 38:01:01:01-38:86, 38:160-38:171, 40:13, 40:19, 40:47, 40:96, 40:109-40:110, 40:117, 40:157, 40:188, 40:201, 40:207, 40:246, 40:292, 40:340, 40:394, 41:46, 41:60, 44:02:01:01-44:08, 44:10-44:45, 44:47-44:74, 44:76-44:89, 44:91-44:128:02, 44:130, 44:132-44:245, 44:247-44:253, 44:255-44:276, 44:278-44:344, 44:346, 44:437, 44:439-44:457, 44:459-44:504, 47:01:01:02-47:01:05, 47:03-47:10, 48:18, 49:01:01:01-49:14, 49:16-49:20, 49:22-49:70, 51:01:01:01-51:24:05, 51:26-51:46, 51:48-51:332, 52:01:01:01-52:101, 53:01:01:01-53:63, 54:12, 55:90, 55:103, 56:07, 56:21, 56:46, 56:65, 57:01:01:01-57:11, 57:13-57:141, 58:01:01:01-58:02:02, 58:04-58:29, 58:31N-58:63, 58:65-58:127, 59:01:01:01-59:12



0197

For *In Vitro* Diagnostic Use
MA123 v01 SSP PI Template
Date: May 2021, Rev. No: 00

101.501-48/12 – including *Taq* polymerase, IFU-01
101.501-48u/12u – without *Taq* polymerase, IFU-02

Visit <https://labproducts.caredx.com> for
“Instructions for Use” (IFU)

Lot No.: **1N1**

Lot-specific information

47	350 bp	1070 bp	Bw6	*07:02:01:01-07:02:77, 07:02:79-07:26, 07:28-07:35, 07:37:01-07:37:02, 07:39-07:80, 07:82-07:148, 07:150-07:179, 07:181N-07:191, 07:193-07:218, 07:220-07:235, 07:237-07:272N, 07:274-07:415N, 08:01:01:01-08:01:56, 08:04:01-08:05, 08:07-08:51, 08:53:01-08:77, 08:79-08:116, 08:118-08:125, 08:127-08:130, 08:132-08:135, 08:137-08:138, 08:140-08:152, 08:154-08:156, 08:158-08:254, 08:256-08:266, 13:09, 13:39, 13:67, 14:01:01:01-14:92, 14:94-14:99, 15:01:01:01-15:01:04, 15:01:06-15:12:03, 15:14-15:15:01:02, 15:18:01:01-15:21:01:02, 15:25:01:01-15:35, 15:37-15:40:02, 15:42, 15:44-15:58, 15:60-15:66, 15:68-15:86, 15:88, 15:90-15:94N, 15:96-15:99, 15:101-15:114, 15:116-15:129, 15:131-15:156, 15:158-15:161, 15:163-15:167, 15:169-15:176, 15:178-15:195, 15:197:01-15:207, 15:209N-15:215, 15:217-15:221, 15:223-15:229, 15:231-15:253, 15:255, 15:257-15:267, 15:269-15:272N, 15:274-15:276, 15:278-15:338, 15:340-15:355, 15:357-15:360, 15:363:01-15:376, 15:378-15:395, 15:397-15:402, 15:404-15:407, 15:409-15:410, 15:412-15:417, 15:419-15:422, 15:425-15:429, 15:431-15:441, 15:443-15:445, 15:447-15:461, 15:463N-15:499, 15:501-15:504, 15:506-15:515, 15:517-15:522, 15:524-15:531, 15:533-15:545, 15:547-15:549N, 15:551-15:554, 15:556-15:574, 15:576-15:585, 18:01:01:01-18:08, 18:10-18:15, 18:17N-18:53, 18:55-18:66, 18:68-18:135:01:02, 18:137-18:178, 18:180-18:193, 18:196-18:201, 27:08, 27:12:01:01-27:12:01:03, 27:18, 27:26, 27:33, 27:40, 27:42, 27:44, 27:89, 27:153, 27:165 ^w , 27:204, 35:01:01:01-35:01:38, 35:01:40-35:02:08, 35:02:10-35:43:01, 35:43:03-35:72, 35:74-35:221, 35:223-35:247, 35:249-35:292, 35:294-35:328, 35:330-35:423, 35:425-35:470, 35:472-35:507, 37:05, 37:11, 37:14 ^w , 37:37, 37:67, 38:156-38:159, 39:01:01:01-39:01:01:17, 39:01:03:01-39:01:14, 39:01:16-39:20, 39:22-39:103, 39:105-39:170, 40:01:01-40:12:02, 40:14:01-40:16:01:02, 40:18, 40:20:01:01-40:40, 40:42-40:46, 40:48-40:75, 40:77-40:95, 40:97-40:108, 40:111-40:116, 40:118N-40:156, 40:158-40:187, 40:189-40:200, 40:202-40:291N, 40:293-40:339, 40:341-40:393, 40:395-40:399N, 40:401-40:475, 41:01:01:01-41:25, 41:27-41:45N, 41:47-41:59, 41:61-41:68, 42:01:01:01-42:02:02, 42:04-42:21, 42:23-42:28, 44:09, 44:46:01-44:46:02, 44:75, 44:90, 44:129, 44:131, 44:254, 44:277, 44:438N, 45:01:01:01-45:01:08, 45:01:10-45:15, 45:17-45:25, 45:27, 46:01:01:01-46:87, 47:02, 47:03 ^w , 48:01:01:01-48:17, 48:19-48:50, 50:01:01:01-50:02:01:02, 50:04-50:20, 50:31-50:74, 54:01:01:01-54:11, 54:13-54:43, 55:01:01:01-55:05, 55:07-55:89N, 55:91-55:102, 55:104-55:111, 56:01:01:01-56:06, 56:08-56:20:02, 56:22-56:45, 56:47-56:64, 56:66-56:77N, 57:12, 58:64, 67:01:01-67:07, 73:01:01:01-73:03, 78:01:01:02-78:10, 81:01:01:01-81:10, 82:01:01:01-82:04, 83:01
48	285 bp	1070 bp	7, 703, 8, 35, 40, 41, 42, 48, 60, 61, 81	*07:02:01:01-07:02:38, 07:02:40-07:06:05, 07:08:01-07:18:02, 07:20-07:32, 07:34-07:39, 07:41-07:52, 07:54-07:59, 07:61-07:76, 07:79-07:83, 07:85:01-07:99, 07:101-07:121, 07:123-07:138, 07:140-07:164, 07:166-07:192, 07:194-07:195, 07:199-07:213, 07:215-07:234, 07:236-07:238, 07:240-07:254, 07:256-07:342, 07:344-07:358, 07:360Q-07:385, 07:387-07:415N, 08:01:01:01-08:01:20, 08:01:22-08:01:24, 08:01:26-08:05, 08:07-08:08N, 08:10-08:11, 08:13-08:15, 08:17-08:30N, 08:32-08:83, 08:85-08:88, 08:90-08:102, 08:104-08:106, 08:108-08:112, 08:114-08:115,



0197

For *In Vitro* Diagnostic Use
MA123 v01 SSP PI Template
Date: May 2021, Rev. No: 00

101.501-48/12 – including *Taq* polymerase, IFU-01
101.501-48u/12u – without *Taq* polymerase, IFU-02

Visit <https://labproducts.caredx.com> for
“Instructions for Use” (IFU)

Lot No.: **1N1**

Lot-specific information

				08:117-08:133, 08:135-08:168, 08:170-08:174, 08:176-08:183, 08:185-08:231, 08:233-08:253, 08:256-08:266, 15:297, 27:164, 35:66, 35:87, 37:07, 40:15-40:16:01:02, 40:30-40:32, 40:34, 40:45, 40:59, 40:80, 40:98, 40:137, 40:160:01-40:160:02, 41:02:01:01-41:02:09, 41:04, 41:10-41:11, 41:13, 41:18-41:19, 41:23-41:24, 41:27, 41:31, 41:36, 41:38-41:43, 41:45N-41:49, 41:51-41:52, 41:55, 41:58, 41:65, 41:68, 42:01:01:01-42:02:02, 42:05:01-42:07, 42:09-42:13, 42:15-42:28, 44:150, 44:166, 44:342, 48:01:01:01-48:01:10, 48:05-48:12, 48:14-48:20, 48:22, 48:27-48:39, 48:41-48:50, 53:15, 81:01:01:01-81:10, C*03:260
49	165 bp, 190 bp	1070 bp	5, 17, 21, 35, 51, 5102, 52, 56, 62, 70, 78	*13:62, 15:01:02, 15:09:01-15:09:02, 15:243, 15:277-15:278, 15:361, 15:435, 27:153, 35:01:10, 35:03:32, 35:04:02, 35:251, 40:26, 40:28, 44:03:40, 44:62, 44:459, 49:18:01, 50:14, 51:01:01:01-51:01:03, 51:01:05-51:01:71, 51:01:73-51:02:03, 51:02:05-51:09:03, 51:11N-51:12, 51:13:02-51:14, 51:16-51:23, 51:24:03-51:24:05, 51:26-51:33, 51:37-51:41N, 51:43-51:44N, 51:46, 51:48-51:61:02, 51:63:01, 51:64-51:80, 51:82-51:91, 51:92:02, 51:94-51:98N, 51:100-51:106:01, 51:107-51:130, 51:132-51:142, 51:145-51:147, 51:149N-51:156, 51:158:01-51:196, 51:198, 51:200-51:219, 51:221-51:224, 51:226-51:294, 51:296-51:299, 51:301-51:332, 52:01:01:01-52:01:04, 52:01:06-52:01:14, 52:01:16-52:13, 52:14:02-52:24, 52:25:02-52:57, 52:59-52:66, 52:68-52:96N, 52:98-52:101, 53:28, 56:05:01-56:06, 56:21, 57:01:32, 58:08:01-58:08:02, 78:01:01:02-78:10
50	260 bp	800 bp	14, 16, 18, 51, 62, 70	*14:06:01-14:06:02, 14:08:01-14:08:02, 14:55-14:56, 14:96, 15:37-15:38:02, 15:185, 15:323, 15:335, 15:364, 15:368, 15:435, 18:01:01:01-18:01:15, 18:01:17-18:01:40, 18:01:42-18:01:44, 18:03:01:01-18:09, 18:12:01-18:13, 18:15, 18:17N-18:20, 18:23N-18:26, 18:28-18:34, 18:36-18:38, 18:40-18:43, 18:45-18:55, 18:57:01-18:57:02, 18:59-18:68, 18:70-18:100, 18:102-18:104, 18:106Q-18:109, 18:111-18:148, 18:151-18:163, 18:166-18:167, 18:169, 18:171-18:178, 18:180-18:188, 18:190-18:201, 39:32, 39:43, 39:48, 40:51, 40:113, 40:163, 51:06:01-51:06:04, 51:45, 51:62, 51:135, 51:194, 51:293, 51:319, 56:31, 67:06, C*02:142, C*05:216:01:01-05:216:01:02, C*07:516, C*07:521:01-07:521:02, C*08:51, C*08:114
51	390 bp	1070 bp	18, 35, 44, 51, 5102, 5103, 52, 53, 61, 78	*18:07:01-18:07:03, 18:29, 18:79, 18:136, 27:23, 35:01:01:01-35:19, 35:21-35:25, 35:27, 35:29:01-35:43:01, 35:43:03-35:62, 35:64:01-35:71, 35:74-35:75, 35:77, 35:79-35:81, 35:83-35:84, 35:86-35:94, 35:96-35:134N, 35:136-35:185, 35:187-35:225, 35:227-35:228, 35:230-35:254, 35:256-35:293, 35:295, 35:297-35:316, 35:318-35:360, 35:362-35:367, 35:369-35:438, 35:440-35:462, 35:464-35:507, 37:21, 37:67, 40:08, 40:13, 40:68?, 40:106?, 40:162?, 40:220?, 40:232?, 44:06, 44:232, 51:01:01:01-51:06:04, 51:08:01:01-51:21, 51:23-51:24:05, 51:26-51:46, 51:48-51:127, 51:129-51:188, 51:190-51:213, 51:215-51:221, 51:223-51:235N, 51:237-51:250, 51:252-51:271, 51:273N-51:309, 51:311-51:332, 52:06:01-52:06:03, 53:01:01:01-53:08:02, 53:10-53:16, 53:18-53:27, 53:29-53:37, 53:39, 53:41-53:63, 78:01:01:02-78:02:02, 78:04, 78:07-78:10



0197

For *In Vitro* Diagnostic Use
MA123 v01 SSP PI Template
Date: May 2021, Rev. No: 00

101.501-48/12 – including *Taq* polymerase, IFU-01
101.501-48u/12u – without *Taq* polymerase, IFU-02

Visit <https://labproducts.caredx.com> for
“Instructions for Use” (IFU)

Lot No.: **1N1**

Lot-specific information

52	380 bp	1070 bp	5, 8, 17, 48, 51, 5102, 5103, 52, 57, 58, 59, 61	*08:03, 08:52, 08:78, 15:361, 27:102, 38:73, 40:13, 40:19, 40:109, 40:117, 40:292, 40:340, 40:394, 41:46, 41:60, 48:18, 49:18:01-49:18:02, 51:01:01:01-51:01:07, 51:01:09-51:01:14, 51:01:16-51:01:39, 51:01:41-51:01:42, 51:01:44-51:12, 51:16-51:24:05, 51:26-51:36, 51:38-51:41N, 51:43-51:44N, 51:46, 51:48-51:49, 51:51-51:53, 51:55-51:61:02, 51:64-51:77, 51:79-51:84, 51:86-51:89, 51:91, 51:93-51:96, 51:98N-51:105, 51:107-51:134, 51:136-51:156, 51:158:01-51:171, 51:173Q-51:181, 51:183-51:191, 51:193-51:196, 51:198-51:213, 51:215, 51:217-51:219, 51:221-51:222, 51:224, 51:226, 51:228-51:246, 51:248-51:250, 51:252-51:260, 51:262-51:273N, 51:275-51:280, 51:282-51:297, 51:299, 51:301-51:318N, 51:320-51:332, 52:01:01:01-52:01:28, 52:01:30-52:11, 52:13, 52:15-52:19, 52:21:01-52:24, 52:27-52:38, 52:40-52:61, 52:64-52:67, 52:69-52:74, 52:76-52:87, 52:89N-52:96N, 52:98-52:101, 53:19, 56:21, 57:02:01:01-57:03:05, 57:05, 57:07, 57:09, 57:17, 57:39, 57:42, 57:46, 57:57, 57:63, 57:66, 57:70, 57:80, 57:82, 57:84, 57:94, 57:96, 57:101, 57:124, 57:137, 58:08:01-58:08:02, 58:27-58:28:02, 58:65, 59:02, 59:11, A*24:146
53	160 bp	1070 bp	44, 51, 54	*08:101, 13:132, 15:434, 35:501, 41:55, 44:24, 44:181, 46:86, 51:39, 54:01:01:01-54:01:09, 54:03-54:04, 54:06-54:38, 54:40-54:43, C*05:30, C*06:125, C*07:441:01-07:441:02, C*16:86, C*16:144, C*16:147
54⁵	125 bp, 150 bp, 260 bp	800 bp	12, 17, 18, 35, 37, 40, 44, 45, 47, 49, 57, 61	*07:359, 08:255, 18:09, 18:54, 18:67, 18:136, 18:194:01:01-18:195, 27:127, 35:45, 35:71, 35:169, 35:309, 35:452, 37:06:01-37:06:02, 40:13, 40:19, 40:47, 40:96, 40:109-40:110, 40:117, 40:157, 40:188, 40:201, 40:292, 40:340, 40:394, 40:458, 41:46, 41:60, 44:02:01:01-44:245, 44:247-44:346, 44:437-44:504, 47:01:01:02-47:01:05, 47:03-47:10, 49:01:01:01-49:02, 49:04:01-49:14, 49:16-49:20, 49:22-49:25, 49:27-49:70, 51:42, 51:112, 53:01:26, 53:22, 53:30, 53:39, 53:62, 57:07, 57:45, 57:51, 57:69, 57:93, 57:119, 58:111, 83:01, A*24:02:37, C*15:25, C*16:85
55⁹	205 bp, 235 bp	1070 bp	7, 703, 27, 35, 40, 42, 48, 60, 61, 81	*07:02:01:01-07:02:38, 07:02:40-07:06:05, 07:08:01-07:11, 07:13, 07:15-07:17, 07:19, 07:21-07:23, 07:25-07:30, 07:32-07:33:03, 07:35-07:42, 07:44N-07:59, 07:61-07:76, 07:79-07:83, 07:85:01-07:99, 07:101-07:130, 07:132-07:136:02, 07:138-07:161N, 07:164-07:192, 07:194-07:195, 07:199-07:213, 07:215-07:219, 07:221-07:222, 07:224, 07:226, 07:228:01-07:234, 07:236-07:238, 07:240-07:247, 07:249-07:254, 07:256-07:268, 07:270-07:357, 07:361-07:377, 07:379-07:385, 07:387-07:415N, 08:40, 08:53:01-08:53:02, 08:79, 08:156, 08:165, 08:171, 08:205, 13:71, 13:108, 15:421, 27:07:01-27:07:06, 27:11, 27:24, 27:32-27:34, 27:43, 27:138, 27:164, 27:180, 27:187, 27:219, 27:233, 35:31, 35:66, 37:07, 40:02:01:01-40:03:02, 40:08-40:09, 40:13, 40:15-40:16:01:02, 40:18-40:19, 40:24, 40:27:01-40:27:03, 40:29, 40:31-40:32, 40:35:01-40:35:02, 40:37, 40:40, 40:45, 40:50:01:01-40:50:01:02, 40:56-40:58, 40:78, 40:80, 40:82, 40:85, 40:89-40:91, 40:94, 40:97-40:98, 40:104-40:105, 40:107, 40:111, 40:115, 40:119, 40:122, 40:142N-40:145, 40:157, 40:164, 40:169, 40:173, 40:176, 40:180-40:181, 40:189, 40:200-40:203, 40:205-40:206, 40:209, 40:211, 40:214, 40:219-40:220, 40:224, 40:226, 40:229, 40:232, 40:246, 40:248, 40:254-40:255, 40:266-40:267, 40:271, 40:274, 40:276, 40:283-40:284, 40:287, 40:289-40:293, 40:296-40:297,



0197

For *In Vitro* Diagnostic Use
MA123 v01 SSP PI Template
Date: May 2021, Rev. No: 00

101.501-48/12 – including *Taq* polymerase, IFU-01
101.501-48u/12u – without *Taq* polymerase, IFU-02

Visit <https://labproducts.caredx.com> for
“Instructions for Use” (IFU)

Lot No.: **1N1**

Lot-specific information

				40:302-40:305, 40:309, 40:314, 40:320, 40:322, 40:331, 40:334-40:335, 40:337N, 40:345N, 40:347, 40:356, 40:359, 40:369, 40:371, 40:375, 40:378, 40:384, 40:390, 40:399N, 40:405, 40:409-40:410, 40:412-40:415, 40:420, 40:432, 40:435, 40:437-40:438N, 40:440-40:442, 40:444, 40:455, 40:457, 40:465, 40:467, 40:470, 40:472, 41:19, 48:01:01:01-48:01:10, 48:04:01:01-48:16, 48:18-48:20, 48:22, 48:24, 48:27-48:36, 48:38-48:39, 48:41-48:50, 51:81, 58:27, 81:01:01:01-81:10, C*02:60, C*03:386, C*07:850
56¹⁴	550 bp	1070 bp	7, 22, 42, 45, 56, 82	*07:04:01-07:04:02, 07:19, 07:25, 07:146, 07:349, 08:123, 08:132, 08:146, 42:01:01:01-42:02:02, 42:04-42:10, 42:12-42:18, 42:20-42:25, 42:27-42:28, 44:90, 45:06, 55:20, 55:56, 56:13, 82:01:01:01 ^w -82:01:03 ^w , 82:02:01:01-82:02:02, 82:03 ^w , 82:04, 83:01
57⁵	105 bp	1070 bp	7, 15, 22, 42, 55, 56, 67, 81, 82	*07:02:01:01-07:02:27, 07:02:29-07:02:49, 07:02:51-07:02:76, 07:02:78-07:02:84, 07:04:01-07:05:01:04, 07:05:03-07:07:03, 07:09:01-07:09:02, 07:11-07:12, 07:14:01-07:15, 07:17-07:26, 07:28-07:31:02, 07:33:01-07:36, 07:39-07:49N, 07:51-07:64, 07:66-07:68:03, 07:70-07:82, 07:84, 07:86-07:124, 07:126-07:132, 07:135N-07:179, 07:181N-07:182N, 07:184-07:206, 07:208-07:218, 07:220-07:227, 07:229:01-07:246, 07:248-07:258, 07:260-07:269, 07:271-07:291, 07:293-07:305, 07:307-07:315N, 07:317-07:332, 07:334-07:367, 07:369-07:399, 07:401-07:408, 07:410-07:415N, 08:123, 08:132, 14:21, 15:255, 15:509, 27:157, 38:26, 42:01:01:01-42:02:02, 42:04-42:06, 42:08-42:10, 42:12-42:25, 42:27-42:28, 55:01:01:01-55:01:24, 55:01:26-55:05, 55:08-55:17, 55:19-55:33, 55:36-55:46, 55:48-55:63, 55:65-55:77, 55:79-55:111, 56:01:01:01-56:05:02, 56:07-56:13, 56:15-56:16, 56:18-56:22, 56:24-56:32, 56:34-56:38N, 56:40-56:41, 56:43, 56:46-56:53, 56:55:01:02-56:66, 56:68-56:77N, 67:01:01-67:01:03, 67:03-67:07, 81:01:01:01-81:04N, 81:06-81:10, 82:01:01:01-82:04, 83:01
58^{5,9}	90 bp, 125 bp, 155 bp, 190 bp	1070 bp	5, 17, 45, 51, 56, 60, 61, 78	*07:65, 07:133, 07:206, 08:26:03, 08:56:03, 08:155, 39:63, 39:69, 40:43, 40:50:01:01-40:50:01:02, 40:166, 41:27, 41:47, 44:90, 44:277, 45:06, 46:40:01 ^w , 49:67, 50:52, 51:20 ^w , 51:208 ^w , 56:05:01, 56:06, 57:01:20, 57:45, 57:51, 57:69, 58:08:01, 58:111, 78:01:01:02-78:01:02, 78:03, 78:07-78:08, A*23:01:14^w
59	460 bp	1070 bp	21, 52, 60, 62	*13:62, 15:01:02, 15:277-15:278, 40:01:06, 40:26, 40:28, 40:95, 41:02:09, 44:03:40, 44:62, 44:459, 48:01:08, 49:18:01, 50:14, 51:310, 52:01:01:01-52:01:04, 52:01:06-52:01:14, 52:01:16-52:05, 52:07-52:13, 52:14:02-52:17, 52:19-52:24, 52:25:02-52:72, 52:74-52:96N, 52:98-52:101, 53:28, 57:01:32, 58:08:01-58:08:02, 78:05-78:06
60⁵	105 bp	800 bp	18, 27, 35, 37, 49, 51, 52, 53	*07:400, 13:58, 15:202, 15:239, 15:308, 18:01:01:01-18:03:01:03, 18:04:01-18:06, 18:08-18:15, 18:17N-18:28, 18:30-18:32, 18:34-18:36, 18:38-18:47, 18:49-18:65, 18:67-18:78, 18:80-18:106Q, 18:108-18:124, 18:126-18:135:01:02, 18:137-18:154N, 18:156:01:01-18:177, 18:179-18:181, 18:183-18:201, 35:20:01-35:20:02, 35:28:01:01-35:28:01:03, 35:72, 35:95, 35:226, 35:296, 35:439:01:01-35:439:01:02, 37:01:01:01-37:01:05, 37:01:07-37:05, 37:07-37:20, 37:22:01-37:25, 37:27, 37:29-37:56, 37:58-37:59, 37:62-37:66, 37:68-37:78, 37:80-37:81, 37:83-37:95, 40:185, 40:209, 40:308, 40:350, 40:365, 44:83, 44:134, 44:445, 45:22, 49:03, 51:07:01-51:07:02, 51:214, 51:222, 51:251, 51:310,



0197

For *In Vitro* Diagnostic Use
MA123 v01 SSP PI Template
Date: May 2021, Rev. No: 00

101.501-48/12 – including *Taq* polymerase, IFU-01 Visit <https://labproducts.caredx.com> for
101.501-48u/12u – without *Taq* polymerase, IFU-02 “Instructions for Use” (IFU)

Lot No.: **1N1**

Lot-specific information

				52:01:01:01-52:01:12, 52:01:14-52:01:48, 52:03-52:05, 52:07-52:15, 52:17-52:21:02, 52:24-52:31:02, 52:33-52:69, 52:71-52:88, 52:90-52:101, 53:09, 53:17:01-53:17:02, 53:28, 53:38, 53:40, 78:05-78:06
61^{5,9}	90 bp, 120 bp, 150 bp, 180 bp	800 bp	7, 35, 61, 62, 73	*07:11, 07:57, 07:75:01:01-07:75:01:02, 07:240, 07:253, 07:340, 13:39, 13:67, 15:57, 15:135, 27:67, 27:75, 35:27, 35:56, 35:185, 35:203, 35:355, 37:05, 37:60, 40:37, 42:15, 44:75, 44:97, 44:254, 73:01:01:01-73:03, 78:06, 78:09-78:10, C*05:01:28^w, C*06:02:39^w
62	435 bp, 495 bp	1070 bp	39, 42, 55, 56, 67	*07:115, 07:214, 07:246, 07:327, 14:21, 38:26, 39:10:01, 39:16, 39:20, 39:63, 39:89, 39:96, 39:99, 39:131, 39:143, 39:145, 42:06, 42:20, 51:11N, 55:13, 55:58, 56:11, 56:22, 67:01:01-67:01:03, 67:03-67:07
63⁵	95 bp	1070 bp	5, 13, 15, 16, 17, 18, 21, 22, 27, 35, 38, 39, 3901, 3902, 44, 46, 48, 49, 51, 5102, 5103, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 62, 63, 67, 70, 71, 72, 75, 76, 78, 82	*07:68:01-07:68:03, 07:100, 07:214, 07:235, 07:237, 07:262, 08:71, 13:01:01:01-13:02:22, 13:02:24-13:04, 13:06-13:09, 13:11-13:20, 13:22:01-13:23, 13:25-13:33, 13:35-13:45, 13:47-13:50, 13:52-13:70, 13:72-13:78, 13:80-13:121, 13:123Q-13:126, 13:128-13:151, 14:13, 14:23, 14:53, 14:56, 14:96, 15:01:01:01-15:01:04, 15:01:06-15:01:39, 15:01:41-15:01:67, 15:03:01:01-15:05:03, 15:07:01:01-15:12:03, 15:14-15:16:04, 15:18:01:01-15:20, 15:23-15:24:02, 15:26N-15:30:01:03, 15:32:01-15:32:02, 15:34:01-15:35, 15:37-15:40:02, 15:42-15:43, 15:45-15:54, 15:56-15:58, 15:60-15:71, 15:73:01:01-15:76, 15:79N-15:87, 15:90-15:99, 15:101-15:105, 15:108-15:111N, 15:113-15:115, 15:117-15:120, 15:122-15:127, 15:129, 15:131-15:136, 15:138, 15:140, 15:142-15:143, 15:145-15:149N, 15:151-15:155, 15:157-15:161, 15:163-15:167, 15:169, 15:171-15:176, 15:178-15:187, 15:189-15:195, 15:197:01-15:203, 15:205-15:206, 15:209N-15:210, 15:212, 15:215, 15:217-15:229, 15:231-15:232, 15:234-15:239, 15:241-15:247, 15:249, 15:251:01-15:264, 15:266-15:270, 15:272N, 15:274-15:282, 15:284-15:286, 15:288, 15:290, 15:292-15:296, 15:298-15:300, 15:303-15:307, 15:309-15:318, 15:320-15:324, 15:326-15:327, 15:329, 15:331-15:338, 15:340, 15:343-15:344, 15:346-15:348, 15:350-15:351, 15:353-15:355, 15:359, 15:361-15:365, 15:367-15:373, 15:376-15:377Q, 15:379-15:383, 15:385-15:393, 15:397-15:398, 15:401-15:402, 15:406-15:410, 15:412-15:417, 15:419, 15:422, 15:426-15:431, 15:433-15:436, 15:439-15:445, 15:447-15:453, 15:455-15:457, 15:459-15:461, 15:464-15:467, 15:469-15:487N, 15:489-15:490, 15:492-15:494, 15:496N-15:499, 15:501-15:504, 15:506-15:515, 15:517-15:522, 15:525-15:531, 15:533-15:536, 15:538-15:542, 15:545, 15:547-15:552, 15:554, 15:556, 15:558-15:563, 15:565, 15:568, 15:570-15:573, 15:576, 15:579-15:583, 15:585, 18:01:01:01-18:01:03, 18:01:05-18:15, 18:17N-18:19, 18:22-18:39, 18:41-18:60, 18:62-18:102, 18:104-18:121, 18:123-18:137, 18:139-18:164, 18:167-18:188, 18:190-18:198, 18:200-18:201, 27:27, 27:41, 27:136, 27:153, 27:168, 27:180, 35:01:01:01-35:01:49, 35:01:51-35:02:07, 35:02:09-35:08:14, 35:10-35:17:04, 35:19-35:30:01:02, 35:32:01-35:43:01, 35:43:03-35:52, 35:54-35:63, 35:65Q-35:72, 35:74-35:86, 35:89-35:113, 35:115-35:117, 35:119-35:130N, 35:132-35:163, 35:165N-35:173:02N, 35:175-35:204, 35:206-35:214, 35:216N-35:229, 35:231-35:233, 35:235-35:259, 35:262-35:320, 35:323-35:330, 35:332-35:365, 35:367-35:371, 35:373-35:374, 35:376-35:408, 35:410-35:425, 35:427N-35:430N,



0197

For In Vitro Diagnostic Use
MA123 v01 SSP PI Template
Date: May 2021, Rev. No: 00

101.501-48/12 – including *Taq* polymerase, IFU-01
101.501-48u/12u – without *Taq* polymerase, IFU-02

Visit <https://labproducts.caredx.com> for
“Instructions for Use” (IFU)

Lot No.: **1N1**

Lot-specific information

	35:432-35:445, 35:447-35:459N, 35:461N-35:469, 35:471-35:507, 37:35, 37:56, 37:77, 37:84, 37:94, 38:01:01:01-38:21, 38:23-38:62, 38:64-38:65, 38:67-38:69, 38:71-38:86, 38:157-38:167, 38:169, 38:171, 39:01:01:01-39:01:01:17, 39:01:03:01-39:16, 39:18-39:20, 39:22-39:67, 39:69-39:135, 39:137-39:147N, 39:149-39:154, 39:156-39:168, 39:170, 40:26, 40:28, 40:35:01-40:35:02, 40:71, 40:77, 40:87:01-40:87:02, 40:95, 40:121, 40:158, 40:184, 40:222, 40:237, 40:368, 41:24, 42:10, 42:17, 44:10, 44:14, 44:17, 44:43:01-44:43:02, 44:45, 44:51, 44:62, 44:77, 44:82, 44:107, 44:123, 44:135, 44:184, 44:213, 44:230, 44:276, 44:339, 44:459, 45:09, 45:14, 46:01:01:01-46:01:05, 46:01:07-46:05, 46:07N-46:44, 46:46-46:53, 46:55N-46:87, 48:02:01-48:02:03, 48:12, 48:14, 48:25, 48:29, 49:04:01-49:04:02, 51:01:01:01-51:01:49, 51:01:51-51:01:64, 51:01:66-51:09:03, 51:11N-51:16, 51:19-51:23, 51:26-51:41N, 51:43-51:46, 51:48-51:80, 51:82-51:84, 51:86-51:147, 51:149N-51:171, 51:173Q-51:196, 51:198, 51:200-51:215, 51:217-51:222, 51:224-51:226, 51:228-51:253, 51:255-51:260, 51:262-51:273N, 51:275-51:278, 51:280-51:297, 51:299-51:322, 51:324-51:332, 52:01:01:01-52:25:02, 52:27-52:53, 52:55-52:62, 52:64-52:87, 52:89N-52:101, 53:01:01:01-53:01:16, 53:01:18-53:06, 53:08:01-53:61, 53:63, 54:01:01:01-54:10, 54:12-54:14, 54:16-54:43, 55:01:01:01-55:03, 55:05, 55:07, 55:09-55:19, 55:21-55:40, 55:42-55:48, 55:50, 55:52-55:57, 55:59-55:85, 55:87-55:111, 56:01:01:01-56:01:03, 56:01:05-56:19N, 56:21-56:77N, 57:01:01:01-57:01:04, 57:01:06-57:03:05, 57:06-57:12, 57:14:01-57:30, 57:33-57:40, 57:42-57:46, 57:48-57:94, 57:96-57:141, 58:01:01:01-58:01:02, 58:01:04-58:01:29, 58:01:31-58:02:02, 58:04-58:26, 58:28:01-58:29, 58:31N-58:45:02, 58:47-58:60, 58:62-58:85, 58:87-58:113, 58:115-58:126, 58:128N, 59:01:01:01-59:01:01:02, 59:03-59:12, 67:01:01-67:02:01:02, 67:04-67:07, 78:01:01:02-78:10, 82:01:01:01-82:04, C*14:92, C*15:126		
64¹⁶	-	-	Negative Control

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 low resolution 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



0197

For *In Vitro* Diagnostic Use
MA123 v01 SSP PI Template
Date: May 2021, Rev. No: 00

101.501-48/12 – including Taq polymerase, IFU-01
101.501-48u/12u – without Taq polymerase, IFU-02

Visit <https://labproducts.caredx.com> for
“Instructions for Use” (IFU)

Lot No.: 1N1

Lot-specific information

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.

³The serological reactivity of all HLA-B alleles is not known. In this table we use the expert-assigned serological grouping in Tissue Antigens (2009) 73:95-170 and the serological grouping of the sequence-defined allele.

⁴For 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.

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

⁶Primer mix 4 may give rise to a lower yield of HLA-specific PCR product than the other HLA-B low resolution primer mixes regarding the B*40, B*41, B*45, B*49 and B*50 alleles.

⁷Primer mixes 4, 5, 39, 45 may give rise to a lower yield of HLA-specific PCR product than the other HLA-B low resolution primer mixes.

⁸Primer mixes 1, 19, 20, 26 and 45 have a tendency to giving rise to primer oligomer formation.

⁹Primer mixes 4, 13, 18, 31, 35, 38, 42, 46, 55, 58 and 61 may have tendencies of unspecific amplifications.

¹⁰Primer mix 25 might faintly amplified the C*17 alleles.

¹¹Primer mix 43 may generate a false positive band of about 800 base pairs. This band should be disregarded when interpreting HLA-B low resolution typings.

¹²The Bw4-associated HLA-A specificities A9, A23, A24, A2403, A25 and A32 are not amplified by the primer pair in primer mix 46.

¹³Primer mix 39 may give rise to a lower yield of HLA-specific PCR product than the other HLA-B low resolution primer mixes in the B*54 alleles.

¹⁴In primer mix 56 the specific PCR product of 550 base pairs may give rise to a lower yield of HLA-specific PCR product than the other HLA-B low primer mixes. Optimized gel electrophoresis run time may need to be considered to ensure separation from the control band.

¹⁵In primer mix 38, the positive control band might be weaker compared to the other HLA-B low resolution primer mixes.

¹⁶Primer mix 64 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 v01 SSP PI Template
Date: May 2021, Rev. No: 00

101.501-48/12 – including *Taq* polymerase, IFU-01
101.501-48u/12u – without *Taq* polymerase, IFU-02

Visit <https://labproducts.caredx.com> for
“Instructions for Use” (IFU)

Lot No.: **1N1**

Lot-specific information
PRIMER SPECIFICATION

Well No.	1	2	3	4	5	6	7	8	9	10	11	12
Length of spec.	110	215	140	105	185	190	290	165	180	180	100	280
PCR product			235	140	235			225	390		195	
				260				285				
								330				
Length of int.	800	1070	1070	800	800	800	1070	1070	1070	800	1070	1070
pos. control ¹												
5'-primer(s) ²	527	97	209	103	103	103	45	45	45	420	206	419
	5'-TgA 3'	5'-TCg 3'	5'-ggC 3'	5'-CCg 3'	5'-CCT 3'	5'-CCg 3'	5'-ggA 3'	5'-ggA 3'	5'-ggA 3'	5'-TTA 3'	5'-AgA 3'	5'-gTC 3'
	539		363	103	103	418		357			416	
	5'-gCg 3'		5'-AgC 3'	5'-CCg 3'	5'-CCT 3'	5'-Agg 3'		5'-Tgg 3'			5'-CCg 3'	
	540		363	361	363			412			420	
	5'-gAC 3'		5'-AgC 3'	5'-AgT 3'	5'-AAT 3'			5'-ATA 3'			5'-TTA 3'	
				363							420	
				5'-AgC 3'							5'-TTC 3'	
3'-primer(s) ³	605	272	309	167	246	246	165	206	1 st I	559	256	3 rd I
	5'-gCT 3'	5'-Tgg 3'	5'-gTg 3'	5'-ACA 3'	5'-TAT 3'	5'-TAT 3'	5'-Tgg 3'	5'-CCT 3'	5'-gAC 3'	5'-CTC 3'	5'-CCC 3'	5'-TAT 3'
		272	312	193	246	572		538	266		272	
		5'-TgA 3'	5'-gCC 3'	5'-CgT 3'	5'-TAT 3'	5'-gCC 3'		5'-gTC 3'	5'-TCC 3'		5'-Tgg 3'	
		272	559	193	559			603			572	
		5'-TgT 3'	5'-CAg 3'	5'-CgT 3'	5'-CTC 3'			5'-gTg 3'			5'-gCg 3'	
				463								
				5'-gCT 3'								
				583								
				5'-gTg 3'								
Well No.	1	2	3	4	5	6	7	8	9	10	11	12



0197

For *In Vitro* Diagnostic Use
MA123 v01 SSP PI Template
Date: May 2021, Rev. No: 00

101.501-48/12 – including *Taq* polymerase, IFU-01
101.501-48u/12u – without *Taq* polymerase, IFU-02

Visit <https://labproducts.caredx.com> for
“Instructions for Use” (IFU)

Lot No.: **1N1**

Lot-specific information

Well No.	13	14	15	16	17	18	19	20	21	22	23	24
Length of spec.	195	105	115	80	100	140	55	210	170	110	395	160
PCR product		395	150		150		245					425
		435					390					
							415					
Length of int.	1070	800	1070	1070	800	1070	1070	800	800	1070	1070	1070
pos. control ¹												
5'-primer(s) ²	142	45	161	167	349	206	45	142	407	246	44	44
	5'-TCT 3'	5'-ggA 3'	5'-Cgg 3'	5'-gCT 3'	5'-CTT 3'	5'-gAC 3'	5'-ggA 3'	5'-TCT 3'	5'-gg 3'	5'-gAA 3'	5'-ggC 3'	5'-ggC 3'
	419	540			355		368	368	409			357
	5'-gTC 3'	5'-gAC 3'			5'-TCA 3'		5'-gTT 3'	5'-gTC 3'	5'-ggC 3'			5'-Tgg 3'
							557		409			
							5'-ggA 3'		5'-ggC 3'			
									420			
									5'-TTA 3'			
3'-primer(s) ³	301	272	234	204	412	301	259	311	544	317	272	302
	5'-gTC 3'	5'-TgC 3'	5'-TCT 3'	5'-TCT 3'	5'-gTT 3'	5'-gCT 3'	5'-gTT 3'	5'-ggg 3'	5'-ggT 3'	5'-ggA 3'	5'-TgC 3'	5'-ggC 3'
	301	272	272		463	302	259	311		320		302
	5'-gTC 3'	5'-TgT 3'	5'-TgA 3'		5'-gCT 3'	5'-ggC 3'	5'-gTT 3'	5'-ggg 3'		5'-AgT 3'		5'-ggT 3'
	570	309	272			311	266	538				477
	5'-CCg 3'	5'-ATC 3'	5'-Tgg 3'			5'-ggT 3'	5'-TCC 3'	5'-gTC 3'				5'-gCg 3'
	572	605				312	272					
	5'-gCg 3'	5'-gCT 3'				5'-AgT 3'	5'-Tgg 3'					
							292					
							5'-gTA 3'					
							572					
							5'-gCg 3'					
Well No.	13	14	15	16	17	18	19	20	21	22	23	24

Well No.	25	26	27	28	29	30	31	32	33	34	35	36
Length of spec.	180	130	105	325	80	215	130	90	90	55	120	390
PCR product		290			115		280	410	175	105	210	430
		465			160					145		
		570			195					395		
					225					430		
					260							
Length of int.	1070	1070	1070	800	1070	800	800	1070	1070	1070	800	1070
pos. control ¹												
5'-primer(s) ²	355	72	540	1 st I	355	141	209	41	209	48	357	49
	5'-TCA 3'	5'-gCT 3'	5'-gAC 3'	5'-CAg 3'	5'-TCA 3'	5'-ATT 3'	5'-ggC 3'	5'-CTg 3'	5'-ggC 3'	5'-gCC 3'	5'-Tgg 3'	5'-CAg 3'
	363	103			418	357	209	368	363	206		
	5'-Agg 3'	5'-CCT 3'			5'-Agg 3'	5'-Tgg 3'	5'-ggg 3'	5'-gTT 3'	5'-AgC 3'	5'-gAA 3'		
		209			499		355			259		
		5'-ggC 3'			5'-TCT 3'		5'-TCA 3'			5'-ggg 3'		
3'-primer(s) ³	499	193	603	282	538	309	299	282	259	272	435	272
	5'-ggA 3'	5'-CgT 3'	5'-gTg 3'	5'-gCC 3'	5'-gTC 3'	5'-ATC 3'	5'-TCA 3'	5'-gCC 3'	5'-gTT 3'	5'-TgT 3'	5'-TCT 3'	5'-TgC 3'
		193	603		572	538	583	418	499	309	527	309
		5'-TgT 3'	5'-gTg 3'		5'-gCA 3'	5'-gTC 3'	5'-gTg 3'	5'-gTC 3'	5'-ggA 3'	5'-ATC 3'	5'-CCT 3'	5'-ATC 3'
		387	605		572		605					
		5'-TCg 3'	5'-gCT 3'		5'-gCg 3'		5'-gCT 3'					
					573							
					5'-AgT 3'							
Well No.	25	26	27	28	29	30	31	32	33	34	35	36



0197

For *In Vitro* Diagnostic Use
MA123 v01 SSP PI Template
Date: May 2021, Rev. No: 00

101.501-48/12 – including *Taq* polymerase, IFU-01
101.501-48u/12u – without *Taq* polymerase, IFU-02

Visit <https://labproducts.caredx.com> for
“Instructions for Use” (IFU)

Lot No.: **1N1**

Lot-specific information

Well No.	37	38	39	40	41	42	43	44	45	46	47	48
Length of spec.	145	300	160	180	180	90	90	95	115	360	350	285
PCR product	210		370	210	205	150			150			
				240		415						
Length of int.	1070	1070	1070	1070	1070	800	1070	1070	1070	1070	1070	1070
pos. control ¹												
5'-primer(s) ²	142	1 st I	15	141	97	15	207	206	165	1 st I	1 st I	355
	5'-TCA 3'	5'-CAG 3'	5'-gCA 3'	5'-ATT 3'	5'-TCg 3'	5'-gCA 3'	5'-ACC 3'	5'-gAC 3'	5'-ACC 3'	5'-CAg 3'	5'-CAg 3'	5'-TCA 3'
	206		418	362	420	209	208		463			363
	5'-gAA 3'		5'-Agg 3'	5'-gAC 3'	5'-TTA 3'	5'-ggC 3'	5'-CgT 3'		5'-TgA 3'			5'-AgC 3'
				362		209	209					
				5'-ggT 3'		5'-ggA 3'	5'-ggA 3'					
				420		449	369					
				5'-TTA 3'		5'-CCC 3'	5'-TAC 3'					
							369					
							5'-TAT 3'					
3'-primer(s) ³	311	259	207	311	259	256	256	259	272	317	311	603
	5'-ggT 3'	5'-CTC 3'	5'-TCC 3'	5'-ggT 3'	5'-gTT 3'	5'-CCC 3'	5'-CCC 3'	5'-gTT 3'	5'-TgC 3'	5'-ggA 3'	5'-ggT 3'	5'-gTg 3'
		259	226	559	559	259	256		538	320		605
		5'-CTC 3'	5'-CAC 3'	5'-CgT 3'	5'-CAg 3'	5'-CTT 3'	5'-CTC 3'		5'-CCA 3'	5'-AgT 3'		5'-gCT 3'
		262	538			263	420					
		5'-TgC 3'	5'-gTC 3'			5'-gTT 3'	5'-gCT 3'					
						559						
						5'-CgT 3'						
Well No.	37	38	39	40	41	42	43	44	45	46	47	48

Well No.	49	50	51	52	53	54	55	56	57	58	59	60
Length of spec.	165	260	390	380	160	125	205	550	105	90	460	105
PCR product	190					150	235			125		
						260				155		
										190		
Length of int.	1070	800	1070	1070	1070	800	1070	1070	1070	1070	1070	800
pos. control ¹												
5'-primer(s) ²	435	363	49	317	106	206	363	272	206	141	256	206
	5'-AAA 3'	5'-Agg 3'	5'-CAg 3'	5'-gCT 3'	5'-CCA 3'	5'-gAA 3'	5'-AgC 3'	5'-CTA 3'	5'-AgA 3'	5'-ATT 3'	5'-ACg 3'	5'-gAC 3'
						234	363			206	272	
						5'-CAA 3'	5'-AgC 3'			5'-gAA 3'	5'-CTC 3'	
						355						
						5'-TCA 3'						
3'-primer(s) ³	559	583	272	412	226	317	527	538	272	256	435	272
	5'-CAg 3'	5'-gTg 3'	5'-TgA 3'	5'-gTT 3'	5'-CAC 3'	5'-ggA 3'	5'-CCT 3'	5'-gTC 3'	5'-TgT 3'	5'-CCC 3'	5'-TCT 3'	5'-Tgg 3'
	583					572	559			292		
	5'-gTg 3'					5'-gCg 3'	5'-CTC 3'			5'-gTC 3'		
						572						
						5'-gTg 3'						
Well No.	49	50	51	52	53	54	55	56	57	58	59	60



0197

For *In Vitro* Diagnostic Use
MA123 v01 SSP PI Template
Date: May 2021, Rev. No: 00

101.501-48/12 – including *Taq* polymerase, IFU-01
101.501-48u/12u – without *Taq* polymerase, IFU-02

Visit <https://labproducts.caredx.com> for
“Instructions for Use” (IFU)

Lot No.: **1N1**

Lot-specific information

Well No.	61	62	63
Length of spec.	90	435	95
PCR product	120	495	
	150		
	180		
Length of int.	800	1070	1070
pos. control ¹			
5'-primer(s) ²	165	272	407
	5'-ACC 3'	5'-CTA 3'	5'-gg 3'
	222	3 rd I	409
	5'-CCA 3'	5'-CTT 3'	5'-ggC 3'
			409
			5'-ggC 3'
3'-primer(s) ³	272	419	463
	5'-TgC 3'	5'-CgA 3'	5'-gCT 3'
	302	621	
	5'-ggT 3'	5'-ggg 3'	
Well No.	61	62	63

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 v01 SSP PI Template
Date: May 2021, Rev. No: 00

101.501-48/12 – including *Taq* polymerase, IFU-01
101.501-48u/12u – without *Taq* polymerase, IFU-02

Visit <https://labproducts.caredx.com> for
“Instructions for Use” (IFU)

Lot No.: 1N1

Lot-specific information

CELL LINE VALIDATION SHEET																					
HLA-B low resolution SSP kit ²																					
					Prod. No.:	Well															
						1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
						202026401	202026402	202026403	202129204	202026405	202129206	202026407	202026408	201890609	202026410	202026411	202026412	202026413	202026414	202026415	202026416
	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		-	-	-	-	+	-	-	-	-	-	-	+	-	-	-	-



0197

For *In Vitro* Diagnostic Use
MA123 v01 SSP PI Template
Date: May 2021, Rev. No: 00

101.501-48/12 – including *Taq* polymerase, IFU-01
101.501-48u/12u – without *Taq* polymerase, IFU-02

Visit <https://labproducts.caredx.com> for
“Instructions for Use” (IFU)

Lot No.: **1N1**

Lot-specific information

CELL LINE VALIDATION SHEET																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																
HLA-B low resolution SSP kit ²																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																
					Well																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																											
					17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																												
					202129217	202026418	202026419	202129220	202130321	202026422	202026423	202129224	202026425	202026426	202026427	202026428	202026429	202026430	202026431	202026432																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																												
Prod. No.:																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																
IHCW cell line ¹			B*																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																													
1	9001	SA	*07:02		-	-	-	-	-	-	-	+	-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-



0197

For *In Vitro* Diagnostic Use
MA123 v01 SSP PI Template
Date: May 2021, Rev. No: 00

101.501-48/12 – including *Taq* polymerase, IFU-01
101.501-48u/12u – without *Taq* polymerase, IFU-02

Visit <https://labproducts.caredx.com> for
“Instructions for Use” (IFU)

Lot No.: **1N1**

Lot-specific information

CELL LINE VALIDATION SHEET																					
HLA-B low resolution SSP kit ²																					
					Well																
						33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48
				Prod. No.:		202026433	202026434	202026435	202026436	202130337	202129238	202026439	202026440	202026441	202026442	202026443	202026444	202026445	202024846	202026447	202026448
	IHWC cell line ¹		B*																		
1	9001 SA		*07:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+
2	9280 LK707		*52:01	*73:01	-	-	+	+	-	+	-	-	-	-	-	-	-	+	+	+	-
3	9011 E4181324		*52:01		-	-	+	+	-	+	-	-	-	-	-	-	-	-	+	-	-
4	9275 GU373		*15:10	*53:01	-	-	-	+	-	-	-	-	-	-	-	-	+	-	+	+	-
5	9009 KAS011		*37:01		-	-	-	-	-	+	-	-	-	-	-	-	-	-	+	-	-
6	9353 SM		*39:01	*51:01	-	-	+	+	-	-	-	-	-	-	-	-	+	-	+	+	-
7	9020 QBL		*18:01		-	-	-	-	-	-	-	-	-	-	-	-	+	-	-	+	-
8	9025 DEU		*35:01		-	-	-	-	-	-	-	-	-	-	-	-	+	-	-	+	-
9	9026 YAR		*38:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-	-
10	9107 LKT3		*54:01		-	-	-	-	-	-	-	+	+	-	-	-	-	-	-	+	-
11	9051 PITOUT		*44:03		-	-	-	-	-	+	-	-	-	-	-	-	-	-	+	-	-
12	9052 DBB		*57:01		-	-	-	+	-	-	-	-	-	-	+	-	-	-	+	-	-
13	9004 JESTHOM		*27:05		-	-	-	-	-	+	-	-	-	-	-	-	-	-	+	-	-
14	9071 OLGA		*15:01	*15:20	-	-	-	-	-	+	-	-	-	-	-	-	-	+	-	+	-
15	9075 DKB		*40:01		-	-	-	-	+	+	-	-	-	-	-	-	-	-	-	+	-
16	9037 SWEIG007		*40:02		-	-	-	-	+	+	-	-	-	-	-	-	-	-	-	+	-
17	9282 CTM3953540		*08:01	*55:01	-	-	+	-	-	-	-	-	+	-	-	-	-	-	-	+	+
18	9257 32367		*14:01	*56:01	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	+	-
19	9038 BM16		*18:01		-	-	-	-	-	-	-	-	-	-	-	-	+	-	-	+	-
20	9059 SLE005		*40:01		-	-	-	-	+	+	-	-	-	-	-	-	-	-	-	+	-
21	9064 AMALA		*15:01		-	-	-	-	-	+	-	-	-	-	-	-	-	+	-	+	-
22	9056 KOSE		*35:03		-	-	-	-	-	-	-	-	-	-	-	-	+	-	-	+	-
23	9124 IHL		*40:02	*56:02	-	-	-	-	+	+	-	-	-	+	-	+	-	-	-	+	-
24	9035 JBUSH		*38:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-	-
25	9049 IBW9		*14:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-
26	9285 WT49		*58:01		-	-	-	+	-	-	-	-	-	-	-	+	-	-	+	-	-
27	9191 CH1007		*07:05	*51:01	-	-	+	+	-	-	-	-	-	-	-	-	+	-	+	+	+
28	9320 BEL5GB		*44:02	*44:03	-	-	-	-	-	+	+	-	-	-	-	-	-	-	+	-	-
29	9050 MOU		*44:03		-	-	-	-	-	+	-	-	-	-	-	-	-	-	+	-	-
30	9021 RSH		*42:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+
31	9019 DUCAF		*18:01		-	-	-	-	-	-	-	-	-	-	-	-	+	-	-	+	-
32	9297 HAG		*41:02		-	-	-	-	+	+	-	-	-	-	-	-	-	-	-	+	+
33	9098 MT14B		*40:01		-	-	-	-	+	+	-	-	-	-	-	-	-	-	-	+	-
34	9104 DHIF		*38:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-	-
35	9302 SSTS		*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

For *In Vitro* Diagnostic Use
MA123 v01 SSP PI Template
Date: May 2021, Rev. No: 00

101.501-48/12 – including *Taq* polymerase, IFU-01
101.501-48u/12u – without *Taq* polymerase, IFU-02

Visit <https://labproducts.caredx.com> for
“Instructions for Use” (IFU)

Lot No.: **1N1**

Lot-specific information

CELL LINE VALIDATION SHEET																						
HLA-B low resolution SSP kit ²																						
					Well																	
					49	50	51	52	53	54	55	56	57	58	59	60	61	62	63			
				Prod. No.:	201903449	201903450	201903451	201903452	201903453	202130354	201903455	201903456	202130357	201903458	201903459	201903460	201903461	201903462	201903463			
	IHWC cell line ¹		B*																			
1	9001 SA		*07:02		-	-	-	-	-	-	+	-	+	-	-	-	-	-	-	-	-	-
2	9280 LK707		*52:01	*73:01	+	-	-	+	-	-	-	-	-	-	+	+	+	-	-	+	+	+
3	9011 E4181324		*52:01		+	-	-	+	-	-	-	-	-	-	+	+	-	-	-	+	+	+
4	9275 GU373		*15:10	*53:01	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+
5	9009 KAS011		*37:01		-	-	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-
6	9353 SM		*39:01	*51:01	+	-	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-	+
7	9020 QBL		*18:01		-	+	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	+
8	9025 DEU		*35:01		-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+
9	9026 YAR		*38:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+
10	9107 LKT3		*54:01		-	-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	+
11	9051 PITOUT		*44:03		-	-	-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-
12	9052 DBB		*57:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+
13	9004 JESTHOM		*27:05		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
14	9071 OLGA		*15:01	*15:20	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+
15	9075 DKB		*40:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
16	9037 SWEIG007		*40:02		-	-	-	-	-	-	+	-	-	-	-	-	-	-	-	-	-	-
17	9282 CTM3953540		*08:01	*55:01	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-	+
18	9257 32367		*14:01	*56:01	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-	+
19	9038 BM16		*18:01		-	+	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	+
20	9059 SLE005		*40:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
21	9064 AMALA		*15:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+
22	9056 KOSE		*35:03		-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+
23	9124 IHL		*40:02	*56:02	-	-	-	-	-	-	+	-	+	-	-	-	-	-	-	-	-	-
24	9035 JBUSH		*38:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+
25	9049 IBW9		*14:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
26	9285 WT49		*58:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+
27	9191 CH1007		*07:05	*51:01	+	-	+	+	-	-	+	-	+	-	-	-	-	-	-	-	-	+
28	9320 BEL5GB		*44:02	*44:03	-	-	-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-
29	9050 MOU		*44:03		-	-	-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-
30	9021 RSH		*42:01		-	-	-	-	-	-	-	+	+	-	-	-	-	-	-	-	-	-
31	9019 DUCAF		*18:01		-	+	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	+
32	9297 HAG		*41:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
33	9098 MT14B		*40:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
34	9104 DHIF		*38:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+
35	9302 S8TO		*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

For *In Vitro* Diagnostic Use
MA123 v01 SSP PI Template
Date: May 2021, Rev. No: 00

101.501-48/12 – including *Taq* polymerase, IFU-01
101.501-48u/12u – without *Taq* polymerase, IFU-02

Visit <https://labproducts.caredx.com> for
“Instructions for Use” (IFU)

Lot No.: **1N1**

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.

One or more 5'-primers and/or 3'-primers in primer solutions 3, 6, 11, 14, 19, 29, 31, 40 to 42 and 58 were tested by separately adding one or two 3'-primers, and one or two 5'-primers accordingly.

In addition, one or more 3'-primers in primer solutions 2, 4, 8, 13, 15, 18, 34 and 36 were tested by separately adding one or two 5'-primers.

In addition, one or more 5'-primers in primer solutions 1, 21, 25, 26, 43, 48, 54, 59 and 61 were tested by separately adding one or two 3'-primers.

In primer solutions 11, 17, 21, 31, 42, 43 and 63 one or two 5'-primers were not possible to be tested, and in primer solutions 3, 9, 22, 27, 29, 38, 39, 42, 46, 54 and 55 one or two 3'-primers were not possible to be tested.



0197

For *In Vitro* Diagnostic Use
MA123 v01 SSP PI Template
Date: May 2021, Rev. No: 00

101.501-48/12 – including *Taq* polymerase, IFU-01
101.501-48u/12u – without *Taq* polymerase, IFU-02

Visit <https://labproducts.caredx.com> for
“Instructions for Use” (IFU)

Lot No.: **1N1**

Lot-specific information

ADDRESSES:

Manufacturer:

CareDx AB, Franzengatan 5, SE-112 51 Stockholm, Sweden.

Tel: +46-8-508 939 00

Fax: +46-8-717 88 18

E-mail: orders-se@caredx.com

Web page: <https://labproducts.caredx.com/>

CareDx Lab Solutions Inc., 901 S. Bolmar St., Suite R, West Chester, PA 19382

Tel: 1-877-653-78171

Fax: 610-344-7989

E-mail: orders-us@caredx.com

Web page: <https://labproducts.caredx.com/>

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



0197

For *In Vitro* Diagnostic Use
MA123 v01 SSP PI Template
Date: May 2021, Rev. No: 00