

101.418-12/04 – including *Taq* pol., IFU-01
101.418-12u/04 – without *Taq* pol., IFU-02

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

Lot No.: **8N9**

Lot-specific information
Olerup SSP® HLA-A*68

Product number:	101.418-12/04 – including <i>Taq</i> pol. 101.418-12u/04u – without <i>Taq</i> pol.
Lot number:	8N9
Expiry date:	2026-04-01
Number of tests:	12 tests – Product No. 101.418-12/12u 4 tests – Product No. 101.418-04/04u
Number of wells per test:	47+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. 8N9.

Complete product documentation consists of generic Instructions for Use (IFU), lot specific Product Insert, Worksheet and Certificate.

**CHANGES COMPARED TO THE PREVIOUS OLERUP SSP®
HLA-A*68 LOT (2K9)**

- The product documentation has been updated for new alleles of IMGT 3.47.0
- The kit resolution focuses on common and well documented (CWD) alleles¹.

¹As described in section Uniquely Identified Alleles.

The HLA-A*68 primer set, specificity and interpretation tables have been updated for the HLA-A alleles described since the previous *Olerup SSP®* HLA-A*68 lot was made (**Lot No. 2K9**).

¹S. J. Mack, P. Cano, J. A. Hollenbach et al.
Common and well-documented HLA alleles: 2012 update to
the CWD catalogue. Tissue Antigens, 2013, 81, 194–203



0197

For *In Vitro* Diagnostic Use
MA123 v01 SSP PI Template
Date: April 2022, Rev. No: 00

101.418-12/04 – including *Taq* pol., IFU-01
 101.418-12u/04 – without *Taq* pol., IFU-02

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

Lot No.: **8N9**

Lot-specific information

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

Well	5'-primer	3'-primer	rationale
9	-	Modified	3'-primer modified for reduced tendency of primer oligomer formation.



0197

For *In Vitro* Diagnostic Use
 MA123 v01 SSP PI Template
 Date: April 2022, Rev. No: 00

101.418-12/04 – including *Taq* pol., IFU-01
101.418-12u/04 – without *Taq* pol., IFU-02

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

Lot No.: **8N9**

Lot-specific information

Well **48** contains Negative Control primer pairs, that will amplify a majority of the *Olerup* SSP® HLA Class I, DRB, DQB1, DPB1 and DQA1 amplicons as well as all the amplicons generated by the control primer pairs matching the human growth hormone gene.

HLA-specific PCR product sizes range from 75 to 200 base pairs.
The PCR products 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: April 2022, Rev. No: 00

101.418-12/04 – including *Taq* pol., IFU-01
101.418-12u/04 – without *Taq* pol., IFU-02

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

Lot No.: **8N9**

Lot-specific information
PRODUCT DESCRIPTION

HLA-A*68 SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for identifying the A*68:01 to A*68:285 alleles.

PLATE LAYOUT

Each test consists of 48 PCR reactions in a 48 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	NC

The 48 well cut PCR plate is marked with ‘HLA-A*68’ in silver gray ink.

Well No. 1 is marked with the Lot No ‘8N9’.

Wells 1 to 47 – HLA-A*68 high resolution primers.

Well 48 – Negative Control (NC).

A faint row of numbers is seen between wells 1 and 2 or wells 7 and 8 of the PCR trays. These stem from the manufacture of the trays, and should be disregarded.

The PCR plates are heat-sealed with a PCR-compatible foil.

Please note: When removing each 48 well PCR plate, make sure that the remaining plates stay sealed. Use a scalpel or a similar instrument to carefully cut the foil between the plates.

INTERPRETATION

Due to the sharing of sequence motifs between HLA-A alleles non-HLA-A*68 alleles will be amplified by some primer mixes. For further details see Specificity Table.

UNIQUELY IDENTIFIED ALLELES

All the HLA-A*68 alleles, i.e. **A*68:01 to A*68:285**, recognized by the HLA Nomenclature Committee in January 2022^{1,2} will be amplified by the primers in the HLA-A*68 subtyping kit³.

The HLA-A*68 kit enables separation of the confirmed HLA-A*68 alleles as listed in the IMGT/HLA database 3.25.0. An HLA allele is listed as confirmed by IMGT/HLA if it has been sequenced by more than a single laboratory or from multiple sources. Current allele confirmation status for HLA-A*68 alleles is listed below.

The HLA-A*68 kit also enables identification of many null and alternatively expressed alleles.



0197

For *In Vitro* Diagnostic Use
MA123 v01 SSP PI Template
Date: April 2022, Rev. No: 00

101.418-12/04 – including *Taq* pol., IFU-01
101.418-12u/04 – without *Taq* pol., IFU-02

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

Lot No.: **8N9**

Lot-specific information

The following HLA-A*68 alleles can be distinguished by the different sizes of the HLA-specific PCR product:

Alleles	Primer mix	Alleles	Primer mix
A*68:19, 68:158	15	A*68:68, 68:106	39
A*68:52, 68:142N	46	A*68:99:01, 68:101:01	42

¹HLA-A alleles listed on the IMGT/HLA web page 2022-January-13, release 3.47.0, www.ebi.ac.uk/imgt/hla.

²Alleles that have been deleted from or renamed in the official WHO HLA Nomenclature up to and including the last IMGT/HLA database release can be retrieved from web page <http://hla.alleles.org/alleles/deleted.html>.

³The HLA-A*68 primer set cannot separate the following alleles. These alleles can be distinguished by the HLA-A low resolution kit and/or the HLA-A*34 high resolution kit.

Alleles
A*68:276Q, 34:02:01:01-34:02:01:03, 34:02:02-34:02:03, 34:02:05-34:02:06, 34:20, 34:22, 34:25-34:26N



0197

101.418-12/04 – including *Taq* pol., IFU-01
101.418-12u/04 – without *Taq* pol., IFU-02

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

Lot No.: **8N9**

Lot-specific information

ALLELE CONFIRMATION STATUS

Allele	Status ¹	Allele	Status ¹	Allele	Status ¹	Allele	Status ¹
A*68:01:01:01	Confirmed	A*68:03:02	Unconfirmed	A*68:46	Confirmed	A*68:93	Confirmed
A*68:01:01:02	Confirmed	A*68:03:03	Confirmed	A*68:47	Unconfirmed	A*68:94N	Unconfirmed
A*68:01:02:01	Confirmed	A*68:04:01	Unconfirmed	A*68:48	Unconfirmed	A*68:95	Unconfirmed
A*68:01:02:02	Confirmed	A*68:04:02	Unconfirmed	A*68:49N	Unconfirmed	A*68:96	Confirmed
A*68:01:02:03	Confirmed	A*68:05	Confirmed	A*68:50	Unconfirmed	A*68:97	Unconfirmed
A*68:01:03	Unconfirmed	A*68:06	Confirmed	A*68:51	Unconfirmed	A*68:98	Unconfirmed
A*68:01:04	Unconfirmed	A*68:07	Confirmed	A*68:52	Unconfirmed	A*68:99	Confirmed
A*68:01:05	Unconfirmed	A*68:08:01	Unconfirmed	A*68:53	Confirmed	A*68:100	Unconfirmed
A*68:01:06	Confirmed	A*68:08:02	Confirmed	A*68:54	Confirmed	A*68:101	Confirmed
A*68:01:07	Unconfirmed	A*68:09	Unconfirmed	A*68:55:01	Confirmed	A*68:102	Unconfirmed
A*68:01:08	Confirmed	A*68:10	Confirmed	A*68:55:02	Unconfirmed	A*68:103:01	Unconfirmed
A*68:01:09	Unconfirmed	A*68:11N	Confirmed	A*68:56	Unconfirmed	A*68:103:02	Unconfirmed
A*68:01:10	Unconfirmed	A*68:12	Confirmed	A*68:57	Unconfirmed	A*68:104:01	Confirmed
A*68:01:11	Unconfirmed	A*68:13:01	Confirmed	A*68:58	Unconfirmed	A*68:104:02	Unconfirmed
A*68:01:12	Unconfirmed	A*68:13:02	Unconfirmed	A*68:59N	Confirmed	A*68:105	Unconfirmed
A*68:01:13	Unconfirmed	A*68:14	Unconfirmed	A*68:60	Confirmed	A*68:106	Confirmed
A*68:01:14	Unconfirmed	A*68:15	Confirmed	A*68:61	Unconfirmed	A*68:107	Unconfirmed
A*68:01:15	Unconfirmed	A*68:16	Confirmed	A*68:62	Unconfirmed	A*68:108	Unconfirmed
A*68:01:16	Unconfirmed	A*68:17	Confirmed	A*68:63	Unconfirmed	A*68:109	Unconfirmed
A*68:01:17	Unconfirmed	A*68:18N	Confirmed	A*68:64	Unconfirmed	A*68:110	Confirmed
A*68:01:18	Unconfirmed	A*68:19	Confirmed	A*68:65	Confirmed	A*68:111	Unconfirmed
A*68:01:19	Unconfirmed	A*68:20	Unconfirmed	A*68:66	Unconfirmed	A*68:112:01	Unconfirmed
A*68:01:20	Confirmed	A*68:21:01	Unconfirmed	A*68:67	Confirmed	A*68:112:02	Confirmed
A*68:01:21	Unconfirmed	A*68:21:02	Unconfirmed	A*68:68	Confirmed	A*68:113	Unconfirmed
A*68:01:22	Confirmed	A*68:22	Unconfirmed	A*68:69	Unconfirmed	A*68:114	Unconfirmed
A*68:01:23	Unconfirmed	A*68:23	Unconfirmed	A*68:70	Unconfirmed	A*68:115	Unconfirmed
A*68:01:24	Confirmed	A*68:24	Confirmed	A*68:71	Unconfirmed	A*68:116	Unconfirmed
A*68:01:25	Confirmed	A*68:25	Confirmed	A*68:72	Confirmed	A*68:117	Confirmed
A*68:01:26	Confirmed	A*68:26	Unconfirmed	A*68:73	Unconfirmed	A*68:118	Unconfirmed
A*68:01:27	Unconfirmed	A*68:27:01	Confirmed	A*68:74	Unconfirmed	A*68:119:01	Unconfirmed
A*68:01:28	Unconfirmed	A*68:27:02	Unconfirmed	A*68:75:01	Unconfirmed	A*68:119:02	Unconfirmed
A*68:01:29	Unconfirmed	A*68:28	Unconfirmed	A*68:75:02	Unconfirmed	A*68:120N	Unconfirmed
A*68:01:30	Unconfirmed	A*68:29	Unconfirmed	A*68:76:01	Unconfirmed	A*68:121	Unconfirmed
A*68:01:31	Confirmed	A*68:30	Unconfirmed	A*68:76:02	Unconfirmed	A*68:122	Unconfirmed
A*68:01:32	Unconfirmed	A*68:31	Confirmed	A*68:77	Unconfirmed	A*68:123	Confirmed
A*68:02:01:01	Confirmed	A*68:32	Unconfirmed	A*68:78	Unconfirmed	A*68:124	Unconfirmed
A*68:02:01:02	Unconfirmed	A*68:33	Confirmed	A*68:79	Unconfirmed	A*68:125	Unconfirmed
A*68:02:01:03	Confirmed	A*68:34	Unconfirmed	A*68:80	Confirmed	A*68:126	Unconfirmed
A*68:02:02	Confirmed	A*68:35	Confirmed	A*68:81	Unconfirmed	A*68:127	Unconfirmed
A*68:02:03	Confirmed	A*68:36	Confirmed	A*68:82	Unconfirmed	A*68:128	Unconfirmed
A*68:02:04	Confirmed	A*68:37	Confirmed	A*68:83	Unconfirmed	A*68:129	Unconfirmed
A*68:02:05	Unconfirmed	A*68:38	Unconfirmed	A*68:84	Unconfirmed	A*68:130	Unconfirmed
A*68:02:06	Unconfirmed	A*68:39	Unconfirmed	A*68:85	Unconfirmed	A*68:131	Unconfirmed
A*68:02:07	Unconfirmed	A*68:40	Confirmed	A*68:86	Confirmed	A*68:132	Unconfirmed
A*68:02:08	Unconfirmed	A*68:41	Unconfirmed	A*68:87	Unconfirmed	A*68:133	Unconfirmed
A*68:02:09	Unconfirmed	A*68:42	Unconfirmed	A*68:88	Unconfirmed	A*68:134	Unconfirmed
A*68:02:10	Unconfirmed	A*68:43:01	Unconfirmed	A*68:89	Unconfirmed	A*68:135	Unconfirmed
A*68:02:11	Unconfirmed	A*68:43:02	Unconfirmed	A*68:90	Unconfirmed	A*68:136	Unconfirmed
A*68:02:12	Unconfirmed	A*68:44	Confirmed	A*68:91	Confirmed	A*68:137	Unconfirmed
A*68:03:01	Confirmed	A*68:45	Unconfirmed	A*68:92	Unconfirmed	A*68:138	Unconfirmed



0197

For *In Vitro* Diagnostic Use
MA123 v01 SSP PI Template
Date: April 2022, Rev. No: 00

101.418-12/04 – including *Taq* pol., IFU-01
101.418-12u/04 – without *Taq* pol., IFU-02

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

Lot No.: **8N9**

Lot-specific information

Allele	Status ¹
A*68:139	Unconfirmed
A*68:140	Unconfirmed
A*68:141	Unconfirmed
A*68:142N	Unconfirmed
A*68:143	Unconfirmed
A*68:144	Unconfirmed
A*68:145	Unconfirmed
A*68:146	Unconfirmed
A*68:147	Unconfirmed
A*68:148Q	Unconfirmed

¹Allele status “confirmed” or “unconfirmed” as listed on the IMGT/HLA web page 2016-July-14, release 3.25.0, www.ebi.ac.uk/imgt/hla.

RESOLUTION IN HOMO- AND HETEROZYGOTES

Results file with resolution in HLA-A*68 homo- and heterozygotes is available upon request.



0197

For *In Vitro* Diagnostic Use
MA123 v01 SSP PI Template
Date: April 2022, Rev. No: 00

101.418-12/04 – including *Taq* pol., IFU-01
101.418-12u/04 – without *Taq* pol., IFU-02

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

Lot No.: **8N9**

Lot-specific information

SPECIFICITY TABLE

HLA-A*68 SSP subtyping

Specificities and sizes of the PCR products of the 47+1 primer mixes used for HLA-A*68 SSP subtyping

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified HLA-A*68 alleles ³	Other amplified HLA-A alleles
1 ⁵	200 bp	800 bp	*68:01:01:01-68:02:20, 68:06-68:14, 68:16-68:19, 68:21:01-68:30, 68:32-68:35:01:02, 68:37-68:45, 68:46 ^w , 68:47-68:56, 68:58:01-68:83, 68:85-68:89, 68:91, 68:93-68:108, 68:110-68:135, 68:137-68:179, 68:181N-68:205N, 68:207-68:226, 68:228-68:248, 68:250-68:254, 68:256-68:268, 68:270-68:284	*01:13, 01:176, 01:194, 02:34-02:35:03, 02:56:01-02:56:02, 02:62, 02:78, 02:103, 02:580, 02:741, 02:907, 03:01:01:01-03:01:08, 03:01:10-03:01:22, 03:01:24-03:01:36, 03:01:38-03:01:82, 03:01:84-03:01:93, 03:01:95-03:07:02, 03:09-03:31, 03:33-03:35, 03:37-03:40, 03:42-03:56, 03:58-03:88, 03:90-03:106, 03:109-03:110, 03:112-03:141, 03:143-03:151, 03:153-03:160, 03:162N-03:171, 03:174-03:175, 03:177, 03:179-03:193, 03:195-03:197:02N, 03:201-03:202, 03:204-03:205, 03:207-03:210, 03:212-03:218, 03:220-03:251, 03:253-03:259, 03:261-03:266N, 03:268-03:272, 03:274-03:329N, 03:331-03:381N, 03:383-03:397, 03:399-03:412, 03:414-03:428, 03:430-03:439, 11:01:01:01-11:01:50, 11:01:52-11:01:114, 11:03-11:13, 11:15:01-11:15:02, 11:20-11:27, 11:29-11:37, 11:39, 11:41-11:44, 11:46-11:50Q, 11:52Q, 11:54:01-11:56, 11:58-11:70:02, 11:72-11:76, 11:79-11:97, 11:99N-11:100, 11:102-11:105, 11:107-11:109N, 11:112, 11:114-11:120, 11:122-11:139, 11:141-11:146, 11:148:01-11:160, 11:162-11:167, 11:169-11:175, 11:177, 11:179-11:189, 11:191-11:200, 11:202-11:222, 11:224-11:234, 11:236-11:249, 11:251N-11:254, 11:257-11:261, 11:263-11:270, 11:272Q-11:280, 11:282-11:286, 11:288-11:296, 11:298-11:304, 11:306-11:307, 11:309-11:311, 11:313Q-11:343, 11:345, 11:347N-11:349, 11:351Q-11:371,



0197

For *In Vitro* Diagnostic Use
MA123 v01 SSP PI Template
Date: April 2022, Rev. No: 00

101.418-12/04 – including *Taq* pol., IFU-01
101.418-12u/04 – without *Taq* pol., IFU-02

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

Lot No.: **8N9**

Lot-specific information

			11:373-11:379, 11:381-11:395, 11:397N-11:410, 11:412, 11:414- 11:417N, 24:19, 24:290, 24:406, 29:159, 30:18, 30:55, 31:89, 31:115, 33:125, 33:131, 34:01:01:01-34:13, 34:15-34:20, 34:22-34:27, 66:01:01:01-66:02:01:03, 66:04, 66:06-66:10, 66:12-66:14, 66:16- 66:27N, 66:29-66:38, 66:40-66:43, 69:01:01:01-69:08, 74:13, C*03:03:43, C*03:82, C*03:184:01
2	435 bp	1070 bp	*68:01:01:01-68:01:61, 68:03:01:01-68:05, 68:08:01:01-68:09, 68:11N- 68:12:02, 68:16-68:17:02, 68:19-68:26, 68:29, 68:32- 68:33, 68:35:01:01-68:39, 68:41-68:43:02, 68:45-68:47, 68:50:01-68:50:02, 68:52, 68:55:01-68:59N, 68:63, 68:65, 68:68-68:73, 68:76:01- 68:76:02, 68:79, 68:83-68:85, 68:87, 68:89-68:91, 68:93- 68:96, 68:98-68:103:02, 68:105:01:01-68:109, 68:111- 68:123, 68:126-68:127, 68:129, 68:131-68:137, 68:139, 68:141-68:146, 68:148Q-68:152, 68:154- 68:159Q, 68:162, 68:164- 68:168, 68:171:01N-68:173, 68:175-68:177, 68:179- 68:183, 68:185, 68:188- 68:192, 68:194-68:197, 68:200, 68:202-68:215, 68:217-68:218, 68:220- 68:224, 68:226-68:235, 68:238-68:241, 68:243- 68:248, 68:251N-68:256, 68:258, 68:260-68:261, 68:263Q-68:271, 68:273, 68:276Q-68:277, 68:279- 68:285
3	195 bp	1070 bp	*68:02:01:01-68:02:21, 68:15, 68:18N, 68:28, 68:31, 68:34, 68:39-68:40, 68:44, 68:48- 68:49N, 68:51, 68:53-68:54, 68:60-68:62, 68:64, 68:67, 68:74, 68:77-68:78, 68:80- 68:82, 68:86, 68:92, 68:97, 68:110, 68:124-68:125, 68:128, 68:138, 68:140, 68:147, 68:153, 68:160, 68:163, 68:169-68:170, *25:47



0197

For *In Vitro* Diagnostic Use
MA123 v01 SSP PI Template
Date: April 2022, Rev. No: 00

101.418-12/04 – including *Taq* pol., IFU-01
101.418-12u/04 – without *Taq* pol., IFU-02

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

Lot No.: **8N9**

Lot-specific information

			68:174, 68:184, 68:186-68:187, 68:193, 68:198, 68:201, 68:216N, 68:219, 68:225, 68:236N-68:237, 68:242, 68:259, 68:262, 68:272, 68:274-68:275, 68:278	
4	180 bp 225 bp	1070 bp	*68:01:41, 68:30 *68:03:01:01-68:03:02, 68:05, 68:20, 68:180, 68:206, 68:255	*02:06:05, 02:99:02 *02:06:05, 02:99:02
5	140 bp 235 bp	800 bp	*68:25, 68:262 *68:04:01-68:04:02	*02:339, 02:407, 02:449, 02:594, 02:743, 02:932, 32:109 *11:98, 11:250, 11:396, 33:51, 66:15
6	230 bp	1070 bp	*68:05, 68:15, 68:20, 68:255	*02:06:05, 02:99:02, 02:122, 02:143
7	145 bp	1070 bp	*68:06, 68:32	*02:52, 02:992
8	160 bp 240 bp	800 bp	*68:07 *68:46	
9	195 bp 250 bp	800 bp	*68:47 *68:08:01:01-68:08:01:02, 68:08:02, 68:63, 68:157, 68:168	*25:19:01-25:19:02, 25:30, 26:43:01-26:43:02, 26:112, 34:02:01:04-34:02:01:07, 34:02:04?, 34:03?-34:04?, 34:06?-34:07?, 34:09?-34:10N?, 34:13?, 34:15?, 66:06, 66:33, 66:43
10	165 bp	800 bp	*68:09, 68:26, 68:129, 68:134, 68:204	*01:12, 01:19, 01:127, 01:136, 01:360, 01:380:01:01-01:380:01:02, 02:662, 03:10, 03:167, 11:01:01:01-11:01:34, 11:01:36-11:01:56, 11:01:58-11:01:103, 11:01:105-11:07:02, 11:10-11:21N, 11:26-11:27, 11:29-11:30, 11:32:01-11:34, 11:36-11:43, 11:45-11:49, 11:51-11:52Q, 11:54:01-11:58, 11:60-11:93, 11:95-11:111, 11:114-11:115N, 11:117-11:129, 11:131-11:139, 11:141-11:157, 11:159-11:161, 11:163-11:175, 11:177-11:182Q, 11:184-11:190, 11:192-11:203, 11:205-11:210N, 11:212-11:215N, 11:217-11:225, 11:227-11:228, 11:230-11:255, 11:257, 11:259-11:268, 11:270, 11:272Q-11:289, 11:291-11:309, 11:311-11:325, 11:327-11:345, 11:347N-11:371, 11:373-11:391, 11:393-11:396, 11:398-11:417N, 24:17:01:01-24:17:01:02, 24:41, 24:208:01-24:208:02:02, 24:296, 24:488, 24:499, 24:503, 24:535, 24:551, 24:555, 24:557, 29:05, 29:33, 29:77, 29:87, 29:104, C*16:67
11⁶	190 bp 160 bp	800 bp	*68:148Q *68:17:01-68:17:02	*01:396Q



0197

For *In Vitro* Diagnostic Use
MA123 v01 SSP PI Template
Date: April 2022, Rev. No: 00

101.418-12/04 – including *Taq* pol., IFU-01
101.418-12u/04 – without *Taq* pol., IFU-02

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

Lot No.: **8N9**

Lot-specific information

	200 bp		*68:10, 68:14, 68:120N	*02:358, 25:77
12	200 bp 405 bp	1070 bp	*68:38, 68:110, 68:120N *68:11N	C*06:139
13	210 bp 240 bp 260 bp	800 bp	*68:12:01-68:12:02, 68:50:01- 68:50:02, 68:117, 68:129, 68:131, 68:230 *68:51 *68:113:01-68:113:02, 68:115, 68:271	*25:59, 26:122 *26:18
14	400 bp	1070 bp	*68:13:01-68:13:02, 68:199N	*02:217:02, 02:419:01, 02:881, 24:309
15⁶	145 bp 200 bp	1070 bp	*68:19 *68:14, 68:80-68:81, 68:158, 68:264	*02:237, 02:809, 03:17:01, 03:171, 24:18, 24:204, 24:213 *02:121, 02:425, 02:517, 02:850, 02:937, 23:47, 24:234, 24:339, 24:347:02, B*53:60, C*06:209:02, C*12:37^w, C*14:132
16	215 bp	1070 bp	*68:15, 68:31, 68:40	*02:122, 02:143
17⁵	175 bp	1070 bp	*68:02:01:01-68:02:10, 68:02:12-68:02:21, 68:15, 68:18N, 68:20, 68:27:01- 68:28, 68:31, 68:34, 68:40, 68:44, 68:48-68:49N, 68:51, 68:53-68:54, 68:60-68:62, 68:64, 68:67, 68:74, 68:77- 68:78, 68:80-68:82, 68:86, 68:92, 68:97, 68:104:01- 68:104:02, 68:110, 68:124- 68:125, 68:128, 68:138, 68:140, 68:147, 68:153, 68:160, 68:163, 68:169- 68:170, 68:174, 68:178, 68:184, 68:186-68:187, 68:193, 68:198, 68:201, 68:216N, 68:219, 68:225, 68:236N-68:237, 68:242, 68:250, 68:259, 68:262, 68:272, 68:274-68:275, 68:278	*02:02:01:01 ^w -02:02:02 ^w , 02:02:04 ^w - 02:02:06 ^w , 02:03:01:01-02:03:11, 02:05:01:01 ^w -02:05:12 ^w , 02:08:01 ^w - 02:08:02 ^w , 02:22:01:01-02:22:02, 02:47 ^w , 02:49:01-02:50, 02:63 ^w , 02:102 ^w , 02:104, 02:115 ^w , 02:117, 02:122, 02:135-02:136, 02:148, 02:154 ^w -02:155 ^w , 02:172 ^w , 02:179 ^w , 02:186 ^w , 02:191, 02:209 ^w , 02:230, 02:232 ^w , 02:253, 02:258, 02:264:01:01-02:264:01:02, 02:267, 02:281, 02:286 ^w , 02:315, 02:320 ^w , 02:323, 02:324 ^w , 02:337 ^w , 02:344 ^w , 02:345, 02:355, 02:359 ^w , 02:370, 02:373N ^w , 02:376 ^w , 02:382, 02:402, 02:412, 02:413 ^w , 02:421 ^w , 02:427, 02:431, 02:433 ^w , 02:447, 02:463, 02:466, 02:480, 02:484 ^w , 02:489 ^w , 02:492 ^w , 02:495 ^w -02:496 ^w , 02:505, 02:507 ^w , 02:517 ^w , 02:529, 02:531 ^w - 02:532 ^w , 02:544, 02:546 ^w , 02:557, 02:568, 02:572 ^w , 02:577 ^w , 02:591:01 ^w -02:591:02 ^w , 02:593 ^w , 02:595, 02:601 ^w , 02:612, 02:626 ^w , 02:631, 02:633-02:634, 02:636 ^w , 02:641, 02:643N ^w , 02:646 ^w , 02:651, 02:655 ^w , 02:666, 02:667 ^w , 02:670 ^w , 02:676 ^w , 02:680, 02:682-02:684, 02:709 ^w , 02:711, 02:717 ^w , 02:731 ^w , 02:734 ^w , 02:766 ^w , 02:774-02:775N, 02:778 ^w , 02:790 ^w -02:791N ^w , 02:799 ^w , 02:807N ^w , 02:809, 02:817 ^w , 02:826Q ^w , 02:833N, 02:838, 02:841, 02:843 ^w , 02:849-02:850, 02:854, 02:860, 02:867 ^w , 02:872 ^w , 02:881 ^w ,



0197

For *In Vitro* Diagnostic Use
MA123 v01 SSP PI Template
Date: April 2022, Rev. No: 00

101.418-12/04 – including *Taq* pol., IFU-01
101.418-12u/04 – without *Taq* pol., IFU-02

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

Lot No.: **8N9**

Lot-specific information

				02:907 ^w , 02:914 ^w , 02:922 ^w , 02:925 ^w , 02:929, 02:949, 02:951 ^w , 02:961 ^w , 02:963 ^w , 02:967 ^w , 02:971, 02:976- 02:977, 02:979, 02:988, 02:990 ^w , 02:997Q, 02:999N ^w , 02:1000, 02:1002, 02:1014, 02:1019 ^w , 02:1025 ^w , 23:02, 23:66, 24:06, 24:87, 24:138, 24:167, 24:285, 24:289, 24:339, 24:381, 25:01:01:01-25:03, 25:05-25:11, 25:13-25:18, 25:20- 25:29, 25:31-25:41, 25:42N ^w , 25:45- 25:58, 25:60-25:80, 26:01:01:01- 26:01:04, 26:01:07-26:07:02, 26:09- 26:26, 26:28-26:39, 26:41-26:42, 26:45-26:47, 26:49-26:66, 26:68- 26:72, 26:74-26:80, 26:82-26:85, 26:87-26:90, 26:92, 26:94-26:111, 26:113-26:123, 26:125-26:145N, 26:147-26:148, 26:151-26:188, 26:190-26:203, 26:205-26:218, 26:220, 31:30, 31:97, 32:10, 32:118, 32:152, 33:94, 33:155, 34:01:01:01- 34:01:07, 34:05, 34:11-34:12, 34:14, 34:16-34:19, 34:23, 34:27, 43:01- 43:03, 66:01:01:01-66:05, 66:07- 66:25, 66:27N-66:31, 66:34-66:42, 74:29, B*07:197, B*15:342, B*27:25, B*27:45, B*27:108, B*27:115, B*27:161, B*27:245, B*27:249, C*02:07, C*02:158, C*04:261^w
18	200 bp	800 bp	*68:26, 68:65, 68:115, 68:131	*01:01:01:01-01:01:65, 01:01:67- 01:04:01:02N, 01:06-01:29, 01:31N- 01:33, 01:35-01:71, 01:73-01:78, 01:80-01:101, 01:103-01:144, 01:146-01:166, 01:168-01:199, 01:201-01:227, 01:229-01:235, 01:237-01:243, 01:245-01:266:02, 01:268-01:270, 01:272-01:283, 01:285N-01:375, 01:377-01:379N, 01:381-01:389, 01:391-01:408, 03:18, 03:97, 03:122, 03:135, 03:167, 11:27, 11:38-11:39, 11:94, 11:209, 11:271, 11:326, 23:53, 23:70, 24:17:01:01-24:17:01:02, 24:41, 24:208:01-24:208:02:02, 24:296, 24:499, 24:503, 24:535, 24:551, 24:557, 25:59, 29:03, 29:33, 80:01:01:01-80:09N
	225 bp		*68:21:01-68:21:03	*01:86, 03:04:01- 03:04:03, 03:345:01:01-03:345:01:02, 11:153:01-11:153:02, 11:351Q
19	325 bp	1070 bp	*68:22	*29:86, 33:63
20^{4,6}	90 bp	1070 bp	*68:23, 68:105:01:01- 68:105:01:02	*01:20, 01:66, 01:73, 01:130, 02:114, 02:246, 02:279, 02:527, 02:582,



0197

For *In Vitro* Diagnostic Use
MA123 v01 SSP PI Template
Date: April 2022, Rev. No: 00

101.418-12/04 – including *Taq* pol., IFU-01
 101.418-12u/04 – without *Taq* pol., IFU-02

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

Lot No.: **8N9**

Lot-specific information

				02:662, 02:927, 02:1029, 03:95, 03:177, 03:343, 11:288, 11:330, 26:204:01:01-26:204:01:02, 29:22, 29:89
21	165 bp	1070 bp	*68:28	*02:49:01, 02:682-02:683, 24:87, 24:285, 24:289, 26:217, 31:97, 66:19, B*07:197, B*27:45, B*27:108, B*27:249
22	215 bp 170 bp	800 bp	*68:24, 68:123 *68:01:01:01-68:01:61, 68:03:01:01-68:05, 68:07, 68:10-68:14, 68:16-68:17:02, 68:19-68:25, 68:29-68:30, 68:32-68:33, 68:35:01:01- 68:39, 68:41-68:43:02, 68:45- 68:47, 68:50:01-68:50:02, 68:52, 68:55:01-68:59N, 68:65-68:66:02, 68:68-68:73, 68:75:01-68:76:02, 68:79, 68:83-68:85, 68:87-68:91, 68:93-68:96, 68:98-68:103:02, 68:105:01:01-68:107, 68:109, 68:111-68:112:02, 68:114:01- 68:114:02, 68:116-68:123, 68:126-68:127, 68:130:01- 68:133, 68:135-68:137, 68:139, 68:141-68:146, 68:148Q-68:152, 68:154- 68:156, 68:158-68:159Q, 68:162, 68:164-68:167, 68:172-68:173, 68:175- 68:177, 68:179-68:183, 68:185, 68:188-68:192, 68:194-68:197, 68:199N- 68:200, 68:202-68:203N, 68:205N-68:215, 68:217- 68:218, 68:220-68:224, 68:226-68:235, 68:239- 68:241, 68:243-68:244:02, 68:246-68:249, 68:251N- 68:258, 68:260-68:261, 68:263Q-68:270, 68:273, 68:277, 68:279-68:285	*01:01:01:01 ^w -01:01:121 ^w , 01:01:122, 01:01:123 ^w - 01:04:01:02N ^w , 01:07 ^w -01:11N ^w , 01:13 ^w -01:18N ^w , 01:20 ^w -01:24 ^w , 01:26 ^w -01:29 ^w , 01:31N ^w -01:33 ^w , 01:35 ^w -01:78 ^w , 01:80 ^w -01:97 ^w , 01:98, 01:99 ^w -01:126 ^w , 01:128 ^w -01:135 ^w , 01:137 ^w -01:144 ^w , 01:146 ^w -01:199 ^w , 01:201 ^w -01:211 ^w , 01:213 ^w - 01:232:02 ^w , 01:234 ^w -01:235 ^w , 01:237 ^w -01:242 ^w , 01:245 ^w -01:270 ^w , 01:272 ^w -01:303:02 ^w , 01:305 ^w - 01:313 ^w , 01:314, 01:315 ^w -01:343 ^w , 01:344, 01:345 ^w -01:359 ^w , 01:361N ^w - 01:363 ^w , 01:365 ^w -01:375 ^w , 01:377 ^w - 01:379N ^w , 01:381 ^w -01:389 ^w , 01:391, 01:392 ^w -01:395 ^w , 01:396Q, 01:397 ^w - 01:402 ^w , 01:403, 01:404 ^w -01:408 ^w , 02:229, 02:527, 02:582, 03:18 ^w , 03:50, 03:66, 03:225, 11:08, 11:44, 11:183, 11:191, 11:269, 25:43, 26:204:01:01-26:204:01:02, 29:01:03, 29:28, 29:79, 36:01:01:01 ^w -36:01:02 ^w , 36:02, 36:03 ^w -36:12 ^w
23	185 bp	1070 bp	*68:01:01:01-68:01:61, 68:03:01:01-68:05, 68:07- 68:14, 68:16-68:17:02, 68:19- 68:25, 68:26 ^w , 68:29-68:30, 68:32-68:33, 68:35:01:01- 68:39, 68:41-68:43:02, 68:45- 68:47, 68:50:01-68:50:02, 68:52, 68:55:01-68:59N, 68:63, 68:66:01-68:66:02, 68:68-68:73, 68:75:01- 68:76:02, 68:79, 68:83-68:85,	*01:200, 01:244, 02:114, 02:229, 02:246, 02:279, 02:527, 02:582, 02:662, 02:681, 02:927, 02:985, 02:1029, 03:01:01:01-03:01:29, 03:01:31-03:01:49, 03:01:51- 03:01:89, 03:01:91-03:17:02, 03:20- 03:39, 03:41-03:42, 03:44:01-03:52, 03:54-03:81, 03:83-03:96, 03:99- 03:102, 03:104, 03:106-03:121, 03:123:01-03:134, 03:136-03:166, 03:168N-03:169, 03:171-03:185,



0197

For *In Vitro* Diagnostic Use
 MA123 v01 SSP PI Template
 Date: April 2022, Rev. No: 00

101.418-12/04 – including *Taq* pol., IFU-01
101.418-12u/04 – without *Taq* pol., IFU-02

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

Lot No.: **8N9**

Lot-specific information

			68:87-68:91, 68:93-68:96, 68:98-68:103:02, 68:105:01:01-68:109, 68:111- 68:114:02, 68:116-68:123, 68:126-68:127, 68:129- 68:130:02, 68:132-68:133, 68:135-68:137, 68:139, 68:141-68:146, 68:149- 68:152, 68:154-68:156, 68:158-68:159Q, 68:162, 68:164-68:168, 68:171:01N- 68:173, 68:175-68:177, 68:179-68:183, 68:185, 68:188-68:192, 68:194- 68:197, 68:199N-68:200, 68:202-68:215, 68:217- 68:218, 68:220-68:224, 68:226-68:235, 68:238- 68:241, 68:243-68:244:02, 68:246-68:249, 68:251N- 68:258, 68:260-68:261, 68:263Q-68:271, 68:273, 68:276Q-68:277, 68:279- 68:285	03:187-03:190, 03:192N-03:193, 03:195-03:196, 03:198-03:199, 03:201-03:207, 03:209-03:225, 03:227-03:235, 03:237-03:259, 03:261, 03:263-03:281, 03:283N- 03:325, 03:327-03:439, 11:04, 11:35, 11:130, 24:488, 29:01:01:01- 29:02:01:36, 29:02:03-29:02:38, 29:04-29:31, 29:34-29:66, 29:68- 29:69, 29:71-29:81, 29:83-29:137, 29:139-29:155, 29:157-29:167, 30:26, 31:03-31:04:02, 31:06, 31:179, 32:04, 32:30:01-32:30:02, 32:32, 33:18:01-33:18:02, 34:02:01:01-34:04, 34:07-34:10N, 34:13, 34:15, 34:20-34:22, 34:24- 34:26N, 36:01:01:01-36:03, 36:05- 36:12, C*16:67
24⁴	85 bp 375 bp	1070 bp	*68:112:01-68:112:02 *68:105:01:01-68:105:01:02	*33:147, 34:15, B*08:131, B*08:136, B*08:139 *02:55, 02:644, 02:741, 02:815, 26:22, 33:22, 66:09, 69:01:01:01- 69:08
25	240 bp 365 bp	1070 bp	*68:29, 68:250, *68:94N	*02:243:01-02:243:03, 24:82, 26:177, 29:155 *26:71N
26⁴	100 bp 190 bp	1070 bp	*68:49N *68:33, 68:80	*02:152, 02:802, 24:141, 33:03:17
27⁴	105 bp 185 bp 235 bp	1070 bp	*68:18N *68:34 *68:43:01-68:43:02	*02:385, 02:529, 33:120 *03:396, 11:219
28	200 bp 230 bp	1070 bp	*68:35:01:01-68:35:01:02, 68:38, 68:110 *68:44	C*06:139 *26:173
29^{4,5,7}	80 bp	800 bp	*68:42, 68:54, 68:61, 68:63, 68:183	*02:03:01:01-02:03:11, 02:26, 02:99:01, 02:117, 02:148, 02:171:02, 02:253, 02:258, 02:264:01:01- 02:264:01:02, 02:281, 02:315, 02:323, 02:345, 02:355, 02:370, 02:393, 02:402, 02:412, 02:427, 02:431, 02:447, 02:463, 02:466, 02:480, 02:489, 02:505, 02:529, 02:541, 02:544, 02:557, 02:568, 02:589, 02:592, 02:595, 02:612, 02:619:02, 02:633-02:634, 02:641, 02:666, 02:684, 02:711, 02:774- 02:775N, 02:782, 02:809, 02:833N,



0197

For *In Vitro* Diagnostic Use
MA123 v01 SSP PI Template
Date: April 2022, Rev. No: 00

101.418-12/04 – including *Taq* pol., IFU-01
101.418-12u/04 – without *Taq* pol., IFU-02

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

Lot No.: **8N9**

Lot-specific information

				02:849-02:850, 02:854, 02:860, 02:914, 02:949, 02:971, 02:976-02:977, 02:979, 02:988, 02:997Q, 02:1000, 03:01:38, 03:123:02, 03:428, 11:25:01, 11:191, 26:01:17, 34:01:07
30	250 bp 145 bp	1070 bp	*68:36-68:37, 68:249	B*44:02:57, B*44:03:19-44:03:20 *02:117, 02:135, 25:01:01:01, 25:01:02-25:01:08, 25:02-25:07, 25:10-25:19:01, 25:20-25:27:02, 25:29-25:30, 26:01:01:01, 26:01:02- 26:01:14, 26:01:16-26:01:25, 26:01:27-26:01:37, 26:02:01, 26:03:01:01, 26:04-26:08:01:01, 26:09-26:10, 26:12:01:01, 26:13, 26:15-26:17, 26:19-26:20:01, 26:21- 26:27, 26:29-26:39, 26:41-26:43:02, 26:45-26:46, 26:48-26:72, 26:74- 26:109, 26:111, 26:113, 26:216, 32:152, 34:01:01:01, 34:01:02, 34:05, 34:11-34:12, 43:01, 66:01:01:01, 66:01:02, 66:01:05, 66:02:01:01, 66:03:01:01, 66:04- 66:15, 66:17, 66:19-66:21, 66:32, 66:35
31⁵	245 bp 220 bp	1070 bp	*68:37 *68:48, 68:50:01-68:50:02, 68:129, 68:137, 68:230	*25:01:01:01-25:04, 25:06-25:07, 25:09-25:21, 25:23-25:25, 25:27:01- 25:80, 26:01:01:01-26:01:25, 26:01:27-26:02:01, 26:03:01:01- 26:10, 26:12:01:01-26:43:02, 26:45- 26:46, 26:48-26:53, 26:55-26:205, 26:207-26:220, 34:01:01:01- 34:01:07, 34:02:01:04-34:02:01:07, 34:02:04 [?] , 34:03 [?] -34:04 [?] , 34:05, 34:06 [?] -34:07 [?] , 34:09 [?] -34:13 [?] , 34:14, 34:15 [?] -34:17 [?] , 34:18-34:19, 34:23, 34:27, 43:01-43:03, 66:01:01:01- 66:01:02, 66:01:04-66:15, 66:17, 66:19-66:43
32^{4,7}	120 bp	800 bp	*68:21:01, 68:21:03, 68:53, 68:215	*02:74:02, 02:159, 02:912
33	150 bp	1070 bp	*68:16, 68:264	
34⁴	105 bp 165 bp	1070 bp	*68:18N *68:55:01-68:55:02, 68:124	*03:163, 03:244, 30:199
35^{6,7}	140 bp 295 bp	1070 bp	*68:59N *68:93, 68:97	*26:132, 32:73, B*44:129
36	195 bp	1070 bp	*68:01:01:01-68:01:01:14, 68:01:03-68:01:05, 68:01:07- 68:01:12, 68:01:14, 68:01:18- 68:01:20, 68:01:28, 68:01:32, 68:01:35, 68:01:38, 68:01:45, 68:01:58, 68:01:60-68:01:61,	*11:10, 25:01:01:01-25:01:03, 25:01:05-25:02, 25:04-25:14, 25:16, 25:18-25:29, 25:31-25:45, 25:48- 25:53, 25:55-25:58, 25:60-25:70, 25:72-25:76, 25:78-25:80, 26:01:01:01-26:01:29,



0197

For *In Vitro* Diagnostic Use
MA123 v01 SSP PI Template
Date: April 2022, Rev. No: 00

101.418-12/04 – including *Taq* pol., IFU-01
101.418-12u/04 – without *Taq* pol., IFU-02

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

Lot No.: **8N9**

Lot-specific information

			68:03:03-68:04:01, 68:08:01:01-68:08:01:02, 68:12:02, 68:21:02-68:22, 68:25-68:27:02, 68:35:01:01- 68:35:01:02, 68:42-68:43:02, 68:50:01, 68:55:01, 68:56, 68:58:01, 68:59N, 68:63, 68:68, 68:72, 68:75:02, 68:76:02, 68:79, 68:87-68:88, 68:94N, 68:99:02, 68:103:01, 68:104:02, 68:106, 68:113:01, 68:114:02, 68:119:01, 68:121:02-68:122, 68:126- 68:127, 68:129, 68:133, 68:135, 68:139, 68:143, 68:151, 68:154, 68:161, 68:165-68:166, 68:171:01N, 68:172, 68:175-68:177, 68:182N, 68:185, 68:188, 68:190-68:191, 68:196, 68:209, 68:211-68:213N, 68:215, 68:223, 68:226- 68:227, 68:230-68:231, 68:239, 68:244:02, 68:246- 68:247, 68:252-68:253, 68:257, 68:267N-68:269N, 68:276Q-68:277, 68:281N- 68:282, 68:284	26:01:31-26:01:47, 26:01:49- 26:01:53, 26:01:55-26:06, 26:08:01:01-26:15, 26:17-26:18, 26:21-26:34, 26:36-26:43:02, 26:45- 26:63, 26:65-26:71N, 26:73-26:82, 26:84-26:88, 26:90-26:91, 26:93- 26:176, 26:178-26:183, 26:185- 26:206N, 26:208-26:220, 33:51, 34:01:01:01-34:07, 34:09-34:18, 34:20-34:27, 66:01:01:01-66:22, 66:24-66:41, 66:43, 69:01:01:01- 69:01:01:03, 69:01:03-69:06, 69:08
37	145 bp 170 bp 285 bp	800 bp	*68:67, 68:192 *68:123 *68:26, 68:65, 68:115, 68:131	*26:125, 34:12?, 66:30 *25:36, 25:59, 25:65, 26:29, 26:49, 26:205, 66:10
38^{6,7}	165 bp	1070 bp	*68:91, 68:140	*25:01:01:01-25:19:02, 25:21-25:37, 25:39-25:80, 26:01:01:01-26:09, 26:11N-26:43:02, 26:45-26:177, 26:179-26:220, 34:01:01:01- 34:01:07, 34:02:01:04-34:02:01:07, 34:02:04?, 34:03?-34:04?, 34:05, 34:06?-34:07?, 34:09?-34:13?, 34:14, 34:15?-34:17?, 34:18-34:19, 34:23, 34:27, 43:01-43:03, 66:01:01:01- 66:01:03, 66:01:05-66:38, 66:40- 66:43
39⁴	95 bp 180 bp	1070 bp	*68:106 *68:68	
40	215 bp	1070 bp	*68:01:01:01-68:01:16, 68:01:18-68:01:61, 68:03:01:01-68:07, 68:10- 68:14, 68:16-68:17:02, 68:19- 68:22, 68:24-68:25, 68:29- 68:30, 68:32-68:33, 68:35:01:01-68:39, 68:41- 68:43:02, 68:45-68:47, 68:50:01-68:50:02, 68:52,	*02:680 ^w , 02:963 ^w , 23:02 ^w , 23:66 ^w , 24:06 ^w , 24:22 ^w , 24:138 ^w , 24:167 ^w , 24:339 ^w , 24:381 ^w , 26:70, 26:176, 29:28, 31:30, 32:10, 32:118, 32:152, 33:94, 33:155, 74:29



0197

For *In Vitro* Diagnostic Use
MA123 v01 SSP PI Template
Date: April 2022, Rev. No: 00

101.418-12/04 – including *Taq* pol., IFU-01
101.418-12u/04 – without *Taq* pol., IFU-02

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

Lot No.: **8N9**

Lot-specific information

68:55:01-68:59N, 68:65-68:66:02, 68:68-68:72, 68:75:01-68:76:02, 68:79, 68:84-68:85, 68:87-68:91, 68:93-68:96, 68:98-68:102, 68:104:01-68:104:02, 68:106-68:109, 68:111-68:114:02, 68:116-68:123, 68:126-68:127, 68:130:01-68:133, 68:135-68:137, 68:139, 68:141-68:144, 68:146, 68:148Q-68:150, 68:152, 68:154-68:156, 68:158-68:159Q, 68:161-68:162, 68:164-68:167, 68:172-68:173, 68:175-68:177, 68:179-68:181N, 68:183, 68:185, 68:188-68:192, 68:194-68:197, 68:199N-68:200, 68:202, 68:205N-68:215, 68:217-68:218, 68:220-68:224, 68:226-68:235, 68:239, 68:241, 68:243-68:249, 68:251N-68:258, 68:260-68:261, 68:263Q-68:270, 68:273, 68:277, 68:279-68:285				
41	135 bp 200 bp	800 bp	*68:144 *68:45, 68:117	*02:939, 32:68 *24:24, 24:67, 24:290, 24:392, 26:16, 30:163, 33:119
42	130 bp 245 bp	1070 bp	*68:60, 68:99:01-68:99:02 *68:101:01	*02:879N, 11:164, 24:394, 33:199 *03:180
43	255 bp	1070 bp	*68:171:01N	
44	190 bp	1070 bp	*68:75:01-68:75:02, 68:96, 68:130:01-68:130:02 *68:159Q	*11:11, 43:01-43:03
45	270 bp 150 bp 220 bp 265 bp	1070 bp	*68:41 *68:72 *68:86, 68:159Q, 68:265	*01:126 *11:301 *02:886, 26:57, B*39:104
46^{4,6}	110 bp 495 bp	1070 bp	*68:52 *68:142N	*02:396
47⁶	220 bp	1070 bp	*68:01:02:01-68:01:02:35, 68:01:06, 68:01:13, 68:01:15- 68:01:17, 68:01:21-68:01:27, 68:01:30-68:01:31, 68:01:33- 68:01:34, 68:01:36-68:01:37, 68:01:39-68:01:44, 68:01:46- 68:01:57, 68:01:59, 68:06- 68:07, 68:08:02-68:09, 68:11N-68:12:01, 68:13:02, 68:16-68:17:02, 68:19, 68:21:01, 68:23-68:24, 68:30, 68:32-68:33, 68:37-68:38,	*11:01:105, 69:01:02



0197

For *In Vitro* Diagnostic Use
MA123 v01 SSP PI Template
Date: April 2022, Rev. No: 00

101.418-12/04 – including *Taq* pol., IFU-01
101.418-12u/04 – without *Taq* pol., IFU-02

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

Lot No.: **8N9**

Lot-specific information

	68:41, 68:47, 68:50:02, 68:52, 68:55:02, 68:58:02, 68:65-68:66:01, 68:69-68:70, 68:73, 68:75:01, 68:76:01, 68:83, 68:85, 68:91, 68:93, 68:95-68:96, 68:98-68:99:01, 68:100-68:102, 68:103:02- 68:104:01, 68:105:01:01- 68:105:01:02, 68:107-68:108, 68:111-68:112:02, 68:113:02- 68:114:01, 68:115-68:116, 68:118, 68:119:02-68:121:01, 68:123, 68:130:02-68:132, 68:134, 68:137, 68:141- 68:142N, 68:144-68:146, 68:148Q-68:150, 68:152, 68:156-68:159Q, 68:162, 68:164, 68:167-68:168, 68:171:02N, 68:173, 68:179, 68:181N, 68:183, 68:189, 68:192, 68:194-68:195, 68:197, 68:200, 68:202- 68:205N, 68:207-68:208, 68:210N, 68:214, 68:217- 68:218, 68:220-68:222, 68:224, 68:228-68:229, 68:233-68:235, 68:238, 68:240-68:241, 68:243- 68:244:01, 68:245N, 68:248, 68:251N, 68:254, 68:256, 68:258, 68:260-68:261, 68:263Q-68:266N, 68:270- 68:271, 68:273, 68:279- 68:280, 68:283
48⁸	- - 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-A*68 SSP typings.

When the primers in a primer mix can give rise to HLA-specific PCR products of more than one length this is indicated if the size difference is more than 20 base pairs. Size differences of 20 base pairs or less are not given. For high resolution SSP kits, the alleles listed are specified according to amplicon length.

Nonspecific amplifications, i.e. a ladder or a smear of bands, may sometimes be seen. GC-rich primers have a higher tendency of giving rise to nonspecific amplifications than other primers.

PCR fragments longer than the control bands may sometimes be observed. Such bands should be disregarded and do not influence the interpretation of the SSP typings.

PCR fragments migrating faster than the control bands, but slower than a 400 bp fragment may be seen in some gel read-outs. Such bands can be disregarded and do not influence the interpretation of the SSP typings. Some primers may give rise to primer oligomer artifacts. Sometimes this phenomenon is an inherent feature of the primer pair(s) of a primer mix. More often it is due to other factors such as too low amount of DNA in the PCR reactions, taking too long time in setting up the PCR reactions, working at elevated room temperature or using thermal cyclers that are not pre-heated.

²The internal positive control primer pairs amplify segments of the human growth hormone gene. The internal positive control bands are 1070 or 800 base pairs respectively, well distribution as outlined in the table. Well number 1 contains the shorter, 800 bp, internal positive control band. The well distribution of the internal controls can help in orientation of the kit on gel photo, as well as allow for kit identification. In the presence of a specific



0197

For *In Vitro* Diagnostic Use
MA123 v01 SSP PI Template
Date: April 2022, Rev. No: 00

101.418-12/04 – including *Taq* pol., IFU-01
101.418-12u/04 – without *Taq* pol., IFU-02

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

Lot No.: 8N9

Lot-specific information

amplification the intensity of the control band often decreases.

³For several HLA Class I alleles 1st and/or 4th exon(s) and beyond, as well as intron nucleotide sequences, are not available. In these instances it is not known whether some of the primers of the SSP sets are completely matched with the target sequences or not. Assumption is made that unknown sequences in these regions are conserved within allelic groups.

⁴HLA-specific PCR products shorter than 125 base pairs have a lower intensity and are less sharp than longer PCR products.

⁵Primer mixes 1, 17, 29 and 31 may give rise to a lower yield of HLA-specific PCR product than the other HLA-A*68 primer mixes.

⁶Primer mixes 11, 15, 20, 35, 38, 46 and 47 may have tendencies of unspecific amplifications.

⁷Primer mixes 29, 32, 35 and 38 have a tendency to giving rise to primer oligomer formation.

⁸Primer mix 48 contains a negative control, which will amplify a majority of HLA amplicons as well as the amplicons generated by the control primer pairs matching the human growth hormone gene. HLA-specific PCR product sizes range from 75 to 200 base pairs and the PCR product generated by the HGH positive control primer pair is 200 base pairs.

Abbreviations

'w', may 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: April 2022, Rev. No: 00

101.418-12/04 – including *Taq* pol., IFU-01
101.418-12u/04 – without *Taq* pol., IFU-02

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

Lot No.: **8N9**

Lot-specific information
PRIMER SPECIFICATION

Well No.	1	2	3	4	5	6	7	8	9	10	11	12
Length of spec.	200	435	195	180	140	230	145	160	195	165	160	200
PCR product				225	235			240	250	190	200	405
Length of int.	800	1070	1070	1070	800	1070	1070	800	800	800	800	1070
pos. control ¹												
5'-primer(s) ²	127 5'-ggg 3' 5'	261 -AAC 3' 5'	106 -CCA 3' 5'	102 -ACT 3' 5'	98 -CTA 3' 5'	102 -ACT 3' 5'	145 -CCA 3' 5'	98 -CTA 3' 5'	2 nd I -CCT 3' 5'	413 -CCg 3' 5'	98 -CTA 3' 5'	47 -g.T 3'
					397 5'-gCC 3' 5'	106 -CCA 3' 5'	414 -gAA 3' 5'	418 -AgC 3'			386 5'-gTA 3' 5'	376 -gCA 3'
											419 5'-ggT 3' 5'	386 -gTA 3'
3'-primer(s) ³	282 5'-gAC 3' 5'	413 -gCC 3' 5'	259 -gTT 3' 5'	240 -ggA 3' 5'	290 -CAA 3' 5'	292 -gTg 3' 5'	259 -gTT 3' 5'	299 -TCA 3' 5'	479 -CCA 3' 5'	538 -CTg 3' 5'	256 -CTC 3' 5'	282 -gAC 3'
	282 5'-gAC 3'			282 5'-gAg 3' 5'	497 -Tgg 3'		506 5'-TgT 3' 5'	539 -TCC 3' 5'	538 -CAg 3' 5'	562 -gCT 3' 5'	538 -CCA 3' 5'	538 -CCA 3'
	295 5'-TCT 3'			292 5'-gTg 3'					538 5'-CAA 3'			
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

Well No.	13	14	15	16	17	18	19	20	21	22	23	24
Length of spec.	210	400	145	215	175	200	325	90	165	170	185	85
PCR product	240		200			225			215			375
Length of int.	800	1070	1070	1070	1070	800	1070	1070	1070	800	1070	1070
pos. control ¹												
5'-primer(s) ²	2 nd I 5'-CCT 3' 5'	28 -TCg 3' 5'	453 -AAA 3' 5'	106 -CCA 3' 5'	395 -gCA 3' 5'	413 -CCg 3' 5'	317 -gCA 3' 5'	362 -gAg 3' 5'	102 -ACT 3' 5'	413 -CCg 3' 5'	413 -CCg 3' 5'	261 -AAC 3'
					413 5'-CCA 3'			5'-gAg 3' 5'	-CCA 3'			
3'-primer(s) ³	497 5'-TgA 3' 5'	255 -Cgg 3' 5'	555 -CCA 3' 5'	278 -ggC 3' 5'	539 -TCC 3' 5'	570 -CCg 3' 5'	362 -TCA 3' 5'	413 -gCC 3' 5'	275 -CCC 3' 5'	539 -TCC 3' 5'	559 -CgT 3' 5'	307 -CCg 3'
	497 5'-TgA 3'		605 5'-gCC 3' 5'	282 -gAg 3'		595 5'-CCg 3'			538 5'-CCg 3' 5'	546 -TAA 3'		307 5'-CCT 3'
	524 5'-CAC 3'		616 5'-CgC 3' 5'	282 -gAg 3'		595 5'-CCT 3'						355 5'-gAC 3'
	545 5'-AgA 3'											
Well No.	13	14	15	16	17	18	19	20	21	22	23	24



0197

For *In Vitro* Diagnostic Use
MA123 v01 SSP PI Template
Date: April 2022, Rev. No: 00

101.418-12/04 – including *Taq* pol., IFU-01
101.418-12u/04 – without *Taq* pol., IFU-02

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

Lot No.: **8N9**

Lot-specific information

Well No.	25	26	27	28	29	30	31	32	33	34	35	36
Length of spec.	240	100	105	200	80	145	220	120	150	105	140	195
PCR product	365	190	185	230	250	245				165	295	
			235									
Length of int. pos. control ¹	1070	1070	1070	1070	800	1070	1070	800	1070	1070	1070	1070
5'-primer(s) ²	28	453	87	121	102	102	2 nd I	506	413	160	341	106
	5'-TCg ^{3'}	5'-AAA ^{3'}	5'-ATT ^{3'}	5'-gCT ^{3'}	5'-ACT ^{3'}	5'-ACT ^{3'}	5'-CCT ^{3'}	5'-gCA ^{3'}	5'-CCg ^{3'}	5'-ACT ^{3'}	5'-ggg ^{3'}	5'-CCg ^{3'}
		666	87	349	489	414				217	413	
		5'-gAA ^{3'}	5'-ATA ^{3'}	5'-CTg ^{3'}	5'-gCA ^{3'}	5'-CAG ^{3'}				5'-ggg ^{3'}	5'-CCg ^{3'}	
			217	376								
			5'-ggg ^{3'}	5'-gCA ^{3'}								
			413									
			5'-CCA ^{3'}									
3'-primer(s) ³	97	512	282	282	308	308	506	578	524	282	355	259
	5'-ggT ^{3'}	5'-ACT ^{3'}	5'-gAC ^{3'}	5'-gAC ^{3'}	5'-TCT ^{3'}	5'-TCT ^{3'}	5'-TgC ^{3'}	5'-Tgg ^{3'}	5'-CAA ^{3'}	5'-gAC ^{3'}	5'-gAT ^{3'}	5'-gTT ^{3'}
	224	605	559	538	317	517		595			512	
	5'-TCT ^{3'}	5'-gCC ^{3'}	5'-CAT ^{3'}	5'-CCA ^{3'}	5'-ggA ^{3'}	5'-CgT ^{3'}		5'-CCg ^{3'}			5'-CCT ^{3'}	
		808			527							
		5'-AgA ^{3'}			5'-CCT ^{3'}							
					527							
					5'-CCT ^{3'}							
Well No.	25	26	27	28	29	30	31	32	33	34	35	36

Well No.	37	38	39	40	41	42	43	44	45	46	47
Length of spec.	145	165	95	215	135	130	255	190	150	110	220
PCR product	170		180		200	245		270	220	495	
	285								265		
Length of int. pos. control ¹	800	1070	1070	1070	800	1070	1070	1070	1070	1070	1070
5'-primer(s) ²	2 nd I	2 nd I	397	363	98	77	2 nd I	98	98	241	102
	5'-CCT ^{3'}	5'-CCT ^{3'}	5'-gCg ^{3'}	5'-ATg ^{3'}	5'-CTC ^{3'}	5'-CTT ^{3'}	5'-CCT ^{3'}	5'-CTA ^{3'}	5'-CTA ^{3'}	5'-g.C ^{3'}	5'-ACT ^{3'}
			486		736	194		666	413	383	
			5'-ATA ^{3'}		5'-ggA ^{3'}	5'-CgA ^{3'}		5'-gAA ^{3'}	5'-CCg ^{3'}	5'-ggA ^{3'}	
					524						
					5'-CCC ^{3'}						
3'-primer(s) ³	430	453	538	538	259	282	540	256	277	453	282
	5'-gCg ^{3'}	5'-TCg ^{3'}	5'-CCA ^{3'}	5'-CCA ^{3'}	5'-gTT ^{3'}	5'-gAC ^{3'}	5'-CTT ^{3'}	5'-CCC ^{3'}	5'-ggT ^{3'}	5'-TCT ^{3'}	5'-gAC ^{3'}
	457				831	616		257	311		
	5'-gTA ^{3'}				5'-TCC ^{3'}	5'-CgT ^{3'}		5'-gCA ^{3'}	5'-ggA ^{3'}		
	570							325	325		
	5'-CCg ^{3'}							5'-gTA ^{3'}	5'-gTA ^{3'}		
								809	521		
								5'-CAT ^{3'}	5'-ggA ^{3'}		
Well No.	37	38	39	40	41	42	43	44	45	46	47



0197

For *In Vitro* Diagnostic Use
MA123 v01 SSP PI Template
Date: April 2022, Rev. No: 00

101.418-12/04 – including *Taq* pol., IFU-01
101.418-12u/04 – without *Taq* pol., IFU-02

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

Lot No.: **8N9**

Lot-specific information

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: April 2022, Rev. No: 00

101.418-12/04 – including *Taq* pol., IFU-01
101.418-12u/04 – without *Taq* pol., IFU-02

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

Lot No.: **8N9**

Lot-specific information

CELL LINE VALIDATION SHEET				HLA-A*68 SSP subtyping kit ²																
				Well																
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	
				Prod. No.:	202239101	202239102	202239103	202239104	202239105	202239106	202239107	202239108	202239109	202239110	202239111	202239112	202239113	202239114	202239115	202239116
	IHWC cell line ¹	A*																		
1	9001 SA	*24:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2	9280 LK707	*02:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3	9011 E4181324	*01:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4	9275 GU373	*30:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
5	9009 KAS011	*01:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
6	9353 SM	*02:01	*26:03	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
7	9020 QBL	*26:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
8	9025 DEU	*31:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
9	9026 YAR	*26:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
10	9107 LKT3	*24:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
11	9051 PITOUT	*29:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
12	9052 DBB	*02:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
13	9004 JESTHOM	*02:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
14	9071 OLGA	*31:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
15	9075 DKB	*24:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
16	9037 SWEIG007	*29:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
17	9282 CTM3953540	*03:01	*80:01	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
18	9257 32367	*33:03	*74:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
19	9038 BM16	*02:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
20	9059 SLE005	*02:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
21	9064 AMALA	*02:17		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
22	9056 KOSE	*02:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
23	9124 IHL	*02:01	*34:01	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
24	9035 JBUSH	*32:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
25	9049 IBW9	*33:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
26	9285 WT49	*02:05		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
27	9191 CH1007	*24:10	*29:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
28	9320 BEL5GB	*02:01	*29:02	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
29	9050 MOU	*29:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
30	9021 RSH	*30:01	*68:02	+	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
31	9019 DUCAF	*30:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
32	9297 HAG	*02:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
33	9098 MT14B	*31:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
34	9104 DHIF	*31:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
35	9302 SSTO	*32:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
36	9024 KT17	*02:06	*11:01	+	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-
37	9065 HHKB	*03:01		+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
38	9099 LZL	*02:17		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
39	9315 CML	*01:01	*03:01	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
40	9134 WHONP199	*02:07	*30:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
41	9055 H0301	*03:01		+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
42	9066 TAB089	*02:07		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
43	9076 T7526	*02:06	*02:07	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
44	9057 TEM	*66:01		+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
45	9239 SHJO	*23:01	*24:02	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
46	9013 SCHU	*03:01		+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
47	9045 TUBO	*02:16	*03:01	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
48	9303 TER-ND	*02:01	*11:01	+	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-



0197

101.418-12/04 – including *Taq* pol., IFU-01
101.418-12u/04 – without *Taq* pol., IFU-02

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

Lot No.: **8N9**

Lot-specific information

CELL LINE VALIDATION SHEET																				
HLA-A*68 SSP subtyping kit ²																				
				Well																
				17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	
				Prod. No.:	202239117	202239118	202239119	202239120	202239121	202239122	202239123	202239124	202239125	202239126	202239127	202239128	202239129	202239130	202239131	202239132
	IHCW cell line ¹			A*																
1	9001	SA	*24:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2	9280	LK707	*02:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3	9011	E4181324	*01:01		-	+	-	-	-	W	-	-	-	-	-	-	-	-	-	-
4	9275	GU373	*30:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
5	9009	KAS011	*01:01		-	+	-	-	-	W	-	-	-	-	-	-	-	-	-	-
6	9353	SM	*02:01	*26:03	+	-	-	-	-	-	-	-	-	-	-	-	-	+	+	-
7	9020	QBL	*26:01		+	-	-	-	-	-	-	-	-	-	-	-	-	+	+	-
8	9025	DEU	*31:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
9	9026	YAR	*26:01		+	-	-	-	-	-	-	-	-	-	-	-	-	+	+	-
10	9107	LKT3	*24:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
11	9051	PITOUT	*29:02		-	-	-	-	-	-	+	-	-	-	-	-	-	-	-	-
12	9052	DBB	*02:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
13	9004	JESTHOM	*02:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
14	9071	OLGA	*31:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
15	9075	DKB	*24:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
16	9037	SWEIG007	*29:02		-	-	-	-	-	-	+	-	-	-	-	-	-	-	-	-
17	9282	CTM3953540	*03:01	*80:01	-	+	-	-	-	-	+	-	-	-	-	-	-	-	-	-
18	9257	32367	*33:03	*74:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
19	9038	BM16	*02:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
20	9059	SLE005	*02:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
21	9064	AMALA	*02:17		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
22	9056	KOSE	*02:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
23	9124	IHL	*02:01	*34:01	+	-	-	-	-	-	-	-	-	-	-	-	-	+	+	-
24	9035	JBUSH	*32:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
25	9049	IBW9	*33:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
26	9285	WT49	*02:05		W	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
27	9191	CH1007	*24:10	*29:01	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-	-
28	9320	BEL5GB	*02:01	*29:02	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-	-
29	9050	MOU	*29:02		-	-	-	-	-	-	+	-	-	-	-	-	-	-	-	-
30	9021	RSH	*30:01	*68:02	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
31	9019	DUCAF	*30:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
32	9297	HAG	*02:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
33	9098	MT14B	*31:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
34	9104	DHIF	*31:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
35	9302	SSTO	*32:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
36	9024	KT17	*02:06	*11:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
37	9065	HHKB	*03:01		-	-	-	-	-	-	+	-	-	-	-	-	-	-	-	-
38	9099	LZL	*02:17		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
39	9315	CML	*01:01	*03:01	-	+	-	-	-	W	+	-	-	-	-	-	-	-	-	-
40	9134	WHONP199	*02:07	*30:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
41	9055	H0301	*03:01		-	-	-	-	-	-	+	-	-	-	-	-	-	-	-	-
42	9066	TAB089	*02:07		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
43	9076	T7526	*02:06	*02:07	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
44	9057	TEM	*66:01		+	-	-	-	-	-	-	-	-	-	-	-	-	+	+	-
45	9239	SHJO	*23:01	*24:02	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
46	9013	SCHU	*03:01		-	-	-	-	-	-	+	-	-	-	-	-	-	-	-	-
47	9045	TUBO	*02:16	*03:01	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-	-
48	9303	TER-ND	*02:01	*11:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-



0197

101.418-12/04 – including *Taq* pol., IFU-01
101.418-12u/04 – without *Taq* pol., IFU-02

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

Lot No.: **8N9**

Lot-specific information

CELL LINE VALIDATION SHEET																			
HLA-A*68 SSP subtyping kit ²																			
				Well															
				33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	
				Prod. No.:	202239133	202239134	202239135	202239136	202239137	202239138	202239139	202239140	202239141	202239142	202239143	202239144	202239145	202239146	202239147
	IHWC cell line ¹		A*																
1	9001 SA		*24:02	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
2	9280 LK707		*02:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
3	9011 E4181324		*01:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
4	9275 GU373		*30:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
5	9009 KAS011		*01:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
6	9353 SM		*02:01	*26:03	-	-	-	+	-	+	-	-	-	-	-	-	-	-	
7	9020 QBL		*26:01		-	-	-	+	-	+	-	-	-	-	-	-	-	-	
8	9025 DEU		*31:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	
9	9026 YAR		*26:01		-	-	-	+	-	+	-	-	-	-	-	-	-	-	
10	9107 LKT3		*24:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	
11	9051 PITOUT		*29:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	
12	9052 DBB		*02:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	
13	9004 JESTHOM		*02:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	
14	9071 OLGA		*31:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	
15	9075 DKB		*24:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	
16	9037 SWEIG007		*29:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	
17	9282 CTM3953540		*03:01	*80:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
18	9257 32367		*33:03	*74:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
19	9038 BM16		*02:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	
20	9059 SLE005		*02:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	
21	9064 AMALA		*02:17		-	-	-	-	-	-	-	-	-	-	-	-	-	-	
22	9056 KOSE		*02:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	
23	9124 IHL		*02:01	*34:01	-	-	-	+	-	+	-	-	-	-	-	-	-	-	
24	9035 JBUSH		*32:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	
25	9049 IBW9		*33:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	
26	9285 WT49		*02:05		-	-	-	-	-	-	-	-	-	-	-	-	-	-	
27	9191 CH1007		*24:10	*29:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
28	9320 BEL5GB		*02:01	*29:02	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
29	9050 MOU		*29:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	
30	9021 RSH		*30:01	*68:02	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
31	9019 DUCAF		*30:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	
32	9297 HAG		*02:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	
33	9098 MT14B		*31:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	
34	9104 DHIF		*31:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	
35	9302 SSTO		*32:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	
36	9024 KT17		*02:06	*11:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
37	9065 HHKB		*03:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	
38	9099 LZL		*02:17		-	-	-	-	-	-	-	-	-	-	-	-	-	-	
39	9315 CML		*01:01	*03:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
40	9134 WHONP199		*02:07	*30:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
41	9055 H0301		*03:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	
42	9066 TAB089		*02:07		-	-	-	-	-	-	-	-	-	-	-	-	-	-	
43	9076 T7526		*02:06	*02:07	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
44	9057 TEM		*66:01		-	-	-	+	-	+	-	-	-	-	-	-	-	-	
45	9239 SHJO		*23:01	*24:02	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
46	9013 SCHU		*03:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	
47	9045 TUBO		*02:16	*03:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
48	9303 TER-ND		*02:01	*11:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	



0197

101.418-12/04 – including *Taq* pol., IFU-01
101.418-12u/04 – without *Taq* pol., IFU-02

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

Lot No.: **8N9**

Lot-specific information

¹The provided cell line HLA specificities are retrieved from the <http://www.ihwg.org/hla> web site. The specificity of an individual cell line may thus be subject to change.

²The specificity of each primer solution in the kit has been tested against 48 well characterized cell line DNAs and where applicable, additional cell line DNAs.

No DNAs carrying the alleles to be amplified by primer solutions 5, 7 to 9, 11 to 16, 19 to 21, 25, 26, 28, 32, 33, 35, 37, 39, 41 to 43, 45 and 46 were available.

The specificities of the primers in primer solutions 5, 7 to 9, 11, 13, 15, 16, 20, 21, 25, 26, 35, 37 and 41 were tested by separately adding additional 5'-primers, respectively additional 3'-primers.

In primer solutions 12, 19, 28, 39, 42 and 46 it was only possible to test the 3'-primers, the 5'-primers were not possible to test.

In primer solutions 14, 32, 33, 43 and 45 it was only possible to test the 5'-primers, the 3'-primers were not possible to test.

In primer solutions 5, 7, 8, 11, 17, 27, 34, 35 and 41 one or two of the 5'-primers were not possible to test.

In primer solutions 1, 8 to 10, 13, 15, 16, 18, 21, 22, 24 to 27, 35, 37 and 44 one, two or three of the 3'-primers were not possible to test.

Additional primers in primer solutions 4, 6, 27, 29 and 44 were tested tested by separately adding either one or two additional 5'-primers, or one additional 3'-primer.



0197

For *In Vitro* Diagnostic Use
MA123 v01 SSP PI Template
Date: April 2022, Rev. No: 00

101.418-12/04 – including *Taq* pol., IFU-01
 101.418-12u/04 – without *Taq* pol., IFU-02

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

Lot No.: **8N9**

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/>

Distributed by:

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: April 2022, Rev. No: 00