

101.519-12 – including *Taq* polymerase  
101.519-12u – without *Taq* polymerase

Visit [www.caredx.com](http://www.caredx.com) for  
“Instructions for Use” (IFU)

Lot No.: **7R0**

Lot-specific information  
**Olerup SSP<sup>®</sup> HLA-B\*18**

<b>Product number:</b>	101.519-12 – including <i>Taq</i> polymerase 101.519-12u – without <i>Taq</i> polymerase
<b>Lot number:</b>	7R0
<b>Expiry date:</b>	2027-01-01
<b>Number of tests:</b>	12
<b>Number of wells per test:</b>	41+1
<b>Storage - pre-aliquoted primers:</b>	dark, between -15°C and -25°C
- PCR Master Mix:	between -15°C and -25°C
- Adhesive PCR seals	RT

**This Product Description is only valid for Lot No. 7R0.**

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

**CHANGES COMPARED TO THE PREVIOUS OLERUP SSP<sup>®</sup>  
HLA-B\*18 LOT (8L6)**

- The product documentation has been updated for new alleles of IMGT 3.50.0
- The kit resolution focuses on common and well documented (CWD) alleles<sup>1</sup>

<sup>1</sup>As described in section Uniquely Identified Alleles.

The HLA-B\*18 primer set, specificity and interpretation tables have been updated for the HLA-B alleles described since the previous *Olerup SSP<sup>®</sup> HLA-B\*18* lot was made (**Lot No. 8L6**).

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	Removed	-	Redundant 5'-primer removed.

<sup>1</sup>S. 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 v02 SSP PI Template  
Date: March 2023, Rev. No: 00

101.519-12 – including *Taq* polymerase  
101.519-12u – without *Taq* polymerase

Visit [www.caredx.com](http://www.caredx.com) for  
“Instructions for Use” (IFU)

Lot No.: **7R0**

Lot-specific information

Well **42** contains Negative Control primer pairs, that will amplify the majority of the *Olerup* SSP<sup>®</sup> 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
<b>5'-primer<sup>1</sup></b>	<b>164</b>	<b>340</b>	<b>440</b>	<b>45</b>	<b>45</b>	<b>43</b>	<b>36</b>
	5'-CAC <sup>3'</sup>	5'-Agg <sup>3'</sup>	5'-TTA <sup>3'</sup>	5'-Tgg <sup>3'</sup>	5'-Tgg <sup>3'</sup>	5'-Tgg <sup>3'</sup>	5'-TAC <sup>3'</sup>
							<b>36</b>
							5'-TAT <sup>3'</sup>
<b>3'-primer<sup>2</sup></b>	<b>231</b>	<b>2<sup>nd</sup> I</b>	<b>507</b>	<b>59</b>	<b>58</b>	<b>57</b>	<b>47</b>
	5'-TgC <sup>3'</sup>	5'-AAA <sup>3'</sup>	5'-TTg <sup>3'</sup>	5'-CTC <sup>3'</sup>	5'-ggC <sup>3'</sup>	5'-CTC <sup>3'</sup>	5'-ACA <sup>3'</sup>
							<b>48</b>
							5'-gCA <sup>3'</sup>
							<b>48</b>
							5'-gCC <sup>3'</sup>
							<b>52</b>
							5'-TgT <sup>3'</sup>
<b>A*</b>	<b>+</b>	<b>+</b>	<b>+</b>				
<b>B*</b>	<b>+</b>	<b>+</b>	<b>+</b>				
<b>C*</b>	<b>+</b>	<b>+</b>	<b>+</b>				
<b>DRB1</b>				<b>+</b>	<b>+</b>		
<b>DRB3</b>				<b>+</b>	<b>+</b>		
<b>DRB5</b>				<b>+</b>			
<b>DQB1</b>					<b>+</b>		
<b>DPB1</b>						<b>+</b>	
<b>DQA1</b>							<b>+</b>

<sup>1</sup>The nucleotide position for HLA class I genes and the codon for HLA class II genes, in the 2<sup>nd</sup> or 3<sup>rd</sup> 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](http://www.ebi.ac.uk/imgt/hla) web site. The sequence of the 3 terminal nucleotides of the primer is given.

<sup>2</sup>The nucleotide position for HLA class I genes and the codon for HLA class II genes, in the 2<sup>nd</sup> or 3<sup>rd</sup> exon or the 2<sup>nd</sup> 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](http://www.ebi.ac.uk/imgt/hla) web site. The sequence of the 3 terminal nucleotides of the primer is given.



0197

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

101.519-12 – including *Taq* polymerase  
101.519-12u – without *Taq* polymerase

Visit [www.caredx.com](http://www.caredx.com) for  
“Instructions for Use” (IFU)

Lot No.: **7R0**

Lot-specific information

## PRODUCT DESCRIPTION

### HLA-B\*18 SSP subtyping

#### CONTENT

The primer set contains 5'- and 3'-primers for identifying the B\*18:01 to B\*18:226 alleles.

#### PLATE LAYOUT

Each test consists of 42 PCR reactions in a 48 well cut PCR plate. Wells 43 to 48 are empty.

1	2	3	4	5	6	7	8
9	10	11	12	13	14	15	16
17	18	19	20	21	22	23	24
25	26	27	28	29	30	31	32
33	34	35	36	37	38	39	40
41	NC	empty	empty	empty	empty	empty	empty

The 48 well cut PCR plate is marked with ‘HLA-B\*18’ in silver/gray ink.

Well No. 1 is marked with the Lot No. ‘7R0’.

Wells 1 to 41 – HLA-B\*18 high resolution primers.

Well 42 – 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-B alleles non-HLA-B\*18 alleles will be amplified by some primer mixes. For further details see Specificity Table.

#### UNIQUELY IDENTIFIED ALLELES

All the HLA-B\*18 alleles, i.e. **B\*18:01 to B\*18:226**, recognized by the HLA Nomenclature Committee in October 2022 will be amplified by the primers in the HLA-B\*18 subtyping kit<sup>1,2</sup>.

The HLA-B\*18 kit enables separation of the confirmed HLA-B\*18 alleles as listed in the IMGT/HLA database 3.29.0. An HLA allele is listed as confirmed by IMGT/HLA if it has been sequenced by more than a single laboratory or from multiple sources. Current allele confirmation status for HLA-B\*18 alleles is listed below.



0197

For *In Vitro* Diagnostic Use

MA123 v02 SSP PI Template

Date: March 2023, Rev. No: 00

101.519-12 – including *Taq* polymerase  
101.519-12u – without *Taq* polymerase

Visit [www.caredx.com](http://www.caredx.com) for  
“Instructions for Use” (IFU)

Lot No.: **7R0**

Lot-specific information

The HLA-B\*18 kit also enables identification of many null and alternatively expressed alleles.

The following HLA-B\*18 alleles can be distinguished by the different sizes of the HLA-specific PCR product:

Alleles	Primer mix	Alleles	Primer mix
B*18:05:01:01- 18:05:01:02, 18:60	6	B*18:36, 18:67	11
B*18:18:01:01- 18:18:01:02, 18:47	29	B*18:37:02, 18:46	27
B*18:23N, 18:28	10	B*18:38, 18:45	28
B*18:34, 18:52	30	B*18:40, 18:51, 18:217	23

<sup>1</sup>HLA-B alleles listed on the IMGT/HLA web page 2022-October-12, release 3.50.0, [www.ebi.ac.uk/imgt/hla](http://www.ebi.ac.uk/imgt/hla).

<sup>2</sup>Alleles 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>.



0197

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

101.519-12 – including *Taq* polymerase  
101.519-12u – without *Taq* polymerase

Visit [www.caredx.com](http://www.caredx.com) for  
“Instructions for Use” (IFU)

Lot No.: 7R0

Lot-specific information

### ALLELE CONFIRMATION STATUS

Allele	Status <sup>1</sup>	Allele	Status <sup>1</sup>	Allele	Status <sup>1</sup>	Allele	Status <sup>1</sup>
B*18:01:01:01	Confirmed	B*18:19	Confirmed	B*18:68	Confirmed	B*18:116	Unconfirmed
B*18:01:01:02	Confirmed	B*18:20	Confirmed	B*18:69	Confirmed	B*18:117	Unconfirmed
B*18:01:01:03	Confirmed	B*18:21	Unconfirmed	B*18:70	Unconfirmed	B*18:118	Unconfirmed
B*18:01:01:04	Unconfirmed	B*18:22	Confirmed	B*18:71	Unconfirmed	B*18:119	Unconfirmed
B*18:01:01:05	Unconfirmed	B*18:23N	Unconfirmed	B*18:72:01	Unconfirmed	B*18:120	Unconfirmed
B*18:01:01:06	Unconfirmed	B*18:24	Unconfirmed	B*18:72:02	Confirmed	B*18:121	Confirmed
B*18:01:01:07	Unconfirmed	B*18:25	Confirmed	B*18:72:03	Unconfirmed	B*18:122	Unconfirmed
B*18:01:02	Unconfirmed	B*18:26	Confirmed	B*18:73	Confirmed	B*18:123	Unconfirmed
B*18:01:03	Unconfirmed	B*18:27	Unconfirmed	B*18:74N	Unconfirmed	B*18:124	Unconfirmed
B*18:01:04	Unconfirmed	B*18:28	Confirmed	B*18:75	Confirmed	B*18:125	Unconfirmed
B*18:01:05	Confirmed	B*18:29	Unconfirmed	B*18:76	Unconfirmed	B*18:126	Unconfirmed
B*18:01:06	Confirmed	B*18:30	Unconfirmed	B*18:77	Confirmed	B*18:127	Unconfirmed
B*18:01:07	Unconfirmed	B*18:31	Unconfirmed	B*18:78	Unconfirmed	B*18:128	Unconfirmed
B*18:01:08	Confirmed	B*18:32	Confirmed	B*18:79	Confirmed	B*18:129	Unconfirmed
B*18:01:09	Unconfirmed	B*18:33	Confirmed	B*18:80	Unconfirmed	B*18:130	Unconfirmed
B*18:01:10	Confirmed	B*18:34	Confirmed	B*18:81	Unconfirmed	B*18:131	Unconfirmed
B*18:01:11	Unconfirmed	B*18:35	Confirmed	B*18:82	Unconfirmed	B*18:132	Unconfirmed
B*18:01:12	Unconfirmed	B*18:36	Unconfirmed	B*18:83	Unconfirmed	B*18:133	Unconfirmed
B*18:01:13	Unconfirmed	B*18:37	Confirmed	B*18:84	Unconfirmed	B*18:134	Unconfirmed
B*18:01:14	Unconfirmed	B*18:38	Unconfirmed	B*18:85	Unconfirmed	B*18:135	Unconfirmed
B*18:01:15	Unconfirmed	B*18:39	Confirmed	B*18:86	Unconfirmed	B*18:136	Confirmed
B*18:01:16	Unconfirmed	B*18:40	Confirmed	B*18:87	Unconfirmed	B*18:137	Unconfirmed
B*18:01:17	Unconfirmed	B*18:41	Unconfirmed	B*18:88	Unconfirmed	B*18:138N	Unconfirmed
B*18:01:18	Unconfirmed	B*18:42	Unconfirmed	B*18:89	Unconfirmed	B*18:139	Unconfirmed
B*18:01:19	Unconfirmed	B*18:43	Confirmed	B*18:90	Unconfirmed		
B*18:01:20	Unconfirmed	B*18:44:01	Confirmed	B*18:91	Unconfirmed		
B*18:01:21	Confirmed	B*18:44:02	Unconfirmed	B*18:92	Unconfirmed		
B*18:01:22	Confirmed	B*18:45	Confirmed	B*18:93	Unconfirmed		
B*18:01:23	Unconfirmed	B*18:46	Unconfirmed	B*18:94N	Confirmed		
B*18:01:24	Unconfirmed	B*18:47	Confirmed	B*18:95	Confirmed		
B*18:01:25	Unconfirmed	B*18:48	Unconfirmed	B*18:96	Unconfirmed		
B*18:02	Confirmed	B*18:49	Confirmed	B*18:97	Unconfirmed		
B*18:03	Confirmed	B*18:50	Confirmed	B*18:98	Unconfirmed		
B*18:04:01	Confirmed	B*18:51	Confirmed	B*18:99	Unconfirmed		
B*18:04:02	Unconfirmed	B*18:52	Unconfirmed	B*18:100	Unconfirmed		
B*18:05	Confirmed	B*18:53	Confirmed	B*18:101	Unconfirmed		
B*18:06	Confirmed	B*18:54	Confirmed	B*18:102	Unconfirmed		
B*18:07:01	Confirmed	B*18:55	Unconfirmed	B*18:103	Unconfirmed		
B*18:07:02	Confirmed	B*18:56	Unconfirmed	B*18:104	Unconfirmed		
B*18:08	Confirmed	B*18:57	Unconfirmed	B*18:105	Unconfirmed		
B*18:09	Confirmed	B*18:58	Unconfirmed	B*18:106	Unconfirmed		
B*18:10	Unconfirmed	B*18:59	Unconfirmed	B*18:107	Unconfirmed		
B*18:11	Confirmed	B*18:60	Confirmed	B*18:108	Unconfirmed		
B*18:12:01	Confirmed	B*18:61	Confirmed	B*18:109	Unconfirmed		
B*18:12:02	Unconfirmed	B*18:62	Unconfirmed	B*18:110	Confirmed		
B*18:13	Confirmed	B*18:63	Unconfirmed	B*18:111	Unconfirmed		
B*18:14	Confirmed	B*18:64	Unconfirmed	B*18:112	Unconfirmed		
B*18:15	Unconfirmed	B*18:65	Unconfirmed	B*18:113	Unconfirmed		
B*18:17N	Confirmed	B*18:66	Unconfirmed	B*18:114	Confirmed		
B*18:18	Unconfirmed	B*18:67	Unconfirmed	B*18:115	Unconfirmed		

<sup>1</sup>Allele status “confirmed” or “unconfirmed” as listed on the IMGT/HLA web page 2017-August-10, release 3.29.0, [www.ebi.ac.uk/imgt/hla](http://www.ebi.ac.uk/imgt/hla).



0197

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

101.519-12 – including *Taq* polymerase  
101.519-12u – without *Taq* polymerase

Visit [www.caredx.com](http://www.caredx.com) for  
“Instructions for Use” (IFU)

Lot No.: **7R0**

Lot-specific information

### RESOLUTION IN HOMO- AND HETEROZYGOTES

Results file with resolution in HLA-B\*18 homo- and heterozygotes is available upon request.



0197

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

101.519-12 – including *Taq* polymerase  
101.519-12u – without *Taq* polymerase

Visit [www.caredx.com](http://www.caredx.com) for  
“Instructions for Use” (IFU)

Lot No.: 7R0

Lot-specific information  
**SPECIFICITY TABLE**

**HLA-B\*18 SSP subtyping**

Specificities and sizes of the PCR products of the 41+1 primer mixes used for HLA-B\*18 SSP subtyping

Primer Mix	Size of spec. PCR product <sup>1</sup>	Size of control band <sup>2</sup>	Amplified HLA-B*18 alleles <sup>3</sup>	Other amplified HLA Class I alleles
1	170 bp	800 bp	*18:01:01:01-18:02:03, 18:04:01-18:08, 18:10-18:15, 18:17N-18:28, 18:30-18:53, 18:55-18:71, 18:73-18:91, 18:93, 18:95-18:101, 18:103-18:106Q, 18:109-18:131:01:02, 18:133-18:135:01:02, 18:137-18:141, 18:143-18:151, 18:153-18:170, 18:173, 18:176-18:193, 18:196-18:197, 18:199-18:202, 18:204-18:226	*15:545, 35:289, 35:487, 48:28
2	260 bp	800 bp	*18:01:01:01-18:01:40, 18:01:42-18:01:49, 18:01:51-18:01:52, 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, 18:190-18:203, 18:205-18:209, 18:211-18:226	*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, 15:610, 39:32, 39:43, 39:48, 40:51, 40:113, 40:163, 51:06:01:01-51:06:04, 51:45, 51:62, 51:135, 51:194, 51:293, 51:319, 51:341, 56:31, 67:06, <b>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, C*08:243, C*08:246</b>
3	260 bp	800 bp	*18:02:01-18:02:02, 18:179	*27:28, 27:62
4 <sup>4</sup>	100 bp	800 bp	*18:03:01:01-18:03:02, 18:152, 18:171, 18:198, 18:203	*07:05:11, 08:04:02, 39:39:02
5 <sup>4</sup>	115 bp	1070 bp	*18:72:01-18:72:03	*07:05:11, 08:04:02, 15:01:38 <sup>w</sup> , 15:64:02, 35:01:57 <sup>w</sup> , 35:02:02 <sup>w</sup> , 35:20:02 <sup>w</sup> , 35:323:01 <sup>w</sup> , 39:39:02, 53:01:26 <sup>w</sup> , <b>C*06:02:101, C*12:301<sup>w</sup></b>
	145 bp		*18:04:01, 18:24, 18:98:02, 18:125	
6	130 bp 200 bp 245 bp	1070 bp	*18:05:01:01-18:05:01:02 *18:31 *18:60	*39:193 *40:67, 47:06 <b>C*02:177</b>



0197

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

101.519-12 – including *Taq* polymerase  
101.519-12u – without *Taq* polymerase

Visit [www.caredx.com](http://www.caredx.com) for  
“Instructions for Use” (IFU)

Lot No.: **7R0**

Lot-specific information

<b>7<sup>4</sup></b>	90 bp 150 bp	1070 bp	*18:41 *18:07:01-18:07:03, 18:79, 18:136 *18:74N	*15:416 *08:176, 35:289, 35:487
	230 bp			<b>C*07:483N</b>
<b>8</b>	190 bp	1070 bp	*18:10, 18:21, 18:35, 18:50	*07:02:01:01-07:02:05, 07:02:07- 07:04:02, 07:07:01:01-07:13, 07:15- 07:16, 07:18:01-07:18:02, 07:21-07:23, 07:25-07:27, 07:29-07:30, 07:33:01- 07:33:03, 07:35-07:39, 07:41-07:42, 07:44N-07:52, 07:54-07:59, 07:61- 07:68:03, 07:70-07:77, 07:79, 07:81- 07:89, 07:91-07:95, 07:98-07:99, 07:101-07:104, 07:106-07:111N, 07:113-07:114, 07:116-07:122, 07:124- 07:130, 07:132-07:136:02, 07:139:01- 07:139:02, 07:141-07:175, 07:177- 07:181N, 07:183-07:196, 07:198- 07:200, 07:202-07:205, 07:208, 07:211- 07:212, 07:215-07:219, 07:221, 07:224, 07:226-07:234, 07:236-07:248, 07:250- 07:257, 07:259, 07:261, 07:263, 07:265- 07:268, 07:271-07:277, 07:279-07:282, 07:285N-07:286, 07:288-07:292, 07:294-07:303:02, 07:305-07:313, 07:315N-07:316N, 07:318N-07:323, 07:325N-07:326, 07:328-07:331, 07:334-07:339, 07:341-07:348, 07:350- 07:351N, 07:354-07:355, 07:361- 07:367, 07:369-07:377, 07:379-07:385, 07:388, 07:390-07:394, 07:396-07:398, 07:400-07:406, 07:409-07:425N, 07:427-07:433, 07:435N-07:442, 07:444-07:463, 07:465-07:466, 07:468N-07:469N, 08:156, 13:26:01- 13:26:02, 13:35, 13:72, 13:174, 15:40:01-15:40:02, 15:47:01-15:47:02, 15:49, 15:52, 15:114, 15:117, 15:124, 15:138, 15:238, 15:241, 15:389, 15:421, 15:519, 27:34, 27:41, 27:136, 35:15:01- 35:15:02, 35:33, 35:66, 35:86, 35:341, 37:07, 40:03:01:01-40:03:02, 40:18, 40:20:01:01-40:20:01:02, 40:24, 40:31- 40:33, 40:44, 40:52, 40:59, 40:98, 40:120, 40:159, 40:267, 40:284, 40:352, 40:522, 46:06, 46:25, 46:30, 48:08, 48:23, 48:46, 53:56, 57:13, 57:25, 58:37, <b>C*02:02:19, C*02:06:01- 02:06:02, C*02:23, C*02:36:01- 02:36:02, C*02:117, C*02:203, C*07:850, C*15:42, C*15:111, C*15:201</b>
<b>9<sup>4</sup></b>	125 bp 255 bp	1070 bp	*18:75 *18:08, 18:27	<b>A*24:220, C*14:76</b>
<b>10<sup>4,6</sup></b>	85 bp 175 bp	<b>800 bp</b>	*18:23N *18:28	*44:108N *15:250, 27:132, 40:226, 57:156



0197

For *In Vitro* Diagnostic Use

MA123 v02 SSP PI Template

Date: March 2023, Rev. No: 00



101.519-12 – including *Taq* polymerase  
101.519-12u – without *Taq* polymerase

Visit [www.caredx.com](http://www.caredx.com) for  
“Instructions for Use” (IFU)

Lot No.: **7R0**

Lot-specific information

Lot No.	Fragment Size	Reference Size	Alleles	Alleles
11 <sup>4</sup>	125 bp	1070 bp	*18:09, 18:54, 18:67, 18:136, 18:194:01:01- 18:195	*44:03:12, 53:01:26, <b>A*24:02:37</b>
	610 bp		*18:36, 18:56-18:58, 18:101	*15:01:38, 15:64:02, 35:02:02, 35:20:02, 35:323:01, <b>A*26:01:16</b>
12 <sup>4</sup>	80 bp	1070 bp	*18:41, 18:73	*15:416
	140 bp		*18:12:01-18:12:02, 18:77 18:178, 18:195	*15:545, 44:445, 48:28
13 <sup>4</sup>	85 bp	1070 bp	*18:13, 18:19, 18:30	*07:218, 07:220, 14:03, 14:112, 15:38:01-15:38:02, 15:368, 44:275, 51:29, 51:61:01-51:61:02, 51:82, 51:217, 51:279, 52:21:01-52:21:02, 52:24, 52:97, <b>A*66:04<sup>w</sup>, C*01:30, C*02:142, C*05:216:01:01- 05:216:01:02, C*06:207, C*08:51, C*08:114, C*08:246, C*12:87, C*14:76</b>
	265 bp		*18:44:01-18:44:02	*14:01:01:01-14:02:08, 14:02:10-14:04, 14:07N, 14:09, 14:11-14:12, 14:14- 14:36, 14:38-14:45, 14:47-14:52, 14:54, 14:57-14:61, 14:63-14:94, 14:97- 14:101N, 14:103-14:113N, <b>C*01:30, C*06:207, C*12:87, C*14:76</b>
14 <sup>4</sup>	110 bp	1070 bp	*18:102, 18:107	*44:03:12
	170 bp		*18:04:01-18:04:02, 18:25, 18:68, 18:107, 18:125	*08:04:02, 15:01:38, 15:64:02, 35:01:57, 35:02:02, 35:20:02, 35:323:01, 44:03:12, 53:01:26
	260 bp		*18:14	*07:218, 07:220, 08:118, 14:05, 14:13, 14:53, 35:519, 40:174, 51:64
15 <sup>4</sup>	95 bp	1070 bp	*18:15, 18:19, 18:30, 18:57:01-18:57:02, 18:152	*07:218, 13:62, 14:01:01:01-14:40, 14:42:01-14:42:02, 14:44-14:45, 14:47- 14:55, 14:57-14:58, 14:60-14:61, 14:63- 14:89, 14:91-14:94, 14:96-14:113N, 15:37-15:38:02, 15:323, 15:335, 15:364, 15:368, 15:435, 15:610, 15:645, 27:153, 35:21, 35:96, 35:188, 35:519, 40:28, 40:51, 40:174, 44:459, 49:09, 50:58, 51:01:01:01-51:01:101, 51:03-51:04:02, 51:06:01:01-51:07:02, 51:11N-51:14, 51:16-51:18, 51:21-51:22, 51:24:01- 51:24:05, 51:26-51:30, 51:32-51:33, 51:35, 51:37-51:39, 51:41N, 51:43, 51:45-51:46, 51:48-51:52, 51:55-51:58, 51:60-51:72, 51:74-51:80, 51:82- 51:92:02, 51:94-51:96, 51:98N-51:107, 51:109-51:114, 51:116-51:119, 51:121, 51:123-51:138, 51:140, 51:142, 51:145, 51:147, 51:149N-51:152, 51:154- 51:156, 51:158:01-51:174:02, 51:176- 51:179, 51:182-51:193:02, 51:195- 51:196, 51:198, 51:200-51:216, 51:218- 51:219, 51:221-51:227, 51:229-51:258, 51:260-51:262, 51:264N-51:273N, 51:277-51:279, 51:281-51:286, 51:288- 51:294, 51:296-51:299, 51:301-51:336, 51:339, 51:341, 51:343-51:344N,



0197

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

101.519-12 – including *Taq* polymerase  
101.519-12u – without *Taq* polymerase

Visit [www.caredx.com](http://www.caredx.com) for  
“Instructions for Use” (IFU)

Lot No.: **7R0**

Lot-specific information

				51:346Q-51:351, 51:353, 51:355-51:358, 51:360-51:370, 51:372-51:375, 52:01:01:01-52:01:32, 52:01:34-52:02:02, 52:04-52:09:02, 52:12-52:18, 52:20-52:27, 52:30-52:66, 52:68-52:70, 52:72-52:73, 52:75-52:110N, 53:06, 53:28, 56:05:01-56:06, 56:21, 58:08:01-58:08:02, 78:01:01:02-78:03, 78:05-78:07, 78:09, <b>A*33:231, C*01:30, C*02:142, C*03:384, C*05:216:01:01-05:216:01:02, C*06:207, C*08:51, C*08:114, C*08:243, C*08:246, C*12:87, C*14:76, C*15:39, C*15:130, C*15:195</b>
<b>16<sup>4</sup></b>	95 bp	1070 bp	*18:19, 18:164	*08:70, 08:281, 13:31, 13:41, 13:131, 13:164, 15:01:44, 15:07:03, 15:27:03, 15:38:02, 15:78:04, 15:269, 35:14:01, 35:14:03, 35:62, 35:163, 35:343, 35:390N, 35:413, 35:512, 37:66, 39:36, 44:146, 44:275, 44:299, 46:01:03, 46:01:16, 50:47, 51:61:02, 52:21:01-52:21:02, 53:70, 54:33, 54:40, 55:21, 56:43, 58:78, <b>A*25:76, A*26:68, C*01:09:01, C*02:02:14, C*06:02:27, C*06:02:95, C*07:22, C*07:138, C*07:812, C*07:847, C*12:03:16, C*12:03:30</b>
	360 bp		*18:17N	
<b>17<sup>5</sup></b>	270 bp	1070 bp	*18:69, 18:204	*37:04:01-37:04:02
<b>18<sup>4,5,6</sup></b>	125 bp 150 bp	1070 bp	*18:32 *18:15, 18:21 <sup>w</sup> , 18:30 <sup>w</sup> , 18:57:01-18:57:02, 18:101, 18:152	*15:192, 15:281, 35:91, 57:113, 58:138 *07:09:01 <sup>w</sup> -07:09:02 <sup>w</sup> , 07:11 <sup>w</sup> , 07:162 <sup>w</sup> , 07:237 <sup>w</sup> , 07:255 <sup>w</sup> , 15:03:01:01-15:03:13, 15:16:01:01-15:16:05, 15:18:01:01-15:18:10, 15:23, 15:29:01:01-15:29:01:02, 15:39:01:01-15:40:02, 15:47:01 <sup>w</sup> -15:47:02 <sup>w</sup> , 15:49 <sup>w</sup> , 15:61-15:62, 15:64:01-15:64:02, 15:65 <sup>w</sup> , 15:67, 15:69, 15:72, 15:74, 15:80, 15:93, 15:95, 15:98, 15:103, 15:108, 15:115, 15:119, 15:127, 15:131-15:132, 15:134, 15:138, 15:153, 15:158, 15:161, 15:173, 15:176, 15:194-15:195, 15:197:01-15:198, 15:210, 15:220:01:01-15:220:02, 15:220:04, 15:221 <sup>w</sup> , 15:223, 15:226N, 15:238, 15:242:01-15:242:02, 15:254-15:255, 15:263, 15:266, 15:268, 15:274, 15:281-15:282, 15:288, 15:290, 15:292-15:294N, 15:306-15:307, 15:310-15:311, 15:314, 15:335, 15:337, 15:351, 15:354, 15:362, 15:364, 15:369, 15:376, 15:379 <sup>w</sup> , 15:380N, 15:382, 15:388-15:389, 15:397, 15:402, 15:408, 15:414, 15:426, 15:433-15:434, 15:436, 15:444, 15:447-15:448, 15:451, 15:475,



0197

For *In Vitro* Diagnostic Use

MA123 v02 SSP PI Template

Date: March 2023, Rev. No: 00

101.519-12 – including *Taq* polymerase  
101.519-12u – without *Taq* polymerase

Visit [www.caredx.com](http://www.caredx.com) for  
“Instructions for Use” (IFU)

Lot No.: **7R0**

Lot-specific information

				15:487N, 15:494, 15:497, 15:502, 15:504:01-15:504:02, 15:508-15:509, 15:511, 15:517, 15:519 <sup>w</sup> , 15:526-15:527, 15:548, 15:550, 15:560, 15:570-15:571, 15:573, 15:582, 15:588, 15:602, 15:607, 15:610, 15:612, 15:614:01:01- 15:614:01:02, 15:616Q-15:617, 15:626, 15:643, 35:11:01-35:11:02, 35:11:03 <sup>w</sup> , 35:21, 35:58, 35:99 <sup>w</sup> , 35:188, 35:232 <sup>w</sup> , 35:277, 35:337:01 <sup>w</sup> -35:337:02 <sup>w</sup> , 35:439:01:01-35:439:01:02, 35:519, 46:03 <sup>w</sup> , 46:08, 46:62 <sup>w</sup> , 46:83, 46:93, 48:25, 49:04:01-49:04:02, 51:37, 51:45, 53:06, 53:08:01-53:08:02, 53:28, 55:14, 55:68, 56:32, 57:13 <sup>w</sup> , 57:22, 58:06, 58:19, 58:46, 58:91, <b>C*01:102<sup>w</sup>,</b> <b>C*03:175, C*03:199, C*03:245,</b> <b>C*05:215<sup>w</sup>, C*08:113, C*15:09:01:01-</b> <b>15:09:02, C*15:19, C*15:27, C*15:61,</b> <b>C*15:107, C*15:126, C*15:143<sup>w</sup>,</b> <b>C*15:194</b>
<b>19<sup>4</sup></b>	105 bp 160 bp 405 bp	1070 bp	*18:06, 18:142 <sup>w</sup> *18:53 *18:39	
<b>20<sup>5</sup></b>	290 bp	1070 bp	*18:20, 18:122, 18:165- 18:166	*07:14:01-07:14:02, 07:17, 07:28, 07:96:01-07:96:02, 07:115, 07:197, 07:225, 07:260, 07:284, 07:359, 08:14, 08:28, 08:49, 08:74, 08:87, 08:111, 08:200, 08:227, 08:255, 13:10, 13:46, 13:51, 13:79, 13:127, 14:01:01:01- 14:12, 14:14-14:22, 14:24-14:52, 14:54- 14:55, 14:57-14:95, 14:97-14:113N, 15:02:01:01-15:02:12, 15:06, 15:13:01- 15:13:03, 15:17:01:01-15:17:07, 15:21:01:01-15:21:01:02, 15:25:01:01- 15:25:04, 15:31:01:01-15:31:01:03, 15:36, 15:44, 15:55, 15:77, 15:88- 15:89:02, 15:106, 15:112, 15:121, 15:128, 15:137, 15:139, 15:144, 15:156, 15:162, 15:168, 15:170, 15:177, 15:196, 15:204, 15:208, 15:213-15:214, 15:216, 15:230, 15:233, 15:240, 15:250, 15:265, 15:271, 15:273, 15:283, 15:289, 15:291, 15:297, 15:301-15:302N, 15:308, 15:319, 15:325, 15:328, 15:330, 15:339, 15:341-15:342, 15:345, 15:356-15:358, 15:360, 15:366, 15:374, 15:378, 15:384:01-15:384:02, 15:394-15:396, 15:399, 15:403-15:405, 15:411, 15:418, 15:420, 15:423-15:425, 15:437-15:438, 15:446, 15:454N, 15:458, 15:462- 15:463N, 15:468, 15:488, 15:491, 15:495, 15:500, 15:505, 15:516, 15:523, 15:532, 15:537, 15:543-15:544N, 15:546Q, 15:553, 15:555, 15:557, 15:564, 15:566-15:567, 15:569,



0197

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

101.519-12 – including Taq polymerase  
101.519-12u – without Taq polymerase

Visit [www.caredx.com](http://www.caredx.com) for  
“Instructions for Use” (IFU)

Lot No.: 7R0

Lot-specific information

			15:574-15:575N, 15:578, 15:584N, 15:589, 15:592, 15:594, 15:596N, 15:603, 15:613, 15:615, 15:619, 15:625, 15:627, 15:629-15:630, 15:642, 15:644-15:645, 27:01-27:06:02, 27:08-27:10, 27:12:01:01-27:19:01:02, 27:21:01-27:21:02, 27:23, 27:25-27:26, 27:28-27:32, 27:35-27:40, 27:42, 27:44-27:104, 27:106-27:124, 27:126-27:129, 27:131-27:135, 27:137-27:152, 27:154-27:163, 27:165-27:167, 27:169-27:179, 27:181-27:186, 27:188-27:214, 27:216-27:217, 27:220-27:222, 27:224-27:232, 27:234-27:250, 27:252-27:264, 35:164, 35:215:01-35:215:02, 35:234, 35:261, 35:366, 35:426, 35:431, 35:446, 35:545, 35:547, 35:555, 37:01:01:01-37:06:02, 37:08, 37:10-37:11, 37:13-37:34, 37:36-37:55, 37:57-37:76, 37:78-37:83, 37:85-37:93, 37:95-37:107, 38:22, 38:170, 39:17, 39:169, 39:171, 40:09, 40:42, 40:60, 40:89, 40:124:01-40:124:02, 40:172, 40:180, 40:280, 40:330, 40:414, 40:422, 40:429, 40:458, 40:498, 41:52, 42:20, 44:02:01:01-44:03:21, 44:03:23-44:03:45, 44:03:47-44:09, 44:11-44:13, 44:15:01:01-44:16, 44:18:01:01-44:30, 44:32-44:42, 44:44, 44:46:01-44:50:03, 44:52N-44:61N, 44:63-44:76, 44:78-44:81, 44:83-44:106, 44:108N-44:121, 44:124-44:134, 44:136-44:165, 44:167-44:183, 44:185-44:212, 44:214-44:229, 44:231-44:245:02, 44:247-44:275, 44:277-44:338, 44:340-44:351, 44:353-44:363, 44:437-44:450, 44:452:01-44:455, 44:457-44:458, 44:460-44:524, 44:526-44:546, 45:01:01:01-45:08, 45:10-45:13, 45:15-45:25, 45:27-45:30, 47:01:01:02-47:12, 48:17, 48:26, 49:01:01:01-49:03, 49:05:01-49:14, 49:16-49:35, 49:37-49:78, 50:01:01:01-50:02:01:02, 50:04:01-50:22, 50:31-50:79, 51:42, 51:85, 51:172, 51:197, 51:216, 51:223, 51:227, 51:261, 51:274, 51:298, 51:359, 52:26, 52:63, 52:88, 53:07, 53:62, 54:15, 55:41, 55:58, 57:04:01-57:05, 57:32, 57:41, 58:114, 58:134, 83:01
21	215 bp	1070 bp	*18:01:01:01-18:01:49, 18:01:51-18:09, 18:12:01-18:15, 18:17N-18:19, 18:22-18:34, 18:36-18:55, 18:57:01-18:57:02, 18:59-18:100, 18:102, 18:104-18:109, 18:111-18:121, 18:123-18:163, 18:167, *07:218, 07:220, 08:118, 13:15, 13:62, 14:13, 14:23, 14:53, 14:56, 14:96, 15:37-15:38:02, 15:185, 15:323, 15:335, 15:364, 15:368, 15:435, 15:610, 27:153, 35:21, 35:24:01-35:24:02, 35:81, 35:96, 35:109, 35:157, 35:188, 35:190, 35:233, 35:287, 35:519, 39:32, 39:43, 39:48, 40:28, 40:51, 40:113, 40:163, 40:174,



0197

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

101.519-12 – including *Taq* polymerase  
101.519-12u – without *Taq* polymerase

Visit [www.caredx.com](http://www.caredx.com) for  
“Instructions for Use” (IFU)

Lot No.: **7R0**

Lot-specific information

Lot No.: <b>7R0</b>		Lot-specific information	
		18:169-18:188, 18:190-18:198, 18:200-18:226	44:459, 51:01:01:01-51:01:49, 51:01:51-51:01:101, 51:03-51:04:02, 51:06:01:01-51:09:03, 51:11N-51:14, 51:16, 51:19-51:22, 51:24:01-51:24:05, 51:26-51:33, 51:35, 51:37-51:39, 51:41N, 51:43-51:46, 51:48-51:53, 51:55-51:58, 51:60-51:80, 51:82-51:84, 51:86-51:92:02, 51:94-51:107, 51:109-51:142, 51:145, 51:147, 51:149N-51:156, 51:158:01-51:171, 51:173Q-51:174:02, 51:176-51:179, 51:181-51:196, 51:198, 51:200-51:215, 51:217-51:219, 51:221-51:222, 51:224-51:226, 51:228-51:253, 51:255-51:260, 51:262-51:273N, 51:275-51:294, 51:296-51:297, 51:299, 51:301-51:322, 51:324-51:344N, 51:346Q-51:351, 51:353-51:358, 51:360-51:375, 52:01:01:01-52:02:02, 52:04-52:10:03, 52:12-52:25:02, 52:27-52:62, 52:64-52:66, 52:68-52:87, 52:89N-52:110N, 53:02, 53:06, 53:28, 56:05:01-56:06, 56:21, 56:31, 56:34, 57:14:01-57:14:02, 58:08:01-58:09, 58:76, 67:06, 78:01:01:02-78:03, 78:05-78:10, <b>C*15:39, C*15:130, C*15:195</b>
<b>22</b>	130 bp 150 bp 270 bp	<b>800 bp</b>	*18:75, 18:77 *18:33 *18:22, 18:69 <sup>w</sup> , 18:105, 18:149-18:150, 18:204 <sup>w</sup>  *14:10, 14:102, 15:645, 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 <sup>w</sup> -37:04:02 <sup>w</sup> , 40:28, 44:190, 44:203:01-44:203:02, 44:275, 44:290, 51:04:01-51:04:02, 51:46, 51:56:01-51:56:03, 51:139, 51:227, 51:281, 51:310, 52:88, 53:02, 53:06, 53:28, 57:14:01-57:14:02, 58:09, 58:76, <b>C*03:384, C*15:39, C*15:130, C*15:195</b>
<b>23</b>	145 bp 160 bp 515 bp	1070 bp	*18:51 *18:53 *18:21, 18:40, 18:61, 18:189, 18:217  *07:05:11, 08:04:02, <b>C*06:02:101</b>
<b>24</b>	460 bp	1070 bp	*18:26, 18:61, 18:97, 18:168, 18:189, 18:191  *07:05:11, 08:04:02, 35:02:02, 35:323:01, 39:39:02
<b>25<sup>4</sup></b>	75 bp 190 bp	1070 bp	*18:48 *18:35, 18:54, 18:95, 18:110, 18:195  *07:68:01-07:68:03, 07:214, 07:237, 07:262:01-07:262:02, 07:424, 15:138, 15:230, 15:241, 15:297, 35:66, 40:77, 40:87:01-40:87:02, 40:121, 40:158, 40:222, 40:237, 40:368, 40:422, 44:150, 46:87, 48:12, 48:14, 48:26, 48:29
<b>26<sup>4,6</sup></b>	90 bp 115 bp 180 bp	1070 bp	*18:42 *18:92 *18:04:01-18:04:02, 18:25, 18:43, 18:107, 18:125  *07:05:11, 15:01:38, 15:64:02, 35:01:57, 35:02:02, 35:20:02, 39:39:02, 44:03:12,



0197

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

101.519-12 – including *Taq* polymerase  
101.519-12u – without *Taq* polymerase

Visit [www.caredx.com](http://www.caredx.com) for  
“Instructions for Use” (IFU)

Lot No.: **7R0**

Lot-specific information

Lot No.: <b>7R0</b>			Lot-specific information	
				53:01:26, <b>A*24:02:37, A*26:01:16, C*12:301</b>
<b>27<sup>4</sup></b>	80 bp	<b>800 bp</b>	*18:37:01-18:37:02, 18:73, 18:125	*07:109, 07:356, 08:176, 48:28
	135 bp		*18:46, 18:74N, 18:78	*13:10, 13:26:01-13:26:02, 13:72, 13:127, 13:160, <b>C*12:120</b>
	175 bp		*18:94N	
<b>28<sup>4</sup></b>	100 bp	<b>800 bp</b>	*18:45	
	175 bp		*18:38, 18:74N, 18:78	*08:83, 13:10-13:11, 13:71, 13:108, 38:38, 40:91, 40:197
	200 bp		*18:95	
<b>29<sup>4,7</sup></b>	65 bp	1070 bp	*18:50	*07:218, 13:15, 14:111, 40:113, 51:16, 51:31, 51:82, 52:08, 73:01:01:01-73:01:01:02, 73:03, 78:08, <b>C*02:142, C*03:384, C*08:246</b>
	120 bp		*18:47	
	255 bp		*18:18:01:01-18:18:01:02	<b>C*07:516</b>
<b>30<sup>4,5</sup></b>	100 bp	<b>800 bp</b>	*18:31	*51:228, 52:28
	145 bp		*18:34	
	420 bp		*18:52, 18:105	*35:01:57, 35:02:02, 35:20:02, 35:323:01, 53:01:26, <b>C*06:02:101, C*12:301</b>
<b>31</b>	135 bp	1070 bp	*18:49, 18:79, 18:108, 18:132, 18:142	*35:27, 35:56, 35:185, 35:203, 35:355, 35:550, 37:05, 37:96, 78:06, 78:09-78:10
<b>32</b>	135 bp	1070 bp	*18:04:01-18:04:02, 18:98:01-18:98:02, 18:125	*15:01:38, 35:01:57, 35:02:02, 35:20:02, 35:323:01, 53:01:26, <b>A*24:02:37, A*26:01:16, C*12:301</b>
<b>33<sup>4</sup></b>	115 bp	1070 bp	*18:72:01-18:72:03	*07:05:11, 08:04:02, 15:01:38 <sup>w</sup> , 15:64:02, 35:01:57 <sup>w</sup> , 35:02:02 <sup>w</sup> , 35:20:02 <sup>w</sup> , 35:323:01 <sup>w</sup> , 39:39:02, 53:01:26 <sup>w</sup> , <b>C*06:02:101, C*12:301<sup>w</sup></b>
<b>34</b>	205 bp	1070 bp	*18:114	
<b>35</b>	225 bp	1070 bp	*18:121	
<b>36<sup>5</sup></b>	160 bp	1070 bp	*18:138N	
<b>37<sup>7</sup></b>	205 bp	1070 bp	*18:10-18:11, 18:21, 18:35, 18:56, 18:58, 18:101, 18:110, 18:164	*07:09:01-07:09:02, 07:11, 07:162, 07:235, 07:237, 07:255, 08:37, 08:89, 08:107, 08:291, 13:04, 13:26:01-13:26:02, 13:72, 15:01:01:01-15:01:04, 15:01:06-15:01:09, 15:01:11-15:01:39, 15:01:41-15:01:78, 15:03:01:01-15:05:03, 15:07:01:01-15:08:02, 15:11:01-15:12:01, 15:12:03, 15:14-15:16:05, 15:18:01:01-15:18:07, 15:18:09-15:20, 15:23-15:24:02, 15:26N-15:29:01:02, 15:32:01-15:35:01:02, 15:39:01:01-15:40:02, 15:43, 15:46-15:47:02, 15:49-15:54, 15:56-15:57, 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, 15:91-15:95, 15:97-15:98, 15:101-15:105, 15:107-15:111N, 15:113-15:120, 15:122-15:127, 15:129, 15:131-15:132, 15:135-15:136, 15:138,



0197

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

101.519-12 – including *Taq* polymerase  
 101.519-12u – without *Taq* polymerase

Visit [www.caredx.com](http://www.caredx.com) for  
 “Instructions for Use” (IFU)

Lot No.: **7R0**

Lot-specific information

15:140-15:143, 15:145-15:149N,  
 15:151-15:155, 15:157-15:161, 15:163-  
 15:167, 15:169, 15:171-15:176, 15:178-  
 15:184, 15:186-15:187, 15:189:01-  
 15:195, 15:197:01-15:203, 15:205-  
 15:207, 15:209N-15:212, 15:215,  
 15:217-15:218Q,  
 15:220:01:01-15:220:02, 15:220:04-  
 15:223, 15:225-15:228, 15:231, 15:234-  
 15:239, 15:241-15:242:02, 15:244-  
 15:247, 15:249, 15:251:01-15:251:03,  
 15:254-15:257, 15:259-15:264, 15:266-  
 15:268, 15:270, 15:272N, 15:274-  
 15:282, 15:284-15:286, 15:288, 15:290,  
 15:292-15:296, 15:299-15:300,  
 15:304N-15:307, 15:309-15:311,  
 15:314-15:318, 15:320-15:322, 15:326-  
 15:327, 15:332-15:333, 15:336-15:337,  
 15:340, 15:343-15:344, 15:346-15:355,  
 15:359, 15:362, 15:365, 15:367, 15:369-  
 15:373, 15:375N-15:377Q, 15:379-  
 15:383, 15:385-15:393, 15:397-15:398,  
 15:401-15:402, 15:406-15:410, 15:412-  
 15:415, 15:417, 15:419, 15:421-15:422,  
 15:426, 15:428-15:434, 15:436, 15:440-  
 15:444, 15:447-15:452, 15:456-15:457,  
 15:459, 15:461, 15:464-15:467, 15:469-  
 15:484, 15:487N, 15:489-15:490,  
 15:492-15:494, 15:496N-15:499,  
 15:501-15:502, 15:504:01-15:504:02,  
 15:507-15:515, 15:517-15:522, 15:524-  
 15:526, 15:528N-15:529, 15:531,  
 15:533-15:536, 15:538-15:540N,  
 15:542, 15:545, 15:547-15:551, 15:554,  
 15:556, 15:558-15:562N, 15:565,  
 15:568, 15:570-15:573, 15:576-15:577,  
 15:579-15:583, 15:587-15:588, 15:590-  
 15:591, 15:593, 15:595, 15:598-15:602,  
 15:604N-15:605, 15:607-15:609,  
 15:612, 15:614:01:01-15:614:01:02,  
 15:616Q-15:618, 15:621-15:624,  
 15:626, 15:628, 15:631-15:636, 15:638-  
 15:641, 15:643, 15:647, 27:41,  
 35:01:01:01-35:01:17, 35:01:19-  
 35:01:35, 35:01:37-35:01:73,  
 35:05:01:01-35:05:01:06, 35:05:03-  
 35:05:06, 35:07-35:08:15, 35:10-  
 35:11:03, 35:14:01-35:17:05, 35:19-  
 35:20:02, 35:23, 35:25-35:30:01:02,  
 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,  
 35:110-35:120, 35:122-35:126,



0197

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



101.519-12 – including *Taq* polymerase  
101.519-12u – without *Taq* polymerase

Visit [www.caredx.com](http://www.caredx.com) for  
“Instructions for Use” (IFU)

Lot No.: **7R0**

Lot-specific information

35:130N-35:132, 35:134N-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,  
35:185-35:187, 35:189, 35:191-35:192,  
35:194, 35:196-35:197, 35:200, 35:202-  
35:203, 35:206-35:210, 35:212,  
35:216N-35:219, 35:222, 35:224-  
35:229, 35:232, 35:238-35:241, 35:244-  
35:245, 35:248-35:250, 35:252-35:255,  
35:259-35:260, 35:262-35:265, 35:268-  
35:269, 35:271, 35:275, 35:277, 35:280,  
35:283-35:284, 35:286, 35:288-35:289,  
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, 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, 35:416-  
35:418, 35:421, 35:427N-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, 35:472-35:473,  
35:475-35:476, 35:479-35:481,  
35:484:01-35:485, 35:488, 35:490-  
35:491, 35:493-35:495, 35:497-35:500,  
35:502-35:504, 35:506, 35:509, 35:512-  
35:518, 35:520, 35:523-35:526, 35:528-  
35:530, 35:532-35:533, 35:536, 35:538,  
35:541-35:542N, 35:548-35:549,  
35:551N-35:552, 35:556Q, 35:558-  
35:559, 35:564, 35:566, 37:35, 37:56,  
37:94, 38:52, 38:88, 39:07, 39:91,  
40:03:01:01-40:03:02, 40:20:01:01-  
40:20:01:02, 40:52, 40:59, 40:159,  
40:267, 40:284, 40:352, 41:51, 42:09,  
44:17, 44:43:01-44:43:02, 44:230,  
44:276, 45:09, 46:01:01:01-46:01:38,  
46:01:40-46:10, 46:12-46:17, 46:19-  
46:60, 46:62-46:63, 46:65-46:69, 46:71-  
46:73, 46:75-46:80, 46:82-46:98N,  
48:02:01-48:02:03, 48:23, 48:25,  
49:04:01-49:04:02, 51:220, 53:01:01:01-  
53:01:06, 53:01:08-53:01:16, 53:01:18-  
53:01:29, 53:03, 53:05:01-53:05:02,  
53:08:01-53:18, 53:20-53:27, 53:29-  
53:30, 53:32, 53:34-53:35, 53:37-53:41,  
53:43:01-53:49, 53:51-53:61, 53:63-  
53:72, 54:06, 54:09, 54:14, 55:14,



0197

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



101.519-12 – including *Taq* polymerase  
101.519-12u – without *Taq* polymerase

Visit [www.caredx.com](http://www.caredx.com) for  
“Instructions for Use” (IFU)

Lot No.: **7R0**

Lot-specific information

				55:23, 55:68, 56:03, 56:09, 56:18, 56:32, 56:50, 57:01:01:01-57:01:32, 57:01:34-57:01:46, 57:06, 57:08, 57:10-57:11, 57:13, 57:15-57:16, 57:18-57:27, 57:29-57:31:02, 57:33-57:38, 57:40, 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, 57:102-57:106, 57:108-57:117, 57:119-57:123, 57:125-57:136, 57:138-57:147, 57:149-57:154, 57:156-57:164, 58:01:01:01-58:01:29, 58:01:31-58:02:02, 58:04-58:07, 58:10N-58:19, 58:21-58:26, 58:29, 58:31N-58:33, 58:35-58:44, 58:46-58:64, 58:66-58:72N, 58:74-58:75, 58:77-58:85, 58:88-58:101, 58:103-58:113, 58:115-58:123, 58:125, 58:127-58:133N, 58:135-58:139, <b>C*01:102, C*02:36:01-02:36:02, C*05:215, C*06:89, C*07:123:01-07:123:02, C*07:173, C*07:294, C*08:113, C*12:113, C*15:09:01:01-15:09:02, C*15:19, C*15:27, C*15:61, C*15:107, C*15:126, C*15:143, C*15:194, C*16:20, C*16:109</b>
<b>38<sup>6</sup></b>	185 bp	1070 bp	*18:154N	
<b>39<sup>4</sup></b>	85 bp	1070 bp	*18:29, 18:98:01-18:98:02	*15:71, 15:175, 15:204, 15:225, 15:344, 15:381, 27:214, 35:50, 35:231, 35:280, 35:323:01-35:323:02, 37:22:01-37:22:03, 40:248, 40:282, 40:351, 40:364, 40:526, 41:12, 41:36, 42:27, 46:14, 49:03, 49:48, 51:151, 52:51, 54:02, 55:16, 56:35, 57:39, 57:73, 58:41, <b>C*03:278, C*16:86</b>
<b>40</b>	180 bp	1070 bp	*18:01:01:01-18:01:08, 18:01:10-18:01:11, 18:01:14-18:03:02, 18:05:01:01-18:07:01, 18:08-18:12:01, 18:13-18:15, 18:17N-18:24, 18:26-18:28, 18:30-18:36, 18:37:02-18:42, 18:44:01-18:47, 18:49-18:106Q, 18:108-18:124, 18:126-18:177, 18:179-18:226	*35:323:01
<b>41</b>	175 bp	1070 bp	*18:81	*07:120, 08:301, 14:61, 15:214, 35:250, 37:93, 39:145, 39:158, 40:150, 40:427, 44:311, 48:45, 51:165, 55:108, 57:29
<b>42<sup>8</sup></b>			<b>Negative Control</b>	



0197

For *In Vitro* Diagnostic Use

MA123 v02 SSP PI Template

Date: March 2023, Rev. No: 00

101.519-12 – including *Taq* polymerase  
101.519-12u – without *Taq* polymerase

Visit [www.caredx.com](http://www.caredx.com) for  
“Instructions for Use” (IFU)

**Lot No.: 7R0**

**Lot-specific information**

<sup>1</sup>Alleles 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\*18 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.

<sup>2</sup>The 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.

<sup>3</sup>For 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.

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

<sup>5</sup>Primer mixes 17, 18, 20, 30 and 36 may have tendencies of unspecific amplifications.

<sup>6</sup>Primer mixes 10, 18, 26 and 38 have a tendency giving rise to primer oligomer formation.

<sup>7</sup>Primer mixes 29 and 37 may give rise to a lower yield of HLA-specific PCR product than the other B\*18 primer mixes.

<sup>8</sup>Primer mix 42 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', might be weakly amplified.



0197

For *In Vitro* Diagnostic Use

MA123 v02 SSP PI Template

Date: March 2023, Rev. No: 00

101.519-12 – including *Taq* polymerase  
101.519-12u – without *Taq* polymerase

Visit [www.caredx.com](http://www.caredx.com) for  
“Instructions for Use” (IFU)

Lot No.: 7R0

Lot-specific information  
**PRIMER SPECIFICATION**

Well No.	1	2	3	4	5	6	7	8	9	10	11	12
Length of spec. PCR product	170	260	260	100	115	130	90	190	125	85	125	80
					145	200	150		255	175	610	140
						245	230					
Length of int. pos. control <sup>1</sup>	800	800	800	800	1070	1070	1070	1070	1070	800	1070	1070
5'-primer(s) <sup>2</sup>	161	363	363	234	130	363	161	412	368	523	234	161
	5'-Cgg 3'	5'-Agg 3'	35'-AAT 35'	35'-CAA 35'	35'-AgT 35'	35'-Agg 35'	35'-Cgg 35'	35'-ATg 35'	35'-gTT 35'	35'-CCA 35'	35'-CAA 35'	35'-Cgg 35'
		363			141		363		368	610		363
		5'-Agg 3'			5'-ATT 3'		5'-Agg 3'		5'-gTg 35'	3'-TgT 3'		5'-Agg 3'
					161				368			
					5'-CgA 3'				5'-gTg 3'			
									499			
									5'-TCg 3'			
3'-primer(s) <sup>3</sup>	292	583	583	292	234	453	272	559	583	3 <sup>rd</sup> I	317	197
	5'-gTA 3'	5'-gTg 35'	35'-gTg 35'	35'-gTC 35'	35'-TCT 35'	35'-TCC 35'	35'-TgA 35'	35'-CTC 35'	35'-gTg 35'	35'-TAT 35'	35'-ggA 35'	35'-gAg 35'
	292					523	414				559	257
	5'-gTA 3'					5'-ACC 35'	35'-TgC 3'				5'-CAg 35'	35'-TCg 3'
	294					568	553					259
	5'-CgA 3'					5'-CTT 35'	35'-CTA 3'					5'-CTC 3'
												414
												5'-TgC 3'
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

Well No.	13	14	15	16	17	18	19	20	21	22	23	24
Length of spec. PCR product	85	110	95	95	270	125	105	290	215	130	145	460
	265	170		360		150	160			150	160	
		260					405			270	515	
Length of int. pos. control <sup>1</sup>	1070	1070	1070	1070	1070	1070	1070	1070	1070	800	1070	1070
5'-primer(s) <sup>2</sup>	361	106	527	41	355	419	234	409	409	161	234	234
	5'-AgT 3'	5'-CCA 35'	35'-TgA 35'	35'-CTA 35'	35'-CCA 35'	35'-gTC 35'	35'-CAA 35'	35'-ggT 35'	35'-ggC 35'	35'-Cgg 35'	35'-CAA 35'	35'-CAA 35'
	539	167		486			3 <sup>rd</sup> I		409	355	3 <sup>rd</sup> I	
	5'-gCg 35'	35'-gCT 3'		5'-ACC 3'			5'-Agg 3'		5'-ggC 35'	35'-TCA 35'	35'-Agg 3'	
	539	363								499		
	5'-gTg 35'	35'-AgC 3'								5'-TCg 3'		
3'-primer(s) <sup>3</sup>	583	234	583	234	583	505	299	3 <sup>rd</sup> I	583	257	340	409
	5'-gTg 35'	35'-TCT 35'	35'-gTg 35'	35'-TCT 35'	35'-gTg 35'	35'-gCT 35'	35'-TCA 35'	35'-TAT 35'	35'-gTg 35'	35'-TCg 35'	35'-ggT 35'	35'-ATg 35'
		583		538		527	353			272	463	
		5'-gTg 3'		5'-CCA 3'		5'-CCT 35'	35'-ggC 3'			5'-TgC 35'	35'-gCg 3'	
							685			583	685	
							5'-ggg 3'			5'-gTg 35'	35'-ggg 3'	
Well No.	13	14	15	16	17	18	19	20	21	22	23	24



0197

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

101.519-12 – including *Taq* polymerase  
101.519-12u – without *Taq* polymerase

Visit [www.caredx.com](http://www.caredx.com) for  
“Instructions for Use” (IFU)

Lot No.: 7R0

Lot-specific information

Well No.	25	26	27	28	29	30	31	32	33	34	35	36
Length of spec.	75	90	80	100	65	100	135	135	115	205	225	160
PCR product	190	115	135	175	120	145						
		180	175	200	255	420						
Length of int.	1070	1070	800	800	1070	800	1070	1070	1070	1070	1070	1070
pos. control <sup>1</sup>												
5'-primer(s) <sup>2</sup>	161	97	161	161	103	234	206	141	161	161	363	464
	5' -Cgg 3' 5'	-TCT 3' 5'	-Cgg 3' 5'	-Cgg 3' 5'	-CCT 3' 5'	-CAA 3' 5'	-gAC 3' 5'	-ATT 3' 5'	-CgA 3' 5'	-Cgg 3' 5'	-Agg 3' 5'	-gAA 3'
	463	160	419	369	368	478		142				
	5' -TgA 3' 5'	-ACC 3' 5'	-gTC 3' 5'	-TAC 3' 5'	-gTC 3' 5'	-CgA 3'		5' -TCg 3'				
		186				560	523					
		5' -AgA 3'			5' -CgA 3' 5'	-CCg 3'						
3'-primer(s) <sup>3</sup>	193	234	197	218	181	368	302	234	234	325	545	583
	5' -CgT 3' 5'	-TCT 3' 5'	-gAg 3' 5'	-gCT 3' 5'	-gTA 3' 5'	-CAT 3' 5'	-ggT 3' 5'	-TCT 3' 5'	-TCT 3' 5'	-gTT 3' 5'	-AgT 3' 5'	-gTg 3'
	301		204	322	583	583						
	5' -gTC 3'		5' -TCT 3' 5'	-gTg 3' 5'	-gTg 3' 5'	-gTg 3'						
	322		294	502								
	5' -gTg 3'		5' -CgT 3' 5'	-CTT 3'								
	605		506	506								
	5' -gCT 3'		5' -TgA 3' 5'	-TgA 3'								
			518									
			5' -CCT 3'									
Well No.	25	26	27	28	29	30	31	32	33	34	35	36

Well No.	37	38	39	40	41
Length of spec.	205	185	85	180	175
PCR product					
Length of int.	1070	1070	1070	1070	1070
pos. control <sup>1</sup>					
5'-primer(s) <sup>2</sup>	419	369	97	97	3 <sup>rd</sup> I
	5' -gTC 3' 5'	-TAC 3' 5'	-TCC 3' 5'	-TCC 3' 5'	-Agg 3'
3'-primer(s) <sup>3</sup>	583	512	142	234	704
	5' -gTA 3' 5'	-CCT 3' 5'	-TgC 3' 5'	-TCT 3' 5'	-CCA 3'
Well No.	37	38	39	40	41

<sup>1</sup>The 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.

<sup>2</sup>The nucleotide position matching the specificity-determining 3'-end of the primer is given. Nucleotide numbering as on the [www.ebi.ac.uk/imgt/hla](http://www.ebi.ac.uk/imgt/hla) web site. The sequence of the 3 terminal nucleotides of the primer is given.

<sup>3</sup>The 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](http://www.ebi.ac.uk/imgt/hla) web site. The sequence of the 3 terminal nucleotides of the primer is given.



0197

For *In Vitro* Diagnostic Use

MA123 v02 SSP PI Template

Date: March 2023, Rev. No: 00

101.519-12 – including *Taq* polymerase  
101.519-12u – without *Taq* polymerase

Visit [www.caredx.com](http://www.caredx.com) for  
“Instructions for Use” (IFU)

Lot No.: **7R0**

Lot-specific information

CELL LINE VALIDATION SHEET																				
HLA-B*18 SSP subtyping kit <sup>2</sup>																				
				Well																
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	
				Prod. No.:	202127601	202127602	202127603	202127604	202127605	202127606	202127607	202127608	202348509	202127610	202127611	202127612	202127613	202127614	202127615	202127616
IHC cell line <sup>1</sup>				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

101.519-12 – including *Taq* polymerase  
101.519-12u – without *Taq* polymerase

Visit [www.caredx.com](http://www.caredx.com) for  
“Instructions for Use” (IFU)

Lot No.: **7R0**

Lot-specific information

CELL LINE VALIDATION SHEET																				
HLA-B*18 SSP subtyping kit <sup>2</sup>																				
				Well																
				17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	
				Prod. No.:	202127617	202127618	202348519	202127620	202127621	202127622	202127623	202127624	202127625	202127626	202127627	202127628	202127629	202127630	202127631	202127632
IHC cell line <sup>1</sup>		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

101.519-12 – including *Taq* polymerase  
 101.519-12u – without *Taq* polymerase

Visit [www.caredx.com](http://www.caredx.com) for  
 “Instructions for Use” (IFU)

Lot No.: **7R0**

Lot-specific information

CELL LINE VALIDATION SHEET													
HLA-B*18 SSP subtyping kit <sup>2</sup>													
				Well									
				33	34	35	36	37	38	39	40	41	
				Prod. No.:	202127633	202127634	202127635	202127636	202127637	202127638	202127639	202127640	202127641
	IHWC cell line <sup>1</sup>	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

101.519-12 – including *Taq* polymerase  
101.519-12u – without *Taq* polymerase

Visit [www.caredx.com](http://www.caredx.com) for  
“Instructions for Use” (IFU)

Lot No.: **7R0**

#### Lot-specific information

<sup>1</sup>The 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.

<sup>2</sup>The 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 to 7, 9 to 12, 14, 16, 17, 19, 22 to 28, 30, 32 to 36, 38 to 39 and 41 were available. The specificities of the primers in primer solutions 5, 7, 9, 11, 12, 14, 16, 17, 19, 22 to 28, 30, 32, 33 and 39 were tested by separately adding additional 5'-primers, respectively 3'-primers.

In primer solutions 6, 34, 35, 38 and 41 only the 5'-primer was possible to test, the 3'-primers were not possible to test. In primer solutions 10 and 36 only the 3'-primer was possible to test, the 5'-primers were not possible to test.

In primer solutions 5, 9, 16, 21, 22, 26 and 30 one or two 5'-primers were not possible to test, and in primer solutions 1, 7, 12, 18, 19, 22, 23, 25 and 27 to 29 one, two or three 3'-primers were not possible to test. In addition, the primers in primer solutions 13 and 29 were tested by separately adding one 5'-primer or one or two 3'-primers.



0197

For *In Vitro* Diagnostic Use

MA123 v02 SSP PI Template

Date: March 2023, Rev. No: 00



101.519-12 – including *Taq* polymerase  
101.519-12u – without *Taq* polymerase

Visit [www.caredx.com](http://www.caredx.com) for  
“Instructions for Use” (IFU)

Lot No.: **7R0**

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](mailto:orders-se@caredx.com)

**Web page:** [www.caredx.com](http://www.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](mailto:orders-us@caredx.com)

**Web page:** [www.caredx.com](http://www.caredx.com)

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



**0197**

For *In Vitro* Diagnostic Use

MA123 v02 SSP PI Template

Date: March 2023, Rev. No: 00