

101.572-12 – including *Taq* polymerase  
101.572-12u – without *Taq* polymerase

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

Lot No.: **3R3**

Lot-specific information

**Olerup SSP® HLA-B\*57:01**

<b>Product number:</b>	101.572-12 – including <i>Taq</i> polymerase 101.572-12u – without <i>Taq</i> polymerase
<b>Lot number:</b>	3R3
<b>Expiry date:</b>	2026-08-01
<b>Number of tests:</b>	12
<b>Number of wells per test:</b>	23+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. 3R3.**

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

**CHANGES COMPARED TO THE PREVIOUS OLERUP SSP®  
HLA-B\*57:01 LOT (8L3).**

- Positive and negative control DNAs are included in the kit.
- The product documentation has been updated for new alleles of IMGT 3.49.0.
- 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\*57:01 primer set, specificity and interpretation tables have been updated for the HLA-B alleles described since the previous *Olerup SSP®* HLA-B\*57:01 lot was made (**Lot No. 8L3**). The kit design is based on IMGT/HLA database 3.49.0.

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

Well	5'-primer	3'-primer	rationale
1	-	Added	3'-primer added for the B*57:01:45 allele.

<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: August 2022, Rev. No: 00

101.572-12 – including *Taq* polymerase  
101.572-12u – without *Taq* polymerase

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

Lot No.: **3R3**

Lot-specific information

Well **24** 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 are 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: August 2022, Rev. No: 00

101.572-12 – including *Taq* polymerase  
101.572-12u – without *Taq* polymerase

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

Lot No.: **3R3**

Lot-specific information

## PRODUCT DESCRIPTION

### HLA-B\*57:01 SSP subtyping

#### CONTENT

The primer set contains 5'- and 3'-primers for identifying the B\*57:01:01 to 57:01:46 alleles.

The primer solutions consist of specific primer mixes, i.e. group-specific primers as well as a **control primer pair** matching non-allelic sequences.

Positive and negative control DNAs are included in the kit:

DNA 1; a B\*57-positive DNA as a positive control, **IHW 9052, DBB, B\*57:01.**

DNA 2; a B\*58-positive DNA as a negative control, **IHW 9285, WT49, B\*58:01.**

(A B\*58:01-positive DNA was chosen as negative control, as this is most similar to the B\*57 group of alleles in the primer matching regions.)

The kit contains enough control DNAs to perform 1 test set up of positive and negative control. If more than 1 test set up per kit are run other positive and negative DNA samples can be used as controls (e.g. positive and negative samples from previous tests).

*Legal notice: The DNA in this kit is included under licensing agreement between CareDx AB and Public Health England.*

#### PLATE LAYOUT

Each test consists of 24 PCR reactions in a 24 well cut PCR plate.

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

The 24 well cut PCR plate is marked with 'B\*57:01' in silver/gray ink.

Well No. 1 is marked with the Lot No. '3R3'.

Wells 1 to 23 – HLA-B\*57:01 primers.

Well 24 – Negative Control (NC).

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

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

**Please note:** When removing each 24 well PCR plate, make sure that the remaining plates stay sealed. Use a scalpel or a similar instrument to carefully cut the foil between the plates.



0197

For *In Vitro* Diagnostic Use  
MA123 v02 SSP PI Template  
Date: August 2022, Rev. No: 00

101.572-12 – including *Taq* polymerase  
101.572-12u – without *Taq* polymerase

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

Lot No.: **3R3**

Lot-specific information

### INTERPRETATION

Due to the sharing of sequence motifs between HLA-B alleles some non-HLA-B\*57 alleles will be amplified by some primer mixes. For further details see Specificity Table.

### UNIQUELY IDENTIFIED ALLELES

HLA-B\*57:01 will give rise to a unique amplification pattern by the primers in the HLA-B\*57:01 kit<sup>1,2</sup>.

<sup>1</sup>HLA-B alleles listed on the IMGT/HLA web page 2022-July-12, release 3.49.0, [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: August 2022, Rev. No: 00

101.572-12 – including *Taq* polymerase  
101.572-12u – without *Taq* polymerase

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

Lot No.: **3R3**

Lot-specific information

## SPECIFICITY TABLE

### HLA-B\*57:01 SSP subtyping

Specificities and sizes of the PCR products of the 23+1 primer mixes used for HLA-B\*57:01 SSP subtyping

Primer Mix	Size of spec. PCR product <sup>1</sup>	Size of control band <sup>2</sup>	Amplified HLA-B*57:01 alleles <sup>3</sup>	Other amplified Class I alleles
1 <sup>4</sup>	90 bp	800 bp	*57:01:01:01-57:01:46	*57:02:01:01-57:04:01, 57:04:03-57:15, 57:17-57:19, 57:21-57:35, 57:37-57:44, 57:46-57:50, 57:52-57:61, 57:63-57:68, 57:70-57:88, 57:90-57:108, 57:110-57:119, 57:121-57:127, 57:129-57:162N, <b>15:462, 58:36</b>
2 <sup>5</sup>	220 bp	800 bp	*57:01:01:01-57:01:46	*57:03:01:01-57:03:05, 57:06-57:08, 57:10, 57:14:01-57:18, 57:20-57:23, 57:25-57:27, 57:29, 57:31:01-57:41, 57:43-57:51, 57:53-57:60, 57:62, 57:64-57:81, 57:84-57:98Q, 57:100-57:111, 57:113-57:117, 57:120-57:128, 57:130N, 57:132-57:133, 57:135-57:139N, 57:141-57:146, 57:148-57:159, 57:162N, <b>35:208:01-35:208:02, 35:317, 37:94, 40:30, 40:34, 44:153, 55:14, 58:14</b>
3 <sup>4</sup>	95 bp 170 bp 215 bp	800 bp		*57:04:01-57:04:03, 57:32, <b>44:153</b> *57:06, 57:18 *57:27
4 <sup>4</sup>	90 bp 105 bp  170 bp	1070 bp		*57:20, 57:62 *57:15, 57:29, <b>14:61, 15:214, 18:81, 35:250, 37:93, 39:145, 39:158, 40:427, 44:311, 51:165, 55:108</b> *57:91, <b>15:626, 53:59</b>
5 <sup>4</sup>	90 bp 165 bp 200 bp 245 bp	800 bp		*57:16, 57:34, <b>58:54</b> *57:23 *57:46, 57:64 *57:07, 57:26, 57:93, 57:119, <b>08:181, 44:153, 55:14, C*06:72</b>
6 <sup>4</sup>	90 bp	1070 bp		*57:02:01:01-57:03:05, 57:07, 57:09, 57:12, 57:17, 57:39, 57:42, 57:46, 57:57, 57:63, 57:66, 57:70, 57:80, 57:84, 57:94, 57:96, 57:101, 57:124, 57:137, 57:155, <b>08:181, 40:30, 40:34</b> *57:08, 57:65, <b>15:403</b>
7 <sup>4</sup>	205 bp 100 bp 140 bp  185 bp	1070 bp		*57:53 *57:13, 57:31:01-57:31:02, <b>07:227, 08:181, 40:30, 40:34, C*06:72</b> *57:50



0197

For *In Vitro* Diagnostic Use  
MA123 v02 SSP PI Template  
Date: August 2022, Rev. No: 00

101.572-12 – including *Taq* polymerase  
101.572-12u – without *Taq* polymerase

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

Lot No.: **3R3**

Lot-specific information

	215 bp 250 bp			*57:09, 57:24, 57:119, <b>08:181</b> *57:13, 57:14:01-57:14:02, 57:25, <b>07:227, 40:30, 40:34</b>
<b>8</b>	160 bp 210 bp	1070 bp		*57:87 *57:10, 57:39, 57:51, 57:73, <b>07:219, 15:446, 58:41</b>
<b>9<sup>4</sup></b>	110 bp 150 bp	<b>800 bp</b>		*57:33, <b>44:450</b> *57:21, 57:40, 57:74, <b>14:20,</b> <b>15:461, 27:188, 35:127, 44:317,</b> <b>50:54, 51:186, 53:41, 55:100,</b> <b>56:80</b>
<b>10</b>	205 bp 240 bp	1070 bp		*57:13, 57:22, 57:57, 57:63, 57:161 <sup>w</sup> , <b>07:227, 55:14, C*06:72<sup>w</sup></b> *57:43
<b>11<sup>4</sup></b>	100 bp	1070 bp	*57:01:01:01- 57:01:46	*57:06, 57:08, 57:10, 57:13-57:16, 57:18-57:27, 57:29-57:31:02, 57:33-57:38, 57:40 <sup>w</sup> , 57:41, 57:43- 57:45, 57:47-57:52, 57:54-57:56, 57:58-57:62, 57:64-57:65, 57:67:01-57:69, 57:71-57:75, 57:77-57:79N, 57:81, 57:85-57:93, 57:95, 57:97-57:98Q, 57:100, 57:102-57:111, 57:113-57:117, 57:119-57:123, 57:125-57:130N, 57:132-57:133, 57:135-57:136, 57:138-57:154, 57:156-57:159, 57:161-57:162N, <b>35:208:01-</b> <b>35:208:02, 35:317, 37:94, 55:14,</b> <b>58:14, C*06:72</b>
<b>12<sup>4</sup></b>	75 bp 140 bp	1070 bp		*57:35, <b>15:625</b> *57:08, 57:60, <b>15:87, 15:403</b>
<b>13<sup>4</sup></b>	105 bp 135 bp	1070 bp		*57:45, 57:51, 57:69, 57:71, 57:88, <b>58:111, A*02:285, A*02:799</b> *57:58, 57:80, 57:90, <b>07:219,</b> <b>58:12, A*02:42:01-02:42:02,</b> <b>A*02:310, A*02:597</b>
<b>14<sup>4</sup></b>	200 bp 115 bp	1070 bp		*57:49 *57:54, 57:96, <b>15:33, 15:248,</b> <b>49:22, 51:126, C*03:87:01-</b> <b>03:87:02, C*03:414, C*05:27,</b> <b>C*05:39, C*05:184, C*08:115,</b> <b>C*08:182</b>
<b>15</b>	135 bp 205 bp 145 bp	1070 bp		*57:47 *57:77, <b>15:617, 44:36, C*03:232</b> *57:56, 57:78, <b>15:340, 35:300,</b> <b>40:218, 44:307, 45:21, 46:28,</b> <b>51:58, 52:82, 58:83</b>
<b>16<sup>4</sup></b>	185 bp 295 bp 65 bp	1070 bp		*57:48, <b>A*23:72, A*33:12</b> *57:55, 57:94, <b>14:104, 44:517</b> *57:67:01, <b>58:14, C*06:72</b>
<b>17<sup>4</sup></b>	90 bp 180 bp	1070 bp		*57:04:01-57:04:03, 57:41, <b>44:153,</b> <b>C*06:72</b> *57:68



0197

For *In Vitro* Diagnostic Use  
MA123 v02 SSP PI Template  
Date: August 2022, Rev. No: 00

101.572-12 – including *Taq* polymerase  
101.572-12u – without *Taq* polymerase

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

Lot No.: **3R3**

Lot-specific information

<b>18<sup>6</sup></b>	170 bp	1070 bp	*57:37, 57:79N
	275 bp		*57:81, <b>44:13, 44:67, 51:170</b>
	300 bp		*57:86, <b>51:356, 53:25</b>
<b>19<sup>4</sup></b>	100 bp	1070 bp	*57:76
	165 bp		*57:92
	215 bp		*57:72
<b>20</b>	240 bp	1070 bp	*57:44, <b>18:167, 44:249</b>
	340 bp		*57:75, <b>35:374, 40:327<sup>?</sup>, 52:81</b>
<b>21<sup>4</sup></b>	100 bp	1070 bp	*57:36
	135 bp		*57:38
	485 bp		*57:05
<b>22</b>	210 bp	1070 bp	*57:85, <b>51:331</b>
<b>23</b>	180 bp	1070 bp	*57:59, <b>40:30, 40:34</b>
<b>24<sup>7</sup></b>	-	-	<b>Negative Control</b>

<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\*57:01 SSP typings.

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

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

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

PCR fragments migrating faster than the control bands, but slower than a 400 bp fragment may be seen in some gel read-outs. Such bands can be disregarded and do not influence the interpretation of the SSP typings.

Some primers may give rise to primer oligomer artifacts. Sometimes this phenomenon is an inherent feature of the primer pair(s) of a primer mix. More often it is due to other factors such as too low amount of DNA in the PCR reactions, taking too long time in setting up the PCR reactions, working at elevated room temperature or using thermal cyclers that are not pre-heated.

<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 1<sup>st</sup> and/or 4<sup>th</sup> 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 mix 2 may give rise to a lower yield of HLA-specific PCR product than the other B\*57:01 primer mixes.

<sup>6</sup>Primer mix 18 has tendency of unspecific amplifications.

<sup>7</sup>Primer mix 24 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 products generated by the HGH positive control primer pair are 200 base pairs.

#### Abbreviations

'w', may be weakly amplified.

'?', nucleotide sequence of the primer matching region not known.



0197

For *In Vitro* Diagnostic Use  
MA123 v02 SSP PI Template  
Date: August 2022, Rev. No: 00

101.572-12 – including *Taq* polymerase  
101.572-12u – without *Taq* polymerase

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

Lot No.: **3R3**

Lot-specific information

## PRIMER SPECIFICATION

Well No.	1	2	3	4	5	6	7	8	9	10	11	12
Length of spec.	90	220	95	90	90	90	100	160	110	205	100	75
PCR product			170	105	165	205	140	210	150	240		140
			215	170	200		185					
					245		215					
							250					
Length of int.	800	800	800	1070	800	1070	1070	1070	800	1070	1070	1070
pos. control <sup>1</sup>												
5'-primer(s) <sup>2</sup>	209 5'-ggC 3'	362 5'-ggT 3'	362 5'-ggT 3'	209 5'-ggC 3'	130 5'-AgT 3'	320 5'-CCC 3'	362 5'-ggT 3'	97 5'-TCC 3'	349 5'-CTT 3'	362 5'-ggT 3'	362 5'-ggT 3'	209 5'-ggC 3'
				646 5'-ACA 3'	200 5'-TCg 3'	362 5'-ggT 3'		103 5'-CCT 3'	352 5'-ACg 3'			
				704 5'-TgT 3'	209 5'-ggA 3'			148 5'-TgA 3'	353 5'-CAA 3'			
					362 5'-ggT 3'				392 5'-CgA 3'			
3'-primer(s) <sup>3</sup>	256 5'-CCC 3'	539 5'-TCA 3'	418 5'-gTC 3'	259 5'-CTT 3'	256 5'-CCC 3'	2 <sup>nd</sup> I 5'-TCg 3'	421 5'-ggT 3'	266 5'-TCC 3'	463 5'-gCT 3'	527 5'-CCT 3'	419 5'-Cgg 3'	244 5'-CTT 3'
	261 5'-gTT 3'		481 5'-gTA 3'	263 5'-gTT 3'	523 5'-ACA 3'	412 5'-gTT 3'	463 5'-gCg 3'			559 5'-Cgg 3'	419 5'-CAg 3'	302 5'-ggC 3'
			500 5'-ggA 3'	271 5'-CAC 3'	559 5'-CgT 3'	521 5'-ggA 3'	505 5'-gCC 3'					320 5'-Agg 3'
			537 5'-Agg 3'	774 5'-ggT 3'	572 5'-gCg 3'		538 5'-gTC 3'					
							559 5'-CTC 3'					
							583 5'-gTg 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
Length of spec.	105	115	145	65	90	170	100	240	100	210	180
PCR product	135	135	185		180	275	165	340	135		
	200	205	295			300	215		485		
Length of int.	1070	1070	1070	1070	1070	1070	1070	1070	1070	1070	1070
pos. control <sup>1</sup>											
5'-primer(s) <sup>2</sup>	97 5'-TCg 3'	395 5'-gCT 3'	106 5'-CCA 3'	362 5'-ggT 3'	362 5'-ggT 3'	230 5'-Agg 3'	362 5'-ggT 3'	49 5'-CAG 3'	209 5'-ggC 3'	390 5'-gAg 3'	362 5'-ggT 3'
	142 5'-TCT 3'	467 5'-CTg 3'	395 5'-gCC 3'			255 5'-gAg 3'					
	160 5'-ACT 3'	485 5'-CAA 3'	757 5'-CCA 3'			877 5'-AC 3'					
	193 5'-CCA 3'					878 5'-gCA 3'					
3'-primer(s) <sup>3</sup>	256 5'-CCC 3'	559 5'-CAg 3'	212 5'-ggT 3'	387 5'-TCg 3'	409 5'-ATA 3'	2 <sup>nd</sup> I 5'-TCg 3'	419 5'-CgA 3'	122 5'-CgA 3'	268 5'-gTg 3'	559 5'-CAg 3'	499 5'-ggA 3'
			214 5'-CCA 3'		502 5'-CTT 3'	916 5'-gAC 3'	488 5'-CCT 3'	220 5'-TgT 3'	302 5'-ggg 3'		
			539 5'-TCA 3'				534 5'-Tgg 3'		409 5'-ATA 3'		
			916 5'-gAC 3'								
Well No.	13	14	15	16	17	18	19	20	21	22	23

<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



0197

For *In Vitro* Diagnostic Use  
MA123 v02 SSP PI Template  
Date: August 2022, Rev. No: 00



**101.572-12 – including *Taq* polymerase**  
**101.572-12u – without *Taq* polymerase**

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

**Lot No.: 3R3**

**Lot-specific information**

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**

101.572-12 – including *Taq* polymerase  
101.572-12u – without *Taq* polymerase

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

Lot No.: **3R3**

Lot-specific information

CELL LINE VALIDATION SHEET																				
HLA-B*57:01 SSP typing kit <sup>2</sup>																				
				Well																
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	
				Prod. No.:	202244501	201893702	201893703	201893704	201893705	201893706	201893707	201911308	201893709	201893710	201893711	201893712	201893713	201911314	201893715	201893716
IHCW 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	9025	JESTHOM	*27:05		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
14	9071	OLGA	*15:01	*15:20	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
15	9075	DKB	*40:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
16	9037	SWEIG007	*40:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
17	9282	CTM3953540	*08:01	*55:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
18	9257	32367	*14:01	*56:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
19	9038	BM16	*18:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
20	9059	SLE005	*40:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
21	9064	AMALA	*15:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
22	9056	KOSE	*35:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
23	9124	IHL	*40:02	*56:02	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
24	9035	JBUSH	*38:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
25	9049	IBW9	*14:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
26	9285	WT49	*58:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
27	9191	CH1007	*07:05	*51:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
28	9320	BEL5GB	*44:02	*44:03	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
29	9050	MOU	*44:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
30	9021	RSH	*42:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
31	9019	DUCAF	*18:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
32	9297	HAG	*41:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
33	9098	MT14B	*40:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
34	9104	DHIF	*38:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
35	9302	SSTO	*44:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
36	9024	KT17	*15:01	*35:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
37	9065	HHKB	*07:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
38	9099	LZL	*15:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
39	9315	CML	*08:01	*27:05	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
40	9134	WHONP199	*13:02	*46:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
41	9055	H0301	*14:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
42	9066	TAB089	*46:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
43	9076	T7526	*46:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
44	9057	TEM	*38:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
45	9239	SHJO	*42:01	*50:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
46	9013	SCHU	*07:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
47	9045	TUBO	*51:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
48	9303	TER-ND	*35:01	*44:03	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-



0197

101.572-12 – including *Taq* polymerase  
101.572-12u – without *Taq* polymerase

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

Lot No.: **3R3**

Lot-specific information

CELL LINE VALIDATION SHEET											
HLA-B*57:01 SSP typing kit <sup>2</sup>											
				Prod. No.:	Well						
					17	18	19	20	21	22	23
					201893717	201893718	201893719	201911320	201911321	202127222	201893723
	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 PTOUT	*44:03			-	-	-	-	-	-	-
12	9052 DBB	*57:01			-	-	-	-	-	-	-
13	9025 JESTHOM	*27:05			-	-	-	-	-	-	-
14	9071 OLGA	*15:01	*15:20		-	-	-	-	-	-	-
15	9075 DKB	*40:01			-	-	-	-	-	-	-
16	9037 SWEIG007	*40:02			-	-	-	-	-	-	-
17	9282 CTM3953540	*08:01	*55:01		-	-	-	-	-	-	-
18	9257 32367	*14:01	*56:01		-	-	-	-	-	-	-
19	9038 BM16	*18:01			-	-	-	-	-	-	-
20	9059 SLE005	*40:01			-	-	-	-	-	-	-
21	9064 AMALA	*15:01			-	-	-	-	-	-	-
22	9056 KOSE	*35:03			-	-	-	-	-	-	-
23	9124 IHL	*40:02	*56:02		-	-	-	-	-	-	-
24	9035 JBUSH	*38:01			-	-	-	-	-	-	-
25	9049 IBW9	*14:02			-	-	-	-	-	-	-
26	9285 WT49	*58:01			-	-	-	-	-	-	-
27	9191 CH1007	*07:05	*51:01		-	-	-	-	-	-	-
28	9320 BEL5GB	*44:02	*44:03		-	-	-	-	-	-	-
29	9050 MOU	*44:03			-	-	-	-	-	-	-
30	9021 RSH	*42:01			-	-	-	-	-	-	-
31	9019 DUCAF	*18:01			-	-	-	-	-	-	-
32	9297 HAG	*41:02			-	-	-	-	-	-	-
33	9098 MT14B	*40:01			-	-	-	-	-	-	-
34	9104 DHIF	*38:01			-	-	-	-	-	-	-
35	9302 SSTO	*44:02			-	-	-	-	-	-	-
36	9024 KT17	*15:01	*35:01		-	-	-	-	-	-	-
37	9065 HHKB	*07:02			-	-	-	-	-	-	-
38	9099 LZL	*15:01			-	-	-	-	-	-	-
39	9315 CML	*08:01	*27:05		-	-	-	-	-	-	-
40	9134 WHONP199	*13:02	*46:01		-	-	-	-	-	-	-
41	9055 H0301	*14:02			-	-	-	-	-	-	-
42	9066 TAB089	*46:01			-	-	-	-	-	-	-
43	9076 T7526	*46:01			-	-	-	-	-	-	-
44	9057 TEM	*38:01			-	-	-	-	-	-	-
45	9239 SHJO	*42:01	*50:01		-	-	-	-	-	-	-
46	9013 SCHU	*07:02			-	-	-	-	-	-	-
47	9045 TUBO	*51:01			-	-	-	-	-	-	-
48	9303 TER-ND	*35:01	*44:03		-	-	-	-	-	-	-



0197

For *In Vitro* Diagnostic Use  
MA123 v02 SSP PI Template  
Date: August 2022, Rev. No: 00

**101.572-12 – including *Taq* polymerase**  
**101.572-12u – without *Taq* polymerase**

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

**Lot No.: 3R3**

**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 3 to 5, 7 to 10 and 12 to 23 were available.

The specificities of the primers in primer solutions 3 to 5, 7, 8, 10, 12 to 17, 19 and 23 were tested by separately adding additional 5'-primers, respectively 3'-primers.

In primer solutions 9, 18 and 22 it was only possible to test the 3'-primers, the 5'-primers were not possible to test.

In primer solutions 20 and 21 it was only possible to test the 5'-primer, the 3'-primers were not possible to test.

In primer solutions 1, 3 to 7, 10 to 12, 15 and 19 one to three 3'-primers were not possible to test, and in primer solutions 4, 5, 8 and 13 to 15 one to three 5'-primers were not possible to test.



**0197**

For *In Vitro* Diagnostic Use

MA123 v02 SSP PI Template

Date: August 2022, Rev. No: 00

101.572-12 – including *Taq* polymerase  
 101.572-12u – without *Taq* polymerase

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

Lot No.: **3R3**

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)

**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](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: August 2022, Rev. No: 00