

101.431-12 – including *Taq* polymerase
101.431-12u – without *Taq* polymerase

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

Lot No.: **8R4**

Lot-specific information
Olerup SSP[®] HLA-A*32

Product number:	101.431-12 – including <i>Taq</i> polymerase 101.431-12u – without <i>Taq</i> polymerase
Lot number:	8R4
Expiry date:	2027-03-01
Number of tests:	12
Number of wells per test:	31+1
Storage - pre-aliquoted primers:	dark, between -15°C and -25°C
- PCR Master Mix:	between -15°C and -25°C
- Adhesive PCR seals	RT

This Product Description is only valid for Lot No. 8R4.

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*32 Lot (7L2)**

- The product documentation has been updated for new alleles of IMGT 3.51.0
- The kit resolution focuses on common and well documented (CWD) alleles¹.

¹As described in section Uniquely Identified Alleles.

The HLA-A*32 primer set, specificity and interpretation tables have been updated for the HLA alleles described since the previous *Olerup SSP[®] HLA-A*32* lot was made (**Lot No. 7L2**).

The HLA-A*32 primer set is unchanged compared to the previous *Olerup SSP[®] HLA-A*32* (**Lot No. 7L2**).

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 v02 SSP PI Template
Date: April 2023, Rev. No: 00

101.431-12 – including *Taq* polymerase
101.431-12u – without *Taq* polymerase

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

Lot No.: **8R4**

Lot-specific information

Well **32** 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 product generated by the positive control primer pair is 200 base pairs.

Length of PCR product	105	200	105	80	75	80	85
5'-primer¹	164	340	440	45	45	43	36
	5'-CAC ^{3'}	5'-Agg ^{3'}	5'-TTA ^{3'}	5'-Tgg ^{3'}	5'-Tgg ^{3'}	5'-Tgg ^{3'}	5'-TAC ^{3'}
							36
							5'-TAT ^{3'}
3'-primer²	231	2nd I	507	59	58	57	47
	5'-TgC ^{3'}	5'-AAA ^{3'}	5'-TTg ^{3'}	5'-CTC ^{3'}	5'-ggC ^{3'}	5'-CTC ^{3'}	5'-ACA ^{3'}
							48
							5'-gCA ^{3'}
							48
							5'-gCC ^{3'}
							52
							5'-TgT ^{3'}
A*	+	+	+				
B*	+	+	+				
C*	+	+	+				
DRB1				+	+		
DRB3				+	+		
DRB5				+			
DQB1					+		
DPB1						+	
DQA1							+

¹The nucleotide position for HLA class I genes and the codon for HLA class II genes, in the 2nd or 3rd exon, matching the specificity-determining 3'-end of the primer is given. Nucleotide and codon numbering as on the www.ebi.ac.uk/imgt/hla web site. The sequence of the 3 terminal nucleotides of the primer is given.

²The nucleotide position for HLA class I genes and the codon for HLA class II genes, in the 2nd or 3rd exon or the 2nd intron, matching the specificity-determining 3'-end of the primer is given in the anti-sense direction. Nucleotide and codon numbering as on the www.ebi.ac.uk/imgt/hla web site. The sequence of the 3 terminal nucleotides of the primer is given.



0197

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

101.431-12 – including *Taq* polymerase
101.431-12u – without *Taq* polymerase

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

Lot No.: **8R4**

Lot-specific information

PRODUCT DESCRIPTION

HLA-A*32 SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for identifying the A*32:01 to A*32:173 alleles.

PLATE LAYOUT

Each test consists of 32 PCR reactions in a 32 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	NC

The 32 well cut PCR plate is marked with ‘HLA-A*32’ in silver/gray ink.

Well No. 1 is marked with the Lot No. ‘8R4’.

Wells 1 to 31– HLA-A*32 high resolution primers.

Well 32 – 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 covered with a PCR-compatible foil.

Please note: When removing each 32 well PCR plate, make sure that the remaining plates stay covered. 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*32 alleles will be amplified by some primer mixes. For further details see Specificity Table.

UNIQUELY IDENTIFIED ALLELES

All the HLA-A*32 alleles, i.e. **A*32:01 to A*32:173 alleles**, recognized by the HLA Nomenclature Committee in January 2023^{1,2} will be amplified by the primers in the HLA-A*32 subtyping kit.

The HLA-A*32 kit enables separation of the confirmed HLA-A*32 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*32 alleles is listed below.



0197

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

101.431-12 – including *Taq* polymerase
101.431-12u – without *Taq* polymerase

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

Lot No.: **8R4**

Lot-specific information

The HLA-A*32 kit also enables identification of many null and alternatively expressed alleles.

The following HLA-A*32 alleles can be distinguished by the different sizes of the HLA-specific PCR product:

Alleles	Primer mix
A*32:10, 32:16, 32:118	12
A*32:21, 32:44	17
A*32:23, 32:54, 32:142	20
A*32:69, 32:112N	28

¹HLA-A alleles listed on the IMGT/HLA web page 2023-January-12, release 3.51.0, 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>.

ALLELE CONFIRMATION STATUS

Allele	Status ¹	Allele	Status ¹	Allele	Status ¹	Allele	Status ¹
A*32:01:01	Confirmed	A*32:09	Unconfirmed	A*32:38	Unconfirmed	A*32:67	Unconfirmed
A*32:01:02	Unconfirmed	A*32:10	Unconfirmed	A*32:39	Unconfirmed	A*32:68	Unconfirmed
A*32:01:03	Confirmed	A*32:11Q	Unconfirmed	A*32:40	Unconfirmed	A*32:69	Confirmed
A*32:01:04	Confirmed	A*32:12	Unconfirmed	A*32:41	Unconfirmed	A*32:70	Unconfirmed
A*32:01:05	Unconfirmed	A*32:13	Unconfirmed	A*32:42	Unconfirmed	A*32:71	Unconfirmed
A*32:01:06	Unconfirmed	A*32:14	Unconfirmed	A*32:43	Unconfirmed	A*32:72	Unconfirmed
A*32:01:07	Unconfirmed	A*32:15	Unconfirmed	A*32:44	Confirmed	A*32:73	Unconfirmed
A*32:01:08	Confirmed	A*32:16	Confirmed	A*32:45N	Confirmed	A*32:74	Unconfirmed
A*32:01:09	Confirmed	A*32:17	Confirmed	A*32:46	Unconfirmed	A*32:75	Unconfirmed
A*32:01:10	Unconfirmed	A*32:18	Confirmed	A*32:47	Confirmed	A*32:76	Unconfirmed
A*32:01:11	Unconfirmed	A*32:19N	Confirmed	A*32:48N	Unconfirmed	A*32:77	Unconfirmed
A*32:01:12	Confirmed	A*32:20	Confirmed	A*32:49	Unconfirmed	A*32:78	Unconfirmed
A*32:01:13	Unconfirmed	A*32:21	Unconfirmed	A*32:50	Unconfirmed	A*32:79	Unconfirmed
A*32:01:14	Confirmed	A*32:22	Unconfirmed	A*32:51	Unconfirmed	A*32:80	Unconfirmed
A*32:01:15	Unconfirmed	A*32:23	Unconfirmed	A*32:52	Unconfirmed	A*32:81	Unconfirmed
A*32:01:16	Unconfirmed	A*32:24	Confirmed	A*32:53	Unconfirmed	A*32:82	Unconfirmed
A*32:01:17	Confirmed	A*32:25	Confirmed	A*32:54	Confirmed	A*32:83	Unconfirmed
A*32:01:18	Unconfirmed	A*32:26	Confirmed	A*32:55:01	Unconfirmed	A*32:84	Unconfirmed
A*32:01:19	Unconfirmed	A*32:27N	Confirmed	A*32:55:02	Unconfirmed	A*32:85	Unconfirmed
A*32:01:20	Unconfirmed	A*32:28	Confirmed	A*32:56N	Unconfirmed	A*32:86	Unconfirmed
A*32:01:21	Unconfirmed	A*32:29	Unconfirmed	A*32:57	Unconfirmed		
A*32:01:22	Unconfirmed	A*32:30	Unconfirmed	A*32:58	Unconfirmed		
A*32:01:23	Unconfirmed	A*32:31	Unconfirmed	A*32:59	Unconfirmed		
A*32:02	Unconfirmed	A*32:32	Unconfirmed	A*32:60	Confirmed		
A*32:03	Confirmed	A*32:33:01	Unconfirmed	A*32:61	Unconfirmed		
A*32:04	Confirmed	A*32:33:02	Unconfirmed	A*32:62	Unconfirmed		
A*32:05	Unconfirmed	A*32:34	Unconfirmed	A*32:63	Unconfirmed		
A*32:06	Confirmed	A*32:35	Unconfirmed	A*32:64	Unconfirmed		
A*32:07	Confirmed	A*32:36	Unconfirmed	A*32:65	Unconfirmed		
A*32:08	Confirmed	A*32:37	Unconfirmed	A*32:66	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.



0197

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

101.431-12 – including *Taq* polymerase
101.431-12u – without *Taq* polymerase

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

Lot No.: **8R4**

Lot-specific information

RESOLUTION IN HOMO- AND HETEROZYGOTES

Results file with resolution in HLA-A*32 homo- and heterozygotes is available upon request.



0197

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

101.431-12 – including *Taq* polymerase
101.431-12u – without *Taq* polymerase

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

Lot No.: **8R4**

Lot-specific information

SPECIFICITY TABLE

HLA-A*32 SSP subtyping

Specificities and sizes of the PCR products of the 31+1 primer mixes used for HLA-A*32 SSP subtyping

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified HLA-A*32 alleles ³	Other amplified HLA-A alleles
1	200 bp	800 bp	*32:01:01:01-32:06, 32:08-32:14, 32:16-32:24, 32:26:01-32:38, 32:40-32:41, 32:43:01-32:63, 32:65-32:78, 32:80-32:92N, 32:94-32:173	*01:01:01:01-01:01:123, 01:01:125-01:01:143, 01:03:01:01-01:04:01:02N, 01:06-01:19, 01:21-01:33, 01:35-01:42, 01:44-01:46, 01:48-01:50, 01:52:01N-01:59, 01:61-01:70, 01:72-01:82, 01:84-01:104, 01:106-01:142, 01:144-01:187, 01:189, 01:191-01:219, 01:221-01:249, 01:251-01:301Q, 01:303:01-01:306, 01:308N-01:341, 01:343-01:404, 01:406-01:411N, 01:413-01:419, 01:421N-01:427, 02:45, 02:56:01-02:56:02, 02:103, 02:195, 02:1022, 03:01:01:01-03:01:03:02, 03:01:05-03:11N, 03:13-03:22:02, 03:25-03:29, 03:31-03:35, 03:37-03:58, 03:60-03:69N, 03:71, 03:73-03:87, 03:90-03:112, 03:114-03:151, 03:153-03:157:01, 03:158-03:193, 03:195-03:197:02N, 03:199, 03:201-03:204, 03:206-03:259, 03:261-03:272, 03:274-03:277, 03:279N-03:302, 03:304-03:458Q, 11:199:01-11:199:03, 11:222, 30:55, 30:166, 30:177, 30:186, 31:21, 36:01:01:01-36:13, 74:01:01:01-74:03:03, 74:05-74:18, 74:22-74:42, 74:44
2	430 bp	1070 bp	*32:01:01:01-32:01:06, 32:01:08-32:01:11, 32:01:13-32:01:47, 32:01:49-32:01:51, 32:01:53-32:02, 32:05-32:27N, 32:29-32:30:01, 32:31-32:33:01, 32:33:03-32:65, 32:67-32:77, 32:79-32:83, 32:85-32:93, 32:95-32:100, 32:102-32:157, 32:159-32:170, 32:172-32:173	*02:829, 29:13
	535 bp		*32:04, 32:52	



0197

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

101.431-12 – including *Taq* polymerase
101.431-12u – without *Taq* polymerase

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

Lot No.: **8R4**

Lot-specific information

Lot No.	Product	Product	Product	Product
3	130 bp	1070 bp	*32:02, 32:22	*11:01:28, 11:01:77, 24:21:03, 24:208:01, 29:05, 29:33, 29:77, 29:87, 29:104, 31:24, 31:136, 33:59, 33:102, 33:150, 33:190
4 ^{4,5}	115 bp	800 bp	*32:02, 32:06, 32:109	*02:24:02, 02:507, 24:21:03, 24:208:01, 29:33, 29:51, 29:80, 31:41, 33:94, 33:150, 74:35
5	165 bp	800 bp	*32:03:01:01-32:03:01:02	
6 ⁴	120 bp 520 bp	1070 bp	*32:20 *32:04, 32:52	*03:152, 03:219, 24:18, 24:204, 24:213
7	135 bp	800 bp	*32:05, 32:17, 32:79	*29:13, 29:172
8 ⁶	165 bp 215 bp	1070 bp	*32:19N *32:07	*03:72, 11:88, 23:51, 24:24, 24:67, 24:145, 24:156, 24:191, 24:290, 24:392, 26:16, 29:37, 29:56, 30:01:01:01-30:04:04, 30:06, 30:09:01:01-30:20, 30:23-30:30, 30:32-30:54, 30:56-30:59N, 30:61-30:78N, 30:80-30:132N, 30:134-30:149, 30:151, 30:153-30:165, 30:167-30:176, 30:178N-30:185, 30:187-30:206, 31:210, 33:119, 68:45, 68:117
9	180 bp	1070 bp	*32:01:01:01-32:01:17, 32:01:19-32:03:01:02, 32:05-32:173	*29:13
10 ⁶	150 bp	800 bp	*32:08, 32:17	*29:13, 29:172
11 ⁴	120 bp 165 bp	1070 bp	*32:20 *32:09	
12	130 bp	1070 bp	*32:10, 32:118, 32:152	*02:507, 29:28, 29:79, 31:30, 31:97, 33:94, 33:155, 74:29, B*07:02:40, C*02:02:15, C*04:175
13	195 bp 155 bp 200 bp	1070 bp	*32:16 *32:11Q *32:15	*31:206Q *01:51, 02:55, 02:644, 02:741, 02:815, 03:24, 25:03, 25:30, 26:20:01-26:20:02, 34:08, 68:71, 69:07
14	215 bp	1070 bp	*32:12, 32:18	*29:06, 29:123, 29:151, 31:51, 33:168, 74:26, C*02:02:15^w, C*03:03:20^w, C*04:175^w, C*07:04:13, C*08:01:15^w
15	165 bp	1070 bp	*32:13	*01:01:114, 23:03:01, 24:21:03, 24:208:01, 29:03, 29:33, 31:05, 31:200, 33:10
16	220 bp 220 bp	1070 bp	*32:18 *32:14	
17 ⁴	75 bp 200 bp	1070 bp	*32:21 *32:44	*29:62, 29:122, 31:45, 33:16 *33:75
18	130 bp 185 bp	1070 bp	*32:24 *32:60	
19 ⁴	110 bp 185 bp	1070 bp	*32:25, 32:45N *32:60	



0197

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

101.431-12 – including *Taq* polymerase
101.431-12u – without *Taq* polymerase

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

Lot No.: 8R4		Lot-specific information		
20^{4,5}	125 bp 220 bp	1070 bp	*32:23 *32:54, 32:142	*33:46 *02:19, 02:294, 02:940, 33:204, 66:08, 68:206
21	150 bp	800 bp	*32:26:01-32:26:02, 32:152	*01:01:114 ^w , 11:01:28, 11:01:77, 29:67, 29:156, 31:24-31:25, 31:200 ^w , 33:61, 33:190, 74:37
22	175 bp 230 bp	1070 bp	*32:56N *32:27N	
23⁴	80 bp 225 bp	1070 bp	*32:28, 32:66, 32:158 *32:53	*02:41, 02:80, 02:117, 02:289:01, 02:304, 02:454, 02:872, 23:45, 24:62, 26:10, 31:67-31:68, 33:32:01, 68:262 *02:480, 02:924-02:925, 33:39, 68:176:01-68:176:02
24	175 bp	800 bp	*32:48N, 32:56N	*02:314:01N, 03:197:01N
25	205 bp	1070 bp	*32:61	
26	115 bp	800 bp	*32:68	
27	180 bp	1070 bp	*32:47	
28⁴	95 bp 270 bp	1070 bp	*32:69 *32:112N	*03:432 *02:748N, 03:91N
29	170 bp	1070 bp	*32:74	
30⁷	140 bp 400 bp	800 bp	*32:117N *32:101Q	
31	205 bp	1070 bp	*32:92N	
32⁸	-	-	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*32 SSP typings.

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

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

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

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

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

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

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



0197

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

101.431-12 – including *Taq* polymerase
101.431-12u – without *Taq* polymerase

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

Lot No.: 8R4

Lot-specific information

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

⁵Primer mixes 4 and 20 may have tendencies of unspecific amplifications.

⁶Primer mixes 8 and 10 may give rise to a lower yield of HLA-specific PCR product than the other A*32 primer mixes.

⁷Primer mix 30 has a tendency to give rise to primer oligomer formation.

⁸Primer mix 32 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: April 2023, Rev. No: 00

101.431-12 – including *Taq* polymerase
101.431-12u – without *Taq* polymerase

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

Lot No.: 8R4

Lot-specific information
PRIMER SPECIFICATION

Well No.	1	2	3	4	5	6	7	8	9	10	11	12
Length of spec.	200	430	130	115	165	120	135	165	180	150	120	130
PCR product		535				520		215			165	195
Length of int. pos. control ¹	800	1070	1070	800	800	1070	800	1070	1070	800	1070	1070
5'-primer(s) ²	98 5'-CTT 3'	302 5'-gAg 3'	448 5'-CCT 3'	448 5'-CCT 3'	180 5'-TTT 3'	101 5'-CAT 3'	180 5'-TTT 3'	98 5'-CTC 3'	180 5'-TTT 3'	180 5'-TTT 3'	101 5'-CAT 3'	448 5'-CCT 3'
	98 5'-CTT 3'					317 5'-gCT 3'		448 5'-CCT 3'	180 5'-TTT 3'		448 5'-CCT 3'	
3'-primer(s) ³	256 5'-CTg 3'	448 5'-CAA 3'	539 5'-TCT 3'	524 5'-CAT 3'	302 5'-ggT 3'	180 5'-TCA 3'	265 5'-CCC 3'	270 5'-ACA 3'	317 5'-ggA 3'	282 5'-gAC 3'	180 5'-TCA 3'	539 5'-TCC 3'
	256 5'-CTg 3'	555 5'-CCA 3'				555 5'-CCA 3'	282 5'-gAC 3'	573 5'-AgT 3'		292 5'-gTg 3'	571 5'-CCg 3'	602 5'-TCA 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.	155	215	165	220	75	130	110	125	150	175	80	175
PCR product	200		220		200	185	185	220		230	225	
Length of int. pos. control ¹	1070	1070	1070	1070	1070	1070	1070	1070	800	1070	1070	800
5'-primer(s) ²	102 5'-ACA 3'	139 5'-TCg 3'	139 5'-TCg 3'	124 5'-gCC 3'	448 5'-CCT 3'	180 5'-TTT 3'	180 5'-TTT 3'	448 5'-CCT 3'	448 5'-CCT 3'	98 5'-CTT 3'	414 5'-CAg 3'	98 5'-CTT 3'
	448 5'-CCT 3'	448 5'-CCT 3'	448 5'-CCT 3'				448 5'-CCT 3'	652 5'-CTg 3'			649 5'-ACA 3'	411 5'-TAg 3'
3'-primer(s) ³	259 5'-gTT 3'	317 5'-ggA 3'	317 5'-ggA 3'	302 5'-ggC 3'	482 5'-Tgg 3'	271 5'-CAT 3'	258 5'-TCg 3'	532 5'-CTT 3'	559 5'-CCT 3'	232 5'-C.g 3'	453 5'-TCT 3'	232 5'-C.g 3'
	563 5'-CgA 3'	616 5'-CgC 3'	570 5'-CCg 3'		608 5'-gCg 3'	323 5'-AgC 3'	323 5'-AgC 3'	829 5'-CTC 3'	559 5'-CCg 3'	286 5'-CTA 3'	831 5'-TCC 3'	538 5'-CAA 3'
							508 5'-CTA 3'					
Well No.	13	14	15	16	17	18	19	20	21	22	23	24

Well No.	25	26	27	28	29	30	31
Length of spec.	205	115	180	95	170	140	205
PCR product				270		400	
Length of int. pos. control ¹	1070	800	1070	1070	1070	800	1070
5'-primer(s) ²	668 5'-ggg 3'	736 5'-ggA 3'	401 5'-CCA 3'	98 5'-CTT 3'	704 5'-TgA 3'	302 5'-gAg 3'	448 5'-CCT 3'
						900 5'-CCg 3'	
3'-primer(s) ³	831 5'-TCC 3'	808 5'-AgA 3'	538 5'-CAA 3'	154 5'-CAT 3'	831 5'-TCC 3'	418 5'-gTg 3'	613 5'-gCg 3'
			327 5'-TTT 3'			998 5'-TCT 3'	
Well No.	25	26	27	28	29	30	31



0197

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

101.431-12 – including *Taq* polymerase
101.431-12u – without *Taq* polymerase

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

Lot No.: 8R4

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 v02 SSP PI Template
 Date: April 2023, Rev. No: 00

101.431-12 – including Taq polymerase
101.431-12u – without Taq polymerase

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

Lot No.: **8R4**

Lot-specific information

CELL LINE VALIDATION SHEET																					
HLA-A*32 SSP subtyping kit ²																					
				Prod. No.:	Well																
					1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	
					201901701	201901702	201901703	201901704	201901705	201901706	201901707	201901708	201901709	201901710	201901711	201901712	201901713	201901714	201901715	201901716	
	IHWC cell line ¹	A*	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

101.431-12 – including Taq polymerase
101.431-12u – without Taq polymerase

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

Lot No.: **8R4**

Lot-specific information

CELL LINE VALIDATION SHEET																			
HLA-A*32 SSP subtyping kit ²																			
				Well															
				17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	
				Prod. No.:	201901717	201901718	201901719	201901720	202026021	201901722	201901723	201901724	201901725	201901726	201901727	201901728	201901729	202026030	201901731
	IHWC cell line ¹	A*	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

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

101.431-12 – including Taq polymerase
101.431-12u – without Taq polymerase

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

Lot No.: 8R4

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 3 to 5, 7, 10 to 19 and 21 to 31 were available. The specificities of the primers in primer solutions 3 to 5, 7, 11 to 15, 18, 21, 23, 24 and 30 were tested by separately adding one or two additional 5'-primers, respectively one or two additional 3'-primers.

In primer solutions 16, 25 to 27 and 29 it was only possible to test the 3'-primers, the 5'-primer was not possible to test.

In primer solutions 10, 17, 19, 22, 28 and 31 it was only possible to test the 5'-primers, the 3'-primers were not possible to test.

In primer solutions 1, 7, 8, 10 to 14, 18, 20, 21, 24 and 30 one of the 3'-primers was not possible to test. In primer solutions 1, 6, 9, 11, 14, 15, 23 and 24 one of the 5'-primers was not possible to test.

In addition, one or more 3'-and/or 5'-primers in primer solutions 6, 8 and 20 were tested by separately adding 5'-primers respectively 3'-primers.



0197

101.431-12 – including *Taq* polymerase
101.431-12u – without *Taq* polymerase

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

Lot No.: **8R4**

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: 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

Web page: www.caredx.com

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



0197

For *In Vitro* Diagnostic Use

MA123 v02 SSP PI Template

Date: April 2023, Rev. No: 00