101.421-06 – including *Taq* polymerase
101.421-06u – without *Taq* polymerase

Visit www.caredx.com for
"Instructions for Use" (IFU)

Lot No.: 8R3 **Lot-specific Information**

Olerup SSP® HLA-A*23

Product number:	**101.421-06 – including *Taq* polymerase** **101.421-06u – without *Taq* polymerase**
Lot number:	**8R3**
Expiry date:	**2027-03-01**
Number of tests:	**6**
Number of wells per test:	**37+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. 8R3.

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*23 LOT (0M5)

- The product documentation has been updated for new alleles of IMGT 3.51.0
- The kit resolution focuses on common and well documented (CWD) alleles[1].

[1]As described in section Uniquely Identified Alleles.

The HLA-A*23 specificity and interpretation tables have been updated for the HLA alleles described since the previous *Olerup* SSP® HLA-A*23 lot was made **(Lot No. 0M5)**.

The HLA-A*23 primer set is unchanged compared to the previous *Olerup* SSP® HLA-A*23 lot **(Lot No. 0M5)**.

[1]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

CE
0197
For *In Vitro* Diagnostic Use

101.421-06 – including *Taq* polymerase
101.421-06u – without *Taq* polymerase

Visit www.caredx.com for **"Instructions for Use" (IFU)**

Lot No.: 8R3 **Lot-specific Information**

Well **38** 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'-primer[1]	**164**	**340**	**440**	**45**	**45**	**43**	**36**
	5'-CAC3'	**5'-Agg3'**	**5'-TTA3'**	**5'-Tgg3'**	**5'-Tgg3'**	**5'-Tgg3'**	**5'-TAC3'**
							36
							5'-TAT3'
3'-primer[2]	**231**	**2nd I**	**507**	**59**	**58**	**57**	**47**
	5'-TgC3'	**5'-AAA3'**	**5'-TTg3'**	**5'-CTC3'**	**5'-ggC3'**	**5'-CTC3'**	**5'-ACA3'**
							48
							5'-gCA3'
							48
							5'-gCC3'
							52
							5'-TgT3'
A*	**+**	**+**	**+**				
B*	**+**	**+**	**+**				
C*	**+**	**+**	**+**				
DRB1				**+**	**+**		
DRB3				**+**	**+**		
DRB5				**+**			
DQB1					**+**		
DPB1						**+**	
DQA1							**+**

[1]The 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.

[2]The 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.

101.421-06 – including *Taq* polymerase
101.421-06u – without *Taq* polymerase

Visit www.caredx.com for **"Instructions for Use" (IFU)**

Lot No.: 8R3 **Lot-specific Information**

PRODUCT DESCRIPTION

HLA-A*23 SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for identifying the A*23:01 to A*23:129 alleles.

PLATE LAYOUT

Each test consists of 38 PCR reactions in a 48 well cut PCR plate. Wells 39 to 48 are empty.
Note: This lot was manufactured using white plastic trays

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	NC	empty	empty
empty	empty	empty	empty	empty	empty	empty	empty

The 48 well cut PCR plate is marked with 'HLA-A*23' in silver/gray ink.
Well No. 1 is marked with the Lot Number '8R3'.
Wells 1 to 37 – HLA-A*23 high resolution primers.
Well 38 – 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 48 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*23 alleles will be amplified by some primer mixes. For further details see Specificity Table.

UNIQUELY IDENTIFIED ALLELES

All the HLA-A*23 alleles, i.e. **A*23:01 to A*23:129 alleles**, recognized by the HLA Nomenclature Committee in January 2023[1,2] will be amplified by the primers in the HLA-A*23 subtyping kit.

The HLA-A*23 kit enables separation of the confirmed HLA-A*23 alleles as listed in the IMGT/HLA database 3.30.0. 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*23 alleles is listed below.

101.421-06 – including *Taq* polymerase
101.421-06u – without *Taq* polymerase

Visit www.caredx.com for **"Instructions for Use" (IFU)**

Lot No.: 8R3 **Lot-specific Information**

The HLA-A*23 kit also enables identification of many null and alternatively expressed alleles.

The following HLA-A*23 alleles can be distinguished by the different sizes of the HLA-specific PCR product:

Alleles	Primer mix	Alleles	Primer mix
A*23:08N, 23:22	7	A*23:16, 23:29	20
A*23:09, 23:26	8	A*23:38N, 23:56	30
A*23:10:01, 23:23	10	A*23:41, 23:42	25

[1]HLA-A alleles listed on the IMGT/HLA web page 2023-January-12, release 3.51.0, www.ebi.ac.uk/imgt/hla.p
[2]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.

ALLELE CONFIRMATION STATUS

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

[1]Allele status "confirmed" or "unconfirmed" as listed on the IMGT/HLA web page 2017-October-27, release 3.30.0, www.ebi.ac.uk/imgt/hla.

RESOLUTION IN HOMO- AND HETEROZYGOTES

Results file with resolution in HLA-A*23 homo- and heterozygotes is available upon request.

CE
0197
For *In Vitro* Diagnostic Use

101.421-06 – including *Taq* polymerase
101.421-06u – without *Taq* polymerase

Visit www.caredx.com for **"Instructions for Use" (IFU)**

Lot No.: 8R3 **Lot-specific Information**

SPECIFICITY TABLE
HLA-A*23 SSP subtyping

Specificities and sizes of the PCR products of the 37+1 primer mixes used for HLA-A*23 SSP subtyping

Primer Mix	Size of spec. PCR product[1]	Size of control band[2]	Amplified HLA-A*23 alleles[3]	Other amplified HLA Class I alleles
1	210 bp	**800 bp**	*23:01:01:01-23:01:37, 23:03:01-23:65, 23:67-23:68, 23:70-23:104, 23:106N-23:112, 23:114-23:127, 23:129	*02:17:02:01-02:17:04, 02:108, 02:110, 02:268, 02:300, 02:303, 02:617, 02:657, 02:1054, 03:347, 24:13:01-24:13:02, 24:18, 24:24, 24:94, 24:188, 24:207:01-24:207:02, 24:228, 24:315, 24:355, 24:392, 24:515, 24:569, 29:07, 29:49, 31:29, 32:170, 33:187, **B*18:27**
2	160 bp	1070 bp	*23:01:01:01-23:02, 23:05-23:42, 23:44-23:68, 23:71-23:78, 23:80-23:82, 23:84N-23:107Q, 23:109, 23:111-23:112, 23:114-23:119, 23:121-23:127, 23:129	*01:88:02-01:88:03, 01:236, 02:19, 02:36-02:37, 02:54, 02:255, 02:417, 02:723, 02:804, 02:848, 02:883, 02:949, 11:209, 24:02:01:01-24:02:41, 24:02:43-24:02:69, 24:02:71-24:02:161, 24:04-24:09N, 24:11N, 24:13:01-24:15, 24:17:01:01-24:17:01:02, 24:19-24:20:02, 24:24-24:32, 24:34-24:64, 24:66-24:74:02, 24:76-24:93, 24:95-24:109, 24:111-24:124, 24:126-24:137, 24:139-24:157, 24:159-24:166, 24:168-24:203, 24:205-24:206, 24:209, 24:212-24:218, 24:220-24:282, 24:284-24:288, 24:290-24:298, 24:301-24:314, 24:316-24:338, 24:341-24:348, 24:350-24:356, 24:358-24:373, 24:375-24:386, 24:388N-24:389N, 24:391-24:440, 24:442-24:458, 24:460:01:01-24:460:01:02, 24:462-24:470, 24:472-24:482, 24:484-24:487, 24:490-24:493, 24:496-24:498, 24:500-24:505, 24:507-24:513Q, 24:516-24:523, 24:525-24:526, 24:528-24:539, 24:541, 24:543-24:550, 24:552-24:554, 24:556N-24:561:02, 24:564-24:569, 24:571-24:589, 33:19, 68:26, 68:65, 68:115, 68:131, 69:09
3[4]	125 bp 270 bp	**800 bp**	*23:03:01-23:03:02:02, 23:70, 23:83 *23:25	*01:301Q, 03:347, 11:139, 24:21:01, 24:21:03, 24:208:01-24:208:02:02, 24:489, 24:499, 24:562, 29:07, 29:49, 31:29, 32:170, 33:187, **B*18:27** *24:313:02
4	200 bp	1070 bp	*23:28	*24:77
5	230 bp	**800 bp**	*23:06	*11:411, 31:36
6[5]	470 bp	1070 bp	*23:07N	*01:04:01:01N-01:04:01:02N, 03:21N, 11:21N, 24:11N, 30:132N
7[4]	95 bp 145 bp 205 bp	**800 bp**	*23:08N *23:39 *23:22	*02:82N, 02:773N *30:22, 30:104

CE
0197

101.421-06 – including *Taq* polymerase
101.421-06u – without *Taq* polymerase

Visit www.caredx.com for **"Instructions for Use" (IFU)**

Lot No.: 8R3 **Lot-specific Information**

8[6]	140 bp 170 bp 215 bp	1070 bp	*23:26, 23:39 *23:48 *23:09	*30:22, 30:104 *24:403 *01:02:01:01-01:02:02, 01:20, 01:188, 01:190, 01:307, 01:412, 01:420N, 24:129
9	235 bp	1070 bp	*23:05	*24:25, 24:308
10	135 bp 240 bp	**800 bp**	*23:23 *23:10:01, 23:43, 23:110[w]	*****24:562**, B*18:27** *01:301Q, 11:139[w], 24:10:01:01[w]-24:10:02[w], 24:46, 24:210[w], 24:300[w], 24:340[w], 24:494[w]-24:495[w], 24:506[w], 24:528
11	200 bp 270 bp	**800 bp**	*23:11N *23:32	*****24:586N **B*51:293**
12	190 bp	1070 bp	*23:12	*24:30, 24:42, 24:309, 25:11, 32:08
13[4]	90 bp 210 bp	**800 bp**	*23:30 *23:02, 23:24, 23:66	*24:531 *02:680, 02:963, 24:06, 24:87, 24:138, 24:167, 24:285, 24:289, 24:339, 24:381
14[4]	85 bp 190 bp 245 bp	1070 bp	*23:53, 23:70 *23:68 *23:04, 23:83, 23:110	*01:301Q, 03:347, 11:139, 24:17:01:01-24:17:01:02, 24:41, 24:208:01-24:208:02:02, 24:488, 24:499, 24:503, 24:535, 29:07, 29:49 *02:17:02:01-02:17:04, 02:108, 02:110, 02:268, 02:300, 02:303, 02:617, 02:657, 02:680, 02:963, 02:1054, 03:347, 11:139, 24:03:01:01-24:03:04, 24:10:01:01-24:10:02, 24:18, 24:22, 24:33, 24:94, 24:125, 24:138, 24:167, 24:204, 24:207:01-24:207:02, 24:210, 24:289, 24:299-24:300, 24:315, 24:339-24:340, 24:374, 24:387, 24:441, 24:459:01-24:459:02, 24:461, 24:483, 24:488, 24:494-24:495, 24:506, 24:515, 24:524, 24:527, 24:540, 24:563, 24:570, 29:07, 29:49, 31:29, 32:170, 33:187, **B*18:27**
15	210 bp 290 bp	1070 bp	*23:01:16, 23:14:01, 23:104 *23:47	*24:13:02, 24:207:02, 24:315, 24:569, **B*18:27** *24:234, 24:339, 24:347:02, 24:459:02
16	175 bp	**800 bp**	*23:14:01-23:14:02, 23:104	*01:301Q, 02:17:02:01[w]-02:17:04[w], 02:804, 03:347, 11:139, 24:02:01:01-24:04, 24:06-24:11N, 24:13:01-24:13:02, 24:17:01:01-24:23, 24:25-24:50, 24:54-24:56:02, 24:58-24:63, 24:66-24:91, 24:93, 24:95-24:113, 24:115-24:129, 24:131-24:137, 24:139-24:167, 24:169-24:187, 24:189-24:193, 24:195-24:198, 24:200-24:210, 24:212-24:221, 24:223-24:227, 24:229-24:290, 24:292, 24:294Q-24:295, 24:297-24:303N, 24:305-24:315, 24:317-24:318, 24:320-24:323N, 24:325-24:341, 24:343, 24:345-24:391, 24:393-24:394, 24:396N-24:407, 24:409-24:411, 24:413-24:457, 24:459:01-24:470, 24:472-24:480, 24:482-24:514N, 24:516-24:531, 24:533-24:550, 24:552-24:554, 24:556N, 24:558-24:573, 24:575-24:588, 33:19

CE
0197
For *In Vitro* Diagnostic Use
MA123 v02 SSP PI Template
Date: April 2023, Rev. No: 00

	205 bp		*23:105	*02:804, 11:139, 24:02:01:01-24:02:15, 24:02:17-24:05:02, 24:07:01:01-24:11N, 24:17:01:01-24:17:01:02, 24:19-24:21:03, 24:23-24:50, 24:55-24:56:02, 24:58-24:63, 24:66-24:86N, 24:88-24:90:02N, 24:93, 24:95-24:106, 24:108-24:113, 24:115-24:132N, 24:134-24:137, 24:139-24:166, 24:168-24:187, 24:189-24:206, 24:208:01-24:210, 24:212-24:221, 24:223-24:226:02, 24:229-24:284, 24:286-24:288, 24:290, 24:292-24:295, 24:297-24:298, 24:300-24:303N, 24:305-24:314, 24:317-24:323N, 24:325-24:326, 24:328-24:338, 24:340-24:354, 24:356-24:380, 24:382-24:411, 24:413-24:457, 24:459:01-24:470, 24:472-24:477, 24:479Q-24:480, 24:482-24:514N, 24:516-24:550, 24:552-24:554, 24:556N, 24:558-24:568N, 24:570-24:573, 24:575-24:589, 26:16, 30:163, 33:19, 33:119, 68:45, 68:117
17[4]	125 bp 225 bp	1070 bp	*23:33 *23:13	*24:386, 30:102 *03:72, 11:88, 24:07:01:01-24:07:04, 24:19, 24:24, 24:131, 24:288, 24:290, 24:294Q, 24:339, 24:347:01-24:347:02, 24:387, 24:406, 24:453, 24:457, 24:477, 24:489, 24:510, 24:528, 24:541, 24:544, 24:566, 24:569, 24:574, 29:37, 29:56, 30:01:01:01-30:01:21, 30:11:01-30:11:02, 30:14L-30:20, 30:23-30:26, 30:30-30:31, 30:35-30:43, 30:48-30:49, 30:52-30:54, 30:56, 30:58-30:60, 30:62-30:63, 30:65, 30:72-30:75, 30:78N, 30:81-30:83, 30:86-30:89, 30:91-30:98, 30:102, 30:104, 30:106, 30:109-30:116, 30:118, 30:120, 30:122-30:123N, 30:125-30:126, 30:128-30:132N, 30:134-30:138, 30:140-30:143, 30:145N, 30:147-30:148, 30:154, 30:159, 30:161, 30:163-30:165, 30:167-30:168, 30:170-30:173, 30:176, 30:178N-30:181, 30:183-30:185, 30:187, 30:190-30:192, 30:194-30:197N, 30:199, 30:201-30:203, 30:205, 68:45, 68:117
18[4]	120 bp	1070 bp	*23:01:01:01-23:01:37, 23:02[w], 23:04-23:23, 23:25-23:33, 23:35-23:56, 23:58-23:65, 23:67-23:68, 23:71-23:82, 23:84N-23:104, 23:106N-23:112, 23:114-23:127, 23:129	*02:01:22, 02:06:04, 02:40:01-02:40:02, 02:51, 02:99:02, 02:130, 02:171:01, 24:13:02, 24:24, 24:207:02, 24:315, 24:392, 24:569, 29:101:01, 31:67-31:68, 32:28, 32:66, 32:158, 33:32:01, 68:08:01:01-68:08:01:02, 68:51[w], 68:168, **B*40:323:02, B*51:136, B*53:60, C*07:204:01, C*07:482**
19[4,7]	120 bp 195 bp	1070 bp	*23:15 *23:46	 *24:66, 24:308, 30:75
20[5]	130 bp 195 bp 230 bp 270 bp	**800 bp**	*23:29 *23:46 *23:16 *23:32	*24:128 *24:66, 24:308, 30:75 *24:297 **B*51:293**

Lot No.: 8R3 **Lot-specific Information**

21[4]	90 bp	**800 bp**	*23:01:01:01-23:02, 23:03:01?, 23:03:02:01-23:04, 23:06-23:07N, 23:08N?, 23:09, 23:10:01?, 23:10:02-23:13, 23:14:01?-23:14:02?, 23:15, 23:16?, 23:18-23:19N, 23:20?-23:25?, 23:26, 23:27?-23:29?, 23:30, 23:31?-23:37:02?, 23:38N, 23:39?-23:55?, 23:56, 23:57?-23:64?, 23:65, 23:66?-23:67?, 23:68, 23:70?-23:75?, 23:76-23:80, 23:81?-23:83?, 23:85-23:95, 23:97-23:103N, 23:105-23:106N, 23:108N, 23:109?, 23:110-23:111, 23:114-23:124, 23:126-23:129	*24:463, 24:515
22[4,5]	90 bp	1070 bp	*23:31, 23:45, 23:53, 23:70	*01:301Q, 03:347, 11:139, 24:17:01:01-24:17:01:02, 24:41, 24:62, 24:106, 24:208:01-24:208:02:02, 24:330, 24:488, 24:499, 24:503, 24:535, 29:07, 29:49, 31:29, 32:170, 33:187
	290 bp		*23:19N	
23[4,7]	80 bp	1070 bp	*23:45	*02:41, 02:80, 02:117, 02:289:01, 02:304, 02:454, 02:872, 24:62, 26:10, 31:67-31:68, 32:28, 32:66, 32:158, 33:32:01, 68:262
	170 bp		*23:20, 23:58	
24[4]	105 bp	**800 bp**	*23:49	*24:444, 30:06, **C*04:361**
	180 bp		*23:21	**C*04:344**
	240 bp		*23:40	*24:302
25[4]	95 bp	**800 bp**	*23:41	*02:221, 29:15, 30:162, 31:78
	205 bp		*23:42	
26[4]	80 bp	1070 bp	*23:36	*24:32, 25:77, 32:05, 32:79
27[4,5]	85 bp	1070 bp	*23:53, 23:70	*01:301Q, 03:347, 11:139, 24:17:01:01-24:17:01:02, 24:41, 24:208:01-24:208:02:02, 24:488, 24:499, 24:503, 24:535, 29:07, 29:49
	200 bp		*23:34, 23:57	*02:17:02:01-02:17:04, 02:108, 02:110, 02:268, 02:300, 02:303, 02:617, 02:657, 02:1054, 24:13:01, 24:94, 24:188, 24:207:01, 24:228, 24:515
	285 bp		*23:35	
28	385 bp	**800 bp**	*23:03:01?, 23:05, 23:08N?, 23:10:01?, 23:14:01?-23:14:02?, 23:16?, 23:17:01:01-23:17:03, 23:20?-23:25?, 23:27?-23:29?, 23:31?-23:37:02?,	*02:19, 02:804, 24:02:01:01-24:02:09, 24:02:11-24:02:96, 24:02:97?, 24:02:98-24:02:122, 24:02:124-24:05:02, 24:06?, 24:07:01:01-24:10:01:02, 24:10:02?, 24:11N, 24:13:01?, 24:13:02-24:14:01:04, 24:15?, 24:17:01:01-24:18, 24:19?, 24:20:01:01-24:21:01, 24:21:02?,

			23:39?-23:55?, 23:57?-23:64?, 23:66?-23:67?, 23:70?-23:75?, 23:81?-23:83?, 23:84N, 23:96, 23:104, 23:107Q, 23:112, 23:125	24:21:03-24:23, 24:24?, 24:25, 24:26?-24:27?, 24:28-24:32, 24:34?, 24:35-24:37, 24:38?-24:40N?, 24:41, 24:42?-24:43?, 24:44, 24:45N?-24:47?, 24:48N, 24:49:01?, 24:49:02-24:50, 24:51?-24:52?, 24:53-24:54, 24:55?, 24:56:01-24:58, 24:59?-24:60N?, 24:61, 24:62?-24:64?, 24:66?-24:67?, 24:68, 24:69?-24:70?, 24:71-24:72, 24:73?-24:78?, 24:79, 24:80?, 24:81, 24:82?-24:85?, 24:86N, 24:87?-24:89?, 24:90:01N, 24:90:02N?-24:92?, 24:93, 24:94?, 24:95, 24:96?, 24:97, 24:98?-24:105?, 24:106, 24:107?-24:115?, 24:116, 24:117?-24:119?, 24:120-24:122, 24:123?-24:127?, 24:128-24:129, 24:130?-24:131?, 24:132N, 24:133?-24:134?, 24:135:01, 24:135:02?, 24:136, 24:137?-24:141?, 24:142:01, 24:142:02?, 24:143, 24:144?-24:147?, 24:148, 24:149?-24:151?, 24:152, 24:153?-24:162?, 24:163N, 24:164?-24:172:01?, 24:172:02-24:172:03, 24:173?-24:182?, 24:183N, 24:184?-24:193?, 24:194, 24:195?-24:206?, 24:207:01-24:207:02, 24:208:01?, 24:208:02:01-24:208:02:02, 24:209?-24:210?, 24:212?-24:214?, 24:215, 24:216?-24:224?, 24:225:01-24:225:02, 24:226:01?, 24:226:02, 24:227?-24:230?, 24:231, 24:232N?, 24:233-24:235, 24:236?-24:237?, 24:238, 24:239?-24:243?, 24:244, 24:245?-24:247?, 24:248-24:252N, 24:253?, 24:254-24:257, 24:258?, 24:259-24:273, 24:274?-24:277?, 24:278N, 24:279?, 24:280, 24:281?-24:285?, 24:286, 24:287?-24:292?, 24:293-24:294Q, 24:295?-24:301?, 24:302, 24:303N?-24:308?, 24:309, 24:310:01?, 24:310:02, 24:311?-24:312N?, 24:313:01, 24:313:02?, 24:314, 24:315?-24:320?, 24:321, 24:322?-24:330?, 24:331, 24:332?-24:340?, 24:341, 24:342?-24:351?, 24:352-24:353, 24:354?, 24:355-24:359N, 24:360?, 24:361-24:364, 24:365?-24:366?, 24:367-24:373, 24:374?-24:386?, 24:388N?, 24:389N, 24:390?-24:393?, 24:394, 24:395?, 24:396N-24:412, 24:413?, 24:414, 24:415?-24:416?, 24:417-24:420, 24:421?, 24:422-24:431:02, 24:432?, 24:433N-24:445N, 24:446?, 24:447Q-24:451, 24:452?, 24:453-24:459:02, 24:461-24:462, 24:464, 24:466-24:470, 24:472-24:514N, 24:516-24:554, 24:556N-24:589, 33:19?
29	170 bp 200 bp 240 bp 290 bp	1070 bp	*23:48 *23:37:01-23:37:02 *23:40 *23:47	*24:403 *24:273, 24:506 *24:302 *24:234, 24:339, 24:347:02, 24:459:02

Lot No.: 8R3 **Lot-specific Information**

30[4]	110 bp 245 bp	1070 bp	*23:56 *23:38N	**C*04:446** *24:61
31	185 bp	1070 bp	*23:44	*03:449
32[4]	85 bp	1070 bp	*23:59	*01:203, 02:671, 11:166, 30:56, 31:85, 32:72, 80:01:01:01-80:09N
33	165 bp	1070 bp	*23:65	*24:298
34[4]	90 bp 170 bp	1070 bp	*23:18 *23:58	*24:267
35[4]	105 bp 260 bp	**800 bp**	*23:49 *23:27	*24:444, 30:06, **C*04:361** ***24:255
36	200 bp	1070 bp	*23:104	
37[5]	195 bp	1070 bp	*23:01:01:01-23:33, 23:35-23:56, 23:58-23:65, 23:67-23:68, 23:70-23:98, 23:100-23:103N, 23:105-23:112, 23:114-23:127, 23:129	*24:24, 24:71, 24:315, 24:392, 24:527, 24:569, 29:07, 29:49, 31:29, 32:170, 33:187, **B*18:27**
38[8]			**Negative Control**	

[1]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-A*23 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 inherit 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.

[2]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.

[3]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.

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

[5]Primer mixes 6, 20, 22, 27 and 37 may give rise to a lower yield of HLA-specific PCR product than the other A*23 primer mixes.

[6]Primer mix 8 may have tendency of unspecific amplification.

[7]Primer mixes 19 and 23 have tendencies to giving rise to primer oligomer formation.

[8]Primer mix 38 contains a negative control, which will amplify a majority of HLA amplicons as well as the amplicons generated by the control primer pairs matching the human growth hormone gene. HLA-

specific PCR product sizes range from 75 to 200 base pairs and the PCR product generated by the HGH positive control primer pair is 200 base pairs.

Abbreviations

'w', may be weakly amplified.

'?', nucleotide sequence information not available for the primer matching sequence.

101.421-06 – including *Taq* polymerase
101.421-06u – without *Taq* polymerase

Visit www.caredx.com for
"Instructions for Use" (IFU)

Lot No.: 8R3 **Lot-specific Information**

PRIMER SPECIFICATION

Well No.	1	2	3	4	5	6	7	8	9	10	11	12
Length of spec.	210	160	125	200	230	470	95	140	235	135	200	190
PCR product			270				145	170		240	270	
							205	215				
Length of int.	800	1070	800	1070	800	1070	800	1070	1070	800	800	1070
pos. control[1]												
5'-primer(s)[2]	368	453	368	98	144	3rd I	98	98	28	368	90	144
	5' -gTT 3'	5' -AAA 3'	5' -gTT 3'	5' -CTC 3'	5' -gCC 3'	5' -ATA 3'	5' -CTC 3'	5' -CTC 3'	5' -TCg 3'	5' -gTT 3'	5' -AgT 3'	5' -gCC 3'
							564				160	
							5' -TgA 3'				5' -ACg 3'	
3'-primer(s)[3]	539	570	453	256	331	621	200	193	92	463	317	292
	5' -TCA 3'	5' -CCg 3'	5' -TCg 3'	5' -CTg 3'	5' -CTC 3'	5' -ggg 3'	5' -TCC 3'	5' -CgA 3'	5' -AAC 3'	5' -gCT 3'	5' -ggA 3'	5' -gTg 3'
			595				262	200		559		
			5' -CCg 3'				5' -TgC 3'	5' -TCC 3'		5' -CCg 3'		
							616	227		571		
							5' -CgT 3'	5' -CTg 3'		5' -CCT 3'		
								271				
								5' -CAT 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.	90	85	210	175	125	120	120	130	90	90	80	105
PCR product	210	190	290	205	225		195	195		290	170	180
		245						230				240
								270				
Length of int.	800	1070	1070	800	1070	1070	1070	800	800	1070	1070	800
pos. control[1]												
5'-primer(s)[2]	368	368	368	98	98	453	418	90	920	368	414	98
	5' -gTT 3'	5' -gTT 3'	5' -gTT 3'	5' -CTC 3'	5' -CTC 3'	5' -AAA 3'	5' -AgC 3'	5' -AgT 3'	5' -CCA 3'	5' -gTT 3'	5' -CAg 3'	5' -CTC 3'
				368			493	228			678	
				5' -gTT 3'			5' -CTg 3'	5' -ATg 3'			5' -AgA 3'	
								379				
								5' -ACA 3'				
								418				
								5' -AgC 3'				
3'-primer(s)[3]	419	413	538	259	181	524	570	317	968	418	453	163
	5' -CgC 3'	5' -gCC 3'	5' -CAg 3'	5' -gTT 3'	5' -gTA 3'	5' -CAC 3'	5' -CCg 3'	5' -ggA 3'	5' -CAg 3'	5' -gTC 3'	5' -TCT 3'	5' -CgC 3'
	530	518	616	502	282	538		570		619	806	238
	5' -CCA 3'	5' -CCT 3'	5' -CgC 3'	5' -CTT 3'	5' -gAC 3'	5' -CAg 3'		5' -CCg 3'		5' -gTT 3'	5' -CTA 3'	5' -CCT 3'
	539	570		539	282						809	299
	5' -TCC 3'	5' -CAC 3'		5' -TCT 3'	5' -gAC 3'						5' -CAA 3'	5' -TCg 3'
Well No.	13	14	15	16	17	18	19	20	21	22	23	24

CE
0197
For *In Vitro* Diagnostic Use

101.421-06 – including *Taq* polymerase
101.421-06u – without *Taq* polymerase

Visit www.caredx.com for
"Instructions for Use" (IFU)

Lot No.: 8R3 **Lot-specific Information**

Well No.	25	26	27	28	29	30	31	32	33	34	35	36	37
Length of spec.	95	80	85	385	170	110	185	85	165	90	105	200	195
PCR product	205		200		200	245				170	260		
			285		240								
					290								
Length of int. pos. control[1]	800	1070	1070	800	1070	1070	1070	1070	1070	1070	800	1070	1070
5'-primer(s)[2]	376	265	368	678	98	98	395	176	453	678	98	368	368
	5' -gCT 3'	5' -CAg 3'	5' -gTT 3'	5' -AgA 3'	5' -CTC 3'	5' -CTC 3'	5' -gCA 3'	5' -gCA 3'	5' -AAA 3'	5' -AgA 3'	5' -CTC 3'	5' -gTT 3'	5' -gTT 3'
	484				368								
	5' -ACg 3'				5' -gTT 3'								
3'-primer(s)[3]	538	302	413	920	227	167	538	218	577	728	163	526	521
	5' -CAA 3'	5' -ggC 3'	5' -gCC 3'	5' -Tgg 3'	5' -CTg 3'	5' -ACC 3'	5' -CAA 3'	5' -gCg 3'	5' -gCC 3'	5' -CCT 3'	5' -CgC 3'	5' -CCg 3'	5' -ggg 3'
			524		255	303				809	316		
			5' -CAT 3'		5' -TCC 3'	5' -AgT 3'				5' -CAA 3'	5' -gAA 3'		
			534		255								
			5' -CgT 3'		5' -TCT 3'								
			614		299								
			5' -Tgg 3'		5' -TCg 3'								
					616								
					5' -CgC 3'								
Well No.	25	26	27	28	29	30	31	32	33	34	35	36	37

[1]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.

[2]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 web site. The sequence of the 3 terminal nucleotides of the primer is given.

[3]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 web site. The sequence of the 3 terminal nucleotides of the primer is given.

101.421-06 – including *Taq* polymerase
101.421-06u – without *Taq* polymerase

Visit www.caredx.com for
"Instructions for Use" (IFU)

Lot No.: 8R3 **Lot-specific Information**

CELL LINE VALIDATION SHEET

HLA-A*23 SSP subtyping kit[2]

					Well															
					1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
				Prod. No.:	202129601	202129602	202129603	202129604	202129605	202129606	202129607	202129608	202129609	202129610	202129611	202129612	202129613	202129614	202129615	202129616
	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		+	-	-	-	-	-	-	-	-	-	-	-	-	+	-	w
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	-	-	-	-	-	-	-	-	-	w	-	-	-	+	-	+
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		+	-	-	-	-	-	-	-	-	-	-	-	-	+	-	w
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	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

CE
0197
For *In Vitro* Diagnostic Use
MA123 v02 SSP PI Template
Date: April 2023, Rev. No: 00

101.421-06 – including *Taq* polymerase
101.421-06u – without *Taq* polymerase

Visit www.caredx.com for **"Instructions for Use" (IFU)**

Lot No.: 8R3 **Lot-specific Information**

CELL LINE VALIDATION SHEET

HLA-A*23 SSP subtyping kit[2]

					Well															
					17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32
				Prod. No.:	202129617	202129618	202129619	202129620	202129621	202129622	202129623	202129624	202129625	202129626	202129627	202129628	202129629	202129630	202129631	202129632
	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	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

CE
0197

101.421-06 – including *Taq* polymerase
101.421-06u – without *Taq* polymerase

Visit www.caredx.com for **"Instructions for Use" (IFU)**

Lot No.: 8R3 **Lot-specific Information**

CELL LINE VALIDATION SHEET

HLA-A*23 SSP subtyping kit[2]

					Well				
					33	34	35	36	37
				Prod. No.:	202129633	202129634	202129635	202129636	202129637
	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	-	-	-	-	-

CE
0197
For *In Vitro* Diagnostic Use
MA123 v02 SSP PI Template
Date: April 2023, Rev. No: 00

101.421-06 – including *Taq* polymerase
101.421-06u – without *Taq* polymerase

Visit www.caredx.com for **"Instructions for Use" (IFU)**

Lot No.: 8R3 **Lot-specific Information**

[1]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.

[2]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, 9, 11, 13, 15, 19, 20, 23 to 26, 29 to 31 and 33 to 36 were available.

The specificities of the primers in primer solutions 3, 13, 15, 19, 20, 23, 26 and 36 were tested by separately adding one or two additional 5'-primers, respectively one or two additional 3'-primers.

In primer solutions 4, 5, 9, 24, 29, 30 and 33 to 35 it was only possible to test the 5'-primers, the 3'-primers were not possible to test.

In primer solutions 11, 25 and 31 it was only possible to test the 3'-primers, the 5'-primers was not possible to test.

In primer solutions 3, 7, 8, 10, 13 to 15, 17, 22, 23 and 27 one or more 3'-primers were not possible to test, and in primer solutions 19 and 20 one or more 5'-primer were not possible to test. In addition, one or more 3'-and/or 5'-primers in primer solutions 7, 8, 10, 12, 14, 16, 18 and 27 were tested by separately adding one additional 5'-primer and/or one additional 3'-primer.

101.421-06 – including *Taq* polymerase
101.421-06u – without *Taq* polymerase

Visit www.caredx.com for **"Instructions for Use" (IFU)**

Lot No.: 8R3 **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: wwwcaredx.com

Distributed by:
CareDx Lab Solutions Inc., 901 S. Bolmar St., Suite R, West Chester, PA 19382
Tel: 1-877-653-78171
Fax: 610-344-7989
E-mail: orders-us@caredx.com
Web page: www.caredx.com

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

CE
0197
For *In Vitro* Diagnostic Use