

101.430-12 – including *Taq* polymerase
101.430-12u – without *Taq* polymerase

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

Lot No.: **6R1**

Lot-specific Information
Olerup SSP[®] HLA-A*31

Product number:	101.430-12 – including <i>Taq</i> polymerase 101.430-12u – without <i>Taq</i> polymerase
Lot number:	6R1
Expiry date:	2027-01-01
Number of tests:	12
Number of wells per test:	42+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. 6R1.

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*31 LOT (8K7)**

- The product documentation has been updated for new alleles of IMGT 3.50.0.
- The kit resolution focuses on common and well documented (CWD) alleles¹.

The HLA-A*31 primer set, specificity and interpretation tables have been updated for the HLA-A alleles described since the previous *Olerup SSP[®] HLA-A*31* lot was made (**Lot No. 8K7**).

The primers of the wells detailed below have been exchanged, added or modified compared to the previous lot (**Lot No. 8K7**).

Well	5'-primer	3'-primer	rationale
1	Added	-	5'-primer added for the A*31:211 allele.



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Well **43** contains Negative Control primer pairs, that will amplify the 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.



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Lot-specific Information

PRODUCT DESCRIPTION

HLA-A*31 SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for identifying the A*31:01 to A*31:217 alleles.

PLATE LAYOUT

Each test consists of 43 PCR reactions in a 48 well cut PCR plate. Wells 44 to 48 are empty.

1	2	3	4	5	6	7	8
9	10	11	12	13	14	15	16
17	18	19	20	21	22	23	24
25	26	27	28	29	30	31	32
33	34	35	36	37	38	39	40
41	42	NC	empty	empty	empty	empty	empty

The 48 well cut PCR plate is marked with ‘HLA-A*31’ in silver/gray ink.

Well No. 1 is marked with the Lot Number ‘6R1’.

Wells 1 to 42 – HLA-A*31 high resolution primers.

Well 43 – 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*31 alleles will be amplified by some primer mixes. For further details see Specificity Table.

UNIQUELY IDENTIFIED ALLELES

All the HLA-A*31 alleles, i.e. **A*31:01 to A*31:217 alleles**, recognized by the HLA Nomenclature Committee in October 2022^{1,2} will be amplified by the primers in the HLA-A*31 subtyping kit³.

The HLA-A*31 kit enables separation of the confirmed HLA- A*31 alleles as listed in the IMGT/HLA database 3.28.0. 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*31 alleles is listed below.



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MA123 v02 SSP PI Template

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Lot-specific Information

The HLA-A*31 kit also enables identification of many null and alternatively expressed alleles.

The following HLA-A*31 alleles can be distinguished by the different sizes of the HLA-specific PCR product:

Alleles	Primer mix	Alleles	Primer mix
A*31:01:02:03N, 31:35	21	A*31:29, 31:59, 31:146	25
A*31:16, 31:46	16	A*31:36, 31:48	29

¹HLA-A alleles listed on the IMGT/HLA web page 2022-October-12, release 3.50.0, www.ebi.ac.uk/imgt/hla.

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

³The A*31 primer set cannot separate the following alleles. These alleles can be distinguished by the HLA-A low resolution and/or HLA-A*33 kits.

Alleles

A*31:89, A*33:125, 33:131



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Lot-specific Information

ALLELE CONFIRMATION STATUS

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

¹Allele status “confirmed” or “unconfirmed” as listed on the IMGT/HLA web page 2017-April-13, release 3.28.0, www.ebi.ac.uk/imgt/hla.

RESOLUTION IN HOMO- AND HETEROZYGOTES

Results file with resolution in HLA-A*31 homo- and heterozygotes is available upon request.



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MA123 v02 SSP PI Template

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Lot-specific Information
SPECIFICITY TABLE

HLA-A*31 SSP subtyping

Specificities and sizes of the PCR products of the 42+1 primer mixes used for HLA-A*31 SSP subtyping

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified HLA-A*31 alleles ³	Other amplified HLA-A alleles
1	155 bp	800 bp	*31:01:02:01-31:07, 31:09-31:43, 31:45-31:86, 31:88, 31:90-31:141N, 31:143-31:194, 31:196-31:217	*01:07, 01:226, 02:185, 02:601, 11:257, 23:21, 24:124, 24:549, 26:19, 26:198, 29:14, 30:12:01-30:12:02, 30:18, 30:55, 30:152, 30:166, 32:128, 34:04, B*15:82, B*15:260, B*15:390, B*40:186:01, C*03:186:01, C*03:349, C*04:315, C*04:344
2⁴	80 bp 215 bp	800 bp	*31:67-31:68 *31:02:01-31:02:02, 31:07-31:08, 31:91, 31:109	*02:41, 02:80, 02:117, 02:289:01, 02:304, 02:454, 02:872, 23:45, 24:62, 26:10, 32:28, 32:66, 32:158, 33:32:01, 68:262 *02:243:01-02:243:03, 24:82, 29:48, 33:08, 33:53, 33:183
3	155 bp	800 bp	*31:03-31:04:02, 31:123	*02:309, 02:454, 03:01:19, 03:103:02, 25:19:01-25:19:02, 25:30, 26:43:01, 26:112:02, 34:02:01:01-34:02:01:08, 34:02:03-34:04, 34:06-34:09, 34:13, 34:15, 34:20-34:22, 34:24-34:26N, 34:28-34:30N, 66:06, 66:43, 74:01:03
4⁷	165 bp	1070 bp	*31:03-31:04:02, 31:06, 31:179	*01:06, 01:200, 01:244, 02:114, 02:246, 02:279, 02:681, 02:985, 02:1029, 03:01:30, 03:01:76, 03:01:90, 03:01:97, 03:01:106, 03:05:01-03:05:02, 03:42, 03:98, 03:105, 03:122, 03:326, 03:332, 03:452, 11:24:01-11:25:03, 11:31, 11:35, 11:158, 23:53, 23:70, 29:01:01:01-29:01:02, 29:01:04-29:02:13, 29:02:15-29:04, 29:06-29:23, 29:25-29:27, 29:29-29:31, 29:34-29:76, 29:78N, 29:80-29:81, 29:83-29:86, 29:88-29:103, 29:105-29:137, 29:139-29:151, 29:153-29:172, 30:26, 32:30:01-32:30:02, 32:32, 33:18:01-33:18:02, 34:02:01:01-34:04, 34:07-34:10N, 34:13, 34:15, 34:20-34:22, 34:24-34:26N, 34:28-34:29N, 68:08:01:01-68:08:02, 68:63, 68:157, 68:168, 80:01:01:01-80:09N



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MA123 v02 SSP PI Template
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5⁴	120 bp 285 bp	800 bp	*31:26, 31:38 *31:03, 31:164	*02:660, 03:184, 32:36 *01:143, 11:43, 26:177, 26:207, 29:66, 33:13, 33:184, C*07:449
6	130 bp 165 bp	800 bp	*31:39, 31:54 *31:05, 31:200	*33:07 *01:01:114, 23:03:01, 24:21:03, 24:208:01, 29:03, 29:33, 32:13, 33:10
7⁷	505 bp	1070 bp	*31:07-31:08, 31:10	*02:81, 02:87, 02:112, 02:124, 02:129, 02:571, 02:829, 03:152, 03:219, 23:01:01:01-23:01:15, 23:01:17-23:01:37, 23:03:01-23:13, 23:14:02-23:26, 23:28-23:33, 23:35-23:37:02, 23:39-23:65, 23:67-23:68, 23:70-23:103N, 23:106N-23:112, 23:114-23:121, 23:123-23:126, 24:13:01, 24:18, 24:24, 24:94, 24:188, 24:207:01, 24:228, 24:355, 24:392, 24:515, 25:19:01-25:19:02, 25:30, 29:13, 32:01:01:01-32:01:05, 32:01:07- 32:01:54, 32:03:01:01-32:09, 32:11Q-32:21, 32:23-32:70, 32:72- 32:100, 32:102-32:106:01:02, 32:108-32:117N, 32:119-32:150, 32:153-32:171
8	155 bp 220 bp	1070 bp	*31:24, 31:27 *31:09	*11:01:28, 11:01:77, 29:67, 29:156, 32:26:02, 32:152, 33:61, 33:127, 33:142, 33:190, 74:37
9⁴	75 bp	1070 bp	*31:01:02:01- 31:01:29, 31:01:31- 31:01:45, 31:01:47- 31:02:02, 31:05, 31:07-31:61, 31:63- 31:66, 31:70-31:119, 31:121-31:178, 31:180-31:217	*02:24:02, 02:65, 02:152, 02:507, 02:829, 11:372, 23:03:01, 23:83, 24:21:03, 29:32, 32:01:01:01- 32:01:06, 32:01:08-32:01:11, 32:01:13-32:01:27, 32:01:29- 32:01:47, 32:01:49-32:03:01:02, 32:05-32:27N, 32:29, 32:31, 32:33:01, 32:33:03-32:47, 32:49- 32:65, 32:67-32:93, 32:95-32:100, 32:102-32:118, 32:120-32:156, 32:159-32:165, 32:167N-32:171, 33:01:01:01-33:01:04, 33:01:06- 33:01:17, 33:03:01:01-33:03:18, 33:03:20-33:03:23, 33:03:25- 33:03:26, 33:03:28-33:17, 33:20- 33:31, 33:33-33:37, 33:39-33:151, 33:153-33:158, 33:160-33:233, 74:01:01:01-74:43, B*15:17:03
10^{4,5}	115 bp 160 bp	1070 bp	*31:41 *31:11:01, 31:56	*02:24:02, 02:507, 24:21:03, 24:208:01, 29:33, 29:51, 29:80, 32:02, 32:06, 32:109, 33:94, 33:150, 74:35
11	135 bp 210 bp	1070 bp	*31:26 *31:12, 31:60N	*02:660, 03:184, 32:36 *02:490N, 02:516N, 02:526, 03:269N, 32:89, 32:132N, 33:162



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12	245 bp	1070 bp	*31:01:02:01-31:06, 31:09, 31:11:01- 31:20, 31:22-31:32, 31:34-31:78, 31:80- 31:209, 31:211- 31:217	*02:243:01-02:243:03, 03:205, 11:43, 26:177, 29:19, 29:39, 29:48, 29:159, 33:01:01:01-33:01:17, 33:03:01:01-33:12, 33:14-33:16, 33:18:01-33:37, 33:39-33:47, 33:49-33:50, 33:52-33:68, 33:70- 33:91, 33:93-33:108, 33:110- 33:118, 33:120-33:146, 33:148- 33:233, 68:29, 68:250
13 ⁴	85 bp	1070 bp	*31:13	*02:251
14 ⁶	150 bp	800 bp	*31:24	*11:01:28, 11:01:77, 29:67, 29:156, 32:26:02, 32:152, 33:61, 33:190, 74:37
15	220 bp 150 bp 225 bp	1070 bp	*31:14N *31:25 *31:15	*32:26:01
16 ⁴	80 bp 165 bp	1070 bp	*31:46 *31:16	*29:12, 29:92, 33:58
17	160 bp 235 bp	1070 bp	*31:25, 31:40 *31:17	*32:26:01
18	155 bp 200 bp	1070 bp	*31:43, 31:62 *31:18	*02:408, 02:590 *02:233:02, 23:43, 33:132
19 ⁴	110 bp 185 bp	1070 bp	*31:19 *31:72	*02:380, 03:52, 30:109
20	325 bp	1070 bp	*31:20	
21 ⁴	75 bp 155 bp 180 bp	1070 bp	*31:35 *31:43, 31:62 *31:21	*01:07 *02:408, 02:590 *01:07, 02:185, 02:601, 30:55, 30:166, 30:177, 30:186
22 ⁴	215 bp 80 bp 155 bp 190 bp	1070 bp	*31:01:02:03N *31:71 *31:27, 31:55 *31:22	*02:327 *33:127, 33:142
23 ⁴	80 bp 165 bp 200 bp	1070 bp	*31:71 *31:40 *31:23	*02:327
24	150 bp 180 bp 220 bp	1070 bp	*31:55 *31:81 *31:28, 31:89, 31:115	*02:104 *03:205, 11:43, 29:172, 33:125, 33:131, 68:29, 68:250
25 ⁵	135 bp 165 bp 245 bp	800 bp	*31:29, 31:146 *31:56 *31:59	*02:507, 23:03:01, 23:83, 24:21:03, 24:208:01, 29:07, 29:154, 32:89, 33:187 *01:297, 24:521
26	130 bp 185 bp	1070 bp	*31:30, 31:39, 31:97 *31:72	*02:507, 29:28, 29:79, 32:10, 32:118, 32:152, 33:94, 33:155, 74:29, B*07:02:40, C*02:02:15, C*04:175



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For *In Vitro* Diagnostic Use
MA123 v02 SSP PI Template
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101.430-12 – including *Taq* polymerase
101.430-12u – without *Taq* polymerase

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27⁴	85 bp	800 bp	*31:31, 31:67-31:68	*02:41, 02:80, 02:117, 02:289:01, 02:304, 02:454, 02:872, 23:45, 24:62, 26:10, 32:28, 32:66, 32:158, 33:32:01, 68:262 *02:72, 02:275, 68:156
28⁴	500 bp 110 bp 175 bp 205 bp	1070 bp	*31:38 *31:32 *31:60N	*02:490N, 02:516N, 03:269N, 32:132N
29⁴	115 bp 180 bp 275 bp	1070 bp	*31:48 *31:44, 31:81 *31:36	*02:140, 02:821, 26:99, 29:130, 33:15 *02:104
30⁵	160 bp 185 bp 245 bp	800 bp	*31:34 *31:87 *31:33	
31⁴	75 bp 120 bp	1070 bp	*31:37 *31:41, 31:54	*02:24:02, 02:507, 24:21:03, 24:208:01, 29:33, 29:51, 29:80, 32:02, 32:06, 32:109, 33:07, 33:94, 33:150, 74:35
32	165 bp	1070 bp	*31:95	*02:970
33	180 bp	1070 bp	*31:96	
34	130 bp	1070 bp	*31:98	
35	160 bp	1070 bp	*31:102	*24:282, 26:46
36	250 bp	1070 bp	*31:105	B*55:66
37	230 bp	1070 bp	*31:111	
38	305 bp	1070 bp	*31:119	
39⁴	110 bp	1070 bp	*31:125	*01:404, 02:324, 02:426, 02:836, 03:316, 11:173
40	290 bp	1070 bp	*31:126N	*02:540N, 33:213N
41	240 bp	1070 bp	*31:131N	
42	155 bp	1070 bp	*31:01:02:01- 31:01:06, 31:01:08- 31:01:33, 31:01:35- 31:07, 31:09-31:21, 31:23-31:88, 31:90- 31:108, 31:110- 31:201N, 31:203- 31:210, 31:212- 31:217	*01:07, 03:01:88, 24:124, 26:01:23, 26:19, 29:14, 30:12:01-30:12:02, 30:18, 30:55, 30:152, 30:166, 68:126
43⁸	-	-	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*31 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.



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For *In Vitro* Diagnostic Use

MA123 v02 SSP PI Template

Date: January 2023, Rev. No: 00

101.430-12 – including *Taq* polymerase
101.430-12u – without *Taq* polymerase

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Lot No.: 6R1**Lot-specific Information**

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.

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

⁵Primer mixes 10, 25 and 30 may have tendencies of unspecific amplifications.

⁶Primer mix 14 may give rise to a lower yield of HLA-specific PCR product than the other HLA-A*31 primer mixes.

⁷Primer mixes 4 and 7 may weakly amplify the A*34:01 allele.

⁸Primer mix 43 contains a negative control, which will amplify the 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.

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Lot No.: **6R1**

Lot-specific Information
PRIMER SPECIFICATION

Well No.	1	2	3	4	5	6	7	8	9	10	11	12
Length of spec. PCR product	155	80 215	155	165	120 285	130 165	505	155 220	75	115 160	135 210	245
Length of int. pos. control ¹	800	800	800	1070	800	800	1070	1070	1070	1070	1070	1070
5'-primer(s) ²	123 5'-Cgg 3'	97 5'-TCA 3'	423 5'-gCT 3'	413 5'-CCg 3'	97 5'-TCA 3'	448 5'-CCT 3'	317 5'-gCT 3'	97 5'-TCA 3'	413 5'-CCA 3'	448 5'-CCT 3'	362 5'-gAA 3'	97 5'-TCA 3'
	125 5'-CgA 3'	414 5'-CAg 3'			445 5'-TCC 3'			448 5'-CCT 3'		706 5'-CgA 3'	375 5'-TgA 3'	
	127 5'-ggg 3'				467 5'-CTA 3'						445 5'-TCC 3'	
3'-primer(s) ³	238 5'-CCT 3'	270 5'-ACT 3'	538 5'-CAA 3'	539 5'-TCA 3'	341 5'-CgT 3'	530 5'-CCT 3'	538 5'-CAA 3'	214 5'-CCA 3'	448 5'-CAA 3'	524 5'-CAT 3'	538 5'-CAA 3'	299 5'-CCA 3'
	238 5'-CCT 3'	453 5'-TCT 3'			538 5'-CAA 3'	536 5'-ACg 3'		278 5'-ggC 3'		565 5'-CAg 3'		
	245 5'-ACg 3'					570 5'-CCg 3'		559 5'-CCg 3'		831 5'-TCC 3'		
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
Well No.	13	14	15	16	17	18	19	20	21	22	23	24
Length of spec. PCR product	85	150 220	150 225	80 165	160 235	155 200	110 185	325	75 155	80 155	80 165	150 180
									180 215	190	200	220
Length of int. pos. control ¹	1070	800	1070	1070	1070	1070	1070	1070	1070	1070	1070	1070
5'-primer(s) ²	413 5'-CCA 3'	448 5'-CCT 3'	98 5'-CAC 3'	98 5'-CAC 3'	98 5'-CAC 3'	413 5'-CCA 3'	488 5'-ggT 3'	302 5'-ggA 3'	2 nd 5'-CTC 3'	97 5'-TCA 3'	98 5'-CAC 3'	97 5'-TCA 3'
		629 5'-CAA 3'	448 5'-CCT 3'	769 5'-Agg 3'	448 5'-CCT 3'		635 5'-gCg 3'	302 5'-ggA 3'	98 5'-CTT 3'	652 5'-CTg 3'	652 5'-CTg 3'	652 5'-CTg 3'
									203 5'-gAA 3'			
									413 5'-CCA 3'			
3'-primer(s) ³	456 5'-TCg 3'	559 5'-CCg 3'	281 5'-AgC 3'	221 5'-ACA 3'	221 5'-ACC 3'	527 5'-CCg 3'	559 5'-CgT 3'	346 5'-AgC 3'	238 5'-CCT 3'	214 5'-CCA 3'	221 5'-ACC 3'	277 5'-ggT 3'
		808 5'-AgA 3'	559 5'-CCT 3'	808 5'-AgA 3'	292 5'-gTT 3'	571 5'-CCT 3'	777 5'-gCA 3'		527 5'-CCg 3'	245 5'-ACg 3'	691 5'-gCC 3'	282 5'-gAC 3'
					559 5'-CCT 3'					691 5'-gCC 3'	811 5'-CAT 3'	763 5'-CAA 3'
										763 5'-CAA 3'		791 5'-AgT 3'
Well No.	13	14	15	16	17	18	19	20	21	22	23	24



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

101.430-12 – including *Taq* polymerase
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Lot No.: **6R1**

Lot-specific Information

Well No.	25	26	27	28	29	30	31	32	33	34	35	36
Length of spec.	135	130	85	110	115	160	75	165	180	130	160	250
PCR product	165	185	500	175	180	185	120					
	245			205	275	245						
Length of int.	800	1070	800	1070	1070	800	1070	1070	1070	1070	1070	1070
pos. control ¹												
5'-primer(s) ²	355	448	235	375	97	97	448	878	386	148	495	28
	5'-CCC 3'	5'-CCT 3'	5'-AgA 3'	5'-TgA 3'	5'-TCA 3'	5'-TCA 3'	5'-CCT 3'	5'-gCA 3'	5'-gTT 3'	5'-TgT 3'	5'-CAC 3'	5'-TCC 3'
	626	635	414	406	652	448						
	5'-CCT 3'	5'-gCg 3'	5'-CAg 3'	5'-gCT 3'	5'-CTg 3'	5'-CCT 3'						
	706			467								
	5'-CgA 3'			5'-CTA 3'								
3'-primer(s) ³	448	536	290	538	238	239	482	899	524	238	616	107
	5'-CAA 3'	5'-ACg 3'	5'-CAA 3'	5'-CAA 3'	5'-CCC 3'	5'-gCT 3'	5'-TgC 3'	5'-ACg 3'	5'-CAC 3'	5'-CCT 3'	5'-CgT 3'	5'-ACT 3'
	831	539	453		331	299	524					
	5'-TCC 3'	5'-TCC 3'	5'-TCT 3'		5'-CTC 3'	5'-CCC 3'	5'-CAT 3'					
		777			727	568	530					
		5'-gCA 3'			5'-CCA 3'	5'-CTg 3'	5'-CCT 3'					
					791							
					5'-AgT 3'							
Well No.	25	26	27	28	29	30	31	32	33	34	35	36

Well No.	37	38	39	40	41	42
Length of spec.	230	305	110	290	240	155
PCR product						
Length of int.	1070	1070	1070	1070	1070	1070
pos. control ¹						
5'-primer(s) ²	620	5 th I	763	369	97	127
	5'-g 3'	5'-TAT 3'	5'-TCA 3'	5'-TAg 3'	5'-TCA 3'	5'-ggg 3'
3'-primer(s) ³	808	1040	831	616	295	243
	5'-AgA 3'	5'-CCC 3'	5'-TCC 3'	5'-CgT 3'	5'-TCA 3'	5'-TCA 3'
Well No.	37	38	39	40	41	42

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.



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101.430-12 – including Taq polymerase
101.430-12u – without Taq polymerase

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Lot No.: **6R1**

Lot-specific Information

CELL LINE VALIDATION SHEET																						
HLA-A*31 SSP subtyping kit ²																						
					Prod No.:	Well																
						1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	
						202347401	202016402	202016403	202016404	202016405	202016406	202016407	202016408	202016409	202016410	202016411	202016412	202016413	202016414	202016415	202016416	
	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

101.430-12 – including Taq polymerase
101.430-12u – without Taq polymerase

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Lot No.: **6R1**

Lot-specific Information

CELL LINE VALIDATION SHEET																			
HLA-A*31 SSP subtyping kit ²																			
			Prod. No.:	Well															
				17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32
				202016417	202016418	202016419	202016420	202016421	202016422	202016423	202016424	202016425	202016426	202016427	202016428	202016429	202016430	202016431	202016432
	IHWC cell line ¹	A*																	
1	9001 SA	*24:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2	9280 LK707	*02:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3	9011 E4181324	*01:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4	9275 GU373	*30:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
5	9009 KAS011	*01:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
6	9353 SM	*02:01	*26:03	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
7	9020 QBL	*26:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
8	9025 DEU	*31:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
9	9026 YAR	*26:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
10	9107 LKT3	*24:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
11	9051 PITOUT	*29:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
12	9052 DBB	*02:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
13	9004 JESTHOM	*02:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
14	9071 OLGA	*31:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
15	9075 DKB	*24:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
16	9037 SWEIG007	*29:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
17	9282 CTM3953540	*03:01	*80:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
18	9257 32367	*33:03	*74:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
19	9038 BM16	*02:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
20	9059 SLE005	*02:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
21	9064 AMALA	*02:17		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
22	9056 KOSE	*02:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
23	9124 IHL	*02:01	*34:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
24	9035 JBUSH	*32:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
25	9049 IBW9	*33:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
26	9285 WT49	*02:05		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
27	9191 CH1007	*24:10	*29:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
28	9320 BEL5GB	*02:01	*29:02	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
29	9050 MOU	*29:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
30	9021 RSH	*30:01	*68:02	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
31	9019 DUCAF	*30:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
32	9297 HAG	*02:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
33	9098 MT14B	*31:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
34	9104 DHIF	*31:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
35	9302 SSTO	*32:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
36	9024 KT17	*02:06	*11:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
37	9065 HHKB	*03:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
38	9099 LZL	*02:17		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
39	9315 CML	*01:01	*03:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
40	9134 WHONP199	*02:07	*30:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
41	9055 H0301	*03:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
42	9066 TAB089	*02:07		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
43	9076 T7526	*02:06	*02:07	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
44	9057 TEM	*66:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
45	9239 SHJO	*23:01	*24:02	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
46	9013 SCHU	*03:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
47	9045 TUBO	*02:16	*03:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
48	9303 TER-ND	*02:01	*11:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-



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101.430-12 – including *Taq* polymerase
101.430-12u – without *Taq* polymerase

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Lot No.: **6R1**

Lot-specific Information

CELL LINE VALIDATION SHEET														
HLA-A*31 SSP subtyping kit ²														
				Prod. No.:	Well									
					33	34	35	36	37	38	39	40	41	42
					202016433	202016434	202016435	202016436	202016437	202016438	202016439	202016440	202016441	202016442
	IHWC cell line ¹	A*												
1	9001 SA	*24:02			-	-	-	-	-	-	-	-	-	-
2	9280 LK707	*02:01			-	-	-	-	-	-	-	-	-	-
3	9011 E4181324	*01:01			-	-	-	-	-	-	-	-	-	-
4	9275 GU373	*30:01			-	-	-	-	-	-	-	-	-	-
5	9009 KAS011	*01:01			-	-	-	-	-	-	-	-	-	-
6	9353 SM	*02:01	*26:03		-	-	-	-	-	-	-	-	-	-
7	9020 QBL	*26:01			-	-	-	-	-	-	-	-	-	-
8	9025 DEU	*31:01			-	-	-	-	-	-	-	-	-	+
9	9026 YAR	*26:01			-	-	-	-	-	-	-	-	-	-
10	9107 LKT3	*24:02			-	-	-	-	-	-	-	-	-	-
11	9051 PITOUT	*29:02			-	-	-	-	-	-	-	-	-	-
12	9052 DBB	*02:01			-	-	-	-	-	-	-	-	-	-
13	9004 JESTHOM	*02:01			-	-	-	-	-	-	-	-	-	-
14	9071 OLGA	*31:01			-	-	-	-	-	-	-	-	-	+
15	9075 DKB	*24:02			-	-	-	-	-	-	-	-	-	-
16	9037 SWEIG007	*29:02			-	-	-	-	-	-	-	-	-	-
17	9282 CTM3953540	*03:01	*80:01		-	-	-	-	-	-	-	-	-	-
18	9257 32367	*33:03	*74:01		-	-	-	-	-	-	-	-	-	-
19	9038 BM16	*02:01			-	-	-	-	-	-	-	-	-	-
20	9059 SLE005	*02:01			-	-	-	-	-	-	-	-	-	-
21	9064 AMALA	*02:17			-	-	-	-	-	-	-	-	-	-
22	9056 KOSE	*02:01			-	-	-	-	-	-	-	-	-	-
23	9124 IHL	*02:01	*34:01		-	-	-	-	-	-	-	-	-	-
24	9035 JBUSH	*32:01			-	-	-	-	-	-	-	-	-	-
25	9049 IBW9	*33:01			-	-	-	-	-	-	-	-	-	-
26	9285 WT49	*02:05			-	-	-	-	-	-	-	-	-	-
27	9191 CH1007	*24:10	*29:01		-	-	-	-	-	-	-	-	-	-
28	9320 BEL5GB	*02:01	*29:02		-	-	-	-	-	-	-	-	-	-
29	9050 MOU	*29:02			-	-	-	-	-	-	-	-	-	-
30	9021 RSH	*30:01	*68:02		-	-	-	-	-	-	-	-	-	-
31	9019 DUCAF	*30:02			-	-	-	-	-	-	-	-	-	-
32	9297 HAG	*02:01			-	-	-	-	-	-	-	-	-	-
33	9098 MT14B	*31:01			-	-	-	-	-	-	-	-	-	+
34	9104 DHIF	*31:01			-	-	-	-	-	-	-	-	-	+
35	9302 SSTO	*32:01			-	-	-	-	-	-	-	-	-	-
36	9024 KT17	*02:06	*11:01		-	-	-	-	-	-	-	-	-	-
37	9065 HHKB	*03:01			-	-	-	-	-	-	-	-	-	-
38	9099 LZL	*02:17			-	-	-	-	-	-	-	-	-	-
39	9315 CML	*01:01	*03:01		-	-	-	-	-	-	-	-	-	-
40	9134 WHONP199	*02:07	*30:01		-	-	-	-	-	-	-	-	-	-
41	9055 H0301	*03:01			-	-	-	-	-	-	-	-	-	-
42	9066 TAB089	*02:07			-	-	-	-	-	-	-	-	-	-
43	9076 T7526	*02:06	*02:07		-	-	-	-	-	-	-	-	-	-
44	9057 TEM	*66:01			-	-	-	-	-	-	-	-	-	-
45	9239 SHJO	*23:01	*24:02		-	-	-	-	-	-	-	-	-	-
46	9013 SCHU	*03:01			-	-	-	-	-	-	-	-	-	-
47	9045 TUBO	*02:16	*03:01		-	-	-	-	-	-	-	-	-	-
48	9303 TER-ND	*02:01	*11:01		-	-	-	-	-	-	-	-	-	-



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For *In Vitro* Diagnostic Use

MA123 v02 SSP PI Template

Date: January 2023, Rev. No: 00

101.430-12 – including *Taq* polymerase
101.430-12u – without *Taq* polymerase

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Lot No.: **6R1**

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 2, 5, 6, 8, 10, 11, 13 and 15 to 41 were available.

The specificities of the primers in primer solutions 2, 5, 6, 8, 10, 16, 21 to 27 and 31 were tested by separately adding one or two additional 5'-primers, respectively one, two or three additional 3'-primers. In primer solutions 13, 15, 17, 18, 20, 29, 30, 36, 38 and 41 it was only possible to test the 5'-primers, the 3'-primers were not possible to be tested. In primer solutions 11, 19, 28, 32 to 35, 37, 39 and 40 it was only possible to test the 3'-primers, the 5'-primers were not possible to be tested. In primer solutions 1, 5, 10, 16, 21 and 25 to 27 one or two 5'-primers were not possible to be tested, and in primer solutions 1, 6, 8, 10, 16, 21 to 24, 26 and 31 one, two or three 3'-primers were not possible to be tested. In addition, one 5'-primer and one 3'-primer in primer solution 14 were tested by separately adding one 3'-primer and one 5'-primer respectively.



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MA123 v02 SSP PI Template

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101.430-12u – without *Taq* polymerase

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“Instructions for Use” (IFU)

Lot No.: **6R1**

Lot-specific Information

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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

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Web page: www.caredx.com

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



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MA123 v02 SSP PI Template

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