

101.613-12 – including *Taq* polymerase, IFU-01
101.613-12u – without *Taq* polymerase, IFU-02

Visit <https://labproducts.caredx.com> for
“Instructions for Use” (IFU)

Lot No.: **0M4**

Lot-specific information

Olerup SSP[®] HLA-C*05

Product number:	101.613-12 – including <i>Taq</i> polymerase 101.613-12u – without <i>Taq</i> polymerase
Lot number:	0M4
Expiry date:	2025-05-01
Number of tests:	12
Number of wells per test:	40+1
Storage - pre-aliquoted primers:	dark at -20°C
- PCR Master Mix:	-20°C
- Adhesive PCR seals	RT
- Product Insert	RT

This Product Description is only valid for Lot No. 0M4.

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-C*05 LOT (3K0)

- The product documentation has been updated for new alleles of IMGT 3.43.0
- The kit resolution focuses on common and well documented (CWD) alleles¹.
- 3 new wells were added to the HLA-C*05 primer set, wells 39-41.

¹As described in section Uniquely Identified Alleles.

The HLA-C*05 specificity and interpretation tables have been updated for the HLA-C alleles described since the previous *Olerup SSP[®]* HLA-C*05 lot was made (**Lot No. 3K0**).

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



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

Well	5'-primer	3'-primer	rationale
1	Removed	-	Superfluous 5'-primer removed.
3	-	Modified	3'-primer modified for improved yield.
4	-	Removed	3'-primer removed, exchanged primer pair moved to primer mix 38.
7	Removed	-	Superfluous 5'-primer removed.
8	-	Moved	3'-primer moved to primer mix 40 for reducing tendency of primer oligomer formation.
18	Modified	-	5'-primer modified for improving HLA-specific amplification.
30	-	Removed	3'-primer removed, exchanged primer pair moved to primer mix 38.
32	Added	-	5'-primer added for improved yield.
38	Added	Added	Primer pair added for the C*05:108 allele. Negative control primer pair moved to primer mix 41.
39	Added	Added	Primer pair added for the C*05:16 and C*05:47 alleles.
40	Added	Added	Primer pair added from primer mix 8.
41	Added	Added	Negative control primer pair added from primer mix 38.



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Well **41** 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-C*05 SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for identifying the C*05:01 to C*05:246 alleles.

PLATE LAYOUT

Each test consists of 41 PCR reactions in a 48 well PCR plate. Wells 42 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
NC	empty	empty	empty	empty	empty	empty	empty

The 48 well cut PCR plate is marked with 'HLA-C*05' in silver/gray ink.

Well No. 1 is marked with the Lot No. '0M4'.

Wells 1 to 40 – HLA-C*05 high resolution primers.

Well 41 – Negative Control (NC).

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

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

Please note: When removing each 48 well PCR plate, make sure that the remaining plates stay sealed. Use a scalpel or a similar instrument to carefully cut the foil between the plates.

INTERPRETATION

Due to the sharing of sequence motifs between HLA-C alleles non-HLA-C*05 alleles will be amplified by some primer mixes. For further details see Specificity Table.

UNIQUELY IDENTIFIED ALLELES

All the HLA-C*05 alleles, i.e. **C*05:01 to C*05:246**, recognized by the HLA Nomenclature Committee in January 2021¹ will be amplified by the primers in the HLA-C*05 subtyping kit².

The HLA-C*05 kit enables separation of the confirmed HLA-C*05 alleles as listed in the IMGT/HLA database 3.24.0. 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-C*05 alleles is listed below.



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Lot-specific information

The HLA-C*05 kit also enables identification of many null and alternatively expressed alleles.

The following HLA-C*05 alleles can be distinguished by the different sizes of the HLA-specific PCR product:

Alleles	Primer mix	Alleles	Primer mix
C*05:03, 05:07N	4	C*05:25, 05:33	11
C*05:08, 05:30, 05:89	10	C*05:28, 05:39	26
C*05:14, 05:93	16	C*05:32, 05:53	30
C*05:15, 05:91N	14	C*05:35, 05:40	25
C*05:21, 05:26	20	C*05:37, 05:41	29
C*05:24, 05:36	23		

¹HLA-C alleles listed on the IMGT/HLA web page 2021-January-18, release 3.43.0, 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>.



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Lot-specific information

ALLELE CONFIRMATION STATUS

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

¹Allele status “confirmed” or “unconfirmed” as listed on the IMGT/HLA web page 2016-April-15, release 3.24.0, www.ebi.ac.uk/imgt/hla.

RESOLUTION IN HOMO- AND HETEROZYGOTES

Results file with resolution in HLA-C*05 homo- and heterozygotes is available upon request.



For In Vitro Diagnostic Use
MA124 v01 SSP PI Template
Date: July 2021, Rev. No: 00

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SPECIFICITY TABLE

HLA-C*05 SSP subtyping

Specificities and sizes of the PCR products of the 40+1 primer mixes used for HLA-C*05 SSP subtyping

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified HLA-C*05 alleles ³	Other amplified HLA Class I alleles
1	155 bp	800 bp	*05:01:01:01-05:01:44, 05:01:46-05:01:57, 05:03-05:08, 05:10-05:11, 05:13-05:16, 05:19-05:51Q, 05:53-05:86, 05:88-05:96, 05:98-05:102, 05:104-05:105, 05:108-05:113N, 05:116-05:127, 05:129-05:133, 05:135-05:142, 05:144-05:150, 05:152-05:200, 05:202Q-05:205, 05:207-05:227, 05:229-05:246	*07:41, 08:02:01:01-08:02:31, 08:04:01:01-08:05, 08:07, 08:12:01:01-08:13, 08:17-08:19:02, 08:23, 08:25, 08:28-08:32, 08:34, 08:37, 08:43, 08:45, 08:47-08:49, 08:52N-08:53, 08:55N, 08:57, 08:62:01-08:63, 08:67-08:71, 08:73-08:77, 08:90, 08:92-08:94, 08:100, 08:103-08:104, 08:107-08:108, 08:110-08:116, 08:120, 08:123, 08:125-08:126, 08:132, 08:134, 08:139-08:140, 08:142, 08:146, 08:149-08:152, 08:156, 08:158-08:159, 08:161N, 08:166-08:172, 08:179-08:185, 08:188, 08:191, 08:195, 08:198, 08:200-08:202, 08:206-08:207, 08:211, 08:213-08:216, 08:218
2	165 bp	1070 bp	*05:01:01:01-05:01:57, 05:03-05:28, 05:30-05:47, 05:49-05:91N, 05:93-05:128N, 05:130-05:154N, 05:156-05:189, 05:191-05:194, 05:196, 05:198-05:246	*02:94, 04:129, 06:05, 06:67, 08:10, 12:21, 12:33, 15:107, 15:178, 17:05
3	150 bp	1070 bp	*05:09:01-05:09:03, 05:17, 05:44:01-05:44:02, 05:52, 05:79, 05:201, 05:206	*01:13, 02:51, 03:87:01-03:87:02, 03:414, 04:223:01-04:223:02, 04:387, 07:130, 08:15:01-08:15:02, 08:51, 12:144, 12:185, 16:27, B*15:33, B*15:248
4⁴	120 bp 285 bp	800 bp	*05:03 *05:07N	*03:490, 07:52 *08:180N
5	225 bp	1070 bp	*05:04:01-05:04:02, 05:103:01-05:103:02, 05:135, 05:188, 05:207, 05:215	*06:129, 07:68, 07:260:01-07:260:02, 07:302, 08:09, 08:11, 08:59, 08:113, 08:152, B*15:337, B*18:83, B*58:76
	285 bp		*05:31	
6	255 bp	1070 bp	*05:05:01-05:05:02, 05:99, 05:135, 05:147-05:148	*03:251, 03:314, 08:62:01-08:62:02, 08:82, 08:144:01-08:144:02, 08:209, A*02:425, A*02:519, A*29:10:01-29:10:02,



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	280 bp		*05:16, 05:85, 05:107, 05:241	A*68:69, B*14:32, B*15:337, B*18:83, B*44:148 *06:129, 07:364, 08:12:01:01- 08:12:01:02, B*14:32
7	265 bp	1070 bp	*05:01:01:01-05:01:57, 05:03-05:04:02, 05:06- 05:08, 05:10-05:16, 05:18:01-05:51Q, 05:53- 05:60, 05:62-05:81, 05:83-05:84, 05:86- 05:106:02, 05:108- 05:134, 05:136-05:142, 05:144-05:146, 05:149- 05:200, 05:202Q-05:205, 05:207-05:232, 05:234- 05:240, 05:242-05:246	*04:120, 06:129, 07:04:01:01- 07:04:21, 07:04:23-07:04:25, 07:11-07:12, 07:41, 07:63, 07:68, 07:101, 07:139, 07:142, 07:181, 07:199:01-07:199:02, 07:260:01-07:260:02, 07:272, 07:302, 07:323-07:324, 07:328- 07:329N, 07:336, 07:338, 07:354-07:355, 07:357-07:358, 07:361, 07:365, 07:378, 07:394- 07:395, 07:403, 07:406, 07:420, 07:426, 07:428, 07:447, 07:459, 07:466-07:467, 07:480, 07:487, 07:501, 07:523, 07:534-07:535, 07:552, 07:562-07:563, 07:569, 07:585-07:586, 07:600:01N- 07:600:02N, 07:622, 07:626, 07:648, 07:651, 07:655-07:656, 07:664, 07:672N, 07:674, 07:693, 07:698, 07:742, 07:751N, 07:780, 07:797N, 07:831, 07:838-07:839N, 07:852, 07:858, 07:868, 07:876, 07:881N, 07:892, 07:895- 07:897, 07:901, 08:01:01:01- 08:01:13, 08:01:15-08:02:25, 08:02:27-08:08:01, 08:09-08:14, 08:16:01-08:50, 08:52N-08:61, 08:63, 08:65-08:69, 08:71, 08:73-08:81, 08:83-08:140, 08:142-08:143, 08:145-08:150, 08:152-08:159, 08:161N- 08:208N, 08:210-08:220, 15:130, 15:229, B*58:76
8⁴	85 bp	800 bp	*05:06	
9⁴	105 bp 175 bp 245 bp	1070 bp	*05:51Q *05:48N *05:113N	
10⁴	95 bp	1070 bp	*05:08, 05:52, 05:89	*02:51, 08:29, 08:31, 12:144, 12:185, B*15:33, B*15:248 *03:247, 06:125, 14:70, 16:85- 16:86, 16:144, 16:147 *08:55N
	250 bp		*05:30	
	320 bp		*05:92N	
11⁴	115 bp 205 bp	1070 bp	*05:33 *05:25, 05:42	*04:129, 06:05, 06:67, 07:101, 07:148, 07:161, 07:583, 08:28, 08:137, 08:168, A*01:203, A*11:166, A*80:01:01:01^w- 80:08N^w



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12⁶	155 bp 225 bp 285 bp	800 bp	*05:97 *05:38 *05:10, 05:148	*08:97 *03:251, 03:314, 08:44, 08:61, 08:82, 08:126, 08:209, 15:130, 15:229, B*44:148, B*58:76
13⁴	95 bp	1070 bp	*05:11, 05:17, 05:27, 05:68, 05:79, 05:184	*03:87:01-03:87:02, 03:414, 07:130, 08:04:01:01-08:04:03, 08:13, 08:57, 08:93, 08:104, 08:113, 08:139, 08:168, 08:182, 08:188, 08:213
14⁴	120 bp 200 bp	1070 bp	*05:12, 05:15 *05:80, 05:91N	*08:153
15⁴	115 bp 185 bp 240 bp	1070 bp	*05:65 *05:34 *05:13	*04:96 *02:93, 04:352, 06:13
16	195 bp 470 bp	1070 bp	*05:14 *05:93	*01:200, 02:170, 03:171, 03:211:01, 04:144, 06:73, 08:20, 08:40, 12:109, 15:221
17	155 bp	1070 bp	*05:12, 05:18:01, 05:18:05-05:18:06, 05:103:02	*03:251, 03:314, 04:120, 06:129, 07:04:11, 07:892, 08:01:01:01-08:01:18, 08:01:20- 08:01:32, 08:03:01:01-08:03:04, 08:06, 08:08:01-08:11, 08:14, 08:16:01-08:16:02, 08:20- 08:22:01:02, 08:24, 08:26N- 08:27, 08:33:02-08:33:04, 08:35-08:36N, 08:38-08:42, 08:44, 08:46, 08:50, 08:54, 08:56, 08:58-08:61, 08:65- 08:66, 08:78-08:89N, 08:91, 08:95-08:99, 08:101-08:102, 08:105-08:106, 08:109, 08:117- 08:119, 08:121N-08:122, 08:124, 08:127N-08:131, 08:133, 08:135-08:138, 08:141Q, 08:143-08:145, 08:147-08:148, 08:153-08:155, 08:157, 08:162-08:165, 08:173N-08:178, 08:186-08:187, 08:189-08:190, 08:192-08:194, 08:196-08:197, 08:199, 08:203- 08:205, 08:208N-08:210, 08:212, 08:217, 08:219-08:220, 15:130, 15:229, B*15:337
18	160 bp 245 bp	1070 bp	*05:87 *05:19, 05:99N	*08:145
19	175 bp	800 bp	*05:20	*01:43, 02:87, 03:280, 03:530, 07:101, 07:148, 07:161, 07:583, 08:01:01:01-08:09, 08:11- 08:12:01:02, 08:14-08:15:02, 08:17, 08:19:01-08:24, 08:26N- 08:54, 08:56-08:63, 08:65- 08:93, 08:95-08:110, 08:112- 08:119, 08:121N-08:145,



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				08:147-08:220, 12:127, 12:203, 16:139
20	260 bp 390 bp	1070 bp	*05:26 *05:21	*04:238
21	230 bp	1070 bp	*05:04:01-05:04:02, 05:22:01-05:22:02, 05:38, 05:103:01-05:103:02, 05:107, 05:135, 05:147- 05:148, 05:207, 05:241	*03:251, 03:314, 06:129, 07:04:01:01-07:04:25, 07:11- 07:12, 07:63, 07:68, 07:101, 07:139, 07:142, 07:181, 07:199:01-07:199:02, 07:260:01-07:260:02, 07:272, 07:302, 07:323-07:324, 07:328- 07:329N, 07:336, 07:338, 07:354-07:355, 07:357-07:358, 07:361, 07:364-07:365, 07:378, 07:394-07:395, 07:403, 07:406, 07:420, 07:426, 07:428, 07:447, 07:459, 07:466-07:467, 07:480, 07:487, 07:501, 07:523, 07:534- 07:535, 07:552, 07:562-07:563, 07:569, 07:585-07:586, 07:600:01N-07:600:02N, 07:622, 07:651, 07:655-07:656, 07:664, 07:672N, 07:674, 07:693, 07:698, 07:742, 07:751N, 07:780, 07:797N, 07:831, 07:838-07:839N, 07:852, 07:858, 07:868, 07:876, 07:881N, 07:895-07:897, 07:901, 08:09, 08:11, 08:83, 08:97, 08:108, 08:152, 08:205, 08:209, B*44:148
22⁴	100 bp	800 bp	*05:23, 05:62, 05:134, 05:143, 05:151	*07:01:48, 07:02:35, 08:07, 08:47, 08:104, 08:188, B*48:04:02
23⁴	85 bp 135 bp	1070 bp	*05:24 *05:36	*07:148, 15:107, 15:178
24	185 bp 265 bp	1070 bp	*05:43 *05:29:01-05:29:02, 05:197	*08:37 *08:13, 08:16:01, 08:25, 08:94
25⁴	105 bp 205 bp	1070 bp	*05:40 *05:35, 05:80	
26⁴	115 bp	1070 bp	*05:27, 05:39, 05:184	*03:87:01-03:87:02, 03:414, 08:115, 08:182, B*15:33, B*15:248
	185 bp 245 bp		*05:28 *05:113N	*06:64
27	155 bp	1070 bp	*05:42, 05:46:01:01- 05:46:01:02	*04:129, 06:67, 07:101, 07:148, 07:161, 07:583, 08:05, 08:21, 08:137, 12:127, 12:203, 17:05
28^{4,5}	115 bp 200 bp	800 bp	*05:65 *05:45	*04:96
29⁶	140 bp 185 bp 260 bp	1070 bp	*05:41 *05:34 *05:37, 05:228	*04:78 *02:93, 04:352, 06:13



101.613-12 – including *Taq* polymerase, IFU-01
101.613-12u – without *Taq* polymerase, IFU-02

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Lot No.: 0M4

Lot-specific information

[illegible]

For *In Vitro* Diagnostic Use
MA124 v01 SSP PI Template
Date: July 2021, Rev. No: 00

101.613-12 – including *Taq* polymerase, IFU-01
101.613-12u – without *Taq* polymerase, IFU-02

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Lot No.: **0M4**

Lot-specific information

				02:132-02:190, 02:192N-02:199, 04:01:72, 04:03:01:01-04:03:07, 04:06:01-04:06:03, 04:42:02, 04:80, 04:103:02, 04:107, 04:140, 04:147, 04:160, 04:171, 04:190, 04:220, 04:256, 04:286, 04:294, 04:299 ^w , 04:304:02, 04:335, 04:337, 04:351:02, 04:357, 04:363, 04:381, 04:383, 04:393, 04:400, 04:402, 06:02:01:01-06:02:01:50, 06:02:03-06:02:09, 06:02:11, 06:02:13-06:02:31, 06:02:33- 06:02:64, 06:02:66-06:02:73, 06:02:75-06:10, 06:12-06:25, 06:27-06:51, 06:53:01-06:121, 06:123, 06:126-06:131, 06:133- 06:146, 06:148-06:168, 06:170- 06:216, 06:218-06:247, 06:249- 06:251, 06:253-06:279, 06:281N-06:316N, 07:07, 07:09, 07:49, 07:76:01-07:76:02, 07:210, 07:238, 07:247, 07:315, 07:328, 07:403, 07:406, 07:598, 08:10, 12:04:01-12:05:02, 12:09, 12:21, 12:33, 12:41, 12:54, 12:60, 12:146, 12:188, 15:02:01:01-15:02:14, 15:02:16, 15:02:18-15:05:07, 15:05:09- 15:05:10, 15:05:13-15:06:03, 15:08:01-15:10:02, 15:11- 15:13:01:02, 15:15-15:18, 15:22-15:24, 15:26-15:42, 15:44:01-15:49, 15:51-15:115N, 15:117-15:133, 15:135-15:143, 15:145N-15:190, 15:192-15:230, 16:02:01:01-16:02:01:04, 16:02:03-16:02:14, 16:02:16- 16:02:17, 16:09, 16:12, 16:19, 16:25, 16:46-16:48, 16:57, 16:60, 16:63, 16:69-16:70, 16:74, 16:77N, 16:84, 16:88- 16:91, 16:99, 16:101-16:104, 16:107-16:108, 16:115, 16:120- 16:121, 16:123N, 16:132N- 16:133, 16:136, 16:140, 16:143- 16:145, 16:153, 16:155-16:156, 16:163, 16:166-16:167, 16:176, 16:179, 17:01:01:02-17:21, 17:23-17:57, 18:01:01:01-18:14
33 ⁴	100 bp	1070 bp	*05:98, 05:197	*01:02:34, 01:21, 02:42, 02:107, 02:152, 04:140, 04:166:01, 04:220, 06:02:72, 06:05, 07:01:74, 07:02:09, 08:14, 08:80, 08:103, 12:16:01, 12:147,



101.613-12 – including *Taq* polymerase, IFU-01
101.613-12u – without *Taq* polymerase, IFU-02

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Lot No.: **0M4**

Lot-specific information

				12:227, 12:279, 15:63, 15:113, 16:80, B*15:436 , B*67:02:01:01-67:02:01:02
34	165 bp 275 bp	1070 bp	*05:128N *05:111, 05:207	*07:68, 07:260:01-07:260:02, 07:302, 08:38
35	505 bp	1070 bp	*05:79	*04:291, 08:10
36	225 bp	1070 bp	*05:154N	*12:105N
37	285 bp	1070 bp	*05:153N	
38	260 bp	1070 bp	*05:108	*01:183, 03:354, 03:533, 06:111
39	225 bp	1070 bp	*05:47, 05:107, 05:147- 05:148	*03:251, 03:314, 08:205, 08:209
	280 bp		*05:16, 05:85, 05:107, 05:241	*06:129, 07:364, 08:12:01:01- 08:12:01:02, B*14:32
40	210 bp	1070 bp	*05:55	
41⁷	-	-	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 C*05 high resolution 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.

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

⁵Primer mix 28 may have a tendency to giving rise to primer oligomer formation.

⁶Primer mixes 12 and 29 may have tendencies of unspecific amplifications.

⁷Primer mix 41 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.

Abbreviations

w: might be weakly amplified.



101.613-12 – including *Taq* polymerase, IFU-01
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Lot No.: **0M4**

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	165	150	120	225	255	265	85	105	95	115	155
				285	285	280			175	250	205	225
									245	320		285
Length of int. pos. control ¹	800	1070	1070	800	1070	1070	1070	800	1070	1070	1070	800
5'-primer(s) ²	485	176	485	355	355	361	379	176	96	28	176	355
	5'-CAA 3'	5'-gCA 3'	5'-CAA 3'	5'-CC 3'	5'-TCC 3'	5'-AgT 3'	5'-ACC 3'	5'-gCA 3'	5'-TC 3'	5'-TCA 3'	5'-gCA 3'	5'-TCA 3'
		176		3 rd I	419	379			166	485		416
		5'-gCA 3'		5'-Cgg 3'	5'-gTC 3'	5'-ACg 3'			5'-CgT 3'	5'-CAA 3'		5'-CCg 3'
						385			485			485
						5'-g.C 3'			5'-CAA 3'			5'-CAg 3'
3'-primer(s) ³	601	302	595	601	601	601	601	221	302	106	248	601
	5'-CTT 3'	5'-ggT 3'	5'-CCT 3'	5'-CTT 3'	5'-CTT 3'	5'-CTT 3'	5'-CTT 3'	5'-ACC 3'	5'-ggT 3'	5'-CAT 3'	5'-AAC 3'	5'-CTT 3'
	601		595	668			601		550	175	341	
	5'-CTg 3'		5'-CCg 3'	5'-TgA 3'			5'-CTg 3'		5'-CAg 3'	5'-CTA 3'	5'-CgT 3'	
			601	862						538		
			5'-CTC 3'	5'-CTT 3'					5'-CCA 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	95	120	115	195	155	160	175	260	230	100	85	185
		200	185	470		245		390			135	265
			240									
Length of int. pos. control ¹	1070	1070	1070	1070	1070	1070	800	1070	1070	800	1070	1070
5'-primer(s) ²	485	176	115	446	486	385	176	28	412	453	176	1 st I
	5'-CAA 3'	5'-gCA 3'	5'-ggA 3'	5'-CgT 3'	5'-ACg 3'	5'-g.C 3'	5'-gCA 3'	5'-TCA 3'	5'-ATg 3'	5'-AAT 3'	5'-gCA 3'	5'-CgA 3'
		453	2 nd I	652		406		322	416			
		5'-AAT 3'	5'-CCA 3'	5'-CCA 3'		5'-gCC 3'		5'-gCC 3'	5'-CCg 3'			
						483						
						5'-gAg 3'						
3'-primer(s) ³	538	256	312	601	601	601	311	118	601	512	218	97
	5'-CAg 3'	5'-CCA 3'	5'-AgT 3'	5'-CTT 3'	5'-CTT 3'	5'-CTT 3'	5'-ggT 3'	5'-gCT 3'	5'-CTT 3'	5'-CCA 3'	5'-gCC 3'	5'-gTC 3'
		337	403	956				419			270	175
		5'-CTA 3'	5'-gCA 3'	5'-CAg 3'				5'-CgA 3'			5'-TAg 3'	5'-CCg 3'
		337	475									
		5'-CTT 3'	5'-ggT 3'									
		527										
		5'-CCA 3'										
Well No.	13	14	15	16	17	18	19	20	21	22	23	24



101.613-12 – including *Taq* polymerase, IFU-01
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Lot No.: **0M4**

Lot-specific information

Well No.	25	26	27	28	29	30	31	32	33	34	35	36
Length of spec.	105	115	155	115	140	70	155	220	100	165	505	225
PCR product	205	185		200	185	175	285			275		
		245			260							
Length of int.	1070	1070	1070	800	1070	1070	1070	1070	1070	1070	1070	1070
pos. control ¹												
5'-primer(s) ²	176 5'-gCA 3'	96 5'-TC 3'	176 5'-gCA 3'	2 nd I 5'-CCA 3'	2 nd I 5'-CCA 3'	176 5'-gCA 3'	355 5'-CCT 3'	118 5'-CCA 3'	142 5'-TCT 3'	368 5'-gTC 3'	312 5'-AAA 3'	2 nd I 5'-CCA 3'
		158 5'-ggg 3'			629 5'-AAG 3'	3 rd I 5'-Cgg 3'	486 5'-ACC 3'	126 5'-ggA 3'		477 5'-gCC 3'		
		485 5'-CAA 3'					486 5'-ACA 3'					
3'-primer(s) ³	241 5'-CgA 3'	302 5'-ggT 3'	289 5'-AgC 3'	403 5'-gCA 3'	430 5'-gCA 3'	311 5'-gTC 3'	601 5'-CTT 3'	302 5'-ggT 3'	201 5'-CTT 3'	601 5'-CTT 3'	526 5'-CgT 3'	514 5'-CTA 3'
	337 5'-CTT 3'	559 5'-CAg 3'	289 5'-AgC 3'	488 5'-CCT 3'	475 5'-ggT 3'	621 5'-Tgg 3'		307 5'-CCA 3'				
	341 5'-CgA 3'				846 5'-CAC 3'							
Well No.	25	26	27	28	29	30	31	32	33	34	35	36

Well No.	37	38	39	40
Length of spec.	285	260	225	210
PCR product			280	
Length of int.	1070	1070	1070	1070
pos. control ¹				
5'-primer(s) ²	61 5'-CCT 3'	862 5'-ACA 3'	361 5'-AgT 3'	176 5'-gCA 3'
			419 5'-gTA 3'	
3'-primer(s) ³	176 5'-ACT 3'	956 5'-CAg 3'	601 5'-CTT 3'	343 5'-T 3'
Well No.	37	38	39	40

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.



101.613-12 – including *Taq* polymerase, IFU-01
101.613-12u – without *Taq* polymerase, IFU-02

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Lot No.: **0M4**

Lot-specific information

CELL LINE VALIDATION SHEET																			
HLA-C*05 SSP subtyping kit																			
					Well ²														
					1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
					16														
					Prod. No.:	202129501	202129502	202129503	202129504	202129505	202129506	202129507	202129508	202129509	202129510	202129511	202129512	202129513	202129514
						202129515	202129516												
					IHWC cell line ¹	C*													
1	9001	SA	*07:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2	9280	LK707	*07:01	*15:05	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3	9011	E4181324	*12:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4	9275	GU373	*03:04	*04:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
5	9009	KAS011	*06:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
6	9353	SM	*03:04	*07:02	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
7	9020	QBL	*05:01		+	+	-	-	-	-	+	-	-	-	-	-	-	-	-
8	9025	DEU	*04:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
9	9026	YAR	*12:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
10	9107	LKT3	*01:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
11	9051	PITOUT	*16:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
12	9052	DBB	*06:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
13	9004	JESTHOM	*01:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
14	9071	OLGA	*01:02	*03:04	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
15	9075	DKB	*03:04		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
16	9037	SWEIG007	*02:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
17	9282	CTM3953540	*03:03	*07:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
18	9257	32367	*01:02	*07:05	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
19	9038	BM16	*07:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
20	9059	SLE005	*03:04		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
21	9064	AMALA	*03:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
22	9056	KOSE	*12:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
23	9124	IHL	*01:02	*15:02	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
24	9035	JBUSH	*12:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
25	9049	IBW9	*08:02		+	-	-	-	-	-	+	-	-	-	-	-	-	-	-
26	9285	WT49	*07:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
27	9191	CH1007	*07:04	*15:27	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-
28	9320	BEL5GB	*05:01	*16:01	+	+	-	-	-	-	+	-	-	-	-	-	-	-	-
29	9050	MOU	*16:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
30	9021	RSH	*17:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
31	9019	DUCAF	*05:01		+	+	-	-	-	-	+	-	-	-	-	-	-	-	-
32	9297	HAG	*17:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
33	9098	MT14B	*03:04		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
34	9104	DHIF	*12:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
35	9302	SSTO	*05:01		+	+	-	-	-	-	+	-	-	-	-	-	-	-	-
36	9024	KT17	*03:03	*04:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
37	9065	HHKB	*07:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
38	9099	LZL	*03:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
39	9315	CML	*02:02	*07:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
40	9134	WHONP199	*01:02	*06:02	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
41	9055	H0301	*08:02		+	-	-	-	-	-	+	-	-	-	-	-	-	-	-
42	9066	TAB089	*01:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
43	9076	T7526	*01:02	*08:01	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-
44	9057	TEM	*12:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
45	9239	SHJO	*06:02	*17:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
46	9013	SCHU	*07:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
47	9045	TUBO	*07:04	*15:02	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-
48	9303	TER-ND	*04:01	*16:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-



101.613-12 – including *Taq* polymerase, IFU-01
101.613-12u – without *Taq* polymerase, IFU-02

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Lot No.: 0M4

Lot-specific information

CELL LINE VALIDATION SHEET																				
HLA-C*05 SSP subtyping kit																				
					Well ²															
					17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32
				Prod. No.:	202129517	202129518	202129519	202129520	202129521	202129522	202129523	202129524	202129525	202129526	202129527	202129528	202129529	202129530	202129531	202129532
	IHCW cell line ¹		C*																	
1	9001	SA	*07:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2	9280	LK707	*07:01	*15:05	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+
3	9011	E4181324	*12:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4	9275	GU373	*03:04	*04:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
5	9009	KAS011	*06:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+
6	9353	SM	*03:04	*07:02	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
7	9020	QBL	*05:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+
8	9025	DEU	*04:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
9	9026	YAR	*12:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
10	9107	LKT3	*01:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
11	9051	PITOUT	*16:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
12	9052	DBB	*06:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+
13	9004	JESTHOM	*01:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
14	9071	OLGA	*01:02	*03:04	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
15	9075	DKB	*03:04		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
16	9037	SWEIG007	*02:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+
17	9282	CTM3953540	*03:03	*07:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
18	9257	32367	*01:02	*07:05	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
19	9038	BM16	*07:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
20	9059	SLE005	*03:04		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
21	9064	AMALA	*03:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
22	9056	KOSE	*12:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
23	9124	IHL	*01:02	*15:02	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+
24	9035	JBUSH	*12:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
25	9049	IBW9	*08:02		-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-
26	9285	WT49	*07:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
27	9191	CH1007	*07:04	*15:27	-	-	-	-	+	-	-	-	-	-	-	-	-	-	+	+
28	9320	BEL5GB	*05:01	*16:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+
29	9050	MOU	*16:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
30	9021	RSH	*17:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+
31	9019	DUCAF	*05:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+
32	9297	HAG	*17:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+
33	9098	MT14B	*03:04		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
34	9104	DHIF	*12:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
35	9302	SSTO	*05:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+
36	9024	KT17	*03:03	*04:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
37	9065	HHKB	*07:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
38	9099	LZL	*03:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
39	9315	CML	*02:02	*07:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+
40	9134	WHONP199	*01:02	*06:02	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+
41	9055	H0301	*08:02		-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-
42	9066	TAB089	*01:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
43	9076	T7526	*01:02	*08:01	+	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-
44	9057	TEM	*12:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
45	9239	SHJO	*06:02	*17:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+
46	9013	SCHU	*07:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
47	9045	TUBO	*07:04	*15:02	-	-	-	-	+	-	-	-	-	-	-	-	-	-	+	+
48	9303	TER-ND	*04:01	*16:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-



For *In Vitro* Diagnostic Use
MA124 v01 SSP PI Template
Date: July 2021, Rev. No: 00

101.613-12 – including *Taq* polymerase, IFU-01
101.613-12u – without *Taq* polymerase, IFU-02

Visit <https://labproducts.caredx.com> for
“Instructions for Use” (IFU)

Lot No.: **0M4**

Lot-specific information

CELL LINE VALIDATION SHEET												
HLA-C*05 SSP subtyping kit												
					Well ²							
					33	34	35	36	37	38	39	40
				Prod. No.:	202129533	202129534	202129535	202129536	202129537	202129538	202129539	202129540
	IHC cell line ¹		C*									
1	9001	SA	*07:02		-	-	-	-	-	-	-	-
2	9280	LK707	*07:01	*15:05	-	-	-	-	-	-	-	-
3	9011	E4181324	*12:02		-	-	-	-	-	-	-	-
4	9275	GU373	*03:04	*04:01	-	-	-	-	-	-	-	-
5	9009	KAS011	*06:02		-	-	-	-	-	-	-	-
6	9353	SM	*03:04	*07:02	-	-	-	-	-	-	-	-
7	9020	QBL	*05:01		-	-	-	-	-	-	-	-
8	9025	DEU	*04:01		-	-	-	-	-	-	-	-
9	9026	YAR	*12:03		-	-	-	-	-	-	-	-
10	9107	LKT3	*01:02		-	-	-	-	-	-	-	-
11	9051	PITOUT	*16:01		-	-	-	-	-	-	-	-
12	9052	DBB	*06:02		-	-	-	-	-	-	-	-
13	9004	JESTHOM	*01:02		-	-	-	-	-	-	-	-
14	9071	OLGA	*01:02	*03:04	-	-	-	-	-	-	-	-
15	9075	DKB	*03:04		-	-	-	-	-	-	-	-
16	9037	SWEIG007	*02:02		-	-	-	-	-	-	-	-
17	9282	CTM3953540	*03:03	*07:01	-	-	-	-	-	-	-	-
18	9257	32367	*01:02	*07:05	-	-	-	-	-	-	-	-
19	9038	BM16	*07:01		-	-	-	-	-	-	-	-
20	9059	SLE005	*03:04		-	-	-	-	-	-	-	-
21	9064	AMALA	*03:03		-	-	-	-	-	-	-	-
22	9056	KOSE	*12:03		-	-	-	-	-	-	-	-
23	9124	IHL	*01:02	*15:02	-	-	-	-	-	-	-	-
24	9035	JBUSH	*12:03		-	-	-	-	-	-	-	-
25	9049	IBW9	*08:02		-	-	-	-	-	-	-	-
26	9285	WT49	*07:01		-	-	-	-	-	-	-	-
27	9191	CH1007	*07:04	*15:29	-	-	-	-	-	-	-	-
28	9320	BEL5GB	*05:01	*16:01	-	-	-	-	-	-	-	-
29	9050	MOU	*16:01		-	-	-	-	-	-	-	-
30	9021	RSH	*17:01		-	-	-	-	-	-	-	-
31	9019	DUCAF	*05:01		-	-	-	-	-	-	-	-
32	9297	HAG	*17:03		-	-	-	-	-	-	-	-
33	9098	MT14B	*03:04		-	-	-	-	-	-	-	-
34	9104	DHIF	*12:03		-	-	-	-	-	-	-	-
35	9302	SSTO	*05:01		-	-	-	-	-	-	-	-
36	9024	KT17	*03:03	*04:01	-	-	-	-	-	-	-	-
37	9065	HHKB	*07:02		-	-	-	-	-	-	-	-
38	9099	LZL	*03:03		-	-	-	-	-	-	-	-
39	9315	CML	*02:02	*07:01	-	-	-	-	-	-	-	-
40	9134	WHONP199	*01:02	*06:02	-	-	-	-	-	-	-	-
41	9055	H0301	*08:02		-	-	-	-	-	-	-	-
42	9066	TAB089	*01:02		-	-	-	-	-	-	-	-
43	9076	T7526	*01:02	*08:01	-	-	-	-	-	-	-	-
44	9057	TEM	*12:03		-	-	-	-	-	-	-	-
45	9239	SHJO	*06:02	*17:01	-	-	-	-	-	-	-	-
46	9013	SCHU	*07:02		-	-	-	-	-	-	-	-
47	9045	TUBO	*07:04	*15:02	-	-	-	-	-	-	-	-
48	9303	TER-ND	*04:01	*16:01	-	-	-	-	-	-	-	-



101.613-12 – including *Taq* polymerase, IFU-01
101.613-12u – without *Taq* polymerase, IFU-02

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“Instructions for Use” (IFU)

Lot No.: 0M4

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 4 to 6, 8 to 12, 14 to 16, 18, 20, 22 to 30 and 33 to 40 were available. The specificities of the primers in primer solutions 4 to 6, 9 to 12, 14, 15, 18, 20, 22 to 24, 26, 27, 29, 33 to 35, 39 and 40 were tested by separately adding additional 5'-primers and 3'-primers accordingly.

In primer solutions 8, 25, 28, 30 and 36 it was only possible to test the 5'-primers, the 3'-primers were not possible to be tested. In primer solutions 16, 37 and 38 it was only possible to test the 3'-primers, the 5'-primers were not possible to be tested. In primer solutions 1, 3, 4, 7, 9 to 11, 14, 15, 20, 23, 29 and 32 one or more 3'-primers were not possible to be tested. In primer solutions 2, 4, 6, 9, 12, 15, 18, 20, 21, 26, 29 and 34 one or two 5'-primers were not possible to be tested. In addition, one 3'-primer in primer solution 3 was tested by separately adding one 5'-primer, and one 5'-primer in primer solution 31 was tested by separately adding one 3'-primer.



101.613-12 – including *Taq* polymerase, IFU-01
101.613-12u – without *Taq* polymerase, IFU-02

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“Instructions for Use” (IFU)

Lot No.: **0M4**

Lot-specific information

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