

101.403-48/12 – including *Taq* pol., IFU-01
 101.403-48u/12u – without *Taq* pol., IFU-02

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

Lot No.: **7K3**

Lot-specific information

Olerup SSP[®] HLA-A low resolution screening

Product number:	101.403-48/12 – including <i>Taq</i> polymerase 101.403-48u/12u – without <i>Taq</i> polymerase
Lot number:	7K3
Expiry date:	2024-01-01
Number of tests:	48 tests – Product No. 101.403-48/48u 12 tests – Product No. 101.403-12/12u
Number of wells per test:	23 +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. 7K3.

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 LOW RESOLUTION SCREENING LOT (2H8)**

- The product documentation has been updated for new alleles of IMGT 3.38.0.
- The kit resolution focuses on common and well documented (CWD) alleles¹

¹As described in section Uniquely Identified Alleles.

The **HLA-A low resolution Screening** primer set, specificity and interpretation tables have been updated for the HLA-A alleles described since the previous *Olerup SSP[®]* HLA-A low resolution Screening lot was made (**Lot No. 2H8**).

The primers of the wells detailed below have been exchanged, modified or added compared to the previous lot (**Lot No. 2H8**).

Well	5'-primer	3'-primer	rationale
1	Added	-	5'-primer added for the A*01:307 allele.
10	-	Added	3'-primer added for the A*26:193 allele.
20	Added	-	5'-primer added for the A*68:105 allele.

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, 194–20

101.403-48/12 – including *Taq* pol., IFU-01
 101.403-48u/12u – without *Taq* pol., IFU-02

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

Lot No.: **7K3**

Lot-specific information

Well **24** contains Negative Control primer pairs, that will amplify a majority of the *Olerup* SSP® HLA Class I, DRB, DQB1, DPB1 and DQA1 amplicons as well as all the amplicons generated by the control primer pairs matching the human growth hormone gene.

HLA-specific PCR product sizes range from 75 to 200 base pairs.

The PCR 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.

101.403-48/12 – including *Taq* pol., IFU-01
 101.403-48u/12u – without *Taq* pol., IFU-02

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

Lot No.: **7K3**

Lot-specific information

PRODUCT DESCRIPTION

HLA-A low resolution screening

CONTENT

The primer set contains 5'- and 3'-primers for grouping the HLA-A*01:01 to A*80:06 alleles into the corresponding serological groups A1 to A80.

PLATE LAYOUT

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

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

The 24 well PCR plate is marked with ‘HLA-A low screening’ in silver/gray ink.

Well No. 1 is marked with the Lot No. ‘7K3’.

Wells 1 to 23 – HLA-A low resolution screening primers.

Well 24 – Negative Control.

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 24 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

Only HLA-A alleles will be amplified by the 24 wells of the HLA-A low resolution screening primer set, except that a few HLA-B and HLA-C alleles will be amplified by some primer mixes. For further details see Specificity Table.

UNIQUELY IDENTIFIED ALLELES

All the HLA-A alleles, i.e. **A*01:01 to A*80:06**, recognized by the HLA Nomenclature Committee in October 2019^{1,2} will be amplified by the primers in the HLA-A low resolution screening primer set³. The HLA-A alleles will be grouped into their corresponding serological specificities.

101.403-48/12 – including *Taq* pol., IFU-01
 101.403-48u/12u – without *Taq* pol., IFU-02

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

Lot No.: **7K3**

Lot-specific information

¹HLA-A alleles listed on the IMGT/HLA web page 2019-October-17, release 3.38.0, 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 following alleles give rise to identical amplification patterns with the HLA-A low resolution primer set. These alleles can be separated by the respective high-resolution primer sets.

Alleles

A*01:26, 01:136, 01:192, A*11:94, 11:112, 11:211, 11:290, 11:326
 A*01:28, 01:229, 01:299, A*11:282
 A*01:43, A*11:271
 A*03:215, 03:225, 03:249, 03:322, A*25:46
 A*11:11, A*34:19
 A*11:116, 11:140, 11:199:01-11:199:02, 11:222, A*66:23
 A*23:14:01-23:14:02, A*24:24, 24:71, 24:315, 24:392
 A*23:66, 23:99, 24:14:01:01-24:15, 24:51-24:53, 24:57, 24:64, 24:94, 24:114,
 24:138, 24:188, 24:222N, 24:228, 24:291, 24:296, 24:304, 24:316, 24:324, 24:412,
 C*04:01:03
 A*26:01:63, 26:57, A*66:12, 66:15
 A*30:01:01:01-30:04:03, 30:06-30:07, 30:09-30:20, 30:22-30:54, 30:56-30:88,
 30:90-30:124, 30:126-30:139, 30:141-30:149, 30:151-30:161, B*07:260
 A*31:08, A*33:53
 A*31:109, A*33:125, 33:131

101.403-48/12 – including *Taq* pol., IFU-01
101.403-48u/12u – without *Taq* pol., IFU-02

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

Lot No.: **7K3**

Lot-specific information
SPECIFICITY TABLE

HLA-A low resolution screening primer set

Specificities and sizes of the PCR products of the 23+1 primer mixes used for HLA-A low resolution screening SSP typing

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	HLA-A serology ³	Amplified HLA-A alleles ⁴
1⁵	120 bp, 145 bp, 225 bp	800 bp	A1, A36	*01:01:01:01-01:04:01:02N, 01:06-01:33, 01:35-01:331N, 03:18, 03:135, 11:94, 11:112, 11:211, 11:226, 11:271, 11:282, 11:290, 11:326, 25:59, 26:120, 36:01-36:09
2	175 bp, 215 bp, 255 bp, 365 bp, 415 bp	800 bp	A2, A19, A28, A203, A210	*02:01:01:01-02:01:15, 02:01:17-02:01:19, 02:01:21-02:01:81, 02:01:83-02:22:02, 02:24:01-02:35:01, 02:35:03-02:47, 02:49:01-02:77, 02:78 ^w , 02:79:01-02:97:02, 02:99:01-02:99:02, 02:101:01-02:128, 02:130-02:570:02, 02:572-02:643N, 02:645-02:828, 02:830-02:899
3⁶	205 bp, 235 bp	1070 bp	A1, A3, A11, A31, A32, A34, A36	*01:12, 01:19, 01:21, 01:126, 01:200, 01:244, 02:338, 03:01:01:01-03:17:02, 03:19-03:74, 03:76-03:94, 03:96-03:134, 03:136-03:176, 03:178N-03:186, 03:188-03:193, 03:195-03:199, 03:201-03:214, 03:216-03:224, 03:226-03:248, 03:250-03:259, 03:261-03:321, 03:323N-03:342N, 03:344-03:346, 03:348-03:374N, 11:03, 11:20, 11:25:01-11:25:02, 11:60, 11:130, 11:158, 11:175, 11:183, 11:209, 11:348, 24:92, 24:458, 31:03 ^w -31:04:01:01 ^w , 31:04:01:02, 32:04, 33:49 ^w , 33:144 ^w , 33:179 ^w , 34:02:01:01-34:04, 34:07-34:10N, 34:13, 34:15, 34:20-34:22, 36:02, 68:103:01-68:103:02, 74:23
4	190 bp	800 bp	A1, A3, A11, A30, A36, A68	*01:01:01:01-01:01:22, 01:01:24-01:01:47, 01:01:49-01:01:64, 01:01:67-01:01:78, 01:01:80-01:04:01:02N, 01:06-01:07, 01:09:01:01-01:11N, 01:13, 01:15N ^w , 01:16N-01:18N, 01:20-01:29, 01:31N-01:33, 01:35-01:78, 01:80-01:98, 01:100-01:144, 01:146, 01:148, 01:150-01:158, 01:160N-01:166, 01:168-01:177, 01:179N-01:199, 01:201-01:204, 01:206-01:207, 01:209-01:213, 01:215-01:227, 01:229-01:235, 01:237-01:243, 01:245-01:266:02, 01:268-01:270, 01:272-01:278, 01:280-01:313, 01:315-01:331N, 02:78, 02:169, 02:829, 03:12, 03:18, 03:88, 03:135, 11:01:01:01-11:27, 11:29-11:52Q, 11:54:01-11:334, 11:336-11:354, 25:43, 25:59, 26:19, 26:72, 26:184, 29:67, 30:08:01-30:08:02, 30:150, 32:64, 34:19, 36:04, 66:23, 68:13:01, 68:66:01-68:66:02, 68:134, 68:178, 74:19, C*03:365, C*12:131
5	160 bp, 335 bp, 505 bp	1070 bp	A3, A9, A23, A24, A2403, A29, A31, A32	*01:301Q, 03:15, 03:19, 03:30, 03:152, 03:273, 03:347, 11:139, 11:325, 23:01:01:01-23:68, 23:70-23:102, 24:02:01:01-24:11N, 24:13:01-24:15, 24:17-24:64, 24:66-24:210, 24:212-24:470, 24:472-24:477, 29:07, 29:49, 31:08, 31:29, 32:05, 32:79, 33:19, 33:53, 33:187, C*04:01:03

101.403-48/12 – including *Taq* pol., IFU-01
 101.403-48u/12u – without *Taq* pol., IFU-02

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

Lot No.: **7K3**

Lot-specific information

6	135 bp, 200 bp	800 bp	A9, A23, A24, A29, A80	*11:166, 23:01:01:01-23:56, 23:58-23:65, 23:67-23:68, 23:70-23:98, 23:100-23:102, 24:24, 24:71, 24:315, 24:392, 29:07, 29:49, 31:29, 31:85, 32:72, 33:187, 80:01:01:01-80:06, B*18:27
7	175 bp, 205 bp	1070 bp	A2, A3, A9, A23, A24, A2403, A26	*01:301Q, 02:17:02:01 ^w , 02:17:03 ^w -02:17:04 ^w , 02:804, 03:347, 11:139, 23:14:01-23:14:02, 24:02:01:01-24:11N, 24:13:01-24:13:02, 24:17-24:50, 24:54-24:56, 24:58-24:63, 24:66-24:91, 24:93, 24:95-24:113, 24:115-24:137, 24:139-24:187, 24:189-24:210, 24:212-24:221, 24:223-24:227, 24:229-24:290, 24:292-24:295, 24:297-24:303N, 24:305-24:315, 24:317-24:323N, 24:325-24:411, 24:413-24:457, 24:459-24:470, 24:472-24:477, 26:16, 33:19, 33:119, 68:45, 68:117
8	165 bp, 200 bp	800 bp	A2, A3, A10, A11, A25, A26, A28, A32, A34, A66, A68, A69	*01:51, 02:55, 02:527, 02:582, 02:644, 02:741, 02:815, 03:24, 03:50, 11:10, 11:183, 11:191, 11:269, 25:01:01:01-25:16, 25:18-25:33, 25:35-25:45, 25:47-25:53, 25:55-25:58, 25:60-25:64, 26:01:01:01-26:01:47, 26:01:49-26:06, 26:08:01:01-26:15, 26:17-26:18, 26:20-26:43:02, 26:45-26:63, 26:65-26:71N, 26:73-26:88, 26:90-26:91, 26:93-26:176, 26:178-26:183, 26:185-26:194, 29:28, 32:15, 33:51, 34:01:01:01-34:18, 34:20-34:23, 66:01:01:01-66:22, 66:24-66:39N, 68:01:01:01-68:177, 68:179-68:227, 69:01:01:01-69:08
9^{5,7}	80 bp	800 bp	A2, A3, A25, A32	*01:298, 02:81, 02:124, 02:829, 25:01:01:01-25:45, 25:47-25:58, 25:60-25:64, 32:01:01:01-32:02, 32:04, 32:06-32:37, 32:39-32:59, 32:61-32:70, 32:72-32:77, 32:81-32:106:01:02, 32:108-32:133N, B*07:81, B*08:52, B*18:67, B*38:41, B*38:67, B*51:185, B*53:05:01-53:05:02, B*53:16, B*53:33, B*57:01:38, 57:60
10^{5,10}	80 bp, 200 bp, 240 bp	800 bp	A10, A26, A43	*01:43, 01:51, 02:644, 11:17, 11:40, 11:223, 11:271, 25:59, 26:01:01:01-26:01:62, 26:02:01-26:02:02, 26:04, 26:07:01-26:20, 26:22-26:29, 26:31-26:43:02, 26:45-26:56, 26:58-26:77, 26:79-26:91, 26:93-26:110, 26:112-26:176, 26:178-26:194, 29:105, 33:13, 33:48, 43:01, 68:84, 68:227
11⁵	80 bp, 175 bp, 500 bp	1070 bp	A1, A9, A10, A11, A26, A31, A34, A66	*01:13, 01:26, 01:28, 01:136, 01:176, 01:192, 01:229, 01:299, 03:63, 03:88, 11:01:01:01-11:27, 11:29-11:52Q, 11:54:01-11:270, 11:272Q-11:334, 11:336-11:354, 24:19, 24:44, 26:03:01:01-26:03:01:02, 26:06, 26:21, 26:78, 26:92, 26:111, 26:152, 26:177, 26:193, 30:125, 30:140, 33:184, 34:01:01:01-34:08, 34:10N-34:23, 66:01:01:01-66:01:05, 66:04-66:11, 66:13-66:14, 66:17-66:20, 66:22-66:24, 66:27N, 66:29-66:33, 66:35-66:38, 69:02, 74:30, 80:02
12⁵	125 bp, 160 bp, 190 bp	800 bp	A1, A3, A10, A25, A26, A31, A34, A43, A66, A74	*01:01:56, 02:309, 02:454, 03:01:19, 03:103:02, 11:11, 25:05-25:06, 26:09, 26:54, 26:91, 31:03-31:04:01:02, 31:123, 34:01:01:01-34:23, 43:01, 66:02-66:03:01:03, 66:16, 66:19, 66:21, 66:25-66:26Q, 66:28N, 66:34, 66:39N, 68:130:01, 74:01:03
13	180 bp, 225 bp	1070 bp	A1, A2, A3, A10, A25,	*01:13, 01:176, 01:194, 02:34-02:35:03, 02:56:01-02:56:02, 02:62, 02:103, 02:135, 02:580, 02:741,

101.403-48/12 – including *Taq* pol., IFU-01
 101.403-48u/12u – without *Taq* pol., IFU-02

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

Lot No.: **7K3**

Lot-specific information

			A26, A34, A43, A66	03:01:01:01-03:01:22, 03:01:24-03:01:82, 03:01:84-03:07:02, 03:09-03:11N, 03:13-03:31, 03:33-03:35, 03:37-03:40, 03:42-03:56, 03:58, 03:60-03:71, 03:73-03:87, 03:90-03:106, 03:109-03:110, 03:112-03:141, 03:143-03:151, 03:153-03:171, 03:174-03:175, 03:177, 03:179-03:193, 03:195-03:197N, 03:201-03:202, 03:204, 03:206-03:210, 03:212-03:218, 03:220-03:251, 03:253-03:259, 03:261-03:266N, 03:268-03:272, 03:274-03:329N, 03:331-03:374N, 11:116, 11:140, 11:199:01-11:199:02, 11:222, 25:01:01:01-25:05, 25:07-25:35, 25:37-25:42N, 25:44-25:49N, 25:51, 25:53-25:58, 25:60-25:64, 26:01:01:01-26:01:63, 26:02:01 ^w -26:02:02 ^w , 26:03:01:01-26:03:01:02, 26:05-26:08:03, 26:10-26:28, 26:29 ^w , 26:30-26:43:02, 26:45-26:48, 26:49 ^w , 26:50-26:74, 26:76-26:77, 26:79-26:90, 26:92-26:194, 30:55, 31:24-31:25, 32:26:01-32:26:02, 33:61, 33:190, 34:08, 43:01, 66:01:01:01-66:01:05, 66:04-66:09, 66:10 ^w , 66:11-66:15, 66:17-66:20, 66:22-66:24, 66:27N, 66:29-66:33, 66:35-66:38, 68:71, 69:07, 74:13, 74:37
14 ^{5,10}	80 bp, 115 bp, 200 bp, 240 bp, 460 bp	1070 bp	A26, A29, A31, A34, A36, A68	*02:237, 02:309, 02:454, 02:809, 03:01:38, 03:95, 03:123:02, 03:171, 03:231:01, 03:343, 11:130, 26:19, 26:22, 29:01:01:01-29:140, 31:03-31:04:01:02, 31:123, 32:42, 34:04, 36:02, 66:09, 68:19, 68:130:02
15 ^{5,8,11}	90 bp, 135 bp, 205 bp	1070 bp	A1, A30	*01:13, 01:28, 01:176, 01:194, 01:229, 01:299, 03:43, 03:82, 03:186, 11:113, 11:162, 11:282, 30:01:01:01-30:04:03, 30:06-30:20, 30:22-30:161, 31:35, B*07:260
16	240 bp, 380 bp, 410 bp	1070 bp	A24, A31, A32	*02:237, 02:809, 03:95, 03:343, 11:306, 29:14, 31:01:02:01-31:167, 32:05, 32:79, 32:128, 33:53, 33:125, 33:131, 74:13
17 ¹¹	140 bp, 180 bp, 240 bp, 260 bp	1070 bp	A1, A2, A3, A25, A32, A74	*01:07, 01:95, 01:289, 01:298, 03:32, 03:43, 03:82, 03:152, 03:186, 03:219, 03:273, 23:64, 24:104, 24:243, 25:03, 25:30, 29:13, 29:39, 29:98, 30:89, 31:21, 31:35, 32:01:01:01-32:133N, 74:07, 74:33, 80:04
18	200 bp, 390 bp	1070 bp	A24, A31, A32, A33, A68, A74	*02:243:01-02:243:03, 24:82, 26:177, 29:48, 29:105, 31:08, 31:109, 32:05, 32:15, 32:79, 32:93, 33:01:01:01-33:01:14, 33:03:01:01-33:37, 33:39-33:193, 68:29, 74:04, 74:21
19	340 bp, 375 bp	800 bp	A2, A19, A68, A74	*01:121, 02:65, 02:407, 02:449, 03:246, 03:282, 32:62, 68:25, 74:01:01:01-74:37
20 ^{10,11}	210 bp, 240 bp	800 bp	A2, A28, A25, A68	*02:34-02:35:03, 02:46, 02:48, 02:56:01-02:56:02, 02:62, 02:70, 02:78, 02:103, 02:129, 02:571, 02:580, 02:651, 02:741, 25:05, 25:59, 26:54, 26:122, 68:01:01:01-68:217, 68:219-68:227
21 ⁵	65 bp, 240 bp, 375 bp, 545 bp	800 bp	A2, A26, A28, A32, A66, A68, A69	*02:55, 02:149, 02:243:01-02:243:03, 02:309, 02:644, 02:741, 02:815, 02:842, 23:57, 24:82, 25:30, 26:22, 26:177, 29:80, 31:41, 32:06, 33:22, 66:06, 66:09, 68:08:02, 68:29, 68:105, 68:157, 69:01:01:01-69:08, 74:35

101.403-48/12 – including *Taq* pol., IFU-01
 101.403-48u/12u – without *Taq* pol., IFU-02

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

Lot No.: **7K3**

Lot-specific information

22^{5,9}	85 bp, 240 bp, 400 bp	800 bp	A2, A36	*02:34-02:35:03, 02:46, 02:48, 02:56:01-02:56:02, 02:62, 02:70, 02:78, 02:103, 02:129, 02:571, 02:576, 02:580, 02:682, 02:741, 03:187, 11:155, 11:226, 31:62, 34:22, 36:01-36:09, 68:11N, 68:41, B*40:359, B*55:96, B*57:65, C*04:31, C*06:137, C*07:569
23^{5,10}	80 bp, 160 bp, 240 bp, 495 bp	800 bp	A2, A3, A24, A26, A28, A36, A68, A80	*02:55, 02:237, 02:671, 02:809, 03:41, 03:63, 03:75, 03:88, 03:95, 03:177, 03:343, 03:347, 11:130, 24:18, 24:204, 24:213, 26:03:01:01-26:03:01:02, 26:05- 26:06, 26:21, 26:30, 26:78, 26:111, 26:177, 33:24, 33:184, 36:02, 68:05, 68:15, 68:20, 68:109, 68:136, 80:01:01:01-80:01:02, 80:03-80:06, C*06:187
24¹²	-	-	-	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 low resolution screening 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.

³The serological reactivity of all HLA-A alleles is not known. In this table we use the expert-assigned serological grouping in Tissue Antigens (2009) 73:95-170 and the serological grouping of the sequence-defined allele.

⁴For 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.

⁵HLA-specific PCR products shorter than 125 base pairs have a lower intensity and are less sharp than longer PCR products.

⁶Primer mix 3 may faintly amplify the A*30:04:01:01-30:04:01:02, 30:04:02-30:04:03 30:06, 30:09, 30:17, 30:29, 30:46, 30:77, 30:89-30:90, 30:99, 30:103, 30:105, 30:117, 30:139, 30:150, 30:160 alleles

⁷Primer mix 9 may weakly amplify the A*34 alleles.

⁸Primer mix 15 may give rise to a lower yield of HLA-specific PCR product than the other HLA-A low primer mixes.

⁹Primer mix 22 might faintly amplify most A*11 alleles.

¹⁰Primer mixes 10, 14, 20 and 23 have a tendency to giving rise to primer oligomer formation.

¹¹Primer mixes 15, 17 and 20 may have tendency of unspecific amplification.

¹²Primer mix 24 contains a negative control, which will amplify a majority of HLA amplicons as well as the amplicons generated by the control primer pairs matching the human growth hormone gene. HLA-specific PCR product sizes range from 75 to 200 base pairs and the PCR product generated by the HGH positive control primer pair is 200 base pairs.

Abbreviations

w: might be weakly amplified.

101.403-48/12 – including *Taq* pol., IFU-01
101.403-48u/12u – without *Taq* pol., IFU-02

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

Lot No.: **7K3**

Lot-specific information

?: nucleotide sequence of the primer matching region not known.

101.403-48/12 – including *Taq* pol., IFU-01
101.403-48u/12u – without *Taq* pol., IFU-02

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

Lot No.: 7K3

Lot-specific information

PRIMER SPECIFICATION

Well No.	1	2	3	4	5	6	7	8	9	10	11	12
Length of spec. PCR product	120	175	205	190	160	135	175	165	80	80	80	125
	145	215	235		335	200	205	200		200	175	160
	225	255			505					240	500	190
		365										
		415										
Length of int. pos. control ¹	800	800	1070	800	1070	800	1070	800	800	800	1070	800
5'-primer(s) ²	98	48	359	98	144	176	98	98	257	98	301	103
	5'-CTT 3'	5'-gCT 3'	5'-gCA 3'	5'-CTA 3'	5'-gCC 3'	5'-gCA 3'	5'-CTC 3'	5'-CTA 3'	5'-Cgg 3'	5'-CTA 3'	5'-Cgg 3'	5'-CCT 3'
	103	78	363	413	317	368	368	102	259	261	302	415
	5'-CCT 3'	5'-TCT 3'	5'-ATA 3'	5'-CCg 3'	5'-gCT 3'	5'-gTT 3'	5'-gTT 3'	5'-ACA 3'	5'-AgA 3'	5'-AAC 3'	5'-ggA 3'	5'-ggT 3'
	123	106	363					413	261		385	423
	5'-AgT 3'	5'-CCA 3'	5'-ATA 3'					5'-CCg 3'	5'-AAC 3'		5'-ggC 3'	5'-gCT 3'
	363								266			
	5'-ATA 3'								5'-ACg 3'			
	363											
	5'-ATg 3'											
3'-primer(s) ³	203	240	527	256	265	270	259	259	302	256	341	257
	5'-TCT 3'	5'-ggA 3'	5'-CCA 3'	5'-CTg 3'	5'-CCC 3'	5'-ACA 3'	5'-gTT 3'	5'-gTT 3'	5'-ggC 3'	5'-CCA 3'	5'-CgT 3'	5'-gCA 3'
	545	292	527	559	368	521	502	259	303	299	521	506
	5'-AgA 3'	5'-gTg 3'	5'-CCT 3'	5'-CCg 3'	5'-CAA 3'	5'-ggg 3'	5'-CTT 3'	5'-gTT 3'	5'-AgA 3'	5'-TCg 3'	5'-ggg 3'	5'-TgT 3'
			527			534	539	538		308		538
			5'-CCT 3'			5'-CgT 3'	5'-TCT 3'	5'-CCA 3'		5'-TCT 3'		5'-CCg 3'
			555									559
			5'-CCA 3'									5'-CTC 3'
			555									559
			5'-gCA 3'									5'-CgT 3'
												559
												5'-CgC 3'
												563
												5'-CgA 3'
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

101.403-48/12 – including *Taq* pol., IFU-01
101.403-48u/12u – without *Taq* pol., IFU-02

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

Lot No.: **7K3**

Lot-specific information

Well No.	13	14	15	16	17	18	19	20	21	22	23
Length of spec.	180	80	90	240	140	200	340	210	65	85	80
PCR product	225	115	135	380	180	390	375	240	240	240	160
		200	205	410	240				375	400	240
		240			260				545		495
		460									
Length of int. pos. control ¹	1070	1070	1070	1070	1070	1070	800	800	800	800	800
5'-primer(s) ²	98	98	203	41	98	41	302	78	28	47	176
	5'-CTT 3'	5'-CAC 3'	5'-gAA 3'	5'-CTT 3'	5'-CTT 3'	5'-CTT 3'	5'-ggA 3'	5'-TCT 3'	5'-TCg 3'	5'-g.T 3'	5'-gCA 3'
	414	219	362	355	180	98	302	106	261	78	261
	5'-CAg 3'	5'-gCA 3'	5'-ggT 3'	5'-CCg 3'	5'-TTT 3'	5'-CAC 3'	5'-ggA 3'	5'-CCA 3'	5'-AAC 3'	5'-TCT 3'	5'-AAC 3'
	423	238	363		203		341	2nd I	502	521	341
	5'-gCT 3'	5'-AgA 3'	5'-ATA 3'		5'-gAA 3'		5'-ggA 3'	5'-CCT 3'	5'-CCC 3'	5'-ggT 3'	5'-ggA 3'
		355	363		418			2nd I		527	355
		5'-CCg 3'	5'-ATA 3'		5'-AgC 3'			5'-CCT 3'		5'-TgC 3'	5'-CCC 3'
		489	363								362
		5'-gCA 3'	5'-ATA 3'								5'-gAg 3'
			369								362
			5'-TAC 3'								5'-gAg 3'
3'-primer(s) ³	282	180	299	238	290	256	397	265	97	265	292
	5'-gAC 3'	5'-TCA 3'	5'-CCA 3'	5'-CCT 3'	5'-CAA 3'	5'-CCC 3'	5'-gAg 3'	5'-CCC 3'	5'-ggT 3'	5'-CCC 3'	5'-gTg 3'
	282	257	411	238	299	259		282	355	282	292
	5'-gAC 3'	5'-gCA 3'	5'-TCA 3'	5'-CCT 3'	5'-TCT 3'	5'-gTT 3'		5'-gAC 3'	5'-gAC 3'	5'-gAC 3'	5'-gTT 3'
	559	418	526	243	317	261		282	524	282	299
	5'-CCC 3'	5'-gTC 3'	5'-CCA 3'	5'-TCA 3'	5'-ggA 3'	5'-gTg 3'		5'-gAC 3'	5'-CAT 3'	5'-gAC 3'	5'-TCT 3'
	560	555		265	555	265		502		570	555
	5'-ACC 3'	5'-CCA 3'		5'-CCC 3'	5'-CCA 3'	5'-CCC 3'		5'-CTT 3'		5'-CAC 3'	5'-CCA 3'
				282		265		506			
				5'-gAC 3'		5'-CCC 3'		5'-TgT 3'			
				555		265					
				5'-CCA 3'		5'-CCA 3'					
Well No.	13	14	15	16	17	18	19	20	21	22	23

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.

101.403-48/12 – including *Taq* pol., IFU-01
 101.403-48u/12u – without *Taq* pol., IFU-02

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

Lot No.: **7K3**

Lot-specific information

CELL LINE VALIDATION SHEET																				
HLA-A low resolution screening primer set ²																				
				Well																
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	
				Prod. No.:	202014801	201900802	201900803	201900804	201900805	201900806	201900807	201900808	201900809	202014810	201900811	201900812	201900813	201900814	201900815	201900816
	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		-	+	-	-	-	-	-	W	-	-	-	-	-	-	-	-	-
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		-	+	-	-	-	-	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	-	+	-	+	-	-	-	-	-	-	+	-	-	-	-	-	-

101.403-48/12 – including *Taq* pol., IFU-01
 101.403-48u/12u – without *Taq* pol., IFU-02

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

Lot No.: **7K3**

Lot-specific information

CELL LINE VALIDATION SHEET											
HLA-A low resolution screening primer set ²											
				Well							
				17	18	19	20	21	22	23	
				Prod. No.:	201900817	201900818	201900819	201907920	201900821	201900822	201900823
	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	-	-	-	-	-	-	-	

101.403-48/12 – including *Taq* pol., IFU-01
101.403-48u/12u – without *Taq* pol., IFU-02

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

Lot No.: 7K3

Lot-specific information

¹The provided cell line HLA specificities are retrieved from the <http://www.ihwg.org/hla> website. 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.

One or more 5'- and 3'-primers in primer solutions 4, 5, 7, 8, 12, 14 to 17 and 20 to 23 were tested by separately adding 3'-primers, respectively 5'-primers. In addition, one or more 5'-primers in primer solutions 1, 9, 13 and 19 were tested by separately adding one or two 3'-primers and one or more 3'-primers in primer solutions 3, 10 and 18 were tested by separately adding one or two 5'-primers.

In primer solutions 2, 3, 9, 11, 12, 15, 20 and 22 one, two or three 5'-primers were not possible to test, and in primer solutions 3, 6, 8, 9, 10, 12, 13, 16 and 18 one or two 3'-primers were not possible to test.

101.403-48/12 – including *Taq* pol., IFU-01
101.403-48u/12u – without *Taq* pol., IFU-02

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

Lot No.: **7K3**

Lot-specific information

101.403-48/12 – including *Taq* pol., IFU-01
 101.403-48u/12u – without *Taq* pol., IFU-02

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

Lot No.: **7K3**

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: <https://labproducts.caredx.com/>

Distributed by:

CareDx GmbH, Löwengasse 47 / 6, AT-1030 Vienna, Austria.

Tel: +43-1-710 15 00

Fax: +43-1-710 15 00 10

E-mail: orders-at@caredx.com

Web page: <https://labproducts.caredx.com/>

CareDx Lab Solutions Inc., 901 S. Bolmar St., Suite R, West Chester, PA 19382

Tel: 1-877-653-78171

Fax: 610-344-7989

E-mail: orders-us@caredx.com

Web page: <https://labproducts.caredx.com/>

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