

101.101-48/12 – including *Taq* polymerase
101.101-48u/12u – without *Taq* polymerase

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

Lot No.: **9L5**

Lot-specific information

Olerup SSP® DR low resolution

Product number:	101.101-48/12 – including <i>Taq</i> pol. 101.101-48u/12u – without <i>Taq</i> pol.
Lot number:	9L5
Expiry date:	2025-02-01
Number of tests:	48 tests – Product No. 101.101-48/48u 12 tests – Product No. 101.101-12/12u
Number of wells per test:	31 + 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. 9L5.

Complete product documentation consists of generic Instructions for Use (IFU), lot specific Product Insert, Worksheet and Certificate.

CHANGES COMPARED TO THE PREVIOUS OLERUP SSP® DR LOW RESOLUTION LOT (3L5)

The DR low resolution primer set, specificity and interpretation tables have been updated for the HLA-DRB1 alleles described since the previous *Olerup SSP®* DR low resolution lot was made (**Lot No. 3L5**). The kit design is based on IMGT/HLA database 3.42.0.

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

Well	5'-primer	3'-primer	rationale
6	Added	-	5'-primer added for the DRB1*13:299 allele.
28	-	-	Internal positive control primer pair exchanged for decreased primer oligomer formation.

Changes in Revision R01 compared to R00:

1. Primer mix 29 may have a tendency of unspecific amplification. A footnote has been added in the specificity table.



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Well **32** 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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PRODUCT DESCRIPTION

DR low resolution

CONTENT

The primer set contains 5'- and 3'-primers for grouping the DRB1*01:01 to DRB1*10:40 alleles into the corresponding serological groups DR1 to DR18 as well as primer pairs for recognizing the DRB3, DRB4 and DRB5 groups of alleles.

PLATE LAYOUT

Each test consists of 32 PCR reactions in a 32 well cut PCR plate.

1	2	3	4	5	6	7	8
9	10	11	12	13	14	15	16
17	18	19	20	21	22	23	24
25	26	27	28	29	30	31	NC

The 32 well cut PCR plate is marked with ‘DR low’ in silver/gray ink.

Well No. 1 is marked with the Lot No. ‘9L5’.

Wells 1 to 31 – DR low resolution primers.

Well 32 – 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 32 well PCR plate, make sure that the remaining plates stay covered. Use a scalpel or a similar instrument to carefully cut the foil between the plates.

INTERPRETATION

Only HLA-DRB alleles will be amplified by the 31 wells of the DR low resolution primer set, **wells 1 to 31**. Thus, the interpretation of DR low resolution typings is not influenced by other HLA class II genes.

UNIQUELY IDENTIFIED ALLELES

All the HLA-DRB1, -DRB3, -DRB4 and -DRB5 alleles, i.e. **DRB1*01:01 to DRB1*10:40**, **DRB3*01:01 to DRB3*03:48**, **DRB4*01:01 to DRB4*03:01N**, **DRB5*01:01 to DRB5*02:29**, recognized by the HLA Nomenclature Committee in October 2020^{1,2} will be amplified by the primers in the DR low resolution SSP kit. The HLA-DRB alleles will be grouped into their corresponding serological specificities³.

¹DRB alleles listed on the IMGT/HLA web page 2020-October-15, release 3.42.0, 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 DR low resolution primer set. These alleles can be separated by the respective high-resolution primer sets.

Alleles

Alleles



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DRB1*08:31, DRB1*11:05

DRB1*12:57, DRB3*02:111

SPECIFICITY TABLE

DR low resolution primer set

Specificities and sizes of the PCR products of the 31+1 primer mixes of the DR low resolution primer set

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	DR serology ³	Amplified HLA-DRB alleles ^{4,6}
1⁶	210 bp, 235 bp, 260 bp	515 bp	1	*01:01:01:01-01:02:13, 01:04-01:38, 01:40N-01:98, 01:100-01:101, 01:103-01:111, 01:113-01:118
2	200 bp	430 bp	1, 103	*01:03:01-01:03:05, 01:39N, 01:42, 01:61, 01:89, 01:99, 01:102, 01:112
3^{6,8}	200 bp, 230 bp	430 bp	2, 15	*15:01:01:01-15:189, 16:66
4¹²	210 bp	430 bp	11, 16	*11:30, 12:57, 16:01:01-16:05:02, 16:07-16:68, DRB3*02:111
5^{5,11,12}	75 bp, 205 bp	515 bp	3, 11, 13, 17, 18	*03:01:01:01-03:11:01, 03:11:03-03:125, 03:127-03:179, 11:07:01-11:07:02, 11:27:02-11:27:03, 11:84:02-11:84:03, 11:103:01-11:103:02, 11:105, 11:107, 11:124:02-11:125, 11:136, 11:173, 13:33:01, 13:61:02, 13:94:01, 13:96:01, 14:38:02, 14:104, 14:111, 14:171, 15:25, 15:37:01, 15:100, 15:104:01, DRB3*02:146
6^{5,11}	75 bp, 210 bp	430 bp	3, 6, 11, 13, 14, 17	*03:01:01:01-03:01:23, 03:01:25-03:01:31, 03:04:01-03:06, 03:08-03:11:01, 03:11:03-03:16, 03:18-03:20, 03:22-03:23, 03:25:01-03:26, 03:28, 03:30-03:31, 03:33-03:34, 03:36-03:37, 03:43-03:48, 03:50-03:52:02, 03:54-03:68N, 03:70-03:73, 03:75-03:86, 03:89, 03:91-03:93, 03:95-03:96, 03:98-03:100:02, 03:104, 03:106-03:114, 03:116-03:118, 03:121-03:130, 03:132-03:149, 03:151-03:153, 03:156N-03:166, 03:168-03:170, 03:172, 03:174N-03:175, 03:177, 08:40, 08:92, 11:02:01:01-11:03:04, 11:11:01, 11:11:03, 11:14:01-11:14:02, 11:16, 11:20-11:21, 11:36, 11:40-11:41, 11:48, 11:59, 11:63:01-11:63:02, 11:65:01-11:65:02, 11:68, 11:70, 11:73, 11:76, 11:79-11:80, 11:83, 11:85-11:87, 11:93, 11:118, 11:122, 11:124:01-11:124:02, 11:127, 11:131-11:132, 11:135, 11:138-11:139, 11:142, 11:151, 11:153, 11:161, 11:168, 11:171, 11:176, 11:182, 11:184, 11:213, 11:229, 11:231, 11:233, 11:237, 11:241-11:242, 11:251, 11:256, 11:260, 11:270, 11:276, 12:73, 13:01:01:01-13:02:01:09, 13:02:02?, 13:02:03-13:04, 13:08, 13:10, 13:15-13:17, 13:19-13:20, 13:22:01-13:24, 13:27:01-13:29, 13:31-13:41, 13:43, 13:45, 13:48, 13:51-13:54, 13:57, 13:59, 13:61:01-13:61:02, 13:63-13:66:02, 13:68-13:76, 13:78-13:81, 13:83-13:85, 13:87-13:99, 13:101-13:102, 13:104-13:107, 13:109, 13:110?, 13:111-13:117, 13:120-13:131, 13:133, 13:135, 13:137N-13:145, 13:147-13:149, 13:151-13:153, 13:155, 13:159, 13:162, 13:165-13:166, 13:167?, 13:168, 13:170-13:180, 13:182-13:188, 13:190-13:191, 13:193-13:194, 13:196, 13:198, 13:200N-13:202, 13:204-13:205, 13:207-13:209,



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7⁵	85 bp, 210 bp	430 bp	3, 6, 11, 13, 14, 1403, 18	*03:02:01-03:03, 03:27, 03:29, 03:38, 03:53, 03:74, 03:88, 03:90, 03:102-03:103, 03:115, 03:119, 03:126, 03:131, 03:154, 03:167, 03:176-03:177, 03:179, 11:13:01 ^w -11:13:02 ^w , 11:26, 11:34, 11:267, 13:15, 13:19, 13:26:01-13:26:02, 13:44, 13:53, 13:57, 13:85-13:86, 13:104, 13:193, 13:198, 13:206, 13:235, 14:02:01:01-14:03:02, 14:06:01-14:06:06, 14:09, 14:12:01-14:13, 14:17-14:21, 14:24, 14:27:01-14:27:02, 14:29-14:30, 14:32:01 ^w -14:32:02 ^w , 14:33, 14:40-14:41, 14:47-14:49, 14:51, 14:63, 14:65 ^w , 14:67, 14:77-14:78, 14:80-14:81, 14:83, 14:85, 14:89, 14:94, 14:98, 14:102, 14:106, 14:108-14:109, 14:115, 14:119, 14:121, 14:135, 14:146, 14:154, 14:156, 14:159-14:160, 14:165, 14:170, 14:174, 14:176-14:177, 14:179, 14:181, 14:183, 14:194-14:195N, 14:198, 14:200, 14:209, 14:212, 14:218, 14:221-14:223, 14:226
8⁵	100 bp, 175 bp	430 bp	3, 4	*04:01:01:01-04:05:11, 04:05:13-04:312N
9^{8,13}	240 bp	430 bp	7	*07:01:01:01-07:01:25, 07:03-07:118N, DRB4*01:66
10⁵	85 bp, 120 bp, 215 bp, 250 bp	515 bp	7, 8, 14	*07:06, 08:01:01-08:01:02, 08:01:04-08:19, 08:21-08:30:03, 08:32-08:56, 08:58-08:66, 08:68:01-08:79, 08:81-08:97, 08:99-08:104, 11:67, 11:193:01-11:193:02, 12:16:01-12:16:03, 12:22, 12:39, 13:171:01, 13:197, 14:15, 14:68:01-14:68:02, 14:93
11^{5,12}	85 bp, 100 bp, 135 bp, 160 bp, 190 bp	430 bp	3, 9, 11	*03:08, 03:65, 03:140, 09:01:02:01-09:45, 11:07:01-11:07:02, 11:103:01-11:103:02, 11:105, 11:107, 11:125, 11:173, DRB3*01:42
12⁶	175 bp	430 bp	9, 10, 11, 13	*03:76, 03:125-03:126, 03:174N, 09:05, 10:01:01:01-10:40, 11:59, 11:80, 11:83, 11:87, 11:135, 11:142, 11:182, 13:27:01-13:27:02, 13:41, 13:71, 13:129, 13:176, 13:277, 14:82, 14:95, 14:132, 14:179
13⁵	100 bp, 175 bp	430 bp	3, 8, 11, 13, 14	*03:08, 03:65, 03:140, 08:31, 08:41, 08:63, 08:75, 11:01:01:01-11:11:01, 11:11:03-11:70, 11:72-11:263, 11:265-11:278
14⁵	90 bp, 110 bp	430 bp	12, 14	*08:32, 08:53, 08:87, 12:01:01:01-12:56, 12:58-12:85, 14:52
15¹²	220 bp	430 bp	6, 8, 11, 13, 14, 1403	*03:76, 03:125, 03:174N, 08:20-08:21, 11:01:01:01-11:01:27, 11:01:28 [?] , 11:01:29-11:04:22, 11:06:01-11:06:03, 11:08:01-11:11:01, 11:11:03-11:12:03, 11:14:01-11:16, 11:18-11:21, 11:23:01-11:25, 11:27:01-11:33, 11:35-11:51, 11:54:01-11:54:02, 11:56-11:66:02, 11:68, 11:70, 11:72-11:81, 11:83-11:88, 11:90-11:97, 11:99-11:102:02, 11:106, 11:108-11:124:02, 11:126-11:135, 11:137-11:142, 11:144-11:158, 11:160-11:172, 11:174-11:192, 11:194:01-11:201, 11:203-11:208, 11:210-11:228, 11:230-11:260, 11:262-11:265, 11:268-11:269, 11:271-11:278, 12:57, 13:01:01:01-13:02:01:09, 13:02:03-13:08, 13:10-13:16, 13:18-13:43, 13:45-13:85, 13:87-13:115, 13:117-13:128, 13:130-13:145, 13:147-13:174, 13:176-13:182, 13:184-13:191, 13:194-



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16^{6,12}	195 bp, 225 bp	430 bp	6, 8, 11, 12, 13, 14	*03:125, 08:01:01-08:01:02, 08:01:04-08:01:05, 08:01:07-08:02:04, 08:04:01-08:09:02, 08:11, 08:16-08:17, 08:20-08:22, 08:24:01-08:24:02, 08:26, 08:28, 08:31, 08:39, 08:41-08:44, 08:50, 08:52, 08:54-08:55, 08:57, 08:59, 08:64, 08:67, 08:70, 08:72-08:73, 08:75, 08:77-08:80, 08:82-08:90, 08:92-08:94, 08:96, 08:98-08:101, 08:103, 11:01:01:01-11:01:17, 11:01:20-11:04:20, 11:04:22-11:06:03, 11:09-11:11:01, 11:11:03-11:12:03, 11:14:01-11:16, 11:20-11:21, 11:23:01-11:25, 11:27:01-11:30, 11:32-11:33, 11:35-11:41, 11:43-11:44, 11:46:01-11:51, 11:54:01-11:56, 11:58:01-11:63:02, 11:65:01-11:70, 11:72, 11:74:01-11:78, 11:80-11:88, 11:90-11:97, 11:99-11:102:02, 11:106, 11:108-11:118, 11:120-11:124:02, 11:126-11:129, 11:133-11:135, 11:137-11:142, 11:144-11:152, 11:154-11:158, 11:160-11:172, 11:174-11:183, 11:185-11:190, 11:192-11:201, 11:203-11:247, 11:249-11:260, 11:262-11:265, 11:269-11:278, 12:02:01:01-12:02:10, 12:13, 12:15-12:16:03, 12:18-12:21, 12:23, 12:26-12:27, 12:31N-12:33, 12:37, 12:42-12:45, 12:49-12:52, 12:55-12:57, 12:60N-12:61, 12:64-12:65, 12:67, 12:69, 12:71, 12:73-12:76, 12:78, 12:80-12:81, 12:85, 13:01:01:01-13:02:01:09, 13:02:03-13:02:17, 13:04-13:05:03, 13:07:01-13:09, 13:11:01-13:11:02, 13:14:01-13:24, 13:26:01-13:29, 13:31-13:32, 13:34-13:36, 13:38-13:43, 13:45-13:55, 13:57, 13:59, 13:61:01-13:65, 13:67-13:76, 13:78-13:80, 13:83-13:84, 13:87, 13:91-13:93, 13:96:01-13:100, 13:102-13:109, 13:111-13:114, 13:116-13:117, 13:121, 13:123-13:132, 13:135-13:136, 13:138-13:150, 13:153, 13:155, 13:158-13:160, 13:162, 13:164-13:166, 13:168-13:169, 13:171:01-13:171:02, 13:173, 13:175, 13:177, 13:179, 13:182-13:187, 13:189-13:192, 13:195, 13:197-13:205, 13:207-13:215, 13:217-13:218, 13:221-13:223, 13:225-13:226, 13:229-13:230, 13:232-13:234, 13:236-13:252N, 13:254-13:288, 13:290-13:294, 13:296-13:298N, 13:300-13:305, 14:15-14:16, 14:22, 14:24-14:25:02, 14:27:01-14:27:02, 14:37, 14:53, 14:73, 14:105, 14:128, 14:226, DRB3*02:111
17¹¹	175 bp	430 bp	3, 6, 11, 13, 14, 1403, 17, 18	*03:01:01:01-03:07:02, 03:09, 03:11:01, 03:11:03-03:41:02, 03:43-03:45, 03:47-03:63, 03:66-03:68N, 03:70-03:86, 03:88-03:91, 03:93-03:110, 03:112-03:129, 03:131-03:139, 03:141-03:155, 03:157-03:161, 03:163-03:172, 03:174N-03:179, 08:20, 11:264, 13:01:01:01-13:16, 13:18-13:42:02, 13:44, 13:46-13:66:02, 13:68-13:102, 13:104-13:115, 13:117-13:121, 13:123-13:158, 13:161-13:164, 13:166-13:170, 13:171:02-13:174, 13:176-13:178, 13:180-13:182, 13:184-13:190, 13:192-13:194, 13:196, 13:198-13:213, 13:215-13:216, 13:218-13:227, 13:229-13:247, 13:249N-13:298N, 13:300-13:305, 14:02:01:01-14:03:02, 14:05:01:01-14:06:06, 14:08 ^w , 14:09, 14:12:01-14:14, 14:17-14:21, 14:23:01-14:24,



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18^{5,9}	55 bp, 100 bp, 145 bp, 195 bp, 240 bp	430 bp	4, 6, 8, 13, 14, 1404	*04:62, 04:69, 04:73:01-04:73:02, 04:105:01-04:105:02, 04:122, 04:146, 04:251, 04:284, 08:08, 11:69, 11:82, 13:45, 13:197, 14:01:01-14:01:02, 14:01:04-14:01:05, 14:04:01:01-14:04:08, 14:07:01-14:07:02, 14:10, 14:16, 14:22, 14:25:01-14:26, 14:28, 14:31-14:32:03, 14:35, 14:37-14:39, 14:49-14:50, 14:53-14:54:01:08, 14:54:03-14:55, 14:57-14:58, 14:60-14:62, 14:68:01-14:71, 14:73-14:76, 14:79, 14:82, 14:86-14:88, 14:90, 14:93, 14:99, 14:101, 14:104-14:105, 14:107, 14:110-14:114, 14:117-14:120, 14:122, 14:124-14:125, 14:128-14:129, 14:131, 14:137N-14:140, 14:142-14:143, 14:145-14:147, 14:149-14:153, 14:157-14:158, 14:163-14:164, 14:166N, 14:168 ^w , 14:171-14:173, 14:178, 14:180, 14:182, 14:184, 14:186, 14:189-14:192, 14:196-14:197N, 14:199, 14:201-14:205, 14:207-14:208, 14:210Q, 14:213-14:217, 14:219-14:220, 14:224-14:225, 14:227, 15:167, DRB4*01:03:01:02N, DRB4*01:03:01:13N, DRB4*01:14N
19^{5,6,7}	110 bp, 145 bp, 170 bp	430 bp	3, 4, 6, 9, 11, 13, 14, 1404	*03:10, 03:126, 03:177, 04:211, 09:01:02:01-09:01:05, 09:01:07-09:02:02, 09:04-09:22, 09:24-09:28, 09:30-09:45, 11:13:01-11:13:02, 11:17, 11:52, 11:202, 12:66, 13:43, 13:159, 13:171:01, 13:179, 13:191, 13:193, 13:217, 14:01:01-14:02:09, 14:04:01:01-14:11, 14:13-14:14, 14:16-14:18, 14:19 ^w , 14:20, 14:21 ^w , 14:22-14:23:04, 14:26, 14:28-14:36, 14:38:01-14:39, 14:41, 14:43-14:52, 14:54:01:01-14:54:03, 14:54:04 ^w , 14:54:05-14:57, 14:59-14:62, 14:64-14:65, 14:68:01-14:68:02, 14:70-14:76, 14:79-14:83, 14:86-14:88, 14:90-14:97, 14:99-14:101, 14:103-14:108, 14:109 ^w , 14:110-14:114, 14:117-14:127:02, 14:129-14:134, 14:137N-14:140, 14:142-14:143, 14:145-14:155, 14:157-14:160, 14:162-14:173, 14:175-14:180, 14:182, 14:184-14:185, 14:187-14:207, 14:209-14:217, 14:219-14:221, 14:224-14:225, 14:227, 15:27, 15:34, 15:54, 15:66:01-15:66:02, 15:122, 15:158, 15:187
20^{5,12,13}	110 bp, 150 bp, 180 bp, 220 bp	430 bp	2 ^w , 3, 4, 6, 8, 11, 13, 14, 1403, 1404, 16 ^w	*03:10, 03:157, 08:03:11 ^w , 08:09:01-08:09:02, 08:20-08:21, 08:32, 08:35, 08:36:02, 08:53, 08:68:01 ^w , 08:70 ^w , 08:87 ^w , 11:13:01-11:13:02, 11:17, 11:23:01-11:23:02, 11:25, 11:31, 11:45, 11:52, 11:55, 11:64, 11:89, 11:96, 11:119, 11:148, 11:159, 11:202, 11:266, 13:13, 13:18, 13:43, 13:45, 13:47, 13:55, 13:119, 13:144, 13:146, 13:154, 13:156, 13:158-13:159, 13:164, 13:171:01, 13:179, 13:191, 13:197, 13:217, 13:232, 13:286, 14:01:01-14:01:05, 14:03:01-14:05:05, 14:07:01-14:08, 14:10-14:12:02, 14:14-14:16, 14:18, 14:22-14:23:04, 14:25:01-14:28, 14:31-14:32:03, 14:34-14:36, 14:38:01-14:40, 14:42-14:45, 14:49-14:50, 14:53-14:65, 14:67-14:79, 14:81-14:82, 14:84-14:93, 14:95-14:97, 14:99-14:105, 14:107, 14:110-14:120, 14:122-14:140, 14:142-



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21	170 bp	430 bp	8, 12, 13, 14	*03:92, 03:162, 08:01:01-08:01:02, 08:01:04-08:04:05, 08:04:07-08:06, 08:09:01-08:10, 08:12-08:14, 08:16-08:18, 08:21-08:24:02, 08:26-08:30:03, 08:32-08:33, 08:35-08:40, 08:42-08:51, 08:53-08:62, 08:64-08:74, 08:76-08:104, 12:09, 12:46, 12:48 ^w , 12:62, 13:17, 13:116, 13:175, 13:214, 13:248, 14:15, 14:52, 14:126:01, 14:175
22⁵	75 bp, 175 bp, 265 bp	515 bp	2, 4, 8, 11, 13, 14	*04:12, 04:18, 04:25, 04:58, 08:04:01-08:04:07, 08:06, 08:10, 08:12, 08:14, 08:20, 08:22, 08:28, 08:54, 08:59, 08:67, 08:70, 08:75, 08:80, 08:83, 08:94, 08:98-08:99, 11:25, 11:67, 11:119, 11:261, 13:18, 13:144, 13:156, 13:164, 14:12:01-14:12:02, 14:15, 14:78, 14:84, 14:156, 14:173, 15:21
23	135 bp	430 bp	8, 12, 13	*03:92, 08:17, 08:28, 08:37, 08:45:01-08:45:02, 08:63, 08:103, 11:67, 11:193:01-11:193:02, 11:209, 11:229, 11:270, 12:01:01:01-12:20, 12:22-12:37, 12:39-12:41, 12:43-12:52, 12:54-12:56, 12:58-12:75, 12:77-12:82, 12:84-12:85, 13:17, 13:175, 13:214, 14:138, 14:175
24¹⁰	170 bp, 195 bp	430 bp	3, 6, 11, 13, 14	*03:12, 03:155, 03:158, 13:03:01:01-13:04, 13:12:01-13:13, 13:21:01-13:21:02, 13:30, 13:32-13:33:03, 13:38, 13:48-13:49, 13:55, 13:58, 13:65-13:66:02, 13:75, 13:81, 13:88-13:90, 13:93-13:95, 13:101, 13:108, 13:115, 13:118, 13:120, 13:122, 13:133-13:134, 13:139, 13:151-13:152, 13:154, 13:161, 13:164, 13:167, 13:169, 13:174, 13:188, 13:194, 13:216, 13:219, 13:227-13:228, 13:230, 13:253, 13:276, 13:295N, 14:13, 14:63, 14:65, 14:78, 14:85, 14:169-14:170, DRB5*01:08:01N-01:08:02N, DRB5*02:26N
25	150 bp	430 bp	2, 4, 6, 11, 13	*03:125, 11:02:05, 11:16, 11:20, 11:40, 11:59, 11:63:02, 11:118, 11:122, 12:73, 13:01:01:01-13:02:01:09, 13:02:03-13:02:17, 13:08, 13:15-13:16, 13:19-13:20, 13:27:01-13:29, 13:31-13:32, 13:34-13:36, 13:39-13:41, 13:43, 13:51-13:53, 13:57, 13:59, 13:61:01-13:61:02, 13:63-13:65, 13:67-13:69, 13:71-13:74, 13:76, 13:78-13:80, 13:83-13:84, 13:87, 13:91-13:93, 13:96:01-13:97:01, 13:98-13:99, 13:102-13:107, 13:109, 13:111-13:114, 13:117, 13:121, 13:123-13:128, 13:130-13:131, 13:135, 13:138-13:143, 13:145, 13:147-13:148, 13:153, 13:155, 13:159-13:160, 13:165-13:166, 13:168, 13:171:01-13:171:02, 13:173, 13:175, 13:177, 13:179, 13:182-13:187, 13:190-13:191, 13:195, 13:198, 13:200N-13:202, 13:205, 13:207-13:212, 13:213 ^w , 13:214-13:215, 13:217-13:218, 13:221-13:223, 13:225-13:226, 13:233-13:234, 13:236-13:245, 13:248-13:252N, 13:254-13:275, 13:278Q-13:283, 13:285, 13:287-13:288, 13:290-13:294, 13:296-13:301, 13:303-13:305, 14:16, 14:57, 15:10
26	145 bp	430 bp	3, 6, 11, 13, 14, 17	*03:01:01:01-03:01:22, 03:01:24-03:01:31, 03:04:01-03:05:03, 03:07:01-03:11:01, 03:11:03-03:16, 03:18-03:25:02, 03:28-03:30, 03:32-03:34, 03:36-03:37, 03:39-03:40, 03:43-03:52:02, 03:54-03:59, 03:61-03:68N, 03:70-03:73, 03:76-03:79, 03:81, 03:83-03:84, 03:86, 03:89, 03:91, 03:93-03:101, 03:104-03:110, 03:112-03:114, 03:116-03:121, 03:123-03:130, 03:132-03:137, 03:139-03:153, 03:156N-03:157,



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27⁸	145 bp, 210 bp, 235 bp	515 bp	4, 6, 8, 11, 13, 14, 1403, 1404	*03:157, 08:09:01-08:09:02, 08:20-08:21, 08:35, 11:03:04, 11:04:17, 11:13:01-11:13:02, 11:17, 11:23:01-11:23:02, 11:25, 11:45, 11:52, 11:55, 11:64, 11:89, 11:119, 11:149, 11:159, 11:202, 11:264, 11:266, 13:01:27, 13:08, 13:13, 13:18, 13:47, 13:55, 13:119, 13:144, 13:146, 13:154, 13:156, 13:158, 13:164, 13:232, 13:286, 14:01:01-14:01:05, 14:02:02 [?] -14:02:03 [?] , 14:02:06 [?] , 14:03:01-14:05:05, 14:07:01-14:08, 14:10-14:12:02, 14:14-14:15, 14:16 [?] , 14:18, 14:19 [?] -14:20 [?] , 14:22 [?] , 14:23:01-14:23:04, 14:25:01 [?] -14:25:02 [?] , 14:26-14:28, 14:29 [?] -14:30 [?] , 14:31-14:32:02, 14:32:03 [?] -14:33 [?] , 14:34-14:36, 14:37 [?] , 14:38:01-14:40, 14:41 [?] , 14:42-14:45, 14:48 [?] -14:49 [?] , 14:50, 14:51 [?] -14:52 [?] , 14:54:01:01-14:65, 14:67-14:68:02, 14:69 [?] , 14:70-14:72, 14:73 [?] -14:74 [?] , 14:75, 14:76 [?] , 14:77-14:78, 14:79 [?] -14:80 [?] , 14:81-14:82, 14:83 [?] , 14:84-14:93, 14:94 [?] , 14:95-14:97, 14:98 [?] , 14:99-14:103, 14:104 [?] -14:109 [?] , 14:110, 14:111 [?] , 14:112-14:118, 14:119 [?] , 14:120, 14:121 [?] , 14:122-14:127:02, 14:128 [?] , 14:129-14:145, 14:146 [?] , 14:147-14:158, 14:159 [?] , 14:160-14:164, 14:165 [?] , 14:166N-14:169, 14:170 [?] , 14:171-14:175, 14:176 [?] , 14:178, 14:179 [?] , 14:180-14:182, 14:183 [?] , 14:184-14:193, 14:196-14:197N, 14:199, 14:201-14:202, 14:203 [?] , 14:204-14:208, 14:210Q-14:211, 14:213-14:220, 14:222N-14:225, 14:227
28^{6,12}	140 bp, 170 bp	515 bp	6, 13, 14	*03:76, 03:126, 03:174N, 03:177, 04:211, 04:230, 12:66 ^w , 13:10, 13:85-13:86, 13:120, 13:170, 13:176, 13:178, 13:193, 13:196, 13:216, 14:02:01:01-14:02:09, 14:06:01-14:06:06, 14:09, 14:13, 14:17, 14:19-14:21, 14:29-14:30, 14:33, 14:41,



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29 ^{5,8,11,12,14}	80 bp, 110 bp, 170 bp, 240 bp	515 bp	52	*12:05, 12:15, 12:57, 14:141, DRB3*01:01:02:01-01:90, DRB3*02:01-02:130, DRB3*02:132-02:150, DRB3*03:01:01:01-03:48
30 ^{9,13}	130 bp, 215 bp	430 bp	53	*10:19, 14:217, 15:141, DRB4*01:01:01:01, DRB4*01:01:01:03-01:137, DRB4*02:01N, DRB4*03:01N
31 ¹⁰	175 bp, 220 bp	430 bp	51	DRB5*01:01:01:01-01:99, DRB5*02:02:01-02:29
32 ¹⁵	-	-		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 DR low resolution SSP subtypings.

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, e.g. the primers in wells 3, 18, 19 and 20.

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 430 or 515 base pairs respectively, well distribution as outlined in the table. Well number 1 contains the longer, 515 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 DRB alleles is not known. In this table we use the information in the HLA Dictionary 2004 on the www.ebi.ac.uk/imgt/hla web site and the expert-assigned serological grouping in Tissue Antigens (2009) 73:95-170.

⁴For several DRB alleles 1st and/or 3rd 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 mixes 1, 3, 12, 16, 19 and 28 have a tendency to giving rise to primer oligomer formation.

⁷Primer mix 19 has a tendency of primer oligomer formation and also has an intense primer cloud due to the high number of primers present in the primer mix.

⁸Primer mixes 3, 9, 27 and 29 may have tendencies of unspecific amplifications.

⁹The DRB4*01:03:01:02N, DRB4*01:03:01:13N and DRB4*01:14N alleles are amplified by the primer pairs in primer mixes 18 and 30, whereas the DRB4*02:01N and DRB4*03:01N null alleles are only amplified by the primer pairs in primer mix 30.

¹⁰The DRB5*01:08:01N-01:08:02N and DRB5*02:26N alleles are amplified by the primer pairs in primer mix 24 in addition to primer mix 31.

¹¹Due to sharing of sequence motifs in codon 38 and 47, DRB3*01:14 will also be amplified in primer mixes 5, 6 and 17 and the DRB3*01:23 and DRB3*02:32 alleles are amplified in mix 5, in addition to primer mix 29.

¹²Due to sharing of sequence motifs, some DRB3 alleles are amplified by primer mixes 4, 5, 11, 15, 16, 20 and 28 in addition to primer mix 29.



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¹³Due to sharing of sequence motifs, some DRB4 alleles are amplified by primer mixes 9 and 20 in addition to primer mix 30.

¹⁴In primer mix 29, the specific PCR product of 240 base pairs may be difficult to distinguish from the internal control band.

¹⁵Primer mix 32 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.

?: nucleotide sequence information not available for the primer matching sequence.



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PRIMER SPECIFICATION

Well No.	1	2	3	4	5	6	7	8	9	10	11	12
Length of spec.	210	200	200	210	75	75	85	100	240	85	85	175
PCR product	235		230		205	210	210	175		120	100	
	260									215	135	
										250	160	
											190	
Length of int.	515	430	430	430	515	430	430	430	430	515	430	430
pos. control ¹												
5'-primer(s) ²	13(124) 5'-A.T 3'	14(129) 5'-gAA 3'	12(121) 5'-CTg 3'	11(119) 5'-gCT 3'	13(125) 5'-gTC 3'	12(122) 5'-TAC 3'	13(125) 5'-gTC 3'	13(124) 5'-AAC 3'	11(118) 5'-AgA 3'	16(133) 5'-gTT 3'	26(165) 5'-TAT 3'	26(164) 5'-gTA 3'
	14(129) 5'-gAA 3'		13(126) 5'-Agg 3'	13(126) 5'-Agg 3'	47(227) 5'-gTT 3'	13(125) 5'-gTC 3'		13(125) 5'-ATA 3'	14(127) 5'-gTA 3'	16(133) 5'-gTT 3'	37(196) 5'-AgA 3'	31(178) 5'-gCg 3'
			13(126) 5'-AAg 3'	13(126) 5'-AAg 3'		16(133) 5'-gTT 3'		13(125) 5'-gTC 3'	14(127) 5'-ATA 3'	16(133) 5'-gCT 3'	58(261) 5'-gAg 3'	
			13(126) 5'-AgA 3'						14(127) 5'-ATA 3'	60(265) 5'-AgT 3'		
3'-primer(s) ³	67(286) 5'-gAg 3'	67(286) 5'-gAT 3'	67(286) 5'-gAT 3'	67(286) 5'-gAA 3'	73(305) 5'-ggC 3'	26(164) 5'-ggT 3'	28(171) 5'-CTC 3'	33(184) 5'-gTg 3'	78(319) 5'-CgC 3'	74(307) 5'-CAg 3'	57(257) 5'-CgA 3'	72(303) 5'-gCA 3'
	67(286) 5'-gAg 3'	67(286) 5'-gAA 3'	67(286) 5'-gAT 3'	67(286) 5'-gAg 3'	73(305) 5'-ggC 3'	67(286) 5'-gAT 3'	70(295) 5'-CTg 3'	58(260) 5'-Cgg 3'	78(319) 5'-gTA 3'	86(344) 5'-CAC 3'	73(305) 5'-ggC 3'	74(307) 5'-CgC 3'
	67(286) 5'-gAT 3'	67(286) 5'-gAA 3'	67(286) 5'-gAT 3'	67(286) 5'-gAg 3'	73(305) 5'-ggC 3'	71(299) 5'-gCT 3'			78(319) 5'-CAA 3'		78(319) 5'-CAC 3'	74(308) 5'-CCT 3'
	70(297) 5'-CTg 3'		70(295) 5'-CTg 3'	70(296) 5'-TgT 3'	73(305) 5'-ggC 3'				78(319) 5'-CAC 3'			
	71(299) 5'-gCg 3'		70(295) 5'-Tg 3'	72(302) 5'-Cgg 3'	73(306) 5'-Tgg 3'							
	73(305) 5'-ggC 3'		70(296) 5'-TCC 3'		74(308) 5'-CCC 3'							
	77(317) 5'-AgT 3'		71(299) 5'-gCg 3'		75(310) 5'-CAA 3'							
	86(344) 5'-CCA 3'		71(299) 5'-gCT 3'		77(317) 5'-AgT 3'							
			72(301) 5'-Cg 3'									
			73(305) 5'-ggC 3'									
			77(317) 5'-AgT 3'									
Well No.	1	2	3	4	5	6	7	8	9	10	11	12



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For *In Vitro* Diagnostic Use
MA123 v02 SSP PI Template
Date: December 2022, Rev. No: 01

101.101-48/12 – including *Taq* polymerase
101.101-48u/12u – without *Taq* polymerase

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

Lot No.: **9L5**

Lot-specific information

Well No.	13	14	15	16	17	18	19	20	21	22	23	24
Length of spec.	100	90	220	195	175	55	110	110	170	75	135	170
PCR product	175	110		225		100	145	150		175		195
						145	170	180		265		
						195		220				
						240						
Length of int.	430	430	430	430	430	430	430	430	430	515	430	430
pos. control ¹												
5'-primer(s) ²	13(125) 5'-gTC 3'	13(124) 5'-Cgg 3'	10(116) 5'-gCT 3'	10(116) 5'-gCT 3'	13(125) 5'-gTC 3'	5(101) 5'-CAA 3'	26(164) 5'-gTA 3'	13(125) 5'-gTC 3'	13(125) 5'-ggg 3'	12(122) 5'-TAg 3'	16(133) 5'-gTT 3'	13(125) 5'-gTC 3'
	16(133) 5'-gTC 3'	16(133) 5'-gTT 3'	12(122) 5'-TAT 3'	12(122) 5'-TAT 3'		37(197) 5'-gTT 3'	34(189) 5'-CAg 3'	34(189) 5'-CAg 3'	16(133) 5'-gCT 3'	74(308) 5'-CCT 3'		108(409) 5'-AgA 3'
	38(200) 5'-CgT 3'		13(125) 5'-gTC 3'	12(123) 5'-ACA 3'		37(197) 5'-gTA 3'	34(189) 5'-CAg 3'	37(196) 5'-AgC 3'	16(133) 5'-gTT 3'			
				13(125) 5'-gTC 3'			34(189) 5'-CCg 3'		16(133) 5'-gTT 3'			
				13(125) 5'-gTg 3'								
				16(133) 5'-gTC 3'								
				16(133) 5'-gTT 3'								
3'-primer(s) ³	58(260) 5'-CCT 3'	28(171) 5'-CTC 3'	70(295) 5'-gTC 3'	67(286) 5'-gAA 3'	57(257) 5'-CAT 3'	42(213) 5'-TCA 3'	57(257) 5'-CAg 3'	57(257) 5'-CAg 3'	57(256) 5'-gCT 3'	57(256) 5'-gCT 3'	47(227) 5'-ggA 3'	57(256) 5'-gCT 3'
	58(260) 5'-CCT 3'	30(175) 5'-gTg 3'	71(299) 5'-gCT 3'	71(298) 5'-CTC 3'	58(260) 5'-Cgg 3'	57(257) 5'-CAg 3'	70(295) 5'-CTg 3'	60(265) 5'-gTg 3'	57(257) 5'-CAT 3'	86(344) 5'-CCA 3'		160(565) 5'-CAT 3'
	58(260) 5'-CCT 3'	38(199) 5'-CAg 3'	71(299) 5'-ACT 3'	71(298) 5'-CgC 3'	58(260) 5'-CAg 3'	71(298) 5'-CgC 3'	70(296) 5'-TCC 3'	70(296) 5'-TCC 3'	57(257) 5'-CAT 3'	86(344) 5'-CAA 3'		
	58(261) 5'-TCT 3'		74(307) 5'-CgT 3'					74(307) 5'-CAg 3'				
			78(319) 5'-CAC 3'									
Well No.	13	14	15	16	17	18	19	20	21	22	23	24



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Lot No.: **9L5**

Lot-specific information

Well No.	25	26	27	28	29	30	31
Length of spec.	150	145	145	140	80	130	175
PCR product			210	170	110	215	220
			235		170		
					240		
Length of int.	430	430	515	515	515	430	430
pos. control ¹							
5'-primer(s) ²	34(189) 5'-CAG 3'	13(125) 5'-gTC 3'	13(125) 5'-gTC 3'	28(171) 5'-gAg 3'	10(116) 5'-gCT 3'	28(170) 5'-gAT 3'	9(112) 5'-TgC 3'
	34(189) 5'-CAG 3'		37(197) 5'-gTT 3'	37(196) 5'-AgA 3'	10(116) 5'-gCT 3'	28(170) 5'-gAg 3'	13(125) 5'-gTA 3'
			114(429) 5'-CTg 3'		11(119) 5'-gCT 3'	105(401) 5'-AAA 3'	
					38(199) 5'-TCC 3'		
3'-primer(s) ³	71(298) 5'-CTC 3'	47(227) 5'-ggA 3'	70(296) 5'-TCC 3'	70(295) 5'-CTg 3'	51(239) 5'-CCC 3'	81(328) 5'-gTA 3'	57(256) 5'-gTC 3'
		48(229) 5'-CCA 3'	74(307) 5'-CAG 3'	71(298) 5'-CTT 3'	60(266) 5'-Agg 3'	87(346) 5'-CTC 3'	57(258) 5'-gCg 3'
			181(630) 5'-CTT 3'		77(317) 5'-AAT 3'	87(346) 5'-CTT 3'	57(258) 5'-gCT 3'
						135(490) 5'-gCT 3'	58(260) 5'-CCT 3'
							70(296) 5'-TgT 3'
Well No.	25	26	27	28	29	30	31

¹The internal positive control primer pairs amplify segments of the human growth hormone gene. The internal positive control bands are 430 or 515 base pairs respectively, well distribution as outlined in the table. Well number 1 contains the longer, 515 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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Lot No.: 9L5

Lot-specific information

[illegible]

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.



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Lot No.: 9L5

Lot-specific information

²The DRB4*01:03:01:02N allele is amplified by primer mix 18 in the 9052 (DBB) cell line.

³The 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 11, 12, 15, 18 and 27 were tested by separately adding one 3'-primer and one 5'-primer respectively.

One or more 5'-primers in primer solutions 4, 6, 16 and 28 were tested by separately adding one 3'-primer. Additional 3'-primers in primer solutions 1 to 3, 5, 9, 20 and 22 were tested by separately adding one, two or four 5'-primers.

In primer solutions 1, 3, 4, 8 to 10, 13 to 16, 19 to 22, 27 and 30 one or more of the 5'-primers were not possible to test. In primer solutions 1 to 6, 9, 13, 15, 17, 21, 22, 26, 30 and 31 one or more of the 3'-primers were not possible to test.



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101.101-48/12 – including *Taq* polymerase
101.101-48u/12u – without *Taq* polymerase

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

Lot No.: **9L5**

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



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For *In Vitro* Diagnostic Use
MA123 v02 SSP PI Template
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