

101.521-24/04 – including *Taq* polymerase
 101.521-24u/04u – without *Taq* polymerase

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

Lot No.: **8R2**

Lot-specific information
Olerup SSP[®] HLA-B*27

Product number:	101.521-24/04 – including <i>Taq</i> pol. 101.521-24u/04u – without <i>Taq</i> pol.
Lot number:	8R2
Expiry date:	2027-03-01
Number of tests:	24 test – Product No. 101.521-24/24u 4 tests – Product No. 101.521-04/04u
Number of wells per test:	46+1
Storage - pre-aliquoted primers:	dark, between -15°C and -25°C
- PCR Master Mix:	between -15°C and -25°C
- Adhesive PCR seals	RT

This Product Description is only valid for Lot No. 8R2.

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-B*27 Lot (9L4)**

- The product documentation has been updated for new alleles of IMGT 3.51.0
- The kit resolution focuses on common and well documented (CWD) alleles¹.

¹As described in section Uniquely Identified Alleles

The HLA-B*27 specificity and interpretation tables have been updated for the HLA-B alleles described since the previous *Olerup SSP[®] HLA-B*27* lot was made (**Lot No. 9L4**).

The HLA-B*27 primer set is unchanged compared to the previous *Olerup SSP[®] HLA-B*27* lot (**Lot No. 9L4**).

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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Well **47** 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-B*27 SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for identifying the B*27:01 to B*27:265 alleles.

PLATE LAYOUT

Each test consists of 47 PCR reactions in a 48 well cut PCR plate. Well 48 is empty.

Note: This lot was manufactured using white plastic trays.

1	2	3	4	5	6	7	8
9	10	11	12	13	14	15	16
17	18	19	20	21	22	23	24
25	26	27	28	29	30	31	32
33	34	35	36	37	38	39	40
41	42	43	44	45	46	NC	empty

The 48 well cut PCR plate is marked with ‘HLA-B*27’ in silver/gray ink.

Well No. 1 is marked with the Lot No. ‘8R2’.

Wells 1 to 46 – HLA-B*27 high resolution primers.

Well 47 – Negative Control (NC).

A faint row of numbers is seen between wells 1 and 2 or wells 7 and 8 of the PCR trays. These stem from the manufacture of the trays, and should be disregarded. The PCR plates are covered with a PCR-compatible foil.

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

INTERPRETATION

Due to the sharing of sequence motifs between HLA-B alleles non-HLA-B*27 alleles will be amplified by some primer mixes. For further details see Specificity Table.

UNIQUELY IDENTIFIED ALLELES

All the HLA-B*27 alleles, i.e. **B*27:01 to B*27:265**, recognized by the HLA Nomenclature Committee in January 2023^{1,2} will be amplified by the primers in the HLA-B*27 subtyping kit³.

The HLA-B*27 kit enables separation of the confirmed HLA-B*27 alleles as listed in the IMGT/HLA database 3.28.0. An HLA allele is listed as confirmed by IMGT/HLA if it has been sequenced by more than a single laboratory or from multiple sources. Current allele confirmation status for HLA-B*27 alleles is listed below.



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Lot-specific information

The HLA-B*27 kit also enables identification of many null and alternatively expressed alleles.

The following HLA-B*27 alleles can be distinguished by the different sizes of the HLA-specific PCR product:

Alleles	Primer mix
B*27:14, 27:81	17
B*27:37, 27:55, 27:101	22
B*27:53, 27:119	13
B*27:60, 27:227	10
B*27:69, 27:173	20
B*27:83, 27:134	35

¹HLA-B alleles listed on the IMGT/HLA web page 2023-January-12, release 3.51.0, 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 HLA-B*27 primer set cannot separate the following alleles. These alleles can be distinguished by the HLA-B low resolution kit and/or the HLA-B*40 respectively the HLA-B*18 high resolution kits.

Alleles

B*27:33, 40:50:01:01-40:50:01:02
B*27:44, 18:165



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ALLELE CONFIRMATION STATUS

Allele	Status ¹	Allele	Status ¹	Allele	Status ¹	Allele	Status ¹
B*27:01	Confirmed	B*27:07:03	Confirmed	B*27:55	Confirmed	B*27:101	Confirmed
B*27:02:01:01	Confirmed	B*27:07:04	Confirmed	B*27:56	Unconfirmed	B*27:102	Unconfirmed
B*27:02:01:02	Unconfirmed	B*27:07:05	Unconfirmed	B*27:57	Unconfirmed	B*27:103	Unconfirmed
B*27:02:01:03	Confirmed	B*27:08	Confirmed	B*27:58	Unconfirmed	B*27:104	Confirmed
B*27:02:02	Unconfirmed	B*27:09	Confirmed	B*27:59N	Confirmed	B*27:105	Unconfirmed
B*27:02:03	Unconfirmed	B*27:10	Confirmed	B*27:60	Confirmed	B*27:106	Unconfirmed
B*27:03	Confirmed	B*27:11	Unconfirmed	B*27:61	Confirmed	B*27:107	Unconfirmed
B*27:04:01	Confirmed	B*27:12	Confirmed	B*27:62	Unconfirmed	B*27:108	Unconfirmed
B*27:04:02	Unconfirmed	B*27:13	Confirmed	B*27:63	Unconfirmed	B*27:109	Unconfirmed
B*27:04:03	Confirmed	B*27:14	Confirmed	B*27:64N	Unconfirmed	B*27:110	Unconfirmed
B*27:04:04	Confirmed	B*27:15	Confirmed	B*27:65N	Unconfirmed	B*27:111	Unconfirmed
B*27:04:05	Unconfirmed	B*27:16	Unconfirmed	B*27:66N	Confirmed	B*27:112	Unconfirmed
B*27:04:06	Unconfirmed	B*27:17	Confirmed	B*27:67	Unconfirmed	B*27:113	Unconfirmed
B*27:05:02:01	Confirmed	B*27:18	Unconfirmed	B*27:68	Unconfirmed	B*27:114	Unconfirmed
B*27:05:02:02	Unconfirmed	B*27:19	Unconfirmed	B*27:69	Unconfirmed	B*27:115	Unconfirmed
B*27:05:02:03	Confirmed	B*27:20	Confirmed	B*27:70	Confirmed	B*27:116	Unconfirmed
B*27:05:02:04Q	Unconfirmed	B*27:21	Unconfirmed	B*27:71	Unconfirmed	B*27:117	Unconfirmed
B*27:05:03	Confirmed	B*27:23	Confirmed	B*27:72	Unconfirmed	B*27:118	Confirmed
B*27:05:04	Unconfirmed	B*27:24	Confirmed	B*27:73	Confirmed	B*27:119	Unconfirmed
B*27:05:05	Confirmed	B*27:25	Confirmed	B*27:74	Unconfirmed	B*27:120	Unconfirmed
B*27:05:06	Unconfirmed	B*27:26	Unconfirmed	B*27:75	Unconfirmed	B*27:121	Unconfirmed
B*27:05:07	Confirmed	B*27:27	Confirmed	B*27:76	Unconfirmed	B*27:122	Unconfirmed
B*27:05:08	Unconfirmed	B*27:28	Unconfirmed	B*27:77	Unconfirmed	B*27:123	Confirmed
B*27:05:09	Confirmed	B*27:29	Unconfirmed	B*27:78	Confirmed	B*27:124	Unconfirmed
B*27:05:10	Confirmed	B*27:30	Confirmed	B*27:79	Unconfirmed	B*27:125	Unconfirmed
B*27:05:11	Unconfirmed	B*27:31	Unconfirmed	B*27:80	Confirmed	B*27:126	Unconfirmed
B*27:05:12	Unconfirmed	B*27:32	Unconfirmed	B*27:81	Unconfirmed	B*27:127	Unconfirmed
B*27:05:13	Unconfirmed	B*27:33	Unconfirmed	B*27:82	Confirmed	B*27:128	Unconfirmed
B*27:05:14	Unconfirmed	B*27:34	Unconfirmed	B*27:83	Confirmed	B*27:129	Unconfirmed
B*27:05:15	Confirmed	B*27:35	Unconfirmed	B*27:84	Unconfirmed	B*27:130	Unconfirmed
B*27:05:16	Unconfirmed	B*27:36	Confirmed	B*27:85	Confirmed	B*27:131	Unconfirmed
B*27:05:17	Unconfirmed	B*27:37	Unconfirmed	B*27:86	Unconfirmed	B*27:132	Unconfirmed
B*27:05:18	Confirmed	B*27:38	Unconfirmed	B*27:87	Unconfirmed	B*27:133	Unconfirmed
B*27:05:19	Unconfirmed	B*27:39	Unconfirmed	B*27:88	Unconfirmed	B*27:134	Confirmed
B*27:05:20	Unconfirmed	B*27:40	Unconfirmed	B*27:89	Unconfirmed	B*27:135	Unconfirmed
B*27:05:21	Confirmed	B*27:41	Unconfirmed	B*27:90:01	Unconfirmed	B*27:136	Unconfirmed
B*27:05:22	Unconfirmed	B*27:42	Confirmed	B*27:90:02	Unconfirmed	B*27:137	Confirmed
B*27:05:23	Confirmed	B*27:43	Unconfirmed	B*27:90:03	Unconfirmed	B*27:138	Unconfirmed
B*27:05:24	Unconfirmed	B*27:44	Unconfirmed	B*27:90:04	Unconfirmed	B*27:139	Unconfirmed
B*27:05:25	Unconfirmed	B*27:45	Unconfirmed	B*27:91	Confirmed	B*27:140	Unconfirmed
B*27:05:26	Unconfirmed	B*27:46	Confirmed	B*27:92	Unconfirmed	B*27:141	Confirmed
B*27:05:27	Confirmed	B*27:47	Confirmed	B*27:93	Unconfirmed	B*27:142	Confirmed
B*27:05:28	Unconfirmed	B*27:48	Confirmed	B*27:94N	Unconfirmed	B*27:143	Unconfirmed
B*27:05:29	Unconfirmed	B*27:49	Confirmed	B*27:95	Unconfirmed	B*27:144	Unconfirmed
B*27:05:30	Unconfirmed	B*27:50:01	Confirmed	B*27:96:01	Unconfirmed	B*27:145	Unconfirmed
B*27:05:31	Unconfirmed	B*27:50:02	Confirmed	B*27:96:02	Unconfirmed	B*27:146	Confirmed
B*27:05:32	Confirmed	B*27:51	Confirmed	B*27:97	Confirmed	B*27:147	Unconfirmed
B*27:06	Confirmed	B*27:52	Confirmed	B*27:98	Unconfirmed	B*27:148	Unconfirmed
B*27:07:01	Confirmed	B*27:53	Confirmed	B*27:99	Unconfirmed	B*27:149	Unconfirmed
B*27:07:02	Unconfirmed	B*27:54	Unconfirmed	B*27:100	Unconfirmed	B*27:150	Unconfirmed



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Allele	Status ¹	Allele	Status ¹
B*27:151	Unconfirmed	B*27:161	Unconfirmed
B*27:152	Unconfirmed		
B*27:153	Unconfirmed		
B*27:154	Unconfirmed		
B*27:155	Unconfirmed		
B*27:156	Unconfirmed		
B*27:157	Unconfirmed		
B*27:158	Unconfirmed		
B*27:159	Unconfirmed		
B*27:160	Unconfirmed		

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

RESOLUTION IN HOMO- AND HETEROZYGOTES

Results file with resolution in HLA-B*27 homo- and heterozygotes is available upon request.



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Lot-specific information
SPECIFICITY TABLE

HLA-B*27 SSP subtyping

Specificities and sizes of the PCR products of the 46+1 primer mixes used for HLA-B*27 SSP subtyping

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified HLA-B*27 alleles ³	Other amplified HLA Class I alleles
1	390 bp	800 bp	*27:01, 27:18, 27:23, 27:29, 27:44, 27:92, 27:131, 27:257	*18:01:01:01-18:01:01:74, 18:01:03-18:01:22, 18:01:24-18:01:32, 18:01:34-18:02:03, 18:04:01-18:15, 18:17N-18:24, 18:26-18:93, 18:95-18:106Q, 18:108-18:131:01:02, 18:133-18:135:01:02, 18:137-18:141, 18:143-18:151, 18:153-18:170, 18:173, 18:175-18:193, 18:195-18:197, 18:199-18:202, 18:204-18:226, 35:01:23, 35:42:01-35:42:02, 37:01:01:01-37:33N, 37:35-37:36, 37:38-37:59, 37:61-37:107, 40:02:01:01-40:06:15, 40:06:17-40:06:31, 40:08:01:01-40:08:01:02, 40:09 [?] , 40:11:01:01-40:11:02, 40:14:01 [?] -40:14:02 [?] , 40:15 [?] , 40:18 [?] , 40:20:01:01-40:20:01:02, 40:24 [?] -40:25 [?] , 40:27:01, 40:27:02 [?] , 40:27:03, 40:28 [?] -40:29 [?] , 40:34 [?] -40:35:02 [?] , 40:35:03, 40:36 [?] , 40:37, 40:39, 40:44 [?] -40:47 [?] , 40:49 [?] , 40:53 [?] , 40:56 [?] -40:58 [?] , 40:61 [?] -40:63 [?] , 40:64:01:01-40:64:02, 40:65 [?] , 40:67 [?] -40:69 [?] , 40:70:01-40:70:02, 40:71 [?] , 40:75 [?] , 40:78, 40:81 [?] -40:88 [?] , 40:89-40:90, 40:91 [?] -40:93 [?] , 40:94, 40:95 [?] -40:96 [?] , 40:97, 40:98 [?] , 40:99, 40:100 [?] -40:101 [?] , 40:103 [?] -40:109 [?] , 40:111, 40:112 [?] , 40:114:02 [?] -40:116 [?] , 40:118N [?] , 40:119-40:120, 40:121 [?] , 40:122, 40:123 [?] , 40:124:02 [?] -40:125:01 [?] , 40:127 [?] , 40:129, 40:130:01 [?] , 40:131 [?] -40:137 [?] , 40:141 [?] , 40:142N-40:144N, 40:145 [?] , 40:148 [?] -40:149 [?] , 40:151 [?] , 40:154 [?] , 40:156 [?] -40:159 [?] , 40:160:02 [?] -40:165 [?] , 40:167 [?] , 40:169 [?] , 40:173 [?] -40:180 [?] , 40:181, 40:182 [?] , 40:184 [?] -40:185 [?] , 40:186:02 [?] -40:190 [?] , 40:192 [?] -40:201 [?] , 40:202, 40:203 [?] -40:213 [?] , 40:214, 40:215 [?] -40:225:01 [?] , 40:225:02, 40:226 [?] -40:228 [?] , 40:229, 40:231 [?] -40:236 [?] , 40:238 [?] -40:244 [?] , 40:246 [?] -40:248 [?] , 40:254-40:255, 40:257 [?] , 40:266-40:271, 40:274 [?] -40:276 [?] , 40:279 [?] -40:283 [?] , 40:284, 40:287 [?] -40:289 [?] , 40:290, 40:291N [?] -40:295 [?] , 40:296, 40:297 [?] -40:300 [?] , 40:302-40:305, 40:306 [?] -40:308 [?] , 40:309, 40:311 [?] -40:313 [?] , 40:314, 40:315 [?] , 40:317 [?] -40:319 [?] , 40:320, 40:322 [?] ,



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2	405 bp	800 bp	*27:02:01:01-27:02:06, 27:30, 27:53, 27:57, 27:62, 27:65N, 27:75, 27:77, 27:83, 27:95, 27:102, 27:119, 27:126, 27:134, 27:157, 27:163, 27:171-27:172, 27:176N, 27:181, 27:188, 27:197, 27:203, 27:213, 27:232, 27:236, 27:245-27:246N, 27:251	*18:67, 18:136, 18:194:01:01-18:194:01:02, 37:34, 40:13, 40:19 [?] , 40:109 [?] , 40:292 [?] , 40:340 [?] , 57:01:44
3⁴	120 bp	1070 bp	*27:03, 27:111, 27:139, 27:151, 27:182, 27:250	
4	200 bp	1070 bp	*27:03, 27:05:02:01- 27:05:59, 27:07:01- 27:07:06, 27:09-27:10, 27:13:01-27:14, 27:16- 27:17, 27:19:01:01- 27:19:01:02, 27:27-27:29, 27:32, 27:34-27:35, 27:37- 27:39, 27:41-27:43, 27:45- 27:52, 27:54-27:56, 27:58- 27:60, 27:64N, 27:67, 27:70-27:74, 27:76, 27:78, 27:80-27:82, 27:84-27:85, 27:87-27:88, 27:90:01- 27:90:04, 27:92-27:94N, 27:96:01-27:99, 27:101, 27:104, 27:111, 27:116- 27:118, 27:121-27:124, 27:127-27:130, 27:132- 27:133, 27:135-27:137, 27:139-27:141, 27:143- 27:146, 27:148, 27:150- 27:152, 27:155, 27:158- 27:162, 27:164,	*37:22:02, 37:95, 40:188, 44:257, 47:01:01:02-47:01:06, 47:05-47:10, 47:12



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5	400 bp	1070 bp	*27:04:01-27:04:06, 27:06:01:01-27:06:02, 27:08, 27:11-27:12:01:03, 27:15, 27:18, 27:20-27:21:02, 27:23-27:26, 27:31, 27:33, 27:36, 27:40, 27:44, 27:61, 27:63, 27:66N, 27:68-27:69, 27:79, 27:86, 27:91, 27:100, 27:103, 27:105-27:109, 27:112-27:115, 27:120, 27:125, 27:131, 27:138, 27:147, 27:149, 27:153-27:154, 27:165, 27:168, 27:173, 27:183, 27:192, 27:202, 27:204:01:01-27:204:01:02, 27:208, 27:210-27:211, 27:214, 27:222, 27:226, 27:229, 27:240, 27:242, 27:257
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6	415 bp	800 bp	*27:01-27:05:03, 27:05:05-27:05:36, 27:05:38-27:07:06, 27:09-27:11, 27:13:01-27:17, 27:19:01:01-27:21:02, 27:23-27:25, 27:27-27:32, 27:34-27:39, 27:41, 27:43, 27:45-27:88, 27:90:01-27:115, 27:117-27:152, 27:154-27:168, 27:170-27:195, 27:197-27:203, 27:205-27:214, 27:216-27:241, 27:243N-27:246N, 27:248-27:259, 27:261N-27:265	*18:09, 18:54, 18:67, 18:136, 18:194:01:01-18:195, 37:01:01:01-37:04:02, 37:06:01-37:10, 37:12-37:36, 37:38-37:57, 37:59-37:66, 37:68-37:95, 37:97-37:107, 40:13, 40:19, 40:47 [?] , 40:96 [?] , 40:109 [?] , 40:157 [?] , 40:188 [?] , 40:201 [?] , 40:292 [?] , 40:340 [?] , 44:02:59, 44:139 ^w , 47:01:01:02-47:01:02, 47:01:04-47:01:05, 47:03, 47:05-47:10, 57:01:44
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11	190 bp	1070 bp	*27:07:01-27:07:06, 27:11, 27:20, 27:24, 27:27, 27:33, 27:43, 27:125, 27:130, 27:164, 27:168, 27:180, 27:187, 27:218-27:219, 27:233, 27:251	*07:05:01:01-07:06:05, 07:32, 07:40, 07:53, 07:69, 07:78, 07:80, 07:90, 07:97, 07:105, 07:112, 07:123, 07:137-07:138, 07:140, 07:176, 07:182N, 07:201N, 07:206-07:207, 07:209-07:210, 07:213-07:214, 07:222, 07:249, 07:258, 07:262:01-07:262:02, 07:264, 07:270, 07:278, 07:283, 07:287, 07:293, 07:304, 07:317, 07:324, 07:327, 07:332-07:333, 07:340, 07:349, 07:352- 07:353, 07:356-07:357, 07:368, 07:387, 07:389, 07:395, 07:399, 07:407-07:408, 07:426Q, 07:434, 07:443, 07:474, 08:40, 08:79:01-08:79:02, 08:165, 08:171, 08:205, 13:01:01:01-13:01:02, 13:01:04-13:02:16, 13:02:18-13:02:22, 13:02:24-13:02:38, 13:07N-13:09, 13:11, 13:13:01-13:23, 13:25, 13:27-13:33, 13:36-13:45, 13:47, 13:49N-13:50, 13:52, 13:54-13:61, 13:63N- 13:71, 13:73-13:78, 13:80-13:85, 13:87- 13:119, 13:123Q-13:125, 13:128-13:130, 13:132-13:145, 13:147-13:157, 13:158 ^w , 13:159-13:163, 13:165-13:173, 13:175- 13:176, 18:189, 35:31, 35:88, 35:230, 35:534, 38:63, 39:47, 39:50, 39:174, 40:01:01-40:01:25, 40:01:27, 40:01:28 ^w , 40:01:29-40:01:31, 40:01:33-40:01:55, 40:01:57-40:02:09, 40:02:11-40:02:17, 40:02:19-40:02:38, 40:04:01:01-40:04:02, 40:06:01:01-40:06:09,



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13	425 bp 215 bp 370 bp	800 bp	*27:13:01-27:13:02 *27:47, 27:244 *27:12:01:01-27:12:01:03, 27:16, 27:92, 27:119, 27:153, 27:242 *27:53, 27:213	*18:33, 37:57, 40:75 [?] , 40:322 [?]
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16⁴	100 bp	1070 bp	*27:19:01:01-27:19:01:02, 27:30, 27:150	*37:102, 57:32
17⁴	100 bp	800 bp	*27:14, 27:81	*44:20, 44:47, 44:100, 44:197, 50:20, 51:85, 51:192, 51:214, 51:261, 51:274, 52:26
	310 bp		*27:51	
18	175 bp	800 bp	*27:24	*07:174, 07:202, 07:222, 07:279, 08:213:01-08:213:02, 40:31, 40:45, 40:80, 48:01:01:01-48:01:11, 48:04:01:01-48:04:02, 48:06-48:07, 48:09, 48:11, 48:15-48:16, 48:18-48:20, 48:22, 48:24, 48:27-48:39, 48:41-48:56, 81:01:01:01-81:10
	415 bp		*27:49	
19⁴	95 bp 240 bp	800 bp	*27:35 *27:25, 27:38, 27:47, 27:50:01-27:50:02, 27:63, 27:76, 27:139, 27:213, 27:244	*38:22 *15:129, 15:342, 15:395, 15:629
20⁴	95 bp 175 bp 215 bp	800 bp	*27:09 *27:36, 27:173 *27:25, 27:45, 27:108, 27:115, 27:161, 27:245, 27:249	*40:469, 48:21, 48:26 *07:197, 15:129, 15:342
	345 bp		*27:69, 27:192	*07:329, 13:151, 15:227, 15:630, 15:641, 18:183, 37:23, 40:213, 40:485, 42:28, 44:338, 51:32, 58:52
21⁴	110 bp	1070 bp	*27:04:01-27:04:06, 27:06:01:01-27:06:02, 27:15, 27:20, 27:21:02, 27:24-27:25, 27:66N, 27:68-27:69, 27:91, 27:100, 27:103, 27:105, 27:109, 27:112-27:115, 27:138, 27:147, 27:149, 27:165, 27:173, 27:192, 27:208, 27:210-27:211, 27:214, 27:222, 27:226, 27:229, 27:240, 27:247, 27:257, 27:262	*37:47
	160 bp		*27:39, 27:137	
22	165 bp 195 bp 235 bp	800 bp	*27:55, 27:149 *27:37 *27:15, 27:28, 27:62, 27:71, 27:249	*18:43, 40:210 [?] , 40:229, 40:399N *18:02:01-18:02:02, 18:179, A*32:89, C*07:05, C*07:538
	375 bp		*27:26, 27:31, 27:101, 27:157	*40:166 [?] , 82:01:01:01-82:04



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 101.521-24u/04u – without *Taq* polymerase

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Lot-specific information

23	235 bp	800 bp	*27:01-27:05:19, 27:05:21-27:06:02, 27:08- 27:10, 27:12:01:01- 27:13:02, 27:16-27:18, 27:20, 27:23, 27:26-27:27, 27:29, 27:31, 27:35-27:37, 27:39-27:42, 27:44-27:46, 27:48-27:61, 27:64N- 27:69, 27:72-27:75, 27:77- 27:80, 27:82-27:124, 27:126, 27:128-27:129, 27:131-27:137, 27:140- 27:149, 27:151-27:152, 27:154-27:163, 27:165- 27:179, 27:181-27:186, 27:188-27:212N, 27:214, 27:216-27:217, 27:220- 27:232, 27:234-27:243N, 27:245-27:248, 27:250, 27:252-27:265	*07:196-07:197, 18:165, 37:02, 40:225:01- 40:225:02, 40:429, 40:469, 47:04-47:05, 48:21, 48:26
24⁸	375 bp	1070 bp	*27:18, 27:29	*15:129, 15:342, 15:395, 37:02, 40:225:02, 40:429, 40:469, 47:04-47:05, 48:21, 48:26
25⁴	85 bp	1070 bp	*27:46, 27:78	A*23:23, A*24:562
26⁴	105 bp 145 bp	1070 bp	*27:52, 27:236 *27:64N	*37:60 *13:103N, 40:118N, 40:291N, A*66:39N, A*80:09N, C*02:216N
27	235 bp 215 bp 320 bp	1070 bp	*27:72 *27:104 *27:57	*37:27
28⁵	145 bp	1070 bp	*27:64N	*13:103N, 40:118N, 40:291N, A*66:39N, A*80:09N, C*02:216N
29⁴	325 bp 70 bp 105 bp 210 bp	1070 bp	*27:48 *27:54, 27:123 *27:67 *27:74	*18:162 *15:594
30^{5,6,7}	160 bp 240 bp	800 bp	*27:59N, 27:137 *27:72-27:73	
31^{4,5}	125 bp 160 bp 265 bp	1070 bp	*27:65N, 27:243N *27:56 *27:118	A*24:185N
32^{4,5}	90 bp	1070 bp	*27:32, 27:70	*07:28, 07:118, 08:14, 08:87, 15:17:01:01- 15:17:07, 15:162, 15:168, 15:177, 15:196, 15:208, 15:216, 15:230, 15:233, 15:269, 15:273, 15:339, 15:356, 15:396, 15:403, 15:411, 15:423-15:424, 15:446, 15:462, 15:500, 15:516, 15:523, 15:532, 15:546Q, 15:553, 15:555, 15:575N, 15:578, 15:603, 15:619, 15:642, 15:644, 18:166, 35:234, 40:124:02, 40:180, 40:240, 40:414, 40:498, 44:02:33, 44:41:01, 44:54, 44:65, 44:106, 44:135, 44:440, C*02:07, C*02:97, C*02:158
	370 bp		*27:85	



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Lot No.: **8R2**

Lot-specific information

33	150 bp 250 bp	1070 bp	*27:84 *27:73, 27:80	*13:130, C*02:11 *40:88
34	160 bp 265 bp	1070 bp	*27:82 *27:118	
35⁴	120 bp 280 bp	1070 bp	*27:134 *27:83	
36	190 bp 350 bp	1070 bp	*27:146 *27:94N	*37:33N
37	185 bp	1070 bp	*27:97, 27:146	*40:454
38	260 bp	1070 bp	*27:28, 27:62	*18:02:01-18:02:03, 18:179
39⁵	345 bp	1070 bp	*27:19:01:01-27:19:01:02, 27:70, 27:127	*15:43, 18:54, 18:108, 18:132, 18:195, 37:12, 37:19:01, 37:44, 37:56, 38:17, 40:188, 44:257
40⁴	95 bp	1070 bp	*27:32	*07:28, 07:118, 08:14, 08:87, 40:180, 40:414, 44:54, 44:106, 44:135
41⁴	105 bp 155 bp	1070 bp	*27:67 *27:91, 27:250	*15:594
42	140 bp	1070 bp	*27:125	*08:120, 08:205, 35:230, 38:43, 38:63, 39:136, 40:01:01-40:01:20, 40:01:22- 40:01:25, 40:01:27, 40:01:29-40:01:31, 40:01:33-40:01:80, 40:07, 40:10:01:01- 40:10:02, 40:12:01-40:12:02, 40:21-40:22N, 40:25, 40:30, 40:34, 40:36, 40:38, 40:43, 40:46-40:49, 40:54-40:55, 40:61-40:63, 40:65-40:67, 40:69, 40:72:01-40:74, 40:76- 40:77, 40:79-40:81, 40:84, 40:87:01-40:88, 40:92, 40:100-40:102, 40:106, 40:108, 40:112-40:113, 40:116-40:118N, 40:123, 40:125:01-40:126, 40:128, 40:130:01- 40:130:02, 40:132, 40:134-40:135, 40:137- 40:141, 40:146-40:147, 40:149-40:156, 40:160:01-40:160:02, 40:163, 40:166, 40:168, 40:170-40:171, 40:175, 40:178- 40:179, 40:182-40:183, 40:185-40:186:02, 40:188, 40:191-40:199, 40:204, 40:207- 40:208, 40:210, 40:212-40:213, 40:215- 40:218, 40:221-40:223, 40:227-40:228, 40:233-40:242, 40:245:01-40:245:02, 40:247, 40:249-40:253, 40:257-40:260, 40:262-40:265N, 40:272-40:273, 40:277- 40:279, 40:281-40:282, 40:285-40:288, 40:298:01-40:301, 40:308, 40:310, 40:312, 40:315-40:316, 40:319, 40:321, 40:323:01- 40:329, 40:332-40:333, 40:336, 40:338N- 40:339, 40:344, 40:346, 40:353:01:01- 40:353:02, 40:357-40:358, 40:360, 40:365, 40:367-40:368, 40:370, 40:372N, 40:377, 40:379:01:01-40:380, 40:381:02-40:383, 40:385-40:386, 40:391-40:398, 40:400- 40:404, 40:406-40:407, 40:416-40:419, 40:421Q, 40:424, 40:426N, 40:428N, 40:430-40:431, 40:433, 40:436, 40:439, 40:443, 40:446-40:448, 40:450, 40:452, 40:456, 40:461-40:463, 40:466, 40:469, 40:474-40:475:02, 40:477, 40:479-40:480,



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Lot-specific information

				40:483N, 40:485-40:486, 40:490-40:491, 40:495, 40:497, 40:499, 40:501-40:503, 40:506N-40:510N, 40:512-40:513, 40:516-40:517, 40:523-40:525, 40:528, 41:38, 44:31, 48:01:01:01-48:01:12, 48:03:01:01-48:04:02, 48:06-48:07, 48:09, 48:11, 48:14-48:16, 48:18-48:22, 48:24, 48:28-48:43:02, 48:45, 48:47-48:57, 51:181, 51:324, 51:338, 52:74, 81:01:01:01-81:10, C*07:775
43⁶	155 bp 290 bp	1070 bp	*27:68 *27:05:02:04Q	*15:201
44	225 bp 255 bp	1070 bp	*27:66N *27:01, 27:142	*13:23, 13:55, 18:09, 37:10, 40:47, 40:96, 40:157, 40:201, 44:15:01:01-44:15:01:02, 44:55, 44:103, 44:188, 44:212, 49:02, 49:70
45	290 bp 150 bp 230 bp	1070 bp	*27:58 *27:84 *27:141	*13:130, C*02:11
46	165 bp	1070 bp	*27:02:01:01 ^w -27:02:06 ^w , 27:30 ^w , 27:57 ^w , 27:62 ^w , 27:65N ^w , 27:77 ^w , 27:83 ^w , 27:89 ^w , 27:95 ^w , 27:102 ^w , 27:110 ^w , 27:126 ^w , 27:134 ^w , 27:142, 27:157 ^w , 27:163 ^w , 27:171 ^w -27:172 ^w , 27:176N ^w , 27:188 ^w , 27:197 ^w , 27:203 ^w , 27:232 ^w , 27:236 ^w , 27:245 ^w -27:246N ^w , 27:251 ^w , 27:262 ^w	*44:97, 44:206
47⁹	-	-	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-B*27 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



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101.521-24/04 – including *Taq* polymerase
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Lot No.: **8R2**

Lot-specific information

with the target sequences or not. Assumption is made that unknown sequences in these regions are conserved within allelic groups.

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

⁵Primer mixes 28, 30, 31, 32 and 39 may have tendencies of unspecific amplifications.

⁶Primer mixes 30 and 43 have a tendency to giving rise to primer oligomer formation.

⁷Primer mix 30 may give rise to a long unspecific amplification product. This band should be disregarded when interpreting the typing results.

⁸Primer mix 24 may give rise to a lower yield of HLA-specific PCR product than the other HLA-B*27 high resolution primer mixes.

⁹Primer mix 47 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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Lot No.: 8R2

Lot-specific information
PRIMER SPECIFICATION

Well No.	1	2	3	4	5	6	7	8	9	10	11	12
Length of spec. PCR product	390	405	120	200	400	415	410	95	205	90	190	210
										185		310
												425
Length of int. pos. control ¹	800	800	1070	1070	1070	800	1070	1070	1070	800	1070	1070
5'-primer(s) ²	72 5'-gCT 3'	72 5'-gCT 3'	167 5'-gCT 3'	141 5'-ATT 3'	72 5'-gCT 3'	72 5'-gCT 3'	72 5'-gCT 3'	363 5'-AAT 3'	363 5'-AAT 3'	363 5'-AAT 3'	412 5'-ATA 3'	14 5'-ggA 3'
				142 5'-TCA 3'				363 5'-AAC 3'				104 5'-CTT 3'
												385 5'-ggT 3'
3'-primer(s) ³	292 5'-gTA 3'	309 5'-ATC 3'	247 5'-ATg 3'	301 5'-gTC 3'	301 5'-gCT 3'	317 5'-ggA 3'	311 5'-ggT 3'	418 5'-gTC 3'	527 5'-CCT 3'	409 5'-ATA 3'	559 5'-CTC 3'	272 5'-TgC 3'
	292 5'-gTA 3'				302 5'-ggC 3'					419 5'-Cgg 3'		3 ^d 5'-TAT 3'
										419 5'-CgA 3'		
										505 5'-gCC 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	215	120	105	100	100	175	95	95	110	165	235	375
	370	345			310	415	240	175	160	195		
	400							215		235		
								345		375		
Length of int. pos. control ¹	800	800	1070	1070	800	800	800	800	1070	800	800	1070
5'-primer(s) ²	72 5'-gCT 3'	72 5'-gCT 3'	206 5'-AgA 3'	355 5'-TCA 3'	72 5'-gCT 3'	72 5'-gCT 3'	363 5'-AAT 3'	363 5'-AAT 3'	167 5'-gCT 3'	72 5'-gCT 3'	363 5'-AAT 3'	272 5'-CTC 3'
	363 5'-AAT 3'	409 5'-ggC 3'			357 5'-Tgg 3'	363 5'-AgC 3'		3 ^d 5'-Agg 3'	704 5'-Tgg 3'	363 5'-AAT 3'	363 5'-AAC 3'	
3'-primer(s) ³	272 5'-TgC 3'	248 5'-AAA 3'	272 5'-Tgg 3'	412 5'-gTg 3'	212 5'-gCT 3'	316 5'-gAA 3'	419 5'-CgA 3'	418 5'-gTg 3'	287 5'-TCA 3'	97 5'-gTA 3'	559 5'-CTC 3'	362 5'-TAT 3'
	301 5'-gTC 3'	486 5'-gCT 3'			418 5'-gTC 3'	499 5'-ggA 3'	559 5'-CAg 3'	499 5'-ggA 3'	288 5'-gTA 3'	280 5'-CTg 3'		
	538 5'-gTC 3'						572 5'-gCg 3'	539 5'-TCC 3'	774 5'-ggT 3'	488 5'-CCA 3'		
								872 5'-TCA 3'		559 5'-CgT 3'		
Well No.	13	14	15	16	17	18	19	20	21	22	23	24



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Lot No.: **8R2**

Lot-specific information

Well No.	25	26	27	28	29	30	31	32	33	34	35	36
Length of spec.	85	105	215	145	70	160	125	90	150	160	120	190
PCR product		145	320	325	105	240	160	370	250	265	280	350
		235			210		265					
Length of int.	1070	1070	1070	1070	1070	800	1070	1070	1070	1070	1070	1070
pos. control ¹												
5'-primer(s) ²	418	206	72	72	104	167	232	72	350	363	363	72
	5'-AgT 3'	5'-gAC 3'	5'-gCT 3'	5'-gCT 3'	5'-CTT 3'	5'-gCT 3'	5'-AgT 3'	5'-gCT 3'	5'-TCg 3'	5'-AAT 3'	5'-AAT 3'	5'-gCT 3'
		367	383	454	209	351	363	369	351			
		5'-TgA 3'	5'-ggC 3'	5'-ACT 3'	5'-ggC 3'	5'-CAA 3'	5'-AAT 3'	5'-TAC 3'	5'-CAA 3'			
		454			363	367			449			
		5'-ACT 3'			5'-AAT 3'	5'-TgA 3'			5'-CCA 3'			
3'-primer(s) ³	463	272	221	227	272	286	317	274	559	482	442	91
	5'-gCT 3'	5'-TgC 3'	5'-ACC 3'	5'-CTC 3'	5'-TgC 3'	5'-CTA 3'	5'-ggA 3'	5'-CTg 3'	5'-CTC 3'	5'-TgA 3'	5'-gAA 3'	5'-ATT 3'
		559	559	559	391	288	482	418		589	603	251
		5'-CTC 3'	5'-CTC 3'	5'-CTC 3'	5'-CCg 3'	5'-gTA 3'	5'-TgC 3'	5'-gTC 3'		5'-CTT 3'	5'-gTg 3'	5'-CCT 3'
						559	589					
						5'-CTC 3'	5'-CTT 3'					
Well No.	25	26	27	28	29	30	31	32	33	34	35	36
Well No.	37	38	39	40	41	42	43	44	45	46		
Length of spec.	185	260	345	95	105	140	155	225	150	165		
PCR product					155		290	255	230			
							290					
Length of int.	1070	1070	1070	1070	1070	1070	1070	1070	1070	1070		
pos. control ¹												
5'-primer(s) ²	72	363	302	363	160	412	341	97	368	167		
	5'-gCT 3'	5'-AAT 3'	5'-ggA 3'	5'-AgC 3'	5'-ACT 3'	5'-ATA 3'	5'-ggC 3'	5'-TCC 3'	5'-gTC 3'	5'-gCT 3'		
					209		662	363	449			
					5'-ggC 3'		5'-CCT 3'	5'-AAT 3'	5'-CCA 3'			
3'-primer(s) ³	83	583	362	418	272	512	2 nd	309	559	292		
	5'-TgC 3'	5'-gTg 3'	5'-TCC 3'	5'-gTC 3'	5'-TgC 3'	5'-CCA 3'	5'-ACC 3'	5'-gTg 3'	5'-CTC 3'	5'-gTC 3'		
	91						774	547				
	5'-ATT 3'						5'-ggT 3'	5'-gTg 3'				
								613				
								5'-gCA 3'				
Well No.	37	38	39	40	41	42	43	44	45	46		

¹The internal positive control primer pairs amplify segments of the human growth hormone gene. The internal positive control bands are 1070 or 800 base pairs respectively, well distribution as outlined in the table. Well number 1 contains the shorter, 800 bp, internal positive control band. The well distribution of the internal controls can help in orientation of the kit on gel photo, as well as allow for kit identification. In the presence of a specific amplification the intensity of the control band often decreases.

²The nucleotide position matching the specificity-determining 3'-end of the primer is given. Nucleotide numbering as on the www.ebi.ac.uk/imgt/hla web site. The sequence of the 3 terminal nucleotides of the primer is given.

³The nucleotide position matching the specificity-determining 3'-end of the primer is given in the anti-sense direction. Nucleotide numbering as on the www.ebi.ac.uk/imgt/hla web site. The sequence of the 3 terminal nucleotides of the primer is given.



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For *In Vitro* Diagnostic Use
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101.521-24/04 – including Taq polymerase
 101.521-24u/04u – without Taq polymerase

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

Lot No.: **8R2**

Lot-specific information

CELL LINE VALIDATION SHEET																				
HLA-B*27 SSP subtyping kit ²																				
				Well ³																
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	
				Prod. No.:	201783501	201783502	201783503	201783504	201783505	201783506	201783507	202022608	201783509	201783510	201783511	201783512	201783513	201783514	201783515	201783516
IHCW cell line ¹		B*																		
1	9001 SA	*07:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2	9280 LK707	*52:01	*73:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3	9011 E4181324	*52:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4	9275 GU373	*15:10	*53:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
5	9009 KAS011	*37:01		+	-	-	-	-	+	-	-	-	-	-	-	-	-	-	-	-
6	9353 SM	*39:01	*51:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
7	9020 QBL	*18:01		+	-	-	-	+	-	+	-	-	-	-	-	-	-	-	-	-
8	9025 DEU	*35:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
9	9026 YAR	*38:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
10	9107 LKT3	*54:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
11	9051 PITOUT	*44:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
12	9052 DBB	*57:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
13	9025 JESTHOM	*27:05		-	-	-	+	-	+	-	+	-	-	-	-	-	-	-	-	-
14	9071 OLGA	*15:01	*15:20	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
15	9075 DKB	*40:01		-	-	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-
16	9037 SWEIG007	*40:02		+	-	-	-	+	-	+	-	-	-	-	+	-	-	-	-	-
17	9282 CTM3953540	*08:01	*55:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
18	9257 32367	*14:01	*56:01	-	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-
19	9038 BM16	*18:01		+	-	-	-	+	-	+	-	-	-	-	-	-	-	-	-	-
20	9059 SLE005	*40:01		-	-	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-
21	9064 AMALA	*15:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
22	9056 KOSE	*35:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
23	9124 IHL	*40:02	*56:02	+	-	-	-	+	-	+	-	-	-	-	+	-	-	-	-	-
24	9035 JBUSH	*38:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
25	9049 IBW9	*14:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
26	9285 WT49	*58:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
27	9191 CH1007	*07:05	*51:01	-	-	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-
28	9320 BEL5GB	*44:02	*44:03	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
29	9050 MOU	*44:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
30	9021 RSH	*42:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
31	9019 DUCAF	*18:01		+	-	-	-	+	-	+	-	-	-	-	-	-	-	-	-	-
32	9297 HAG	*41:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
33	9098 MT14B	*40:01		-	-	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-
34	9104 DHIF	*38:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
35	9302 SSTO	*44:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
36	9024 KT17	*15:01	*35:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
37	9065 HHKB	*07:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
38	9099 LZL	*15:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
39	9315 CML	*08:01	*27:05	-	-	-	+	-	+	-	+	-	-	-	-	-	-	-	-	-
40	9134 WHONP199	*13:02	*46:01	-	-	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-
41	9055 H0301	*14:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
42	9066 TAB089	*46:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
43	9076 T7526	*46:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
44	9057 TEM	*38:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
45	9239 SHJO	*42:01	*50:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
46	9013 SCHU	*07:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
47	9045 TUBO	*51:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
48	9303 TER-ND	*35:01	*44:03	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-



0197

101.521-24/04 – including *Taq* polymerase
 101.521-24u/04u – without *Taq* polymerase

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

Lot No.: **8R2**

Lot-specific information

CELL LINE VALIDATION SHEET																				
HLA-B*27 SSP subtyping kit ²																				
				Well ³																
				17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	
				Prod. No.:	201783517	201783518	201783519	201783520	201783521	201783522	202022623	202022624	201783525	201783526	201783527	201783528	201783529	202022630	201783531	201783532
IHCW cell line ¹			B*																	
1	9001	SA	*07:02	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2	9280	LK707	*52:01	*73:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3	9011	E4181324	*52:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4	9275	GU373	*15:10	*53:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
5	9009	KAS011	*37:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
6	9353	SM	*39:01	*51:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
7	9020	QBL	*18:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
8	9025	DEU	*35:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
9	9026	YAR	*38:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
10	9107	LKT3	*54:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
11	9051	PITOUT	*44:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
12	9052	DBB	*57:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
13	9025	JESTHOM	*27:05		-	-	-	-	-	-	+	-	-	-	-	-	-	-	-	-
14	9071	OLGA	*15:01	*15:20	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
15	9075	DKB	*40:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
16	9037	SWEIG007	*40:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
17	9282	CTM3953540	*08:01	*55:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
18	9257	32367	*14:01	*56:01	-	-	-	-	-	+	-	-	-	-	-	-	-	-	-	-
19	9038	BM16	*18:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
20	9059	SLE005	*40:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
21	9064	AMALA	*15:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
22	9056	KOSE	*35:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
23	9124	IHL	*40:02	*56:02	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
24	9035	JBUSH	*38:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
25	9049	IBW9	*14:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
26	9285	WT49	*58:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
27	9191	CH1007	*07:05	*51:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
28	9320	BEL5GB	*44:02	*44:03	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
29	9050	MOU	*44:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
30	9021	RSH	*42:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
31	9019	DUCAF	*18:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
32	9297	HAG	*41:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
33	9098	MT14B	*40:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
34	9104	DHIF	*38:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
35	9302	SSTO	*44:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
36	9024	KT17	*15:01	*35:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
37	9065	HHKB	*07:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
38	9099	LZL	*15:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
39	9315	CML	*08:01	*27:05	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-	-
40	9134	WHONP199	*13:02	*46:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
41	9055	H0301	*14:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
42	9066	TAB089	*46:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
43	9076	T7526	*46:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
44	9057	TEM	*38:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
45	9239	SHJO	*42:01	*50:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
46	9013	SCHU	*07:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
47	9045	TUBO	*51:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
48	9303	TER-ND	*35:01	*44:03	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-



0197

101.521-24/04 – including *Taq* polymerase
 101.521-24u/04u – without *Taq* polymerase

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 “Instructions for Use” (IFU)

Lot No.: **8R2**

Lot-specific information

CELL LINE VALIDATION SHEET																		
HLA-B*27 SSP subtyping kit ²																		
				Well ³														
				33	34	35	36	37	38	39	40	41	42	43	44	45	46	
				Prod. No.:	202022633	201783534	201783535	201783536	201783537	201783538	201783539	201783540	201783541	201783542	201783543	201783544	202022645	201783546
IHCW cell line ¹		B*																
1	9001 SA	*07:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2	9280 LK707	*52:01	*73:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3	9011 E4181324	*52:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4	9275 GU373	*15:10	*53:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
5	9009 KAS011	*37:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
6	9353 SM	*39:01	*51:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
7	9020 QBL	*18:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
8	9025 DEU	*35:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
9	9026 YAR	*38:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
10	9107 LKT3	*54:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
11	9051 PITOUT	*44:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
12	9052 DBB	*57:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
13	9004 JESTHOM	*27:05		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
14	9071 OLGA	*15:01	*15:20	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
15	9075 DKB	*40:01		-	-	-	-	-	-	-	-	-	+	-	-	-	-	-
16	9037 SWEIG007	*40:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
17	9282 CTM3953540	*08:01	*55:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
18	9257 32367	*14:01	*56:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
19	9038 BM16	*18:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
20	9059 SLE005	*40:01		-	-	-	-	-	-	-	-	-	+	-	-	-	-	-
21	9064 AMALA	*15:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
22	9056 KOSE	*35:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
23	9124 IHL	*40:02	*56:02	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
24	9035 JBUSH	*38:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
25	9049 IBW9	*14:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
26	9285 WT49	*58:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
27	9191 CH1007	*07:05	*51:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
28	9320 BEL5GB	*44:02	*44:03	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
29	9050 MOU	*44:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
30	9021 RSH	*42:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
31	9019 DUCAF	*18:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
32	9297 HAG	*41:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
33	9098 MT14B	*40:01		-	-	-	-	-	-	-	-	-	+	-	-	-	-	-
34	9104 DHIF	*38:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
35	9302 SSTO	*44:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
36	9024 KT17	*15:01	*35:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
37	9065 HHKB	*07:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
38	9099 LZL	*15:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
39	9315 CML	*08:01	*27:05	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
40	9134 WHONP199	*13:02	*46:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
41	9055 H0301	*14:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
42	9066 TAB089	*46:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
43	9076 T7526	*46:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
44	9057 TEM	*38:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
45	9239 SHJO	*42:01	*50:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
46	9013 SCHU	*07:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
47	9045 TUBO	*51:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
48	9303 TER-ND	*35:01	*44:03	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-



0197

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

101.521-24/04 – including *Taq* polymerase
101.521-24u/04u – without *Taq* polymerase

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

Lot No.: **8R2**

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.

³The C*07:05 allele is amplified by primer mixes 10 and 22 in the 9257/32367 cell line. No DNAs carrying the alleles to be amplified by primer solutions 12, 16, 19, 25 to 31, 33 to 37, 39 to 41 and 43 to 45 were available. The specificities of the primers in primer solutions 12, 16, 19, 25 to 31, 35, 39 to 41, 43 and 44 were tested by separately adding additional 5'-primers, respectively additional 3'-primers. In primer solution 34, 36 and 37 it was only possible to test the 5'-primers, the 3'-primers were not possible to test. In primer solutions 33 and 45 it was only possible to test the 3'-primers, the 5'-primers were not possible to test. In primer solutions 10, 13, 17, 18, 20 to 22, 27 to 32, 35, 43 and 44 one or two of the 3'-primers were not possible to test. In primer solutions 8, 12, 23, 26 to 31, 41 and 43 one or two of the 5'-primers were not possible to test. Additional primers in primer solutions 4, 10, 13 to 14, 17 to 18, 20 to 22 and 32 were tested by separately adding one or two additional 5'-primers and /or one additional 3'-primer.



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

101.521-24/04 – including *Taq* polymerase
101.521-24u/04u – without *Taq* polymerase

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

Lot No.: **8R2**

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: www.caredx.com

Distributed by:

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

Tel: 1-877-653-78171

Fax: 610-344-7989

E-mail: orders-us@caredx.com

Web page: www.caredx.com

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



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For *In Vitro* Diagnostic Use

MA123 v02 SSP PI Template

Date: April 2023, Rev. No: 00