

101.571-06 – including *Taq* polymerase
101.571-06u – without *Taq* polymerase

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

Lot No.: **1R6**

Lot-specific information
Olerup SSP® HLA-B*56

Product number:	101.571-06 – including <i>Taq</i> polymerase 101.571-06u – without <i>Taq</i> polymerase
Lot number:	1R6
Expiry date:	2026-09-01
Number of tests:	6
Number of wells per test:	23+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. 1R6.

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*56 LOT (0H2)**

- The product documentation has been updated for new alleles of IMGT 3.49.0.
- The kit resolution focuses on common and well documented (CWD) alleles¹.

¹As described in section Uniquely Identified Alleles.

The HLA-B*56 specificity and interpretation tables have been updated for the HLA-B alleles described since the previous *Olerup SSP®* HLA-B*56 lot was made (**Lot No. 0H2**). The kit design is based on IMGT/HLA database 3.49.0.

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

Well	5'-primer	3'-primer	rationale
5	-	Added	3'-primer added from well 19.
19	-	Moved	3'-primer moved to well 5, for improved HLA-specific amplification.



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Well **24** 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*56 SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for identifying the B*56:01 to B*56:87 alleles.

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-B*56’ in silver/gray ink.

Well No. 1 is marked with the Lot No. ‘1R6’.

Wells 1 to 23 – HLA-B*56 high resolution primers.

Well 24 – 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 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

Due to the sharing of sequence motifs between HLA-B alleles non-HLA-B*56 alleles will be amplified by some primer mixes. For further details see Specificity Table.

UNIQUELY IDENTIFIED ALLELES

All the HLA-B*56 alleles, i.e. **B*56:01 to B*56:87**, recognized by the HLA Nomenclature Committee in July 2022^{1,2} will be amplified by the primers in the HLA-B*56 subtyping kit.

The HLA-B*56 kit enables separation of the confirmed HLA-B*56 alleles as listed in the IMGT/HLA database 3.33.0. 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*56 alleles is listed below.

The HLA-B*56 kit also enables identification of many null and alternatively expressed alleles.

The following HLA-B*56 alleles can be distinguished by the different sizes of the HLA-specific PCR product:



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Lot-specific information

Alleles	Primer mix	Alleles	Primer mix
B*56:01:01:05S, 56:45	22	B*56:18, 07:65	22
B*56:16, 56:55:01:02	18	B*56:19N, 56:29	19
B*56:17, 56:26	21		

The HLA-B*56 primer set cannot separate the following alleles. These alleles can be distinguished by the HLA-B low resolution kit and/or the respective high resolution kits:

Alleles

B*56:01:13, 13:54, 55:22, 55:41, 55:46

B*56:01:14, 54:03, 54:40

B*56:09, 56:60, 35:78

B*56:21, 51:272

B*56:23, 55:31, 55:78

B*56:42, 56:44, 50:75

B*56:50, 55:13, 55:27-55:28:01, 55:32, 55:58, 55:81

B*56:54, 55:18

B*56:67-56:68, 13:03, 13:120, 13:164, 15:552, 44:339, 46:11, 49:01:01:01-49:01:07, 49:01:09-49:01:18, 49:01:20-49:03, 49:06, 49:08-49:14, 49:16-49:17, 49:19N-49:24, 49:26-49:39, 49:41-49:46, 49:48-49:49, 49:51-49:60N, 49:62-49:75, 49:77-49:78, 50:01:01:01-50:01:01:13, 50:01:03-50:01:13, 50:01:15-50:01:20, 50:01:22-50:02:01:02, 50:05-50:08, 50:10-50:11, 50:13, 50:15, 50:18-50:19, 50:21, 50:32, 50:34-50:38, 50:40, 50:43-50:44, 50:46-50:48, 50:50, 50:52-50:59, 50:62-50:74, 50:76, 50:78-50:79, 51:15, 59:04

¹HLA-B alleles listed on the IMGT/HLA web page 2022-July-12, release 3.49.0, www.ebi.ac.uk/imgt/hla.

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



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Lot-specific information

ALLELE CONFIRMATION STATUS

Allele	Status ¹	Allele	Status ¹	Allele	Status ¹	Allele	Status ¹
B*56:01:01:01	Confirmed	B*56:04:02	Unconfirmed	B*56:22	Unconfirmed	B*56:42	Unconfirmed
B*56:01:01:02	Confirmed	B*56:05:01	Confirmed	B*56:23	Unconfirmed	B*56:43	Unconfirmed
B*56:01:01:03	Confirmed	B*56:05:02	Confirmed	B*56:24	Unconfirmed	B*56:44	Unconfirmed
B*56:01:01:04	Confirmed	B*56:06	Confirmed	B*56:25	Confirmed	B*56:45	Unconfirmed
B*56:01:01:05S	Unconfirmed	B*56:07	Confirmed	B*56:26	Confirmed	B*56:46	Unconfirmed
B*56:01:01:06	Unconfirmed	B*56:08	Unconfirmed	B*56:27	Confirmed	B*56:47	Unconfirmed
B*56:01:02	Confirmed	B*56:09	Unconfirmed	B*56:28N	Confirmed	B*56:48	Unconfirmed
B*56:01:03	Confirmed	B*56:10	Confirmed	B*56:29	Unconfirmed	B*56:49	Unconfirmed
B*56:01:04	Confirmed	B*56:11	Unconfirmed	B*56:30	Unconfirmed	B*56:50	Unconfirmed
B*56:01:05	Unconfirmed	B*56:12	Unconfirmed	B*56:31	Unconfirmed	B*56:51	Unconfirmed
B*56:01:06	Unconfirmed	B*56:13	Unconfirmed	B*56:32	Unconfirmed	B*56:52	Unconfirmed
B*56:01:07	Unconfirmed	B*56:14	Confirmed	B*56:33	Unconfirmed	B*56:53	Unconfirmed
B*56:01:08	Unconfirmed	B*56:15	Confirmed	B*56:34	Unconfirmed	B*56:54	Unconfirmed
B*56:01:09	Unconfirmed	B*56:16	Confirmed	B*56:35	Unconfirmed	B*56:55:01:01	Unconfirmed
B*56:01:10	Unconfirmed	B*56:17	Unconfirmed	B*56:36	Confirmed	B*56:55:01:02	Confirmed
B*56:01:11	Unconfirmed	B*56:18	Unconfirmed	B*56:37	Unconfirmed	B*56:56	Unconfirmed
B*56:02:01	Confirmed	B*56:19N	Unconfirmed	B*56:38N	Unconfirmed	B*56:57	Unconfirmed
B*56:02:02	Confirmed	B*56:20:01	Unconfirmed	B*56:39	Unconfirmed		
B*56:03	Confirmed	B*56:20:02	Unconfirmed	B*56:40	Unconfirmed		
B*56:04:01	Confirmed	B*56:21	Unconfirmed	B*56:41	Unconfirmed		

¹Allele status “confirmed” or “unconfirmed” as listed on the IMGT/HLA web page 2018-July-11, release 3.33.0, www.ebi.ac.uk/imgt/hla.

RESOLUTION IN HOMO- AND HETEROZYGOTES

Results file with resolution in HLA-B*56 homo- and heterozygotes is available upon request.



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SPECIFICITY TABLE

HLA-B*56 SSP subtyping

Specificities and sizes of the PCR products of the 23+1 primer mixes used for HLA-B*56 SSP subtyping

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified HLA-B*56 alleles ³	Other amplified HLA Class I alleles
1 ^{4,7}	125 bp	800 bp	*56:01:01:01-56:02:03, 56:07-56:11, 56:13-56:17, 56:19N, 56:22-56:26, 56:28N-56:30, 56:33-56:47, 56:50-56:56, 56:58-56:62, 56:64-56:70, 56:72-56:87	*07:235, 13:01:01:01-13:02:30, 13:02:32-13:04, 13:06-13:09, 13:11-13:20, 13:22:01-13:23, 13:25-13:34, 13:36-13:61, 13:63N-13:64, 13:66-13:70, 13:72-13:78, 13:80-13:107, 13:109-13:165, 13:167-13:173, 14:22, 14:37, 14:55, 14:102, 15:16:01:01-15:16:05, 15:20, 15:34:01-15:34:02, 15:42, 15:62, 15:67, 15:85-15:86, 15:95, 15:137, 15:194, 15:222, 15:242:02, 15:254, 15:303, 15:362, 15:393, 15:407-15:408, 15:485-15:486, 15:550, 15:552, 15:587, 15:599, 15:602, 15:613, 15:623, 18:22, 18:52, 18:105, 27:14, 35:01:01:01-35:01:42, 35:01:44-35:05:02, 35:05:04-35:08:15, 35:10-35:11:03, 35:13-35:15:02, 35:19-35:21, 35:23-35:30:01:02, 35:33-35:38, 35:40N-35:42:02, 35:45-35:50, 35:52, 35:54-35:58, 35:60, 35:62-35:63, 35:65Q-35:66, 35:68:01-35:72, 35:74-35:78, 35:80-35:85, 35:89-35:98, 35:100-35:101:02, 35:103-35:112:02, 35:115-35:116, 35:119-35:124, 35:126-35:134N, 35:136-35:148, 35:150:01-35:163, 35:166-35:173:02N, 35:175-35:178, 35:180-35:184, 35:186-35:195, 35:197-35:198, 35:200, 35:202-35:204, 35:206-35:207, 35:209-35:214, 35:216N-35:229, 35:231-35:232, 35:235-35:241, 35:243-35:250, 35:252-35:259, 35:261-35:264, 35:267-35:275, 35:277-35:316, 35:318-35:320, 35:322-35:330, 35:332-35:345, 35:347-35:371, 35:373-35:408, 35:410-35:413, 35:415-35:424, 35:426-35:470, 35:472-35:473, 35:477-35:483, 35:485-35:524, 35:526-35:533, 35:536-35:538, 35:540-35:546, 35:548, 35:550-35:555, 35:557-35:562, 37:101, 40:28, 44:10, 44:15:01:01-44:15:01:02, 44:18:01:01-44:18:01:02, 44:48, 44:256, 44:276, 44:339-44:340, 44:355, 44:481, 45:01:01:01-45:25, 45:28N-45:30, 46:11, 46:18, 46:33, 46:53, 46:67, 48:02:01-48:02:03, 48:25, 49:01:01:01-49:01:18, 49:01:20-49:14, 49:16-49:39, 49:41-49:60N, 49:62-49:78, 50:01:01:01-50:01:01:13, 50:01:03-50:01:13, 50:01:15-50:02:01:02, 50:05-50:19, 50:21, 50:31-50:50, 50:52-50:59, 50:62-50:79, 51:15, 51:56:01-51:56:03, 51:157, 51:158:02, 51:225, 51:300, 51:372, 53:01:01:01-53:06, 53:08:01-53:43:02, 53:45-53:61, 53:63-53:70, 54:01:01:01-54:01:05, 54:01:07-54:05N, 54:07-54:08N, 54:10, 54:12-54:36, 54:39-54:41, 54:43-54:44, 54:46,



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2	400 bp	1070 bp	*56:01:01:01-56:13, 56:15-56:32, 56:34-56:41, 56:43, 56:45-56:53, 56:55:01:02-56:66, 56:69-56:87	*07:65, 07:209, 07:271, 13:54, 27:77, 27:129, 27:157, 27:204:01:01-27:204:01:02, 35:76, 35:78, 35:561, 40:166 [?] , 40:492, 44:90, 44:356, 44:453, 51:272, 54:01:01:01-54:06, 54:08N-54:23, 54:25-54:46, 55:01:01:01-55:05, 55:07-55:17, 55:19-55:33, 55:35-55:46, 55:48-55:63, 55:65-55:117N, 55:119-55:120, 55:122-55:129, 81:01:01:01-81:01:05, 81:03 [?] -81:04N [?] , 81:06 [?] -81:08 [?] , 81:09-81:10, 82:01:01:01-82:04, 83:01
3	180 bp	1070 bp	*56:01:01:01-56:01:12, 56:01:14-56:02:03, 56:04:01:01-56:04:04, 56:07-56:08, 56:13-56:14, 56:16-56:17, 56:19N-56:20:02, 56:24-56:30, 56:33-56:49, 56:51-56:53, 56:55:01:02-56:59, 56:61-56:65, 56:67-56:87	*13:03, 13:48, 13:120, 13:146, 13:164, 15:73:01:01-15:73:01:02, 15:303, 15:486, 15:552, 35:432, 35:446, 35:545, 40:71, 44:10, 44:15:01:01-44:15:01:02, 44:18:01:01-44:18:01:02, 44:140, 44:339-44:340, 44:355, 45:01:01:01-45:01:12, 45:04-45:07, 45:11-45:23, 45:24 ^w , 45:25, 45:27-45:28N, 45:30, 46:11, 49:01:01:01-49:01:07, 49:01:09-49:03, 49:06, 49:08-49:14, 49:16-49:17, 49:19N-49:49, 49:51-49:60N, 49:62-49:75, 49:77-49:78, 50:01:01:01-50:02:01:02, 50:04:01-50:08, 50:10-50:13, 50:15-50:19, 50:21, 50:32, 50:34-50:38, 50:40-50:44, 50:46-50:48, 50:50-50:79, 51:15, 51:62, 51:106:01-51:106:02, 51:223, 51:225, 52:25:01-52:25:02, 54:03, 54:33, 54:40, 58:73, 59:04, 59:12, 82:01:01:01-82:04, C*03:19^w, C*03:102^w
4⁴	105 bp	800 bp	*56:02:01:01-56:02:03, 56:04:01:01-56:04:04, 56:10, 56:51, 56:56-56:57, 56:63, 56:66	*07:182N, 07:424, 13:11, 15:18:03, 15:73:01:01-15:73:01:02, 15:86, 15:224, 15:486, 18:191, 39:17, 40:48, 40:71, 40:377, 49:47:01-49:47:02, 50:51, 51:62, 54:38, 82:01:01:01-82:04, C*01:90, C*01:136, C*01:145:01N, C*02:06:01-02:06:02, C*02:47, C*05:132, C*06:168, C*06:224, C*07:289, C*07:536, C*07:725, C*08:207, C*12:03:66, C*12:15, C*12:208, C*15:37, C*15:58, C*15:72
5	175 bp 285 bp	1070 bp	*56:40 *56:03	*13:125, 18:163, 35:559, 40:10:02, 54:01:02, 54:01:09, 55:35
	390 bp		*56:08, 56:14	
6^{4,8}	105 bp	800 bp	*56:05:01	*07:206, 08:26:03, 08:56:03, 18:125, 27:05:18:01-27:05:18:02, 39:63, 51:267
	150 bp		*56:32	*07:09:01 ^w -07:09:02 ^w , 07:11 ^w , 07:162 ^w , 07:237 ^w , 07:255 ^w , 15:03:01:01-15:03:13,



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16	165 bp	800 bp	*56:36	*07:177, 08:87, 08:255, 15:578, 27:127, 27:157, 40:166, 44:02:01:01-44:02:77, 44:06, 44:08-44:09, 44:11-44:12, 44:16, 44:19N-44:24, 44:27:01:01-44:27:04, 44:33-44:34:02, 44:41:01-44:41:02, 44:44, 44:48-44:49, 44:52N-44:53:02, 44:55, 44:59:01-44:59:02, 44:63, 44:66-44:68, 44:71-44:74, 44:80, 44:83-44:84:02, 44:86-44:87, 44:89-44:91, 44:93, 44:95, 44:97, 44:99-44:102, 44:104, 44:106, 44:112-44:113, 44:116, 44:118-44:119, 44:121, 44:126:01-44:127, 44:131-44:132, 44:137-44:138Q, 44:142, 44:145, 44:148-44:149N, 44:151-44:152, 44:162, 44:168-44:173, 44:176-44:177, 44:179, 44:185, 44:187, 44:190-44:191, 44:195N-44:196, 44:200-44:201, 44:206, 44:208, 44:211-44:212, 44:214, 44:216, 44:218-44:221, 44:225, 44:229, 44:235, 44:238, 44:240-44:244, 44:249, 44:253-44:255, 44:257, 44:260-44:262, 44:265, 44:267N, 44:269-44:270:02, 44:273-44:274, 44:279, 44:287, 44:289, 44:291-44:293, 44:296-44:297, 44:301, 44:303N, 44:306N, 44:311-44:315, 44:320-44:322, 44:326-44:327, 44:329, 44:331, 44:334N-44:335, 44:337-44:338, 44:341N-44:344, 44:350-44:351, 44:353, 44:356-44:357, 44:437, 44:439, 44:441-44:442, 44:445-44:446, 44:448N-44:449N, 44:451-44:453, 44:455, 44:457, 44:461-44:464:01:02, 44:467-44:468, 44:470, 44:473, 44:477-44:480Q, 44:482, 44:484, 44:492, 44:494-44:495, 44:497-44:499, 44:502-44:503, 44:505, 44:515, 44:517-44:518, 44:520-44:521, 44:523N, 44:526, 44:528, 44:532, 44:534-44:535, 44:537, 44:540, 44:543-44:544N, 45:06, 51:274, 83:01
17^{4,6}	80 bp 180 bp	1070 bp	*56:38N *56:05:01-56:06, 56:15, 56:21	*07:20, 07:24, 07:60, 07:100, 07:131, 07:220, 07:223, 07:358, 07:464, 08:21, 08:25, 08:175, 13:62, 13:86, 15:09:01-15:10:08, 15:30:01:01-15:30:01:03, 15:37, 15:45, 15:48, 15:63, 15:90, 15:99, 15:150, 15:243, 15:248, 15:287, 15:312-15:313, 15:324, 15:329, 15:338, 15:361, 15:427, 15:435, 15:439, 15:445, 15:455, 15:503, 15:506, 15:530, 15:541, 15:563, 15:611, 15:620, 27:76, 27:153, 35:02:01:01-35:02:19, 35:04:01:01-35:04:03, 35:09:01:01-35:09:04, 35:12:01:01-35:12:04, 35:18, 35:22:01:01-35:22:01:02, 35:34, 35:39, 35:44, 35:81, 35:83, 35:95, 35:129N, 35:149, 35:154, 35:162, 35:172, 35:182-35:184, 35:199, 35:201, 35:211, 35:220, 35:233, 35:251:01-35:251:02, 35:258, 35:266, 35:270, 35:273, 35:285, 35:292, 35:309, 35:311, 35:316, 35:321, 35:323:01-35:323:02, 35:335, 35:339, 35:357, 35:361, 35:366-35:367, 35:372, 35:374, 35:377-35:379, 35:384, 35:387, 35:391, 35:396, 35:403, 35:407, 35:410, 35:419, 35:425, 35:443, 35:463, 35:474, 35:477, 35:483, 35:487, 35:492, 35:501, 35:505, 35:508N, 35:522, 35:535, 35:539, 35:550, 35:553, 35:555,



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101.571-06 – including *Taq* polymerase
101.571-06u – without *Taq* polymerase

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				35:557, 35:562, 40:05:01:01-40:05:02, 40:26, 40:28, 40:63, 40:92, 40:174, 40:324, 40:343, 40:496, 41:17, 41:62, 44:62, 44:77, 44:82, 44:107, 44:123, 44:184, 44:213, 44:459, 45:29, 46:74, 46:81, 49:18:01-49:18:02, 50:14, 51:01:01:01-51:01:14, 51:01:16-51:01:31, 51:01:33-51:01:38, 51:01:40-51:01:58, 51:01:60-51:09:03, 51:11N-51:12, 51:18-51:20, 51:22-51:24:05, 51:26-51:30, 51:32-51:33, 51:35, 51:38-51:41N, 51:43-51:44N, 51:46, 51:48-51:61:02, 51:64-51:80, 51:83-51:84, 51:86-51:91, 51:94-51:96, 51:98N-51:100, 51:102-51:105, 51:107-51:142, 51:145-51:152, 51:154-51:156, 51:158:01-51:171, 51:173Q-51:181, 51:183-51:191, 51:193:01-51:196, 51:198-51:213, 51:215, 51:217-51:219, 51:221-51:222, 51:224, 51:226, 51:228-51:250, 51:252-51:260, 51:262-51:273N, 51:275-51:279, 51:282-51:294, 51:296-51:297, 51:299, 51:301-51:318N, 51:320-51:339, 51:341-51:351, 51:353-51:358, 51:360-51:374, 52:01:01:01-52:01:20, 52:01:22-52:07:02, 52:09:01-52:13, 52:15-52:24, 52:27-52:36, 52:38, 52:40-52:61, 52:64-52:66, 52:68-52:70, 52:72-52:74, 52:76-52:83, 52:85-52:87, 52:89N-52:96N, 52:98-52:109, 53:19, 53:36, 53:42, 55:08, 55:51, 57:02:01:01-57:03:05, 57:05, 57:07, 57:09, 57:12, 57:17, 57:28N, 57:39, 57:42, 57:46, 57:57, 57:63, 57:66, 57:70, 57:80, 57:82, 57:84, 57:94, 57:96, 57:101, 57:124, 57:137, 57:155, 58:08:01-58:08:02, 58:28:01-58:28:02, 58:65, 78:01:01:02-78:06, 78:09-78:10, C*03:81, C*03:152, C*03:317, C*03:382, C*03:388, C*03:526
18^{4,5}	65 bp 295 bp	800 bp	*56:55:01:02 *56:16	*38:02:08, 38:167, 40:149, 41:22, 49:25, 50:77, 54:21, 55:10, 57:58, 57:80, 67:06 [?] -67:07 [?] , 82:01:01:01-82:04
19⁴	405 bp 75 bp 185 bp	800 bp	*56:28N *56:29 *56:19N	*07:176, 07:438 *39:40:01N-39:40:02N
20⁶	215 bp	1070 bp	*56:01:14	*07:02:19, 08:01:67, 15:01:04, 15:01:43, 15:12:03, 18:01:20, 18:72:02, 37:01:04, 40:94, 46:77, 51:01:18, 54:01:01:01-54:01:01:08, 54:01:03-54:46, 55:02:07, 58:01:08
21^{4,6}	115 bp	800 bp	*56:17, 56:23, 56:42, 56:44, 56:54	*07:16, 07:37:01-07:37:02, 07:50, 07:75:01:01-07:75:01:02, 07:91, 07:207, 07:228:01-07:228:02, 07:306, 08:23, 08:54:01-08:54:02, 08:110, 08:265, 08:295, 14:14, 14:18, 14:73, 15:03:01:01-15:03:09, 15:03:11-15:03:13, 15:09:01-15:10:08, 15:18:01:01-15:18:10, 15:29:01:01-15:29:01:02, 15:37, 15:47:01-15:47:02, 15:49, 15:51-15:52, 15:54, 15:62, 15:64:01-15:64:02, 15:68-15:69, 15:72, 15:74, 15:80, 15:90-15:91, 15:93, 15:98-15:99, 15:103, 15:108, 15:114, 15:123-15:124, 15:127, 15:131-15:134, 15:151, 15:153, 15:156, 15:158, 15:161, 15:173, 15:176, 15:186, 15:197:01-15:198, 15:200, 15:210, 15:220:01:01-15:221, 15:226N,



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	170 bp		*56:26	
22⁴	105 bp 175 bp	800 bp	*56:06, 56:45 *56:18, 56:31-56:32, 56:36	*07:65, 07:134, 35:76, 35:561 *07:177, 08:37, 08:89, 08:107, 08:291, 14:56, 15:50, 15:69, 15:93, 15:186, 15:199, 15:348, 15:368, 15:449, 15:494, 15:497, 18:01:01:01-18:01:13, 18:01:15-18:01:17, 18:01:19-18:09, 18:11-18:15, 18:17N-18:19, 18:22-18:25, 18:27-18:34, 18:37:01-18:40, 18:42-18:49, 18:51-18:55, 18:59-18:60, 18:62-18:85, 18:87-18:96, 18:98:01-18:100, 18:102-18:105, 18:107-18:121, 18:123-18:147, 18:149-18:163, 18:167, 18:170-18:188, 18:190, 18:192-18:198, 18:200-18:204, 18:206-18:212, 18:214-18:216, 18:218-18:224, 27:157, 35:35, 35:93, 35:188, 35:190, 35:262, 35:277, 35:343, 37:35, 37:56, 38:52, 38:88, 39:07, 39:43, 39:91, 40:166, 41:51, 42:09, 44:90, 44:356, 45:06, 46:03, 46:21:01-46:21:02, 46:29, 46:83, 53:69, 54:09, 54:14, 55:14, 55:23, 55:68, 57:26, 58:05, 58:35, 58:76, 58:84, C*01:102, C*05:215, C*06:89, C*07:123:01-07:123:02, C*07:173, C*07:294, C*08:113, C*12:113, C*15:09:01:01-15:09:02, C*15:19, C*15:27, C*15:61, C*15:107, C*15:126, C*15:143, C*15:194, C*16:20, C*16:109
	270 bp		*56:01:01:05S	
23⁴	85 bp	1070 bp	*56:20:01-56:20:02	*07:78, 13:166, 40:48, 40:377, 45:27, 49:40, 50:60, C*01:90, C*07:536, C*08:207, C*15:91, C*15:128
	350 bp		*56:24	
24⁹			Negative Control	



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Lot-specific information

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*56 high resolution SSP typings. When the primers in a primer mix can give rise to HLA-specific PCR products of more than one length this is indicated if the size difference is more than 20 base pairs. Size differences of 20 base pairs or less are not given. For high resolution SSP kits, the alleles listed are specified according to amplicon length.

Nonspecific amplifications, i.e. a ladder or a smear of bands, may sometimes be seen. GC-rich primers have a higher tendency of giving rise to nonspecific amplifications than other primers.

PCR fragments longer than the control bands may sometimes be observed. Such bands should be disregarded and do not influence the interpretation of the SSP typings.

PCR fragments migrating faster than the control bands, but slower than a 400 bp fragment may be seen in some gel read-outs. Such bands can be disregarded and do not influence the interpretation of the SSP typings.

Some primers may give rise to primer oligomer artifacts. Sometimes this phenomenon is an inherent feature of the primer pair(s) of a primer mix. More often it is due to other factors such as too low amount of DNA in the PCR reactions, taking too long time in setting up the PCR reactions, working at elevated room temperature or using thermal cyclers that are not pre-heated.

²The internal positive control primer pairs amplify segments of the human growth hormone gene. The internal positive control bands are 1070 or 800 base pairs respectively, well distribution as outlined in the table. Well number 1 contains the shorter, 800 bp, internal positive control band. The well distribution of the internal controls can help in orientation of the kit on gel photo, as well as allow for kit identification. In the presence of a specific amplification the intensity of the control band often decreases.

³For several HLA Class I alleles 1st and/or 4th exon(s) and beyond, as well as intron nucleotide sequences, are not available. In these instances it is not known whether some of the primers of the SSP sets are completely matched with the target sequences or not. Assumption is made that unknown sequences in these regions are conserved within allelic groups.

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

⁵Primer mix 7 and 18 may give rise to a lower yield of HLA-specific PCR product than the other B*56 primer mixes.

⁶Primer mixes 8, 10, 13, 17, 20 and 21 may have tendencies of unspecific amplifications.

⁷Primer mixes 1, 9, 13 and 14 have a tendency to giving rise to primer oligomer formation.

⁸Primer mix 6 may give rise to a long unspecific amplification product of approx. 670 bp in some HLA-B alleles. This band should be disregarded in the interpretation of HLA-B*56 typings.

⁹Primer mix 24 contains a negative control, which will amplify the majority of the 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.

'w', may be weakly amplified.

'?', nucleotide sequence information not available for the primer matching sequence.



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Lot-specific information

PRIMER SPECIFICATION

Well No.	1	2	3	4	5	6	7	8	9	10	11	12
Length of spec. PCR product	125	400	180	105	175	105	120	380	145	150	105	150
					285	150	170		205			180
					390							
Length of int. pos. control ¹	800	1070	1070	800	1070	800	800	1070	800	800	800	800
5'-primer(s) ²	379	41	420	355	48	141	142	317	206	355	357	420
	5'-ACC 3'	5'-CTg 3'	5'-TTA 3'	5'-CCC 3'	5'-gCC 3'	5'-ATT 3'	5'-TCg 3'	5'-gCT 3'	5'-AgA 3'	5'-TCA 3'	5'-Tgg 3'	5'-TTA 3'
			420		874	419	357		419			
			5'-CTA 3'		5'-CgC 3'	5'-gTC 3'	5'-Tgg 3'		5'-gTC 3'			
3'-primer(s) ³	463	272	559	420	165	204	272	412	309	463	420	527
	5'-gCT 3'	5'-TgT 3'	5'-CAg 3'	5'-gCT 3'	5'-Tgg 3'	5'-TCT 3'	5'-TgC 3'	5'-gTT 3'	5'-gTg 3'	5'-gCT 3'	5'-gCT 3'	5'-CCT 3'
	463	277	564		269	527	435		583			559
	5'-gCT 3'	5'-ggC 3'	5'-ACT 3'		5'-ACT 3'	5'-CCT 3'	5'-TCT 3'		5'-gTg 3'			5'-CgT 3'
					916							
					5'-gAT 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
Length of spec. PCR product	70	80	160	165	80	65	75	215	115	105	85
	180		385		180	295	185		170	175	350
						405				270	
Length of int. pos. control ¹	1070	800	1070	800	1070	800	800	1070	800	800	1070
5'-primer(s) ²	420	379	41	144	166	15	206	1 st I	206	144	420
	5'-TTC 3'	5'-ACg 3'	5'-CTg 3'	5'-ACC 3'	5'-CgT 3'	5'-gCA 3'	5'-AgA 3'	5'-CAg 3'	5'-AgA 3'	5'-ACC 3'	5'-TTA 3'
	420		420	418	419	1049	419			206	701
	5'-TTC 3'		5'-TTA 3'	5'-Agg 3'	5'-gTA 3'	5'-C 3'	5'-gTT 3'			5'-gAC 3'	5'-CCT 3'
	530									419	
	5'-ggT 3'									5'-gTC 3'	
										756	
										5'-ACT 3'	
3'-primer(s) ³	559	420	252	272	204	142	239	175	277	272	463
	5'-CAg 3'	5'-gCT 3'	5'-TCT 3'	5'-TgT 3'	5'-TCT 3'	5'-TgA 3'	5'-gCT 3'	5'-CCg 3'	5'-ggC 3'	5'-TgT 3'	5'-gCg 3'
			269	538	559	252	564		292	559	916
			5'-ACT 3'	5'-gTC 3'	5'-CAg 3'	5'-TCT 3'	5'-ACT 3'		5'-gTA 3'	5'-CgT 3'	5'-gAT 3'
			538			1075			335	4 th I	
			5'-gTC 3'			5'-CAT 3'			5'-CgT 3'	5'-gCT 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.



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MA123 v02 SSP PI Template
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101.571-06u – without *Taq* polymerase

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Lot No.: **1R6**

Lot-specific information

CELL LINE VALIDATION SHEET																				
HLA-B*56 SSP subtyping kit ²																				
				Well																
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	
				Prod. No.:	202242401	202242402	202242403	202242404	202242405	202242406	202242407	202242408	202242409	202242410	202242411	202242412	202242413	202242414	202242415	202242416
	IHWC 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	W	+	+	+	-	-	-	-	-	-	-	-	-	-	-	-
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	+	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-



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101.571-06 – including *Taq* polymerase
101.571-06u – without *Taq* polymerase

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“Instructions for Use” (IFU)

Lot No.: **1R6**

Lot-specific information

CELL LINE VALIDATION SHEET											
HLA-B*56 SSP subtyping kit ²											
				Well							
				17	18	19	20	21	22	23	
				Prod. No.:	202242417	202242418	202242419	202242420	202242421	202242422	202242423
IHC 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	-	-	-	-	-	-	



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For *In Vitro* Diagnostic Use
MA123 v02 SSP PI Template
Date: September 2022, Rev. No: 00

101.571-06 – including *Taq* polymerase
101.571-06u – without *Taq* polymeraseVisit www.caredx.com for
“Instructions for Use” (IFU)**Lot No.: 1R6****Lot-specific information**

¹The provided cell line HLA specificities are retrieved from the <http://www.ihwg.org/hla> web site. The specificity of an individual cell line may thus be subject to change.

²The specificity of each primer solution in the kit has been tested against 48 well characterized cell line DNAs and where applicable, additional cell line DNAs.

No DNAs carrying the alleles to be amplified by primer solutions 19 and 23 were available. The specificities of the primers in primer solution 23 was tested by separately adding additional 5'-primers, respectively additional 3'-primers. In primer solution 19, it was only possible to test the 5'-primers, the 3'-primers were not possible to test. In primer solutions 1 to 3, 15, 18, 21 and 22 one or two 3'-primers were not possible to test, and in primer solutions 3, 5, 13, 17 and 23 one 5'-primer was not possible to test. Additional 5'-primers and 3'-primers in primer solutions 5, 6, 15 to 18 and 22 were tested by separately adding 5'-primers and/or 3'-primers.

**0197**For *In Vitro* Diagnostic Use
MA123 v02 SSP PI Template
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101.571-06 – including *Taq* polymerase
101.571-06u – without *Taq* polymerase

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

Lot No.: **1R6**

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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