

101.127-12/04 – including *Taq* polymerase
 101.127-12u/04u – without *Taq* polymerase

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

Lot No.: **4R9**

Lot-specific information

Olerup SSP[®] DRB1*08

Product number:	101.127-12/04 – including <i>Taq</i> pol. 101.127-12u/04u – without <i>Taq</i> pol.
Lot number:	4R9
Expiry date:	2026-12-01
Number of tests:	12 tests – Product No. 101.127-12/12u 4 tests – Product No. 101.127-04/04u
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. 4R9.

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

CHANGES COMPARED TO THE PREVIOUS OLERUP SSP[®] DRB1*08 LOT (6L6)

- The product documentation has been updated for new alleles of IMGT 3.50.0.
- The kit resolution focuses on common and well documented (CWD) alleles¹.

¹As described in section Uniquely Identified Alleles.

The DRB1*08 primer set, specificity and interpretation tables have been updated for the DRB1 alleles described since the previous *Olerup SSP[®]* DRB1*08 lot was made (**Lot No. 6L6**).

The DRB1*08 primer set is unchanged compared to the previous *Olerup SSP[®]* DRB1*08 (**Lot No. 6L6**).

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

Changes in Revision R01 compared to R00:

1. Primer mix 21 amplifies the DRB1*11:03:01-11:03:04, 11:11:01, 11:11:03, 11:40-11:41, 11:59, 11:63:01-11:63:02, 11:76, 11:85, 11:122, 11:138-11:139, 11:151, 11:161, 11:168, 11:176, 11:213, 11:231, 11:233, 11:237, 11:241, 11:260 and 11:301N and the DRB1*13:24:01:01-13:24:01:03, 13:54, 13:63, 13:75, 13:111, 13:247 and 13:307 alleles. This has been corrected in the Specificity and Interpretation Tables.



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

HLA-specific PCR product sizes range from 75 to 200 base pairs.
 The PCR product generated by the positive control primer pair is 200 base pairs.

Length of PCR product	105	200	105	80	75	80	85
5'-primer¹	164	340	440	45	45	43	36
	5'-CAC ^{3'}	5'-Agg ^{3'}	5'-TTA ^{3'}	5'-Tgg ^{3'}	5'-Tgg ^{3'}	5'-Tgg ^{3'}	5'-TAC ^{3'}
							36
							5'-TAT ^{3'}
3'-primer²	231	2nd I	507	59	58	57	47
	5'-TgC ^{3'}	5'-AAA ^{3'}	5'-TTg ^{3'}	5'-CTC ^{3'}	5'-ggC ^{3'}	5'-CTC ^{3'}	5'-ACA ^{3'}
							48
							5'-gCA ^{3'}
							48
							5'-gCC ^{3'}
							52
							5'-TgT ^{3'}
A*	+	+	+				
B*	+	+	+				
C*	+	+	+				
DRB1				+	+		
DRB3				+	+		
DRB5				+			
DQB1					+		
DPB1						+	
DQA1							+

¹The nucleotide position for HLA class I genes and the codon for HLA class II genes, in the 2nd or 3rd exon, matching the specificity-determining 3'-end of the primer is given. Nucleotide and codon numbering as on the www.ebi.ac.uk/imgt/hla web site. The sequence of the 3 terminal nucleotides of the primer is given.

²The nucleotide position for HLA class I genes and the codon for HLA class II genes, in the 2nd or 3rd exon or the 2nd intron, matching the specificity-determining 3'-end of the primer is given in the anti-sense direction. Nucleotide and codon numbering as on the www.ebi.ac.uk/imgt/hla web site. The sequence of the 3 terminal nucleotides of the primer is given.



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PRODUCT DESCRIPTION

DRB1*08 SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for identifying the DRB1*08:01 to DRB1*08:117 alleles.

PLATE LAYOUT

Each test consists of 24 PCR reactions in a 24 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	NC

The 24 well cut PCR plate is marked with ‘DRB1*08’ in silver/gray ink.

Well No. 1 is marked with the Lot No. ‘4R9’.

Wells 1 to 23 – DRB1*08 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 DRB1 alleles, non-DRB1*08 alleles will be amplified by some primer mixes. For further details see Specificity Table.

UNIQUELY IDENTIFIED ALLELES

All the phenotypically different DRB1*08 alleles, i.e. **DRB1*08:01 to DRB1*08:117**, recognized by the HLA Nomenclature Committee in October 2022^{1,2} will be amplified by the primers in the DRB1*08 subtyping kit.

The DRB1*08 kit enables separation of the confirmed DRB1*08 alleles as listed in the IMGT/HLA database 3.31.0. 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 DRB1*08 alleles is listed below.

The DRB1*08 kit also enables identification of many null and alternatively expressed alleles.



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¹DRB1 alleles listed on the IMGT/HLA web page 2022-October-12, release 3.50.0, 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>.

ALLELE CONFIRMATION STATUS

Allele	Status ¹	Allele	Status ¹	Allele	Status ¹	Allele	Status ¹
DRB1*08:01:01	Confirmed	DRB1*08:11	Confirmed	DRB1*08:37	Unconfirmed	DRB1*08:66	Unconfirmed
DRB1*08:01:02	Unconfirmed	DRB1*08:12	Confirmed	DRB1*08:38	Unconfirmed	DRB1*08:67	Unconfirmed
DRB1*08:01:04	Confirmed	DRB1*08:13	Confirmed	DRB1*08:39	Unconfirmed	DRB1*08:68:01	Unconfirmed
DRB1*08:01:05	Unconfirmed	DRB1*08:14	Confirmed	DRB1*08:40	Unconfirmed	DRB1*08:68:02	Unconfirmed
DRB1*08:01:06	Unconfirmed	DRB1*08:15	Confirmed	DRB1*08:41	Unconfirmed	DRB1*08:69	Unconfirmed
DRB1*08:02:01:01	Confirmed	DRB1*08:16	Confirmed	DRB1*08:42	Unconfirmed	DRB1*08:70	Unconfirmed
DRB1*08:02:01:02	Unconfirmed	DRB1*08:17	Confirmed	DRB1*08:43	Confirmed	DRB1*08:71	Unconfirmed
DRB1*08:02:02	Confirmed	DRB1*08:18	Confirmed	DRB1*08:44	Confirmed	DRB1*08:72	Unconfirmed
DRB1*08:02:03	Unconfirmed	DRB1*08:19	Confirmed	DRB1*08:45:01	Confirmed	DRB1*08:73	Unconfirmed
DRB1*08:02:04	Unconfirmed	DRB1*08:20	Confirmed	DRB1*08:45:02	Unconfirmed	DRB1*08:74	Unconfirmed
DRB1*08:03:02:01	Confirmed	DRB1*08:21	Unconfirmed	DRB1*08:46	Unconfirmed	DRB1*08:75	Unconfirmed
DRB1*08:03:02:02	Unconfirmed	DRB1*08:22	Confirmed	DRB1*08:47	Unconfirmed	DRB1*08:76	Unconfirmed
DRB1*08:03:03	Confirmed	DRB1*08:23	Unconfirmed	DRB1*08:48	Unconfirmed	DRB1*08:77	Unconfirmed
DRB1*08:03:04	Unconfirmed	DRB1*08:24:01	Unconfirmed	DRB1*08:49	Confirmed	DRB1*08:78N	Unconfirmed
DRB1*08:03:05	Unconfirmed	DRB1*08:24:02	Unconfirmed	DRB1*08:50	Unconfirmed	DRB1*08:79	Unconfirmed
DRB1*08:03:06	Unconfirmed	DRB1*08:25	Unconfirmed	DRB1*08:51	Unconfirmed	DRB1*08:80	Unconfirmed
DRB1*08:03:07	Unconfirmed	DRB1*08:26	Unconfirmed	DRB1*08:52	Confirmed	DRB1*08:81	Unconfirmed
DRB1*08:04:01	Confirmed	DRB1*08:27	Unconfirmed	DRB1*08:53	Unconfirmed	DRB1*08:82	Unconfirmed
DRB1*08:04:02	Confirmed	DRB1*08:28	Unconfirmed	DRB1*08:54	Unconfirmed		
DRB1*08:04:03	Unconfirmed	DRB1*08:29	Unconfirmed	DRB1*08:55	Unconfirmed		
DRB1*08:04:04	Unconfirmed	DRB1*08:30:01	Unconfirmed	DRB1*08:56	Unconfirmed		
DRB1*08:04:05	Confirmed	DRB1*08:30:02	Unconfirmed	DRB1*08:57	Unconfirmed		
DRB1*08:04:06	Confirmed	DRB1*08:30:03	Confirmed	DRB1*08:58	Unconfirmed		
DRB1*08:04:07	Unconfirmed	DRB1*08:31	Unconfirmed	DRB1*08:59	Unconfirmed		
DRB1*08:05	Confirmed	DRB1*08:32	Confirmed	DRB1*08:60N	Unconfirmed		
DRB1*08:06	Confirmed	DRB1*08:33	Unconfirmed	DRB1*08:61	Unconfirmed		
DRB1*08:07	Confirmed	DRB1*08:34	Unconfirmed	DRB1*08:62	Unconfirmed		
DRB1*08:08	Confirmed	DRB1*08:35	Confirmed	DRB1*08:63	Confirmed		
DRB1*08:09	Confirmed	DRB1*08:36:01	Unconfirmed	DRB1*08:64	Unconfirmed		
DRB1*08:10	Confirmed	DRB1*08:36:02	Unconfirmed	DRB1*08:65	Unconfirmed		

¹Allele status “confirmed” or “unconfirmed” as listed on the IMGT/HLA web page 2018-January-19, release 3.31.0, www.ebi.ac.uk/imgt/hla.

RESOLUTION IN HOMO- AND HETEROZYGOTES

Results file with resolution in DRB1*08 homo- and heterozygotes is available upon request.



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SPECIFICITY TABLE

DRB1*08 SSP subtyping

Specificities and sizes of the PCR products of the 23+1 primer mixes used for
 DRB1*08 SSP subtyping

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified DRB1*08 alleles ³	Other amplified DRB1 alleles
1	165 bp	515 bp	*08:01:01:01-08:01:02, 08:01:04-08:01:07, 08:03:02:01-08:03:14, 08:05-08:06:01:02, 08:10, 08:12, 08:14, 08:16-08:18, 08:22-08:23, 08:26-08:27, 08:29, 08:32-08:33, 08:35-08:40, 08:43, 08:46-08:51, 08:53-08:56, 08:58, 08:60N-08:62, 08:64-08:66, 08:68:01-08:71, 08:74, 08:76-08:79, 08:86-08:88, 08:90-08:93, 08:95-08:97, 08:100, 08:102, 08:104-08:105, 08:107-08:112, 08:114-08:117	*12:46
2 ⁵	170 bp	430 bp	*08:02:01:01-08:02:05, 08:04:01:01-08:04:07, 08:09:01-08:09:02, 08:13, 08:21, 08:24:01-08:24:02, 08:28, 08:30:01-08:30:03, 08:42, 08:44-08:45:02, 08:59, 08:67, 08:72-08:73, 08:81-08:85, 08:89N, 08:94, 08:98-08:99, 08:101, 08:103, 08:106	*03:92, 12:09, 12:48 ^w , 12:62, 12:76, 13:17, 13:116, 13:175, 13:214, 14:15, 14:52, 14:126:01-14:126:02, 14:175
3 ⁶	195 bp	430 bp	*08:01:01:01-08:01:02, 08:01:04-08:02:05, 08:04:01:01-08:09:02, 08:11:01:01-08:11:01:02, 08:16-08:17, 08:21-08:22, 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, 08:93-08:94, 08:96, 08:98-08:101, 08:103, 08:105-08:109, 08:111-08:114, 08:116-08:117	*11:05, 11:67, 11:193:01-11:193:02, 11:209, 12:02:01:01-12:02:13, 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, 12:55-12:56, 12:60N-12:61, 12:64-12:65, 12:67, 12:69, 12:71, 12:74N-12:76, 12:78, 12:80-12:81, 12:85, 12:92-12:94, 12:97-12:98N, 12:100, 14:15, 14:73
4	195 bp	430 bp	*08:03:02:01-08:03:14, 08:10, 08:12, 08:14-08:15, 08:18-08:19, 08:23, 08:25, 08:27, 08:29-08:30:03, 08:32-08:38, 08:40, 08:45:01-08:47, 08:49, 08:51, 08:53, 08:56, 08:58, 08:60N-08:63, 08:65-08:66, 08:68:01-08:69, 08:71, 08:74, 08:76, 08:91-08:92, 08:95, 08:97, 08:104, 08:110, 08:115	*11:270, 12:01:01:01-12:01:12, 12:03:02-12:06, 12:08-12:11, 12:14, 12:17, 12:22, 12:24N-12:25, 12:28-12:30, 12:34-12:36, 12:38-12:41, 12:46-12:48, 12:53-12:54, 12:58-12:59, 12:63, 12:68, 12:70, 12:72N, 12:77, 12:79, 12:82, 12:84, 12:86N-12:91, 12:95, 12:99, 13:17, 13:116, 13:175, 13:214
5 ⁵	225 bp	515 bp	*08:01:01:01-08:01:02, 08:01:04-08:03:12, 08:03:14-08:04:07,	*03:157, 11:23:01-11:23:02, 11:25, 11:45, 11:55, 11:64, 11:67, 11:119,



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			08:06:01:01-08:13, 08:15-08:17, 08:19-08:20, 08:22-08:23, 08:26-08:28, 08:30:01-08:30:03, 08:32-08:39, 08:42, 08:44-08:46, 08:48-08:55, 08:57-08:66, 08:68:01-08:91, 08:93-08:97, 08:99-08:101, 08:103-08:105, 08:107, 08:109-08:117	13:13, 13:18, 13:47, 13:55, 13:119, 13:144, 13:146, 13:154, 13:156, 13:158:01-13:158:02, 13:164, 13:232, 13:286, 13:331, 14:03:01-14:03:02, 14:12:01-14:12:02, 14:15, 14:27:01-14:27:02, 14:40, 14:55, 14:63, 14:67, 14:77-14:78, 14:84-14:85, 14:89, 14:102, 14:115-14:116, 14:135-14:136, 14:144, 14:156, 14:164, 14:173-14:174, 14:181, 14:218, 14:222N-14:223, 14:239
6	215 bp	430 bp	*08:05, 08:18, 08:24:01-08:25, 08:31, 08:40-08:41, 08:47, 08:92, 08:102	*11:193:01-11:193:02, 11:209, 11:229, 11:270, 12:01:01:01-12:21, 12:23-12:41, 12:44-12:56, 12:58-12:65, 12:67-12:82, 12:84-12:87, 12:89-12:100, 13:17, 13:116, 13:175, 13:214, 14:31, 14:52
7	250 bp	430 bp	*08:01:01:01-08:01:02, 08:01:04-08:03:14, 08:05, 08:07-08:09:02, 08:11:01:01-08:11:01:02, 08:13-08:19, 08:21, 08:23-08:27, 08:29-08:30:03, 08:32-08:53, 08:56, 08:58, 08:60N-08:63, 08:66, 08:68:01-08:69, 08:71-08:74, 08:76-08:79, 08:81-08:82, 08:84-08:93, 08:95-08:97, 08:100-08:117	*11:193:01-11:193:02, 12:16:01-12:16:03, 12:22, 12:39:01-12:39:02, 14:68:01-14:68:02, 14:93
8	250 bp	430 bp	*08:04:01:01-08:04:07, 08:06:01:01-08:06:01:02, 08:10, 08:12, 08:22, 08:28, 08:31, 08:54, 08:59, 08:67, 08:70, 08:75, 08:83, 08:94, 08:98-08:99	*03:92, 11:67, 11:209, 11:229, 11:270, 12:01:01:01-12:15, 12:17-12:21, 12:23-12:38, 12:40-12:41, 12:43-12:56, 12:58-12:82, 12:84-12:100, 13:17, 13:116, 13:175, 13:214, 14:04:01:01-14:04:09, 14:11:01:01-14:11:01:02, 14:15, 14:28, 14:31, 14:50:01-14:50:02, 14:52, 14:71, 14:73, 14:76, 14:79, 14:107, 14:120, 14:126:01-14:126:02, 14:138, 14:145, 14:148, 14:152N, 14:175, 14:180, 14:196, 14:201, 14:205:01-14:206, 14:210Q, 14:220, 14:224, 14:229, 14:233, 14:241
9^d	125 bp	430 bp	*08:26, 08:35-08:36:02	*03:12, 03:158, 04:202, 13:32, 13:65, 13:93, 13:120, 13:139, 14:13, 14:63, 14:65, 14:78, 14:85, 14:169-14:170
10	175 bp		*08:14	
	205 bp	515 bp	*08:40, 08:92	*11:229, 11:270, 12:73, 13:17, 13:116, 13:175, 13:214
	250 bp		*08:12, 08:22	*12:01:01:01-12:02:13, 12:04-12:15, 12:17-12:18, 12:20-12:21, 12:23-12:38, 12:40-12:41,



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11	170 bp	515 bp	*08:08, 08:15, 08:31, 08:41, 08:63, 08:75	12:43-12:56, 12:58-12:82, 12:84- 12:100, 14:28 *11:67, 11:193:01-11:193:02, 11:209, 11:229, 11:270, 12:04, 12:49, 12:96, 14:04:01:01- 14:04:09, 14:11:01:01- 14:11:01:02, 14:28, 14:31, 14:50:01-14:50:02, 14:68:01- 14:68:02, 14:71, 14:73, 14:76, 14:79, 14:93, 14:107, 14:120, 14:138, 14:145, 14:148, 14:152N, 14:180, 14:196, 14:201, 14:205:01, 14:206, 14:210Q, 14:220, 14:224, 14:229, 14:233, 14:241
12 ⁴	95 bp 145 bp 195 bp 220 bp	430 bp	*08:27, 08:114 *08:44, 08:104 *08:13, 08:48 *08:43	*12:12, 12:62
13	135 bp 165 bp 190 bp 260 bp	430 bp	*08:33 *08:11:01:01-08:11:01:02 *08:82 *08:39	*14:205:02
14	135 bp	430 bp	*08:17, 08:28, 08:37, 08:45:01- 08:45:02, 08:63, 08:103, 08:113	*03:92, 11:67, 11:193:01- 11:193:02, 11:209, 11:229, 11:270, 12:01:01:01-12:20, 12:22- 12:37, 12:39:01-12:41, 12:43- 12:52, 12:54-12:56, 12:58-12:75, 12:77-12:82, 12:84-12:100, 13:17, 13:175, 13:214, 14:138, 14:175
15	250 bp 170 bp	430 bp	*08:60N *08:19, 08:25, 08:34, 08:49, 08:52, 08:113	*12:01:01:01-12:01:07, 12:01:09- 12:02:05, 12:02:07-12:03:03, 12:05-12:08, 12:10-12:17, 12:19:01-12:32, 12:34-12:41, 12:43-12:45, 12:50-12:56, 12:58- 12:61, 12:63-12:75, 12:77-12:82, 12:84-12:95, 12:97-12:100
16 ⁴	70 bp	430 bp	*08:03:02:01-08:03:14, 08:10, 08:12, 08:14, 08:18, 08:23, 08:27, 08:29, 08:32-08:33, 08:35- 08:38, 08:40, 08:46-08:47, 08:49, 08:51, 08:53, 08:56, 08:58, 08:60N-08:62, 08:65-08:66, 08:68:01-08:69, 08:71, 08:74, 08:76, 08:91-08:92, 08:95, 08:97, 08:104, 08:110, 08:115	*04:12, 04:86, 04:106, 04:136, 12:46, 13:03:01:01-13:04, 13:12:01-13:13, 13:30, 13:32- 13:33:03, 13:38, 13:48, 13:58, 13:65-13:66:02, 13:81, 13:89:01- 13:89:02, 13:93-13:95, 13:101, 13:115, 13:118, 13:120, 13:122, 13:139, 13:151-13:152, 13:154, 13:161, 13:167, 13:174, 13:188, 13:194, 13:216, 13:219, 13:227- 13:228, 13:253, 13:295N, 13:317, 13:319N, 13:321, 13:329N, 14:63, 14:78, DRB3*02:131
17 ⁴	75 bp	430 bp	*08:04:01:01-08:04:01:05, 08:04:04-08:04:07, 08:06:01:01- 08:06:01:02, 08:10, 08:12, 08:20,	*04:12, 04:18, 04:25, 04:58, 11:25, 11:67, 11:119, 13:18, 13:144, 13:156, 13:164,



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	115 bp 265 bp		08:22, 08:28, 08:54, 08:59, 08:67, 08:70, 08:75, 08:80, 08:83, 08:94, 08:98-08:99 *08:14	14:12:01-14:12:02, 14:15, 14:78, 14:84, 14:156, 14:173, 15:21 *03:190, 11:261 *03:190, 11:261
18	120 bp	430 bp	*08:17, 08:28, 08:37, 08:45:01- 08:45:02, 08:63, 08:103, 08:113	*03:157, 11:23:01-11:23:02, 11:25, 11:45, 11:55, 11:64, 11:67, 11:119, 13:18, 13:119, 13:144, 13:146, 13:154, 13:156, 13:158:01-13:158:02, 13:286, 13:331, 15:21
	150 bp		*08:09:01-08:09:02, 08:21, 08:32, 08:35, 08:87	*13:232, 14:15, 14:40, 14:55, 14:77, 14:84, 14:136, 14:164, 14:173
19⁴	100 bp 170 bp	515 bp	*08:16, 08:38 *08:07, 08:49	
20⁴	125 bp	515 bp	*08:06:01:01-08:06:01:02, 08:10, 08:12, 08:22, 08:54, 08:70	*03:12, 03:158, 04:10:01-04:11:04, 04:11:06-04:12, 04:67, 04:91, 04:126, 04:136, 04:147, 04:201, 04:203, 04:207, 04:250, 04:303, 12:46, 13:04, 13:32, 13:48, 13:58, 13:75, 13:81, 13:89:01-13:89:02, 13:93-13:94:02, 13:108, 13:164, 13:169, 13:276, 13:307, 14:65, 14:78, 14:169-14:170, 15:12, DRB5*02:33
21⁴	55 bp 200 bp	430 bp	*08:78N *08:20	*11:01:01:01, 11:01:01:03- 11:01:17, 11:01:20-11:01:27, 11:01:28?, 11:01:29-11:01:47, 11:03:01-11:04:20, 11:04:22, 11:06:01-11:06:03, 11:09:01:01- 11:11:01, 11:11:03-11:12:03, 11:15:01:01-11:15:02, 11:23:01- 11:25, 11:27:01-11:29:02, 11:32- 11:33, 11:35, 11:37:01-11:41, 11:43:01:01-11:44, 11:46:01- 11:47, 11:49:01-11:51, 11:54:01- 11:54:02, 11:56, 11:58:01- 11:63:02, 11:66:01-11:66:02, 11:72, 11:74:01-11:78, 11:80- 11:81, 11:83-11:85, 11:87-11:88, 11:90-11:97, 11:99-11:102:02, 11:106, 11:108-11:117:02, 11:120-11:123, 11:126, 11:128- 11:129, 11:133-11:135, 11:137- 11:142, 11:144-11:152, 11:154- 11:158, 11:160-11:170, 11:172, 11:174-11:183, 11:185-11:190, 11:192, 11:194:01-11:201, 11:203-11:208, 11:210-11:228, 11:230-11:241, 11:243-11:247, 11:249-11:250N, 11:252-11:255, 11:257-11:260, 11:262-11:265, 11:269, 11:271-11:275,



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For *In Vitro* Diagnostic Use
 MA123 v02 SSP PI Template
 Date: April 2023, Rev. No: 01

101.127-12/04 – including *Taq* polymerase
 101.127-12u/04u – without *Taq* polymerase

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

Lot No.: **4R9**

Lot-specific information

				11:277-11:279, 11:281-11:282, 11:284-11:285, 11:287N, 11:289, 11:291-11:292, 11:294N-11:307, 13:05:01:01-13:05:03, 13:07:01- 13:07:02, 13:11:01-13:11:02, 13:14:01-13:14:03, 13:18, 13:21:01:01-13:21:02, 13:24:01:01-13:24:01:03, 13:26:01-13:26:02, 13:42:01- 13:42:02, 13:46-13:47, 13:49:01- 13:50:03, 13:54-13:55, 13:62- 13:63, 13:75, 13:100, 13:108, 13:111, 13:132, 13:136, 13:144, 13:150, 13:158:01-13:158:02, 13:164, 13:169, 13:189, 13:197, 13:199, 13:203, 13:229-13:230, 13:232, 13:246-13:247, 13:277, 13:284, 13:286, 13:302, 13:307, 14:22, 14:25:01-14:25:02, 14:27:01-14:27:02, 14:53, 14:105, 14:128
22	130 bp 165 bp 215 bp	430 bp	*08:23 *08:19 *08:29	*12:66, 14:04:01:01-14:04:09, 14:11:01:01-14:11:01:02, 14:28, 14:50:02, 14:68:01-14:68:02, 14:71, 14:73, 14:93, 14:120, 14:126:01-14:126:02, 14:138, 14:145, 14:148, 14:152N, 14:175, 14:180, 14:196, 14:201, 14:205:01-14:206, 14:210Q, 14:220, 14:224, 14:229, 14:233, 14:241
23	220 bp 250 bp	430 bp	*08:43 *08:04:01:01-08:04:01:05, 08:04:04-08:04:07, 08:06:01:01- 08:06:01:02, 08:10, 08:28, 08:31, 08:54, 08:59, 08:67, 08:70, 08:75, 08:83, 08:94, 08:98-08:99	*03:92, 11:67, 11:209, 11:229, 11:270, 12:03:02-12:03:03, 12:19:01-12:19:02, 13:17, 13:116, 13:175, 13:214, 14:04:01:01- 14:04:09, 14:11:01:01- 14:11:01:02, 14:15, 14:31, 14:50:01-14:50:02, 14:52, 14:73, 14:76, 14:79, 14:107, 14:120, 14:126:01-14:126:02, 14:138, 14:145, 14:148, 14:152N, 14:175, 14:180, 14:196, 14:201, 14:205:01-14:206, 14:210Q, 14:220, 14:224, 14:229, 14:233, 14:241
24	-	-	Negative Control	



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101.127-12/04 – including *Taq* polymerase
101.127-12u/04u – without *Taq* polymerase

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Lot No.: **4R9**

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 DRB1*08 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.

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.

³For several DRB1 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.

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

⁵Primer mixes 2 and 5 may have tendencies of unspecific amplifications.

⁶Primer mix 3 might have a tendency to giving rise to primer oligomer formation.

⁷Primer mix 24 contains a negative control, which will amplify a majority of HLA amplicons as well as the amplicons generated by the control primer pairs matching the human growth hormone gene. HLA-specific PCR product sizes range from 75 to 200 base pairs and the PCR product generated by the HGH positive control primer pair is 200 base pairs.

Abbreviations

'w': may be weakly amplified.

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



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For *In Vitro* Diagnostic Use
MA123 v02 SSP PI Template
Date: April 2023, Rev. No: 01

101.127-12/04 – including *Taq* polymerase
101.127-12u/04u – without *Taq* polymerase

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

Lot No.: **4R9**

Lot-specific information

PRIMER SPECIFICATION

Well No.	1	2	3	4	5	6	7	8	9	10	11	12
Length of spec. PCR product	165	170	195	195	225	215	250	250	125	205	170	95
									175	250		145
												195
												220
Length of int. pos. control ¹	515	430	430	430	515	430	430	430	430	515	515	430
5'-primer(s) ²	16(133) 5'-gTT 3'	16(133) 5'-gTT 3'	16(133) 5'-gTT 3'	16(133) 5'-gTT 3'	12(122) 5'-TAC 3'	16(133) 5'-gTT 3'	16(133) 5'-gTT 3'	16(133) 5'-gTT 3'	12(122) 5'-TAG 3'	16(133) 5'-gTT 3'	16(133) 5'-gTT 3'	16(133) 5'-gTT 3'
	16(133) 5'-gCT 3'		16(133) 5'-gCT 3'	16(133) 5'-gTT 3'			16(133) 5'-gCT 3'		25(161) 5'-gCT 3'			
	16(133) 5'-gTT 3'		16(133) 5'-gTC 3'				16(133) 5'-gTT 3'		32(181) 5'-TCC 3'			
3'-primer(s) ³	57(256) 5'-gCT 3'	57(257) 5'-CAT 3'	67(286) 5'-gAA 3'	67(286) 5'-gAT 3'	74(307) 5'-CAG 3'	74(307) 5'-CgC 3'	86(344) 5'-CAC 3'	86(344) 5'-CCA 3'	57(256) 5'-gCT 3'	71(299) 5'-gCT 3'	58(261) 5'-TCC 3'	34(188) 5'-CTC 3'
		57(257) 5'-CAT 3'		67(286) 5'-gAT 3'				86(344) 5'-CAA 3'		85(341) 5'-CAG 3'	58(261) 5'-TCC 3'	51(239) 5'-CCA 3'
		58(261) 5'-TCA 3'										67(286) 5'-gAg 3'
												76(313) 5'-gTA 3'

Well No.	13	14	15	16	17	18	19	20	21	22	23
Length of spec. PCR product	135	135	170	70	75	120	100	125	55	130	220
	165	250			115	150	170		200	165	250
	190				265					215	
	260										
Length of int. pos. control ¹	430	430	430	430	430	430	515	515	430	430	430
5'-primer(s) ²	16(133) 5'-gTT 3'	16(133) 5'-gTT 3'	16(133) 5'-gTT 3'	57(258) 5'-AgC 3'	12(122) 5'-TAG 3'	37(196) 5'-AgC 3'	16(133) 5'-gTT 3'	57(258) 5'-AgC 3'	13(125) 5'-gTC 3'	16(133) 5'-gTT 3'	16(133) 5'-gTT 3'
					74(308) 5'-CCT 3'	37(197) 5'-gTT 3'			64(277) 5'-gCT 3'		
						47(227) 5'-gTT 3'					
3'-primer(s) ³	48(229) 5'-CCA 3'	47(227) 5'-ggA 3'	57(257) 5'-CgA 3'	67(286) 5'-gAT 3'	37(197) 5'-CgT 3'	74(307) 5'-CAG 3'	33(184) 5'-gTg 3'	86(344) 5'-CCA 3'	67(286) 5'-gAA 3'	45(220) 5'-CCT 3'	76(313) 5'-gTA 3'
	57(257) 5'-CAg 3'	85(340) 5'-A.C 3'	61(270) 5'-TTg 3'	67(286) 5'-gAT 3'	86(344) 5'-CCA 3'		37(196) 5'-gTC 3'			57(256) 5'-gAT 3'	85(341) 5'-CAA 3'
	66(284) 5'-AgC 3'						57(257) 5'-CAA 3'			74(308) 5'-CCT 3'	
	88(350) 5'-AgT 3'						61(270) 5'-TTg 3'				

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.



0197

For *In Vitro* Diagnostic Use
MA123 v02 SSP PI Template
Date: April 2023, Rev. No: 01

101.127-12/04 – including *Taq* polymerase
 101.127-12u/04u – without *Taq* polymerase

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Lot No.: **4R9**

Lot-specific information

CELL LINE VALIDATION SHEET																				
DRB1*08 SSP subtyping kit ²																				
				Well																
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	
				Prod. No.:	201779801	201779802	202025403	201779804	201779805	201779806	201779807	201779808	201779809	201779810	201779811	201779812	202025413	201779814	201779815	201779816
	IHWC cell line ¹	DRB1																		
1	9001 SA	*01:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2	9280 LK707	*15:02	*04:05	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3	9011 E4181324	*15:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4	9275 GU373	*03:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
5	9009 KAS011	*16:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
6	9353 SM	*04:07	*08:03	+	-	-	+	+	-	+	-	-	-	-	-	-	-	-	-	+
7	9020 QBL	*03:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
8	9025 DEU	*04:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
9	9026 YAR	*04:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
10	9107 LKT3	*04:05		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
11	9051 PITOUT	*07:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
12	9052 DBB	*07:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
13	9004 JESTHOM	*01:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
14	9071 OLGA	*08:02		-	+	+	-	+	-	+	-	-	-	-	-	-	-	-	-	-
15	9075 DKB	*09:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
16	9037 SWEIG007	*11:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
17	9282 CTM3953540	*03:01	*13:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
18	9257 32367	*09:01	*11:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
19	9038 BM16	*12:01		-	-	-	+	-	+	-	+	-	+	-	-	-	+	+	-	-
20	9059 SLE005	*13:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
21	9064 AMALA	*14:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
22	9056 KOSE	*13:02	*14:54	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
23	9124 IHL	*08:03	*14:14	+	-	-	+	+	-	+	-	-	-	-	-	-	-	-	-	+
24	9035 JBUSH	*11:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
25	9049 IBW9	*07:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
26	9285 WT49	*03:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
27	9191 CH1007	*04:05	*10:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
28	9320 BEL5GB	*04:16	*07:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
29	9050 MOU	*07:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
30	9021 RSH	*03:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
31	9019 DUCAF	*03:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
32	9297 HAG	*13:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+
33	9098 MT14B	*04:04		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
34	9104 DHIF	*11:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
35	9302 SSTO	*04:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
36	9024 KT17	*04:03	*04:06	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
37	9065 HHKB	*13:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
38	9099 LZL	*14:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
39	9315 CML	*03:01	*04:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
40	9134 WHONP199	*07:01	*09:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
41	9055 H0301	*13:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
42	9066 TAB089	*08:03		+	-	-	+	+	-	+	-	-	-	-	-	-	-	-	-	+
43	9076 T7526	*09:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
44	9057 TEM	*14:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
45	9239 SHJO	*07:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
46	9013 SCHU	*15:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
47	9045 TUBO	*11:04	*12:01	-	-	-	+	-	+	-	+	-	+	-	-	-	+	+	-	-
48	9303 TER-ND	*01:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-



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101.127-12/04 – including *Taq* polymerase
 101.127-12u/04u – without *Taq* polymerase

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Lot No.: **4R9**

Lot-specific information

CELL LINE VALIDATION SHEET												
DRB1*08 SSP subtyping kit²					Well							
					17	18	19	20	21	22	23	
					Prod. No.:	202018517	202025418	201779819	201779820	202025421	201779822	201779823
IHWC cell line¹			DRB1									
1	9001	SA	*01:01		-	-	-	-	-	-	-	-
2	9280	LK707	*15:02	*04:05	-	-	-	-	-	-	-	-
3	9011	E4181324	*15:02		-	-	-	-	-	-	-	-
4	9275	GU373	*03:01		-	-	-	-	-	-	-	-
5	9009	KAS011	*16:01		-	-	-	-	-	-	-	-
6	9353	SM	*04:07	*08:03	-	-	-	-	-	-	-	-
7	9020	QBL	*03:01		-	-	-	-	-	-	-	-
8	9025	DEU	*04:01		-	-	-	-	-	-	-	-
9	9026	YAR	*04:02		-	-	-	-	-	-	-	-
10	9107	LKT3	*04:05		-	-	-	-	-	-	-	-
11	9051	PITOUT	*07:01		-	-	-	-	-	-	-	-
12	9052	DBB	*07:01		-	-	-	-	-	-	-	-
13	9004	JESTHOM	*01:01		-	-	-	-	-	-	-	-
14	9071	OLGA	*08:02		-	-	-	-	-	-	-	-
15	9075	DKB	*09:01		-	-	-	-	-	-	-	-
16	9037	SWEIG007	*11:01		-	-	-	-	+	-	-	-
17	9282	CTM3953540	*03:01	*13:01	-	-	-	-	-	-	-	-
18	9257	32367	*09:01	*11:01	-	-	-	-	+	-	-	-
19	9038	BM16	*12:01		-	-	-	-	-	-	-	-
20	9059	SLE005	*13:02		-	-	-	-	-	-	-	-
21	9064	AMALA	*14:02		-	-	-	-	-	-	-	-
22	9056	KOSE	*13:02	*14:54	-	-	-	-	-	-	-	-
23	9124	IHL	*08:03	*14:14	-	-	-	-	-	-	-	-
24	9035	JBUSH	*11:01		-	-	-	-	+	-	-	-
25	9049	IBW9	*07:01		-	-	-	-	-	-	-	-
26	9285	WT49	*03:01		-	-	-	-	-	-	-	-
27	9191	CH1007	*04:05	*10:01	-	-	-	-	-	-	-	-
28	9320	BEL5GB	*04:16	*07:01	-	-	-	-	-	-	-	-
29	9050	MOU	*07:01		-	-	-	-	-	-	-	-
30	9021	RSH	*03:02		-	-	-	-	-	-	-	-
31	9019	DUCAF	*03:01		-	-	-	-	-	-	-	-
32	9297	HAG	*13:03		-	-	-	-	-	-	-	-
33	9098	MT14B	*04:04		-	-	-	-	-	-	-	-
34	9104	DHIF	*11:01		-	-	-	-	+	-	-	-
35	9302	SSTO	*04:03		-	-	-	-	-	-	-	-
36	9024	KT17	*04:03	*04:06	-	-	-	-	-	-	-	-
37	9065	HHKB	*13:01		-	-	-	-	-	-	-	-
38	9099	LZL	*14:02		-	-	-	-	-	-	-	-
39	9315	CML	*03:01	*04:01	-	-	-	-	-	-	-	-
40	9134	WHONP199	*07:01	*09:01	-	-	-	-	-	-	-	-
41	9055	H0301	*13:02		-	-	-	-	-	-	-	-
42	9066	TAB089	*08:03		-	-	-	-	-	-	-	-
43	9076	T7526	*09:01		-	-	-	-	-	-	-	-
44	9057	TEM	*14:01		-	-	-	-	-	-	-	-
45	9239	SHJO	*07:01		-	-	-	-	-	-	-	-
46	9013	SCHU	*15:01		-	-	-	-	-	-	-	-
47	9045	TUBO	*11:04	*12:01	-	-	-	-	+	-	-	-
48	9303	TER-ND	*01:03		-	-	-	-	-	-	-	-



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For *In Vitro* Diagnostic Use
 MA123 v02 SSP PI Template
 Date: April 2023, Rev. No: 01

101.127-12/04 – including *Taq* polymerase
 101.127-12u/04u – without *Taq* polymerase

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

Lot No.: **4R9**

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 9, 12 and 21 were available.

The specificities of the primers in primer solutions 9 and 21 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer.

In primer solution 12 it was only possible to test the 5'-primer, the 3'-primers were not possible to test.

In primer solutions 2, 8, 13 to 15, 19, 22 and 23 one or two 3'-primers were not possible to test, and in primer solution 1, 3, 7, 9, 17 and 21 one or two 5'-primers were not possible to test.

The primers in primer solutions 2, 10, 11 and 17 to 19 were tested by separately adding one additional 5'-primer or one or two additional 3'-primers.



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101.127-12/04 – including *Taq* polymerase
101.127-12u/04u – without *Taq* polymerase

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

Lot No.: **4R9**

Lot-specific information

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