

101.116-24/03 – including *Taq* polymerase
 101.116-24u/03u – without *Taq* polymerase

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

Lot No.: **9R5**

Lot-specific information

Olerup SSP[®] DRB1*13

Product number:	101.116-24/03 – including <i>Taq</i> pol. 101.116-24u/03u – without <i>Taq</i> pol.
Lot number:	9R5
Expiry date:	2027-05-01
Number of tests:	24 tests – Product No. 101.116-24/24u 3 tests – Product No. 101.116-03/03u
Number of wells per test:	57+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. 9R5.

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*13 LOT (0M3)**

- 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 DRB1*13 primer set, specificity and interpretation tables have been updated for the DRB alleles described since the previous *Olerup SSP[®] DRB1*13* lot was made (**Lot No. 0M3**).

The primers of the wells detailed below have been exchanged, added or modified compared to the previous lot (**Lot No. 0M3**).

Well	5'-primer	3'-primer	rationale
1	-	Added	3'-primer added for the DRB1*13:01:41 allele.
44	Removed	-	5'-primer removed for improved HLA-specific amplification.

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, 194–2.

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Well **58** 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 products sizes range from 75 to 200 base pairs. The PCR products 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.



0197

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

101.116-24/03 – including *Taq* polymerase
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Lot-specific information

PRODUCT DESCRIPTION

DRB1*13 SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for identifying the DRB1*13:01 to DRB1*13:335 alleles.

PLATE LAYOUT

Each test consists of 58 PCR reactions in a 64 well cut PCR plate. Wells 59 to 64 are 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	47	48
49	50	51	52	53	54	55	56
57	NC	empty	empty	empty	empty	empty	empty

The 64 well cut PCR plate is marked with ‘DRB1*13’ in silver/gray ink.

Well No. 1 is marked with the Lot No 9R5.

Wells 1 to 57 – DRB1*13 high resolution primers.

Well 58 – 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.

INTERPRETATION

Due to the sharing of sequence motifs between DRB1 alleles non-DRB1*13 alleles will be amplified by some primer mixes. For further details see Specificity Table.

UNIQUELY IDENTIFIED ALLELES

All the DRB1*13 alleles, i.e. **DRB1*13:01 to DRB1*13:335**, recognized by the HLA Nomenclature Committee in January 2023^{1,2} will be amplified by the primers in the DRB1*13 subtyping kit³.

The DRB1*13 kit enables separation of the confirmed DRB1*13 alleles as listed in the IMGT/HLA database 3.26.0. 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*13 alleles is listed below.



0197

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Lot-specific information

The DRB1*13 kit also enables identification of many null and alternatively expressed alleles.

The following DRB1*13 alleles can be distinguished by the different sizes of the HLA-specific PCR product:

Alleles	Primer mix
DRB1*13:28:01-13:28:02, 13:221	23, 56
DRB1*13:80, 13:242:01	34
DRB1*13:92, 13:98	36

¹DRB1 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 following alleles cannot be separated by the HLA-DRB1*13 primer set. These alleles can be distinguished by the DR low resolution kit and/or the respective high resolution kit.

Alleles

DRB1*13:17, DRB1*11:229, 11:270

DRB1*13:165, DRB1*11:20

DRB1*13:193, DRB1*14:95



0197

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ALLELE CONFIRMATION STATUS

Allele	Status ¹	Allele	Status ¹	Allele	Status ¹	Allele	Status ¹
DRB1*13:01:01:01	Confirmed	DRB1*13:13	Confirmed	DRB1*13:55	Unconfirmed	DRB1*13:101	Confirmed
DRB1*13:01:01:02	Unconfirmed	DRB1*13:14:01	Confirmed	DRB1*13:56	Confirmed	DRB1*13:102	Unconfirmed
DRB1*13:01:02	Unconfirmed	DRB1*13:14:02	Confirmed	DRB1*13:57	Unconfirmed	DRB1*13:103	Unconfirmed
DRB1*13:01:03	Confirmed	DRB1*13:14:03	Unconfirmed	DRB1*13:59	Confirmed	DRB1*13:104	Confirmed
DRB1*13:01:04	Unconfirmed	DRB1*13:15	Confirmed	DRB1*13:60	Unconfirmed	DRB1*13:105	Confirmed
DRB1*13:01:05	Unconfirmed	DRB1*13:16	Confirmed	DRB1*13:61:01	Unconfirmed	DRB1*13:106	Confirmed
DRB1*13:01:06	Unconfirmed	DRB1*13:17	Confirmed	DRB1*13:61:02	Confirmed	DRB1*13:107	Unconfirmed
DRB1*13:01:07	Unconfirmed	DRB1*13:18	Confirmed	DRB1*13:62	Unconfirmed	DRB1*13:109	Unconfirmed
DRB1*13:01:08	Confirmed	DRB1*13:19	Confirmed	DRB1*13:63	Unconfirmed	DRB1*13:110	Unconfirmed
DRB1*13:01:09	Unconfirmed	DRB1*13:20	Confirmed	DRB1*13:64	Unconfirmed	DRB1*13:111	Confirmed
DRB1*13:01:10	Confirmed	DRB1*13:21:01	Confirmed	DRB1*13:65	Unconfirmed	DRB1*13:112	Confirmed
DRB1*13:01:11	Unconfirmed	DRB1*13:21:02	Confirmed	DRB1*13:66:01	Unconfirmed	DRB1*13:113N	Unconfirmed
DRB1*13:01:12	Unconfirmed	DRB1*13:22	Confirmed	DRB1*13:66:02	Confirmed	DRB1*13:114	Confirmed
DRB1*13:01:13	Unconfirmed	DRB1*13:23:01	Confirmed	DRB1*13:67	Unconfirmed	DRB1*13:115	Unconfirmed
DRB1*13:01:14	Unconfirmed	DRB1*13:23:02	Unconfirmed	DRB1*13:68	Unconfirmed	DRB1*13:116	Unconfirmed
DRB1*13:01:15	Unconfirmed	DRB1*13:24	Unconfirmed	DRB1*13:69	Unconfirmed	DRB1*13:117	Unconfirmed
DRB1*13:01:16	Unconfirmed	DRB1*13:25	Confirmed	DRB1*13:70	Confirmed	DRB1*13:118	Unconfirmed
DRB1*13:02:01	Confirmed	DRB1*13:26:01	Confirmed	DRB1*13:71	Unconfirmed	DRB1*13:119	Unconfirmed
DRB1*13:02:02	Confirmed	DRB1*13:26:02	Unconfirmed	DRB1*13:72	Unconfirmed	DRB1*13:120	Confirmed
DRB1*13:02:03	Unconfirmed	DRB1*13:27	Confirmed	DRB1*13:73	Unconfirmed	DRB1*13:121	Unconfirmed
DRB1*13:02:04	Unconfirmed	DRB1*13:28	Confirmed	DRB1*13:74	Unconfirmed	DRB1*13:122	Unconfirmed
DRB1*13:02:05	Confirmed	DRB1*13:29	Confirmed	DRB1*13:75	Unconfirmed	DRB1*13:123	Unconfirmed
DRB1*13:02:06	Unconfirmed	DRB1*13:30	Unconfirmed	DRB1*13:76	Unconfirmed	DRB1*13:124	Confirmed
DRB1*13:02:07	Unconfirmed	DRB1*13:31	Confirmed	DRB1*13:77	Unconfirmed	DRB1*13:125	Unconfirmed
DRB1*13:02:08	Unconfirmed	DRB1*13:32	Unconfirmed	DRB1*13:78	Unconfirmed	DRB1*13:126	Unconfirmed
DRB1*13:02:09	Unconfirmed	DRB1*13:33:01	Unconfirmed	DRB1*13:79	Confirmed	DRB1*13:127	Unconfirmed
DRB1*13:02:10	Unconfirmed	DRB1*13:33:03	Confirmed	DRB1*13:80	Unconfirmed	DRB1*13:128	Confirmed
DRB1*13:02:11	Unconfirmed	DRB1*13:34	Unconfirmed	DRB1*13:81	Confirmed	DRB1*13:129	Unconfirmed
DRB1*13:02:12	Unconfirmed	DRB1*13:35	Unconfirmed	DRB1*13:82	Confirmed	DRB1*13:130	Unconfirmed
DRB1*13:03:01	Confirmed	DRB1*13:36	Confirmed	DRB1*13:83	Unconfirmed	DRB1*13:131	Unconfirmed
DRB1*13:03:02	Confirmed	DRB1*13:37	Confirmed	DRB1*13:84	Unconfirmed	DRB1*13:132	Unconfirmed
DRB1*13:03:04	Confirmed	DRB1*13:38	Confirmed	DRB1*13:85	Unconfirmed	DRB1*13:133	Unconfirmed
DRB1*13:03:05	Unconfirmed	DRB1*13:39	Unconfirmed	DRB1*13:86	Unconfirmed	DRB1*13:134	Confirmed
DRB1*13:03:06	Unconfirmed	DRB1*13:40	Confirmed	DRB1*13:87	Confirmed	DRB1*13:135	Unconfirmed
DRB1*13:04	Confirmed	DRB1*13:41	Confirmed	DRB1*13:88	Unconfirmed	DRB1*13:136	Unconfirmed
DRB1*13:05:01	Confirmed	DRB1*13:42	Confirmed	DRB1*13:89	Confirmed	DRB1*13:137N	Confirmed
DRB1*13:05:02	Unconfirmed	DRB1*13:43	Unconfirmed	DRB1*13:90	Confirmed	DRB1*13:139	Unconfirmed
DRB1*13:05:03	Unconfirmed	DRB1*13:44	Unconfirmed	DRB1*13:91	Confirmed	DRB1*13:140	Unconfirmed
DRB1*13:06	Confirmed	DRB1*13:45	Confirmed	DRB1*13:92	Confirmed	DRB1*13:141	Confirmed
DRB1*13:07:01	Confirmed	DRB1*13:46	Unconfirmed	DRB1*13:93	Confirmed	DRB1*13:142N	Unconfirmed
DRB1*13:07:02	Unconfirmed	DRB1*13:47	Unconfirmed	DRB1*13:94:01	Unconfirmed	DRB1*13:143	Unconfirmed
DRB1*13:08	Confirmed	DRB1*13:48	Confirmed	DRB1*13:94:02	Unconfirmed	DRB1*13:144	Unconfirmed
DRB1*13:09	Confirmed	DRB1*13:49	Confirmed	DRB1*13:95	Confirmed	DRB1*13:145	Unconfirmed
DRB1*13:10	Confirmed	DRB1*13:50:01	Confirmed	DRB1*13:96:01	Confirmed	DRB1*13:146	Unconfirmed
DRB1*13:11:01	Confirmed	DRB1*13:50:02	Unconfirmed	DRB1*13:96:02	Confirmed	DRB1*13:147	Confirmed
DRB1*13:11:02	Confirmed	DRB1*13:50:03	Confirmed	DRB1*13:97:01	Confirmed	DRB1*13:148	Confirmed
DRB1*13:12:01	Confirmed	DRB1*13:51	Unconfirmed	DRB1*13:97:02	Unconfirmed	DRB1*13:149	Unconfirmed
DRB1*13:12:02	Unconfirmed	DRB1*13:52	Confirmed	DRB1*13:98	Unconfirmed	DRB1*13:150	Confirmed
DRB1*13:12:03	Unconfirmed	DRB1*13:53	Unconfirmed	DRB1*13:99	Unconfirmed	DRB1*13:151	Unconfirmed
DRB1*13:12:04	Unconfirmed	DRB1*13:54	Confirmed	DRB1*13:100	Unconfirmed	DRB1*13:152	Confirmed



0197

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

101.116-24/03 – including *Taq* polymerase
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Lot-specific information

Allele	Status ¹	Allele	Status ¹	Allele	Status ¹
DRB1*13:153	Unconfirmed	DRB1*13:183	Confirmed	DRB1*13:214	Unconfirmed
DRB1*13:154	Unconfirmed	DRB1*13:184	Unconfirmed	DRB1*13:215	Unconfirmed
DRB1*13:155	Unconfirmed	DRB1*13:185N	Unconfirmed	DRB1*13:216	Unconfirmed
DRB1*13:156	Unconfirmed	DRB1*13:186	Unconfirmed	DRB1*13:217	Unconfirmed
DRB1*13:157	Unconfirmed	DRB1*13:187	Unconfirmed	DRB1*13:218	Unconfirmed
DRB1*13:158	Confirmed	DRB1*13:188	Unconfirmed	DRB1*13:219	Unconfirmed
DRB1*13:159	Unconfirmed	DRB1*13:189	Unconfirmed	DRB1*13:220	Unconfirmed
DRB1*13:160	Unconfirmed	DRB1*13:190	Unconfirmed	DRB1*13:221	Unconfirmed
DRB1*13:161	Unconfirmed	DRB1*13:191	Unconfirmed	DRB1*13:222	Unconfirmed
DRB1*13:162	Unconfirmed	DRB1*13:192	Unconfirmed	DRB1*13:223	Unconfirmed
DRB1*13:163	Unconfirmed	DRB1*13:193	Unconfirmed	DRB1*13:224	Unconfirmed
DRB1*13:164	Unconfirmed	DRB1*13:194	Unconfirmed	DRB1*13:225	Unconfirmed
DRB1*13:165	Unconfirmed	DRB1*13:195	Unconfirmed	DRB1*13:226	Unconfirmed
DRB1*13:166	Confirmed	DRB1*13:197	Unconfirmed		
DRB1*13:167	Unconfirmed	DRB1*13:198	Unconfirmed		
DRB1*13:169	Confirmed	DRB1*13:199	Confirmed		
DRB1*13:170	Unconfirmed	DRB1*13:200N	Unconfirmed		
DRB1*13:171:01	Unconfirmed	DRB1*13:201	Unconfirmed		
DRB1*13:171:02	Unconfirmed	DRB1*13:202	Unconfirmed		
DRB1*13:172	Unconfirmed	DRB1*13:203	Unconfirmed		
DRB1*13:173	Unconfirmed	DRB1*13:204	Unconfirmed		
DRB1*13:174	Unconfirmed	DRB1*13:205	Unconfirmed		
DRB1*13:175	Unconfirmed	DRB1*13:206	Confirmed		
DRB1*13:176	Unconfirmed	DRB1*13:207	Unconfirmed		
DRB1*13:177	Unconfirmed	DRB1*13:208	Unconfirmed		
DRB1*13:178	Unconfirmed	DRB1*13:209	Unconfirmed		
DRB1*13:179	Unconfirmed	DRB1*13:210	Unconfirmed		
DRB1*13:180	Unconfirmed	DRB1*13:211	Unconfirmed		
DRB1*13:181	Unconfirmed	DRB1*13:212	Unconfirmed		
DRB1*13:182	Unconfirmed	DRB1*13:213	Confirmed		

¹Allele status “confirmed” or “unconfirmed” as listed on the IMGT/HLA web page 2016-October-14, release 3.26.0, www.ebi.ac.uk/imgt/hla.

RESOLUTION IN HOMO- AND HETEROZYGOTES

Results file with resolution in DRB1*13 homo- and heterozygotes is available upon request.



0197

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Lot-specific information
SPECIFICITY TABLE

DRB1*13 SSP subtyping

Specificities and sizes of the PCR products of the 57+1 primer mixes used for DRB1*13 SSP subtyping

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified DRB1*13 alleles ³	Other amplified DRB alleles
1	175 bp	515 bp	*13:01:01:01-13:16:01:02, 13:18-13:42:02, 13:44, 13:46-13:66:02, 13:68-13:102, 13:104-13:115, 13:117:01:01-13:121, 13:123-13:158:02, 13:161-13:164, 13:166-13:174, 13:176-13:178, 13:180-13:182, 13:184-13:190, 13:192-13:194, 13:196-13:213, 13:215-13:216, 13:218-13:227, 13:229-13:247, 13:249N-13:298N, 13:300-13:335	*03:01:01:01-03:01:08, 03:01:10-03:07:02, 03:09, 03:11:01, 03:11:03-03:41:02, 03:43-03:45, 03:47-03:63, 03:66-03:68N, 03:70-03:86, 03:88-03:91, 03:93-03:110, 03:112-03:129, 03:131-03:139, 03:141-03:155, 03:157-03:161, 03:163-03:172, 03:174N-03:188, 03:191-03:205, 08:20, 11:264, 14:02:01:01-14:03:02, 14:05:01:01-14:06:06, 14:09, 14:12:01-14:14, 14:17-14:21, 14:23:01:01-14:24, 14:27:01-14:27:02, 14:29-14:30, 14:33, 14:36-14:37, 14:40-14:45, 14:47-14:48, 14:51, 14:56, 14:59, 14:63-14:65, 14:67, 14:77-14:78, 14:80-14:81, 14:83-14:85, 14:89, 14:91, 14:94-14:96, 14:98, 14:100-14:103, 14:106, 14:108-14:109, 14:115-14:116, 14:121, 14:123, 14:127:01-14:127:02, 14:134-14:136, 14:144, 14:154-14:156, 14:159-14:161, 14:165, 14:167, 14:169-14:170, 14:174, 14:176-14:179, 14:181, 14:183, 14:187-14:188N, 14:194-14:195N, 14:198, 14:209, 14:212, 14:218, 14:221, 14:223, 14:226, 14:239, 14:242:01-14:242:02, 14:246, DRB3*01:14
2	200 bp	430 bp	*13:01:01:01-13:04, 13:06, 13:08-13:10, 13:12:01-13:13, 13:15-13:16:01:02, 13:19, 13:22:01:01-13:23:02, 13:27:01-13:28:02, 13:30-13:41, 13:45, 13:48, 13:51-13:53, 13:57-13:59, 13:61:01-13:61:02, 13:64-13:66:02, 13:68-13:70, 13:72-13:73, 13:74 ^w , 13:76-13:77, 13:79-13:85, 13:87, 13:89:01-13:99, 13:101-13:102, 13:104-13:107, 13:109-13:110, 13:112-13:113N, 13:115, 13:117:01:01-13:118, 13:120-13:131, 13:135, 13:137N-13:139, 13:141-13:143, 13:145-13:148, 13:151-13:157, 13:159, 13:161-13:163, 13:165-13:168, 13:170-13:174,	*03:125, 11:02:01:01-11:02:07, 11:14:01:01-11:14:02, 11:16:01:01-11:16:01:02, 11:18-11:21, 11:31, 11:45, 11:48, 11:65:01-11:65:02, 11:70, 11:73, 11:82, 11:86, 11:98, 11:118:01-11:119, 11:124:01-11:124:02, 11:127, 11:132, 11:171, 11:184, 11:191, 11:242, 11:251, 11:256, 11:276, 11:280, 11:290, 11:293, 14:16, 14:24, 14:37, 14:63, 14:67, 14:78, 14:226



0197

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

101.116-24/03 – including *Taq* polymerase
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Lot No.: **9R5**

Lot-specific information

			13:176-13:177, 13:179, 13:181-13:182, 13:185N- 13:188, 13:190-13:191, 13:194, 13:198, 13:200N- 13:202, 13:204-13:205, 13:207-13:213, 13:215-13:222, 13:225-13:228, 13:233-13:234, 13:236-13:245, 13:249N- 13:275, 13:278Q, 13:280- 13:283, 13:285, 13:287- 13:295N, 13:297-13:298N, 13:300-13:301, 13:303-13:306, 13:308-13:325, 13:327-13:335	
3	200 bp	430 bp	*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	*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, 11:54:01-11:56, 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, 11:277-11:279, 11:281- 11:282, 11:284-11:285, 11:287N, 11:289, 11:291-11:292, 11:294N-11:308, 11:310- 11:311, 14:22, 14:25:01-14:25:02, 14:27:01-14:27:02, 14:53, 14:105, 14:128
4	170 bp	430 bp	*13:03:01:01-13:04, 13:12:01- 13:13, 13:21:01:01-13:21:02, 13:30, 13:32-13:33:03, 13:38, 13:48-13:49:02, 13:55, 13:58, 13:65-13:66:02, 13:75, 13:81, 13:88-13:90, 13:93-13:95, 13:101, 13:108, 13:115, 13:118, 13:120, 13:122, 13:133-13:134, 13:139, 13:151-13:152, 13:154, 13:161, 13:164, 13:167, 13:169, 13:174, 13:188, 13:194, 13:216, 13:219, 13:227-13:228, 13:230, 13:253, 13:276, 13:295N,	*03:12, 03:155, 03:158, 14:13, 14:63, 14:65, 14:78, 14:85, 14:169-14:170



0197

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

101.116-24/03 – including *Taq* polymerase
 101.116-24u/03u – without *Taq* polymerase

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 “Instructions for Use” (IFU)

Lot No.: **9R5**

Lot-specific information

			Lot-specific information	
5	220 bp	430 bp	13:307, 13:317, 13:319N, 13:321, 13:329N, 13:333 *13:03:01:01-13:03:12, 13:05:01:01-13:07:02, 13:10- 13:12:04, 13:12:05 ^w , 13:13- 13:14:03, 13:18, 13:21:01:01- 13:21:02, 13:25-13:26:02, 13:30, 13:33:01-13:33:03, 13:37, 13:42:01-13:42:02, 13:44, 13:46-13:47, 13:49:01- 13:50:03, 13:55-13:56, 13:58, 13:60, 13:62, 13:66:01- 13:66:02, 13:77, 13:81-13:82, 13:85-13:86, 13:88-13:90, 13:94:01-13:95, 13:100- 13:101, 13:108, 13:115, 13:118-13:120, 13:122, 13:132-13:134, 13:136, 13:144, 13:146, 13:150- 13:152, 13:154, 13:156- 13:158:02, 13:161, 13:163- 13:164, 13:169-13:170, 13:172, 13:174, 13:176, 13:178, 13:180, 13:181 ^w , 13:189, 13:193-13:194, 13:196-13:197, 13:199, 13:203, 13:206, 13:216, 13:219, 13:224, 13:227- 13:232, 13:235, 13:246, 13:253, 13:277, 13:284, 13:286, 13:295N, 13:302, 13:317, 13:319N, 13:321, 13:329N-13:331, 13:333	03:76, 03:126, 03:157, 03:174N, 03:177, 08:20, 11:01:01:01, 11:01:01:03-11:01:26, 11:01:27 ^w , 11:01:28 [?] , 11:01:29-11:01:47, 11:04:01:01-11:04:22, 11:06:01-11:06:03, 11:08:01-11:08:02, 11:08:03 ^w , 11:09:01:01-11:10:02, 11:12:01-11:13:02, 11:15:01:01-11:15:02, 11:17-11:19:03, 11:23:01-11:29:02, 11:31-11:35, 11:37:01- 11:39, 11:42:01, 11:42:02 ^w , 11:43:01:01- 11:47, 11:49:01-11:50, 11:52, 11:54:01- 11:58:02, 11:60-11:62:02, 11:64, 11:66:01- 11:66:02, 11:72-11:75, 11:77-11:81, 11:83-11:84:03, 11:87-11:97, 11:99- 11:102:02, 11:106, 11:108-11:117:02, 11:119-11:121, 11:123, 11:126, 11:128- 11:135, 11:137, 11:140-11:150, 11:152- 11:160, 11:162-11:163, 11:165:01-11:167, 11:169N-11:170, 11:172, 11:174-11:175, 11:177-11:192, 11:194:01-11:208, 11:210- 11:212, 11:214-11:228, 11:230, 11:232, 11:234-11:236, 11:238-11:240, 11:243- 11:250N, 11:252-11:255, 11:257-11:259, 11:262-11:269, 11:271-11:275, 11:277- 11:287N, 11:289, 11:291-11:292, 11:294N-11:300, 11:302-11:308, 11:310- 11:312, 14:01:01:01-14:03:02, 14:05:01:01-14:09, 14:12:01-14:14, 14:17- 14:23:04, 14:25:01-14:27:02, 14:29-14:30, 14:32:01-14:36, 14:38:01-14:45, 14:47- 14:49, 14:51, 14:53-14:55, 14:58-14:60, 14:62-14:65, 14:67, 14:69-14:70, 14:72, 14:74-14:75, 14:77-14:78, 14:80-14:86, 14:88-14:92N, 14:94-14:97, 14:99-14:103, 14:105-14:106, 14:108-14:110, 14:112- 14:119, 14:121-14:125, 14:127:01, 14:128- 14:136, 14:139-14:140, 14:142, 14:144, 14:146-14:147, 14:149-14:151, 14:153- 14:170, 14:173-14:174, 14:176-14:179, 14:181, 14:183-14:195N, 14:197N-14:198, 14:200, 14:202-14:204, 14:207-14:209, 14:211-14:219, 14:221-14:223, 14:225, 14:227-14:228, 14:230, 14:232, 14:234- 14:240, 14:242:01-14:246, 14:248
6	215 bp	515 bp	*13:01:01:01-13:02:22, 13:04, 13:08-13:09, 13:15- 13:16:01:02, 13:19- 13:20:01:03, 13:22:01:01- 13:24:01:03, 13:27:01- 13:29:01:02, 13:31-13:32, 13:34-13:36, 13:38-13:41, 13:43, 13:45, 13:48, 13:51- 13:54, 13:57, 13:59, 13:61:01- 13:61:02, 13:63-13:65,	*03:125, 11:02:01:01-11:03:04, 11:11:01, 11:11:03, 11:14:01:01-11:14:02, 11:16:01:01-11:16:01:02, 11:20-11:21, 11:36, 11:40-11:41, 11:48, 11:55, 11:59, 11:63:01-11:63:02, 11:65:01-11:65:02, 11:68-11:70, 11:76, 11:82, 11:85-11:86, 11:118:01-11:118:02, 11:122, 11:124:01- 11:124:02, 11:127, 11:138-11:139, 11:151, 11:161, 11:168, 11:171, 11:176, 11:213, 11:231, 11:233, 11:237, 11:241-11:242,



0197

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

101.116-24/03 – including *Taq* polymerase
 101.116-24u/03u – without *Taq* polymerase

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

Lot No.: **9R5**

Lot-specific information

			13:68-13:76, 13:78-13:80, 13:83-13:84, 13:87, 13:91- 13:93, 13:96:01-13:99, 13:102, 13:104-13:107, 13:109, 13:111-13:114, 13:117:01:01- 13:117:01:02, 13:121, 13:123- 13:131, 13:135, 13:138- 13:143, 13:145-13:149, 13:153, 13:155, 13:159, 13:162, 13:165-13:166, 13:168, 13:171:01-13:171:02, 13:173, 13:177, 13:179, 13:182, 13:184-13:187, 13:190-13:192, 13:198, 13:200N-13:202, 13:204- 13:205, 13:207-13:213, 13:215, 13:217-13:218, 13:221-13:223, 13:225-13:226, 13:233-13:234, 13:236-13:245, 13:247, 13:249N-13:252N, 13:254-13:276, 13:278Q- 13:283, 13:285, 13:287- 13:288, 13:290-13:294, 13:296-13:298N, 13:300- 13:301, 13:303-13:316, 13:318, 13:320, 13:322N- 13:328, 13:331-13:332, 13:334-13:335	11:251, 11:256, 11:260, 11:276, 11:290, 11:293, 11:301N, 14:16, 14:24, 14:37, 14:226
7	200 bp	430 bp	*13:02:01:01-13:02:22, 13:05:01:01-13:05:03, 13:26:01-13:26:02, 13:29:01:01-13:29:01:02, 13:31, 13:34, 13:36, 13:39, 13:41, 13:50:01-13:50:03, 13:56, 13:63, 13:65, 13:67, 13:73-13:74, 13:85, 13:96:01- 13:96:02, 13:99, 13:103- 13:104, 13:115, 13:119- 13:120, 13:123-13:124, 13:126, 13:128, 13:136, 13:139-13:140, 13:142N- 13:143, 13:145, 13:147, 13:155, 13:157-13:159, 13:165, 13:168, 13:170- 13:172, 13:179, 13:189, 13:196, 13:198-13:199, 13:202-13:203, 13:207-13:212, 13:220, 13:225, 13:235- 13:237, 13:239-13:241, 13:243-13:244, 13:255N, 13:257, 13:264-13:265, 13:268N-13:269, 13:275, 13:277, 13:280, 13:282, 13:285, 13:288-13:289N, 13:292-13:293,	*03:01:41-03:02:06, 03:05:01-03:05:03, 03:09, 03:14, 03:27, 03:29, 03:38, 03:53, 03:74, 03:81, 03:88, 03:90, 03:102-03:103, 03:115, 03:122, 03:130-03:131, 03:154, 03:167, 03:176, 03:178-03:179, 03:188, 04:77, 04:102, 04:113, 04:225, 08:73, 11:09:01:01-11:09:01:02, 11:20, 11:28:01:01-11:28:03, 11:87, 11:122, 14:02:01:01-14:02:07, 14:02:09-14:03:02, 14:09, 14:13, 14:19, 14:24, 14:27:01- 14:27:02, 14:30, 14:46-14:48, 14:51, 14:63, 14:67, 14:85, 14:89, 14:98, 14:109, 14:115, 14:134-14:135, 14:144, 14:174, 14:179, 14:194, 14:198, 14:200, 14:209, 14:218, 14:222N-14:223, 14:226, 14:239, 14:242:01-14:242:02, 16:08, DRB3*01:08, DRB3*01:46, DRB3*01:52, DRB3*01:71, DRB3*02:06, DRB3*02:20, DRB5*01:70



0197

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

101.116-24/03 – including *Taq* polymerase
 101.116-24u/03u – without *Taq* polymerase

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 “Instructions for Use” (IFU)

Lot No.: **9R5**

Lot-specific information

				13:296-13:298N, 13:301-13:302, 13:306, 13:310N, 13:312, 13:318, 13:320, 13:325, 13:331-13:332, 13:334	
8	190 bp	430 bp	*13:01:01:01-13:01:41, 13:06, 13:09-13:10, 13:15, 13:18, 13:20:01:01-13:20:01:03, 13:27:01-13:28:02, 13:32, 13:35, 13:40, 13:42:01-13:43, 13:51, 13:53, 13:59, 13:61:01-13:61:02, 13:69, 13:71, 13:77-13:80, 13:87, 13:91-13:93, 13:98, 13:102, 13:105, 13:110-13:114, 13:117:01:01-13:117:01:02, 13:121, 13:125, 13:127, 13:129-13:131, 13:137N-13:138, 13:141, 13:144, 13:146, 13:148, 13:153, 13:156, 13:160, 13:163, 13:166, 13:173, 13:176-13:178, 13:181, 13:183-13:187, 13:190-13:193, 13:200N-13:201, 13:205, 13:213-13:215, 13:217-13:218, 13:221-13:223, 13:226, 13:233, 13:238, 13:242:01-13:242:02, 13:245, 13:248-13:249N, 13:251-13:252N, 13:254, 13:256, 13:258-13:263, 13:266-13:267, 13:270-13:274, 13:279, 13:281, 13:283, 13:287, 13:291, 13:294, 13:299-13:300, 13:303-13:305, 13:308-13:309, 13:311, 13:313, 13:322N-13:324N, 13:326-13:328	*03:01:01:01-03:01:41, 03:03, 03:06-03:08, 03:10-03:11:01, 03:11:03-03:13:02, 03:15:01:01-03:16, 03:18-03:20, 03:22-03:24, 03:26, 03:28, 03:32-03:34, 03:36-03:37, 03:39, 03:42, 03:45-03:48, 03:50-03:51, 03:52:02, 03:54-03:56, 03:58-03:62, 03:64-03:73, 03:76-03:80, 03:82-03:87, 03:89, 03:91-03:101, 03:104, 03:106-03:114, 03:116-03:117, 03:119-03:121, 03:124-03:129, 03:132-03:153, 03:156N-03:166, 03:168-03:175, 03:177, 03:180-03:187, 03:189N-03:205, 04:211, 04:230, 11:16:01:01-11:16:01:02, 11:40, 11:58:01, 11:59, 11:83, 11:113, 11:115, 11:182, 11:280, 12:58, 14:06:01-14:06:06, 14:12:01-14:12:02, 14:17-14:18, 14:21, 14:29, 14:33, 14:52, 14:59, 14:64, 14:78, 14:80-14:81, 14:83, 14:95, 14:106, 14:108, 14:121, 14:132-14:133, 14:154, 14:165, 14:170, 14:176-14:177, 14:195N, 14:212, 14:246, 15:32, 15:192, DRB3*03:10	
9	270 bp	430 bp	*13:02:01:01-13:03:12, 13:05:01:01-13:05:03, 13:07:01-13:07:02, 13:12:01-13:14:03, 13:21:01:01-13:21:02, 13:23:01-13:23:02, 13:25-13:26:02, 13:29:01:01-13:31, 13:33:01-13:34, 13:36-13:39, 13:41, 13:45-13:47, 13:49:01-13:50:03, 13:55-13:56, 13:60, 13:62-13:63, 13:65-13:66:02, 13:73-13:74, 13:82, 13:85-13:86, 13:88, 13:90, 13:95-13:97:02, 13:99-13:101, 13:104, 13:107, 13:115, 13:118-13:120, 13:122-13:124, 13:126, 13:128, 13:132-13:136,	*03:01:41-03:02:06, 03:05:01-03:05:03, 03:09, 03:14, 03:17, 03:27, 03:29, 03:35, 03:38, 03:40-03:41:02, 03:53, 03:74, 03:81, 03:88, 03:90, 03:102-03:103, 03:115, 03:122, 03:130-03:131, 03:154-03:155, 03:167, 03:176, 03:178-03:179, 03:188, 11:01:01:01, 11:01:01:03-11:01:27, 11:01:28?, 11:01:29-11:01:47, 11:08:01-11:11:01, 11:11:03-11:12:03, 11:14:01:01-11:15:02, 11:19:01-11:20, 11:23:01-11:24:02, 11:26-11:29:02, 11:31-11:33, 11:37:01-11:37:02, 11:39, 11:45, 11:49:01-11:49:02, 11:51, 11:53, 11:61-11:62:02, 11:64, 11:66:01-11:66:02, 11:68-11:69, 11:72-11:75, 11:79-11:82, 11:87, 11:90-11:91, 11:93-11:97, 11:99-11:101:03, 11:103:01-11:103:02,	



0197

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

101.116-24/03 – including *Taq* polymerase
 101.116-24u/03u – without *Taq* polymerase

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

Lot No.: **9R5**

Lot-specific information

			13:139-13:140, 13:142N-13:143, 13:145, 13:147, 13:151-13:152, 13:154-13:155, 13:157-13:159, 13:161, 13:165, 13:167-13:168, 13:170-13:172, 13:174, 13:179-13:180, 13:182, 13:188-13:189, 13:194, 13:196-13:199, 13:202-13:203, 13:207-13:212, 13:216, 13:219-13:220, 13:224-13:225, 13:227-13:230, 13:232, 13:235-13:237, 13:239-13:241, 13:243-13:244, 13:247, 13:250, 13:253, 13:255N, 13:257, 13:264-13:265, 13:268N-13:269, 13:275, 13:277, 13:280, 13:282, 13:285-13:286, 13:288-13:289N, 13:292-13:293, 13:295N-13:298N, 13:301-13:302, 13:306, 13:310N, 13:312, 13:316-13:321, 13:325, 13:329N-13:335	11:105-11:112, 11:114, 11:117:01-11:117:02, 11:120-11:122, 11:125-11:126, 11:128, 11:133-11:134, 11:136, 11:140-11:145, 11:147:01-11:147:02, 11:149-11:150, 11:152, 11:154-11:155, 11:157-11:158, 11:162, 11:164, 11:166-11:170, 11:172, 11:175, 11:177-11:178, 11:183-11:186, 11:188, 11:191-11:192, 11:195, 11:197, 11:199, 11:204-11:205, 11:208, 11:212, 11:215, 11:219, 11:222, 11:225-11:226, 11:228, 11:232, 11:234-11:240, 11:243, 11:245, 11:247-11:248Q, 11:250N, 11:252, 11:254, 11:257, 11:259, 11:262-11:263, 11:265-11:266, 11:268-11:269, 11:271-11:275, 11:277-11:279, 11:281, 11:283, 11:285-11:286, 11:289, 11:291, 11:294N-11:296, 11:298-11:299, 11:302-11:303N, 11:305, 11:308, 11:311, 14:02:01:01-14:02:07, 14:02:09-14:03:02, 14:07:01-14:07:03, 14:09, 14:13-14:14, 14:19, 14:22, 14:24-14:25:02, 14:27:01-14:27:02, 14:30, 14:36, 14:40-14:42, 14:44:01-14:44:03, 14:47-14:49, 14:51, 14:53, 14:63, 14:67, 14:69, 14:77, 14:85, 14:89, 14:94, 14:98, 14:102, 14:109, 14:115-14:116, 14:119, 14:134-14:135, 14:144, 14:159, 14:164, 14:174, 14:179, 14:181, 14:194, 14:198, 14:200, 14:208-14:209, 14:218, 14:222N-14:223, 14:226, 14:239, 14:242:01-14:242:02, 14:244,
10	260 bp	430 bp	*13:01:01:01-13:01:41, 13:04, 13:06, 13:08-13:11:02, 13:15, 13:18-13:20:01:03, 13:22:01:01-13:22:02, 13:24:01:01-13:24:01:03, 13:27:01-13:28:02, 13:32, 13:35, 13:40, 13:42:01-13:44, 13:48, 13:51-13:54, 13:57-13:59, 13:61:01-13:61:02, 13:64, 13:68-13:72, 13:75-13:81, 13:83-13:84, 13:87, 13:89:01-13:89:02, 13:91-13:94:02, 13:98, 13:102, 13:105-13:106, 13:108, 13:110-13:114, 13:117:01:01-13:117:01:02, 13:121, 13:125, 13:127, 13:129-13:131, 13:137N-13:138, 13:141, 13:144, 13:146, 13:148-13:150, 13:153, 13:156, 13:162-13:164, 13:166, 13:169, 13:173, 13:176-13:178, 13:181, 13:184-13:187, 13:190-13:193,	DRB3*01:14 *03:01:01:01-03:01:41, 03:03-03:04:02, 03:06-03:08, 03:10-03:11:01, 03:11:03-03:13:02, 03:15:01:01-03:16, 03:18-03:26, 03:28, 03:30-03:34, 03:36-03:37, 03:39, 03:43-03:52:02, 03:54-03:56, 03:58-03:62, 03:64-03:68N, 03:70-03:73, 03:75-03:80, 03:82-03:86, 03:89, 03:91, 03:93-03:101, 03:104-03:110, 03:112-03:114, 03:116-03:121, 03:124-03:129, 03:132-03:153, 03:156N-03:161, 03:163-03:166, 03:168-03:172, 03:174N-03:175, 03:177, 03:180-03:187, 03:189N, 03:191-03:205, 08:20, 11:02:01:01-11:04:22, 11:06:01-11:07:02, 11:13:01-11:13:02, 11:16:01:01-11:18, 11:21, 11:25, 11:34-11:36, 11:38, 11:40-11:44, 11:46:01-11:48, 11:50, 11:52, 11:54:01-11:60, 11:63:01-11:63:02, 11:65:01-11:65:02, 11:70, 11:76-11:78, 11:83-11:85, 11:88-11:89, 11:92, 11:98, 11:102:01-11:102:02, 11:113, 11:115-11:116, 11:118:01-11:119, 11:123-11:124:02, 11:127, 11:129-11:132, 11:135, 11:137-11:139, 11:146, 11:148, 11:151, 11:153, 11:156, 11:159-11:161, 11:163,



0197

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

101.116-24/03 – including *Taq* polymerase
 101.116-24u/03u – without *Taq* polymerase

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

Lot No.: **9R5**

Lot-specific information

			13:200N-13:201, 13:204-13:206, 13:213, 13:215, 13:217-13:218, 13:221-13:223, 13:226, 13:231, 13:233-13:234, 13:238, 13:242:01-13:242:02, 13:245-13:246, 13:249N, 13:251-13:252N, 13:254, 13:256, 13:258-13:263, 13:266-13:267, 13:270-13:274, 13:276, 13:278Q-13:279, 13:281, 13:283-13:284, 13:287, 13:291, 13:294, 13:300, 13:303-13:305, 13:307-13:309, 13:311, 13:313-13:314, 13:322N-13:324N, 13:326-13:328	11:165:01-11:165:02, 11:171, 11:173-11:174, 11:176, 11:179-11:182, 11:187, 11:189-11:190, 11:194:01-11:194:02, 11:196, 11:198, 11:200-11:203, 11:206-11:207, 11:210-11:211, 11:213-11:214, 11:216-11:218, 11:220-11:221, 11:223-11:224, 11:227, 11:230-11:231, 11:233, 11:241-11:242, 11:244, 11:246N, 11:249, 11:251, 11:253, 11:255-11:256, 11:258, 11:260, 11:264, 11:267, 11:276, 11:280, 11:282, 11:284, 11:287N, 11:290, 11:292-11:293, 11:297Q, 11:300-11:301N, 11:304, 11:306-11:307, 11:310, 11:312, 14:01:01:01-14:01:05, 14:05:01:01-14:06:06, 14:08, 14:12:01-14:12:02, 14:16-14:18, 14:20-14:21, 14:23:01:01-14:23:04, 14:26, 14:29, 14:32:01-14:35, 14:37-14:39, 14:43, 14:45, 14:54:01:01-14:56, 14:58-14:60, 14:62, 14:64-14:65, 14:70, 14:72, 14:74-14:75, 14:78, 14:80-14:84, 14:86-14:88, 14:90-14:92N, 14:95-14:97, 14:99-14:101, 14:103-14:106, 14:108, 14:110-14:114, 14:117-14:118, 14:121-14:125, 14:127:01-14:133, 14:136-14:137N, 14:139-14:140, 14:146-14:147, 14:149-14:151, 14:153-14:158, 14:160-14:163, 14:165-14:173, 14:176-14:178, 14:183-14:193, 14:195N, 14:197N, 14:202-14:204, 14:207, 14:211-14:217, 14:219, 14:221, 14:227-14:228, 14:230, 14:232, 14:234-14:238, 14:240, 14:243, 14:245-14:246, 14:248
11	210 bp	430 bp	*13:09, 13:20:01:01-13:20:01:03, 13:25, 13:29:01:01-13:29:01:02, 13:43, 13:56, 13:60, 13:71, 13:78, 13:88, 13:119, 13:129, 13:134, 13:149, 13:180, 13:192, 13:224, 13:231, 13:235, 13:314, 13:326	*11:08:01-11:08:03, 11:36, 11:42:01-11:42:02, 11:57, 11:64, 11:68-11:69, 11:82, 11:130, 11:286, 11:312, 14:03:01-14:03:02, 14:12:01-14:12:02, 14:24, 14:37, 14:40, 14:69, 14:74, 14:77, 14:84-14:85, 14:98, 14:102, 14:115-14:116, 14:135, 14:144, 14:156, 14:173-14:174, 14:181, 14:218, 14:222N-14:223, 14:226, 14:235, 14:239
12	220 bp	430 bp	*13:01:01:01-13:04, 13:08, 13:10, 13:12:05, 13:15-13:16:01:02, 13:19-13:20:01:03, 13:22:01:01-13:24:01:03, 13:26:01, 13:27:01-13:29:01:02, 13:31-13:41, 13:42:02-13:43, 13:45, 13:48, 13:49:02, 13:51-13:54, 13:57, 13:59-13:61:02, 13:63-13:66:02, 13:68-13:81, 13:83-13:85, 13:87-13:99, 13:101-13:102, 13:104-13:107, 13:109, 13:111-13:115, 13:117:01:01-13:117:01:02,	*03:76, 03:125, 03:174N, 11:01:03, 11:01:10-11:01:11, 11:02:01:01-11:03:04, 11:04:07, 11:08:03, 11:11:01, 11:11:03, 11:14:01:01-11:14:02, 11:16:01:01-11:16:01:02, 11:19:02, 11:20-11:21, 11:36, 11:40-11:41, 11:42:02, 11:48, 11:59, 11:63:01-11:63:02, 11:65:01-11:65:02, 11:68, 11:70, 11:73, 11:76, 11:79, 11:85-11:86, 11:93, 11:118:01-11:118:02, 11:122, 11:124:01-11:124:02, 11:127, 11:131-11:132, 11:138-11:139, 11:151, 11:153, 11:161, 11:168, 11:171, 11:176, 11:184, 11:213, 11:231, 11:233, 11:237, 11:241-11:242, 11:251, 11:256, 11:260,



0197

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

101.116-24/03 – including *Taq* polymerase
 101.116-24u/03u – without *Taq* polymerase

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

Lot No.: **9R5**

Lot-specific information

			13:120-13:128, 13:130-13:131, 13:133, 13:135, 13:137N-13:143, 13:145, 13:147-13:149, 13:151-13:153, 13:155, 13:159, 13:162-13:163, 13:165-13:168, 13:170-13:174, 13:176-13:182, 13:184-13:188, 13:190-13:191, 13:194, 13:196, 13:198, 13:200N-13:202, 13:204-13:205, 13:207-13:209, 13:212-13:213, 13:215-13:219, 13:221, 13:223, 13:225-13:227, 13:230, 13:233-13:234, 13:236-13:245, 13:247, 13:249N-13:276, 13:278Q-13:283, 13:285, 13:287-13:294, 13:296-13:298N, 13:300-13:301, 13:303-13:313, 13:315-13:320, 13:322N-13:325, 13:327-13:329N, 13:332-13:335	11:276, 11:290, 11:293, 11:301N, 14:16, 14:19, 14:21, 14:32:03, 14:109
13	145 bp	515 bp	*13:03:01:01-13:03:12, 13:07:01-13:08, 13:12:01-13:13, 13:19, 13:26:01-13:26:02, 13:32-13:33:03, 13:36-13:38, 13:40, 13:47-13:49:02, 13:53, 13:55, 13:58, 13:60, 13:65, 13:70, 13:72, 13:76, 13:81, 13:84-13:85, 13:88-13:90, 13:94:01-13:95, 13:101, 13:108, 13:115, 13:118, 13:120, 13:122, 13:133-13:135, 13:149, 13:151-13:152, 13:159, 13:164, 13:167, 13:174, 13:180, 13:182, 13:188-13:189, 13:191, 13:194, 13:198, 13:216, 13:219, 13:227-13:228, 13:230-13:232, 13:235, 13:246, 13:253, 13:262, 13:295N, 13:307, 13:316-13:317, 13:319N, 13:321, 13:329N, 13:333	*03:02:01:01-03:03, 03:06, 03:17, 03:26-03:27, 03:31, 03:35, 03:38, 03:41:01-03:41:02, 03:60, 03:74-03:75, 03:80, 03:85, 03:88, 03:90, 03:102-03:103, 03:115, 03:122, 03:131, 03:154-03:155, 03:158, 03:167, 03:176, 03:179, 08:20, 11:17, 11:37:01-11:37:02, 11:41, 11:48, 11:50, 11:52, 11:56, 11:83, 11:107, 11:145, 11:149, 11:170-11:171, 11:183-11:184, 11:189, 11:200, 11:249, 11:264, 11:273, 14:01:01:01-14:03:01, 14:05:01:01-14:09, 14:12:01-14:14, 14:16, 14:18-14:20, 14:22-14:27:02, 14:29, 14:32:01-14:32:03, 14:34, 14:36-14:41, 14:43-14:45, 14:47-14:49, 14:51, 14:54:01:01-14:56, 14:58-14:60, 14:62-14:63, 14:67, 14:69-14:70, 14:74-14:75, 14:77-14:78, 14:80-14:92N, 14:94, 14:96-14:106, 14:108-14:119, 14:121-14:125, 14:127:01-14:127:02, 14:129-14:131, 14:133, 14:135-14:137N, 14:139-14:140, 14:142, 14:144, 14:146-14:147, 14:149, 14:151, 14:153-14:174, 14:176-14:178, 14:181, 14:183-14:185, 14:188N-14:195N, 14:197N-14:198, 14:200, 14:202-14:204, 14:207, 14:209, 14:211-14:219, 14:222N-14:223, 14:225-14:228, 14:230, 14:232, 14:234-14:240, 14:242:01-14:246, 14:248,

DRB3*01:14



0197

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

101.116-24/03 – including *Taq* polymerase
 101.116-24u/03u – without *Taq* polymerase

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

Lot No.: **9R5**

Lot-specific information

14	145 bp	430 bp	*13:04, 13:08, 13:17, 13:19, 13:22:01:01-13:24:01:03, 13:38, 13:45, 13:48, 13:54, 13:57, 13:64, 13:70, 13:72, 13:75-13:76, 13:83, 13:97:02, 13:107, 13:116, 13:135, 13:149, 13:162, 13:175, 13:182, 13:195, 13:204, 13:247, 13:250, 13:276, 13:307, 13:312, 13:316	*04:02:01-04:02:07, 04:14, 04:37, 04:106, 04:124, 04:132-04:134, 04:138, 04:143, 04:161, 04:204, 04:210, 04:238, 04:259, 04:287, 04:299N, 04:325, 04:336, 04:348, 08:92, 11:02:01:01-11:02:04, 11:02:06-11:03:04, 11:11:01, 11:11:03, 11:14:01:01-11:14:02, 11:21, 11:36, 11:41, 11:48, 11:55, 11:63:01, 11:65:01-11:65:02, 11:68, 11:70, 11:76, 11:85-11:86, 11:118:02, 11:124:01-11:124:02, 11:127, 11:138-11:139, 11:151, 11:161, 11:168, 11:171, 11:176, 11:213, 11:229, 11:231, 11:233, 11:237, 11:241-11:242, 11:251, 11:256, 11:260, 11:270, 11:290, 11:293, 11:301N, 11:309, 14:16, 14:57
15⁴	85 bp	515 bp	*13:15, 13:19, 13:26:01-13:26:02, 13:53, 13:57, 13:85, 13:86 ^w , 13:104, 13:198, 13:235	*03:02:01:01-03:03, 03:27, 03:29, 03:38, 03:53, 03:74, 03:88, 03:90, 03:102-03:103, 03:115, 03:119, 03:131, 03:154, 03:167, 03:176, 03:179, 14:02:01:01-14:03:02, 14:06:01-14:06:06, 14:12:01-14:13, 14:18-14:20, 14:24, 14:27:01-14:27:02, 14:29, 14:40-14:41, 14:47-14:49, 14:51, 14:63, 14:67, 14:77-14:78, 14:81, 14:83, 14:85, 14:89, 14:94, 14:98, 14:102 ^w , 14:106, 14:108-14:109, 14:115, 14:135, 14:154, 14:156, 14:159-14:160, 14:165, 14:170, 14:174, 14:176-14:177, 14:181, 14:194-14:195N, 14:198, 14:200, 14:209, 14:212, 14:218, 14:222N-14:223, 14:226, 14:239, 14:242:01-14:242:02
16	150 bp	430 bp	*13:01:01:01-13:02:01:14, 13:02:03-13:02:22, 13:08, 13:15-13:16:01:02, 13:19-13:20:01:03, 13:27:01-13:29:01:02, 13:31-13:32, 13:34-13:36, 13:39-13:41, 13:43, 13:51-13:53, 13:57, 13:59, 13:61:01-13:61:02, 13:63-13:65, 13:67-13:69, 13:71-13:74, 13:76, 13:78-13:80, 13:83-13:84, 13:87, 13:91-13:93, 13:96:01-13:97:01, 13:98-13:99, 13:102-13:107, 13:109, 13:111-13:114, 13:117:01:01-13:117:01:02, 13:121, 13:123-13:128, 13:130-13:131, 13:135, 13:138-13:143, 13:145, 13:147-13:148, 13:153, 13:155, 13:159-13:160, 13:165-13:166, 13:168, 13:171:01-13:171:02, 13:173, 13:175, 13:177, 13:179, 13:182-13:187, 13:190-13:191, 13:195,	*03:125, 11:02:05, 11:16:01:01-11:16:01:02, 11:20, 11:40, 11:59, 11:63:02, 11:118:01, 11:122, 12:73, 14:16, 14:57, 15:10, DRB3*02:160



0197

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

101.116-24/03 – including *Taq* polymerase
 101.116-24u/03u – without *Taq* polymerase

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

Lot No.: **9R5**

Lot-specific information

			13:198, 13:200N-13:202, 13:205, 13:207-13:212, 13:213 ^w , 13:214-13:215, 13:217-13:218, 13:221-13:223, 13:225-13:226, 13:233-13:234, 13:236-13:245, 13:248- 13:252N, 13:254-13:275, 13:278Q-13:283, 13:285, 13:287-13:288, 13:290-13:294, 13:296-13:301, 13:303-13:306, 13:308-13:311, 13:313, 13:315, 13:318, 13:320, 13:322N-13:325, 13:327- 13:328, 13:332, 13:334-13:335	
17	220 bp	430 bp	*13:02:02, 13:12:05, 13:26:01, 13:42:02, 13:49:02, 13:60, 13:77, 13:163, 13:181, 13:289N	*11:01:03, 11:01:10-11:01:11, 11:04:07, 11:08:03, 11:19:02, 11:42:02, 14:32:03
18⁴	110 bp 230 bp	430 bp	*13:87 *13:13, 13:18, 13:33:02- 13:33:03, 13:47, 13:55, 13:61:01, 13:94:02, 13:96:02, 13:119, 13:144, 13:146, 13:154, 13:156, 13:158:01- 13:158:02, 13:164, 13:232, 13:286, 13:331	*03:01:02:01-03:01:02:02, 03:02:02, 03:05:03, 03:11:03, 03:13:02, 03:17, 03:24, 03:27, 03:35, 03:81, 03:130, 03:157, 03:167, 03:188, 08:20, 11:07:02, 11:23:01-11:23:02, 11:25, 11:27:01, 11:45, 11:55, 11:64, 11:84:01, 11:119, 11:124:01, 11:136, 11:138, 14:03:01-14:03:02, 14:12:01-14:12:02, 14:27:01-14:27:02, 14:38:01, 14:40, 14:47, 14:55, 14:63, 14:67, 14:77-14:78, 14:84-14:85, 14:89, 14:98, 14:102, 14:115-14:116, 14:127:01, 14:135-14:136, 14:144, 14:156, 14:164- 14:165, 14:173-14:174, 14:181, 14:218, 14:222N-14:223, 14:239, 14:244, DRB3*01:14
19⁴	110 bp	430 bp	*13:87, 13:106, 13:216, 13:266	*03:26, 03:33, 03:44, 11:44, 11:49:01- 11:50, 11:85, 11:127, 11:249, 11:273, 11:278, 11:286, 14:97, 14:221
	205 bp 260 bp		*13:74 *13:16:01:01-13:16:01:02	*11:86
20⁵	215 bp	515 bp	*13:17, 13:67, 13:116, 13:175, 13:195, 13:214	*08:40, 08:92, 11:229, 11:270, 12:73, DRB3*02:27, DRB3*02:160
21⁵	175 bp	515 bp	*13:27:01-13:27:02, 13:41, 13:71, 13:176 *13:103, 13:160	*03:76, 03:125, 03:174N, 11:59
22⁴	220 bp 110 bp 175 bp	430 bp	*13:68 *13:31, 13:46, 13:54, 13:77, 13:100, 13:162, 13:180, 13:260, 13:330 *13:13 [?] , 13:30 [?] , 13:33:01 [?] , 13:52 [?] , 13:105	*11:24:01-11:24:02 *03:38, 03:79, 03:85, 03:96, 14:48, 14:174, 14:177, DRB3*01:14
	280 bp			*03:12 [?] , 11:26 [?] , 11:40 [?] , 11:100, 14:19 [?] , 14:213



0197

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

101.116-24/03 – including *Taq* polymerase
 101.116-24u/03u – without *Taq* polymerase

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

Lot No.: **9R5**

Lot-specific information

23⁴	115 bp	430 bp	*13:34, 13:64, 13:136, 13:174, 13:204, 13:221, 13:250	*03:43, 03:71:01, 11:76, 11:114, 11:183, 11:196, 11:302, 14:41, 14:77, 14:110, 14:218, DRB3*01:14
	245 bp		*13:01:03, 13:02:13, 13:28:01- 13:28:02, 13:76, 13:163, 13:193, 13:242:02	*03:01:17, 03:15:02, 03:73, 03:97, 03:145, 11:01:05, 11:01:10, 11:04:03, 11:06:02, 11:13:01-11:13:02, 11:17, 11:52, 11:54:01, 11:159, 11:202, 11:283, 14:01:01:01- 14:01:01:03, 14:01:03-14:01:05, 14:05:01:01-14:05:02, 14:05:04-14:05:05, 14:07:01-14:07:02, 14:08, 14:14, 14:18, 14:23:01:01-14:23:04, 14:26, 14:32:02- 14:32:03, 14:34-14:36, 14:39, 14:42- 14:44:01, 14:44:03-14:45, 14:54:01:01- 14:56, 14:58-14:60, 14:62, 14:64-14:65, 14:70, 14:72, 14:82, 14:86-14:88, 14:90- 14:92N, 14:95-14:97, 14:99-14:101, 14:104-14:105, 14:110-14:114, 14:117- 14:118, 14:122-14:125, 14:127:02, 14:129- 14:134, 14:137N, 14:139-14:140, 14:142, 14:146-14:147, 14:149-14:151, 14:153- 14:155, 14:157-14:158, 14:160-14:163, 14:166N-14:169, 14:172-14:173, 14:178, 14:184-14:193, 14:197N, 14:202-14:204, 14:207, 14:211, 14:213-14:217, 14:219, 14:225, 14:227-14:228, 14:230, 14:232, 14:234-14:238, 14:240, 14:243, 14:245- 14:246, 14:248
24	145 bp	515 bp	*13:35, 13:161, 13:185N	*03:13:01-03:13:02, 03:38, 03:79, 03:88, 03:167, 11:116, 11:120, 14:48, 14:64, 14:109, 14:115, 14:177, DRB3*01:14
	180 bp		*13:39, 13:54, 13:77-13:79, 13:100, 13:162-13:163, 13:181	*03:12 [?] , 03:16 [?] , 03:83, 11:26 [?] , 11:40 [?] , 14:19 [?]
	280 bp		*13:13 [?] , 13:30 [?] , 13:33:01 [?] , 13:45 [?] , 13:52 [?] , 13:166	
25⁴	110 bp	430 bp	*13:03:01:01-13:04, 13:07:01- 13:08, 13:11:01-13:14:03, 13:19, 13:21:01:01-13:25, 13:30, 13:33:01-13:33:03, 13:37-13:38, 13:44-13:49:02, 13:52, 13:54-13:55, 13:57- 13:58, 13:60, 13:66:01- 13:66:02, 13:70, 13:72, 13:75- 13:76, 13:81-13:84, 13:86, 13:88-13:90, 13:94:01-13:95, 13:97:01-13:97:02, 13:100- 13:101, 13:107-13:108, 13:118, 13:122, 13:132- 13:135, 13:149-13:150, 13:152, 13:154, 13:161- 13:162, 13:164, 13:167, 13:169, 13:180, 13:182, 13:188, 13:194, 13:197, 13:206, 13:219, 13:224, 13:227-13:232, 13:246-13:247, 13:253, 13:276, 13:284,	*03:04:01-03:04:02, 03:17, 03:21, 03:25:01-03:25:02, 03:30-03:31, 03:35, 03:40-03:41:02, 03:49, 03:75, 03:105, 03:118, 03:155, 08:20, 11:01:01:01, 11:01:01:03-11:01:27, 11:01:28 [?] , 11:01:29-11:01:31, 11:01:33-11:04:22, 11:06:01-11:08:03, 11:10:01-11:11:01, 11:11:03-11:14:02, 11:17-11:19:03, 11:21, 11:23:01-11:23:02, 11:25-11:27:03, 11:29:01-11:29:02, 11:31-11:39, 11:41- 11:43:01:02, 11:45-11:48, 11:51-11:57, 11:60-11:66:02, 11:68-11:70, 11:72-11:75, 11:77-11:82, 11:84:01-11:84:03, 11:86, 11:88-11:103:02, 11:105-11:112, 11:116- 11:121, 11:123-11:126, 11:128-11:181, 11:184-11:192, 11:194:01-11:195, 11:197- 11:208, 11:210-11:228, 11:230-11:248Q, 11:250N-11:258, 11:260, 11:262-11:269, 11:271-11:272Q, 11:274-11:277, 11:279, 11:281-11:285, 11:287N, 11:289-11:301N, 11:303N-11:308, 11:310-11:312,



0197

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

101.116-24/03 – including *Taq* polymerase
 101.116-24u/03u – without *Taq* polymerase

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

Lot No.: **9R5**

Lot-specific information

			13:286, 13:295N, 13:307, 13:314, 13:316-13:317, 13:319N, 13:321, 13:329N- 13:330, 13:333, 13:335	14:01:01:01-14:01:05, 14:05:01:01- 14:05:05, 14:07:01-14:08, 14:14, 14:16, 14:20, 14:22-14:23:04, 14:25:01-14:26, 14:32:01-14:32:03, 14:34-14:40, 14:42- 14:45, 14:49, 14:53-14:56, 14:58, 14:60, 14:62, 14:65, 14:69-14:70, 14:72, 14:74- 14:75, 14:82, 14:84, 14:86-14:88, 14:90- 14:92N, 14:94, 14:96, 14:99-14:105, 14:111-14:114, 14:116-14:119, 14:122- 14:125, 14:127:01-14:131, 14:136- 14:137N, 14:139-14:140, 14:142, 14:146- 14:147, 14:149-14:151, 14:153, 14:155- 14:164, 14:166N, 14:168-14:169, 14:171- 14:173, 14:178, 14:181, 14:183-14:193, 14:197N, 14:202-14:204, 14:207-14:208, 14:211, 14:213-14:217, 14:219, 14:225, 14:227, 14:230, 14:232, 14:234-14:238, 14:240, 14:243-14:245, 14:248
26 ^{4,5,7}	140 bp 90 bp	430 bp	*13:185N *13:150	*11:39, 11:43:01:01-11:43:01:02, 11:50, 11:115, 11:145, 11:151, 11:168, 11:174, 16:73, DRB3*02:111
	140 bp		*13:05:01:01-13:05:03, 13:18, 13:26:01-13:26:02, 13:42:01- 13:42:02, 13:50:02-13:50:03, 13:63, 13:111, 13:132, 13:136, 13:144, 13:158:01-13:158:02, 13:189, 13:199, 13:203, 13:232, 13:277, 13:302	*08:09:01-08:09:02, 08:21, 08:70, 08:87, 11:01:12, 11:04:04, 11:09:01:01-11:10:02, 11:12:02, 11:22, 11:28:02, 11:29:02, 11:40, 11:46:01, 11:58:01, 11:59, 11:62:02, 11:63:02, 11:83, 11:87, 11:113, 11:115, 11:122, 11:149, 11:165:02, 11:182, 11:189-11:190, 11:218, 11:264, 14:15, 14:22, 14:27:01-14:27:02, 14:73, 14:105, 16:01:01:02-16:01:01:03, 16:01:18, 16:72-16:73
27 ⁵	145 bp	515 bp	*13:01:01:01-13:01:08, 13:01:10-13:01:22, 13:01:24- 13:02:22, 13:04-13:06, 13:09- 13:11:02, 13:14:01- 13:16:01:02, 13:18, 13:20:01:01-13:25, 13:27:01- 13:31, 13:34, 13:39, 13:41- 13:46, 13:50:01-13:52, 13:54, 13:56-13:57, 13:59, 13:61:01- 13:64, 13:66:01-13:66:02, 13:68-13:69, 13:71, 13:73- 13:75, 13:77-13:80, 13:82- 13:83, 13:86-13:87, 13:91- 13:93, 13:96:01-13:100, 13:102, 13:104-13:107, 13:109-13:114, 13:117:01:01- 13:117:01:02, 13:119, 13:121, 13:123-13:132, 13:136-13:148, 13:150, 13:153-13:158:02, 13:162-13:163, 13:165-13:166, 13:168-13:173, 13:176, 13:178-13:179, 13:181, 13:184-13:187, 13:190,	*03:01:01:01-03:01:22, 03:01:24-03:01:41, 03:04:01-03:05:03, 03:07:01:01-03:11:01, 03:11:03-03:16, 03:18-03:25:02, 03:28- 03:30, 03:32-03:34, 03:36-03:37, 03:39- 03:40, 03:43-03:52:02, 03:54-03:59, 03:61-03:68N, 03:70-03:73, 03:76-03:79, 03:81, 03:83-03:84, 03:86, 03:89, 03:91, 03:93-03:101, 03:104-03:110, 03:112- 03:114, 03:116-03:121, 03:123-03:130, 03:132-03:137, 03:139-03:153, 03:156N- 03:157, 03:159-03:161, 03:163-03:166, 03:168-03:172, 03:174N-03:175, 03:177- 03:178, 03:180, 03:182-03:189N, 03:191- 03:205, 11:01:01:01, 11:01:01:03- 11:01:06, 11:01:08-11:01:27, 11:01:28 [?] , 11:01:29-11:04:13, 11:04:15-11:04:22, 11:06:01-11:11:01, 11:11:03-11:16:01:02, 11:18-11:21, 11:23:01-11:29:02, 11:31- 11:36, 11:38-11:40, 11:42:01-11:47, 11:49:01-11:49:02, 11:51, 11:53-11:55, 11:57-11:66:02, 11:68-11:70, 11:72-11:82, 11:84:01-11:87, 11:89-11:103:02, 11:105- 11:106, 11:108-11:144, 11:146-11:148,



0197

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

101.116-24/03 – including *Taq* polymerase
 101.116-24u/03u – without *Taq* polymerase

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

Lot No.: **9R5**

Lot-specific information

			13:192-13:193, 13:196-13:197, 13:199-13:213, 13:215, 13:217-13:218, 13:220-13:226, 13:229, 13:233-13:234, 13:236-13:245, 13:247, 13:249N-13:252N, 13:254- 13:261, 13:263-13:294, 13:296-13:298N, 13:300- 13:306, 13:308-13:315, 13:318, 13:320, 13:322N- 13:328, 13:330-13:332, 13:335	11:150-11:169N, 11:172-11:182, 11:185- 11:188, 11:190-11:192, 11:194:01-11:199, 11:201-11:208, 11:210-11:228, 11:230- 11:248Q, 11:250N-11:260, 11:262-11:263, 11:265-11:269, 11:271-11:272Q, 11:274- 11:287N, 11:289-11:308, 11:310-11:312, 14:17, 14:21, 14:30, 14:33, 14:35, 14:42, 14:53, 14:64-14:65, 14:72, 14:95, 14:128, 14:132, 14:134, 14:179, 14:186-14:187, 14:208, 14:221
28	160 bp	430 bp	*13:01:01:01-13:01:41, 13:04, 13:06, 13:09-13:11:02, 13:15, 13:17-13:18, 13:20:01:01- 13:20:01:03, 13:22:01:01- 13:22:02, 13:24:01:01- 13:24:01:03, 13:27:01- 13:28:02, 13:35, 13:42:01- 13:44, 13:51-13:52, 13:54, 13:57, 13:59, 13:61:01- 13:61:02, 13:64, 13:68-13:69, 13:71, 13:75, 13:77-13:80, 13:83, 13:87, 13:91-13:93, 13:98, 13:102, 13:105-13:106, 13:110-13:114, 13:117:01:01- 13:117:01:02, 13:121, 13:125, 13:127, 13:129-13:131, 13:137N-13:138, 13:141, 13:144, 13:146, 13:148, 13:150, 13:153, 13:156, 13:160, 13:162-13:163, 13:166, 13:169, 13:173, 13:175-13:178, 13:181, 13:183-13:184, 13:186-13:187, 13:190, 13:192-13:193, 13:200N-13:201, 13:204- 13:206, 13:213-13:215, 13:217-13:218, 13:221-13:223, 13:226, 13:233-13:234, 13:238, 13:242:01-13:242:02, 13:245, 13:248-13:249N, 13:251-13:252N, 13:254, 13:256, 13:258-13:261, 13:263, 13:266-13:267, 13:270-13:274, 13:276, 13:278Q-13:279, 13:281, 13:283-13:284, 13:287, 13:291, 13:294, 13:299- 13:300, 13:303-13:305, 13:308-13:309, 13:311, 13:313-13:314, 13:322N- 13:324N, 13:326-13:328	*01:44:01-01:44:02, 03:01:01:01-03:01:15, 03:01:17-03:01:41, 03:04:01-03:04:02, 03:07:01:01-03:08, 03:10-03:11:01, 03:11:03-03:13:02, 03:15:01:01-03:16, 03:18-03:25:02, 03:28, 03:30, 03:32-03:34, 03:36-03:37, 03:39, 03:42-03:52:02, 03:54-03:56, 03:58-03:59, 03:61-03:62, 03:64-03:73, 03:76, 03:78-03:79, 03:82- 03:84, 03:86-03:87, 03:91-03:101, 03:104- 03:114, 03:116-03:121, 03:124-03:129, 03:132-03:153, 03:156N-03:157, 03:159- 03:166, 03:168-03:175, 03:177, 03:180- 03:187, 03:189N-03:205, 04:42, 04:59, 04:147, 04:156, 04:210, 04:230, 04:284:01-04:284:02, 04:291, 04:323, 08:28, 11:02:01:01-11:04:22, 11:06:01- 11:07:02, 11:13:01-11:13:02, 11:16:01:01- 11:16:01:02, 11:18, 11:21, 11:25, 11:34- 11:36, 11:38, 11:40, 11:42:01-11:44, 11:46:01-11:47, 11:54:01-11:55, 11:57- 11:60, 11:63:01-11:63:02, 11:65:01- 11:65:02, 11:67, 11:70, 11:76-11:78, 11:84:01-11:85, 11:89, 11:92, 11:98, 11:102:01-11:102:02, 11:104, 11:113, 11:115-11:116, 11:118:01-11:119, 11:123- 11:124:02, 11:127, 11:129-11:132, 11:135, 11:137-11:139, 11:146, 11:148, 11:151, 11:153, 11:156, 11:159-11:161, 11:163, 11:165:01-11:165:02, 11:173-11:174, 11:176, 11:179-11:182, 11:187, 11:190, 11:194:01-11:194:02, 11:196, 11:198, 11:201-11:203, 11:206-11:207, 11:209- 11:211, 11:213-11:214, 11:216-11:218, 11:220-11:221, 11:223-11:224, 11:227, 11:229-11:231, 11:233, 11:241-11:242, 11:244, 11:246N, 11:251, 11:253, 11:255- 11:256, 11:258, 11:260-11:261, 11:267, 11:270, 11:276, 11:280, 11:282, 11:284, 11:287N-11:288, 11:290, 11:292-11:293, 11:297Q, 11:300-11:301N, 11:304, 11:306-11:307, 11:309-11:310, 11:312, 12:01:01:01-12:10, 12:12-12:15, 12:17- 12:20, 12:23-12:37, 12:40-12:52, 12:54- 12:56, 12:58-12:75, 12:77-12:103, 14:17,



0197

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

101.116-24/03 – including *Taq* polymerase
 101.116-24u/03u – without *Taq* polymerase

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

Lot No.: **9R5**

Lot-specific information

				14:21, 14:33, 14:35, 14:64-14:65, 14:72, 14:95, 14:128, 14:132, 14:138, 14:175, 14:186-14:187, 14:221, 15:01:01:01-15:01:26, 15:01:28-15:01:30, 15:01:32-15:01:51, 15:03:01:01-15:06:04, 15:09-15:10, 15:12-15:13, 15:16-15:18, 15:20-15:25, 15:28, 15:32-15:33, 15:35-15:37:02, 15:40-15:43, 15:45-15:46, 15:49-15:57:02, 15:59, 15:61-15:62, 15:64-15:67, 15:69-15:73, 15:75-15:77, 15:79, 15:81-15:84, 15:86-15:87, 15:89-15:95, 15:97-15:98, 15:100, 15:102, 15:106-15:114, 15:116-15:117, 15:120-15:121, 15:123-15:125, 15:127-15:130, 15:132-15:139, 15:141-15:148N, 15:150-15:151, 15:153, 15:157-15:158, 15:160, 15:162-15:166, 15:168-15:178, 15:180N-15:187, 15:190-15:193, 15:195-15:197, 15:199-15:205, 15:207N-15:209N, 15:211, 15:214-15:216, 16:33, 16:36, 16:58, 16:66, DRB3*03:26, DRB4*01:51, DRB5*02:20
29	155 bp	430 bp	*13:15, 13:19, 13:53, 13:57, 13:85, 13:104, 13:195, 13:198, 13:216	*08:32, 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, 12:29-12:30, 12:34-12:36, 12:38-12:40, 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, 14:63, 14:67, 14:78, DRB3*02:131, DRB3*02:160
30⁴	85 bp	515 bp	*13:01:01:01-13:01:06, 13:01:08-13:01:41, 13:04, 13:08, 13:15, 13:17, 13:19-13:20:01:03, 13:22:01:01-13:22:02, 13:24:01:01-13:24:01:03, 13:27:01-13:28:02, 13:32, 13:35, 13:40, 13:43, 13:48, 13:51-13:54, 13:57, 13:59, 13:61:01-13:61:02, 13:64, 13:68-13:72, 13:75-13:76, 13:78-13:80, 13:83-13:84, 13:87, 13:91-13:93, 13:98, 13:102, 13:105-13:106, 13:110-13:114, 13:116-13:117:01:02, 13:121, 13:125, 13:127, 13:130-13:131, 13:138, 13:141, 13:146, 13:148-13:149, 13:153, 13:160, 13:162, 13:166, 13:173, 13:175, 13:177, 13:183, 13:185N-13:187, 13:190-13:191, 13:200N-13:201, 13:204-13:205, 13:213-13:215, 13:217-13:218, 13:221-13:222, 13:226, 13:233-13:234,	*01:42, 01:61, 03:125, 04:02:01-04:02:07, 04:37, 04:124, 04:133-04:134, 04:138, 04:143, 04:161, 04:204, 04:210, 04:237-04:238, 04:259, 04:287, 04:299N, 04:325, 04:336, 04:348, 11:02:01:01-11:03:04, 11:16:01:01-11:16:01:02, 11:21, 11:36, 11:40-11:41, 11:48, 11:55, 11:59, 11:63:01-11:63:02, 11:65:01-11:65:02, 11:70, 11:76, 11:85, 11:118:01-11:118:02, 11:124:01-11:124:02, 11:127, 11:138-11:139, 11:151, 11:161, 11:171, 11:176, 11:213, 11:229, 11:231, 11:233, 11:241-11:242, 11:251, 11:256, 11:260, 11:270, 11:276, 11:290, 11:293, 11:301N, 11:309, 12:73, 14:16, 14:57, 15:10



0197

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

101.116-24/03 – including *Taq* polymerase
 101.116-24u/03u – without *Taq* polymerase

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

Lot No.: **9R5**

Lot-specific information

			13:238, 13:242:01-13:242:02, 13:245, 13:248-13:249N, 13:251-13:252N, 13:254, 13:256, 13:258-13:263, 13:266-13:267, 13:270-13:274, 13:276, 13:278Q, 13:281, 13:283, 13:287, 13:291, 13:294, 13:299-13:300, 13:303-13:305, 13:307-13:309, 13:311, 13:313, 13:322N- 13:324N, 13:327-13:328	
31	145 bp 175 bp 205 bp	515 bp	*13:152, 13:204 *13:59 *13:72	
32	220 bp	430 bp	*13:02:02, 13:03:01:01- 13:03:12, 13:10, 13:12:05, 13:26:01, 13:33:01-13:33:03, 13:37, 13:42:02, 13:49:02, 13:60, 13:66:01-13:66:02, 13:77, 13:81, 13:85, 13:88- 13:90, 13:94:01-13:95, 13:101, 13:115, 13:120, 13:122, 13:133, 13:151-13:152, 13:163, 13:167, 13:170, 13:172, 13:174, 13:176, 13:178, 13:180-13:181, 13:188, 13:194, 13:196, 13:216, 13:219, 13:227, 13:230, 13:253, 13:289N, 13:317, 13:319N, 13:329N, 13:333	*03:76, 03:174N, 11:01:03, 11:01:10- 11:01:11, 11:04:07, 11:08:03, 11:19:02, 11:42:02, 11:73, 11:79, 11:93, 11:131- 11:132, 11:153, 11:184, 14:19, 14:21, 14:32:03, 14:109
33⁴	80 bp	430 bp	*13:43, 13:45, 13:179, 13:217	*03:10, 11:31, 11:96, 11:148, 11:293, 11:312, 12:96, 14:35, 14:53, 14:72, 14:128, 14:132, 14:138, 14:186, 14:208, 15:187
34	145 bp 210 bp 255 bp	515 bp	*13:80, 13:292 *13:178 *13:58, 13:81, 13:163, 13:242:01-13:242:02, 13:284	*03:16 *03:20, 03:145, 11:06:01-11:06:03, 11:21, 11:47, 11:57, 11:129, 11:174, 14:29, 14:99
35	150 bp 280 bp	430 bp	*13:51 *13:13 [?] , 13:30 [?] , 13:33:01 [?] , 13:52 [?] , 13:105	*03:12 [?] , 11:26 [?] , 11:40 [?] , 11:100, 14:19 [?] , 14:213
36⁴	75 bp 170 bp 260 bp	430 bp	*13:92 *13:90, 13:113N *13:98	*11:177, 14:26 *11:233
37⁴	100 bp	515 bp	*13:32, 13:65, 13:93, 13:120, 13:139	*03:12, 03:158, 14:13, 14:63, 14:78, 14:85, 14:170
38⁴	70 bp	430 bp	*13:33:01, 13:61:02, 13:94:01, 13:96:01	*01:89, 03:19, 03:125, 03:171, 11:124:02, 15:37:01, 15:57:02, 15:104:01
39⁴	80 bp 130 bp 280 bp	515 bp	*13:102 *13:95 *13:13 [?] , 13:30 [?] , 13:33:01 [?] , 13:52 [?] , 13:166	*03:153, 14:158 *03:12 [?] , 03:83, 11:26 [?] , 11:40 [?]



0197

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

101.116-24/03 – including *Taq* polymerase
 101.116-24u/03u – without *Taq* polymerase

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 “Instructions for Use” (IFU)

Lot No.: **9R5**

Lot-specific information

40⁴	90 bp 120 bp 160 bp	515 bp	*13:101 *13:91 *13:99, 13:113N	*14:118
41⁴	55 bp	430 bp	*13:50:01-13:50:03, 13:69, 13:115, 13:172, 13:189, 13:312	*03:52:01-03:52:02, 04:41, 04:77, 04:102, 04:113, 04:225, 04:230, 04:250, 04:301, 08:73, 11:28:01:01-11:28:03, 11:58:01- 11:58:02, 11:115, 15:192, 16:08
42	225 bp	430 bp	*13:112, 13:128, 13:183	
43	195 bp	430 bp	*13:117:01:01-13:117:01:02, 13:190, 13:269	*03:146, 11:260, 11:295, 12:99, 16:69
44⁵	145 bp	430 bp	*13:15, 13:19, 13:53, 13:57, 13:85, 13:104, 13:195, 13:198	
45	135 bp 255 bp	430 bp	*13:148 *13:141, 13:147	*03:56, 11:160-11:161, 14:191, 14:239
46	135 bp 205 bp 260 bp	430 bp	*13:148 *13:137N, 13:142N *13:147	
47⁶	165 bp	430 bp	*13:73	
48⁴	115 bp	430 bp	*13:45, 13:197	*04:62, 04:69, 04:146, 04:235, 04:251, 08:08, 11:293, 14:25:01-14:25:02, 14:53, 14:58, 14:69, 14:128, 14:185-14:186, 14:208, 14:250, 15:187
49	210 bp	430 bp	*13:199	
50	220 bp	430 bp	*13:183, 13:200N	
51	150 bp	430 bp	*13:188, 13:206	*04:03:01:01-04:03:22, 04:07:01:01- 04:07:06, 04:11:01:01-04:11:07, 04:17:01- 04:17:02, 04:27, 04:39, 04:50-04:52, 04:59-04:60, 04:69, 04:71, 04:74:02, 04:88, 04:92-04:93, 04:95:02-04:97, 04:100-04:101, 04:109-04:110, 04:129, 04:136, 04:142N, 04:146, 04:148, 04:150, 04:154, 04:156, 04:160, 04:163, 04:165, 04:169-04:170, 04:172, 04:181, 04:183, 04:188, 04:195, 04:197-04:199, 04:203, 04:209, 04:218, 04:222, 04:226:01- 04:226:02, 04:228, 04:234, 04:246, 04:249, 04:251, 04:256, 04:262-04:263, 04:269, 04:278-04:279, 04:291, 04:293- 04:295, 04:298, 04:300N, 04:303, 04:307, 04:311, 04:315-04:316, 04:324, 04:329N- 04:330, 04:337, 04:340, 04:344, 04:349- 04:353, 04:356-04:357, 04:360, 08:29, 11:53-11:54:02, 11:89, 11:150, 11:159, 11:267, 11:283, 14:42, 14:58, 14:161, 14:186, 14:250
52⁴	125 bp	430 bp	*13:208	*15:01:32, 16:01:15
53	150 bp 195 bp	430 bp	*13:124 *13:187	*01:25, 10:40, 12:64, 15:93, DRB5*01:60
54	235 bp	430 bp	*13:33:01, 13:61:02, 13:94:01, 13:96:01	*03:01:01:01-03:01:01:25, 03:01:03- 03:01:16, 03:01:18-03:02:01:02, 03:02:03- 03:05:02, 03:06-03:11:01, 03:12-03:13:01, 03:16, 03:18-03:23, 03:25:01-03:26,



0197

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

101.116-24/03 – including *Taq* polymerase
 101.116-24u/03u – without *Taq* polymerase

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Lot No.: **9R5**

Lot-specific information

				03:28-03:34, 03:36-03:41:02, 03:43-03:68N, 03:70-03:77, 03:79-03:80, 03:82-03:86, 03:88-03:89, 03:91, 03:93-03:96, 03:98-03:110, 03:112-03:125, 03:127-03:129, 03:131-03:132, 03:134-03:144, 03:146-03:161, 03:163-03:166, 03:168, 03:170-03:172, 03:174N-03:184, 03:186-03:187, 03:189N, 03:192-03:204N, 11:07:01, 11:27:02-11:27:03, 11:84:02-11:84:03, 11:103:01-11:103:02, 11:107, 11:124:02-11:125, 11:173, 14:38:02, 14:171
55⁵	155 bp	430 bp	*13:213	
56⁴	115 bp	430 bp	*13:34, 13:64, 13:136, 13:174, 13:204, 13:221, 13:250	*03:43, 03:71:01, 11:76, 11:114, 11:183, 11:196, 11:302, 14:41, 14:77, 14:110, 14:218, DRB3*01:14
	210 bp		*13:178	
	255 bp		*13:28:01-13:28:02	*03:73
57	155 bp	430 bp	*13:215	*11:291
58^{6,9}	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 DRB1*13 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 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 20, 21, 26, 27, 44 and 55 may have tendencies of unspecific amplifications.

⁶Primer mix 47 has a tendency to giving rise to primer oligomer formation.

⁷Primer mix 26 may faintly amplify DRB1*12:02 alleles.

⁹Primer mix 58 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 products generated by the HGH positive control primer pair is 200 base pairs.



0197

101.116-24/03 – including *Taq* polymerase
101.116-24u/03u – without *Taq* polymerase

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Lot No.: **9R5**

Lot-specific information

Abbreviations:

w: may be weakly amplified.

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



0197

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

101.116-24/03 – including *Taq* polymerase
 101.116-24u/03u – without *Taq* polymerase

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 “Instructions for Use” (IFU)

Lot No.: **9R5**

Lot-specific information
PRIMER SPECIFICATION

Well No.	1	2	3	4	5	6	7	8	9	10	11	12
Length of spec. PCR product	175	200	200	170	220	215	200	190	270	260	210	220
Length of int. pos. control ¹	515	430	430	430	430	515	430	430	430	430	430	430
5'-primer(s) ²	13(125) 5'-gTC 3'	13(125) 5'-gTC 3'	13(125) 5'-gTC 3'	13(125) 5'-gTC 3'	13(125) 5'-gTC 3'	13(125) 5'-gTC 3'	37(196) 5'-AgA 3'	37(196) 5'-AgA 3'	13(125) 5'-gTC 3'	13(125) 5'-gTC 3'	13(125) 5'-gTC 3'	13(125) 5'-gTC 3'
3'-primer(s) ³	58(260) 5'-Cgg 3'	67(286) 5'-gAT 3'	67(286) 5'-gAA 3'	57(256) 5'-gCT 3'	71(298) 5'-CTT 3'	71(298) 5'-CTC 3'	86(344) 5'-CAC 3'	86(344) 5'-CCA 3'	86(344) 5'-CAC 3'	86(344) 5'-CCA 3'	67(286) 5'-gAg 3'	71(299) 5'-gCT 3'
	58(260) 5'-CAg 3'	67(286) 5'-gAT 3'	67(286) 5'-gAA 3'		71(298) 5'-CCT 3'	71(298) 5'-CgC 3'	93(364) 5'-CCT 3'		93(364) 5'-CCT 3'		67(286) 5'-gAg 3'	72(303) 5'-gCg 3'
	58(260) 5'-CCg 3'	67(286) 5'-gAT 3'			74(307) 5'-CAg 3'						71(299) 5'-gCg 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	145	145	85	150	220	110	110	215	175	110	115	145
						230	205		220	175	245	180
							260			280		280
Length of int. pos. control ¹	515	430	515	430	430	430	430	515	515	430	430	515
5'-primer(s) ²	13(125) 5'-gTC 3'	34(189) 5'-CAA 3'	13(125) 5'-gTC 3'	34(189) 5'-CAg 3'	13(125) 5'-gTC 3'	13(125) 5'-gTC 3'	13(125) 5'-gTC 3'	10(116) 5'-gCT 3'	12(122) 5'-TAT 3'	13(125) 5'-gTC 3'	13(125) 5'-gTC 3'	13(125) 5'-gTC 3'
		34(189) 5'-CAA 3'		34(189) 5'-CAg 3'				16(133) 5'-gTT 3'	26(164) 5'-gTA 3'			
		37(197) 5'-gTT 3'										
3'-primer(s) ³	47(227) 5'-ggT 3'	71(298) 5'-CTC 3'	28(171) 5'-CTC 3'	71(298) 5'-CTC 3'	72(303) 5'-gCg 3'	37(196) 5'-gAT 3'	37(196) 5'-gAT 3'	71(299) 5'-gCT 3'	71(299) 5'-gCT 3'	37(196) 5'-gTC 3'	38(199) 5'-CAg 3'	46(223) 5'-CTA 3'
						74(307) 5'-CAg 3'	38(200) 5'-gCg 3'			57(257) 5'-CgA 3'	78(321) 5'-CAA 3'	48(230) 5'-CCA 3'
						77(318) 5'-TAA 3'	68(290) 5'-CCC 3'			93(365) 5'-gCT 3'	84(337) 5'-CCg 3'	60(266) 5'-Agg 3'
							86(344) 5'-CAT 3'				84(337) 5'-CCT 3'	93(365) 5'-gCg 3'
Well No.	13	14	15	16	17	18	19	20	21	22	23	24



0197

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

101.116-24/03 – including *Taq* polymerase
 101.116-24u/03u – without *Taq* polymerase

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Lot No.: **9R5**

Lot-specific information

Well No.	25	26	27	28	29	30	31	32	33	34	35	36
Length of spec.	110	90	145	160	155	85	145	220	80	145	150	75
PCR product	140	140					175			210	280	170
							205			255		260
Length of int.	430	430	515	430	430	515	515	430	430	515	430	430
pos. control ¹												
5'-primer(s) ²	13(125) 5'-gTC 3'	34(189) 5'-CAg 3'	13(125) 5'-gTC 3'	47(227) 5'-gTT 3'	28(171) 5'-gAg 3'	71(299) 5'-CgA 3'	16(135) 5'-CAA 3'	13(125) 5'-gTC 3'	47(227) 5'-gTT 3'	13(125) 5'-gTC 3'	13(125) 5'-gTC 3'	13(125) 5'-gTC 3'
		34(189) 5'-CAg 3'			28(171) 5'-gAg 3'		27(167) 5'-CCA 3'					
		51(239) 5'-gAg 3'					37(197) 5'-gTT 3'					
3'-primer(s) ³	37(196) 5'-gTA 3'	67(286) 5'-gAA 3'	47(227) 5'-ggA 3'	86(344) 5'-CCA 3'	67(286) 5'-gAT 3'	86(344) 5'-CCA 3'	71(299) 5'-gCT 3'	71(298) 5'-CTT 3'	60(265) 5'-gTg 3'	48(229) 5'-CCA 3'	50(235) 5'-CAA 3'	25(161) 5'-ACT 3'
	37(196) 5'-ggA 3'	67(286) 5'-gAA 3'	48(229) 5'-CCA 3'		67(286) 5'-gAT 3'			72(303) 5'-gCg 3'		70(295) 5'-CTC 3'	93(365) 5'-gCT 3'	53(245) 5'-CCA 3'
	37(196) 5'-gAA 3'									85(341) 5'-CAg 3'		56(254) 5'-TAA 3'
	46(223) 5'-CTA 3'											86(343) 5'-CAT 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	47	48
Length of spec.	100	70	80	90	55	225	195	145	135	135	165	115
PCR product			130	120					255	205		
			280	160						260		
Length of int.	515	430	515	515	430	430	430	430	430	430	430	430
pos. control ¹												
5'-primer(s) ²	37(196) 5'-AgA 3'	67(286) 5'-ACA 3'	13(125) 5'-gTC 3'	13(125) 5'-gTC 3'	32(181) 5'-TCT 3'	6(103) 5'-CAT 3'	126(464) 5'-CAT 3'	32(181) 5'-TCC 3'	13(125) 5'-gTC 3'	13(125) 5'-gTC 3'	25(161) 5'-gCT 3'	32(181) 5'-TCT 3'
						13(125) 5'-gTg 3'	133(484) 5'-TCT 3'					
	57(256) 5'-gCT 3'	77(317) 5'-AgT 3'	26(164) 5'-ggg 3'	30(176) 5'-Agg 3'	37(196) 5'-gTT 3'	71(299) 5'-gCT 3'	181(630) 5'-CTT 3'	67(286) 5'-gAT 3'	44(217) 5'-CAA 3'	44(217) 5'-CAA 3'	67(286) 5'-gAT 3'	57(257) 5'-CAg 3'
3'-primer(s) ³			43(214) 5'-gTA 3'	39(202) 5'-gCA 3'					82(332) 5'-AgC 3'	64(277) 5'-CTA 3'		
			93(365) 5'-gCg 3'	51(239) 5'-CCT 3'					86(343) 5'-ACT 3'	71(298) 5'-CTA 3'		
				53(245) 5'-CCA 3'						86(343) 5'-ACT 3'		
Well No.	37	38	39	40	41	42	43	44	45	46	47	48



0197

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

101.116-24/03 – including *Taq* polymerase
 101.116-24u/03u – without *Taq* polymerase

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Lot No.: **9R5**

Lot-specific information

Well No.	49	50	51	52	53	54	55	56	57
Length of spec.	210	220	150	125	150	235	155	115	155
PCR product					195			210 255	
Length of int.	430	430	430	430	430	430	430	430	430
pos. control ¹									
5'-primer(s) ²	10(115) 5'-AgA 3'	9(114) 5'-TAg 3'	37(197) 5'-gTA 3'	105(401) 5'-AAA 3'	23(154) 5'-AgT 3'	13(125) 5'-gTC 3'	32(183) 5'-CAg 3'	13(125) 5'-gTC 3'	142(511) 5'-ggA 3'
		13(125) 5'-gTg 3'			38(199) 5'-ACA 3'				
	67(286) 5'-gAA 3'	71(298) 5'-CTC 3'	74(308) 5'-CCT 3'	133(485) 5'-TCA 3'	74(308) 5'-CCg 3'	77(317) 5'-AgT 3'	71(298) 5'-CTC 3'	38(199) 5'-CAg 3'	179(624) 5'-ACg 3'
3'-primer(s) ³								70(295) 5'-CTC 3'	
								84(337) 5'-CCg 3'	
								84(337) 5'-CCT 3'	
Well No.	49	50	51	52	53	54	55	56	57

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: May 2023, Rev. No: 00

101.116-24/03 – including *Taq* polymerase
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Lot No.: **9R5**

Lot-specific information

CELL LINE VALIDATION SHEET																			
DRB1*13 SSP subtyping kit ²																			
				Well															
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
				Prod. No.:															
				202351501	202351502	202351503	202351504	202351505	202351506	202351507	202351508	202351509	202351510	202351511	202351512	202351513	202351514	202351515	202351516
	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		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-



0197

101.116-24/03 – including *Taq* polymerase
 101.116-24u/03u – without *Taq* polymerase

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 “Instructions for Use” (IFU)

Lot No.: **9R5**

Lot-specific information

CELL LINE VALIDATION SHEET																			
DRB1*13 SSP subtyping kit ²																			
				Well															
				17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32
				202351517	202351518	202351519	202351520	202351521	202351522	202351523	202351524	202351525	202351526	202351527	202351528	202351529	202351530	202351531	202351532
				Prod. No.:															
				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		-	-	-	-	-	-	-	-	-	-	-	-	-	-	



101.116-24/03 – including *Taq* polymerase
101.116-24u/03u – without *Taq* polymerase

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“Instructions for Use” (IFU)

Lot No.: **9R5**

Lot-specific information

CELL LINE VALIDATION SHEET																				
DRB1*13 SSP subtyping kit ²																				
				Well																
				33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	
				Prod. No.:	202351533	202351534	202351535	202351536	202351537	202351538	202351539	202351540	202351541	202351542	202351543	202351544	202351545	202351546	202351547	202351548
IHCW 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		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	



0197

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

101.116-24/03 – including *Taq* polymerase
 101.116-24u/03u – without *Taq* polymerase

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

Lot No.: **9R5**

Lot-specific information

CELL LINE VALIDATION SHEET														
DRB1*13 SSP subtyping kit ²														
					Well									
					49	50	51	52	53	54	55	56	57	
					Prod. No.:	202351549	202351550	202351551	202351552	202351553	202351554	202351555	202351556	202351557
IHCW 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		-	-	-	-	-	-	-	-	-	



0197

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

101.116-24/03 – including *Taq* polymerase
101.116-24u/03u – without *Taq* polymerase

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Lot No.: **9R5**

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 17, 19 to 21, 24, 31, 33 to 36, 38 to 43, 45 to 50, 52, 53 and 55 to 57 were available.

The specificities of the primers in primer solutions 17, 19 to 21, 24, 31, 33, 34, 38, 41, 48 and 56 were tested by separately adding additional 5'-primers and 3'-primers.

In primer solutions 35, 36, 39, 40, 45, 46 and 52 it was only possible to test the 5'-primer, the 3'-primers were not possible to be tested.

In primer solutions 42, 43, 47, 49, 50, 53, 55 and 57 it was only possible to test the 3'-primer, the 5'-primers were not possible to be tested.

In primer solutions 21, 26 and 31 one or two of the 5'-primers were not possible to test.

In primer solutions 1, 7, 9, 18, 19, 22 to 25, 27, 34 and 56 one, two or three of the 3'-primers were not possible to test.

In addition, one or more primers in primer solutions 2, 5, 6, 11, 12, 14, 18, 23, 26 and 32 were tested by separately adding one or two 5'-primers or one 3'-primer accordingly.



0197

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

101.116-24/03 – including *Taq* polymerase
 101.116-24u/03u – without *Taq* polymerase

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

Lot No.: **9R5**

Lot-specific information

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