

DRB1*04

101.114-24/03 – including *Taq* polymerase

101.114-24u/03u – without *Taq* polymerase

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

Lot No.: 7R5

Lot-specific information

Olerup SSP[®] DRB1*04

Product number:	101.114-24/03 – including <i>Taq</i> pol. 101.114-24u/03u – without <i>Taq</i> pol.
Lot number:	7R5
Expiry date:	2027-02-01
Number of tests:	24 tests – Product No. 101.114-24/24u 3 tests – Product No. 101.114-03/03u
Number of wells per test:	47+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. 7R5.

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*04 LOT (2N9)

- 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*04 primer set, specificity and interpretation tables have been updated for the DRB1 alleles reported since the previous Olerup SSP[®] DRB1*04 lot was made (**Lot No. 2N9**).

The DRB1*04 primer set is unchanged compared to the previous lot (**Lot No. 2N9**).

¹S. J. Mack, P. Cano, J. A. Hollenbach et al.
Common and well-documented HLA alleles: 2012 update to
the CWD catalogue. Tissue Antigens, 2013, 81, 194–203



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Date: February 2023, Rev. No: 00

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Well **48** contains Negative Control primer pairs, that will amplify the majority of the Olerup SSP® HLA Class I, DRB, DQB1, DPB1 and DQA1 amplicons as well as all the amplicons generated by the control primer pairs matching the human growth hormone gene.

HLA-specific PCR product sizes range from 75 to 200 base pairs.

The PCR product generated by the positive control primer pair is 200 base pairs.

Length of PCR product	105	200	105	80	75	80	85
5'-primer¹	164	340	440	45	45	43	36
	5'-CAC3'	5'-Agg3'	5'-TTA3'	5'-Tgg3'	5'-Tgg3'	5'-Tgg3'	5'-TAC3'
							36
							5'-TAT3'
3'-primer²	231	2nd I	507	59	58	57	47
	5'-TgC3'	5'-AAA3'	5'-TTg3'	5'-CTC3'	5'-ggC3'	5'-CTC3'	5'-ACA3'
							48
							5'-gCA3'
							48
							5'-gCC3'
							52
							5'-TgT3'
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*04 SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for identifying the DRB1*04:01 to DRB1*04:343 alleles.

PLATE LAYOUT

Each test consists of 48 PCR reactions in a 48 well cut PCR plate.

1	2	3	4	5	6	7	8
9	10	11	12	13	14	15	16
17	18	19	20	21	22	23	24
25	26	27	28	29	30	31	32
33	34	35	36	37	38	39	40
41	42	43	44	45	46	47	NC

The 48 well cut PCR plate is marked with 'DRB1*04' in silver/gray ink.

Well No. 1 is marked with the Lot No. '7R5'.

Wells 1 to 47 – DRB1*04 primers.

Well 48 – Negative Control (NC).

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

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

INTERPRETATION

Due to the sharing of sequence motifs between DRB1 alleles, non-DRB1*04 alleles will be amplified by some primer mixes. In addition, DRB3 and DRB5 alleles will be amplified by some primer mixes. For further details see Specificity Table.

UNIQUELY IDENTIFIED ALLELES

All the phenotypically different DRB1*04 alleles, i.e. **DRB1*04:01 to DRB1*04:343**, recognized by the HLA Nomenclature Committee in October 2022^{1,2} will be amplified by the primers in the DRB1*04 subtyping kit.

The DRB1*04 kit enables separation of the confirmed DRB1*04 alleles as listed in the IMGT/HLA database 3.27.0. 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*04 alleles is listed below.



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The DRB1*04 kit also enables identification of many null and alternatively expressed alleles.

The following DRB1*04 alleles can be distinguished by the different sizes of the HLA-specific PCR product:

Alleles	Primer mix	Alleles	Primer mix
DRB1*04:16, 04:151	12	DRB1*04:49, 04:219	27
DRB1*04:23, 04:180	12	DRB1*04:79, 04:211, 04:301	42
DRB1*04:27, 04:110	20	DRB1*04:89, 04:178N	38
DRB1*04:39, 04:101	19	DRB1*04:117, 04:119N	47

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>.



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ALLELE CONFIRMATION STATUS

Allele	Status ¹	Allele	Status ¹	Allele	Status ¹	Allele	Status ¹
DRB1*04:01:01:01	Confirmed	DRB1*04:05:05	Confirmed	DRB1*04:25	Confirmed	DRB1*04:72:01	Unconfirmed
DRB1*04:01:01:02	Unconfirmed	DRB1*04:05:06	Unconfirmed	DRB1*04:26	Confirmed	DRB1*04:72:02	Confirmed
DRB1*04:01:02	Confirmed	DRB1*04:05:07	Unconfirmed	DRB1*04:27	Unconfirmed	DRB1*04:73	Unconfirmed
DRB1*04:01:03	Unconfirmed	DRB1*04:05:08	Unconfirmed	DRB1*04:28	Unconfirmed	DRB1*04:74	Confirmed
DRB1*04:01:04	Unconfirmed	DRB1*04:05:09	Confirmed	DRB1*04:29	Unconfirmed	DRB1*04:75	Unconfirmed
DRB1*04:01:05	Confirmed	DRB1*04:05:10	Confirmed	DRB1*04:30	Unconfirmed	DRB1*04:76	Unconfirmed
DRB1*04:01:06	Confirmed	DRB1*04:05:11	Confirmed	DRB1*04:31	Confirmed	DRB1*04:77	Unconfirmed
DRB1*04:01:07	Unconfirmed	DRB1*04:05:13	Confirmed	DRB1*04:32	Confirmed	DRB1*04:78	Unconfirmed
DRB1*04:01:08	Unconfirmed	DRB1*04:05:14	Confirmed	DRB1*04:33	Confirmed	DRB1*04:79	Confirmed
DRB1*04:01:09	Unconfirmed	DRB1*04:05:15	Unconfirmed	DRB1*04:34	Confirmed	DRB1*04:80	Unconfirmed
DRB1*04:01:10	Confirmed	DRB1*04:05:16	Unconfirmed	DRB1*04:35	Unconfirmed	DRB1*04:81N	Unconfirmed
DRB1*04:01:11	Unconfirmed	DRB1*04:05:17	Unconfirmed	DRB1*04:36	Confirmed	DRB1*04:82	Unconfirmed
DRB1*04:01:12	Confirmed	DRB1*04:05:18	Unconfirmed	DRB1*04:37	Unconfirmed	DRB1*04:83	Confirmed
DRB1*04:01:13	Unconfirmed	DRB1*04:06:01	Confirmed	DRB1*04:38	Confirmed	DRB1*04:84	Unconfirmed
DRB1*04:01:14	Unconfirmed	DRB1*04:06:02	Unconfirmed	DRB1*04:39	Confirmed	DRB1*04:85	Unconfirmed
DRB1*04:01:15	Unconfirmed	DRB1*04:06:03	Unconfirmed	DRB1*04:40	Confirmed	DRB1*04:86	Unconfirmed
DRB1*04:01:16	Unconfirmed	DRB1*04:06:04	Unconfirmed	DRB1*04:41	Confirmed	DRB1*04:87	Confirmed
DRB1*04:01:17	Unconfirmed	DRB1*04:06:05	Unconfirmed	DRB1*04:42	Confirmed	DRB1*04:88	Confirmed
DRB1*04:02:01	Confirmed	DRB1*04:06:06	Unconfirmed	DRB1*04:43	Confirmed	DRB1*04:89	Confirmed
DRB1*04:02:02	Unconfirmed	DRB1*04:07:01	Confirmed	DRB1*04:44:01	Unconfirmed	DRB1*04:90	Unconfirmed
DRB1*04:02:03	Unconfirmed	DRB1*04:07:02	Unconfirmed	DRB1*04:44:02	Unconfirmed	DRB1*04:91	Unconfirmed
DRB1*04:02:04	Unconfirmed	DRB1*04:07:03	Confirmed	DRB1*04:45	Confirmed	DRB1*04:92	Unconfirmed
DRB1*04:02:05	Confirmed	DRB1*04:07:04	Confirmed	DRB1*04:46	Unconfirmed	DRB1*04:93	Unconfirmed
DRB1*04:03:01	Confirmed	DRB1*04:07:05	Unconfirmed	DRB1*04:47	Unconfirmed	DRB1*04:94:01N	Unconfirmed
DRB1*04:03:02	Confirmed	DRB1*04:08:01	Confirmed	DRB1*04:48	Unconfirmed	DRB1*04:95:01	Confirmed
DRB1*04:03:03	Unconfirmed	DRB1*04:08:02	Confirmed	DRB1*04:49	Unconfirmed	DRB1*04:95:02	Unconfirmed
DRB1*04:03:04	Unconfirmed	DRB1*04:08:03	Unconfirmed	DRB1*04:50	Confirmed	DRB1*04:96	Confirmed
DRB1*04:03:05	Confirmed	DRB1*04:08:04	Unconfirmed	DRB1*04:51	Unconfirmed	DRB1*04:97	Unconfirmed
DRB1*04:03:06	Unconfirmed	DRB1*04:09	Confirmed	DRB1*04:52	Unconfirmed	DRB1*04:98:01	Unconfirmed
DRB1*04:03:07	Unconfirmed	DRB1*04:10:01	Confirmed	DRB1*04:53:01	Unconfirmed	DRB1*04:98:02	Confirmed
DRB1*04:03:08	Confirmed	DRB1*04:10:02	Unconfirmed	DRB1*04:53:02	Unconfirmed	DRB1*04:99	Confirmed
DRB1*04:03:09	Confirmed	DRB1*04:10:03	Unconfirmed	DRB1*04:54	Confirmed	DRB1*04:100	Confirmed
DRB1*04:03:10	Unconfirmed	DRB1*04:11:01	Confirmed	DRB1*04:55	Unconfirmed	DRB1*04:101	Confirmed
DRB1*04:03:11	Unconfirmed	DRB1*04:11:02	Unconfirmed	DRB1*04:56:01	Unconfirmed	DRB1*04:102	Unconfirmed
DRB1*04:03:12	Confirmed	DRB1*04:11:03	Unconfirmed	DRB1*04:56:02	Confirmed	DRB1*04:103	Unconfirmed
DRB1*04:03:13	Confirmed	DRB1*04:11:04	Unconfirmed	DRB1*04:57	Unconfirmed	DRB1*04:104	Unconfirmed
DRB1*04:04:01	Confirmed	DRB1*04:12	Confirmed	DRB1*04:58	Unconfirmed	DRB1*04:105:01	Confirmed
DRB1*04:04:02	Unconfirmed	DRB1*04:13	Confirmed	DRB1*04:59	Unconfirmed	DRB1*04:105:02	Confirmed
DRB1*04:04:03	Confirmed	DRB1*04:14	Confirmed	DRB1*04:60	Unconfirmed	DRB1*04:106	Unconfirmed
DRB1*04:04:04	Unconfirmed	DRB1*04:15	Confirmed	DRB1*04:61	Unconfirmed	DRB1*04:107	Unconfirmed
DRB1*04:04:05	Unconfirmed	DRB1*04:16	Confirmed	DRB1*04:62	Unconfirmed	DRB1*04:108	Confirmed
DRB1*04:04:06	Unconfirmed	DRB1*04:17:01	Confirmed	DRB1*04:63	Confirmed	DRB1*04:109	Unconfirmed
DRB1*04:04:07	Confirmed	DRB1*04:17:02	Confirmed	DRB1*04:64	Unconfirmed	DRB1*04:110	Unconfirmed
DRB1*04:04:08	Unconfirmed	DRB1*04:18	Confirmed	DRB1*04:65	Unconfirmed	DRB1*04:111	Unconfirmed
DRB1*04:04:09	Unconfirmed	DRB1*04:19	Confirmed	DRB1*04:66	Unconfirmed	DRB1*04:112	Unconfirmed
DRB1*04:04:10	Unconfirmed	DRB1*04:20	Confirmed	DRB1*04:67	Unconfirmed	DRB1*04:113	Unconfirmed
DRB1*04:05:01	Confirmed	DRB1*04:21	Unconfirmed	DRB1*04:68	Confirmed	DRB1*04:114	Confirmed
DRB1*04:05:02	Unconfirmed	DRB1*04:22	Unconfirmed	DRB1*04:69	Unconfirmed	DRB1*04:115	Unconfirmed
DRB1*04:05:03	Confirmed	DRB1*04:23	Unconfirmed	DRB1*04:70	Unconfirmed	DRB1*04:116	Confirmed
DRB1*04:05:04	Confirmed	DRB1*04:24	Unconfirmed	DRB1*04:71	Unconfirmed	DRB1*04:117	Confirmed



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Lot-specific information

Allele	Status ¹	Allele	Status ¹	Allele	Status ¹	Allele	Status ¹
DRB1*04:118	Unconfirmed	DRB1*04:147	Unconfirmed	DRB1*04:177	Unconfirmed	DRB1*04:207	Unconfirmed
DRB1*04:119N	Unconfirmed	DRB1*04:148	Confirmed	DRB1*04:178N	Unconfirmed	DRB1*04:208	Unconfirmed
DRB1*04:120N	Unconfirmed	DRB1*04:149	Unconfirmed	DRB1*04:179	Unconfirmed	DRB1*04:209	Unconfirmed
DRB1*04:121	Unconfirmed	DRB1*04:150	Confirmed	DRB1*04:180	Unconfirmed	DRB1*04:210	Unconfirmed
DRB1*04:122	Unconfirmed	DRB1*04:151	Unconfirmed	DRB1*04:181	Unconfirmed	DRB1*04:211	Unconfirmed
DRB1*04:123	Confirmed	DRB1*04:152	Unconfirmed	DRB1*04:182	Confirmed	DRB1*04:212N	Confirmed
DRB1*04:124	Unconfirmed	DRB1*04:153	Unconfirmed	DRB1*04:183	Unconfirmed	DRB1*04:213	Confirmed
DRB1*04:125	Unconfirmed	DRB1*04:154	Confirmed	DRB1*04:184	Unconfirmed	DRB1*04:214N	Unconfirmed
DRB1*04:126	Unconfirmed	DRB1*04:155	Unconfirmed	DRB1*04:185	Unconfirmed	DRB1*04:215	Unconfirmed
DRB1*04:127	Confirmed	DRB1*04:156	Unconfirmed	DRB1*04:186N	Unconfirmed	DRB1*04:216	Unconfirmed
DRB1*04:128	Unconfirmed	DRB1*04:157N	Unconfirmed	DRB1*04:187	Unconfirmed	DRB1*04:217	Unconfirmed
DRB1*04:129	Confirmed	DRB1*04:158N	Unconfirmed	DRB1*04:188	Unconfirmed	DRB1*04:218	Unconfirmed
DRB1*04:130	Unconfirmed	DRB1*04:159	Unconfirmed	DRB1*04:189	Unconfirmed	DRB1*04:219	Unconfirmed
DRB1*04:131:01	Unconfirmed	DRB1*04:160	Unconfirmed	DRB1*04:190	Unconfirmed	DRB1*04:220	Unconfirmed
DRB1*04:131:02	Unconfirmed	DRB1*04:161	Unconfirmed	DRB1*04:191	Unconfirmed	DRB1*04:221	Unconfirmed
DRB1*04:132	Unconfirmed	DRB1*04:162	Unconfirmed	DRB1*04:192	Confirmed		
DRB1*04:133	Unconfirmed	DRB1*04:163	Unconfirmed	DRB1*04:193	Unconfirmed		
DRB1*04:134	Unconfirmed	DRB1*04:164	Unconfirmed	DRB1*04:194	Unconfirmed		
DRB1*04:135	Unconfirmed	DRB1*04:165	Unconfirmed	DRB1*04:195	Unconfirmed		
DRB1*04:136	Unconfirmed	DRB1*04:166	Unconfirmed	DRB1*04:196	Unconfirmed		
DRB1*04:137	Unconfirmed	DRB1*04:167	Unconfirmed	DRB1*04:197	Unconfirmed		
DRB1*04:138	Confirmed	DRB1*04:168	Confirmed	DRB1*04:198	Unconfirmed		
DRB1*04:139	Unconfirmed	DRB1*04:169	Unconfirmed	DRB1*04:199	Unconfirmed		
DRB1*04:140	Unconfirmed	DRB1*04:170	Unconfirmed	DRB1*04:200	Unconfirmed		
DRB1*04:141	Unconfirmed	DRB1*04:171	Unconfirmed	DRB1*04:201	Unconfirmed		
DRB1*04:142N	Unconfirmed	DRB1*04:172	Unconfirmed	DRB1*04:202	Unconfirmed		
DRB1*04:143	Unconfirmed	DRB1*04:173	Unconfirmed	DRB1*04:203	Confirmed		
DRB1*04:144	Unconfirmed	DRB1*04:174	Unconfirmed	DRB1*04:204	Unconfirmed		
DRB1*04:145	Unconfirmed	DRB1*04:175	Unconfirmed	DRB1*04:205	Confirmed		
DRB1*04:146	Unconfirmed	DRB1*04:176	Unconfirmed	DRB1*04:206	Unconfirmed		

¹Allele status “confirmed” or “unconfirmed” as listed on the IMGT/HLA web page 2017-January-20, release 3.27.0, www.ebi.ac.uk/imgt/hla.

RESOLUTION IN HOMO- AND HETEROZYGOTES

Results file with resolution in DRB1*04 homo- and heterozygotes is available upon request.



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SPECIFICITY TABLE

DRB1*04 SSP subtyping

Specificities and sizes of the PCR products of the 47+1 primer mixes used for
DRB1*04 SSP subtyping

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified DRB1*04 alleles ³	Other amplified DRB alleles
1	215 bp	515 bp	*04:01:01:01-04:01:23, 04:09:01:01-04:09:01:02, 04:13, 04:16, 04:21, 04:26, 04:33, 04:35, 04:38:01:01-04:38:01:02, 04:62-04:63, 04:67, 04:72:01-04:72:02, 04:76, 04:100, 04:111-04:115, 04:117, 04:119N, 04:123, 04:125, 04:127, 04:130:01-04:130:02, 04:135, 04:139, 04:145, 04:150-04:151, 04:153, 04:158N-04:159, 04:171, 04:174-04:175, 04:179, 04:184, 04:187, 04:190, 04:192, 04:194, 04:196, 04:200, 04:208, 04:215-04:217, 04:233, 04:236, 04:239, 04:241-04:243, 04:248, 04:253-04:254, 04:257, 04:261, 04:266N-04:268, 04:270-04:271, 04:273-04:274, 04:280N-04:281, 04:285, 04:296, 04:304, 04:317, 04:321, 04:324, 04:326, 04:331, 04:334-04:335, 04:338, 04:341, 04:343, 04:346-04:347	
2	215 bp	430 bp	*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, 04:237-04:238, 04:259, 04:287, 04:299N, 04:325, 04:336, 04:348	*14:57
3	225 bp	430 bp	*04:03:01:01-04:03:21, 04:06:01-04:07:06, 04:11:01:01-04:11:07, 04:17:01-04:17:02, 04:20, 04:27, 04:39, 04:41, 04:46, 04:49-04:52, 04:59-04:60, 04:65, 04:69, 04:71, 04:74:02, 04:78, 04:85, 04:88, 04:91-04:93, 04:95:02-04:97, 04:100-04:102, 04:109-04:110, 04:114, 04:129, 04:136, 04:142N, 04:144, 04:146, 04:148, 04:150, 04:154, 04:156, 04:160, 04:163, 04:165, 04:169-04:170, 04:172, 04:176, 04:181, 04:183, 04:188, 04:195, 04:197-04:199, 04:203, 04:209, 04:218-04:219, 04:222, 04:226:01-04:226:02, 04:228, 04:234-04:235, 04:246, 04:249, 04:251, 04:256, 04:260, 04:262-04:263, 04:269, 04:277-04:279, 04:291, 04:293-04:295, 04:298, 04:300N, 04:303, 04:307, 04:311, 04:315-04:316, 04:324,	*14:10:01:01-14:10:01:02, 14:143



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Lot-specific information

			04:329N-04:330, 04:333, 04:337, 04:340, 04:344, 04:349-04:353	
4	225 bp	515 bp	*04:01:01:01-04:02:07, 04:04:01:01- 04:04:16, 04:04:18-04:05:11, 04:05:13- 04:05:23, 04:08:01:01-04:10:03, 04:13- 04:16, 04:19, 04:21, 04:23-04:24, 04:26, 04:28-04:30, 04:32-04:38:01:02, 04:40, 04:42-04:43, 04:44:01 ^w , 04:44:02-04:45, 04:47-04:48, 04:53:01-04:53:02, 04:56:01-04:57, 04:61-04:63, 04:67- 04:68, 04:70, 04:72:01, 04:72:02 ^w , 04:73:01-04:73:02, 04:75-04:77, 04:79- 04:84, 04:87, 04:89, 04:99, 04:104- 04:108, 04:111-04:113, 04:115-04:125, 04:127-04:128, 04:130:01-04:130:02, 04:131:01 ^w , 04:131:02-04:135, 04:138- 04:139, 04:141, 04:143, 04:145, 04:147, 04:149, 04:151-04:153, 04:158N- 04:159, 04:161-04:162, 04:164, 04:166, 04:168, 04:171, 04:173-04:175, 04:177- 04:180, 04:182, 04:184, 04:187, 04:189- 04:190, 04:192-04:194, 04:196, 04:200- 04:202, 04:204-04:208, 04:210-04:211, 04:213-04:217, 04:220-04:221, 04:223- 04:225, 04:227, 04:230-04:233, 04:236- 04:243, 04:245, 04:247N-04:248, 04:250, 04:252-04:255, 04:257-04:259, 04:261, 04:264N-04:268, 04:270- 04:276, 04:280N-04:282, 04:284:01- 04:290, 04:292, 04:296-04:297, 04:299N, 04:301-04:302, 04:304- 04:306, 04:308-04:310, 04:312N- 04:314, 04:317-04:323, 04:325-04:328, 04:331-04:332, 04:334-04:336, 04:338- 04:339, 04:341-04:343, 04:345-04:348	*11:22, 14:57, 14:182
5	170 bp	430 bp	*04:05:01:01-04:05:11, 04:05:13- 04:05:23, 04:09:01:01-04:12, 04:17:01- 04:17:02, 04:24, 04:28-04:30, 04:45, 04:48, 04:57, 04:67, 04:77, 04:80- 04:81N, 04:83-04:84, 04:86-04:87, 04:89-04:91, 04:103-04:104, 04:106- 04:107, 04:116, 04:125-04:126, 04:131:01-04:131:02, 04:136-04:137, 04:147, 04:152, 04:162, 04:173, 04:178N, 04:191, 04:201-04:203, 04:207, 04:213-04:214N, 04:227, 04:232, 04:245, 04:250, 04:255, 04:264N, 04:286N, 04:289, 04:292, 04:303, 04:305, 04:319-04:320, 04:328	
6 ⁴	115 bp	430 bp	*04:06:01-04:06:07, 04:19-04:21, 04:46, 04:49, 04:65, 04:68, 04:78, 04:84-04:85, 04:91, 04:99, 04:114, 04:144, 04:176, 04:186N, 04:219, 04:235, 04:244, 04:260, 04:277, 04:325	



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7	260 bp	430 bp	*04:01:01:01-04:01:23, 04:05:01:01-04:05:11, 04:05:13-04:05:23, 04:07:01:01-04:09:01:02, 04:14, 04:16-04:17:02, 04:19-04:21, 04:24, 04:26, 04:28-04:31, 04:33, 04:35, 04:38:01:01-04:38:01:02, 04:43, 04:45, 04:47-04:48, 04:54, 04:57, 04:61-04:63, 04:69, 04:72:01-04:72:02, 04:74:01-04:77, 04:80-04:84, 04:86-04:87, 04:89-04:90, 04:92, 04:98:01-04:98:02, 04:102-04:107, 04:111-04:113, 04:115-04:117, 04:119N, 04:123, 04:125, 04:127-04:132, 04:135, 04:137, 04:139-04:141, 04:145, 04:151-04:153, 04:155, 04:158N-04:159, 04:162, 04:166, 04:170-04:175, 04:178N-04:179, 04:184-04:185, 04:187-04:192, 04:194, 04:196-04:197, 04:199-04:200, 04:202, 04:205-04:206, 04:208-04:209, 04:212N-04:214N, 04:216-04:217, 04:222, 04:225, 04:227, 04:231-04:233, 04:236, 04:239, 04:241-04:243, 04:245-04:246, 04:248-04:249, 04:252-04:257, 04:261-04:266N, 04:268-04:271, 04:273-04:274, 04:278, 04:280N-04:281, 04:283, 04:285-04:286N, 04:289, 04:292, 04:296-04:297, 04:304-04:305, 04:314-04:315, 04:317, 04:319-04:321, 04:324, 04:326, 04:328, 04:331, 04:334-04:335, 04:337-04:338, 04:341, 04:343-04:344, 04:346-04:347, 04:351	*11:22, 14:143
8	260 bp	430 bp	*04:02:01-04:04:19, 04:06:01-04:06:07, 04:10:01-04:13, 04:15, 04:18, 04:22-04:23, 04:25, 04:27, 04:32, 04:36-04:37, 04:39-04:42, 04:44:01-04:44:02, 04:46, 04:49-04:53:02, 04:55-04:56:02, 04:58-04:60, 04:65, 04:67-04:68, 04:70-04:71, 04:73:01-04:73:02, 04:78-04:79, 04:85, 04:88, 04:91, 04:93-04:97, 04:99-04:101, 04:108-04:110, 04:114, 04:118, 04:120N-04:122, 04:124, 04:126, 04:133-04:134, 04:136, 04:138, 04:142N-04:144, 04:146-04:150, 04:154, 04:156-04:157N, 04:161, 04:163-04:165, 04:167-04:169, 04:176-04:177, 04:180-04:183, 04:186N, 04:193, 04:198, 04:201, 04:203-04:204, 04:207, 04:210-04:211, 04:218-04:221, 04:223-04:224, 04:226:01-04:226:02, 04:228, 04:230, 04:234-04:235, 04:237-04:238, 04:240, 04:244, 04:247N, 04:250-04:251, 04:258-04:260, 04:267N, 04:272, 04:275-04:277, 04:279, 04:282, 04:284:01-04:284:02, 04:287-04:288, 04:290-04:291,	*14:10:01:01-14:10:01:02, 14:57, 14:182



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			04:293-04:295, 04:299N-04:303, 04:306-04:309, 04:311-04:313, 04:316, 04:318, 04:322-04:323, 04:325, 04:327, 04:329N-04:330, 04:332-04:333, 04:336, 04:339-04:340, 04:342, 04:345, 04:348-04:350, 04:352-04:353	
9	215 bp	430 bp	*04:03:01:01-04:04:04, 04:04:05 ^w , 04:04:06-04:05:07, 04:05:08 ^w , 04:05:09- 04:05:11, 04:05:13-04:08:04, 04:08:05 ^w , 04:10:01-04:11:07, 04:12 ^w , 04:15, 04:17:01-04:17:02, 04:18 ^w , 04:19-04:20, 04:23-04:24, 04:25 ^w , 04:27-04:30, 04:31 ^w , 04:32, 04:36, 04:39-04:46, 04:47 ^w , 04:48-04:52, 04:53:01 ^w , 04:53:02, 04:54 ^w -04:55 ^w , 04:56:01- 04:57, 04:58 ^w , 04:59-04:61, 04:68- 04:71, 04:74:01-04:74:02, 04:77- 04:81N, 04:82 ^w , 04:83-04:85, 04:86 ^w , 04:87-04:96, 04:99 ^w , 04:101-04:102, 04:103 ^w , 04:104, 04:107-04:110, 04:116, 04:118, 04:120N-04:121, 04:126 ^w , 04:129, 04:131:01-04:131:02, 04:136- 04:137, 04:142N, 04:144, 04:146- 04:149, 04:152, 04:154, 04:156- 04:157N, 04:162-04:165, 04:166 ^w , 04:167-04:170, 04:172, 04:176- 04:178N, 04:180-04:183, 04:185 ^w , 04:186N, 04:189 ^w , 04:191 ^w , 04:193, 04:195, 04:197-04:199, 04:201-04:203, 04:205-04:207, 04:209, 04:211- 04:214N, 04:218-04:228, 04:230- 04:232, 04:234-04:235, 04:240, 04:244- 04:247N, 04:249-04:252, 04:255- 04:256, 04:258, 04:260, 04:262-04:265, 04:269, 04:272, 04:275-04:279, 04:282, 04:286N, 04:288-04:292, 04:294- 04:295, 04:297-04:298, 04:300N- 04:303, 04:305-04:309, 04:311-04:316, 04:318-04:320, 04:322-04:323, 04:327- 04:330, 04:332-04:333, 04:337, 04:339- 04:340, 04:342, 04:344-04:345, 04:349- 04:353	*11:22, 14:10:01:01- 14:10:01:02, 14:143, 14:182
10	170 bp	515 bp	*04:01:01:01-04:04:19, 04:05:18, 04:06:01-04:08:05, 04:11:03, 04:13- 04:16, 04:18-04:23, 04:25, 04:27, 04:31- 04:33, 04:35-04:44:02, 04:46-04:47, 04:49-04:56:02, 04:58-04:61, 04:63, 04:65, 04:68, 04:70-04:76, 04:78-04:79, 04:85, 04:88, 04:92-04:98:02, 04:100- 04:102, 04:105:01-04:105:02, 04:109- 04:115, 04:117-04:124, 04:127- 04:130:02, 04:132-04:135, 04:138- 04:145, 04:148-04:151, 04:153-04:159, 04:161, 04:163-04:168, 04:170-04:172,	*11:22, 14:57



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			04:174-04:177, 04:179-04:190, 04:192-04:200, 04:204-04:206, 04:208-04:212N, 04:215-04:226:02, 04:228, 04:230-04:231, 04:233-04:234, 04:236-04:244, 04:246-04:249, 04:252-04:254, 04:256-04:263, 04:265-04:285, 04:287-04:288, 04:290-04:291, 04:293-04:302, 04:304, 04:306-04:309, 04:311-04:318, 04:321-04:327, 04:329N-04:353	
11	175 bp	430 bp	*04:15, 04:61, 04:138, 04:145, 04:154, 04:170, 04:265, 04:291, 04:323, 04:339	*11:22
	220 bp		*04:22, 04:98:02, 04:283	
12	180 bp	515 bp	*04:16, 04:180	
	265 bp		*04:23, 04:52, 04:151, 04:203, 04:207	
13	170 bp	430 bp	*04:46	
	225 bp		*04:12, 04:18, 04:25, 04:31, 04:54-04:55, 04:58, 04:86, 04:103, 04:126, 04:185, 04:191	
14⁶	210 bp	430 bp	*04:02:01-04:02:07, 04:12, 04:14, 04:18, 04:38:01-04:38:01:02, 04:48, 04:53:01-04:53:02, 04:56:01-04:56:02, 04:73:01 ^w -04:73:02 ^w , 04:82, 04:86, 04:88, 04:99-04:100, 04:105:01 ^w -04:105:02 ^w , 04:106-04:107, 04:124-04:125, 04:133-04:134, 04:136, 04:138, 04:161, 04:185, 04:204-04:205, 04:210, 04:237-04:238, 04:259, 04:284:01 ^w -04:284:02 ^w , 04:287, 04:325, 04:336, 04:344, 04:348	*14:57
15	175 bp	430 bp	*04:123	*01:10
	215 bp		*04:34	
16	170 bp	430 bp	*04:116, 04:148	*07:73, 11:126, 15:64, DRB3*02:159, DRB3*03:05, DRB5*01:65
17	190 bp	430 bp	*04:15, 04:25, 04:36, 04:47, 04:54, 04:57, 04:191, 04:265	*11:22
18	145 bp	430 bp	*04:28, 04:35, 04:42-04:43, 04:59, 04:147, 04:156, 04:199, 04:210, 04:230, 04:284:01-04:284:02, 04:291, 04:323	*11:22
19	140 bp	515 bp	*04:39	
	210 bp		*04:24, 04:69, 04:78, 04:101, 04:168, 04:251	*14:10:01-01-14:10:01:02, 14:143, 14:182
20⁴	100 bp	430 bp	*04:63, 04:110, 04:161, 04:253, 04:264N	
	175 bp		*04:40	
	255 bp		*04:27	
21⁵	155 bp	515 bp	*04:29	
	210 bp		*04:37, 04:58, 04:73:01-04:73:02, 04:105:01-04:105:02, 04:122, 04:132, 04:206, 04:284:01-04:284:02	
22⁵	230 bp	430 bp	*04:32, 04:50, 04:139, 04:166	
23	135 bp	430 bp	*04:33	
	255 bp		*04:201	



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24⁴	85 bp	430 bp	*04:01:01:01-04:01:23, 04:09:01:01-04:09:01:02, 04:16, 04:21, 04:26, 04:33-04:35, 04:38:01:01 ^w -04:38:01:02 ^w , 04:62-04:64, 04:66, 04:72:01-04:72:02, 04:76, 04:98:01-04:98:02, 04:111-04:113, 04:115, 04:117, 04:119N, 04:123, 04:125 ^w , 04:127-04:128, 04:130:01-04:130:02, 04:135, 04:139-04:141, 04:145, 04:151, 04:153, 04:155, 04:158N-04:159, 04:171, 04:174, 04:175 ^w , 04:179 ^w , 04:184, 04:187-04:188, 04:190, 04:192, 04:194, 04:196, 04:200, 04:208, 04:216-04:217, 04:233, 04:236, 04:239, 04:241-04:243, 04:248, 04:253-04:254, 04:257, 04:261, 04:266N, 04:268, 04:270-04:271, 04:273-04:274, 04:280N-04:281, 04:283, 04:285, 04:296, 04:304, 04:317, 04:321, 04:324, 04:326, 04:331, 04:334-04:335, 04:338, 04:341, 04:343, 04:346-04:347	*01:10, 01:16, 03:02:01:01-03:02:06, 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 ^w , 03:103, 03:115, 03:122, 03:130-03:131, 03:154-03:155, 03:167, 03:176, 03:178-03:179, 03:188 ^w , 11:53 ^w , 11:79, 11:103:01-11:103:02, 11:105, 11:107, 11:125 ^w , 11:136, 13:196 ^w , 14:19, 14:109, 14:141, 15:103 ^w , DRB3*01:01:02:01-01:18, DRB3*01:20:01:30, DRB3*01:31^w, DRB3*01:32-01:33, DRB3*01:35-01:41, DRB3*01:43-01:48, DRB3*01:50-01:110, DRB3*02:02:01:01-02:02:12, DRB3*02:02:14-02:03, DRB3*02:05:01-02:10, DRB3*02:11^w, DRB3*02:12-02:13, DRB3*02:15-02:16, DRB3*02:17^w, DRB3*02:18-02:23, DRB3*02:25, DRB3*02:27-02:47, DRB3*02:49-02:57, DRB3*02:59-02:64, DRB3*02:66-02:88, DRB3*02:90-02:102, DRB3*02:105, DRB3*02:107-02:110, DRB3*02:112-02:130, DRB3*02:132-02:140, DRB3*02:142, DRB3*02:144-02:159, DRB3*02:161-02:170, DRB3*02:172, DRB3*02:174, DRB3*02:176-02:180, DRB3*02:182-02:185, DRB3*03:03, DRB3*03:06, DRB3*03:56
25⁴	125 bp 230 bp 260 bp	430 bp	*04:26 *04:45 *04:64	
26	200 bp	515 bp	*04:01:01:01-04:01:23, 04:03:01:01-04:05:11, 04:05:13-04:11:07, 04:13, 04:16-04:17:02, 04:19-04:24, 04:26-04:33, 04:35, 04:39-04:46, 04:48-04:52, 04:55, 04:57, 04:59-04:63, 04:65,	*14:10:01:01-14:10:01:02, 14:143, 14:182



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27⁴	115 bp	515 bp	*04:10:01-04:11:04, 04:11:06-04:12, 04:60, 04:67, 04:91, 04:126, 04:136, 04:147, 04:201, 04:203, 04:207, 04:219, 04:250, 04:303	*03:12, 03:158, 08:06:01:01-08:06:01:02, 08:10, 08:12, 08:22, 08:54, 08:70, 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
28⁴	265 bp 90 bp	430 bp	*04:49 *04:11:01:01-04:11:04, 04:11:06-04:11:07, 04:17:01-04:17:02, 04:91, 04:136, 04:203, 04:303	*08:29, 13:188, 14:169
29^{4,5}	75 bp	430 bp	*04:07:01:01-04:07:06, 04:17:01-04:17:02, 04:20, 04:69, 04:74:01-04:74:02, 04:92, 04:102, 04:129, 04:160, 04:170, 04:172, 04:197, 04:199, 04:209, 04:212N, 04:222, 04:246, 04:249, 04:256, 04:262-04:263, 04:269, 04:278, 04:315, 04:324, 04:337, 04:344, 04:351	*01:17, 09:01:02:01-09:01:05, 09:01:08-09:02:02, 09:04-09:05, 09:07-09:08, 09:10-09:52N, 10:29, 11:283, 14:07:01-14:07:03, 14:14, 14:36, 14:42, 14:44:01-14:44:03, 14:51, 14:68:01-14:68:02, 14:93, 14:134, 14:143, 14:244, DRB4*01:60, DRB5*01:12 DRB3*02:84
30⁴	270 bp 80 bp	430 bp	*04:19 [?] -04:21 [?] , 04:64, 04:192, 04:213 *04:09:01:01-04:09:01:02, 04:67, 04:106, 04:125	*08:40, 08:92, 13:03:01:01-13:04, 13:32-13:33:03, 13:38, 13:48, 13:65-13:66:02, 13:75, 13:81, 13:88-13:89:02, 13:93-13:95, 13:101, 13:115, 13:120, 13:122, 13:133, 13:139, 13:151-13:152, 13:167 [?] , 13:174, 13:188, 13:194, 13:216, 13:219, 13:227, 13:230, 13:253, 13:276, 13:307, 13:317, 13:319N, 13:329N



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31 ^{4,5,6}	85 bp	430 bp	*04:14, 04:106, 04:132	*01:03:01:01-01:03:05, 01:39N, 01:89, 01:99, 01:102, 01:127, 07:138, 08:40, 08:92, 11:11:01, 11:11:03, 11:14:01:01- 11:14:02, 11:20, 11:68, 11:73, 11:93, 11:122, 11:168, 11:184, 11:237, 13:02:01:01- 13:02:03, 13:02:05-13:02:09, 13:02:11-13:03:12, 13:23:01- 13:23:02, 13:29:01:01- 13:29:01:02, 13:31, 13:33:01-13:34, 13:36-13:39, 13:41, 13:45, 13:63, 13:65- 13:67, 13:73-13:74, 13:85, 13:88, 13:90, 13:95- 13:97:02, 13:99, 13:101, 13:103-13:104, 13:107, 13:115, 13:120, 13:122- 13:124, 13:126, 13:128, 13:135, 13:139, 13:143, 13:145, 13:147, 13:151- 13:152, 13:155, 13:159, 13:165, 13:167-13:168, 13:170-13:172, 13:174, 13:179-13:180, 13:182, 13:188, 13:194-13:195, 13:198, 13:202, 13:207- 13:212, 13:216, 13:219- 13:220, 13:225, 13:227, 13:230, 13:236-13:237, 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, 13:280, 13:282, 13:285, 13:288- 13:289N, 13:292-13:293, 13:297-13:298N, 13:301, 13:306, 13:310N, 13:312, 13:316-13:320, 13:325, 13:329N, 13:331-13:332, DRB3*02:160
	200 bp		*04:214N	
	260 bp		*04:64	
32 ⁴	120 bp	430 bp	*04:01:01:01-04:05:01:10, 04:05:03- 04:05:11, 04:05:13-04:05:14, 04:05:16- 04:05:23, 04:07:01:01-04:18, 04:22- 04:33, 04:35-04:45, 04:47-04:48, 04:50- 04:63, 04:67, 04:69-04:77, 04:79-04:83, 04:86-04:90, 04:92-04:95:02, 04:97- 04:98:02, 04:100-04:113, 04:115- 04:132, 04:134-04:143, 04:145-04:151, 04:153-04:159, 04:161-04:163, 04:166- 04:175, 04:177-04:183, 04:185,	*11:22



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For *In Vitro* Diagnostic Use

MA123 v02 SSP PI Template

Date: February 2023, Rev. No: 00

DRB1*04

101.114-24/03 – including *Taq* polymerase

101.114-24u/03u – without *Taq* polymerase

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

Lot No.: 7R5

Lot-specific information

			04:187-04:216, 04:218, 04:220-04:223, 04:225-04:227, 04:230, 04:232-04:234, 04:236-04:237, 04:239-04:243, 04:245- 04:259, 04:261-04:276, 04:278-04:309, 04:311-04:324, 04:326-04:353	
33	215 bp	430 bp	*04:158N	
34⁵	270 bp	515 bp	*04:19 [?] -04:21 [?] , 04:34, 04:66, 04:160, 04:192, 04:213, 04:229	DRB3*02:84
35	210 bp 245 bp	430 bp	*04:81N *04:51, 04:70, 04:260	
36⁴	120 bp 180 bp	515 bp	*04:96 *04:71	*03:149
37	225 bp	430 bp	*04:22, 04:44:01-04:44:02, 04:65, 04:72:01-04:72:02, 04:74:01-04:74:02, 04:95:01-04:95:02, 04:131:01- 04:131:02, 04:140, 04:244, 04:283	
38	140 bp 225 bp	430 bp	*04:89 *04:73:01-04:73:02, 04:75, 04:105:01- 04:105:02, 04:122, 04:178N, 04:284:01- 04:284:02, 04:293	
39⁴	100 bp 175 bp	430 bp	*04:83 *04:15, 04:61-04:62, 04:69, 04:138, 04:145-04:146, 04:154, 04:170, 04:235, 04:251, 04:265, 04:291, 04:323, 04:339	*11:22, 14:10:01:01- 14:10:01:02, 14:57, 14:143, 14:182
40	145 bp 200 bp	430 bp	*04:30, 04:85 *04:38:01:01-04:38:01:02, 04:56:01- 04:56:02, 04:88, 04:100, 04:107, 04:125, 04:205, 04:344	
41	165 bp 205 bp	430 bp	*04:76, 04:108 *04:182	
42⁴	110 bp	430 bp	*04:41, 04:77, 04:102, 04:113, 04:152, 04:164, 04:211, 04:225, 04:230, 04:250, 04:301 *04:79	*14:10:01:01-14:10:01:02, 14:57, 14:143, 14:182
43⁴	140 bp 125 bp	515 bp	*04:80, 04:179, 04:209, 04:218	*11:53, 11:125, 11:173
44	165 bp 240 bp	430 bp	*04:127 *04:87, 04:94:01N, 04:120N, 04:129, 04:157N, 04:186N, 04:212N, 04:347	
45	240 bp	515 bp	*04:03:08, 04:04:04, 04:10:02, 04:44:01, 04:72:02, 04:74:01, 04:95:01, 04:131:01, 04:140, 04:157N, 04:244	
46⁴	75 bp 200 bp	430 bp	*04:92, 04:274, 04:315, 04:342, 04:353 *04:214N	
47	140 bp 250 bp	430 bp	*04:117 *04:119N, 04:142N	
48⁷	-	-	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*04 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.



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For *In Vitro* Diagnostic Use

MA123 v02 SSP PI Template

Date: February 2023, Rev. No: 00

DRB1*04

101.114-24/03 – including *Taq* polymerase

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Lot No.: 7R5

Lot-specific information

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 21, 22, 29, 31 and 34 may have tendencies of unspecific amplifications.

⁶Primer mixes 14 and 31 have a tendency to giving rise to primer oligomer formation.

⁷Primer mix 48 contains a negative control, which will amplify the majority of HLA amplicons as well as the amplicons generated by the control primer pairs matching the human growth hormone gene. HLA-specific PCR product sizes range from 75 to 200 base pairs and the PCR product generated by the HGH positive control primer pair is 200 base pairs.

Abbreviations

w: might be weakly amplified.

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



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For *In Vitro* Diagnostic Use

MA123 v02 SSP PI Template

Date: February 2023, Rev. No: 00

DRB1*04

101.114-24/03 – including *Taq* polymerase

101.114-24u/03u – without *Taq* polymerase

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Lot No.: **7R5**

Lot-specific information

PRIMER SPECIFICATION

Well No.	1	2	3	4	5	6	7	8	9	10	11	12
Length of spec. PCR product	215	215	225	225	170	115	260	260	215	170	175	180
											220	265
Length of int. pos. control ¹	515	430	430	515	430	430	430	430	430	515	430	515
5'-primer(s) ²	13(125) 5'-ACA 3'	13(125) 5'-ACA 3'	13(125) 5'-ACA 3'	13(124) 5'-AAC 3'	13(125) 5'-ACA 3'	13(125) 5'-ACA 3'	13(125) 5'-ACA 3'	13(125) 5'-ACA 3'	13(125) 5'-ACA 3'	13(125) 5'-ACA 3'	13(125) 5'-ACA 3'	13(125) 5'-ACA 3'
			13(125) 5'-ACC 3'	13(125) 5'-ACA 3'								
3'-primer(s) ³	71(298) 5'-CTT 3'	71(298) 5'-CTC 3'	74(308) 5'-CCT 3'	74(308) 5'-CCg 3'	57(256) 5'-gCT 3'	37(197) 5'-Cgg 3'	86(344) 5'-CAC 3'	86(344) 5'-CCA 3'	71(298) 5'-TCT 3'	57(256) 5'-ATC 3'	58(260) 5'-CCT 3'	59(262) 5'-CTg 3'
	71(298) 5'-TTT 3'				57(256) 5'-gCT 3'				71(298) 5'-CCT 3'	57(256) 5'-ATC 3'	73(305) 5'-ggC 3'	88(351) 5'-AAT 3'
					57(256) 5'-gCT 3'					57(256) 5'-gTC 3'		
										58(261) 5'-TCC 3'		
										58(261) 5'-TCA 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	170	210	175	170	190	145	140	100	155	230	135	85
			215				210	175	210		255	
								255				
Length of int. pos. control ¹	430	430	430	430	430	430	515	430	515	430	430	430
5'-primer(s) ²	13(125) 5'-ACA 3'	13(125) 5'-ACA 3'	13(125) 5'-ACC 3'	44(217) 5'-ACA 3'	13(125) 5'-ACA 3'	13(125) 5'-ACA 3'	13(125) 5'-ACA 3'	13(125) 5'-ACA 3'	13(125) 5'-ACA 3'	13(125) 5'-ACA 3'	39(203) 5'-gCA 3'	71(299) 5'-gAA 3'
			26(165) 5'-TTg 3'								104(397) 5'-CTg 3'	71(299) 5'-gAA 3'
3'-primer(s) ³	56(253) 5'-AgC 3'	67(286) 5'-gAT 3'	71(298) 5'-CTT 3'	86(344) 5'-CCA 3'	60(265) 5'-gTT 3'	47(227) 5'-ggA 3'	46(225) 5'-TAg 3'	33(184) 5'-gTT 3'	51(239) 5'-CCA 3'	72(302) 5'-CCT 3'	71(299) 5'-gCT 3'	86(344) 5'-CAC 3'
	74(307) 5'-CAg 3'	67(286) 5'-gAT 3'		86(344) 5'-CAC 3'	67(286) 5'-gAA 3'		70(296) 5'-TCC 3'	58(260) 5'-CgC 3'	67(286) 5'-gAg 3'	78(319) 5'-gTg 3'	174(609) 5'-ACg 3'	
		67(286) 5'-gAT 3'						85(341) 5'-CAg 3'	71(298) 5'-CgC 3'			
		73(304) 5'-ggA 3'										
Well No.	13	14	15	16	17	18	19	20	21	22	23	24



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For *In Vitro* Diagnostic Use

MA123 v02 SSP PI Template

Date: February 2023, Rev. No: 00

DRB1*04

101.114-24/03 – including *Taq* polymerase

101.114-24u/03u – without *Taq* polymerase

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Lot No.: **7R5**

Lot-specific information

Well No.	25	26	27	28	29	30	31	32	33	34	35	36
Length of spec.	125	200	115	90	75	80	85	120	215	270	210	120
PCR product	230		265		270		200				245	180
	260						260					
Length of int.	430	515	515	430	430	430	430	430	430	515	430	515
pos. control ¹												
5'-primer(s) ²	13(125) 5'-ATA 3'	13(125) 5'-ACA 3'	11(118) 5'-AgA 3'	57(258) 5'-AgC 3'	6(103) 5'-CAA 3'	57(258) 5'-AgC 3'	13(125) 5'-ATA 3'	13(125) 5'-ACA 3'	13(125) 5'-ACA 3'	6(103) 5'-CAA 3'	13(125) 5'-ACA 3'	20(145) 5'-ACC 3'
	23(155) 5'-gCC 3'		57(258) 5'-AgC 3'		13(125) 5'-ATA 3'		34(187) 5'-ACT 3'			13(125) 5'-gTC 3'		41(208) 5'-TCA 3'
	58(259) 5'-ATA 3'		63(275) 5'-CAA 3'		74(308) 5'-CgA 3'		71(299) 5'-CgA 3'			13(125) 5'-ACC 3'		
							71(299) 5'-CAA 3'					
3'-primer(s) ³	86(344) 5'-CAC 3'	67(286) 5'-gAg 3'	86(344) 5'-CCA 3'	74(308) 5'-CCT 3'	86(344) 5'-CAC 3'	71(299) 5'-gCT 3'	86(344) 5'-CAC 3'	37(197) 5'-CgT 3'	72(301) 5'-CCg 3'	86(344) 5'-CAC 3'	69(293) 5'-..T 3'	67(286) 5'-gAg 3'
		67(288) 5'-AgA 3'						39(203) 5'-AgT 3'			81(328) 5'-gTA 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
Length of spec.	225	140	100	145	165	110	125	165	240	75	140
PCR product		225	175	200	205	140		240		200	250
Length of int.	430	430	430	430	430	430	515	430	515	430	430
pos. control ¹											
5'-primer(s) ²	13(125) 5'-ACA 3'	13(125) 5'-ACA 3'	13(125) 5'-ACA 3'	13(125) 5'-ACA 3'	13(125) 5'-ACA 3'	13(125) 5'-ACA 3'	37(197) 5'-gTA 3'	13(125) 5'-ACA 3'	13(125) 5'-ACA 3'	34(187) 5'-ACT 3'	13(125) 5'-ACA 3'
							123(454) 5'-TCC 3'			196(674) 5'-ACA 3'	
3'-primer(s) ³	71(298) 5'-CCA 3'	46(224) 5'-ACC 3'	33(185) 5'-ggA 3'	46(223) 5'-CTT 3'	53(244) 5'-CAT 3'	37(196) 5'-gTT 3'	67(286) 5'-gAA 3'	55(251) 5'-gCg 3'	77(317) 5'-AAT 3'	86(344) 5'-CAC 3'	46(223) 5'-CTg 3'
	77(317) 5'-AgT 3'	71(299) 5'-gCg 3'	57(257) 5'-CAg 3'	49(233) 5'-CCA 3'	57(256) 5'-ATg 3'	37(197) 5'-CgA 3'	149(534) 5'-TTC 3'	78(321) 5'-CAT 3'	83(336) 5'-CCA 3'	207(706) 5'-CAT 3'	83(336) 5'-CCC 3'
	77(318) 5'-TAA 3'	77(318) 5'-TAg 3'	58(260) 5'-CCT 3'	67(286) 5'-gAT 3'	67(287) 5'-ggg 3'	47(226) 5'-gTg 3'		81(328) 5'-gTA 3'			83(336) 5'-CCT 3'
Well No.	37	38	39	40	41	42	43	44	45	46	47

¹The internal positive control primer pairs amplify segments of the human growth hormone gene. The internal positive control bands are 430 or 515 base pairs respectively, well distribution as outlined in the table. Well number 1 contains the longer, 515 bp, internal positive control band. The well distribution of the internal controls can help in orientation of the kit on gel photo, as well as allow for kit identification. In the presence of a specific amplification the intensity of the control band often decreases.

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

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



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

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Lot-specific information

[illegible]

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

DRB1*04

101.114-24/03 – including *Taq* polymerase

101.114-24u/03u – without *Taq* polymerase

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

Lot No.: **7R5**

Lot-specific information

CELL LINE VALIDATION SHEET																																		
DRB1*04 SSP subtyping kit ²																																		
					Well																													
						17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32													
				Prod. No.		201781317	201781318	201781319	201781320	201781321	201781322	201781323	201781324	201781325	201781326	201781327	201781328	202349329	201781330	201781331	201781332													
	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	*14:01	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	+	-												
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: February 2023, Rev. No: 00

DRB1*04

101.114-24/03 – including *Taq* polymerase

101.114-24u/03u – without *Taq* polymerase

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Lot No.: **7R5**

Lot-specific information

CELL LINE VALIDATION SHEET																				
DRB1*04 SSP subtyping kit ²																				
					Well															
						33	34	35	36	37	38	39	40	41	42	43	44	45	46	47
				Prod. No.		202349333	201781334	201781335	201781336	202132337	201781338	201781339	201781340	201781341	201781342	201781343	201781344	201781345	201781346	201781347
	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	*14:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
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: February 2023, Rev. No: 00

DRB1*04**101.114-24/03 – including *Taq* polymerase****101.114-24u/03u – without *Taq* polymerase**Visit www.caredx.com for
“Instructions for Use” (IFU)**Lot No.: 7R5****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 11, 13, 15 to 23, 25, 33 to 39 and 41 to 47 were available. The specificities of the primers in primer solutions 11, 13, 15, 17 to 21, 23, 35, 37 to 39, 42, 43, 45 and 46 were tested by separately adding one or two additional 5'-primers or one additional 3'-primer accordingly. In primer solutions 16, 25, 34 and 36 it was only possible to test the 3'-primers, the 5'-primers were not possible to be tested. In primer solutions 22, 33, 41, 44 and 47 it was only possible to test the 5'-primers, the 3'-primers were not possible to be tested. One or two 3'-primers in primer solutions 1, 5, 10, 12 to 14, 17, 19 to 21, 23, 26, 32, 35, 37 to 40, 42, 43, 45 and 46 were not possible to be tested. In primer solutions 3, 15, 23, 24, 27, 29, 31, 43 and 46 one or two 5'-primers were not possible to be tested. In addition, one 3'-primer in primer solution 10 was tested by separately adding one 5'-primer.

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MA123 v02 SSP PI Template

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DRB1*04

101.114-24/03 – including *Taq* polymerase

101.114-24u/03u – without *Taq* polymerase

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

Lot No.: **7R5**

Lot-specific information

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Web page: www.caredx.com

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