

101.111-24/06 – including *Taq* polymerase
101.111-24u/06u – without *Taq* polymerase

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“Instructions for Use” (IFU)

Lot No.: **4S0**

Lot-specific information
Olerup SSP[®] DRB1*01

Product number:	101.111-24/06 – including <i>Taq</i> pol. 101.111-24u/06u – without <i>Taq</i> pol.
Lot number:	4S0
Expiry date:	2027-09-01
Number of tests:	24 test – Product No. 101.111-24/24u 6 tests – Product No. 101.111-06/06u
Number of wells per test:	23+1
Storage - pre-aliquoted primers:	dark, between -15°C and -25°C
- PCR Master Mix:	between -15°C and -25°C
- Adhesive PCR seals	RT

This Product Description is only valid for Lot No. 4S0.

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*01 LOT (1S5)**

- The product documentation has been updated for new alleles of IMGT 3.53.0.
- The kit resolution focuses on common and well documented (CWD) alleles¹.

¹As described in section Uniquely Identified Alleles.

The DRB1*01 primer set, specificity and interpretation tables have been updated for the DRB1 alleles described since the previous *Olerup SSP[®] DRB1*01* lot was made (**Lot No. 1S5**).

The DRB1*01 primer set is unchanged compared to the previous *Olerup SSP[®] DRB1*01* (**Lot No. 1S5**).



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

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

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

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

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



0197

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

101.111-24/06 – including *Taq* polymerase
101.111-24u/06u – without *Taq* polymerase

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Lot-specific information

PRODUCT DESCRIPTION

DRB1*01 SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for identifying the DRB1*01:01 to DRB1*01:146 alleles.

PLATE LAYOUT

Each test consists of 24 PCR reactions in a 24 well PCR plate.

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	NC

The 24 well PCR plate is marked with 'DRB1*01' in silver/gray ink.

Well No. 1 is marked with the Lot No. '4S0'.

Wells 1 to 23 – DRB1*01 high resolution primers.

Well 24 – Negative Control (NC).

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

Please note: When removing each 24 well PCR plate, make sure that the remaining plates stay covered. Use a scalpel or a similar instrument to carefully cut the foil between the plates.

INTERPRETATION

Due to the sharing of sequence motifs between DRB1 alleles non-DRB1*01 alleles will be amplified by some primer mixes. For further details see Specificity Table.

UNIQUELY IDENTIFIED ALLELES

All the DRB1*01 alleles, i.e. **DRB1*01:01 to DRB1*01:146**, recognized by the HLA Nomenclature Committee in July 2023^{1,2} will be amplified by the primers in the DRB1*01 subtyping kit.

The DRB1*01 kit enables separation of the confirmed DRB1*01 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*01 alleles is listed below.

The DRB1*01 kit also enables identification of many null and alternatively expressed alleles.



0197

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Lot No.: **4S0**

Lot-specific information

The following DRB1*01 alleles can be distinguished by the different sizes of the HLA-specific PCR product:

Alleles	Primer mix
DRB1*01:40N, 01:67	19

¹DRB1 alleles listed on the IMGT/HLA web page 2023-July-12, release 3.53.0, www.ebi.ac.uk/imgt/hla.

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

ALLELE CONFIRMATION STATUS

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

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.



0197

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Lot No.: 4S0

Lot-specific information

RESOLUTION IN HOMO- AND HETEROZYGOTES

Results file with resolution in DRB1*01 homo- and heterozygotes is available upon request.



0197

For *In Vitro* Diagnostic Use
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Lot No.: **4S0**

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SPECIFICITY TABLE

DRB1*01 SSP subtyping

Specificities and sizes of the PCR products of the 23+1 primer mixes used for
DRB1*01 SSP subtyping

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified DRB1*01 alleles ³	Other amplified DRB alleles
1	255 bp	515 bp	*01:01:01:01-01:01:46, 01:03:01:01-01:03:05, 01:05, 01:07-01:19, 01:21-01:22, 01:24:01-01:25, 01:27-01:33N, 01:36-01:41, 01:45, 01:47-01:53, 01:55-01:56, 01:59-01:60, 01:62:01N-01:73, 01:75, 01:77-01:80, 01:82, 01:84, 01:89-01:92, 01:95, 01:98-01:100, 01:102-01:110, 01:112-01:113, 01:115, 01:117, 01:119-01:121, 01:124-01:125, 01:127-01:135, 01:137, 01:139, 01:141, 01:143-01:146	
2	235 bp	430 bp	*01:01:36, 01:02:01:01-01:02:05, 01:02:07-01:02:13, 01:20:02, 01:23, 01:26, 01:34, 01:43-01:44:02, 01:46, 01:54, 01:57, 01:74, 01:76, 01:81, 01:83, 01:86-01:88, 01:93-01:94, 01:96-01:97, 01:111, 01:114, 01:118, 01:122-01:123, 01:126, 01:136, 01:138, 01:140, 01:142	
3	200 bp	515 bp	*01:01:01:01-01:02:13, 01:04-01:14, 01:16-01:21, 01:22 ^w , 01:25-01:29:01, 01:30-01:32, 01:34-01:38, 01:40N-01:41, 01:43-01:50, 01:52N-01:53, 01:56-01:60, 01:62:01N-01:88, 01:91Q-01:98, 01:100-01:101, 01:103-01:110, 01:113-01:126, 01:128-01:130, 01:132-01:133, 01:135-01:146	DRB3*03:01:08
4	180 bp 210 bp	430 bp	*01:62:01N *01:03:01:01-01:03:05, 01:10, 01:39N, 01:42, 01:61, 01:89, 01:99, 01:102, 01:127	
5	210 bp 230 bp	430 bp	*01:29:01, 01:74, 01:118 *01:04, 01:11:01-01:11:02, 01:16, 01:35, 01:55, 01:89, 01:101	DRB3*03:01:08
6	135 bp 215 bp	430 bp	*01:05, 01:31 *01:29:01-01:29:02, 01:74, 01:118	
7	210 bp	430 bp	*01:03:01:01-01:03:05, 01:15, 01:17, 01:39N, 01:42, 01:61, 01:89, 01:102, 01:114, 01:118, 01:127	
8⁴	115 bp 175 bp 210 bp	430 bp	*01:50 *01:27 *01:07	*14:112, DRB3*01:47



0197

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

101.111-24/06 – including *Taq* polymerase
101.111-24u/06u – without *Taq* polymerase

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“Instructions for Use” (IFU)

Lot No.: **4S0**

Lot-specific information

9⁴	110 bp 255 bp	430 bp	*01:08 *01:04, 01:06, 01:20:01-01:20:02, 01:61, 01:85, 01:101	
10	210 bp 250 bp	430 bp	*01:06, 01:09, 01:15 *01:52N	
11	140 bp 210 bp	430 bp	*01:18:01-01:18:02, 01:44:01-01:44:02 *01:10, 01:68N	
12	140 bp 180 bp 215 bp	430 bp	*01:31 *01:26, 01:37 *01:12	
13⁴	85 bp 150 bp 215 bp	430 bp	*01:13 *01:28 *01:01:43, 01:23, 01:51, 01:111	
14	170 bp 205 bp	430 bp	*01:14 *01:01:43, 01:23-01:24:02, 01:51, 01:54, 01:68N, 01:111	
15	150 bp 220 bp	430 bp	*01:28 *01:16, 01:21, 01:55, 01:90, 01:101	
16	200 bp 230 bp	430 bp	*01:24:01-01:24:02, 01:54 *01:19, 01:21	
17⁴	125 bp 230 bp 260 bp	430 bp	*01:30 *01:27 *01:22	*13:165, DRB3*02:63 DRB3*01:47
18^{4,5}	115 bp 230 bp	430 bp	*01:50 *01:25	*10:40, DRB5*01:60 DRB4*01:132
19⁴	125 bp 235 bp 270 bp	430 bp	*01:67 *01:77, 01:119 *01:39N-01:40N	*14:196
20	205 bp 235 bp	430 bp	*01:33N *01:77, 01:119	*14:196
21⁴	90 bp 180 bp 250 bp	430 bp	*01:34 *01:62:01N *01:32	
22	205 bp 250 bp	430 bp	*01:36 *01:52N	
23	255 bp	430 bp	*01:02:01:01-01:02:13, 01:23, 01:26, 01:34-01:35, 01:42-01:44:02, 01:46, 01:54, 01:57-01:58, 01:74, 01:76, 01:81, 01:83, 01:86-01:88, 01:93-01:94, 01:96- 01:97, 01:111, 01:114, 01:116, 01:118, 01:122-01:123, 01:126, 01:136, 01:138, 01:140, 01:142	
24⁶	-	-	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 DRB*01 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



0197

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

101.111-24/06 – including *Taq* polymerase
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Lot No.: 4S0

Lot-specific information

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 mix 18 may have tendency of unspecific amplification and may give rise to a lower yield of HLA-specific PCR product than the other DRB1*01 primer mixes.

⁶Primer mix 24 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.



0197

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MA123 v02 SSP PI Template
Date: September 2023, Rev. No: 00

101.111-24/06 – including *Taq* polymerase
101.111-24u/06u – without *Taq* polymerase

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Lot No.: **4S0**

Lot-specific information

PRIMER SPECIFICATION

Well No.	1	2	3	4	5	6	7	8	9	10	11	12
Length of spec. PCR product	255	235	200	180	210	135	210	115	110	210	140	140
				210	230	215		175	255	250	210	180
								210				215
Length of int. pos. control ¹	515	430	515	430	430	430	430	430	430	430	430	430
5'-primer(s) ²	11(119) 5'-gCT 3' 14(129) 5'-gAA 3'	14(129) 5'-gAA 3'	14(129) 5'-gAA 3'	14(129) 5'-gAA 3'	14(129) 5'-gAA 3'	14(129) 5'-gAA 3'	14(129) 5'-gAA 3'	10(115) 5'-ggg 3' 23(154) 5'-Agg 3' 110(417) 5'-CAC 3'	14(129) 5'-gAA 3'	14(129) 5'-gAA 3'	14(129) 5'-gAA 3'	14(129) 5'-gAA 3'
3'-primer(s) ³	85(341) 5'-CAA 3'	78(321) 5'-CAA 3'	67(286) 5'-gAg 3' 67(286) 5'-gAg 3'	61(270) 5'-TTT 3' 71(299) 5'-gCT 3'	70(296) 5'-TCC 3' 77(317) 5'-AAT 3' 77(317) 5'-AgT 3'	45(220) 5'-CCT 3' 48(230) 5'-CCT 3' 70(296) 5'-TCC 3' 72(303) 5'-gCA 3'	67(286) 5'-gAT 3' 67(286) 5'-gAT 3' 74(308) 5'-CCT 3'	67(286) 5'-gAg 3' 135(490) 5'-gCC 3'	37(197) 5'-CgT 3' 85(341) 5'-CAA 3'	71(298) 5'-CgC 3' 83(336) 5'-CCC 3'	47(227) 5'-ggA 3' 70(295) 5'-CTA 3' 71(298) 5'-CTT 3'	48(230) 5'-CCT 3' 60(266) 5'-Agg 3' 72(302) 5'-CCA 3'
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

Well No.	13	14	15	16	17	18	19	20	21	22	23
Length of spec. PCR product	85	170	150	200	125	115	125	205	90	205	255
	150	205	220	230	230	230	235	235	180	250	
	215				260		270		250		
Length of int. pos. control ¹	430	430	430	430	430	430	430	430	430	430	430
5'-primer(s) ²	14(129) 5'-gAA 3'	14(129) 5'-gAA 3'	14(129) 5'-gAA 3'	14(129) 5'-gAA 3'	12(123) 5'-AAC 3' 23(154) 5'-Agg 3' 59(262) 5'-CCA 3'	23(154) 5'-AgT 3' 110(417) 5'-CAC 3'	9(114) 5'-TgA 3' 105(401) 5'-AAA 3'	13(124) 5'-A.T 3' 105(401) 5'-AAA 3'	14(129) 5'-gAA 3'	14(129) 5'-gAA 3'	14(129) 5'-gAA 3'
3'-primer(s) ³	30(175) 5'-gAg 3'	57(257) 5'-CAg 3'	51(239) 5'-CCA 3'	67(286) 5'-gAT 3'	86(344) 5'-CAC 3'	86(344) 5'-CAC 3'	86(344) 5'-CAC 3'	67(286) 5'-gAg 3'	31(178) 5'-gAC 3'	69(293) 5'-gCC 3'	85(341) 5'-CAg 3'
	51(239) 5'-CCA 3'	67(286) 5'-gAT 3'	73(305) 5'-ggC 3'	76(313) 5'-gTT 3'		135(490) 5'-gCC 3'	133(485) 5'-TCT 3'	170(595) 5'-AAA 3'	61(270) 5'-TTT 3'	83(336) 5'-CCC 3'	
	72(303) 5'-gCg 3'	70(295) 5'-CTA 3'	78(319) 5'-CAC 3'	78(319) 5'-CAC 3'			170(595) 5'-AAA 3'		84(337) 5'-CCT 3'		
		72(303) 5'-gCg 3'									
Well No.	13	14	15	16	17	18	19	20	21	22	23



0197

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

101.111-24/06 – including *Taq* polymerase
101.111-24u/06u – without *Taq* polymerase

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Lot No.: **4S0**

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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: September 2023, Rev. No: 00

101.111-24/06 – including *Taq* polymerase
101.111-24u/06u – without *Taq* polymerase

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

Lot No.: 4S0

Lot-specific information

CELL LINE VALIDATION SHEET																						
DRB1*01 SSP subtyping kit ²																						
				Production No.	Well																	
					1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16		
					202356601	202356602	202356603	202356604	202356605	202356606	202356607	202356608	202356609	202356610	202356611	202356612	202356613	202356614	202356615	202356616		
	IHCW cell line ¹		DRB1																			
1	9001	SA	*01:01	*04:05	+	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-		
2	9280	LK707	*15:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
3	9011	E4181324	*15:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
4	9275	GU373	*03:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
5	9009	KAS011	*16:01	*08:03	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
6	9353	SM	*04:07		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
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	*13:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
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		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
18	9257	32367	*09:01		*11:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
19	9038	BM16	*12:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
20	9059	SLE005	*13:02			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
21	9064	AMALA	*14:02	*14:54	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
22	9056	KOSE	*13:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
23	9124	IHL	*08:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
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			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
29	9050	MOU	*07:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
30	9021	RSH	*03:02			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
31	9019	DUCAF	*03:01	*04:06	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
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		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
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	*12:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
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		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
48	9303	TER-ND	*01:03		+	-	-	+	-	-	+	-	-	-	-	-	-	-	-	-	-	



0197

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

101.111-24/06 – including *Taq* polymerase
101.111-24u/06u – without *Taq* polymerase

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“Instructions for Use” (IFU)

Lot No.: **4S0**

Lot-specific information

CELL LINE VALIDATION SHEET												
DRB1*01 SSP subtyping kit ²												
					Well							
						17	18	19	20	21	22	23
				Production No.		202356617	202356618	202356619	202356620	202356621	202356622	202356623
	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: September 2023, Rev. No: 00

101.111-24/06 – including *Taq* polymerase
101.111-24u/06u – without *Taq* polymerase

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Lot No.: 4S0

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 5, 6 and 8 to 22 were available. The specificities of the primers in primer solutions 5, 6, 9 to 16, 19 and 20 were tested by separately adding one or more additional 5'-primers, respectively one additional 3'-primer. In primer solutions 8, 17 and 18 it was only possible to test the 3'-primers, the 5'-primers were not possible to be tested. In primer solutions 21 and 22 it was only possible to test the 5'-primer, the 3'-primers were not possible to be tested. In primer solutions 4, 6, 10 to 16, 19 and 20 one or two 3'-primers were not possible to be tested. In primer solutions 19 and 20, one 5'-primer was not possible to be tested. In addition, two 3'-primers in primer solution 7 were tested by separately adding 5'-primers.



0197

For *In Vitro* Diagnostic Use
MA123 v02 SSP PI Template
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101.111-24/06 – including *Taq* polymerase
101.111-24u/06u – without *Taq* polymerase

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“Instructions for Use” (IFU)

Lot No.: **4S0**

Lot-specific information

ADDRESSES:

Manufacturer:

CareDx AB, Franzengatan 5, SE-112 51 Stockholm, Sweden.

Tel: +46-8-508 939 00

Fax: +46-8-717 88 18

E-mail: orders-se@caredx.com

Web page: www.caredx.com

Distributed by:

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

Tel: 1-877-653-78171

Fax: 610-344-7989

E-mail: orders-us@caredx.com

Web page: www.caredx.com

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



0197

For *In Vitro* Diagnostic Use

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