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Lot No.: **0V3** Lot-specific information

Olerup SSP® DPA1

Product number: 101.331-24/06 – including *Taq* pol.

101.331-24u/06u - without *Taq* pol.

Lot number: 0V3

Expiry date: 2028-11-01

Number of tests: 24 tests – Product No. 101.331-24/24u

6 tests - Product No. 101.331-06/06u

Number of wells per test: 22+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. 0V3.

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

CHANGES COMPARED TO THE PREVIOUS OLERUP SSP® DPA1 LOT (5R1)

- The product documentation has been updated for new alleles of IMGT 3.56.0.
- The kit resolution focuses on common and well documented (CWD) alleles¹.

The DPA1 specificity and interpretation tables have been updated for the DPA1 alleles described since the previous *Olerup* SSP® DPA1 lot was made (Lot No. 5R1).

The DPA1 primer set is unchanged compared to the previous *Olerup* SSP® DPA1 (Lot No. 5R1).

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



¹As described in section Uniquely Identified Alleles.



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Lot No.: **0V3** Lot-specific information

Well **23** contains <u>Negative Control primer pairs</u>, 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	105	200	105	80	75	80	85
product							
5'-primer ¹	164	340	440	45	45	43	36
_	5'-CAC3'	^{5'} -Agg ^{3'}	^{5'} -TTA3'	⁵ '-Tgg ³ '	⁵ '-Tgg ³ '	^{5'} -Tgg ^{3'}	5'-TAC3'
							36
							^{5'} -TAT ^{3'}
3'-primer ²	231	2 nd 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'-ACA3'
							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 codonnumbering 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.

DPA1 Product Insert Page 3 of 12

101.331-24/06 - including *Taq* polymerase 101.331-24u/06u - without Taq polymerase

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Lot No.: **0V3 Lot-specific information**

PRODUCT DESCRIPTION

DPA1 SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for identifying the DPA1*01:03 to DPA1*04:06 alleles.

PLATE LAYOUT

Each test consists of 23 PCR reactions in a 24 well cut PCR plate. Wells 24 is empty.

1	2	3	4	5	6	7	8
9	10	11	12	13	14	15	16
17	18	19	20	21	22	NC	empty

The 24 well cut PCR plate is marked with 'DPA1' in silver/gray ink.

Well No. 1 is marked with the Lot No. '0V3'.

Wells 1 to 22 – DPA1 high resolution primers.

Well 23 – 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 heat-sealed with a PCR-compatible foil.

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

INTERPRETATION

Only DPA1 alleles will be amplified by the DPA1 typing kit. Thus, the interpretation of DPA1 typings is not influenced by the DPA2 gene.

For further details see Specificity Table.

UNIQUELY IDENTIFIED ALLELES

All the DPA1 alleles, i.e. DPA1*01:03 to DPA1*01:201, DPA1*02:01 to DPA1*02:130, DPA1*03:01 to DPA1*03:18 and DPA1*04:01 to DPA1*04:06, recognized by the HLA Nomenclature Committee in April 2024^{1,2} will be amplified by the primers in the DPA1 typing kit³.

The DPA1 kit enables separation of the phenotypically different DPA1 alleles listed in the IMGT/HLA database 3.34.0, October 2018.

alleles listed on the IMGT/HLA web page 2024-April-10, release 3.56.0, ¹DPA1 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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101.331-24/06 – including *Taq* polymerase 101.331-24u/06u – without *Taq* polymerase

Visit <u>www.caredx.com</u> for "Instructions for Use" (IFU)

Lot No.: **0V3** Lot-specific information

³The following alleles give rise to identical amplification patterns with the DPA1 resolution primer set.

Alleles

DPA1*01:05, 04:05 DPA1*02:03:02, DPA1*03:07:02, 03:154

RESOLUTION IN HOMO- AND HETEROZYGOTES

Results file with resolution in DPA1 homo- and heterozygotes is available upon request.

DPA1 Product Insert Page 5 of 12

101.331-24/06 – including *Taq* polymerase 101.331-24u/06u – without *Taq* polymerase

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Lot No.: **0V3** Lot-specific information

SPECIFICITY TABLE

DPA1 SSP typing

Specificities and sizes of the PCR products of the 22+1 primer mixes used for DPA1 SSP typing

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified DPA1 ³ alleles
14	85 bp	515 bp	*01:03:01:01-01:03:02, 01:03:04-01:03:31, 01:03:33- 01:05, 01:07-01:11:02, 01:12:01, 01:12:03-01:26, 01:28- 01:61, 01:63-01:110, 01:112-01:117, 01:119N-01:132, 01:134-01:153, 01:155:01:01-01:177, 01:179-01:201, 02:03:03-02:03:05, 04:01:01:01-04:06
2	255 bp	515 bp	*01:03:01:01-01:03:13, 01:03:15-01:04:04, 01:06:01-01:12:03, 01:14-01:38, 01:40-01:57, 01:59-01:61, 01:63-01:180, 01:182-01:201, 02:21:01-02:21:04, 02:50:01-02:50:02
3	160 bp 205 bp	430 bp	*02:11 *01:03:01:01-01:03:57, 01:06:01-01:07, 01:09-01:57, 01:59-01:61, 01:63-01:150, 01:152-01:201, 02:21:01-02:21:04, 02:27:01-02:27:03, 02:50:01-02:50:02, 03:01:01:01-03:02, 03:04-03:06:03, 03:09, 03:11N-03:14, 03:16-03:18
4 ^{4,5}	115 bp	430 bp	*01:04:01-01:04:04, 01:08, 01:151, 03:03
5 ^{4,7}	105 bp	430 bp	*01:03:27, 01:05, 01:58:01:01-01:58:01:02, 01:62, 02:01:01:01-02:01:01:04, 02:01:01:06-02:02:02:05, 02:02:02:07-02:19, 02:21:01, 02:21:04-02:27:01, 02:28:01-02:42, 02:44-02:49, 02:51-02:59:01, 02:60-02:130, 03:07:02-03:08, 03:15, 04:01:01:01-04:06
6	160 bp 195 bp 255 bp	515 bp	*01:10, 02:04 *01:06:01-01:06:05, 02:21:01-02:21:04, 02:27:01- 02:27:03, 02:50:01-02:50:02, 03:06:01-03:06:03 *01:13
74	100 bp	430 bp	*01:06:01-01:06:05, 02:01:01:01-02:01:01:04, 02:01:01:06-02:01:31, 02:08-02:09:02, 02:11, 02:13N, 02:16, 02:18-02:19, 02:21:01-02:21:04, 02:24, 02:26:01:01-02:26:01:02, 02:29, 02:31-02:32N, 02:34:01:01-02:34:01:02, 02:36-02:37, 02:39-02:40, 02:43, 02:45:01-02:46, 02:49-02:50:02, 02:53, 02:55, 02:57, 02:59:01-02:61, 02:65-02:66:02N, 02:69:01-02:70, 02:74N-02:75, 02:77-02:80N, 02:82, 02:84, 02:86-02:87, 02:91, 02:93-02:94N, 02:97-02:99, 02:101:01-02:102Q, 02:104, 02:106-02:111, 02:114-02:116, 02:118-02:123, 02:125, 02:129-02:130
84	100 bp	430 bp	*02:02:02:01-02:02:02:05, 02:02:07-02:02:15, 02:04-02:07:04, 02:10, 02:12:01-02:12:02, 02:14-02:15, 02:17, 02:20, 02:25, 02:27:01-02:27:03, 02:30, 02:33, 02:35, 02:38Q, 02:41N-02:42, 02:44, 02:47:01-02:48, 02:51-02:52N, 02:54, 02:56Q, 02:58, 02:62-02:64Q, 02:67-02:68, 02:71-02:73, 02:76, 02:81, 02:83, 02:85, 02:88-02:90, 02:92, 02:95-02:96, 02:100, 02:103, 02:105,



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Lot No.: **0V3** Lot-specific information

9	Lot No.:	0 4 3	LO	-specific information
02:07:04, 02:10, 02:12:01-02:12:02, 02:14-02:15, 02:17, 02:20, 02:20, 02:20, 02:25, 02:25, 02:25, 02:244, 02:444, 02:47:01-02:48, 02:51-02:52N, 02:54, 02:66, 02:78, 02:63, 02:68, 02:74-02:73, 02:76, 02:81, 02:63, 02:88, 02:88, 02:88, 02:88, 02:88, 02:88, 02:88, 02:88, 02:88, 02:88, 02:88, 02:88, 02:88, 02:88, 02:88, 02:88, 02:89, 02:92, 02:95-02:96, 02:100, 02:103, 02:113, 02:113, 02:117, 02:124, 02:126-02:128, 03:02 104 85 bp 515 bp 10:10303, 01:11:03, 01:12:02, 02:03:01-02:03:02, 02:22:01-02:22:02, 03:01:01:01-03:01:03, 03:02-03:05:020, 03:07:01-03:18 114 90 bp 515 bp 10:11:01-01:12:03, 03:01:01:01-03:01:04, 03:03-03:06:03, 03:09-03:14, 03:16-03:18 12 205 bp 430 bp 10:107 12 205 bp 430 bp 10:109, 02:06, 02:15-02:16, 02:30, 02:41N², 02:67-02:68, 02:92, 03:14 14 130 bp 515 bp 10:107-01:08, 01:11:01-01:11:03, 02:05, 02:21:01-02:22:04, 02:27:01-02:27:03, 02:50:01-02:50:02, 02:65, 03:04 15 245 bp 430 bp 10:03:03, 01:06:03-01:06:04, 01:11:03, 01:12:02, 02:21:01-02:21:04, 02:27:01-02:27:03, 02:50:01-02:50:02, 02:65, 03:04 168 90 bp 430 bp 10:03:03, 01:06:03-01:06:04, 01:11:03, 01:12:02, 02:21:01-02:21:03-02:21:04, 02:27:01-02:27:03, 02:50:01-02:27:03, 02:50:01, 03:01:01:01-03:01:03, 03:02-03:06:03, 03:09-03:14, 03:16-03:18 168 90 bp 430 bp 10:03:03, 01:04:02², 01:12:01-01:12:02, 01:33:01-03:14, 03:16-03:18 174 85 bp 430 bp 10:03:04, 02:04:04, 02:27:01-02:27:03, 02:50:01, 03:01:01:01-03:01:03, 03:02-03:06:03, 03:09-03:14, 03:18-03:18 175 245 bp 430 bp 10:03:04, 02:04:04, 02:27:01-02:27:03, 02:50:01, 03:01:01:01-02:01:01:03, 02:02:02:02, 02:02:02, 02:02:02, 02:02:02, 02:02:02, 02:02:02, 02:02:02, 02:02:02, 02:02:02, 02:02:02, 02:02:02:02, 02:02:02, 02:02:02, 02:02:02, 02:02:02, 02:02:02, 02:02:02, 02:02:02:02, 02:02:02:02, 02:02:02:02, 02:02:02:02, 02:02:02:02:02:02, 02:02:02:02, 02:02:02:02, 02:02:02:02, 02:02:02:02:02, 02:02:02:02:02, 02:02:02:02:02, 02:02:02:02, 02:02:02:02, 02:02:02:02, 02:02:02:02, 02:02:02:02:02:02, 02:02:02:02, 02:02:02:02, 02:02:02:02, 02:02:02:02, 02:02:02:02:02, 02:02:02:02, 02:02:				
1146 90 bp 515 bp 03:10:00:00:00:00:00:00:00:00:00:00:00:00:	9	205 bp	430 bp	02:07:04, 02:10, 02:12:01-02:12:02, 02:14-02:15, 02:17, 02:20, 02:22:01-02:22:02, 02:25, 02:27:01-02:27:03, 02:30, 02:33, 02:35, 02:38Q, 02:41N-02:42, 02:44, 02:47:01-02:48, 02:51-02:52N, 02:54, 02:56Q, 02:58, 02:62-02:64Q, 02:67-02:68, 02:71-02:73, 02:76, 02:81, 02:83, 02:85, 02:88-02:90, 02:92, 02:95-02:96, 02:100, 02:103, 02:105, 02:112-02:113, 02:117, 02:124, 02:126-
135 bp	10 ⁴	85 bp	515 bp	02:22:01-02:22:02, 03:01:01:01-03:01:03, 03:02-
12	11 ^{4,6}	·	515 bp	*01:12:01-01:12:03, 03:01:01:01-03:01:04, 03:03- 03:06:03, 03:09-03:14, 03:16-03:18
13.4.6 90 bp 430 bp *01:09, 02:06, 02:15-02:16, 02:30, 02:41N², 02:67-02:68, 02:92, 03:14 14 130 bp 515 bp *01:07-01:08, 01:11:01-01:11:03, 02:05, 02:21:01-02:27:03, 02:50:01-02:50:02, 02:65, 03:04 15 245 bp 430 bp *01:03:03, 01:06:03-01:06:04, 01:11:03, 01:12:02, 02:21:01, 02:21:03, 02:27:01-02:27:03, 02:50:01, 03:01:01:01-03:01:03, 03:02-03:06:03, 03:09-03:14, 03:16-03:18 168 90 bp 430 bp *02:07:01:01-02:07:03, 02:12:01, 02:27:02, 02:52N, 02:60, 02:73, 02:90, 03:06:02 174 85 bp 430 bp *01:03:10, 01:04:02², 01:12:01-01:12:02, 01:33:01-01:33:02, 01:40², 01:46²-01:47², 01:51²-01:53², 01:58:01:01-01:58:01:02, 01:62, 01:66N², 01:95, 01:111², 01:123N², 01:154N², 02:01:01:01-02:01:01:04, 02:01:01:06-02:01:00?-02:02:00; 02:02:02:07-02:02:02:02:07-02:02:02:02:07-02:02:02:02:02:02:02:02:02:02:02:02:02:0	12		430 bp	
14 130 bp 515 bp *01:07-01:08, 01:11:01-01:11:03, 02:05, 02:21:01-02:50:02, 02:65, 03:04 15 245 bp 430 bp *01:03:03, 01:06:03-01:06:04, 01:11:03, 01:12:02, 02:21:01, 02:21:03-02:21:04, 02:27:01-02:27:03, 02:50:01, 03:01:01:01-03:01:03, 03:02-03:06:03, 03:09-03:14, 03:16-03:18 168 90 bp 430 bp *02:07:01:01-02:07:03, 02:12:01, 02:27:02, 02:52N, 02:60, 02:73, 02:90, 03:06:02 174 85 bp 430 bp *01:03:10, 01:04:02², 01:12:01-01:12:02, 01:33:01-01:33:02, 01:40², 01:46²-01:47², 01:51²-01:53², 01:58:01:01-01:58:01:02, 01:62, 01:66N², 01:95, 01:111², 01:123N², 01:154N², 02:01:01:01-02:01:01:04, 02:01:01:06-02:01:02-03, 02:01:07-02:02:02:07-02:02:02:07-02:02:02:07-02:02:02:07-02:02:02:07-02:02:02:07-02:02:02:07-02:02:02:07-02:02:02:07-02:02:02:07-02:02:02:07-02:02:02:07-02:02:02:07-02:02:02:07-02:02:02:07-02:02:02:02:07-02:02:02:07-02:02:02:02:07-02:02:02:07-02:02:02:02:07-02:02:02:02:07-02:02:02:02:07-02:02:02:02:07-02:02:02:02:07-02:02:02:02:07-02:02:02:02:02:02:02-02:03:02:02:02:02:02:02:02:02:02:02:02:02:02:		•	•	*01:09, 02:06, 02:15-02:16, 02:30, 02:41N ² , 02:67-02:68,
02:21:01, 02:21:03-02:21:04, 02:27:01-02:27:03, 02:50:01, 03:01:01:01-03:01:03, 03:02-03:06:03, 03:09-03:14, 03:16-03:18 168 90 bp 430 bp *02:07:01:01-02:07:03, 02:12:01, 02:27:02, 02:52N, 02:60, 02:73, 02:90, 03:06:02 174 85 bp 430 bp *01:03:10, 01:04:02², 01:12:01-01:12:02, 01:33:01-01:33:02, 01:40², 01:46²-01:47², 01:51²-01:53², 01:58:01:01-01:58:01:02, 01:62, 01:66N², 01:95, 01:111², 01:123N², 01:154N², 02:01:01-02:02:03, 02:01:01.04, 02:01:06²-02:01:06²-02:01:06²-02:01:02:03, 02:01:03³, 02:02:02:02-02-02:02:07-02:02:02:07-02:02:03:01², 02:03:01², 02:03:02²-02:03:05, 02:04²-02:05², 02:06-02:10, 02:11², 02:12:01-02:21:01, 02:21:02², 02:27:02²-02:25², 02:26:01:01-02:21:01, 02:21:02², 02:27:03²-02:32N, 02:34:01:01-02:240, 02:41N², 02:42-02:46, 02:47:01², 02:47:01²-02:40, 03:01:01-03:01:01:15, 03:01:03-03:01:04, 03:02²-03:03³, 03:04-03:05:01:02Q, 03:06:02², 03:06:03², 03:06:03, 03:07:01², 03:07:02-03:17, 04:02:01:01-04:04, 04:06 184 185 bp 430 bp *01:15, 01:62, 02:09:01:01-02:09:02, 02:47:01-02:47:02, 03:08 19 135 bp 430 bp *01:14, 01:68, 02:08, 02:60 20 140 bp 430 bp *01:17 21 135 bp 430 bp *02:10 228 90 bp 430 bp *02:10	14	130 bp		*01:07-01:08, 01:11:01-01:11:03, 02:05, 02:21:01- 02:21:04, 02:27:01-02:27:03, 02:50:01-02:50:02, 02:65,
02:60, 02:73, 02:90, 03:06:02 174 85 bp 430 bp *01:03:10, 01:04:02°, 01:12:01-01:12:02, 01:33:01-01:33:02, 01:46°, 01:46°-01:47°, 01:51°-01:53°, 01:58:01:01-01:58:01:02, 01:66, 01:66N°, 01:95, 01:1111°, 01:123N°, 01:154N°, 02:01:01:01-02:01:01:04, 02:01:01:06-02:01:02:03, 02:01:03°, 02:01:04, 02:01:05°-02:01:06°, 02:01:07-02:02:05, 02:02:02:07-02:02:02:17Q, 02:02:03°-02:02:06°, 02:02:07-02:02:17Q, 02:02:03°-02:02:06°, 02:02:07-02:02:10, 02:11°, 02:11°, 02:11:01-02:21:01, 02:21:02°, 02:21:03-02:24, 02:25°, 02:26:01:01-02:27:01, 02:21:02°, 02:27:03-02:32N, 02:34:01:01-02:27:01, 02:27:02°, 02:27:03-02:32N, 02:34:01:01-02:40, 02:41N°, 02:42-02:46, 02:47:01°, 02:47:02°, 02:73°, 02:54-02:58, 02:60-02:72, 02:73°, 02:74N-02:84, 02:86-02:116, 02:117°, 02:118-02:130, 03:01:01-03:01:01-03:01:012Q, 03:06:02°, 03:06:03°, 03:06:03°, 03:07:01°, 03:07:02-03:17, 04:02:01:01-04:04, 04:06 184 185 bp 430 bp *01:15, 01:62, 02:09:01:01-02:09:02, 02:47:01-02:47:02, 03:08 19 135 bp 430 bp *01:14, 01:68, 02:08, 02:60 20 140 bp 430 bp *01:17 21 135 bp 430 bp *02:10 228 90 bp 430 bp *02:10	15	245 bp	430 bp	02:21:01, 02:21:03-02:21:04, 02:27:01-02:27:03, 02:50:01, 03:01:01:01-03:01:03, 03:02-03:06:03, 03:09-
01:33:02, 01:40², 01:46²-01:47², 01:51²-01:53², 01:58:01:01-01:58:01:02, 01:62, 01:66N², 01:95, 01:111², 01:123N², 01:154N², 02:01:01:01-02:01:04, 02:01:01:06-02:01:02:03, 02:01:03², 02:01:04, 02:01:05²- 02:01:06², 02:01:07-02:02:05, 02:02:02:07- 02:02:02:17Q, 02:02:03²-02:02:06², 02:02:07-02:02:15, 02:03:01², 02:03:02-02:03:05, 02:04²-02:05², 02:06-02:10, 02:11², 02:12:01-02:21:01, 02:21:02², 02:21:03-02:24, 02:25², 02:26:01:01-02:27:01, 02:27:02², 02:27:03- 02:32N, 02:34:01:01-02:40, 02:41N², 02:42-02:46, 02:47:01², 02:47:02-02:49, 02:51-02:52N, 02:53², 02:54- 02:58, 02:60-02:72, 02:73², 02:74N-02:84, 02:86-02:116, 02:117², 02:118-02:130, 03:01:01:01-03:01:01:15, 03:01:03-03:01:04, 03:02²-03:03², 03:04-03:05:01:02Q, 03:06:02², 03:06:03, 03:07:01², 03:07:02-03:17, 04:02:01:01-04:04, 04:06 184	16 ⁸	90 bp	430 bp	
03:08 19				01:33:02, 01:40°, 01:46°-01:47°, 01:51°-01:53°, 01:58:01:01-01:58:01:02, 01:62, 01:66N°, 01:95, 01:111°, 01:123N°, 01:154N°, 02:01:01:01-02:01:01:04, 02:01:01:06-02:01:02:03, 02:01:03°, 02:01:04, 02:01:05°-02:01:06°, 02:01:07-02:02:05, 02:02:07-02:02:02:17Q, 02:02:03°-02:02:06°, 02:02:07-02:02:15, 02:03:01°, 02:03:02-02:03:05, 02:04°-02:05°, 02:06-02:10, 02:11°, 02:12:01-02:21:01, 02:21:02°, 02:21:03-02:24, 02:25°, 02:26:01:01-02:27:01, 02:27:02°, 02:27:03-02:32N, 02:34:01:01-02:40, 02:41N°, 02:42-02:46, 02:47:01°, 02:47:02-02:49, 02:51-02:52N, 02:53°, 02:54-02:58, 02:60-02:72, 02:73°, 02:74N-02:84, 02:86-02:116, 02:117°, 02:118-02:130, 03:01:01-03:01:01:15, 03:01:03-03:01:04, 03:02°-03:03°, 03:04-03:05:01:02Q, 03:06:02°, 03:06:03, 03:07:01°, 03:07:02-03:17, 04:02:01:01-04:04, 04:06
20 140 bp 430 bp *01:17 21 135 bp 430 bp *02:10 228 90 bp 430 bp *02:12:01-02:12:02, 02:60	-	·	·	03:08
21 135 bp 430 bp *02:10 228 90 bp 430 bp *02:12:01-02:12:02, 02:60	19	135 bp	430 bp	*01:14, 01:68, 02:08, 02:60
22 ⁸ 90 bp 430 bp *02:12:01-02:12:02, 02:60	20	140 bp	430 bp	*01:17
· · · · · · · · · · · · · · · · · · ·	21	135 bp	430 bp	*02:10
23 ^{7,9} - Negative Control	22 ⁸	90 bp	430 bp	*02:12:01-02:12:02, 02:60
	23 ^{7,9}	-	-	Negative Control



For *In Vitro* Diagnostic Use MA124 v02 SSP PI Template Date: November 2024, Rev. No: 00 PA1 Product Insert Page 7 of 12

101.331-24/06 – including *Taq* polymerase 101.331-24u/06u – without *Taq* polymerase

Visit www.caredx.com for "Instructions for Use" (IFU)

Lot No.: **0V3** Lot-specific information

¹Alleles are assigned by the presence of specific PCR product(s). However, the sizes of the specific PCR products may be helpful in the interpretation of DPA1 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 inherit 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 DPA1 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.

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

⁵Primer mix 4 may faintly amplify the DPA1*04:01 allele.

⁶Primer mixes 11 and 13 may have tendencies of unspecific amplifications.

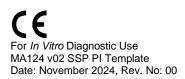
⁷Primer mixes 5 and 23 may have tendencies to giving rise to primer oligomer formations.

⁸Primer mixes 16 and 22 may give rise to a lower yield of HLA-specific PCR product than the other DPA1 primer mixes.

⁹Primer mix 23 contains a negative control, which will amplify the majority of the HLA amplicons as well as the amplicons generated by the control primer pairs matching the human growth hormone gene. HLA-specific PCR product sizes range from 75 to 200 base pairs and the PCR product generated by the HGH positive control primer pair is 200 base pairs.

<u>Abbreviations</u>

'?', nucleotide sequence of the primer matching sequence is not known.



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101.331-24/06 – including *Taq* polymerase 101.331-24u/06u – without *Taq* polymerase

Visit <u>www.caredx.com</u> for "Instructions for Use" (IFU)

Lot No.: **0V3** Lot-specific information

PRIMER SPECIFICATION

Well No.	1	2	3	4	5	6	7	8	9	10	11	12
Length of spec.	85	255	160	115	105	160	100	100	205	85	90	205
PCR product			205			195	150				135	
						255						
Length of int.	515	515	430	430	430	515	430	430	430	515	515	430
pos. control1												
5'-primer(s) ²	15(138)	11(125)	28(177)	4(103)	84(345)	11(125)	11(125)	11(125)	11(125)	15(138)	51(244)	18(145)
	^{5'} -ACg ^{3'}	5' -CgC 3'	5' -gAA 3'	5' -Cgg 3'	5' -AAT 3'	5' -CgT 3'	5' -CgC 3'	5' -CAT 3'	5' -CAT 3'	5' -ACC 3'	^{5'} -AAA ^{3'}	^{5'} -gAA ^{3'}
						31(185)					66(290)	
						5' -gCA 3'					5' -ATC 3'	
						43(222)						
						^{5'} -TgT ^{3'}						
3'-primer(s) ³	31(184)	83(340)	68(296)	28(177)	2 nd I	69(298)	31(184)	31(184)	66(290)	31(184)	83(340)	73(310)
. (,			5' -TgC 3'			5' -gTC 3'		5' -CTg 3'				
			83(340)			83(340)						
			^{5'} -ggT ^{3'}			5' -ggT 3'	5' -CTT 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
Length of spec.	90	130	245	90	85	185	135	140	135	90
PCR product										
Length of int.	430	515	430	430	430	430	430	430	430	430
pos. control ¹										
5'-primer(s) ²	4(103)	50(242)	15(138)	20(153)	190(661)	28(177)	190(661)	88(355)	96(379)	224(764)
	5' -Cgg 3'	^{5'} -CCg ^{3'}	5' -ACC 3'	^{5'} -ggA ^{3'}	5' -CAA 3'	^{5'} -gAA ^{3'}	5' -CAA 3'	5' -CTC 3'	^{5'} -Agg ^{3'}	5' -CCA 3'
	190(662)	51(244)								
	5' -AAT 3'	^{5'} -AAA ^{3'}								
3'-primer(s) ³	23(161)	76(320)	83(340)	37(204)	204(705)	76(319)	218(746)	120(453)	127(473)	down ⁴
- 1 (-)	^{5'} -ACg ^{3'}	^{5'} -AAT ^{3'}	^{5'} -ggT ^{3'}	^{5'} -TTA ^{3'}	5' -CCC 3'	5' -ACA 3'	5' -AAT 3'	5' -CAC 3'	5' -CCg 3'	^{5'} -T ^{3'}
	204(705)						224(764)			
	5' -CCC 3'	^{5'} -ggT ^{3'}					5' -CCT 3'			
Well No.	13	14	15	16	17	18	19	20	21	22

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.

⁴Primer located in the 3'untranslated region.



Product Insert

101.331-24/06 – including Taq polymerase 101.331-24u/06u – without Taq polymerase

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Lot No.: **0V3** Lot-specific information

	CELL LINE VALIDATION SHEET																			
				DPA	\1	SS	Р	kit²	2											
												W	ell							
					1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
						~	~	-	10	~		_				~	~		10	<u></u>
				.:	8	602	900	09	909	909	09	909	09	610	6	612	613	617	615	616
				Ž	159	159	159	159	159	159	159	459	159	159	159	159	459	159	459	159
				Prod No.	20245960	202459602	202459603	202459604	202459605	202459606	202459607	202459608	202459609	202459610	202459611	202459612	202459613	202459614	202459615	202459616
		.	-		N	(A	CA	CA	(A	CA	CA	CA	(A	(A	(A	(A	(/	N	CA	(1
4		C cell line ¹		PA1	_															
1	9001	-	*01:03		+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-
3		LK707 E4181324	*01:03		+	+	+	-	-	-	-	-	-	-	-	-	-	-	÷	-
4		GU373	*02:01	*04:01	+	+	+	-	+	-	+	-	-	-	-	+	-	-	÷	-
5		KAS011	*01:03	*02:01	+	+	+	-	+	-	+	-	-	-	-	-	_	-	Ē	-
6	9353		*02:02	02.01	-	-	-	-	+	-	-	+	+	-	-	-	-	-	-	-
7	9020		*01:03		+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-
8	9025		*01		+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-
9	9026		*01:03		+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-
10	9107	LKT3	*02:02		-	-	-	-	+	-	-	+	+	-	-	-	-	-	-	-
11	9051	PITOUT	*01:03		+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-
12	9052	DBB	*01:03		+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-
13		JESTHOM	*01:03		+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-
14		OLGA	*01:03		+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-
15	9075		*01:03		+	+	+	-	-	-	-	-	-	-	-	-	-	-	Ŀ	-
16		SWEIG007	*01:03		+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-
17		CTM3953540	*01:03	*02:01	+	+	+	-	+	-	+	-	-	-	-	-	-	-	Ŀ	-
18		32367	*01:03	*03:01	+	+	+	-	-	-	-	-	-	+	+	-	-	-	+	-
19		BM16	*01:03		+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-
20		SLE005 AMALA	*01:03		+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-
22		KOSE	*01:03	*02:01	+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	
23	9124		*01:03	02.01	+	+	+	-	+	-	+	-	H	-	-	-	-	-	÷	-
24		JBUSH	*01:03		+	+	+	-	-	-	-	-	-	-	-	-	-	-	÷	
25		IBW9	*02:01		-	-	-	-	+	-	+	-	-	-	-	-	-	-	-	-
26		WT49	*01:03		+	+	+	-	÷	-	-	-	-	-	-	-	-	-	-	-
27		CH1007	*01:03	*04:01	+	+	+	-	+	-	-	-	-	-	-	+	-	-	-	-
28		BEL5GB	*01:03		+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-
29	9050	MOU	*01:03		+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-
30	9021	RSH	*02:02	*03:01	-	-	+	-	+	-	-	+	+	+	+	-	-	-	+	-
31	9019	DUCAF	*01:03		+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-
32	9297		*01:03		+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-
33		MT14B	*01:03		+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-
34	9104		*01:03		+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-
35		SSTO	*01:03		+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-
36		KT17	*02:02		-	-	-	-	+	-	-	+	+	-	-	-	-	-	-	-
37		HHKB	*01:03		+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-
38	9099		*01:03	*00:04	+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-
39	9315		*01:03	*02:01	+	+	+	-	+	-	+	-	-	-	-	-	-	-	-	-
40 41		WHONP199 H0301	*02:02 *02:01		-	-	-	-	+	=	+	+	+	-	-	=	<u>-</u>	-	÷	ᆜ
42		TAB089	*02:01		-	-	-	-	+	-	-	+	+	-	-	-	-	-		-
43		T7526	*04:01		+	-	-	-	+	-	-	-	-	-	-	+	-	-	-	-
44	9057		*01:03		+	+	+	-	-	-	-	-	-	-	-	-	_	-	-	-
45		SHJO	*01:03	*03:01	+	+	+	-	-	-	-	-	-	+	+	-	-	-	+	-
46		SCHU	*01:03		+	+	+	-	-	-	-	-	-	-	-	-	-	-	÷	-
47		TUBO	*01:03		+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-
48		TER-ND	*01:03		+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-

For *In Vitro* Diagnostic Use MA124 v02 SSP PI Template Date: November 2024, Rev. No: 00

Product Insert

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101.331-24/06 – including Taq polymerase 101.331-24u/06u – without Taq polymerase

Visit <u>www.caredx.com</u> for "Instructions for Use" (IFU)

Lot No.: **0V3** Lot-specific information

CELL LINE VALIDATION SHEET DPA1 SSP kit ²											
		DP	A1 S	SP kit	2						
							W	ell			
					17	18	19	20	21	22	
					7	8	9	0	1	2	
				9	961	961	961	362	362	362	
				- 5	459	456	456	456	459	458	
				Prod. No.:	202459617	202459618	202459619	202459620	202459621	202459622	
	ILI\A/	C cell line ¹	DE	PA1	.,	.,	.,	.,	.,		
1	9001		*01:03	AI	-	_	_	_	_	_	
2		LK707	*01:03		_	_	_		_		
3		E4181324	*01:03		-	-	-	-	-	-	
4		GU373	*02:01	*04:01	+	-	-	-	-	-	
5		KAS011	*01:03	*02:01	+	-	-	-	-	-	
6	9353		*02:02	02.0.	+	-	-	-	-	-	
7	9020		*01:03		-	-	-	-	-	-	
8	9025		*01		-	-	-	-	-	-	
9	9026		*01:03		-	-	-	-	-	-	
10		LKT3	*02:02		+	-	-	-	-	-	
11		PITOUT	*01:03		-	-	-	-	-	-	
12	9052	DBB	*01:03		-	-	-	-	-	-	
13	9004	JESTHOM	*01:03		-	-	-	-	-	-	
14	9071	OLGA	*01:03		-	-	-	-	-	-	
15	9075	DKB	*01:03		-	-	-	-	-	-	
16	9037	SWEIG007	*01:03		-	-	-	-	-	-	
17	9282	CTM3953540	*01:03	*02:01	+	-	-	-	-	-	
18	9257	32367	*01:03	*03:01	+	-	-	-	-	-	
19		BM16	*01:03		-	-	-	-	-	-	
20		SLE005	*01:03		-	-	-	-	-	-	
21		AMALA	*01:03		-	-	-	-	-	-	
22		KOSE	*01:03	*02:01	+	-	-	-	-	-	
23	9124		*01:03		-	-	-	-	-	-	
24		JBUSH	*01:03		-	-	-	-	-	-	
25		IBW9	*02:01		+	-	-	-	-	-	
26 27		WT49 CH1007	*01:03	*04.04	-	-	-	-	-	-	
28		BEL5GB	*01:03	*04:01	-	-	-	-	-	-	
29		MOU	*01:03			-	-	\exists	-		
30	9050		*02:02	*03:01	+	_	_		_		
31		DUCAF	*01:03	03.01	H	_	_	-	-		
32		HAG	*01:03		-	_	_		_	_	
33		MT14B	*01:03		-	-	-	-	-	-	
34	9104		*01:03		-	-	-	-	-	-	
35		SSTO	*01:03		-	-	-	-	-	-	
36		KT17	*02:02		+	-	-	-	-	-	
37		HHKB	*01:03		-	-	-	-	-	-	
38	9099		*01:03		-	-	-	-	-	-	
39	9315		*01:03	*02:01	+	-	-	-	-	-	
40	9134	WHONP199	*02:02		+	_	_	-	-	-	
41	9055	H0301	*02:01		+	-	-	-	-	-	
42	9066	TAB089	*02:02		+	-	-	-	-	-	
43	9076	T7526	*04:01		-	-	-	-	-	-	
44	9057		*01:03		-	-	-	-	-	-	
45		SHJO	*01:03	*03:01	+	-	-	-	-	-	
46		SCHU	*01:03		-	-	-	-	-	-	
47		TUBO	*01:03		-	-	-	-	-	-	
48	9303	TER-ND	*01:03		<u> </u>	-	-	-	-	-	





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101.331-24/06 – including *Taq* polymerase 101.331-24u/06u – without *Taq* polymerase

Visit <u>www.caredx.com</u> for "Instructions for Use" (IFU)

Lot No.: **0V3** 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 allele to be amplified by primer solutions 6, 13, 14 and 18 to 22 were available.

The specificities of the primers in primer solutions 6, 13, 14 and 21 were tested by separately adding one additional 5'-primer and one additional 3'-primer, respectively. In primer solutions 18, 19 and 22 it was only possible to test the 5'-primers, the 3'-primers were not possible to test. In primer solution 20 it was only possible to test the 3'-primers, the 5'-primers were not possible to test. In primer solutions 6, 11, 13 and 14 one or two 5'-primers were not possible to test, and in primer solutions 3, 6, 7, 13 and 14 one or two 3'-primers were not possible to test.

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Lot No.: **0V3** Lot-specific information

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