

HLA-B\*51:11N Product Insert Page 1 of 8

101.851-12 – including *Taq* polymerase 101.851-12u – without *Taq* polymerase

Visit <a href="https://labproducts.caredx.com">https://labproducts.caredx.com</a> for "Instructions for Use" (IFU)

Lot No.: **7L7** Lot-specific Information

Olerup SSP® HLA-B\*51:11N

Product number: 101.851-12 – including *Taq* polymerase

101.851-12u – without *Taq* polymerase

Lot number: 7L7

Expiry date: 2024-11-01

Number of tests: 12 Number of wells per test: 2+1

Storage - pre-aliquoted primers: dark at -20°C

PCR Master Mix: -20°C
Adhesive PCR seals
Product Insert
RT

## This Product Description is only valid for Lot No. 7L7.

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

# CHANGES COMPARED TO THE PREVIOUS *OLERUP* SSP® HLA-B\*51:11N Lot (4K5).

The HLA-B\*51:11N specificity and interpretation tables have been updated compared the previous *Olerup* SSP® HLA-B\*51:11N lot (Lot No. 4K5). The kit design is based on IMGT/HLA database 3.41.0.

The HLA-B\*51:11N primer set is unchanged compared to the previous *Olerup* SSP® HLA-B\*51:11N (Lot No. 4K5).





HLA-B\*51:11N Product Insert Page 2 of 8

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Well **3** 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 <sup>1</sup>	164	340	440	45	45	43	36
_	5'-CAC3'	5'-Agg <sup>3'</sup>	<sup>5'</sup> -TTA3'	<sup>5</sup> '-Tgg <sup>3</sup> '	<sup>5'</sup> -Tgg <sup>3'</sup>	<sup>5</sup> '-Tgg <sup>3</sup> '	5'-TAC3'
							36
							<sup>5'</sup> -TAT <sup>3'</sup>
3'-primer <sup>2</sup>	231	2 <sup>nd</sup> I	507	59	58	57	47
•	<sup>5</sup> '-TgC <sup>3</sup> '	<sup>5'</sup> -AAA <sup>3'</sup>	<sup>5</sup> '-TTg <sup>3</sup> '	5'-CTC3'	<sup>5'</sup> -ggC <sup>3'</sup>	5'-CTC3'	5'-ACA3'
							48
							<sup>5'</sup> -gCA <sup>3'</sup>
							48
							<sup>5'</sup> -gCC <sup>3'</sup>
							52
<b>a</b> .t.							5'-TgT <sup>3'</sup>
<b>A</b> *	+	+	+				
B*	+	+	+				
C*	+	+	+				
DRB1				+	+		
DRB3				+	+		
DRB5				+			
DQB1					+		
DPB1						+	
DQA1							+

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

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



HLA-B\*51:11N Product Insert Page 3 of 8

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## PRODUCT DESCRIPTION

**HLA-B\*51:11N SSP subtyping** 

#### CONTENT

The primer set contains 5'- and 3'-primers for identifying the HLA-B\*51:11N allele.

### PLATE LAYOUT

Each test consists of 3 PCR reactions in an 8 well cut PCR plate. Wells 4 to 8 are empty.

1 2 NC empty empty empty empty empty

The 8 well cut PCR plate is marked with the Lot No. '7L7' in silver/gray ink. Well No. 1 is marked with the Lot No. '7L7'.

Wells 1 to 2 – HLA-B\*51:11N high resolution primers.

Well 3 – 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 8 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

Due to the sharing of sequence motifs between HLA-B alleles non-HLA-B\*51:11N alleles will be amplified by primer mix 1. For further details see Specificity Table.

#### **UNIQUELY IDENTIFIED ALLELES**

The HLA-B\*51:11N allele will give rise to a unique amplification pattern by the primers in the HLA-B\*51:11N kit<sup>1,2</sup>.

<sup>1</sup>HLA-B alleles listed on the IMGT/HLA web page 2020-July-13, release 3.41.0, www.ebi.ac.uk/imgt/hla.

<sup>2</sup>Alleles 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.

Product Insert

Page 4 of 8

101.851-12 – including *Taq* polymerase 101.851-12u – without *Taq* polymerase

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Lot No.: **7L7** Lot-specific Information

## SPECIFICITY TABLE

## **HLA-B\*51:11N SSP subtyping**

## Specificities and sizes of the PCR products of the 2+1 primer mixes used for HLA-B\*51:11N SSP subtyping

Primer Mix	Size of spec. PCR product <sup>1</sup>	Size of control band <sup>2</sup>	Amplified HLA-B alleles
13	95 bp	800 bp	*07:65**, 07:134**, 08:32, 08:133, 08:180, 08:239, 15:308, 18:01:01:01-18:03:01:02, 18:04:01-18:11, 18:13-18:15, 18:17N-18:36, 18:38-18:47, 18:49-18:65, 18:67-18:106Q, 18:108-18:124, 18:126-18:177, 18:179-18:194, 35:01:01-35:01:55, 35:01:57-35:08:04, 35:08:06-35:09:03, 35:11:01-35:12:04, 35:14:01-35:15:02, 35:17:01-35:18, 35:20:01-35:24:02, 35:27, 35:29:01-35:43:01, 35:43:03-35:45, 35:48, 35:50-35:62, 35:64:01-35:68:02, 35:70-35:72, 35:74-35:75, 35:76**, 35:77-35:79, 35:81-35:153, 35:155-35:185, 35:187-35:190, 35:192-35:197, 35:199-35:206, 35:208:01-35:209, 35:211-35:216N, 35:218-35:225, 35:227-35:253, 35:255-35:269, 35:272-35:273, 35:275-35:310, 35:312-35:316, 35:319-35:360, 35:362-35:449, 35:451-35:476, 35:478-35:489, 37:08, 37:67, 38:06-38:07, 39:19:01-39:19:02, 44:06, 45:22, 51:01:01:01-51:24:05, 51:26-51:46, 51:48-51:103, 51:105-51:111, 51:113-51:117, 51:119-51:146, 51:148-51:230:01:03, 51:232-51:266, 51:268-51:283, 51:285-51:309, 51:311-51:321, 53:01:01:01-53:16, 53:18-53:27, 53:29, 53:31-53:37, 53:40-53:62, 56:06*, 56:45*, 78:01:01:02-78:04, 78:07-78:10
2	495 bp	1070 bp	*51:11N
34	-	-	Negative Control

<sup>&</sup>lt;sup>1</sup>Alleles 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 HLA-B\*51:11N SSP typings.

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.

<sup>2</sup>The internal positive control primer pairs amplify segments of the human growth hormone gene. The





HLA-B\*51:11N Product Insert Page 5 of 8

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Lot No.: **7L7** Lot-specific Information

internal positive control bands are 1070 or 800 base pairs respectively, well distribution as outlined in the table. Well number 1 contains the shorter, 800 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.

<sup>3</sup>HLA-specific PCR products shorter than 125 base pairs have a lower intensity and are less sharp than longer PCR products.

<sup>4</sup>Primer mix 3 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.





HLA-B\*51:11N Product Insert Page 6 of 8

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Lot No.: **7L7** Lot-specific Information

## PRIMER SPECIFICATION

Well No.	1	2		
Length of spec.	95	495		
PCR product				
Length of int.	800	1070		
pos. control <sup>1</sup>				
5'-primer(s) <sup>2</sup>	206	3 <sup>rd</sup> I		
	<sup>5'</sup> -gAC <sup>3'</sup>	5' -CTT 3'		
3'-primer(s) <sup>3</sup>	259	621		
	<sup>5'</sup> -gTT <sup>3'</sup>	<sup>5'</sup> -ggg <sup>3'</sup>		
Well No.	1	2		

<sup>1</sup>The internal positive control primer pairs amplify segments of the human growth hormone gene. The internal positive control bands are 1070 or 800 base pairs respectively, well distribution as outlined in the table. Well number 1 contains the shorter, 800 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.

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

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



HLA-B\*51:11N Product Insert Page 7 of 8

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Lot No.: I LI							
CELL LINE VALIDATION SHEET							
HLA-B*51:11N SSP kit <sup>2</sup>							
					W	Well	
					1	2	
				Prod No.:	201782101	201782102	
	IHV	/C cell line <sup>1</sup>	HL	HLA-B			
1	9001		*07:02		1-	-1	
2	9280	LK707	*52:01	*73:01	-	-	
3	9011	E4181324	*52:01		-	-	
4	9275	GU373	*15:10	*53:01	+	-	
5	9009	KAS011	*37:01		-	-	
6	9353		*39:01	*51:01	+	-	
7	9020		*18:01		+	-	
8	9025		*35:01		+	-	
9		YAR	*38:01		-	-	
10		LKT3	*54:01		-		
11		PITOUT	*44:03		-	-	
12	9052		*57:01		-	-	
13	9004	JESTHOM	*27:05		ļ-	-	
14		OLGA	*15:01	*15:20	ļ -	-	
15	9075		*40:01		-	-	
16	9037		*40:02		ļ-	-	
17		CTM3953540	*08:01	*55:01	ļ-		
18		32367	*14:01	*56:01	ļ-	-	
19	9038	BM16	*18:01		+	-	
20		SLE005	*40:01		<u>  - </u>	<u>-</u>	
21		AMALA	*15:01		ļ-	-	
22		KOSE	*35:03		+	-	
23	9124		*40:02	*56:02	ļ -	-	
24		JBUSH	*38:01		ļ-	-	
25		IBW9	*14:02		ļ-	-	
26		WT49	*58:01		ļ -	-	
27	9191		*07:05	*51:01	+	-	
28		BEL5GB	*44:02	*44:03	١-	-	
29		MOU	*44:03		١-	-	
30	9021		*42:01		<u>  - </u>	<u>-</u>	
31		DUCAF	*18:01		+	-	
32	9297		*41:02		1-	-	
33		MT14B	*40:01		-	-	
34	9104		*38:01		-	-	
35		SSTO	*44:02	*05.04	-	-	
36		KT17	*15:01	*35:01	+	-	
37		HHKB	*07:02		1-	-	
38	9099		*15:01	*07.05	1-	-	
39	9315		*08:01	*27:05	1-	-	
40		WHONP199	*13:02	*46:01	<del>-</del>	ᆜ	
41		H0301	*14:02		+-		
42		TAB089	*46:01		ļ-	-	
43	9076		*46:01		μ-	-	
44	9057		*38:01	*50.04	ļ-	-	
45		SHJO	*42:01	*50:01	1-	-	
46		SCHU	*07:02		1.	-	
47	9045		*51:01	*44.00	+	-	
48	9303	TER-ND	*35:01	*44:03	+	-	

<sup>&</sup>lt;sup>1</sup>The provided cell line HLA specificities are retrieved from the <a href="http://www.ihwg.org/hla">http://www.ihwg.org/hla</a> web site. The specificity of an individual cell line may thus be subject to change.

<sup>&</sup>lt;sup>2</sup>The 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.





HLA-B\*51:11N Product Insert Page 8 of 8

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#### 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: https://labproducts.caredx.com/

Distributed by:

CareDx GmbH, Löwengasse 47 / 6, AT-1030 Vienna, Austria.

**Tel:** +43-1-710 15 00 **Fax:** +43-1-710 15 00 10 **E-mail:** orders-at@caredx.com

Web page: https://labproducts.caredx.com/

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: <a href="https://labproducts.caredx.com/">https://labproducts.caredx.com/</a>

For information on CareDx distributors worldwide, contact CareDx GmbH.

