

101.428-12 – including *Taq* polymerase, IFU-01  
101.428-12u – without *Taq* polymerase, IFU-02

Visit <https://labproducts.caredx.com> for  
“Instructions for Use” (IFU)

Lot No.: **9F9**

Lot-specific Information  
**Olerup SSP<sup>®</sup> HLA-A\*29**

Product number:	101.428-12 – including <i>Taq</i> polymerase 101.428-12u – without <i>Taq</i> polymerase
Lot number:	9F9
Expiry date:	2021-12-01
Number of tests:	12
Number of wells per test:	27+1
Storage - pre-aliquoted primers:	dark at -20°C
- PCR Master Mix:	-20°C
- Adhesive PCR seals	RT
- Product Insert	RT

**This Product Description is only valid for Lot No. 9F9.**

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

**CHANGES COMPARED TO THE PREVIOUS OLERUP SSP<sup>®</sup>  
HLA-A\*29 LOT (7D7)**

The HLA-A\*29 kit is updated for new alleles to enable separation of:

- Confirmed<sup>1</sup> alleles as listed in the IMGT/HLA database
- Null and Alternatively expressed alleles

Four wells have been added to HLA-A\*29, wells **25 to 28**.

The format of the Worksheet has been changed.

<sup>1</sup>As described in section Uniquely Identified Alleles.

The HLA-A\*29 primer set, specificity and interpretation tables have been updated for the HLA-A alleles described since the previous *Olerup SSP<sup>®</sup>* HLA-A\*29 lot was made (**Lot No. 7D7**). The kit design is based on IMGT/HLA database 3.29.0.

101.428-12 – including *Taq* polymerase, IFU-01  
101.428-12u – without *Taq* polymerase, IFU-02

Visit <https://labproducts.caredx.com> for  
“Instructions for Use” (IFU)

Lot No.: **9F9**

**Lot-specific Information**

The primers of the wells detailed below have been exchanged, added or modified compared to the previous lot.

Well	5'-primer	3'-primer	rationale
6	-	-	Exchange of positive control primer pair for decreased tendency of primer oligomer formation.
7	-	Added	3'-primers added for the A*29:82 and A*29:06 alleles.
23	Added	-	5'-primer added for the A*29:81 allele.
24	Added	Added	Negative control moved to well 28, primer pair added for the A*29:71 allele.
25	New	New	New primer pair added for the A*29:90 allele.
26	New	New	New primer pair added for the A*29:103 allele.
27	New	New	New primer pair added for the A*29:81 allele.
28	-	-	Negative control added from well 24.

Changes in revision R01 compared to R00:

1. The expiration date has been altered due to extension of shelf-life.

101.428-12 – including *Taq* polymerase, IFU-01  
 101.428-12u – without *Taq* polymerase, IFU-02

Visit <https://labproducts.caredx.com> for  
 “Instructions for Use” (IFU)

Lot No.: **9F9**

Lot-specific Information

Well **28** contains Negative Control primer pairs, that will amplify more than 95% of the *Olerup* SSP<sup>®</sup> 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 430 base pairs.

Length of PCR product	105	200	105	80	75	80	85
<b>5'-primer<sup>1</sup></b>	<b>164</b>	<b>340</b>	<b>440</b>	<b>45</b>	<b>45</b>	<b>43</b>	<b>36</b>
	5'-CAC <sup>3'</sup>	5'-Agg <sup>3'</sup>	5'-TTA <sup>3'</sup>	5'-Tgg <sup>3'</sup>	5'-Tgg <sup>3'</sup>	5'-Tgg <sup>3'</sup>	5'-TAC <sup>3'</sup>
							36
							5'-TAT <sup>3'</sup>
<b>3'-primer<sup>2</sup></b>	<b>231</b>	<b>2<sup>nd</sup> I</b>	<b>507</b>	<b>59</b>	<b>58</b>	<b>57</b>	<b>47</b>
	5'-TgC <sup>3'</sup>	5'-AAA <sup>3'</sup>	5'-TTg <sup>3'</sup>	5'-CTC <sup>3'</sup>	5'-ggC <sup>3'</sup>	5'-CTC <sup>3'</sup>	5'-ACA <sup>3'</sup>
							48
							5'-gCA <sup>3'</sup>
							48
							5'-gCC <sup>3'</sup>
							52
							5'-TgT <sup>3'</sup>
<b>A*</b>	<b>+</b>	<b>+</b>	<b>+</b>				
<b>B*</b>	<b>+</b>	<b>+</b>	<b>+</b>				
<b>C*</b>	<b>+</b>	<b>+</b>	<b>+</b>				
<b>DRB1</b>				<b>+</b>	<b>+</b>		
<b>DRB3</b>				<b>+</b>	<b>+</b>		
<b>DRB5</b>				<b>+</b>			
<b>DQB1</b>					<b>+</b>		
<b>DPB1</b>						<b>+</b>	
<b>DQA1</b>							<b>+</b>

<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 [www.ebi.ac.uk/imgt/hla](http://www.ebi.ac.uk/imgt/hla) 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 [www.ebi.ac.uk/imgt/hla](http://www.ebi.ac.uk/imgt/hla) web site. The sequence of the 3 terminal nucleotides of the primer is given.

101.428-12 – including *Taq* polymerase, IFU-01  
101.428-12u – without *Taq* polymerase, IFU-02

Visit <https://labproducts.caredx.com> for  
“Instructions for Use” (IFU)

Lot No.: **9F9**

Lot-specific Information

## PRODUCT DESCRIPTION

### HLA-A\*29 SSP subtyping

#### CONTENT

The primer set contains 5'- and 3'-primers for identifying the A\*29:01 to A\*29:103 alleles.

#### PLATE LAYOUT

Each test consists of 28 PCR reactions in a 32 well cut PCR plate. Wells 29 to 32 are empty.

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	NC	empty	empty	empty	empty

The 32 well cut PCR plate is marked with 'HLA-A\*29' in silver/gray ink.

Well No. 1 is marked with the Lot No. '9F9'.

Wells 1 to 27 – HLA-A\*29 high resolution primers.

Well 28 – 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 32 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 HLA-A alleles, non-HLA-A\*29 alleles will be amplified by some primer mixes. For further details see Specificity Table.

#### UNIQUELY IDENTIFIED ALLELES

All the HLA-A\*29 alleles, i.e. **A\*29:01 to A\*29:103 alleles**, recognized by the HLA Nomenclature Committee in August 2017<sup>1,2</sup> will be amplified by the primers in the HLA-A\*29 subtyping kit.

The HLA-A\*29 kit enables separation of the confirmed HLA-A\*29 alleles as listed in the IMGT/HLA database. 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 HLA-A\*29 alleles is listed below.

The HLA-A\*29 kit also enables identification of null and alternatively expressed alleles.

101.428-12 – including *Taq* polymerase, IFU-01  
 101.428-12u – without *Taq* polymerase, IFU-02

Visit <https://labproducts.caredx.com> for  
 “Instructions for Use” (IFU)

Lot No.: **9F9**

**Lot-specific Information**

The following HLA-A\*29 alleles can be distinguished by the different sizes of the HLA-specific PCR product:

Alleles	Primer mix
A*29:06, 29:34	7
A*29:07, 29:46	8
A*29:11, 29:92	13
A*29:20, 29:82	7

<sup>1</sup>HLA-A alleles listed on the IMGT/HLA web page 2017-August-10, release 3.29.0, [www.ebi.ac.uk/imgt/hla](http://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>.

101.428-12 – including *Taq* polymerase, IFU-01  
 101.428-12u – without *Taq* polymerase, IFU-02

Visit <https://labproducts.caredx.com> for  
 “Instructions for Use” (IFU)

Lot No.: **9F9**

Lot-specific Information

### ALLELE CONFIRMATION STATUS

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

<sup>1</sup>Allele status “confirmed” or “unconfirmed” as listed on the IMGT/HLA web page 2017-August-10, release 3.29.0, [www.ebi.ac.uk/imgt/hla](http://www.ebi.ac.uk/imgt/hla).

### RESOLUTION IN HOMO- AND HETEROZYGOTES

Results file with resolution in HLA-A\*29 homo- and heterozygotes is available upon request.

101.428-12 – including *Taq* polymerase, IFU-01  
 101.428-12u – without *Taq* polymerase, IFU-02

Visit <https://labproducts.caredx.com> for  
 “Instructions for Use” (IFU)

Lot No.: **9F9**

Lot-specific Information  
**SPECIFICITY TABLE**

**HLA-A\*29 SSP subtyping**

Specificities and sizes of the PCR products of the 27+1 primer mixes used for HLA-A\*29 SSP subtyping

Primer Mix	Size of spec. PCR product <sup>1</sup>	Size of control band <sup>2</sup>	Amplified HLA-A*29 alleles <sup>3</sup>	Other amplified HLA-A alleles
<b>1</b>	480 bp	<b>800 bp</b>	*29:01:01:01-29:01:06, 29:01:08-29:01:09, 29:12, 29:15-29:17, 29:20, 29:24, 29:28, 29:33, 29:48-29:49, 29:55-29:58, 29:60-29:62, 29:67, 29:71, 29:76-29:77, 29:79, 29:81-29:83, 29:98-29:99, 29:101	
<b>2</b>	130 bp	1070 bp	*29:01:01:02N	
<b>3</b>	440 bp	<b>800 bp</b>	*29:02:01:01-29:02:03, 29:02:05-29:11, 29:13-29:14, 29:19, 29:21-29:23, 29:26-29:27, 29:29-29:32, 29:34-29:47, 29:50-29:54, 29:59, 29:63, 29:65-29:66, 29:68-29:70, 29:72-29:75, 29:78N, 29:80, 29:84-29:97, 29:100, 29:102-29:103	*11:01:42, 30:01:11, 68:130:02
<b>4<sup>4</sup></b>	110 bp 165 bp	<b>800 bp</b>	*29:35, 29:51, 29:69, 29:73 *29:03, 29:33	*02:24:02, 02:507 *23:03:01, 24:21:03, 24:208, 31:05, 32:13, 33:10
<b>5</b>	130 bp 185 bp	1070 bp	*29:04 *29:23	
<b>6<sup>4</sup></b>	105 bp 130 bp	<b>800 bp</b>	*29:19 *29:05, 29:33, 29:40, 29:77, 29:87	*11:01:28, 11:01:77, 24:21:03, 24:208, 31:24, 32:02, 32:22, 33:59, 33:102
<b>7<sup>4</sup></b>	105 bp 210 bp	1070 bp	*29:19-29:20, 29:34 *29:06	*31:51, 32:12, 74:26, <b>B*08:01:07<sup>w</sup>, B*15:02:07<sup>w</sup>, B*15:17:03, B*27:07:05, B*41:01:05<sup>w</sup>, B*55:02:10, C*02:02:15<sup>w</sup>, C*03:03:20<sup>w</sup>, C*04:175<sup>w</sup>, C*08:01:15<sup>w</sup></b>
<b>8<sup>4</sup></b>	475 bp 85 bp 160 bp	<b>800 bp</b>	*29:82 *29:07, 29:49 *29:46	*11:139, 23:53, 23:70, 24:17, 24:41, 24:208
<b>9<sup>4,5</sup></b>	80 bp 170 bp	1070 bp	*29:16 *29:08N	*01:157, 03:27, 11:233
<b>10<sup>4,6</sup></b>	90 bp	<b>800 bp</b>	*29:09, 29:33, 29:51, 29:73	*02:24:02, 02:507, 03:01:18, 11:01:28, 11:01:77, 24:21:03, 24:208, 31:24, 32:33:01, 33:34

101.428-12 – including *Taq* polymerase, IFU-01  
101.428-12u – without *Taq* polymerase, IFU-02

Visit <https://labproducts.caredx.com> for  
“Instructions for Use” (IFU)

Lot No.: **9F9**

Lot-specific Information

	165 bp		*29:17, 29:43	
	215 bp		*29:54	
<b>11<sup>4</sup></b>	110 bp	<b>800 bp</b>	*29:14, 29:35	<b>C*08:01:15</b>
	190 bp		*29:10:01-29:10:02, 29:23	
<b>12<sup>4,5</sup></b>	80 bp	<b>800 bp</b>	*29:02:04, 29:18, 29:48	*03:01:39, 32:01:01:01-32:01:07, 32:01:09-32:01:17, 32:01:19-32:03, 32:05-32:55:02, 32:57-32:69, 32:71, 32:73-32:103, 68:01:28, 74:01:01-74:13, 74:15-74:28
	145 bp		*29:78N	
<b>13<sup>4,5,7</sup></b>	90 bp	1070 bp	*29:11, 29:51, 29:73	*02:24:02, 02:507
	165 bp		*29:12, 29:92	*31:16, 33:58
	260 bp		*29:55	
<b>14</b>	200 bp	1070 bp	*29:01:01:01-29:13, 29:15-29:17, 29:19-29:36, 29:38-29:47, 29:49-29:55, 29:57-29:103	
<b>15</b>	240 bp	1070 bp	*29:01:01:01-29:12, 29:14-29:18, 29:20-29:36, 29:38, 29:40-29:47, 29:49-29:55, 29:57-29:97, 29:99-29:103	*01:143, 31:79, 33:13, 33:48
<b>16<sup>4,5</sup></b>	95 bp	1070 bp	*29:15	*02:221, 23:41, 31:78
	160 bp		*29:21, 29:43	
	190 bp		*29:53	
<b>17<sup>4</sup></b>	100 bp	1070 bp	*29:51, 29:69, 29:73	*02:24:02, 02:507
	130 bp		*29:24, 29:40	
	190 bp		*29:27, 29:53	
	215 bp		*29:54	
<b>18</b>	225 bp	1070 bp	*29:37, 29:56	*32:07, 33:119
	260 bp		*29:36	
<b>19<sup>6</sup></b>	160 bp	1070 bp	*29:25	
	260 bp		*29:55	
	505 bp		*29:26	
<b>20<sup>4,5</sup></b>	105 bp	1070 bp	*29:44, 29:64	*02:65, 11:01:28, 11:01:77, 31:123, 32:01:01:01-32:01:06, 32:01:08-32:01:11, 32:01:13-32:03, 32:05-32:27N, 32:29-32:30:01, 32:31-32:33:01, 32:34-32:65, 32:67-32:93, 32:95-32:100, 32:102-32:103, 74:01:01-74:28, <b>B*15:17:03, B*27:07:05, B*41:01:05, B*55:02:10</b>
<b>21</b>	185 bp	1070 bp	*29:22	*01:20, 01:66, 01:130, 02:19, 02:44, 02:149, 02:309, 02:408, 02:436, 02:619, 03:95, 24:14:01:01-24:14:01:02, 24:93, 24:324, 26:22, 30:47, 31:99, 33:22, 66:09, <b>C*02:74</b>
<b>22<sup>4</sup></b>	115 bp	<b>800 bp</b>	*29:29	*01:148, 11:128, 26:85, 68:58:01-68:58:02



101.428-12 – including *Taq* polymerase, IFU-01  
101.428-12u – without *Taq* polymerase, IFU-02

Visit <https://labproducts.caredx.com> for  
“Instructions for Use” (IFU)

Lot No.: **9F9**

Lot-specific Information

	260 bp		*29:13	*24:82, 31:07-31:08, 31:10, 32:42
<b>23<sup>4</sup></b>	75 bp	1070 bp	*29:32	*02:24:02, 02:65, 02:152, 02:507, 23:03:01, 23:83, 24:21:03, 31:01:02:01-31:02, 31:05, 31:07-31:61, 31:63-31:66, 31:70-31:119, 31:121-31:127, 32:01:01:01-32:01:06, 32:01:08-32:01:11, 32:01:13-32:03, 32:05-32:27N, 32:29, 32:31, 32:33:01, 32:34-32:47, 32:49-32:65, 32:67-32:93, 32:95-32:100, 32:102-32:103, 33:01:01:01-33:01:04, 33:01:06-33:01:10, 33:03:01-33:03:18, 33:03:20-33:03:23, 33:03:25-33:03:26, 33:03:28-33:17, 33:20-33:31, 33:33-33:37, 33:39-33:130, 74:01:01-74:28, <b>B*15:17:03</b>
	510 bp		*29:81	
<b>24<sup>4</sup></b>	125 bp	1070 bp	*29:71	*31:77
<b>25<sup>4</sup></b>	110 bp	1070 bp	*29:90	*31:108, 33:110
<b>26</b>	185 bp	1070 bp	*29:103	
<b>27</b>	510 bp	1070 bp	*29:81	
<b>28<sup>8</sup></b>	-	-	<b>Negative Control</b>	

<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-A\*29 SSP typings.

When the primers in a primer mix can give rise to HLA-specific PCR products of more than one length this is indicated if the size difference is more than 20 base pairs. Size differences of 20 base pairs or less are not given. For high resolution SSP kits, the alleles listed are specified according to amplicon length.

Nonspecific amplifications, i.e. a ladder or a smear of bands, may sometimes be seen. GC-rich primers have a higher tendency of giving rise to nonspecific amplifications than other primers.

PCR fragments longer than the control bands may sometimes be observed. Such bands should be disregarded and do not influence the interpretation of the SSP typings.

PCR fragments migrating faster than the control bands, but slower than a 400 bp fragment may be seen in some gel read-outs. Such bands can be disregarded and do not influence the interpretation of the SSP typings.

Some primers may give rise to primer oligomer artifacts. Sometimes this phenomenon is an inherent feature of the primer pair(s) of a primer mix. More often it is due to other factors such as too low amount of DNA in the PCR reactions, taking too long time in setting up the PCR reactions, working at elevated room temperature or using thermal cyclers that are not pre-heated.

<sup>2</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

101.428-12 – including *Taq* polymerase, IFU-01  
 101.428-12u – without *Taq* polymerase, IFU-02

Visit <https://labproducts.caredx.com> for  
 “Instructions for Use” (IFU)

**Lot No.: 9F9**

**Lot-specific Information**

identification. In the presence of a specific amplification the intensity of the control band often decreases.

<sup>3</sup>For several HLA Class I alleles 1st and/or 4th 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.

<sup>4</sup>HLA-specific PCR products shorter than 125 base pairs have a lower intensity and are less sharp than longer PCR products.

<sup>5</sup>Primer mixes 9, 12, 13, 16 and 20 may have tendencies of unspecific amplifications.

<sup>6</sup>Primer mixes 10 and 19 have a tendency giving rise to primer oligomer formation.

<sup>7</sup>Primer mix 13 may give rise to a lower yield of HLA-specific PCR product than the other A\*29 primer mixes.

<sup>8</sup>Primer mix 28 contains a negative control, which will amplify more than 95% 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 430 base pairs.

‘w’, might be weakly amplified.

101.428-12 – including *Taq* polymerase, IFU-01  
101.428-12u – without *Taq* polymerase, IFU-02

Visit <https://labproducts.caredx.com> for  
“Instructions for Use” (IFU)

Lot No.: **9F9**

Lot-specific Information

## PRIMER SPECIFICATION

Well No.	1	2	3	4	5	6	7	8	9	10	11	12
Length of spec. PCR product	480	130	440	110	130	105	105	85	80	90	110	80
				165	185	130	210	160	170	165	190	145
							475			215		
Length of int. pos. control <sup>1</sup>	<b>800</b>	1070	<b>800</b>	<b>800</b>	1070	<b>1070</b>	1070	<b>800</b>	1070	<b>800</b>	<b>800</b>	<b>800</b>
5'-primer(s) <sup>2</sup>	180	808	219	448	180	219	219	368	97	82	180	180
	5'-TTT <sup>3'</sup>	5'-CgT <sup>3'</sup>	5'-gCA <sup>3'</sup>	5'-CCT <sup>3'</sup>	5'-TTT <sup>3'</sup>	5'-gCA <sup>3'</sup>	5'-gCA <sup>3'</sup>	5'-gTT <sup>3'</sup>	5'-TCA <sup>3'</sup>	5'-ACC <sup>3'</sup>	5'-TTT <sup>3'</sup>	5'-TTT <sup>3'</sup>
						448	448	652	413	130	448	
						5'-CCT <sup>3'</sup>	5'-CCT <sup>3'</sup>	5'-CTg <sup>3'</sup>	5'-CCg <sup>3'</sup>	5'-AgA <sup>3'</sup>	5'-CCT <sup>3'</sup>	
										140		
										5'-CAA <sup>3'</sup>		
										448		
										5'-CCT <sup>3'</sup>		
3'-primer(s) <sup>3</sup>	376	895	376	506	268	282	282	413	224	257	238	218
	5'-gTg <sup>3'</sup>	5'-CTC <sup>3'</sup>	5'-gTC <sup>3'</sup>	5'-TgT <sup>3'</sup>	5'-ATg <sup>3'</sup>	5'-gAg <sup>3'</sup>	5'-gAg <sup>3'</sup>	5'-gCC <sup>3'</sup>	5'-TCT <sup>3'</sup>	5'-gCA <sup>3'</sup>	5'-CCT <sup>3'</sup>	5'-gCg <sup>3'</sup>
				526	326	533	282	773	454	497	326	286
				5'-CAT <sup>3'</sup>	5'-TgA <sup>3'</sup>	5'-gCC <sup>3'</sup>	5'-gAg <sup>3'</sup>	5'-gCT <sup>3'</sup>	5'-CTg <sup>3'</sup>	5'-Tgg <sup>3'</sup>	5'-TgA <sup>3'</sup>	5'-CTA <sup>3'</sup>
				570		539	412			502	526	
				5'-CCg <sup>3'</sup>		5'-TCT <sup>3'</sup>	5'-CCC <sup>3'</sup>			5'-CTT <sup>3'</sup>	5'-CAT <sup>3'</sup>	
							616				601	
							5'-CgC <sup>3'</sup>				5'-CTT <sup>3'</sup>	
							616					
							5'-CgC <sup>3'</sup>					
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	90	200	240	95	100	225	160	105	185	115	75	125
	165			160	130	260	260			260	510	
	260			190	190		505					
					215							
Length of int. pos. control <sup>1</sup>	1070	1070	1070	1070	1070	1070	1070	1070	1070	<b>800</b>	1070	1070
5'-primer(s) <sup>2</sup>	97	98	98	107	82	41	98	385	355	98	221	448
	5'-TCA <sup>3'</sup>	5'-CAC <sup>3'</sup>	5'-CAC <sup>3'</sup>	5'-CgC <sup>3'</sup>	5'-ACC <sup>3'</sup>	5'-CTT <sup>3'</sup>	5'-CAC <sup>3'</sup>	5'-ggC <sup>3'</sup>	5'-CCg <sup>3'</sup>	5'-CAC <sup>3'</sup>	5'-ACA <sup>3'</sup>	5'-CCT <sup>3'</sup>
	448			134	107		3 <sup>rd</sup> I			355	413	
	5'-CCT <sup>3'</sup>			5'-CCT <sup>3'</sup>	5'-CgC <sup>3'</sup>		5'-ATA <sup>3'</sup>			5'-CCA <sup>3'</sup>	5'-CCA <sup>3'</sup>	
				140	448							
				5'-CAA <sup>3'</sup>	5'-CCT <sup>3'</sup>							
				484								
				5'-ACg <sup>3'</sup>								
3'-primer(s) <sup>3</sup>	221	257	299	257	257	97	217	448	497	317	448	530
	5'-ACA <sup>3'</sup>	5'-gCA <sup>3'</sup>	5'-TCg <sup>3'</sup>	5'-gCA <sup>3'</sup>	5'-gCA <sup>3'</sup>	5'-ggA <sup>3'</sup>	5'-TgA <sup>3'</sup>	5'-CAA <sup>3'</sup>	5'-TgA <sup>3'</sup>	5'-ggA <sup>3'</sup>	5'-CAA <sup>3'</sup>	5'-CCA <sup>3'</sup>
	316			538	506	131	316			430		
	5'-gCT <sup>3'</sup>			5'-CAA <sup>3'</sup>	5'-TgT <sup>3'</sup>	5'-ggA <sup>3'</sup>	5'-gCT <sup>3'</sup>			5'-gCT <sup>3'</sup>		
	494			533			667					
	5'-TCg <sup>3'</sup>			5'-gCC <sup>3'</sup>			5'-ggT <sup>3'</sup>					
	497			545								
	5'-Tgg <sup>3'</sup>			5'-AgC <sup>3'</sup>								
				595								
				5'-CCA <sup>3'</sup>								
Well No.	13	14	15	16	17	18	19	20	21	22	23	24

101.428-12 – including *Taq* polymerase, IFU-01  
 101.428-12u – without *Taq* polymerase, IFU-02

Visit <https://labproducts.caredx.com> for  
 “Instructions for Use” (IFU)

Lot No.: **9F9**

Lot-specific Information

Well No.	25	26	27
Length of spec. PCR product	110	185	510
Length of int. pos. control <sup>1</sup>	1070	1070	1070
5'-primer(s) <sup>2</sup>	448	98	221
	5'-CCT 3'	5'-CAC 3'	5'-ACA 3'
3'-primer(s) <sup>3</sup>	518	242	448
	5'-CCA 3'	5'-CCA 3'	5'-CAA 3'
Well No.	25	26	27

<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 [www.ebi.ac.uk/imgt/hla](http://www.ebi.ac.uk/imgt/hla) 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 [www.ebi.ac.uk/imgt/hla](http://www.ebi.ac.uk/imgt/hla) web site. The sequence of the 3 terminal nucleotides of the primer is given.

101.428-12 – including Taq polymerase, IFU-01  
 101.428-12u – without Taq polymerase, IFU-02

Visit <https://labproducts.caredx.com> for  
 “Instructions for Use” (IFU)

Lot No.: **9F9**

Lot-specific Information

CELL LINE VALIDATION SHEET																				
HLA-A*29 SSP subtyping kit <sup>2</sup>																				
				Well																
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	
				201323601	201323602	201323603	201666104	201444905	201786806	201786807	201323608	201444909	201444910	201444911	201666112	201444913	201323614	201323615	201444916	
	HLWC cell line <sup>1</sup>	A*	A*	Lot No.:																
1	9001 SA	*24:02			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
2	9280 LK707	*02:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
3	9011 E4181324	*01:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
4	9275 GU373	*30:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
5	9009 KAS011	*01:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
6	9353 SM	*02:01	*26:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
7	9020 QBL	*26:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
8	9007 DEM	*31:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
9	9026 YAR	*26:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
10	9107 LKT3	*24:02			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
11	9051 PITOUT	*29:02			-	-	+	-	-	-	-	-	-	-	-	-	+	+	-	
12	9052 DBB	*02:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
13	9004 JESTHOM	*02:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
14	9071 OLGA	*31:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
15	9075 DKB	*24:02			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
16	9037 SWEIG007	*29:02			-	-	+	-	-	-	-	-	-	-	-	-	+	+	-	
17	9282 CTM3953540	*03:01	*80:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
18	9257 32367	*33:03	*74:01		-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	
19	9038 BM16	*02:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
20	9059 SLE005	*02:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
21	9064 AMALA	*02:17			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
22	9056 KOSE	*02:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
23	9124 IHL	*02:01	*34:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
24	9035 JBUSH	*32:01			-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	
25	9049 IBW9	*33:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
26	9285 WT49	*02:05			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
27	9191 CH1007	*24:10	*29:01		+	-	-	-	-	-	-	-	-	-	-	-	+	+	-	
28	9320 BEL5GB	*02:01	*29:02		-	-	+	-	-	-	-	-	-	-	-	-	+	+	-	
29	9050 MOU	*29:02			-	-	+	-	-	-	-	-	-	-	-	-	+	+	-	
30	9021 RSH	*30:01	*68:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
31	9019 DUCAF	*30:02			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
32	9297 HAG	*02:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
33	9098 MT14B	*31:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
34	9104 DHIF	*31:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
35	9302 SSTO	*32:01			-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	
36	9024 KT17	*02:06	*11:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
37	9065 HHKB	*03:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
38	9099 LZL	*02:17			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
39	9315 CML	*01:01	*03:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
40	9134 WHONP199	*02:07	*30:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
41	9055 H0301	*03:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
42	9066 TAB089	*02:07			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
43	9076 T7526	*02:06	*02:07		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
44	9057 TEM	*66:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
45	9239 SHJO	*23:01	*24:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
46	9013 SCHU	*03:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
47	9045 TUBO	*02:16	*03:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
48	9303 TER-ND	*02:01	*11:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	

101.428-12 – including *Taq* polymerase, IFU-01  
 101.428-12u – without *Taq* polymerase, IFU-02

Visit <https://labproducts.caredx.com> for  
 “Instructions for Use” (IFU)

Lot No.: **9F9**

Lot-specific Information

CELL LINE VALIDATION SHEET														
HLA-A*29 SSP subtyping kit <sup>2</sup>														
				Well										
				17	18	19	20	21	22	23	24	25	26	27
				201666117	201444924	201444919	201786820	201323621	201444922	201786823	201786824	201786825	201786826	201786827
			Lot No.:											
	IHC cell line <sup>1</sup>	A*	A*											
1	9001 SA	*24:02		-	-	-	-	-	-	-	-	-	-	-
2	9280 LK707	*02:01		-	-	-	-	-	-	-	-	-	-	-
3	9011 E4181324	*01:01		-	-	-	-	-	-	-	-	-	-	-
4	9275 GU373	*30:01		-	-	-	-	-	-	-	-	-	-	-
5	9009 KAS011	*01:01		-	-	-	-	-	-	-	-	-	-	-
6	9353 SM	*02:01	*26:03	-	-	-	-	-	-	-	-	-	-	-
7	9020 QBL	*26:01		-	-	-	-	-	-	-	-	-	-	-
8	9007 DEM	*31:01		-	-	-	-	-	-	+	-	-	-	-
9	9026 YAR	*26:01		-	-	-	-	-	-	-	-	-	-	-
10	9107 LKT3	*24:02		-	-	-	-	-	-	-	-	-	-	-
11	9051 PITOUT	*29:02		-	-	-	-	-	-	-	-	-	-	-
12	9052 DBB	*02:01		-	-	-	-	-	-	-	-	-	-	-
13	9004 JESTHOM	*02:01		-	-	-	-	-	-	-	-	-	-	-
14	9071 OLGA	*31:01		-	-	-	-	-	-	+	-	-	-	-
15	9075 DKB	*24:02		-	-	-	-	-	-	-	-	-	-	-
16	9037 SWEIG007	*29:02		-	-	-	-	-	-	-	-	-	-	-
17	9282 CTM3953540	*03:01	*80:01	-	-	-	-	-	-	-	-	-	-	-
18	9257 32367	*33:03	*74:01	-	-	-	+	-	-	+	-	-	-	-
19	9038 BM16	*02:01		-	-	-	-	-	-	-	-	-	-	-
20	9059 SLE005	*02:01		-	-	-	-	-	-	-	-	-	-	-
21	9064 AMALA	*02:17		-	-	-	-	-	-	-	-	-	-	-
22	9056 KOSE	*02:01		-	-	-	-	-	-	-	-	-	-	-
23	9124 IHL	*02:01	*34:01	-	-	-	-	-	-	-	-	-	-	-
24	9035 JBUSH	*32:01		-	-	-	+	-	-	+	-	-	-	-
25	9049 IBW9	*33:01		-	-	-	-	-	-	+	-	-	-	-
26	9285 WT49	*02:05		-	-	-	-	-	-	-	-	-	-	-
27	9191 CH1007	*24:10	*29:01	-	-	-	-	-	-	-	-	-	-	-
28	9320 BEL5GB	*02:01	*29:02	-	-	-	-	-	-	-	-	-	-	-
29	9050 MOU	*29:02		-	-	-	-	-	-	-	-	-	-	-
30	9021 RSH	*30:01	*68:02	-	-	-	-	-	-	-	-	-	-	-
31	9019 DUCAF	*30:02		-	-	-	-	-	-	-	-	-	-	-
32	9297 HAG	*02:01		-	-	-	-	-	-	-	-	-	-	-
33	9098 MT14B	*31:01		-	-	-	-	-	-	+	-	-	-	-
34	9104 DHIF	*31:01		-	-	-	-	-	-	+	-	-	-	-
35	9302 SSTO	*32:01		-	-	-	+	-	-	+	-	-	-	-
36	9024 KT17	*02:06	*11:01	-	-	-	-	-	-	-	-	-	-	-
37	9065 HHKB	*03:01		-	-	-	-	-	-	-	-	-	-	-
38	9099 LZL	*02:17		-	-	-	-	-	-	-	-	-	-	-
39	9315 CML	*01:01	*03:01	-	-	-	-	-	-	-	-	-	-	-
40	9134 WHONP199	*02:07	*30:01	-	-	-	-	-	-	-	-	-	-	-
41	9055 H0301	*03:01		-	-	-	-	-	-	-	-	-	-	-
42	9066 TAB089	*02:07		-	-	-	-	-	-	-	-	-	-	-
43	9076 T7526	*02:06	*02:07	-	-	-	-	-	-	-	-	-	-	-
44	9057 TEM	*66:01		-	-	-	-	-	-	-	-	-	-	-
45	9239 SHJO	*23:01	*24:02	-	-	-	-	-	-	-	-	-	-	-
46	9013 SCHU	*03:01		-	-	-	-	-	-	-	-	-	-	-
47	9045 TUBO	*02:16	*03:01	-	-	-	-	-	-	-	-	-	-	-
48	9303 TER-ND	*02:01	*11:01	-	-	-	-	-	-	-	-	-	-	-

101.428-12 – including *Taq* polymerase, IFU-01  
 101.428-12u – without *Taq* polymerase, IFU-02

Visit <https://labproducts.caredx.com> for  
 “Instructions for Use” (IFU)

Lot No.: **9F9**

**Lot-specific Information**

<sup>1</sup>The 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.

<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.

No DNAs carrying the alleles to be amplified by primer solutions 2, 4 to 7, 9 to 11, 13, 17 to 19, 21, 22 and 24 to 27 were available.

The specificities of the primers in primer solutions 4, 6, 7, 10, 11, 13, 17, 18, 21 and 22 were tested by separately adding one, two or three additional 5'-primers, respectively one or two additional 3'-primers.

In primer solutions 2, 5, 9, 19 and 24 to 26 it was only possible to test the 5'-primers, the 3'-primers were not possible to test.

In primer solution 27 it was only possible to test the 3'-primer, the 5'-primer was not possible to test.

In primer solution 4, 6, 7, 8, 11 to 13, 17, 18 and 22 one or more of the 3'-primers were not possible to test, and in primer solutions 10, 16, 17 and 23 one, two or three of the 5'-primers were not possible to test. Additional primers in primer solutions 8 and 16 were tested by separately adding one 3'-primer respectively one 5'-primer.

101.428-12 – including *Taq* polymerase, IFU-01  
 101.428-12u – without *Taq* polymerase, IFU-02

Visit <https://labproducts.caredx.com> for  
 “Instructions for Use” (IFU)

Lot No.: **9F9**

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](mailto: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](mailto: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](mailto:orders-us@caredx.com)

**Web page:** <https://labproducts.caredx.com/>

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