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.: 3H6

Lot-specific Information

Olerup SSP® HLA-A*29

Product number:	**101.428-12 – including *Taq* polymerase** **101.428-12u – without *Taq* polymerase**
Lot number:	**3H6**
Expiry date:	**2023-03-01**
Number of tests:	**12**
Number of wells per test:	**29+1**
Storage - pre-aliquoted primers:	**dark at -20ºC**
- PCR Master Mix:	**-20ºC**
- Adhesive PCR seals	**RT**
- Product Insert	**RT**

This Product Description is only valid for Lot No. 3H6.

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-A*29 LOT (9F9)

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

- Null and Alternatively expressed alleles
- The product documentation has been updated for new alleles of IMGT 3.34.0.

Two wells has been added to HLA-A*29, wells **29 and 30**.

The format of the Worksheet has been changed.

The HLA-A*29 primer set, specificity and interpretation tables have been updated for the HLA-A alleles described since the previous *Olerup* SSP® HLA-A*29 lot was made **(Lot No. 9F9)**.

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
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Lot No.: 3H6 **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	Moved	Moved	Primer pair moved to primer mix 29 for decreased primer oligomer formation.
7	Moved	Moved	Primer pair moved to primer mix 29.
28	Added	Added	Negative control moved to primer mix 30. Primer pair added for the A*29:112N allele.
29	Added	Added	Primer pair added from primer mix 6. Primer pair added from primer mix 7.
30	-	-	Negative control added from well 28.

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

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Lot No.: 3H6 **Lot-specific Information**

Well **30** contains Negative Control primer pairs, that will amplify more than 95% 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 430 base pairs.

Length of PCR product	**105**	**200**	**105**	**80**	**75**	**80**	**85**
5'-primer[1]	**164**	**340**	**440**	**45**	**45**	**43**	**36**
	5'-CAC3'	**5'-Agg3'**	**5'-TTA3'**	**5'-Tgg3'**	**5'-Tgg3'**	**5'-Tgg3'**	**5'-TAC3'**
							36
							5'-TAT3'
3'-primer[2]	**231**	**2nd I**	**507**	**59**	**58**	**57**	**47**
	5'-TgC3'	**5'-AAA3'**	**5'-TTg3'**	**5'-CTC3'**	**5'-ggC3'**	**5'-CTC3'**	**5'-ACA3'**
							48
							5'-gCA3'
							48
							5'-gCC3'
							52
							5'-TgT3'
A*	+	+	+				
B*	+	+	+				
C*	+	+	+				
DRB1				+	+		
DRB3				+	+		
DRB5				+			
DQB1					+		
DPB1						+	
DQA1							+

[1]The 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.

[2]The 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.

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

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Lot No.: 3H6 **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*29:121 alleles.

PLATE LAYOUT

Each test consists of 29 PCR reactions in a 32 well cut PCR plate. Wells 31 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	28	29	NC	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. '3H6'.
Wells 1 to 29 – HLA-A*29 high resolution primers.
Well 30 – 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*29:121 alleles**, recognized by the HLA Nomenclature Committee in October 2018[1,2] 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 3.29.0. 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 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

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Lot No.: 3H6 **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*29:07, 29:46	8
A*29:11, 29:92	13
A*29:20, 29:82	29

[1]HLA-A alleles listed on the IMGT/HLA web page 2018-October-18, release 3.34.0, www.ebi.ac.uk/imgt/hla.
[2]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

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Lot No.: 3H6 **Lot-specific Information**

ALLELE CONFIRMATION STATUS

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

[1]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.

RESOLUTION IN HOMO- AND HETEROZYGOTES

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

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

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Lot No.: 3H6

Lot-specific Information

SPECIFICITY TABLE

HLA-A*29 SSP subtyping

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

Primer Mix	Size of spec. PCR product[1]	Size of control band[2]	Amplified HLA-A*29 alleles[3]	Other amplified HLA-A alleles
1	480 bp	**800 bp**	*29:01:01:01-29:01:06, 29:01:08-29:01:11, 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, 29:107, 29:110, 29:113, 29:115, 29:117-29:118	
2	130 bp	1070 bp	*29:01:01:02N	
3	440 bp	**800 bp**	*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, 29:102-29:106, 29:108, 29:111-29:112N, 29:114, 29:116, 29:119-29:121	*11:01:42, 30:01:11, 68:130:02
4[4]	110 bp 165 bp	**800 bp**	*29:35, 29:51, 29:69, 29:73 *29:03, 29:33	*02:24:02, 02:507, 32:109 *23:03:01, 24:21:03, 24:208:01, 31:05, 32:13, 33:10
5	130 bp 185 bp	1070 bp	*29:04 *29:23	
6	130 bp	1070 bp	*29:05, 29:33, 29:40, 29:77, 29:87, 29:104	*11:01:28, 11:01:77, 24:21:03, 24:208:01, 31:24, 31:136, 32:02, 32:22, 33:59, 33:102, 33:150
7	210 bp	1070 bp	*29:06	*31:51^{w}, 32:12^{w}, 74:26^{w}, **B*08:01:07^{w}, B*15:02:07^{w}, B*15:17:03^{w}, B*27:07:05^{w}, B*41:01:05^{w}, B*55:02:10^{w}, C*02:02:15^{w}, C*03:03:20^{w}, C*04:175^{w}, C*07:04:13^{w}, C*08:01:15^{w}**
8[4]	85 bp 160 bp	**800 bp**	*29:07, 29:49 *29:46	*11:139, 23:53, 23:70, 24:17, 24:41, 24:208:01-24:208:02

CE 0197

For *In Vitro* Diagnostic Use.

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

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9[4,5]	80 bp 170 bp	1070 bp	*29:16 *29:08N	*01:157, 03:27, 11:233
10[4,6]	90 bp	**800 bp**	*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, 24:208:01, 31:24, 32:33:01, 32:109, 33:34
	165 bp 215 bp		*29:17, 29:43 *29:54	
11[4]	110 bp 190 bp	**800 bp**	*29:14, 29:35 *29:10:01-29:10:02, 29:23	**C*07:04:13, C*08:01:15**
12[4,5]	80 bp	**800 bp**	*29:01:11, 29:02:04, 29:18, 29:48	*03:01:39, 32:01:01:01-32:01:07, 32:01:09-32:01:17, 32:01:19-32:01:29, 32:01:31-32:03, 32:05-32:55:02, 32:57-32:69, 32:71, 32:73-32:107, 32:109-32:112N, 32:114-32:118, 68:01:28, 68:01:36, 74:01:01-74:01:05, 74:01:07-74:13, 74:15-74:32N
	145 bp		*29:78N	
13[4,5,7]	90 bp 165 bp 260 bp	1070 bp	*29:11, 29:51, 29:73 *29:12, 29:92 *29:55	*02:24:02, 02:507, 32:109 *31:16, 33:58
14	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, 29:57-29:104, 29:106-29:121	
15	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, 29:99-29:121	*01:143, 31:79, 33:13, 33:48
16[4,5]	95 bp 160 bp 190 bp	1070 bp	*29:15 *29:21, 29:43 *29:53	*02:221, 23:41, 31:78
17[4]	100 bp 130 bp 190 bp 215 bp	1070 bp	*29:51, 29:69, 29:73 *29:24, 29:40 *29:27, 29:53 *29:54	*02:24:02, 02:507, 32:109
18	225 bp 260 bp	1070 bp	*29:37, 29:56 *29:36	*32:07, 33:119
19[6]	160 bp 260 bp 505 bp	1070 bp	*29:25 *29:55 *29:26	
20[4,5]	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, 32:01:13-32:01:30, 32:01:32-32:03, 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, 32:102-32:118, 74:01:01-74:32N
21	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, 11:288, 24:14:01:01-24:14:01:03, 24:93, 24:324, 26:22, 30:47, 31:99, 33:22, 66:09, **B*08:204, C*02:74**
22[4]	115 bp	**800 bp**	*29:29	*01:148, 11:128, 26:85, 33:139, 68:58:01-68:58:02
	260 bp		*29:13	*24:82, 31:07-31:08, 31:10, 32:42
23[4]	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, 31:121-31:146, 32:01:01:01-32:01:06, 32:01:08-32:01:11, 32:01:13-32:01:27, 32:01:29-32:03, 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, 32:102-32:118, 33:01:01:01-33:01:04, 33:01:06-33:01:12, 33:03:01:01-33:03:18, 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, 33:39-33:151, 33:153-33:158, 33:160-33:163, 74:01:01-74:32N, **B*15:17:03**
	510 bp		*29:81	
24[4]	125 bp	1070 bp	*29:71	*31:77
25[4]	110 bp	1070 bp	*29:90	*31:108, 33:110
26	185 bp	1070 bp	*29:103	
27	510 bp	1070 bp	*29:81	
28[4]	95 bp	1070 bp	*29:112N	*33:76
29[4]	105 bp	1070 bp	*29:19, 29:20, 29:34	
	475 bp		*29:82	
30[8]	-	-	**Negative Control**	

[1]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

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101.428-12u – without *Taq* polymerase, IFU-02 **"Instructions for Use" (IFU)**

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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.

[2]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.

[3]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.

[4]HLA-specific PCR products shorter than 125 base pairs have a lower intensity and are less sharp than longer PCR products.

[5]Primer mixes 9, 12, 13, 16 and 20 may have tendencies of unspecific amplifications.

[6]Primer mixes 10 and 19 have a tendency giving rise to primer oligomer formation.

[7]Primer mix 13 may give rise to a lower yield of HLA-specific PCR product than the other A*29 primer mixes.

[8]Primer mix 30 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
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Lot No.: 3H6

Lot-specific Information

PRIMER SPECIFICATION

Well No.	1	2	3	4	5	6	7	8	9	10	11	12
Length of spec.	480	130	440	110	130	130	210	85	80	90	110	80
PCR product				165	185			160	170	165	190	145
										215		
Length of int.	800	1070	800	800	1070	1070	1070	800	1070	800	800	800
pos. control[1]												
5'-primer(s)[2]	180	808	219	448	180	448	448	368	97	82	180	180
	5'-TTT-3'	5'-CgT-3'	5'-gCA-3'	5'-CCT-3'	5'-TTT-3'	5'-CCT-3'	5'-CCT-3'	5'-gTT-3'	5'-TCA-3'	5'-ACC-3'	5'-TTT-3'	5'-TTT-3'
								652	413	130	448	
								5'-CTg-3'	5'-CCg-3'	5'-AgA-3'	5'-CCT-3'	
										140		
										5'-CAA-3'		
										448		
										5'-CCT-3'		
3'-primer(s)[3]	376	895	376	506	268	533	616	413	224	257	238	218
	5'-gTg-3'	5'-CTC-3'	5'-gTC-3'	5'-TgT-3'	5'-ATg-3'	5'-gCC-3'	5'-CgC-3'	5'-gCC-3'	5'-TCT-3'	5'-gCA-3'	5'-CCT-3'	5'-gCg-3'
				526	326	539		773	454	497	326	286
				5'-CAT-3'	5'-TgA-3'	5'-TCT-3'		5'-gCT-3'	5'-CTg-3'	5'-Tgg-3'	5'-TgA-3'	5'-CTA-3'
				570						502	526	
				5'-CCg-3'						5'-CTT-3'	5'-CAT-3'	
											601	
											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	23	24
Length of spec.	90	200	240	95	100	225	160	105	185	115	75	125
PCR product	165			160	130	260	260			260	510	
	260			190	190		505					
					215							
Length of int.	1070	1070	1070	1070	1070	1070	1070	1070	1070	800	1070	1070
pos. control[1]												
5'-primer(s)[2]	97	98	98	107	82	41	98	385	355	98	221	448
	5'-TCA-3'	5'-CAC-3'	5'-CAC-3'	5'-CgC-3'	5'-ACC-3'	5'-CTT-3'	5'-CAC-3'	5'-ggC-3'	5'-CCg-3'	5'-CAC-3'	5'-ACA-3'	5'-CCT-3'
	448			134	107		3rd I			355	413	
	5'-CCT-3'			5'-CCT-3'	5'-CgC-3'		5'-ATA-3'			5'-CCA-3'	5'-CCA-3'	
				140	448							
				5'-CAA-3'	5'-CCT-3'							
				484								
				5'-ACg-3'								
3'-primer(s)[3]	221	257	299	257	257	97	217	448	497	317	448	530
	5'-ACA-3'	5'-gCA-3'	5'-TCg-3'	5'-gCA-3'	5'-gCA-3'	5'-ggA-3'	5'-TgA-3'	5'-CAA-3'	5'-TgA-3'	5'-ggA-3'	5'-CAA-3'	5'-CCA-3'
	316			538	506	131	316			430		
	5'-gCT-3'			5'-CAA-3'	5'-TgT-3'	5'-ggA-3'	5'-gCT-3'			5'-gCT-3'		
	494				533		667					
	5'-TCg-3'				5'-gCC-3'		5'-ggT-3'					
	497				545							
	5'-Tgg-3'				5'-AgC-3'							
					595							
					5'-CCA-3'							
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.: 3H6 **Lot-specific Information**

Well No.	25	26	27	28	29
Length of spec.	110	185	510	95	105
PCR product					475
Length of int.	1070	1070	1070	1070	1070
pos. control[1]					
5'-primer(s)[2]	448	98	221	288	219
	5' -CCT 3'	5' -CAC 3'	5' -ACA 3'	5' -..g 3'	5' -gCA 3'
3'-primer(s)[3]	518	242	448	341	282
	5' -CCA 3'	5' -CCA 3'	5' -CAA 3'	5' -Cgg 3'	5' -gAg 3'
					282
					5' -gAg 3'
					412
					5' -CCC 3'
Well No.	25	26	27	28	29

[1]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.

[2]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 web site. The sequence of the 3 terminal nucleotides of the primer is given.

[3]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 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

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Lot No.: 3H6 **Lot-specific Information**

CELL LINE VALIDATION SHEET

HLA-A*29 SSP subtyping kit[2]

					Well															
					1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
				Lot No.:	201901601	201901602	201901603	201901604	201901605	201901606	201901607	201901608	201901609	201901610	201901611	201901612	201901613	201901614	201901615	201901616
	IHWC cell line[1]		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.: 3H6 **Lot-specific Information**

CELL LINE VALIDATION SHEET

HLA-A*29 SSP subtyping kit[2]

					Well												
					17	18	19	20	21	22	23	24	25	26	27	28	29
				Lot No.:	201901617	201901618	201901619	201901620	201901621	201901622	201901623	201901624	201901625	201901626	201901627	201901628	201901629
	IHWC cell line[1]		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 Visit https://labproducts.caredx.com for
101.428-12u – without *Taq* polymerase, IFU-02 **"Instructions for Use" (IFU)**

Lot No.: 3H6 Lot-specific Information

[1]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.

[2]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 29 were available.

The specificities of the primers in primer solutions 4, 6, 10, 11, 13, 17, 18, 21, 22 and 29 were tested by separately adding one, two or three additional 5'-primers, respectively one or two additional 3'-primers.

In primer solutions 2, 5, 7, 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 solutions 27 and 28 it was only possible to test the 3'-primer, the 5'-primer was not possible to test.

In primer solution 4, 6, 8, 11 to 13, 17, 18, 22 and 29 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

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Lot No.: 3H6 **Lot-specific Information**

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