

101.567-12 – including *Taq* pol., IFU-01
101.567-12u – without *Taq* pol., IFU-02

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

Lot No.: **1K8**

Lot-specific information
Olerup SSP® HLA-B*57

Product number:	101.567-12 – including <i>Taq</i> polymerase 101.567-12u – without <i>Taq</i> polymerase
Lot number:	1K8
Expiry date:	2023-09-01
Number of tests:	12
Number of wells per test:	31+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. 1K8.

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*57 LOT (3H0)**

The HLA-B*57 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 3.36.0

The HLA-B*57 primer set, specificity and interpretation tables have been updated for the HLA-B alleles described since the previous *Olerup SSP®* HLA-B*57 lot was made (**Lot No. 3H0**).

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

Well	5'-primer	3'-primer	rationale
11	Modified	-	5'-primer modified for improved HLA-specific amplification.
15	-	-	Positive control primer pair exchanged for reduced tendency of primer oligomer formation.

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Well **32** contains Negative Control primer pairs, that will amplify a majority of the *Olerup* SSP® HLA Class I, DRB, DQB1, DPB1 and DQA1 amplicons as well as all the amplicons generated by the control primer pairs matching the human growth hormone gene.

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

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

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

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

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Lot-specific information

PRODUCT DESCRIPTION

HLA-B*57 SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for identifying the B*57:01 to B*57:120 alleles.

PLATE LAYOUT

Each test consists of 32 PCR reactions in a 32 well cut PCR plate.

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	30	31	NC

The 32 well cut PCR plate is marked with ‘HLA-B*57’ in silver/gray ink.

Well No. 1 is marked with the Lot No. ‘1K8’.

Wells 1 to 31 – HLA-B*57 high resolution primers.

Well 32 – 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 32 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*57 alleles will be amplified by some primer mixes. For further details see Specificity Table.

UNIQUELY IDENTIFIED ALLELES

All the HLA-B*57 alleles, i.e. **B*57:01 to B*57:120**, recognized by the HLA Nomenclature Committee in April 2019^{1,2} will be amplified by the primers in the HLA-B*57 subtyping kit.

The HLA-B*57 kit enables separation of the confirmed HLA-B*57 alleles as listed in the IMGT/HLA database 3.25.0. 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-B*57 alleles is listed below.

The HLA-B*57 kit also enables identification of null and alternatively expressed alleles.

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Lot-specific information

The following HLA-B*57 alleles can be distinguished by the different sizes of the HLA-specific PCR product:

Alleles	Primer mix
B*57:15, 57:37, 57:55	7
B*57:25, 57:41	19

¹HLA-B alleles listed on the IMGT/HLA web page 2019-April-19 release 3.36.0, www.ebi.ac.uk/imgt/hla.

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

ALLELE CONFIRMATION STATUS

Allele	Status ¹	Allele	Status ¹	Allele	Status ¹	Allele	Status ¹
B*57:01:01	Confirmed	B*57:06	Unconfirmed	B*57:35	Confirmed	B*57:65	Unconfirmed
B*57:01:02	Unconfirmed	B*57:07	Unconfirmed	B*57:36	Unconfirmed	B*57:66	Unconfirmed
B*57:01:03	Confirmed	B*57:08	Unconfirmed	B*57:37	Unconfirmed	B*57:67:01	Confirmed
B*57:01:04	Unconfirmed	B*57:09	Confirmed	B*57:38	Unconfirmed	B*57:67:02	Unconfirmed
B*57:01:05	Confirmed	B*57:10	Unconfirmed	B*57:39	Confirmed	B*57:68	Unconfirmed
B*57:01:06	Unconfirmed	B*57:11	Confirmed	B*57:40	Confirmed	B*57:69	Unconfirmed
B*57:01:07	Confirmed	B*57:12	Unconfirmed	B*57:41	Confirmed	B*57:70	Unconfirmed
B*57:01:08	Confirmed	B*57:13	Confirmed	B*57:42	Unconfirmed	B*57:71	Unconfirmed
B*57:01:09	Unconfirmed	B*57:14:01	Confirmed	B*57:43	Confirmed	B*57:72	Unconfirmed
B*57:01:10	Confirmed	B*57:14:02	Unconfirmed	B*57:44	Confirmed	B*57:73	Confirmed
B*57:01:11	Unconfirmed	B*57:15	Confirmed	B*57:45	Unconfirmed	B*57:74	Unconfirmed
B*57:01:12	Unconfirmed	B*57:16	Unconfirmed	B*57:46	Unconfirmed	B*57:75	Unconfirmed
B*57:01:13	Unconfirmed	B*57:17	Confirmed	B*57:47	Unconfirmed	B*57:76	Unconfirmed
B*57:01:14	Confirmed	B*57:18	Unconfirmed	B*57:48	Unconfirmed	B*57:77	Confirmed
B*57:01:15	Unconfirmed	B*57:19	Unconfirmed	B*57:49	Confirmed	B*57:78	Confirmed
B*57:01:16	Unconfirmed	B*57:20	Confirmed	B*57:50	Unconfirmed	B*57:79N	Unconfirmed
B*57:01:17	Unconfirmed	B*57:21	Confirmed	B*57:51	Unconfirmed	B*57:80	Unconfirmed
B*57:01:18	Unconfirmed	B*57:22	Confirmed	B*57:52	Unconfirmed	B*57:81	Unconfirmed
B*57:01:19	Unconfirmed	B*57:23	Confirmed	B*57:53	Unconfirmed	B*57:82	Unconfirmed
B*57:01:20	Unconfirmed	B*57:24	Confirmed	B*57:54	Unconfirmed	B*57:83	Unconfirmed
B*57:01:21	Unconfirmed	B*57:25	Unconfirmed	B*57:55	Unconfirmed		
B*57:01:22	Unconfirmed	B*57:26	Confirmed	B*57:56	Unconfirmed		
B*57:02:01	Confirmed	B*57:27	Unconfirmed	B*57:57	Confirmed		
B*57:02:02	Confirmed	B*57:28N	Unconfirmed	B*57:58	Confirmed		
B*57:03:01:01	Confirmed	B*57:29	Confirmed	B*57:59	Unconfirmed		
B*57:03:01:02	Unconfirmed	B*57:30	Unconfirmed	B*57:60	Unconfirmed		
B*57:03:02	Unconfirmed	B*57:31	Unconfirmed	B*57:61	Confirmed		
B*57:04:01	Confirmed	B*57:32	Confirmed	B*57:62	Unconfirmed		
B*57:04:02	Unconfirmed	B*57:33	Unconfirmed	B*57:63	Confirmed		
B*57:05	Confirmed	B*57:34	Confirmed	B*57:64	Unconfirmed		

¹Allele status “confirmed” or “unconfirmed” as listed on the IMGT/HLA web page 2016-July-14, release 3.25.0, www.ebi.ac.uk/imgt/hla.

RESOLUTION IN HOMO- AND HETEROZYGOTES

Results file with resolution in HLA-B*57 homo- and heterozygotes is available upon request.

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Lot-specific information
SPECIFICITY TABLE

HLA-B*57 SSP subtyping

Specificities and sizes of the PCR products of the 31+1 primer mixes used for HLA-B*57 SSP subtyping

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified HLA-B*57 alleles ³	Other amplified HLA Class I alleles
1	150 bp	800 bp	*57:01:01:01-57:01:04, 57:01:06-57:10, 57:12, 57:14:01-57:30, 57:32-57:46, 57:48-57:73, 57:75-57:81, 57:84-57:117, 57:119-57:120	*07:235, 07:359, 08:49, 13:01:01:01-13:01:14, 13:06-13:07N, 13:12:01-13:13:02, 13:17, 13:20, 13:22:01-13:23, 13:25-13:26:02, 13:28-13:29, 13:36, 13:39, 13:43, 13:50-13:52, 13:57, 13:60-13:61, 13:63N, 13:73, 13:76N-13:80, 13:83, 13:86-13:87, 13:90, 13:92, 13:95, 13:106-13:107, 13:109-13:110, 13:122, 13:129, 14:10, 15:02:01:01-15:02:12, 15:13:01-15:13:02, 15:20-15:21:01:02, 15:25:01-15:25:04, 15:36, 15:44, 15:62, 15:77, 15:80, 15:85, 15:88-15:89, 15:106, 15:112, 15:121, 15:139, 15:144, 15:154, 15:165, 15:170, 15:194, 15:204, 15:213-15:214, 15:223, 15:240, 15:250, 15:265, 15:271, 15:283, 15:289, 15:291, 15:297, 15:301-15:302N, 15:308, 15:319, 15:325, 15:328, 15:330, 15:341, 15:345, 15:357-15:358, 15:366, 15:374, 15:378, 15:393-15:394, 15:399, 15:402, 15:404, 15:407, 15:418, 15:420, 15:425, 15:437-15:438, 15:454N, 15:458, 15:460, 15:463N, 15:468, 15:491, 15:495, 15:505, 18:22, 18:69, 18:105, 18:149-18:150, 27:19, 27:30, 27:127, 27:150, 35:01:01:01-35:01:54, 35:02:01:01-35:04:03, 35:06-35:08:11, 35:10-35:17:03, 35:19-35:21, 35:23-35:30, 35:33-35:36, 35:38-35:42:02, 35:45-35:50, 35:52, 35:54-35:57, 35:59:01-35:59:02, 35:61:01-35:63, 35:65Q, 35:69-35:71, 35:74, 35:76-35:78, 35:80-35:85, 35:90-35:96, 35:98, 35:100-35:101:02, 35:103-35:113, 35:115-35:116, 35:120-35:126, 35:128-35:134N, 35:136-35:150:02, 35:152-35:173:02N, 35:175-35:184, 35:186-35:198, 35:200-35:204, 35:206-35:229, 35:231, 35:233, 35:236-35:250, 35:252-35:259, 35:261-35:264, 35:266-35:272, 35:274-35:275, 35:277-35:291, 35:293-35:320, 35:322-35:330, 35:332-35:366, 35:370-35:371, 35:373-35:388, 35:390N-35:408, 35:410-35:415, 35:417-35:426, 35:428Q-35:432, 35:434-35:436, 37:01:01:01-37:01:07, 37:01:09, 37:01:11-37:01:16, 37:03N-37:06:02, 37:08,

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Lot No.: **1K8**

Lot-specific information

				37:10-37:11, 37:13-37:43, 37:45-37:50, 37:52-37:80, 37:82N-37:87, 38:20:01-38:20:02, 39:42, 40:28, 44:02:01:01-44:02:33, 44:02:35-44:02:57, 44:02:59-44:14, 44:16-44:17, 44:19N, 44:21-44:30, 44:32-44:40, 44:42-44:46, 44:48-44:52N, 44:55-44:64:02, 44:66-44:98, 44:101-44:105, 44:107-44:134, 44:136-44:137, 44:139-44:157, 44:159-44:165, 44:167-44:181, 44:183, 44:185-44:191, 44:194-44:196, 44:198N-44:212, 44:214-44:229, 44:231-44:235, 44:237N-44:245, 44:247-44:304, 44:306N-44:338, 44:340-44:342, 44:344-44:346, 44:437, 46:33, 46:67, 48:02:01-48:02:03, 48:25, 49:61, 50:17, 51:04:01-51:04:02, 51:42, 51:46, 51:56:01-51:56:03, 51:139, 51:227, 51:281, 52:88, 53:01:01:01-53:13, 53:15-53:40, 53:42-53:43:02, 53:45-53:46, 53:48N-53:56, 55:14, 56:09, 56:11-56:12, 56:60, 58:01:01:01-58:01:02, 58:01:04-58:01:15, 58:01:17-58:01:31, 58:04-58:05, 58:09-58:15, 58:17N, 58:19, 58:21-58:24, 58:28:01-58:29, 58:31N-58:37, 58:39N-58:42, 58:44-58:45:02, 58:47-58:59:02, 58:62-58:103, 58:105-58:108, 83:01, C*03:102, C*03:263:01-03:263:03, C*15:126
2⁴	100 bp	1070 bp	*57:01:01:01-57:01:36, 57:06, 57:08, 57:10, 57:13-57:16, 57:18-57:27, 57:29-57:31, 57:33-57:38, 57:40 ^w , 57:41, 57:43-57:45, 57:47-57:52, 57:54-57:56, 57:58-57:62, 57:64-57:65, 57:67:01-57:69, 57:71-57:75, 57:77-57:79N, 57:81, 57:85-57:93, 57:95, 57:97-57:98Q, 57:100, 57:102-57:111, 57:113-57:117, 57:119-57:120	*35:208:01-35:208:02, 35:317, 55:14, 58:14, C*06:72
3	220 bp	1070 bp	*57:01:01:01-57:01:36, 57:03:01:01-57:03:04, 57:06-57:08, 57:10, 57:14:01-57:18, 57:20-57:23, 57:25-57:27, 57:29, 57:31-57:41, 57:43-57:51, 57:53-57:60, 57:62, 57:64-57:81, 57:84-57:98Q, 57:100-57:111, 57:113-57:117, 57:120	*35:208:01-35:208:02, 35:317, 40:30, 40:34, 44:153, 55:14, 58:14
4⁴	100 bp	800 bp	*57:02:01-57:03:04, 57:05, 57:07, 57:09,	*07:137, 08:60, 08:76 ^w , 08:129, 08:181, 13:13:01-13:13:02, 13:21, 13:86,

101.567-12 – including *Taq* pol., IFU-01
101.567-12u – without *Taq* pol., IFU-02

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“Instructions for Use” (IFU)

Lot No.: **1K8**

Lot-specific information

Lot No.: 1K8		Lot-specific information	
		57:12, 57:17, 57:39, 57:42, 57:46, 57:57, 57:63, 57:66, 57:70, 57:80, 57:84, 57:94, 57:96, 57:101	35:02:01:01-35:02:12, 35:04:01-35:04:03, 35:06 ^w , 35:09:01-35:09:03, 35:12:01-35:12:04, 35:18, 35:59:01 ^w , 35:81, 35:83, 35:88, 35:95, 35:129N, 35:149, 35:154, 35:157, 35:162, 35:172, 35:182-35:184, 35:201, 35:211, 35:220, 35:230, 35:233, 35:258, 35:266, 35:270, 35:285, 35:309, 35:311, 35:316, 35:321, 35:323, 35:335, 35:339, 35:357, 35:361, 35:366, 35:372, 35:374, 35:377-35:379, 35:384, 35:387, 35:391, 35:396, 35:403, 35:410, 35:419, 35:425, 37:01:01:01 ^w , 37:01:02 ^w -37:01:11 ^w , 37:03N ^w -37:06:02 ^w , 37:08 ^w , 37:10 ^w -37:11 ^w , 37:12, 37:13 ^w -37:18 ^w , 37:19:01-37:19:02, 37:20 ^w -37:24 ^w , 37:26 ^w -37:34 ^w , 37:36 ^w -37:43 ^w , 37:45 ^w -37:50 ^w , 37:52 ^w -37:55 ^w , 37:57 ^w -37:61 ^w , 37:84, 38:20:01 ^w , 39:42 ^w , 40:04:01-40:04:02, 40:28, 40:30, 40:34, 40:64:01:01-40:64:02, 40:68, 40:99 ^w , 40:129, 40:137, 40:160:01-40:160:02, 40:343, 41:48, 42:13, 44:62, 44:77, 44:82 ^w , 48:17 ^w , 51:04:01-51:04:02, 51:46, 51:56:01-51:56:03, 51:139, 53:19, 53:36, 56:12, 58:28:01-58:28:02, 58:65, C*03:317, C*03:382, C*05:10^w, C*15:24
5	220 bp	1070 bp	*57:02:01-57:02:02, 57:04:01-57:04:03, 57:12-57:13, 57:19, 57:28N, 57:30, 57:42, 57:63 *07:227, C*06:72
6⁴	95 bp	1070 bp	*57:04:01-57:04:03, 57:32 *44:153
	180 bp		*57:06
	205 bp		*57:30
7⁴	105 bp	1070 bp	*57:15
	170 bp		*57:37
	295 bp		*57:55, 57:94
8⁴	90 bp	1070 bp	*57:16
	200 bp		*57:49
	250 bp		*57:07, 57:93, 57:119 *44:153
9⁵	170 bp	1070 bp	*57:09, 57:13, 57:22, 57:57, 57:63 *07:02:01:01-07:24, 07:26-07:47, 07:49N-07:50, 07:52-07:154, 07:156-07:163, 07:165-07:201N, 07:203-07:208, 07:210-07:219, 07:221-07:222, 07:224-07:225, 07:227-07:234, 07:236-07:260, 07:262-07:300, 07:302-07:331, 07:333-07:345, 07:347-07:358, 08:20:01-08:20:02, 08:53:01-08:53:02, 08:79, 08:156, 13:16, 13:20, 13:31, 13:48, 13:62, 13:128, 13:131, 14:01:01:01-14:40, 14:42, 14:44-14:55, 14:57-14:58, 14:60-14:68, 15:01:01:01-15:01:04, 15:01:06-15:04:04, 15:06-15:17:04, 15:17:06-15:19, 15:21:01:01-15:21:01:02, 15:23-15:30:01:02, 15:32:01-15:40:02, 15:42-15:47:02, 15:49-15:50,

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Lot No.: **1K8**

Lot-specific information

15:53-15:54, 15:56-15:58, 15:60-15:74,
15:76-15:82, 15:85, 15:87, 15:89-15:90,
15:92-15:99, 15:101-15:104, 15:106, 15:108-
15:110, 15:112-15:113, 15:115-15:122,
15:125-15:129, 15:131-15:135, 15:137-
15:144, 15:146-15:150, 15:152-15:154,
15:156-15:161, 15:163-15:175, 15:177-
15:178, 15:180-15:184, 15:187, 15:189-
15:199, 15:201-15:217, 15:219-15:221,
15:223, 15:225-15:234, 15:236, 15:238-
15:249, 15:251:01-15:274, 15:276-15:282,
15:284-15:311, 15:313-15:331, 15:333-
15:347, 15:349:01-15:382, 15:384-15:392,
15:394-15:395, 15:397-15:406, 15:408-
15:410, 15:412-15:414, 15:416-15:420,
15:422-15:448, 15:450-15:484, 15:486-
15:498, 15:500-15:506, 15:508-15:517,
15:519-15:520Q, 18:15, 18:19, 18:21, 18:30,
18:57:01-18:57:02, 18:101, 18:152, 18:164,
27:04:01-27:04:06, 27:06:01:01-27:06:01:02,
27:10, 27:15, 27:18, 27:20-27:21, 27:24-
27:25, 27:40, 27:54, 27:63, 27:66N, 27:68-
27:69, 27:79, 27:86, 27:91-27:92, 27:100,
27:103, 27:105-27:109, 27:112-27:115,
27:120, 27:138, 27:149, 27:153, 27:165,
27:168, 27:173, 27:183, 27:192, 35:11:01-
35:11:03, 35:14:01-35:14:03, 35:21,
35:43:01, 35:43:03-35:44, 35:58, 35:67,
35:79, 35:86, 35:96, 35:99, 35:102, 35:117-
35:118, 35:135, 35:167, 35:185, 35:188,
35:213, 35:232, 35:265, 35:277, 35:337:01-
35:337:02, 35:343, 35:384, 35:390N, 35:413,
37:07, 37:13, 38:10, 38:32, 39:18, 39:35-
39:36, 39:107, 40:05:01:01-40:05:01:02,
40:15-40:16, 40:23, 40:26, 40:28, 40:32,
40:51, 40:95, 40:98, 40:148, 40:158, 40:161,
40:174, 40:183, 40:198, 40:309, 40:355,
42:19, 44:76, 44:79:01-44:79:02, 44:146,
44:150, 46:01:01-46:05, 46:07N-46:08,
46:10, 46:12, 46:14-46:17, 46:20, 46:22-
46:24, 46:26-46:32, 46:34-46:42, 46:44-
46:76, 47:10, 48:05, 48:08, 48:15, 48:25,
49:01:01:01-49:10, 49:12-49:14, 49:16-
49:44, 49:46-49:54, 49:56-49:63,
50:01:01:01-50:02, 50:04-50:20, 50:31-
50:48, 50:50-50:63, 51:01:01:01-51:04:02,
51:06:01-51:07:02, 51:11N-51:14, 51:16-
51:18, 51:21-51:24:05, 51:26-51:30, 51:32-
51:39, 51:41N, 51:43, 51:45-51:46, 51:48-
51:52, 51:55-51:72, 51:74-51:80, 51:82-
51:92:02, 51:94-51:96, 51:98N-51:107,
51:109-51:114, 51:116-51:119, 51:121,
51:123-51:138, 51:140, 51:142-51:147,
51:149N-51:152, 51:154-51:156, 51:158:01-
51:180, 51:182-51:193, 51:195-51:216,
51:218-51:227, 51:229-51:258,

101.567-12 – including *Taq* pol., IFU-01
101.567-12u – without *Taq* pol., IFU-02

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“Instructions for Use” (IFU)

Lot No.: **1K8**

Lot-specific information

		51:260-51:262, 51:264N-51:273N, 51:277-51:279, 51:281, 52:01:01:01-52:01:32, 52:01:34-52:02:02, 52:04-52:09:02, 52:11-52:18, 52:20-52:27, 52:30-52:70, 52:72-52:73, 52:75-52:88, 53:06, 53:08:01-53:08:02, 53:28, 54:06, 54:20, 54:33, 55:01:01:01-55:01:18, 55:03, 55:05, 55:09, 55:11, 55:14-55:15, 55:17, 55:21, 55:24-55:25, 55:28-55:29, 55:31, 55:33, 55:36, 55:38, 55:40, 55:44-55:45, 55:52-55:53, 55:55N-55:56, 55:58-55:60, 55:64, 55:66, 55:68, 55:73-55:76, 55:78-55:79, 55:84-55:85, 55:87, 55:90-55:95, 55:97N-55:103, 56:03, 56:05:01-56:06, 56:21, 56:25, 56:32, 56:37, 56:66, 58:06, 58:08:01-58:08:02, 58:19, 58:46, 58:78, 58:91, 78:01:01:01-78:03, 78:05-78:07, 78:09		
10	210 bp	1070 bp	*57:08	*15:403
11	215 bp 250 bp	800 bp	*57:09, 57:24, 57:119 *57:14:01-57:14:02, 57:43	*08:181
12⁴	90 bp	1070 bp	*57:02:01-57:03:04, 57:07, 57:09, 57:12, 57:17, 57:39, 57:42, 57:46, 57:57, 57:63, 57:66, 57:70, 57:80, 57:84, 57:94, 57:96, 57:101	*08:181, 40:30, 40:34
13⁴	90 bp	800 bp	*57:01:01:01-57:04:01, 57:04:03-57:15, 57:17- 57:19, 57:21-57:35, 57:37-57:44, 57:46- 57:50, 57:52-57:61, 57:63-57:68, 57:70- 57:88, 57:90-57:108, 57:110-57:119	*15:462, 58:36
14	135 bp 195 bp	1070 bp	*57:17 *57:10	*44:189, C*07:239 *07:219
15^{4,6}	110 bp 145 bp	800 bp	*57:29, 57:33 *57:11	*14:61, 15:214, 18:81, 35:250, 39:145, 40:427, 44:311, 51:165 *14:01:01:01-14:02:08, 14:02:10-14:04, 14:07N, 14:09, 14:11-14:12, 14:14-14:36, 14:38-14:52, 14:54, 14:57-14:68, 15:510, 18:44:01-18:44:02, 39:79, 50:51, 54:38, 58:02:01-58:02:02, 58:06-58:07, 58:25, 58:38, 58:43, 58:60, 58:104, C*01:32:01- 01:32:02, C*06:20, C*14:82, C*16:98, C*16:102, C*16:110
16⁴	85 bp 160 bp	1070 bp	*57:12 *57:18	*08:119, 14:24, 35:226, 39:92, 58:64
17	140 bp 210 bp	1070 bp	*57:13, 57:31 *57:13, 57:22, 57:27, 57:57, 57:63	*07:227, 08:181, 40:30, 40:34, C*06:72 *07:227, 55:14, C*06:72^w
18	165 bp	1070 bp	*57:23	

101.567-12 – including *Taq* pol., IFU-01
101.567-12u – without *Taq* pol., IFU-02

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“Instructions for Use” (IFU)

Lot No.: **1K8**

Lot-specific information

Lot No.: 1K8		Lot-specific information		
19⁴	90 bp	1070 bp	*57:04:01-57:04:03, 57:41	*44:153, C*06:72
	240 bp		*57:13, 57:25, 57:43	*07:227, 40:30, 40:34
20⁴	90 bp	1070 bp	*57:20	*08:181, 55:14, C*06:72
	240 bp		*57:26	
21⁴	120 bp	1070 bp	*57:33, 57:98Q	*35:127, 50:54, 55:100
	150 bp		*57:21	
22⁴	95 bp	800 bp	*57:34	*58:54
	140 bp		*57:40, 57:98Q	*14:20, 15:461, 44:317
23^{4,7}	75 bp	1070 bp	*57:35	*13:02:06, 13:26:01, 13:72, 13:127, 15:16:03, 15:20, 15:85, 15:194, 15:393, 15:407, 35:46, 35:207, 46:01:07, 46:33, 58:36, C*01:73
	100 bp		*57:36	
	465 bp		*57:05, 57:67:01	
24	230 bp	1070 bp	*57:77	*44:36, A*03:174, A*11:65, A*24:247, C*01:170, C*04:83
	270 bp		*57:40	*15:461, 40:284, 44:317, C*07:511, C*15:121
25	235 bp	1070 bp	*57:44	*44:249, A*32:29
26	155 bp	1070 bp	*57:58, 57:80	*07:219, 58:12, A*02:42:01-02:42:02, A*02:310
27	235 bp	1070 bp	*57:61	
28	200 bp	1070 bp	*57:39, 57:51, 57:73	*58:41
29	150 bp	1070 bp	*57:78	*15:340, 35:300, 40:218, 44:307, 45:21, 46:28, 51:58, 52:82, 58:83
30	175 bp	1070 bp	*57:79N	
31	390 bp	1070 bp	*57:01:01:01-57:04:03, 57:06-57:32, 57:34- 57:47, 57:49-57:66, 57:67:02-57:76, 57:78- 57:84, 57:86-57:109, 57:111-57:120	*07:219, 15:16:01:01-15:16:02, 15:17:01:01- 15:17:07, 15:67, 15:95, 15:162, 15:168, 15:177, 15:196, 15:208, 15:216, 15:222, 15:230, 15:254, 15:268, 15:273, 15:356, 15:361-15:362, 15:396, 15:403, 15:408, 15:411, 15:423-15:424, 15:446, 15:462, 15:500, 15:516, 58:08:01-58:08:02, 58:20, 58:27-58:28:01, 58:59:02, 58:73
32⁸	-	-	Negative Control	

¹Alleles are assigned by the presence of specific PCR product(s). However, the sizes of the specific PCR products may be helpful in the interpretation of HLA-B*57 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.

²The 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

101.567-12 – including *Taq* pol., IFU-01
101.567-12u – without *Taq* pol., IFU-02

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“Instructions for Use” (IFU)

Lot No.: 1K8

Lot-specific information

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.

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

³For 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. Assumptions is made that unknown sequences in these regions are conserved within allelic groups.

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

⁵Primer mix 9 may have tendencies of unspecific amplifications.

⁶Primer mix 15 has a tendency to giving rise to primer oligomer formation.

⁷Primer mix 23 may give rise to a lower yield of HLA-specific PCR product than the other HLA-B*57 resolution primer mixes.

⁸Primer mix 32 contains a negative control, which will amplify a 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.

101.567-12 – including *Taq* pol., IFU-01
101.567-12u – without *Taq* pol., IFU-02

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Lot No.: **1K8**

Lot-specific information
PRIMER SPECIFICATION

Well No.	1	2	3	4	5	6	7	8	9	10	11	12
Length of spec. PCR product	150	100	220	100	220	95	105	90	170	210	215	90
						180	170	200			250	
						205	295	250				
Length of int. pos. control ¹	800	1070	1070	800	1070	1070	1070	1070	1070	1070	800	1070
5'-primer(s) ²	355	362	362	355	362	362	209	97	527	320	362	362
	5'-TCA 3'	5'-ggT 3'	5'-ggT 3'	5'-TCA 3'	5'-ggT 3'	5'-ggT 3'	5'-ggC 3'	5'-TCg 3'	5'-TgA 3'	5'-CCC 3'	5'-ggT 3'	5'-ggT 3'
							757	209				
							5'-CCA 3'	5'-ggA 3'				
							878	362				
							5'-gCA 3'	5'-ggT 3'				
3'-primer(s) ³	463	419	539	412	539	418	271	256	3 rd I	2 nd I	538	412
	5'-gCT 3'	5'-Cgg 3'	5'-TCA 3'	5'-gTT 3'	5'-TCC 3'	5'-gTC 3'	5'-CAC 3'	5'-CCC 3'	5'-TAT 3'	5'-TCg 3'	5'-gTC 3'	5'-gTT 3'
		419				500	916	572			559	
		5'-CAg 3'				5'-ggA 3'	5'-gAC 3'	5'-gCg 3'			5'-Cgg 3'	
						527					583	
						5'-CCg 3'					5'-gTg 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. PCR product	90	135	110	85	140	165	90	90	120	95	75	230
		195	145	160	210		240	240	150	140	100	270
											465	
Length of int. pos. control ¹	800	1070	800	1070	1070	1070	1070	1070	1070	800	1070	1070
5'-primer(s) ²	209	103	361	256	362	130	362	209	352	200	209	353
	5'-ggC 3'	5'-CCT 3'	5'-AgT 3'	5'-ACg 3'	5'-ggT 3'	5'-AgT 3'	5'-ggT 3'	5'-ggC 3'	5'-ACg 3'	5'-TCg 3'	5'-ggC 3'	5'-CAA 3'
		446	392	362				362	373	353		395
		5'-CgA 3'	5'-CgA 3'	5'-ggT 3'				5'-ggT 3'	5'-gCg 3'	5'-CAA 3'		5'-gCT 3'
			704						392	373		
			5'-TgT 3'						5'-CgA 3'	5'-gCg 3'		
3'-primer(s) ³	256	256	463	302	463	256	409	259	463	256	244	583
	5'-CCC 3'	5'-CCC 3'	5'-gCT 3'	5'-ggC 3'	5'-gCg 3'	5'-CCC 3'	5'-ATA 3'	5'-CTT 3'	5'-gCT 3'	5'-CCC 3'	5'-CTT 3'	5'-gTA 3'
		539	774	481	527		559	559		463	268	
		5'-TCA 3'	5'-ggT 3'	5'-gTA 3'	5'-CCT 3'		5'-CTC 3'	5'-CgT 3'		5'-gCT 3'	5'-gTg 3'	
					537		559				387	
					5'-Agg 3'		5'-Cgg 3'				5'-TCg 3'	
Well No.	13	14	15	16	17	18	19	20	21	22	23	24

101.567-12 – including *Taq* pol., IFU-01
101.567-12u – without *Taq* pol., IFU-02

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“Instructions for Use” (IFU)

Lot No.: **1K8**

Lot-specific information

Well No.	25	26	27	28	29	30	31
Length of spec. PCR product	235	155	235	200	150	175	390
Length of int. pos. control¹	1070	1070	1070	1070	1070	1070	1070
5'-primer(s)²	122	142	362	97	106	877	281
	5' -CCT 3'	5' -TCT 3'	5' -ggT 3'	5' -TCC 3'	5' -CCA 3'	5' -.AC 3'	5' -CTC 3'
3'-primer(s)³	317	256	554	256	214	916	387
	5' -ggA 3'	5' -CCC 3'	5' -CCC 3'	5' -CCC 3'	5' -CCA 3'	5' -gAC 3'	5' -TCC 3'
Well No.	25	26	27	28	29	30	31

¹The 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.

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.

101.567-12 – including *Taq* pol., IFU-01
101.567-12u – without *Taq* pol., IFU-02

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“Instructions for Use” (IFU)

Lot No.: **1K8**

Lot-specific information

CELL LINE VALIDATION SHEET																				
HLA-B*57 SSP subtyping kit²																				
				Well																
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	
				Prod. No.:	201909001	201909002	201909003	201909004	201909005	201909006	201909007	201909008	201909009	201909010	201909011	201909012	201909013	201909014	201909015	201909016
IHWC cell line ¹		B*																		
1	9001	SA	*07:02	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-
2	9280	LK707	*52:01	*73:01	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-
3	9011	E4181324	*52:01		-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-
4	9275	GU373	*15:10	*53:01	+	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-
5	9009	KAS011	*37:01		+	-	-	W	-	-	-	-	-	-	-	-	-	-	-	-
6	9353	SM	*39:01	*51:01	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-
7	9020	QBL	*18:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
8	9025	DEU	*35:01		+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
9	9026	YAR	*38:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
10	9107	LKT3	*54:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
11	9051	PITOUT	*44:03		+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
12	9052	DBB	*57:01		+	+	+	-	-	-	-	-	-	-	-	+	-	-	-	-
13	9004	JESTHOM	*27:05		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
14	9071	OLGA	*15:01	*15:20	+	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-
15	9075	DKB	*40:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
16	9037	SWEIG007	*40:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
17	9282	CTM3953540	*08:01	*55:01	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-
18	9257	32367	*14:01	*56:01	-	-	-	-	-	-	-	+	-	-	-	-	-	-	+	-
19	9038	BM16	*18:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
20	9059	SLE005	*40:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
21	9064	AMALA	*15:01		-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-
22	9056	KOSE	*35:03		+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
23	9124	IHL	*40:02	*56:02	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
24	9035	JBUSH	*38:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
25	9049	IBW9	*14:02		-	-	-	-	-	-	-	+	-	-	-	-	-	-	+	-
26	9285	WT49	*58:01		+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
27	9191	CH1007	*07:05	*51:01	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-
28	9320	BEL5GB	*44:02	*44:03	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
29	9050	MOU	*44:03		+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
30	9021	RSH	*42:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
31	9019	DUCAF	*18:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
32	9297	HAG	*41:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
33	9098	MT14B	*40:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
34	9104	DHIF	*38:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
35	9302	SSTO	*44:02		+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
36	9024	KT17	*15:01	*35:01	+	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-
37	9065	HHKB	*07:02		-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-
38	9099	LZL	*15:01		-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-
39	9315	CML	*08:01	*27:05	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
40	9134	WHONP199	*13:02	*46:01	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-
41	9055	H0301	*14:02		-	-	-	-	-	-	-	+	-	-	-	-	-	-	+	-
42	9066	TAB089	*46:01		-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-
43	9076	T7526	*46:01		-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-
44	9057	TEM	*38:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
45	9239	SHJO	*42:01	*50:01	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-
46	9013	SCHU	*07:02		-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-
47	9045	TUBO	*51:01		-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-
48	9303	TER-ND	*35:01	*44:03	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

101.567-12 – including *Taq* pol., IFU-01
101.567-12u – without *Taq* pol., IFU-02

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Lot No.: **1K8**

Lot-specific information

CELL LINE VALIDATION SHEET																				
HLA-B*57 SSP subtyping kit ²																				
				Well																
				17	18	19	20	21	22	23	24	25	26	27	28	29	30	31		
				Prod. No.:	201909017	201909018	201909019	201909020	201909021	201909022	201909023	201909024	201909025	201909026	201909027	201909028	201909029	201909030	201909031	
IHC cell line ¹		B*																		
1	9001 SA	*07:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
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 SM	*39:01	*51:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
7	9020 QBL	*18:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
8	9025 DEU	*35:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
9	9026 YAR	*38:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
10	9107 LKT3	*54:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
11	9051 PITOUT	*44:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
12	9052 DBB	*57:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	
13	9004 JESTHOM	*27:05		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
14	9071 OLGA	*15:01	*15:20	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-	-	
15	9075 DKB	*40:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
16	9037 SWEIG007	*40:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
17	9282 CTM3953540	*08:01	*55:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
18	9257 32367	*14:01	*56:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
19	9038 BM16	*18:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
20	9059 SLE005	*40:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
21	9064 AMALA	*15:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
22	9056 KOSE	*35:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
23	9124 IHL	*40:02	*56:02	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
24	9035 JBUSH	*38:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
25	9049 IBW9	*14:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
26	9285 WT49	*58:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
27	9191 CH1007	*07:05	*51:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
28	9320 BEL5GB	*44:02	*44:03	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
29	9050 MOU	*44:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
30	9021 RSH	*42:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
31	9019 DUCAF	*18:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
32	9297 HAG	*41:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
33	9098 MT14B	*40:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
34	9104 DHIF	*38:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
35	9302 SSTO	*44:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
36	9024 KT17	*15:01	*35:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
37	9065 HHKB	*07:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
38	9099 LZL	*15:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
39	9315 CML	*08:01	*27:05	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
40	9134 WHONP199	*13:02	*46:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
41	9055 H0301	*14:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
42	9066 TAB089	*46:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
43	9076 T7526	*46:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
44	9057 TEM	*38:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
45	9239 SHJO	*42:01	*50:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
46	9013 SCHU	*07:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
47	9045 TUBO	*51:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
48	9303 TER-ND	*35:01	*44:03	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	

101.567-12 – including Taq pol., IFU-01
101.567-12u – without Taq pol., IFU-02

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

Lot No.: 1K8

Lot-specific information

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

²The specificity of each primer solution in the kit has been tested against 48 well characterized cell line DNAs and where applicable, additional cell line DNAs.

No DNAs carrying the alleles to be amplified by primer solutions 6 to 8, 11, 14, 16 to 22 and 24 to 30 were available. The specificities of the primers in primer solutions 6 to 8, 11, 14, 16, 17, 19, 20, 26 and 28 were tested by separately adding additional 5'-primers, respectively additional 3'-primers. In primer solutions 27 and 29 it was only possible to test the 5'-primer, the 3'-primer was not possible to test. In primer solutions 18, 21, 22, 24, 25 and 30 it was only possible to test the 3'-primers, the 5'-primers were not possible to test. In primer solutions 2, 6, 7, 11, 16, 17, 19, 20 and 23 one or two of the 3'-primers were not possible to test, and in primer solutions 7, 8, 14 and 15 one or two of the 5'-primers were not possible to test. One additional 3'-primer in primer solution 15 was tested by separately adding one 5'-primer.

101.567-12 – including *Taq* pol., IFU-01
101.567-12u – without *Taq* pol., IFU-02

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Lot No.: **1K8**

Lot-specific information

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