

101.501.48/12 – including *Taq* pol., IFU-01
 101.501.48u/12u – without *Taq* pol., IFU-02

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 “Instructions for Use” (IFU)

Lot No.: **03N**

Lot-specific information

Olerup SSP[®] HLA-B low resolution

Product number:	101.501-48/12 – including <i>Taq</i> pol. 101.501-48u/12u – without <i>Taq</i> pol.
Lot number:	03N
Expiry date:	2014-June-01
Number of tests:	48 tests – Product No. 101.501-48/48u 12 tests – Product No. 101.501-12/12u
Number of wells per test:	63 + 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. 03N.

CHANGES COMPARED TO THE PREVIOUS *OLERUP SSP*[®] HLA-B LOW RESOLUTION LOT

Sixteen wells have been added to the HLA-B low kit, wells **49 to 64**.

The Lot-specific information for HLA B low resolution including and without *Taq* polymerase is now described in one common Product Insert.

The HLA-B low resolution specificity and interpretation tables have been updated for the HLA-B alleles reported since the previous *Olerup SSP*[®] HLA-B low resolution lot (**Lot No. 98M**) was made.

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

Well	5'-primer	3'-primer	rationale
9	Moved	Moved	Primer pair moved to well 49, for improved resolution.
48	Moved, added	Moved, added	Negative control moved to well 64, primer pair added for improved resolution.
49	New, modified	New	Primer pair from well 9, modified 5'-primer for improved specificity and yield.
50	New	New	Improved resolution of B*18 and B*35 alleles.
51	New	New	Improved resolution of B*18 and B*35 alleles, and of B*14 and B*39 alleles.

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52	New	New	Resolution of the heterozygous ambiguity B*35:01:01,51:01:02=53:01:01,78:02:01.
53	New	New	Improved resolution of B*54 alleles.
54	New	New	Improved resolution of B*44 alleles and of B*37 alleles.
55	New	New	Improved resolution of B*51 and B*52 alleles, and of the B*44:02 allele.
56	New	New	Improved resolution of B*42 alleles.
57	New	New	Improved resolution of B*55 alleles.
58	New	New	Improved allelic resolution.
59	New	New	Improved resolution of B*51 and B*52 alleles.
60	New	New	Improved resolution of B*13 and B*58 alleles.
61	New	New	Improved resolution of B*15 and B*46 alleles.
62	New	New	Improved allelic resolution.
63	New	New	Improved resolution of B*14 and B*39 alleles.
64	Moved	Moved	Negative control, from well 48.

Changes in revision R01 compared to R00:

1. A footnote in the Specificity table, by mistake put on primer mix 20, has been removed.

Changes in revision R02 compared to R01:

1. Primer mix 54 may give rise to an HLA-specific PCR product of 650 bp, in addition to products of 150 and 260 bp. This has been corrected in the Specificity and Interpretation tables.

Changes in revision R03 compared to R02:

1. Primer mix 19 does not amplify the B*15:101 allele. This has been corrected in the Specificity and Interpretation tables.

Changes in revision R04 compared to R03:

1. Primer mix 19 does not amplify the B*44:10 allele. This has been corrected in the Specificity and Interpretation Tables.

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Well **64** contains Negative Control primer pairs, that will amplify more than 95% of the *Olerup SSP*[®] HLA Class I, DRB, DQB1 and DPB1 amplicons as well as amplicons generated by a control primer pair.

PCR product sizes range from 75 to 430 base pairs.

The PCR product generated by the control primer pair is 430 base pairs.

Length of PCR product	105	200	105	80	75	80
5'-primer¹	164	340	440	45	45	43
	⁵ -CAC ³	⁵ -Agg ³	⁵ -TTA ³	⁵ -Tgg ³	⁵ -Tgg ³	⁵ -Tgg ³
3'-primer²	231	2nd I	507	59	58	57
	⁵ -TgC ³	⁵ -AAA ³	⁵ -TTg ³	⁵ -CTC ³	⁵ -ggC ³	⁵ -CTC ³
A*	+	+	+			
B*	+	+	+			
C*	+	+	+			
DRB1				+	+	
DRB3				+	+	
DRB5				+		
DQB1					+	
DPB1						+

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 low resolution SSP typing

CONTENT

The primer set contains 5'- and 3'-primers for grouping the B*07:02 to B*83:01 alleles into the corresponding serological groups B7 to B81 as well as primer pairs for recognizing the Bw4 and Bw6 sequence motifs.

PLATE LAYOUT

Each test consists of 64 PCR reactions in a 64 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	32
33	34	35	36	37	38	39	40
41	42	43	44	45	46	47	48
49	50	51	52	53	54	55	56
57	58	59	60	61	62	63	64

Wells 1 to 63 – HLA-B low resolution primers.

Well 64 – Negative Control.

The 64 well cut PCR plate is marked with ‘HLA-B low’ in silver/gray ink.

Well No. 1 is marked with the Lot No. ‘03N’.

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.

INTERPRETATION

Only HLA-B alleles will be amplified by the HLA-B low resolution typing kit, except that primer mix 1 will amplify the C*02:23 and C*04:77 alleles, primer mix 3 will amplify the C*03:05, C*03:25 and C*03:27 alleles, primer mix 4 will amplify the C*01:30 allele, primer mix 6 will amplify the A*23:31, A*24:106 and C*16:10 alleles, primer mix 8 will amplify the C*07:46 allele, primer mix 13 will amplify the A*24:174 allele, primer mix 17 will amplify the C*03:102 allele, primer mix 21 will amplify the C*15:51 allele, primer mix 25 will amplify the C*03:129 allele, primer mix 29 will amplify the C*15:25 allele, primer mix 31 will amplify the C*15:39 allele, primer mix 40 will amplify the C*15:02:04 allele, primer mix 41 will amplify the C*03:12, C*03:19 and C*03:102 alleles, primer mix 43 will weakly amplify the C*02:06 and C*02:47 alleles, primer mix 45 will amplify the A*26:68, A*68:56, C*06:20 and C*12:50 alleles, primer mix 50 will amplify the C*08:51 allele, primer mix 52 will amplify the A*24:146 allele, primer mix 53 will amplify the C*05:30 allele, primer mix 54 will amplify the C*15:25 allele and primer mix 57 will amplify the C*07:46 allele.

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Thus, the interpretation of HLA-B low resolution typings is only influenced by these six HLA-A alleles and 22 HLA-C alleles, and not by other alleles of other HLA class I genes.

UNIQUELY IDENTIFIED ALLELES

All the HLA-B alleles recognized by the HLA Nomenclature Committee in October 2011¹ will be amplified by the primers in the HLA-B low resolution SSP kit. The HLA-B alleles will be grouped into their corresponding serological specificities^{2,3}.

¹HLA-B alleles listed on the IMGT/HLA web page 2011-October-10, release 3.6.0, www.ebi.ac.uk/imgt/hla.

²It is not possible to identify all serological splits and combinations of the B15 group of alleles, as the serological reactivity of several of the B*15 alleles is not known.

The resolution has been updated to fulfill the NMDP medium resolution confirmatory typing requirements effective from February 1st 2001.

DNA-based HLA-B typing resolution required:

B*07:xx, B*08:xx, B*13:xx, B*14:xx, B*18:xx, B*27:xx, B*15:22, B*35:xx, B*37:xx, B*38:xx, B*39:xx, B*40:05, B*41:xx, B*42:xx, B*44:xx, B*45:xx, B*46:xx, B*47:xx, B*48:xx, B*49:xx, B*50:xx, B*51:xx, B*52:xx, B*53:xx, B*54:xx, B*55:xx, B*56:xx, B*57:xx, B*58:xx, B*59:xx, B*67:xx, B*73:xx, B*78:xx, B*81:xx, B*82:xx,

B*40EJD^a 40:01, 40:07, 40:10, 40:12, 40:14, 40:15, 40:16

B*40EJB^b 40:02, 40:03, 40:04, 40:06, 40:08, 40:09, 40:11, 40:13,
40:18, 40:19, 40:20

B*15EJA^c 15:01, 15:04, 15:05, 15:06, 15:07, 15:20, 15:24, 15:25,
15:26N, 15:27, 15:28, 15:30, 15:32, 15:33, 15:34, 15:35,
15:36, 15:38, 15:39, 15:40, 15:43, 15:45

B*15AHM^d 15:16, 15:17

B*15EHZ^e 15:03, 15:09, 15:10, 15:18, 15:23, 15:29, 15:37, 15:47

B*15CYP^f 15:02, 15:08, 15:11, 15:15, 15:21, 15:31, 15:44

B*15AND^g 15:12, 15:14, 15:19

B*1513^h

^aB60 serologic equivalent cluster.

^bB61 serologic equivalent cluster.

^cB62 serologic equivalent cluster.

^dB63 serologic equivalent cluster.

^eB70 serologic equivalent cluster.

^fB75 serologic equivalent cluster.

^gB76 serologic equivalent cluster.

^hB77 serologic equivalent cluster.

³The B*55:23 and 55:32 and the B*56:18 and 56:32 alleles give rise to identical amplification patterns with the HLA-B low resolution primer set. These alleles can be separated by the respective high resolution primer sets.

The B*57:01:01-57:01:04, 57:01:06-57:01:12, 57:06, 57:08, 57:10, 57:15-57:16, 57:18-57:20, 57:22-57:23, 57:25-57:27, 57:29-57:30, 57:33-57:38, 57:40, 57:43-57:44, 57:48-57:50 and 57:52 and the B*58:36 alleles give rise to identical amplification patterns with the HLA-B low resolution primer set. These alleles can be separated by the respective high resolution primer sets.

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SPECIFICITY TABLE

HLA-B low resolution SSP typing

Specificities and sizes of the PCR products of the 63+1 primer mixes used for HLA-B low resolution SSP typing

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	HLA-B serol. ³	Amplified HLA-B alleles ^{4,5}
1^{6,10}	110 bp	800 bp	7, 703, 40, 41, 42, 48, 61	*07:02:01-07:18:02, 07:20-07:32, 07:34-07:39, 07:41-07:47, 07:49N-07:50, 07:52, 07:54-07:59, 07:61-07:99, 07:101-07:121, 07:123-07:138, 07:140-07:143, 15:138, 15:230, 37:07, 40:15-40:16, 40:23, 40:32, 40:98, 40:136, 40:158, 41:08, 42:05:01-42:05:02, 48:05, 48:08, 48:15, C*02:23, C*04:77
2	215 bp	1070 bp	8, 44	*08:01:01-08:05, 08:07-08:25, 08:27-08:49, 08:51-08:61, 08:63-08:64, 08:66-08:78, 15:142, 15:180, 44:49, 51:68
3	140 bp, 235 bp	1070 bp	7, 8, 13, 15, 35, 4005, 44, 49, 61, 62, 77	*07:20, 07:24, 07:60, 07:100, 07:131, 08:21, 08:25, 13:01:01-13:04, 13:06-13:08Q, 13:10-13:23, 13:25-13:38, 13:40-13:52, 15:07:01-15:07:02, 15:36 ^w , 15:45, 15:55, 15:68, 15:89 ^w , 15:126, 15:205, 15:207, 35:05:01-35:05:02, 35:16-35:17, 35:22, 35:30, 35:51, 35:58, 35:72, 35:89, 35:97, 35:113-35:114, 35:125, 35:164, 40:05, 40:71, 40:174, 44:08 ^w , 44:54, 44:57 ^w , 44:60, 44:106, 44:110, 44:135, 46:12, 46:20, 51:64, 53:14, 55:51, 58:18, C*03:05, C*03:25, C*03:27
4^{7,8}	130 bp, 265 bp	800 bp	12, 13, 14, 17, 21, 35, 40, 41, 44, 45, 47, 49, 50, 60, 61, 64, 65	*13:01:01-13:04, 13:06-13:13, 13:15-13:23, 13:25-13:52, 14:01:01-14:04, 14:07N, 14:09, 14:11-14:12, 14:14-14:28, 15:46, 15:53, 15:106, 15:212, 18:44, 35:46-35:47, 35:63, 35:154, 40:01:01-40:01:23, 40:07, 40:10:01-40:10:02, 40:14:01-40:16, 40:22N-40:23, 40:25, 40:30-40:34, 40:36, 40:38, 40:42-40:43, 40:45, 40:47-40:49, 40:51-40:55, 40:58-40:63, 40:65-40:67, 40:69, 40:72:01-40:73, 40:76-40:77, 40:79-40:81, 40:84, 40:87:01-40:88, 40:92, 40:100-40:102, 40:106, 40:108, 40:110, 40:112-40:114, 40:116-40:118N, 40:121, 40:123-40:126, 40:128-40:130, 40:132, 40:134-40:136, 40:139-40:141, 40:146-40:147, 40:150-40:156, 40:158, 40:160, 40:163-40:164, 40:166, 40:168, 40:171-40:172, 40:175, 41:01-41:19, 44:02:01:01-44:03:06, 44:03:08-44:05:03, 44:09-44:39, 44:41:01-44:43:02, 44:45-44:56N, 44:58N-44:80, 44:82, 44:84-44:102, 44:104-44:110, 44:112-44:129, 44:132-44:133, 44:135-44:137, 45:01-45:13, 47:01:01:01-47:08,

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5⁸	185 bp, 235 bp	800 bp	7, 16, 17, 27, 2708, 37, 38, 3901, 3902, 39, 64, 67	49:01:01-49:02, 49:04-49:20, 50:01:01-50:02, 50:04-50:06, 50:08-50:15, 57:45, 57:51, C*01:30 *14:01:01-14:01:02, 14:07N-14:08, 14:10, 14:12, 14:14, 14:19, 14:26, 27:01-27:05:15, 27:05:17-27:06, 27:08-27:10, 27:12-27:13, 27:16-27:18, 27:20, 27:23, 27:26-27:27, 27:29, 27:31, 27:35-27:37, 27:39-27:42, 27:44-27:46, 27:48-27:61, 27:64N-27:69, 27:72-27:75, 27:77-27:80, 27:82-27:86, 37:02, 38:01:01-38:02:02, 38:03, 38:07-38:24, 38:26-38:32, 38:34N-38:37, 39:01:01:01-39:01:01:02L, 39:01:03-39:01:08, 39:01:10-39:02:01, 39:03, 39:05:01-39:09, 39:11, 39:14-39:15, 39:18, 39:19:02, 39:22, 39:24:01-39:44, 39:46-39:48, 39:50-39:62, 39:64-39:68, 47:04-47:05, 48:21, 48:26, 67:01:01, 67:03
6	190 bp	800 bp	14, 35, 38, 39, 65	*07:28, 14:02:01-14:02:02, 14:02:04-14:02:05, 14:03-14:06:02, 14:09, 14:11, 14:13, 14:15-14:18, 14:20, 14:22-14:23, 14:25, 14:27, 15:77, 15:189, 15:233, 35:26, 38:05, 38:33, 39:04, 44:16, 44:37, 44:64:01-44:64:02, 44:91, 44:132, 52:26, 57:04, A*23:31, A*24:106, C*16:10
7	290 bp	1070 bp	15, 22, 62, 63, 71, 72, 75, 76, 77, 46	*15:01:01:01-15:01:03, 15:01:06-15:02:05, 15:03:03-15:08, 15:10:02-15:11:03, 15:11:05-15:15, 15:17:01:01-15:17:02, 15:19-15:21, 15:24-15:28, 15:30-15:36, 15:38:01-15:40, 15:42-15:46, 15:48, 15:50, 15:55-15:58, 15:60, 15:63, 15:65-15:66, 15:70-15:71, 15:73, 15:75-15:79N, 15:81-15:89, 15:92, 15:94N, 15:96-15:97, 15:101-15:102, 15:104-15:107, 15:109-15:113, 15:116-15:118, 15:120-15:122, 15:125-15:126, 15:128-15:129, 15:135-15:150, 15:152, 15:154-15:155, 15:157, 15:159-15:160, 15:162-15:172, 15:174-15:175, 15:177-15:179, 15:181N-15:185, 15:187-15:196, 15:199, 15:201-15:209N, 15:211, 15:213-15:219, 15:223-15:225, 15:227-15:228, 15:230-15:234, 15:236, 46:01:01-46:30
8	165 bp, 220 bp, 330 bp	1070 bp	5, 8, 12, 21, 22, 37, 41, 42, 44, 45, 48, 51, 56, 57, 60, 62, 70, 71, 72, 82	*08:01:01-08:05, 08:08N-08:12:03, 08:15-08:19N, 08:21-08:24, 08:26-08:27, 08:29-08:36, 08:38-08:39, 08:41-08:48, 08:50-08:54, 08:56-08:69, 08:71-08:73, 08:75-08:76, 08:78, 13:46, 15:03:01-15:03:03, 15:09-15:10:02, 15:18:01-15:18:04, 15:23, 15:29, 15:37, 15:46-15:47, 15:49, 15:51-15:54, 15:61-15:62, 15:64, 15:69, 15:72, 15:74, 15:80, 15:83, 15:90-15:91, 15:93, 15:98-15:99, 15:103, 15:106, 15:108, 15:114-15:115, 15:119, 15:123-15:124, 15:127, 15:131-15:134, 15:143, 15:151, 15:153, 15:156, 15:158, 15:161, 15:173, 15:176, 15:186, 15:197-15:198, 15:200, 15:210, 15:212, 15:220-15:221, 15:226N,

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9	390 bp	1070 bp	63	*15:16:01-15:17:02, 15:67, 15:95, 15:162, 15:168, 15:177, 15:196, 15:208, 15:216, 15:222, 15:230
10	180 bp	800 bp	13, 22, 55, 60	*07:78, 13:01:01-13:02:12, 13:07N-13:09, 13:11, 13:14-13:20, 13:22:01-13:23, 13:25, 13:27-13:34, 13:36-13:45, 13:47, 13:49N-13:50, 13:52, 40:48, 45:10, 49:07, 55:09, 55:22, 55:24
11⁶	105 bp, 195 bp	1070 bp	8, 12, 27, 38, 39, 3902, 40, 44, 45, 48, 60, 70, 71, 72, 82	*07:27, 07:50, 08:04, 08:17, 08:54, 15:03:01- 15:03:03, 15:47, 15:49, 15:54, 15:61-15:62, 15:64, 15:68-15:69, 15:91, 15:98, 15:103, 15:123, 15:127, 15:131-15:132, 15:151, 15:156, 15:158, 15:173, 15:210, 15:220, 15:235, 18:37, 27:18, 27:29, 37:28, 38:03, 39:02:01-39:02:02, 39:08, 39:13:01-39:13:02, 39:23, 39:39, 39:49, 40:12, 40:46, 40:93, 42:11, 44:10, 44:15, 44:18, 44:40, 44:44, 44:130, 45:01, 45:05-45:07, 45:11-45:13, 48:01:01-48:05, 48:07- 48:27, 49:20, 50:02, 52:16, 55:18, 82:01-82:03
12	280 bp	1070 bp	5, 7, 8, 13, 15, 16, 17, 18, 22, 35, 40, 42, 44, 46, 48, 49, 51, 53, 55, 56, 57, 58, 60, 61, 62, 63, 70, 71, 72, 75, 76, 77, 78	*07:09, 07:11, 07:17, 08:28, 08:35, 08:37, 13:04, 13:10, 13:26, 15:01:01:01-15:01:04, 15:01:06-15:08, 15:11:01-15:16:03, 15:18:01-15:21, 15:23-15:29, 15:31-15:36, 15:38:01-15:40, 15:43-15:44, 15:46- 15:47, 15:49-15:57, 15:60-15:62, 15:64-15:72, 15:74- 15:76, 15:78:01-15:82, 15:84-15:85, 15:87-15:89, 15:91-15:98, 15:101-15:129, 15:131-15:132, 15:134- 15:136, 15:138-15:149N, 15:151-15:161, 15:163- 15:167, 15:169-15:176, 15:178-15:187, 15:189- 15:195, 15:197-15:207, 15:209N-15:215, 15:217- 15:223, 15:225-15:228, 15:231-15:232, 15:234- 15:236, 18:01:01-18:15, 18:17N-18:25, 18:27-18:40, 18:42-18:60, 18:62-18:68, 27:41, 35:01:01:01- 35:01:29, 35:05:01-35:05:02, 35:07-35:08:05, 35:10- 35:11:02, 35:14:01-35:17, 35:19-35:21, 35:23-35:30, 35:32:01-35:32:02, 35:35, 35:37, 35:40N-35:43:01, 35:45-35:54, 35:57-35:58, 35:61-35:64, 35:66-35:69, 35:71-35:72, 35:76-35:80, 35:82, 35:86, 35:89-35:94, 35:97, 35:99-35:105, 35:107-35:108:02, 35:110- 35:126, 35:130N-35:135, 35:137-35:148, 35:158- 35:159, 35:161, 35:165N-35:166, 35:168, 35:170- 35:171, 35:173N-35:178, 35:180, 35:43:02, 35:186, 39:07, 39:43, 40:03, 40:20, 40:38, 40:52, 40:59- 40:60, 40:105, 40:158-40:159, 42:09, 44:17,

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41	180 bp	1070 bp	12, 15, 21, 22, 44, 45, 49, 50, 51, 56, 61, 62,	*13:03, 13:48, 15:73, 40:71, 44:10, 44:15, 44:18, 45:01, 45:04-45:07, 45:11-45:13, 46:11, 49:01:01-49:03, 49:06, 49:08-49:17, 49:19N-49:20, 50:01:01-50:02, 50:04-50:08, 50:10-50:13, 50:15, 51:15,

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42^{6,10}	90 bp, 240 bp	800 bp	57	*55:14, 57:01:01-57:44, 57:46-57:50, 57:52, 58:36
43^{6,12}	90 bp	1070 bp	5, 13, 15, 17, 39, 55, 56, 58, 60, 61, 62, 71	*13:11, 15:18:03, 15:73, 15:224, 39:17, 40:48, 40:71, 51:62, 52:25, 56:02, 56:04, 56:10, 58:01:01-58:02, 58:04-58:35, C*02:06^w, C*02:47^w
44⁶	95 bp	1070 bp	8, 18, 22, 35, 37, 38, 39, 44, 51, 5102, 5103, 53, 78	*07:65 ^w , 07:134 ^w , 08:32, 18:01:01-18:11, 18:13-18:15, 18:17N-18:36, 18:38-18:47, 18:49-18:65, 18:67-18:68, 35:01:01:01-35:08:04, 35:09:01-35:09:03, 35:11:01-35:12:03, 35:14:01-35:15, 35:17-35:18, 35:20:01-35:24:02, 35:27, 35:29-35:45, 35:48, 35:50-35:62, 35:64-35:68:02, 35:70-35:72, 35:74-35:75, 35:76 ^w , 35:77-35:79, 35:81-35:153, 35:155-35:184, 35:43:02, 37:08, 38:06-38:07, 39:19:01-39:19:02, 44:06, 51:01:01-51:24:04, 51:26-51:46, 51:48-51:103, 51:105-51:111, 51:113-51:117, 51:119-51:126, 53:01:01-53:16, 53:18-53:27, 56:06 ^w , 78:01:01-78:04, 78:07
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46¹³	360 bp	1070 bp	Bw4	-

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47	350 bp	1070 bp	Bw6	-
48	285 bp	800 bp	7, 703, 8, 35, 40, 41, 42, 48, 60, 61, 81	*07:02:01-07:06, 07:08-07:18:02, 07:20-07:32, 07:34-07:39, 07:41-07:52, 07:54-07:59, 07:61-07:76, 07:79-07:83, 07:85-07:99, 07:101-07:121, 07:123-07:138, 07:140-07:143, 08:01:01-08:05, 08:07-08:08N, 08:10-08:11, 08:13-08:15, 08:17-08:78, 35:66, 35:87, 37:07, 40:15-40:16, 40:30-40:32, 40:34, 40:45, 40:59, 40:80, 40:98, 40:137, 40:160, 41:02:01-41:02:04, 41:04, 41:10-41:11, 41:13, 41:18-41:19, 42:01:01-42:02, 42:05:01-42:07, 42:09-42:13, 42:15-42:16, 48:01:01-48:01:03, 48:05-48:12, 48:14-48:20, 48:22, 48:27, 53:15, 81:01-81:05
49	165 bp, 190 bp	1070 bp	5, 17, 21, 35, 51, 5102, 52, 56, 62, 70, 78	*15:01:02, 15:09, 35:01:10, 35:04:02, 40:26, 40:28, 44:62, 49:18, 50:14, 51:01:01-51:01:03, 51:01:05-51:02:03, 51:02:05-51:09:02, 51:11N-51:12, 51:13:02-51:14, 51:16-51:23, 51:24:03-51:24:04, 51:26-51:33, 51:37-51:41N, 51:43-51:44N, 51:46, 51:48-51:61, 51:63-51:80, 51:82-51:91, 51:94-51:98N, 51:100-51:126, 52:01:01:01-52:01:04, 52:01:06-52:13, 52:15-52:24, 52:26-52:27, 56:05:01-56:06, 56:21, 58:08:01-58:08:02, 78:01:01-78:07
50	260 bp	800 bp	14, 16, 18, 51, 62, 70	*14:06:01-14:06:02, 14:08, 15:37-15:38:02, 15:185, 18:01:01-18:01:14, 18:03-18:09, 18:12-18:13, 18:15, 18:17N-18:20, 18:23N-18:26, 18:28-18:34, 18:36-18:38, 18:40-18:43, 18:45-18:55, 18:57, 18:59-18:68, 39:32, 39:43, 39:48, 40:51, 40:113, 40:163, 51:06:01-51:06:02, 51:45, 51:62, 56:31, C*08:51
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52	380 bp	1070 bp	5, 8, 17, 48, 51, 5102, 5103, 52, 57, 58, 59, 61	*08:03, 08:52, 08:78, 40:13, 40:19, 40:109, 40:117, 48:18, 49:18, 51:01:01-51:01:07, 51:01:09-51:01:14, 51:01:16-51:12, 51:16-51:24:04, 51:26-51:36, 51:38-51:41N, 51:43-51:44N, 51:46, 51:48-51:49, 51:51-51:53, 51:55-51:61, 51:64-51:77, 51:79-51:84, 51:86-51:89, 51:91, 51:93-51:96, 51:98N-51:105, 51:107-51:126, 52:01:01:01-52:11, 52:13, 52:15-52:19, 52:21-52:24, 52:27, 53:19, 56:21, 57:02:01-57:03:02, 57:05, 57:07, 57:09, 57:17, 57:39, 57:42, 57:46,

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54	150 bp, 260 bp, 650 bp	1070 bp	17, 35, 37, 40, 44, 45, 47, 49, 57, 61	*35:45, 35:71, 35:169, 37:06, 40:13, 40:19, 40:47, 40:96, 40:109-40:110, 40:117, 40:132, 40:157, 44:02:01:01-44:137, 45:01-45:03, 45:05-45:07, 45:09, 45:11-45:13, 47:01:01:01-47:01:02, 47:03- 47:08, 49:01:01-49:02, 49:04-49:20, 50:02, 51:42, 51:112, 53:22, 57:07, 57:45, 57:51, 83:01, C*15:25
55	235 bp	1070 bp	7, 703, 27, 35, 40, 48, 60, 61, 81	*07:02:01-07:06, 07:08-07:11, 07:13, 07:15-07:17, 07:21-07:23, 07:25-07:30, 07:32-07:33, 07:35-07:42, 07:44-07:59, 07:61-07:76, 07:79-07:83, 07:85-07:99, 07:101-07:130, 07:132-07:136, 07:138-07:143, 08:40, 27:07:01, 27:11, 27:24, 27:32-27:34, 27:43, 35:31, 35:66, 37:07, 40:02:01-40:03, 40:08-40:09, 40:13, 40:15-40:16, 40:18-40:19, 40:24, 40:27:01- 40:27:02, 40:29, 40:31-40:32, 40:35, 40:37, 40:40, 40:45, 40:50, 40:56-40:58, 40:78, 40:80, 40:82, 40:85, 40:89-40:91, 40:94, 40:97-40:98, 40:104- 40:105, 40:107, 40:111, 40:115, 40:119, 40:122, 40:142N-40:145, 40:157, 40:164, 40:169, 40:173, 40:176, 41:19, 48:01:01-48:01:03, 48:04-48:16, 48:18-48:20, 48:22, 48:24, 48:27, 51:81, 58:27, 81:01-81:05
56	550 bp	1070 bp	7, 22, 42, 45, 56, 82	*07:04, 07:19, 07:25, 42:01:01-42:02, 42:04-42:10, 42:12-42:16, 44:90, 45:06, 55:20, 56:13, 82:01- 82:03, 83:01
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58⁶	90 bp, 125 bp, 155 bp, 190 bp	1070 bp	5, 17, 45, 51, 56, 60, 61, 78	*07:65, 07:133, 39:63, 40:43, 40:50, 40:166, 44:90, 45:06, 51:20 ^w , 56:05:01, 56:06, 57:45, 57:51, 58:08:01, 78:01:01-78:01:02, 78:03, 78:07

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60⁶	105 bp	800 bp	18, 27, 35, 37, 49, 51, 52, 53	*15:202, 18:01:01-18:06, 18:08-18:15, 18:17N-18:28, 18:30-18:32, 18:34-18:36, 18:38-18:47, 18:49-18:65, 18:67-18:68, 35:20:01-35:20:02, 35:28, 35:72, 35:95, 37:01:01-37:01:05, 37:01:07-37:05, 37:07-37:20, 37:22-37:25, 37:27, 37:29-37:31, 44:83, 44:134, 49:03, 51:07:01-51:07:02, 52:01:01:01-52:01:10, 52:03-52:05, 52:07-52:15, 52:17-52:21, 52:24-52:27, 53:09, 53:17:01-53:17:02, 78:05-78:06
61^{6,9}	90 bp, 120 bp, 150 bp, 180 bp	800 bp	7, 35, 61, 62, 73	*07:11, 07:57, 07:75, 13:39, 15:57, 15:135, 27:67, 27:75, 35:27, 35:56, 35:43:02, 37:05, 40:37, 42:15, 44:75, 44:97, 73:01-73:02, 78:06
62	435 bp	1070 bp	39, 42, 55, 56, 67	*07:115, 14:21, 38:26, 39:10:01, 39:16, 39:20, 39:63, 42:06, 55:13, 56:11, 56:22, 67:01:01-67:01:02, 67:03
63⁶	95 bp	1070 bp	5, 13, 15, 16, 17, 18, 21, 22, 27, 35, 38, 39, 3901, 3902, 44, 46, 48, 49, 51, 5102, 5103, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 62, 63, 67, 70, 71, 72, 75, 76, 78, 82	*07:68:01-07:68:03, 07:100, 08:71, 13:01:01-13:04, 13:06-13:09, 13:11-13:20, 13:22:01-13:23, 13:25-13:33, 13:35-13:45, 13:47-13:50, 13:52, 14:13, 14:23, 15:01:01:01-15:01:04, 15:01:06-15:01:24, 15:03:01-15:05:02, 15:07:01-15:12, 15:14-15:16:03, 15:18:01-15:20, 15:23-15:24, 15:26N-15:30, 15:32, 15:34-15:35, 15:37-15:40, 15:42-15:43, 15:45-15:54, 15:56-15:58, 15:60-15:71, 15:73-15:76, 15:79N-15:87, 15:90-15:99, 15:101-15:105, 15:108-15:111N, 15:113-15:115, 15:117-15:120, 15:122-15:127, 15:129, 15:131-15:136, 15:138, 15:140, 15:142-15:143, 15:145-15:149N, 15:151-15:155, 15:157-15:161, 15:163-15:167, 15:169, 15:171-15:176, 15:178-15:187, 15:189-15:195, 15:197-15:203, 15:205-15:206, 15:209N-15:210, 15:212, 15:215, 15:217-15:229, 15:231-15:232, 15:234-15:236, 18:01:01-18:01:03, 18:01:05-18:01:13, 18:02-18:15, 18:17N-18:19, 18:22-18:39, 18:41-18:60, 18:62-18:68, 27:27, 27:41, 35:01:01:01-35:08:05, 35:10-35:17, 35:19-35:30, 35:32:01-35:52, 35:54-35:63, 35:65Q-35:72, 35:74-35:86, 35:89-35:113, 35:115-35:117, 35:119-35:130N, 35:132-35:163, 35:165N-35:173N, 35:175-35:184, 35:43:02, 35:186, 38:01:01-38:21, 38:23-38:37, 39:01:01:01-39:01:01:02L, 39:01:03-39:16, 39:18-39:20, 39:22-39:67, 40:26, 40:28, 40:35, 40:71, 40:77, 40:87:01-40:87:02, 40:95, 40:121, 40:158, 42:10, 44:10, 44:14, 44:17, 44:43:01-44:43:02, 44:45, 44:51, 44:62, 44:77, 44:82, 44:107, 44:123, 44:135, 45:09, 46:01:01-46:01:05, 46:01:07-46:05, 46:07N-46:30, 48:02:01-48:02:02, 48:12,

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64¹⁴	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 low resolution SSP typings.

When the primers in a primer mix can give rise to specific PCR products of more than one length this is indicated if the size difference is 20 base pairs or more. Size differences shorter than 20 base pairs are not given. For high resolution SSP kits the respective lengths of the specific PCR product(s) of the alleles amplified by these primer mixes are given.

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 two different control primer pairs give rise to either an internal positive control band of 1070 base pairs, for most wells, or a band of 800 base pairs, for some wells.

Well number 1 contains the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to help in the correct orientation of the HLA-B low resolution typing.

In addition, wells number 4 to 6, 10, 17, 20, 21, 30, 35, 42, 48, 50, 60 and 61 contain the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to allow kit identification.

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

³The serological reactivity of all HLA-B alleles is not known. In this table we use the expert-assigned serological grouping in Tissue Antigens (2009) 73:95-170 and the serological grouping of the sequence-defined allele.

⁴Nucleotide sequence information is available for only exons 2 and 3 of many HLA Class I alleles and for only exon 2 of many HLA Class II alleles and not for other exons or for the introns of these alleles. We assume that unknown sequences in these exons and in the introns are conserved within loci and within allelic groups.

⁵Due to sharing of sequence motifs, primer mix 1 will amplify the C*02:23 and C*04:77 alleles, primer mix 3 will amplify the C*03:05, C*03:25 and C*03:27 alleles, primer mix 4 will amplify the C*01:30 allele, primer mix 6 will amplify the A*23:31, A*24:106 and C*16:10 alleles, primer mix 8 will amplify the C*07:46 allele, primer mix 13 will amplify the A*24:174 allele, primer mix 17 will amplify the C*03:102 allele, primer mix 21 will amplify the C*15:51 allele, primer mix 25 will amplify the C*03:129 allele, primer mix 29 will amplify the C*15:25 allele, primer mix 31 will amplify the C*15:39 allele, primer mix 40 will amplify the C*15:02:04 allele, primer mix 41 will amplify the C*03:12, C*03:19 and C*03:102 alleles, primer mix 43 will weakly amplify the

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C*02:06 and C*02:47 alleles, primer mix 45 will amplify the A*26:68, A*68:56, C*06:20 and C*12:50 alleles, primer mix 50 will amplify the C*08:51 allele, primer mix 52 will amplify the A*24:146 allele, primer mix 53 will amplify the C*05:30 allele, primer mix 54 will amplify the C*15:25 allele and primer mix 57 will amplify the C*07:46 allele.

⁶Specific PCR fragments shorter than 125 base pairs have a lower intensity and are less sharp than longer PCR bands.

⁷Primer mix 4 may yield less specific PCR product than the other HLA-B low resolution primer mixes in B*40, B*41, B*45, B*49 and B*50 alleles.

⁸Primer mixes 4, 5, 39 and 45 give a lower yield of specific PCR product than the other HLA-B low resolution primer mixes.

⁹Primer mixes 39 and 61 may give rise to nonspecific amplifications.

¹⁰Primer mixes 1, 15, 19, 20 and 42 may give rise to a primer oligomer artifact.

¹¹The C*17:01 to C*17:04 alleles might be faintly amplified by primer mix 25.

¹²Primer mixes 32 and 43 may generate a false positive band of about 800 base pairs. This band should be disregarded when interpreting HLA-B low resolution typings.

¹³The Bw4-associated HLA-A specificities A9, A23, A24, A2403, A25 and A32 are not amplified by the primer pair in primer mix 46.

¹⁴Primer mix 64 contains a negative control, which will amplify more than 95% of HLA amplicons as well as the amplicons generated by control primer pairs. PCR product sizes range from 75 to 200 base pairs. The PCR product generated by the control primer pair is 430 base pairs.

‘w’, might be weakly amplified.

‘?’, nucleotide sequence information not available for the primer matching sequence.

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INTERPRETATION TABLE																																			
HLA-B low resolution SSP																																			
Amplification patterns of the B*07:02 to B*83:01 alleles																																			
		Well ⁶																																	
		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	32		
Length of spec.		110	215	140	130	185	190	290	165	390	180	105	280	195	105	115	80	150	135	60	210	170	110	395	160	180	290	105	325	115	215	130	90		
PCR product(s)				235	265	235			330			195		435	395	150				400	245			425					260	225	195	115	270	130	410
Length of int. pos. control ¹		800	1070	1070	800	800	800	1070	1070	1070	800	1070	1070	1070	1070	1070	1070	800	1070	1070	800	800	1070	1070	1070	1070	1070	1070	1070	800	1070	1070	1070	1070	
Well No.		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	32		
Well No.		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	32		
HLA-B allele ²	ser. ³																																		
*07:02:01-07:02:29, 07:05:01-07:06, 07:10, 07:13, 07:15, 07:21-07:23, 07:26, 07:29-07:30, 07:35, 07:39, 07:41-07:42, 07:44-07:46, 07:49N, 07:52, 07:55-07:56, 07:58-07:59, 07:61-07:64, 07:66-07:67N, 07:70-07:72, 07:74, 07:76, 07:79-07:80, 07:82-07:83, 07:86-07:99, 07:101-07:114, 07:116-07:121, 07:124-07:130, 07:132, 07:135N-07:136, 07:138, 07:140-07:143	B7, Null, -	1																						24				28							
*07:03, 07:08, 07:16, 07:32, 07:37	B703, B7, -	1																						24											
*07:04, 07:25	B7	1												14										24				27	28						
*07:07, 07:77	B7, -	1																						24						28					
*07:09, 07:17	B7	1											12											24						28					
*07:11	B7	1											12											24						28					
*07:12, 07:14, 07:18:01-07:18:02, 07:137	B7, -	1																						24						28					
*07:19	B7, 42																							24						28					
*07:20, 07:24, 07:131	B7, -	1	3																					24						28					
*07:27	-	1										11									20														
*07:28	B7	1				6																		24						28					
*07:31, 07:34, 07:43	B7, B42	1																						24						28					
*07:33, 07:40, 07:53, 07:122, 07:139	B7, -																							24						28					
*07:36, 07:81	B7, -	1																												28					
*07:38	-	1																																	
*07:47	B7	1																						24						w					
*07:48, 07:51	B7																							24						28					
*07:50	-	1										11												24											
*07:54, 07:123	B7, -	1																						24						28					
*07:57, 07:75	B7, -	1																						24						28					
*07:60	-		3																					24						28					
*07:65	-	1																		18									28						32
*07:68:01-07:68:03	-	1																						24						28					
*07:69, 07:85	-	1																						23	24										
*07:73	-	1														16								24						28					
*07:78	-	1									10													24						28					
Well No.		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	32		

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 101.501.48u/12u – without *Taq* pol., IFU-02

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Well No.		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	32		
*07:84	–	1																						24			28								
*07:100	–			3																				24			28								
*07:115	–	1																						24			28								
*07:133	–	1																						24			28								
*07:134	–	1																18						24			28								
*08:01:01-08:01:16, 08:05, 08:08N, 08:10, 08:15, 08:18-08:19N, 08:22-08:24, 08:27, 08:29-08:31, 08:33-08:34, 08:39, 08:41-08:48, 08:51, 08:53, 08:56-08:59, 08:61, 08:63-08:64, 08:66-08:69, 08:72N-08:73, 08:75	B8, Null, –	2							8															24			27								
*08:02	B8	2							8																		27								
*08:03, 08:52, 08:78	B8, –	2							8																		27								
*08:04	B8, –	2							8			11												24			27								
*08:07, 08:14, 08:74, 08:77	B8, –	2																						24			27								
*08:09	B8	2							8															24			27			30					
*08:11	B8	2							8															24			27								
*08:12:01-08:12:03, 08:16	B8	2							8															24			27								
*08:13, 08:20, 08:70	B8, –	2																						24											
*08:17, 08:54	–	2							8			11												24			27								
*08:21	B8	2	3						8															24			27								
*08:25	B8	2	3																					24											
*08:26, 08:50, 08:62	B8, –								8															24			27								
*08:28, 08:37	B8, –	2											12											24			27								
*08:32	B8	2							8										18					24			27								
*08:35	–	2							8			12												24			27								
*08:36	–	2							8																		27								
*08:38	–	2							8															24			27								
*08:40	–	2																						24											
*08:49	–	2																17		20				24			27			29					
*08:55	–	2																					21	24											
*08:60, 08:76	–	2							8															24			27			29					
*08:65	–								8															23	24		27								
*08:71	–	2							8															24			27								
*13:01:01-13:01:06, 13:17, 13:20, 13:22:01-13:23, 13:25, 13:28-13:29, 13:43, 13:50, 13:52	B13, –		3	4							10							17																	
*13:02:01-13:02:12, 13:08Q, 13:15, 13:18-13:19, 13:27, 13:30, 13:32-13:33, 13:37-13:38, 13:40, 13:42, 13:44-13:45, 13:47, 13:49N	B13, Null, –		3	4							10																								
*13:03	B49, B15		3	4																															
*13:04	B49, B15		3	4								12																							
*13:06	B13		3	4														17																	
*13:07N	Null		3	4							10							17																	
*13:09	–			4							10																								
*13:10	B13		3	4									12																						
*13:11	B13		3	4							10																								
*13:12-13:13	B13		3	4														17																	
*13:14	B13		3								10																								
*13:16	B13		3	4							10																								
*13:21	–		3	4																															
Well No.		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	32		

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 101.501.48u/12u – without *Taq* pol., IFU-02

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Well No.		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	32			
*13:26	–			3	4								12					17																		
*13:31	–			3	4						10																									
*13:34	–			3	4						10																									
*13:35	–			3	4																															
*13:36	–			3	4						10							17																		
*13:39	–				4						10							17																		
*13:41	–			3	4						10																									
*13:46	–			3	4				8																							30				
*13:48	–			3	4																															
*13:51	–			3	4													17																		
*14:01:01-14:01:02, 14:12, 14:14, 14:26	B64, –				4	5																	23	24												
*14:02:01-14:02:02, 14:02:04, 14:03-14:04, 14:09, 14:11, 14:15-14:18, 14:20, 14:22, 14:25	B65, B14, –				4		6																23	24												
*14:02:03, 14:02:06, 14:24, 14:28	B65, –				4																		23	24												
*14:02:05	B65				4		6																23													
*14:05	B14						6																23	24												
*14:06:01-14:06:02	B14						6																23	24												
*14:07N, 14:19	Null, –				4	5																	23	24												
*14:08	–					5																	23	24												
*14:10	–					5												17					23	24									31			
*14:13	–						6																23	24												
*14:21	–				4																			24				28								
*14:23	–				4		6																23	24												
*14:27	–				4		6																23	24												
*15:01:01:01-15:01:01:02N, 15:01:03, 15:01:06-15:01:16, 15:01:18, 15:01:20-15:01:24, 15:26N-15:27:03, 15:32, 15:34-15:35, 15:50, 15:56, 15:60, 15:70-15:71, 15:75, 15:79N, 15:81-15:82, 15:92, 15:94N, 15:96-15:97, 15:102, 15:104-15:105, 15:109-15:111N, 15:113, 15:117-15:118, 15:122, 15:125, 15:129, 15:140, 15:145-15:147, 15:152, 15:159-15:160, 15:163-15:164, 15:166-15:167, 15:169, 15:171-15:172, 15:174-15:175, 15:178, 15:181N-15:184, 15:187, 15:190N, 15:192-15:193, 15:201, 15:203, 15:206, 15:217, 15:225, 15:227-15:228, 15:231-15:232, 15:234	B62, Null, –							7				12							19																	
*15:01:02	B62							7				12								19																
*15:01:04	B62											12									19															
*15:01:17, 15:05:01-15:05:02, 15:39:01-15:40, 15:65, 15:84, 15:136, 15:155, 15:179, 15:195, 15:199, 15:218Q-15:219	B62, –							7				12									19															
*15:01:19, 15:28, 15:120, 15:149N	B62, Null, –							7				12									19															

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Well No.		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	32	
*15:02:01-15:02:05, 15:88, 15:112, 15:121, 15:139, 15:170, 15:213-15:214	B75, –							7				12						17	19															
*15:03:01-15:03:02, 15:47, 15:49, 15:61, 15:98, 15:103, 15:123, 15:127, 15:132, 15:151, 15:158, 15:173, 15:210, 15:220, 15:235	B72, B70, –								8			11 12								19														
*15:03:03	B72							7 8				11 12								19														
*15:04	B62							7				12								19														
*15:06, 15:33, 15:78:01-15:78:03, 15:107, 15:141	B62, –							7				12								19														
*15:07:01-15:07:02, 15:126, 15:205	B62, –			3				7				12								19														
*15:08, 15:11:01-15:11:03, 15:11:05, 15:15, 15:148, 15:191, 15:209N, 15:215	B75, B62, Null, –							7				12								19														
*15:09	B70								8						14					19														
*15:10:01, 15:90, 15:99, 15:133, 15:229	B71, –								8						14					19														
*15:10:02	B71							7 8							14					19														
*15:11:04	B75											12								19														
*15:12, 15:14, 15:19	B76							7				12 13								19														
*15:13:01-15:13:02	B77, –							7				12		14				17	19															
*15:16:01-15:16:03, 15:67, 15:95	B63, –									9		12		14						19														
*15:17:01:01-15:17:02, 15:162, 15:168, 15:177, 15:196, 15:208, 15:216	B63, –							7	9					14						19														
*15:18:01-15:18:02, 15:18:04, 15:51-15:52, 15:108, 15:114, 15:119, 15:134, 15:153, 15:176, 15:197-15:198, 15:200, 15:221, 15:226N	B71, B70, Null, –								8			12		14						19														
*15:18:03	B71								8			12		14						19														
*15:20	B62							7				12						17	19															
*15:21, 15:44	B75							7				12		14				17	19															
*15:23, 15:115	B70, B5, –								8			12		14						19														
*15:24, 15:87, 15:157	B62, B15, –							7				12		14						19														
*15:25:01-15:25:03, 15:204	B62, –							7				12						17	19															
*15:29	B70								8			12								19														
*15:30, 15:58, 15:63	B62							7												19														
*15:31	B75							7				12								19														
*15:36	–			w				7				12						17	19															
*15:37	B70								8					14						19														
*15:38:01-15:38:02	B62							7				12								19														
*15:42	B15							7												19														
*15:43	B15							7				12								19														
*15:45	B62			3				7												19														
*15:46	–				4			7 8				12								19														
*15:48	B62							7												19														
*15:53, 15:212	–				4				8			12								19														
*15:54	B72								8			11 12								19														
*15:55	B15			3				7				12								19														
*15:57	B62							7				12								19														w
*15:62	–								8			11 12						17	19															
*15:64	B71								8			11 12								19														

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33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58	59	60	61	62	63	64		Well No.	
33														47																			B75, –	*15:02:01-15:02:05, 15:88, 15:112, 15:121, 15:139, 15:170, 15:213-15:214
					38									47																		B72, B70, –	*15:03:01-15:03:02, 15:47, 15:49, 15:61, 15:98, 15:103, 15:123, 15:127, 15:132, 15:151, 15:158, 15:173, 15:210, 15:220, 15:235	
					38									47																		B72	*15:03:03	
	w				38							45	47																			B62	*15:04	
					38									47																		B62, –	*15:06, 15:33, 15:78:01-15:78:03, 15:107, 15:141	
					38							45	47																			B62, –	*15:07:01-15:07:02, 15:126, 15:205	
33												45	47																			B75, B62, Null, –	*15:08, 15:11:01-15:11:03, 15:11:05, 15:15, 15:148, 15:191, 15:209N, 15:215	
														47	49																	B70	*15:09	
														47																		B71, –	*15:10:01, 15:90, 15:99, 15:133, 15:229	
														47																		B71	*15:10:02	
33												45	47																			B75	*15:11:04	
					38							45	47																				B76	*15:12, 15:14, 15:19
33													46																				B77, –	*15:13:01-15:13:02
	35												46																				B63, –	*15:16:01-15:16:03, 15:67, 15:95
													46																				B63, –	*15:17:01:01-15:17:02, 15:162, 15:168, 15:177, 15:196, 15:208, 15:216
															47																		B71, B70, Null, –	*15:18:01-15:18:02, 15:18:04, 15:51-15:52, 15:108, 15:114, 15:119, 15:134, 15:153, 15:176, 15:197-15:198, 15:200, 15:221, 15:226N
										43				47																			B71	*15:18:03
					38									47																			B62	*15:20
33														47																			B75	*15:21, 15:44
													46																				B70, B5, –	*15:23, 15:115
					38							45	46																				B62, B15, –	*15:24, 15:87, 15:157
					38									47																			B62, –	*15:25:01-15:25:03, 15:204
														47																			B70	*15:29
					38							45	47																				B62	*15:30, 15:58, 15:63
33														47																			B75	*15:31
					38								46																				–	*15:36
														47	50																		B70	*15:37
					38							45	47	50																			B62	*15:38:01-15:38:02
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					38							45	46																				B15	*15:43
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Negative Control



101.501.48/12 – including *Taq* pol., IFU-01
 101.501.48u/12u – without *Taq* pol., IFU-02

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*15:68	-			3									11	12																							
*15:69	B72								8				11	12						19		21															
*15:72	B71								8					12		14					19																
*15:73	B62								7												19																
*15:74	B72								8					12							19																
*15:76	-								7					12							19															28	
*15:77	B62						6	7												17	19																
*15:80	B70								8					12		14				17	19																
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*15:137	-								7												19																
*15:138	-	1							7					12							19																
*15:142	-		2						7					12							19																
*15:143	-								7	8				12							19																
*15:144	-								7					12						17	19																
*15:150, 15:188	-								7												19																
*15:156	-								8					11	12						19																
*15:161	-								8					12	13	14					19																
*15:180	-		2											12																							
*15:185	-								7					12							19																
*15:186	-								8					12		14					19		21														
*15:189	-						6	7						12		14					19																
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*15:202	-								7					12							18	19															
*15:207	-			3					7					12							19																
*15:222	-									9				12		14					19																
*15:224	-								7												19																
*15:230	-	1							7					9		14					19																
*15:233	-						6	7													19																
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*18:01:04, 18:01:14, 18:20, 18:40	B18, -													12		15				18																	
*18:02, 18:10-18:11, 18:14, 18:27, 18:35, 18:39, 18:58	B18, -													12		15				18																	
*18:04	B18													12		15				18																	
*18:07:01-18:07:02	B18, -													12		15				18																	
*18:09	B18													12		15																					

101.501.48/12 – including *Taq* pol., IFU-01
 101.501.48u/12u – without *Taq* pol., IFU-02

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					38							45	47																	63	B62	*15:66			
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					38								47											57						63	B72	*15:69			
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					38								47																	63	B72	*15:74			
w												45	47																	63	-	*15:76			
					38							45	47																	63	B62	*15:77			
													47																		63	B70	*15:80		
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					38							45	47																		63	-	*15:101		
					37	38							47																				-	*15:106	
					38								47																				B62	*15:116	
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					38							45	47																			63	-	*15:142	
					37							45	47																			63	-	*15:143	
33												45	47																			-	*15:144		
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					38								47			50																63	-	*15:185	
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												46																					63	-	*15:222
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												46																					-	*15:230	
					38							45	47																				-	*15:233	
					38							45	47																			63	-	*15:236	
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33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58	59	60	61	62	63	64		Well No.		



101.501.48/12 – including *Taq* pol., IFU-01
 101.501.48u/12u – without *Taq* pol., IFU-02

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*18:12	B18												12			15		18																				
*18:19	B18												12			15		18																				
*18:21	-												12			15		18																				
*18:22	B18												12			15		17	18													31						
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*18:29	-												12					18																				
*18:33	-												12			15		18																				
*18:37	-											11	12			15																						
*18:44	-				4								12			15		18																				
*18:48	-												12			15											26											
*18:49	-												12			15																						
*18:54	-												12	13		15					20																	
*18:56	-												12	13		15		18																				
*18:61	-															15		18																				
*18:66	-												12			15																						
*18:67	-												12			15																						
*27:01	B27					5										16													28					w				
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*27:18	-					5						11				16																						
*27:19	B27															16	17												28							32		
*27:23	-					5										16																						
*27:24	B27															16													28								32	
*27:25	B27															16													28								32	
*27:27	B27					5										16													28								32	
*27:29	B27					5						11				16																						
*27:30	B27															16	17												28								32	
*27:33	-															16													28								32	
*27:41	-					5						12				16													28								32	
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*27:62	-															16													28								32	
*27:67	-					5																							28								32	
*27:75	-					5																							28								32	
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					38									47			50										60		63		B18	*18:12	
											44	45	47				50										60		63		B18	*18:19	
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					37								47			50													63		-	*18:48	
											44		47			50											60		63		-	*18:49	
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											44		47			50											60				-	*18:61	
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			36								44	46			50												60		63		-	*18:67	
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												46																	63			B27	*27:27
												46																				B27	*27:29
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			36		38							46												57							-	*27:62	
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			36		38						45	46																61			-	*27:75	
			36		38							46																			-	*27:77	
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Negative Control



101.501.48/12 – including *Taq* pol., IFU-01
 101.501.48u/12u – without *Taq* pol., IFU-02

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											44			47				51											63				B35, Null, –	*35:01:01:01-35:01:09, 35:01:11-35:01:29, 35:07-35:08:04, 35:11:01-35:11:02, 35:15, 35:23, 35:29, 35:40N-35:42:01, 35:48, 35:50, 35:52, 35:54, 35:57, 35:61, 35:77, 35:90-35:94, 35:100-35:101:02, 35:103-35:105, 35:107-35:108:02, 35:110-35:112, 35:116, 35:120-35:124, 35:126, 35:130N, 35:132-35:134N, 35:137-35:148, 35:158-35:159, 35:161, 35:165N-35:166, 35:168, 35:170-35:171, 35:173N, 35:175-35:178, 35:180		
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											44			47				51												63			B35, Null, –	*35:02:01-35:03:02, 35:03:04 35:04:01, 35:04:03, 35:06, 35:12:01-35:12:03, 35:33-35:34, 35:36, 35:39, 35:55, 35:59, 35:65Q, 35:70, 35:74, 35:83-35:84, 35:98, 35:106, 35:128-35:129N, 35:136, 35:149-35:150, 35:152-35:153, 35:155-35:156, 35:160, 35:162, 35:167, 35:172, 35:179, 35:181-35:184		
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*38:07	B38					5																21															
*38:08	B38					5																21	22	23													
*38:10, 38:36-38:37	B38, –					5																	22	23													
*38:17	–					5								13							20	21	22	23													
*38:20	–					5												17				21	22	23													
*38:22	–					5											16						22	23													
*38:26	–					5																21	22					28									
*38:30	–					5			8														22	23													
*38:35	–					5																21	23														
*39:01:01:01-39:01:01:02L, 39:01:03-39:01:05, 39:01:07- 39:01:08, 39:01:10-39:01:12, 39:03, 39:05:01-39:06:02, 39:09, 39:11, 39:14-39:15, 39:24:01, 39:26-39:29, 39:31, 39:35, 39:37, 39:41, 39:44, 39:46, 39:51-39:57, 39:59-39:62, 39:64-39:67	B3901, B39, Low B39, –					5																21		23	24												
*39:01:06, 39:38Q, 39:40N	B3901, B39, Null					5																21		23	24												
*39:01:09, 39:12, 39:45	B3901, B39, –																					21		23	24												
*39:02:01, 39:08	B3902, B39					5						11										21			24												
*39:02:02, 39:13:01- 39:13:02, 39:23, 39:49	B3902, B39, –											11										21			24												
*39:04	B39						6															21		23	24												
*39:07	B16					5							12									21		23	24												
*39:10:01, 39:16, 39:20	B39																					21			24												
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101.501.48/12 – including *Taq* pol., IFU-01
 101.501.48u/12u – without *Taq* pol., IFU-02

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101.501.48/12 – including *Taq* pol., IFU-01
 101.501.48u/12u – without *Taq* pol., IFU-02

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Negative Control



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*42:10	-								8																24		27	28					
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101.501.48/12 – including *Taq* pol., IFU-01
 101.501.48u/12u – without *Taq* pol., IFU-02

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Well No.		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	32		
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*44:75	–				4													17														29			
*44:83	–																	17														29			
*44:90	–				4													17											28	29			32		
*44:95	–				4													17														29			
*44:97	–				4													17											28	29			32		
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*45:06	B45				4				8			11												24				28					30		
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*48:13	–											11												24											
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101.501.48/12 – including *Taq* pol., IFU-01
 101.501.48u/12u – without *Taq* pol., IFU-02

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Lot-specific information

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Negative Control



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 101.501.48u/12u – without *Taq* pol., IFU-02

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Well No.		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	32	
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*49:01:02, 49:11	B49, –				4																													
*49:02	B49				4																													
*49:03	B49																																	
*49:04	B49				4								12																					
*49:05	B49				4								12																					
*49:07	–				4						10																							
*49:18	–				4																													
*49:20	–				4							11																						
*50:01:01-50:01:03, 50:04-50:05, 50:08, 50:10-50:11, 50:13	B50, –				4																			24										
*50:02	B45				4						11													24										
*50:06	–				4																			24										
*50:07	–																							24										
*50:09	–				4																			24										
*50:12	–				4																			24										
*50:14	–				4																			24										
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*51:01:02, 51:02:02, 51:05, 51:09:02, 51:89, 51:103, 51:116, 51:119	B51, B5102, –																																	
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101.501.48/12 – including *Taq* pol., IFU-01
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33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58	59	60	61	62	63	64	Well No.						
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	34	35			38								46									54											B49	*49:05				
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Well No.		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	32	
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*51:17-51:18	B51																																30	
*51:20	B51								8																								30	
*51:22	B51																																30	
*51:24:01	B51																																30	
*51:24:02	B51																								24								30	
*51:24:03-51:24:04	B51, -																							24								30		
*51:36	B51								8																								30	
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*51:45	-												12																				30	
*51:54, 51:78	-																																	
*51:59	-																																30	
*51:61	-																																30	
*51:62	-																																30	
*51:64	-				3																												30	
*51:68	-			2																													30	
*51:81	-																																30	
*51:85	-																																30	
*51:93	-																																	
*51:97	-								8				12																				30	
*51:101	-																							21									30	
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*51:106	-																																	30
*51:112	-																																	30
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*52:01:02, 52:01:04, 52:01:09, 52:03, 52:09	B52, -																																	30
*52:01:05	B52																																	
*52:01:10	-																								22									
*52:02	B52																																30	
*52:06:01-52:06:02	B52																																30	
*52:12	-																																	
*52:14	-																																	
*52:16	-												11																					
*52:18	-																																	
*52:19	-								8																								30	
*52:20	-																																	
*52:21	-																																30	
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*53:03, 53:11-53:13	B53, B35												12						17															
*53:04	B53																		17															
*53:06	B53, B51												12						17												30	31		
Well No.		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	32	

101.501.48/12 – including *Taq* pol., IFU-01
 101.501.48u/12u – without *Taq* pol., IFU-02

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 “Instructions for Use” (IFU)

Lot No.: **03N**

Lot-specific information

33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58	59	60	61	62	63	64		Well No.	
		36						41			44		46					51												63	-	*51:15		
		35	36								44		46			49	51	52													B51	*51:17-51:18		
		35	36								44		46			49	51	52							w					63	B51	*51:20		
		35	36								44		46			49		52													63	B51	*51:22	
		35	36								44		46					51	52													B51	*51:24:01	
		35	36								44		46					51	52													B51	*51:24:02	
		35	36								44		46			49	51	52													B51, -	*51:24:03-51:24:04		
		35	36								44		46					51	52												63	B51	*51:36	
		35	36								44		46			49	51														63	B51, -	*51:37, 51:63	
		35	36								44		46			49	51	52	53												63	B51	*51:39	
		36									44		46					51			54											-	*51:42	
		36									44		46					50	51												63	-	*51:45	
		35									44		46			49	51														63	-	*51:54, 51:78	
		36									44		46			49	51	52													63	-	*51:59	
		w	36								44	45	46			49	51	52													63	-	*51:61	
		36						41		43	44		46					50	51												63	-	*51:62	
		36									44		46			49	51	52														63	-	*51:64
		35	36								44		46			49	51	52														63	-	*51:68
		36									44		46					51	52			55										-	*51:81	
		35	36								44		46			49	51															-	*51:85	
		35	36								44		46					51	52													63	-	*51:93
		35	36								44		46			49	51															63	-	*51:97
		35	36								44		46			49	51	52														63	-	*51:101
		35	36										46			49	51	52														63	Null, -	*51:104, 51:118N
		35	36					41			44		46			49	51															63	-	*51:106
		34	35	36									46			49	51	52	54													63	-	*51:112
		35	36			38							46			49		52									59	60			63	B52, -	*52:01:01-52:01:02, 52:01:03, 52:01:06-52:01:08, 52:04-52:05, 52:07-52:08, 52:10:01-52:11, 52:13, 52:15, 52:17, 52:24, 52:27	
		35	36			38						46			49		52									59	60			63	B52, -	*52:01:02, 52:01:04, 52:01:09, 52:03, 52:09		
		35	36			38						46					52									60				63	B52	*52:01:05		
		35	36			38						46			49		52								59	60				63	-	*52:01:10		
		35	36			38						46			49		52								59					63	B52	*52:02		
		35	36			38						46			49		51	52													63	B52	*52:06:01-52:06:02	
		35	36			38						46			49										59	60					63	-	*52:12	
		35	36			38						46													60						63	-	*52:14	
		35	36			38						46			49		52								59						63	-	*52:16	
		35	36			38						46			49		52								60						63	-	*52:18	
		35	36			38						46			49		52								59	60					63	-	*52:19	
		35				38						46			49										59	60					63	-	*52:20	
		35	36			38						45	46			49		52							59	60					63	-	*52:21	
		35	36			38						46			49		52								59						63	-	*52:22-52:23	
		35	36			38		41		43		46														60					63	-	*52:25	
		35	36			38						46			49										59	60						-	*52:26	
		36									44		46					51													63	B53, -	*53:01:01-53:01:05, 53:05, 53:08:01-53:08:02, 53:10, 53:16, 53:18, 53:20-53:21, 53:23-53:27	
		36									44		46					51													63	B53	*53:02	
											44		46					51													63	B53, B35	*53:03, 53:11-53:13	
		36									44		46					51													63	B53	*53:04	
		36									44		46					51													63	B53, B51	*53:06	
33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58	59	60	61	62	63	64		Well No.	

Negative Control



101.501.48/12 – including *Taq* pol., IFU-01
 101.501.48u/12u – without *Taq* pol., IFU-02

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Lot No.: **03N**

Lot-specific information

Well No.		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	32					
*53:07	B53																	17																				
*53:09	B53											12						17																				
*53:14	–			3								12																										
*53:15	–											12						17																				
*53:17:01-53:17:02	–											12						17																				
*53:19	–																	17																				
*53:22	–											12	13					17														29						
*54:01:01, 54:07-54:08N, 54:10, 54:13, 54:16-54:19, 54:21-54:24	B54, Null, –																																		28		32	
*54:01:02	–																																		28		32	
*54:02, 54:05N	B54, Null																																		28		32	
*54:03	B22																																		28		32	
*54:04	B54																																		28		32	
*54:06	–												12																						28		32	
*54:09, 54:14	–												12																						28		32	
*54:11	B54																									24								28		32		
*54:12	–																																		28		32	
*54:15	–																																		28		32	
*54:20	–																																		28		32	
*55:01:01-55:01:06, 55:01:08, 55:03, 55:05, 55:11, 55:15, 55:25, 55:29, 55:31, 55:33, 55:36, 55:38, 55:44-55:45, 55:52-55:54	B55, –																																			28		32
*55:01:07, 55:02:01- 55:02:06, 55:10, 55:12, 55:16, 55:19, 55:26, 55:30, 55:37, 55:39, 55:42-55:43, 55:47-55:48, 55:50	B55, –																																			28		32
*55:04, 55:49	B55, –																																		28		32	
*55:07, 55:35	B54, –																																		28		32	
*55:08	B56																																		28		32	
*55:09, 55:24	B22, B55											10																							28		32	
*55:13	B55																																		28		32	
*55:14	–												12					17																	28		32	
*55:17, 55:28	B55, –																																		28		32	
*55:18	–												11																							28		32
*55:20	B22								8																										27	28	30	32
*55:21	B55																																		28		32	
*55:22	B22												10																						28		32	
*55:23, 55:32, 56:18, 56:32 ⁴	B55, –													12																					28		32	
*55:27, 55:46	B55, –																																		28		32	
*55:34	–																																		28		32	
*55:40	–																																		28		32	
*55:41	–																																		28		32	
*55:51	–				3																														28		32	
*56:01:01-56:01:03, 56:08, 56:14, 56:16, 56:24, 56:26- 56:30	B56, Null, –																																			28		32
*56:01:04, 56:20:01	B56, –																																		28		32	
*56:02, 56:04	B56																																		28		32	
*56:03	B22, 15												12																						28		32	
*56:05:01	B56																																		28		32	
*56:05:02	B56																																		28		32	

101.501.48/12 – including *Taq* pol., IFU-01
 101.501.48u/12u – without *Taq* pol., IFU-02

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Lot No.: **03N**

Lot-specific information

33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58	59	60	61	62	63	64		Well No.
		36									44		46					51														B53	*53:07
											44		46														60			63	B53	*53:09	
		36									44		46					51													-	*53:14	
		36									44		46	48				51													-	*53:15	
		36	38										46													60			63	-	*53:17:01-53:17:02		
		36									44		46					51	52												-	*53:19	
		36									44		46					51		54											-	*53:22	
						39	40							47						53											B54, Null, -	*54:01:01, 54:07-54:08N, 54:10, 54:13, 54:16-54:19, 54:21-54:24	
							40							47						53											-	*54:01:02	
						39	40							47																	B54, Null	*54:02, 54:05N	
						39	41							47						53											B22	*54:03	
						39								47						53											B54	*54:04	
						39						45	47							53											-	*54:06	
						39							47							53											-	*54:09, 54:14	
						39							47							53											B54	*54:11	
34						39	40					46								53											-	*54:12	
						39							47							53											-	*54:15	
	35					39	40						47							53											-	*54:20	
		35					40							47												57						B55, -	*55:01:01-55:01:06, 55:01:08, 55:03, 55:05, 55:11, 55:15, 55:25, 55:29, 55:31, 55:33, 55:36, 55:38, 55:44-55:45, 55:52-55:54
							40							47												57						B55, -	*55:01:07, 55:02:01-55:02:06, 55:10, 55:12, 55:16, 55:19, 55:26, 55:30, 55:37, 55:39, 55:42-55:43, 55:47-55:48, 55:50
														47												57						B55, -	*55:04, 55:49
							40							47																		B54, -	*55:07, 55:35
														47																	B56	*55:08	
		35												47																	B22, B55	*55:09, 55:24	
														47											57		62	63			B55	*55:13	
										42				47											57						-	*55:14	
		35												47											57						B55, -	*55:17, 55:28	
						38	40							47											57						-	*55:18	
														47										56	57						B22	*55:20	
		w					40					45	47												57						B55	*55:21	
													47																			B22	*55:22
													47													57					B55, -	*55:23, 55:32, 56:18, 56:32 ⁴	
													47													57					B55, -	*55:27, 55:46	
						38	40						47													57					-	*55:34	
		35				38	40						47													57					-	*55:40	
							40						47													57					-	*55:41	
													47																		-	*55:51	
										41				47																		B56, Null, -	*56:01:01-56:01:03, 56:08, 56:14, 56:16, 56:24, 56:26-56:30
										41				47																		B56, -	*56:01:04, 56:20:01
										41	43			47																	B56	*56:02, 56:04	
												45	47																		B22, 15	*56:03	
		35					40						47				49										58				B56	*56:05:01	
		35											47				49														B56	*56:05:02	

Negative Control



101.501.48/12 – including *Taq* pol., IFU-01
 101.501.48u/12u – without *Taq* pol., IFU-02

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Lot No.: **03N**

Lot-specific information

Well No.		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	32	
*56:06	B78																		18										28			32		
*56:07	B56																													28			32	
*56:09	B56												12						17										28			32		
*56:10	B55																												28			32		
*56:11	B56																		17										28			32		
*56:12	B22																		17										28			32		
*56:13	B56								8																				28	30		32		
*56:15, 56:19N	B56, Null																												28			32		
*56:17	B56																																	
*56:20:02	–																							24				28				32		
*56:21	–																												28				32	
*56:22	–																												28				32	
*56:23	–																																	
*56:25	–																													28				32
*56:31	–												12																28				32	
*57:01:01-57:01:04, 57:01:06-57:01:12, 57:06, 57:08, 57:10, 57:15-57:16, 57:18-57:20, 57:22-57:23, 57:25-57:27, 57:29-57:30, 57:33-57:38, 57:40, 57:43-57:44, 57:48-57:50, 57:52, 58:36 ⁵	B57, –												12						17															
*57:01:05, 57:13, 57:31, 57:47	B57, –												12																					
*57:02:01-57:03:02, 57:17, 57:39, 57:42, 57:46	B57, –																		17															
*57:04	B57						6												17															
*57:05	B57																		17															
*57:07	B57																		17												29			
*57:09	B57								8										17												29			
*57:11, 57:21	B57, –												12																					
*57:12	B57																		17															
*57:14	–												12						17													31		
*57:24	–												12						17											29				
*57:28N	Null																		17															
*57:32	–																		17															
*57:41	–												12						17															
*57:45, 57:51	–				4								12						17															
*58:01:01-58:01:02, 58:01:04-58:01:09, 58:04-58:05, 58:10N-58:15, 58:19, 58:21-58:24, 58:29-58:33, 58:35	B58, Null, –												12						17															
*58:01:03	B58												12																					
*58:02, 58:06, 58:16, 58:25-58:26	B58, –												12																					
*58:07	B58												12	13																				
*58:08:01	B17, B5																														30			
*58:08:02	–																																	
*58:09	B17												12						17														31	
*58:17N	Null												12						17															
*58:18	–				3								12																					
*58:20	–																																	
*58:27	–																																	
*58:28	–																		17															
*58:34	–																		17															
Well No.		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	32	

101.501.48/12 – including *Taq* pol., IFU-01
 101.501.48u/12u – without *Taq* pol., IFU-02

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Lot No.: **03N**

Lot-specific information

33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58	59	60	61	62	63	64		Well No.		
		35					40			w				47		49									58				63		B78	*56:06			
								41						46															63		B56	*56:07			
														47															63		B56	*56:09			
							40			43				47											57				63		B55	*56:10			
														47														62	63		B56	*56:11			
														47											57				63		B22	*56:12			
								41						47										56					63		B56	*56:13			
														47															63		B56, Null	*56:15, 56:19N			
								41						47															63		B56	*56:17			
								41						47																	-	*56:20:02			
	34	35											46			49			52										63		-	*56:21			
														47														62	63		-	*56:22			
							40							47											57				63		-	*56:23			
		35						41						47															63		-	*56:25			
														47		50									57				63		-	*56:31			
																																			*57:01:01-57:01:04, 57:01:06 57:01:12, 57:06, 57:08, 57:10, 57:15-57:16, 57:18- 57:20, 57:22-57:23, 57:25- 57:27, 57:29-57:30, 57:33- 57:38, 57:40, 57:43-57:44, 57:48-57:50, 57:52, 58:36 ⁵
		36						42					46																63		B57, -				
		36						42					46																		B57, -	*57:01:05, 57:13, 57:31, 57:47			
		36						42					46						52										63		B57, -	*57:02:01-57:03:02, 57:17, 57:39, 57:42, 57:46			
		36						42					46																		B57	*57:04			
		36						42					46						52												B57	*57:05			
		36						42					46						52				54							63		B57	*57:07		
		36						42					46						52											63		B57	*57:09		
		36						42					46																	63		B57, -	*57:11, 57:21		
		36						42					46																		B57	*57:12			
		36						42					46			47															-	*57:14			
		36						42					46																		-	*57:24			
		36						42					46																		Null	*57:28N			
		36						42					46																		-	*57:32			
		36						42					46																		-	*57:41			
	34	36											46											54		58			63		-	*57:45, 57:51			
																																			*58:01:01-58:01:02, 58:01:04 58:01:09, 58:04-58:05, 58:10N-58:15, 58:19, 58:21- 58:24, 58:29-58:33, 58:35
																																B58, Null, -			
																																B58	*58:01:03		
																																B58, -	*58:02, 58:06, 58:16, 58:25- 58:26		
																																B58	*58:07		
																										58					B17, B5	*58:08:01			
																																-	*58:08:02		
																																B17	*58:09		
																																Null	*58:17N		
																																-	*58:18		
																																-	*58:20		
																																-	*58:27		
																																-	*58:28		
																																-	*58:34		

Negative Control



101.501.48/12 – including *Taq* pol., IFU-01
 101.501.48u/12u – without *Taq* pol., IFU-02

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Lot No.: **03N**

Lot-specific information

33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58	59	60	61	62	63	64	Well No.	
	34						40						46											57					63		B59, –	*59:01:01:01-59:01:01:02, 59:05	
	34												46						52					57						B59	*59:02		
	34												46											57					63	–	*59:03		
	34							41					46																63	–	*59:04		
														47											57				62	63	B67	*67:01:01	
														47											57				62	63	B67	*67:01:02	
														47															63	–	*67:02		
														47											57				62	–	*67:03		
												45	47															61		B73, –	*73:01-73:02		
	35						40				44		47			49		51								58			63	B78, –	*78:01:01-78:01:02, 78:07		
	35										44		47			49		51											63	B78, B35	*78:02:01, 78:04		
	35						40				44		47			49		51											63	B78	*78:02:02		
	35						40				44		47			49									58			63	B78	*78:03			
	35						38						47			49											59	60	63	–	*78:05		
	35						38						47			49											59	60	61	63	–	*78:06	
33													47	48									55							B81	*81:01		
33													47	48									55							B81	*81:02		
33													47	48									55							Null, –	*81:03-81:05		
								41					47														56		63	B82, –	*82:01-82:03		
							39						47										54	56						–	*83:01		
																			52														A*23:31, A*24:106, C*16:10
																																	A*24:146
																																	A*24:174
												45																					A*26:68, A*68:56, C*06:20, C*12:50
																																	C*01:30
																																	C*02:06, C*02:47
											w																						C*02:23, C*04:77
																																	C*03:05, C*03:25, C*03:27
								41																									C*03:12, C*03:19
								41																									C*03:102
																																	C*03:129
																								53									C*05:30
																										57							C*07:46
																	50																C*08:51
							40																										C*15:02:04
																								54									C*15:25
																																	C*15:39
																																	C*15:51
33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58	59	60	61	62	63	64	Well No.	

Negative Control

¹The internal positive control primer pairs amplify segments of the human growth hormone gene. The two different control primer pairs give rise to either an internal positive control band of 1070 base pairs, for most wells, or a band of 800 base pairs, for some wells.

Well number 1 contains the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to help in the correct orientation of the HLA-B low resolution typing. In addition, wells number 4 to 6, 10, 17, 20, 21, 30, 35, 42, 48, 50, 60 and 61 contain the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to allow kit identification.

²The sequence of the B*0701 allele has been shown to be in error. The sequence of the B*08:06 allele has been shown to be identical to B*08:20. The sequence of the B*1305 allele has been shown to be identical to B*13:04. The B*1324 allele has been renamed B*13:22:02

101.501.48/12 – including *Taq* pol., IFU-01
101.501.48u/12u – without *Taq* pol., IFU-02

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Lot No.: 03N**Lot-specific information**

The B*150105 allele has been corrected and renamed B*15:120

The B*1522 allele has been renamed B*35:43.

The sequence of the B*1541 allele has been shown to be identical to B*15:39.

The B*1559 allele has been renamed B*35:44.

The B*15:100 allele has never been assigned.

The sequence of the B*1816 allele has been shown to be identical to B*18:14.

The sequence of the B*27051 allele has been shown to be identical to B*27:05:02.

The sequence of the B*2722 allele has been shown to be identical to the corrected B*27:06 sequence.

The B*35:43:02 allele has been renamed B*35:185.

The B*3573 allele has been renamed B*35:08:03.

The sequence of the B*39012 allele has been shown to be identical to B*39:01:01:01.

The sequence of the B*3921 allele has been shown to be identical to B*39:24.

The sequence of the B*4017 allele has been shown to be identical to B*40:16.

The sequence of the B*4041 allele has been shown to be identical to B*40:40.

The sequence of the B*4203 allele has never been assigned.

The sequence of the B*4401 allele has been shown to be identical to B*44:02:01:01.

The sequence of the B*5003 allele has been shown to be identical to B*50:02.

The sequence of the B*5125 allele has been shown to be identical to B*51:22.

The B*5147 allele has been renamed B*51:09:02.

The sequence of the B*5506 allele has been shown to be identical to B*55:04.

The sequence of the B*5803 allele has never been assigned.

The B*7901 allele has been renamed B*15:18:01.

The B*9530 allele has been renamed B*15:27:02.

³The serological reactivity of all HLA-B alleles is not known. In this table we use the expert-assigned serological grouping in Tissue Antigens (2009) 73:95-170 and the serological grouping of the sequence-defined allele.

⁴The B*55:23 and 55:32 and the B*56:18 and 56:32 alleles give rise to identical amplification patterns with the HLA-B low resolution primer set. These alleles can be separated by the respective high resolution primer sets.

⁵The B*57:01:01-57:01:04, 57:01:06-57:01:12, 57:06, 57:08, 57:10, 57:15-57:16, 57:18-57:20, 57:22-57:23, 57:25-57:27, 57:29-57:30, 57:33-57:38, 57:40, 57:43-57:44, 57:48-57:50 and 57:52 and the B*58:36 alleles give rise to identical amplification patterns with the HLA-B low resolution primer set. These alleles can be separated by the respective high resolution primer sets.

⁶Primer mix 64 contains a negative control, which will amplify more than 95% of HLA amplicons as well as the amplicons generated by control primer pairs. PCR product sizes range from 75 to 200 base pairs. The PCR product generated by the control primer pair is 430 base pairs.

‘ser’, serological HLA specificity.

‘w’, might be weakly amplified.

‘?’, nucleotide sequence information not available for the primer matching sequence.

101.501.48/12 – including *Taq* pol., IFU-01
 101.501.48u/12u – without *Taq* pol., IFU-02

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Lot No.: 03N

Lot-specific information

Primers

Well No.	1	2	3	4	5	6	7	8	9	10	11	12
Length of spec. PCR product(s)	110	215	140 235	130 265	185 235	190	290	165 220 330	390	180	105 195	280
Length of int. pos. control ¹	800	1070	1070	800	800	800	1070	1070	1070	800	1070	1070
5'-primer(s) ²	527 5'-TgA 3'	97 5'-TCg 3'	209 5'-ggC 3'	103 5'-CCg 3'	103 5'-CCT 3'	103 5'-CCg 3'	45 5'-ggA 3'	45 5'-ggA 3'	45 5'-ggA 3'	420 5'-TTA 3'	206 5'-AgA 3'	419 5'-gTC 3'
	540 5'-gAC 3'		363 5'-AgC 3'	103 5'-CCg 3'	103 5'-CCT 3'	418 5'-Agg 3'		357 5'-Tgg 3'			420 5'-TTA 3'	
			363 5'-AgC 3'	361 5'-AgT 3'	363 5'-AAT 3'			412 5'-ATA 3'				
3'-primer(s) ³	605 5'-gCT 3'	272 5'-Tgg 3'	309 5'-gTg 3'	193 5'-CgT 3'	246 5'-TAT 3'	246 5'-TAT 3'	165 5'-Tgg 3'	206 5'-CCT 3'	266 5'-TCC 3'	559 5'-CTC 3'	272 5'-Tgg 3'	3 rd I 5'-TAT 3'
		272 5'-TgA 3'	559 5'-CAg 3'	193 5'-CgT 3'	246 5'-TAT 3'	572 5'-gCC 3'		538 5'-gTC 3'			572 5'-gCg 3'	
				583 5'-gTg 3'	559 5'-CTC 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(s)	195	105 395 435	115 150	80	150	135	60 245 400	210	170	110	395	160 425
Length of int. pos. control ¹	1070	1070	1070	1070	800	1070	1070	800	800	1070	1070	1070
5'-primer(s) ²	142 5'-TCT 3'	45 5'-ggA 3'	161 5'-Cgg 3'	167 5'-gCT 3'	355 5'-TCA 3'	206 5'-gAC 3'	45 5'-ggA 3'	142 5'-TCT 3'	409 5'-ggC 3'	246 5'-gAA 3'	44 5'-ggC 3'	44 5'-ggC 3'
	419 5'-gTC 3'	540 5'-gAC 3'					368 5'-gTT 3'	368 5'-gTC 3'	420 5'-TTA 3'			357 5'-Tgg 3'
							557 5'-ggA 3'					
3'-primer(s) ³	301 5'-gTC 3'	272 5'-TgC 3'	234 5'-TCT 3'	204 5'-TCT 3'	463 5'-gCT 3'	302 5'-ggC 3'	259 5'-gTT 3'	311 5'-ggg 3'	544 5'-ggT 3'	317 5'-ggA 3'	272 5'-TgC 3'	302 5'-ggC 3'
	301 5'-gTC 3'	309 5'-ATC 3'	272 5'-TgA 3'				259 5'-gTT 3'	311 5'-ggg 3'				302 5'-ggT 3'
	570 5'-CCg 3'	605 5'-gCT 3'	272 5'-Tgg 3'				266 5'-TCC 3'	538 5'-gTC 3'				477 5'-gCg 3'
	572 5'-gCg 3'						272 5'-Tgg 3'					
							292 5'-gTA 3'					
							572 5'-gCg 3'					
Well No.	13	14	15	16	17	18	19	20	21	22	23	24

101.501.48/12 – including *Taq* pol., IFU-01
 101.501.48u/12u – without *Taq* pol., IFU-02

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Lot No.: **03N**

Lot-specific information

Well No.	25	26	27	28	29	30	31	32	33	34	35	36
Length of spec. PCR product(s)	180	290	105	325	115	215	130	90	90	145	120	430
Length of int. pos. control ¹	1070	1070	1070	1070	1070	800	1070	1070	1070	1070	800	1070
5'-primer(s) ²	355 5'-TCA 3'	72 5'-gCT 3'	540 5'-gAC 3'	1 st I 5'-CAG 3'	355 5'-TCA 3'	141 5'-ATT 3'	209 5'-ggC 3'	41 5'-CTg 3'	209 5'-ggC 3'	48 5'-gCC 3'	357 5'-Tgg 3'	49 5'-CAG 3'
	363 5'-Agg 3'				418 5'-Agg 3'	357 5'-Tgg 3'	209 5'-ggg 3'	368 5'-gTT 3'	363 5'-AgC 3'	206 5'-gAA 3'		
					499 5'-TCT 3'		355 5'-TCA 3'					
3'-primer(s) ³	499 5'-ggA 3'	193 5'-CgT 3'	603 5'-gTg 3'	282 5'-gCC 3'	538 5'-gTC 3'	309 5'-ATC 3'	299 5'-TCA 3'	282 5'-gCC 3'	259 5'-gTT 3'	309 5'-ATC 3'	435 5'-TCT 3'	309 5'-ATC 3'
		193 5'-TgT 3'	605 5'-gCT 3'		572 5'-gCg 3'	538 5'-gTC 3'	583 5'-gTg 3'	418 5'-gTC 3'	499 5'-ggA 3'		527 5'-CCT 3'	
Well No.	25	26	27	28	29	30	31	32	33	34	35	36

Well No.	37	38	39	40	41	42	43	44	45	46	47	48
Length of spec. PCR product(s)	145	300	160	180	180	90	90	95	115	360	350	285
Length of int. pos. control ¹	1070	1070	1070	1070	1070	800	1070	1070	1070	1070	1070	800
5'-primer(s) ²	206 5'-gAA 3'	1 st I 5'-CAG 3'	15 5'-gCA 3'	141 5'-ATT 3'	420 5'-TTA 3'	209 5'-ggC 3'	209 5'-ggA 3'	206 5'-gAC 3'	165 5'-ACC 3'	1 st I 5'-CAG 3'	1 st I 5'-CAG 3'	355 5'-TCA 3'
			418 5'-Agg 3'	420 5'-TTA 3'		209 5'-ggA 3'	369 5'-TAC 3'		463 5'-TgA 3'			363 5'-AgC 3'
						362 5'-ggT 3'						
3'-primer(s) ³	311 5'-ggT 3'	259 5'-CTC 3'	175 5'-CCg 3'	311 5'-ggT 3'	559 5'-CAG 3'	256 5'-CCC 3'	256 5'-CCC 3'	259 5'-gTT 3'	272 5'-TgC 3'	317 5'-ggA 3'	311 5'-ggT 3'	603 5'-gTg 3'
		259 5'-CTC 3'	538 5'-gTC 3'	559 5'-CgT 3'		259 5'-CTT 3'	256 5'-CTC 3'		538 5'-CCA 3'			605 5'-gCT 3'
		262 5'-TgC 3'				559 5'-CgT 3'	420 5'-gCT 3'					
Well No.	37	38	39	40	41	42	43	44	45	46	47	48

101.501.48/12 – including *Taq* pol., IFU-01
 101.501.48u/12u – without *Taq* pol., IFU-02

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Lot No.: **03N**

Lot-specific information

Well No.	49	50	51	52	53	54	55	56	57	58	59	60
	165	260	390	380	160	150	235	550	640	90	450	105
	190					260				125		
						650				155		
										190		
Length of int. pos. control ¹	1070	800	1070	1070	1070	1070	1070	1070	1070	1070	1070	800
5'-primer(s) ²	435	363	49	317	106	206	363	272	206	141	272	206
	5'-AAA 3'	5'-Agg 3'	5'-CAg 3'	5'-gCT 3'	5'-CCA 3'	5'-gAA 3'	5'-AgC 3'	5'-CTA 3'	5'-AgA 3'	5'-ATT 3'	5'-CTC 3'	5'-gAC 3'
						355	363			206		
						5'-TCA 3'	5'-AgC 3'			5'-gAA 3'		
3'-primer(s) ³	559	583	272	412	226	317	559	538	559	256	435	272
	5'-CAG 3'	5'-gTg 3'	5'-TgA 3'	5'-gTT 3'	5'-CAC 3'	5'-ggA 3'	5'-CTC 3'	5'-gTC 3'	5'-CgT 3'	5'-CCC 3'	5'-TCT 3'	5'-Tgg 3'
	583					572				292		
	5'-gTg 3'					5'-gCg 3'				5'-gTC 3'		
						572						
						5'-gTg 3'						
Well No.	49	50	51	52	53	54	55	56	57	58	59	60

Well No.	61	62	63
Length of spec. PCR product(s)	90	435	95
	120		
	150		
	180		
Length of int. pos. control ¹	800	1070	1070
5'-primer(s) ²	165	272	407
	5'-ACC 3'	5'-CTA 3'	5'-gg 3'
	222		409
	5'-CCA 3'		5'-ggC 3'
3'-primer(s) ³	272	419	463
	5'-TgC 3'	5'-CgA 3'	5'-gCT 3'
	302		
	5'-ggT 3'		
Well No.	61	62	63

¹The internal positive control primer pairs amplify segments of the human growth hormone gene. The two different control primer pairs give rise to either an internal positive control band of 1070 base pairs, for most wells, or a band of 800 base pairs, for some wells. Well number 1 contains the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to help in the correct orientation of the HLA-B low resolution typing. In addition, wells number 4 to 6, 10, 17, 20, 21, 30, 35, 42, 48, 50, 60 and 61 contain the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to allow kit identification.

²The nucleotide position, in the 1st, 2nd or 3rd exon or in the 1st intron, 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, in the 2nd, or 3rd exon or the 3rd intron, 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.

101.501.48/12 – including *Taq* pol., IFU-01
 101.501.48u/12u – without *Taq* pol., IFU-02

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Lot No.: **03N**

Lot-specific information

CELL LINE VALIDATION SHEET																			
HLA-B low resolution SSP kit																			
			Prod. No.:	Well															
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
				201190001	201190002	201190003	201190004	201190005	201190006	201190007	201190008	201192409	201190010	201190011	201190012	201190013	201190014	201190015	201190016
	IHWC cell line	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	-	-	-	+	-	-	-	-	-	-	+	-	-	-		

101.501.48/12 – including *Taq* pol., IFU-01
 101.501.48u/12u – without *Taq* pol., IFU-02

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Lot No.: **03N**

Lot-specific information

				Well															
				17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32
Prod. No.:				201190017	201190018	201190019	201192420	201190021	201190022	201190023	201190024	201190025	201190026	201190027	201190028	201190029	201190030	201190031	201190032
IHCW cell line		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	+	+	-	-	-	-	-	-	-	-	-	+	-	-	-

101.501.48/12 – including *Taq* pol., IFU-01
 101.501.48u/12u – without *Taq* pol., IFU-02

Visit www.olerup-ssp.com for
 “Instructions for Use” (IFU)

Lot No.: **03N**

Lot-specific information

				Well																
				33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	
				Prod. No.:	201190033	201190034	201190035	201190036	201190037	201190038	201190039	201190040	201190041	201190042	201190043	201190044	201190045	201190046	201190047	201188648
IHCW cell line		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	-	-	-	-	-	+	-	-	-	-	-	+	-	+	+	-

101.501.48/12 – including *Taq* pol., IFU-01
 101.501.48u/12u – without *Taq* pol., IFU-02

Visit www.olerup-ssp.com for
 “Instructions for Use” (IFU)

Lot No.: **03N**

Lot-specific information

CELL LINE VALIDATION SHEET																		
HLA-B low resolution SSP kit																		
			Prod. No.:	Well														
				49	50	51	52	53	54	55	56	57	58	59	60	61	62	63
				201192449	201192450	201192451	201192452	201192453	201192454	201192455	201192456	201192457	201192458	201192459	201192460	201192461	201192462	201192463
	IHWC cell line	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	-	-	+	-	-	+	-	-	-	-	-	-	-	-	+

101.501.48/12 – including *Taq* pol., IFU-01
 101.501.48u/12u – without *Taq* pol., IFU-02

Visit www.olerup-ssp.com for
 “Instructions for Use” (IFU)

Lot No.: **03N**

Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-B low resolution SSP

Product number: 101.501-48/12 – including *Taq* pol.
 101.501-48u/12u – without *Taq* pol.
 Lot number: 03N
 Expiry date: 2014-June-01
 Number of tests: 48 tests – Product No. 101.501-48/48u
 12 tests – Product No. 101.501-12/12u
 Number of wells per test: 63 + 1

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2011-900-01	25	2011-900-25	49	2011-924-49
2	2011-900-02	26	2011-900-26	50	2011-924-50
3	2011-900-03	27	2011-900-27	51	2011-924-51
4	2011-900-04	28	2011-900-28	52	2011-924-52
5	2011-900-05	29	2011-900-29	53	2011-924-53
6	2011-900-06	30	2011-900-30	54	2011-924-54
7	2011-900-07	31	2011-900-31	55	2011-924-55
8	2011-900-08	32	2011-900-32	56	2011-924-56
9	2011-924-09	33	2011-900-33	57	2011-924-57
10	2011-900-10	34	2011-900-34	58	2011-924-58
11	2011-900-11	35	2011-900-35	59	2011-924-59
12	2011-900-12	36	2011-900-36	60	2011-924-60
13	2011-900-13	37	2011-900-37	61	2011-924-61
14	2011-900-14	38	2011-900-38	62	2011-924-62
15	2011-900-15	39	2011-900-39	63	2011-924-63
16	2011-900-16	40	2011-900-40		
17	2011-900-17	41	2011-900-41		
18	2011-900-18	42	2011-900-42		
19	2011-900-19	43	2011-900-43		
20	2011-924-20	44	2011-900-44		
21	2011-900-21	45	2011-900-45		
22	2011-900-22	46	2011-900-46		
23	2011-900-23	47	2011-900-47		
24	2011-900-24	48	2011-886-48		

The specificity of each primer solution of the kit has been tested against 48 well characterized IHWC cell line DNAs.

Additional 3'-primers in primer solutions 2, 3, 6, 13 to 15, 19, 29, 31, 35, 40 and 58 were tested by separately adding additional 5'-primers.

Additional 5'-primers in primer solutions 1, 3, 6, 14, 19, 21, 25, 29, 31, 40, 48, 58 and 61 were tested by separately adding additional 3'-primers.

In primer solutions 31 and 42 one 5'-primer was not possible to test and in primer solutions 38, 42, 54 and 61 one 3'-primer was not possible to test.

101.501.48/12 – including *Taq* pol., IFU-01
101.501.48u/12u – without *Taq* pol., IFU-02

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“Instructions for Use” (IFU)

Lot No.: **03N**

Lot-specific information

The negative control primer pairs, **Production No. 2011-917-01**, can detect contamination with PCR products diluted 10^{-7} .

Results: No false positive or false negative amplifications were obtained.

Date of approval: 2012-April-20

Approved by:

Production Quality Control

101.501.48/12 – including *Taq* pol., IFU-01
101.501.48u/12u – without *Taq* pol., IFU-02

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“Instructions for Use” (IFU)

Lot No.: **03N**

Lot-specific information

Declaration of Conformity

Product name: *Olerup* SSP® HLA-B low resolution
Product number: 101.501-48/48u, -12/12u
Lot number: 03N

Intended use: HLA-B low resolution histocompatibility testing

Manufacturer: *Olerup* SSP AB
Franzengatan 5
SE-112 51 Stockholm, Sweden
Phone: +46-8-717 88 27
Fax: +46-8-717 88 18

We, *Olerup* SSP AB, hereby declare that this product, to which this Declaration of Conformity relates is in conformity with the following Standard(s) and other normative document(s) ISO 9001:2008 and ISO 13485:2003, following the provisions of the 98/79/EC Directive on *in vitro* diagnostic medical devices, Annex II List B, conformity assessed using Annex IV, as transposed into the national laws of the Member States of the European Union.

The Technical Documentation File is maintained at *Olerup* SSP AB, Franzengatan 5, SE-112 51 Stockholm, Sweden.

Notified Body: Lloyd's Register Quality Assurance Limited, Hiramford, Middlemarch Office Village, Siskin Drive, Coventry CV3 4FJ, United Kingdom. (Notified Body number: 0088.)

Stockholm, Sweden
2012-April-20

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs

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