

101.569-06 – including *Taq* polymerase, IFU-01 Rev. No. 03101.569-06u – without *Taq* polymerase, IFU-02 Rev. No. 03Visit www.olerup-ssp.com for

“Instructions for Use” (IFU)

Lot No.: **95N**

Lot-specific information

Olerup SSP[®] HLA-B*54

Product number:	101.569-06 – including <i>Taq</i> polymerase 101.569-06u – without <i>Taq</i> polymerase
Lot number:	95N
Expiry date:	2014-December-01
Number of tests:	6
Number of wells per test:	20
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. 95N.

**CHANGES COMPARED TO THE PREVIOUS OLERUP SSP[®]
HLA-B*54 LOT (30M)**

The HLA-B*54 specificity and interpretation tables have been updated for the HLA-B alleles described since the previous *Olerup SSP[®]* HLA-B*54 lot was made (**Lot No. 30M**).

The HLA-B*54 kit is updated for new alleles to enable separation of:

- Confirmed¹ alleles as listed in the IMGT/HLA database
- Polymorphisms in exons outside of the region encoding the peptide binding domain
- Null and Alternatively expressed alleles

The Lot-specific information for HLA-B*54 including and without *Taq* polymerase is now described in one common Product Insert.

¹As described in section Uniquely Identified Alleles.

The HLA-B*54 primer set is unchanged compared to the previous lot.

Change in revision R01 compared to R00:

1. Primer mix 5 may amplify the C*03:19 and C*03:102 alleles. A foot note has been added in the Specificity Table.

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PRODUCT DESCRIPTION

HLA-B*54 SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for identifying the B*54:01 to B*54:26 alleles.

PLATE LAYOUT

Each test consists of 20 PCR reactions in a 24 well PCR plate. Wells 21 to 24 are empty.

1	2	3	4	5	6	7	8
9	10	11	12	13	14	15	16
17	18	19	20	empty	empty	empty	empty

The 24 well PCR plate is marked with ‘HLA-B*54’ in silver/gray ink.

Well No. 1 is marked with the Lot Number ‘95N’.

A faint row of numbers is seen between wells 1 and 2 or wells 7 and 8 of the PCR trays. These stem from the manufacture of the trays, and should be disregarded.

The PCR plates are covered with a PCR-compatible foil.

Please note: When removing each 24 well PCR plate, make sure that the remaining plates stay covered. Use a scalpel or a similar instrument to carefully cut the foil between the plates.

INTERPRETATION

The interpretation of HLA-B*54 SSP subtypings will be influenced by nine B*07, nine B*08, most B*13, most B*15, the B*18, eleven B*27, most B*35, the B*37:01:04, most B*38, most B*39, most B*40, ten B*41, two B*42, sixteen B*44, thirteen B*45, the B*46, most B*48, the B*49, the B*50, most B*51, the B*52, most B*53, most B*55, most B*56, many B*57, most B*58, most B*59, the B*67, the B*78, the B*81 and B*82 alleles when present on the other haplotype. In addition, the C*02:03 allele will be amplified by primer mix 9, the C*03:137 and C*07:102 alleles will be amplified by primer mix 4 and the C*05:30 allele will be amplified by primer mix 3.

UNIQUELY IDENTIFIED ALLELES

All the HLA-B*54 alleles, i.e. **B*54:01 to B*54:26**, recognized by the HLA Nomenclature Committee in April 2012¹ will be amplified by the primers in the HLA-B*54 subtyping kit.

The HLA-B*54 kit enables separation of the confirmed HLA-B*54 alleles as listed in the IMGT/HLA database. An HLA allele is listed as confirmed by IMGT/HLA if it has been sequenced by more than a single laboratory or from multiple sources. Current allele confirmation status for HLA-B*54 alleles is listed below.

The HLA-B*54 kit also enables identification of polymorphisms in exons outside of the region encoding the peptide binding domain and of null and alternatively expressed alleles.

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Lot-specific information

The B*54:17 and B*54:18 alleles may be distinguished by the different sizes of the specific PCR products generated by primer mix 16.

¹HLA-B alleles listed on the IMGT/HLA web page 2012-April-12, release 3.8.0, www.ebi.ac.uk/imgt/hla.

ALLELE CONFIRMATION STATUS

Allele	Status ¹	Allele	Status ¹	Allele	Status ¹
B*54:01:01	Confirmed	B*54:10	Confirmed	B*54:20	Unconfirmed
B*54:01:02	Unconfirmed	B*54:11	Unconfirmed	B*54:21	Unconfirmed
B*54:02	Unconfirmed	B*54:12	Unconfirmed	B*54:22	Unconfirmed
B*54:03	Unconfirmed	B*54:13	Confirmed	B*54:23	Unconfirmed
B*54:04	Unconfirmed	B*54:14	Confirmed	B*54:24	Unconfirmed
B*54:05N	Unconfirmed	B*54:15	Unconfirmed	B*54:25	Unconfirmed
B*54:06	Unconfirmed	B*54:16	Unconfirmed	B*54:26	Unconfirmed
B*54:07	Unconfirmed	B*54:17	Unconfirmed		
B*54:08N	Unconfirmed	B*54:18	Unconfirmed		
B*54:09	Unconfirmed	B*54:19	Unconfirmed		

¹Allele status “confirmed” or “unconfirmed” as listed on the IMGT/HLA web page 2012-April-12, release 3.8.0, www.ebi.ac.uk/imgt/hla.

RESOLUTION IN HOMO- AND HETEROZYGOTES

A total of 27 alleles generate 24 amplification patterns that can be combined in 300 homozygous and heterozygous combinations. 128 of these genotypes do not give rise to unique amplification patterns. The different lengths of the specific PCR products were not considered in these calculations.

```

+++----- ----- ---- *54:01:01, *54:01:01 = *54:01:01, *54:01:02
++-----+ -----+- ---- *54:06, *54:14 = *54:14, *54:14
++-----+ +----- - ---- *54:06, *54:09 = *54:09, *54:09
++-----+ ------+- ---- *54:04, *54:15 = *54:15, *54:15
++-----+ -+----- - ---- *54:04, *54:11 = *54:11, *54:11
+++----- ----- -++ *54:01:01, *54:24 = *54:01:02, *54:24 = *54:24, *54:24
+++----- ----- -+- *54:01:01, *54:23 = *54:01:02, *54:23 = *54:23, *54:23
+++----- ----- -+- *54:01:01, *54:21 = *54:01:02, *54:21 = *54:21, *54:21
+++----- ----- + ---- *54:01:01, *54:17 = *54:01:02, *54:17 = *54:17, *54:17
+++----- -----+- ---- *54:01:01, *54:16 = *54:01:02, *54:16 = *54:16, *54:16
+++----- -----+- ---- *54:01:01, *54:07 = *54:01:02, *54:07 = *54:07, *54:07
+++----- -----+- ---- *54:01:01, *54:13 = *54:01:02, *54:13 = *54:13, *54:13
+++----- -++----- - ---- *54:01:01, *54:12 = *54:01:02, *54:12 = *54:12, *54:12
+++----- -+----- - ---- *54:01:01, *54:22 = *54:01:02, *54:22 = *54:22, *54:22
+++----- -+----- - ---- *54:01:01, *54:10 = *54:01:02, *54:10 = *54:10, *54:10
+++-----+ ----- - ---- *54:01:01, *54:06 = *54:01:02, *54:06
+++-----+ ----- - ---- *54:01:01, *54:05N = *54:01:02, *54:05N
+++-----+ ----- - ---- *54:01:01, *54:04 = *54:01:02, *54:04
+++-----+ ----- - ---- *54:01:01, *54:03 = *54:01:02, *54:03 = *54:03, *54:03
++++----- ----- - ---- *54:01:01, *54:02 = *54:01:01, *54:19 = *54:01:02, *54:02 =
*54:01:02, *54:19 = *54:02, *54:19 = *54:19, *54:19
+-----+-----+- ---- *54:04, *54:14 = *54:06, *54:15 = *54:14, *54:15
+++----- -+----- +---- *54:01:01, *54:20 = *54:01:02, *54:20 = *54:10, *54:20 = *54:20,

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	*54:20
+++-----+ - - - - - + - - - - -	*54:01:01, *54:14 = *54:01:02, *54:14 = *54:06, *54:16 = *54:14, *54:16
+++-----+ + - - - - - - - - - -	*54:01:01, *54:09 = *54:01:02, *54:09
+++++--- - - - - - + - - - - -	*54:01:01, *54:15 = *54:01:02, *54:15 = *54:04, *54:16 = *54:15, *54:16
+++---+--- - - + - - - - - - - - - -	*54:01:01, *54:11 = *54:01:02, *54:11 = *54:04, *54:22 = *54:11, *54:22
+++---+--- - - - - - - - - - -	*54:01:01, *54:08N = *54:01:02, *54:08N = *54:03, *54:04 = *54:03, *54:08N = *54:04, *54:08N = *54:08N, *54:08N
+++++--- - - - - - - - - - - +	*54:02, *54:24 = *54:19, *54:24
+++++--- - - - - - - - - - - - + -	*54:02, *54:23 = *54:19, *54:23
+++++--- - - - - - - - - - - - + - -	*54:02, *54:21 = *54:19, *54:21
+++++--- - - - - - - - - - - - + - - -	*54:02, *54:17 = *54:17, *54:19
+++++--- - - - - - - - - - - - + - - - -	*54:02, *54:16 = *54:16, *54:19
+++++--- - - - - - - - - - - - + - - - -	*54:02, *54:07 = *54:07, *54:19
+++++--- - - - - - - - - - - - + - - - -	*54:02, *54:13 = *54:13, *54:19
+++++--- - - - - - - - - - - - + - - - -	*54:02, *54:12 = *54:12, *54:19
+++++--- - - - - - - - - - - - + - - - -	*54:02, *54:22 = *54:19, *54:22
+++++--- - - - - - - - - - - - + - - - -	*54:02, *54:10 = *54:10, *54:19
+++++--- + - - - - - - - - - - - - - - -	*54:02, *54:06 = *54:06, *54:19
+++++--- + - - - - - - - - - - - - - - -	*54:02, *54:04 = *54:04, *54:19
+++++--- - - - - - - - - - - - - - - -	*54:02, *54:03 = *54:03, *54:19
+++---+--- - - - - - - - - - - - - - - -	*54:11, *54:16 = *54:15, *54:22
+++---+--- - - - - - - - - - - - - - - -	*54:03, *54:15 = *54:08N, *54:15 = *54:08N, *54:16
+++---+--- - - - - - - - - - - - - - - -	*54:03, *54:11 = *54:08N, *54:11 = *54:08N, *54:22
+++++--- - - - - - - - - - - - - - - -	*54:02, *54:20 = *54:19, *54:20
+++++--- + - - - - - - - - - - - - - - -	*54:02, *54:14 = *54:14, *54:19
+++++--- + - - - - - - - - - - - - - - -	*54:02, *54:09 = *54:09, *54:19
+++++--- + - - - - - - - - - - - - - - -	*54:02, *54:15 = *54:15, *54:19
+++++--- + - - - - - - - - - - - - - - -	*54:02, *54:11 = *54:11, *54:19
+++++--- + - - - - - - - - - - - - - - -	*54:02, *54:08N = *54:08N, *54:19

*54:01:01= *54:01:01 and 54:25-54:26

*54:17= *54:17 and 54:18

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SPECIFICITY TABLE**HLA-B*54 SSP subtyping**

Specificities and sizes of the PCR products of the 20 primer mixes used for HLA-B*54 SSP subtyping

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified HLA-B*54 alleles ³	Other amplified HLA Class I alleles ⁴
1	215 bp	800 bp	*54:01:01, 54:02-54:26	*07:02:19, 15:01:04, 37:01:04, 40:94, 51:01:18, 58:01:08
2 ⁵	105 bp	1070 bp	*54:01:01-54:03, 54:05N, 54:07-54:08N, 54:10, 54:12-54:13, 54:16-54:26	*07:78, 13:02:01-13:03, 13:08Q-13:09, 13:14-13:16, 13:18-13:19, 13:27, 13:30-13:34, 13:37-13:38, 13:40-13:42, 13:44-13:45, 13:48-13:49N, 13:53-13:54, 15:42, 35:60, 44:15, 44:18, 45:01, 45:03-45:08, 45:10-45:14, 46:11, 46:18, 49:01:01-49:03, 49:06-49:17, 49:19N-49:20, 50:01:01-50:02, 50:04-50:08, 50:10-50:11, 50:13, 50:15, 51:15, 52:25, 55:01:01-55:01:03, 55:01:05-55:01:06, 55:01:08-55:03, 55:05, 55:07, 55:09-55:12, 55:15-55:16, 55:18-55:19, 55:21-55:22, 55:24-55:26, 55:29-55:31, 55:33-55:38, 55:40-55:41, 55:43, 55:45-55:48, 55:50, 55:52, 55:54-55:56, 56:01:01-56:01:04, 56:07-56:08, 56:13-56:14, 56:16-56:17, 56:19N-56:20:02, 56:23-56:30, 56:33-56:35, 59:01:01:01-59:01:01:02, 59:04-59:05
3 ⁶	160 bp	1070 bp	*54:01:01-54:01:02, 54:03-54:04, 54:06-54:26	*44:24, 51:39, C*05:30
4 ⁷	160 bp	1070 bp	*54:02, 54:19	*07:13, 07:110, 38:11, 67:02, C*03:137, C*07:102^w
5 ¹⁰	180 bp	1070 bp	*54:03, 54:08N	*13:03, 13:48, 15:73, 40:71, 44:10, 44:15, 44:18, 44:140, 45:01, 45:04-45:07, 45:11-45:14, 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, 50:15-50:16, 51:15, 51:62, 51:106, 52:25, 56:01:01-56:02, 56:04, 56:07-56:08, 56:13-56:14, 56:16-56:17, 56:20:01-56:20:02, 56:24-56:30, 56:33-56:35, 59:04, 82:01-82:03

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6^{5,8}	105 bp, 235 bp	1070 bp	*54:04, 54:08N, 54:11, 54:15	*07:84, 08:09, 08:84, 13:35, 15:83, 27:14, 27:81, 40:06:01:01-40:06:05, 40:44, 40:53, 40:70, 40:75, 40:83, 40:93, 40:95-40:96, 40:103, 40:109- 40:110, 40:127, 40:131, 40:148, 40:161-40:162, 40:165, 40:167, 40:177, 40:190, 41:01, 41:05-41:07, 41:09, 41:12, 41:14, 41:16-41:17, 41:20, 42:04, 44:20, 44:47, 44:100, 49:18, 50:14, 51:01:01-51:03, 51:05, 51:07:01- 51:12, 51:14, 51:16-51:24:04, 51:26- 51:34, 51:36, 51:38-51:41N, 51:43- 51:44N, 51:48-51:55, 51:57-51:58, 51:60-51:61, 51:65-51:80, 51:82-51:91, 51:93-51:96, 51:98N, 51:100-51:105, 51:107-51:130, 52:01:01:01-52:13, 52:15-52:24, 52:26-52:29, 55:17, 55:20, 55:27-55:28, 56:05:01-56:06, 56:15, 56:21, 58:08:01-58:08:02, 59:02, 78:01:01-78:07
7	140 bp	1070 bp	*54:05N	
8	280 bp	1070 bp	*54:06, 54:09, 54:14	*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, 15:46-15:47:02, 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, 15:234-15:242, 15:244, 18:01:01:01- 18:15, 18:17N-18:25, 18:27-18:40, 18:42-18:60, 18:62-18:71, 27:41, 35:01:01:01-35:01:31, 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, 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,

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9	200 bp	1070 bp	*54:09	*07:48, 08:13, 08:25, 08:40 ^w , 08:55, 13:10-13:11, 15:05:01-15:05:02, 15:31, 15:48, 15:52, 15:55, 15:91, 15:107, 15:114, 15:123-15:124, 15:136, 15:151, 15:185-15:186, 15:188, 15:224, 15:235, 15:237 ^w , 18:01:01:01-18:01:05, 18:01:07-18:01:16, 18:03-18:07:02, 18:09-18:12, 18:13 ^w , 18:14, 18:17N, 18:20, 18:23N-18:26, 18:28-18:29, 18:31-18:51, 18:53-18:55, 18:58-18:71, 27:07:01-27:07:02, 27:11, 27:32-27:34, 27:43, 27:70, 35:05:01-35:05:02, 35:22, 35:31-35:32:02, 35:51, 35:66 ^w , 35:68:02, 35:72, 35:89, 35:97, 35:114, 35:151, 35:199, 38:01:01-38:09, 38:11- 38:19, 38:21, 38:23, 38:25-38:29, 38:31, 38:33-38:40, 39:01:01:01- 39:01:01:02L, 39:01:03-39:05:02, 39:07, 39:10:01-39:10:02, 39:12-39:17, 39:19:01-39:20, 39:22-39:23, 39:25N- 39:32, 39:37-39:41, 39:43-39:49, 39:51- 39:56, 39:58-39:59, 39:61, 39:63, 39:65-39:73, 40:01:01-40:01:03,

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				40:01:05-40:01:11, 40:01:13-40:02:08, 40:02:10-40:03, 40:07-40:11:01, 40:12-40:14:03, 40:18-40:22N, 40:24-40:25, 40:27:01-40:27:02, 40:29, 40:31, 40:33, 40:35-40:40, 40:42-40:43, 40:45-40:50, 40:52, 40:54-40:58, 40:61-40:63, 40:65-40:67, 40:69, 40:71-40:74, 40:76-40:82, 40:84-40:85, 40:87:01-40:92, 40:94, 40:97, 40:99, 40:101-40:102, 40:104-40:108, 40:111-40:119, 40:121-40:123, 40:124:02, 40:126, 40:128, 40:130, 40:132-40:135, 40:138-40:142N, 40:144N-40:147, 40:149-40:157, 40:163-40:164, 40:166, 40:168-40:172, 40:175-40:176, 40:178-40:182, 40:184-40:189, 40:191-40:193, 44:31, 44:54, 44:65, 44:82, 44:135, 46:06, 46:13:01-46:13:03, 46:19, 46:21:01-46:21:02, 46:26, 48:01:01-48:01:03, 48:03:01, 48:04, 48:06-48:07, 48:09-48:14, 48:16, 48:18, 48:20, 48:22-48:23, 48:24 ^w , 48:27, 51:81, 53:14, 55:04, 55:08, 55:49, 55:51, 56:02, 56:04, 56:10, 56:18, 56:31, 58:16, 58:18, 58:20, 58:27, 67:01:01-67:03, 81:01-81:05, C*02:03
10	225 bp	1070 bp	*54:10, 54:20	*07:78, 07:84, 13:18, 13:31, 13:41, 15:04, 15:137, 39:33, 40:161, 51:05, 51:29, 51:54, 51:61, 51:82, 52:21, 52:24, 55:09, 55:21, 55:37, 55:52
11	185 bp	1070 bp	*54:11, 54:22	
12	150 bp	1070 bp	*54:12	
13	135 bp	1070 bp	*54:13	
14	210 bp	800 bp	*54:07	
15⁵	95 bp	1070 bp	*54:14-54:16	*07:84, 13:04, 13:35, 15:04, 15:16:01-15:16:03, 15:67, 15:95, 15:155, 15:222, 35:37, 40:44, 40:159, 44:20, 44:47, 44:100, 45:09, 49:04-49:05, 51:37, 51:90, 51:92, 52:12, 52:26, 55:23, 55:27, 55:46
16⁹	210 bp, 340 bp	1070 bp	*54:17-54:18	
17	210 bp	1070 bp	*54:20	*07:78, 07:84, 13:16, 13:31 ^w , 13:48, 15:04 ^w , 15:16:01-15:16:03, 15:42, 15:67, 15:95, 15:137 ^w , 40:95, 40:148,

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				40:161, 49:01:01, 49:01:03-49:10, 49:12-49:20, 50:01:01-50:02, 50:04-50:11, 50:13-50:16, 51:01:01-51:03, 51:07:01-51:07:02, 51:11N-51:14, 51:16-51:18, 51:21-51:24:04, 51:26-51:30, 51:32-51:35, 51:37-51:39, 51:41N, 51:43, 51:48-51:53, 51:55, 51:57-51:58, 51:60, 51:61 ^w , 51:63, 51:65-51:71, 51:74-51:80, 51:82-51:86, 51:88-51:90, 51:92, 51:94-51:96, 51:98N-51:107, 51:109-51:114, 51:116-51:121, 51:123-51:131, 52:01:01:01-52:02, 52:04-52:09, 52:11-52:18, 52:20, 52:21 ^w , 52:22-52:29, 55:01:01-55:01:06, 55:01:08-55:01:09, 55:03, 55:05, 55:09, 55:11, 55:15, 55:17, 55:21 ^w , 55:24-55:25, 55:28-55:29, 55:31, 55:33, 55:36, 55:38, 55:40, 55:44-55:45, 55:52-55:55N, 56:05:01-56:06, 56:21, 56:25, 58:08:01-58:08:02, 78:01:01-78:03, 78:05-78:07
18	295 bp	1070 bp	*54:21	*40:149, 55:10, 56:16, 82:01-82:03
19	230 bp	1070 bp	*54:23	
20	205 bp	1070 bp	*54:24	

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*54 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 length of the specific PCR product(s) of the alleles amplified by these primer mixes is 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*54 subtyping.

In addition, well 14 contains the primer pair giving rise to the shorter, 800 bp, internal positive control in order to allow kit identification.

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

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³For several HLA-B alleles 1st, 4th and 5th exon or intron nucleotide sequences are not available. In these instances it is not known whether some of the primers of the SSP sets are completely matched with the target sequences or not. We assume that unknown sequences in these regions are conserved within allelic groups.

⁴Due to the sharing of sequence motifs between HLA-B alleles non-HLA-B*54 alleles will be amplified by primer mixes 1 to 6, 8 to 10, 15, 17 and 18. In addition, the C*02:03 allele will be amplified by primer mix 9, the C*03:137 and C*07:102 alleles will be amplified by primer mix 4 and the C*05:30 allele will be amplified by primer mix 3.

⁵Specific PCR fragments shorter than 125 base pairs have a lower intensity than longer PCR bands.

⁶Primer mix 3 may give a lower yield of specific PCR product than the other B*54 primer mixes.

⁷Primer mix 4 may have tendencies of non-specific amplification.

⁸Primer mix 6: Specific PCR fragment of 105 bp in the B*54:04, 54:11 and 54:15 and in the B*07:84, 08:09, 08:84, 13:35, 15:83, 27:14, 27:81, 40:06:01:01-40:06:05, 40:44, 40:53, 40:70, 40:75, 40:83, 40:93, 40:95-40:96, 40:103, 40:109-40:110, 40:127, 40:131, 40:148, 40:161-40:162, 40:165, 40:167, 40:177, 40:190, 41:01, 41:05-41:07, 41:09, 41:12, 41:14, 41:16-41:17, 41:20, 42:04, 44:20, 44:47, 44:100, 49:18, 50:14, 51:01:01-51:03, 51:05, 51:07:01-51:12, 51:14, 51:16-51:24:04, 51:26-51:34, 51:36, 51:38-51:41N, 51:43-51:44N, 51:48-51:55, 51:57-51:58, 51:60-51:61, 51:65-51:80, 51:82-51:91, 51:93-51:96, 51:98N, 51:100-51:105, 51:107-51:130, 52:01:01:01-52:13, 52:15-52:24, 52:26-52:29, 55:17, 55:20, 55:27-55:28, 56:05:01-56:06, 56:15, 56:21, 58:08:01-58:08:02, 59:02 and 78:01:01-78:07 alleles. Specific PCR fragment of 235 bp in the B*54:08N allele.

⁹Primer mix 16: Specific PCR fragment of 210 bp in the B*54:18 allele. Specific PCR fragment of 340 bp in the B* 54:17 allele.

¹⁰Primer mix 5 may amplify the C*03:19 and C*03:102 alleles.

‘w’, may be weakly amplified.

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Lot-specific information

INTERPRETATION TABLE												
HLA-B*54 SSP subtyping												
Amplification patterns of the B*54:01 to 54:26 alleles												
	Well ⁶											
	1	2	3	4	5	6	7	8	9	10	11	12
Length of spec.	215	105	160	160	180	105	140	280	200	225	185	150
PCR product(s)						235						
Length of int. pos. control ¹	800	1070	1070	1070	1070	1070	1070	1070	1070	1070	1070	1070
5'-primer ²	5'-CAG ^{3'} 1 st I	5'-Tgg ^{3'} 357	5'-CCA ^{3'} 106	5'-CCT ^{3'} 103	5'-TTA ^{3'} 420	5'-Tgg ^{3'} 357	5'-CCA ^{3'} 106	5'-gTC ^{3'} 419	5'-TAC ^{3'} 369	5'-Tgg ^{3'} 357	5'-Tgg ^{3'} 357	5'-Agg ^{3'} 206
				5'-gTT ^{3'} 110								
				5'-CCT ^{3'} 103								
3'-primer(s) ³	5'-CCg ^{3'} 175	5'-gCT ^{3'} 420	5'-CAC ^{3'} 226	5'-CAC ^{3'} 226	5'-CTA ^{3'} 553	5'-CgT ^{3'} 419	5'-TCC ^{3'} 207	5'-TAT ^{3'} 3 rd I	5'-CCA ^{3'} 527	5'-TCC ^{3'} 539	5'-ggA ^{3'} 499	5'-ggA ^{3'} 317
					5'-Cag ^{3'} 559	5'-CTA ^{3'} 553			5'-CCA ^{3'} 527			
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
HLA-B allele ⁴												
*54:01:01, 54:25-54:26	1	2	3									
*54:01:02		2	3									
*54:02	1	2		4								
*54:03	1	2	3		5							
*54:04	1		3			6						
*54:05N	1	2					7					
*54:06	1		3					8				
*54:07	1	2	3									
*54:08N	1	2	3		5	6						
*54:09	1		3					8	9			
*54:10	1	2	3							10		
*54:11	1		3			6					11	
*54:12	1	2	3									12
*54:13	1	2	3									
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

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Lot-specific information

INTERPRETATION TABLE									
HLA-B*54 SSP subtyping									
Amplification patterns of the B*54:01 to 54:26 alleles									
Well⁶									
13	14	15	16	17	18	19	20		
135	210	95	210	210	295	230	205	Length of spec.	
			340					PCR product(s)	
1070	800	1070	1070	1070	1070	1070	1070	Length of int. pos. control ¹	
133	106	357	89	357	15	106	106	5'-primer ²	
5'-CCg ^{3'}	5'-CCA ^{3'}	5'-Tgg ^{3'}	5'-gAA ^{3'}	5'-Tgg ^{3'}	5'-gCA ^{3'}	5'-CCA ^{3'}	5'-CCA ^{3'}		
			5'-Agg ^{3'}						
226	275	412	259	527	142	294	272	3'-primer(s) ³	
5'-CAC ^{3'}	5'-CCA ^{3'}	5'-gTC ^{3'}	5'-gTT ^{3'}	5'-CCT ^{3'}	5'-TgA ^{3'}	5'-CgC ^{3'}	5'-TgA ^{3'}		
		412	916						
		5'-gTC ^{3'}	5'-gAT ^{3'}						
13	14	15	16	17	18	19	20	Well No.	
								HLA-B allele ⁴	
								*54:01:01, 54:25-54:26	
								*54:01:02	
								*54:02	
								*54:03	
								*54:04	
								*54:05N	
								*54:06	
	14							*54:07	
								*54:08N	
								*54:09	
								*54:10	
								*54:11	
								*54:12	
13								*54:13	
13	14	15	16	17	18	19	20	Well No.	

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Lot No.: **95N**

Lot-specific information

Length of spec.	215	105	160	160	180	105	140	280	200	225	185	150
PCR product(s)						235						
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
*54:14	1		3					8				
*54:15	1		3			6						
*54:16	1	2	3									
*54:17, 54:18 ⁵	1	2	3									
*54:19	1	2	3	4								
*54:20	1	2	3							10		
*54:21	1	2	3									
*54:22	1	2	3								11	
*54:23	1	2	3									
*54:24	1	2	3									
*07:02:19, 37:01:04	1											
*07:09, 07:11, 07:17, 08:28, 08:35, 08:37, 13:26, 15:01:01:01-15:01:03, 15:01:06-15:03:03, 15:06-15:08, 15:11:01-15:15, 15:18:01-15:21, 15:23-15:29, 15:32-15:36, 15:38:01-15:40, 15:43-15:44, 15:46-15:47:02, 15:49-15:51, 15:53-15:54, 15:56-15:57, 15:60-15:62, 15:64-15:66, 15:68- 15:72, 15:74-15:76, 15:78:01-15:82, 15:84-15:85, 15:87- 15:89, 15:92-15:94N, 15:96-15:98, 15:101-15:106, 15:108- 15:113, 15:115-15:122, 15:125-15:129, 15:131-15:132, 15:134-15:135, 15:138-15:149N, 15:152-15:154, 15:156- 15:161, 15:163-15:167, 15:169-15:176, 15:178-15:184, 15:187, 15:189-15:195, 15:197-15:207, 15:209N-15:215, 15:217-15:221, 15:223, 15:225-15:228, 15:231-15:232, 15:234, 15:236, 15:238-15:242, 15:244, 18:01:06, 18:02, 18:08, 18:15, 18:18-18:19, 18:21-18:22, 18:27, 18:30, 18:52, 18:56-18:57, 27:41, 35:01:01:01-35:01:31, 35:07- 35:08:05, 35:10-35:11:02, 35:14:01-35:17, 35:19-35:21, 35:23-35:30, 35:35, 35:40N-35:43, 35:45-35:50, 35:52- 35:54, 35:57-35:58, 35:61-35:64, 35:67-35:68:01, 35:69, 35:71, 35:76-35:80, 35:82, 35:86, 35:90-35:94, 35:99- 35:105, 35:107-35:108:02, 35:110-35:113, 35:115-35:126, 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, 35:185-35:192, 35:194, 35:196-35:197, 35:200, 40:59-40:60, 40:158, 42:09, 44:17, 44:43:01-44:43:02, 44:144, 46:01:01-46:05, 46:07N-46:10, 46:12, 46:14-46:17, 46:20, 46:22-46:25, 46:27-46:30, 48:02:01-48:02:02, 48:25, 51:45, 51:97, 53:01:01-53:03, 53:05-53:06, 53:08:01-53:13, 53:15-53:18, 53:20-53:27, 55:14, 55:32, 56:03, 56:09, 56:32, 57:01:01-57:01:13, 57:06, 57:08, 57:10-57:11, 57:13- 57:16, 57:18-57:27, 57:29-57:31, 57:33-57:38, 57:40-57:41, 57:43-57:45, 57:47-57:56, 58:01:01-58:01:07, 58:01:09- 58:02, 58:04-58:07, 58:09-58:15, 58:17N, 58:19, 58:21- 58:26, 58:29-58:33, 58:35-58:36								8				
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

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Lot-specific information

135	210	95	340	210	295	230	205	Length of spec.
13	14	15	16	17	18	19	20	PCR product(s)
13	14	15	16	17	18	19	20	Well No.
		15						*54:14
		15						*54:15
		15						*54:16
			16					*54:17, 54:18 ⁵
								*54:19
				17				*54:20
					18			*54:21
								*54:22
						19		*54:23
							20	*54:24
								*07:02:19, 37:01:04
								*07:09, 07:11, 07:17, 08:28, 08:35, 08:37, 13:26, 15:01:01:01-15:01:03, 15:01:06-15:03:03, 15:06-15:08, 15:11:01-15:15, 15:18:01-15:21, 15:23-15:29, 15:32-15:36, 15:38:01-15:40, 15:43-15:44, 15:46-15:47:02, 15:49-15:51, 15:53-15:54, 15:56-15:57, 15:60-15:62, 15:64-15:66, 15:68- 15:72, 15:74-15:76, 15:78:01-15:82, 15:84-15:85, 15:87- 15:89, 15:92-15:94N, 15:96-15:98, 15:101-15:106, 15:108- 15:113, 15:115-15:122, 15:125-15:129, 15:131-15:132, 15:134-15:135, 15:138-15:149N, 15:152-15:154, 15:156- 15:161, 15:163-15:167, 15:169-15:176, 15:178-15:184, 15:187, 15:189-15:195, 15:197-15:207, 15:209N-15:215, 15:217-15:221, 15:223, 15:225-15:228, 15:231-15:232, 15:234, 15:236, 15:238-15:242, 15:244, 18:01:06, 18:02, 18:08, 18:15, 18:18-18:19, 18:21-18:22, 18:27, 18:30, 18:52, 18:56-18:57, 27:41, 35:01:01:01-35:01:31, 35:07- 35:08:05, 35:10-35:11:02, 35:14:01-35:17, 35:19-35:21, 35:23-35:30, 35:35, 35:40N-35:43, 35:45-35:50, 35:52- 35:54, 35:57-35:58, 35:61-35:64, 35:67-35:68:01, 35:69, 35:71, 35:76-35:80, 35:82, 35:86, 35:90-35:94, 35:99- 35:105, 35:107-35:108:02, 35:110-35:113, 35:115-35:126, 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, 35:185-35:192, 35:194, 35:196-35:197, 35:200, 40:59-40:60, 40:158, 42:09, 44:17, 44:43:01-44:43:02, 44:144, 46:01:01-46:05, 46:07N-46:10, 46:12, 46:14-46:17, 46:20, 46:22-46:25, 46:27-46:30, 48:02:01-48:02:02, 48:25, 51:45, 51:97, 53:01:01-53:03, 53:05-53:06, 53:08:01-53:13, 53:15-53:18, 53:20-53:27, 55:14, 55:32, 56:03, 56:09, 56:32, 57:01:01-57:01:13, 57:06, 57:08, 57:10-57:11, 57:13- 57:16, 57:18-57:27, 57:29-57:31, 57:33-57:38, 57:40-57:41, 57:43-57:45, 57:47-57:56, 58:01:01-58:01:07, 58:01:09- 58:02, 58:04-58:07, 58:09-58:15, 58:17N, 58:19, 58:21- 58:26, 58:29-58:33, 58:35-58:36
13	14	15	16	17	18	19	20	Well No.



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Lot-specific information

Length of spec.	215	105	160	160	180	105	140	280	200	225	185	150
PCR product(s)						235						
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
*07:13, 07:110, C*03:137				4								
*07:48, 08:13, 08:25, 08:55, 13:11, 15:48, 15:188, 15:224, 18:26, 18:41, 18:61, 27:07:01-27:07:02, 27:11, 27:32-27:34, 27:43, 27:70, 35:22, 35:31, 35:151, 35:199, 38:01:01-38:09, 38:12-38:19, 38:21, 38:23, 38:25-38:29, 38:31, 38:33-38:40, 39:01:01:01-39:01:01:02L, 39:01:03-39:05:02, 39:10:01-39:10:02, 39:12-39:17, 39:19:01-39:20, 39:22-39:23, 39:25N-39:32, 39:37-39:41, 39:44-39:49, 39:51-39:56, 39:58-39:59, 39:61, 39:63, 39:65-39:73, 40:01:01-40:01:03, 40:01:05-40:01:11, 40:01:13-40:02:08, 40:02:10-40:02:15, 40:07-40:11:01, 40:12-40:14:03, 40:18-40:19, 40:21-40:22N, 40:24-40:25, 40:27:01-40:27:02, 40:29, 40:31, 40:33, 40:35-40:37, 40:39-40:40, 40:42-40:43, 40:45-40:50, 40:54-40:58, 40:61-40:63, 40:65-40:67, 40:69, 40:72:01-40:74, 40:76-40:82, 40:84-40:85, 40:87:01-40:92, 40:97, 40:99, 40:101-40:102, 40:104, 40:106-40:108, 40:111-40:119, 40:121-40:123, 40:124:02, 40:126, 40:128, 40:130, 40:132-40:135, 40:138-40:142N, 40:144N-40:147, 40:150-40:157, 40:163-40:164, 40:166, 40:168-40:172, 40:175-40:176, 40:178-40:182, 40:184-40:189, 40:191-40:193, 44:31, 44:54, 44:65, 44:82, 44:135, 48:01:01-48:01:03, 48:03:01, 48:04, 48:06-48:07, 48:09-48:13, 48:16, 48:18, 48:20, 48:22, 48:27, 51:81, 55:04, 55:08, 55:49, 55:51, 56:10, 58:20, 58:27, 67:01:01-67:01:02, 67:03, 81:01-81:05, C*02:03								9				
*07:78, 55:09, 55:52		2								10		
*07:84						6				10		
*08:09, 08:84, 15:83, 27:14, 27:81, 40:06:01:01-40:06:05, 40:53, 40:70, 40:75, 40:83, 40:93, 40:96, 40:103, 40:109-40:110, 40:127, 40:131, 40:162, 40:165, 40:167, 40:177, 40:190, 41:01, 41:05-41:07, 41:09, 41:12, 41:14, 41:16-41:17, 41:20, 42:04, 51:08-51:10, 51:19-51:20, 51:31, 51:36, 51:40, 51:44N, 51:72-51:73, 51:87, 51:91, 51:93, 51:108, 51:115, 51:122, 52:03, 52:10:01-52:10:02, 52:19, 55:20, 56:15, 59:02, 78:04						6						
*08:40, 48:24									w			
*13:02:01-13:02:12, 13:08Q-13:09, 13:14-13:15, 13:19, 13:27, 13:30, 13:32-13:34, 13:37-13:38, 13:40, 13:42, 13:44-13:45, 13:49N, 13:53-13:54, 35:60, 45:03, 45:08, 45:10, 46:18, 55:02:01-55:02:06, 55:07, 55:12, 55:16, 55:18-55:19, 55:22, 55:26, 55:30, 55:34-55:35, 55:41, 55:43, 55:47-55:48, 55:50, 55:56, 56:19N, 56:23, 59:01:01:01-59:01:01:02, 59:05		2										
*13:03, 44:15, 44:18, 45:01, 45:04-45:07, 45:11-45:14, 46:11, 49:01:02, 49:11, 51:15, 56:01:01-56:01:04, 56:07-56:08, 56:13-56:14, 56:17, 56:20:01-56:20:02, 56:24, 56:26-56:30, 56:33-56:35, 59:04		2			5							
Well No.	1	2	3	4	5	6	7	8	9	10	11	12



101.569-06 – including *Taq* polymerase, IFU-01 Rev. No. 03
 101. 569-06u – without *Taq* polymerase, IFU-02 Rev. No. 03

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Lot No.: **95N**

Lot-specific information

135	210	95	210	210	295	230	205	Length of spec.
13	14	15	16	17	18	19	20	PCR product(s)
								Well No.
			340					*07:13, 07:110, C*03:137
								*07:48, 08:13, 08:25, 08:55, 13:11, 15:48, 15:188, 15:224, 18:26, 18:41, 18:61, 27:07:01-27:07:02, 27:11, 27:32-27:34, 27:43, 27:70, 35:22, 35:31, 35:151, 35:199, 38:01:01-38:09, 38:12-38:19, 38:21, 38:23, 38:25-38:29, 38:31, 38:33-38:40, 39:01:01:01-39:01:01:02L, 39:01:03-39:05:02, 39:10:01-39:10:02, 39:12-39:17, 39:19:01-39:20, 39:22-39:23, 39:25N-39:32, 39:37-39:41, 39:44-39:49, 39:51-39:56, 39:58-39:59, 39:61, 39:63, 39:65-39:73, 40:01:01-40:01:03, 40:01:05-40:01:11, 40:01:13-40:02:08, 40:02:10-40:02:15, 40:07-40:11:01, 40:12-40:14:03, 40:18-40:19, 40:21-40:22N, 40:24-40:25, 40:27:01-40:27:02, 40:29, 40:31, 40:33, 40:35-40:37, 40:39-40:40, 40:42-40:43, 40:45-40:50, 40:54-40:58, 40:61-40:63, 40:65-40:67, 40:69, 40:72:01-40:74, 40:76-40:82, 40:84-40:85, 40:87:01-40:92, 40:97, 40:99, 40:101-40:102, 40:104, 40:106-40:108, 40:111-40:119, 40:121-40:123, 40:124:02, 40:126, 40:128, 40:130, 40:132-40:135, 40:138-40:142N, 40:144N-40:147, 40:150-40:157, 40:163-40:164, 40:166, 40:168-40:172, 40:175-40:176, 40:178-40:182, 40:184-40:189, 40:191-40:193, 44:31, 44:54, 44:65, 44:82, 44:135, 48:01:01-48:01:03, 48:03:01, 48:04, 48:06-48:07, 48:09-48:13, 48:16, 48:18, 48:20, 48:22, 48:27, 51:81, 55:04, 55:08, 55:49, 55:51, 56:10, 58:20, 58:27, 67:01:01-67:01:02, 67:03, 81:01-81:05, C*02:03
				17				*07:78, 55:09, 55:52
		15		17				*07:84
								*08:09, 08:84, 15:83, 27:14, 27:81, 40:06:01:01-40:06:05, 40:53, 40:70, 40:75, 40:83, 40:93, 40:96, 40:103, 40:109-40:110, 40:127, 40:131, 40:162, 40:165, 40:167, 40:177, 40:190, 41:01, 41:05-41:07, 41:09, 41:12, 41:14, 41:16-41:17, 41:20, 42:04, 51:08-51:10, 51:19-51:20, 51:31, 51:36, 51:40, 51:44N, 51:72-51:73, 51:87, 51:91, 51:93, 51:108, 51:115, 51:122, 52:03, 52:10:01-52:10:02, 52:19, 55:20, 56:15, 59:02, 78:04
								*08:40, 48:24
								*13:02:01-13:02:12, 13:08Q-13:09, 13:14-13:15, 13:19, 13:27, 13:30, 13:32-13:34, 13:37-13:38, 13:40, 13:42, 13:44-13:45, 13:49N, 13:53-13:54, 35:60, 45:03, 45:08, 45:10, 46:18, 55:02:01-55:02:06, 55:07, 55:12, 55:16, 55:18-55:19, 55:22, 55:26, 55:30, 55:34-55:35, 55:41, 55:43, 55:47-55:48, 55:50, 55:56, 56:19N, 56:23, 59:01:01:01-59:01:01:02, 59:05
								*13:03, 44:15, 44:18, 45:01, 45:04-45:07, 45:11-45:14, 46:11, 49:01:02, 49:11, 51:15, 56:01:01-56:01:04, 56:07-56:08, 56:13-56:14, 56:17, 56:20:01-56:20:02, 56:24, 56:26-56:30, 56:33-56:35, 59:04
13	14	15	16	17	18	19	20	Well No.

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Lot No.: **95N**

Lot-specific information

Length of spec.	215	105	160	160	180	235	105	140	280	200	225	185	150
PCR product(s)													
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	
*13:04, 15:155, 15:222, 35:37, 40:159, 45:09, 55:23								8					
*13:10, 15:05:01-15:05:02, 15:31, 15:52, 15:55, 15:91, 15:107, 15:114, 15:123-15:124, 15:136, 15:151, 15:185-15:186, 15:235, 18:01:01:01-18:01:05, 18:01:07-18:01:16, 18:03-18:07:02, 18:09-18:12, 18:14, 18:17N, 18:20, 18:23N-18:25, 18:28-18:29, 18:31-18:40, 18:42-18:51, 18:53-18:55, 18:58-18:60, 18:62-18:71, 35:05:01-35:05:02, 35:32:01-35:32:02, 35:51, 35:68:02, 35:72, 35:89, 35:97, 35:114, 39:07, 39:43, 40:03, 40:20, 40:38, 40:52, 40:105, 46:06, 46:13:01-46:13:03, 46:19, 46:21:01-46:21:02, 46:26, 48:14, 48:23, 53:14, 56:18, 56:31, 58:16, 58:18								8	9				
*13:16, 15:42, 49:07, 55:01:01-55:01:03, 55:01:05-55:01:06, 55:01:08-55:01:09, 55:03, 55:05, 55:11, 55:15, 55:24-55:25, 55:29, 55:31, 55:33, 55:36, 55:38, 55:40, 55:45, 55:54-55:55N		2											
*13:18, 13:41, 55:37		2									10		
*13:31, 55:21		2									10		
*13:35, 40:44, 44:20, 44:47, 44:100, 55:27						6							
*13:48, 49:01:01, 49:01:03-49:03, 49:06, 49:08-49:10, 49:12-49:17, 49:19N-49:20, 50:01:01-50:02, 50:04-50:08, 50:10-50:11, 50:13, 50:15, 52:25, 56:25		2			5								
*15:01:04, 58:01:08	1							8					
*15:04								8		10			
*15:16:01-15:16:03, 15:67, 15:95, 49:04-49:05, 51:37								8					
*15:73, 44:10, 44:140, 50:12, 51:62					5								
*15:137										10			
*15:237, 18:13, 35:66								8	w				
*38:11, 67:02				4					9				
*39:33										10			
*40:71, 56:02, 56:04					5				9				
*40:94	1								9				
*40:95, 40:148, 49:18, 50:14, 51:01:01-51:01:17, 51:01:19-51:03, 51:07:01-51:07:02, 51:11N-51:12, 51:14, 51:16-51:18, 51:21-51:24:04, 51:26-51:28, 51:30, 51:32-51:34, 51:38, 51:41N, 51:43, 51:48-51:53, 51:55, 51:57-51:58, 51:60, 51:65-51:71, 51:74-51:80, 51:83-51:86, 51:88-51:89, 51:94-51:96, 51:98N, 51:100-51:105, 51:107, 51:109-51:114, 51:116-51:121, 51:123-51:130, 52:01:01:01-52:02, 52:04-52:09, 52:11, 52:13, 52:15-52:18, 52:20, 52:22-52:23, 52:27-52:29, 55:17, 55:28, 56:05:01-56:06, 56:21, 58:08:01-58:08:02, 78:01:01-78:03, 78:05-78:07						6							
*40:149									9				
*40:161, 51:29, 51:82, 52:24						6				10			
*44:24, C*05:30			3										
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	

101.569-06 – including *Taq* polymerase, IFU-01 Rev. No. 03
 101.569-06u – without *Taq* polymerase, IFU-02 Rev. No. 03

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Lot No.: **95N**

Lot-specific information

135	210	95	210	210	295	230	205	Length of spec. PCR product(s)
13	14	15	16	17	18	19	20	Well No.
		15						*13:04, 15:155, 15:222, 35:37, 40:159, 45:09, 55:23
								*13:10, 15:05:01-15:05:02, 15:31, 15:52, 15:55, 15:91, 15:107, 15:114, 15:123-15:124, 15:136, 15:151, 15:185-15:186, 15:235, 18:01:01:01-18:01:05, 18:01:07-18:01:16, 18:03-18:07:02, 18:09-18:12, 18:14, 18:17N, 18:20, 18:23N-18:25, 18:28-18:29, 18:31-18:40, 18:42-18:51, 18:53-18:55, 18:58-18:60, 18:62-18:71, 35:05:01-35:05:02, 35:32:01-35:32:02, 35:51, 35:68:02, 35:72, 35:89, 35:97, 35:114, 39:07, 39:43, 40:03, 40:20, 40:38, 40:52, 40:105, 46:06, 46:13:01-46:13:03, 46:19, 46:21:01-46:21:02, 46:26, 48:14, 48:23, 53:14, 56:18, 56:31, 58:16, 58:18
				17				*13:16, 15:42, 49:07, 55:01:01-55:01:03, 55:01:05-55:01:06, 55:01:08-55:01:09, 55:03, 55:05, 55:11, 55:15, 55:24-55:25, 55:29, 55:31, 55:33, 55:36, 55:38, 55:40, 55:45, 55:54-55:55N *13:18, 13:41, 55:37
				w				*13:31, 55:21
		15						*13:35, 40:44, 44:20, 44:47, 44:100, 55:27
				17				*13:48, 49:01:01, 49:01:03-49:03, 49:06, 49:08-49:10, 49:12-49:17, 49:19N-49:20, 50:01:01-50:02, 50:04-50:08, 50:10-50:11, 50:13, 50:15, 52:25, 56:25 *15:01:04, 58:01:08
		15		w				*15:04
		15		17				*15:16:01-15:16:03, 15:67, 15:95, 49:04-49:05, 51:37 *15:73, 44:10, 44:140, 50:12, 51:62
				w				*15:137
								*15:237, 18:13, 35:66
								*38:11, 67:02
								*39:33
								*40:71, 56:02, 56:04
								*40:94
				17				*40:95, 40:148, 49:18, 50:14, 51:01:01-51:01:17, 51:01:19-51:03, 51:07:01-51:07:02, 51:11N-51:12, 51:14, 51:16-51:18, 51:21-51:24:04, 51:26-51:28, 51:30, 51:32-51:34, 51:38, 51:41N, 51:43, 51:48-51:53, 51:55, 51:57-51:58, 51:60, 51:65-51:71, 51:74-51:80, 51:83-51:86, 51:88-51:89, 51:94-51:96, 51:98N, 51:100-51:105, 51:107, 51:109-51:114, 51:116-51:121, 51:123-51:130, 52:01:01:01-52:02, 52:04-52:09, 52:11, 52:13, 52:15-52:18, 52:20, 52:22-52:23, 52:27-52:29, 55:17, 55:28, 56:05:01-56:06, 56:21, 58:08:01-58:08:02, 78:01:01-78:03, 78:05-78:07
					18			*40:149
				17				*40:161, 51:29, 51:82, 52:24
								*44:24, C*05:30
13	14	15	16	17	18	19	20	Well No.

101.569-06 – including *Taq* polymerase, IFU-01 Rev. No. 03101.569-06u – without *Taq* polymerase, IFU-02 Rev. No. 03Visit www.olerup-ssp.com for

“Instructions for Use” (IFU)

Lot No.: **95N**

Lot-specific information

Well No.	1	2	3	4	5	6	7	8	9	10	11	12
Length of spec.	215	105	160	160	180	105	140	280	200	225	185	150
PCR product(s)						235						
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
*50:09, 51:13:01-51:13:02, 51:35, 51:99, 51:131, 52:14, 55:01:04, 55:44, 55:53												
*50:16, 51:106					5							
*51:01:18	1					6						
*51:05, 51:54						6				10		
*51:39			3			6						
*51:61, 52:21						6				10		
*51:63								8				
*51:90, 52:12, 52:26						6						
*51:92												
*55:10		2										
*55:46		2										
*56:16		2			5							
*82:01-82:03					5							
C*07:102				w								
HLA-B allele												
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

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*54 subtyping.

In addition, well 14 contains the primer pair giving rise to the shorter, 800 bp, internal positive control in order to allow kit identification.

²The nucleotide position, in the 1st, 2nd, 3rd or 4th exon or 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, 3rd or 5th 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.

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 101. 569-06u – without *Taq* polymerase, IFU-02 Rev. No. 03

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Lot No.: **95N**

Lot-specific information

13	14	15	16	17	18	19	20	Well No.
135	210	95	210	210	295	230	205	Length of spec.
			340					PCR product(s)
13	14	15	16	17	18	19	20	Well No.
				17				*50:09, 51:13:01-51:13:02, 51:35, 51:99, 51:131, 52:14, 55:01:04, 55:44, 55:53
				17				*50:16, 51:106
				17				*51:01:18
								*51:05, 51:54
				17				*51:39
				w				*51:61, 52:21
				17				*51:63
		15		17				*51:90, 52:12, 52:26
		15		17				*51:92
					18			*55:10
		15						*55:46
					18			*56:16
					18			*82:01-82:03
								C*07:102
								HLA-B allele
13	14	15	16	17	18	19	20	Well No.

⁴HLA-B*54 alleles in bold lettering are listed as confirmed alleles on the on the IMGT/HLA web page www.ebi.ac.uk/imgt/hla, release 3.8.0, April 2012.

⁵The B*54:17 and B*54:18 alleles may be distinguished by the different sizes of the specific PCR products generated by primer mix 16.

⁶Primer mix 6: Specific PCR fragment of 105 bp in the B*54:04, 54:11 and 54:15 and in the B*07:84, 08:09, 08:84, 13:35, 15:83, 27:14, 27:81, 40:06:01:01-40:06:05, 40:44, 40:53, 40:70, 40:75, 40:83, 40:93, 40:95-40:96, 40:103, 40:109-40:110, 40:127, 40:131, 40:148, 40:161-40:162, 40:165, 40:167, 40:177, 40:190, 41:01, 41:05-41:07, 41:09, 41:12, 41:14, 41:16-41:17, 41:20, 42:04, 44:20, 44:47, 44:100, 49:18, 50:14, 51:01:01-51:03, 51:05, 51:07:01-51:12, 51:14, 51:16-51:24:04, 51:26-51:34, 51:36, 51:38-51:41N, 51:43-51:44N, 51:48-51:55, 51:57-51:58, 51:60-51:61, 51:65-51:80, 51:82-51:91, 51:93-51:96, 51:98N, 51:100-51:105, 51:107-51:130, 52:01:01:01-52:13, 52:15-52:24, 52:26-52:29, 55:17, 55:20, 55:27-55:28, 56:05:01-56:06, 56:15, 56:21, 58:08:01-58:08:02, 59:02 and 78:01:01-78:07 alleles. Specific PCR fragment of 235 bp in the B*54:08N allele.

Primer mix 16: Specific PCR fragment of 210 bp in the B*54:18 allele. Specific PCR fragment of 340 bp in the B* 54:17 allele.

'w', may be weakly amplified.

101.569-06 – including *Taq* polymerase, IFU-01 Rev. No. 03
 101. 569-06u – without *Taq* polymerase, IFU-02 Rev. No. 03

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Lot No.: **95N**

Lot-specific information

CELL LINE VALIDATION SHEET																				
HLA-B*54 SSP subtyping kit																				
				Well																
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	
				Prod. No.:	201203501	201203502	201203503	201203504	201203505	201203506	201203507	201203508	201203509	201203510	201203511	201203512	201203513	201203514	201203515	201203516
	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	9025 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	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-

101.569-06 – including *Taq* polymerase, IFU-01 Rev. No. 03
 101. 569-06u – without *Taq* polymerase, IFU-02 Rev. No. 03

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 “Instructions for Use” (IFU)

Lot No.: **95N**

Lot-specific information

CELL LINE VALIDATION SHEET								
HLA-B*54 SSP subtyping kit								
				Well				
				17	18	19	20	
				Prod. No.:	201203517	201203518	201203519	201203520
	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	9025 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	-	-	-	-	

101.569-06 – including *Taq* polymerase, IFU-01 Rev. No. 03Visit www.olerup-ssp.com for101.569-06u – without *Taq* polymerase, IFU-02 Rev. No. 03

“Instructions for Use” (IFU)

Lot No.: **95N**

Lot-specific information

CERTIFICATE OF ANALYSIS**Olerup SSP® HLA-B*54 SSP**

Product number: 101.569-06 – including *Taq* polymerase
 101.569-06u – without *Taq* polymerase

Lot number: 95N

Expiry date: 2014-December-01

Number of tests: 6

Number of wells per test: 20

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2012-035-01	9	2012-035-09	17	2012-035-17
2	2012-035-02	10	2012-035-10	18	2012-035-18
3	2012-035-03	11	2012-035-11	19	2012-035-19
4	2012-035-04	12	2012-035-12	20	2012-035-20
5	2012-035-05	13	2012-035-13		
6	2012-035-06	14	2012-035-14		
7	2012-035-07	15	2012-035-15		
8	2012-035-08	16	2012-035-16		

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

No DNAs carrying the alleles to be amplified by primer solutions 4, 7, 11 to 14, 16, 19 and 20 were available. The specificities of the primers in primer solutions 4, 11, 12 and 16 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer solutions 7, 14, 19 and 20 it was only possible to test the 5'-primer, the 3'-primers were not possible to test. In primer solution 13 it was only possible to test the 3'-primer, the 5'-primer was not possible to test. One 5'-primer in primer solutions 4 and 16 and one 3'-primer in primer solution 5 and 6 was not possible to test. In addition, one 3'-primer in primer solution 15 was tested by separately adding an additional 5'-primer.

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

Date of approval: 2012-June-29

Approved by:

Production Quality Control

101.569-06 – including *Taq* polymerase, IFU-01 Rev. No. 03
101.569-06u – without *Taq* polymerase, IFU-02 Rev. No. 03

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

Lot No.: **95N**

Lot-specific information

Declaration of Conformity

Product name: *Olerup* SSP® HLA-B*54
Product number: 101.569-06/06u
Lot number: 95N

Intended use: HLA-B*54 high 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-June-29

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs

101.569-06 – including *Taq* polymerase, IFU-01 Rev. No. 03
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Lot No.: **95N**

Lot-specific information

101.569-06 – including *Taq* polymerase, IFU-01 Rev. No. 03
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101.569-06 – including *Taq* polymerase, IFU-01 Rev. No. 03
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Visit www.olerup-ssp.com for
“Instructions for Use” (IFU)

Lot No.: **95N**

Lot-specific information

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Fax: +46-8-717 88 18

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Web page: <http://www.olerup-ssp.com>

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Tel: 1-877-OLERUP1

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Web page: <http://www.olerup.com>

For information on *Olerup* SSP distributors worldwide, contact **Olerup GmbH**.