

101.549-06– including *Taq* polymerase, IFU-01  
101. 549-06u – without *Taq* polymerase, IFU-02

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“Instructions for Use” (IFU)

Lot No.: 22S

Lot-specific information  
**Olerup SSP® HLA-B\*53**

Product number:	101.549-06 – including <i>Taq</i> polymerase
	101.549-06u – without <i>Taq</i> polymerase
Lot number:	22S
Expiry date:	2015-October-01
Number of tests:	6
Number of wells per test:	22
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. 22S.**

**CHANGES COMPARED TO THE PREVIOUS OLERUP SSP®  
HLA-B\*53 LOT (73N).**

The HLA-B\*53 kit is updated for new alleles to enable separation of:

- Confirmed<sup>1</sup> 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

Two wells have been added to the HLA-B\*53 kit, wells **21 to 22**.

The Lot-specific information for HLA-B\*53 including and without *Taq* polymerase is now described in one common Product Insert.

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

The HLA-B\*53 specificity and interpretation tables have been updated for the HLA-B alleles described since the previous *Olerup SSP® HLA-B\*53* lot was made (**Lot No. 73N**).

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

Well	5'-primer	3'-primer	rationale
13	Added	-	5'-primer added for resolution of the B*58:39N and the B*53:01 alleles.
15	Moved	Moved	Primer pair moved to well 22, exchanged positive control primer pair.
21	New	New	New primer pair for resolution of the B*52:03 and B*52:10:01-52:10:02 and the B*53:19 alleles.
22	New	New	Primer pair from well 15.

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## PRODUCT DESCRIPTION

### HLA-B\*53 SSP typing

#### CONTENT

The primer set contains 5'- and 3'-primers for identifying the B\*53:01 to B\*53:29 alleles.

#### PLATE LAYOUT

Each HLA-B\*53 test consists of 22 PCR reactions in a 24 well cut PCR plate. Wells 23 to 24 are empty.

1	2	3	4	5	6	7	8
9	10	11	12	13	14	15	16
17	18	19	20	21	22	empty	empty

The 24 well PCR plate is marked with ‘HLA-B\*53’ in silver/gray ink.

Well No. 1 is marked with the Lot No. ’22S’.

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

The PCR plates are heat-sealed with a PCR-compatible foil.

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

#### INTERPRETATION

The interpretation of HLA-B\*53 SSP subtypings will be influenced by most B\*07, seventeen B\*08, most B\*13, the B\*14, most B\*15, the B\*18, most B\*27, most B\*35, the B\*37, the B\*38, most B\*39, the B\*40, three B\*41, two B\*42, the B\*44, the B\*45, the B\*46, the B\*47, the B\*48, the B\*49, the B\*50, several B\*51, several B\*52, the B\*54, the B\*55, the B\*56, the B\*57, the B\*58, the B\*59, the B\*67, the B\*78, the B\*81, the B\*82 and the B\*83:01 alleles when present on the other haplotype.

In addition, the A\*02:188 and A\*24:174 alleles will be weakly amplified by primer mix 10, the C\*02:56, C\*06:20 and C\*07:81 alleles will be weakly amplified by primer mix 11, the C\*02:60, C\*07:294 and C\*08:08 alleles will be amplified by primer mix 14 the C\*03:12, C\*03:19, C\*03:26 and C\*03:102 alleles will be weakly amplified by primer mix 4, the C\*03:28, C\*03:49 and C\*14:20 alleles will be amplified by primer mix 20, the C\*03:36 and C\*03:77 alleles will be amplified by mix 9, the C\*04:08 and C\*05:39 alleles will be amplified by primer mixes 4 and 20, the C\*04:34 allele will be amplified by primer mixes 4 and 9, the C\*05:27, C\*08:41, C\*15:15 and C\*17:07 alleles will be amplified by primer mix 4, the C\*07:68, C\*07:140 and 07:151 alleles will be amplified by primer mix 5, the C\*07:168 allele will be amplified by primer mix 7 and weakly by primer mix 11, , the C\*12:87 allele will be amplified by primer mix 6 and the C\*15:39 allele will be amplified by primer mix 2.

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### UNIQUELY IDENTIFIED ALLELES

All the HLA-B\*53, i.e. **B\*53:01 to B\*53:29**, recognized by the HLA Nomenclature Committee in January 2013<sup>1</sup> will be amplified by the primers in the HLA-B\*53 SSP kit<sup>2</sup>.

The HLA-B\*53 kit enables separation of the confirmed HLA-B\*53 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\*53 alleles is listed below.

The HLA-B\*53 kit also enables identification of polymorphisms in exons outside of the region encoding the peptide binding domain and of null and alternatively expressed alleles.

The HLA-B\*53 subtyping cannot distinguish the following silent mutations: the B\*53:01:01-53:01:08 alleles, the \*53:08:01-53:08:02 and the B\*53:17:01-53:17:02 alleles.

<sup>1</sup>HLA-B alleles listed on the IMGT/HLA web page 2013-January-11, release 3.11.0, [www.ebi.ac.uk/imgt/hla](http://www.ebi.ac.uk/imgt/hla).

<sup>2</sup>The B\*53:03 and the 35:203 alleles give rise to identical amplification patterns with the HLA-B\*53 subtyping kit. These alleles can be distinguished by the HLA-B low resolution kit and/or the HLA-B\*35 subtyping kit.

### ALLELE CONFIRMATION STATUS

Allele	Status <sup>1</sup>	Allele	Status <sup>1</sup>
B*53:01:01	<b>Confirmed</b>	B*53:13	Unconfirmed
B*53:01:02	Unconfirmed	B*53:14	Unconfirmed
B*53:01:03	Unconfirmed	<b>B*53:15</b>	<b>Confirmed</b>
B*53:01:04	Unconfirmed	B*53:16	Unconfirmed
<b>B*53:01:05</b>	<b>Confirmed</b>	B*53:17:01	Unconfirmed
B*53:01:06	Unconfirmed	B*53:17:02	Unconfirmed
B*53:01:07	Unconfirmed	<b>B*53:18</b>	<b>Confirmed</b>
B*53:01:08	Unconfirmed	<b>B*53:19</b>	<b>Confirmed</b>
B*53:02	Unconfirmed	<b>B*53:20</b>	<b>Confirmed</b>
B*53:03	Unconfirmed	B*53:21	Unconfirmed
B*53:04	Unconfirmed	<b>B*53:22</b>	<b>Confirmed</b>
<b>B*53:05</b>	<b>Confirmed</b>	B*53:23	Unconfirmed
B*53:06	Unconfirmed	<b>B*53:24</b>	<b>Confirmed</b>
B*53:07	Unconfirmed	B*53:25	Unconfirmed
B*53:08:01	Unconfirmed	B*53:26	Unconfirmed
B*53:08:02	Unconfirmed	B*53:27	Unconfirmed
<b>B*53:09</b>	<b>Confirmed</b>	B*53:28	Unconfirmed
B*53:10	Unconfirmed	B*53:29	Unconfirmed
B*53:11	Unconfirmed		
B*53:12	Unconfirmed		

<sup>1</sup>Allele status “confirmed” or “unconfirmed” as listed on the IMGT/HLA web page 2013-January-11, release 3.11.0, [www.ebi.ac.uk/imgt/hla](http://www.ebi.ac.uk/imgt/hla).

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#### **RESOLUTION IN HOMO- AND HETEROZYGOTES**

A total of 38 alleles generate 25 amplification patterns that can be combined in 325 homozygous and heterozygous combinations. 166 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.

```

+----- +----- ----- *53:04, *53:07 = *53:07, *53:07
----- +----- ----- *53:09, *53:09 = *53:09, *53:13
----- +----- ----- *53:12, *53:12 = *53:12, *53:13
+----- +----- ----- *53:01:01, *53:23 = *53:23, *53:23
+----- +----- ----- *53:01:01, *53:21 = *53:21, *53:21
+----- +----- ----- *53:01:01, *53:20 = *53:20, *53:20
+----- +----- ----- *53:01:01, *53:17:01 = *53:17:01, *53:17:01
+----- +----- ----- *53:01:01, *53:14 = *53:14, *53:14
+----- +----- ----- *53:11, *53:22 = *53:11, *53:24 = *53:22, *53:24
+----- +----- ----- *53:01:01, *53:13 = *53:01:01, *53:22 = *53:13, *53:22
+----- +----- ----- *53:01:01, *53:04 = *53:01:01, *53:18 = *53:04, *53:18 = *53:18, *53:18
+----- +----- ----- *53:01:01, *53:03 = *53:01:01, *53:15 = *53:03, *53:15 = *53:15, *53:15
+----- +----- ----- *53:06, *53:06 = *53:06, *53:08:01
+----- +----- ----- *53:01:01, *53:10 = *53:10, *53:10 = *53:10, *53:14
+----- +----- ----- *53:01:01, *53:11 = *53:13, *53:24
+----- +----- ----- *53:13, *53:23 = *53:22, *53:23
+----- +----- ----- *53:13, *53:21 = *53:21, *53:22
+----- +----- ----- *53:13, *53:20 = *53:20, *53:22
+----- +----- ----- *53:01:01, *53:09 = *53:09, *53:17:01 = *53:09, *53:22 = *53:13, *53:17:01 =
*53:17:01, *53:22
+----- +----- ----- *53:13, *53:14 = *53:14, *53:22
+----- +----- ----- *53:01:01, *53:12 = *53:12, *53:22
+----- +----- ----- *53:04, *53:24 = *53:18, *53:24
+----- +----- ----- *53:04, *53:23 = *53:18, *53:23
+----- +----- ----- *53:04, *53:21 = *53:18, *53:21
+----- +----- ----- *53:04, *53:20 = *53:18, *53:20
+----- +----- ----- *53:04, *53:17:01 = *53:17:01, *53:18
+----- +----- ----- *53:04, *53:14 = *53:14, *53:18
+----- +----- ----- *53:01:01, *53:07 = *53:07, *53:18
+----- +----- ----- *53:04, *53:13 = *53:13, *53:18 = *53:18, *53:22
+----- +----- ----- *53:03, *53:19 = *53:15, *53:19
+----- +----- ----- *53:03, *53:24 = *53:15, *53:24
+----- +----- ----- *53:03, *53:23 = *53:15, *53:23
+----- +----- ----- *53:03, *53:21 = *53:15, *53:21
+----- +----- ----- *53:03, *53:20 = *53:15, *53:20
+----- +----- ----- *53:03, *53:17:01 = *53:15, *53:17:01
+----- +----- ----- *53:03, *53:14 = *53:14, *53:15
+----- +----- ----- *53:03, *53:08:01 = *53:08:01, *53:15
+----- +----- ----- *53:16, *53:16 = *53:16, *53:24
+----- +----- ----- *53:01:01, *53:05 = *53:03, *53:05 = *53:05, *53:05 = *53:05, *53:15
+----- +----- ----- *53:03, *53:22 = *53:13, *53:15 = *53:15, *53:22
+----- +----- ----- *53:03, *53:04 = *53:03, *53:18 = *53:04, *53:15 = *53:15, *53:18
+----- +----- ----- *53:01:01, *53:02 = *53:02, *53:02
+----- +----- ----- *53:06, *53:28 = *53:08:01, *53:28 = *53:28, *53:28
+----- +----- ----- *53:09, *53:24 = *53:11, *53:17:01
+----- +----- ----- *53:10, *53:13 = *53:10, *53:22
+----- +----- ----- *53:04, *53:10 = *53:07, *53:10 = *53:07, *53:14 = *53:10, *53:18
+----- +----- ----- *53:04, *53:11 = *53:11, *53:18
+----- +----- ----- *53:04, *53:09 = *53:09, *53:18
+----- +----- ----- *53:04, *53:12 = *53:12, *53:18
+----- +----- ----- *53:03, *53:10 = *53:10, *53:15
+----- +----- ----- *53:01:01, *53:16 = *53:03, *53:16 = *53:05, *53:16 = *53:05, *53:24 = *53:15,
*53:16
+----- +----- ----- *53:11, *53:16 = *53:16, *53:22
+----- +----- ----- *53:05, *53:12 = *53:05, *53:13 = *53:05, *53:22 = *53:12, *53:15

```

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+++++- ++++++ -----	*53:03, *53:07 = *53:07, *53:15
++-+-- ++++++ -----	*53:04, *53:05 = *53:05, *53:18
++-+-- ++++++ -----	*53:01:01, *53:06 = *53:02, *53:06 = *53:02, *53:08:01
++-+-- ++++++ -----	*53:02, *53:12 = *53:02, *53:13 = *53:02, *53:22
++-+-- ++++++ -----	*53:02, *53:04 = *53:02, *53:18
++-+-- ++++++ -----	*53:02, *53:03 = *53:02, *53:05 = *53:02, *53:15
++-+-- ++++++ -----	*53:05, *53:11 = *53:12, *53:16 = *53:13, *53:16
++-+-- ++++++ -----	*53:04, *53:16 = *53:16, *53:18
++-+-- ++++++ -----	*53:01:01, *53:28 = *53:02, *53:28 = *53:06, *53:17:01 = *53:17:01, *53:28
++-+-- ++++++ -----	*53:06, *53:12 = *53:06, *53:13
++-+-- ++++++ -----	*53:03, *53:06 = *53:05, *53:06 = *53:06, *53:15
++-+-- ++++++ -----	*53:06, *53:09 = *53:09, *53:28 = *53:12, *53:28 = *53:13, *53:28
++-+-- ++++++ -----	*53:03, *53:28 = *53:05, *53:28 = *53:15, *53:28

\*53:01:01 = \*53:01:01-53:01:08 53:25-53:27 and 53:29

\*53:08:01 = \*53:08:01-53:08:02

\*53:17:01 = \*53:17:01-53:17:02

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Lot-specific information  
**SPECIFICITY TABLE**

**HLA-B\*53 SSP subtyping**

**Specificities and sizes of the PCR products of the 22 primer mixes used for HLA-B\*53 SSP subtyping**

Primer Mix	Size of spec. PCR product <sup>1</sup>	Size of control band <sup>2</sup>	Amplified HLA-B*53 alleles <sup>3</sup>	Other amplified HLA Class I alleles <sup>4</sup>
1	145 bp	<b>800 bp</b>	*53:01:01-53:02, 53:04-53:08:02, 53:10, 53:14-53:29	*18:67, 37:34, 38:06-38:07, 44:06, 49:03, 51:01:01-51:01:39, 51:02:01-51:24:04, 51:26-51:46, 51:48-51:53, 51:55-51:77, 51:79-51:103, 51:105-51:111, 51:113-51:146, 51:148-51:150, 52:01:01-52:01:17, 52:03-52:15, 52:17-52:19, 52:21-52:31, 58:01:01-58:02, 58:04-58:16, 58:18-58:29, 58:31N-58:35, 58:37-58:40
2 <sup>6</sup>	270 bp	1070 bp	*53:02, 53:06, 53:28	*14:10, 18:22, 18:69, 35:21, 35:24:01-35:24:02, 35:81, 35:96, 35:109, 35:157, 35:188, 35:190, 37:04:01-37:04:02, 40:28, 51:04, 51:46, 51:56:01-51:56:02, 51:139, 57:14, 58:09, <b>C*15:39</b>
3 <sup>8,9</sup>	135 bp, 290 bp	<b>800 bp</b>	*53:03, 53:05, 53:15-53:16	*08:49, 08:60, 08:76, 18:54, 18:67, 27:52, 35:203, 37:01:01-37:01:05, 37:01:07-37:05, 37:07-37:09, 37:12-37:13, 37:15-37:27, 37:30N-37:33N, 37:35-37:36, 42:13, 52:09
4	190 bp	<b>800 bp</b>	*53:04, 53:07, 53:18	*13:03, 13:48, 14:19, 14:27, 15:58, 15:73, 15:133, 15:137, 15:229, 15:253, 35:03:01-35:03:05, 35:03:07-35:03:12, 35:06, 35:13, 35:36, 35:38, 35:55-35:56, 35:59, 35:70, 35:74-35:75, 35:84-35:85, 35:98, 35:106, 35:109, 35:127-35:128, 35:136, 35:150-35:153, 35:155-35:156, 35:160, 35:163, 35:167, 35:169, 35:179, 35:181, 35:193, 35:195, 35:198, 35:204-35:205, 35:221, 35:223, 38:30, 39:32-39:33, 39:74, 40:71, 44:10, 44:15, 44:18, 44:117 <sup>w</sup> , 44:140, 45:01-45:02, 45:04-45:07, 45:11-45:14, 46:11, 49:01:01-49:03, 49:06, 49:08-49:17, 49:19N-49:25, 50:01:01-50:02, 50:04-50:13, 50:15-50:19, 51:13:01-51:13:02, 51:15, 51:62, 51:92, 51:106, 52:14, 52:25, 54:03, 56:01:01-56:01:04, 56:02, 56:04, 56:07-56:08, 56:11, 56:13-56:14, 56:16-56:17, 56:20:01-56:20:02, 56:22, 56:24-56:30, 56:33-56:39, 58:33-58:34, 59:04, 82:01-

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				82:03, <b>C*03:12<sup>w</sup>, C*03:19<sup>w</sup>, C*03:26<sup>w</sup>, C*03:102<sup>w</sup>, C*04:08, C*04:34, C*05:27, C*05:39, C*08:41, C*15:15, C*17:07</b>
5	150 bp	<b>800 bp</b>	*53:09, 53:11- 53:13, 53:22	*08:28, 08:35, 08:37, 08:89, 13:58, 15:51, 15:179, 15:199, 15:218Q, 18:09, 18:56, 35:115, 37:10, 37:35, 41:24, 42:09, 44:17, 44:83, 44:134, 45:09, 51:54, 51:78:01- 51:78:02, 51:97, 52:20, 57:24, <b>C*07:68, C*07:140, C*07:151</b>
6 <sup>6,10</sup>	205 bp, 235 bp	<b>800 bp</b>	*53:02, 53:05- 53:06, 53:12, 53:16, 53:28	*13:25, 15:38:01-15:38:02, 15:115, 15:185, 18:01:01:01-18:09, 18:12-18:15, 18:17N- 18:20, 18:22-18:25, 18:27-18:34, 18:36- 18:40, 18:42-18:55, 18:57, 18:59-18:60, 18:62-18:86, 35:21, 35:24:01-35:24:02, 35:188, 35:190, 39:43, 44:15, 44:109, 51:37, 51:45, 51:63, 51:97, 56:31, 57:14, 58:09, <b>C*12:87</b>
7	130 bp	<b>800 bp</b>	*53:07, 53:10	*15:32, 18:18, 37:01:01-37:01:09, 37:03N- 37:06, 37:08, 37:10-37:11, 37:13-37:18, 37:20-37:37, 39:09, <b>C*07:168</b>
8	170 bp	1070 bp	*53:06, 53:08:01- 53:08:02, 53:28	*07:02:01-07:24, 07:26-07:47, 07:49N- 07:50, 07:52-07:154, 07:156-07:163, 07:165-07:181N, 08:20, 08:53:01-08:53:02, 08:79, 13:16, 13:20, 13:31, 13:48, 13:62, 14:01:01-14:33, 15:01:01:01-15:01:04, 15:01:06-15:04, 15:06-15:19, 15:21, 15:23- 15:30, 15:32-15:40, 15:42-15:47:02, 15:49- 15:50, 15:53-15:54, 15:56-15:58, 15:60- 15:74, 15:76-15:82, 15:85, 15:87, 15:89- 15:90, 15:92-15:99, 15:101-15:104, 15:106, 15:108-15:110, 15:112-15:113, 15:115- 15:122, 15:125-15:129, 15:131-15:135, 15:137-15:144, 15:146-15:150, 15:152- 15:154, 15:156-15:161, 15:163-15:175, 15:177-15:178, 15:180-15:184, 15:187, 15:189-15:199, 15:201-15:217, 15:219- 15:221, 15:223, 15:225-15:234, 15:236, 15:238-15:249, 15:251-15:268, 18:15, 18:19, 18:21, 18:30, 18:57, 27:04:01- 27:04:03, 27:06, 27:10, 27:15, 27:18, 27:20- 27:21, 27:24-27:25, 27:40, 27:54, 27:63, 27:66N, 27:68-27:69, 27:79, 27:86, 27:91- 27:92, 27:100, 35:11:01-35:11:03, 35:14:01- 35:14:02, 35:21, 35:43:01-35:44, 35:58, 35:67, 35:79, 35:86, 35:96, 35:99, 35:102, 35:117-35:118, 35:135, 35:167, 35:185, 35:188, 35:213, 37:07, 37:13, 38:10, 38:32,

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39:18, 39:35-39:36, 40:05, 40:15-40:16,  
 40:23, 40:26, 40:28, 40:32, 40:51, 40:95,  
 40:98, 40:148, 40:158, 40:161, 40:174,  
 40:183, 40:198, 44:76, 44:79, 44:146,  
 44:150, 46:01:01-46:05, 46:07N-46:08,  
 46:10, 46:12, 46:14-46:17, 46:20, 46:22-  
 46:24, 46:26-46:32, 46:34-46:38, 48:05,  
 48:08, 48:15, 48:25, 49:01:01-49:10, 49:12-  
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**12<sup>5</sup>**      105 bp      1070 bp

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**101.549-06– including *Taq* polymerase, IFU-01**  
**101. 549-06u – without *Taq* polymerase, IFU-02**

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**Lot No.: 22S****Lot-specific information**

51:01:01-51:04, 51:06:01-51:07:02,  
 51:09:01-51:19, 51:21-51:24:04, 51:26-  
 51:28, 51:30-51:35, 51:37-51:43, 51:45-  
 51:46, 51:48-51:52, 51:53<sup>w</sup>, 51:56:01-51:60,  
 51:62-51:71, 51:72<sup>w</sup>, 51:73-51:81, 51:83-  
 51:86, 51:87<sup>w</sup>, 51:88-51:90, 51:91<sup>w</sup>, 51:92-  
 51:96, 51:98N-51:119, 51:120<sup>w</sup>, 51:121-  
 51:140, 51:142-51:150, 52:01:01-52:18,  
 52:20, 52:22-52:23, 52:25-52:27, 52:28<sup>w</sup>-  
 52:29<sup>w</sup>, 52:30-52:31, 54:01:01-54:05N,  
 54:07-54:09, 54:11-54:19, 54:21-54:28,  
 55:01:01-55:05, 55:07-55:08, 55:10-55:19,  
 55:22-55:36, 55:38-55:51, 55:53, 55:54<sup>w</sup>,  
 55:55N, 55:58, 56:01:01-56:02, 56:04-56:12,  
 56:14-56:39, 57:01:01-57:01:14, 57:03:01-  
 57:03:02, 57:06-57:08, 57:10-57:11, 57:14-  
 57:18, 57:20-57:23, 57:25-57:26, 57:29,  
 57:31-57:41, 57:43-57:62, 58:01:01-58:02,  
 58:04-58:21, 58:23-58:29, 58:31N-58:40,  
 59:01:01:01-59:05, 67:01:01-67:03,  
 78:01:01-78:07, 81:01-81:06

17	275 bp	1070 bp	*53:20	
18 <sup>7</sup>	140 bp	1070 bp	*53:21	*07:134, 18:01:01:01-18:03, 18:05-18:15, 18:17N-18:24, 18:26-18:36, 18:38-18:47, 18:49-18:65, 18:67, 18:69-18:86, 27:52, 35:50, 35:84, 35:162, 35:197, 37:01:01- 37:05, 37:07-37:27, 37:29-37:30N, 37:32- 37:37, 38:06-38:07, 39:19:01-39:19:02, 40:209, 51:57, 51:103, 51:116
19 <sup>5</sup>	125 bp	1070 bp	*53:23	*07:65, 07:134, 08:32, 18:03, 35:29:01- 35:29:02, 35:69, 35:76, 35:136, 35:186 <sup>w</sup> , 37:37, 39:19:01-39:19:02, 51:20, 56:06, 78:01:01-78:01:02, 78:03, 78:07
20 <sup>5</sup>	60 bp	1070 bp	*53:11, 53:16, 53:24	*07:20, 07:24, 07:60, 15:65, 15:84, 15:99, 15:221, 15:237, 35:08:01-35:08:06, 35:18, 35:45, 35:61:01-35:61:02, 35:80, 35:99- 35:100, 35:105, 35:142, 35:156, 35:158, 35:164, 35:172, 35:174, 35:176, 35:187, 35:192, 35:206, 35:225, 39:33, 44:28:01- 44:28:02, 44:76, 51:05, 51:29, 51:54, 52:24, 57:02:01-57:02:02, 57:04-57:05, 57:12, 57:19, 57:28N, 57:30, 57:42, 58:22, <b>C*03:28, C*03:49, C*04:08, C*05:39,    C*14:20</b>
21	135 bp	1070 bp		*35:01:10, 35:04:02, 40:01:06, 51:05 <sup>w</sup> , 51:09:01-51:09:02, 51:31, 51:40, 51:54 <sup>w</sup> ,

**101.549-06– including Taq polymerase, IFU-01**  
**101.549-06u – without Taq polymerase, IFU-02**

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<b>22</b>	205 bp	1070 bp	*53:19	51:73, 51:93, 51:108, 51:122, 51:139, 52:03, 52:10:01-52:10:02, 78:04
				*35:02:01-35:02:05, 35:81, 35:83, 35:95, 35:129N, 35:146, 35:154, 35:162, 35:172, 35:182-35:184, 35:211, 35:220, 45:12

<sup>1</sup>Alleles are assigned by the presence of specific PCR product(s). However, the sizes of the specific PCR products may be helpful in the interpretation of HLA-B\*53 SSP typings.

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

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

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

PCR fragments migrating faster than the control bands, but slower than a 400 bp fragment may be seen in some gel read-outs. Such bands can be disregarded and do not influence the interpretation of the SSP typings. Some primers may give rise to primer oligomer artifacts. Sometimes this phenomenon is an inherit feature of the primer pair(s) of a primer mix. More often it is due to other factors such as too low amount of DNA in the PCR reactions, taking too long time in setting up the PCR reactions, working at elevated room temperature or using thermal cyclers that are not pre-heated.

<sup>2</sup>The 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\*53 subtyping.

In addition, wells number 3 to 7 and 11 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.

<sup>3</sup>For several HLA Class I alleles 1<sup>st</sup> and/or 4<sup>th</sup> exon(s) and beyond, as well as intron nucleotide sequences, are not available. In these instances it is not known whether some of the primers of the SSP sets are completely matched with the target sequences or not. We assume that unknown sequences in these regions are conserved within allelic groups.

<sup>4</sup>Due to the sharing of sequence motifs between HLA-B alleles non-HLA-B\*53 alleles will be amplified by all B\*53 primer mixes except primer mix 17. In addition, the A\*02:188 and A\*24:174 alleles will be weakly amplified by primer mix 10, the C\*02:56, C\*06:20 and C\*07:81 alleles will be weakly amplified by primer mix 11, the C\*02:60, C\*07:294 and C\*08:08 alleles will be amplified by primer mix 14 the C\*03:12, C\*03:19, C\*03:26 and C\*03:102 alleles will be weakly amplified by primer mix 4, the C\*03:28, C\*03:49 and C\*14:20 alleles will be amplified by primer mix 20, the C\*03:36 and C\*03:77 alleles will be amplified by mix 9, the C\*04:08 and C\*05:39 alleles will be amplified by primer mixes 4 and 20, the C\*04:34 allele will be amplified by primer mixes 4 and 9, the C\*05:27, C\*08:41, C\*15:15 and C\*17:07 alleles will be amplified by primer mix 4, the C\*07:68, C\*07:140 and 07:151 alleles will be amplified by primer mix 5, the C\*07:168 allele will be amplified by primer mix 7 and weakly by primer mix 11, , the C\*12:87 allele will be amplified by primer mix 6 and the C\*15:39 allele will be amplified by primer mix 2.

<sup>5</sup>HLA-specific PCR products shorter than 125 base pairs have a lower intensity and are less sharp than longer PCR products.

<sup>6</sup>Primer mixes 2 and 6 may have tendencies of unspecific amplifications.

<sup>7</sup>Primer mixes 9, 11, 14 and 18 may give rise to a lower yield of HLA-specific PCR product than the other B\*53 primer mixes.

<sup>8</sup>Primer mix 3 has a tendency to giving rise to primer oligomer formation.

<sup>9</sup>Primer mix 3: Specific PCR fragment of 135 bp in the B\*53:03, 53:05 and 53:16 and the B\*18:54, 18:67, 27:52, 35:203, 37:01:01-37:01:05, 37:01:07-37:05, 37:07-37:09, 37:12-37:13, 37:15-37:27, 37:30N-37:33N, 37:35-37:36 and 52:09 alleles. Specific PCR fragment of 290 bp in the B\*53:15 and the 08:49, 08:60, 08:76 and 42:13 alleles.

**101.549-06– including *Taq* polymerase, IFU-01  
101. 549-06u – without *Taq* polymerase, IFU-02**

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<sup>10</sup>Primer mix 6: Specific PCR fragment of 205 bp in the B\*53:02, 53:06 and 53:28 and the 15:38:01-15:38:02, 15:185, 18:01:01:01-18:09, 18:12-18:15, 18:17N-18:20, 18:22-18:25, 18:27-18:34, 18:36-18:40, 18:42-18:55, 18:57, 18:59-18:60, 18:62-18:86, 35:21, 35:24:01-35:24:02, 35:188, 35:190, 39:43, 51:37, 51:45, 51:63, 51:97, 56:31, 57:14 and 58:09 and in the C\*12:87alleles. Specific PCR fragment of 235 bp in the the B\*53:05, 53:12 and 53:16 and the B\*13:25, 15:115, 44:15 and 44:109 alleles.

<sup>11</sup>Primer mix 14: Specific PCR fragment of 95 bp in the B\*53:14 and the B\*07:09, 07:11, 07:17, 07:115, 08:28, 08:35, 08:37, 08:69, 14:05, 15:07:01-15:07:02, 15:55, 15:68, 18:14, 35:05:03, 35:51, 35:58, 35:66, 35:72, 39:24:01-39:24:02, 39:37, 39:76, 40:03, 41:18, 41:24, 42:09 and 46:12 and in the C\*02:60, C\*07:294 and C\*08:08 alleles. Specific PCR fragment of 130 bp in the B\*53:10 allele.

‘w, may be weakly amplified.

101.549-06– including *Taq* polymerase, IFU-01  
 101. 549-06u – without *Taq* polymerase, IFU-02

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Lot No.: 22S

Lot-specific information

**INTERPRETATION TABLE****HLA-B\*53 SSP subtyping****Amplification patterns of the B\*53:01 to B\*53:29 alleles**

	Well <sup>6</sup>											
	1	2	3	4	5	6	7	8	9	10	11	12
Length of spec.	145	270	135	190	150	205	130	170	75	150	85	105
PCR product(s)			290			235						
Length of int. pos. control <sup>1</sup>	800	1070	800	800	800	800	800	1070	1070	800	800	1070
5'-primer(s) <sup>2</sup>	206	355	206	49	206	106	106	527	527	419	419	357
	5' -gAC 3'	5' -TCA 3'	5' -gAC 3'	5' -CAG 3'	5' -gAC 3'	5' -CCA 3'	5' -CCA 3'	5' -TgA 3'	5' -TgT 3'	5' -gTC 3'	5' -gTC 3'	
			355	419	419	419	368					
3'-primer(s) <sup>3</sup>	309	583	301	79	309	302	197	3 <sup>rd</sup> I	559	527	419	419
	5' -ATC 3'	5' -gTg 3'	5' -gTC 3'	5' -gTA 3'	5' -gTC 3'	5' -ggC 3'	5' -gAA 3'	5' -TAT 3'	5' -CAG 3'	5' -CCA 3'	5' -gTC 3'	5' -Tgg 3'
			302	559	538	583	463					
			603		538	583	463					
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
HLA-B allele <sup>4</sup>												
*53:01:01-53:01:08, 53:25-53:27, 53:29	1								9	10	11	
*53:02	1	2				6			9	10	11	
*53:03, 35:203 <sup>5</sup>			3						9	10	11	
*53:04	1			4					9			
*53:05	1		3			6			9	10	11	
*53:06	1	2				6	8					11
*53:07	1			4			7		9			
*53:08:01-53:08:02	1						8			11		
*53:09					5				9	10	11	
*53:10	1						7		9	10	11	
*53:11					5				9	w	11	
*53:12					5	6			9	10	11	
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

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 101.549-06u – without *Taq* polymerase, IFU-02

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Lot-specific information

INTERPRETATION TABLE													
HLA-B*53 SSP subtyping													
Amplification patterns of the B*53:01 to B*53:29 alleles													
Well <sup>6</sup>													
13	14	15	16		17	18	19	20	21	22			
90	95	105	160		275	140	125	60	135	205			Length of spec. PCR product(s)
	130												Length of int. pos. control <sup>1</sup>
1070	1070	1070	1070		1070	1070	1070	1070	1070	1070			5'-primer(s) <sup>2</sup>
208	106	206	539		77	106	209	539	435	397			
5' -Cgt 3'	5' -CCA 3'	5' -gAC 3'	5' -gCT 3'		5' -CTT 3'	5' -CCg 3'	5' -ggA 3'	5' -gCg 3'	5' -AAA 3'	5' -gCT 3'			
209	363												
5' -ggA 3'	5' -AgC 3'												
256	197	272	3 <sup>rd</sup> I	309	206	292	559	527	559				3'-primer(s) <sup>3</sup>
5' -CTC 3'	5' -gAA 3'	5' -Tgg 3'	5' -TAT 3'	5' -ATC 3'	5' -CCg 3'	5' -gTC 3'	5' -CAG 3'	5' -CCA 3'	5' -CAG 3'				
256	419					292							
5' -CCC 3'	5' -Cgg 3'			5' -gTC 3'									
419													
5' -CgA 3'													
13	14	15	16		17	18	19	20	21	22			Well No.
													HLA-B allele <sup>4</sup>
				16									*53:01:01-53:01:08, 53:25-53:27, 53:29
				16									*53:02
				16									*53:03, 35:203 <sup>5</sup>
				16									*53:04
				16									<b>*53:05</b>
				16									*53:06
				16									*53:07
				16									*53:08:01-53:08:02
		15	16										<b>*53:09</b>
	14	16											*53:10
							20						*53:11
													*53:12
13	14	15	16		17	18	19	20	21	22			Well No.

**101.549-06– including Taq polymerase, IFU-01**  
**101. 549-06u – without Taq polymerase, IFU-02**

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**Lot No.: 22S****Lot-specific information**

Length of spec.	145	270	135	190	150	205	130	170	75	150	85	105
PCR product(s)			290			235						
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
*53:13					5				9	10	11	
*53:14	1								9	10	11	
<b>*53:15</b>	1		3						9	10	11	
*53:16	1		3			6			9	w	11	
*53:17:01-53:17:02	1								9	10	11	
<b>*53:18</b>	1			4					9	10	11	
<b>*53:19</b>	1								9			
<b>*53:20</b>	1								9	10	11	
*53:21	1								9	10	11	
<b>*53:22</b>	1				5				9		11	
*53:23	1								9	10	11	
<b>*53:24</b>	1								9	w	11	
*53:28	1	2				6		8				11
*07:02:01-07:08, 07:10, 07:12-07:16, 07:18:01-07:19, 07:21-07:23, 07:27-07:33, 07:35-07:42, 07:44-07:47, 07:49N-07:50, 07:52-07:59, 07:61-07:64, 07:66-07:77, 07:79, 07:81-07:114, 07:116-07:130, 07:132- 07:133, 07:135N-07:146, 07:148-07:154, 07:156-07:163, 07:165-07:181N, 08:20, 08:53:01-08:53:02, 08:79, 14:03, 15:30, 15:33, 15:45, 15:63, 15:77-15:78:03, 15:116, 15:141, 15:150, 15:168, 15:233, 15:248, 27:25, 35:44, 35:118, 35:213, 39:18, 39:36, 40:15-40:16, 40:23, 40:32, 40:98, 40:161, 40:198, 44:146, 44:150, 46:01:06, 48:05, 48:08, 57:09, 57:13							8					
*07:09, 07:11, 07:17, 07:115									8			
*07:20, 07:24, 07:60, 15:99, 44:76									8			
*07:26, 07:34, 07:43, 07:80, 07:131, 07:147, 13:20, 13:62, 14:01:01-14:02:08, 14:04, 14:06:01-14:09, 14:11-14:18, 14:20-14:26, 14:28-14:33, 15:09-15:10:02, 15:17:01:01- 15:17:02, 15:37, 15:72, 15:90, 15:177, 15:196, 15:208, 15:216, 15:230, 15:243, 15:252, 27:04:01-27:04:03, 27:06, 27:10, 27:15, 27:18, 27:20-27:21, 27:24, 27:40, 27:54, 27:63, 27:66N, 27:68-27:69, 27:79, 27:86, 27:91-27:92, 27:100, 38:10, 38:32, 39:35, 40:05, 40:26, 40:51, 40:95, 40:148, 40:174, 40:183, 44:79, 48:15, 49:18, 50:14, 50:20, 51:01:40, 51:104, 51:112, 51:147, 52:02, 52:16, 55:01:04, 55:01:07, 55:17, 55:28, 55:44, 55:53, 55:58, 56:05:01- 56:05:02, 56:21, 57:57, 78:02:01-78:02:02								8				
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

**101.549-06– including Taq polymerase, IFU-01**  
**101.549-06u – without Taq polymerase, IFU-02**

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90	95	105	160	275	140	125	60	135	205	
		<b>130</b>								
<b>13</b>	<b>14</b>	<b>15</b>	<b>16</b>	<b>17</b>	<b>18</b>	<b>19</b>	<b>20</b>	<b>21</b>	<b>22</b>	<b>Well No.</b>
			<b>16</b>							*53:13
	<b>14</b>		<b>16</b>							*53:14
			<b>16</b>							<b>*53:15</b>
					<b>20</b>					*53:16
		<b>15</b>	<b>16</b>							*53:17:01-53:17:02
			<b>16</b>							<b>*53:18</b>
			<b>16</b>				<b>22</b>			<b>*53:19</b>
			<b>16</b>	<b>17</b>						<b>*53:20</b>
			<b>16</b>	<b>18</b>						*53:21
										<b>*53:22</b>
			<b>16</b>	<b>19</b>						*53:23
					<b>20</b>					<b>*53:24</b>
		<b>15</b>	<b>16</b>							*53:28
										*07:02:01-07:08, 07:10, 07:12-07:16, 07:18:01-07:19, 07:21-07:23, 07:27-07:33, 07:35-07:42, 07:44-07:47, 07:49N-07:50, 07:52-07:59, 07:61-07:64, 07:66-07:77, 07:79, 07:81-07:114, 07:116-07:130, 07:132- 07:133, 07:135N-07:146, 07:148-07:154, 07:156-07:163, 07:165-07:181N, 08:20, 08:53:01-08:53:02, 08:79, 14:03, 15:30, 15:33, 15:45, 15:63, 15:77-15:78:03, 15:116, 15:141, 15:150, 15:168, 15:233, 15:248, 27:25, 35:44, 35:118, 35:213, 39:18, 39:36, 40:15-40:16, 40:23, 40:32, 40:98, 40:161, 40:198, 44:146, 44:150, 46:01:06, 48:05, 48:08, 57:09, 57:13
	<b>14</b>									*07:09, 07:11, 07:17, 07:15
				<b>20</b>						*07:20, 07:24, 07:60, 15:99, 44:76
			<b>16</b>							*07:26, 07:34, 07:43, 07:80, 07:131, 07:147, 13:20, 13:62, 14:01:01-14:02:08, 14:04, 14:06:01-14:09, 14:11-14:18, 14:20-14:26, 14:28-14:33, 15:09-15:10:02, 15:17:01:01- 15:17:02, 15:37, 15:72, 15:90, 15:177, 15:196, 15:208, 15:216, 15:230, 15:243, 15:252, 27:04:01-27:04:03, 27:06, 27:10, 27:15, 27:18, 27:20-27:21, 27:24, 27:40, 27:54, 27:63, 27:66N, 27:68-27:69, 27:79, 27:86, 27:91-27:92, 27:100, 38:10, 38:32, 39:35, 40:05, 40:26, 40:51, 40:95, 40:148, 40:174, 40:183, 44:79, 48:15, 49:18, 50:14, 50:20, 51:01:40, 51:104, 51:112, 51:147, 52:02, 52:16, 55:01:04, 55:01:07, 55:17, 55:28, 55:44, 55:53, 55:58, 56:05:01- 56:05:02, 56:21, 57:57, 78:02:01-78:02:02
<b>13</b>	<b>14</b>	<b>15</b>	<b>16</b>	<b>17</b>	<b>18</b>	<b>19</b>	<b>20</b>	<b>21</b>	<b>22</b>	<b>Well No.</b>

**101.549-06– including *Taq* polymerase, IFU-01**  
**101.549-06u – without *Taq* polymerase, IFU-02**

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**Lot No.: 22S****Lot-specific information**

Length of spec.	145	270	135	190	150	205	130	170	75	150	85	105
PCR product(s)			290			235						
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
*07:48, 08:13, 08:55, 13:01:01-13:01:06, 13:02:15, 13:06-13:07N, 13:11-13:13, 13:17, 13:21-13:23, 13:28-13:29, 13:35-13:36, 13:39, 13:43, 13:47, 13:50-13:52, 13:57, 13:59-13:61, 13:63N, 15:86, 15:162, 15:188, 15:224, 27:01-27:03, 27:05:02-27:05:18, 27:05:20-27:05:22, 27:07:01-27:09, 27:11- 27:14, 27:16-27:17, 27:19, 27:23, 27:26- 27:37, 27:39, 27:42-27:44, 27:46, 27:48- 27:51, 27:53, 27:55-27:62, 27:64N-27:65N, 27:67, 27:70-27:75, 27:77-27:78, 27:80- 27:85, 27:87-27:90:02, 27:93-27:99, 35:03:06, 35:31, 35:33, 35:65Q, 35:88, 38:01:01-38:05, 38:08-38:09, 38:11-38:23, 38:25-38:29, 38:31, 38:33-38:42, 39:01:01- 39:01:01:03, 39:01:03-39:06:02, 39:10:01- 39:10:02, 39:12-39:17, 39:20, 39:22-39:23, 39:25N-39:31, 39:34, 39:38Q-39:42, 39:44- 39:73, 39:75, 39:77-39:81, 40:01:01- 40:01:05, 40:01:07-40:02:17, 40:04, 40:06:01:01-40:14:03, 40:18-40:19, 40:21- 40:22N, 40:24-40:25, 40:27:01-40:27:02, 40:29-40:31, 40:33-40:37, 40:39-40:40, 40:42- 40:50, 40:53-40:58, 40:61-40:62, 40:64- 40:70, 40:72:01-40:91, 40:93-40:94, 40:96- 40:97, 40:99-40:104, 40:106-40:127, 40:129- 40:135, 40:137-40:147, 40:149-40:157, 40:160:01-40:160:02, 40:162-40:173, 40:175- 40:182, 40:184, 40:186-40:197, 40:199- 40:208, 40:210-40:221, 40:223-40:230, 40:232-40:233, 44:30-44:31, 44:64:01- 44:64:02, 44:92, 44:124, 44:160, 44:163, 47:01:01:01-47:08, 48:01:01-48:01:04, 48:03:01-48:04, 48:06-48:07, 48:09-48:13, 48:16-48:18, 48:20-48:22, 48:26-48:30, 54:04, 54:11, 54:15, 55:04, 55:13, 55:27, 55:39, 55:42, 55:49, 56:10, 56:12, 57:46, 59:02-59:03, 67:01:01-67:03, 81:01-81:06												
*07:65									8			
*07:78, 13:31, 54:20, 55:09, 55:21, 55:52, 55:56									8			12
*07:134									8			
*07:164, 27:05:19												
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

**101.549-06– including Taq polymerase, IFU-01**  
**101.549-06u – without Taq polymerase, IFU-02**

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**“Instructions for Use” (IFU)**

**Lot No.: 22S****Lot-specific information**

90	95	105	160	275	140	125	60	135	205	
13	14	15	16	17	18	19	20	21	22	Well No.
										*07:48, 08:13, 08:55, 13:01:01-13:01:06, 13:02:15, 13:06-13:07N, 13:11-13:13, 13:17, 13:21-13:23, 13:28-13:29, 13:35-13:36, 13:39, 13:43, 13:47, 13:50-13:52, 13:57, 13:59-13:61, 13:63N, 15:86, 15:162, 15:188, 15:224, 27:01-27:03, 27:05:02-27:05:18, 27:05:20-27:05:22, 27:07:01-27:09, 27:11- 27:14, 27:16-27:17, 27:19, 27:23, 27:26- 27:37, 27:39, 27:42-27:44, 27:46, 27:48- 27:51, 27:53, 27:55-27:62, 27:64N-27:65N, 27:67, 27:70-27:75, 27:77-27:78, 27:80- 27:85, 27:87-27:90:02, 27:93-27:99, 35:03:06, 35:31, 35:33, 35:65Q, 35:88, 38:01:01-38:05, 38:08-38:09, 38:11-38:23, 38:25-38:29, 38:31, 38:33-38:42, 39:01:01:01- 39:01:01:03, 39:01:03-39:06:02, 39:10:01- 39:10:02, 39:12-39:17, 39:20, 39:22-39:23, 39:25N-39:31, 39:34, 39:38Q-39:42, 39:44- 39:73, 39:75, 39:77-39:81, 40:01:01- 40:01:05, 40:01:07-40:02:17, 40:04, 40:06:01:01-40:14:03, 40:18-40:19, 40:21- 40:22N, 40:24-40:25, 40:27:01-40:27:02, 40:29-40:31, 40:33-40:37, 40:39-40:40, 40:42- 40:50, 40:53-40:58, 40:61-40:62, 40:64- 40:70, 40:72:01-40:91, 40:93-40:94, 40:96- 40:97, 40:99-40:104, 40:106-40:127, 40:129- 40:135, 40:137-40:147, 40:149-40:157, 40:160:01-40:160:02, 40:162-40:173, 40:175- 40:182, 40:184, 40:186-40:197, 40:199- 40:208, 40:210-40:221, 40:223-40:230, 40:232-40:233, 44:30-44:31, 44:64:01- 44:64:02, 44:92, 44:124, 44:160, 44:163, 47:01:01:01-47:08, 48:01:01-48:01:04, 48:03:01-48:04, 48:06-48:07, 48:09-48:13, 48:16-48:18, 48:20-48:22, 48:26-48:30, 54:04, 54:11, 54:15, 55:04, 55:13, 55:27, 55:39, 55:42, 55:49, 56:10, 56:12, 57:46, 59:02-59:03, 67:01:01-67:03, 81:01-81:06
										*07:65
										*07:78, 13:31, 54:20, 55:09, 55:21, 55:52, 55:56
										*07:134
										*07:164, 27:05:19
										Well No.
13	14	15	16	17	18	19	20	21	22	

**101.549-06– including Taq polymerase, IFU-01**  
**101.549-06u – without Taq polymerase, IFU-02**

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**“Instructions for Use” (IFU)**

**Lot No.: 22S****Lot-specific information**

Length of spec.	145	270	135	190	150	205	130	170	75	150	85	105
PCR product(s)			290			235						
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
*08:21, 27:47, 41:17, 44:02:01:01-44:02:07, 44:02:09-44:02:27, 44:05:01, 44:05:03- 44:05:04, 44:08-44:09, 44:11-44:12, 44:14, 44:19N-44:20, 44:22-44:25, 44:27:01- 44:27:02, 44:33-44:35, 44:41:01-44:42, 44:44, 44:48-44:49, 44:51-44:53, 44:55, 44:58N-44:59:02, 44:62-44:63, 44:66-44:68, 44:70-44:75, 44:78, 44:80, 44:84, 44:86- 44:91, 44:93, 44:95, 44:97, 44:99-44:100, 44:104, 44:106, 44:113, 44:116, 44:118- 44:119, 44:121, 44:123, 44:126:01-44:127, 44:131, 44:133, 44:136-44:139, 44:142Q, 44:145, 44:148-44:149N, 44:151-44:152, 44:158, 44:162, 44:168-44:172, 83:01, C*03:36, C*03:77								9				
*08:25, 15:48, 27:38, 27:76, 35:04:01, 35:04:03, 35:09:01-35:09:03, 35:12:01- 35:12:03, 35:22, 35:34, 35:39, 35:149, 35:199, 35:201, 35:214, 40:63, 40:92, 44:03:01-44:03:16, 44:03:18-44:03:19, 44:07, 44:13, 44:26, 44:29, 44:32, 44:36-44:40, 44:45-44:47, 44:50, 44:54, 44:57, 44:60- 44:61N, 44:65, 44:69, 44:77, 44:81-44:82, 44:85, 44:94, 44:96, 44:98, 44:103, 44:105, 44:107-44:108N, 44:110-44:111, 44:114- 44:115, 44:120, 44:122, 44:125, 44:128- 44:130, 44:135, 44:141, 44:143, 44:147, 44:153-44:157, 44:159, 44:161, 44:164- 44:165, 44:167, 55:08, 55:51, 56:15, 57:03:01- 57:03:02, 57:07, 57:17, 57:32, 57:39								9				
*08:28, 08:35, 08:37, 42:09					5							
*08:32												
*08:49, 08:60, 08:76, 42:13		3										
*08:69, 41:18, C*02:60, C*07:294, C*08:08												
*08:89, C*07:68, C*07:140, C*07:151					5							
*13:02:01-13:02:14, 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, 13:53-13:56N, 35:60, 46:18, 54:01:01-54:02, 54:05N, 54:07-54:08N, 54:12- 54:13, 54:16-54:19, 54:21-54:28, 55:02:01- 55:02:06, 55:07, 55:10, 55:12, 55:16, 55:18- 55:19, 55:22, 55:26, 55:30, 55:34-55:35, 55:41, 55:43, 55:46-55:48, 55:50, 56:19N, 56:23, 59:01:01-59:01:01:02, 59:05											12	
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

**101.549-06– including Taq polymerase, IFU-01**  
**101. 549-06u – without Taq polymerase, IFU-02**

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**“Instructions for Use” (IFU)**

**Lot No.: 22S****Lot-specific information**

90	95	105	160	275	140	125	60	135	205	
13	14	15	16	17	18	19	20	21	22	Well No.
										*08:21, 27:47, 41:17, 44:02:01:01-44:02:07, 44:02:09-44:02:27, 44:05:01, 44:05:03- 44:05:04, 44:08-44:09, 44:11-44:12, 44:14, 44:19N-44:20, 44:22-44:25, 44:27:01- 44:27:02, 44:33-44:35, 44:41:01-44:42, 44:44, 44:48-44:49, 44:51-44:53, 44:55, 44:58N-44:59:02, 44:62-44:63, 44:66-44:68, 44:70-44:75, 44:78, 44:80, 44:84, 44:86- 44:91, 44:93, 44:95, 44:97, 44:99-44:100, 44:104, 44:106, 44:113, 44:116, 44:118- 44:119, 44:121, 44:123, 44:126:01-44:127, 44:131, 44:133, 44:136-44:139, 44:142Q, 44:145, 44:148-44:149N, 44:151-44:152, 44:158, 44:162, 44:168-44:172, 83:01, C*03:36, C*03:77
			16							*08:25, 15:48, 27:38, 27:76, 35:04:01, 35:04:03, 35:09:01-35:09:03, 35:12:01- 35:12:03, 35:22, 35:34, 35:39, 35:149, 35:199, 35:201, 35:214, 40:63, 40:92, 44:03:01-44:03:16, 44:03:18-44:03:19, 44:07, 44:13, 44:26, 44:29, 44:32, 44:36-44:40, 44:45-44:47, 44:50, 44:54, 44:57, 44:60- 44:61N, 44:65, 44:69, 44:77, 44:81-44:82, 44:85, 44:94, 44:96, 44:98, 44:103, 44:105, 44:107-44:108N, 44:110-44:111, 44:114- 44:115, 44:120, 44:122, 44:125, 44:128- 44:130, 44:135, 44:141, 44:143, 44:147, 44:153-44:157, 44:159, 44:161, 44:164- 44:165, 44:167, 55:08, 55:51, 56:15, 57:03:01- 57:03:02, 57:07, 57:17, 57:32, 57:39
	14									*08:28, 08:35, 08:37, 42:09
			19							*08:32
										*08:49, 08:60, 08:76, 42:13
	14									*08:69, 41:18, C*02:60, C*07:294, C*08:08
										*08:89, C*07:68, C*07:140, C*07:151
			16							*13:02:01-13:02:14, 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, 13:53-13:56N, 35:60, 46:18, 54:01:01-54:02, 54:05N, 54:07-54:08N, 54:12- 54:13, 54:16-54:19, 54:21-54:28, 55:02:01- 55:02:06, 55:07, 55:10, 55:12, 55:16, 55:18- 55:19, 55:22, 55:26, 55:30, 55:34-55:35, 55:41, 55:43, 55:46-55:48, 55:50, 56:19N, 56:23, 59:01:01-59:01:01:02, 59:05
13	14	15	16	17	18	19	20	21	22	Well No.

**101.549-06– including Taq polymerase, IFU-01**  
**101.549-06u – without Taq polymerase, IFU-02**

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**“Instructions for Use” (IFU)**

**Lot No.: 22S****Lot-specific information**

Length of spec.	145	270	135	190	150	205	130	170	75	150	85	105
PCR product(s)			290			235						
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
*13:03, 46:11, 49:11, 54:03, 56:01:01-56:01:04, 56:07-56:08, 56:14, 56:16-56:17, 56:20:01-56:20:02, 56:24, 56:26-56:30, 56:33-56:36, 56:38N-56:39, 59:04				4					9			12
*13:04, 15:05:01-15:05:02, 15:20, 15:91, 15:123, 15:136, 15:151, 15:155, 15:222, 15:235, 35:01:01:01-35:01:09, 35:01:11-35:01:21, 35:01:23-35:01:37, 35:05:01-35:05:02, 35:07, 35:10, 35:16-35:17, 35:19, 35:23, 35:25-35:27, 35:30, 35:32:01-35:32:02, 35:37, 35:40N-35:42:02, 35:46-35:49, 35:52, 35:54, 35:57, 35:63, 35:68:01-35:68:02, 35:71, 35:77-35:78, 35:82, 35:89-35:92, 35:94, 35:97, 35:101:01-35:101:02, 35:103-35:104, 35:107-35:108:02, 35:110-35:113, 35:116, 35:119-35:126, 35:130N-35:134N, 35:137-35:139, 35:143-35:145N, 35:147-35:148, 35:159, 35:161, 35:165N, 35:168, 35:170-35:171, 35:173N, 35:175, 35:177-35:178, 35:189, 35:191, 35:194, 35:196, 35:200, 35:202, 35:207-35:210, 35:212, 35:215-35:219, 35:222, 35:224, 44:43:01-44:43:02, 46:13:01-46:13:03, 46:19, 46:33, 48:02:01-48:02:03, 56:09, 57:01:01-57:01:02, 57:01:04, 57:01:06-57:01:11, 57:01:13-57:01:14, 57:06, 57:08, 57:10-57:11, 57:15-57:16, 57:18, 57:20-57:21, 57:23, 57:29, 57:33-57:38, 57:40, 57:44-57:45, 57:48-57:56, 57:58-57:62, 58:36								9	10	11		
*13:10									10	w		
*13:16, 15:42, 49:07, 50:31, 55:01:01-55:01:03, 55:01:05-55:01:06, 55:01:08-55:01:10, 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, 55:55N								8			12	
*13:18, 13:41, 45:08, 45:10, 54:10, 55:37, 55:57												12
*13:25						6						
*13:26, 15:52, 15:114, 15:124, 15:186, 27:41, 35:01:22, 35:15, 35:35, 35:93, 35:140, 35:180, 39:07, 40:222, 46:21:01-46:21:02, 48:14, 54:09, 54:14, 55:23, 55:32, 56:18, 57:01:03, 57:01:12, 57:25-57:26, 57:43									10	11		
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

**101.549-06– including Taq polymerase, IFU-01**  
**101.549-06u – without Taq polymerase, IFU-02**

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**“Instructions for Use” (IFU)**

**Lot No.: 22S****Lot-specific information**

90	95	105	160	275	140	125	60	135	205	
130										
13	14	15	16	17	18	19	20	21	22	Well No.
			16							*13:03, 46:11, 49:11, 54:03, 56:01:01-56:01:04, 56:07-56:08, 56:14, 56:16-56:17, 56:20:01-56:20:02, 56:24, 56:26-56:30, 56:33-56:36, 56:38N-56:39, 59:04
			16							*13:04, 15:05:01-15:05:02, 15:20, 15:91, 15:123, 15:136, 15:151, 15:155, 15:222, 15:235, 35:01:01:01-35:01:09, 35:01:11-35:01:21, 35:01:23-35:01:37, 35:05:01-35:05:02, 35:07, 35:10, 35:16-35:17, 35:19, 35:23, 35:25-35:27, 35:30, 35:32:01-35:32:02, 35:37, 35:40N-35:42:02, 35:46-35:49, 35:52, 35:54, 35:57, 35:63, 35:68:01-35:68:02, 35:71, 35:77-35:78, 35:82, 35:89-35:92, 35:94, 35:97, 35:101:01-35:101:02, 35:103-35:104, 35:107-35:108:02, 35:110-35:113, 35:116, 35:119-35:126, 35:130N-35:134N, 35:137-35:139, 35:143-35:145N, 35:147-35:148, 35:159, 35:161, 35:165N, 35:168, 35:170-35:171, 35:173N, 35:175, 35:177-35:178, 35:189, 35:191, 35:194, 35:196, 35:200, 35:202, 35:207-35:210, 35:212, 35:215-35:219, 35:222, 35:224, 44:43:01-44:43:02, 46:13:01-46:13:03, 46:19, 46:33, 48:02:01-48:02:03, 56:09, 57:01:01-57:01:02, 57:01:04, 57:01:06-57:01:11, 57:01:13-57:01:14, 57:06, 57:08, 57:10-57:11, 57:15-57:16, 57:18, 57:20-57:21, 57:23, 57:29, 57:33-57:38, 57:40, 57:44-57:45, 57:48-57:56, 57:58-57:62, 58:36
			16							*13:10
			16							*13:16, 15:42, 49:07, 50:31, 55:01:01-55:01:03, 55:01:05-55:01:06, 55:01:08-55:01:10, 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, 55:55N
			16							*13:18, 13:41, 45:08, 45:10, 54:10, 55:37, 55:57
			16							*13:25
			16							*13:26, 15:52, 15:114, 15:124, 15:186, 27:41, 35:01:22, 35:15, 35:35, 35:93, 35:140, 35:180, 39:07, 40:222, 46:21:01-46:21:02, 48:14, 54:09, 54:14, 55:23, 55:32, 56:18, 57:01:03, 57:01:12, 57:25-57:26, 57:43
13	14	15	16	17	18	19	20	21	22	Well No.

**101.549-06– including *Taq* polymerase, IFU-01**  
**101.549-06u – without *Taq* polymerase, IFU-02**

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**“Instructions for Use” (IFU)**

**Lot No.: 22S****Lot-specific information**

Length of spec.	145	270	135	190	150	205	130	170	75	150	85	105
PCR product(s)			290			235						
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
*13:48, 49:01:01, 49:01:03-49:02, 49:06, 49:08-49:10, 49:12-49:17, 49:19N-49:25, 50:01:01-50:01:02, 50:02, 50:04-50:08, 50:10-50:11, 50:13, 50:15, 50:18-50:19, 56:25, 56:37				4				8				12
*13:58					5							12
*14:05								8				
*14:10, 35:96, 40:28		2						8				
*14:19, 14:27, 15:133, 15:229, 15:253, 35:167, 50:09, 50:12, 50:16-50:17				4				8				
*15:01:01:01-15:01:04, 15:01:06-15:01:31, 15:04, 15:08, 15:11:01-15:12, 15:14-15:15, 15:19, 15:24, 15:26N-15:28, 15:34-15:35, 15:43, 15:46-15:47:02, 15:49-15:50, 15:53-15:54, 15:56-15:57, 15:60, 15:66, 15:70-15:71, 15:76, 15:79N, 15:81-15:82, 15:85, 15:87, 15:92, 15:94N, 15:96-15:97, 15:101-15:102, 15:104, 15:109-15:110, 15:113, 15:117-15:118, 15:120, 15:122, 15:125-15:126, 15:129, 15:135, 15:140, 15:142-15:143, 15:146-15:149N, 15:152, 15:154, 15:157, 15:159-15:160, 15:163-15:167, 15:169, 15:171-15:172, 15:174-15:175, 15:178, 15:180-15:184, 15:187, 15:189-15:193, 15:201, 15:203, 15:205-15:207, 15:209N, 15:211-15:212, 15:215, 15:217, 15:225, 15:227-15:228, 15:231-15:232, 15:234, 15:236, 15:241, 15:244-15:247, 15:249, 15:251, 15:256-15:262N, 15:264, 15:267, 35:14:01-35:14:02, 35:43:01, 35:67, 35:79, 35:86, 35:102, 35:117, 35:135, 35:185, 46:01:01-46:01:05, 46:01:07-46:05, 46:07N, 46:10, 46:14-46:17, 46:20, 46:22-46:24, 46:27-46:32, 46:34-46:38, 54:06, 56:03							8			11		
*15:02:01-15:02:06, 15:06, 15:13:01-15:13:02, 15:21, 15:25:01-15:25:03, 15:36, 15:44, 15:89, 15:106, 15:112, 15:121, 15:139, 15:156, 15:170, 15:204, 15:213-15:214, 15:240, 49:05								8			w	
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

**101.549-06– including Taq polymerase, IFU-01**  
**101.549-06u – without Taq polymerase, IFU-02**

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**“Instructions for Use” (IFU)**

**Lot No.: 22S****Lot-specific information**

90	95	105	160	275	140	125	60	135	205	
130										
13	14	15	16	17	18	19	20	21	22	Well No.
			16							*13:48, 49:01:01, 49:01:03-49:02, 49:06, 49:08-49:10, 49:12-49:17, 49:19N-49:25, 50:01:01-50:01:02, 50:02, 50:04-50:08, 50:10-50:11, 50:13, 50:15, 50:18-50:19, 56:25, 56:37
		15	16							*13:58
	14		16							*14:05
			16							*14:10, 35:96, 40:28
			16							*14:19, 14:27, 15:133, 15:229, 15:253, 35:167, 50:09, 50:12, 50:16-50:17
										*15:01:01:01-15:01:04, 15:01:06-15:01:31, 15:04, 15:08, 15:11:01-15:12, 15:14-15:15, 15:19, 15:24, 15:26N-15:28, 15:34-15:35, 15:43, 15:46-15:47:02, 15:49-15:50, 15:53-15:54, 15:56-15:57, 15:60, 15:66, 15:70-15:71, 15:76, 15:79N, 15:81-15:82, 15:85, 15:87, 15:92, 15:94N, 15:96-15:97, 15:101-15:102, 15:104, 15:109-15:110, 15:113, 15:117-15:118, 15:120, 15:122, 15:125-15:126, 15:129, 15:135, 15:140, 15:142-15:143, 15:146-15:149N, 15:152, 15:154, 15:157, 15:159-15:160, 15:163-15:167, 15:169, 15:171-15:172, 15:174-15:175, 15:178, 15:180-15:184, 15:187, 15:189-15:193, 15:201, 15:203, 15:205-15:207, 15:209N, 15:211-15:212, 15:215, 15:217, 15:225, 15:227-15:228, 15:231-15:232, 15:234, 15:236, 15:241, 15:244-15:247, 15:249, 15:251, 15:256-15:262N, 15:264, 15:267, 35:14:01-35:14:02, 35:43:01, 35:67, 35:79, 35:86, 35:102, 35:117, 35:135, 35:185, 46:01:01-46:01:05, 46:01:07-46:05, 46:07N, 46:10, 46:14-46:17, 46:20, 46:22-46:24, 46:27-46:32, 46:34-46:38, 54:06, 56:03
			16							*15:02:01-15:02:06, 15:06, 15:13:01-15:13:02, 15:21, 15:25:01-15:25:03, 15:36, 15:44, 15:89, 15:106, 15:112, 15:121, 15:139, 15:156, 15:170, 15:204, 15:213-15:214, 15:240, 49:05
13	14	15	16	17	18	19	20	21	22	Well No.

**101.549-06– including Taq polymerase, IFU-01**  
**101.549-06u – without Taq polymerase, IFU-02**

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**“Instructions for Use” (IFU)**

**Lot No.: 22S****Lot-specific information**

Length of spec.	145	270	135	190	150	205	130	170	75	150	85	105
PCR product(s)			290			235						
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
*15:03:01-15:03:04, 15:16:01-15:16:03, 15:18:01-15:18:05, 15:23, 15:29, 15:39:01- 15:40, 15:61-15:62, 15:64:01-15:64:02, 15:67, 15:69, 15:74, 15:80, 15:93, 15:95, 15:98, 15:103, 15:108, 15:119, 15:127, 15:131-15:132, 15:134, 15:138, 15:153, 15:158, 15:161, 15:173, 15:194-15:195, 15:197-15:198, 15:210, 15:219-15:220, 15:223, 15:226N, 15:238, 15:242, 15:254- 15:255, 15:263, 15:265-15:266, 15:268, 35:11:01-35:11:03, 40:158, 46:08, 48:25, 49:04, 55:14, 56:32, 57:22							8			11		
*15:07:01-15:07:02, 15:68, 46:12							8			11		
*15:31, 44:144, 57:41								9	10	w		
*15:32					7	8				11		
*15:38:01-15:38:02					6	8				11		
*15:51, 15:179, 35:115, 44:17, 45:09, 57:24				5				9		11		
*15:55								9	10	w		
*15:58, 15:73, 15:137		4			8							
*15:65, 15:221, 35:99					8			11				
*15:75, 15:105, 15:111N, 15:145										11		
*15:84, 15:237, 35:08:01-35:08:06, 35:45, 35:61:01-35:61:02, 35:80, 35:100, 35:105, 35:142, 35:158, 35:176, 35:187, 35:192, 35:206, 35:225, 57:19								9	w	11		
*15:88, 15:250										w		
*15:107, 35:53N, 35:64:01-35:64:02, 35:114, 57:01:05, 57:31, 57:47								9	10			
*15:115					6	8				11		
*15:128, 15:144						8				w		
*15:176, 15:200										11		
*15:185					6			9	10	11		
*15:199				5		8				11		
*15:202, 15:239						8				11		
*15:218Q				5						11		
*18:01:01:01-18:01:03, 18:01:05-18:02, 18:05- 18:06, 18:08, 18:12, 18:17N, 18:23N-18:24, 18:27-18:28, 18:31-18:32, 18:34, 18:38- 18:39, 18:42-18:47, 18:49-18:53, 18:55, 18:59-18:60, 18:62-18:65, 18:70-18:78, 18:80- 18:86					6				10	11		
*18:01:04, 18:40					6				10			
*18:03					6				10	11		
*18:04, 18:25, 18:68					6				10	11		
*18:07:01-18:07:02, 18:29, 18:33, 18:79					6				10	11		
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

**101.549-06– including *Taq* polymerase, IFU-01  
101. 549-06u – without *Taq* polymerase, IFU-02**

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**“Instructions for Use” (IFU)**

Lot No.: 22S

## **Lot-specific information**

90	95	105	160	275	140	125	60	135	205	
			130							
13	14	15	16	17	18	19	20	21	22	Well No.
			16							*15:03:01-15:03:04, 15:16:01-15:16:03, 15:18:01-15:18:05, 15:23, 15:29, 15:39:01- 15:40, 15:61-15:62, 15:64:01-15:64:02, 15:67, 15:69, 15:74, 15:80, 15:93, 15:95, 15:98, 15:103, 15:108, 15:119, 15:127, 15:131-15:132, 15:134, 15:138, 15:153, 15:158, 15:161, 15:173, 15:194-15:195, 15:197-15:198, 15:210, 15:219-15:220, 15:223, 15:226N, 15:238, 15:242, 15:254- 15:255, 15:263, 15:265-15:266, 15:268, 35:11:01-35:11:03, 40:158, 46:08, 48:25, 49:04, 55:14, 56:32, 57:22
14			16							*15:07:01-15:07:02, 15:68, 46:12
		16								*15:31, 44:144, 57:41
										*15:32
14	16									*15:38:01-15:38:02
										*15:51, 15:179, 35:115, 44:17, 45:09, 57:24
										*15:55
										*15:58, 15:73, 15:137
				20						*15:65, 15:221, 35:99
					20					*15:75, 15:105, 15:111N, 15:145
										*15:84, 15:237, 35:08:01-35:08:06, 35:45, 35:61:01-35:61:02, 35:80, 35:100, 35:105, 35:142, 35:158, 35:176, 35:187, 35:192, 35:206, 35:225, 57:19
		w								*15:88, 15:250
		16								*15:107, 35:53N, 35:64:01-35:64:02, 35:114, 57:01:05, 57:31, 57:47
		16								*15:115
		w								*15:128, 15:144
		16								*15:176, 15:200
										*15:185
										*15:199
		15								*15:202, 15:239
										*15:218Q
		15	16	18						*18:01:01:01-18:01:03, 18:01:05-18:02, 18:05- 18:06, 18:08, 18:12, 18:17N, 18:23N-18:24, 18:27-18:28, 18:31-18:32, 18:34, 18:38- 18:39, 18:42-18:47, 18:49-18:53, 18:55, 18:59-18:60, 18:62-18:65, 18:70-18:78, 18:80- 18:86
		15	16	18						*18:01:04, 18:40
		15	16	18	19					*18:03
		15	16							*18:04, 18:25, 18:68
		16	18							*18:07:01-18:07:02, 18:29, 18:33, 18:79
13	14	15	16	17	18	19	20	21	22	Well No.

**101.549-06– including *Taq* polymerase, IFU-01**  
**101.549-06u – without *Taq* polymerase, IFU-02**

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**“Instructions for Use” (IFU)**

**Lot No.: 22S****Lot-specific information**

Length of spec.	145	270	135	190	150	205	130	170	75	150	85	105
PCR product(s)			290			235						
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
*18:09					5	6				10	11	
*18:10-18:11, 18:35										10	11	
*18:13						6				w	11	
*18:14						6				10	11	
*18:15, 18:57						6	8				11	
*18:18						6	7			10	11	
*18:19, 18:30						6	8				11	
*18:20						6				10	w	
*18:21								8				
*18:22, 18:69		2				6				10	11	
*18:26, 18:41, 18:61, 40:209												
*18:36						6			9	10	11	
*18:37, 18:48, 18:66, 39:43, 56:31						6				10	11	
*18:54			3			6				10	11	
*18:56					5				9		11	
*18:58									9	10	11	
*18:67	1		3			6				10	11	
*27:52			3									
*35:01:10									9	10	11	
*35:02:01-35:02:05, 35:83, 35:129N, 35:154, 35:182-35:184, 35:211, 35:220									9			
*35:03:01-35:03:05, 35:03:07-35:03:12, 35:06, 35:13, 35:36, 35:55-35:56, 35:59, 35:70, 35:74-35:75, 35:85, 35:98, 35:106, 35:127-35:128, 35:150-35:153, 35:155, 35:160, 35:179, 35:181, 35:193, 35:195, 35:198, 35:204-35:205, 35:221, 35:223, 39:32, 39:74, 40:71, 44:10, 56:02, 56:04, 56:11, 56:22				4					9			
*35:04:02, 78:04									9			
*35:05:03, 35:51									9	10	11	
*35:18, 35:164, 44:28:01-44:28:02, 57:02:01- 57:02:02, 57:04-57:05, 57:12, 57:28N, 57:42									9			
*35:20:01-35:20:02, 35:28, 35:226									9	10	11	
*35:21, 35:188	2				6		8				11	
*35:24:01-35:24:02, 57:14	2				6				9	10	11	
*35:29:01-35:29:02, 35:69, 35:76									9	10	11	
*35:38, 35:163, 35:169, 38:30, 44:140, 45:02, 82:01-82:03, C*04:34				4					9			
*35:50, 35:197									9	10	11	
*35:58								8			11	
*35:62, 57:27									9	w	11	
*35:66										w	11	
*35:72									9	10	11	
<b>Well No.</b>	1	2	3	4	5	6	7	8	9	10	11	12

**101.549-06– including Taq polymerase, IFU-01**  
**101.549-06u – without Taq polymerase, IFU-02**

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**“Instructions for Use” (IFU)**

**Lot No.: 22S****Lot-specific information**

90	95	105	160	275	140	125	60	135	205	
130										
13	14	15	16	17	18	19	20	21	22	Well No.
		15	16		18					*18:09
		15	16		18					*18:10-18:11, 18:35
		15			18					*18:13
	14	15	16		18					*18:14
		15	16		18					*18:15, 18:57
		15	16		18					*18:18
		15			18					*18:19, 18:30
		15	16		18					*18:20
		15			18					*18:21
		15	16		18					*18:22, 18:69
		15	16		18					*18:26, 18:41, 18:61, 40:209
		15	16		18					*18:36
			16							*18:37, 18:48, 18:66, 39:43, 56:31
		15	16		18					*18:54
		15			18					*18:56
		15	16		18					*18:58
		15	16		18					*18:67
			16		18					*27:52
			16				21			*35:01:10
			16					22		*35:02:01-35:02:05, 35:83, 35:129N, 35:154, 35:182-35:184, 35:211, 35:220
										*35:03:01-35:03:05, 35:03:07-35:03:12, 35:06, 35:13, 35:36, 35:55-35:56, 35:59, 35:70, 35:74-35:75, 35:85, 35:98, 35:106, 35:127-35:128, 35:150-35:153, 35:155, 35:160, 35:179, 35:181, 35:193, 35:195, 35:198, 35:204-35:205, 35:221, 35:223, 39:32, 39:74, 40:71, 44:10, 56:02, 56:04, 56:11, 56:22
			16							*35:04:02, 78:04
	14		16							*35:05:03, 35:51
						20				*35:18, 35:164, 44:28:01-44:28:02, 57:02:01-57:02:02, 57:04-57:05, 57:12, 57:28N, 57:42
		15	16							*35:20:01-35:20:02, 35:28, 35:226
			16							*35:21, 35:188
			16							*35:24:01-35:24:02, 57:14
			16		19					*35:29:01-35:29:02, 35:69, 35:76
										*35:38, 35:163, 35:169, 38:30, 44:140, 45:02, 82:01-82:03, C*04:34
			16		18					*35:50, 35:197
	14		16							*35:58
										*35:62, 57:27
	14									*35:66
	14	15	16							*35:72
13	14	15	16	17	18	19	20	21	22	Well No.

**101.549-06– including Taq polymerase, IFU-01**  
**101.549-06u – without Taq polymerase, IFU-02**

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**“Instructions for Use” (IFU)**

**Lot No.: 22S****Lot-specific information**

Length of spec.	145	270	135	190	150	205	130	170	75	150	85	105
PCR product(s)			290			235						
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
*35:81		2							9			
*35:84				4					9			
*35:95									9			
*35:109		2		4					9			
*35:136				4					9			
*35:141, 46:25									9		11	
*35:146									9	10	11	
*35:156, 39:33				4					9			
*35:157		2										
*35:162									9			
*35:166									9	10	11	
*35:172									9			
*35:174									9	w		
*35:186									9	10	11	
*35:190		2				6				10	11	
*37:01:01-37:01:05, 37:01:07-37:01:09, 37:03N, 37:05, 37:08, 37:15-37:18, 37:20, 37:22-37:25, 37:27, 37:30N, 37:32-37:33N, 37:36			3				7					
*37:01:06							7					
*37:02			3									
*37:04:01-37:04:02		2	3				7					
*37:06, 37:28							7					
*37:07			3					8				
*37:09, 37:12, 37:19			3									
*37:10					5		7					
*37:11, 37:14, 37:29							7					
*37:13			3				7	8				
*37:21, 37:26			3				7					
*37:31			3				7					
*37:34		1					7					
*37:35			3		5		7			11		
*37:37							7					
*38:06-38:07		1										
*39:09							7					
*39:19:01-39:19:02												
*39:24:01-39:24:02, 39:37, 39:76												
*40:01:06												
*40:03									10			
*40:20, 40:38, 40:52, 40:59-40:60, 40:105, 40:159, 46:06, 48:23									10			
*40:185												
*41:24					5					11		
*44:02:08, 44:101									w			
<b>Well No.</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>7</b>	<b>8</b>	<b>9</b>	<b>10</b>	<b>11</b>	<b>12</b>

**101.549-06– including *Taq* polymerase, IFU-01  
101. 549-06u – without *Taq* polymerase, IFU-02**

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**“Instructions for Use” (IFU)**

Lot No.: 22S

## **Lot-specific information**

**101.549-06– including Taq polymerase, IFU-01**  
**101.549-06u – without Taq polymerase, IFU-02**

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**“Instructions for Use” (IFU)**

**Lot No.: 22S****Lot-specific information**

Length of spec.	145	270	135	190	150	205	130	170	75	150	85	105
PCR product(s)			290			235						
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
*44:03:17									w			
*44:06, 51:08, 51:44N, 51:141	1								9			
*44:15				4		6			9		12	
*44:18, 45:01, 45:04-45:07, 45:13-45:14, 56:13				4					9		12	
*44:83, 44:134					5				9			
*44:109						6			9			
*44:117				w					9			
*45:03									9		12	
*45:11				4							12	
*45:12				4					9		12	
*46:09									9	11		
*46:26							8	9	9	10	11	
*49:01:02			4			8					12	
*49:03, 52:25	1		4			8					12	
*50:01:03			4			8					12	
*51:01:01-51:01:39, 51:02:01-51:03, 51:06:01- 51:06:02, 51:11N-51:12, 51:14, 51:16-51:18, 51:21-51:24:04, 51:26-51:28, 51:30, 51:32- 51:35, 51:38-51:39, 51:41N, 51:43, 51:48- 51:52, 51:58-51:60, 51:64-51:71, 51:74- 51:77, 51:79-51:80, 51:83-51:86, 51:88- 51:90, 51:94-51:96, 51:98N-51:102, 51:105, 51:107, 51:109-51:111, 51:113-51:114, 51:117-51:119, 51:121, 51:123-51:138, 51:140, 51:142-51:146, 51:149N-51:150, 52:01:13, 52:06:01-52:06:02, 52:22-52:23	1					8						
*51:04, 51:46, 51:56:01-51:56:02	1	2						8				
*51:05	1								9			
*51:07:01-51:07:02, 52:01:01:01-52:01:12, 52:01:14-52:01:17, 52:04-52:05, 52:07-52:08, 52:11-52:13, 52:15, 52:17-52:18, 52:26- 52:27, 52:30-52:31	1						8					
*51:09:01-51:09:02, 51:40, 51:73, 51:108, 51:122	1								9			
*51:10, 51:81, 51:115	1											
*51:13:01-51:13:02, 51:62, 51:92, 51:106	1		4				8					
*51:15	1		4						9		12	
*51:19, 51:42, 51:148	1								9			
*51:20	1								9			
*51:29	1						8					
*51:31, 51:93	1											
*51:36, 51:55, 51:61:01-51:61:02, 51:82	1							8				
*51:37, 51:45, 51:63	1					6		8			11	
*51:53, 51:120	1											
<b>Well No.</b>	1	2	3	4	5	6	7	8	9	10	11	12

**101.549-06– including Taq polymerase, IFU-01**  
**101. 549-06u – without Taq polymerase, IFU-02**

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**“Instructions for Use” (IFU)**

**Lot No.: 22S****Lot-specific information**

90	95	105	160	275	140	125	60	135	205	
			<b>130</b>							
<b>13</b>	<b>14</b>	<b>15</b>	<b>16</b>	<b>17</b>	<b>18</b>	<b>19</b>	<b>20</b>	<b>21</b>	<b>22</b>	<b>Well No.</b>
			<b>16</b>							*44:03:17
										*44:06, 51:08, 51:44N, 51:141
										*44:15
										*44:18, 45:01, 45:04-45:07, 45:13-45:14, 56:13
		<b>15</b>								*44:83, 44:134
		<b>16</b>								*44:109
										*44:117
										*45:03
										*45:11
						<b>22</b>				*45:12
										*46:09
		<b>16</b>								*46:26
										*49:01:02
<b>15</b>	<b>16</b>									*49:03, 52:25
										*50:01:03
			<b>16</b>							*51:01:01-51:01:39, 51:02:01-51:03, 51:06:01- 51:06:02, 51:11N-51:12, 51:14, 51:16-51:18, 51:21-51:24:04, 51:26-51:28, 51:30, 51:32- 51:35, 51:38-51:39, 51:41N, 51:43, 51:48- 51:52, 51:58-51:60, 51:64-51:71, 51:74- 51:77, 51:79-51:80, 51:83-51:86, 51:88- 51:90, 51:94-51:96, 51:98N-51:102, 51:105, 51:107, 51:109-51:111, 51:113-51:114, 51:117-51:119, 51:121, 51:123-51:138, 51:140, 51:142-51:146, 51:149N-51:150, 52:01:13, 52:06:01-52:06:02, 52:22-52:23
		<b>16</b>								*51:04, 51:46, 51:56:01-51:56:02
				<b>20</b>	<b>w</b>					*51:05
<b>15</b>	<b>16</b>									*51:07:01-51:07:02, 52:01:01:01-52:01:12, 52:01:14-52:01:17, 52:04-52:05, 52:07-52:08, 52:11-52:13, 52:15, 52:17-52:18, 52:26- 52:27, 52:30-52:31
		<b>16</b>				<b>21</b>				*51:09:01-51:09:02, 51:40, 51:73, 51:108, 51:122
		<b>16</b>								*51:10, 51:81, 51:115
		<b>16</b>								*51:13:01-51:13:02, 51:62, 51:92, 51:106
		<b>16</b>								*51:15
		<b>16</b>								*51:19, 51:42, 51:148
			<b>19</b>							*51:20
				<b>20</b>						*51:29
		<b>16</b>				<b>21</b>				*51:31, 51:93
										*51:36, 51:55, 51:61:01-51:61:02, 51:82
		<b>16</b>								*51:37, 51:45, 51:63
			<b>w</b>							*51:53, 51:120
<b>13</b>	<b>14</b>	<b>15</b>	<b>16</b>	<b>17</b>	<b>18</b>	<b>19</b>	<b>20</b>	<b>21</b>	<b>22</b>	<b>Well No.</b>

**101.549-06– including Taq polymerase, IFU-01**  
**101.549-06u – without Taq polymerase, IFU-02**

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**“Instructions for Use” (IFU)**

**Lot No.: 22S****Lot-specific information**

Length of spec.	145	270	135	190	150	205	130	170	75	150	85	105
PCR product(s)			290			235						
Well No.	1	2	3	4	5	6	7	8	9	10	11	12
*51:54					5				9			
*51:57, 51:103, 51:116	1						8					
*51:72, 51:87, 51:91	1						8					
*51:78:01-51:78:02					5		8					
*51:97	1				5	6			9		11	
*51:139	1	2							9			
*52:03, 52:10:01-52:10:02	1								9			
*52:09	1		3				8					
*52:14	1			4				8				
*52:19	1								9			
*52:20					5		8					
*52:21	1						8					
*52:24	1						8					
*52:28-52:29	1											
*55:54											12	
*56:01:05									9		12	
*56:06, 78:01:01-78:01:02, 78:03, 78:07							8					
*57:30											11	
*58:01:01-58:01:02, 58:01:04-58:02, 58:04, 58:07, 58:10N-58:16, 58:18, 58:21, 58:23-58:26, 58:29, 58:31N-58:32, 58:39N-58:40	1								9	10	11	
*58:01:03	1								9	10		
*58:05	1										11	
*58:06, 58:19	1						8				11	
*58:08:01-58:08:02	1						8					
*58:09	1	2				6			9	10	11	
*58:17N									9	10	11	
*58:20, 58:27	1											
*58:22	1								9	w	11	
*58:28	1								9			
*58:33	1			4					9	10	11	
*58:34	1			4					9			
*58:35, 58:37-58:38	1								10	11		
*78:05-78:06							8					
A*02:188, A*24:174										w		
C*02:56, C*06:20, C*07:81											w	
C*03:12, C*03:19, C*03:26, C*03:102					w							
C*03:28, C*03:49, C*14:20												
C*04:08, C*05:39				4								
C*05:27, C*08:41, C*15:15, C*17:07				4								
C*07:168							7				w	
C*12:87							6					
C*15:39		2										
<b>Well No.</b>	1	2	3	4	5	6	7	8	9	10	11	12

**101.549-06– including Taq polymerase, IFU-01**  
**101.549-06u – without Taq polymerase, IFU-02**

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**“Instructions for Use” (IFU)**

**Lot No.: 22S****Lot-specific information**

90	95	105	160	275	140	125	60	135	205	
130										
13	14	15	16	17	18	19	20	21	22	Well No.
					20	w				*51:54
			16	18						*51:57, 51:103, 51:116
			w							*51:72, 51:87, 51:91
			16							*51:78:01-51:78:02
										*51:97
			16				21			*51:139
		15	16				21			*52:03, 52:10:01-52:10:02
		15	16							*52:09
		15	16							*52:14
		15								*52:19
		15	16							*52:20
		15								*52:21
		15			20					*52:24
		15	w							*52:28-52:29
		w								*55:54
		16								*56:01:05
		16		19						*56:06, 78:01:01-78:01:02, 78:03, 78:07
					20					*57:30
13			16							*58:01:01-58:01:02, 58:01:04-58:02, 58:04, 58:07, 58:10N-58:16, 58:18, 58:21, 58:23-58:26, 58:29, 58:31N-58:32, 58:39N-58:40
13			16							*58:01:03
13			16							*58:05
13			16							*58:06, 58:19
13			16							*58:08:01-58:08:02
13			16							*58:09
13			16							*58:17N
13			16							*58:20, 58:27
13				20						*58:22
13			16							*58:28
13			16							*58:33
13			16							*58:34
13			16							*58:35, 58:37-58:38
		15	16							*78:05-78:06
										A*02:188, A*24:174
										C*02:56, C*06:20, C*07:81
										C*03:12, C*03:19, C*03:26, C*03:102
				20						C*03:28, C*03:49, C*14:20
				20						C*04:08, C*05:39
										C*05:27, C*08:41, C*15:15, C*17:07
										C*07:168
										C*12:87
										C*15:39
13	14	15	16	17	18	19	20	21	22	Well No.

**101.549-06– including *Taq* polymerase, IFU-01**  
**101. 549-06u – without *Taq* polymerase, IFU-02**

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**“Instructions for Use” (IFU)**

## Lot No.: 22S

### Lot-specific information

<sup>1</sup>The 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\*53 subtyping. In addition, wells number 3 to 7, and 11 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.

<sup>2</sup>The nucleotide position, in the 1<sup>st</sup>, 2<sup>nd</sup> or 3<sup>rd</sup> exon, matching the specificity-determining 3'-end of the primer is given. Nucleotide numbering as on the [www.ebi.ac.uk/imgt/hla](http://www.ebi.ac.uk/imgt/hla) web site. The sequence of the 3 terminal nucleotides of the primer is given.

<sup>3</sup>The nucleotide position, in the 2<sup>nd</sup> or 3<sup>rd</sup> exon or the 3<sup>rd</sup> 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](http://www.ebi.ac.uk/imgt/hla) web site. The sequence of the 3 terminal nucleotides of the primer is given.

<sup>4</sup>HLA-B\*53 alleles in bold lettering are listed as confirmed alleles on the on the IMGT/HLA web page [www.ebi.ac.uk/imgt/hla](http://www.ebi.ac.uk/imgt/hla), release 3.11.0, January 2013.

<sup>5</sup>The B\*53:03 and the 35:203 alleles give rise to identical amplification patterns with the HLA-B\*53 subtyping kit. These alleles can be distinguished by the HLA-B low resolution kit and/or the HLA-B\*35 subtyping kit.

<sup>6</sup>Primer mix 3: Specific PCR fragment of 135 bp in the B\*53:03, 53:05 and 53:16 and the B\*18:54, 18:67, 27:52, 35:203, 37:01:01-37:01:05, 37:01:07-37:05, 37:07-37:09, 37:12-37:13, 37:15-37:27, 37:30N-37:33N, 37:35-37:36 and 52:09 alleles. Specific PCR fragment of 290 bp in the B\*53:15 and the 08:49, 08:60, 08:76 and 42:13 alleles.

<sup>10</sup>Primer mix 6: Specific PCR fragment of 205 bp in the B\*53:02, 53:06 and 53:28 and the 15:38:01-15:38:02, 15:185, 18:01:01:01-18:09, 18:12-18:15, 18:17N-18:20, 18:22-18:25, 18:27-18:34, 18:36-18:40, 18:42-18:55, 18:57, 18:59-18:60, 18:62-18:86, 35:21, 35:24:01-35:24:02, 35:188, 35:190, 39:43, 51:37, 51:45, 51:63, 51:97, 56:31, 57:14 and 58:09 and in the C\*12:87alleles. Specific PCR fragment of 235 bp in the the B\*53:05, 53:12 and 53:16 and the B\*13:25, 15:115, 44:15 and 44:109 alleles.

<sup>11</sup>Primer mix 14: Specific PCR fragment of 95 bp in the B\*53:14 and the B\*07:09, 07:11, 07:17, 07:115, 08:28, 08:35, 08:37, 08:69, 14:05, 15:07:01-15:07:02, 15:55, 15:68, 18:14, 35:05:03, 35:51, 35:58, 35:66, 35:72, 39:24:01-39:24:02, 39:37, 39:76, 40:03, 41:18, 41:24, 42:09 and 46:12 and in the C\*02:60, C\*07:294 and C\*08:08 alleles. Specific PCR fragment of 130 bp in the B\*53:10 allele.

**101.549-06– including Taq polymerase, IFU-01**  
**101.549-06u – without Taq polymerase, IFU-02**

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**“Instructions for Use” (IFU)**

Lot No.: 22S

Lot-specific information

			Prod. No.:	Well														
1	2	3		4	5	6	7	8	9	10	11	12	13	14	15	16		
IHWG 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	-	-	-	-	-	-	+	+	+	+	-	-	-	+

**101.549-06– including Taq polymerase, IFU-01**  
**101.549-06u – without Taq polymerase, IFU-02**

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**“Instructions for Use” (IFU)**

Lot No.: 22S

Lot-specific information

<b>CELL LINE VALIDATION SHEET</b>							
<b>HLA-B*53 SSP subtyping kit</b>							
	Prod. No.:	<b>Well</b>					
		17	18	19	20	21	22
		201317317	201317318	201317319	201317320	201317321	201317322
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	-	-	-	-

**101.549-06 – including Taq polymerase, IFU-01  
101. 549-06u – without Taq polymerase, IFU-02**

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“Instructions for Use” (IFU)

**Lot No.: 22S**

**Lot-specific information**  
**CERTIFICATE OF ANALYSIS**

**Olerup SSP® HLA-B\*53 SSP**

<b>Product number:</b>	<b>101.549-06 – including Taq polymerase 101.549-06u – without Taq polymerase</b>
<b>Lot number:</b>	<b>22S</b>
<b>Expiry date:</b>	<b>2015-October-01</b>
<b>Number of tests:</b>	<b>6</b>
<b>Number of wells per test:</b>	<b>22</b>

**Well specifications:**

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2013-173-01	9	2013-173-09	17	2013-173-17
2	2013-173-02	10	2013-173-10	18	2013-173-18
3	2013-173-03	11	2013-173-11	19	2013-173-19
4	2013-173-04	12	2013-173-12	20	2013-173-20
5	2013-173-05	13	2013-173-13	21	2013-173-21
6	2013-173-06	14	2013-173-14	22	2013-173-22
7	2013-173-07	15	2013-173-15		
8	2013-173-08	16	2013-173-16		

The specificity of each primer solution of the HLA-B\*53 primer set has been tested against 48 well characterized IHWC cell line DNAs.

No DNAs carrying the alleles to be amplified by primer solutions 2, 5, 17 and 21 were available. The specificities of the primers in primer solutions 2, 5 and 21 were tested by separately adding one additional 3'-primer, respectively one additional 5'-primer. In primer solution 17 it was only possible to test the 3'-primer, the 5'-primer was not possible to test.

In primer solutions 4, 6 and 13 one of the 3'-primers was not possible to test, and in primer mix 13 one 5'-primer was not possible to test.

Additional primers in primer solutions 3, 4, 6, 14 and 19 were tested by separately adding one additional 3'-primer and/or one additional 5'-primer.

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

**Date of approval:** 2013-May-27

**Approved by:**

**Production Quality Control**

101.549-06– including *Taq* polymerase, IFU-01  
101.549-06u – without *Taq* polymerase, IFU-02

Visit [www.olerup-ssp.com](http://www.olerup-ssp.com) for  
“Instructions for Use” (IFU)

Lot No.: 22S

Lot-specific information

## Declaration of Conformity

**Product name:** Olerup SSP® HLA-B\*53

**Product number:** 101.549-06/06u

**Lot number:** 22S

**Intended use:** HLA-B\*53 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 13485:2012, 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

2013-May-27

Ann-Cathrin Jareman  
Head of QA and Regulatory Affairs

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**Lot-specific information**

**ADDRESSES:**

**Manufacturer:**

**Olerup SSP AB, Franzengatan 5, SE-112 51 Stockholm, Sweden.**

**Tel:** +46-8-717 88 27

**Fax:** +46-8-717 88 18

**E-mail:** [info-ssp@olerup.com](mailto:info-ssp@olerup.com)

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

**Distributed by:**

**Olerup GmbH, Löwengasse 47 / 6, AT-1030 Vienna, Austria.**

**Tel:** +43-1-710 15 00

**Fax:** +43-1-710 15 00 10

**E-mail:** [support-at@olerup.com](mailto:support-at@olerup.com)

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

**Olerup Inc., 901 S. Bolmar St., Suite R, West Chester, PA 19382**

**Tel:** 1-877-OLERUP1

**Fax:** 610-344-7989

**E-mail:** [info.us@olerup.com](mailto:info.us@olerup.com)

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

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