

101.565-12– including *Taq* pol., IFU-01  
101.565-12u – without *Taq* pol., IFU-02

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

Lot No.: **20V**

Lot-specific information  
**Olerup SSP® HLA-B\*38**

Product number:	101.565-12– including <i>Taq</i> polymerase 101.565-12u – without <i>Taq</i> polymerase
Lot number:	20V
Expiry date:	2016-July-01
Number of tests:	12
Number of wells per test:	23+1
Storage - pre-aliquoted primers:	dark at -20°C
- PCR Master Mix:	-20°C
- Adhesive PCR seals	RT
- Product Insert	RT

**This Product Description is only valid for Lot No. 20V.**

Complete product documentation consists of generic Instructions for Use (IFU), lot specific Product Insert, Worksheet and Certificate.

**CHANGES COMPARED TO THE PREVIOUS OLERUP SSP®  
HLA-B\*38 Lot(27R)**

The HLA-B\*38 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

A well containing Negative Control primer pairs has been added.

The format of the Product Insert and Worksheet have been changed.

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

The HLA-B\*38 specificity and interpretation tables have been updated for the HLA-B alleles described since the previous *Olerup SSP®* HLA-B\*38 lot was made (**Lot No. 27R**).

As of lot series V, the Specificity Table is included in the lot-specific Product Insert, and the Interpretation Table is included in the Worksheet.

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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
11	-	Added	3'-primer added from well 19.
19	Added	Moved	3'-primer moved to well 11, primer pair added from well 24.
23	-	Added	3'-primer added for the B*38:31 allele.
24	Moved	Moved	Primer pair moved to well 19, Negative Control

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Well **24** contains Negative Control primer pairs, that will amplify more than 95% of the *Olerup SSP®* HLA Class I, DRB, DQB1 and DPB1 amplicons as well as amplicons generated by a control primer pair.

PCR product sizes range from 75 to 430 base pairs.  
The PCR product generated by the control primer pair is 430 base pairs.

Length of PCR product	105	200	105	80	75	80
<b>5'-primer<sup>1</sup></b>	<b>164</b>	<b>340</b>	<b>440</b>	<b>45</b>	<b>45</b>	<b>43</b>
	5'-CAC <sup>3'</sup>	5'-Agg <sup>3'</sup>	5'-TTA <sup>3'</sup>	5'-Tgg <sup>3'</sup>	5'-Tgg <sup>3'</sup>	5'-Tgg <sup>3'</sup>
<b>3'-primer<sup>2</sup></b>	<b>231</b>	<b>2<sup>nd</sup> I</b>	<b>507</b>	<b>59</b>	<b>58</b>	<b>57</b>
	5'-TgC <sup>3'</sup>	5'-AAA <sup>3'</sup>	5'-TTg <sup>3'</sup>	5'-CTC <sup>3'</sup>	5'-ggC <sup>3'</sup>	5'-CTC <sup>3'</sup>
<b>A*</b>	<b>+</b>	<b>+</b>	<b>+</b>			
<b>B*</b>	<b>+</b>	<b>+</b>	<b>+</b>			
<b>C*</b>	<b>+</b>	<b>+</b>	<b>+</b>			
<b>DRB1</b>				<b>+</b>	<b>+</b>	
<b>DRB3</b>				<b>+</b>	<b>+</b>	
<b>DRB5</b>				<b>+</b>		
<b>DQB1</b>					<b>+</b>	
<b>DPB1</b>						<b>+</b>

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

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

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## PRODUCT DESCRIPTION

### HLA-B\*38 SSP subtyping

#### CONTENT

The primer set contains 5'- and 3'-primers for identifying the B\*38:01 to B\*38:45 alleles.

#### PLATE LAYOUT

Each test consists of 24 PCR reactions in a 24 well cut PCR plate.

1	2	3	4	5	6	7	8
9	10	11	12	13	14	15	16
17	18	19	20	21	22	23	NC

The 24 well cut PCR plate is marked with 'HLA-B\*38' in silver/gray ink.

Well No. 1 is marked with the Lot No. '27R'.

Wells 1 to 23 – HLA-B\*38 high resolution primers.

Well 24 – Negative Control (NC).

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

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

**Please note:** When removing each 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

Due to the sharing of sequence motifs between HLA-B alleles, non-HLA-B\*38 alleles will be amplified by primer mixes 1 to 17 and 19 to 23. In addition, a few HLA-C alleles will be amplified by primer mixes 8, 19, 22 and 23.

For further details see Specificity Table.

#### UNIQUELY IDENTIFIED ALLELES

All the HLA-B\*38 alleles, i.e. **B\*38:01 to B\*38:45**, recognized by the HLA Nomenclature Committee in October 2013<sup>1,2</sup> are amplified by the primers in the HLA-B\*38 subtyping kit.

The HLA-B\*38 kit enables separation of the confirmed HLA-B\*38 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\*38 alleles is listed below.

The HLA-B\*38 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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The HLA-B\*38 subtyping kit cannot distinguish the silent mutations in the B\*38:01:01 and 38:01:03 to 38:01:07, the B\*38:02:01 and B\*38:02:02 and the 38:02:04-38:02:05 alleles.

The following HLA-B\*38 alleles can be distinguished by the different sizes of the HLA-specific PCR product:

Alleles	Primer mix
B*38:11, 38:19	16
B*38:17, 39:37 <sup>3</sup>	16

<sup>1</sup>HLA-B alleles listed on the IMGT/HLA web page 2013-October-11, release 3.14.0, [www.ebi.ac.uk/imgt/hla](http://www.ebi.ac.uk/imgt/hla).

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

<sup>3</sup>The B\*38:17 and B\*39:37 alleles give rise to identical amplification patterns with the HLA-B\*38 primer set. These two alleles can be distinguished by the different sizes of the HLA-specific PCR product in primer mix 16.

**ALLELES CONFIRMATION STATUS**

Allele	Status <sup>1</sup>	Allele	Status <sup>1</sup>	Allele	Status <sup>1</sup>
<b>B*38:01:01</b>	<b>Confirmed</b>	<b>B*38:11</b>	<b>Confirmed</b>	<b>B*38:31</b>	<b>Confirmed</b>
B*38:01:02	Unconfirmed	<b>B*38:12</b>	<b>Confirmed</b>	<b>B*38:32</b>	<b>Confirmed</b>
B*38:01:03	Unconfirmed	<b>B*38:13</b>	<b>Confirmed</b>	<b>B*38:33</b>	<b>Confirmed</b>
<b>B*38:01:04</b>	<b>Confirmed</b>	B*38:14	Unconfirmed	B*38:34N	Unconfirmed
B*38:01:05	Unconfirmed	<b>B*38:15</b>	<b>Confirmed</b>	B*38:35	Unconfirmed
<b>B*38:01:06</b>	<b>Confirmed</b>	B*38:16	Unconfirmed	<b>B*38:36</b>	<b>Confirmed</b>
B*38:01:07	Unconfirmed	B*38:17	Unconfirmed	<b>B*38:37</b>	<b>Confirmed</b>
<b>B*38:02:01</b>	<b>Confirmed</b>	B*38:18	Unconfirmed	B*38:38	Unconfirmed
<b>B*38:02:02</b>	<b>Confirmed</b>	B*38:19	Unconfirmed	B*38:39	Unconfirmed
B*38:02:03	Unconfirmed	<b>B*38:20</b>	<b>Confirmed</b>	B*38:40	Unconfirmed
B*38:02:04	Unconfirmed	B*38:21	Unconfirmed	B*38:41	Unconfirmed
B*38:02:05	Unconfirmed	B*38:22	Unconfirmed	B*38:42	Unconfirmed
B*38:03	Unconfirmed	B*38:23	Unconfirmed	B*38:43	Unconfirmed
B*38:04	Unconfirmed	<b>B*38:24</b>	<b>Confirmed</b>	B*38:44	Unconfirmed
B*38:05	Unconfirmed	B*38:25	Unconfirmed	B*38:45	Unconfirmed
<b>B*38:06</b>	<b>Confirmed</b>	B*38:26	Unconfirmed		
B*38:07	Unconfirmed	<b>B*38:27</b>	<b>Confirmed</b>		
B*38:08	Unconfirmed	B*38:28	Unconfirmed		
<b>B*38:09</b>	<b>Confirmed</b>	<b>B*38:29</b>	<b>Confirmed</b>		
B*38:10	Unconfirmed	B*38:30	Unconfirmed		

<sup>1</sup>Allele status “confirmed” or “unconfirmed” as listed on the IMGT/HLA web page 2013-October-11, release 3.14.0, [www.ebi.ac.uk/imgt/hla](http://www.ebi.ac.uk/imgt/hla).

**RESOLUTION IN HOMO- AND HETEROZYGOTES**

Results file with resolution in HLA-B\*38 homo- and heterozygotes is available upon request.

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Lot-specific information  
**SPECIFICITY TABLE**

**HLA-B\*38 SSP subtyping**

Specificities and sizes of the PCR products of the 23+1 primer mixes used for HLA-B\*38 SSP subtyping

Primer Mix	Size of spec. PCR product <sup>1</sup>	Size of control band <sup>2</sup>	Amplified HLA-B*38 alleles <sup>3</sup>	Other amplified HLA-B alleles <sup>4</sup>
<b>1</b>	185 bp	<b>800 bp</b>	*38:01:01-38:02:02, 38:02:04-38:03, 38:07-38:24, 38:26-38:32, 38:34N-38:45	*07:02:32, 14:01:01-14:01:04, 14:07N-14:08, 14:10, 14:12, 14:14, 14:19, 14:26, 14:32, 27:07:04 <sup>w</sup> , 39:01:01:01-39:01:01:03, 39:01:03-39:01:08, 39:01:10-39:02:01, 39:03, 39:05:01-39:06:02, 39:07-39:09, 39:11, 39:14-39:15, 39:18, 39:19:02, 39:22, 39:24:01-39:30, 39:31 <sup>w</sup> , 39:32-39:39:01, 39:40:01N-39:44, 39:46-39:48, 39:50-39:62, 39:64-39:71, 39:73-39:75, 39:77, 39:79-39:82, 67:01:01, 67:03
<b>2</b>	190 bp	<b>800 bp</b>	*38:01:01-38:02:05, 38:04-38:12, 38:15, 38:17-38:25, 38:27, 38:29-38:40, 38:42-38:45	*07:16, 07:27, 07:37-07:38, 07:50, 07:75, 07:91, 07:180, 08:03, 08:23, 08:54, 08:110, 14:14, 14:18, 15:03:01-15:03:04, 15:09-15:10:02, 15:18:01-15:18:05, 15:23, 15:29, 15:37, 15:47:01-15:47:02, 15:49, 15:51-15:52, 15:54, 15:62, 15:64:01-15:64:02, 15:68-15:69, 15:72, 15:74, 15:80, 15:90-15:91, 15:93, 15:98-15:99, 15:103, 15:108, 15:114-15:115, 15:119, 15:123-15:124, 15:127, 15:131-15:134, 15:151, 15:153, 15:156, 15:158, 15:161, 15:173, 15:176, 15:186, 15:197-15:198, 15:200, 15:210, 15:220-15:221, 15:226N, 15:229, 15:235, 15:238, 15:242-15:243, 15:251-15:253, 15:263, 15:266, 15:274-15:275, 15:281-15:282, 15:290, 18:01:01:01-18:01:01:02, 18:01:03-18:02, 18:05-18:15, 18:17N-18:28, 18:30-18:79, 18:81-18:93, 35:25, 35:124-35:125, 35:142, 35:162, 37:01:01-37:21, 37:23-37:36, 37:38-37:42N, 39:05:01-39:05:02, 39:07-39:08, 39:11, 39:13:01-39:13:02, 39:20, 39:37, 39:49, 39:55-39:56, 40:12, 40:149, 41:22, 42:11, 44:130, 44:156, 48:01:01-48:02:01, 48:02:03-48:32, 49:25, 51:116, 52:16, 52:27, 57:58, 58:12
<b>3</b>	170 bp	<b>800 bp</b>	*38:01:01-38:02:05, 38:04-38:05, 38:08-38:15, 38:17-38:25, 38:27, 38:29-38:45	*07:69, 07:85, 07:180, 08:65, 14:01:01-14:20, 14:22-14:35, 14:37, 15:09-15:10:02, 15:18:01-15:18:05, 15:23, 15:37, 15:51-15:52, 15:72, 15:80, 15:90, 15:93, 15:99, 15:108, 15:114-15:115, 15:119, 15:124, 15:133-15:134, 15:153, 15:161, 15:176, 15:186, 15:197-15:198, 15:200, 15:221, 15:226N, 15:229, 15:238, 15:243, 15:252, 15:263, 15:275, 15:290, 18:33, 39:01:01:01-39:01:01:03, 39:01:03-39:01:16, 39:03-39:07, 39:09, 39:11-39:12, 39:14-39:15, 39:18-39:19:02, 39:22, 39:24:01-39:38Q, 39:40:01N-39:48, 39:50-39:51, 39:53, 39:55-39:57, 39:59-39:62, 39:64-39:82

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<b>4<sup>5</sup></b>	105 bp	1070 bp	*38:01:01-38:01:07, 38:05, 38:09-38:14, 38:16, 38:19-38:22, 38:24, 38:26-38:28, 38:30-38:34N, 38:36-38:42	*49:26, 52:01:10
<b>5</b>	210 bp	1070 bp	*38:02:01-38:04, 38:08, 38:15, 38:18, 38:23, 38:29, 38:35, 38:43-38:45	*07:149, 08:02, 15:115, 18:09, 37:10, 44:130, 44:156
<b>6<sup>6</sup></b>	175 bp	<b>800 bp</b>	*38:03, 38:34N	*07:27, 07:50, 08:04, 08:17, 08:54, 08:110, 15:03:01-15:03:04, 15:47:01-15:47:02, 15:54, 15:61-15:62, 15:64:01-15:64:02, 15:68-15:69, 15:91, 15:98, 15:103, 15:123, 15:127, 15:131-15:132, 15:151, 15:156, 15:158, 15:173, 15:210, 15:220, 15:235, 15:242, 15:251, 15:253, 15:266, 15:274, 15:281-15:282, 18:01:01:01-18:03, 18:05-18:06, 18:08-18:15, 18:17N-18:28, 18:30-18:32, 18:34-18:78, 18:81-18:94N, 37:01:01-37:20, 37:23-37:25, 37:27-37:42N, 39:02:01-39:02:02, 39:08, 39:13:01-39:13:02, 39:23, 39:39:01-39:39:02, 39:49, 40:12, 40:149, 41:22, 42:11, 44:130, 44:156, 48:01:01-48:02:01, 48:02:03-48:05, 48:07-48:30, 48:32, 49:25, 52:16, 52:27
<b>7<sup>6</sup></b>	160 bp	<b>800 bp</b>	*38:03-38:04, 38:25	*08:17, 08:38, 08:54, 08:101, 15:03:01-15:03:04, 15:47:01-15:47:02, 15:49, 15:54, 15:61-15:62, 15:68-15:69, 15:74, 15:91, 15:98, 15:103, 15:123, 15:127, 15:131-15:132, 15:151, 15:156, 15:158, 15:173, 15:210, 15:220, 15:235, 15:242-15:243, 15:251, 15:253, 15:266, 15:274, 15:281-15:282, 18:12, 37:01:01-37:07, 37:09-37:21, 37:23-37:42N, 39:02:01-39:02:02, 39:08, 39:13:01-39:13:02, 39:22-39:23, 39:49, 40:12, 40:149, 41:22, 42:11, 44:130, 44:156, 48:01:01-48:02:01, 48:02:03-48:05, 48:07-48:15, 48:17-48:32, 49:25, 52:16, 52:27
	195 bp		*38:21, 38:34N	
<b>8</b>	185 bp	<b>800 bp</b>	*38:05, 38:33	*14:02:01-14:02:02, 14:02:04-14:02:05, 14:02:07-14:03, 14:04 <sup>w</sup> , 14:05-14:06:02, 14:09, 14:11, 14:13, 14:15-14:18, 14:20, 14:22-14:23, 14:25, 14:27, 14:29-14:31, 14:33-14:37, 15:189, 35:26, 39:04, <b>C*02:02:07, C*05:01:06</b>
	230 bp		*38:15, 38:20, 38:22	*15:265, 35:35, 37:40, 39:42, <b>C*15:51</b>
<b>9</b>	145 bp	1070 bp	*38:06-38:07	*18:67, 37:34, 44:06, 49:03, 51:01:01-51:01:39, 51:01:41-51:24:05, 51:26-51:46, 51:48-51:53, 51:55-51:77, 51:79-51:103, 51:105-51:111, 51:113-51:146, 51:148-51:154, 52:01:01:01-52:01:19, 52:03-52:15, 52:17-52:19, 52:21-52:31, 53:01:01-53:02, 53:04-53:08:02, 53:10, 53:14-

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	205 bp		*38:21	53:29, 58:01:01-58:02, 58:04-58:16:02, 58:18-58:29, 58:31N-58:35, 58:37-58:43, 58:45-58:48
<b>10<sup>5</sup></b>	85 bp	1070 bp	*38:07, 38:12	*39:19:02
	145 bp		*38:16	*49:26
	180 bp		*38:33	*14:11, 14:28, 15:189, 35:26, 39:04, 49:26
<b>11<sup>5</sup></b>	90 bp	1070 bp	*38:13	
	145 bp		*38:08, 38:18, 38:27	*18:86
<b>12<sup>5</sup></b>	90 bp	<b>800 bp</b>	*38:09, 38:14, 38:26, 38:41	*07:02:32, 14:01:01-14:02:02, 14:02:04-14:02:05, 14:02:07, 14:02:08 <sup>w</sup> , 14:02:09-14:13, 14:15-14:17, 14:19-14:20, 14:22-14:37, 15:189, 39:01:01:01-39:01:01:03, 39:01:03, 39:01:05-39:01:08, 39:01:10-39:02:01, 39:03-39:04, 39:06:01-39:06:02, 39:09, 39:12, 39:14-39:15, 39:18, 39:19:02, 39:22, 39:24:01, 39:24:02 <sup>w</sup> , 39:25N-39:26, 39:27 <sup>w</sup> , 39:28-39:36, 39:38Q-39:39:01, 39:40:01N-39:48, 39:50-39:54, 39:57-39:62, 39:64-39:82, 67:01:01, 67:03
<b>13</b>	175 bp	<b>800 bp</b>	*38:01:01, 38:01:03-38:07, 38:09, 38:11-38:21, 38:23-38:28, 38:31-38:35, 38:38-38:44	*08:55, 39:01:01:01-39:01:01:03, 39:01:03-39:06:03, 39:08-39:14, 39:16, 39:18-39:20, 39:22-39:24:02, 39:26-39:28, 39:31, 39:35, 39:37-39:42, 39:44-39:46, 39:48, 39:51-39:54, 39:56-39:73, 39:75-39:81, 39:83, 40:184, 51:101, 58:20, 67:01:01-67:03
<b>14</b>	170 bp	1070 bp	*38:10, 38:32	*07:02:01-07:24, 07:26-07:47, 07:49N-07:50, 07:52-07:154, 07:156-07:163, 07:165-07:201N, 07:203-07:204, 08:20, 08:53:01-08:53:02, 08:79, 13:16, 13:20, 13:31, 13:48, 13:62, 14:01:01-14:37, 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, 15:251-15:274, 15:276-15:282, 15:284-15:291, 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, 27:103, 27:105-27:107, 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, 35:232, 37:07, 37:13, 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, 42:19, 44:76, 44:79, 44:146, 44:150, 46:01:01-46:05, 46:07N-46:08, 46:10, 46:12,



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<b>15</b>	230 bp	1070 bp	*38:01:01-38:02:05, 38:04, 38:06-38:12, 38:15-38:25, 38:27-38:32, 38:34N-38:40, 38:42-38:45	*07:16, 07:27, 07:37-07:38, 07:50, 07:75, 07:91, 07:180, 13:14, 14:14, 15:68, 15:71, 15:175, 18:01:01:01-18:01:01:02, 18:01:03-18:01:12, 18:01:14-18:02, 18:05-18:15, 18:17N-18:24, 18:26-18:67, 18:69, 18:71-18:93, 27:01, 27:18, 27:23, 27:29, 27:44, 27:92, 35:50, 35:84, 35:162, 35:197, 35:231, 37:01:01-37:36, 37:38-37:42N, 39:05:01-39:05:02, 39:07-39:08, 39:11, 39:13:01-39:13:02, 39:20, 39:37, 39:49, 39:55-39:56, 40:02:01-40:06:07, 40:08-40:09, 40:11:01-40:11:02, 40:13, 40:18-40:20, 40:24, 40:26-40:29, 40:35, 40:37, 40:39-40:40, 40:44, 40:56, 40:64, 40:68, 40:70-40:71, 40:74-40:75, 40:78, 40:82-40:83, 40:85-40:86, 40:89-40:91, 40:93-40:99, 40:103-40:105, 40:107, 40:109, 40:111, 40:115, 40:119-40:120, 40:122, 40:127, 40:131, 40:133Q, 40:142N-40:145, 40:148-40:149, 40:157, 40:159, 40:161-40:162, 40:165, 40:167, 40:169, 40:173-40:174, 40:176-40:177, 40:180-40:181, 40:184, 40:189-40:190, 40:200-40:203, 40:205-40:206, 40:209-40:211, 40:214, 40:220, 40:224-40:226, 40:229, 40:232, 40:243-40:244, 40:246, 40:248, 42:11, 44:103, 44:130-44:131, 48:01:01-48:21, 48:23-48:32, 51:57, 51:103, 51:116, 53:21, 57:10
<b>16</b>	220 bp	1070 bp	*38:19	*08:55, 39:03, 39:14, 39:24:01-39:24:02, 39:29, 39:37, 39:76
	350 bp		*38:11	*07:13, 07:110, 08:101, 67:02
	425 bp		*38:17	*07:27, 40:188 <sup>?</sup>
<b>17</b>	150 bp	<b>800 bp</b>	*38:23	*39:73
<b>18</b>	160 bp	1070 bp	*38:24, 38:37	
<b>19</b>	175 bp	1070 bp	*38:10, 38:30, 38:36	*07:05:01-07:06, 07:32, 07:34, 07:40, 07:53, 07:69, 07:78, 07:80, 07:90, 07:97, 07:105, 07:112, 07:123,

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<b>20</b>	265 bp	1070 bp	*38:28	*07:56:01-07:56:02, 07:72, 08:26, 08:56:01-08:56:02, 39:63, 40:21 <sup>?</sup> , 40:58 <sup>?</sup> , 40:137 <sup>?</sup> , 40:248 <sup>?</sup> , 41:12, 49:03
<b>21<sup>5</sup></b>	115 bp	1070 bp	*38:30	*08:49, 08:71, 13:46, 15:51, 15:83, 15:179, 15:199, 15:218Q, 18:56, 27:47, 35:38, 35:115, 35:169, 37:01:01-37:01:09, 37:03N-37:06, 37:08, 37:10-

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<b>22</b>	175 bp	1070 bp	*38:29 *15:69, 15:186, 35:35, 39:07, 39:15, 39:29, 39:49, 39:55, <b>C*15:51</b>
<b>23</b>	155 bp	1070 bp	*38:10, 38:32 *07:05:01-07:06, 07:32, 07:34, 07:40, 07:53, 07:69, 07:78, 07:80, 07:90, 07:97, 07:105, 07:112, 07:123, 07:137-07:138, 07:140, 07:176, 07:182N, 07:201N, 08:20, 08:79, 13:16, 13:20, 13:31 <sup>w</sup> , 13:48, 13:62, 14:13, 15:09, 15:30 <sup>w</sup> , 15:42, 15:58 <sup>w</sup> , 15:73 <sup>w</sup> , 15:150 <sup>w</sup> , 15:229, 15:243, 15:252, 27:20, 27:24, 35:44 <sup>w</sup> , 39:35, 39:36 <sup>w</sup> , 40:05, 40:15-40:16, 40:23, 40:26, 40:28, 40:51, 40:95, 40:148, 40:158, 40:161, 40:174, 40:183, 40:198, 42:19, 48:05, 48:15, 51:01:01-51:01:18, 51:01:19 <sup>w</sup> , 51:01:20-51:01:30, 51:01:32-51:02:02, 51:02:04-51:04, 51:06:01-51:07:02, 51:11N-51:14, 51:16, 51:21-51:24:05, 51:26-51:30, 51:32-51:35, 51:38-51:39, 51:41N, 51:43, 51:46, 51:48-51:53, 51:55-51:60, 51:61:01 <sup>w</sup> -51:61:02 <sup>w</sup> , 51:62-51:71, 51:74-51:80, 51:82-51:84, 51:86, 51:88-51:89, 51:95-51:96, 51:98N-51:107, 51:109-51:114, 51:116-51:121, 51:123-51:134, 51:136-51:138, 51:140, 51:142-51:145, 51:147, 51:149N-51:152, 51:154, 52:01:01:01-52:01:10, 52:01:12-52:02:02, 52:04-52:09, 52:11, 52:13-52:18, 52:20, 52:21 <sup>w</sup> , 52:22-52:25, 52:27-52:32, 54:20, 55:01:01-55:01:11, 55:03, 55:05, 55:09, 55:11, 55:15, 55:17, 55:21 <sup>w</sup> , 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, 55:59-55:60, 56:05:01-56:06, 56:21, 56:25, 56:37, 57:57, 57:63, 58:08:01-58:08:02, 78:01:01-78:03, 78:05-78:07, <b>C*02:68<sup>w</sup>, C*15:24</b>
	210 bp		*38:31
<b>24<sup>7</sup></b>	-	-	<b>Negative Control</b>

<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\*38 SSP typings. When the primers in a primer mix can give rise to HLA-specific PCR products of more than one length this is indicated if the size difference is more than 20 base pairs. Size differences of 20 base pairs or less are not given. For high resolution SSP kits, the alleles listed are specified according to amplicon length.

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**Lot-specific information**

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.

<sup>2</sup>The internal positive control primer pairs amplify segments of the human growth hormone gene. The internal positive control bands are 1070 or 800 base pairs respectively, well distribution as outlined in the table. Well number 1 contains the shorter, 800 bp, internal positive control band. The well distribution of the internal controls can help in orientation of the kit on gel photo, as well as allow for kit identification. In the presence of a specific amplification the intensity of the control band often decreases.

<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. Assumption is made 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\*38 alleles will be amplified by primer mixes 1 to 17 and 19 to 23. In addition, a few HLA-C alleles will be amplified by primer mixes 8, 19, 22 and 23.

<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 6 and 7 may have tendencies of primer oligomer formation.

<sup>7</sup>Primer mix 24 contains a negative control, which will amplify more than 95% of HLA amplicons as well as the amplicons generated by control primer pairs. PCR product sizes range from 75 to 200 base pairs. The PCR product generated by the control primer pair is 430 base pairs.

‘w’, might be weakly amplified.

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

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**PRIMER SPECIFICATION**

Well No.	1	2	3	4	5	6	7	8	9	10	11	12
Length of spec. PCR product	185	190	170	105	210	175	160	185	145	85	90	90
							195	230	205	145	145	
										180		
Length of int. pos. control <sup>1</sup>	800	800	800	1070	1070	800	800	800	1070	1070	1070	800
5'-primer(s) <sup>2</sup>	103 5'-CCT 3'	142 5'-TCT 3'	142 5'-TCT 3'	246 5'-gAA 3'	142 5'-TCT 3'	142 5'-TCT 3'	142 5'-TCT 3'	103 5'-CCg 3'	206 5'-gAC 3'	106 5'-CCA 3'	246 5'-gAA 3'	246 5'-gAA 3'
							382 5'-TgC 3'	346 5'-ggC 3'	382 5'-TgC 3'	142 5'-TCA 3'	463 5'-TgA 3'	483 5'-gAg 3'
								355 5'-TCA 3'		193 5'-CCA 3'	660 5'-gAA 3'	
								363 5'-AAT 3'		206 5'-gAC 3'		
3'-primer(s) <sup>3</sup>	246 5'-TAT 3'	292 5'-gTA 3'	272 5'-TgC 3'	309 5'-ATC 3'	309 5'-gTg 3'	272 5'-Tgg 3'	259 5'-CTC 3'	246 5'-TAT 3'	309 5'-ATC 3'	246 5'-TAT 3'	296 5'-CTA 3'	292 5'-gTC 3'
	246 5'-TAT 3'	292 5'-gTA 3'				286 5'-CTA 3'	286 5'-CTA 3'	544 5'-ggT 3'	544 5'-ggT 3'		343 5'-T 3'	292 5'-gTC 3'
		292 5'-gTA 3'					544 5'-ggT 3'				559 5'-CAT 3'	544 5'-ggT 3'
											774 5'-ggT 3'	
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

Well No.	13	14	15	16	17	18	19	20	21	22	23
Length of spec. PCR product	175	170	230	220	150	160	175	265	115	175	155
				350							210
				425							
Length of int. pos. control <sup>1</sup>	800	1070	1070	1070	800	1070	1070	1070	1070	1070	1070
5'-primer(s) <sup>2</sup>	412 5'-ATA 3'	527 5'-TgA 3'	103 5'-CCT 3'	44 5'-ggC 3'	355 5'-CCT 3'	533 5'-ggg 3'	412 5'-ATA 3'	44 5'-ggC 3'	463 5'-TgA 3'	412 5'-ATg 3'	412 5'-ATA 3'
			103 5'-CCT 3'	363 5'-AgC 3'		547 5'-CCC 3'					
3'-primer(s) <sup>3</sup>	544 5'-ggT 3'	3 <sup>rd</sup> I 5'-TAT 3'	292 5'-gTA 3'	226 5'-CAC 3'	463 5'-gCT 3'	3 <sup>rd</sup> I 5'-TAT 3'	544 5'-ggC 3'	142 5'-TgC 3'	538 5'-gTC 3'	544 5'-ggT 3'	527 5'-CCT 3'
			292 5'-gTA 3'	301 5'-gTC 3'							581 5'-ATg 3'
			292 5'-gTA 3'	544 5'-ggT 3'							
Well No.	13	14	15	16	17	18	19	20	21	22	23

<sup>1</sup>The internal positive control primer pairs amplify segments of the human growth hormone gene. The internal positive control bands are 1070 or 800 base pairs respectively, well distribution as outlined in the table. Well number 1 contains the shorter, 800 bp, internal positive control band. The well distribution of the internal controls can help in orientation of the kit on gel photo, as well as allow for kit identification. In the presence of a specific amplification the intensity of the control band often decreases.

<sup>2</sup>The nucleotide position matching the specificity-determining 3'-end of the primer is given. Nucleotide numbering as on the [www.ebi.ac.uk/imgt/hla](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 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.

101.565-12– including *Taq* pol., IFU-01  
101.565-12u – without *Taq* pol., IFU-02

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Lot No.: **20V**

Lot-specific information

<b>CELL LINE VALIDATION SHEET</b>																						
<b>HLA-B*38 SSP subtyping kit<sup>2</sup></b>																						
					Well																	
					1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16		
					Prod. No.:	201186401	201075902	201075903	201075904	201186405	201206806	201206807	201075908	201075909	201206810	201328711	201075912	201075913	201075914	201075915	201075916	
		IHC cell line <sup>1</sup>	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	PTOUT	*44:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
12	9052	DBB	*57:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
13	9004	JESTHOM	*27:05		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
14	9071	OLGA	*15:01	*15:20	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-	-
15	9075	DKB	*40:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
16	9037	SWEIG007	*40:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-	-
17	9282	CTM3953540	*08:01	*55:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-	-
18	9257	32367	*14:01	*56:01	+	-	+	-	-	-	-	-	-	-	-	+	-	+	+	-	-	-
19	9038	BM16	*18:01		-	+	-	-	-	+	-	-	-	-	-	-	-	-	-	+	-	-
20	9059	SLE005	*40:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
21	9064	AMALA	*15:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-	-	-
22	9056	KOSE	*35:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
23	9124	IHL	*40:02	*56:02	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-	-
24	9035	JBUSH	*38:01		+	+	+	+	-	-	-	-	-	-	-	-	+	-	+	+	-	-
25	9049	IBW9	*14:02		-	-	+	-	-	-	-	+	-	-	-	+	-	+	+	-	-	-
26	9285	WT49	*58:01		-	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-	-
27	9191	CH1007	*07:05	*51:01	-	-	-	-	-	-	-	-	+	-	-	-	-	-	+	-	-	-
28	9320	BEL5GB	*44:02	*44:03	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
29	9050	MOU	*44:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
30	9021	RSH	*42:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
31	9019	DUCAF	*18:01		-	+	-	-	-	+	-	-	-	-	-	-	-	-	-	+	-	-
32	9297	HAG	*41:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
33	9098	MT14B	*40:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
34	9104	DHIF	*38:01		+	+	+	+	-	-	-	-	-	-	-	-	+	-	+	-	-	-
35	9302	SSTO	*44:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
36	9024	KT17	*15:01	*35:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-	-
37	9065	HHKB	*07:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-	-
38	9099	LZL	*15:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-	-
39	9315	CML	*08:01	*27:05	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
40	9134	WHONP199	*13:02	*46:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-	-
41	9055	H0301	*14:02		-	-	+	-	-	-	-	+	-	-	-	+	-	+	-	-	-	-
42	9066	TAB089	*46:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-	-
43	9076	T7526	*46:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-	-
44	9057	TEM	*38:01		+	+	+	+	-	-	-	-	-	-	-	-	+	-	+	-	-	-
45	9239	SHJO	*42:01	*50:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-	-
46	9013	SCHU	*07:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-	-
47	9045	TUBO	*51:01		-	-	-	-	-	-	-	-	+	-	-	-	-	-	-	+	-	-
48	9303	TER-ND	*35:01	*44:03	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

101.565-12– including *Taq pol.*, IFU-01  
101.565-12u – without *Taq pol.*, IFU-02

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Lot No.: **20V**

Lot-specific information

CELL LINE VALIDATION SHEET											
HLA-B*38 SSP subtyping kit <sup>2</sup>											
				Well							
				17	18	19	20	21	22	23	
				Prod. No.:	201206817	201328718	201206824	201206820	201186421	201186422	201328723
	IHWC cell line <sup>1</sup>	B*									
1	9001 SA	*07:02		-	-	-	-	-	-	-	-
2	9280 LK707	*52:01	*73:01	-	-	+	-	-	-	-	+
3	9011 E4181324	*52:01		-	-	+	-	-	-	-	+
4	9275 GU373	*15:10	*53:01	-	-	-	-	-	-	-	-
5	9009 KAS011	*37:01		-	-	-	-	+	-	-	-
6	9353 SM	*39:01	*51:01	-	-	+	-	-	-	-	+
7	9020 QBL	*18:01		-	-	-	-	-	-	-	-
8	9025 DEU	*35:01		-	-	-	-	-	-	-	-
9	9026 YAR	*38:01		-	-	-	-	-	-	-	-
10	9107 LKT3	*54:01		-	-	+	-	-	-	-	-
11	9051 PITOUT	*44:03		-	-	-	-	-	-	-	-
12	9052 DBB	*57:01		-	-	-	-	-	-	-	-
13	9004 JESTHOM	*27:05		-	-	-	-	-	-	-	-
14	9071 OLGA	*15:01	*15:20	-	-	-	-	-	-	-	-
15	9075 DKB	*40:01		-	-	+	-	-	-	-	-
16	9037 SWEIG007	*40:02		-	-	+	-	-	-	-	-
17	9282 CTM3953540	*08:01	*55:01	-	-	+	-	-	-	-	+
18	9257 32367	*14:01	*56:01	-	-	-	-	-	-	-	-
19	9038 BM16	*18:01		-	-	-	-	-	-	-	-
20	9059 SLE005	*40:01		-	-	-	-	-	-	-	-
21	9064 AMALA	*15:01		-	-	-	-	-	-	-	-
22	9056 KOSE	*35:03		-	-	-	-	-	-	-	-
23	9124 IHL	*40:02	*56:02	-	-	-	-	-	-	-	-
24	9035 JBUSH	*38:01		-	-	-	-	-	-	-	-
25	9049 IBW9	*14:02		-	-	-	-	-	-	-	-
26	9285 WT49	*58:01		-	-	-	-	-	-	-	-
27	9191 CH1007	*07:05	*51:01	-	-	-	-	-	-	-	+
28	9320 BEL5GB	*44:02	*44:03	-	-	-	-	+	-	-	-
29	9050 MOU	*44:03		-	-	-	-	-	-	-	-
30	9021 RSH	*42:01		-	-	+	-	-	-	-	-
31	9019 DUCAF	*18:01		-	-	-	-	-	-	-	-
32	9297 HAG	*41:02		-	-	+	-	-	-	-	-
33	9098 MT14B	*40:01		-	-	+	-	-	-	-	-
34	9104 DHIF	*38:01		-	-	-	-	-	-	-	-
35	9302 SSTO	*44:02		-	-	-	-	+	-	-	-
36	9024 KT17	*15:01	*35:01	-	-	-	-	-	-	-	-
37	9065 HHKB	*07:02		-	-	-	-	-	-	-	-
38	9099 LZL	*15:01		-	-	-	-	-	-	-	-
39	9315 CML	*08:01	*27:05	-	-	+	-	-	-	-	-
40	9134 WHONP199	*13:02	*46:01	-	-	+	-	-	-	-	-
41	9055 H0301	*14:02		-	-	-	-	-	-	-	-
42	9066 TAB089	*46:01		-	-	-	-	-	-	-	-
43	9076 T7526	*46:01		-	-	-	-	-	-	-	-
44	9057 TEM	*38:01		-	-	-	-	-	-	-	-
45	9239 SHJO	*42:01	*50:01	-	-	+	-	-	-	-	-
46	9013 SCHU	*07:02		-	-	-	-	-	-	-	-
47	9045 TUBO	*51:01		-	-	+	-	-	-	-	+
48	9303 TER-ND	*35:01	*44:03	-	-	-	-	-	-	-	-

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

101.565-12– including *Taq pol.*, IFU-01  
101.565-12u – without *Taq pol.*, IFU-02

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**Lot No.: 20V**

**Lot-specific information**

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

No DNAs carrying the alleles to be amplified by primer solutions 10, 11 and 16 to 18 and 20 were available. The specificities of the primers in primer solutions 10, 11, 16, 17 and 20 were tested by separately adding one or more additional 5'-primers, respectively one or more additional 3'-primers. In primer solution 18 it was only possible to test the 3'-primer, the 5'-primers were not possible to test. In primer solutions 7, 8, 9 and 11, one of the 5'-primers was not possible to test, and in primer solutions 6, 7, 11 and 23 one or two of the 3'-primers were not possible to test. Additional primers in primer solutions 8 and 9 were tested by separately adding one or two 5'-primers or 3'-primers.



101.565-12– including *Taq* pol., IFU-01  
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Lot No.: **20V**

Lot-specific information

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