

101.430-12 – including *Taq* polymerase, IFU-01
101.430-12u – without *Taq* polymerase, IFU-02

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“Instructions for Use” (IFU)

Lot No.: **4F2**

Lot-specific Information
Olerup SSP® HLA-A*31

| | |
|---|---|
| Product number: | 101.430-12 – including <i>Taq</i> polymerase 101.430-12u – without <i>Taq</i> polymerase |
| Lot number: | 4F2 |
| Expiry date: | 2020-02-01 |
| Number of tests: | 12 |
| Number of wells per test: | 39+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. 4F2.

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-A*31 LOT (1D7)**

The HLA-A*31 kit is updated for new alleles to enable separation of:

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

Eight wells have been added to HLA-A*31, wells **33 to 40**.

The format of the Worksheet has been changed.

¹As described in section Uniquely Identified Alleles.

The HLA-A*31 primer set, specificity and interpretation tables have been updated for the HLA-A alleles described since the previous *Olerup SSP®* HLA-A*31 lot was made (**Lot No. 1D7**). The kit design is based on IMGT/HLA database 3.28.0.

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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 |
|-------------|------------------|------------------|--|
| 32 | Added | Added | Negative Control moved to well 40, primer pair added for the A*31:95 allele. |
| 33 | New | New | New primer pair added for the A*31:96 allele. |
| 34 | New | New | New primer pair added for the A*31:98 allele. |
| 35 | New | New | New primer pair added for the A*31:102 allele. |
| 36 | New | New | New primer pair added for the A*31:105 allele. |
| 37 | New | New | New primer pair added for the A*31:111 allele. |
| 38 | New | New | New primer pair added for the A*31:119 allele. |
| 39 | New | New | New primer pair added for the A*31:125 allele. |
| 40 | - | - | Negative Control Added from well 32. |

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Well **40** contains Negative Control primer pairs, that will amplify more than 95% of the *Olerup SSP*[®] HLA Class I, DRB, DQB1, DPB1 and DQA1 amplicons as well as all the amplicons generated by the control primer pairs matching the human growth hormone gene.

HLA-specific PCR product sizes range from 75 to 200 base pairs.
The PCR product generated by the positive control primer pair is 430 base pairs.

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

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

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

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Lot-specific Information
PRODUCT DESCRIPTION

HLA-A*31 SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for identifying the A*31:01 to A*31:125 alleles.

PLATE LAYOUT

Each test consists of 40 PCR reactions in a 48 well cut PCR plate. Wells 41 to 48 are empty.

| | | | | | | | |
|-------|-------|-------|-------|-------|-------|-------|-------|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 |
| 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 |
| 25 | 26 | 27 | 28 | 29 | 30 | 31 | 32 |
| 33 | 34 | 35 | 36 | 37 | 38 | 39 | NC |
| empty | empty | empty | empty | empty | empty | empty | empty |

The 32 well cut PCR plate is marked with ‘HLA-A*31’ in silver/gray ink.

Well No. 1 is marked with the Lot Number ‘4F2’.

Wells 1 to 39 – HLA-A*31 high resolution primers.

Well 40 – 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 48 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-A alleles non-HLA-A*31 alleles will be amplified by some primer mixes. For further details see Specificity Table.

UNIQUELY IDENTIFIED ALLELES

All the HLA-A*31 alleles, i.e. **A*31:01 to A*31:125 alleles**, recognized by the HLA Nomenclature Committee in April 2017^{1,2} will be amplified by the primers in the HLA-A*31 subtyping kit³.

The HLA-A*31 kit enables separation of the confirmed HLA- A*31 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- A*31 alleles is listed below.

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Lot-specific Information

The HLA-A*31 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 following HLA-A*31 alleles can be distinguished by the different sizes of the HLA-specific PCR product:

| Alleles | Primer mix | Alleles | Primer mix |
|-----------------------|------------|------------------|------------|
| A*31:01:02:03N, 31:35 | 21 | A*31:36, 31:48 | 29 |
| A*31:16, 31:46 | 16 | A*31:44, A*33:15 | 29 |
| A*31:29, 31:59 | 25 | | |

¹HLA-A alleles listed on the IMGT/HLA web page 2017-April-13, release 3.28.0, www.ebi.ac.uk/imgt/hla.

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

³The A*31 primer set cannot separate the A*31:89 from the A*33:125 allele. These alleles can be distinguished by the HLA-A low resolution and/or HLA-A*33 kits.

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Lot-specific Information

ALLELE CONFIRMATION STATUS

| Allele | Status ¹ | Allele | Status ¹ | Allele | Status ¹ | Allele | Status ¹ |
|----------------------|---------------------|----------------|---------------------|----------------|---------------------|-----------------|---------------------|
| A*31:01:02:01 | Confirmed | A*31:13 | Unconfirmed | A*31:53 | Unconfirmed | A*31:93 | Unconfirmed |
| A*31:01:02:02 | Unconfirmed | A*31:14N | Unconfirmed | A*31:54 | Confirmed | A*31:94 | Unconfirmed |
| A*31:01:02:03N | Unconfirmed | A*31:15 | Confirmed | A*31:55 | Unconfirmed | A*31:95 | Unconfirmed |
| A*31:01:02:04 | Confirmed | A*31:16 | Confirmed | A*31:56 | Confirmed | A*31:96 | Confirmed |
| A*31:01:02:05 | Unconfirmed | A*31:17 | Confirmed | A*31:57 | Unconfirmed | A*31:97 | Unconfirmed |
| A*31:01:02:06 | Unconfirmed | A*31:18 | Confirmed | A*31:58 | Unconfirmed | A*31:98 | Confirmed |
| A*31:01:03 | Unconfirmed | A*31:19 | Confirmed | A*31:59 | Unconfirmed | A*31:99 | Unconfirmed |
| A*31:01:04 | Confirmed | A*31:20 | Confirmed | A*31:60N | Unconfirmed | A*31:100 | Unconfirmed |
| A*31:01:05 | Unconfirmed | A*31:21 | Unconfirmed | A*31:61 | Unconfirmed | A*31:101 | Unconfirmed |
| A*31:01:06 | Unconfirmed | A*31:22 | Confirmed | A*31:62 | Unconfirmed | A*31:102 | Confirmed |
| A*31:01:07 | Unconfirmed | A*31:23 | Unconfirmed | A*31:63 | Unconfirmed | A*31:103 | Unconfirmed |
| A*31:01:08 | Unconfirmed | A*31:24 | Confirmed | A*31:64 | Unconfirmed | A*31:104 | Unconfirmed |
| A*31:01:09 | Unconfirmed | A*31:25 | Unconfirmed | A*31:65 | Unconfirmed | A*31:105 | Confirmed |
| A*31:01:10 | Unconfirmed | A*31:26 | Confirmed | A*31:66 | Unconfirmed | A*31:106 | Unconfirmed |
| A*31:01:11 | Unconfirmed | A*31:27 | Confirmed | A*31:67 | Unconfirmed | A*31:107 | Unconfirmed |
| A*31:01:12 | Unconfirmed | A*31:28 | Confirmed | A*31:68 | Confirmed | A*31:108 | Unconfirmed |
| A*31:01:13 | Unconfirmed | A*31:29 | Unconfirmed | A*31:69 | Unconfirmed | A*31:109 | Unconfirmed |
| A*31:01:14 | Unconfirmed | A*31:30 | Unconfirmed | A*31:70 | Unconfirmed | A*31:110 | Unconfirmed |
| A*31:01:15 | Unconfirmed | A*31:31 | Confirmed | A*31:71 | Unconfirmed | A*31:111 | Confirmed |
| A*31:01:16 | Unconfirmed | A*31:32 | Unconfirmed | A*31:72 | Unconfirmed | A*31:112 | Unconfirmed |
| A*31:01:17 | Unconfirmed | A*31:33 | Unconfirmed | A*31:73 | Unconfirmed | A*31:113 | Unconfirmed |
| A*31:01:18 | Unconfirmed | A*31:34 | Unconfirmed | A*31:74 | Unconfirmed | A*31:114 | Unconfirmed |
| A*31:01:19 | Unconfirmed | A*31:35 | Unconfirmed | A*31:75 | Unconfirmed | A*31:115 | Unconfirmed |
| A*31:01:20 | Unconfirmed | A*31:36 | Confirmed | A*31:76 | Unconfirmed | A*31:116 | Unconfirmed |
| A*31:01:21 | Unconfirmed | A*31:37 | Unconfirmed | A*31:77 | Unconfirmed | A*31:117 | Unconfirmed |
| A*31:01:22 | Unconfirmed | A*31:38 | Confirmed | A*31:78 | Unconfirmed | A*31:118 | Unconfirmed |
| A*31:01:23 | Unconfirmed | A*31:39 | Confirmed | A*31:79 | Unconfirmed | A*31:119 | Unconfirmed |
| A*31:01:24 | Confirmed | A*31:40 | Confirmed | A*31:80 | Unconfirmed | A*31:120 | Unconfirmed |
| A*31:01:25 | Unconfirmed | A*31:41 | Confirmed | A*31:81 | Unconfirmed | A*31:121 | Unconfirmed |
| A*31:02 | Confirmed | A*31:42 | Unconfirmed | A*31:82 | Unconfirmed | A*31:122 | Unconfirmed |
| A*31:03 | Unconfirmed | A*31:43 | Confirmed | A*31:83 | Unconfirmed | A*31:123 | Unconfirmed |
| A*31:04 | Confirmed | A*31:44 | Confirmed | A*31:84 | Unconfirmed | A*31:124 | Unconfirmed |
| A*31:05 | Confirmed | A*31:45 | Unconfirmed | A*31:85 | Unconfirmed | A*31:125 | Unconfirmed |
| A*31:06 | Confirmed | A*31:46 | Unconfirmed | A*31:86 | Unconfirmed | | |
| A*31:07 | Unconfirmed | A*31:47 | Unconfirmed | A*31:87 | Unconfirmed | | |
| A*31:08 | Confirmed | A*31:48 | Confirmed | A*31:88 | Unconfirmed | | |
| A*31:09 | Confirmed | A*31:49 | Unconfirmed | A*31:89 | Unconfirmed | | |
| A*31:10 | Unconfirmed | A*31:50 | Unconfirmed | A*31:90 | Unconfirmed | | |
| A*31:11 | Confirmed | A*31:51 | Unconfirmed | A*31:91 | Unconfirmed | | |
| A*31:12 | Confirmed | A*31:52 | Unconfirmed | A*31:92 | Unconfirmed | | |

¹Allele status “confirmed” or “unconfirmed” as listed on the IMGT/HLA web page 2017-April-13, release 3.28.0, www.ebi.ac.uk/imgt/hla.

RESOLUTION IN HOMO- AND HETEROZYGOTES

Results file with resolution in HLA-A*31 homo- and heterozygotes is available upon request.

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Lot-specific Information
SPECIFICITY TABLE

HLA-A*31 SSP subtyping

Specificities and sizes of the PCR products of the 39+1 primer mixes used for
HLA-A*31 SSP subtyping

| Primer Mix | Size of spec. PCR product ¹ | Size of control band ² | Amplified HLA-A*31 alleles ³ | Other amplified HLA-A alleles |
|----------------------|--|-----------------------------------|---|---|
| 1 | 155 bp | 800 bp | *31:01:02:01-31:07, 31:09-31:43, 31:45-31:86, 31:88, 31:90-31:125 | *01:07, 01:226, 02:185, 02:601, 11:257, 23:21, 24:124, 26:19, 29:14, 30:12, 30:18, 30:55, 34:04, B*15:82, B*15:260, B*15:390, B*40:186:01, C*03:186:01, C*03:349 |
| 2⁴ | 80 bp 215 bp | 800 bp | *31:67-31:68 *31:02, 31:07-31:08, 31:91, 31:109 | *02:41, 02:80, 02:117, 02:289:01, 02:304, 02:454, 23:45, 24:62, 26:10, 32:28, 32:66, 33:32:01 *02:243:01-02:243:02, 24:82, 29:48, 33:08, 33:53 |
| 3 | 155 bp | 800 bp | *31:03-31:04, 31:123 | *02:309, 02:454, 03:01:19, 25:19:01-25:19:02, 25:30, 26:43:01, 34:02:01, 34:02:03-34:04, 34:06-34:09, 34:13, 34:15, 66:06, 74:01:03 |
| 4⁶ | 165 bp | 1070 bp | *31:03-31:04, 31:06 | *01:06, 01:200, 02:114, 02:246, 02:279, 02:681, 03:01:30, 03:05:01-03:05:02, 03:42, 03:98, 03:105, 03:122, 11:24:01-11:25:02, 11:31, 11:35, 11:158, 23:53, 23:70, 29:01:01:01-29:01:02, 29:01:04-29:02:13, 29:02:15-29:04, 29:06-29:23, 29:25-29:27, 29:29-29:31, 29:34-29:76, 29:78N, 29:80-29:81, 29:83-29:86, 29:88-29:99, 30:26, 32:30:01-32:30:02, 32:32, 33:18:01-33:18:02, 34:02:01-34:04, 34:07-34:10N, 34:13, 34:15, 68:08:01-68:08:02, 68:63, 68:157, 80:01:01:01-80:03 |
| 5⁴ | 120 bp 285 bp | 800 bp | *31:26, 31:38 *31:03 | *02:660, 03:184, 32:36 *01:143, 11:43, 29:66, 33:13, C*07:449 |
| 6 | 130 bp 165 bp | 800 bp | *31:39, 31:54 *31:05 | *33:07 *23:03:01, 24:21:03, 24:208, 29:03, 29:33, 32:13, 33:10 |
| 7⁶ | 505 bp | 1070 bp | *31:07-31:08, 31:10 | *02:81, 02:87, 02:112, 02:124, 02:129, 02:571, 03:152, 03:219, 23:01:01:01-23:01:15, 23:01:17-23:01:20, 23:03:01-23:13, 23:14:02-23:26, 23:28-23:33, |

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| | | | | |
|-------------------------|----------------------------|---------------|--|--|
| | | | | 23:35-23:37:02, 23:39-23:65, 23:67-23:68, 23:70-23:83, 24:13:01, 24:18, 24:24, 24:94, 24:188, 24:207:01, 24:228, 24:355, 25:19:01-25:19:02, 25:30, 29:13, 32:01:01:01- 32:01:05, 32:01:07-32:01:27, 32:03-32:09, 32:11Q-32:21, 32:23-32:70, 32:72-32:100 |
| 8 | 155 bp 220 bp | 1070 bp | *31:24, 31:27 *31:09 | *11:01:28, 29:67, 32:26:02, 33:61, 33:127 |
| 9⁴ | 75 bp | 1070 bp | *31:01:02:01-31:02, 31:05, 31:07-31:61, 31:63-31:66, 31:70- 31:119, 31:121-31:125 | *02:24:02, 02:65, 02:152, 02:507, 23:03:01, 23:83, 24:21:03, 29:32, 32:01:01:01- 32:01:06, 32:01:08-32:01:11, 32:01:13-32:03, 32:05-32:27N, 32:29, 32:31, 32:33:01, 32:34- 32:47, 32:49-32:65, 32:67- 32:93, 32:95-32:100, 33:01:01:01-33:01:04, 33:01:06- 33:01:10, 33:03:01-33:03:18, 33:03:20-33:03:23, 33:03:25- 33:03:26, 33:03:28-33:17, 33:20-33:31, 33:33-33:37, 33:39-33:128, 74:01:01-74:28, B*15:17:03 |
| 10^{4,5} | 115 bp | 1070 bp | *31:41 | *02:24:02, 02:507, 24:21:03, 24:208, 29:33, 29:51, 29:80, 32:02, 32:06, 33:94 |
| 11 | 160 bp 135 bp 210 bp | 1070 bp | *31:11, 31:56 *31:26 *31:12, 31:60N | *02:660, 03:184, 32:36 *02:490N, 02:516N, 02:526, 03:269N, 32:89 |
| 12 | 245 bp | 1070 bp | *31:01:02:01-31:06, 31:09, 31:11-31:20, 31:22-31:32, 31:34- 31:78, 31:80-31:125 | *02:243:01-02:243:02, 03:205, 11:43, 29:19, 29:39, 29:48, 33:01:01:01-33:01:10, 33:03:01- 33:12, 33:14-33:16, 33:18:01- 33:37, 33:39-33:47, 33:49- 33:50, 33:52-33:68, 33:70- 33:91, 33:93-33:108, 33:110- 33:118, 33:120-33:128, 68:29 |
| 13⁴ | 85 bp | 1070 bp | *31:13 | *02:251 |
| 14⁷ | 150 bp | 800 bp | *31:24 | *11:01:28, 29:67, 32:26:02, 33:61 |
| 15 | 220 bp 150 bp 225 bp | 1070 bp | *31:14N *31:25 *31:15 | *32:26:01 |
| 16⁴ | 80 bp 165 bp | 1070 bp | *31:46 *31:16 | *29:12, 29:92, 33:58 |
| 17 | 160 bp 235 bp | 1070 bp | *31:25, 31:40 *31:17 | *32:26:01 |
| 18 | 155 bp 200 bp | 1070 bp | *31:43, 31:62 *31:18 | *02:408, 02:590 *23:43 |

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| | | | | |
|-----------------------|--------------------------------------|---------------|--|--|
| 19⁴ | 110 bp 185 bp | 1070 bp | *31:19 *31:72 | *02:380, 03:52, 30:109 |
| 20 | 325 bp | 1070 bp | *31:20 | |
| 21⁴ | 75 bp 155 bp 180 bp 215 bp | 1070 bp | *31:35 *31:43, 31:62 *31:21 *31:01:02:03N | *01:07 *02:408, 02:590 *01:07, 02:185, 02:601, 30:55 |
| 22⁴ | 80 bp 155 bp 190 bp | 1070 bp | *31:71 *31:27, 31:55 *31:22 | *02:327 *33:127 |
| 23⁴ | 80 bp 165 bp 200 bp | 1070 bp | *31:71 *31:40 *31:23 | *02:327 |
| 24 | 150 bp 180 bp 220 bp | 1070 bp | *31:55 *31:81 *31:28, 31:89, 31:115 | *02:104 *03:205, 11:43, 33:125, 68:29 |
| 25⁵ | 135 bp 165 bp 245 bp | 800 bp | *31:29 *31:56 *31:59 | *02:507, 23:03:01, 23:83, 24:21:03, 24:208, 29:07, 32:89 |
| 26 | 130 bp | 1070 bp | *31:30, 31:39, 31:97 | *02:507, 29:28, 29:79, 32:10, 33:94, B*07:02:40, C*02:02:15, C*04:175 |
| 27⁴ | 185 bp 85 bp | 800 bp | *31:72 *31:31, 31:67-31:68 | *02:41, 02:80, 02:117, 02:289:01, 02:304, 02:454, 23:45, 24:62, 26:10, 32:28, 32:66, 33:32:01 *02:72, 02:275, 68:156 |
| 28⁴ | 500 bp 110 bp 175 bp 205 bp | 1070 bp | *31:38 *31:32 *31:60N | *02:490N, 02:516N, 03:269N |
| 29⁴ | 115 bp 180 bp 275 bp | 1070 bp | *31:48 *31:44, 31:81 *31:36 | *02:140, 26:99, 33:15 *02:104 |
| 30⁵ | 160 bp 185 bp 245 bp | 800 bp | *31:34 *31:87 *31:33 | |
| 31⁴ | 75 bp 120 bp | 1070 bp | *31:37 *31:41, 31:54 | *02:24:02, 02:507, 24:21:03, 24:208, 29:33, 29:51, 29:80, 32:02, 32:06, 33:07, 33:94 |
| 32 | 165 bp | 1070 bp | *31:95 | |
| 33 | 180 bp | 1070 bp | *31:96 | |
| 34 | 130 bp | 1070 bp | *31:98 | |
| 35 | 160 bp | 1070 bp | *31:102 | *24:282, 26:46 |
| 36 | 250 bp | 1070 bp | *31:105 | B*55:66 |
| 37 | 230 bp | 1070 bp | *31:111 | |
| 38 | 305 bp | 1070 bp | *31:119 | |
| 39⁴ | 110 bp | 1070 bp | *31:125 | *02:324, 02:426, 11:173 |
| 40⁸ | - | - | Negative Control | |

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Lot-specific Information

¹Alleles are assigned by the presence of specific PCR product(s). However, the sizes of the specific PCR products may be helpful in the interpretation of HLA-A*31 SSP typings.

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

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

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

PCR fragments migrating faster than the control bands, but slower than a 400 bp fragment may be seen in some gel read-outs. Such bands can be disregarded and do not influence the interpretation of the SSP typings.

Some primers may give rise to primer oligomer artifacts. Sometimes this phenomenon is an inherent feature of the primer pair(s) of a primer mix. More often it is due to other factors such as too low amount of DNA in the PCR reactions, taking too long time in setting up the PCR reactions, working at elevated room temperature or using thermal cyclers that are not pre-heated.

²The internal positive control primer pairs amplify segments of the human growth hormone gene. The internal positive control bands are 1070 or 800 base pairs respectively, well distribution as 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.

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

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

⁵Primer mixes 10, 25 and 30 may have tendencies of unspecific amplifications.

⁶Primer mixes 4 and 7 may weakly amplify the A*34:01 allele.

⁷Primer mix 14 may give rise to a lower yield of HLA-specific PCR product than the other HLA-A*31 primer mixes.

⁸Primer mix 40 contains a negative control, which will amplify more than 95% of HLA amplicons as well as the amplicons generated by the control primer pairs matching the human growth hormone gene. HLA-specific PCR product sizes range from 75 to 200 base pairs and the PCR product generated by the HGH positive control primer pair is 430 base pairs.

101.430-12 – including *Taq* polymerase, IFU-01
101.430-12u – without *Taq* polymerase, IFU-02

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“Instructions for Use” (IFU)

Lot No.: **4F2**

Lot-specific Information
PRIMER SPECIFICATION

| Well No. | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
|--|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|
| Length of spec. | 155 | 80 | 155 | 165 | 120 | 130 | 505 | 155 | 75 | 115 | 135 | 245 |
| PCR product | | 215 | | | 285 | 165 | | 220 | | 160 | 210 | |
| Length of int. pos. control ¹ | 800 | 800 | 800 | 1070 | 800 | 800 | 1070 | 1070 | 1070 | 1070 | 1070 | 1070 |
| 5'-primer(s) ² | 127 5'-ggg 3' | 97 5'-TCA 3' | 423 5'-gCT 3' | 413 5'-CCg 3' | 97 5'-TCA 3' | 448 5'-CCT 3' | 317 5'-gCT 3' | 97 5'-TCA 3' | 413 5'-CCA 3' | 448 5'-CCT 3' | 362 5'-gAA 3' | 97 5'-TCA 3' |
| | | 414 5'-CAg 3' | | | 445 5'-TCC 3' | | | 448 5'-CCT 3' | | 706 5'-CgA 3' | 375 5'-TgA 3' | |
| | | | | | 467 5'-CTA 3' | | | | | | 445 5'-TCC 3' | |
| 3'-primer(s) ³ | 238 5'-CCT 3' | 270 5'-ACT 3' | 538 5'-CAA 3' | 539 5'-TCA 3' | 341 5'-CgT 3' | 530 5'-CCT 3' | 538 5'-CAA 3' | 214 5'-CCA 3' | 448 5'-CAA 3' | 524 5'-CAT 3' | 538 5'-CAA 3' | 299 5'-CCA 3' |
| | 238 5'-CCT 3' | 453 5'-TCT 3' | | | 538 5'-CAA 3' | 536 5'-ACg 3' | | 278 5'-ggC 3' | | 565 5'-CAg 3' | | |
| | 245 5'-ACg 3' | | | | | 570 5'-CCg 3' | | 559 5'-CCg 3' | | 831 5'-TCC 3' | | |
| Well No. | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |

| Well No. | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 |
|--|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|--------------------------------|------------------|------------------|------------------|
| Length of spec. | 85 | 150 | 150 | 80 | 160 | 155 | 110 | 325 | 75 | 80 | 80 | 150 |
| PCR product | | 220 | 225 | 165 | 235 | 200 | 185 | | 155 | 155 | 165 | 180 |
| | | | | | | | | | 180 | 190 | 200 | 220 |
| | | | | | | | | | 215 | | | |
| Length of int. pos. control ¹ | 1070 | 800 | 1070 | 1070 | 1070 | 1070 | 1070 | 1070 | 1070 | 1070 | 1070 | 1070 |
| 5'-primer(s) ² | 413 5'-CCA 3' | 448 5'-CCT 3' | 98 5'-CAC 3' | 98 5'-CAC 3' | 98 5'-CAC 3' | 413 5'-CCA 3' | 488 5'-ggT 3' | 302 5'-ggA 3' | 2 nd I 5'-CTC 3' | 97 5'-TCA 3' | 98 5'-CAC 3' | 97 5'-TCA 3' |
| | | 629 5'-CAA 3' | 448 5'-CCT 3' | 769 5'-Agg 3' | 448 5'-CCT 3' | | 635 5'-gCg 3' | 302 5'-ggA 3' | 98 5'-CTT 3' | 652 5'-CTg 3' | 652 5'-CTg 3' | 652 5'-CTg 3' |
| | | | | | | | | | 203 5'-gAA 3' | | | |
| | | | | | | | | | 413 5'-CCA 3' | | | |
| 3'-primer(s) ³ | 456 5'-TCg 3' | 559 5'-CCg 3' | 281 5'-AgC 3' | 221 5'-ACA 3' | 221 5'-ACC 3' | 527 5'-CCg 3' | 559 5'-CgT 3' | 346 5'-AgC 3' | 238 5'-CCT 3' | 214 5'-CCA 3' | 221 5'-ACC 3' | 277 5'-ggT 3' |
| | | 808 5'-AgA 3' | 559 5'-CCT 3' | 808 5'-AgA 3' | 292 5'-gTT 3' | 571 5'-CCT 3' | 777 5'-gCA 3' | | 527 5'-CCg 3' | 245 5'-ACg 3' | 691 5'-gCC 3' | 282 5'-gAC 3' |
| | | | | | 559 5'-CCT 3' | | | | | 691 5'-gCC 3' | 811 5'-CAT 3' | 763 5'-CAA 3' |
| | | | | | | | | | | 763 5'-CAA 3' | | 791 5'-AgT 3' |
| Well No. | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 |

101.430-12 – including *Taq* polymerase, IFU-01
101.430-12u – without *Taq* polymerase, IFU-02

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Lot No.: **4F2**

Lot-specific Information

| Well No. | 25 | 26 | 27 | 28 | 29 | 30 | 31 | 32 | 33 | 34 | 35 | 36 |
|---|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|
| Length of spec. PCR product | 135 165 | 130 185 | 85 500 | 110 175 | 115 180 | 160 185 | 75 120 | 165 | 180 | 130 | 160 | 250 |
| | 245 | | | 205 | 275 | 245 | | | | | | |
| Length of int. pos. control ¹ | 800 | 1070 | 800 | 1070 | 1070 | 800 | 1070 | 1070 | 1070 | 1070 | 1070 | 1070 |
| 5'-primer(s) ² | 355 5'-CCC 3' | 448 5'-CCT 3' | 235 5'-AgA 3' | 375 5'-TgA 3' | 97 5'-TCA 3' | 97 5'-TCA 3' | 448 5'-CCT 3' | 878 5'-gCA 3' | 386 5'-gTT 3' | 148 5'-TgT 3' | 495 5'-CAC 3' | 28 5'-TCC 3' |
| | 626 5'-CCT 3' | 635 5'-gCg 3' | 414 5'-CAg 3' | 406 5'-gCT 3' | 652 5'-CTg 3' | 448 5'-CCT 3' | | | | | | |
| | 706 5'-CgA 3' | | | 467 5'-CTA 3' | | | | | | | | |
| 3'-primer(s) ³ | 448 5'-CAA 3' | 536 5'-ACg 3' | 290 5'-CAA 3' | 538 5'-CAA 3' | 238 5'-CCC 3' | 239 5'-gCT 3' | 482 5'-TgC 3' | 899 5'-ACg 3' | 524 5'-CAC 3' | 238 5'-CCT 3' | 616 5'-CgT 3' | 107 5'-ACT 3' |
| | 831 5'-TCC 3' | 539 5'-TCC 3' | 453 5'-TCT 3' | | 331 5'-CTC 3' | 299 5'-CCC 3' | 524 5'-CAT 3' | | | | | |
| | | 777 5'-gCA 3' | | | 727 5'-CCA 3' | 568 5'-CTg 3' | 530 5'-CCT 3' | | | | | |
| | | | | | 791 5'-AgT 3' | | | | | | | |
| Well No. | 25 | 26 | 27 | 28 | 29 | 30 | 31 | 32 | 33 | 34 | 35 | 36 |

| Well No. | 37 | 38 | 39 |
|---|------------------|--------------------------------|------------------|
| Length of spec. PCR product | 230 | 305 | 110 |
| Length of int. pos. control ¹ | 1070 | 1070 | 1070 |
| 5'-primer(s) ² | 620 5'-g 3' | 5 th I 5'-TAT 3' | 763 5'-TCA 3' |
| 3'-primer(s) ³ | 808 5'-AgA 3' | 1040 5'-CCC 3' | 831 5'-TCC 3' |
| Well No. | 37 | 38 | 39 |

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

²The nucleotide position matching the specificity-determining 3'-end of the primer is given. Nucleotide numbering as on the www.ebi.ac.uk/imgt/hla web site. The sequence of the 3 terminal nucleotides of the primer is given.

³The nucleotide position matching the specificity-determining 3'-end of the primer is given in the anti-sense direction. Nucleotide numbering as on the www.ebi.ac.uk/imgt/hla web site. The sequence of the 3 terminal nucleotides of the primer is given.

101.430-12 – including *Taq* polymerase, IFU-01
101.430-12u – without *Taq* polymerase, IFU-02

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Lot No.: **4F2**

Lot-specific Information

| CELL LINE VALIDATION SHEET | | | | | | | | | | | | | | | | | | | | |
|---|------|------------------------|--------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|
| HLA-A*31 SSP subtyping kit ² | | | | | | | | | | | | | | | | | | | | |
| | | | | Well | | | | | | | | | | | | | | | | |
| | | | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | |
| | | | | Prod No.: | 201439101 | 201439102 | 201439103 | 201439104 | 201439105 | 201439106 | 201439107 | 201439108 | 201439109 | 201439110 | 201439111 | 201439112 | 201439113 | 201439114 | 201439115 | 201439116 |
| | HW | Cell line ¹ | A* | A* | | | | | | | | | | | | | | | | |
| 1 | 9001 | SA | *24:02 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 2 | 9280 | LK707 | *02:01 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 3 | 9011 | E4181324 | *01:01 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 4 | 9275 | GU373 | *30:01 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 5 | 9009 | KAS011 | *01:01 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 6 | 9353 | SM | *02:01 | *26:03 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 7 | 9020 | QBL | *26:01 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 8 | 9025 | DEU | *31:01 | | + | - | - | - | - | - | - | - | + | - | - | + | - | - | - | - |
| 9 | 9026 | YAR | *26:01 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 10 | 9107 | LKT3 | *24:02 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 11 | 9051 | PITOUT | *29:02 | | - | - | - | + | - | - | - | - | - | - | - | - | - | - | - | - |
| 12 | 9052 | DBB | *02:01 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 13 | 9004 | JESTHOM | *02:01 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 14 | 9071 | OLGA | *31:01 | | + | - | - | - | - | - | - | - | + | - | - | + | - | - | - | - |
| 15 | 9075 | DKB | *24:02 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 16 | 9037 | SWEIG007 | *29:02 | | - | - | - | + | - | - | - | - | - | - | - | - | - | - | - | - |
| 17 | 9282 | CTM3953540 | *03:01 | *80:01 | - | - | - | + | - | - | - | - | - | - | - | - | - | - | - | - |
| 18 | 9257 | 32367 | *33:03 | *74:01 | - | - | - | - | - | - | - | - | + | - | - | + | - | - | - | - |
| 19 | 9038 | BM16 | *02:01 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 20 | 9059 | SLE005 | *02:01 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 21 | 9064 | AMALA | *02:17 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 22 | 9056 | KOSE | *02:01 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 23 | 9124 | IHL | *02:01 | *34:01 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 24 | 9035 | JBUSH | *32:01 | | - | - | - | - | - | - | + | - | + | - | - | - | - | - | - | - |
| 25 | 9049 | IBW9 | *33:01 | | - | - | - | - | - | - | - | - | + | - | - | + | - | - | - | - |
| 26 | 9285 | WT49 | *02:05 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 27 | 9191 | CH1007 | *24:10 | *29:01 | - | - | - | + | - | - | - | - | - | - | - | - | - | - | - | - |
| 28 | 9320 | BEL5GB | *02:01 | *29:02 | - | - | - | + | - | - | - | - | - | - | - | - | - | - | - | - |
| 29 | 9050 | MOU | *29:02 | | - | - | - | + | - | - | - | - | - | - | - | - | - | - | - | - |
| 30 | 9021 | RSH | *30:01 | *68:02 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 31 | 9019 | DUCAF | *30:02 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 32 | 9297 | HAG | *02:01 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 33 | 9098 | MT14B | *31:01 | | + | - | - | - | - | - | - | - | + | - | - | + | - | - | - | - |
| 34 | 9104 | DHIF | *31:01 | | + | - | - | - | - | - | - | - | + | - | - | + | - | - | - | - |
| 35 | 9302 | SSTO | *32:01 | | - | - | - | - | - | - | + | - | + | - | - | - | - | - | - | - |
| 36 | 9024 | KT17 | *02:06 | *11:01 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 37 | 9065 | HHKB | *03:01 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 38 | 9099 | LZL | *02:17 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 39 | 9315 | CML | *01:01 | *03:01 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 40 | 9134 | WHONP199 | *02:07 | *30:01 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 41 | 9055 | H0301 | *03:01 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 42 | 9066 | TAB089 | *02:07 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 43 | 9076 | T7526 | *02:06 | *02:07 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 44 | 9057 | TEM | *66:01 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 45 | 9239 | SHJO | *23:01 | *24:02 | - | - | - | - | - | - | - | + | - | - | - | - | - | - | - | - |
| 46 | 9013 | SCHU | *03:01 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 47 | 9045 | TUBO | *02:16 | *03:01 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 48 | 9303 | TER-ND | *02:01 | *11:01 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |

101.430-12 – including *Taq* polymerase, IFU-01
101.430-12u – without *Taq* polymerase, IFU-02

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Lot No.: **4F2**

Lot-specific Information

| CELL LINE VALIDATION SHEET | | | | | | | | | | | | | | | | | | | | |
|---|------|------------|--------|------------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|
| HLA-A*31 SSP subtyping kit ² | | | | | | | | | | | | | | | | | | | | |
| | | | | Well | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | |
| | | | | Prod. No.: | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 | 31 | 32 |
| | | | | | 201439117 | 201439118 | 201439119 | 201439120 | 201782021 | 201439122 | 201439123 | 201560124 | 201439125 | 201439126 | 201439127 | 201439128 | 201439129 | 201439130 | 201439131 | 201782040 |
| IHCW cell line ¹ | | A* | | | | | | | | | | | | | | | | | | |
| 1 | 9001 | SA | *24:02 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 2 | 9280 | LK707 | *02:01 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 3 | 9011 | E4181324 | *01:01 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 4 | 9275 | GU373 | *30:01 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 5 | 9009 | KAS011 | *01:01 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 6 | 9353 | SM | *02:01 | *26:03 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 7 | 9020 | QBL | *26:01 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 8 | 9025 | DEU | *31:01 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 9 | 9026 | YAR | *26:01 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 10 | 9107 | LKT3 | *24:02 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 11 | 9051 | PITOUT | *29:02 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 12 | 9052 | DBB | *02:01 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 13 | 9004 | JESTHOM | *02:01 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 14 | 9071 | OLGA | *31:01 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 15 | 9075 | DKB | *24:02 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 16 | 9037 | SWEIG007 | *29:02 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 17 | 9282 | CTM3953540 | *03:01 | *80:01 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 18 | 9257 | 32367 | *33:03 | *74:01 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 19 | 9038 | BM16 | *02:01 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 20 | 9059 | SLE005 | *02:01 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 21 | 9064 | AMALA | *02:17 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 22 | 9056 | KOSE | *02:01 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 23 | 9124 | IHL | *02:01 | *34:01 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 24 | 9035 | JBUSH | *32:01 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 25 | 9049 | IBW9 | *33:01 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 26 | 9285 | WT49 | *02:05 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 27 | 9191 | CH1007 | *24:10 | *29:01 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 28 | 9320 | BEL5GB | *02:01 | *29:02 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 29 | 9050 | MOU | *29:02 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 30 | 9021 | RSH | *30:01 | *68:02 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 31 | 9019 | DUCAF | *30:02 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 32 | 9297 | HAG | *02:01 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 33 | 9098 | MT14B | *31:01 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 34 | 9104 | DHIF | *31:01 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 35 | 9302 | SSTO | *32:01 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 36 | 9024 | KT17 | *02:06 | *11:01 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 37 | 9065 | HHKB | *03:01 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 38 | 9099 | LZL | *02:17 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 39 | 9315 | CML | *01:01 | *03:01 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 40 | 9134 | WHONP199 | *02:07 | *30:01 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 41 | 9055 | H0301 | *03:01 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 42 | 9066 | TAB089 | *02:07 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 43 | 9076 | T7526 | *02:06 | *02:07 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 44 | 9057 | TEM | *66:01 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 45 | 9239 | SHJO | *23:01 | *24:02 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 46 | 9013 | SCHU | *03:01 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 47 | 9045 | TUBO | *02:16 | *03:01 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 48 | 9303 | TER-ND | *02:01 | *11:01 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |

101.430-12 – including *Taq* polymerase, IFU-01
101.430-12u – without *Taq* polymerase, IFU-02

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Lot No.: **4F2**

Lot-specific Information

| CELL LINE VALIDATION SHEET | | | | | | | | | | | |
|---|------|------------|--------|------------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|
| HLA-A*31 SSP subtyping kit ² | | | | | | | | | | | |
| | | | | Well | | | | | | | |
| | | | | 33 | 34 | 35 | 36 | 37 | 38 | 39 | |
| | | | | Prod. No.: | 201782033 | 201782034 | 201782035 | 201782036 | 201782037 | 201782038 | 201782039 |
| IHWC cell line ¹ | | A* | | | | | | | | | |
| 1 | 9001 | SA | *24:02 | - | - | - | - | - | - | - | |
| 2 | 9280 | LK707 | *02:01 | - | - | - | - | - | - | - | |
| 3 | 9011 | E4181324 | *01:01 | - | - | - | - | - | - | - | |
| 4 | 9275 | GU373 | *30:01 | - | - | - | - | - | - | - | |
| 5 | 9009 | KAS011 | *01:01 | - | - | - | - | - | - | - | |
| 6 | 9353 | SM | *02:01 | *26:03 | - | - | - | - | - | - | |
| 7 | 9020 | QBL | *26:01 | - | - | - | - | - | - | - | |
| 8 | 9025 | DEU | *31:01 | - | - | - | - | - | - | - | |
| 9 | 9026 | YAR | *26:01 | - | - | - | - | - | - | - | |
| 10 | 9107 | LKT3 | *24:02 | - | - | - | - | - | - | - | |
| 11 | 9051 | PITOUT | *29:02 | - | - | - | - | - | - | - | |
| 12 | 9052 | DBB | *02:01 | - | - | - | - | - | - | - | |
| 13 | 9004 | JESTHOM | *02:01 | - | - | - | - | - | - | - | |
| 14 | 9071 | OLGA | *31:01 | - | - | - | - | - | - | - | |
| 15 | 9075 | DKB | *24:02 | - | - | - | - | - | - | - | |
| 16 | 9037 | SWEIG007 | *29:02 | - | - | - | - | - | - | - | |
| 17 | 9282 | CTM3953540 | *03:01 | *80:01 | - | - | - | - | - | - | |
| 18 | 9257 | 32367 | *33:03 | *74:01 | - | - | - | - | - | - | |
| 19 | 9038 | BM16 | *02:01 | - | - | - | - | - | - | - | |
| 20 | 9059 | SLE005 | *02:01 | - | - | - | - | - | - | - | |
| 21 | 9064 | AMALA | *02:17 | - | - | - | - | - | - | - | |
| 22 | 9056 | KOSE | *02:01 | - | - | - | - | - | - | - | |
| 23 | 9124 | IHL | *02:01 | *34:01 | - | - | - | - | - | - | |
| 24 | 9035 | JBUSH | *32:01 | - | - | - | - | - | - | - | |
| 25 | 9049 | IBW9 | *33:01 | - | - | - | - | - | - | - | |
| 26 | 9285 | WT49 | *02:05 | - | - | - | - | - | - | - | |
| 27 | 9191 | CH1007 | *24:10 | *29:01 | - | - | - | - | - | - | |
| 28 | 9320 | BEL5GB | *02:01 | *29:02 | - | - | - | - | - | - | |
| 29 | 9050 | MOU | *29:02 | - | - | - | - | - | - | - | |
| 30 | 9021 | RSH | *30:01 | *68:02 | - | - | - | - | - | - | |
| 31 | 9019 | DUCAF | *30:02 | - | - | - | - | - | - | - | |
| 32 | 9297 | HAG | *02:01 | - | - | - | - | - | - | - | |
| 33 | 9098 | MT14B | *31:01 | - | - | - | - | - | - | - | |
| 34 | 9104 | DHIF | *31:01 | - | - | - | - | - | - | - | |
| 35 | 9302 | SSTO | *32:01 | - | - | - | - | - | - | - | |
| 36 | 9024 | KT17 | *02:06 | *11:01 | - | - | - | - | - | - | |
| 37 | 9065 | HHKB | *03:01 | - | - | - | - | - | - | - | |
| 38 | 9099 | LZL | *02:17 | - | - | - | - | - | - | - | |
| 39 | 9315 | CML | *01:01 | *03:01 | - | - | - | - | - | - | |
| 40 | 9134 | WHONP199 | *02:07 | *30:01 | - | - | - | - | - | - | |
| 41 | 9055 | H0301 | *03:01 | - | - | - | - | - | - | - | |
| 42 | 9066 | TAB089 | *02:07 | - | - | - | - | - | - | - | |
| 43 | 9076 | T7526 | *02:06 | *02:07 | - | - | - | - | - | - | |
| 44 | 9057 | TEM | *66:01 | - | - | - | - | - | - | - | |
| 45 | 9239 | SHJO | *23:01 | *24:02 | - | - | - | - | - | - | |
| 46 | 9013 | SCHU | *03:01 | - | - | - | - | - | - | - | |
| 47 | 9045 | TUBO | *02:16 | *03:01 | - | - | - | - | - | - | |
| 48 | 9303 | TER-ND | *02:01 | *11:01 | - | - | - | - | - | - | |

101.430-12 – including *Taq* polymerase, IFU-01
101.430-12u – without *Taq* polymerase, IFU-02

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Lot No.: **4F2**

Lot-specific Information

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

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

No DNAs carrying the alleles to be amplified by primer solutions 2, 5, 6, 8, 10, 11, 13 and 15 to 39 were available.

The specificities of the primers in primer solutions 2, 5, 6, 8, 10, 16, 21 to 27 and 31 were tested by separately adding one or two additional 5'-primers, respectively one, two or three additional 3'-primers. In primer solutions 13, 15, 17, 18, 20, 29, 30, 36 and 38 it was only possible to test the 5'-primers, the 3'-primers were not possible to test. In primer solutions 11, 19, 28, 32 to 35, 37 and 39 it was only possible to test the 3'-primers, the 5'-primers were not possible to test. In primer solution 5, 10, 16, 21 and 25 to 27 one or two 5'-primers were not possible to test, and in primer solutions 1, 6, 8, 10, 16, 21 to 24, 26 and 31 one, two or three 3'-primers were not possible to test. Additional primers in primer solution 14 were tested by separately adding one 5'-primer respectively one 3'-primer.

101.430-12 – including *Taq* polymerase, IFU-01
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Lot No.: **4F2**

Lot-specific Information

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Fax: +46-8-717 88 18

E-mail: olerup-se@caredx.com

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

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