

101.842-12 – including *Taq* polymerase, IFU-01  
101.842-12u – without *Taq* polymerase, IFU-02

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“Instructions for Use” (IFU)

Lot No.: **6E2**

Lot-specific information

## **Olerup SSP® HLA-A\*11 Add-on**

|   |   |
|---|---|
| <b>Product number:</b>                  | <b>101.842-12 – including <i>Taq</i> polymerase</b><br><b>101.842-12u – without <i>Taq</i> polymerase</b> |
| <b>Lot number:</b>                      | <b>6E2</b>  |
| <b>Expiry date:</b>                     | <b>2019-05-01</b>   |
| <b>Number of tests:</b>                 | <b>12</b>   |
| <b>Number of wells per test:</b>        | <b>2+1</b>  |
| <b>Storage - pre-aliquoted primers:</b> | <b>dark at -20°C</b>  |
| - PCR Master Mix:                       | <b>-20°C</b>  |
| - Adhesive PCR seals                    | <b>RT</b>   |
| - Product Insert                        | <b>RT</b>   |

### **This Product Description is only valid for Lot No. 6E2.**

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-A11 ADD-ON LOT (90X)**

The HLA-A\*11 specificity and interpretation tables have been updated for the HLA-A alleles described since the previous *Olerup SSP®* HLA-A\*11 Add-on lot was made (**Lot No. 90X**). The kit design is based on IMGT/HLA database 3.25.0.

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.

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

| <b>Well</b> | <b>5'-primer</b> | <b>3'-primer</b> | <b>rationale</b>          |
|-------------|------------------|------------------|---------------------------|
| 3           | -                | -                | Updated negative control. |

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Well 3 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                   |
|------------------------------|----------------------|-------------------------|----------------------|----------------------|----------------------|----------------------|----------------------|
| <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>            | <b>36</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> | 5'-TAC <sup>3'</sup> |
|                              |                      |                         |                      |                      |                      |                      | 36                   |
|                              |                      |                         |                      |                      |                      |                      | 5'-TAT <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>            | <b>47</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> | 5'-ACA <sup>3'</sup> |
|                              |                      |                         |                      |                      |                      |                      | 48                   |
|                              |                      |                         |                      |                      |                      |                      | 5'-gCA <sup>3'</sup> |
|                              |                      |                         |                      |                      |                      |                      | 48                   |
|                              |                      |                         |                      |                      |                      |                      | 5'-gCC <sup>3'</sup> |
|                              |                      |                         |                      |                      |                      |                      | 52                   |
|                              |                      |                         |                      |                      |                      |                      | 5'-TgT <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>             |                      |
| <b>DQA1</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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Lot-specific information

## PRODUCT DESCRIPTION

### HLA-A\*11 Add-on SSP subtyping

#### CONTENT

The primer set contains 5'- and 3'-primers for distinguishing the HLA-A\*11:02 and 11:110 alleles.

#### PLATE LAYOUT

Each test consists of 3 PCR reactions in an 8 well cut PCR plate. Wells 4 to 8 are empty.

|   |   |    |       |       |       |       |       |
|---|---|----|-------|-------|-------|-------|-------|
| 1 | 2 | NC | empty | empty | empty | empty | empty |
|---|---|----|-------|-------|-------|-------|-------|

The 8 well cut PCR plate is marked with the Lot No. '6E2' in silver/gray ink.

Well No. 1 is marked with the Lot No. '6E2'.

Wells 1 to 2 – HLA-A\*11 Add-on high resolution primers.

Well 3 – 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 heat-sealed with a PCR-compatible foil.

**Please note:** When removing each 8 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

Due to the sharing of sequence motifs between HLA-A alleles some non-HLA-A\*11 alleles will be amplified by primer mix 2.

For further details see Specificity Table.

#### UNIQUELY IDENTIFIED ALLELES

The HLA-A\*11:02 and 11:110 alleles give different patterns in the HLA-A\*11 Add-on kit<sup>1,2</sup>.

The HLA-A\*11 Add-on kit cannot distinguish the silent mutations in the A\*11:02:01-11:02:06 alleles.

<sup>1</sup>Based on HLA-A alleles listed on the IMGT/HLA web page 2016-July-14, release 3.25.0, [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>.

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**SPECIFICITY TABLE**

**HLA-A\*11 Add-on SSP subtyping**

**Specificities and sizes of the PCR products of the 2+1 primer mixes used for HLA-A\*11 Add-on SSP subtyping**

| Primer Mix           | Size of spec. PCR product <sup>1</sup> | Size of control band <sup>2</sup> | Amplified HLA-A*11:02//11:110 alleles | Other amplified HLA-A alleles <sup>3,4</sup>                                       |
|----------------------|--|-----------------------------------|---------------------------------------|--|
| <b>1</b>             | 270 bp                                 | <b>800 bp</b>                     | *11:02:01-11:02:06, 11:110            | *11:14, 11:16, 11:38, 11:57, 11:77, 11:101, 11:113, 11:140, 11:147, 11:176, 11:201 |
| <b>2<sup>5</sup></b> | 210 bp                                 | 1070 bp                           | *11:110                               | *02:294, 32:54, 66:08  |
| <b>3<sup>6</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-A\*11 Add-on SSP typings.

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-A alleles some non-HLA-A\*11 alleles will be amplified by primer mix 2.

<sup>5</sup>Primer mix 2 may give rise to a lower yield of HLA-specific PCR product than the other A\*11 Add-on primer mixes.

<sup>6</sup>Primer mix 3 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.

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## PRIMER SPECIFICATION

| Well No.                                    | 1          | 2          |
|---|------------|------------|
| Length of spec.                             | 270        | 210        |
| PCR product                                 |            |            |
| Length of int.<br>pos. control <sup>1</sup> | 800        | 1070       |
| 5'-primer(s) <sup>2</sup>                   | 28         | 831        |
|   | 5' -TCC 3' | 5' -gAg 3' |
| 3'-primer(s) <sup>3</sup>                   | 127        | 899        |
|   | 5' -CTT 3' | 5' -ACg 3' |
| Well No.                                    | 1          | 2          |

<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.

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| CELL LINE VALIDATION SHEET           |                             |            |        |        |            |           |
|--------------------------------------|-----------------------------|------------|--------|--------|------------|-----------|
| HLA-A*11 Add-on SSP kit <sup>2</sup> |                             |            |        |        |            |           |
|                                      |                             |            |        |        | Well       |           |
|                                      |                             |            |        |        | 1          | 2         |
|                                      |                             |            |        |        | Prod. No.: |           |
|                                      |                             |            |        |        | 201295901  | 201295902 |
|                                      | IHCW cell line <sup>1</sup> |            | 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 | -          | -         |

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<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.

<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 solution 2 was available. The specificities of the primers in primer solution 2 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer.

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