

101.863-12 – including *Taq* polymerase, IFU-01 Rev. No. 03
101.863-12u – without *Taq* polymerase, IFU-02 Rev. No. 03

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

Lot No.: **26N**

Lot-specific information

Olerup SSP[®] HLA-C*07 Add-on

| | |
|----------------------------------|---|
| Product number: | 101.863-12 – including <i>Taq</i> polymerase 101.863-12u – without <i>Taq</i> polymerase |
| Lot number: | 26N |
| Expiry date: | 2014-August-01 |
| Number of tests: | 12 |
| Number of wells per test: | 5 |
| 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. 26N.

The Lot-specific information for HLA-C*07 Add-on including and without *Taq* polymerase is described in one common Product Insert.

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PRODUCT DESCRIPTION

HLA-C*07 Add-on SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for distinguishing the HLA-C*07:06 and C*07:18 from the C*07:01 allele, the C*07:50 from the C*07:02 allele and the C*07:11 from the C*07:04 allele.

PLATE LAYOUT

Each test consists of 5 PCR reactions in an 8 well cut PCR plate. Wells 6 to 8 are empty.

| | | | | | | | |
|---|---|---|---|---|-------|-------|-------|
| 1 | 2 | 3 | 4 | 5 | empty | empty | empty |
|---|---|---|---|---|-------|-------|-------|

The 8 well cut PCR plate is marked with the Lot No. '26N' in silver/gray ink.

Well No. 1 is marked with the Lot No. '26N'.

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

The interpretation of HLA-C*07 Add-on SSP subtypings will be influenced by all C*07 alleles.

UNIQUELY IDENTIFIED ALLELES

The HLA-C*07:06 and C*07:18 and the C*07:01, the C*07:50 and the C*07:02 and the C*07:11 and the C*07:04 alleles are uniquely separated from each other in the HLA-C*07 Add-on kit¹.

The HLA-C*07 Add-on kit cannot distinguish the silent mutations in the C*07:01:01-07:01:24 alleles, the 07:02:01:01-07:02:29 alleles or the C*07:04:01-C*07:04:07 alleles.

¹Based on HLA-C alleles listed on the IMGT/HLA web page 2012-January-12, release 3.7.0, www.ebi.ac.uk/imgt/hla.

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SPECIFICITY TABLE

HLA-C*07 Add-on SSP subtyping

Specificities and sizes of the PCR products of the 5 primer mixes used for HLA-C*07 Add-on SSP subtyping

| Primer Mix | Size of spec. PCR product ¹ | Size of control band ² | Amplified HLA-C*07 alleles ^{3,4} |
|----------------|--|-----------------------------------|---|
| 1 ⁶ | 245 bp, 425 bp | 800 bp | *07:01:01-07:33N, 07:35-07:220 |
| 2 | 505 bp | 1070 bp | *07:06 |
| 3 | 225 bp | 1070 bp | *07:06, 07:18-07:19 |
| 4 ⁵ | 80 bp | 1070 bp | *07:11 |
| 5 ⁵ | 80 bp | 1070 bp | *07:50 |

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-C*07 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.

²The internal positive control primer pairs amplify segments of the human growth hormone gene. The two different control primer pairs give rise to either an internal positive control band of 1070 base pairs, for most wells, or a band of 800 base pairs, for some wells.

Well number 1 contains the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to help in the correct orientation of the HLA-C*07 Add-on subtyping.

³For several HLA-C alleles 1st and 4th to 7th exon or intron nucleotide sequences are not available. In these instances it is not known whether some of the primers of the SSP sets are completely matched with the target sequences or not. We assume that unknown sequences in these exons are conserved within allelic groups.

⁴Due to the sharing of sequence motifs between HLA-C alleles all C*07 alleles will be amplified by primer mix 1.

⁵Short specific PCR fragments are less intense and not as sharp as longer specific bands.

⁶The primer pairs in wells 1 will give rise to two HLA-specific PCR fragments for many C*07 alleles.

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| INTERPRETATION TABLE | | | | | |
|--|------------|------------|-------------------|------------|------------|
| HLA-C*07 Add-on SSP typing | | | | | |
| | Well | | | | |
| | 1 | 2 | 3 | 4 | 5 |
| Length of spec. | 245 | 505 | 225 | 80 | 80 |
| PCR product | 425 | | | | |
| Length of int. | 800 | 1070 | 1070 | 1070 | 1070 |
| pos. control ¹ | | | | | |
| 5'-primer(s) ² | 47 | 992 | 5 th I | 1049 | 1049 |
| | 5' -Agg 3' | 5' -TAA 3' | 5' -gTC 3' | 5' -g 3' | 5' -C 3' |
| | 648 | | | | |
| | 5' -CAC 3' | | | | |
| 3'-primer(s) ³ | 302 | 1016 | 1043 | 1087 | 1087 |
| | 5' -ggC 3' | 5' -CAC 3' | 5' -CAA 3' | 5' -AgC 3' | 5' -AgT 3' |
| | 853 | | | | |
| | 5' -CAT 3' | | | | |
| Well No. | 1 | 2 | 3 | 4 | 5 |
| HLA-C allele ⁴ | | | | | |
| *07:01:01-07:05, 07:07-07:10, 07:12-07:17, 07:20-07:33N, 07:35-07:49, 07:51-07:220 | 1 | | | | |
| *07:06 | 1 | 2 | 3 | | |
| *07:11 | 1 | | | 4 | |
| *07:18-07:19 | 1 | | 3 | | |
| *07:50 | 1 | | | | 5 |
| HLA-C allele | | | | | |
| Well No. | 1 | 2 | 3 | 4 | 5 |

¹The internal positive control primer pairs amplify segments of the human growth hormone gene. The two different control primer pairs give rise to either an internal positive control band of 1070 base pairs, for most wells, or a band of 800 base pairs, for some wells.

Well number 1 contains the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to help in the correct orientation of the HLA-C*07 Add-on subtyping.

²The nucleotide position, in the 1st, 4th, 5th or 7th exon or the 5th intron, matching the specificity-determining 3'-end of the primer is given. Nucleotide numbering as on the www.ebi.ac.uk/imgt/hla web site. The sequence of the 3 terminal nucleotides of the primer is given.

³The nucleotide position, in the 2nd, 4th, 6th or 7th exon, 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.

⁴The HLA-Cw*0734 allele has been renamed to HLA-C*07:27:02.

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| CELL LINE VALIDATION SHEET | | | | | | | | | | |
|-----------------------------------|------|------------|-----------|--------|-------------|-----------|-----------|-----------|-----------|--|
| HLA-C*07 Add-on SSP kit | | | | | | | | | | |
| | | | | | Well | | | | | |
| | | | | | 1 | 2 | 3 | 4 | 5 | |
| | | | | | 201296401 | 201296402 | 201296403 | 201296404 | 201296405 | |
| | | | | | Lot No.: | | | | | |
| IHWC cell line | | | C* | | | | | | | |
| 1 | 9001 | SA | *07:02 | | + | - | - | - | - | |
| 2 | 9280 | LK707 | *07:01 | *15:05 | + | - | - | - | - | |
| 3 | 9011 | E4181324 | *12:02 | | - | - | - | - | - | |
| 4 | 9275 | GU373 | *03:04 | *04:01 | - | - | - | - | - | |
| 5 | 9009 | KAS011 | *06:02 | | - | - | - | - | - | |
| 6 | 9353 | SM | *03:04 | *07:02 | + | - | - | - | - | |
| 7 | 9020 | QBL | *05:01 | | - | - | - | - | - | |
| 8 | 9025 | DEU | *04:01 | | - | - | - | - | - | |
| 9 | 9026 | YAR | *12:03 | | - | - | - | - | - | |
| 10 | 9107 | LKT3 | *01:02 | | - | - | - | - | - | |
| 11 | 9051 | PITOUT | *16:01 | | - | - | - | - | - | |
| 12 | 9052 | DBB | *06:02 | | - | - | - | - | - | |
| 13 | 9004 | JESTHOM | *01:02 | | - | - | - | - | - | |
| 14 | 9071 | OLGA | *01:02 | *03:04 | - | - | - | - | - | |
| 15 | 9075 | DKB | *03:04 | | - | - | - | - | - | |
| 16 | 9037 | SWEIG007 | *02:02 | | - | - | - | - | - | |
| 17 | 9282 | CTM3953540 | *03:03 | *07:01 | + | - | - | - | - | |
| 18 | 9257 | 32367 | *01:02 | *07:05 | + | - | - | - | - | |
| 19 | 9038 | BM16 | *07:01 | | + | - | - | - | - | |
| 20 | 9059 | SLE005 | *03:04 | | - | - | - | - | - | |
| 21 | 9064 | AMALA | *03:03 | | - | - | - | - | - | |
| 22 | 9056 | KOSE | *12:03 | | - | - | - | - | - | |
| 23 | 9124 | IHL | *01:02 | *15:02 | - | - | - | - | - | |
| 24 | 9035 | JBUSH | *12:03 | | - | - | - | - | - | |
| 25 | 9049 | IBW9 | *08:02 | | - | - | - | - | - | |
| 26 | 9285 | WT49 | *07:01 | | - | - | - | - | - | |
| 27 | 9191 | CH1007 | *07:04 | *15:05 | + | - | - | - | - | |
| 28 | 9320 | BEL5GB | *05:01 | *16:01 | + | - | - | - | - | |
| 29 | 9050 | MOU | *16:01 | | - | - | - | - | - | |
| 30 | 9021 | RSH | *17:01 | | - | - | - | - | - | |
| 31 | 9019 | DJCAF | *05:01 | | - | - | - | - | - | |
| 32 | 9297 | HAG | *17:01 | *17:03 | - | - | - | - | - | |
| 33 | 9098 | MT14B | *03:04 | | - | - | - | - | - | |
| 34 | 9104 | DHIF | *12:03 | | - | - | - | - | - | |
| 35 | 9302 | SSTO | *05:01 | | - | - | - | - | - | |
| 36 | 9024 | KT17 | *03:03 | *04:01 | - | - | - | - | - | |
| 37 | 9065 | HHKB | *07:02 | | + | - | - | - | - | |
| 38 | 9099 | LZL | *03:03 | | - | - | - | - | - | |
| 39 | 9315 | CML | *02:02 | *07:01 | + | - | - | - | - | |
| 40 | 9134 | WHONP199 | *01:02 | *06:02 | - | - | - | - | - | |
| 41 | 9055 | H0301 | *08:02 | | - | - | - | - | - | |
| 42 | 9066 | TAB089 | *01:02 | | - | - | - | - | - | |
| 43 | 9076 | T7526 | *01:02 | *08:01 | - | - | - | - | - | |
| 44 | 9057 | TEM | *12:03 | | - | - | - | - | - | |
| 45 | 9239 | SHJO | *06:02 | *17:01 | - | - | - | - | - | |
| 46 | 9013 | SCHU | *07:02 | | + | - | - | - | - | |
| 47 | 9045 | TUBO | *07:04 | *15:02 | + | - | - | - | - | |
| 48 | 9303 | TER-ND | *04:01 | *16:01 | - | - | - | - | - | |

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CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-C*07 Add-on SSP

Product number: 101.863-12 – including *Taq* polymerase
101.863-12u – without *Taq* polymerase

Lot number: 26N

Expiry date: 2014-August-01

Number of tests: 12

Number of wells per test: 5

Well specifications:

| Well No. | Production No. |
|----------|----------------|
| 1 | 2012-964-01 |
| 2 | 2012-964-02 |
| 3 | 2012-964-03 |
| 4 | 2012-964-04 |
| 5 | 2012-964-05 |

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

No DNAs carrying the alleles to be amplified by primer solutions 4 and 5 were available. The specificity of the primers in primer solutions 4 and 5 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer.

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

Date of approval: 2012-March-09

Approved by:

Production Quality Control

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Declaration of Conformity

Product name: Olerup SSP® HLA-C*07 Add-on
Product number: 101.863-12/12u
Lot number: 26N

Intended use: HLA-C*07 histocompatibility testing

Manufacturer: Olerup SSP AB
Franzengatan 5
SE-112 51 Stockholm, Sweden
Phone: +46-8-717 88 27
Fax: +46-8-717 88 18

We, Olerup SSP AB, hereby declare that this product, to which this Declaration of Conformity relates is in conformity with the following Standard(s) and other normative document(s) ISO 9001:2008 and ISO 13485:2003, following the provisions of the 98/79/EC Directive on *in vitro* diagnostic medical devices, Annex III, as transposed into the national laws of the Member States of the European Union.

The Technical Documentation File is maintained at Olerup SSP AB, Franzengatan 5, SE-112 51 Stockholm, Sweden.

Notified Body: Lloyd's Register Quality Assurance Limited, Hiramford, Middlemarch Office Village, Siskin Drive, Coventry CV3 4FJ, United Kingdom. (Notified Body number: 0088.)

Stockholm, Sweden
2012-May-10

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs

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