

101.708-24– including *Taq* polymerase, IFU-01
 101.708-24u – without *Taq* polymerase, IFU-02

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

Lot No.: **96N**

Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-A-B-DR-DQ SSP Combi Tray

Product number: 101.708-24 – including *Taq* pol.
 101.708-24u – without *Taq* pol.
Lot number: 96N
Expiry date: 2014-December-01
Number of tests: 24 tests
Number of wells per test: 95 +1

Well specifications:

| Well No. | Production No. | Well No. | Production No. | Well No. | Production No. |
|----------|----------------|----------|----------------|----------|----------------|
| 1 | 2011-931-01 | 9 | 2012-019-10 | 17 | 2012-019-18 |
| 2 | 2012-019-02 | 10 | 2012-019-11 | 18 | 2012-019-19 |
| 3 | 2011-931-03 | 11 | 2012-019-12 | 19 | 2012-019-20 |
| 4 | 2012-019-04 | 12 | 2012-019-13 | 20 | 2012-019-21 |
| 5 | 2012-019-06 | 13 | 2012-019-14 | 21 | 2012-019-23 |
| 6 | 2012-019-07 | 14 | 2012-019-15 | | |
| 7 | 2012-019-08 | 15 | 2012-019-16 | | |
| 8 | 2012-019-09 | 16 | 2012-019-17 | | |

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

Additional 5'- and/or 3'-primers in primer solutions 1, 3 to 7, 9, 11 and 13 to 21 were tested by separately adding additional 3'-primers or 5'-primers. One or two primers in primer solutions 2, 3, 7, 8, 9, 10, 14, 17 and 18 were not possible to test.

| Well No. | Production No. | Well No. | Production No. | Well No. | Production No. |
|----------|----------------|----------|----------------|----------|----------------|
| 22 | 2011-886-48 | 38 | 2011-900-18 | 54 | 2011-900-36 |
| 23 | 2011-900-02 | 39 | 2011-900-19 | 55 | 2011-900-37 |
| 24 | 2011-900-03 | 40 | 2012-981-20 | 56 | 2011-900-38 |
| 25 | 2011-900-04 | 41 | 2011-900-21 | 57 | 2011-900-39 |
| 26 | 2011-900-05 | 42 | 2011-900-22 | 58 | 2011-900-40 |
| 27 | 2011-900-06 | 43 | 2011-900-23 | 59 | 2011-900-41 |
| 28 | 2011-900-07 | 44 | 2011-900-24 | 60 | 2011-900-42 |
| 29 | 2011-900-08 | 45 | 2011-900-25 | 61 | 2011-900-44 |
| | | | | | |
| 30 | 2011-900-09 | 46 | 2011-900-27 | 62 | 2012-981-45 |
| 31 | 2011-900-10 | 47 | 2011-900-28 | 63 | 2011-900-46 |
| 32 | 2012-011-11 | 48 | 2011-900-29 | 64 | 2011-900-47 |
| 33 | 2011-900-13 | 49 | 2011-900-31 | | |
| 34 | 2011-900-14 | 50 | 2011-900-32 | | |
| 35 | 2011-900-15 | 51 | 2011-900-33 | | |
| 36 | 2011-900-16 | 52 | 2011-900-34 | | |
| 37 | 2011-900-17 | 53 | 2011-900-35 | | |

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

Additional 5'-primers and/or 3'-primers in primer solutions 22 to 24, 27, 33 to 35, 39, 41, 45, 48, 49, 53 and 58 were tested by separately adding additional 3'-primers or 5'-primers. One or two primers in primer solutions 49, 56 and 60 were not possible to test.

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| Well No. | Production No. | Well No. | Production No. | Well No. | Production No. |
|----------|----------------|----------|----------------|----------|----------------|
| 65 | 2012-972-01 | 73 | 2012-972-09 | 81 | 2012-972-17 |
| 66 | 2012-972-02 | 74 | 2012-972-10 | 82 | 2012-006-18 |
| 67 | 2012-972-03 | 75 | 2012-972-11 | 83 | 2012-006-19 |
| 68 | 2012-972-04 | 76 | 2012-972-12 | 84 | 2012-972-20 |
| 69 | 2012-972-05 | 77 | 2012-972-13 | 85 | 2012-972-29 |
| 70 | 2012-972-06 | 78 | 2012-972-14 | 86 | 2012-972-30 |
| 71 | 2012-972-07 | 79 | 2012-972-15 | 87 | 2012-972-31 |
| 72 | 2012-972-08 | 80 | 2012-972-16 | | |

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

Additional 5'-primers and/or 3'-primers in primer solutions 65, 67, 68, 70, 73 to 76, 79, 80, 82 and 84 were tested by separately adding additional 3'-primers, respectively additional 5'-primers.

One, two or three of the primers in primer solutions 65, 67, 68, 72 to 74, 77, 79, 80 and 86 were not possible to test.

| Well No. | Production No. |
|----------|----------------|
| 88 | 2011-948-01 |
| 89 | 2011-948-02 |
| 90 | 2011-948-03 |
| 91 | 2011-948-04 |
| 92 | 2011-948-05 |
| 93 | 2011-948-06 |
| 94 | 2011-948-07 |
| 95 | 2011-948-08 |

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

One additional 5'-primer in primer solutions 89 and 95 were tested by separately adding one additional 3'-primer.

The negative control primer pairs, **Production No. 2012-002-01**, can detect contamination with PCR products diluted 10^{-7} .

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

Date of approval: 2012-June-20

Approved by



Production Quality Control

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Lot-specific information

Declaration of Conformity

Product name: *Olerup* SSP® HLA-A-B-DR-DQ SSP Combi Tray
Product number: 101.708-24/24u
Lot number: 96N

Intended use: HLA-A, HLA-B, HLA-DR and HLA-DQ low resolution histo-compatibility 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 II List B, conformity assessed using Annex IV, as transposed into the national laws of the Member States of the European Union.

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

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

Stockholm, Sweden
2012-June-20

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs