# CERTIFICATE OF ANALYSIS

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

**Product number:** 101.708-24 – including *Taq* pol.
**Lot number:** 24M
**Expiry date:** 2013-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 | 2010-787-01 | 9 | 2010-787-10 | 17 | 2010-733-18 |
| 2 | 2010-787-02 | 10 | 2010-787-11 | 18 | 2010-733-19 |
| 3 | 2010-733-03 | 11 | 2011-875-12 | 19 | 2010-787-20 |
| 4 | 2010-733-04 | 12 | 2010-733-13 | 20 | 2010-733-21 |
| 5 | 2010-787-06 | 13 | 2010-787-14 | 21 | 2010-787-23 |
| 6 | 2010-733-07 | 14 | 2010-733-15 | | |
| 7 | 2010-733-08 | 15 | 2010-787-16 | | |
| 8 | 2010-733-09 | 16 | 2010-787-17 | | |

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 one or more 3'-primers, respectively 5'-primers. One primer in primer solutions 2, 3, 9, 10, 14, 17 and 18 was not possible to test.

| Well No. | Production No. | Well No. | Production No. | Well No. | Production No. |
|---|---|---|---|---|---|
| 22 | 2009-633-48 | 38 | 2010-734-18 | 54 | 2010-788-36 |
| 23 | 2010-734-02 | 39 | 2010-788-19 | 55 | 2010-734-37 |
| 24 | 2010-788-03 | 40 | 2011-823-20 | 56 | 2010-788-38 |
| 25 | 2010-734-04 | 41 | 2010-734-21 | 57 | 2010-734-39 |
| 26 | 2011-858-05 | 42 | 2010-734-22 | 58 | 2010-734-40 |
| 27 | 2010-734-06 | 43 | 2010-734-23 | 59 | 2010-734-41 |
| 28 | 2010-734-07 | 44 | 2010-788-24 | 60 | 2010-734-42 |
| 29 | 2010-734-08 | 45 | 2010-788-25 | 61 | 2010-734-44 |
| | | | | | |
| 30 | 2010-734-09 | 46 | 2010-734-27 | 62 | 2010-734-45 |
| 31 | 2010-734-10 | 47 | 2010-734-28 | 63 | 2010-734-46 |
| 32 | 2010-734-11 | 48 | 2011-858-29 | 64 | 2010-734-47 |
| 33 | 2010-734-13 | 49 | 2011-823-31 | | |
| 34 | 2010-734-14 | 50 | 2010-734-32 | | |
| 35 | 2010-788-15 | 51 | 2011-823-33 | | |
| 36 | 2010-734-16 | 52 | 2010-734-34 | | |
| 37 | 2010-734-17 | 53 | 2010-734-35 | | |

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

| Well No. | Production No. | Well No. | Production No. | Well No. | Production No. |
|---|---|---|---|---|---|
| 65 | 2011-851-01 | 73 | 2011-851-09 | 81 | 2011-851-17 |
| 66 | 2011-851-02 | 74 | 2011-851-10 | 82 | 2011-851-18 |
| 67 | 2011-851-03 | 75 | 2011-851-11 | 83 | 2011-851-19 |
| 68 | 2011-851-04 | 76 | 2011-851-12 | 84 | 2011-851-20 |
| 69 | 2011-851-05 | 77 | 2011-851-13 | 85 | 2011-851-21 |
| 70 | 2011-851-06 | 78 | 2011-851-14 | 86 | 2011-851-22 |
| 71 | 2011-851-07 | 79 | 2011-851-15 | 87 | 2011-851-23 |
| 72 | 2011-851-08 | 80 | 2011-851-16 | | |

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 | 2011-852-01 |
| 89 | 2011-852-02 |
| 90 | 2011-852-03 |
| 91 | 2011-852-04 |
| 92 | 2011-852-05 |
| 93 | 2011-852-06 |
| 94 | 2011-852-07 |
| 95 | 2011-852-08 |

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. 2010-760-01**, can detect contamination with PCR products diluted $10^{-7}$.

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

***Date of approval:*** 2011-October-06

***Approved by***

Åsa Olausson

**Quality Control, Supervisor**

# Declaration of Conformity

**Product name:** *Olerup* SSP® HLA-A-B-DR-DQ SSP Combi Tray
**Product number:** 101.708-24
**Lot number:** 24M

**Intended use:** HLA-A, HLA-B, HLA-DR and HLA-DQ low resolution histo-compatibility testing

**Manufacturer:** *Olerup* SSP AB
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***Phone:*** +46-8-717 88 27
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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.

The Authorized Representative located within the Community is: *Olerup* SSP AB.

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
2011-October-06

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs