**CERTIFICATE OF ANALYSIS**

***Olerup* SSP® HLA-A\*68**

Product number: 101.418-12/04 – including *Taq* pol.

101.418-12u/04u – without *Taq* pol.

Lot number: 3G9

Expiry date: 2021-03-01

Number of tests: 12 tests – Product No. 101.418-12/12u

4 tests – Product No. 101.418-04/04u

Number of wells per test: 47+1

**Well specifications:**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Well No. | Production No. | Well No. | Production No. | Well No. | | Production No. | |
| 1 | 2016-725-01 | 17 | 2016-725-17 | 33 | | 2016-725-33 | |
| 2 | 2016-725-02 | 18 | 2016-725-18 | 34 | | 2016-725-34 | |
| 3 | 2016-725-03 | 19 | 2016-725-19 | 35 | | 2016-725-35 | |
| 4 | 2016-725-04 | 20 | 2016-725-20 | 36 | | 2016-725-36 | |
| 5 | 2016-725-05 | 21 | 2016-725-21 | 37 | | 2018-919-37 | |
| 6 | 2016-725-06 | 22 | 2016-725-22 | 38 | | 2016-725-38 | |
| 7 | 2016-725-07 | 23 | 2016-725-23 | 39 | | 2016-725-39 | |
| 8 | 2016-725-08 | 24 | 2016-725-24 | 40 | | 2016-725-40 | |
|  |  |  |  |  | |  | |
| 9 | 2016-725-09 | 25 | 2016-725-25 | 41 | | 2018-919-41 | |
| 10 | 2016-725-10 | 26 | 2016-725-26 | 42 | | 2016-725-42 | |
| 11 | 2016-725-11 | 27 | 2016-725-27 | 43 | | 2016-725-43 | |
| 12 | 2016-725-12 | 28 | 2016-725-28 | 44 | | 2018-919-44 | |
| 13 | 2018-919-13 | 29 | 2016-725-29 | 45 | | 2018-919-45 | |
| 14 | 2016-725-14 | 30 | 2016-725-30 | 46 | | 2016-725-46 | |
| 15 | 2016-725-15 | 31 | 2016-725-31 | 47 | 2016-725-47 | |
| 16 | 2016-725-16 | 32 | 2016-725-32 |

The negative control primer pairs, **Production No. 2018-947-01**, can detect contamination with PCR products diluted 10-7.

**Results of Quality Control:** No false positive or false negative amplifications obtained.

***Date of approval:***

***Approved by:***

**Production Quality Control**

Declaration of Conformity

**Product name:** *Olerup* SSP® HLA-A\*68

**Product number:** 101.418-12/12u, 04/04u

**Lot number:** 3G9

**Intended use:** HLA-A\*68 high resolution histocompatibility testing

**Manufacturer:** *Olerup* SSP AB

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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 EN ISO 13485:2012, following the provisions of the 98/79/EC Directive on *in vitro* diagnostic medical devices, Annex II List B, 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, 1 Trinity Park, Bickenhill Lane, Birmingham B37 7ES, United Kingdom.

(Notified Body number: 0088.)

Stockholm, Sweden

Emil Jonsson

Head of QA