

**Certificates**

**101.221-12 – including *Taq* pol., IFU-01**

**101.221-12u – without *Taq* pol., IFU-02**

Visit [www.olerup.com](http://www.olerup.com) for  
“Instructions for Use” (IFU)

**Lot No.: 2F4**

**Lot-specific information**

**CERTIFICATE OF ANALYSIS**

**Olerup SSP® DQB1 high resolution for frequent alleles**

**Product number:** 101.221-12 – including *Taq* polymerase

101.221-12u – without *Taq* polymerase

**Lot number:** 2F4

**Expiry date:** 2020-01-01

**Number of tests:** 12 tests

**Number of wells per test:** 95+ 1

**Well specifications:**

| Well No. | Production No. | Well No. | Production No. | Well No. | Production No. |
|----------|----------------|----------|----------------|----------|----------------|
| 1        | 2016-682-01    | 33       | 2017-803-33    | 65       | 2016-682-65    |
| 2        | 2016-682-02    | 34       | 2017-803-34    | 66       | 2017-803-66    |
| 3        | 2015-500-03    | 35       | 2017-803-35    | 67       | 2017-803-67    |
| 4        | 2015-500-04    | 36       | 2016-682-36    | 68       | 2015-500-68    |
| 5        | 2017-803-05    | 37       | 2015-500-37    | 69       | 2017-803-69    |
| 6        | 2015-500-06    | 38       | 2017-803-38    | 70       | 2015-500-70    |
| 7        | 2015-500-07    | 39       | 2017-803-39    | 71       | 2017-803-71    |
| 8        | 2016-682-08    | 40       | 2017-803-40    | 72       | 2017-803-72    |
| 9        | 2015-500-09    | 41       | 2017-803-41    | 73       | 2017-803-73    |
| 10       | 2017-803-10    | 42       | 2017-803-42    | 74       | 2017-803-74    |
| 11       | 2015-500-11    | 43       | 2015-500-43    | 75       | 2017-803-75    |
| 12       | 2017-803-12    | 44       | 2017-803-44    | 76       | 2017-803-76    |
| 13       | 2017-803-13    | 45       | 2017-803-45    | 77       | 2017-803-77    |
| 14       | 2016-682-14    | 46       | 2015-500-46    | 78       | 2017-803-78    |
| 15       | 2017-803-15    | 47       | 2015-500-47    | 79       | 2017-803-79    |
| 16       | 2015-500-16    | 48       | 2015-500-48    | 80       | 2017-803-80    |
| 17       | 2017-803-17    | 49       | 2017-803-49    | 81       | 2016-682-81    |
| 18       | 2017-803-18    | 50       | 2017-803-50    | 82       | 2015-500-82    |
| 19       | 2015-500-19    | 51       | 2017-803-51    | 83       | 2015-500-83    |
| 20       | 2015-500-20    | 52       | 2015-500-52    | 84       | 2017-803-84    |
| 21       | 2017-803-21    | 53       | 2016-682-53    | 85       | 2017-803-85    |
| 22       | 2015-500-22    | 54       | 2017-803-54    | 86       | 2017-803-86    |
| 23       | 2015-500-23    | 55       | 2016-682-55    | 87       | 2017-803-87    |
| 24       | 2016-682-24    | 56       | 2017-803-56    | 88       | 2017-803-88    |
| 25       | 2017-803-25    | 57       | 2016-682-57    | 89       | 2016-682-89    |
| 26       | 2015-500-26    | 58       | 2017-803-58    | 90       | 2017-803-90    |
| 27       | 2015-500-27    | 59       | 2016-682-59    | 91       | 2017-803-91    |
| 28       | 2015-500-28    | 60       | 2016-682-60    | 92       | 2017-803-92    |
| 29       | 2015-500-29    | 61       | 2017-803-61    | 93       | 2016-682-93    |
| 30       | 2017-803-30    | 62       | 2017-803-62    | 94       | 2017-803-94    |
| 31       | 2015-500-31    | 63       | 2017-803-63    | 95       | 2015-500-95    |
| 32       | 2015-500-32    | 64       | 2016-682-64    |          |                |

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Lot No.: **2F4**

Lot-specific information

The negative control primer pairs, **Production No. 2016-746-01**, can detect contamination with PCR products diluted  $10^{-7}$ .

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

**Date of approval:** 170829

**Approved by:**



**Production Quality Control**

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**Lot No.: 2F4**

**Lot-specific information**

**Declaration of Conformity**

**Product name:** Olerup SSP® DQB1 High

**Product number:** 101.221-12/12u

**Lot number:** 2F4

**Intended use:** DQB1 high resolution 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 EN ISO 13485:2012, 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.

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

Stockholm, Sweden



Emil Jonsson  
 Head of QA

*Sept 6. 2017*