

101.101-48/12 – including *Taq* pol., IFU-01  
 101.101-48u/12u – without *Taq* pol., IFU-02

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

Lot No.: **13R**

Lot-specific information

## CERTIFICATE OF ANALYSIS

### Olerup SSP® DR low resolution

**Product number:** 101.101-48/12 – including *Taq* pol.  
 101.101-48u/12u – without *Taq* pol.  
**Lot number:** 13R  
**Expiry date:** 2015-April-01  
**Number of tests:** 48 tests – Product No. 101.101-48/48u  
 12 tests – Product No. 101.101-12/12u  
**Number of wells per test:** 31 + 1

### Well specifications:

| Well No. | Production No. | Well No. | Production No. | Well No. | Production No. |
|----------|----------------|----------|----------------|----------|----------------|
| 1        | 2012-972-01    | 13       | 2012-972-13    | 25       | 2012-055-25    |
| 2        | 2012-972-02    | 14       | 2012-972-14    | 26       | 2012-055-26    |
| 3        | 2012-972-03    | 15       | 2012-055-15    | 27       | 2012-055-27    |
| 4        | 2012-972-04    | 16       | 2012-972-16    | 28       | 2012-055-28    |
| 5        | 2012-972-05    | 17       | 2012-972-17    | 29       | 2012-972-29    |
| 6        | 2012-972-06    | 18       | 2012-006-18    | 30       | 2012-972-30    |
| 7        | 2012-972-07    | 19       | 2012-006-19    | 31       | 2012-972-31    |
| 8        | 2012-972-08    | 20       | 2012-972-20    |          |                |
| 9        | 2012-055-09    | 21       | 2012-055-21    |          |                |
| 10       | 2012-972-10    | 22       | 2012-055-22    |          |                |
| 11       | 2012-972-11    | 23       | 2012-055-23    |          |                |
| 12       | 2012-972-12    | 24       | 2012-055-24    |          |                |

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

The reactivities of additional 3'-primers in primer solutions 1, 3, 4, 9 to 11, 18, 20, 22 and 27 were tested by separately adding one or more additional 5'-primers. Additional 5'-primers in primer solutions 6, 11, 12, 15, 16, 18 and 27 were tested by separately adding another 3'-primer.

One or more of the 5'-primers in primer solutions 1, 3, 4, 8 to 10, 13, 15, 16 and 22 and one or two of the 3'-primers in primer solutions 1, 3, 4, 13, 15, 21, 26 and 30 were not possible to test.

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-October-26

**Approved by:**

  
 Ann-Cathrin Jareman  
 Head of QA and Regulatory Affairs

101.101-48/12 – including *Taq* pol., IFU-01  
101.101-48u/12u – without *Taq* pol., IFU-02

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

Lot No.: 13R

Lot-specific information

## Declaration of Conformity

**Product name:** Olerup SSP® DR low resolution  
**Product number:** 101.101-48/48u, -12/12u  
**Lot number:** 13R

**Intended use:** DRB1 low 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 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-October-26

Ann-Cathrin Jareman  
Head of QA and Regulatory Affairs