

101.201-48/12– including *Taq* pol., IFU-01  
101.201-48u/12u– without *Taq* pol., IFU-02

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

Lot No.: **11S**

Lot-specific information

## CERTIFICATE OF ANALYSIS

### **Olerup SSP® DQ low resolution SSP**

Product number:

101.201-48/12 - including *Taq* pol.

101.201-48u/12u - without *Taq* pol.

Lot number:

11S

Expiry date:

2015-October-01

Number of tests:

48 tests – Product No. 101.201-48/48u

12 tests – Product No. 101.201-12/48u

Number of wells per test:

8

#### **Well specifications:**

Well No.	Production No.
1	2013-161-01
2	2013-161-02
3	2013-161-03
4	2013-161-04
5	2013-161-05
6	2013-161-06
7	2013-161-07
8	2013-161-08

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

Additional 5'-primer in primer solution 2 was tested by separately adding another 3'-primer.

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

**Date of approval:** 2013-April-26

**Approved by:**



**Production Quality Control**

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## Declaration of Conformity

**Product name:** *Olerup* SSP® DQ low resolution  
**Product number:** 101.201-48/48u, -12/12u  
**Lot number:** 11S

**Intended use:** DQB1 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 13485:2012, 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  
2013-April-26

Ann-Cathrin Jareman  
Head of QA and Regulatory Affairs