

101.201-48/12– including *Taq* pol., IFU-01 Rev. No. 03
101.201-48u/12u– without *Taq* pol., IFU-02 Rev. No. 03

Visit www.olerup-ssp.com for
“Instructions for Use” (IFU)

Lot No.: **87N**

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: 87N
Expiry date: 2014-November-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	2011-948-01
2	2011-948-02
3	2011-948-03
4	2011-948-04
5	2011-948-05
6	2011-948-06
7	2011-948-07
8	2011-948-08

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

Additional 5'-primers in primer solutions 2 and 8 were tested by separately adding another 3'-primer.

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

Date of approval: 2012-May-25

Approved by:



Production Quality Control

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Lot-specific information

Declaration of Conformity

Product name: *Olerup* SSP® DQ low resolution
Product number: 101.201-48/48u, -12/12u
Lot number: 87N

Intended use: DQB1 low resolution histocompatibility testing

Manufacturer: *Olerup* SSP AB
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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 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
2012-May-25



Ann-Cathrin Jareman
Head of QA and Regulatory Affairs