

CERTIFICATE OF ANALYSIS**Olerup SSP® DQ low resolution SSP**

Product number:

101.201-48u/12u – without *Taq* pol.

Lot number:

39M

Expiry date:

2013-December-01

Number of tests:

48 tests – Product No. 101.201-48u

12 tests – Product No. 101.201-12u

Number of wells per test:

8

Well specifications:

Well No.	Production No.
1	2011-880-01
2	2011-880-02
3	2011-880-03
4	2011-880-04
5	2011-880-05
6	2011-880-06
7	2011-880-07
8	2011-880-08

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

One additional 5'-primer in primer solutions 2 and 8 was tested by separately adding another 3'-primer.

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

Date of approval: 2011-June-29

Approved by:



Quality Control, Supervisor

Lot No.: **39M**

Lot-specific information

www.olerup-ssp.com

Declaration of Conformity

Product name: *Olerup* SSP® DQ low resolution
Product number: 101.201-48u/12u
Lot number: 39M

Intended use: DQB1 low 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 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
2011-June-29



Olle Olerup
Managing Director

