

101.864-12 – including *Taq* polymerase, IFU-01 Rev. No. 03
101.864-12u – without *Taq* polymerase, IFU-02 Rev. No. 03

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

Lot No.: **27N**

Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-C*08 Add-on SSP

Product number: 101.864-12 – including *Taq* polymerase
101.864-12u – without *Taq* polymerase
Lot number: 27N
Expiry date: 2014-August-01
Number of tests: 12
Number of wells per test: 2

Well specifications:

Well No.	Production No.
1	2012-965-01
2	2012-965-02

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

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

Date of approval: 2012-March-09

Approved by:



Production Quality Control

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Lot-specific information

Declaration of Conformity

Product name: *Olerup* SSP® HLA-C*08 Add-on

Product number: 101.864-12/12u

Lot number: 27N

Intended use: HLA-C*08 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.

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-May-10


Ann-Cathrin Jareman
Head of QA and Regulatory Affairs