

101.851-12 – including *Taq* polymerase
101.851-12u – without *Taq* polymerase

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

Lot No.: 35V

Lot-specific Information

www.olerup-ssp.com

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-B*51:11N SSP

Product number:	101.851-12 – including <i>Taq</i> polymerase 101.851-12u - without <i>Taq</i> polymerase
Lot number:	35V
Expiry date:	2016-August-01
Number of tests:	12
Number of wells per test:	2+1

Well specifications:

Well No.	Production No.
1	2011-899-01
2	2011-899-02

The negative control primer pairs, **Production No. 2013-271-01**, can detect contamination with PCR products diluted 10^{-7} .

Results of Quality Control: No false positive or false negative amplifications obtained.

Date of approval: 2014-March-12

Approved by:



Production Quality Control

101.851-12 – including *Taq* polymerase
101.851-12u – without *Taq* polymerase

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

Lot No.: **35V**

Lot-specific Information

www.olerup-ssp.com

Declaration of Conformity

Product name: Olerup SSP® HLA-B*51:11N

Product number: 101.851-12/12u

Lot number: 35V

Intended use: HLA-B*51:11N 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 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, Middlesbrough Office Village, Siskin Drive, Coventry CV3 4FJ, United Kingdom.
(Notified Body number: 0088.)

Stockholm, Sweden
2014-March-12



Ann-Cathrin Jareman
Head of QA and Regulatory Affairs