101.572-12– including *Taq* pol., IFU-01
101. 572-12u– without *Taq* pol., IFU-02

Visit www.olerup-ssp.com for **"Instructions for Use" (IFU)**

Lot No.: 14R **Lot-specific information**

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-B*57:01 SSP

Product number: **101.572-12 – including *Taq* polymerase**
101.572-12u – without *Taq* polymerase
Lot number: **14R**
Expiry date: **2015-February-01**
Number of tests: **12**
Number of wells per test: **15+1**

Well specifications:

Well No.	Production No.	Well No.	Production No.
1	2011-845-01	9	2011-845-09
2	2011-845-02	10	2012-056-10
3	2011-845-03	11	2011-845-11
4	2011-845-04	12	2011-845-12
5	2011-845-05	13	2012-056-13
6	2011-845-06	14	2012-056-14
7	2012-056-07	15	2012-056-15
8	2011-922-08		

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

No DNAs carrying the alleles to be amplified by primer solutions 3 to 5, 7 to 10 and 12 to 15 were available. The specificities of the primers in primer solutions 3 to 5, 7, 8, 10 and 13 to 15 were tested by separately adding one to four additional 5'-primers, respectively one or two 3'-primers. In primer solution 9 it was only possible to test the 3'-primer, the 5'-primers were not possible to test. In primer solution 12 it was only possible to test the 5'-primer, the 3'-primers were not possible to test.
In primer solutions 3, 4, 7, 10, 11 and 15 one to three 3'-primers were not possible to test, and in primer solutions 4, 5, 8, 10, 14 and 15 one to three 5'-primers were not possible to test.

The negative control primer pairs, **Production No. 2012-002-01**, can detect contamination with PCR products diluted 10^{-7}.

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

Date of approval: 2012-August-23

Approved by:

Production Quality Control

CE
0088

Declaration of Conformity

Product name: *Olerup* SSP® HLA-B*57:01
Product number: 101.572-12/12u
Lot number: 14R

Intended use: HLA-B*57:01 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 13485:2003, 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, Middlemarch Office Village, Siskin Drive, Coventry CV3 4FJ, United Kingdom. (Notified Body number: 0088.)

Stockholm, Sweden
2013-August-23

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs