101.546-06 – including *Taq* pol., IFU-01
101.546-06u – without *Taq* pol., IFU-02
Lot No.: 96S

Visit www.olerup-ssp.com for
"Instructions for Use" (IFU)
Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-B*48 SSP

Product number: **101.546-06 – including *Taq* polymerase**
101.546-06u – without *Taq* polymerase
Lot number: **96S**
Expiry date: **2016-May-01**
Number of tests: **6**
Number of wells per test: **16**

Well specifications:

Well No.	Production No.	Well No.	Production No.
1	2013-257-01	9	2013-257-09
2	2013-257-02	10	2013-257-10
3	2013-257-03	11	2013-257-11
4	2013-257-04	12	2013-257-12
5	2013-257-05	13	2013-257-13
6	2013-257-06	14	2013-257-14
7	2013-257-07	15	2013-257-15
8	2013-257-08	16	2013-257-16

The specificity of each primer solution of the HLA-B*48 primer set has been tested against 48 well characterized IHWC cell line DNAs.

No DNAs carrying the alleles to be amplified by primer solutions 6 and 8 were available. The specificities of the primers in these primer solutions were tested by separately adding additional 3'-primers, respectively additional 5'-primers. In primer solutions 6 and 8, one or two 5'-primers were not possible to test, and in primer solutions 9 and 14 two 3'-primers were not possible to test. Additional 5'-primers in primer solutions 5, 12, 14 and 16 were tested by separately adding an additional 3'-primer, and one additional 3'-primer in primer solution 12 was tested by separately adding an additional 5'-primer.

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

Date of approval: 2013-December-13

Approved by:

Åsa Olausson

Production Quality Control

CE
0088

101.546-06 – including *Taq* pol., IFU-01
101.546-06u – without *Taq* pol., IFU-02

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

Lot No.: 96S **Lot-specific information**

Declaration of Conformity

Product name: *Olerup* SSP® HLA-B*48
Product number: 101.546-06/06u
Lot number: 96S

Intended use: HLA-B*48 high resolution 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, Middlemarch Office Village, Siskin Drive, Coventry CV3 4FJ, United Kingdom. (Notified Body number: 0088.)

Stockholm, Sweden
2013-December-13

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs