101.543-06 – including *Taq* pol., IFU-01
101.543-06u – without *Taq* pol., IFU-02

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

Lot No.: **35R** Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-B*42 SSP

Product number: 101.543-06 – including *Taq* pol.
101.543-06u – without *Taq* pol.
Lot number: 35R
Expiry date: 2015-March-01
Number of tests: 6
Number of wells per test: 15

Well specifications:

Well No.	Production No.	Well No.	Production No.
1	2009-606-01	9	2009-606-09
2	2009-606-02	10	2012-078-10
3	2009-606-03	11	2009-606-11
4	2009-606-04	12	2010-783-12
5	2009-606-05	13	2010-783-13
6	2009-606-06	14	2011-890-14
7	2011-890-07	15	2010-783-15
8	2011-890-08		

The specificity of each primer solution of the HLA-B*42 primer set has been tested against 48 well characterized IHWC cell line DNAs.

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

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

Date of approval: 2012-October-11

Approved by:

Åsa Olausson

Production Quality Control

101.543-06 – including *Taq* pol., IFU-01
101.543-06u – without *Taq* pol., IFU-02

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Lot No.: 35R

Lot-specific information

Declaration of Conformity

Product name: *Olerup* SSP® HLA-B*42
Product number: 101.543-06/06u
Lot number: 35R

Intended use: HLA-B*42 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 13485:2003, 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
2012-October-11

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs