

101.544-06 – including *Taq* pol., IFU-01101.544-06u – without *Taq* pol., IFU-02Visit www.olerup-ssp.com for

“Instructions for Use” (IFU)

Lot No.: **08R**

Lot-specific information

CERTIFICATE OF ANALYSIS**Olerup SSP® HLA-B*46 SSP**

Product number:

101.544-06– including *Taq* polymerase101.544-06u – without *Taq* polymerase

Lot number:

08R

Expiry date:

2015-March-01

Number of tests:

6

Number of wells per test:

24

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2011-936-01	9	2011-936-09	17	2011-936-17
2	2011-936-02	10	2011-936-10	18	2011-936-18
3	2011-936-03	11	2011-936-11	19	2011-936-19
4	2011-936-04	12	2012-049-12	20	2011-936-20
5	2011-936-05	13	2011-936-13	21	2011-936-21
6	2011-936-06	14	2011-936-14	22	2011-936-22
7	2011-936-07	15	2011-936-15	23	2011-936-23
8	2012-049-08	16	2011-936-16	24	2011-936-24

The specificity of each primer solution of the HLA-B*46 primer set has been tested against 48 well characterized IHWC cell line DNAs.

No DNAs carrying the alleles to be amplified by primer solutions 2 to 4, 6, 7, 10 to 12, 15, 17, 18 and 20 to 23 were available. The specificities of the primers in primer solutions 3, 4, 6, 10 to 12, 15, 17 and 20 were tested by separately adding one or two additional 5'-primers, respectively one or two additional 3'-primers. In primer solutions 2, 7, 18, 21 and 23 it was only possible to test the 5'-primer, the 3'-primer was not possible to test. In primer solution 22 it was only possible to test the 3'-primer, the 5'-primer was not possible to test.

In primer solutions 4 and 10 one of the 5'-primers was not possible to test, and in primer solutions 6, 8, 12, 13, 15 and 16 one of the 3'-primers was not possible to test. Additional 5'-primers in primer solutions 13 and 16 were tested by separately adding one 3'-primer.

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

Date of approval: 2012-October-12

Approved by:



Production Quality Control

101.544-06 – including *Taq* pol., IFU-01
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Declaration of Conformity

Product name: Olerup SSP® HLA-B*46

Product number: 101.544-06/06u

Lot number: 08R

Intended use: HLA-B*46 high resolution 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 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-12

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs