

101.547-06 – including *Taq* pol., IFU-01101.547-06u – without *Taq* pol., IFU-02Visit [www.olerup-ssp.com](http://www.olerup-ssp.com) for

“Instructions for Use” (IFU)

Lot No.: **56S**

Lot-specific information

[www.olerup-ssp.com](http://www.olerup-ssp.com)**CERTIFICATE OF ANALYSIS****Olerup SSP® HLA-B\*49 SSP**

Product number:

**101.547-06 – including *Taq* polymerase****101.547-06u – without *Taq* polymerase**

Lot number:

**56S**

Expiry date:

**2015-January-01**

Number of tests:

**6**

Number of wells per test:

**16****Well specifications:**

| Well No. | Production No. | Well No. | Production No. |
|----------|----------------|----------|----------------|
| 1        | 2011-911-01    | 9        | 2012-077-09    |
| 2        | 2013-210-02    | 10       | 2011-911-10    |
| 3        | 2012-077-03    | 11       | 2011-911-11    |
| 4        | 2011-911-04    | 12       | 2011-911-12    |
| 5        | 2011-911-05    | 13       | 2011-911-13    |
| 6        | 2011-911-06    | 14       | 2011-911-14    |
| 7        | 2011-911-07    | 15       | 2011-911-15    |
| 8        | 2011-911-08    | 16       | 2011-911-16    |

The specificity of each primer solution of the HLA-B\*49 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, 4, 9 to 11 and 14 to 16 were available. The specificities of the primers in primer solutions 2, 4, 9, 11 and 16 were tested by separately adding additional 3'-primers, respectively additional 5'-primers. In primer solution 10, 14 and 15, it was only possible to test the 5'-primer, the 3'-primer was not possible to test. In primer solutions 2 and 16, one 5'-primer was not possible to test, and in primer solutions 8 and 9, one 3'-primer was not possible to test. One additional 5'-primer and one additional 3'-primer in primer solution 3 were tested by separately adding one 3'-primer respectively one 3'-primer.

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

**Date of approval:** 2013-August-19

**Approved by:**



**Head of R & D**

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## Declaration of Conformity

**Product name:** *Olerup* SSP® HLA-B\*49  
**Product number:** 101.547-06/06u  
**Lot number:** 56S

**Intended use:** HLA-B\*49 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-August-19

Ann-Cathrin Jareman  
Head of QA and Regulatory Affairs