

101.522-24/03– including *Taq* pol., IFU-01  
 101.522-24u/03u – without *Taq* pol., IFU-02

Visit [www.olerup-ssp.com](http://www.olerup-ssp.com) for  
 “Instructions for Use” (IFU)

Lot No.: **54S**

Lot-specific information

## CERTIFICATE OF ANALYSIS

### Olerup SSP® HLA-B\*35 SSP

Product number:

101.522-24/03 – including *Taq* pol.  
 101.522-24u/03u – without *Taq* pol.

Lot number:

**54S**

Expiry date:

**2016-February-01**

Number of tests:

**24 tests – Product No. 101.522-24/24u**

**3 tests – Product No. 101.522-03/03u**

Number of wells per test:

**79**

### Well specifications:

| Well No. | Production No. | Well No. | Production No. | Well No. | Production No. |
|----------|----------------|----------|----------------|----------|----------------|
| 1        | 2012-058-01    | 31       | 2012-058-31    | 61       | 2012-058-61    |
| 2        | 2012-058-02    | 32       | 2012-058-32    | 62       | 2012-058-62    |
| 3        | 2012-058-03    | 33       | 2012-058-33    | 63       | 2012-058-63    |
| 4        | 2012-058-04    | 34       | 2012-058-34    | 64       | 2012-058-64    |
| 5        | 2012-058-05    | 35       | 2012-058-35    | 65       | 2012-058-65    |
| 6        | 2012-058-06    | 36       | 2013-206-36    | 66       | 2012-058-66    |
| 7        | 2012-058-07    | 37       | 2012-058-37    | 67       | 2012-058-67    |
| 8        | 2012-058-08    | 38       | 2012-058-38    | 68       | 2012-058-68    |
| 9        | 2012-058-09    | 39       | 2012-058-39    | 69       | 2012-058-69    |
| 10       | 2012-058-10    | 40       | 2012-058-40    | 70       | 2013-206-70    |
|          |                |          |                |          |                |
| 11       | 2012-058-11    | 41       | 2013-206-41    | 71       | 2012-058-71    |
| 12       | 2012-058-12    | 42       | 2012-058-42    | 72       | 2012-058-72    |
| 13       | 2012-058-13    | 43       | 2012-058-43    | 73       | 2012-058-73    |
| 14       | 2012-058-14    | 44       | 2012-058-44    | 74       | 2012-058-74    |
| 15       | 2012-058-15    | 45       | 2012-058-45    | 75       | 2012-058-75    |
| 16       | 2012-058-16    | 46       | 2013-206-46    | 76       | 2012-058-76    |
| 17       | 2013-206-17    | 47       | 2012-058-47    | 77       | 2013-206-77    |
| 18       | 2012-058-18    | 48       | 2012-058-48    | 78       | 2012-058-78    |
| 19       | 2013-206-19    | 49       | 2013-206-49    | 79       | 2012-058-79    |
| 20       | 2012-058-20    | 50       | 2013-206-50    |          |                |
|          |                |          |                |          |                |
| 21       | 2012-058-21    | 51       | 2012-058-51    |          |                |
| 22       | 2012-058-22    | 52       | 2012-058-52    |          |                |
| 23       | 2012-058-23    | 53       | 2012-058-53    |          |                |
| 24       | 2012-058-24    | 54       | 2013-206-54    |          |                |
| 25       | 2012-058-25    | 55       | 2012-058-55    |          |                |
| 26       | 2012-058-26    | 56       | 2012-058-56    |          |                |
| 27       | 2012-058-27    | 57       | 2012-058-57    |          |                |
| 28       | 2012-058-28    | 58       | 2012-058-58    |          |                |
| 29       | 2012-058-29    | 59       | 2012-058-59    |          |                |
| 30       | 2012-058-30    | 60       | 2012-058-60    |          |                |

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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 10, 35, 36, 41 to 44, 50 to 71, 74 and 76 to 79 were available.

The specificities of the primers in primer solutions 10, 35, 36, 41, 43, 44, 50, 58, 61, 63, 64, 68, 69 and 77 were tested by separately adding one or two additional 5'-primers, respectively one or two additional 3'-primers.

In primer solutions 42, 52 to 55, 57, 62, 67 and 74 it was only possible to test the 5'-primers, the 3'-primers were not possible to test.

In primer solutions 51, 56, 59, 60, 65, 66, 70, 71, 76, 78 and 79 it was only possible to test the 3'-primers, the 5'-primers were not possible to test.

In primer solutions 10, 16, 33, 35, 36, 43, 64, 69 and 77 one, two or three of the 5'-primers were not possible to test, and in primer solutions 10, 12, 41, 43, 44, 49, 50, 58, 61, 64, 69, 75 and 77 one or two of the 3'-primers were not possible to test.

Additional primers in primer solutions 3, 22, 26, 31 and 33 were tested by separately adding one 5'-primer and/or one 3'-primer.

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

**Date of approval:** 2013-September-04

**Approved by:**

**Production Quality Control**

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## Declaration of Conformity

**Product name:** *Olerup* SSP® HLA-B\*35  
**Product number:** 101.522-24/24u, -03/03u  
**Lot number:** 54S

**Intended use:** HLA-B\*35 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-September-04

Ann-Cathrin Jareman  
Head of QA and Regulatory Affairs