

Lot No.: **55M**

Lot-specific information

www.olerup-ssp.com

## CERTIFICATE OF ANALYSIS

### Olerup SSP® HLA-C\*08 SSP

**Product number:** 101.623-12u – without Taq polymerase  
**Lot number:** 55M  
**Expiry date:** 2014-February-01  
**Number of tests:** 12  
**Number of wells per test:** 29

#### Well specifications:

| Well No. | Production No. | Well No. | Production No. | Well No. | Production No. |
|----------|----------------|----------|----------------|----------|----------------|
| 1        | 2010-758-01    | 11       | 2010-758-11    | 21       | 2010-758-21    |
| 2        | 2010-758-02    | 12       | 2010-758-12    | 22       | 2011-898-22    |
| 3        | 2010-758-03    | 13       | 2010-758-13    | 23       | 2010-758-23    |
| 4        | 2010-758-04    | 14       | 2010-758-14    | 24       | 2011-898-24    |
| 5        | 2010-758-05    | 15       | 2010-758-15    | 25       | 2011-898-25    |
| 6        | 2010-758-06    | 16       | 2010-758-16    | 26       | 2011-898-26    |
| 7        | 2010-758-07    | 17       | 2010-758-17    | 27       | 2011-898-27    |
| 8        | 2010-758-08    | 18       | 2010-758-18    | 28       | 2011-898-28    |
| 9        | 2011-898-09    | 19       | 2010-758-19    | 29       | 2011-898-29    |
| 10       | 2010-758-10    | 20       | 2010-758-20    |          |                |

The specificity of each primer solution of the HLA-C\*08 primer set has been tested against 48 well characterized cell line DNAs.

No DNAs carrying the alleles to be amplified by primer solutions 5 to 11, 14, 15, 17 to 20 and 23 to 29 were available. The specificity of the primers in primer solutions 5, 7 to 9, 11, 14, 15, 17 to 20, 24, 25, 28 and 29 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer solutions 6, 10, 26 and 27 it was only possible to test the 5'-primer, the 3'-primer was not possible to test. In primer solutions 23 it was only possible to test the 3'-primer, the 5'-primer was not possible to test. In primer solution 8, 9, 11, 14, 18 and 19, one or two 5'-primers were not possible to test. In primer solution 16, one additional 5'-primer and one additional 3'-primer were tested by separately adding one 3'-primer respective one 5'-primer. In primer solution 22, one additional 5'-primer was tested by separately adding one 3'-primer.

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

**Date of approval:** 2011-September-16

**Approved by:**



**Quality Control, Supervisor**

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## Declaration of Conformity

**Product name:** *Olerup* SSP® HLA-C\*08  
**Product number:** 101.623-12u  
**Lot number:** 55M

**Intended use:** HLA-C\*08 high resolution histocompatibility testing

**Manufacturer:** *Olerup* SSP AB  
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**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 III, 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.

The Authorized Representative located within the Community is: *Olerup* SSP AB.

Stockholm, Sweden  
2011-September-16



Ann-Cathrin Jareman  
Head of QA and Regulatory Affairs