

Lot No.: 1D5

Lot-specific information

## CERTIFICATE OF ANALYSIS

### Olerup SSP® HLA-C\*15 SSP

**Product number:** 101.626-12 – including Taq polymerase  
 101.626-12u – without Taq polymerase  
**Lot number:** 1D5  
**Expiry date:** 2018-June-01  
**Number of tests:** 12  
**Number of wells per test:** 37+1

#### Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2015-599-01	17	2013-290-17	33	2015-599-33
2	2013-290-02	18	2015-599-18	34	2015-599-34
3	2013-290-03	19	2013-290-19	35	2015-599-35
4	2013-290-04	20	2015-503-20	36	2015-599-37
5	2015-503-05	21	2015-503-21	37	2015-599-37
6	2013-290-06	22	2015-503-22		
7	2013-290-07	23	2013-290-23		
8	2013-290-08	24	2015-503-24		
9	2013-290-09	25	2013-290-25		
10	2013-290-10	26	2015-503-26		
11	2013-290-11	27	2015-599-27		
12	2015-503-12	28	2015-503-28		
13	2013-290-13	29	2015-503-29		
14	2013-290-14	30	2013-290-30		
15	2013-290-15	31	2015-599-31		
16	2013-290-16	32	2015-599-32		

The negative control primer pairs, **Production No. 2015-617-01**, can detect contamination with PCR products diluted 10<sup>-7</sup>.

**Results of Quality Control:** No false positive or false negative amplifications obtained.

**Date of approval:**

2015-12-21

**Approved by:**



**Production Quality Control**

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## Declaration of Conformity

**Product name:** Olerup SSP® HLA-C\*15  
**Product number:** 101.626-12/12u  
**Lot number:** 1D5

**Intended use:** HLA-C\*15 high resolution histocompatibility testing

**Manufacturer:** Olerup SSP AB  
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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 EN ISO 13485:2012, 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.

Stockholm, Sweden  
 2015-Dec-21

Daniel Malica  
 Head of QA and Regulatory Affairs