

Lot No.: **6H0**

Lot-specific information

## CERTIFICATE OF ANALYSIS

### Olerup SSP® HLA-C\*02

Product number: 101.622-12 – including *Taq* polymerase  
 101.622-12u – without *Taq* polymerase  
 Lot number: 6H0  
 Expiry date: 2021-11-01  
 Number of tests: 12  
 Number of wells per test: 43+1

#### Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2019-041-01	17	2014-466-17	33	2015-579-33
2	2014-466-02	18	2014-466-18	34	2015-579-34
3	2016-710-03	19	2014-466-19	35	2015-579-35
4	2014-466-04	20	2015-579-20	36	2018-918-36
5	2015-579-05	21	2014-466-21	37	2019-041-37
6	2014-466-06	22	2014-466-22	38	2016-710-38
7	2014-466-07	23	2014-466-23	39	2019-041-39
8	2014-466-08	24	2014-466-24	40	2016-710-40
9	2014-466-09	25	2014-466-25	41	2018-918-41
10	2014-466-10	26	2015-579-26	42	2018-918-42
11	2014-466-11	27	2015-579-27	43	2019-041-43
12	2014-466-12	28	2016-710-28		
13	2014-466-13	29	2014-466-29		
14	2014-466-14	30	2019-041-30		
15	2015-579-15	31	2014-466-31		
16	2019-041-16	32	2015-579-32		

The negative control primer pairs, **Production No. 2018-947-01**, 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:** 2019-05-15

**Approved by:** *Rebecca Salme*

#### Production Quality Control



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## Declaration of Conformity

**Product name:** Olerup SSP® HLA-C\*02

**Product number:** 101.622-12/12u

**Lot number:** 6H0

**Intended use:** HLA-C\*02 high resolution histocompatibility testing

**Manufacturer:** Olerup SSP AB  
Franzégatan 5  
SE-112 51 Stockholm, Sweden  
**Phone:** +46-8-508 939 00  
**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) EN ISO 13485:2016, 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, Franzégatan 5, SE-112 51 Stockholm, Sweden.

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

Stockholm, Sweden

Date: 20170516

  
Emil Jonsson  
Head of Quality Assurance

