

Lot No.: **2G2**

Lot-specific information  
**CERTIFICATE OF ANALYSIS**

**Olerup SSP<sup>®</sup> HLA-A\*25**

Product number: 101.423-06 – including *Taq* polymerase  
101.423-06u – without *Taq* polymerase  
Lot number: 2G2  
Expiry date: 2020-12-01  
Number of tests: 6  
Number of wells per test: 15+1


**Well specifications:**

Well No.	Production No.	Well No.	Production No.
1	2018-903-01	9	2018-903-09
2	2016-671-02	10	2018-903-10
3	2016-671-03	11	2016-671-11
4	2016-671-04	12	2016-671-12
5	2016-671-05	13	2016-671-13
6	2018-903-06	14	2016-671-14
7	2018-903-07	15	2016-671-15
8	2016-671-08		

The negative control primer pairs, **Production No. 2017-845-01**, 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:** 20180629

**Approved by:**   
:firmo av Rebecca Salve

**Production Quality Control**

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## Declaration of Conformity

**Product name:** *Olerup* SSP® HLA-A\*25

**Product number:** 101.423-06/06u

**Lot number:** 2G2

**Intended use:** HLA-A\*25 high resolution histocompatibility testing

**Manufacturer:** *Olerup* SSP AB  
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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 EN ISO 13485:2012, following the provisions of the 98/79/EC Directive on *in vitro* diagnostic medical devices, Annex II List B, 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, 1 Trinity Park, Bickenhill Lane, Birmingham B37 7ES, United Kingdom.  
(Notified Body number: 0088.)

Stockholm, Sweden



Emil Jonsson  
Head of QA