

Lot No.: **5G2**

Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP[®] DPA1

Product number:

101.331-24/06 – including *Taq* pol.

101.331-24u/06u – without *Taq* pol.

Lot number:

5G2

Expiry date:

2020-12-01

Number of tests:

24 tests – Product No. 101.331-24/24u

6 tests – Product No. 101.331-06/06u

Number of wells per test:

19+1

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2016-706-01	9	2016-706-09	17	2018-933-17
2	2016-706-02	10	2016-706-10	18	2018-933-18
3	2016-706-03	11	2016-706-11	19	2018-933-19
4	2016-706-04	12	2016-706-12		
5	2016-706-05	13	2018-933-13		
6	2016-706-06	14	2016-706-14		
7	2016-706-07	15	2016-706-15		
8	2016-706-08	16	2018-933-16		

The negative control primer pairs, **Production No. 2017-845-01**, can detect contamination with PCR products diluted 10^{-7} .

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

Date of approval:

20180627

Approved by:



Production Quality Control

101.331-24/06 – including *Taq* pol., IFU-01Visit www.olerup.com for101.331-24u/06u – without *Taq* pol., IFU-02**"Instructions for Use" (IFU)****Lot No.: 5G2****Lot-specific information****Declaration of Conformity****Product name:** Olerup SSP® DPA1**Product number:** 101.331-24/24u, -06/06u**Lot number:** 5G2**Intended use:** HLA-DPA1 high resolution histocompatibility testing

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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



Emil Jonsson
Head of QA