

101.704-48/12 – including *Taq* pol., IFU-01
 101.704-48u/12u – without *Taq* pol., IFU-02

Visit www.olerup.com for
 “Instructions for Use” (IFU)

Lot No.: **0G6**

Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP[®] DQ-DR SSP Combi Tray

Product number: 101.704-48/12 – including *Taq* pol.
 101.704-48u/12u – without *Taq* pol.
Lot number: 0G6
Expiry date: 2020-10-01
Number of tests: 48 tests – Product No. 101.704-48/48u
 12 tests – Product No. 101.704-12/12u
Number of wells per test: 46 + 1

Well specifications:

Well No.	Production No.	Well No.	Production No.
1	2017-890-01	9	2017-883-09
2	2017-890-02	10	2017-883-10
3	2017-855-03	11	2017-883-11
4	2017-890-04	12	2017-883-12
5	2017-855-05	13	2017-883-13
6	2017-883-06	14	2017-883-14
7	2017-890-07	15	2017-883-15
8	2017-848-08		

Well No.	Production No.	Well No.	Production No.
16	2016-734-01	32	2018-889-17
17	2016-734-02	33	2016-734-18
18	2016-734-03	34	2017-854-19
19	2018-889-04	35	2016-734-20
20	2017-880-05	36	2016-699-21
21	2016-734-06	37	2018-889-22
22	2016-734-07	38	2016-699-23
23	2016-734-08	39	2016-699-24
24	2018-889-09	40	2016-699-25
25	2018-889-10	41	2016-699-26
26	2018-889-11B	42	2018-889-27
27	2016-751-12	43	2017-827-28
28	2016-734-13	44	2016-734-29
29	2016-734-14	45	2016-751-30
30	2017-827-15	46	2017-827-31
31	2016-734-16		

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.

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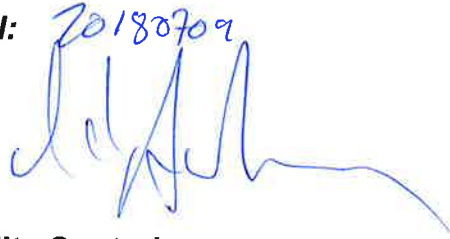
Lot No.: **0G6**

Lot-specific information

Date of approval:

20180709

Approved by:



Production Quality Control

101.704-48/12 – including *Taq* pol., IFU-01
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Declaration of Conformity

Product name: Olerup SSP® DQ-DR SSP Combi Tray
Product number: 101.704-48/48u, -12/12u
Lot number: 0G6

Intended use: DQB1 and DRB1 low resolution histocompatibility testing

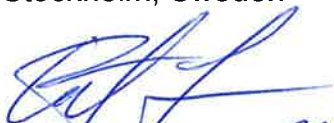
Manufacturer: Olerup SSP AB
 Franzengatan 5
 SE-112 51 Stockholm, Sweden
Phone: +46-8-717 88 27
Fax: +46-8-717 88 18

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, conformity assessed using Annex IV, 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

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