

101.103.48/12 – including *Taq* pol., IFU-01  
 101.103.48u/12u – without *Taq* pol., IFU-02

Visit [www.olerup.com](http://www.olerup.com) for  
 “Instructions for Use” (IFU)

Lot No.: **2G1**

Lot-specific information

## CERTIFICATE OF ANALYSIS

### Olerup SSP<sup>®</sup> DR low resolution screening

**Product number:** 101.103-48/12 – including *Taq* pol.  
 101.103-48u/12u – without *Taq* pol.  
**Lot number:** 2G1  
**Expiry date:** 2020-10-01  
**Number of tests:** 48 tests – Product No. 101.103-48/48u  
 12 tests – Product No. 101.103-12/12u  
**Number of wells per test:** 23 + 1

#### Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2016-734-01	9	2016-734-09	17	2016-734-17
2	2016-734-02	10	2018-889-10	18	2016-734-18
3	2016-734-03	11	2018-889-11	19	2017-854-19
4	2018-889-04	12	2016-751-12	20	2016-734-20
5	2017-880-05	13	2016-734-13	21	2016-734-29
6	2016-734-06	14	2016-734-14	22	2016-751-30
7	2016-734-07	15	2017-827-15	23	2017-827-31
8	2016-734-08	16	2016-734-16		

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:** 20180505

**Approved by:**



#### Production Quality Control

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## Declaration of Conformity

**Product name:** Olerup SSP® DR low resolution screening  
**Product number:** 101.103-48/48u, -12/12u  
**Lot number:** 2G1

**Intended use:** 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

20180525