

101.215-12 – including *Taq* pol., IFU-01
 101.215-12u – without *Taq* pol., IFU-02

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

Lot No.: **5E2**

Lot-specific Information

CERTIFICATE OF ANALYSIS

Olerup SSP® DQB1*04 SSP

Product number: 101.215-12 – including *Taq* polymerase
 101.215-12u – without *Taq* polymerase
Lot number: 5E2
Expiry date: 2019-04-01
Number of tests: 12
Number of wells per test: 18+1

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2015-507-01	9	2014-321-09	17	2016-737-17
2	2015-507-02	10	2014-321-10	18	2016-737-18
3	2015-507-03	11	2016-737-11		
4	2014-321-04	12	2015-507-12		
5	2014-321-05	13	2014-321-13		
6	2015-507-06	14	2014-321-14		
7	2015-507-07	15	2016-737-15		
8	2014-321-08	15	2016-737-16		

The negative control primer pairs, **Production No. 2016-695-01**, can detect contamination with PCR products diluted 10⁻⁷.

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

Date of approval: 16/11/21

Approved by:



Production Quality Control

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Lot-specific Information

Declaration of Conformity

Product name: *Olerup* SSP® DQB1*04
Product number: 101.215-12/12u
Lot number: 5E2

Intended use: DQB1*04 resolution histocompatibility testing

Manufacturer: *Olerup* SSP AB
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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 III, as transposed into the national laws of the Member States of the European Union.

Stockholm, Sweden
2016-Nov-22



Daniel Malica
Head of QA and Regulatory Affairs