

101.521-24/04 – including *Taq* polymerase, IFU-01
101.521-24u/04u – without *Taq* polymerase, IFU-02

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

Lot No.: 5D3

Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-B*27 SSP

Product number: 101.521-24/04 – including *Taq* pol.
101.521-24u/04u – without *Taq* pol.
Lot number: 5D3
Expiry date: 2018-07-01
Number of tests: 24 test – Product No. 101.521-24/24u
4 tests – Product No. 101.521-04/04u
Number of wells per test: 44+1

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2016-629-01	17	2012-945-17	33	2013-123-33
2	2012-945-02	18	2013-123-18	34	2016-629-34
3	2012-945-03	19	2012-945-19	35	2016-629-35
4	2013-123-04	20	2012-945-20	36	2013-123-36
5	2012-945-05	21	2012-945-21	37	2013-123-37
6	2012-945-06	22	2012-945-22	38	2013-123-38
7	2012-945-07	23	2012-945-23	39	2013-123-39
8	2012-945-08	24	2013-123-24	40	2013-123-40
9	2012-945-09	25	2012-945-25	41	2014-404-41
10	2012-945-10	26	2012-945-26	42	2014-404-42
11	2016-629-11	27	2016-629-27	43	2014-404-43
12	2012-945-12	28	2012-945-28	44	2014-404-44
13	2012-945-13	29	2012-945-29		
14	2012-945-14	30	2012-945-30		
15	2013-123-15	31	2016-629-31		
16	2014-404-16	32	2012-945-32		

The negative control primer pairs, **Production No. 2015-617-01**, can detect contamination with PCR products diluted 10^{-7} .

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

Date of approval:

2016-02-23

Approved by:



Production Quality Control

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Lot-specific information

Declaration of Conformity

Product name: *Olerup* SSP® HLA-B*27

Product number: 101.521-24/04
101.521-24u/04u

Lot number: 5D3

Intended use: HLA-B*27 high 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
2016-Feb-24



Daniel Malica
Head of QA and Regulatory Affairs