Lot No.: 3H4

Lot-specific Information

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-B*08

Product number:	**101.513-24/04 – including *Taq* polymerase** **101.513-24/04u – without *Taq* polymerase**
Lot number:	**3H4**
Expiry date:	**2021-07-01**
Number of tests:	**24 tests – Product No. 101.513-24/24u** **4 tests – Product No. 101.513-04/04u**
Number of wells per test:	**47+1**

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2018-930-01	17	2018-930-17	33	2018-930-33
2	2018-930-02	18	2018-930-18	34	2018-930-34
3	2018-930-03	19	2018-930-19	35	2018-930-35
4	2018-930-04	20	2018-930-20	36	2018-930-36
5	2018-930-05	21	2018-930-21	37	2018-930-37
6	2018-930-06	22	2018-930-22	38	2018-930-38
7	2018-930-07	23	2018-930-23	39	2018-930-39
8	2018-930-08	24	2018-930-24	40	2018-930-40
9	2018-930-09	25	2018-930-25	41	2018-930-41
10	2018-930-10	26	2018-930-26	42	2018-930-42
11	2018-930-11	27	2018-930-27	43	2018-930-43
12	2018-930-12	28	2018-930-28	44	2018-930-44
13	2018-930-13	29	2018-930-29	45	2018-930-45
14	2018-930-14	30	2018-930-30	46	2018-930-46
15	2019-014-15	31	2018-930-31	47	2018-930-47
16	2018-930-16	32	2018-930-32		

The negative control primer pairs, **Production No. 2018-947-01**, can detect contamination with PCR products diluted 10^{-7}.

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

Approved by: Rebecka Sollme
2019-02-14

Production Quality Control

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Lot No.: 3H4 **Lot-specific Information**

Declaration of Conformity

Product name: *Olerup* SSP® HLA-B*08
Product number: 101.513-24/24u, -04/04u
Lot number: 3H4

Intended use: HLA- B*08 high resolution histocompatibility testing

Manufacturer: *Olerup* SSP AB
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SE-112 51 Stockholm, Sweden
Phone: +46-8-508 939 00
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) EN ISO 13485:2016, 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.

The Authorized Representative located within the Community is: *Olerup* SSP AB.

Notified Body: Lloyd's Register Quality Assurance Limited, 1 Trinity Park, Bickenhill Lane, Birmingham B37 7ES, United Kingdom.
(Notified Body number: 0088.)

Stockholm, Sweden
Date: 20190214

Emil Jonsson
Head of Quality Assurance

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For *In Vitro* Diagnostic Use
MA100 v01 CoA_DoC IVD Annex II List B
Date: February 2019, Rev. No: 00