

101.615-24/04 – including *Taq* pol., IFU-01
101.615-24u/04u – without *Taq* pol., IFU-02

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

Lot No.: **7E6**

Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-C*07 SSP

Product number:

101.615-24/04 – including *Taq* pol.
101.615-24u/04u – without *Taq* pol.

Lot number:

7E6

Expiry date:

2021-03-01

Number of tests:

24 tests – Product No. 101.615-24/24u
4 tests – Product No. 101.615-04/04u

Number of wells per test:

93+1

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2014-381-01	33	2014-381-33	65	2017-759-65
2	2014-381-02	34	2017-759-34	66	2017-759-66
3	2016-624-03	35	2016-624-35	67	2017-759-67
4	2016-624-04	36	2014-381-36	68	2017-759-68
5	2014-381-05	37	2014-381-37	69	2017-759-69
6	2014-381-06	38	2017-759-38	70	2017-759-70
7	2014-381-07	39	2014-381-39	71	2017-759-71
8	2014-381-08	40	2016-624-40	72	2017-759-72
9	2014-381-09	41	2014-381-41	73	2017-759-73
10	2014-381-10	42	2017-759-42	74	2014-381-74
11	2014-381-11	43	2017-759-43	75	2017-759-75
12	2014-381-12	44	2017-759-44	76	2016-624-76
13	2014-381-13	45	2014-381-45	77	2017-759-77
14	2017-759-14	46	2016-624-46	78	2016-624-78
15	2014-381-15	47	2014-381-47	79	2014-381-79
16	2014-381-14	48	2017-759-48	80	2017-759-80
17	2014-381-17	49	2017-759-49	81	2014-381-81
18	2017-759-18	50	2017-759-50	82	2017-759-82
19	2014-381-19	51	2017-759-51	83	2017-759-83
20	2014-381-20	52	2014-381-52	84	2017-759-84
21	2014-381-21	53	2017-759-53	85	2017-759-85
22	2014-381-22	54	2017-759-54	86	2017-759-86
23	2014-381-23	55	2014-381-55	87	2017-759-87
24	2014-381-24	56	2017-759-56	88	2017-759-88
25	2016-624-25	57	2017-759-57	89	2017-759-89
26	2014-381-26	58	2014-381-58	90	2016-624-90
27	2017-759-27	59	2017-759-59	91	2016-624-91
28	2017-759-28	60	2017-759-60	92	2017-759-92
29	2014-381-29	61	2017-759-61	93	2017-759-93
30	2017-759-30	62	2017-759-62		
31	2017-759-31	63	2017-759-63		
32	2014-381-32	64	2017-759-64		



101.615-24/04 – including *Taq* pol., IFU-01
101.615-24u/04u – without *Taq* pol., IFU-02

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

Lot No.: **7E6**

Lot-specific information

The negative control primer pairs, **Production No. 2016-746-01**, can detect contamination with PCR products diluted 10^{-7} .

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

Date of approval: 2019-05-02

Approved by: Rebecca Salme

Production Quality Control



101.615-24/04 – including *Taq* pol., IFU-01
101.615-24u/04u – without *Taq* pol., IFU-02

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

Lot No.: **7E6**

Lot-specific information

Declaration of Conformity

Product name: *Olerup* SSP[®] HLA-C*07
Product number: 101.615-24/24u, -04/04u
Lot number: 7E6

Intended use: HLA-C*07 high resolution histocompatibility testing

Manufacturer: *Olerup* SSP AB
Franzéngatan 5
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 III, as transposed into the national laws of the Member States of the European Union.

The Technical Documentation File is maintained at *Olerup* SSP AB, Franzéngatan 5, SE-112 51 Stockholm, Sweden.

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

Stockholm, Sweden

Date: 2019 08 06


Emil Jonsson
Head of Quality Assurance

Change in revision R01 compared to R00:

1. The expiration date has been altered due to extension of shelf-life.

