

101.501-48/12 – including *Taq* polymerase, IFU-01  
101.501-48u/12u – without *Taq* polymerase, IFU-02

Visit <https://labproducts.caredx.com> for  
"Instructions for Use" (IFU)

Lot No.: **5H1**

Lot-specific information

## CERTIFICATE OF ANALYSIS

### Olerup SSP® HLA-B low resolution

**Product number:** 101.501-48/12 – including *Taq* pol.  
101.501-48u/12u – without *Taq* pol.  
**Lot number:** 5H1  
**Expiry date:** 2021-10-01  
**Number of tests:** 48 tests – Product No. 101.501-48/48u  
12 tests – Product No. 101.501-12/12u  
**Number of wells per test:** 63 + 1

#### Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2018-906-01	25	2018-906-25	49	2019-034-49
2	2019-034-02	26	2019-034-26	50	2019-034-50
3	2018-906-03	27	2018-906-27	51	2019-034-51
4	2019-034-04	28	2018-906-28	52	2019-034-52
5	2018-906-05	29	2018-906-29	53	2019-034-53
6	2018-906-06	30	2018-906-30	54	2019-034-54
7	2018-999-07	31	2018-906-31	55	2019-034-55
8	2018-906-08	32	2018-906-32	56	2019-034-56
9	2018-906-09	33	2018-906-33	57	2019-034-57A
10	2018-906-10	34	2018-906-34	58	2019-034-58
11	2018-906-11	35	2018-906-35	59	2019-034-59
12	2018-906-12	36	2018-906-36	60	2019-034-60
13	2018-906-13	37	2018-906-37	61	2019-034-61
14	2019-034-14	38	2018-999-38	62	2019-034-62
15	2018-906-15	39	2018-999-39	63	2019-034-63
16	2018-906-16	40	2018-906-40		
17	2018-906-17	41	2018-999-41		
18	2018-906-18	42	2018-906-42		
19	2018-906-19	43	2018-906-43		
20	2019-034-20	44	2018-906-44		
21	2018-906-21	45	2018-906-45		
22	2018-906-22	46	2018-906-46		
23	2018-906-23	47	2018-906-47		
24	2018-906-24	48	2018-906-48		

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.

**Date of approval:** 2019-05-22

**Approved by:** *Robert Salme*

#### Production Quality Control



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For *In Vitro* Diagnostic Use  
MA100 v02 CoA\_DoC IVD Annex II List B  
Date: April 2019, Rev. No: 00

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## Declaration of Conformity

**Product name:** Olerup SSP® HLA-B low resolution  
**Product number:** 101.501-48/48u, -12/12u  
**Lot number:** 5H1

**Intended use:** HLA-B low resolution histocompatibility testing

**Manufacturer:** Olerup SSP AB  
 Franzengatan 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 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: 2019-05-23

Terese Wasell  
 Head of Regulatory Affairs



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