101.401-48/12 – including *Taq* polymerase
101.401-48u/12u – without *Taq* polymerase

Visit www.caredx.com for "Instructions for Use" (IFU)

Lot No.: 3V2 Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-A low resolution

Product number: 101.401-48/12 – including *Taq* polymerase
101.401-48u/12u – without *Taq* polymerase

Lot number: 3V2

Expiry date: 2029-12-01

Number of tests: 48 tests – Product No. 101.401-48/48u
12 tests – Product No. 101.401-12/12u

Number of wells per test: 31 + 1

Well specifications:

Well No.	Production No.	Well No.	Production No.
1	2025-634-01	17	2025-643-17
2	2025-643-02	18	2025-643-18
3	2025-634-03	19	2025-643-19
4	2025-643-04	20	2025-643-20
5	2025-643-05	21	2025-643-21
6	2025-643-06	22	2025-643-22
7	2025-643-07	23	2025-643-23
8	2025-643-08	24	2025-643-24
9	2025-643-09	25	2025-634-25
10	2025-643-10	26	2025-634-26
11	2025-643-11	27	2025-643-27
12	2025-643-12	28	2025-643-28
13	2025-643-13	29	2025-634-29
14	2025-643-14	30	2025-634-30
15	2025-643-15	31	2025-634-31
16	2025-643-16		

The negative control primer pairs, **Production No. 2025-639-01**, can detect contamination with PCR products diluted 10^{-7}.

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

Date of approval: 2026-01-28

Approved by:

Romero

Production Quality Control

CE
0197
For *In Vitro* Diagnostic Use
MA100 v07 CoA_DoC IVD Annex II List B
Date: January 2026, Rev. No: 00

101.401-48/12 – including *Taq* polymerase
101.401-48u/12u – without *Taq* polymerase

Visit www.caredx.com for
"Instructions for Use" (IFU)

Lot No.: 3V2

Lot-specific information

Declaration of Conformity

Product name:	*Olerup* SSP® HLA-A low resolution
Product number:	101.401-48/48u, -12/12u
Lot number:	3V2
Intended use:	HLA-A low resolution histocompatibility testing
Manufacturer:	CareDx AB Franzéngatan 5 SE-112 51 Stockholm, Sweden ***Phone:*** +46-8-508 939 00 ***Fax:*** +46-8-717 88 18

We, CareDx 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 *CareDx* AB, Franzéngatan 5, SE-112 51 Stockholm, Sweden.

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

Notified Body: TÜV Rheinland LGA products, Tillystrasse 2, D-90431 Nürnberg, Germany. (Notified Body number: 0197.)

Stockholm, Sweden
Date:
2026-01-29

Quality Assurance

CE
0197
For *In Vitro* Diagnostic Use
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Date: January 2026, Rev. No: 00