

101.522-24/03 – including *Taq* pol., IFU-01
101.522-24u/03u – without *Taq* pol., IFU-02

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

Lot No.: **4H6**

Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP[®] HLA-B*35

Product number:

101.522-24/03 – including *Taq* pol.
101.522-24u/03u – without *Taq* pol.

Lot number:

4H6

Expiry date:

2021-09-01

Number of tests:

24 tests – Product No. 101.522-24/24u
3 tests – Product No. 101.522-03/03u

Number of wells per test:

94+1

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2018-931-01	33	2018-931-33	65	2018-931-65
2	2018-931-02	34	2018-931-34	66	2018-931-66
3	2018-931-03	35	2018-931-35	67	2018-931-67
4	2018-931-04	36	2018-931-36	68	2018-931-68
5	2018-931-05	37	2018-931-37	69	2018-931-69
6	2018-931-06	38	2018-931-38	70	2018-931-70
7	2018-931-07	39	2018-931-39	71	2018-931-71
8	2018-931-08	40	2018-931-40	72	2018-931-72
9	2018-931-09	41	2019-029-41	73	2018-931-73
10	2018-931-10	42	2018-931-42	74	2018-931-74
11	2018-931-11	43	2019-029-43	75	2018-931-75
12	2018-931-12	44	2018-931-44	76	2018-931-76
13	2018-931-13	45	2018-931-45	77	2018-931-77
14	2018-931-14	46	2018-931-46	78	2018-931-78
15	2018-931-15	47	2018-931-47	79	2018-931-79
16	2018-931-16	48	2018-931-48	80	2018-931-80
17	2018-931-17	49	2019-029-49	81	2018-931-81
18	2018-931-18	50	2018-931-50	82	2018-931-82
19	2018-931-19	51	2018-931-51	83	2018-931-83
20	2018-931-20	52	2018-931-52	84	2018-931-84
21	2018-931-21	53	2018-931-53	85	2018-931-85
22	2018-931-22	54	2018-931-54	86	2018-931-86
23	2018-931-23	55	2018-931-55	87	2018-931-87
24	2018-931-24	56	2018-931-56	88	2018-931-88
25	2018-931-25	57	2018-931-57	89	2019-029-89
26	2018-931-26	58	2018-931-58	90	2018-931-90
27	2018-931-27	59	2018-931-59	91	2018-931-91
28	2018-931-28	60	2018-931-60	92	2018-931-92
29	2018-931-29	61	2018-931-61	93	2018-931-93
30	2018-931-30	62	2018-931-62	94	2019-029-94
31	2018-931-31	63	2018-931-63		
32	2018-931-32	64	2018-931-64		



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For *In Vitro* Diagnostic Use
MA100 v04 CoA_DoC IVD Annex II List B
Date: June 2020, Rev. No: 01

101.522-24/03 – including *Taq* pol., IFU-01
101.522-24u/03u – without *Taq* pol., IFU-02

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Lot No.: **4H6**

Lot-specific information

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: 2020-06-29

Approved by:



Production Quality Control



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For *In Vitro* Diagnostic Use
MA100 v04 CoA_DoC IVD Annex II List B
Date: June 2020, Rev. No: 01

101.522-24/03 – including **Taq pol.**, IFU-01
101.522-24u/03u – without **Taq pol.**, IFU-02

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“Instructions for Use” (IFU)

Lot No.: 4H6

Lot-specific information

Declaration of Conformity

Product name: Olerup SSP® HLA-B*35
Product number: 101.522-24/24u, -03/03u
Lot number: 4H6

Intended use: HLA-B*35 high resolution histocompatibility testing

Manufacturer: CareDx AB
Franzengatan 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*, Franzengatan 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:

2020-06-29

Quality Assurance



Changes in revision R01 compared to R00:

1. Primer mix 93 may give rise to a lower yield of HLA-specific PCR product than the other HLA-B*35 primer mixes. A footnote for the correction above has been added under the specificity table.



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