

101.122-24/06 – including *Taq* polymerase  
101.122-24u/06u – without *Taq* polymerase

Visit [www.caredx.com](http://www.caredx.com) for  
“Instructions for Use” (IFU)

Lot No.: 1V5

Lot-specific information

## CERTIFICATE OF ANALYSIS

## Olerup SSP® DRB4

Product number:

101.122-24/06 – including *Taq* pol.

Lot number:

1V5

Expiry date:

2029-10-01

Number of tests:

24 tests – Product No. 101.122-24/24u

Number of wells per test:

6 tests – Product No. 101.122-06/06u

31+1

## Well specifications:

Well No.	Production No.	Well No.	Production No.
1	2024-616-01	17	2024-616-17
2	2024-616-02	18	2024-616-18
3	2024-616-03	19	2024-616-19
4	2024-616-04	20	2024-616-20
5	2024-616-05	21	2024-616-21
6	2024-616-06	22	2024-616-22
7	2024-616-07B	23	2024-616-23
8	2024-616-08	24	2024-616-24
9	2024-616-09	25	2024-616-25
10	2024-616-10	26	2024-616-26
11	2024-616-11	27	2024-616-27
12	2024-616-12	28	2024-616-28
13	2024-616-13	29	2024-616-29
14	2024-616-14	30	2024-616-30
15	2024-616-15	31	2024-616-31
16	2024-616-16		

The negative control primer pairs, Production No. 2025-632-01, can detect contamination with PCR products diluted 10<sup>-7</sup>.

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

**Date of approval:** 2025-10-20

**Approved by:**



Production Quality Control



0197

For *In Vitro* Diagnostic Use  
MA100 v07 CoA DoC IVD Annex II List B  
Date: October 2025, Rev. No: 00

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**Declaration of Conformity**

**Product name:** Olerup SSP® DRB4  
**Product number:** 101.122-24/24u, -06/06u  
**Lot number:** 1V5

**Intended use:** DRB4 high 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.

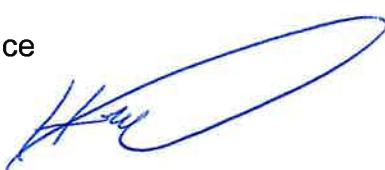
Notified Body: TÜV Rheinland LGA products, Tillystrasse 2, D-90431 Nürnberg, Germany. (Notified Body number: 0197.)

Stockholm, Sweden

Date:

2025-10-23

Quality Assurance



CE  
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