

101.803-01/101.804-01/101.805-01

Visit www.caredx.com for

Lot No.: **QW8**

"Instructions for Use" (IFU)

Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP® Master mix with Taq polymerase

Product number: 101.803-01/101.804-01/805-01

Lot number: QW8

Volume: Product No. 101.803-01 – 312 µl

Product No. 101.804-01 – 750 µl

Product No. 101.805-01 – 1125 µl

Expiry date: 2030-02-01

The Master Mix lot is tested against an older approved lot as reference. Typings with both Master Mix lots are performed with an HLA Class I and an HLA Class II kit.

Results: No false positive or false negative amplifications obtained. All amplifications are of similar strength and specificity.

Date of approval: 2025-12-10

Approved by:



Production Quality Control



101.803-01/101.804-01/101.805-01

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"Instructions for Use" (IFU)

Lot-specific information

Declaration of Conformity

Product name: Master mix with Taq polymerase
Product number: 101.803-01/101.804-01/101.805-01
Lot number: QW8

Intended use: Master mix for *Olerup SSP*® Typing Kits

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 III, 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.

Stockholm, Sweden

Date: 2025-12-15



Quality Assurance

