101.803-01/101.804-01/101.805-01
Lot No.: QW6

Visit www.caredx.com for
"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:	**QW6**
Volume:	**Product No. 101.803-01 – 312 µl**
	Product No. 101.804-01 – 750 µl
	Product No. 101.805-01 – 1125 µl
Expiry date:	**2029-02-01**

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: 2024-12-13

Approved by:

Romeo

Production Quality Control

CE

101.803-01/101.804-01/101.805-01
Lot No.: **QW6**

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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:	QW6
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: 2024-12-20

TU DU

Quality Assurance

CE