

101.803-01/101.804-01/101.805-01

Lot No.: QW8

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

Lot-specific information

**CERTIFICATE OF ANALYSIS****Olerup SSP<sup>®</sup> Master mix with Taq polymerase**

Product number: 101.803-01/101.804-01/101.805-01  
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



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Lot No.: **QW8**Visit [www.caredx.com](http://www.caredx.com) for  
"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

