



100-pack

P1001AD011



SalivaPOD™¹ - DNA/RNA for PCR

Saliva Collection of DNA/RNA for PCR analysis

WHEN SAMPLING TIME, CAPACITY, PATIENT
COMPLIANCE AND SENSITIVITY COUNTS

Intended Purpose (Area of Use)

"The SalivaPOD™ is a single-use device intended for use by a lay person for the collection and short-term storage of oral fluid specimens. The lay person may perform, or the healthcare professional performs, the transfer of the specimen into a transport culture medium, a buffer solution or one or more diagnostic reagents for further transport to a testing laboratory, or for immediate analysis and diagnostic use."



SalivaPOD™¹ - Collector and Injector





Description, information and benefits

- Minimizes work load for healthcare professionals and Test-and-Trace teams
- Substantial improvement of patient convenience and test-and-trace compliance
- Substantial reduction of need for PPE and work hours during sampling
- Easy-to-use for the home setting
- Standardizes saliva collection of DNA/RNA for PCR analysis - with controlled and precise titration of optimal volume of saliva prior to transfer/injection into a compatible 16mm diameter UTM vial, eliminating risk of cross contamination and false positive test results
- SalivaPOD™ can be used as an injector into other tubes /vials without the closed screw-fit connection

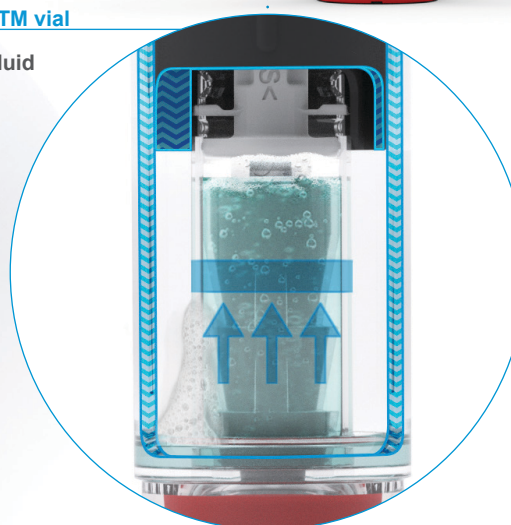
Structural design elements

- SalivaPOD™ Mouthpiece with structural filtering function supports pipetting with robot by allowing low viscosity saliva to enter the volume chamber
- 8 arrows and '360° Fill-to-Line mark' collects ca. 1 ml saliva, with air bubbles above line
- Over-flow threshold guarantees maximum 1.5 ml saliva may be injected into UTM vial
- Over-flow chamber is sealed off for transport, after push-down injection of fluid
- Re-usable, writeable label for multipurpose application
- Every label prepared with printed TWIN Unique QR code for integration with eHealth systems
- Easy-to-open IFU Package Insert with 14 languages
- Interactive eIFU SalivaCODE™ App with optional oral reading of text

Material specifications - technical info

Volume chamber:	 Transparent Polypropylene ²
Mouthpiece:	 ABS ²
Protection cap:	 Polycarbonate/ABS ²
Bottom screw cap:	 Polypropylene ²

Mouthpiece top part :	Female luer slip connector
Bottom Screw Threads:	Fits 16mm UTM® from Copan
Fill-to-Line (bubbles above line):	Approx. 1 ml saliva injected into vial
Over-flow threshold:	Max. 1.5 ml saliva injected into vial



Transfer saliva
through
mouthpiece

Fill-to-Line

Air bubbles
above line

= ca. 1 ml



SalivaPOD™¹ - Packaging, Details

Secondary packaging

Material Closed plastic bag with 100 pcs SalivaPOD in soft blister

100 x Primary packaging

Material High quality foil and Flexpeel® Tyvek 2FS CR27 - Strong material supporting proper storage and use

Blister Blister stays open and does not return to the initial configuration after opening (no memory).

1 x IFU paper insert for reference

About Paper Package insert 32 mm x approx 70 mm x 7 mm

Languages Norwegian, Swedish, Danish, Finnish, English, Spanish, German, French, Italian, Czech, Polish, Somali, Arabic

Content 1. Saliva sampling procedure
2. Transfer of saliva into a compatible laboratory vial

eIFU PRINT READY IFU (A4 size) can be downloaded from website ifu.salivapod.com for distribution
SalivaCODE App can be used as eIFU for the saliva collection procedure
eIFU and downloadable IFUs can be expanded with selected languages

100 x SalivaPOD™



Transport packaging - tertiary

Material Cardboard non bleached material. Outer dimensions are 305 mm x 205 mm x 222 mm

Label In the upper left corner of a short side on the tertiary box

Content P1001AD011 : 1 closed plastic bag (100 pcs SalivaPOD™ + 1 paper IFU) PRINT-ready eIFU access ONLINE

Pallets (EUR/EPAL)

Full pallet: 2 half-pallets, stacked
Size: 80cm x 120cm x 210cm

	Product description	Art.no	Quantity (cases x pcs.)	SalivaPODs per half-pallet	W cm	D cm	H cm	Weight (kg.)
Half-pallet	SalivaPOD™ 100 blister packs 1 IFU + eIFU access	P1001AD011	60 cases x 100	6 000	80	120	105	200

Attach the gray cap according to instructions

Push the gray cap to isolate saliva sample inside the inner chamber



Attach compatible UTM vial

Twist and completely press down the gray cap to transfer the saliva into the vial

If using SalivaCODE app for registration, transfer QR label to the laboratory vial



Unscrew the SalivaPOD™ and seal the UTM vial with the vial cap

Ready for professional PCR analysis



The True Potential of **SalivaPOD™**¹



Manufacturing capacity, origin

Designed in Norway by ConceptoMed AS - Manufactured and assembled in Sweden

If National Healthcare Authorities switch to saliva based mass screening, ConceptoMed can substantially **scale up capacity in a short time frame**



SalivaPOD™ as the core sampling device

SalivaPOD™ could be the **CORE DEVICE** of home based test-quarantine-trace programs

SalivaPOD™ can be used for **extremely efficient sample collection without the use of PPE and professional work-force in transport/entry points/university/school/work-place settings** as part of a test-and-trace programme

SalivaPOD™ screw-fits onto vials in broad use today

SalivaPOD™ **fits seamlessly into existing PCR based diagnostics hardware** compatible vials with 16mm x 100mm Universal Transport Medium tubes from e.g. COPAN



eIFU SalivaCODE™

Interactive App/eIFU guides the user to ensure optimal sampling quality

Printed text and optional oral reading of text

The App can quickly be expanded to include unlimited number of languages

Prepared for integration of QR code usage to link saliva specimen with National eHealth solutions and Test-and-Trace systems

WWW.SALIVAPOD.COM

© Designed in Norway - Manufactured in Sweden · SalivaPOD™ is a patent pending technology

1. CE marked, Class 1, single use, non-sterile medical device, according to MDR
2. Material Data Sheets on file - all materials are Medical Grade. No silicone oil or other additives

