



Single pack

P1001ADO01



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

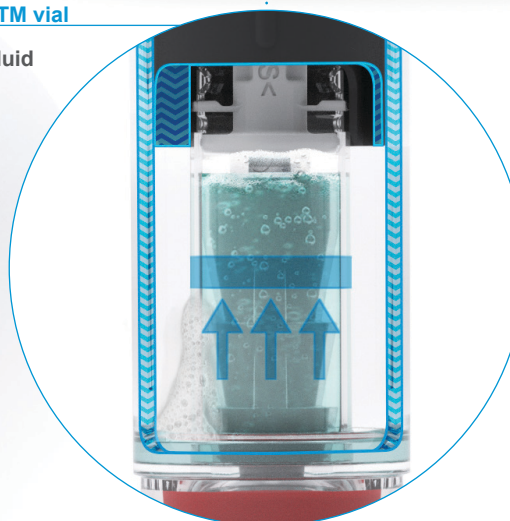
Structural design elements

- 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
- 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:	<input checked="" type="checkbox"/> Transparent Polypropylene ²
Mouthpiece:	<input type="checkbox"/> ABS ²
Protection cap:	<input checked="" type="checkbox"/> Polycarbonate/ABS ²
Bottom screw cap:	<input checked="" type="checkbox"/> 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

Single Pack Sec. packaging

- Material** Cardboard material. Outer dimensions are 39 mm x 38 mm x 145 mm
- Label** IFU and secondary label on the side of the secondary box
- Content in box** Primary packing with SalivaPOD™ IFU paper insert, 13 languages

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).

IFU paper insert

- About** Paper Package insert with alternative sticker label 32 mm x approx 70 mm x 7 mm
- Languages** Norwegian, Swedish, Danish, Finnish, English, Spanish, German, French, Italian, Czech, Polish, Somali, Arabic
- Content**
 - Saliva sampling procedure
 - Transfer of saliva into a compatible laboratory vial



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** P1001AD001 : 50 pcs of Secondary boxes (50 pcs single box SalivaPOD™ + paper IFU insert)
- Label** In the lower right corner of a short side on the tertiary box

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™ 1 blister pack 1 IFU	P1001AD001	60 cases x 50	3 000	80	120	105	105

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

