SALIVA POD®

Single pack - P1001AD001

100-pack - P1001AD011

SalivaPOD®[1]

Straw-based Saliva Collection for Optimal Assay Performance

WHEN SAMPLING TIME, CAPACITY AND PATIENT COMPLIANCE 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."

ConceptoMed

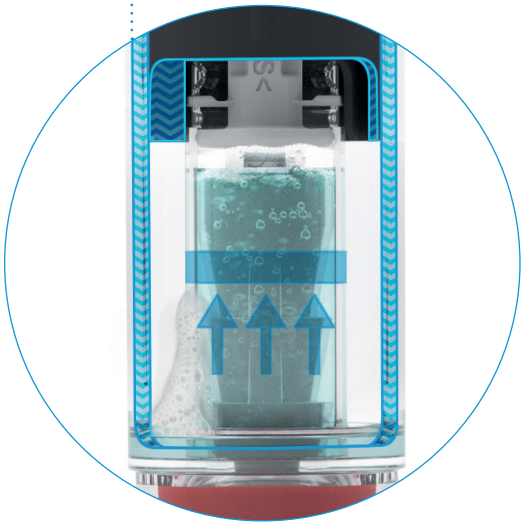
PDS-10-P1001CD019-001 SalivaPOD ENGLISH - 20230425

SalivaPOD®[1] - Collector and Injector

Description, information and benefits

- **Premium STRAW-based** saliva sampling device delivering **low viscosity samples**
- **Easy-to-use for the home setting**
- Standardizes saliva collection for delivery of **optimal assay performance in lab processing**
  - ► Low variance in saliva-to-preservative ratio due to c**ontrolled and precise titration of optimal volume of saliva**
  - ► **The closed system transfer to preservative tube eliminates risk of cross contamination and false test results**
- **Minimizes work load for healthcare professionals**
- Substantial **improvement of patient convenience**, compared to funnel based systems

Structural design elements



- The SalivaPOD™ Mouthpiece **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 1.4 ml saliva may be injected into 16 mm vial**
- Every label prepared with printed **TWIN Unique QR code for integration with eHealth systems**
- Easy-to-open **IFU Package Insert with 13 languages**
- Available interactive **eIFU SalivaCODE™ App** with optional oral reading of text
- Optional peel-off label on the IFU paper insert (single version only) for manual written marking of sample

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 tubes from Copan, BD ++
Fill-to-Line (bubbles above line):	Approx. 1 ml saliva injected into vial
Over-flow threshold:	Max. 1.4 ml saliva injected into vial

Primary device 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	Step 1. Saliva sampling procedure Step 2. Transfer of saliva into a compatible laboratory vial
eIFU	PRINT READY IFU (A4 size) can also 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

SalivaPOD®[1] - Content and Packaging

Single Pack

Secondary packaging

Material	Cardboard material. Outer dimensions: 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

Outer packaging (tertiary)

Material	Cardboard material. Outer dimensions: 300 mm x 207 mm x 217 mm
Label	Tertiary case label on the side of the tertiary box
Content in box	50 pcs SalivaPOD™ secondary pack, single-packs per case

100-pack

Secondary packaging

Material	Closed plastic bag with 100 pcs SalivaPOD in soft blister inside cardboard tertiary packaging (cardboard box)
IFU	1 pc IFU insert outside the secondary pack, for illustration Bundle of 100 pcs ”Quick-Guide for collection procedure” incl. by default (Norwegian + English)

Outer packaging (tertiary)

Material	Corrugated 3mm cardboard material. Outer dimensions: 300 mm x 207 mm x 217 mm
Content in box	1 sec.pack. bag of 100 pcs. SalivaPOD devices in primary packaging 1 single IFU for reference (outside sec.pack) Bundle of 100 pcs ”Quick-Guide for collection procedure” incl. by default (Norwegian + English)

User steps

SalivaPOD™ screw-fits onto vials in broad use today

SalivaPOD™ **fits seamlessly into existing diagnostics hardware** compatible vials (Ø 16mm tubes from e.g. COPAN, BD ++)

SalivaPOD®[1] - SKUs, Ordering details

	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
Half-pallet	SalivaPOD™ *100 blister pack* *1 IFU* *100 simple IFUs*	P1001AD011	60 cases x 100	6 000	80	120	105	155

Pallets (EUR/EPAL)

Full pallet: 2 half-pallets, stacked
Size: 80cm x 120cm x (105cm x 2)

Manufacturing - country of origin

Designed in Norway by ConceptoMed AS
Manufactured and assembled in Sweden

SalivaCODE™ - App service - Optional LIMS API

SALIVA CODE

Google Play

Available on the App Store

eIFU SalivaCODE™ is available

- Works with SalivaPOD™ QR codes.
- Interactive App/eIFU guides the user, ensuring optimal collection.
- Printed text/images/videos and optional oral reading of text
- Includes 13 languages today
- API available for integration of QR code usage to link saliva specimen with Laboratory Information Management Systems

SalivaPOD® is widely protected by granted and pending patents in USA, Canada, Europe, Asia

ConceptoMed

1. CE marked, Class 1, single use, non-sterile medical device, according to MDR. FDA listed as exempt device.
2. Material Data Sheets on file - all materials are Medical Grade.

FDA listed, reg.no: REN# 3013576743, ON# 10054844

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