INOOlab Capillary Blood Sample Collection Kit

for Vitamin D

SAMPLE COLLECTION KIT FOR
DRIED CAPILLARY BLOOD
FOR THE DETERMINATION OF
25-HYDROXY-VITAMIN D USING THE
„FluoBolt™-VITAMIN D“ MEF-FIA
FROM FIANOSTICS

FOR RESEARCH USE ONLY
NOT FOR USE IN DIAGNOSTIC PROCEDURES

CAT.NO. INO-2201B-R

FIANOSTICS
Fluorescence Immunoassays

rev.no. 260423

CONTENT

1) PURPOSE AND EXPLANATION

This product is used to collect a defined amount of capillary blood using the so-called "Volumetric Adsorptive Micro Sampling" (VAMS™) method of NEOTERYX LLC (Torrrance CA, USA). The blood sample is applied to a sponge on a sampling tip (MITRA™) which can hold a precisely defined amount of capillary blood (in this case 20 µl).

The sample is then dried at room temperature and sent to a specialist laboratory for the determination of 25-Hydroxy-Vitamin D using the FluoBolt™-Vitamin D fluorescence immunoassay (Cat No. FIA-1709) by FIANOSTICS (details on how to perform the test can be found in the instructions for use of FIA-1709).

2) CONTENTS OF THE KIT

- Collection unit: Mitra™ sampling tip in plastic housing with barcode. *Attention: The housing may vary in shape*
- Alcohol swab to disinfect the fingertip
- Gauze swab
- Band aid
- Desiccant bag
- Information sheet for the customer with QR-Code
- Declaration of consent
- Instructions for use for pharmacy and medical staff

3) MATERIALS REQUIRED BUT NOT SUPPLIED

- Lancets for perforation of the fingertip

4) COLLECTION OF CUSTOMER DATA

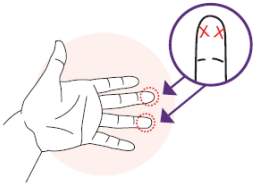
Open the grey resealable kit bag and remove the materials. Have the patient fill out and sign the consent form. **Put the consent form back in the bag.**

Hand the customer information to the test person and tell them to **keep it safe, as it contains the QR code for retrieving the results**, which can be used as an alternative to retrieving the results via e-mail link if the e-mail for retrieving the results has not been received.

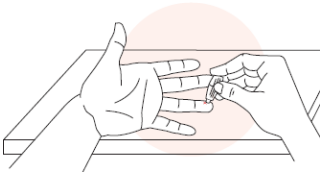
5) SAMPLING

5.1. Ask the subject to warm their hands by rubbing them together.

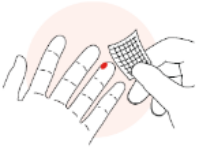
5.2. Select a finger for blood collection. Suitable places are marked in the adjacent graphic:



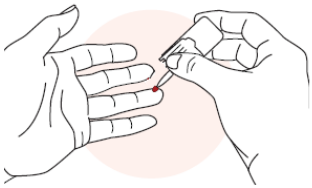
5.3. Disinfect the selected area with the alcohol swab and pierce the test person in the finger with a commercially available disposable lancet. To do this, place the test person's hand on a hard surface. Position the lancet on the side of the fingertip and penetrate the fingertip



5.4. Wipe away the first drop of blood with the gauze swab. It can take up to 20 seconds for a drop of blood to form. If necessary, gently massage the pierced finger upwards until a drop forms.



5.5. Collect the sample by touching the drop of blood with the tip of the sampling unit. First, wait until it turns completely red. Then count 2 seconds. Finally, slowly remove the tip from the blood. **You can touch the tip to the drop of blood several times to fill it.**



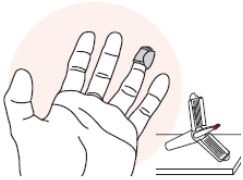
Stellen Sie sicher, dass die Probenahmespitze ordnungsgemäß gefüllt ist.

Eine unzureichende Entnahme tritt auf, wenn: 1) Die Probenahmespitze zu früh vom Blut gelöst wird. Halten Sie die Spitze solange an das Blut, bis keine weiße Stelle verbleibt. 2) Der Blutfluss stoppt. Wiederholen Sie in diesem Fall die Schritte 5.3.–5.5 mit der gleichen Spitze, bis diese völlig rot wird.

Übermäßige Entnahme | Unzureichende Entnahme | Ordnungsgemäße Entnahme

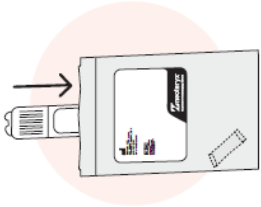
Eine übermäßige Entnahme tritt auf, wenn Blut von oben auf die Probenahmespitze tropft. Führen Sie die Spitze immer zum Blut, wie in Schritt 5.5 dargestellt.

5.6. Place the collection unit on a hard surface and apply the band aid to the subject's finger.



5.7. Close the dispenser by lifting the sides until they touch at the top. Press them together until you hear a click.

5.8. Insert the sampling unit into the resealable sample bag and close it with the adhesive tape. Make sure the desiccant is still in the bag.



5.9. Store the sample bag at room temperature (18-25°C) for a maximum of 3 days. Then send the sample to FIANOSTICS GmbH, Viktor Kaplan Strasse 2, Object E, 2. Floor, 2700 Wiener Neustadt using the carrier of your choice.

6) NOTES

Intended application: The INOOlab Capillary Blood Sample Collection (BSC) Kit is a non-sterile disposable product that serves as a sampler and sample container for the storage and transport of blood or other biological fluids by means of the so-called Mitra unit of Neoteryx, LLC.

Intended User: The INOOlab Capillary Blood Sample Collection (BSC) Kit is intended to be used exclusively by laboratory, pharmaceutical and health professionals as a container for the collection and transport of blood.

7. LITERATURE

Quantification of 25-hydroxyvitamin D2 and D3 in Mitra® devices with volumetric absorptive microsampling technology (VAMS®) by UHPLC-HRMS for regular vitamin D status monitoring
Tuma C et al., J Pharm Biomed Anal, 2023 May 10;228:115314. doi: 10.1016

Assessment of vitamin D status using Mitra™ volumetric absorptive microsampling (VAMS) device
Tang J.C. et al., 9 Sep 2017, ASBMR 2017 Annual Meeting - United States

Development of a quantitative LC-MS/MS analysis for measurement of circulating 25-hydroxyvitamin D using Volumetric Absorptive Microsampling (VAMS). Ball N. et al, Mass Matters. 18-21. 2017

Vitamin D testing and treatment: a narrative review of current evidence. Pilz S. et al. Endocr Connect. 2019 Feb 1;8(2):R27-R43. doi: 10.1530/EC-18-0432

Vitamin D status in healthy populations worldwide: a systematic review protocol. Dunlop E. et al. JBI Evid Synth. 2023;10.11124/JBIES-22-00354. doi:10.11124/JBIES-22-00354

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