INOOlab Capillary Blood Sample Collection Kit

for COVID-19 Antibodies

SAMPLE COLLECTION KIT FOR
DRIED CAPILLARY BLOOD
FOR THE DETERMINATION OF
ANTIBODIES AGAINST SARS-CoV-2
USING THE "Cov19 FluoBolt ™ -DUO-SN"
MEF-FIA FROM FIANOSTICS

FOR RESEARCH USE ONLY

NOT FOR USE IN DIAGNOSTIC PROCEDURES

CAT.NO. INO-2201A-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 antibodies against SARS-CoV-2 using the Cov19 FluoBolt ™-DUO SN fluorescence immunoassay (Cat No. FIA-1708-C5) by FIANOSTICS (details on how to perform the test can be found in the instructions for use of FIA-1708-C5).

A list of specialist laboratories that can carry out this test can be requested from FIANOSTICS via email (office@fianostics.at).

2) CONTENTS OF THE KIT

- Collection unit: Mitra™ sampling tip in plastic housing with barcode. *Attention: The housing may vary in shape*
- Alcohol swabs to disinfect the fingertip
- Band aid
- Desiccant bag
- Information sheet for the customer
- Instructions for use for pharmacy staff

3) MATERIALS REQUIRED BUT NOT SUPPLIED

- Lancets for perforation of the fingertip

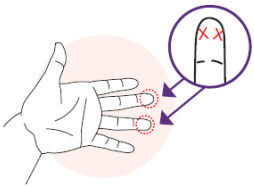
4) COLLECTION OF CUSTOMER DATA

Scan the barcode or type the 10-digit number into the portal (https://inoolab.onlinebefunde.com/erfassung) provided by us and enter the required customer data.

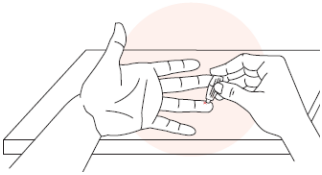
5) SAMPLING

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:

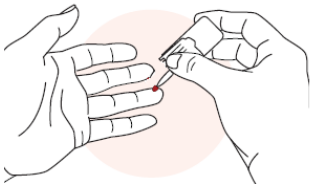


5.3. Disinfect the selected area with the alcohol swab and pierce the test person in the finger with a commercially available disposable lancet. To do this, place the test person's hand on a hard surface. Position the lancet on the side of the fingertip and penetrate the fingertip.



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.**



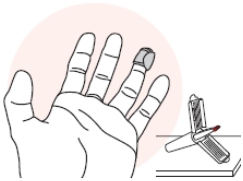
ensure sampling tips are filled correctly

Under-sampling occurs when: 1) The sampling tip is removed from the blood too soon. Touch tip to blood until no white remains. 2) Blood flow stops. If this happens, repeat steps 4-6 with same tip until it turns fully red.

over-sampled | under-sampled | correctly sampled

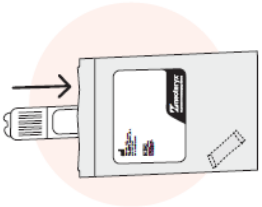
Over-sampling occurs when blood is dripped onto the sampling tip from above. Always touch sampling tip to blood drop as shown in step 5.5.

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) until it is collected by FIANOSTICS or by a courier appointed by FIANOSTICS for proper processing in the laboratory.

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 and health professionals as a container for the collection and transport of blood or other biological fluids.

7. LITERATURE

Volumetric absorptive microsampling: its use in COVID-19 research and testing.
Rudge J, Kushon S.Bioanalysis. 2021 Dec;13(24):1851-1863

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Wang J, Li D, Zhou Q, Wiltse A, Zand MS. Front Immunol. 2021 Jul 27;12:696370**.**

Microsampling: A role to play in Covid-19 diagnosis, surveillance, treatment and clinical trials.
Rajadhyaksha M, Londhe V.Drug Test Anal. 2021 Jul;13(7):1238-1248.

Whole blood stability evaluation of monoclonal antibody therapeutics using volumetric absorptive microsampling.
Li H, Myzithras M, Bolella E, Leonard A, Ahlberg, J.Bioanalysis. 2021 Apr;13(8):621-629.

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Harahap Y, Diptasaadya R, Purwanto DJ.
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Quantitative microsampling for bioanalytical applications related to the SARS-CoV-2 pandemic: Usefulness, benefits and pitfalls.
Protti M, Mandrioli R, Mercolini L, J Pharm Biomed Anal. 2020 Nov 30;191:113

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