

2024-08-29

→REF KST80100EP (UDI-DI: 04050598009592) | KST80100G5 (UDI-DI: 04050598009608) | KST80100GP (UDI-DI: 04050598009615)

Intended purpose

The collection set is an *in-vitro* diagnostic intended for the collection of capillary blood from the fingertip and the following application of the blood onto a filter paper within the test letter as well as the subsequent dispatch of the dried blood sample to a professional laboratory. The collection set is intended for the safe collection and shipment of blood samples for the subsequent determination of 25(OH)-vitamin D in a professional laboratory. The collection set is suitable for use by laypersons from 18 years old and is intended for single use.

Included materials

KST80100EP (1 set) | KST80100G5 (5 sets) | KST80100GP (20 sets)

1 | 5 | 20 **sampling devices**
SAMPLING DEVICE

Immundiagnostik AG,
Bensheim, Germany



1 | 5 | 20 **alcohol pads**
WIPE C E

B. Braun Melsungen AG,
Melsungen, Germany



2 | 7 | 22 **lancets**
LANCET

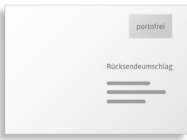
Sarstedt AG & Co.,
Nümbrecht, Germany
C E 0124 STERILE R



1 | 5 | 20 **plasters**
PLASTER C E

BSN medical GmbH,
Hamburg, Germany

1 | 5 | 20 **envelopes**



1 | 5 | 20 **desiccant bags**

Important notes

- Read and follow the test instructions carefully.
- Remove test components only when using them immediately.
The pressure seal bag containing the test components contains a desiccant bag that should remain permanently in the pressure seal bag. Please do not open the desiccant bag. It is used to protect the sample from humidity during transport and must therefore remain in the pressure seal bag. Open the pressure seal bag as briefly as possible and remove the components with the exception of the desiccant bag. After taking the sample, put the test letter with completely dried sample back into the pressure seal bag, in which the desiccant bag is also located, and close it carefully. This is the only way to ensure that your sample reaches the laboratory dry. High humidity can falsify the test result!
- Put a clean disposable cloth ready (e.g. handkerchief, kitchen roll).
- Serious incidents must be reported to **Immundiagnostik AG** and the national regulatory authorities.

Sample extraction

1. Label the sampling device in block letters on the front page with the requested information and sign the Data Privacy Policy.
2. **Capillary blood sampling**
Note: Please ensure good blood circulation in your hands. For this purpose, you can, for example, lightly massage your hands or circle your arms for a few seconds.
 - a. Wash your hands with soap and warm water and wipe them with a clean, dry towel.
 - b. Remove the lancet from the bag, put lancet and alcohol pad ready.
 - c. Prepare lancet: Turn the yellow protection pin clockwise and remove it.
 - d. Massage the fingertip and wipe it with an alcohol pad. Wait until the fingertip is dry. Press the lancet with the unsecured end firmly onto the side of the fingertip and then press the yellow release button.
Wipe off the first drop of blood with a clean cloth. Point the hand with the punctured finger downwards and gently squeeze the finger in direction of the fingertip to ensure sufficient capillary blood flow.
 - e. Hold the finger over the provided circular and pre-punched sample window (spot) and let the blood drop directly from the finger in the spot (Fig. 1) until it is filled. The size of the spot is selected to absorb 50 µl of blood. That is why it is important to drain as much blood, that the spot is completely filled with capillary blood.
3. Air-dry the test for **at least 60 minutes**, then put it together with the desiccant bag into the provided resealable bag. **Please note:** Do not expose the sampling device to direct sunlight! **Do not dry on radiators!**

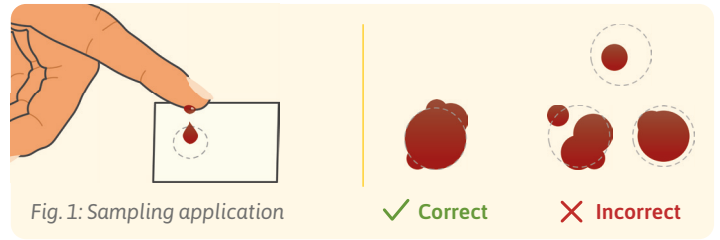


Fig. 1: Sampling application

✓ Correct

✗ Incorrect

4. Clean all contaminated surfaces carefully. Dispose all test components in conventional garbage. Treat all materials and specimens used as potentially infectious and dispose of them according to regulations.
5. Send the sampling device (together with the desiccant bag) in a closed envelope within the next **48 hours** to the laboratory.
6. The sample is analyzed in the laboratory. You will receive the results by mail from **Preventis GmbH**.
7. If you have any questions please contact **Preventis GmbH**.

Test characteristics

Measuring range: The test measures vitamin D in a concentration range of 2,3 to 150 ng/mL.

Interferences: The test shows no interferences with biotin.

The evaluation of the **PreventID® Vital-D** is performed with the modified ELISA diagnostics specifically developed for dry blood samples by **Immundiagnostik**. We assume no responsibility for the correctness of results gained with other assays.

REV	Changes	Date
003	Graphical adaptations. Intended purpose: Restriction of the intended users.	2024-08-29

CE IVD

Temperature limit

Manufacturer

STERILE R Sterilized using irradiation

LOT Batch number

REF Catalogue number

→REF To be used with

Use by

Follow test instructions

Σ n Contents sufficient for <n> tests

Not reusable

Keep away from sunlight

In vitro diagnostic device: only to be used outside of the body

Contains human blood or plasma derivatives

UDI Unique device identifier



PREVENTIS

Vertrieb/Distribution:

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