

Capitainer®DIP70

INSTRUCTIONS FOR USE

Valid for article numbers: 310-0001 (Single Device)
and 310-0050 (50 pcs box)

Intended purpose:

The Capitainer®DIP70 device is used to collect and store a defined urine volume as a dried sample for future analysis.

Introduction:

The intended users are healthcare professionals or laypersons. The sampling card is dipped in urine. Each sample disc absorbs and stores 70 µl of a urine sample. The sampling card is placed in the drying pouch and sent to the lab for analysis.

Provided by Capitainer:

Capitainer®DIP70 Sampling device: A sampling card (a) and drying pouch (b).

Recommended materials, not provided by Capitainer:

Sample ID, sample container*, absorbent paper. Follow the instructions provided by the manufacturers for all materials used. **Ensure that the urine sample container has dimensions that allow for convenient immersion of the sampling card.*

Product performance:

The product generates 2 x 70 µl of dried urine sample with a volume precision of <6% CV and a relative bias of <5% compared to the reference method.

Product storage and handling:

Storage conditions before use: Store at 15°C-28°C with a relative humidity of 15%-70%. Avoid exposure to direct sunlight and moisture. Unopened packages remain stable under these conditions until the expiration date printed on the label.

Device performance is guaranteed under the following conditions: temperature between 15°C and 35°C, and relative humidity between 15% and 90%.

Post-sampling transport:

Each analyzing laboratory is responsible for validating appropriate shipping conditions for the analytes under investigation. Our paper-based shipping method is designed to reduce waste and minimize the carbon footprint of your workflows. However, for sensitive analytes, aluminum-coated plastic bags and desiccant pouches may be required.

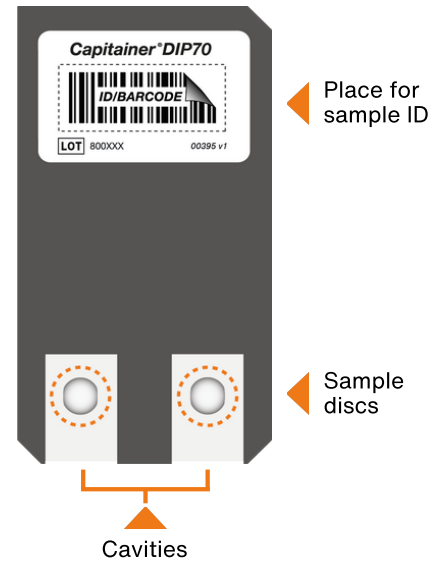
Cautions during sampling:

- Do not touch the sampling discs or the sample cavities.
- Check that the expiration date has not passed.
- Ensure to collect enough urine in the sample container so that the sample cavities can be fully immersed before dipping.
- Make sure to firmly tap the dipped end on an absorbent paper three times to remove any excess liquid.
- Any serious incident involving the medical device must be reported to Capitainer AB and the relevant authority in the Member State where the user or patient resides.

Waste disposal:

All used materials must be handled and disposed of according to local regulations.

Sampling card (a).



Drying pouch (b).



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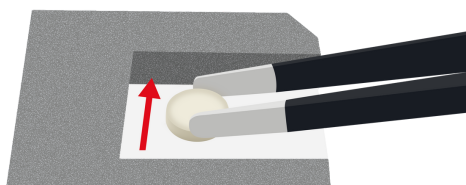


Sample preparation and downstream analysis:

Take out the sampling card (a) from the drying pouch (b). Visually confirm that the discs are attached to the card and that the samples are fully dried. The drying time can vary based on the environment.

For disc removal you may use Capitainer's semi-automated bench top instrument PH96, or remove them manually using Capitainer's MH1t or tweezers.

For manual removal, always use tweezers with flat tips. Place the card on a flat surface with the sample disc facing upward and the cavities positioned to the side. Grip the disc on both sides at the cavity opening and gently slide it towards the inner wall of the cavity until it detaches.



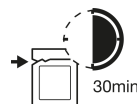
After removing the sample disc, proceed with sample elution. The choice of elution protocol and buffer depends on the analyte and the downstream analysis platform. Published methods for conventional DBS samples are also applicable to Capitainer's sampling products and can serve as a guideline.

Read more at <https://capitainer.com>

The laboratory conducting the analysis is responsible for validating the assay results against gold standard methods.

Cautions during laboratory use:

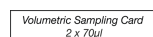
- Take general safety precautions when handling urine
- Note that the device is only validated for use with urine.
- Make sure the sample disc is completely dry before analysis. A wet disc might not detach correctly from the card. It is recommended to let the sample dry overnight.

Symbols and Explanations:

Use the card within 30 minutes of opening the package.



Place for sample ID.



Volumetric sampling card 2 x 70µl.

Before you start:

- Read through the full instructions.



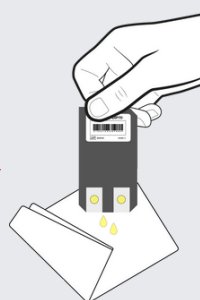
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Hold the device upright and immerse both sample discs **once only** for **5-10 seconds** in the urine, just until the cavities are fully covered.

2

X3



Remove the device from the urine sample and tap the dipped end firmly on the absorbent paper three times to remove excess liquid.

3



Place the sample ID in the designated area on the sampling card (a).

4



Place the card back into the drying pouch (b) and close the opening with the flap. Return the pouch to the laboratory.

