neoteryx by TRAJAN

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Instructions for Use

Staza™ Device (IVD)

These instructions apply to the following Staza™ Device configurations:

- Staza Device in Specimen Bag with Dessicant

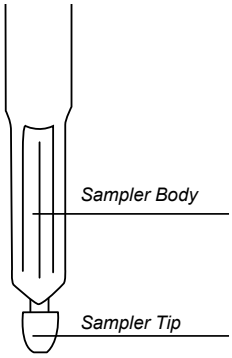
IMPORTANT – Read the entire instructions before use!

Intended Use:

A single-use, non-sterile device intended to contain biological specimens from ex-vivo sources for transport and storage in order that the matter contained therein can be archived and/or used effectively for diagnostic examination.

Device Description:

The intended user is a healthcare professional or a layperson. The biological specimen is typically taken from a container (e.g., tube, cup). Each sampler tip (contained within the Staza Device) is gently applied to the ex-vivo sample for 12 seconds in total. This process is repeated for each sampler tip in the device. Once all sampler tips have been filled, the device outer housing is clicked closed to secure the sample(s).



Materials Provided:

- Staza Device
- Specimen Bag with Desiccant
- Sample ID Barcode (if requested)

Product Specifications:

- Sample Type: Biological fluids
- Sample Volume: 20, or 30 µL
- Substrate: Hydrophilic porous polymer
- Volumetric Precision (%RSD): ≤ 5%
- Typical sampling time (per sampling tip): 12 sec
- Number of Samples Collected: Up to 4
- Shelf Life: Refer to expiry date on product label
- Device Storage: Up to 30°C
- Sample Storage: The guidelines for sample storage are analyte dependent and will need to be determined by device end-user

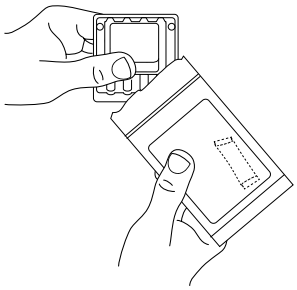
Warnings and Precautions:

- Single use only for a single individual.
- Do not use after expiration date.
- For external use only.
- Devices should be transported/mailed to the analytical laboratory, and appropriate documentation maintained according to local regulations and the analytical laboratory procedures and policies.
- Do not use if device packaging has been opened or damaged.
- Laboratories must validate use of product for their specific assay.
- Observe universal biological risk precautions.
- All used materials with biological residues must be handled with care and disposed of safely in accordance with local regulations.
- Any serious incident in relationship with the Staza device should be reported as soon as possible to Trajan Scientific and Medical (neo.support@trajanscimed.com) and the competent authority of the Member State in which the user and/or subject is established.
- Please reach out to neo.support@trajanscimed.com in case of multiple under-sampling events.

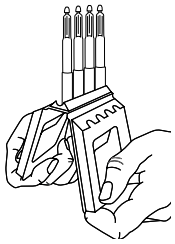
Electronic IFU can be accessed at www.neoteryx.com/collect or scan the QR code to access.

Instructions for Sampling:

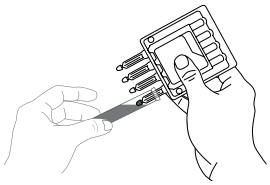
1. Tear open the specimen bag using the pre-slit notch. Remove the device from the specimen bag. Do not remove the desiccant from specimen bag.



2. Open the device by pulling tabs on device apart from each other until the two flaps are folded downwards. **NOTE**: Do NOT remove sampler tips from sampler bodies. Do NOT remove sampler bodies from device.



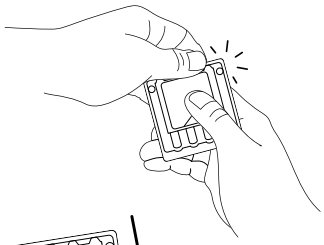
3. **Touch sampler tip to surface of specimen.** Count 12 seconds and remove from specimen. It is OK to apply the sampler tip to the specimen several times to fill the sampler tip.



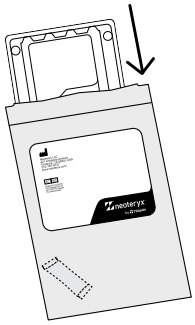
IMPORTANT!

- **Do NOT fully submerge the sampler tip in the specimen.**
- **Sampler tip should always point downward towards floor as illustrated.**
- **Do NOT drip specimen onto the sampler tip**
- **Ensure sampler tips are filled correctly (Figure 1).**

4. Repeat step 3 with remaining samplers in device.

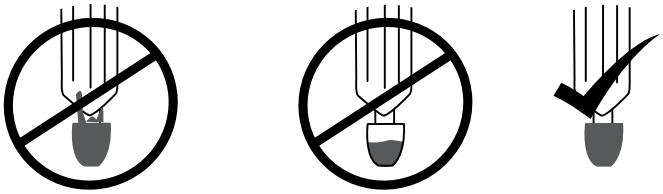


5. Close device by lifting the flaps to meet at the top. Press together the two tabs.



6. Insert device into the specimen bag and seal shut. Ensure the desiccant is still in the bag.

Ensure sampler tips are filled correctly.



Over-sampling occurs when:
1. Specimen is dripped onto the sampler tip from above.
2. The entire sampler tip is submerged in the specimen.

Under-sampling occurs when:
1. The sampler tip is removed from the specimen too soon. Touch tip to specimen for 12 seconds in total.
2. Refer to Warnings and Precautions section in case of multiple under-sampling events.

Correctly sampled

Figure 1

For further assistance, please do not hesitate to contact us: neo.support@trajanscimed.com

Specifications are subject to change.

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