

TECHNICAL SUPPORT

For technical assistance, please contact our Technical Services Department at (859) 254-1221 or email at techservice-toxicology@neogen.com. Representatives are available Monday – Friday from 8:00 am – 6:00 pm EST.

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NEOSAL® ORAL FLUID COLLECTION SYSTEM

COLLECTOR INSTRUCTIONS PRODUCT #128101 & 128101–25 (25 PACK)

FORENSIC USE ONLY

INTENDED USE: The NeoSal Oral Fluid Collection System is intended for the collection and transportation of oral fluid specimens collected from between the cheek and gum. This device is intended for Forensic Use Only and is not intended for home use.

Oral fluid samples collected with the NeoSal Oral Fluid Collection System can be screened for drugs of abuse using Neogen designed ELISA test kits or other drug monitoring kits validated by the testing laboratory.

DESCRIPTION

The NeoSal Oral Fluid Collection System consists of an absorbent pad (Collection Pad) affixed to a plastic handle and a proprietary buffer solution in a plastic tube (Buffer Tube). The Collection Pad contains no artificial stimulants to induce oral fluid production. NeoSal incorporates a Sample Volume Adequacy Indicator (SVAI) built into the device to ensure a suitable volume of oral fluid is collected. The Buffer Tube contains a preservative buffer solution designed for excellent recovery of drug analytes from the Collection Pad as well as ensuring stability of the sample during transportation and storage.

The unique design of the white NeoSal handle allows for easy removal of the Collection Pad at the laboratory by allowing the pad and handle to be discarded. No additional steps are required to separate the pad from the handle or to use filters, plungers or centrifugation to prepare the sample. The unique design of the NeoSal Buffer Tube allows the blue cap to be stored in the bottom of the Buffer Tube for easy access at the time of laboratory processing. The convenient tube size allows the NeoSal Buffer Tube to be directly loaded onto most 12 x 75 automated instrument sample racks, eliminating the laboratory's requirement to transfer the sample to a secondary tube for sample processing.

PRINCIPLE OF THE NEOSAL ORAL FLUID COLLECTION SYSTEM

The NeoSal Collection Pad is placed between the cheek and gum which enhances the flow of oral fluid onto the absorbent Collection Pad.

After collecting the sample, the saturated Collection Pad is inserted into the Buffer Tube and the handle is tightly screwed into the Buffer Tube. The sample is then ready to be transported to a laboratory for processing and testing.

The proprietary buffer is specifically designed to achieve excellent recovery of drug analytes from the Collection Pad. The use of additional filters, plungers and centrifuges is not required.

STORAGE OF UNUSED NEOSAL ORAL FLUID COLLECTION DEVICES

Store unopened NeoSal Oral Fluid Collection Devices at room temperature (18-25°C). Do not store in direct sunlight.

MATERIALS PROVIDED

1. **Oral Fluid Collection Device** (white handle) – Highly absorbent/stimulant free Collection Pad and Sample Volume Adequacy Indicator (SVAI) built into the device.
2. **Buffer Tube** (blue cap) – Containing 2.1 mL of proprietary blue colored buffer designed for maximum stability and extraction of drug analytes from the Collection Pad. Note: The blue cap for the Buffer Tube is designed to be stored in the bottom of the tube after opening. The blue cap is for use by the laboratory. Do not discard.

MATERIALS NEEDED BUT NOT PROVIDED

1. Timer
2. Disposable gloves

OPTIONAL MATERIALS (FOR LABORATORY USE)

1. NeoSal Buffer – Additional buffer can be purchased separately for use by the laboratory.
2. Buffer Tube caps (blue) – Additional Buffer Tube caps can be purchased separately by the laboratory.

WARNINGS AND PRECAUTIONS

1. Collection Device and Buffer Tube are for single use only.
2. Donor should not consume blue-colored liquid provided in buffer tube.
3. Used collection device(s) and samples should be treated as potentially hazardous/infectious and handled appropriately.
4. Collection Device is provided in non-sterile form.
5. Avoid contamination of the Collection Pad and buffer solution with foreign matter and always wear gloves during the collection process.

WARNINGS AND PRECAUTIONS CONTINUED

6. Donor should not eat, drink or chew gum 15 minutes prior to use.
7. Do not use the Collection Pad if the package has been previously opened.
8. Do not use if Collection Pad is wet.
9. Do not use if the Buffer Tube is empty or has been damaged.
10. Do not use Collection Device beyond the expiration date printed on the pouch.
11. During sample collection, ensure that the donor does not chew or suck on the absorbent collection pad.
12. If the sample collection has not been completed within 10 minutes, discard the device. If an additional sample collection is required, use a new Collection Device and have the donor wait 15 minutes before starting the collection process again.
13. Screening of the oral fluid samples collected using the NeoSal Oral Fluid Collection System can be performed using Neogen Corporation's ELISA test kits. Use with other assays must be properly validated by the laboratory conducting the testing.

DIRECTIONS FOR USE

Please read the complete instructions before proceeding to collect oral fluid using the NeoSal Oral Fluid Collection System. Failure to follow these instructions carefully could produce less than satisfactory results.

1. Prior to collection:
 - a. The donor should wait at least 15 minutes after ingesting any food, liquids or chewing gum/candies before collecting a sample.
 - b. Check expiration date on the NeoSal package. Do not use device beyond expiration date.

- c. Record donor information on the Buffer Tube label or follow the donor identification and chain of custody procedures provided by the testing laboratory.

2. Open package and remove Collection Pad by white handle. Do not touch the Collection Pad. (Figure 1) The Sample Volume Adequacy Indicator (SVAI) will have a visible line in the clear plastic window prior to collection of sample. This line will turn distinctly blue when sufficient sample has been collected. (Figure 2)
3. For best results, pool saliva in the mouth. Then, insert the end of the Collection Pad into the saliva pool between the cheek and gum line. (Figure 3) The donor should not talk or bite the device during collection.
4. The donor should keep the Collection Pad in mouth until the Sample Volume Adequacy Indicator (SVAI) forms a distinct blue line across the clear plastic window. Typical collection time is 1-2 minutes; some donors will take up to 10 minutes to collect sufficient sample volume. The Collection Pad can be periodically removed to check the SVAI, but immediately return to the mouth and continue with collection until a distinct blue line forms in the clear window. (Figure 4)
5. Remove the Buffer Tube from the packaging and hold in an upright position. Unscrew the blue cap from the Buffer Tube to open. Push the blue cap into the bottom of the tube for storage. Do not discard the cap. Do not spill or remove the fluid from the tube. After sufficient oral fluid has been collected, insert the Collection Pad into the tube and screw the white handle tightly into the tube. (Figure 5)

6. After the Collection Pad has been secured in the Buffer Tube, gently invert the tube 4 or 5 times to thoroughly distribute the buffer solution into the collection pad. The sample is now ready for shipment to a testing laboratory. (Figure 6)

STORAGE AND TRANSPORTATION OF ORAL FLUID SAMPLES

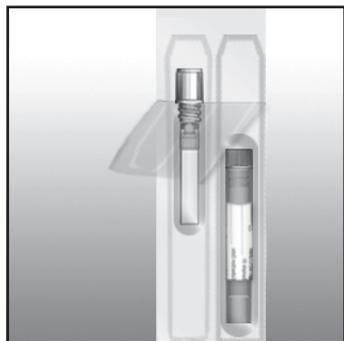
Collected samples must be stored and transported in the Buffer Tube with the blue cap inserted firmly in the bottom of the tube.

PERFORMANCE CHARACTERISTICS AND SPECIFICATIONS

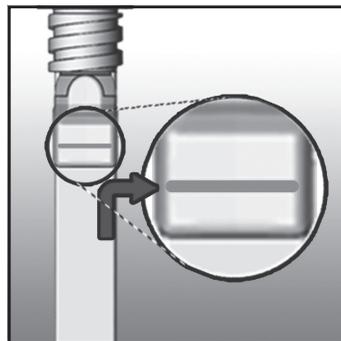
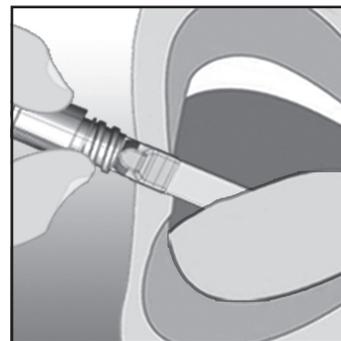
Neogen's Oral Fluid ELISA assays can accurately and reliably detect drugs of abuse in samples collected with the NeoSal Oral Fluid Collection System. Independent laboratory studies have shown there is good agreement between assay results and confirmation testing by GC/MS or LC/MS/MS.

ORAL FLUID COLLECTION SYSTEM ORDERING INFORMATION

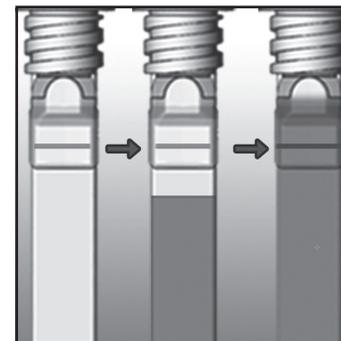
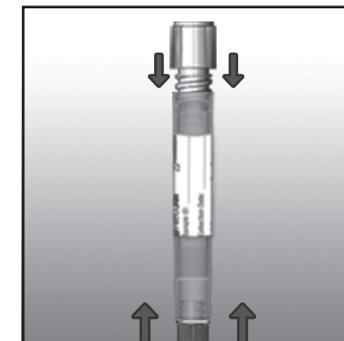
Product	Product #	Size
NeoSal Oral Fluid Collection System	128101-25	25 pack
NeoSal Buffer	120176 120177	500 mL 1L
Buffer Tube caps	128102-25 128102-50	25 pack 50 pack

FIGURE 1


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FIGURE 2

FIGURE 3


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FIGURE 4

FIGURE 5


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FIGURE 6
