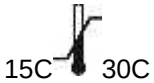
# VioOne™ Sample Collection Device

## Key Symbols Used

| | | | |
|---|---|---|---|
|  | Catalogue Number |  | Consult Instructions For Use |
|  | Batch Code |   | Temperature Limit |
|  | Expiration Date |  | Keep Away from Sunlight |
|  | Do Not Reuse | | |

**INTENDED USE**

The VioOne™ Sample Collection Device is used for the collection, storage, transport, and processing of samples including oral fluid specimens.

This in vitro diagnostic device is intended for prescription use only.

## Summary and Explanation of the VioOne™ Sample Collection Device

Oral fluid is described as the combination of glandular and cellular material present in the oral cavity. Oral fluid samples have been used in various applications including the assessment of therapeutic drug levels, monitoring of drugs of abuse and infectious disease diagnosis including HIV.

Oral Fluid samples are readily accessible and allow for observable collection eliminating privacy issues and the chance for sample adulteration.

The VioOne™ device not only collects oral fluid samples, but has a built in design to allow processing of samples without the need of additional equipment or materials. The Device is supplied as a **Sample Collection Unit** and a **Sample Collection Tube** containing **Sample Collection Buffer**. The oral fluid sample is collected by allowing oral fluid to accumulate in the mouth then running the Sample Collection Unit pad along the upper and lower gum line, across the inside of the cheeks, and under the tongue, to soak up the accumulated fluid and collect cells.

The Sample Collection Unit is then inserted into the Sample Collection Tube and screwed on, thereby placing the sample containing pad into the Sample Collection Buffer. VioOne™ will be shipped as one unit to the laboratory for processing. Once at the laboratory, the collection pad will be removed from the Sample Collection Tube by unscrewing the red cap and pulling the rod with attached pad through the narrow passage of the Sample Collection Unit. The sample/buffer mix will wring out into the Sample Collection Tube which can be capped and stored until testing.

## Materials:

Sample Collection Device:

The Sample Collection Device is supplied in two parts:

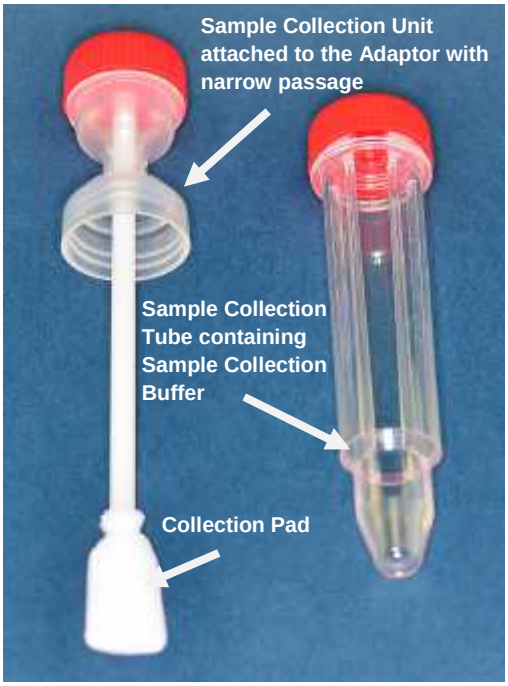
1. The **Sample Collection Unit** (used to collect the sample), composed of the Collection Pad, Rod, Adaptor with narrow passage, and Screw Cap is supplied individually wrapped.

2. The **Sample Collection Tube** contains 1.0 mL of Sample Collection Buffer and Screw Cap. Sample Collection Buffer is composed of Citrate Buffer, non-ionic surfactant, and 0.1% ProClin 950 as preservative.

Accessory Items:

Extra **Caps** are supplied for capping the Sample Collection Tube after sample processing is complete.

**Figure 1**




No additional materials or equipment are required to collect or process the sample.

## WARNINGS AND PRECAUTIONS

- Read the entire Package Insert prior to the collection and testing of Oral Fluid Samples. Optimal results will be obtained by strict adherence to this protocol. Accurate and precise pipetting, as well as following the exact time and temperature requirements prescribed are essential. Any deviation from this may yield invalid data.
- Do not open any of the packaging until ready for use.
- Handle samples and materials contacting samples as potentially infectious biological materials in accordance with “Universal Precautions for the Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus and Bloodborne Pathogens in Health-Care Setting” (CDC, Administration).
- Occupational Safety and Health Administration (OSHA) regulations apply to personnel collecting and handling samples.
- Sample Collection Devices are breakable and care should be taken when handling.
- Do not touch the pad at the end of the Sample Collection Unit.
- Do not use the Sample Collection Device if packaging has already been opened or appears damaged.
- Do not use the Sample Collection Device past the expiration date on the outer package(s).
- Federal, state and local regulations for human biological test samples apply when transporting oral fluid samples that may contain etiologic agents.

### Storage Conditions for VioOne™ Sample Collection Devices

Prior to sample collection, VioOne™ Sample Collection Device should be stored at Room Temperature (15-30°C). Exposure to higher temperatures should be avoided.

## Directions for Use:

### To collect an Oral Fluid Sample using the Sample Collection Device:

Allow excess saliva to accumulate in the mouth.

Remove the Sample Collection Unit from the package and unwrap being careful not to touch the absorbent pad at the end opposite the cap.

Place the absorbent pad into the mouth and run the pad along the upper and lower gum lines, across the insides of the cheeks and under the tongue. This will collect cells and oral fluid contained in the oral cavity. (Figure 2)

**Figure 2**

Remove the Cap from the Sample Collection Tube and place the absorbent pad into the Sample Collection Tube and screw the Sample Collection Unit onto the Sample Collection Tube. (Figure 3)

**Figure 3**

The sample collection process is now complete.

### Sample Transport

Ensure red cap on top of the Sample Collection Unit is screwed on tightly.

Ensure the Adaptor is fully engaged to the top of the Sample Collection Tube and is screwed on tightly.

Pack Sample Collection Tubes in the upright position for shipping.

**To process the Oral Fluid Sample collected using the Sample Collection Device**:

Hold the Sample Collection device upright.

If the Device has been on its side or upside down upon receipt, return to the upright position and allow it to sit for a minimum of 10 minutes prior to processing to allow all fluid to drain back to the bottom of the Sample Collection Tube.

Remove the red cap at the top of the unit by twisting it off.

Carefully pull the cap attached to the rod and pad out of the Sample Collection Tube and through the Adaptor. The narrow opening of the Adaptor will squeeze the pad releasing the sample/buffer mix (Figure 4). Discard the rod and pad after releasing the sample buffer mix from the pad.

Remove the Adaptor from the Sample Collection Tube by unscrewing the Adaptor from the threads at the top of the tube.

Place the extra cap provided with the Sample Collection Device on the Sample Collection Tube.

The Sample is now ready for testing.

**Figure 4**

## Storage and Transportation of Samples

Collected Samples, prior to Sample Processing, may be stored in contact with the collection pad at 2-37°C for a maximum of five days.

Collected Samples, post processing (removal of the collection pad), may be stored at 2-37°C for a maximum of 28 days. Processed samples may also be stored at -20°C for up to 6 weeks.

During Transportation, samples can withstand temperatures up to 45°C for a maximum of 7 days. However, temperatures over 37°C for prolonged periods of time should be avoided if possible.

## Performance Characteristics

The performance characteristics of oral fluids collected and processed with the VioOne™ Sample Collection Device must be evaluated by the user in conjunction with any specific *in vitro* diagnostic assay. The aforementioned evaluation must include the establishment of new performance characteristics for the specific assay.

## VioOne™ Sample Collection Device

50-VioOne™ Sample Collection Device Product Number 400050

## Package of Caps for the Sample Collection Tube

50 caps/bag Product Number 40-01903

## For Order and Inquiries, please contact

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