



## **COLLECTION OF ORAL-FLUID SAMPLES WITH THE ORAL-EZE® ORAL-FLUID COLLECTION SYSTEM**

### **A - NAME AND INTENDED USE**

The Oral-Eze® Oral-Fluid Collection System is intended for use by individuals under the supervision of trained professionals to collect, contain, and preserve oral-fluid specimens after collection and during transport from the collection area to the laboratory.

### **B - SUMMARY AND EXPLANATION OF THE ORAL-EZE® ORAL-FLUID COLLECTION SYSTEM**

The Oral-Eze® Oral-Fluid Collection System consists of an absorbent pad and plastic shield mounted on a plastic handle for the collection of an oral-fluid sample (Oral-Eze® Oral-Fluid Collector), and a collection tube (Oral-Fluid Collection Tube) for the stabilization and transportation of the specimen.

During collection the pad and plastic are placed between the lower gum and cheek with the plastic shield facing outward. The pad absorbs oral-fluid in the mouth onto the cotton fibers. The use of pure cotton fibers reduces the chance for allergic reactions in donors. The production of oral-fluid in the mouth is a natural process, and the collected fluid can be tested for the presence of selected analytes, including drugs and drug metabolites.

The Oral-Eze® Oral-Fluid Collector has a built-in sample window to ensure adequacy of sample collection. A non-toxic indicator dye travels with the sample as it is absorbed into the portion of the pad contained in the handle, and a blue color appears in the window when the collected volume reaches adequate levels. The dye is wholly contained within the handle and never comes into contact with the donor. After the sample is collected, the pad is ejected from the handle into the collection tube, which contains a buffer preservative solution. The portion of the pad containing the dye remains attached to the handle and is disposed of with the handle.

Some drugs and drug metabolites are not stable in oral-fluid. The buffer preservative solution in the tube serves to preserve the collected specimen during transportation to the testing laboratory.

### **C - PRINCIPLES OF THE ORAL-FLUID COLLECTION PROCEDURE**

The Oral-Eze® Oral-Fluid Collection System consists of an untreated absorbent pad and plastic shield attached to a plastic handle and a buffer preservative solution in a plastic container. The specimen is collected by having the subject place the pad and the plastic shield between the lower gum and cheek with the plastic shield facing the cheek until a blue color appears in the sample adequacy window, or the collection time reaches 10 minutes. The subject then promptly ejects the pad into the vial containing the buffer preservative solution by placing the thumb on the ridges of the handle and sliding forward. The vial is then capped by the subject and transported to a qualified lab for testing.

### **D - WARNINGS FOR USERS**

1. Handle specimens and materials contacting specimens as if capable of transmitting infection, in accordance with Universal Precautions.
2. Dispose of all specimens and materials used to perform the test as though they contain infectious agents. Disposal should comply with all applicable waste disposal requirements.
3. Occupational Safety and Health Administration (OSHA) regulations (29 CFR 1910) apply to personnel collecting and handling specimens.
4. Federal, state, and local regulations for human biologic test specimens apply to the transportation of oral-fluid specimens collected with the Oral-Eze® Oral-Fluid Collection System which may contain etiologic agents (39 CRF 111).
5. Use freshly prepared 10% bleach or other appropriate disinfectants to decontaminate surfaces in the event of a specimen spill. **NOTE: SOLUTIONS AND MATERIALS CONTAINING BLEACH SHOULD NOT BE AUTOCLAVED.**

### **E - PRECAUTIONS FOR USERS**

1. Oral-Fluid Collection Tubes are breakable and should be handled with care.
2. Avoid contamination of the Oral-Eze® Oral-Fluid Collector and the Oral-Fluid Collection Tube with foreign matter.
3. Do not use the Oral-Eze® Oral-Fluid Collector if the package has been opened.
4. Do not touch the collection pad or plastic shield on the Oral-Eze® Oral-Fluid Collector with fingers before or after specimen collection.
5. Do not use if the collection pad is wet.
6. Do not use beyond the expiration date shown on the Oral-Eze® Oral-Fluid Collection System package.
7. Do not use the collector if indicator dye is visible in the sample adequacy window or on the collection pad outside of the handle before use.

## **F - DIRECTIONS FOR USE OF THE ORAL-EZE® ORAL-FLUID COLLECTION SYSTEM**

### **Materials Provided**

1. Oral-Eze® Oral-Fluid Collector containing an absorbent pad and plastic shield with handle and sample adequacy window.
2. Oral-Fluid Collection Tube containing a buffer preservative solution.

### **Materials Required but not Provided**

1. Timer capable of measuring intervals of at least 10 minutes.
2. If the oral-fluid specimens are not collected from subjects in a medical setting, the trained collecting agent should be provided with sealable containers to safely handle the specimens (e.g., sealable plastic bags).

### **Storage of Unused Oral-Eze® Oral-Fluid Collection Systems**

Store unused Oral-Eze® Oral-Fluid Collection Systems at room temperature (15°- 30°C). Exposure to higher temperatures (> 40°C) should be avoided. Protect from prolonged exposure to direct sunlight.

### **Directions**

1. Instruct the donor to empty mouth of gum, food, tobacco, etc. prior to oral-fluid collection. If donor's mouth is not empty immediately prior to collection, have subject rinse his/her mouth with water (up to 4 oz) and wait a minimum of 10 minutes before collecting a specimen.
2. Instruct the donor to pool saliva into the mouth for a brief period prior to collection
3. Peel open the Oral-Eze® Oral-Fluid Collection System package just far enough for easy removal of the handle of the Oral-Eze® Oral-Fluid Collector. (Note: Do not use the collection pad if the package has been previously opened, if the collection pad is wet, or if indicator dye is visible in the round, sample adequacy window prior to use.)
4. Instruct the donor to use the handle to remove the collector from the packet. (Note: Do not touch the collection pad with fingers before or after specimen collection).
5. Instruct the donor to guide the Oral-Eze® Oral-Fluid Collector into his/her mouth and place the collection pad and plastic shield between the lower cheek and gum with the plastic shield facing the cheek (The pad should be oriented so that the round window in the handle is facing towards the center of the mouth). Instruct the donor to direct saliva towards the pad.

6. Start a 10 minute timer. Instruct the subject to keep the pad stationary (the pad should not be chewed or sucked). The collection process is complete when the blue color appears in the round (sample adequacy) window of the handle, or when collection time reaches 10 minutes, whichever occurs first.
7. When the collection is completed, remove the Oral-Fluid Collection Tube from the package. Hold the tube upright and open the cap on the Oral-Fluid Collection Tube. Instruct the donor to remove the Oral-Eze® Oral-Fluid Collector from his/her mouth and to guide the pad into the opened Oral-Fluid Collection Tube. (Note: Do not place collector back in mouth after it has been placed in the Oral-Fluid Collection Tube.)
8. With the pad in the Oral-Fluid Collection Tube, instruct the donor to place his/her thumb on the ridges of the Oral-Eze® Oral-Fluid Collector handle and push forward to eject the pad from the handle and into the Oral-Fluid Collection Tube. After ejection, close the cap on the Oral-Fluid Collection Tube and firmly press down cap until completely sealed. The plastic handle may be discarded in household trash.
9. Complete the facility's applicable chain of custody procedures to prepare and ship the specimen to the testing laboratory.

## **G - SAMPLE STORAGE AND SHIPMENT**

Specimens collected with the Oral-Fluid Collector (collection pad containing oral-fluid) must be stored and transported to the testing laboratory in the Oral-Fluid Collection Tube containing the buffer preservative solution.

Collected specimens may be transported to the laboratory at ambient temperature via ground or overnight courier. Specimens should be protected from impact, direct sunlight, and temperatures exceeding 40°C. The shipping of specimens collected with the Oral-Eze® Collection System should comply with all applicable federal and state laws and regulations.

After receipt at the laboratory, oral-fluid specimens collected with the Oral-Eze® Oral-Fluid Collection System should be stored at 2 - 30°C. Specimens can be stored for a maximum of 21 days from the time of collection, including the time for shipping and testing.

Manufactured by: Thermo Fisher Scientific, 2039 McMillan Street, Auburn, AL 36382