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.

Summary and Explanation of the Test
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.

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 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.

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.

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.