



Oral Fluid Drug Test

Oral Specimen Collection Device

IVD For *In Vitro* Diagnostic Use

NAME AND INTENDED USE

The Intercept® Oral Specimen Collection Device is intended for use in the collection, preservation and transport of oral specimens.

This device is intended for use by trained professionals only and is not intended for home use. Oral specimens collected with the Intercept® Oral Specimen Collection Device may be tested for drugs of abuse using the OraSure Technologies Intercept® MICRO-PLATE assays or the Roche DAT Oral Fluid assays on automated clinical chemistry analyzers.

PRINCIPLE OF THE INTERCEPT® ORAL SPECIMEN COLLECTION DEVICE

The Intercept® Oral Specimen Collection Device was developed for the purpose of collecting, preserving, and transporting oral specimens.

Saliva is a complex mixture of parotid, submandibular, sublingual and minor salivary gland secretions mixed with mucin, bacteria, leukocytes, sloughed epithelial cells, gingival crevicular fluid, and mucosal transudate. Mucosal transudate is the fluid derived from the passive transport of serum components through the oral mucosa into the mouth.

The Oral Specimen Collection Device consists of a treated, absorbent cotton fiber pad affixed to a plastic shaft (Oral Specimen Collection Pad) and a preservative solution in a plastic container (Oral Specimen Vial). The Oral Specimen Collection Pad, impregnated with a mixture of common salts and gelatin, creates a hypertonic environment that produces an osmotic gradient across the buccal and gingival mucosae. The pad is placed in contact with the gingival mucosa (between the lower gum and cheek) which enhances the flow of mucosal transudate onto the absorptive cotton fibers of the pad.

Following collection of the oral specimen, the Oral Specimen Collection Pad is removed from the mouth and is placed into the Oral Specimen Vial. The Oral Specimen Vial contains a preservative solution that inhibits the growth of oral microorganisms recovered on the Oral Specimen Collection Pad. The vial is sealed with a plastic cap and transported to a laboratory for processing and testing.

PRECAUTIONS

1. Oral Specimen Vials are breakable and should be handled with care.
2. Handle specimens and materials contacting specimens as if potentially infectious biological materials in accordance with “Universal Precaution for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and other Bloodborne Pathogens in Health-Care Settings” (CDC, *MMWR*, June 24, 1998). It has been reported that infectious HIV can be isolated from oral fluid of some patients. When detectable in oral fluid, infectious virus is present at low levels compared with blood and may be inactivated by salivary inhibitors.
3. Occupational Safety and Health Administration (OSHA) regulations 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 which may contain etiologic agents.
5. Use freshly prepared 10% bleach to decontaminate surfaces in the event of a spill of a collected specimen.
6. Avoid contamination of the Oral Specimen Collection Pad and Preservative solution with foreign matter.
7. Do not use the Oral Specimen Collection Pad if the package has been previously opened.
8. Do not touch the Oral Specimen Collection Pad with fingers before or after specimen collection.
9. Do not use if the Oral Specimen Collection Pad is wet.
10. Do not use device beyond expiration date shown on the device package.
11. Do not use if the Oral Specimen Vial is empty or has been damaged.

MATERIALS PROVIDED WITH EACH DEVICE (REF 3001-2869)

1. One treated, cotton fiber Oral Specimen Collection Pad on a plastic shaft (REF 3001-0895). The treatment ingredients are: Sodium chloride, citric acid, sodium benzoate, potassium sorbate, gelatin, sodium hydroxide, deionized water. All ingredients on the pad are on the FDA Generally Recognized As Safe (GRAS) list.
2. One Oral Specimen Vial containing blue Preservative solution (REF 3001-0896). Preservative ingredients: Chlorhexidine digluconate, Flag Blue dye, Tween 20, deionized water.

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer capable of timing five (5) minutes.



25°C STORAGE OF UNUSED INTERCEPT® ORAL SPECIMEN COLLECTION DEVICES

Store unused Oral Specimen Collection Devices at room temperature (18-25°C/64-77°F). Protect from prolonged exposure to direct sunlight.

DIRECTIONS FOR USE

Wait at least ten (10) minutes after ingesting any food, drink, or drugs before collecting a sample.

A second (bilateral) Intercept® Collection Device collection may be required to assure that the laboratory has adequate sample to perform the required screening and confirmatory analyses. This may be accomplished by collecting one collection device on one side of the mouth followed by a second device on the other side of the mouth (sequential method), or by using two collection devices at one time, one on either side of the mouth (simultaneous method).

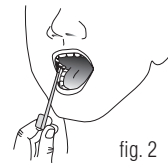
For the sequential collection method, follow the Intercept® Collection Device Directions for Use for the first collection. After the first collection procedure is complete, repeat the procedure on the other side of the mouth.

For the simultaneous collection method, follow the Intercept® Collection Device Directions for Use, but have the subject place one Collection Device on each side of the mouth between the cheek and lower gum.

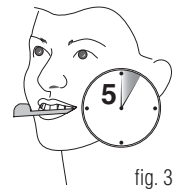
1. Open the Intercept® package containing the Oral Specimen Collection Pad and the Oral Specimen Vial.
2. Turn the Oral Specimen Collection Pad package so that the label is facing upward. Open the package where indicated by peeling apart the two sides of the package far enough to allow easy removal of the Pad. (fig. 1)
3. Use the plastic shaft of the device to pull the Pad out of the packaging sleeve. Do not touch the Pad. Be careful to not pull the Pad off the shaft.
4. Place the Pad inside the mouth between the lower gum and cheek with the Pad oriented down. Gently rub the Pad back and forth along the gum line until the Pad is moist. (fig. 2)



NOTE: If desired or required by the customer, a bilateral collection of sample may be performed. Place a pad on each side of the inside of the mouth between lower gum and cheek with both pads oriented down. Gently rub back and forth along the gum line until both pads are moist.



5. Begin timing for five (5) minutes. Keep the Pad in place against the lower gum for (5) minutes. (fig. 3)
6. Remove the Oral Specimen Vial from the package. Record identification information and date of collection on the Vial label, unless another documentation method will be used.



7. Hold the Oral Specimen Vial in an upright position and gently rock the cap back and forth to open the Vial. Avoid spilling the contents. (fig. 4)



fig. 4

8. After five minutes, remove the Pad from the mouth. Insert the Pad into the blue liquid at the bottom of the Vial. (fig. 5)

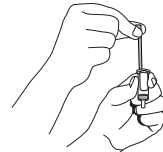


fig. 5

9. Break the plastic shaft of the Oral Specimen Collection Pad by bending the shaft against the side of the Vial and in a direction away from people. The shaft is scored to make it easier to break. (fig. 6)

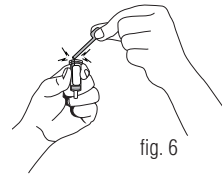


fig. 6

10. Place the cap onto the Vial. The cap will “snap” into place when secure. (fig. 7)



fig. 7

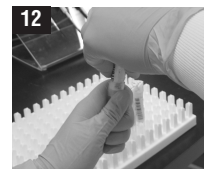
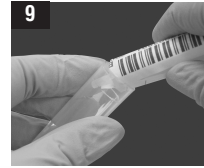
11. Follow the directions provided on the applicable custody and control form to prepare and mail the sample to a laboratory for testing.

STORAGE AND TRANSPORTATION OF ORAL SPECIMENS

1. Collected specimens must be stored and transported in the Oral Specimen Vial.
2. Refer to the individual assay package inserts for specific storage conditions for collected specimens.

INTERCEPT® SAMPLE PREPARATION FOR THE LABORATORY

1. Invert Intercept® Specimen Vial so tip is facing upwards and tap cap end on bench to move the collection pad away from the tip of the vial. (see picture 8).
2. Point Intercept® Specimen Vial tip away from you. Using the inside wall of a centrifuge tube break the vial tip. The recommended type of centrifuge tube is 67x16.8mm or 75x16mm polypropylene and compatible centrifuge caps. (see pictures 9 and 10)
3. Push Intercept® Specimen Vial into centrifuge tube, invert and place in centrifuge. (see picture 11)
4. Centrifuge for 5 minutes at 600-800 g, which on most tabletop models of centrifuges equates to 3,000 rpm.
5. Remove Intercept® Specimen Vial with twisting motion. Diluted oral fluid sample is in centrifuge tube ready to be pipetted for testing. (see picture 12)
6. For short term storage, store diluted oral fluid in capped centrifuge tube at 2-8°C.
























PERFORMANCE CHARACTERISTICS

The OraSure Technologies Intercept® MICRO-PLATE assays and the Roche DAT Oral Fluid assays can accurately and reliably detect drugs of abuse in samples collected with the Intercept® Oral Specimen Collection Device. Studies have shown that there is good agreement between assay results and confirmation testing by gas chromatography/mass spectrometry (GC/MS or GC/MS/MS). (Refer to the individual assay package inserts for specific performance data.)

KIT CONFIGURATIONS

Components Each Intercept® Package Containing: (REF 3001-2869)	REF Intercept #503-0509 500 Count	REF Intercept #503-0510 50 Count	REF Intercept # 503-0511 500 Count	REF Intercept # 503-0512 50 Count	REF Intercept # 503-0513 25 Count
Oral Specimen Vial (1) (REF 3001-0896)	500	50	500	50	25
Oral Specimen Collection Pad (1) (REF 3001-0895)	500	50	500	50	25

EXPLANATION OF SYMBOLS

 <p>Avoid Prolonged Exposure to Direct Sunlight</p>	 <p>Do Not Reuse</p>
 <p>Batch Code</p>	 <p><i>In Vitro</i> Diagnostic Medical Device</p>
 <p>Catalog Number</p>	 <p>Manufacturer</p>
 <p>Caution, Consult Accompanying Documents</p>	 <p>Temperature Limitation</p>
 <p>Consult Instructions for Use</p>	 <p>Use By</p>
 <p>Calibrator</p>	 <p>Package Insert</p>
 <p>Collection Device</p>	 <p>Part Number</p>
 <p>Collection Date</p>	 <p>Subject ID#</p>
 <p>Contents</p>	 <p>Oral Specimen Collection Device</p>
 <p>Control</p>	 <p>Oral Specimen Vial</p>
 <p>Peel Open Here</p>	



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Made in USA

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(001) 610-882-1820 Outside the USA