

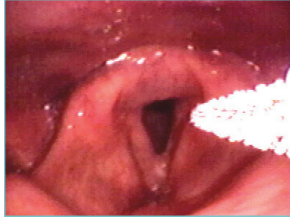
EndoCDx-Laryngopharyngeal Brush Biopsy

Summary of Instructions for Use*

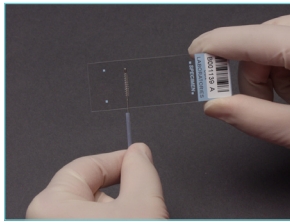


- 1 Prior to inserting biopsy brush, it is suggested that most **laryngeal lesions** be **anesthetized** by inserting a topical anesthetic* through operator channel of scope. Retract brush tip into its surrounding sheath and pass down biopsy channel.

*Although the anesthetic agent and dose should be determined by the physician, in the EndoCDx clinical trial, a 2cc solution of 4% topical lidocaine, repeated 1-3 times, administered with patient adducting the vocal cords, resulted in the desired anesthetic effects.



- 2 Place brush tip against lesion and apply firm pressure by angulating the scope. Rotate brush handle and repeatedly pass brush back and forth over lesion **until pinpoint bleeding is observed**.



- 3 Retract brush tip into its surrounding sheath and remove brush from channel. Evenly **spread cellular material** from brush onto bar-coded side of enclosed glass slide.



- 4 **Immediately** empty contents of a complete fixative packet onto slide, saturating all cellular material. Set slide to dry for 15 minutes.



- 5 **Clip off bristle portion of brush** into enclosed vial. Place closed vial into resealable bag with supplied absorbent padding.



- 6 Place **dry slide** in slide holder and securely shut.



- 7 The **completed mailer** should include:
1. test requisition form with all required data completed
2. one slide in slide holder
3. brush tip in vial in resealable bag
Place in prepaid mailer for overnight delivery to CDx Laboratories.

At CDx Laboratories, the specimen will be analyzed by specially-trained pathologists assisted by computer analysis. A report will be faxed and mailed to your office.

Laryngopharyngeal Brush Biopsy
EndoCDx
Microscopic Description: Dysplastic epithelial cells
Cellular Representation: Squamous epithelial cells
Diagnosis: Dysplastic squamous epithelial cells

* For detailed instructions, please refer to the complete instruction sheet provided in each test kit.