Performing the OralCDx® Brush Biopsy

The OralCDx® Computer-Assisted Transepithelial Brush Biopsy is a laboratory test used to rule out dysplasia and cancer in white and/or red oral lesions.

THE BRUSH BIOPSY SHOULD BE USED FOR
- Red, white, or mixed (red and white) lesions
- Chronic ulcerations
- Evaluating mucocutaneous disorders (e.g., lichen planus) unresponsive to treatment
- Follow-up of a persistent lesion despite a benign diagnosis from a previous brush or scalpel biopsy
- Patients with a history of oral or other head and neck cancer, who have evidence of mucosal changes

THE BRUSH BIOPSY SHOULD NOT BE USED FOR
- Lesions with intact normal epithelium (fibroma, mucocele, hemangioma)
- Submucosal masses
- Melanocytic lesions (pigmented brown)
- Vermillion border of the lip (dry surface)
- Any location outside the oral cavity
- Verrucous carcinoma (a rare variant of oral squamous cell carcinoma, most commonly appears clinically as a verrucous, exophytic mass often with a white pebbly, warty surface resembling a cauliflower. The lesion is typically slow growing and often displays multiple folds with deep clefts in between)

INSTRUCTIONS FOR USE

KIT COMPONENTS
- Test form and instructions included in kit
- Pre-barcoded slide
- Slide holder
- Fixative (intra pouch included)
- 2 Biopsy brushes
- Vial with solution and vial stand
- Bag with absorbent padding for vial

IMPORTANT TO NOTE
- A lesion that changes or persists requires follow-up testing
- Each kit should be used to test only one lesion- for patients with multiple lesions, a separate kit should be used for each lesion
- As indicated in the instructions, each kit is used to obtain 2 samples of the lesion. The first brush is used to collect a sample that is transferred to the slide and fixed, after which the brush is placed into the supplied vial. The second brush is used to re-brush the lesion and is inserted directly into the vial without the preparation of a slide
- A fragment of tissue should NOT be submitted using this kit- a histology kit which contains a formalin vial is required
- A topical anesthetic can be used - please wipe off any remaining topical anesthetic prior to performing the brush biopsy
- Photographs of lesions are encouraged
- If you have a particular differential diagnosis, note it on the test form
**UTILIZATION OF THE BIOPSY BRUSH**

To help insure that a complete full-thickness sample of the oral epithelium is obtained with the biopsy brush, rotate the instrument clockwise a sufficient number of times and with sufficient pressure *(indicated by slight bend in brush handle)* so that pinpoint bleeding occurs, demonstrating penetration into the subepithelium.

Pressure can generally be best obtained by using the flat end of the brush. However, either the flat or circular ends can be used.

**PREPARATION**
- Open the test kit and lay out the contents on a clean surface
- Remove slide from holder
- Remove vial from bag
- Confirm that the numeric portion of the barcodes on the slide and vial match the barcode on the test form
- Pre-rip fixative pouch and prop up
- Remove first brush from packaging
- Moisten brush using patient saliva, saline, or have patient rinse with water

**BRUSHING THE LESION** *(Brush 1)*
- Rotate brush against lesion until blush red or pinpoint bleeding is observed
- Either the flat or circular ends of the brush can be used *(see section on utilization of brush)*
- For lesions larger than 10mm, your brushing should include the margins of the lesion

**TRANSFERRING SAMPLE TO THE SLIDE**
- **IMMEDIATELY** after brushing, gently drag brush over slide, using a rotating motion as you drag *(transfer using same end of brush utilized for obtaining the specimen)*
- Remain within bracketed area

See back panel for brushing suggestions for specific lesion types
**Fixing the Sample**
- **Immediately (Within 10 seconds)** fold pouch in half and squeeze liquid over sample
- Flood slide with fixative
- Set aside to dry (10 min) while continuing with next step
- Open vial cap and insert brush into vial
- Close cap and seal tightly

**Re-Brushing the Lesion (Brush 2)**
- Remove second brush from packaging
- Rotate brush against lesion until blush red or pinpoint bleeding is observed
- Either the flat or circular ends of the brush can be used (see section on utilization of brush)
- For lesions larger than 10mm, your brushing should include the margins of the lesion

*See back for technique suggestions for specific lesion types*

**Preparing the Vial**
- Without the preparation of a slide, insert brush into vial. Vial should now contain 2 brushes
- Close cap and seal tightly
- Complete label
- Return vial to small pouch and seal pouch

**Packaging**
- Complete the test form (shaded areas are required fields) and insert into outer pocket of kit bag
- Insert slide into holder and snap shut, then complete label on slide holder
- Insert slide holder and pouch with vial into kit bag
- Place completed bag into box/mailer
- Seal kit
- Return to CDx Diagnostics via UPS (800-PICK-UPS)

*Completed mailer should contain:*
1. Completed Test form
2. Slide in slide holder
3. Bag with vial containing 2 brushes
Technique suggestions for specific lesion types

**WHITE LESIONS**
- Rotate the brush until pink tissue or pinpoint bleeding is observed
- For lesions larger than 10mm, also brush along the edge of the lesion

**THICKLY-KERATINIZED WHITE LESIONS**
Including Chewing Tobacco Lesions
- Prior to brushing, scrape the top of the lesion with a blunt instrument (*such as the edge of a metal spatula or plastic instrument*) to remove dead superficial cells
- For lesions larger than 10mm, also brush along the edge of the lesion

**RED LESIONS**
- Brush along the perimeter of the lesion to minimize bleeding
- Since red lesions are usually thin, applying excessive pressure will result in bleeding, which may obscure the specimen
- If excessive bleeding occurs, stop and immediately transfer the specimen from the brush to the slide

**ULCERATED LESIONS**
- Brush along the perimeter of the lesion where it meets the healthy tissue
- Do NOT brush the center of the ulcer, since it does not have viable epithelium and excess blood may obscure the specimen
- If excessive bleeding occurs, stop and immediately transfer the specimen from the brush to the slide

**QUESTIONS REGARDING TECHNIQUE AND TESTING?**
Call the OralCDx Consult Team at 877-71-BRUSH (877-712-7874)

REFERENCE:
1. Modified from Felefli S and Flaitz CM; The oral brush biopsy: It’s easy as 1,2,3. Texas Dental Journal 2000; 117:30-4.