

## Product Information

OraStripdx is a point-of-care in vitro test for the semiquantitative detection of oral thiols in dogs. The concentration of thiols in canine oral fluids has been shown to be directly related to the progression of periodontal disease.<sup>1</sup> Because visual examination of the gingivae does not disclose the full extent of progressive periodontal disease within the periodontium, use of OraStripdx as part of routine patient work-up can detect thiol concentrations that reflect active periodontal disease.<sup>1</sup> OraStripdx may be routinely incorporated into wellness exams in conjunction with diagnostic tests such as fecal, heartworm and blood work.<sup>1</sup>

## Intended Use (Use Only As Directed)

- For routine use by veterinary professionals in the awake dog for the detection of thiols associated with periodontal disease.
- Use OraStripdx in conjunction with routine oral examinations in the awake patient during wellness exams.
- Appropriate for use in dogs scheduled to undergo examination under anesthesia: In this case use OraStripdx *prior to administration of any anticholinergic or anesthetic agents that may cause dry mouth.*
- OraStripdx should *not* be used on overtly bleeding gums, as blood can interfere with the OraStripdx test result.
- For dogs with a positive (+, ++, or +++) OraStripdx test result, a Dental Care Plan (dental diagnostic evaluation; therapeutic and home care regimens) may be recommended and discussed with the client.
- Discuss wellness, preventive dental care and daily oral health maintenance with the client to ensure optimal home care.
- Retest patient at least once every year, and preferably every 3-6 months.
- The OraStripdx test result obtained during follow-up evaluation may be compared to earlier OraStripdx test results to monitor the progression of periodontal disease and to assess the effectiveness of the Dental Care Plan.
- For further diagnostic recommendations, see AAHA Dental Care Guidelines, J Am Anim Hosp Assoc 41:1-7 (2013). These Guidelines recommend dental evaluations for dogs as young as five months of age:
  - *"In many instances...the examiner will underestimate the conditions present because it is impossible to visualize all oral structures when the patient is awake."*
  - *"Evaluate disease status, such as periodontal disease, on the conscious patient with products that allow an assessment of periodontal health without placing the patient under anesthesia."*
  - *"A diagnostic test strip for the measurement of dissolved thiol levels can be used as an exam room indicator of gingival health and periodontal status."*

## Instructions for Use (Please Refer Also to Panel Graphics on Opposite Side)

Personal protective equipment routinely employed in veterinary practice should be worn when collecting oral fluid samples. Open the OraStripdx cylindrical container and carefully remove a single test strip, then close the container.

### • Sample Collection

*In general, particulate matter and blood can interfere with proper interpretation of the OraStripdx test result. Use gentle pressure to glide the pad of the OraStripdx test strip along the gingival margin, where the teeth meet the gums. Avoid applying excessive pressure, which could dislodge plaque or cause bleeding, but use sufficient pressure to collect fluid onto the test pad.*

- Place your index finger on the non-pad side of the test strip, so the pad is supported by the end of the finger.
  - Lift the dog's upper lip.
  - Gently glide the pad along the entire maxillary facial (buccal and labial) gingival margin, where the gums meet the teeth. This collection procedure, which collects a mixed gingival crevicular / salivary fluid onto the pad, should take no more than 10 seconds.
  - Remove the test strip from the dog's mouth.
  - Wait at least 10 seconds after completing the collection procedure, then read the result.
- ### • Reading the OraStripdx Test Result
- Hold the OraStripdx test strip next to the colors shown on the vial label.
  - Determine and record the region (negative; +; ++; or +++) on the vial label colors that matches the *most intense color* seen on the pad of the test strip. The absence of a yellow coloration denotes a **negative** result; +, ++, or +++ denotes a **positive** result of low, moderate, or high thiol concentration, respectively.
  - If the color on the pad is not uniform, *use the most intense color seen on the pad.* A non-uniform color is still a valid result. This can occur if the gingival tissues are very dry or if periodontal infection is localized or unevenly distributed.
  - Read the OraStripdx test result **no more than 5 minutes** after collecting the sample.
- ### • Interpreting the OraStripdx Test Result
- **Negative** Indicates a **healthy** periodontal status not associated with periodontal infection. For dogs with a history of periodontal disease, this value reflects controlled management of active periodontal disease, and continuation of maintenance treatment modalities may be warranted.
  - **Positive** (+, ++, or +++) indicates the likely presence of **active periodontal disease** within the periodontium.
- ### • Communicating the OraStripdx Test Result
- Discuss with your client the importance of following a Dental Care Plan and returning for follow-up appointments.
  - The Dental Care Plan should be based upon patient history and may include dental prophylaxis, professional dental cleanings, periodontal therapy, home care, and a comprehensive dental evaluation, including radiographs, under general anesthesia.

## Interfering Substances

Highly pigmented substances such as blood can interfere with the ability to read and interpret the OraStripdx test result. Therefore, the sample should be gently collected in such a way that no blood contacts the pad during sample collection. Similarly, avoid contacting heavy tartar deposits during sample collection, as these can also obscure the test result.

## Principle of Operation

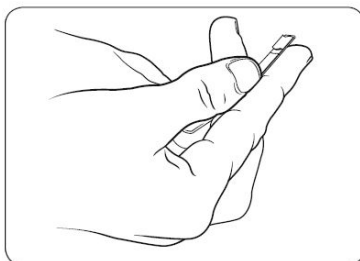
Upon contact with a sample of oral fluid (obtained from the gingival margin), OraStripdx provides an objective visual signal related to the concentration of thiols (also called mercaptans or sulfhydryl compounds) present in the sample. Thiols are produced by microorganisms closely associated with active periodontal disease. When left untreated, active periodontal disease can lead to progressive tissue destruction and loss of tooth attachment. Periodontal disease can be associated with systemic (e.g., cardiovascular, renal, and hepatic) diseases and other serious conditions adversely impacting quality of life.

## Clinical Background

A positive OraStripdx test result is generated when there are thiols in canine oral fluid collected from the gingival margin. Thiols disclosed by OraStripdx provide a measure of the presence and severity of active periodontal infection. Regular use of OraStripdx as part of routine patient work-up has been shown to detect and monitor underlying active periodontal disease.<sup>1</sup> Clinical data have associated low test values (negative, or very low positive) with healthier periodontal status.<sup>1</sup> In dogs, active periodontal disease involves infection of the gums by anaerobic microorganisms including those from the genera *Porphyromonas* (such as *P. gingivalis*) and *Treponema* (such as *T. denticola*).<sup>2</sup> When such microbes are present within subgingival biofilms, they are known to produce large quantities of metabolic products called thiols<sup>3</sup> which can disrupt gum tissue and destroy healthy bone by inducing bone loss. Thiols disrupt epithelial integrity<sup>4</sup>; cause death of gingival epithelial cells through apoptosis<sup>5</sup>; and induce bone loss through stimulation of osteoclasts<sup>6</sup> and inhibition of osteoblasts.<sup>7</sup> In dogs, periodontal disease is associated with adverse systemic outcomes<sup>8</sup>, as well as with hepatic, renal and cardiovascular lesions.<sup>9</sup>

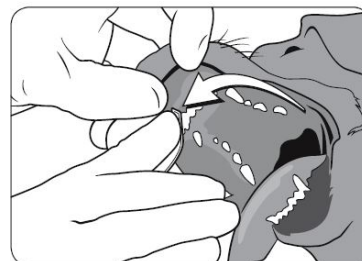
## Literature Cited

- <sup>1</sup> Manfra Marretta S, Leesman M, Burgess-Cassler A, McClure GD Jr, Buelow M, Finn M (2012) Can Vet J. 53:1260-1265; Goldstein G, Chapman A, Herzog L, McClure GD (2016) J Veterinar Sci Techno. 7:1-4; Queck KE, Chapman A, Herzog LJ, Shell-Martin T, Burgess-Cassler A, McClure GD (2018) J Am Anim Hosp Assoc. 54:132-137.
- <sup>2</sup> Isogai H, Kosako Y, Benno Y, Isogai E (1999). Zentralbl Veterinarmed B. 46(7):467-73; Hardham J, Dreier K, Wong J, Sfintescu C, Evans RT (2005). Vet Microbiol. 106(1-2):119-28; Nordhoff M et al (2008). Veterinary Microbiol. 127:334-342.
- <sup>3</sup> Yoshida A, Yoshimura M, Ohara N, Yoshimura S, Nagashima S, Takehara T, Nakayama K (2009). J Periodontol. 80(11):1845-51; Chen W, Kajiya M, Giro G, Ouhara K, Mackler HE, Mawardi H, Boisvert H, Duncan MJ, Sato K, Kawai T (2010). Biochem Biophys Res Commun. 391(1):645-50.
- <sup>4</sup> Ng W, Tonzetich J (1984). J Dent Res. 63(7):994-7; Johnson P, Yaegaki K, Tonzetich J (1996). J Periodontal Res. 31(5):323-9.
- <sup>5</sup> Calenic B, Yaegaki K, Murata T, Imai T, Aoyama I, Sato T, li H (2010). J Periodontal Res. 45(1):31-7.
- <sup>6</sup> Irie K, Ekuni D, Yamamoto T, Morita M, Yaegaki K, li H, Imai T (2009). Arch Oral Biol. 54(8):723-9; li H, Imai T, Yaegaki K, Irie K, Ekuni D, Morita M (2010). J Periodontol. 81(11):1691-7.
- <sup>7</sup> Imai T, li H, Yaegaki K, Murata T, Sato T, Kamoda T (2009). J Periodontol. 80(12):2028-34.
- <sup>8</sup> Rawlinson JE, Goldstein RE, Reiter AM, Attwater DZ, Harvey CE (2011). J Am Vet Med Assoc. 238(5):601-9.
- <sup>9</sup> DeBowes LJ, Mosier D, Logan E, Harvey CE, Lowry S, Richardson DC (1996). J Vet Dent. 13(2):57-60.



1

- > PLACE YOUR INDEX FINGER BEHIND THE NON-PAD SIDE OF THE ORASTRIP TEST.



3

- > GENTLY GLIDE PAD ALONG ENTIRE MAXILLARY FACIAL GINGIVAL MARGIN, WHERE THE GUMS MEET THE TEETH.

2

- > GENTLY LIFT DOG'S UPPER LIP.



4

- > WAIT 10 SECONDS. COMPARE COLOR DEVELOPED ON THE PAD TO COLORS ON THE VIAL LABEL.



OraStripdx.com