Dental Learning
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Product Focus:

OralDNA Labs' MyPerioPath

The American Dental Association has reported that 75% of adults in the United States are affected by some form of periodontal disease.[1] Periodontal disease is the primary cause of tooth loss and has been linked to such systemic ailments as cardiovascular disease and uncontrolled diabetes.[2, 3] However, traditional methods of periodontal disease diagnosis are often subjective and are based on signs and symptoms that occur after the disease process has damaged the periodontium. Interpretation of radiographic findings and measurement of diseased periodontal pockets might vary among even the most experienced clinicians.

Technological advances, such as the phase microscope, provided clinicians with a means of viewing individual pathogens that were active inside a periodontal lesion. Using the microscope, the dentist—and the patient—could see cocci, rods, and even motile spirochetes removed from a plaque sample. Although it is a useful motivational tool, the microscope did not identify exactly which pathogen(s) were present in (or causing) the patient's periodontal infection.

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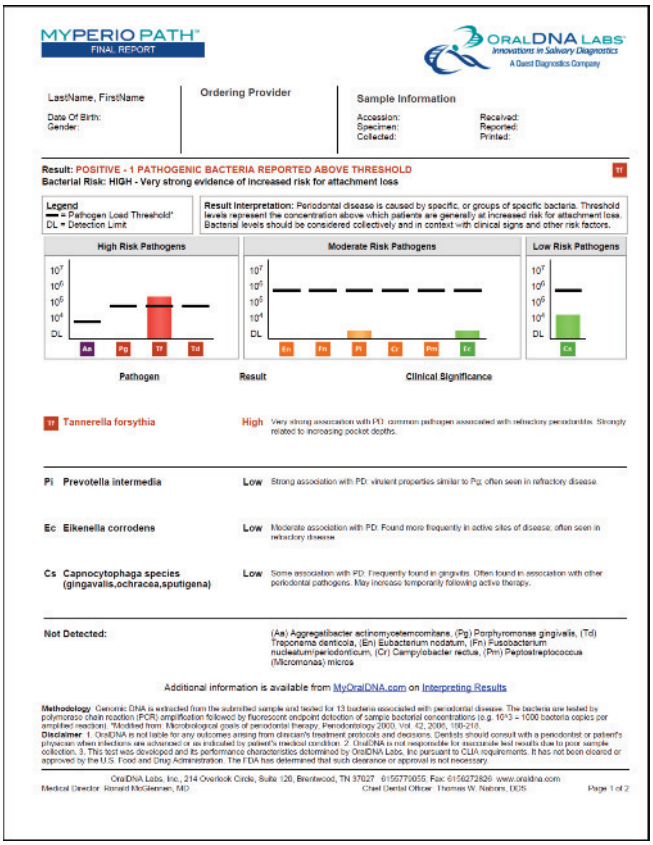
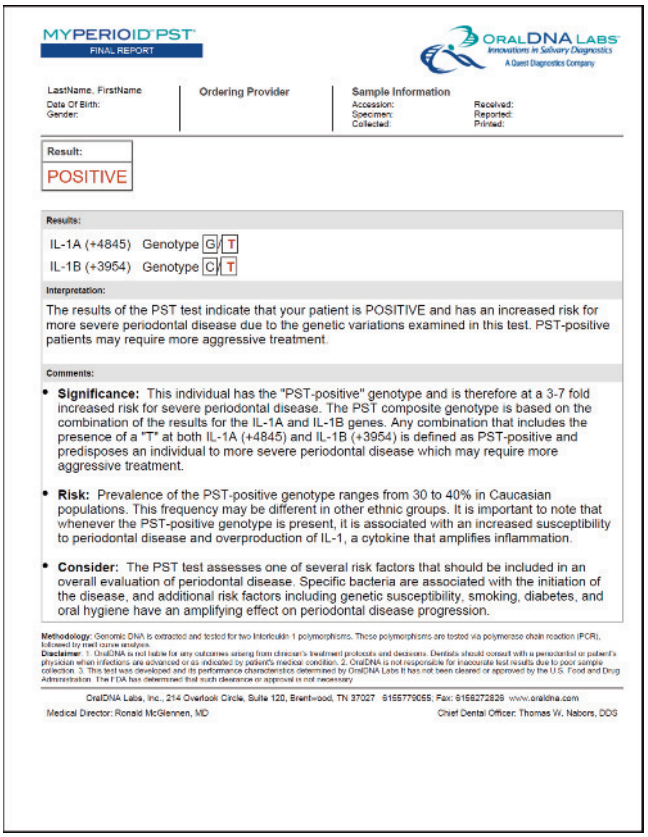


Figure 1—MyPerioPath result report indicating high levels of *T forsythia*.

Culturing bacteria removed from periodontal pockets with sterile paper points provided dentists with a means to identify specific bacteria in a specific pocket. The bacteria-laden paper points must be shipped to the laboratory overnight where the bacteria are allowed to grow and then are identified—a process taking 10 to 14 days. Although bacteria are indeed identified, the laboratory report does not include a "bacterial load" or number of bacteria present.

Chairside tests, such as the BANA Enzymatic Test (Oratec Corp), provide clinicians with a quick and inex-



MYPERIOID PST
FINAL REPORT

ORALDNA LABS
Innovations in Salivary Diagnostics
A Quest Diagnostics Company

LastName, FirstName:
Date Of Birth:
Gender:

Ordering Provider

Sample Information
Accession:
Specimen:
Collected:
Received:
Reported:
Printed:

Result:
POSITIVE

Results:
IL-1A (+4845) Genotype G T
IL-1B (+3954) Genotype C T

Interpretation:
The results of the PST test indicate that your patient is POSITIVE and has an increased risk for more severe periodontal disease due to the genetic variations examined in this test. PST-positive patients may require more aggressive treatment.

Comments:
- **Significance:** This individual has the "PST-positive" genotype and is therefore at a 3-7 fold increased risk for severe periodontal disease. The PST composite genotype is based on the combination of the results for the IL-1A and IL-1B genes. Any combination that includes the presence of a "T" at both IL-1A (+4845) and IL-1B (+3954) is defined as PST-positive and predisposes an individual to more severe periodontal disease which may require more aggressive treatment.
- **Risk:** Prevalence of the PST-positive genotype ranges from 30 to 40% in Caucasian populations. This frequency may be different in other ethnic groups. It is important to note that whenever the PST-positive genotype is present, it is associated with an increased susceptibility to periodontal disease and overproduction of IL-1, a cytokine that amplifies inflammation.
- **Consider:** The PST test assesses one of several risk factors that should be included in an overall evaluation of periodontal disease. Specific bacteria are associated with the initiation of the disease, and additional risk factors including genetic susceptibility, smoking, diabetes, and oral hygiene have an amplifying effect on periodontal disease progression.

Methodology: Genomic DNA is extracted and tested for two interleukin 1 polymorphisms. These polymorphisms are tested via polymerase chain reaction (PCR), followed by melt curve analysis.
Disclaimer: 1. OralDNA is not liable for any outcomes arising from clinician's treatment protocols and decisions. Dentists should consult with a periodontist or patient's physician when infections are advanced or as indicated by patient's medical condition. 2. OralDNA is not responsible for inaccurate test results due to poor sample collection. 3. This test was developed and its performance characteristics determined by OralDNA Labs. It has not been cleared or approved by the U.S. Food and Drug Administration. The FDA has determined that such clearance or approval is not necessary.

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Figure 2—Result report for MyPerioID PST indicating patient is genetically susceptible to periodontal disease.

pensive means of identifying the presence of 3 bacteria in a sample of subgingival plaque. This system tests for enzymes found in *Treponema denticola*, *Porphyromonas gingivalis*, and *Bacteroides forsythus*, anaerobic bacteria highly associated with adult periodontitis. This test does not provide information regarding the number of bacteria present nor does it identify other harmful pathogens.

Identifying and Quantifying Pathogens

The age of salivary diagnostic testing provides dentists opportunities to use a saliva sample for identification of a variety of periodontal pathogens *plus* a determination of the number of these bacteria present. OralDNA Labs' MyPerioPath tests for the presence of 11 bacterial pathogens that have been identified as tissue invasive, scaling/root planing resistant, and linked to serious systemic health issues.[4-8] Using this information, the dentist can more accurately predict the outcome of periodontal therapy, treat the patient *earlier*—before severe clinical signs and symptoms—and have a positive impact on the patient's overall health.

The following case demonstrates usage of MyPerioPath for gathering baseline patient information, development and implementation of a treatment plan, posttherapy reevaluation, and revision of therapy following retesting.

Case Study

The patient is a 37-year-old female with a family history of heart disease. At the time of initial testing, her home care consisted of brushing twice daily with a power toothbrush and flossing each evening. Dental care since 30 years of age included a routine prophy every 3 months. At the time of saliva specimen collection, periodontal findings included three 4-mm pockets (distolingual of second molars), 2 sites bleeding on probing, and no visible signs of radiographic bone loss.

MyPerioPath test results indicated *Tannerella forsythia* (*T forsythia*) above the threshold or concentration at which patients are considered at risk for increased attachment loss (Figure 1). *T forsythia* is associated with refractory periodontal disease and increased risk of heart attack.[8] The patient additionally tested positive for the interleukin-1 gene mutation (Figure 2; MyPerioID PST, OralDNA Labs), signifying a genetic susceptibility to increased inflammatory response. Recommended treatment at this time was full mouth disinfection: prophy (code 1110), 30 minutes of sulcus debridement with ultrasonic scaler, and a systemic antibiotic (metronidazole 500 mg, twice a day for 8 days).

Three months later, a posttherapy saliva specimen was collected (Figure 3). At this time, *T forsythia* was no longer detected; however, lower spectrum bacteria were elevated. This elevation often occurs after more pathogenic bacteria are reduced or eradicated. As the patient is genotype positive for interleukin-1 gene mutation, she is at greater risk for infection with the lower level bacteria. Recommended treatment at this time was periodontal maintenance therapy (code 4910); no additional systemic antibiotic was recommended. The patient will be retested at her next recare visit.

Use of these diagnostic tests provided the dentist with valuable information regarding what was happening on a cellular level in this patient's mouth. Although clinical signs did not indicate a severe periodontal condition, the continued elevated level of pathogenic bacteria indicated an ongoing infection. Given the patient's family history of cardiovascular disease, progressively worsening periodontal disease could dramatically impact her systemic health.

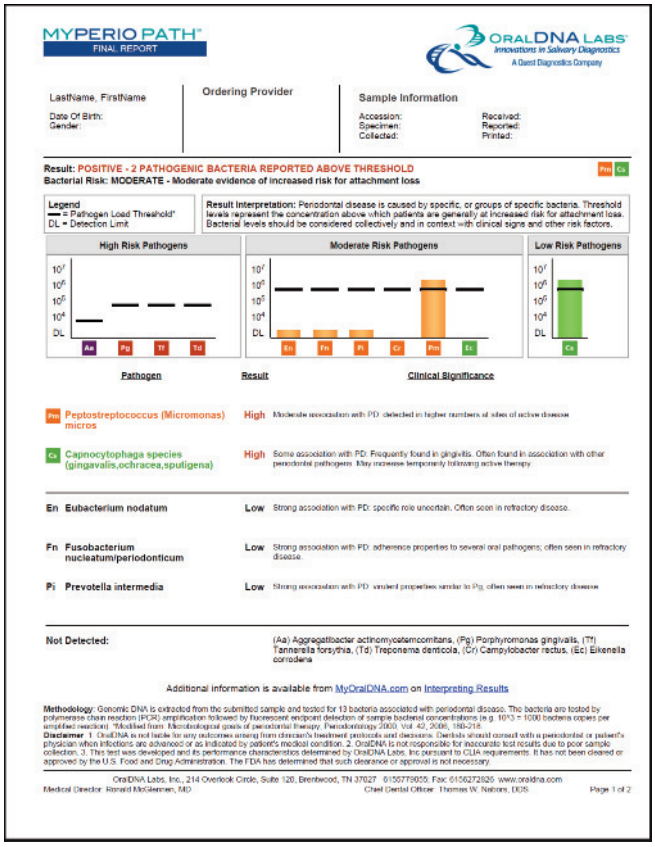

Figure 3—Post-therapy (Follow-up) MyPerioPath result report indicate eradication of T forsythia with an elevation of lower risk pathogens.

Conclusion

Diagnostic tests such as MyPerioPath allow the clinician to diagnose earlier, treat more aggressively, and more closely monitor a patient's oral condition. These tests should become standard procedure in the dental office to ensure the most positive outcome for each case.

Disclosure:
Cynthia T. Hughes, RDH, MEd, and Diane Larson, RDH, are Clinical Specialists for OralDNA Labs, Inc.

References

1. American Dental Association. For the dental patient. Women and periodontal disease. *J Am Dent Assoc.* 2002;133:671.
2. Iwai T. Periodontal bacteremia and various vascular diseases. *J Periodontal Res.* 2009;44:689-694.
3. Dunning T. Periodontal disease—the overlooked diabetes complication. *Nephrol Nurs J*. 2009;36:489-496.
4. Slots J, Ting M. Systemic antibiotics in the treatment of periodontal disease. *Periodontology 2000*. 2002;28:106-176.
5. Rose LF, Steinberg BJ, Minsk L. The relationship between periodontal disease and systemic conditions. *Compend Contin Educ Dent*. 2000;21:870-878.
6. Friedewald VE, Kornman KS, Beck JD, et al. The American Journal of Cardiology and Journal of Periodontology editors consensus: periodontitis and atherosclerotic cardiovascular disease. *J Periodontol.* 2009;80:1021-1032.
7. Mealey BL, Oates TW. Diabetes mellitus and periodontal diseases. *J Periodontol.* AAP Commissioned Review. 2006;77:1289-1303.
8. Study shows link between perio pathogens and heart disease. Available at: http://www.drbicuspid.com/index.aspx?sec=nws&sub=rad&pag=dis&ItemId=301693. Accessed August 25, 2010.