ALERT 2™

FINAL REPORT

ORALDNA LABS™ Innovations in Salivary Diagnostics

Doe, Jane
Date Of Birth: 06/01/1970 (47 yrs)
Gender: Female

Ordering Provider
Ronald McGlennen MD
7400 Flying Cloud Drive
Eden Prairie, MN 55344
855-672-5362

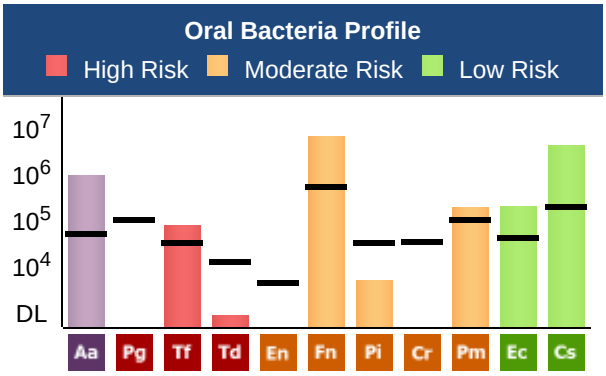
Sample Information
Specimen#: 3033032170
Accession#: 201706-11186
Specimen: Oral Rinse(P)

Collected: 05/30/2017
Received: 05/31/2017
Reported: 06/01/2017 13:06

SUMMARY OF TEST RESULTS

MyPerioPath®

- The MyPerioPath® test measures 11 types of bacteria known to cause periodontitis (gum disease) and increased risk for cardiovascular disease. These bacteria are also associated with diabetes, adverse pregnancy outcomes, rheumatoid arthritis, and other systemic illnesses.
- 8 of the 11 bacteria types were detected in the submitted sample. 6 of these are above the treatment threshold level.
- The levels of Aa are of particular concern. This bacterial type is associated with an earlier age of onset, and an aggressive clinical course.



MyPerioID® IL-6

- The MyPerioID® test determines the nucleotide sequence at one region of the Interleukin 6 gene, a key marker of a person's immune system and inflammation response.
- Your test result shows a G/G genotype, which is categorized as high risk for periodontal inflammation.
- This result implies a greater lifetime risk of chronic periodontitis, and for other conditions such as heart disease, arthritis, diabetes and some cancers.

Gene Marker	Risk Category
Interleukin 6	HIGH

Integrative Summary / Treatment Considerations

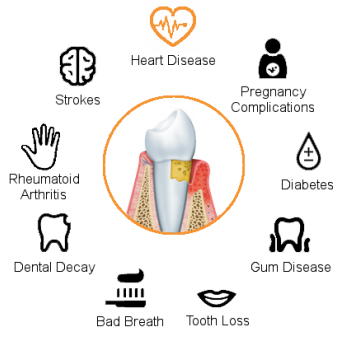
- The combination of these two test results show the signs of an existing or emerging periodontal infection and the likelihood of a heightened or increased inflammatory response to those high and moderate risk bacteria.
- Based on these test results, we recommend that you seek dental consultation and treatment.
- Your treatment options include various approaches to remove plaque above and below the gumline using scaling and root planing or lasers, and the selective use of tray delivery systems for disinfectants or local and systemic use of antibiotics.
- A follow-up test is recommended to monitor the effectiveness of current treatments and to determine the type and frequency of future care.

Discover the Facts...

what you may not know about oral bacteria and how it relates to overall health

A heart attack is triggered by the blockage of one of the arteries that supply the heart muscle with oxygen rich blood. Occlusion of the coronary arteries are now known to be caused not only by deposition of bad cholesterol, but by the migration and entrapment of oral bacteria, such as Porphyromonas gingivalis, or Pg. In a recent review article by Drs. Brad Bale and Amy Doneen, they describe how oral bacteria can no longer be viewed as associated with heart attacks, but as a cause.

Bale, BF, Doneen, A L, Vigerust, DJ. High-risk periodontal pathogens contribute to the pathogenesis of atherosclerosis Postgrad Med J. 2017 Apr;93(1098):215-220.



Learn more by visiting www.oraldna.com

MYPERIOPATH®

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MYPERIOPATH MOLECULAR ANALYSIS OF PERIODONTAL AND SYSTEMIC PATHOGENS

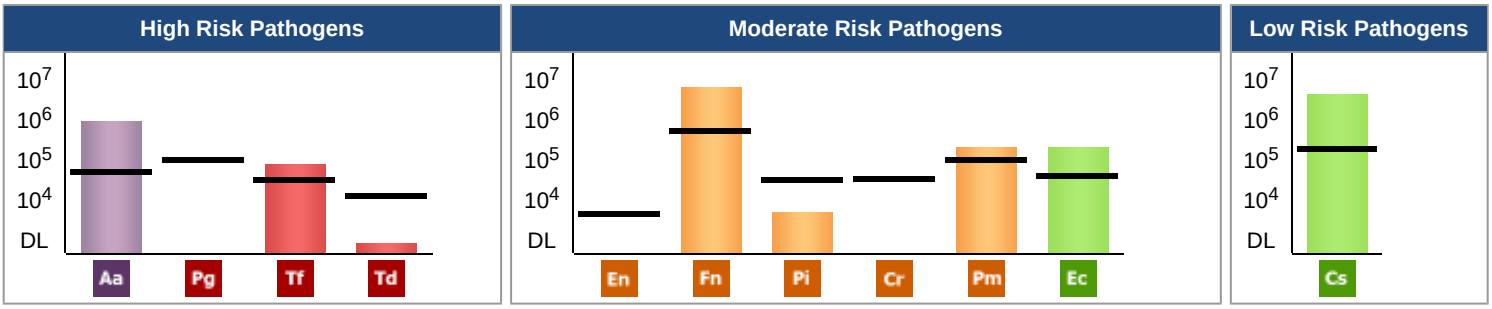
Result: PATHOGENIC BACTERIA DETECTED, 6 ABOVE THERAPEUTIC THRESHOLD

Aa Tf Fn Pm Ec Cs

Bacterial Risk: HIGH - Very strong evidence of increased risk for attachment loss

Legend
▬ = Therapeutic Threshold*
DL = Detection Limit

Result Interpretation: Periodontal disease is caused by specific, or groups of specific bacteria. Threshold levels represent the concentration above which patients are generally at increased risk for attachment loss. Bacterial levels should be considered collectively and in context with clinical signs and other risk factors.



Pathogen	Result	Clinical Significance
Aa **Aggregatibacter actinomycetemcomitans**	**High**	Very strong association with PD: Transmittable, tissue invasive, and pathogenic at relatively low bacterial counts. Associated with aggressive forms of disease.
Tf **Tannerella forsythia**	**High**	Very strong association with PD: common pathogen associated with refractory periodontitis. Strongly related to increasing pocket depths.
Fn **Fusobacterium nucleatum/periodonticum**	**High**	Strong association with PD: adherence properties to several oral pathogens; often seen in refractory disease.
Pm **Peptostreptococcus (Micromonas) micros**	**High**	Moderate association with PD: detected in higher numbers at sites of active disease.
Ec **Eikenella corrodens**	**High**	Moderate association with PD: Found more frequently in active sites of disease; often seen in refractory disease.
Cs **Capnocytophaga species (gingavalis,ochracea,sputigena)**	**High**	Some association with PD: Frequently found in gingivitis. Often found in association with other periodontal pathogens. May increase temporarily following active therapy.
Td Treponema denticola	**Low**	Very strong association with PD: invasive in cooperation with other bacteria. Usually seen in combination with other bacteria.
Pi Prevotella intermedia	**Low**	Strong association with PD: virulent properties similar to Pg; often seen in refractory disease.

Not Detected: (Pg) Porphyromonas gingivalis, (En) Eubacterium nodatum, (Cr) Campylobacter rectus

Additional information is available from OralDNA.com

Methodology: Genomic DNA is extracted from the submitted sample and tested for 10 species-specific bacteria and 1 genus of bacteria known to cause periodontal disease. The bacteria are assayed by real-time quantitative polymerase chain reaction (qPCR). Bacterial loads are reported in log copies per mL of sample (e.g. 1x10^3 = 1000 bacteria copies per mL of collection). *Modified from: Microbiological goals of periodontal therapy; Periodontology 2000, Vol. 42, 2006, 180-218. This test was developed, and its performance characteristics determined by OralDNA Labs pursuant to CLIA requirements. This test 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.

MYPERIOPATH®
CLINICAL CONSIDERATIONS

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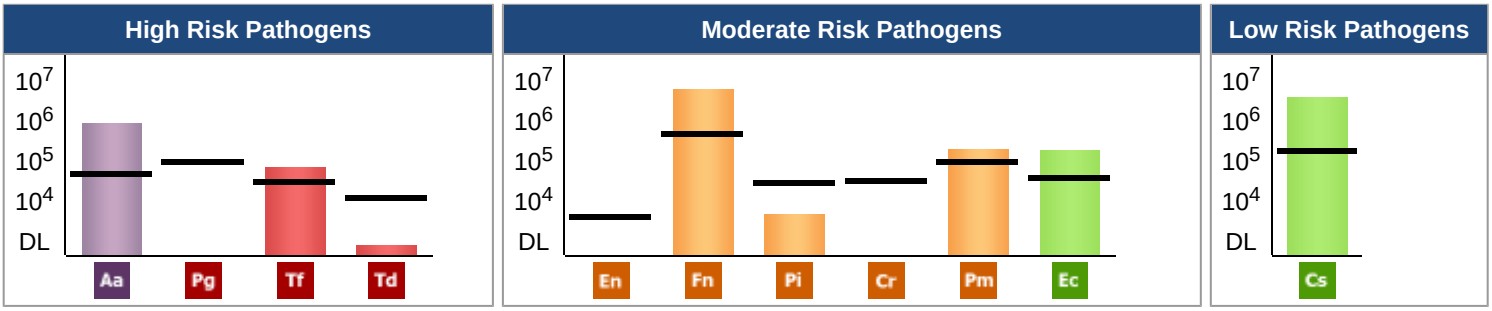

Treatment Considerations

☑ **Office Periodontal Therapy:** Protocols to disrupt biofilm and reduce pathogens.

☑ **Systemic Antibiotic Option to Augment Therapy at Clinician's Discretion:**
Clinician to determine if local antimicrobials (e.g. Chlorhexidine) and/or local antibiotics (e.g. Arestin) are sufficient to resolve infection. Published guidelines suggest (subject to allergy, drug interaction, and other medical considerations) the following as a possible adjunct to treatment based on patient's bacterial profile: Amoxicillin 500 mg tid for 8-10 days AND Metronidazole 500 mg bid for 8-10 days, depending on the severity of infection.

Note: The prescribing doctor is responsible for patient therapy. Consider the patient's dental and medical history (e.g. pregnancy/nursing, diabetes, immuno-suppression, other patient medications) when evaluating the use of antibiotic medications. Many antibiotics may impact/interact with other medications and may produce adverse side effects. Review the manufacturer warnings for any contraindications, or consult with the patient's physician if there are concerns with the selected antibiotic regimen.

☑ **Home Care:** Office recommended procedures to daily disrupt biofilm and reduce pathogens.

☑ **Reassessment:** Compare clinical signs and bacterial levels pre- and post-treatment.
- A 2nd sample should be collected six to eight weeks post-therapy.

Additional Risk Factors

Clinical		Diagnostic			Medical	
BOP	☐	Localized	☐	Type V Refractory Periodontitis; ADA Code 4900 ☐	Family History of PD	☐
Inflammation/Swelling	☑	Generalized	☑	Type IV (>6mm); Advanced Periodontitis; ADA Code 4800 ☐	Pregnant/Nursing	☐
Bone Loss	☐			Type III (4-6mm); Moderate Periodontitis; ADA Code 4700 ☑	Immunosupressed	☐
Redness/Discoloration	☐			Type II (3-4mm); Mild Periodontitis; ADA Code 4600 ☐	Diabetes	☐
Halitosis/Malodor	☐			Type I (1-3mm); Gingivitis; ADA Code 4500 ☐	Cardiovascular Disease	☑
				Good Periodontal Health ☐	Current Smoker	☐

Antibiotic Allergies: None Reported

Tooth Numbers	3	9	14	19	24	30
Pocket Depths	4mm	4mm	5mm	4mm	4mm	3mm

Additional information is available from OralDNA.com

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Medical Director

MYPERIOID®

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MOLECULAR DETECTION OF IL-6 PERIODONTAL RISK FACTORS

Genotype	Risk
G/G	HIGH

Interpretation:

This individual's interleukin 6 genotype (IL6) is G/G. This MyPerioID result indicates your patient has a high risk for periodontal inflammation due to the genetic variation examined in this test.

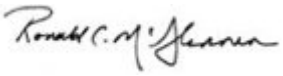
Comments:

- Significance: The prevalence of the G/G genotype is reported to be higher in individuals with moderate to severe chronic periodontitis and aggressive periodontitis than in individuals with no periodontal disease. This finding was independent of other risk factors such as age, smoking, ethnic origin. The 'G' allele is associated with overproduction of interleukin-6 (IL-6) cytokine in the presence of pathogenic periodontal bacteria.

- Risk: Individuals carrying an IL6 G allele are associated with increased odds of the concomitant detection of A. actinomycetemcomitans, P. gingivalis and T. forsynthensis.

- Consider: IL-6 is a potent stimulator of osteoclast differentiation and bone resorption, is an inhibitor of bone formation, and overproduction has been implicated in systemic diseases such as juvenile chronic arthritis, rheumatoid arthritis, osteoporosis, Paget's disease and Sjogren's syndrome. The MyPerioID 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 periodontal disease. Additional risk factors including other genetic markers, smoking, diabetes, and oral hygiene have an amplifying effect on disease progression and duration. The incidence of IL6 genotypes is reported to vary by ethnicity. Additional testing, such as MyPerioPath, may be considered if not already performed.

Methodology: Genomic DNA is extracted and tested for the interleukin 6 genetic variation located at position -174 (rs1800795). This genetic variation is tested by methods of the polymerase chain reaction, endonuclease digestion and resultant restriction fragment detection by automated microcapillary electrophoresis.
Disclaimer: The reported genotypes are a subset of the group of genes that comprise the complete immune system. This genetic analysis may not detect specific immunologic diseases or predict the health and effectiveness of a person's immunity for specific diseases. Such an evaluation may require genetic counseling and testing directed to characterize those genetic conditions. This test was developed and its performance characteristics determined by OralDNA Labs. It has not been cleared or approved by the US Food and Drug Administration.



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