

FINAL REPORT

Sample, Report

Date Of Birth: 09/20/1974 (43 yrs)

Gender: Female Patient Id: 920

Patient Location: Test Location A

Ordering Provider Ronald McGlennen MD

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

Sample Information

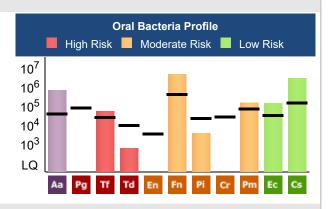
Specimen#: 5033032170 Accession#: 201807-12481 Specimen: Oral Rinse(P) Collected: 07/17/2018 Received: 07/18/2018 10:28 Reported: 07/19/2018 14:00

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SUMMARY OF TEST RESULTS

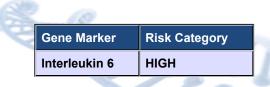
MyPerioPath[®]

- 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.



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





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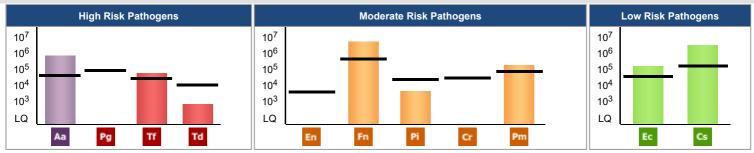
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MYPERIOPATH MOLECULAR ANALYSIS OF PERIODONTAL AND SYSTEMIC PATHOGENS

Results



Legend: The result graphic displays the bacterial level in genome copies/milliliter in log10 values. The limit of quantification (LQ) is the lowest bacterial level that can be repeatedly measured. The Reference Lines, displayed as black lines through each bar graph, indicate the mean bacterial level observed in patients with ADA III (moderate to severe, and/or with an average pocket depth (PD) of 4-5 mm) chronic periodontitis.

Interpretation of Results

- This result shows 2 high risk (🔤, 🞹) and 2 moderate risk (🔤, 🔼) pathogens above the therapeutic threshold. High levels of 🙉 , 🖾 are frequently part of this complex bacterial profile.
- The bacterial species T and/or A are strongly associated with chronic periodontitis, are transmissible and tissue invasive even at low amounts of these organisms. Moreover, 🏧 is pathogenic due to virulence factors that the organism expresses, resulting in inflammation that leads to tissue destruction. Note: the bacterial species make is commonly resistant to various treatments, and may be a reservoir of antibiotic resistance.
- The detected pathogens are also risk factors for various systemic diseases, including atherosclerosis, type 2 diabetes, arthritis, dementia and several types of cancer. Periodontal infections involving [10] have been associated with widespread and tissue invasive diseases of the lung, pancreas, heart, and bone. The spread of 6 infections is direct and often associated with abscess formation.

Treatment Considerations: to be determined by the healthcare professional

- Mechanical/Debridement: Scaling and root planing (SRP) is a mainstay of therapy to disrupt biofilm, remove plaque and debride compromised tissue. This patient harbors a series of pathogens (🔤 , 🔟 , 🔼 , 📂) that may be refractory to this treatment.
- **Systemic Antibiotics:** This patient has indicated no allergies.



Amoxicillin 500 mg tid for 8-10 days AND Metronidazole 500 mg bid for 8-10 days As always, use antibiotics with care

- Local Antibiotics and Chemical Hygiene: As an adjunct to SRP, sub-antimicrobial doses of doxycycline hyclate lower collagenase activity and reduce periodontal pocket depth. Alternatively, locally delivered antimicrobial agents (LDA) including minocycline microspheres, doxycycline hyclate in an absorbable polymer, or chlorhexidine in a gelatin matrix have been shown to decrease pocket depth modestly.
- Pocket or Field Decontamination: Laser decontamination as an adjunct therapy to SRP may be beneficial in reducing probing depth and bacterial loads. The consideration of using lasers as an adjunct to SRP is dependent on type of laser used and the particular protocol.
- Chemical and Gaseous antiseptics: Chlorhexidine or Povidine iodine rinses can reduce periodontal pocket depth. Prescription tray application of peroxide gel, as an adjunct to frequent periodontal maintenance appointments for refractory patients, demonstrated significant reductions in bleeding on probing. Ozone is a volatile antiseptic that can disrupt microbial membranes.
- Probiotics and Prebiotics: Probiotics are live, beneficial bacteria, typically administered as a food or dietary supplement. Prebiotics are non-digestible ingredients that promote growth of commensal bacteria. Research shows that prebiotics and probiotics control the growth of pathogens and reverse tissue destruction caused by periodontitis.
- Periodontal Surgery: When clinical signs & symptoms of a periodontal infection persist, or periodontal anatomy is not conducive to health, periodontal surgical evaluation and/or intervention may be indicated.

Follow up Recommendations

- Good periodontal health depends on compliance of a home care regimen as detailed by your healthcare provider. Daily brushing, flossing, as well as attention to nutrition, proper rest and cessation of smoking are essential.
- Follow-up testing between 6-12 weeks with MyPerioPath is recommended. Persistence of bleeding on probing is often indicative of unresolved infection. Retesting will identify residual or refractory bacteria. Currently there is not a cure for periodontal disease, only periods of remission.
- Assessment of a patient's level of inflammation with Celsus One is valuable in deciding the frequency of patient recall and treatment.

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Sample Information

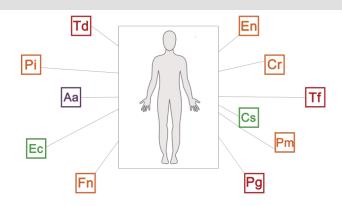
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Clinical Considerations

Reason for Testing	Clinical	Diagnostic	Medical History
✓ Not Provided	_		✓ Past History of Smoking✓ Cardiovascular Disease✓ Diabetes

Systemic Effects of Oral Pathogens



Cancer

Cardiovascular Health

Joint and Musculoskeletal Health

Dementia and Brain Health

Metabolic Health

Healthy Pregnancy

Chronic gum disease, involving As, Po, Td, Tt, & In is a risk factor for the development of certain cancers including ones involving the pancreas, esophagus, colon, lungs, and the head and neck. Additionally, untreated gum disease is a cause of ongoing inflammation, which may promote the

advancing growth of

tumors.

Select bacteria such as

AB, Td, TT, Po, Pi, & Fn

can leak from blood

vessels in the gums and

travel to the heart, where

cholesterol and other

lipids deposit. These

bacteria can incite

inflammation in arteries,

and if occluded, cause a

heart attack. A goal of

treatment is to minimize

the levels of these

bacteria as much and as

long as possible.

The periodontal bacteria Po, Fn & Co are a cause of arthritis. The oral inflammation caused by these bacteria also leads to total body inflammation which, combined with changes in a person's immunity, may result in chronic joint diseases like rheumatoid arthritis.

Recent medical studies point to poor oral health, and high levels of the bacteria Pg, CG in our gums, increasing the risk of developing dementias such as Alzheimer's.

Obesity, lack of exercise and chronic gum disease involving the bacteria [Aa], [1d], [17], [9], & [10] cause chronic inflammation.

Inflammation can damage the pancreas where insulin is produced, possibly leading to diabetes.

Also, diabetes worsens oral health by increasing the level of harmful bacteria in the gums.

Methodology: Genomic DNA is extracted from the submitted sample and tested for 10 species-specific bacteria [Aa: Aggregatibacter actinomycetemcomitans, Pg: Porphyromonas gingivalis, Tf: Tannerella forsythia, Td: Treponema denticola, En: Eubacterium nodatum, Fn: Fusobacterium nucleatum/periodontium, Pi: Prevotella intermedia, Cr: Campylobacter rectus, Pm: Peptostreptococcus (Micromonas) micros, Ec: Eikenella corrodens] and 1 genus of bacteria [Cs: Capnocytophaga species (gingavalis, ochracea, sputigena)] known to cause periodontal disease. The bacteria are assayed by real-time quantitative polymerase chain reaction (qPCR). Bacterial levels are reported in log 10 copies per mL of sample (e.g. 1x10^3 = 1000 bacteria copies per mL of collection). Cross-reactivity is possible with Leptotrichia buccalis, Fusobacterium hwasooki, and Capnocytophaga granulosa. 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.

Ronald McGlennen MD, FCAP, FACMG, ABMG

Medical Director



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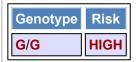
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Reason for Testing: Evaluation of Systemic Disease

Related info: Not Provided Patient History: Not Provided

MOLECULAR DETECTION OF IL-6 PERIODONTAL RISK FACTORS



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.

Romate C. M. Henren

Ronald McGlennen MD, FCAP, FACMG, ABMG

Medical Director

PL-000415-E