FINAL REPORT

ALERT2™

SAMPLE, REPORT

Date of Birth: 09/20/1980 (42 yrs)
Gender: Male
Patient ID: 920-L
Patient Location: Test Site A

ORDERING PROVIDER

Ronald McGlennen MD
7400 Flying Cloud Drive
Suite 150
Eden Prairie, MN 55344
855-672-5362

SAMPLE INFORMATION

Specimen#: 5631001002
Accession#: 202306-03434
Specimen: Oral Rinse(P)

Collected: 06/28/2023
Received: 06/29/2023 12:09
Reported: 06/30/2023 14:56

ORALDNA® LABS

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CLIA#: 24D1033809
CAP#: 7190878

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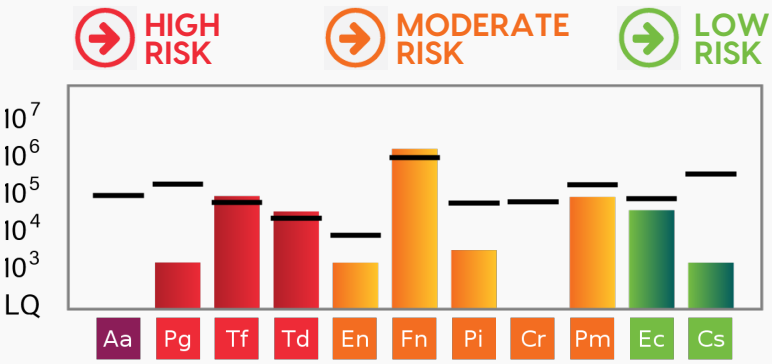
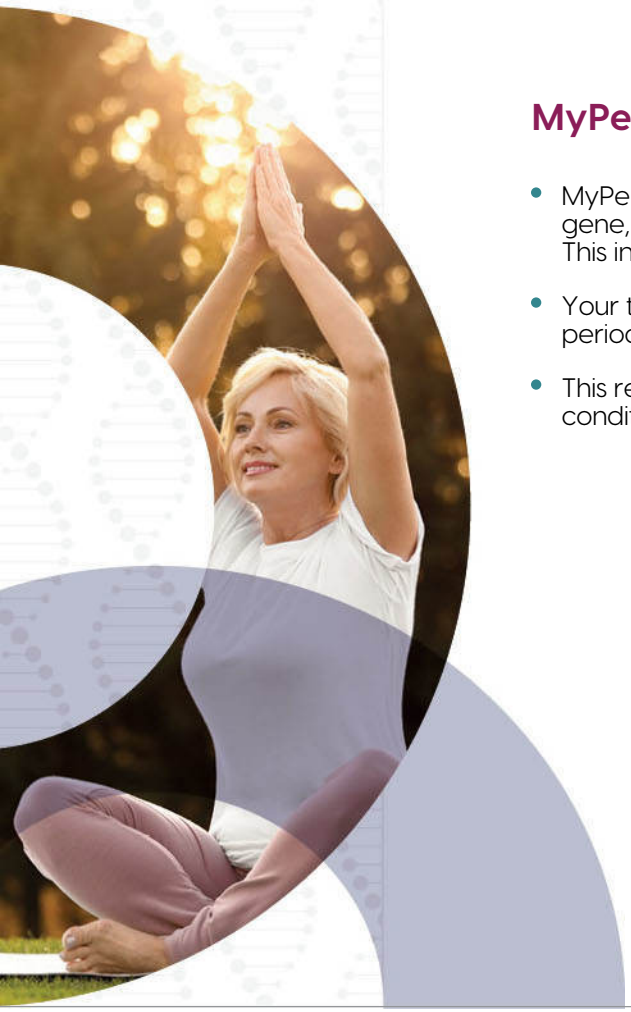
SUMMARY OF TEST RESULTS

MyPerioPath®

- MyPerioPath® measures 11 types of bacteria known to cause periodontitis (gum disease). These bacteria are also associated with diabetes, increased risk of cardiovascular disease, adverse pregnancy outcomes, rheumatoid arthritis, dementia, and other systemic illnesses.
- 9 of the 11 bacteria types were detected in the submitted sample. 3 of these are above the Reference Line(s).
- The levels of Tf and Td are of particular concern. These aggressive bacterial types are associated with disease recurrence and possible systemic effects.

Oral Bacteria Profile





MyPerioID® IL-6

Gene Marker	Risk Category
Interleukin 6	HIGH

- MyPerioID® determines the nucleotide sequence at one region of the Interleukin 6 gene, a key marker of a person's immune system and inflammation response. This information assesses the risk of inflammation based on your genetics.
- 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

- 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, dental consultation and treatment should be considered. A follow-up test is recommended to monitor the effectiveness of current treatments and to determine the type and frequency of future care.
- Celsus One™ test can help further examine a series of genetic markers to detail your inflammatory risk.

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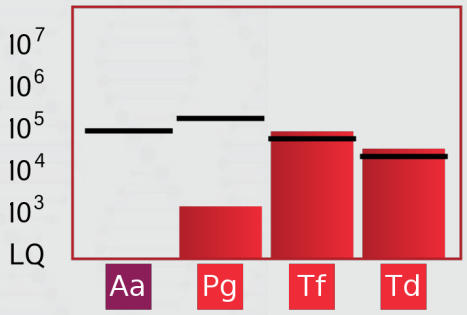
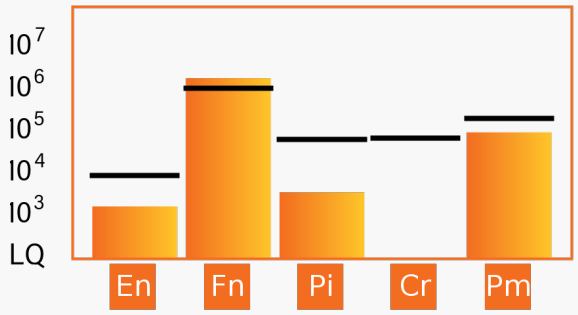
MYPERIOPATH® MOLECULAR ANALYSIS OF PERIODONTAL AND SYSTEMIC PATHOGENS

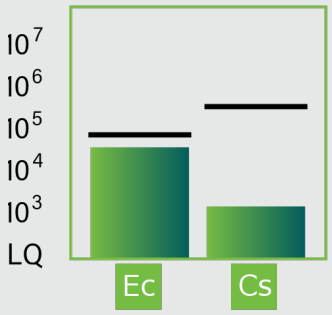
HIGH RISK PATHOGENS



MODERATE RISK PATHOGENS



LOW RISK PATHOGENS



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 (10^2). The Reference Lines, displayed as black lines on each bar graph, indicate the mean bacterial level observed in patients with chronic periodontitis AAP Stage I-II. Reference Lines are not to be used as a basis of treatment.

INTERPRETATION OF RESULTS

For full names of bacteria - see Test Methodology.

- This result shows 2 high risk (**Tf**, **Td**) and 1 moderate risk (**Fn**) pathogens above the Reference Lines (see Legend).
- Scaling and root planing (SRP) resistant microorganisms **Pg**, **Tf**, **Pi**, **Pm** may not respond to mechanical debridement alone. Tissue invasive microorganisms **Pg**, **Tf**, **Td** can be refractory to treatment. The microbiological characteristics of these bacteria are virulent and transmissible. Adjunctive therapies should be considered to address these bacteria.
- **Td** is a motile and highly proteolytic, gram-negative spirochete and possesses proteins needed for adherence and invasion of host cells, thus leading to tissue destruction. **Td** has been shown to accelerate vascular disease of the aorta.

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SUGGESTED THERAPIES:

To be determined by the healthcare professional

Mechanical/Debridement:

Disruption of biofilm including the removal of plaque and calculus deposits is needed to shift the oral microbiome. This action stimulates the tissue to heal.

Adjunctive Therapies:

Personalized treatment is sometimes needed to address the more resistant bacteria in the profile. Therapies could include some or all but are not limited to:

- Systemic Antibiotics
- Chemical Hygiene
- Antiseptics
- Localized Probiotics
- Localized Antimicrobials
- Lasers
- Tray Delivered Medicaments
- Localized Prebiotics

*The most recent research of the use of adjunctive therapies as monotherapies is not well documented.

Surgical Referral:

When clinical signs and symptoms of a periodontal infection persist, or periodontal anatomy is not conducive to health, periodontal surgical evaluation and/or intervention may be indicated.

Co-Management Referral:

Various bacteria can incite inflammation throughout the body. (See Systemic Effects). These bacteria are important to consider as a source of chronic and systemic inflammation. Additional evaluation for risk of disease may be indicated.

ANTIBIOTIC OPTIONS

RECOMMENDED TREATMENT

Metronidazole 500 mg bid for 8-10 days

This patient has indicated no allergies. If patient has intolerance to the first choice consider:

2ND CHOICE

Clindamycin 150 or 300 mg tid for 8-10 days

3RD CHOICE

Ciprofloxacin 500 mg bid for 8-10 days

The use of systemic antibiotics should be administered responsibly. Dosage/Duration dependent on severity of infection.

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FOLLOW UP RECOMMENDATIONS

Follow up testing between **6-12 weeks post therapy** 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.

Maintenance of periodontal health involves a home care regimen as detailed by your health care provider. Other factors to consider for achieving and maintaining health are attention to nutrition, stress reduction, proper rest, cessation of smoking, as well as emotional connectivity.

The natural history of periodontal disease consists of periods of remission and relapse. **Remission** is established when signs of inflammation are absent at any level of bacteria, and **relapse** is the reappearance of active disease. Consider testing annually or when signs of relapse occur.

CLINICAL CONSIDERATIONS

Diagnostic

- ✔ Periodontal Classification: Not Provided

Reason for Testing

- ✔ Active Periodontal Disease

Clinical

- ✔ Bone Loss (<15%)

Medical History

- ✔ Diabetes

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SYSTEMIC EFFECTS OF ORAL PATHOGENS

CARDIOVASCULAR HEALTH

Select bacteria such as **Aa**, **Td**, **Tf**, **Pg**, **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.

CANCER

Chronic gum disease, involving **Aa**, **Pg**, **Td**, **Tf**, & **Fn** 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.

JOINT AND MUSCULOSKELETAL HEALTH

The periodontal bacteria **Pg**, **Fn**, & **Ec** are a cause of arthritis. The oral inflammation caused by these bacteria also leads to total body inflammation which, combined with changes in a persons immunity, may result in chronic joint diseases like rheumatoid arthritis.

DEMENTIA AND BRAIN HEALTH

Recent medical studies point to poor oral health, and high levels of the bacteria **Pg**, **Cr**, & **Cs** in our gums, increasing the risk of developing dementia such as Alzheimers.

HEALTHY PREGNANCY

Bacteria associated with gum disease, especially **Aa**, **Pg**, **Tf**, **Ec**, & **Fn** are known to put a pregnancy at risk for pre-term birth, decreased birth weight and even blood infection in the placenta or newborn. Every pregnant woman should be tested for these harmful bacteria.

METABOLIC HEALTH

Obesity, lack of exercise and chronic gum disease involving the bacteria **Aa**, **Pg**, **Td**, **Tf**, & **Fn** 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. The analytical and performance characteristics of this laboratory-developed test (LDT) were determined by OralDNA Labs pursuant to Clinical Laboratory Improvement Amendments (CLIA 88) requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration.

Ronald C. McGlennen

Ronald McGlennen MD, FCAP, FACMG, ABMG
Medical Director

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Reason for Testing	Active Periodontal Disease
Related Info	Not Provided
Patient History	Diabetes

MYPERIOID® MOLECULAR DETECTION OF IL-6 PERIODONTAL RISK FACTORS

Genotype	Risk
G/G	HIGH

Interpretation:

This individual's interleukin 6 genotype (IL-6) 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.

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, and ethnic origin. The 'G' allele is associated with overproduction of IL-6 cytokine in the presence of pathogenic periodontal bacteria.

Risk:

Individuals carrying an IL-6 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 of IL-6 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 IL-6 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 IL-6 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. The analytical and performance characteristics of this laboratory-developed test (LDT) were determined by OralDNA Labs pursuant to Clinical Laboratory Improvement Amendments (CLIA 88) requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration.

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