HR5™
HIGH RISK PATHOGEN TEST

DO YOU HAVE BLEEDING GUMS?

Oral bacteria make their way into the bloodstream and place you at risk.

7x
increased risk of **Adverse Pregnancy Outcomes** including pre-term birth and low birth weight
Source: AAOSH

95%
of Americans with **Diabetes** also have periodontal disease. Periodontal disease lowers glycemic control
Source: AAOSH

70%
more likely to develop **Alzheimer's Disease** in people who suffer from gum disease for more than 10 years
Source: Alz Res Therapy (2017)

12%
higher risk of **Premature Death** in women who have a history of periodontal disease
Source: Journal of the American Heart Association (2017)

Increases risk of **Cancer** including oral, esophageal, lung, colorectal, pancreatic, and breast cancers
Source: AAOSH

80%
of American adults over 35 have some form of Gum Disease
The American Academy for Oral Systemic Health (AAOSH)

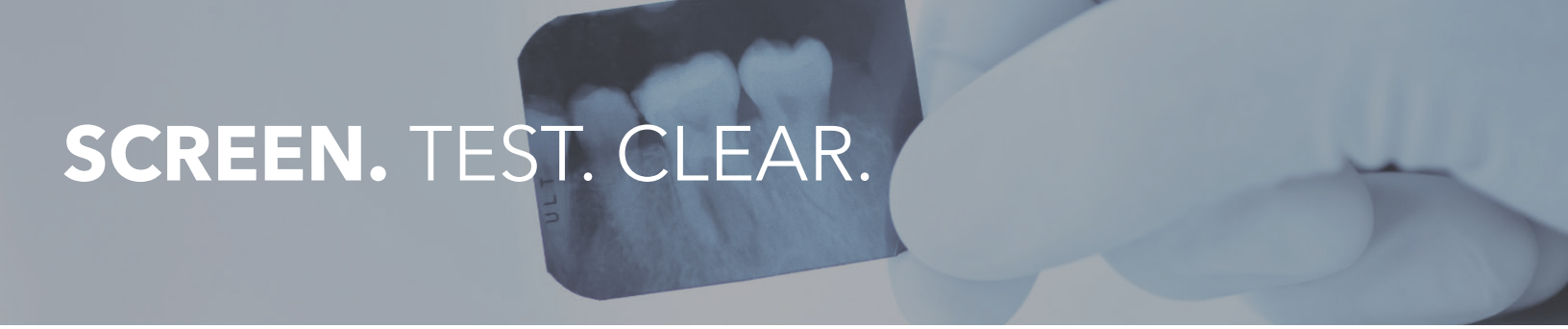
50%
Up to 50% of heart attacks and strokes are triggered by oral pathogens
Source: Circulation (2013)

IS YOUR MOUTH PUTTING YOUR BODY AT RISK?

Evidence shows that 5 high risk oral pathogens are causative drivers of inflammation and disease.

SCREEN. TEST. CLEAR.

directdiagnostics.com



SCREEN. TEST. CLEAR.

1 HEALTHY

- Measurement 1-3mm
- No bleeding
- No bone loss
- No infection

2 GINGIVITIS

- Measurement 1-3mm+
- BLEEDING
- No bone loss
- INFECTION in the tissue

3 PERIODONTAL DISEASE

- Measurement 4mm+
- BLEEDING
- Bone loss 1mm+
- INFECTION in the tissue and bone

Save Teeth and Save Lives.

HR5™
HIGH RISK PATHOGEN TEST

Aa
Aggregatibacter actinomycetemcomitans

Pg
Porphyromonas gingivalis

Td
Treponema denticola

Tf
Tannerella forsythia

Fn
Fusobacterium nucleatum

Why Test?

Testing is the first step in early detection and prevention

- Testing determines the cause and severity of the infection
- Testing provides a medical diagnosis
- Testing validates treatment
- Testing identifies early stages of infection

DIRECT DIAGNOSTICS

HR5: HIGH RISK PATHOGEN TEST

Patient Name	**JAMES KIRK**	Accession	5699871	Facility	Enterprise Dentistry
DOB	3/17/2170	Date Collected	8/12/2221	Clinician	Bones
Patient ID	498760	Date Reported	8/14/2221	Phone	512-550-2010

Thank you for entrusting us with your High-Risk Pathogen Test. This unique and important medical test quantifies the most serious and high-risk oral pathogens that cause Periodontitis (tooth loss), Peri-Implantitis (Implant loss), and Systemic Inflammation throughout the body. Learn more by visiting www.directdiagnostics.com.

Test Name: HR5
Test Type PCR Test
Specimen Source: Saliva
Relative Risk Categories:
Low | Moderate | High

Date: [Date Resulted]

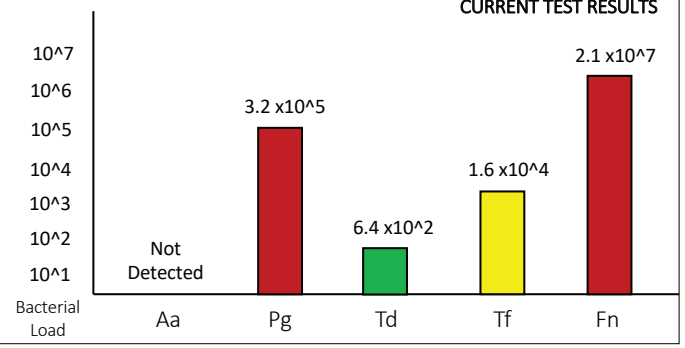
PRIOR TEST RESULTS

Aa	Pg	Td	Tf	Fn
Not Detected	6.7 x10^5	1.2 x10^3	9.5 x10^4	3.4 x10^7

Existing Medical History

Yes	C. V. Disease
Yes	Heart Attack
No	Ischemic Stroke
No	Diabetes (I/II)
No	Antibiotic Allergy
No	Current Smoker
No	Pregnant

CURRENT TEST RESULTS



Aggregatibacter actinomycetemcomitans [Aa] is a primary cause of rapid alveolar bone loss in both children and adults, severe periodontitis and dental implant failure. Research studies have shown this pathogen increases risk for Cardiovascular Disease, Ischemic Stroke, Brain Abscesses, & Heart Infections. 10^2

***Porphyromonas gingivalis* [Pg]** is a primary cause of alveolar bone loss, periodontitis and implant failure. Research studies have shown this pathogen increases risk for Heart Attack, Ischemic Stroke, Type Two Diabetes, Dementia, Alzheimer's Disease, and other inflammatory diseases. 10^3

***Treponema denticola* [Td]** is a primary cause of periodontitis and implant failure. Recent studies have also demonstrated its association with Dementia and Alzheimer's Disease. 10^3 ↔ 10^5

***Tannerella forsythia* [Tf]** is a primary cause of periodontitis and implant failure. It's effect on other health issues is not well known. 10^3 ↔ 10^5

***Fusobacterium nucleatum* [Fn]** is associated with periodontitis and implant failure. Among the systemic issues is that it has been associated with preterm birth, low birth weight babies, and even fetal death. This pathogen tends to facilitate the movement of other oral pathogens into the circulatory system. 10^6 ↔ 10^7

Your oral health professional will discuss personalized treatment options. When used in conjunction with other health related risk factors, your clinician can design a personalized treatment plan to reduce these pathogens to an acceptable level: thus, preventing tooth loss, implant loss, and systemic exposure.

This test performed by Paratus Diagnostics, 3055 Hunter Rd, San Marcos, TX 78666 CLIA# 45D2190910. Negative results do not preclude infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information (Source: FDA). Disclaimer: This test was developed and its performance characteristics were determined by Paratus Diagnostics. The U.S. Food and Drug Administration has not approved or cleared this test; FDA clearance or approval is not currently required for clinical use as the laboratory is regulated and qualified under CLIA to perform high complexity testing.

PERSONALIZED THERAPY GUIDE

Based on Test Results

Airway to Pathogens to Plaque

- ☐ Sleep disordered breathing, sleep apnea, high ADMA
- ☐ HR5 present: Aa, Pg, Td, Tf, Fn
- ☐ Resistant strains to scaling & root planing; Aa, Pg, Tf
- ☐ CIMT - soft plaque present, high coronary calcium score
- ☐ Inflammatory panel: MPO, Plac2, insulin resistance, diabetes
- ☐ Genetics: Haptoglobin, APOE, MTHFR, 9p21, Kif6, 4q25
- ☐ GI dysbiosis, leaky gut, gluten sensitivity

Therapies

- ☐ Gingival therapy / biofilm debridement (general biofilm low level reduction)
- ☐ Scaling and root planing (low level reduction, Td, Fn)
- ☐ Airflow / air polishing : dependent on powder- low level reductions, Aa, Pg, Tf, Fn)
- ☐ Ozone: bacteria, viruses, molds, fungi (general low level reduction) *
- ☐ Lasers / Photodynamic therapy (low level reductions, Aa, Pg, Tf)
- ☐ Customized tray system (depending on product in trays)
- ☐ Surgery (general low level reduction Td, Fn)

Antibiotics

- ☐ Systemic anitbiotics: based on test results, medical history and resistant strains (when taking address GI protocol)
- ☐ Locally applied:
  - ☐ Minocycline (Pg, Tf, Td)
  - ☐ Doxycycline (Pg, Fn)

Probiotics: Pre & Post

- ☐ Oral probiotic
  - ☐ S. salivarius (Fn)
  - ☐ S.uberis, S. rattus, S. oralis (Aa, Pg, Tf)
- ☐ GI Probiotic
  - ☐ L. acidophilus, B. bifidum, L. paracasei, L. lactis, L. rhamnosus, L. gasseri, L. salvaris, etc. (general repopulation)
  - ☐ L. reuteri (Fn)
  - ☐ S. boulardii (is a yeast - antibiotic resistant)
- ☐ Prebiotics
  - ☐ Oligosaccharides, inulin, polyphenols, etc.
- ☐ Postbiotics
  - ☐ Buytrate, glutamine, amino acids, enzymes, etc.

Antioxidants

- ☐ Homeopathic, natural, essential oils (general low level reductions, Aa, Pg, Fn)
- ☐ Polyphenols: xylitol, erythritol, trehalose (general low level reductions, Pg, balances pH)
- ☐ Zinc (Fn)

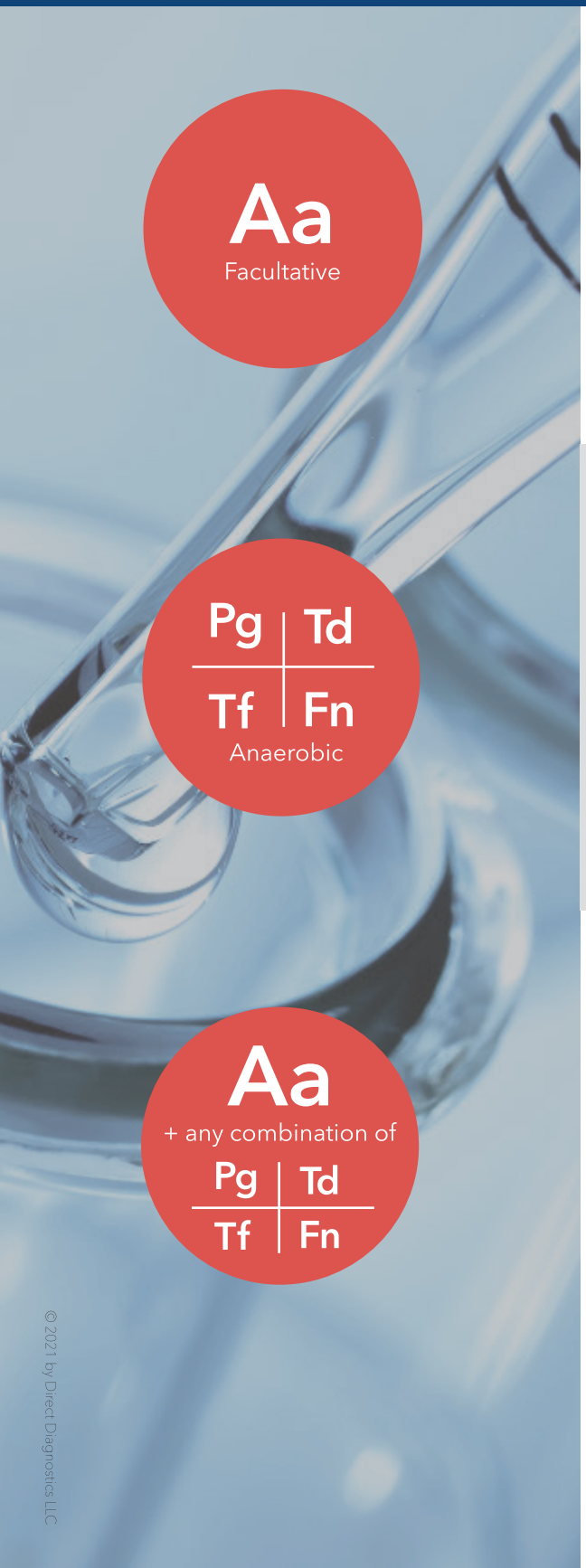
Antiseptics / Antimicrobials

- ☐ Chlorhexidine (general low level reduction Aa, Pg, Td)*
- ☐ CPC, chlorates, chlorites, chlorines (general low level reduction Aa, Td)*
- ☐ Fluorides (general low level reduction)*
- ☐ Hydrogen peroxide (general low level reductions Aa, Fn)*
- ☐ Iodines: molecular & povidone (general low level reductions, viruses, yeast, fungi, Aa, Pg, Tf)*

** contraindicated in medically compromised patients*

ANTIBIOTIC GUIDE

Based on Test Results



Aa
Facultative

First Choice
- Amoxicillin 500mg tid 8 days
- Option: Moxifloxacin 500mg tid 8 days

Second Choice (if allergic to 1st choice)
- Ciprofloxacin 500mg bid 8 days

Third Choice (if allergic to 2nd choice)
- Doxycycline 100mg bid 10 days

Pg | Td
Tf | Fn
Anaerobic

First Choice
- Metronidazole 500mg bid 8 days
- Option: Tinidazole 2gms QD 2-5 days

Second Choice (if allergic to 1st choice)
- Clindamycin 150mg qid or 300mg tid 7 days

Third Choice (if allergic to 2nd choice)
- Azithromycin 500mg 1st day, 250mg bid next 3 days

Aa
+ any combination of
Pg | Td
Tf | Fn

First Choice
- Amoxicillin 500mg tid & Metronidazole 500mg bid 8 days
- Option: Amoxicillin 500mg tid & Tinidazole 2gms QD 2-5 days

Second Choice (if allergic to 1st choice)
- Ciprofloxacin 500mg bid & Metronidazole 500mg bid 8 days
- Option: Clindamycin 150 qid or 300mg tid 7 days

Third Choice (if allergic to 2nd choice)
- Doxycycline 100mg bid 10 days

Oral Saliva Collection

PATIENT RULES

1. **30 minutes prior** - no food, beverages, gum, tobacco, brushing, etc.
   15 minutes prior - no water or in-office pre-rinse

2. **4 weeks prior -** no antibiotics or dental cleanings
   *Anitbiotic pre-medication prior to testing is okay

3. **Fill to 1ml red line**
   - Place mouth on tube to allow saliva to flow
   - Bubbles are okay but confirm liquid reaches the red line

4. **Tips for generating saliva**
   - Practice slow and shallow nasal breathing technique
   - Place gentle pressure on the side of the tongue
   - Move the jaw, tongue, or yawn
   - Purse lips as if sucking on a sour lemon

WHO TO TEST?

Stop Guessing and Start Testing

1
Gingivitis
1 bleeding point

2
Periodontal Disease
Active and perio maintenance

3
Restorative Care
Implants, surgery, root canals, etc.

DIRECT DIAGNOSTICS