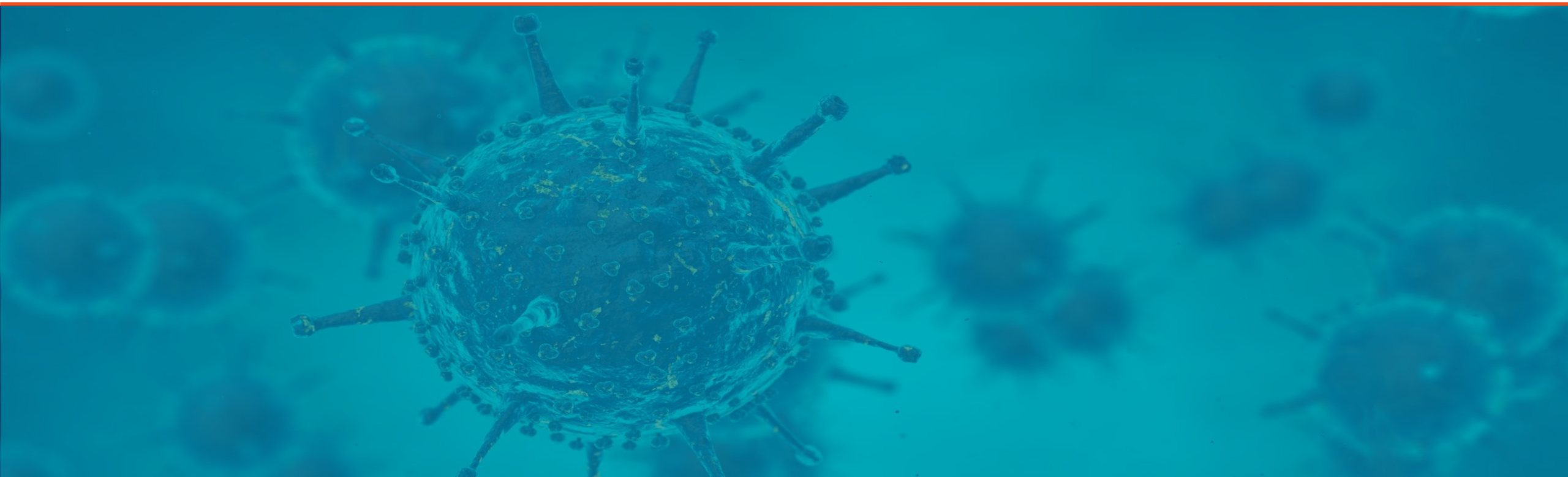
VIGILANTBIOSCIENCES®

An Innovator and Developer of OPMD & Early Cancer Diagnostics



VIGILANTBIOSCIENCES®

Our Mission

To ***save lives*** by providing world-class ***early detection*** solutions for cancer and OPMD

Our First Early Cancer Detection Product

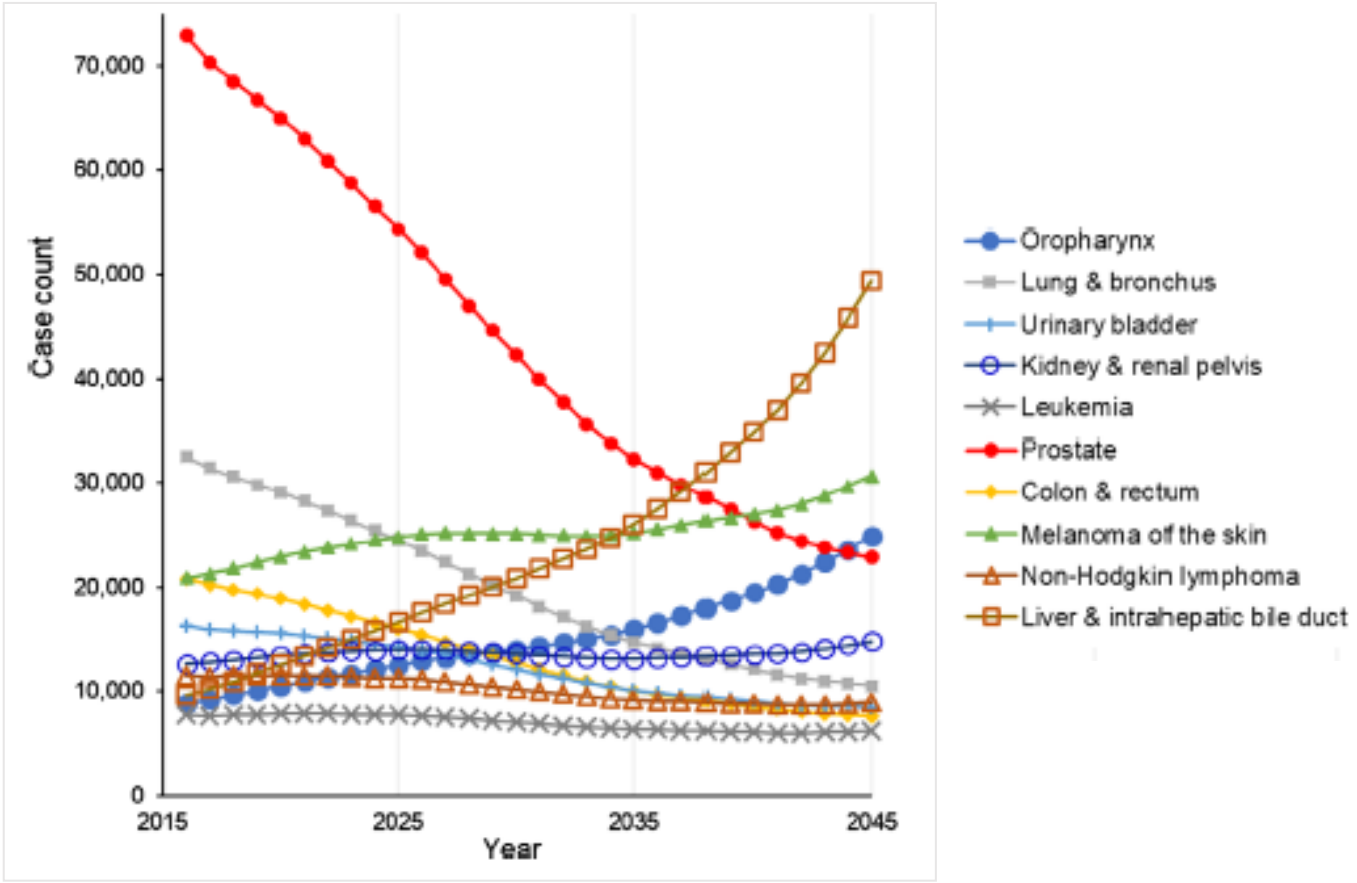
The **BeVigilant™ OraFusion™ System** aids clinicians with identifying patients at risk for **oral cancer**.

Current State of Oral Cancer – The Problem

- 700,000+ new cases globally per year
- Projected to be 3rd most prevalent cancer among men in US in 20 years
- * >73% of cases diagnosed late-stage
- 5-year survival rate: <50%
- Survival rate early-stage >80%
- Mis-diagnosis #2 reason Dentist get sued (avg settlement >$2.5M)

Key Point:
The current standard needs to be improved. The dental industry needs a tool to help!

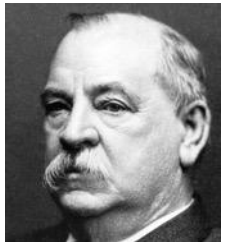
M.D. Anderson Cancer Center Report



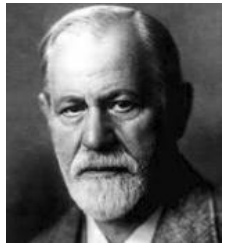
** Vigilant is trying to solve this problem!*

Oral Cancer is an Indiscriminate Disease

Ulysses S. Grant, *1884*



Grover Cleveland, *1893*



Sigmund Freud, *1923*

Jim Thorpe *1950*

Humphrey Bogart, *1956*

Ed Sullivan, *1974*

Sammy Davis, Jr., *1989*

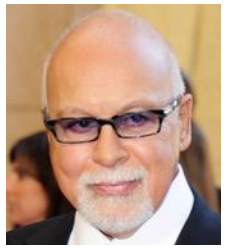
Lana Turner *1992*

Bill Tuttle *1993*

Diane von Furstenburg, *1994*

Brett Butler *1996*

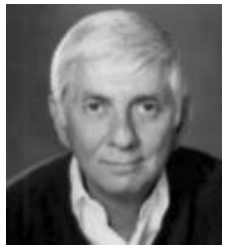
George Harrison, *1998*



Rene Angelil *1999*

Rod Stewart *2000*

Eddie Van Halen, *2000*

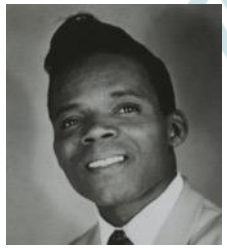


Aaron Spelling, *2001*

Roger Ebert *2002*

Hubert Green *2003*

Susan Buffett *2003*



Hank Ballard *2003*

Colleen Zenk *2007*

Michael Douglas, *2010*

Larry Hagman, *2011*

Jim Kelly *2013*

Michael Cooper, *2014*

Jamie Dimon *2014*

Val Kilmer *2015*

Erin Moran *2016*

Stanley Tucci *2017*

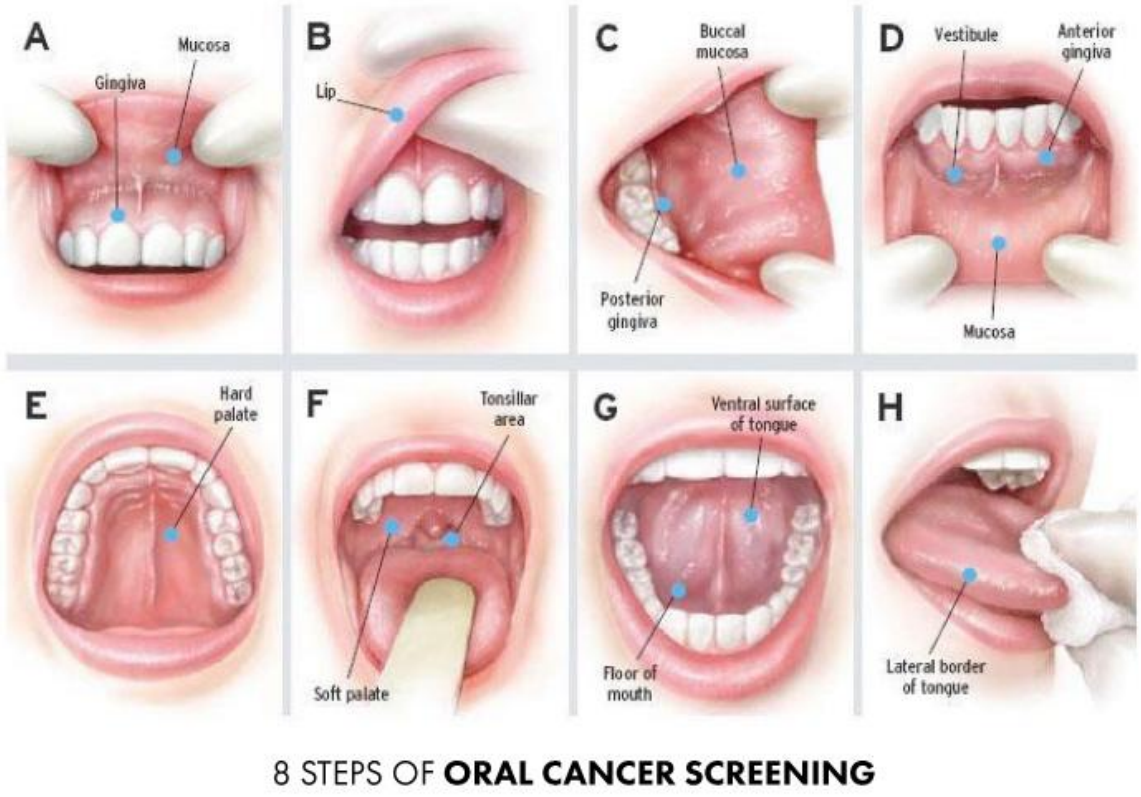
Dick Vitale, *2022*

Current Standard of Care – Oral Visual Exam

- Oral cancer screening
  - Performed by Dentist / Hygienist
  - Looking for signs of cancer or precancer
  - **~29% patients have an oral abnormality**
- ADA recommends every visit on every patient
- Dentist's is responsible and liable to detect oral abnormalities, diagnosing and referring patients
- **Accuracy: ~50/50**

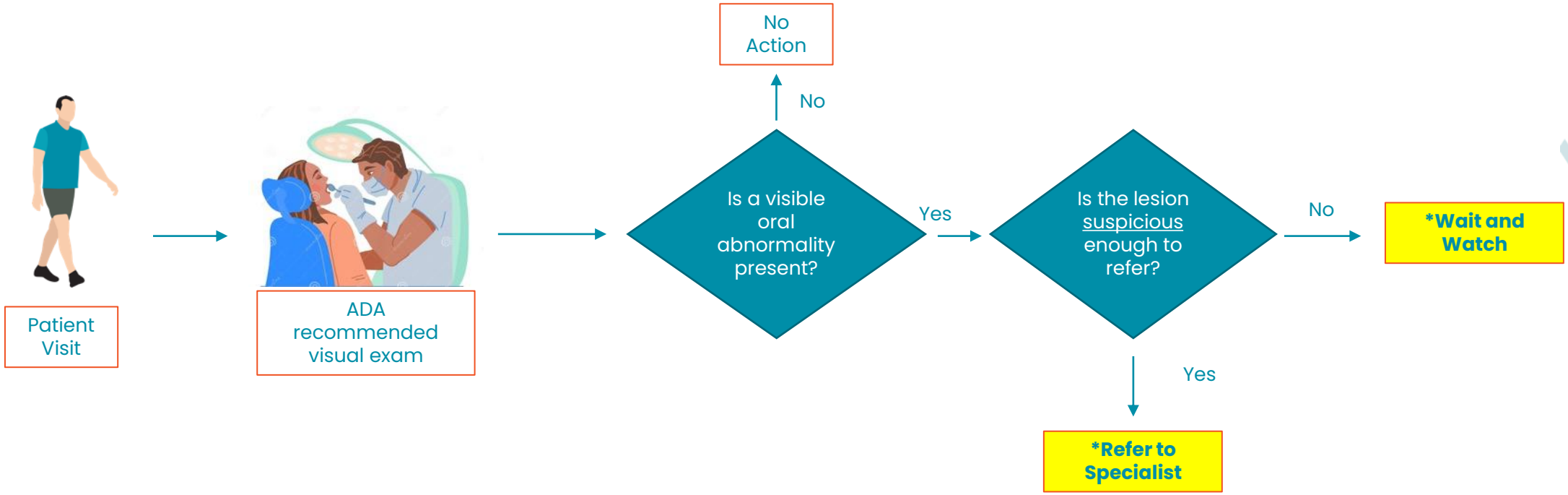
Key Point:

Visual Exam is not enough to accurately detect early-stage cancer



8 STEPS OF **ORAL CANCER SCREENING**

Current Standard Clinical Workflow



The current process only works when the lesion is obviously suspicious … late-stage cancers!

Results:
>73% diagnosed late-stage
< 50% survival Rate

***Current Key Decision**

Visual Exam - Examples

- Diagnosis:
- TRAUMATIC ULCER

- Diagnosis:
- EARLY SQUAMOUS CELL CARCINOMA

Visual Exam - Examples

- Diagnosis:
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The BeVigilant™ OraFusion™ Platform

First-of-its-kind risk assessment / diagnostic device provides exceptional accuracy

Intelligent software for clinical risk factor assessment

Ora-3D™ lateral flow immunoassay with multiple proprietary biomarkers

Whole saliva disposable collection device

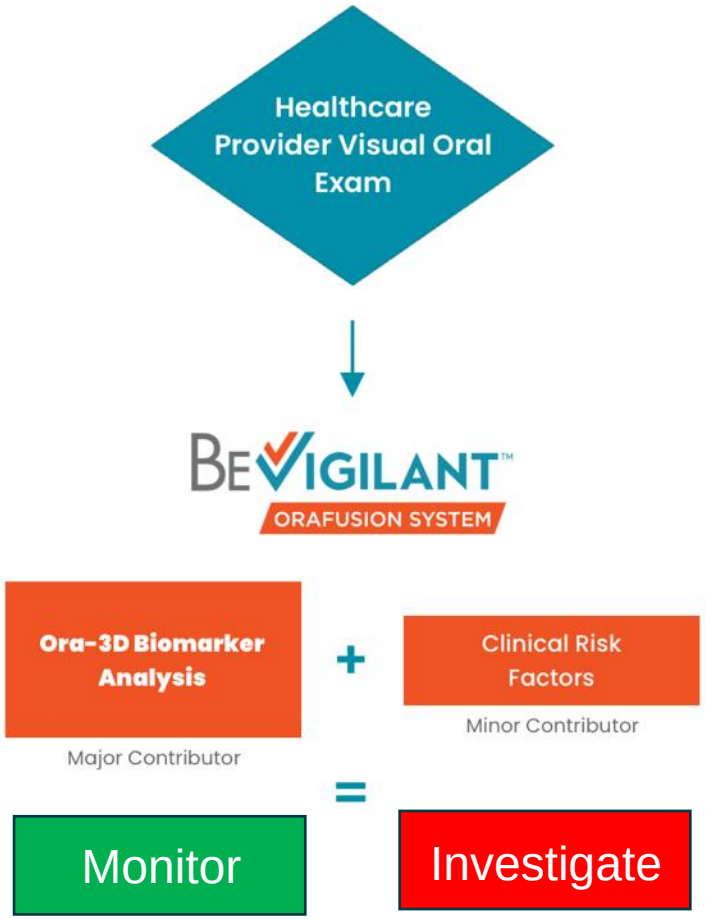
The OraFusion™ System is designed for use with small amounts (<1 ml) of whole fresh saliva.

How it Works – Fusion of Information

- Biomarkers in Saliva (major contributor)
  - Exact concentrations
  - Relationship to each other
  - How they are affected by other factors (such as age)
- Clinical Risk Factors (minor contributor)
  - Age, Gender, Tobacco and Alcohol
- AI / ML Algorithm driven
- Simple, actionable results
- Extremely accurate
  - Se, Sp, NPV ~93%

Key Point:

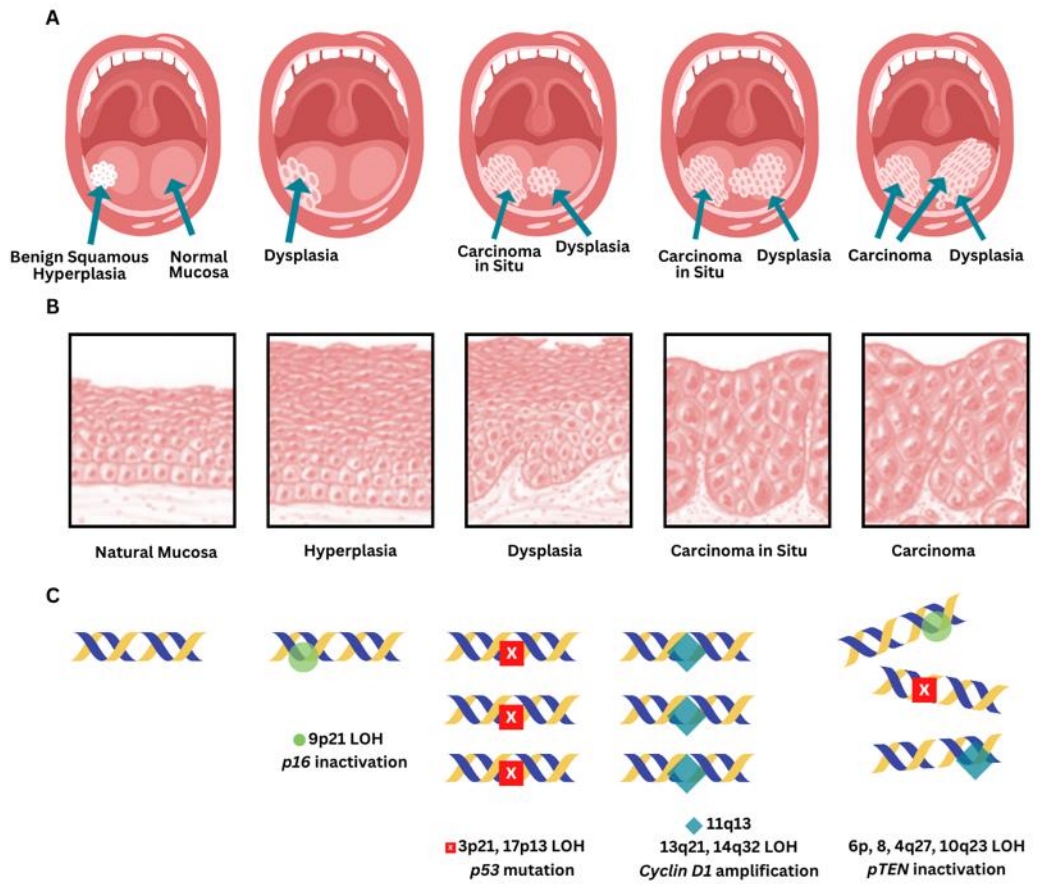
Accuracy improves with the fusion of results … 1 + 1 = 3



Progression of an Oral Abnormality to Oral Cancer

- Over 3000 proteomic & peptide biomarkers naturally exist in saliva
- As a lesion starts to exhibit cancerous behavior - biomarkers become overexpressed
- Identifying the concentrations of these biomarkers assist in the early detection
- Vigilant identified two proteomic biomarkers present in early stages

Key Point:
Precise biomarker concentration detection is essential to early diagnosis



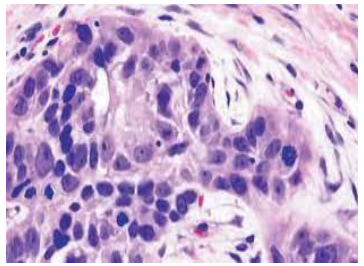
Elevated risk of Cancer

The Future of Early Cancer Detection

Multifactorial Oral Cancer Risk Stratification → Intervention & Assessment → Health Economics

- Population studies
- Identify risk factors
- Algorithm development

- Advanced Data Analysis
- Early-Stage Detection
- Likelihood of Cancer
- Simple Personalized Output
  - Low/Mod/Elevated
- Software Implemented Algorithm
- Improved Screening



- Improved High Risk Surveillance
- Specialized Treatment Plans
- Better Outcomes
  - Uptake of Risk Assessments
  - Uptake of Screening
  - Acceptance with Knowledge

Harm vs Benefit

Pre-Diagnostic (Risk Assessment) → Diagnostics

Benefit to General Dentist

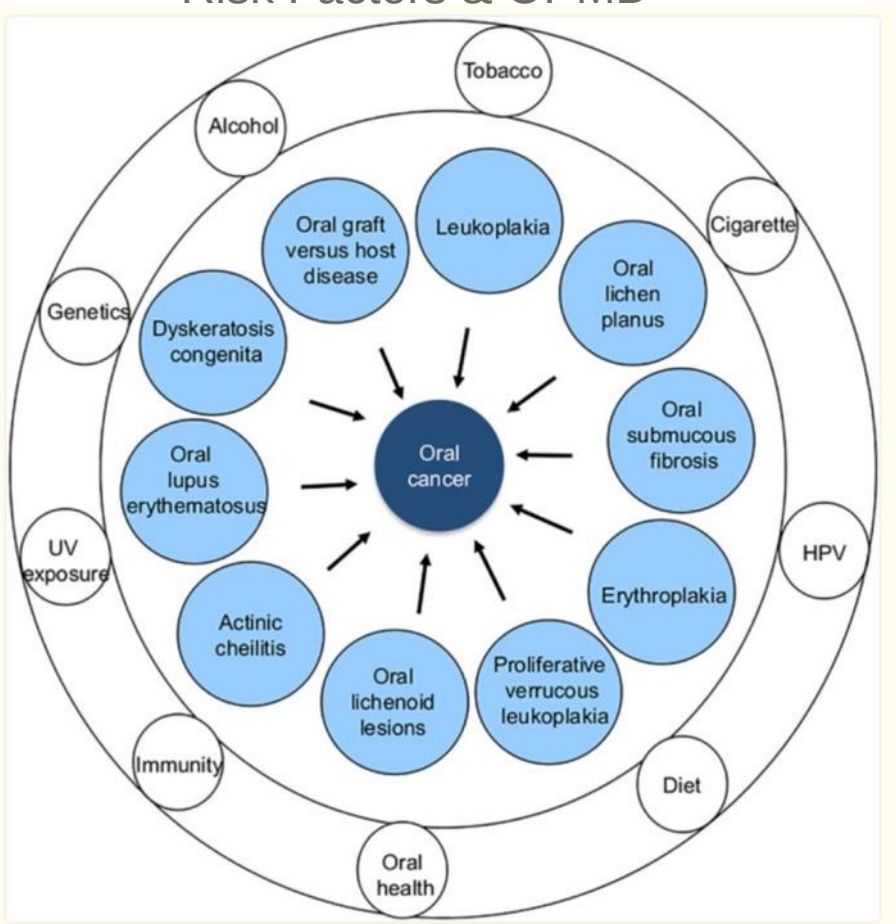
When to Use the OraFusion Test

- Oral Potentially Malignant Disorders (OPMD) could lead to oral cancer and should all be tested
- Dentist face the decision on how to treat these disorders on a regular basis
- Liability for diagnosis occurs from the moment the patient enters the practice

Key Point:

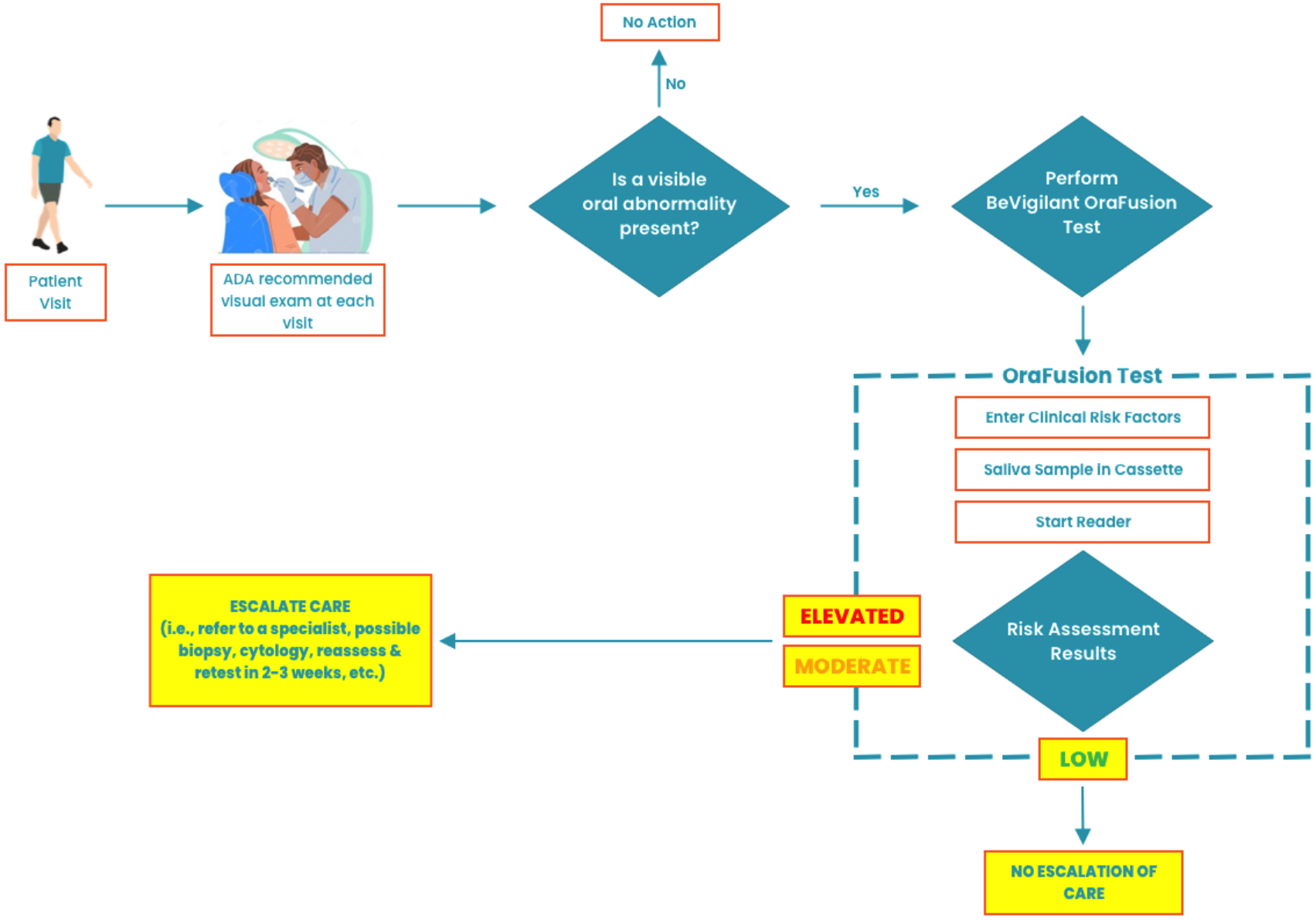
All OPMDs should be tested to prevent late-stage diagnosis

Risk Factors & OPMD



*NIH: Oral Potentially Malignant Disorders, Pratima Kumari; Priyanka Debta; Anshuman Dixit

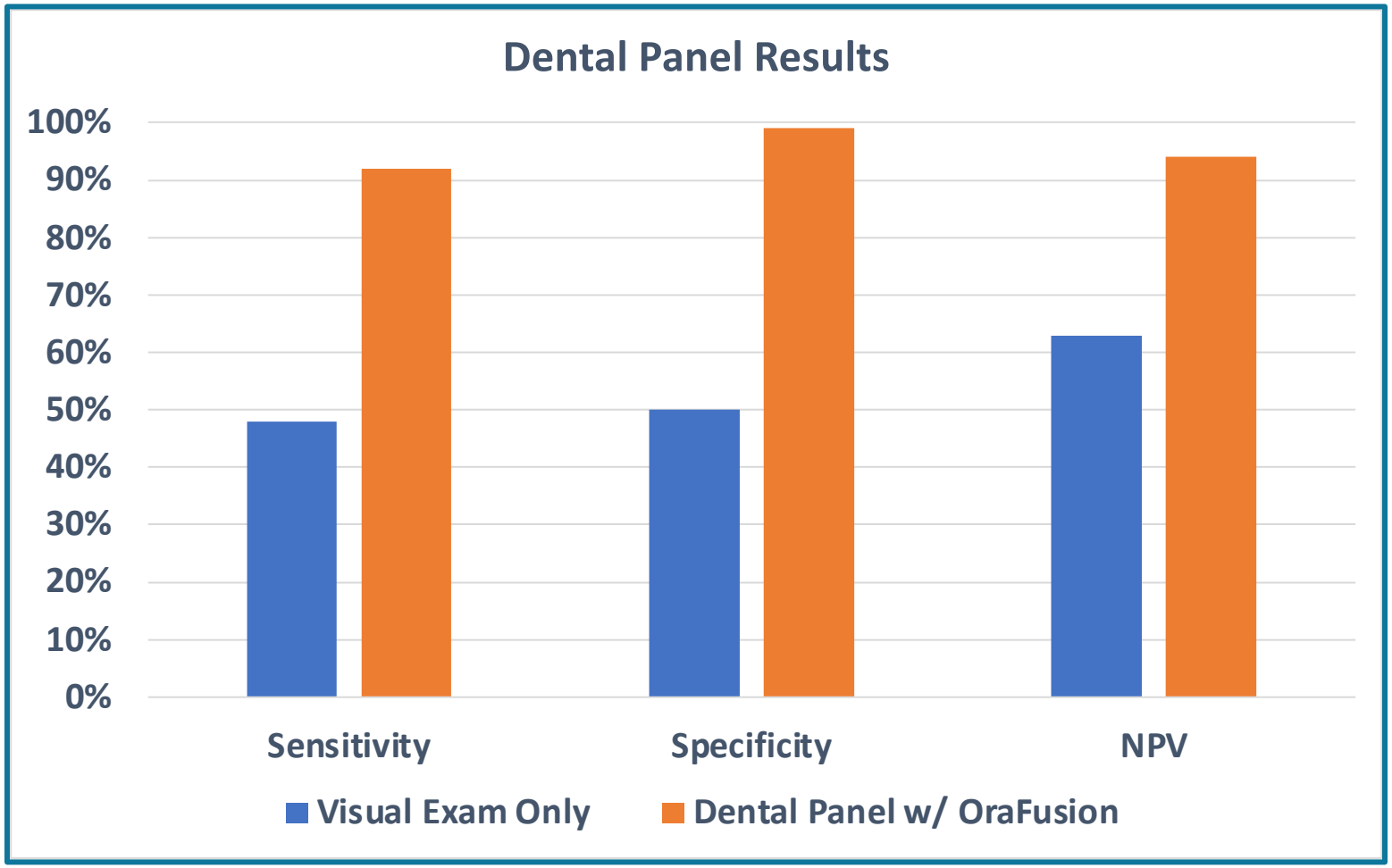
Recommended Clinical Workflow for OraFusion Test



CONFIDENTIAL & PROPRIETARY

Clinical Study Results – *FDA Pending*

A dramatic improvement in clinician's ability to properly assess patients for risk of oral cancer



"Essentially doubling my accuracy in properly assessing patients for oral cancer is amazing!"

Dr. Thomas, Orlando FL (Dental Panel member)

Benefits to Dentists – Make them the Hero … Save a life

- Accurately assess patients
  - Unlikely cancerous behavior - ***Peace of Mind***
  - Likely cancer or precancer – ***Sense of Urgency***
- Objective evidence that clinician should take action – ***Escalate Care***
- Increase Patient follow through
  - Follow up with Specialist – Get a biopsy
- Decrease Liability
  - Reduce malpractice risk of mis-diagnosis

Keys to Patient Communication:

- Elevate the status of the practice
  - Health care provided
  - Concern for patient's well being
- Clinician does not have to tell the patient they have cancer (that comes from biopsy)
  - Objective measure of "suspicious" abnormality
  - Need to escalate care
  - A specialist can rule out biggest concern
  - *Odds have it, it's nothing, but what if it's something!*
- **Catch the problem *Early*, before it's too late**

Get Checked … BeVigilant™