

Viome Precision Health Pro Test

Clinical Overview, June 2026

Executive Summary

Viome Life Sciences represents a paradigm shift in personalized healthcare, utilizing proprietary metatranscriptomic technology to analyze the dynamic gene expression of both human and microbial cells. Our CLIA-certified platform enables clinicians to move beyond traditional diagnostics toward comprehensive, molecular-level understanding of patient health, facilitating early intervention and precision medicine approaches that can detect disease risk years before clinical symptoms manifest.

Key Statistics:

- 1M+ Biological samples processed
- 500K+ Individuals from 100+ countries
- 30+ Disease models built from molecular data
- 22M+ Health insights delivered via biological pathway analysis

Key Highlights:

- CLIA Certified Laboratory
 - 10+ US and International Patents
 - 20+ Peer-reviewed and Preprint Publications
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Revolutionary RNA and AI Technology Platform

The Science: Why RNA Analysis Surpasses DNA-Based Methods

Viome's metatranscriptomic technology represents the most advanced approach to understanding human-microbe interactions and their effects on human health. Unlike DNA sequencing, which only identifies what organisms or genes are present (the "potential"), RNA sequencing reveals what these organisms are actually doing (the "activity"). This distinction is critical for clinical applications because:

Fundamental Scientific Advantages:

- Live vs. Dead Distinction: RNA degrades rapidly after cell death, ensuring we only measure active, living microorganisms that impact health
- Real-Time Activity: RNA reflects current gene expression, providing a dynamic snapshot of biological processes as they occur
- Functional Insights: Measures actual biochemical pathway activity rather than just genetic potential
- Human-Microbe Integration: Simultaneous analysis of human host and microbial gene expression reveals complex interactions
- Environmental Response: RNA expression changes in response to diet, stress, medications, and lifestyle factors

Technical Superiority: Viome vs. Other Commercial Methods

Most microbiome companies use outsourced, research grade tests; Viome runs its own, state-of-the-art, automated, clinically licensed laboratory.

16S rRNA Sequencing:

- Identifies ~50-75% of bacteria only
- Genus-level resolution (poor specificity)
- High false positive rates
- No functional pathway data
- Cannot detect viruses, fungi, parasites
- Highly variable results between runs

Metagenomic DNA Analysis:

- Identifies genetic potential only
- Cannot distinguish live from dead organisms
- No real-time activity measurement
- Limited functional insights
- No human gene expression data
- Static snapshot of genetic content

Viome Metatranscriptomics:

- All microorganisms: bacteria, viruses, fungi, parasites
- Species and strain-level identification
- Real-time biochemical pathway activity
- Human and microbial RNA simultaneously
- Live organism activity only
- Highly reproducible, low contamination

Laboratory Excellence and Quality Controls

Viome's CLIA-certified laboratory in Bothell, WA represents the pinnacle of molecular diagnostics, with proprietary methods that have solved the major technical challenges plaguing metatranscriptomic analysis:

Technical Challenges & Solutions:

Sample Contamination:

- Industry Standard: Variable, uncontrolled
- Viome Solution: Proprietary manufacturing and environmental controls
- Clinical Impact: Eliminates false positives and ensures accuracy

Barcode Hopping:

- Industry Standard: 0.2-6% cross-contamination
- Viome Solution: <1 part per million (~10,000x better)
- Clinical Impact: Enables accurate detection of low-abundance biomarkers

Sample Stability:

- Industry Standard: Immediate freezing required
- Viome Solution: 28 days stable at room temperature
- Clinical Impact: Global accessibility and patient convenience

Pathogen Safety:

- Industry Standard: Live pathogens in samples
- Viome Solution: Complete inactivation at collection
- Clinical Impact: Safe shipping and laboratory handling

Reproducibility:

- Industry Standard: High variability
- Viome Solution: Automated laboratory with high reproducibility, which is regularly confirmed using CLIA proficiency testing procedures
- Clinical Impact: Reliable longitudinal monitoring

Artificial Intelligence and Data Analysis

Viome has built the world's largest metatranscriptomic database, containing over 1 quadrillion RNA nucleotides from more than 1 million biological samples. This massive dataset powers sophisticated AI algorithms that support a wide range of clinical applications.

AI-Driven Clinical Intelligence:

- Pathway Quantification: Measures activity of 10,000+ biochemical reactions using weighted machine learning models
- Disease Risk Prediction: Calculates odds ratios for 20+ chronic diseases using case-control analysis drawn from 1M+ samples
- Personalized Recommendations: Generates individualized food and supplement recommendations based on molecular profile
- Glycemic Response Modeling: Predicts blood sugar response to specific foods for each individual
- Biological Age Assessment: Calculates biological age from molecular features with 5% precision
- Disease Classification: Machine learning models classify whether a sample is associated with disease phenotypes
- Longitudinal Analysis: Tracks molecular changes over time to assess intervention efficacy
- AI-driven Education and Support: A chatbot available on web and mobile apps support the interpretation and application of health insights and recommendations for providers and patients

Key Highlights:

- Over 100 molecular pathway scores analyzed per patient
 - Population-normalized scoring
 - Trend analysis over time
 - 20+ peer-reviewed and pre-print publications
 - 1+ quadrillion RNA nucleotides analyzed
 - 65 trillion molecular features extracted
 - FDA breakthrough device designation
 - Technology developed at Los Alamos National Laboratory
 - 37,000+ microbial genomes
 - 98.5M gene catalog
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Clinical Applications & Molecular Insights

Precision Health PRO Test: Multi-System Analysis

The Precision Health PRO test represents the most comprehensive molecular health assessment available, analyzing three distinct physiological systems to provide a complete picture of patient health status and disease risk.

Think of the human body as ~100,000 biochemical reactions, about half run by our own genes and the other half run by the oral and gut microbiome. These biochemical reactions enable all bodily functions, such as digestion, nutrient transport, energy production, immune system function, hormone production and response, neurotransmitter production and response, detoxification, etc. Using Viome's molecular tests, we define three states of health:

1. **Healthy state:** All biochemical reactions run at an optimal speed, ensuring mental, physical, cognitive, and immune health.
2. **Pre-symptomatic state:** Some of the chemical reactions become too slow or too fast. This may cause higher ApoB, lower bile acids, less protein digestion, too much oxidative stress, too much sulfide gas, or increased inflammation. These physiological anomalies are presymptomatic and can only be measured by molecular tests. Viome's tests go beyond the ~100 traditional biomarkers and measure more than 10,000 of them. Viome tests don't only quantify these biomarkers (reactions), all results are actionable - they are converted to individualized nutritional recommendations to modulate these reactions back to healthy levels. Take, for example, the intestinal sulfide gas: high production can lead to diarrhea and intestinal permeability. Viome's tests quantify sulfide production and provide precise nutritional recommendations that reduce it back to normal levels.
3. **Disease state:** When enough of the reactions break down, we experience symptoms. Traditional medicine waits until this state, which is more difficult to treat, already has a negative impact on the patient's quality of life, and can cause permanent damage that cannot be reversed.

Clinical Utility of Viome Precision Health Pro with Disease Risk Stratification

The Precision Health Pro (PH PRO) assessment provides clinicians with actionable molecular insights through integrated analysis of gut, oral, and blood biomarkers. This multi-omic approach enables early identification of disease risk and personalized intervention strategies before clinical symptoms manifest.

Diagnostic Enhancement

Early Risk Detection: The PH PRO identifies increased disease risk through molecular dysfunction patterns, enabling intervention during pre-symptomatic stages. Disease Risk Stratification quantifies cumulative odds for 20+ chronic conditions including IBS, cardiovascular disease, metabolic disorders, and neurocognitive conditions.

Root Cause Analysis: Rather than treating symptoms, clinicians can address underlying molecular imbalances. For example, elevated sulfide gas production, low butyrate synthesis, and impaired bile acid metabolism may collectively indicate heightened IBS-Type D risk (cumulative odds 5.23), guiding targeted gut microbiome interventions.

Biological Age Assessment: The BioAge score reveals accelerated aging from oxidative stress, inflammation, and metabolic dysfunction—independent of chronological age—providing objective markers for healthspan optimization.

Treatment Personalization

Precision Nutrition Plans: Each report includes personalized food recommendations (emphasize/minimize/avoid) and targeted supplement protocols based on 50+ pathway scores. This eliminates trial-and-error approaches to dietary intervention.

Medication Interaction Screening: Automated identification of food-drug and supplement-drug interactions (e.g., fexofenadine with citrus fruits) prevents adverse events and optimizes therapeutic efficacy.

Objective Treatment Monitoring: Serial testing tracks molecular pathway changes over time, enabling clinicians to quantify intervention effectiveness and adjust protocols based on objective biomarkers rather than subjective symptom reports.

Clinical Area Applications

Gastrointestinal: Pathway analysis reveals specific dysbiosis patterns (butyrate production, bile acid metabolism, gas production) that inform targeted probiotic selection, dietary fiber modification, and anti-inflammatory interventions.

Cardiometabolic: TMA production, homocysteine, and renin-angiotensin pathway activities provide early cardiovascular risk signals. Uremic toxin and vitamin D pathway dysfunction identify kidney-heart axis dysfunction before traditional biomarkers decline.

Neurocognitive: Gut-brain axis assessment through neurotransmitter precursor pathways (GABA, serotonin), anxiety-associated pathways, and cortisol signaling enables integrative mental health treatment combining microbiome optimization with conventional therapies.

Immunological: Oxalate metabolism, uremic toxin clearance, and microbiome-induced stress scores identify immune dysfunction drivers, guiding interventions for chronic fatigue, autoimmune conditions, and inflammatory disorders.

Clinical Workflow Integration

The PH PRO complements standard laboratory testing by revealing functional impairments before biomarker abnormalities appear. Clinicians can:

- Stratify patients by molecular risk profile for preventive care prioritization
- Design evidence-based integrative treatment protocols combining nutrition, supplements, and medications
- Monitor treatment response with objective molecular endpoints
- Provide patients with concrete, personalized action plans that enhance adherence

Evidence Base

All disease risk associations are supported by Viome's proprietary research (published and in-process) and peer-reviewed scientific literature. The platform analyzes thousands of molecular features across multiple sample types, providing comprehensive assessment unavailable through conventional single-biomarker testing.

Note: Disease risk stratification indicates increased odds based on molecular patterns and is not diagnostic. Results must be confirmed through standard diagnostic evaluation by qualified healthcare professionals.

Sample Types and Analysis:

Stool Microbiome:

- Molecular Analysis: Gut microbial quantitative gene expression (many millions), species identification (many thousands), gut metabolite pathways, inflammatory markers, aging markers
- Key Health Scores: Butyrate production, inflammation, gas production, bile acid metabolism
- Clinical Applications: IBS risk, IBD risk, metabolic health, digestive optimization

Oral Microbiome:

- Molecular Analysis: Saliva microbial quantitative gene expression (many millions), species identification (many thousands), inflammatory markers, aging markers
- Key Health Scores: Periodontal health, caries risk, systemic inflammation
- Clinical Applications: Periodontal disease, cardiovascular risk, cancer screening

Human Blood:

- Molecular Analysis: Capillary blood quantitative gene expression, aging markers
- Key Health Scores: Biological age, inflammaging, cellular stress, mitochondrial function
- Clinical Applications: Aging assessment, disease risk, intervention monitoring

Disease Risk Stratification: Scientific Methodology

Viome's disease risk models are built using rigorous epidemiological methods, analyzing molecular patterns in large case-control cohorts. Each disease model is validated through multiple statistical approaches described below.

Statistical Validation Framework:

- Case-Control Design: Age, sex, and BMI-matched cohorts with thousands of participants per disease
- Odds Ratio Calculation: Statistical significance testing with 95% confidence intervals
- Multi-Feature Analysis: Combines multiple molecular pathways for cumulative risk assessment
- Literature Validation: Each pathway connection supported by peer-reviewed research
- Clinical Correlation: Risk scores validated against clinical outcomes and standard biomarkers
- Population Benchmarking: Scores normalized against healthy population distributions

Molecular Pathway Examples: Clinical Significance

Each molecular score reflects the activity of specific biochemical pathways that directly impact health. Here are key examples of how molecular dysfunction translates to disease risk:

Butyrate Production Pathways:

Function: Butyrate is a short-chain fatty acid produced by beneficial gut bacteria that serves as the primary energy source for colon cells and has powerful anti-inflammatory properties.

Clinical Impact: Low butyrate production is associated with increased intestinal permeability ("leaky gut"), systemic inflammation, and higher risk of IBS, IBD, and colorectal cancer.

Intervention: Specific fiber types, resistant starches, and targeted probiotics can restore butyrate production.

TMA Production Pathways:

Function: Trimethylamine (TMA) is produced by gut bacteria from dietary choline and carnitine, then converted to TMAO by the liver.

Clinical Impact: Elevated TMAO levels are strongly associated with cardiovascular disease, stroke, and kidney disease through mechanisms involving endothelial dysfunction and atherosclerosis promotion.

Intervention: Dietary modifications to reduce TMA-producing substrates and microbiome modulation.

Cellular Stress Pathways:

Function: Measures gene expression related to oxidative stress, DNA damage response, and cellular senescence in peripheral blood cells.

Clinical Impact: Elevated cellular stress accelerates biological aging, increases cancer risk, and predicts poor response to stress and disease.

Intervention: Antioxidant supplementation, stress management, and targeted nutritional support.

Oral Pathogen Activity:

Function: Quantifies gene expression of known periodontal pathogens and their virulence factors in saliva samples.

Clinical Impact: High pathogen activity predicts periodontal disease progression and systemic inflammation that contributes to cardiovascular disease.

Intervention: Targeted oral hygiene protocols, antimicrobial treatments, and immune support.

Clinical Report Example: Comprehensive Analysis

Precision Health PRO Report: Patient Jane Doe

The following represents the first page of an actual clinical report generated by Viome's platform, demonstrating the depth and clinical relevance of molecular insights provided to healthcare providers.

Patient Name	Date of Birth	Gender	Provider Name	Collection Date	Results Date
Doe, Jane	11/01/1969	Female	Dr. James Cohen	N/A	05/25/2026

DISEASE RISK SUMMARY

 Disease Risk Scores use a cumulative odds ratio (COR) statistic to determine patient risk relative to Viome's overall population cohort. Only high disease & pathway risk scores are shown below.

Disease Risk & COR Scores: **High** (COR >= 5.0) **HIGH** COR VALUE **23** Microbiome Pathway Scores: **Attention** (0-35) 

HIGH IBS-Type C

IBS-Type C risk is elevated, driven by **Attention** pathway scores including Biofilm, Chemotaxis, and Virulence Pathways, Flagellar Assembly Pathways, and Methane Gas Production Pathways.

HIGH Fatty Liver Disease

Fatty Liver Disease risk is elevated, driven by **Attention** pathway scores including Biofilm, Chemotaxis, and Virulence Pathways, Flagellar Assembly Pathways, and GABA Production Pathways.

DISEASE RISK DETAILS

IBS-Type C

HIGH 6.04

IBS-Type C risk is elevated, driven by **Attention** pathway scores including Biofilm, Chemotaxis, and Virulence Pathways, Flagellar Assembly Pathways, and Methane Gas Production Pathways.

SYSTEM & SAMPLE	PATHWAYS	SCORE	CLINICAL NOTE	NUTRITION RECOMMENDATIONS
 Gastrointestinal 	Biofilm, Chemotaxis, and Virulence Pathways	9 	Pathogenic bacteria and their virulence factors can impair gut motility, contributing to constipation. Gut motility is intricately tied to microbial metabolism, intestinal permeability, and host signaling — all of which interact to affect gastrointestinal function.	✓ Emphasize Apple Cider Vinegar, Bone Broth (Fish), Cranberry, Oyster Mushrooms, Pea Protein Powder, Pomegranate, Sauerkraut
 Gastrointestinal 	Flagellar Assembly Pathways	12 	IBS-C-related dysbiosis shifts gut bacteria toward flagellated species, increasing flagellin exposure at the gut lining. Flagellin activates innate immune signaling, promoting barrier dysfunction, low-grade inflammation, and heightened gut sensitivity characteristic of IBS-C.	✗ Avoid Amaranth, Artichoke, Beef (Fatty), Beef (Lean), Black Beans, Buckwheat, Buffalo Meat, Cashews, Chicory Root, Clams, Hemp Hearts, Hemp Milk, Hemp Protein Powder, Jerusalem Artichoke, Jicama, Lamb, Onion, Pecans, Pinto Beans, Scallops +1 more
 Gastrointestinal 	Methane Gas Production Pathways	29 	Methane-producing gut microbes slow intestinal transit time. In IBS-C, elevated methane levels are associated with reduced gut motility, which contributes to the constipation characteristic of this condition.	○ Supplements L. acidophilus NCFM, L. plantarum 299v, Vitamin C (Ascorbic Acid)

Clinical Report Interpretation Guide

The Precision Health PRO report provides healthcare providers with a comprehensive molecular analysis that reveals the underlying biological mechanisms driving patient health and disease risk. Each component of the report offers specific clinical insights:

Report Components & Clinical Significance:

- High IBS-Type C: Driven by abnormal Serotonin Promoting Microbe activity, Biofilm, Chemotaxis, Virulence Pathways, Methane Gas Production Pathways, and Flagellar Assembly Pathways.
- High Fatty Liver Disease: Based on abnormal Bile Acid Metabolism Pathways and Butyrate Production Pathways.
- Disease Risk Details: Detailing Molecular Pathway Scores' clinical notes along with food and supplement recommendations.

Report includes 15+ system-specific scores with trend analysis and peer-reviewed intervention protocols

Provider Value Proposition & Clinical Integration

Transforming Clinical Practice Through Molecular Insights

Viome's Precision Health PRO platform offers healthcare providers a revolutionary approach to patient care that moves beyond traditional reactive medicine to proactive, molecular-level health optimization. This represents a fundamental shift in how providers can deliver value to patients while building a differentiated practice.

Clinical Advantages for Healthcare Providers

Enhanced Diagnostic Capabilities:

- Early Disease Detection: Identify molecular dysfunction 5-10 years before clinical symptoms appear, enabling preventive interventions that can halt or reverse disease progression
- Root Cause Analysis: Move beyond symptom management to address underlying molecular mechanisms driving patient health issues
- Precision Diagnostics: Distinguish between similar conditions (IBS-C vs IBS-D) based on molecular signatures rather than symptom overlap
- Biomarker Integration: Combine molecular pathway analysis with traditional biomarkers for comprehensive patient assessment

- Subclinical Assessment: Detect biological age acceleration, chronic inflammation, and metabolic dysfunction before laboratory abnormalities appear

Personalized Treatment Protocols:

- Evidence-Based Recommendations: Move beyond generic dietary advice to molecularly-targeted nutrition protocols based on individual pathway analysis
- Supplement Optimization: Eliminate guesswork in supplement selection with personalized formulations targeting specific molecular dysfunctions
- Drug Interaction Assessment: Identify potential interactions between patient medications and recommended foods/supplements
- Intervention Monitoring: Track molecular changes over time to assess treatment efficacy and adjust protocols accordingly
- Patient-Specific Protocols: Tailor interventions based on individual genetic expression, microbiome composition, and metabolic status

Practice Enhancement and Differentiation

Revenue Generation Opportunities:

- Premium Service Offering: Position practice as precision medicine leader with cutting-edge molecular diagnostics

Patient Engagement and Retention Benefits:

- Mobile App Platform: Patients receive ongoing support through comprehensive mobile application with personalized recommendations, progress tracking, and educational content
- Actionable Results: Unlike traditional tests that often leave patients wondering "what now?", Viome provides specific, implementable recommendations
- Longitudinal Relationship: Regular re-testing creates ongoing patient engagement and loyalty to the practice
- Patient Education: Molecular insights help patients understand the "why" behind recommendations, improving compliance
- Outcome Tracking: Visible molecular improvements motivate patients and demonstrate provider value

Competitive Market Positioning

Traditional Medicine Approach:

- Reactive disease management
- Generic lifestyle recommendations
- Limited preventive capabilities
- Symptom-based treatment

- Standard laboratory testing only

Functional Medicine Practices:

- Basic microbiome testing (16S)
- Generic supplement protocols
- Limited molecular insights
- Subjective assessment methods
- No integrated AI recommendations

Viome-Enhanced Practice:

- Proactive molecular optimization
- AI-driven personalized protocols
- Comprehensive pathway analysis
- Predictive disease modeling
- Integrated multi-system assessment First-to-market advantage with only clinically licensed metatranscriptomic platform globally | CLIA-certified quality standards

Viome Provider Portal & Implementation Framework

Comprehensive Provider Support System

Viome has developed a complete ecosystem to support healthcare providers in successfully integrating precision molecular diagnostics into their practice. Our provider-focused infrastructure ensures seamless implementation, ongoing education, and continuous clinical support.

Viome Provider Portal: Advanced Practice Management

Accessible at viomepro.com/practice, the Viome Provider Portal serves as the central hub for all provider activities, offering sophisticated practice management tools designed specifically for precision medicine integration.

Portal Features:

Test Ordering System:

- **Functionality:** Secure ordering with bulk capabilities and patient tracking
- **Provider Benefit:** Streamlined workflow, efficient patient management, audit trail

Results Dashboard:

- **Functionality:** Comprehensive clinical reports with interpretation guides and reference materials
- **Provider Benefit:** Quick assessment, clinical decision support, patient consultation preparation

Patient Management:

- **Functionality:** Longitudinal tracking, progress monitoring
- **Provider Benefit:** Continuity of care, outcome measurement, treatment optimization

Educational Resources:

- **Functionality:** Clinical training materials, case studies, scientific literature, webinars
- **Provider Benefit:** Ongoing education, clinical competency, confidence in recommendations

EMR Integration:

- **Functionality:** Software API to receive Viome PDF results report electronically and integrate into Practice EMR system as desired (In the next phase, bi-directional order mgmt and health data exchange)
- **Provider Benefit:** Practice can store Viome PDF results along with all other relevant health information for patients

Practice Analytics:

- **Functionality:** Patient outcome tracking, practice performance metrics, revenue analysis
- **Provider Benefit:** Quality improvement, business optimization, ROI measurement

Implementation Timeline and Support Structure

Phase 1: Foundation Setup (Weeks 1-4)

- **Provider Onboarding:** Account setup, portal training session
- **Staff Education:** Comprehensive clinical training for clinical and administrative staff on test ordering, sample handling, and result interpretation
- **Workflow Integration:** Customization of clinic workflows to incorporate Viome testing into existing patient care protocols
- **Marketing Support:** Patient education materials, website content, and promotional resources for practice marketing
- **Billing Setup:** Integration with practice management systems, insurance verification protocols, and reimbursement guidance

Phase 2: Clinical Launch (Weeks 5-8)

- Pilot Patient Cohort: Begin with 20-50 patients to optimize workflows and gain experience with result interpretation
- Clinical Support: Dedicated clinical liaison for case discussions, complex result interpretation, and treatment planning guidance
- Quality Assurance: Review of initial cases to ensure optimal clinical integration and patient outcomes
- Patient Feedback: Collection and analysis of patient experience data to refine protocols and improve satisfaction
- Staff Optimization: Refinement of roles and responsibilities based on initial experience and workflow efficiency

Phase 3: Full Implementation (Weeks 9-16)

- Scale-Up Strategy: Expansion to full patient population with optimized workflows and proven protocols
- Advanced Training: Deep-dive clinical education on complex cases, intervention optimization, and longitudinal monitoring
- Outcome Tracking: Implementation of systematic outcome measurement and quality improvement processes
- Business Development: Strategies for practice growth, corporate wellness programs, and referral network expansion
- Continuous Improvement: Ongoing optimization based on patient outcomes, provider feedback, and evolving clinical evidence

Clinical Decision Support Tools

Integrated Clinical Resources:

- Interpretation Guides: Detailed explanation of each molecular score with clinical significance and intervention recommendations
- Treatment Protocols: Evidence-based intervention guidelines for specific molecular dysfunctions and disease risks
- Drug Interaction Database: Comprehensive database of food-drug and supplement-drug interactions based on patient medications
- Case Studies: Real-world examples of successful interventions and patient outcomes across various conditions
- Scientific Literature: Curated collection of peer-reviewed research supporting each molecular pathway and intervention
- Clinical Algorithms: Decision trees for complex cases and multi-system dysfunctions

Quality Assurance and Regulatory Compliance

Viome maintains the highest standards of clinical laboratory quality and regulatory compliance, ensuring providers can confidently integrate our platform into their practice:

Quality Standards:

CLIA Certification:

- Viome Implementation: License 50D2224932, comprehensive quality management system
- Provider Assurance: Regulatory compliance, insurance acceptance, legal protection

Data Security:

- Viome Implementation: HIPAA-compliant infrastructure, enterprise-grade security, encrypted transmission
- Provider Assurance: Patient privacy protection, regulatory compliance, risk mitigation

Clinical Validation:

- Viome Implementation: 20+ peer-reviewed and pre-print publications, FDA breakthrough device designation
 - Provider Assurance: Scientific credibility, clinical confidence, patient trust
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Clinical Validation & Evidence-Based Outcomes

Rigorous Scientific Validation Framework

Viome's clinical efficacy is supported by extensive peer-reviewed research, randomized controlled trials, and real-world evidence studies. Our platform represents one of the most thoroughly validated precision medicine technologies available to healthcare providers.

Randomized Controlled Trial Results

Viome has conducted multiple gold-standard RCTs demonstrating significant clinical outcomes across various chronic conditions. These studies provide healthcare providers with confidence in recommending Viome's interventions:

Key Trial Outcomes:

Blinded, randomized, placebo-controlled trials with a 90 day nutritional intervention using the Viome Precision Nutrition Program

- Pre-diabetes: -0.42% HbA1c Reduction vs placebo, p=0.028
- IBS: 64% transitioned from constipated to healthy vs 10% placebo, p = 0.00087
- Anxiety: 50% transitioned from anxiety to healthy vs 28% placebo, p = 0.018

Disease Phenotype Validation

Viome has validated molecular pathway scores with disease phenotypes across the gut health spectrum.

Validation Studies:

Validation of IBS and subtypes:

- Population Size: Stool samples from 71,220 individuals
- Key Findings: Significant gut molecular pathways associated with IBS, IBS-C, and IBS-D
- Clinical Significance: Molecular pathways can guide IBS interventions

Validation of IBD and subtypes:

- Population Size: Stool samples from 87,594 individuals
- Key Findings: Significant gut molecular pathways associated with IBD, Crohns, & Colitis
- Clinical Significance: Molecular pathways can guide IBD interventions

Validation of GERD:

- Population Size: Saliva samples from 14,129 individuals
- Key Findings: Significant oral molecular pathways associated with GERD
- Clinical Significance: Molecular pathways can guide GERD interventions

FDA Recognition and Regulatory Validation

FDA Breakthrough Device Designation

Viome's oral and throat cancer screening test received FDA Breakthrough Device Designation, a recognition reserved for devices that provide more effective treatment or diagnosis of life-threatening conditions. This designation validates several key aspects of our technology platform:

- Clinical Utility: Demonstrated superior performance compared to current standard of care methods
- Technical Innovation: Recognition of metatranscriptomic technology as a breakthrough diagnostic approach
- Regulatory Pathway: Expedited FDA review process for continued platform development
- Clinical Credibility: Federal validation of Viome's scientific and clinical approach

Real-World Evidence and Population Studies

Beyond controlled trials, Viome has generated extensive real-world evidence demonstrating clinical utility across diverse patient populations:

Population-Scale Validation Studies:

- Disease Risk Modeling: Case-control studies across 1M+ samples establishing disease risk algorithms for 30+ chronic conditions
- Longitudinal Outcomes: Multi-year tracking of patient molecular changes and clinical outcomes following Viome interventions
- Adherence: Superior compliance rates compared to generic dietary and lifestyle interventions

Publication Portfolio and Scientific Impact

Viome's research has been published in premier scientific journals, establishing our platform as a leader in precision medicine and molecular diagnostics:

High-Impact Publications:

- Nature Press (NPJ Genomic Medicine and Scientific Reports)
- Cell Press (iScience)
- American Journal of Lifestyle Medicine
- Diabetes Therapy Journal
- Oral Oncology Journal
- BMC Gastroenterology
- Biotechniques (multiple publications)

Research Impact Areas:

- Metatranscriptomic technology development
 - Precision nutrition clinical outcomes
 - Disease risk prediction algorithms
 - Biological aging biomarkers
 - Cancer screening diagnostics
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Selected Scientific Publications

Foundational Research Publications

Viome's scientific foundation is built upon extensive peer-reviewed research published in leading journals. These publications establish the clinical validity, technical superiority, and therapeutic efficacy of our metatranscriptomic platform.

Key Publications:

1. A Robust Metatranscriptomic Technology for Population-Scale Studies of Diet, Gut Microbiome, and Human Health
 - International Journal of Genomics. October 2019.
 - <https://www.hindawi.com/journals/ijg/2019/1718741/>
 - Establishes the technical foundation and clinical validation of Viome's metatranscriptomic platform for population-scale health studies.
2. A clinically validated human capillary blood transcriptome test for global systems biology studies
 - Biotechniques, vol 69, No 4, August 10, 2020.
 - <https://www.future-science.com/doi/10.2144/btn-2020-0088>
 - Clinical validation of finger prick blood transcriptome analysis with high correlation to venous blood samples, enabling convenient sample collection.
3. The salivary metatranscriptome as an accurate diagnostic indicator of oral cancer
 - NPJ Genomic Medicine (Nature Press). December 8, 2021.
 - <https://www.nature.com/articles/s41525-021-00257-x>
 - Breakthrough research demonstrating superior oral/throat cancer detection, leading to FDA breakthrough device designation.
4. Gut microbiome activity contributes to individual variation in glycemic response in adults
 - Diabetes Therapy Journal. November 19, 2021.
 - <https://link.springer.com/article/10.1007/s13300-021-01174-z>
 - Validates personalized glycemic response prediction based on microbiome analysis, enabling precision nutrition recommendations.
5. Pathogen detection and characterization from throat swabs using unbiased metatranscriptomic analyses
 - International Journal of Infectious Diseases, Vol 122, September 7, 2022.
 - Demonstrates comprehensive pathogen detection capabilities of metatranscriptomic technology for infectious disease diagnosis.
6. A clinically validated human saliva metatranscriptomic test for global systems biology studies
 - Biotechniques, Vol 74, No 1, January 9, 2023.
 - <https://www.future-science.com/doi/10.2144/btn-2022-0104>
 - Clinical validation of saliva-based metatranscriptomic analysis with high reproducibility and 28-day sample stability.

7. Multi-omics profiles of the intestinal microbiome in irritable bowel syndrome and its bowel habit subtypes
 - Microbiome Vol 11, January 10, 2023.
 - Comprehensive analysis of IBS subtypes using multi-omics approaches, establishing molecular signatures for IBS-C and IBS-D.
8. Data-Driven Precision Nutrition Improves Clinical Outcomes and Risk Scores for IBS, Depression, Anxiety, and T2D
 - American Journal of Lifestyle Medicine. November 23, 2023.
 - <https://journals.sagepub.com/eprint/GAUFZV7N6YNJTUZSMJG9/full>
 - Landmark clinical outcomes study demonstrating significant improvements in chronic disease symptoms following precision nutrition interventions.
9. An accurate aging clock developed from large-scale gut microbiome and human gene expression data
 - iScience (Cell Press). January 19, 2024.
 - [https://www.cell.com/iscience/fulltext/S2589-0042\(23\)02615-9](https://www.cell.com/iscience/fulltext/S2589-0042(23)02615-9)
 - Development and validation of biological age assessment using combined gut microbiome and human gene expression analysis.
10. A novel method for sampling subgingival microbiome - a comparative metatranscriptomic study
 - BioTechniques. February 6, 2024.
 - Innovative sampling methodology for oral microbiome analysis enabling comprehensive periodontal health assessment.
11. Microbial functional pathways based on metatranscriptomic profiling enable effective saliva-based health assessments for precision wellness
 - Computational and Structural Biotechnology Journal (CSBJ). January 29, 2024.
 - [https://www.csbj.org/article/S2001-0370\(24\)00019-9/fulltext](https://www.csbj.org/article/S2001-0370(24)00019-9/fulltext)
 - Comprehensive analysis of saliva-based health assessments using functional pathway analysis for precision wellness applications.
12. The human gut microbiome activity is resilient and stable for up to six months: a large stool metatranscriptomic study
 - MDPI Microorganisms. April 6, 2026.
 - <https://www.mdpi.com/2076-2607/14/4/835>
 - Stool metatranscriptomic study showing that microbial composition and active gene expression stay stable for up to six months in healthy individuals, and return to baseline within ~7 days after major perturbations like colonoscopy prep - confirming that a single Viome snapshot reflects a patient's stable metabolic state.
13. Metatranscriptomics-Derived Disease Risk Scores as a Preventive, Diagnostic, and Treatment Support Tool
 - medrxiv.org. June 5, 2026.
 - <https://www.medrxiv.org/content/10.64898/2026.05.29.26354333v1>
 - Development and independent validation of the Disease Risk Score (DRS) framework that converts pathway activity from stool, saliva, and blood into

disease-specific risk estimates; positioning DRS as an adjunct to clinical evaluation.

Ongoing Research and Future Publications

Viome continues to advance the field through ongoing research collaborations and clinical studies. Several additional publications are currently in peer review or preparation, covering advanced topics in precision medicine, therapeutic interventions, and diagnostic applications.

Research Areas in Development:

- Cancer Detection: Expansion of oral/throat cancer screening to additional cancer types using multi-sample analysis
- Neurological Conditions: Molecular signatures for Alzheimer's disease, Parkinson's disease, and cognitive decline
- Autoimmune Diseases: Precision medicine approaches for rheumatoid arthritis, multiple sclerosis, and inflammatory conditions
- Cardiovascular Health: Advanced risk modeling for heart disease using integrated molecular signatures
- Therapeutic Development: Molecular targets for drug discovery based on metatranscriptomic insights

Complete publication list available at www.viome.com/publications | Research partnerships with leading academic institutions | Ongoing clinical trials across multiple therapeutic areas

Contact Information & Implementation Next Steps

Viome Leadership Team and Key Contacts

Executive Leadership:

- Guru Banavar, PhD – Founding Chief Technology Officer
- Momo Vuyisich, PhD – Founding Chief Science Officer

Provider Relations:

- Michael Bass, MD - Global Medical Director, Board Certified Gastroenterologist
- Grant Antoine, ND - Medical Science Liaison, Provider Training Director

Account Management:

- Crystal May

- Eliana Dougherty

Operations:

- Jim Dermend

Essential Resources for Partnership Development

Viome Provider Portal and Training Infrastructure:

- Primary Provider Website: www.viomepro.com - Clinical information, training resources, and partnership details
- Test Ordering Portal: viomepro.com/practice - Secure ordering system with patient management capabilities
- Clinical Education Platform: Comprehensive training curriculum including certification programs, case studies, and ongoing education
- Technical Support Center: Dedicated provider support team with clinical expertise and rapid response capabilities
- Marketing Resource Library: Patient education materials, website content, promotional resources, and practice development tools
- Clinical Decision Support: Interpretation guides, treatment protocols, and evidence-based intervention recommendations

Scientific and Regulatory Documentation:

- Complete Publications Database: www.viome.com/publications - Full peer-reviewed research portfolio with abstracts and clinical significance
- Clinical Evidence Library: White papers, methodology documentation, and detailed clinical validation studies
- Regulatory Compliance: CLIA certification documentation, FDA breakthrough device materials, and quality assurance protocols
- Clinical Study Database: Ongoing research opportunities, collaborative study protocols, and outcome data
- Data Security Framework: compliance documentation, enterprise security measures, and privacy protection protocols

Laboratory and Quality Assurance Information

Viome Life Sciences CLIA-Certified Laboratory

Corporate and Laboratory Address: 11724 NE 195th Street, Suite 101 Bothell, WA 98011

Regulatory Certifications:

- CLIA License: 50D2224932
- Washington State MTS: 61169179

- New York State clinical license (CLEP), more strict than all other states.

Quality Metrics and Performance:

- Processing Capacity: 20,000+ samples per month
- Contamination Rate: <1 part per million
- Sample Stability: 28 days at room temperature

Laboratory Leadership:

- Dr. James Fuller, Laboratory Director
- CLIA-certified personnel
- Automated quality control systems
- Comprehensive quality management

Recommended Action Plan for Partnership Implementation

Implementation Action Items:

Executive Strategy Session (Week 1-2):

- Key Stakeholders: Partner C-suite, Viome business development team
- Expected Outcomes: Strategic alignment, partnership framework, decision timeline

Clinical Deep Dive Presentation (Week 2-3):

- Key Stakeholders: Medical staff, clinical operations, Viome clinical experts
- Expected Outcomes: Technical understanding, clinical workflow planning, training needs assessment

Financial Analysis and Modeling (Week 3-4):

- Key Stakeholders: Business operations, finance teams, partnership negotiators
- Expected Outcomes: ROI projections, pricing models, revenue optimization strategies

Pilot Program Design (Week 4-6):

- Key Stakeholders: Implementation team, IT, clinical staff, training coordinators
- Expected Outcomes: Detailed implementation plan, success metrics, risk mitigation strategies

Contract Negotiation (Week 6-8):

- Key Stakeholders: Legal teams, business development, executive leadership
- Expected Outcomes: Partnership agreement, terms optimization, launch authorization

Immediate Next Steps and Contact Protocol

Priority Actions for Partner Leadership:

- Schedule Clinical Exploration: Book Michael Bass, MD at <https://calendar.app.google/bcytti5pdVVL4x8i7> or Grant Antoine, ND at <https://calendly.com/grant-antoine-viome/precision-health-pro-consult> for comprehensive clinical discussion
- Review Clinical Evidence: Access complete publication portfolio and clinical validation studies at www.viome.com/publications
- Schedule Business / Integration Discussion: Book a session with Crystal May or Eliana Dougherty at <https://calendly.com/d/cvjy-v5h-3xb/viome-pro-discovery-call>
- Explore Viome Provider Portal: Request access to Viome Pro platform for system evaluation
- Conduct Internal Assessment: Evaluate internal readiness, patient demographics, and strategic alignment with precision medicine goals
- Financial Planning: Develop preliminary financial models and integration timelines based on practice specifics and growth objectives

Commitment to Innovation and Partnership Excellence

Viome Life Sciences is committed to democratizing healthcare through precision medicine, making molecular-level health insights accessible to providers and patients worldwide. Our mission of making "illness optional" drives continuous innovation in technology development, clinical validation, and provider support.

Ongoing Platform Development:

- Technology Evolution: Continuous advancement in metatranscriptomic analysis, AI algorithms, and clinical applications
- Clinical Expansion: Development of additional disease risk models, therapeutic targets, and intervention protocols
- Global Scaling: International expansion, regulatory approvals, and cross-cultural clinical validation
- Integration Capabilities: Enhanced EMR integration, telemedicine platforms, and wearable device connectivity
- Therapeutic Development: Translation of molecular insights into targeted therapeutic interventions and drug discovery
- Provider Support: Continuous improvement of training programs, clinical tools, and practice development resources