

F R O S T & S U L L I V A N

OPTINA DIAGNOSTICS

2022 TECHNOLOGY INNOVATION LEADER

*NORTH AMERICAN
HYPERSPECTRAL RETINAL
IMAGING INDUSTRY*

Best Practices Criteria for World-Class Performance

Frost & Sullivan applies a rigorous analytical process to evaluate multiple nominees for each Award category before determining the final Award recipient. The process involves a detailed evaluation of best practices criteria across two dimensions for each nominated company. Optina Diagnostics excels in many of the criteria in the North American hyperspectral retinal imaging space.

AWARD CRITERIA	
<i>Technology Leverage</i>	<i>Business Impact</i>
Commitment to Innovation	Financial Performance
Commitment to Creativity	Customer Acquisition
Stage Gate Efficiency	Operational Efficiency
Commercialization Success	Growth Potential
Application Diversity	Human Capital

Need for Easily Accessible and Early Alzheimer's Disease Diagnosis

The global population distribution is experiencing a shift, with the number of people over the age of 60 expected to double between 2015 and 2050, from 12% to 22%, according to the World Health Organization (WHO).¹ Based on the limited time physicians spend with their patients, highly precise and instantaneous diagnostics are needed to help them provide patients with accurate overall health insights during a single visit.

Alzheimer's disease is the most common cause of dementia in the elderly, and the number of people in the United States affected by Alzheimer's disease is expected to reach 13 million by 2050. The disease becomes fatal in 1 in 3 senior individuals. Mild cognitive impairment, which affects the individual's memory and cognitive capabilities, is the early stage of Alzheimer's disease; however, less than 1 in 5 in the United States are aware of their condition, and almost half of the physicians experience challenges when diagnosing mild cognitive impairment.²

Positron emission tomography (PET) imaging scan is the only US Food and Drug Administration (FDA)-approved and conventionally used technique to detect the cerebral amyloid status for diagnosing Alzheimer's disease. A PET scan is a minimally invasive procedure involving a radioactive drug injected

¹ WHO; October 4, 2021; "[Ageing and health](#)"

² Alzheimer's Association; "[Alzheimer's Disease Facts and Figures](#)"

into the individual before the evaluation. For patients, the procedure is expensive and not easily accessible. PET imaging scans are often performed during the disease's later stage; therefore, primary

physicians and neurologists often diagnose Alzheimer's disease based on clinical symptoms, which can lead to missed diagnoses.

"Optina Diagnostics' hyperspectral retinal imaging is a simple procedure involving a low-cost table-top hyperspectral camera, where the patient is exposed to a rapid rainbow of images. Primary care physicians and neurospecialists can run rapid amyloid status tests in their offices and clinics on cognitively impaired patients during their regular clinical evaluations and then deliver automated same-day results. The awAIl™ cerebral amyloid status test, therefore, increases the accessibility of Alzheimer's disease diagnostics with precise early-stage diagnosis, delaying or reversing the disease because of timely intervention."

*- Dr. M. Sneha Maria,
Industry Analyst*

With the increasing geriatric population worldwide, Frost & Sullivan concludes that non-invasive and easily accessible diagnostic tests for Alzheimer's disease that can provide immediate results are urgently needed. Abnormal levels of beta-amyloid proteins in the brain clump and form plaque, disrupting neuron function. The neurodegeneration can lead to memory loss and cognitive disability, as in Alzheimer's disease. Beta-amyloid proteins can also lead to neuronal cell death in the later stages of Alzheimer's disease. Frost & Sullivan notes that patients with memory loss and mild cognitive impairment

should be subjected to rapid cerebral amyloid status tests at the physician's office to enable early diagnosis and to achieve better outcomes.

Artificial Intelligence (AI) and Hyperspectral Retinal Imaging: Early and Affordable Diagnosis of Alzheimer's Disease

Founded in 2011, Canada-based Optina Diagnostics is a medical diagnostics company that develops non-invasive and early diagnostic tests for systemic diseases based on hyperspectral retinal imaging. The company is developing an AI-driven Retinal Deep Phenotyping™ platform to identify biomarkers for systemic diseases, and its awAIl™ cerebral amyloid status test facilitates the early diagnosis of Alzheimer's disease. The test involves the company's FDA 510-k cleared Optina-4C™, a hyperspectral camera that captures the patient's retinal images at a speed of 92 images per second at different wavelengths, processing the light intensities to detect the beta-amyloid status from the retinal features.

The awAIl™ cerebral amyloid status test is both non-invasive and inexpensive, compared to conventional PET scans. Optina Diagnostics's hyperspectral retinal imaging is a simple procedure involving a low-cost table-top hyperspectral camera, where the patient is exposed to a rapid rainbow of images. Primary care physicians and neurospecialists can run rapid amyloid status tests in their offices and clinics on cognitively impaired patients during their regular clinical evaluations and then deliver automated same-day results. The awAIl™ cerebral amyloid status test, therefore, increases the accessibility of Alzheimer's disease diagnostics with precise early-stage diagnosis, delaying or reversing the disease because of timely intervention.

Compared to other competitors that are exploring retinal imaging for Alzheimer's disease diagnosis, Frost & Sullivan points out that Optina Diagnostics has developed the most advanced technology that is closer to commercialization. The company's retinal imaging platform that enables Alzheimer's disease diagnosis

"The awAIr™ cerebral amyloid status test, the first application from the combination of AI and hyperspectral camera, will amply equip physicians and neurospecialists with the necessary tools for the early and accurate diagnosis of Alzheimer's disease in the office or clinic. Identifying Alzheimer's disease as the underlying cause of memory loss and cognitive impairment will allow patients and physicians to plan support and the next treatment steps."

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received the FDA Breakthrough Device designation in 2019, and the test is currently undergoing pivotal clinical studies. The awAIr™ cerebral amyloid status test is the most data-rich platform and excels in data quality, compared to competitive tests that are in the market or under development.

Optina Diagnostics is partnering with pharmaceutical companies to apply the hyperspectral camera and Optina-4C™ to develop biomarkers. A single retinal scan generates inestimable image pixels of data, each of which

contributes to a continuous reflectance spectrum. The phenotypic changes revealed by the digital retinal features extracted from the hyperspectral retinal images can be used as indicators for eye conditions and several systemic diseases having manifestation in the fundus, including cardiovascular diseases and neurological diseases, such as Alzheimer's disease. The company builds AI algorithms for the precise phenotypic characterization of diseases based on the data-rich retina images. With the hyperspectral camera, the company plans to develop multiple AI-driven tests for numerous systemic diseases.

Frost & Sullivan considers the potential of Optina-4C™ and the AI-driven Retinal Deep Phenotyping™ platform as disruptive and noteworthy; they can accurately diagnose multiple systemic diseases in the early stage through simple, cost-effective, and easily accessible retinal imaging.

A Critical Technology with Enormous Growth Potential

Based on the enormous benefits, Optina Diagnostics' technology is already in huge demand from both patients and healthcare providers alike worldwide. The awAIr™ cerebral amyloid status test, the first application from the combination of AI and hyperspectral camera, will amply equip physicians and neurospecialists with the necessary tools for the early and accurate diagnosis of Alzheimer's disease in the office or clinic. Identifying Alzheimer's disease as the underlying cause of memory loss and cognitive impairment will allow patients and physicians to plan support and the next treatment steps. Eye specialists can adopt the platform to support neurospecialists and physicians in the diagnostic process by performing safe and optimal retinal scans. In addition to contributing to a patient's brain healthcare, eye specialists can expand the services of their clinics to new disease areas; as such, the technology will revolutionize Alzheimer's disease management with early diagnosis and intervention.

Optina Diagnostics collaborates with patients, physicians, and eye specialists to understand the relationship between the retina and brain health. The company has clinical trial sites worldwide, including in the United States, Australia, Europe, and Canada; however, it plans to enter the US market first, followed by Canada. Furthermore, the company is receiving technology requests from Asia and South America.

Investors have substantially backed Optina Diagnostics, raising over \$25 million to date. In 2022, the Alzheimer's Drug Discovery Foundation (ADDF) invested \$2.1 million to support the pivotal clinical studies on the test. The company raised \$20.1 million in 2021 in a Series A funding round led by DigitalDx Ventures, Boehringer Ingelheim, and other investors. Moreover, Optina Diagnostics generates revenue from its biomarker development projects with pharmaceutical companies.

In addition to its use for Alzheimer's disease, the company's Retinal Deep Phenotyping™ platform is set to transform the landscape of diagnostics in many other systemic diseases by providing access to novel and unprecedented diagnostic data for investigation. Frost & Sullivan's own analysis suggests that the enormous growth potential of Optina Diagnostics's technology is highly commendable.

Optina Diagnostics has forced a breakthrough with the support of its interdisciplinary human capital, which includes biologists, engineers, AI scientists, physicists, physicians, and eye specialists. The dynamic and agile team is highly inspired by the vision and mission of the company, and the goal alignment has enabled fast-paced growth within a decade and high morale, even during the COVID-19 pandemic. Frost & Sullivan research indicates that Optina Diagnostics' promising technology and purpose-driven team will significantly impact the industry in the years to come.

Conclusion

With the rising global geriatric population, Frost & Sullivan analysts expect the prevalence of systemic diseases to increase as well. Alzheimer's disease, one of the major causes of dementia in the elderly, is conventionally diagnosed using PET imaging scans, which are expensive, invasive and not easily accessible.

Optina Diagnostics has developed the awAIr™ cerebral amyloid status test, a combination of AI and hyperspectral retinal imaging, which enables the non-invasive, cost-effective early diagnosis of Alzheimer's disease at the physician's office. This data-rich platform is the most accurate in the industry. Early diagnosis of the underlying cause of memory loss and cognitive impairment could enable patients and physicians to make more informed decisions on interventions; as such, the company's technology is in high demand worldwide. In addition, the company is developing an AI-driven Retinal Deep Phenotyping™ platform that can enable diagnostic tests for multiple systemic diseases. Frost & Sullivan firmly believes that the company's dynamic and mission-driven team will champion this transformation in the diagnostics industry.

With its strong overall performance, Optina Diagnostics earns Frost & Sullivan's 2022 North American Technology Innovation Leadership Award in the hyperspectral retinal imaging industry.

What You Need to Know about the Technology Innovation Leadership Recognition

Frost & Sullivan's Technology Innovation Leadership Award recognizes the company that has introduced the best underlying technology for achieving remarkable product and customer success while driving future business value.

Best Practices Award Analysis

For the Technology Innovation Leadership Award, Frost & Sullivan analysts independently evaluated the criteria listed below.

Technology Leverage

Commitment to Innovation: Continuous emerging technology adoption and creation enables new product development and enhances product performance

Commitment to Creativity: Company leverages technology advancements to push the limits of form and function in the pursuit of white space innovation

Stage Gate Efficiency: Technology adoption enhances the stage gate process for launching new products and solutions

Commercialization Success: Company displays a proven track record of taking new technologies to market with a high success rate

Application Diversity: Company develops and/or integrates technology that serves multiple applications and multiple environments

Business Impact

Financial Performance: Strong overall financial performance is achieved in terms of revenues, revenue growth, operating margin, and other key financial metrics

Customer Acquisition: Customer-facing processes support efficient and consistent new customer acquisition while enhancing customer retention

Operational Efficiency: Company staff performs assigned tasks productively, quickly, and to a high-quality standard

Growth Potential: Growth is fostered by a strong customer focus that strengthens the brand and reinforces customer loyalty

Human Capital: Commitment to quality and to customers characterize the company culture, which in turn enhances employee morale and retention

About Frost & Sullivan

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The Growth Pipeline Engine™

Frost & Sullivan's proprietary model to systematically create ongoing growth opportunities and strategies for our clients is fuelled by the Innovation Generator™.

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Key Impacts:

- **Growth Pipeline:** Continuous Flow of Growth Opportunities
- **Growth Strategies:** Proven Best Practices
- **Innovation Culture:** Optimized Customer Experience
- **ROI & Margin:** Implementation Excellence
- **Transformational Growth:** Industry Leadership



The Innovation Generator™

Our 6 analytical perspectives are crucial in capturing the broadest range of innovative growth opportunities, most of which occur at the points of these perspectives.

Analytical Perspectives:

- **Mega Trend (MT)**
- **Business Model (BM)**
- **Technology (TE)**
- **Industries (IN)**
- **Customer (CU)**
- **Geographies (GE)**

