ADVANCING VISION CARE THROUGH THE ENHANCED MONITORING AND DIAGNOSIS OF RETINAL DISEASES
Notal Vision®, Ltd. is a leader in its industry, developing the best tools for effectively managing AMD and was founded in 2000 by Barak Azmon, M.D. and Yair Alster, M.D. Drs. Azmon and Alster, clinically trained ophthalmologists, observed how devastating vision loss can be on a patient’s quality of life. Their vision was to develop better methods of detecting age-related macular degeneration (AMD) that could allow doctors to treat patients at an earlier stage and possibly prevent any loss of sight.

Drs. Azmon and Alster formed a strong team of medical and scientific professionals who developed a technology called Preferential Hyperacuity Perimetry (PHP). This technology became the foundation for Notal Vision, Ltd. products.

A true pioneer in the eye care industry, Notal Vision, Ltd. has developed and introduced the first home-based monitoring system for AMD patients, the ForeseeHome® AMD Monitoring Program.

The first generation of the PHP technology was introduced in 2004 with the launch of the Preview PHP, a device used by patients in the eye doctor’s office. In 2006, launched an updated version of this office based device and in 2009, sold this product line to Reichert Ophthalmic Instruments in order to focus on a home-based telemonitoring solution. Notal Vision, Ltd. is no longer affiliated with the office based version of the PHP technology.

Notal Vision, Ltd. received FDA clearance for the ForeseeHome AMD Monitor in December 2009. In July 2010, the National Eye Institute (NEI), a division of the National Institutes of Health (NIH) began conducting a secondary study to AREDS2 with the ForeseeHome. Enrollment ended in November 2012, with over 1500 patients at risk of progression to wet AMD, an unprecedented number for a medical device study. In April 2013, the Data and Safety Monitoring Committee (DSMC) ended the study early due to positive results.

In October 2013, Notal Vision, Inc. began the official launch of the ForeseeHome AMD Monitoring Program. This revolutionary program is available to patients at risk of vision loss from wet AMD through Retina Specialists across the U.S.

Notal Vision, Inc.’s U.S. office and distribution center is located in Chantilly, VA, with corporate headquarters in Tel Aviv, Israel.
MANAGEMENT TEAM

Quinton Oswald  | Chief Executive Officer
Mr. Oswald brings extensive ophthalmic development and commercialization experience to Notal Vision, previously holding CEO positions with Neurotech and SARcode Bioscience. Prior to that, he was responsible for the successful launch of Lucentis® at Genentech, and led the U.S. and Canada marketing efforts for Visudyne® as the Sr. Vice-President for North America Ophthalmology at Novartis.

Susan Orr, O.D.  | Chief Medical Officer & VP Medical Affairs
Dr. Orr has over 19 years of ophthalmic and retina strategy, development, and operational experience. Prior to joining Notal Vision, Dr. Orr served as Leader of Global Medical Affairs, Strategy, and Search & Evaluation for the Ophthalmology franchise at Janssen Pharmaceuticals, Inc., a division of Johnson & Johnson, and held key R&D and marketing leadership positions during her 17 year tenure at Alcon, a Novartis company.

Gidi Benyamini  | General Manager, Notal Vision, Ltd.
Mr. Benyamini has over 13 years of experience in Ophthalmology Prior to joining Notal Vision, he was VP of Engineering and Manufacturing at LaserComm, a telecommunications company based in Dallas, Texas. Prior to that, he held various positions in the Israeli hi-tech industry.

Scott Jones  | Chief Commercial Officer
Mr. Jones has over 25 years of experience in the pharmaceutical, biotech, and device industries. He has held several senior management positions in sales, marketing, reimbursement, and government affairs while at Novartis and QLT.

Shirley Kleinman  | Chief Financial Officer
Prior to joining Notal Vision, Ms. Kleinman worked in Management consulting & the start-up industry in Israel. She holds a BA in economics and sociology From Tel Aviv University and an MBA from IE Business School.

Jim Niebanck  | VP Marketing & Sales
Mr. Niebanck has over 25 years of experience in sales, marketing and operational leadership positions most recently as Head of Strategy and Operations at Novartis prior to joining Notal Vision. During Mr. Niebanck’s tenure at Novartis, he was also responsible for marketing Visudyne®.

Muki Rapp, Ph.D.  | VP Research & Development
Dr. Rapp has over 14 years of experience in heading R&D projects in Ophthalmology. Prior to joining Notal Vision, he worked as a senior SW engineer in several start-up companies. He holds a Ph.D. and M.Sc. in neuroscience and a B.Sc. in computer science from the Hebrew University of Jerusalem.
INDEPENDENT DIAGNOSTIC TESTING
FACILITY (IDTF) PERFORMANCE STANDARDS

Below is a list of the performance standards that an IDTF must meet in order to obtain or maintain their Medicare billing privileges. These standards, in their entirety, can be found in 42 C.F.R section 410.33(g).

1. Operate its business in compliance with all applicable Federal and State licensure and regulatory requirements for the health and safety of patients.

2. Provides complete and accurate information on its enrollment application. Changes in ownership, changes of location, changes in general supervision, and adverse legal actions must be reported to the Medicare fee-for-service contractor on the Medicare enrollment application within 30 calendar days of the change. All other changes to the enrollment application must be reported within 90 calendar days.

3. Maintain a physical facility on an appropriate site. For the purposes of this standard, a post office box, commercial mail box, hotel or motel is not considered an appropriate site.
   (i) The physical facility, including mobile units, must contain space for equipment appropriate to the services designated on the enrollment application, facilities for hand washing, adequate patient privacy accommodations, and the storage of both business records and current medical records within the office setting of the IDTF, or IDTF home office, not within the actual mobile unit.
   (ii) IDTF suppliers that provide services remotely and do not see beneficiaries at their practice location are exempt from providing hand washing and adequate patient privacy accommodations.

4. Have all applicable diagnostic testing equipment available at the physical site excluding portable diagnostic testing equipment. A catalog of portable diagnostic equipment, including diagnostic testing equipment serial numbers, must be maintained at the physical site. In addition, portable diagnostic testing equipment must be available for inspection within two business days of a CMS inspection request. The IDTF must maintain a current inventory of the diagnostic testing equipment, including serial and registration numbers, provide this information to the designated fee-for-service contractor upon request, and notify the contractor of any changes in equipment within 90 days.

5. Maintain a primary business phone under the name of the designated business. The primary business phone must be located at the designated site of the business, or within the home office of the mobile IDTF units. The telephone number or toll free numbers must be available in a local directory and through directory assistance.

6. Have a comprehensive liability insurance policy of at least $300,000 per location that covers both the place of business and all customers and employees of the IDTF. The policy must be carried by a non-relative owned company. Failure to maintain required insurance at all times will result in revocation of the IDTF’s billing privileges retroactive to the date the insurance lapsed. IDTF suppliers are responsible for providing the contact information for the issuing insurance agent and the underwriter. In addition, the IDTF must –
   (i) Ensure that the insurance policy must remain in force at all times and provide coverage of at least $300,000 per incident; and
   (ii) Notify the CMS designated contractor in writing of any policy changes or cancellations.

7. Agree not to directly solicit patients, which include, but is not limited to, a prohibition on telephone, computer, or in-person contacts. The IDTF must accept only those patients referred for diagnostic testing by an attending physician, who is furnishing a consultation or treating a beneficiary for a specific medical
problem and who uses the results in the management of the beneficiary’s specific medical problem. Nonphysician practitioners may order tests as set forth in §410.32(a)(3).

8. Answer, document, and maintain documentation of a beneficiary’s written clinical complaint at the physical site of the IDTF (For mobile IDTFs, this documentation would be stored at their home office.) This includes, but is not limited to, the following:
   (i) The name, address, telephone number, and health insurance claim number of the beneficiary.
   (ii) The date the complaint was received; the name of the person receiving the complaint; and a summary of actions taken to resolve the complaint.
   (iii) If an investigation was not conducted, the name of the person making the decision and the reason for the decision.

9. Openly post these standards for review by patients and the public.

10. Disclose to the government any person having ownership, financial, or control interest or any other legal interest in the supplier at the time of enrollment or within 30 days of a change.

11. Have its testing equipment calibrated and maintained per equipment instructions and in compliance with applicable manufacturers suggested maintenance and calibration standards.

12. Have technical staff on duty with the appropriate credentials to perform tests. The IDTF must be able to produce the applicable Federal or State licenses or certifications of the individuals performing these services.

13. Have proper medical record storage and be able to retrieve medical records upon request from CMS or its fee-for-service contractor within 2 business days.

14. Permit CMS, including its agents, or its designated fee-for-service contractors, to conduct unannounced, on-site inspections to confirm the IDTF’s compliance with these standards. The IDTF must be accessible during regular business hours to CMS and beneficiaries and must maintain a visible sign posting the normal business hours of the IDTF.

15. With the exception of hospital-based and mobile IDTFs, a fixed base IDTF does not include the following:
   (i) Sharing a practice location with another Medicare-enrolled individual or organization.
   (ii) Leasing or subleasing its operations or its practice location to another Medicare enrolled individual or organization.
   (iii) Sharing diagnostic testing equipment using in the initial diagnostic test with another Medicare-enrolled individual or organization.

16. Enrolls in Medicare for any diagnostic testing services that it furnishes to a Medicare beneficiary, regardless of whether the service is furnished in a mobile or fixed base location.

17. Bills for all mobile diagnostic services that are furnished to a Medicare beneficiary, unless the mobile diagnostic service is part of a service provided under arrangement as described in section 1861(w)(1) of the Act.