



iDiagnostics - the Handheld Future of Medicine Open Innovation Platform for Collaborative Development of Advanced Molecular Diagnostics



iDiagnostics with cartridges

*Turn your cell phone
into rapid, accurate,
yet affordable
molecular diagnostics,
using iDiagnostics.*

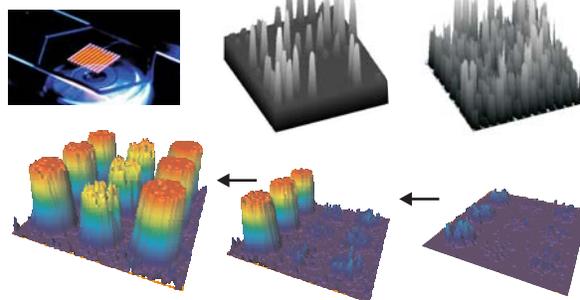
Molecular iDiagnostics (TIRF microarray)

TIRF Labs introduces *iDiagnostics* (real-time TIRF microarray) - a novel molecular diagnostics platform, which is supersensitive, accurate, and rapid, yet affordable for home use. If you are developing fluorescence, electro-chemi-luminescence (ECL), or bioluminescence bioassays for diagnosing or prognosing, we invite you to collaborate. We will help you to interface your assays with *iDiagnostics* platform and will be delighted to license your technology. Ask about *u*TIRF and *iDiagnostics* Application Development Kit (ADK). Visit *iDiagnostics.net* website.

iDiagnostics features a novel type of real-time microarray that simultaneously detects protein, nucleic acid, and metabolite biomarkers. It requires no or minimal sample preparation and is capable of detecting from a single to several thousands of molecular markers in a 50-microliter sample of biological fluids, including whole blood. High sensitivity and the broad dynamic range of *iDiagnostics* covers the entire spectrum of clinically significant concentrations. Limit of Detection (LOD) for micro-RNA is $\sim 10^{-18}$ M. For proteins and metabolites LOD depends on the assay; for certain antibody-based assays LOD is $\sim 10^{-15}$ M.

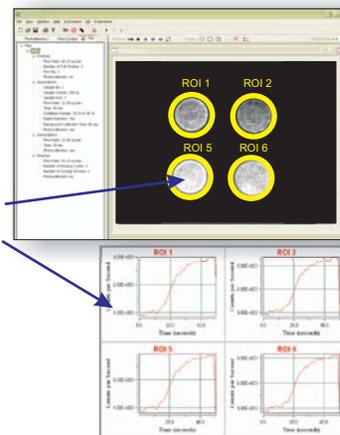
Classical TIRF microarrays operate with small, sub-monolayer amounts of antibodies and DNA probes immobilized on the surface; fluorescence signal is small, a low light photodetector, e.g. EMCCD camera is necessary. In *iDiagnostics* the signal of TIRF arrays is enhanced by 3D encapsulation, which captures the excitation light and becomes an integral part of the lightguide. 3D encapsulation allows for using larger amounts of antibodies per unit area of bioassay spot. The signal from such arrays is a thousand-fold greater than that in classical arrays. CCD cameras of cell phones are sensitive enough to detect the signal. *iDiagnostics* is ideal platform for interfacing antibody-based bioassays for detecting proteins and molecular beacon assays for measuring nucleic acids. See page 2 and visit *iDiagnostics.net* website for more information.

Real-time protein, nucleic acid, and metabolite TIRF microarrays



Data Acquisition and Processing

iDiagnostics software selects respective Regions of Interest (ROI), builds sensorgram for each bioassay, and determines concentrations of protein, nucleic acid, and metabolite markers. Limit of detection for micro-RNA $\sim 10^{-18}$ M, proteins and metabolites $\sim 10^{-15}$ M.





iDiagnostics, uTIRF, and Application Development Kit Open Innovation Molecular Diagnostics Platform

iDiagnostics - the handheld future of precision medicine
accurate, rapid, personalized, yet affordable molecular diagnostics

OPEN INNOVATION APPROACH for collaborative development of molecular diagnostic applications

If you are developing a molecular diagnostics (MDx) system based on fluorescence or electro-chemi-luminescence assays, we are offering to you an exciting opportunity to collaborate. We will help you with unique hardware, software, cartridge blanks, development tools, reagent kits, methods and protocols to facilitate the interfacing of your assays with advanced iDiagnostics platform. We will be delighted to license your Intellectual Property (IP) and offer you the opportunity to license our IP to develop precise and rapid, yet affordable devices for molecular diagnosis and prognosis.

The iDiagnostics platform provides unprecedented precision and rapid diagnosing due to its superior sensitivity, multiplicity, and fast response rate. The platform is several orders of magnitude more sensitive and more accurate than traditional methods. One of the advantages of iDiagnostics involves simultaneous detection of multiple molecular markers of different **classes**, including proteins, nucleic acids, and metabolites. Detection of different classes of markers is necessary for minimization of the rate of false positive responses.

iDiagnostics employs 3D-encapsulated real-time TIRF microarrays that include internal controls and standards for normalization and calibration, which provides high reliability and broad dynamic range to iDiagnostics analyses. The platform also supports other luminescence assays, including Electro-Chemi-Luminescence (ECL). iDiagnostics integrates optics, microfluidics, electronics, electrochemical system, and nanoengineered assays into a small handheld device. Real-time TIRF microarrays are capable of parallel detecting up to thousands of analytes, including proteins, nucleic acids, toxins and chemical agents.

iDiagnostics requires no or minimal sample preparation and can analyze complex biological fluids, including whole blood, saliva, and urine. It employs reagentless bioassays based on molecular beacons and sandwich-format antibody-based assays. Typically, molecular markers are detected in several seconds or a few minutes after the sample is applied.

Applications for the iDiagnostics platform include early diagnosing of cancer, heart diseases, STD, influenza, other infectious diseases, food and water safety, biodefense, forensic, military, environmental, and agricultural analyses.

Our goal is to make accurate iDiagnostics available to every one. Open Innovation Approach, which we use in this project, is well suited for collaborative development of advanced diagnostic products. If you are interested to become a part of this exciting project please send us an email to <info@turf-labs.com>.

The Giving Pledge Opportunity in the Area of Molecular Diagnostics

Our goal is to make accurate iDiagnostics affordable to every family around the globe. At the initial stage, we will distribute uTIRF biodetection station and iDiagnostics Application Development Kit (ADK) to diagnostic research groups. In our lab in North Carolina we will develop tests for prostate and pancreatic cancer, food and water safety. We seek private and institutional donations, U.S. government and international grants for the initial stage - Phase 1.

TIRF Labs does Not pursue a commercial goal in iDiagnostics project, despite the fact that the market of molecular diagnostics is large and rapidly growing. We do not wish that iDiagnostics becomes one more expensive tool available only for small group of individuals. Our goal is to make accurate molecular diagnostics affordable, so that every family could afford to have it in their medical cabinet.

After 9/11 followed by anthrax letters attack, the U.S. government spent ~\$80 Billion on biodefense. There is no analytical technique, which has not been tried for molecular diagnostics. However, all existing methods are inaccurate, slow, bulky, or too costly. The iDiagnostics platform is several orders of magnitude more accurate and rapid, yet affordable.

Social impact. iDiagnostics will change the paradigm of medicine; it will relocate the diagnosing from medical centers to individuals, make the diagnosing accurate, rapid, minimally invasive, and affordable for all. It will help to prevent spreading of infectious diseases and enable personalized medicine. Individuals will become the owners of information about their health; they will decide what to do with the diagnostic data - email them to a medical doctor or keep on their files for the future.

Open Innovation Approach. TIRF Labs offers to biodetection community research groups the iDiagnostics ADK and uTIRF detection station for development of diagnostic tests for medicine and for use in many other areas of lifesciences. We have received large response from the diagnostic community and will use the feedback to further advance iDiagnostics platform and methods. We will support our collaborators 24/7 to facilitate interfacing of bioassays, sample preparation, and data analysis. Applications for iDiagnostics platform include diagnosing and prognosing of cancer, heart diseases, infectious diseases, longevity studies, food and water safety, environmental and agricultural applications, preventative and counter-measures against bioterrorism and naturally occurring diseases.