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### FOR IMMEDIATE RELEASE

## STUDY SHOWS NEW NON-INVASIVE DEVICE SCREENS DIABETES BETTER THAN FASTING PLASMA GLUCOSE TEST

### Diabetes Biomarkers Found in Skin Shown to Correlate Well with Diabetes Risk

WASHINGTON, D.C., June 12, 2006 — Researchers today reported a new non-invasive technology that uses fluorescent light to detect the presence of abnormal concentrations of diabetes-related biological markers found in skin was able to significantly outperform fasting plasma glucose (FPG) as a screening test for pre-diabetes and type 2 diabetes. Results from a clinical study presented at the 66<sup>th</sup> annual Scientific Sessions of the American Diabetes Association, held here, showed a prototype medical device using the technology was able to identify 20 percent more patients with type 2 diabetes or its precursor. The study was conducted by researchers from the University of New Mexico School of Medicine, TriCore Reference Labs, InLight Solutions and VeraLight — the developer of the non-invasive diabetes screening device it calls, “Scout.”

### **Skin AGEs Predict Diabetes and Its Complications**

Previous studies have shown that the presence of so-called “advanced glycation endproducts,” or AGEs, found in skin correlate well with diabetes and are a predictor of the disease’s serious complications. Analogous to a “diabetes odometer,” AGEs are a sensitive metric for the cumulative damage the body has endured due to the effects of abnormally high blood sugar. They affect the proteins that make up blood vessels, connective tissue and skin, and are thought to be major factors in aging and age-related chronic diseases. According to medical experts, non-invasive skin detection of AGEs could replace the fasting plasma glucose test as the medical workhorse for screening people suspected of having diabetes.

“AGEs have been well-recognized as a diabetes biomarker and as a predictor of complications that may lead to blindness and kidney disease,” said Robert E. Ratner, M.D., vice president of scientific affairs at Medstar Research Institute, Baltimore-Washington area’s largest healthcare delivery system. “Until the advent of VeraLight’s technology and the Scout system, a skin biopsy was the only way to detect AGEs which made them impractical for clinical use. With a simple, non-invasive technology, skin AGEs will be a valuable tool for identifying people with sub-clinical disease. Lack of a fasting requirement, overall convenience and superior accuracy may make this the technology of choice for diabetes and pre-diabetes screening.”

### **Scout Technology More Sensitive Than Fasting Glucose Test**

The study was undertaken in 328 subjects at risk for diabetes or pre-diabetes to evaluate VeraLight’s non-invasive Scout technology against the FPG test, which measures a patient’s blood sugar after a 12-hour fast. The oral glucose tolerance test, which measures blood glucose two hours after oral administration of a 75-gram glucose load, was used as a confirmatory test. The subjects in the study ranged in age from 21 to 88 years old. The results were analyzed to compare each test’s “receiver-operator charac-

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teristics” — a statistical measure that graphically illustrates a test’s false-positive relationship to sensitivity (a measure of true positives). At the lower, impaired fasting glucose threshold of 100 milligrams per deciliter (mg/dl), the FPG sensitivity was 57.5 percent with a specificity (a measure of true normals) of 78 percent. At that specificity, the Scout sensitivity was 68.9 percent, showing the ability to detect 20 percent more individuals with diabetes or its precursor.

### **VeraLight Scout**

Weighting about 10 pounds, the VeraLight Scout utilizes proprietary fluorescence spectroscopic technology that does not require patient fasting. The subject inserts the palm-side of the forearm into the system, which resembles a drug-store blood-pressure monitor. In about a minute the Scout shines various wavelengths of light on the skin to stimulate fluorescence that is measured by the machine to provide an indication of diabetes risk based on the presence of AGEs. The instrument optically calibrates for skin pigmentation so that performance is not diminished by skin coloration. A specially designed fiber-optic probe couples the excitation light to the subject and relays resulting skin fluorescence to a detection module. The system’s software utilizes multivariate statistical techniques that are applied to the spectra to obtain a diabetes risk score.

### **Need for Early and More Accurate Diabetes Screening**

More than 73 million Americans — one third of the adult population — now have diabetes or may be on their way to getting it, according to a NIDDK study published in the June issue of *Diabetes Care*. The study showed 9.3 percent of adults age 20 and older (19.3 million people) had diabetes in 1999-2002. While the prevalence of undiagnosed diabetes has remained essentially stable since 1988-1994 at 2.8 percent, the prevalence of diagnosed diabetes rose sharply during the same period — from 5.1 percent to 6.5 percent of the population.

Another 26 percent of Americans had impaired fasting glucose, a form of pre-diabetes. In pre-diabetes, glucose levels are higher than normal, even though they are not yet high enough for a diagnosis of diabetes. Pre-diabetes often leads to diabetes if steps are not taken to prevent it.

Due to their inaccuracy and inconvenience, current screening methods for diabetes are grossly inadequate. The result is that 50% of diabetics are not identified until they present 5-to-9 years into the disease with one or more (often irreversible) complications. A more accurate and convenient screening method could dramatically reduce the costs and morbidity associated with such complications, allowing patients to halt or reverse disease progression.

In 2002 the United States spent \$132 billion on diabetes treatment and complications, or approximately 10 percent of all national healthcare expenditures. Most of this was for complications — yet numerous clinical studies have demonstrated the effectiveness of early therapeutic intervention in preventing the disease or mitigating these complications.

### **About VeraLight**

VeraLight, based in Albuquerque, N. M., is a privately held medical instrumentation company that was established in 2004 as an independent spinout of InLight Solutions to focus on a comprehensive approach to non-invasive diabetes screening. The company’s mission is to help stem the tide of the worldwide diabetes epidemic through early diabetes detection, thus enabling initiation of therapies that can prevent diabetes or reduce its complications. VeraLight develops and acquires intellectual property, products, and services that contribute to this mission. For more information see <http://www.veralight.com>.