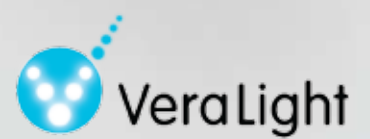


INVESTIGATIONAL DEVICE

SCOUT DS

Non-invasive diabetes screening



Scout DS™ non-invasive diabetes screening.

SIMPLE TEST PROCEDURE

- 1 Load electronic prepaid test key.



- 2 Enter patient age.



- 3 Place arm in cradle.
Results will display in approximately 60 seconds.



SCOUT DS IS DESIGNED TO PROVIDE SUPERIOR PERFORMANCE AND CONVENIENCE

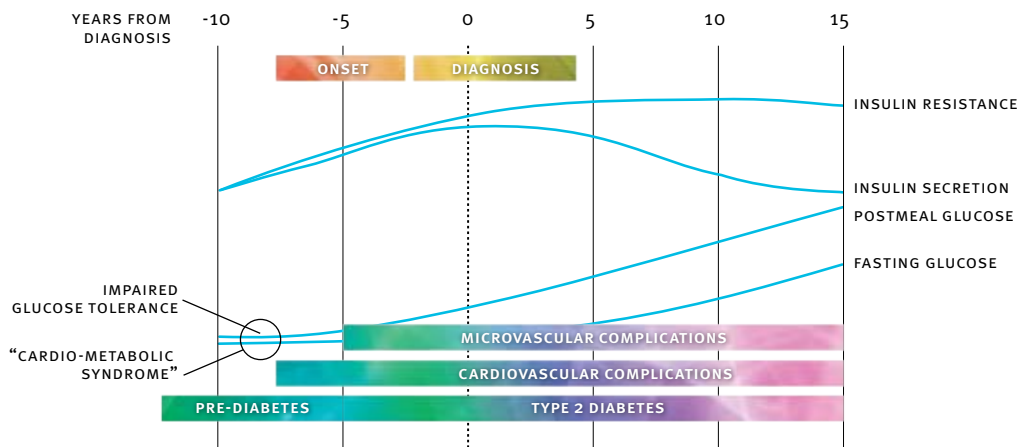
- **Superior performance versus FPG**
Better sensitivity contributes to earlier disease detection and more effective interventions
- **Non-invasive**
No blood draw or bio hazards
- **No fasting**
Allows opportunistic testing any time and reduces non-compliance
- **One minute test time**
Facilitates patient counseling at point of care
- **Advanced glycation end products measurement**
Well established biomarker for diabetes and a sensitive summary metric for long-term glycemic exposure
- **Easy to use**
Three-step procedure with factory calibration and on-board controls

Urgency of early diabetes detection.

Diabetes is a costly national epidemic due in part to the micro- and macrovascular complications that begin years before diagnosis.^{1,2} Not surprisingly, screening to detect the over 60 million people with undiagnosed type 2 and pre-diabetes is a serious national priority. To reinforce the importance of screening to both health professionals and patients, the American Diabetes Association (ADA) issued updated screening guidelines, revised its care algorithms for Impaired Fasting Glucose (IFG) and Impaired Glucose Tolerance (IGT), and instituted several

national direct-to-consumer diabetes awareness campaigns.³ In further support of aggressive diabetes detection, The Centers for Medicare and Medicaid Services (CMS) approved diabetes screening under a National Coverage Decision—an extraordinary move as Medicare rarely extends payment for disease prevention.⁴ Finally, the recent DREAM trial results provide perhaps the most important call to action—much of diabetes can be prevented or delayed if detected early.⁵

NATURAL HISTORY OF TYPE 2 DIABETES^{1,2}



Diagnosis of diabetes typically doesn't occur until 7 to 9 years post onset.

Current screening methods inadequate.

Despite comprehensive screening guidelines and reimbursement, diagnosis of diabetes typically doesn't occur until 7–9 years post onset when 50% of patients have one or more complications.^{6,7} Contributing to the problem of late diagnosis, current screening methods are inconvenient and perform poorly:

Not practical. The Fasting Plasma Glucose (FPG) test requires a fasting blood draw; and the Oral Glucose Tolerance Test (OGTT) requires fasting, ingestion of a glucose load, and multiple blood samples. These features contribute to screening inaccessibility, non-compliance, and under utilization.

Weak detection. The FPG test misses up to 60% of the people it is trying to identify due to poor sensitivity, and the OGTT suffers from poor reproducibility with a Coefficient of Variation (CV) of 18%.^{8,9} These deficiencies can lead to false-negative results and add to the undiagnosed problem. The situation is exacerbated since the results may not *appear* suspect, particularly in the case of pre-diabetes where patients may be asymptomatic.

SCREENING CRITERIA

The ADA recommends screening for individuals with one or more diabetes risk factors, and that all adults aged 45 years and older be considered for screening every 3 years.

Risk Factors for Type 2 Diabetes*

- Age \geq 45 years
- Overweight (BMI \geq 25 kg/m²)
- Family history of diabetes
- Habitual physical inactivity
- Race/ethnicity (African-Americans, Hispanic-Americans, Native Americans, Asian-Americans, and Pacific Islanders)
- Previously identified IFG or IGT
- History of Gestational Diabetes Mellitus
- Hypertension \geq 140/90 mm Hg in adults
- HDL cholesterol \leq 35 mg/dl or a triglyceride level \geq 250 mg/dl
- Polycystic ovary syndrome
- History of vascular disease

*American Diabetes Association

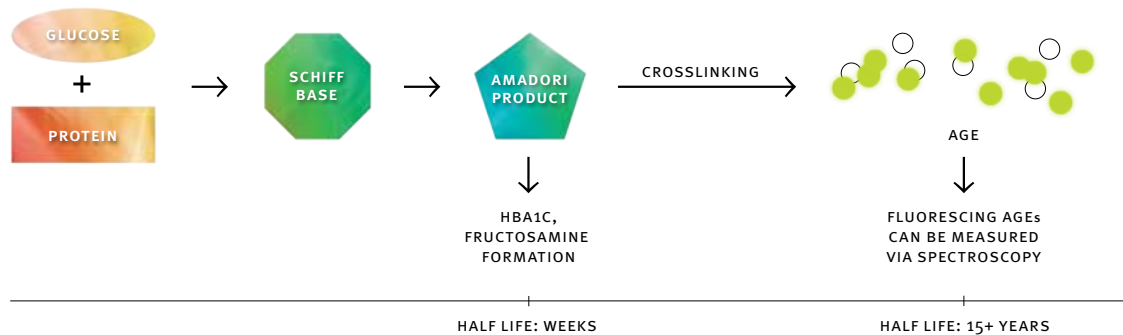
A better metric for early diabetes detection.

A BETTER METRIC FOR EARLY DETECTION – ADVANCED GLYCATION END PRODUCTS (AGEs)

The DCCT and other studies have demonstrated that **elevated skin AGEs are a biomarker of diabetes and are predictive of future diabetic complications.**^{10,11} This is because people with diabetes and pre-diabetes accumulate skin AGEs faster than healthy individuals. AGEs are analogous to a *diabetes odometer* and represent an irreversible, front-line metric for the

long-term cumulative damage the body has endured from abnormally high blood sugar and oxidative stress. This makes skin AGEs an excellent gauge of glycemic assault and an early indicator of diabetes. Unfortunately, until now, widespread clinical measurement of skin AGEs has been impractical because it involves a punch biopsy and a highly complex and expensive assay.

AGE FORMATION (MAILLARD REACTION)



SCOUT DS™ NON-INVASIVE AGE TEST FOR TYPE 2 AND PRE-DIABETES SCREENING

Advances in fluorescent spectroscopy have enabled the development of a non-invasive system that measures skin AGEs *in vivo* in about 60 seconds. SCOUT DS, the product of VeraLight's proprietary SAGE technology, is a portable desktop system weighing about 10 pounds.¹² **After the subject places the palm side of their forearm into the cradle, the device shines multiple wavelengths of light into the skin causing the AGEs to fluoresce. The instrument optically calibrates for skin pigmentation, making the measurement impervious to variations in skin color.**

A specially designed fiber-optic probe sends excitation light to the subject and relays resulting skin fluorescence to the detection module where the result is calculated. As with all diabetes screening methods, an additional test is required to confirm diagnosis. The recommended confirmation for SCOUT DS is an OGTT.

SCOUT DS will report a value from 0 to 100 which represents the likelihood of that subject having abnormal glucose tolerance. To facilitate interpretation, users will be provided guidelines referenced against comparable thresholds on the FPG and OGTT continuums.



Prototype Scout DS™ shows superior diabetes detection.

SCOUT DS OUTPERFORMS FPG AND HBA1C

A study utilizing a SCOUT DS prototype to screen 351 subjects with risk factors for type 2 diabetes showed the **SCOUT DS prototype significantly outperformed both FPG and HbA1c by detecting 29% more patients with type 2 and pre-diabetes than FPG and 17% more cases than HbA1c.**¹²

Abnormal Glucose Tolerance Screening Method	Threshold	Sensitivity	Absolute Difference	Relative Difference
SCOUT DS PROTOTYPE	50	74.7%	—	—
FPG	100 mg/dL	58.0%	16.7%	28.8%
HBA1C	5.8%	63.8%	10.9%	17.1%

Specificity is 78% across all tests (22% false positive rate).
 Oral glucose tolerance test was used as confirmatory test.
 95% Confidence Interval (CI) = ± 9.3%

SUPERIOR PERFORMANCE DETECTING IMPAIRED GLUCOSE TOLERANCE

Further evaluation of a sub-cohort of the clinical data showed the **SCOUT DS prototype device was able to identify 78% more individuals with IGT than the FPG test and 47% more than the HbA1c test.** This performance reinforces skin AGEs as a highly sensitive summary metric for early diabetes screening.¹³

Impaired Glucose Tolerance Screening Method	Threshold	Sensitivity	Absolute Difference	Relative Difference
SCOUT DS PROTOTYPE	51	73.7%	—	—
FPG	100 mg/dL	41.5%	32.2%	77.6%
HBA1C	5.8%	50.2%	23.5%	46.8%

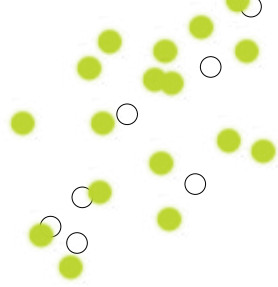
Specificity is 80% across all tests (20% false positive rate).
 Oral glucose tolerance test was used as confirmatory test.
 95% Confidence Interval (CI) = ± 11.5%



SCOUT DS is designed to provide superior performance and convenience in diabetes screening.

DEFINITIONS

- Sensitivity** Probability the test correctly identifies a positive result.
- Specificity** Probability the test correctly identifies a negative result.



800 Bradbury SE, Suite 217
Albuquerque, New Mexico 87106
Phone (505) 272-7023

www.VeraLight.com

VeraLight clinical trials.

VeraLight Inc., based in Albuquerque, New Mexico, is a privately held medical instrumentation company developing the SCOUT DS for diabetes screening. The company is currently testing the system's final configuration and will be conducting clinical trials at 20 sites involving over 6,000 patients. US FDA marketing submission is planned for late 2007. If you are interested in finding out more about these clinical trials or have an interest in participating, please contact Clinical.Research@VeraLight.com.

For more information and to join VeraLight's e-mail list, please visit www.VeraLight.com.

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