SCOUT DS®

Noninvasive Diabetes Screening for Type 2 and Prediabetes
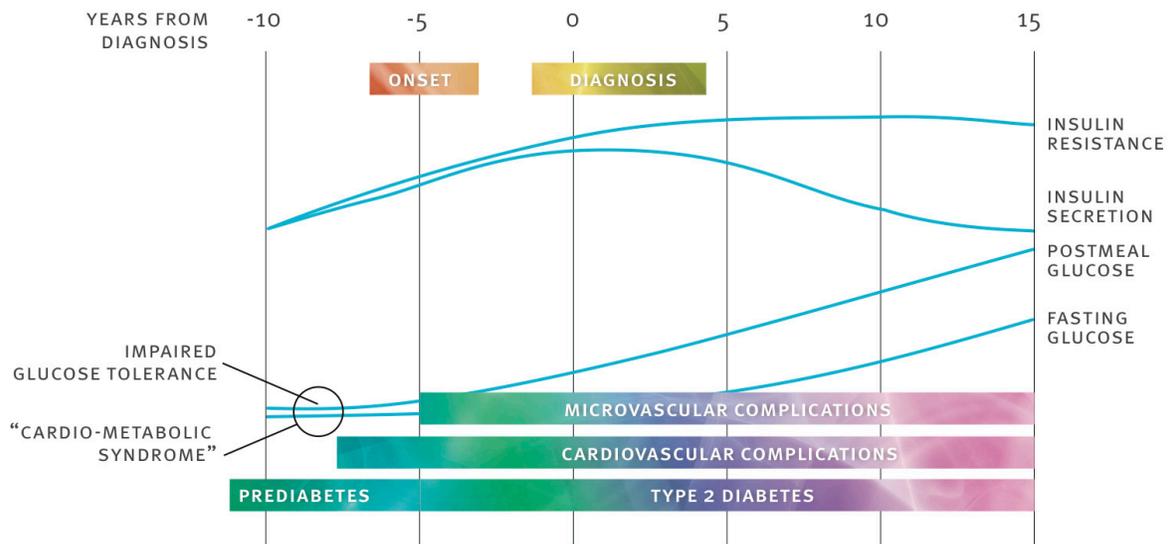
NO BLOOD · NO FASTING · NO WAITING

VeraLight

Urgency of early diabetes detection.

Diabetes is a costly global epidemic due in part to the micro- and macrovascular complications that begin years before diagnosis.[1,2] Additionally, much of diabetes can be prevented or delayed if detected early.[3] However, despite comprehensive screening guidelines, diagnosis of diabetes typically doesn't occur until 5–9 years post onset when 50% of patients have one or more complications.[4,5]

Current screening methods inadequate.

Contributing to the problem of late diagnosis is weak test sensitivity and the need for a blood draw. Screening access is further complicated as most test methods require fasting or a trip to a lab.

NATURAL HISTORY OF TYPE 2 DIABETES[1,2]

YEARS FROM DIAGNOSIS: -10   -5   0   5   10   15

ONSET   DIAGNOSIS

INSULIN RESISTANCE
INSULIN SECRETION
POSTMEAL GLUCOSE
FASTING GLUCOSE

IMPAIRED GLUCOSE TOLERANCE
"CARDIO-METABOLIC SYNDROME"

MICROVASCULAR COMPLICATIONS
CARDIOVASCULAR COMPLICATIONS
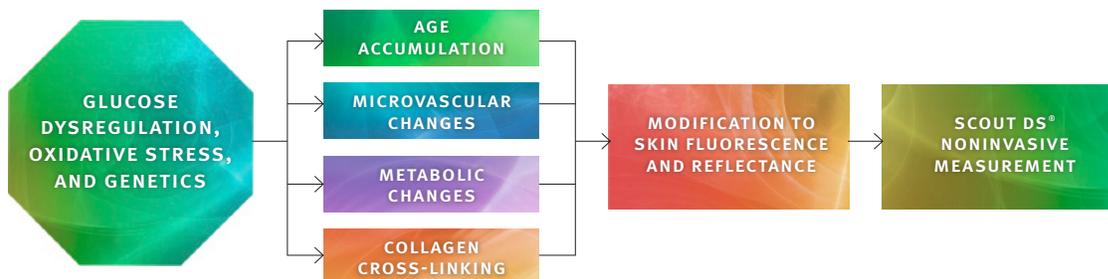PREDIABETES   TYPE 2 DIABETES

Better metrics for early diabetes detection.

Increases in glucose dysregulation and oxidative stress cause measurable changes in early diabetes-related biomarkers. The SCOUT Diabetes Score is derived via measurements of fluorescence and reflectance from these biomarkers found in the skin of the forearm, including:

· Measures of glycemic exposure and oxidative stress including Advanced Glycation End Products (AGEs) and connective tissue cross-links
· Measures of metabolic change including NADH and FAD
· Measures of microvascular changes

A proprietary algorithm transforms measurements from these biomarkers, corrects for skin tone, and reports a SCOUT Diabetes Score.

GLUCOSE DYSREGULATION, OXIDATIVE STRESS, AND GENETICS

AGE ACCUMULATION
MICROVASCULAR CHANGES
METABOLIC CHANGES
COLLAGEN CROSS-LINKING

MODIFICATION TO SKIN FLUORESCENCE AND REFLECTANCE

SCOUT DS® NONINVASIVE MEASUREMENT

SCOUT DS® Noninvasive diabetes screening.

Benefits

Noninvasive
No blood draw or biohazards

No fasting
Allows opportunistic testing any time

Fast, immediate results
Facilitates patient counseling at point of service

Easy to use
Three-step procedure with factory calibration and on-board controls

Superior sensitivity[6,7]
Contributes to earlier disease detection

No test strips to handle
Just enter pre-paid test key

SIMPLE TEST PROCEDURE
1. Enter patient age and gender
2. Place arm in cradle
3. Results in as little as 80 seconds

SCOUT DS® shows superior detection
of abnormal glucose tolerance versus either FPG or A1C...

TEST[6]	THRESHOLD	SENSITIVITY (%) [95% CI]	FALSE POSITIVE RATE (%) [95% CI]	ABSOLUTE SENSITIVITY DIFFERENCE	RELATIVE SENSITIVITY DIFFERENCE
SCOUT	SCOUT DIABETES SCORE = 50	75.2 [70.8 – 79.2]	42.1 [37.4 – 47.0]	–	–
FPG	ADA 5.6 MMOL/L (100 MG/DL)	56.0 [51.1 – 60.7]	23.7 [19.9 – 28.1]	19.2%	34%
	WHO 6.1 MMOL/L (110 MG/DL)	37.6 [33.1 – 42.4]	7.4 [5.2 – 10.3]	37.6%	100%
A1C	ADA 5.7%	72.5 [67.9 – 76.6]	43.5 [38.8 – 48.3]	2.7%	4%
	IEC 6.0%	46.8 [42.0 – 51.6]	15.1 [11.9 – 18.8]	28.4%	61%

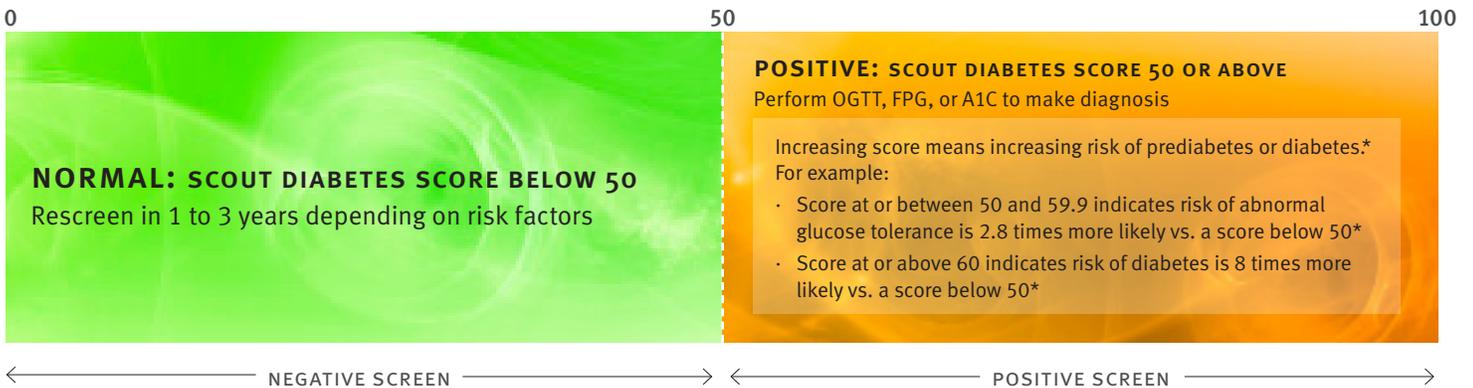### ... and of dysglycemia (HbA1c$\geq$6.0%) versus Random Capillary Glucose...

TEST[7]	THRESHOLD	SENSITIVITY (%) [95% CI]	FALSE POSITIVE RATE (%) [95% CI]	ABSOLUTE SENSITIVITY DIFFERENCE	RELATIVE SENSITIVITY DIFFERENCE
SCOUT	SCOUT DIABETES SCORE = 50	83.8 [76.7 – 89.1]	32.8 [27.4 – 38.7]	–	–
RCG	6.1 MMOL/L (110 MG/DL)	33.1 [25.7 – 41.4]	19.1 [14.8 – 24.3]	50.7%	254%

... and of diabetes (HbA1c$\geq$6.5%) versus Random Capillary Glucose.
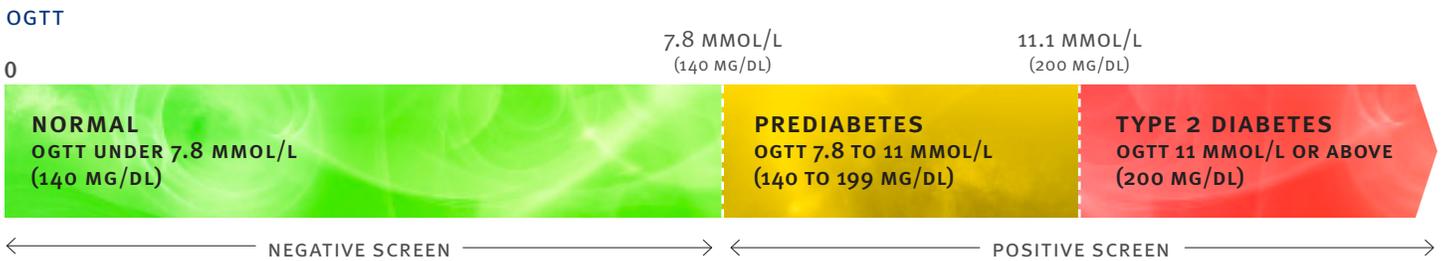
TEST[7]	THRESHOLD	SENSITIVITY (%) [95% CI]	FALSE POSITIVE RATE (%) [95% CI]	ABSOLUTE SENSITIVITY DIFFERENCE	RELATIVE SENSITIVITY DIFFERENCE
SCOUT	SCOUT DIABETES SCORE = 50	98.0 [89.3 – 99.6]	43.6 [38.5 – 48.8]	–	–
RCG	6.1 MMOL/L (110 MG/DL)	44.9 [31.9 – 58.7]	20.9 [17.0 – 25.5]	53.1%	218%

ADA = American Diabetes Association, WHO = World Health Organization, IEC = International Expert Committee

Interpretation of results.

SCOUT DS®

0   50   100

NORMAL: SCOUT DIABETES SCORE BELOW 50
Rescreen in 1 to 3 years depending on risk factors

POSITIVE: SCOUT DIABETES SCORE 50 OR ABOVE
Perform OGTT, FPG, or A1C to make diagnosis

Increasing score means increasing risk of prediabetes or diabetes.*
For example:
- Score at or between 50 and 59.9 indicates risk of abnormal glucose tolerance is 2.8 times more likely vs. a score below 50*
- Score at or above 60 indicates risk of diabetes is 8 times more likely vs. a score below 50*

← —————— NEGATIVE SCREEN —————— → ← —————— POSITIVE SCREEN —————— →

The SCOUT Diabetes Score reference method is the 2 hour 75g Oral Glucose Tolerance Test (OGTT).

OGTT

0   7.8 MMOL/L   11.1 MMOL/L
                                         (140 MG/DL)   (200 MG/DL)

NORMAL
OGTT UNDER 7.8 MMOL/L
(140 MG/DL)

PREDIABETES
OGTT 7.8 TO 11 MMOL/L
(140 TO 199 MG/DL)

TYPE 2 DIABETES
OGTT 11 MMOL/L OR ABOVE
(200 MG/DL)

← —————— NEGATIVE SCREEN —————— → ← —————— POSITIVE SCREEN —————— →

* Based on a prospective study of 471 subjects at risk for type 2 diabetes by American Diabetes Association criteria and 267 subjects with previously diagnosed type 2 diabetes.

Who should be screened?

In general, patients aged 40 or older should be tested approximately every three years.
If any of the listed risk factors apply, they should be tested earlier and/or more often.

- Overweight
- Physical inactivity
- Insulin resistance
- Family history of diabetes
- High risk ethnic group
- Vascular disease

- Hypertension
- Dyslipidemia
- Complications associated with diabetes
- Gestational diabetes
- Delivery of a macrosomic infant
- Polycystic ovary syndrome

1. Ramio-Halsted B.A., et al. *Primary Care*. 1999;26:771–789.

2. Nathan D.M. *New England Journal of Medicine*. 2002;347:1342–1349.

3. DREAM (Diabetes Reduction Assessment with ramipril and rosiglitazone Medication) Gerstein H.C. et al. *The Lancet*. 2001;344:1343–1350.

4. Harris M.I., et al. *Diabetes Metab Res Rev*. 2001;16:230–236.

5. Manley S.M., et al. *Diabetes Res*. 1990;13:1–11.

6. Sensitivity, specificity, and associated 95% confidence intervals for SCOUT DS, the FPG test, and the A1C test from the ENGINE trial. Results based on an analysis set of 471 subjects, all at risk for type 2 diabetes by American Diabetes Association criteria.

7. Sensitivity, specificity, and associated 95% confidence intervals for SCOUT DS and RCG test from the GREECE trial. Results based on an analysis set of 409 subjects, all at risk for type 2 diabetes by American Diabetes Association criteria.

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