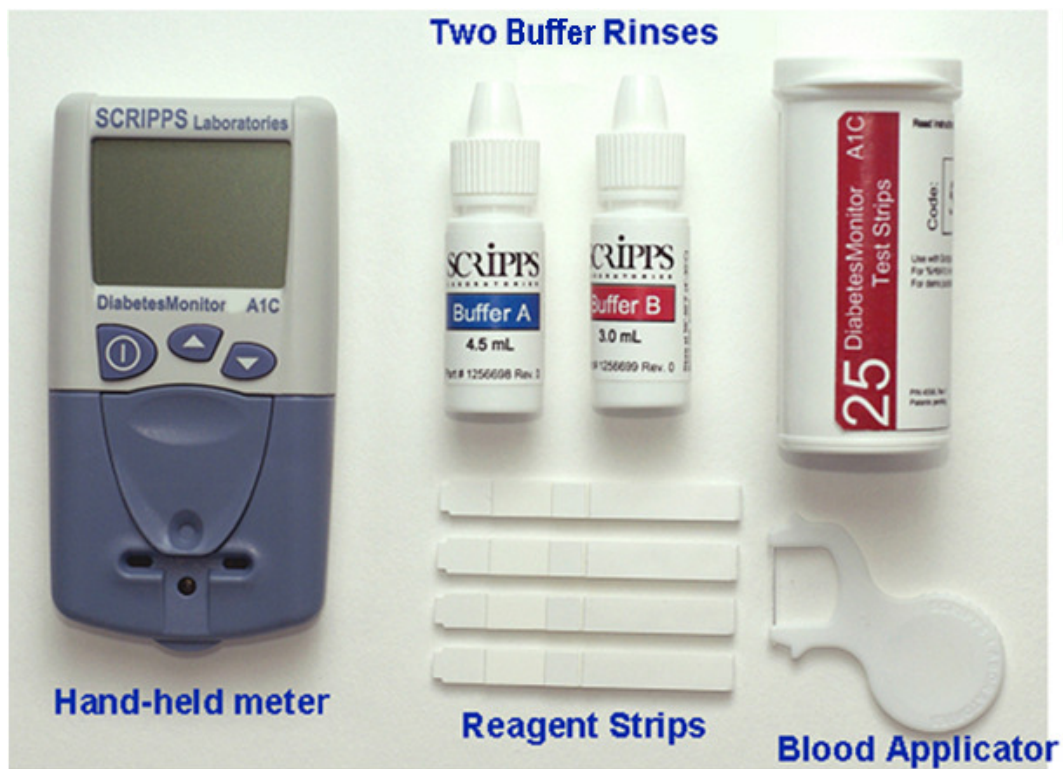


Scripps Laboratories has demonstrated feasibility of a proprietary low cost system for measuring percent hemoglobin A1c (HbA1c). A sample system is shown below.



**Business Goal:**

- Scripps Laboratories is interested in licensing the technology of the Scripps HbA1c System (patents and know-how) for adaptation into a finished product.

**Assay Principle:**

- The Scripps assay is a boronate affinity method.
- Both total and glycosylated hemoglobin are measured on the same disposable assay device.

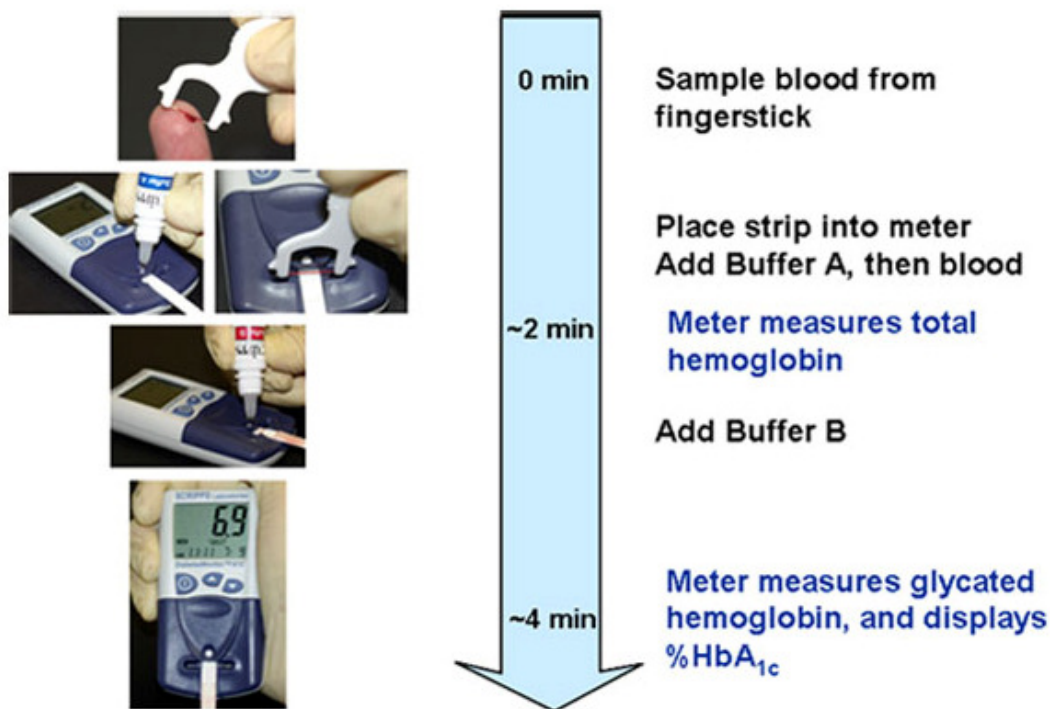
- Disposable:** Low cost, assay test strip.
- Test Meter:** Possible to use glucometer type reflectometer
- Assay Range:** 3 to 13% DCCT harmonized HbA<sub>1c</sub>
- Patent Status:** US Patent Issued - 7,195,923 and 7,695,973  
Foreign Patents - Canada, China, France, Germany, Great Britain, India, Israel, Italy, Japan, Mexico, South Africa

**Stability:**

- Assay strip contains no potentially labile components such as enzymes, antibodies or chromogenic markers.
- Preliminary studies indicate stability at room temperature and 45°C with desiccation.

**Steps for Running an Assay:**

- The steps involved in running an assay are shown below utilizing the proof-of-concept assay system.
- Both total and glycated hemoglobin are measured on a single strip using a single whole blood sample, and percent glycated hemoglobin is measured.



## Advantages & Features:

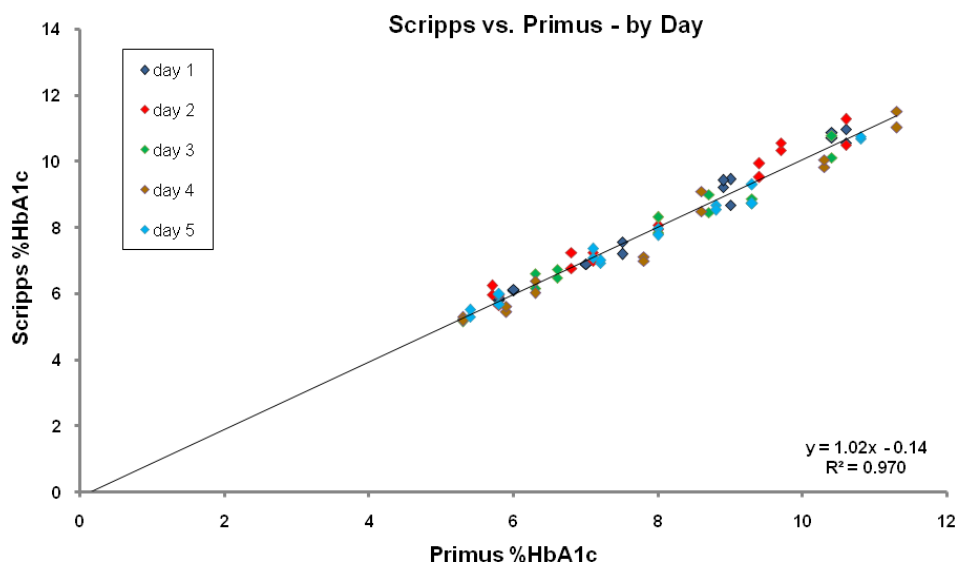
1. Small Sample Size: 2-3  $\mu\text{L}$  fingerstick
2. Whole blood capillary sample with no pre-treatment
3. All measurements are made on the same area of the matrix, minimizing system error
4. Short assay time: ~5 minutes
5. Low cost, test strip
6. Boronate affinity method - will not be affected by the labile fraction of glycated hemoglobin or by the presence of hemoglobin variants in the sample

## Proof-of-Concept Assay Results

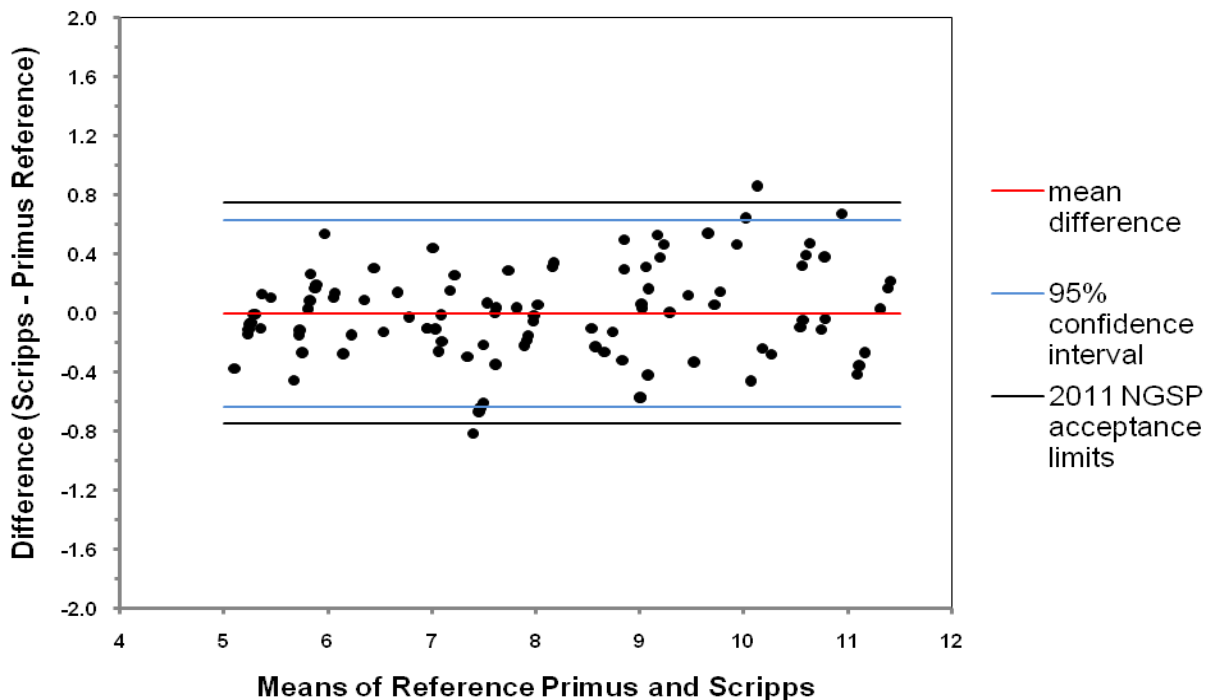
Assay performance data was collected from assays of clinical samples and control materials:

- The clinical sample assay results (ratios) were proportional to the NGSP reference method and could be harmonized with the DCCT
- The Scripps method met NGSP certification criteria for agreement with reference methods
- The twenty-day precision study showed CV's of  $\leq 4\%$  for HbA1c at 5% and at 11%

The agreement of the Scripps method to the NGSP Primus reference method is shown below. There was no difference between days in the correlation.



The Bland-Altman plot of the correlation data is shown below. The Scripps method passed the NGSP criteria for agreement to a reference method.



### Stability Data

The test strips show excellent stability at room temperature and 45°C with desiccation.

