

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



**Business goal** - Establish distribution channels

**Development stage:**

- Feasibility shown
- Finalizing design based on partner input

### Assay principle:

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

**Disposable** – assay test strip

**Meter** – glucometer type reflectometer

**Assay range** – 3 to 13% DCCT harmonized HbA<sub>1c</sub>

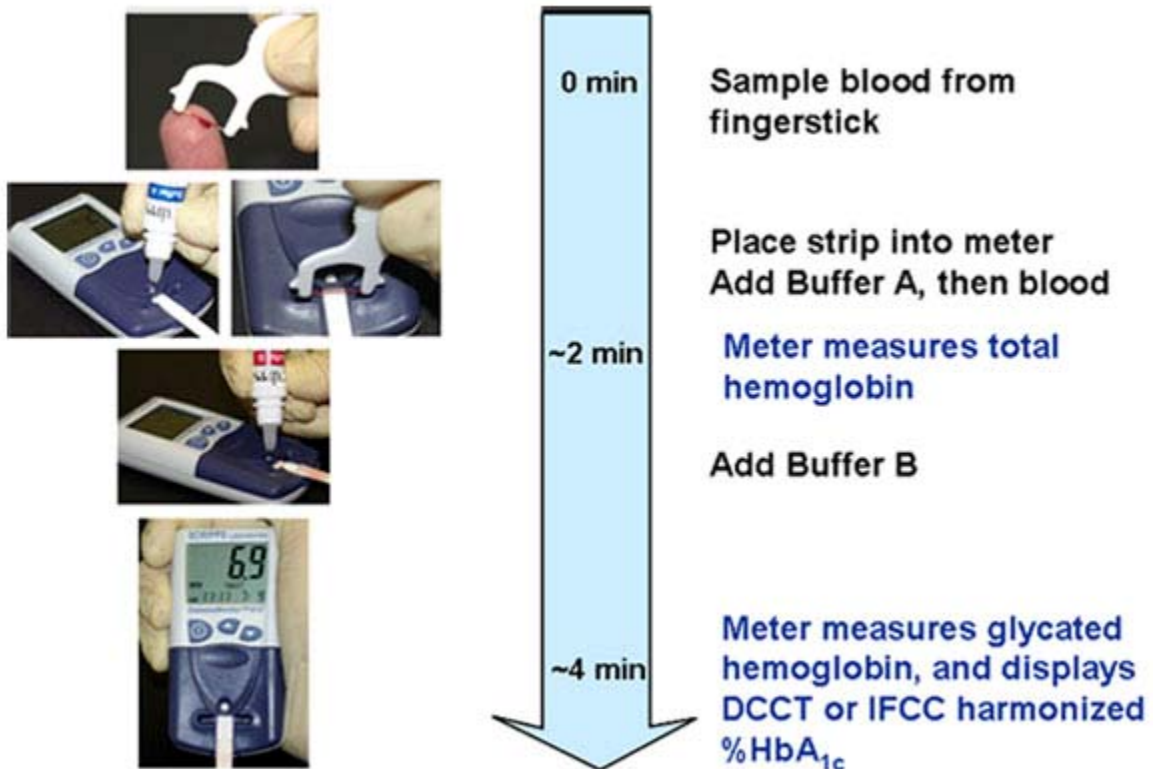
**Patent status** - US patent issued; PCT patents pending

### Stability:

- Assay strip contains no potentially labile components such as proteins or indicators
- Preliminary studies indicate good stability at room temperature and 45°C with desiccation.

### User interface and assay time:

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



## **Advantages and features:**

1. Small sample size: 2-3  $\mu\text{L}$  fingerstick
2. Technique independent
3. Whole blood capillary sample with no pre-treatment
4. Reports DCCT harmonized %HbA1c
5. All measurements are made on the same area of the matrix, minimizing system error
6. Short assay time: ~5 minutes
7. Low cost disposable and reflectance meter
8. Boronate affinity method - will not be affected by the labile fraction of glycated hemoglobin or by the presence of hemoglobin variants in the sample

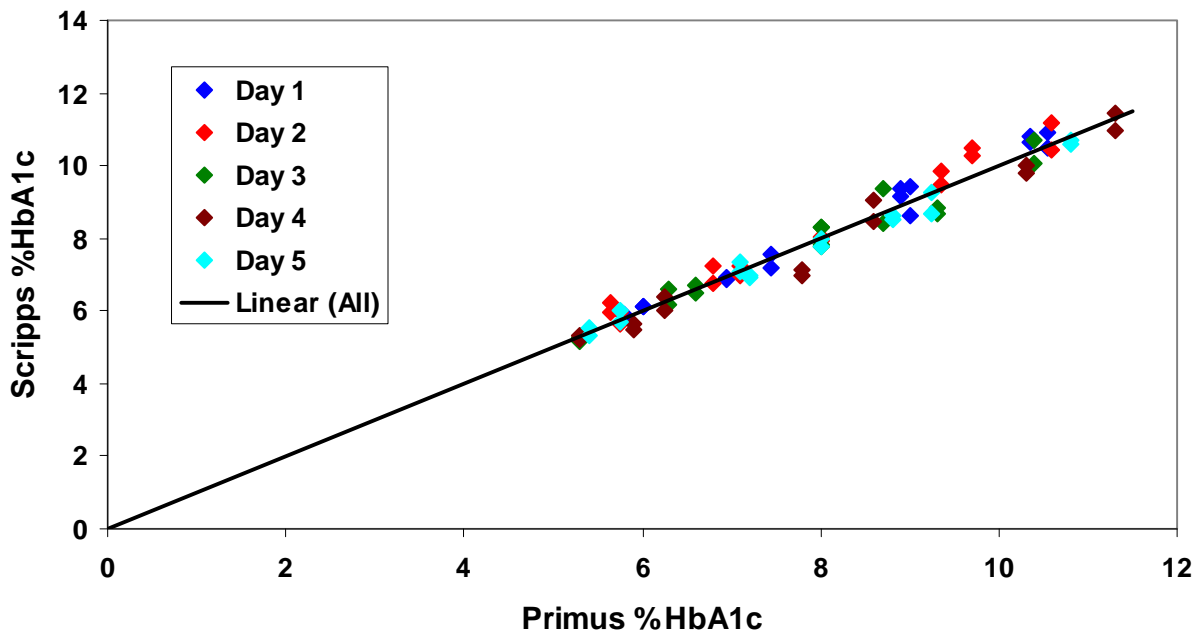
## Results of pre-prototype evaluation

Assay performance data was collected using a pre-prototype system to assay clinical samples and control material:

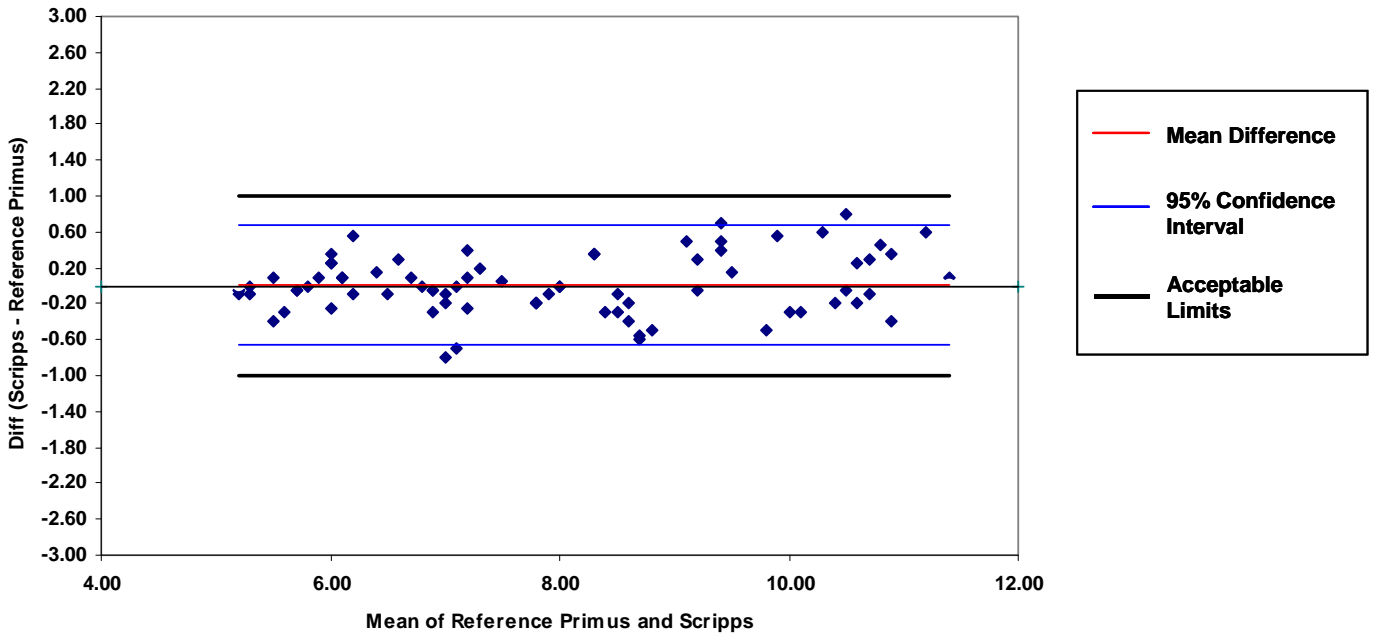
1. The clinical sample assay results (ratios) were proportional to the NGSP reference method and could **be harmonized with the DCCT**
2. The Scripps method **met NGSP certification criteria for agreement with reference methods**
3. The twenty-day precision study showed CV's of  $\leq 4\%$  for HbA1c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

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

Scripps Duplicates vs Primus by Day



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



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

