

Point-of-care HbA1c Test Using A Novel Direct Enzymatic Method

Chen X, Liu L, Hood S. and Yuan C. Diazyme Laboratory, Poway, CA 92064

INTRODUCTION

The American Diabetes Association (ADA) recommends the hemoglobin A1C test, or HbA1c, as the best way to determine a patient's blood glucose control over the past 2-3 months. The Diabetes Control and Complications Trial (DCCT) confirmed the importance of the HbA1c test and that lowering the HbA1c number can potentially reduce the development of complications from diabetes and improve a patient's chance of staying healthy. The HbA1c test is usually done in a clinical laboratory by sending a patient blood sample to a laboratory and forwarding the test results to the patient's physician in a few days. Recent studies have shown that an instant HbA1c result at the time of the patient's visit to the doctor's office can significantly improve patient's glycemic control by making immediate necessary adjustments of treatment or patient behavior or both. Therefore, a point-of-care device for the HbA1c test that can provide accurate and reliable HbA1c results at doctor's office is highly desirable.

METHOD

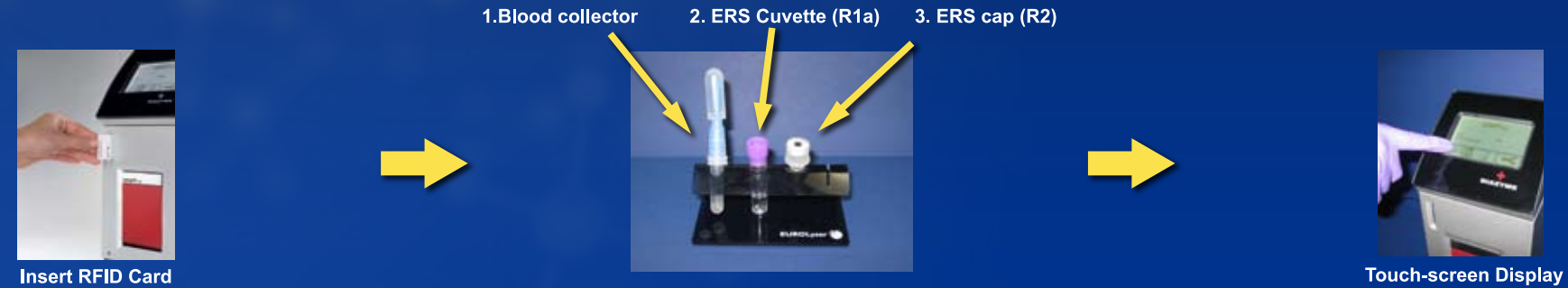
Diazyme, recently, developed a point-of-care HbA1c test using a novel direct enzymatic method and a portable device (Smart 700). The direct enzymatic HbA1c assay method utilizes specific enzyme (FVO) to quantify glycosylated hemoglobin amount without the need for a separate measurement of the total amount of hemoglobin, whereas the portable device utilizes an optical detection system (700 nm) with a two-reagent based cartridge and a RF-ID card.

PROCEDURE:

The test consists of two simple steps as follows:

- 1). Take 20 μ L of blood sample from a fingerstick with a sample collector where the blood is immediately lysed in the collector.
- 2). Add 150 μ L of the lysed blood sample to the reagent cuvette which is inserted into the Smart 700. The test result is reported in 8 min after pressing the start key on the screen of the Smart 700.

PREPARATION OF TEST SYSTEM:



APPLICATION:



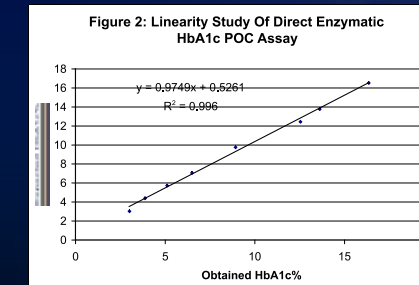
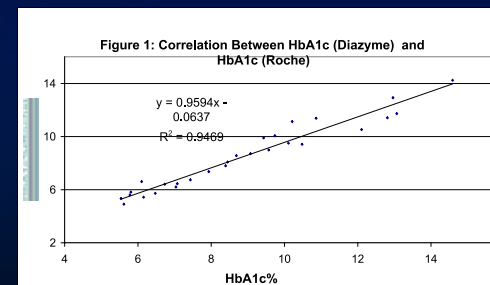
RESULTS

The Smart 700 results correlate well with results obtained by the HPLC (Tosoh) and immunoassay (Roche) methods as shown in the figure 1. Other features of the Smart 700 HbA1c test include wide dynamic range of 4.5-16% HbA1c (Figure 2); high precision with CV < 5% (Table 1); high accuracy comparable to large lab results; results traceable to NGSP values; no interference from Hb variants like HbC, HbE, and HbS ; no calibration needed; and cost effective.

Table 1: Precision Study Of Direct Enzymatic HbA1c POC Assay

In this study, one whole blood specimen containing 7.6%, two whole blood controls containing 5.5% and 11.3% HbA1c were tested with 2 runs per day with duplicates over 10 working days with first 5 days using Reagent Lot 1 and the next 5 days using Reagent Lot 2 on three different SMART HbA1c POC Devices respectively. The results are summarized in the following table:

Sample	5.5% HbA1c	7.6% HbA1c	11.3% HbA1c
Data Points	40	40	40
Mean	5.54%	7.80%	11.29%
SD	0.25%	0.26%	0.28%
CV	4.54%	3.35%	2.48%



Smart 700 HbA1c

CONCLUSION

A novel direct enzymatic method and a portable device (Smart 700) for a point-of-care HbA1c test have been developed at Diazyme Lab. The assay kit and the device can be used at doctor's office and may also be used at home for HbA1c self-monitoring by patients.