Development of a Capillary Blood Mail-in Kit for the Measurement of Hemoglobin A1c

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INTRODUCTION/ BACKGROUND

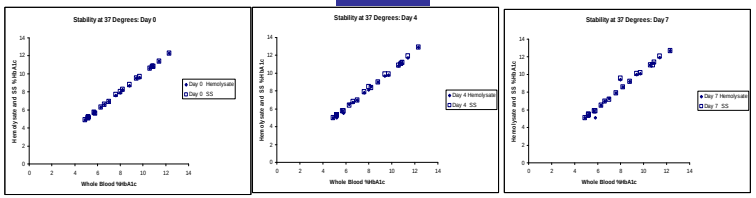
It is estimated that in the United States diabetes affects 25 million children and adults and is a major cause of morbidity and mortality. Cost of diabetes in the United States is over $175 billion a year. To optimize insulin dose, diabetic patients regularly measure their blood glucose. Random glucose measurement does not provide indication of long-term glucose control. The long-term indicator of glucose control is the hemoglobin A1c (HbA1c). It provides average blood glucose level of the previous 2 to 3 months. In most cases, for HbA1c testing, patients come to clinical laboratories for blood draw. It is time consuming and inconvenient. In recent years efforts have been made to develop sample mail-in kit where the blood sample can be collected at home and mailed to a testing laboratory. We present the development of a stabilizing solution (SS) and mail-in kit for Hb A1c testing. With this kit, after a simple finger prick, a patient collects blood using a capillary tube. The blood-containing capillary tube is dropped in a tube containing SS, and is mailed to the laboratory in a pre-stamped box in a regular mail.

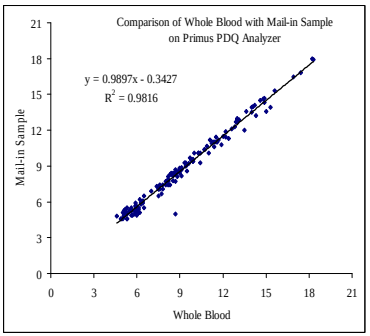
MATERIALS AND METHODS

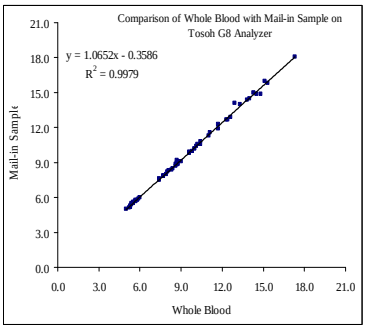
Validation of the kit included:

- Comparing HbA1c levels in the whole blood to hemolysate and SS immediately after preparation of the samples.
- Testing stability of HbA1c in SS for 4 and 7 days at 4oC, room temperature and 37oC.
- Mailing the samples in the regular mail and comparing the values of HbA1c in mailed-in samples to the whole blood samples on two different technologies.
  - Primus PDQ
  - Tosoh G8
- It took 2-10 days, for the mail-in samples to reach the laboratory

Results







SUMMARY AND CONCLUSION

No significant difference was found in the values of HbA1c in various test groups. In conclusion, we have developed a convenient mail-in kit for the measurement of HbA1c. The advantages of mail-in kit for HbA1c measurement include patients' satisfaction as it negates the need for venipuncture and laboratory visit for sample collection, and the availability of results to a physician before the patient's visit for optimal care.