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

Uttam Garg, Nancy Reddig, Joseph Niesen, Tripti Arora and Angela Ferguson
Department of Pathology and Laboratory Medicine, Children’s Mercy Hospitals and Clinics, and University of Missouri
School of Medicine, Kansas City MO

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

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.