

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

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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.

Validation of the kit included 1) Comparing HbA1c levels in the whole blood to hemolysate and SS immediately after preparation of the samples, 2) Stability of HbA1c in SS for 4 and 7 days at 4°C, room temperature and 37°C, 3) mailing the samples in the regular mail and comparing the values of HbA1c in mailed-in samples to the whole blood samples. The data for some of these comparisons are shown in the Table below. 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.

**Table: Comparison of HbA1c (%) in whole blood with hemolysate and stabilizing solution on 2 different analyzers**

	<b>Whole Blood</b>	<b>Hemolysate</b>	<b>SS</b>	<b>Mail-in Sample</b>	<b>HbA1c Range</b>	<b>Regression equation</b>	<b>R<sup>2</sup></b>
<b>Primus PDQ</b>	9.1	8.9	8.9	8.7	4.6-18.5	$y=1.0044x-0.2956$	0.9821
<b>Tosoh G8</b>	9.2	9.2	9.2	9.3	4.9-18.1	$y=1.025x-0.1303$	0.9989