

Blood stabilization medium for use in HbA1c at-home sampling and mail-in analysis

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The Innovation: Children's Mercy, Kansas City has developed an inexpensive, cyanide free blood stabilization medium for use in short-duration shipment of small samples, such as for at home collection of blood samples for HbA1c tests

Background:

Diabetic patients measure blood glucose regularly to optimize their insulin dose. The long-term indicator of glucose control is the hemoglobin A1c blood test, which provides average blood glucose level over the previous 2 to 3 months. In the past, patients were required to leave home and visit a laboratory where blood samples were drawn and analyzed. Patients can now extract a finger-stick specimen at home and mail it to a testing laboratory, balancing the convenience of at-home sampling and the accuracy available only in an analytical laboratory.

Accuracy of these test requires that the sample remain biochemically stabilized from the time it is extracted until its arrival at the laboratory. However, a recent study evaluating the accuracy of three commercial home-use HbA1c tests concluded that none of these currently available tests produced the National Glycohemoglobin Standardization goal of $\geq 90\%$ measurements within 5% of a DCCT venous reference.¹

Innovation:

- An inexpensive, cyanide free blood stabilization medium for use in short-duration shipment of small samples, such as for at home collection of blood samples for HbA1c tests
- Possible co-distribution with laboratory analytical systems

Advantages:

- Increases patient satisfaction by eliminating venipuncture and laboratory visits for sample collection
- Optimizes patient care: results are available to physician prior to office or telehealth visit
- Easily adapted to volume production with companion shipment kit
- Inexpensive to produce
- Ready for use with all common laboratory analyzers

Status:

- Validated by current use for more than 10 years at Children's Mercy, Kansas City
- Direct comparison of mail-in kit results to "gold standard" methods demonstrate sample stability for at least 7 days
- In an independent study of the Children's Mercy kit, HbA1c measurements from capillary samples were within 5% of contemporaneously obtained venous samples for 99% of samples shipped with or without a cold-pack²
- No patent application will be filed. Stabilization solution is confidential

Publications:

1. Jacobsen, Laura M et al. "Accuracy of Three Commercial Home-Use Hemoglobin A1c Tests." *Diabetes technology & therapeutics* vol. 24,11 (2022): 789-796
2. Beck, Roy W. et al. "An Evaluation of Two Capillary Sample Collection Kits for Laboratory Measurement of HbA1c." *Diabetes technology & therapeutics* vol. 23,8 (2021): 537-545

Licensing: Children's Mercy, Kansas City seeks to have discussions with companies that are interested in licensing the formulation.