

Evidence Table

Clinical Area: Home A1c tests
Reference: Parkes J, Ray R, Kerestan S et al. Prospective evaluation of accuracy, precision, and reproducibility of an at-home hemoglobin A1c sampling kit. *Diab Tech Ther* 1999; 1: 411-419.

Study Type: Comparison of diagnostic tests

Study Aim: To evaluate the FlexSite B-D A1c At-home test.

Outcomes

- *Primary:* Correlation between test results.

Design

- *Number of subjects:* n=59
- *Description of study population:* 49 adults, 10 children.
- *Inclusion criteria:* Type 1 or type 2 diabetes for >1 year; ≥ 5 years old.
- *Exclusion criteria:* Known red blood cell or hemoglobin abnormalities.
- *Procedure:* 1) Clinical study: Patients performed 2 or 6 fingersticks (depending on age) and applied capillary blood samples to the test filter paper in an in-clinic setting. In addition, venous blood was spotted onto 9 additional test papers by a member of the study staff. Test papers were dried overnight and sent to the laboratory for analysis. Samples were evaluated by the Cobas Integra Hemoglobin A method and the Bio-Rad Variant HPLC method. The method used to evaluate dried blood in the commercially available test is the Cobas Integra method.
2) Laboratory study: Venous blood was collected from 21 patients and spotted onto the test paper by laboratory technicians. Samples were dried overnight and subjected to extreme temperatures to simulate conditions when samples are mailed. To mimic heat conditions, samples were exposed to various temperature regimes over 12 hour cycles (to simulate day and night) and for 48 hours (to simulate samples left in mailbox over weekend).

Validity

- *Independent blind comparison with a gold standard?* The study compared performance of the B-D A1c At-home test when samples were collected by patients versus study staff. Samples collected by study staff served as the gold standard. In addition, the study compared the method of evaluating samples (a variation of the Cobas Integra method) to the standard Cobas Integra method and to the Bio-Rad Variant HPLC method.
- *Was "normal" defined?* No.
- *Appropriate spectrum of disease?* NA.
- *Consecutive patients?* Not addressed.
- *Completeness of follow-up:* Not reported, appeared to be complete.
- *Methods described in enough detail to enable you to replicate the test?* Difficult to understand study methodology.
- *Reproducible results?* Uncertain.
- *Industry involvement?* Yes.

- **Conclusions regarding validity of methods:** The study did not evaluate the sensitivity or specificity of the home A1c test compared to a gold standard. The test was compared to other tests, but sensitivity and specificity compared to a gold standard was not determined.

Results

Comparison of results from patient-collected and clinical staff collected samples was not reported.

Correlation between B-D A1c at-home test versus standard Cobas Integra hemoglobin A1c assay (using the same samples)

There was a high degree of correlation between the two test results ($r^2=94.7\%$).

Correlation between B-D A1c at-home test versus Bio-Rad Variant HPLC

There was a high degree of correlation between the two test results ($r^2=92.3\%$).

Precision and reproducibility of the B-D A1c at-home test

Within-subject reproducibility of repeated tests within the 3-to 10-day window: The coefficient of variation (CV) of reproducibility among 59 patients was 2.7% (authors state that the recommended variation is less than 5%).

Effect of heat on mailed samples

In a separate study, the authors determined that the maximum mailbox temperature (black rural mailbox, during St. Louis summer) was 136°F/58 °C at an ambient temperature of 106°F. Another investigation found a maximum temperature of mailed packages was 145 °F.

Control (samples kept at room temperature): mean HbA1c=9.5%

Samples exposed to 12 hour cycles of 35/45°C for 1 or 2 days: Mean HbA1c not significantly different from control.

Samples exposed to 45/55 °C for 1 day: Mean HbA1c not significantly different from control.

Samples exposed to 45/55 °C for 2 days: Mean HbA1c was significantly lower than the control.

Samples exposed to 55/65 °C for 1 or 2 days: Mean HbA1c was significantly lower than the control.

Authors' Conclusions

“The B-D A1c kit combines the accuracy, precision, and reproducibility of a clinical laboratory test with the convenience of in-home sample collection.”

Reviewer's Conclusions

The authors found a high correlation between the method used to analyze in-home samples and two standard methods of establishing A1c levels. However, the accuracy e.g. sensitivity and specificity was not reported. Moreover, the authors did not report differences in accuracy between samples collected by patients versus clinical staff. The authors were affiliated with either the manufacturer or another medical technology company (Beckton Dickinson).