TECHNICAL ARTICLE

# Stability of Reacted Chemstrip bG

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**Reacted Chemstrip bG glucose reagent strips have been reported to retain their color changes for up to 7 days. Thus, patients could theoretically measure their blood glucose and mail their reacted test strips to their physicians for reanalysis. To test the stability of reacted Chemstrip bG blood glucose measurements, 268 Chemstrip bG test strips were reacted with blood obtained from 67 insulin-dependent diabetic patients, stored in desiccator vials, and read daily for 5 consecutive days with an Accu-Chek II blood glucose meter. Although Chemstrip bG blood glucose values significantly correlated with initial reference Beckman glucose analyzer glucose determinations for all 5 days, a steady significant decay in blood glucose readings over time was observed, and clinically accurate strip readings declined from 94% to 68%. Because this decay appeared consistent, correction factors were calculated with regression analyses. The correction factor for day 5 Accu-Chek II readings reduced measurement error by 77%. When applied to a different validation sample, this correction factor decreased day 5 error by 73%. Hence, it seems that correction factors may be applied to delayed readings of Chemstrips obtained with Accu-Chek II that would correct for the observed reduction in blood glucose readings. From these results, we conclude that delayed readings of Chemstrip bG test strips with the Accu-Chek II are not sufficiently accurate for clinical decision making or research purposes unless mathematically corrected. *Diabetes Care* 11:288–91, 1988**

Past research suggests that reacted Chemstrip bG test strips (Boehringer Mannheim, Indianapolis, IN) can be reliably reread visually for as long as 7 days if stored in a desiccator vial (1,2). Based on these results, Chemstrip bG test strips were used to test the accuracy of self-estimations of blood glucose levels by patients with insulin-dependent diabetes mellitus (IDDM). Patients estimated their blood glucose level at various times before measuring their blood glucose with Chemstrips. Strips were mailed back to our laboratory for analysis. Although stored in desiccator vials as suggested by the manufacturer, laboratory readings of these reacted strips did not appear reliable over even a short period. It was therefore decided to test the stability of reacted Chemstrip bG glucose readings with an Accu-Chek II across a broad range of blood glucose values.

## MATERIALS AND METHODS

Venous blood samples were collected in EDTA tubes from 67 IDDM patients during routine clinic visits (sample 1). Four Chemstrip bG glucose reagent strips were reacted with each blood sample within 2 h of collection and read immediately with an Accu-Chek II reflectance meter (Boehringer Mannheim) according to the manufacturer's instructions. Simultaneous reference plasma glucose values were determined in duplicate with a Beckman glucose analyzer (Fullerton, CA). Reacted strips were immediately stored at room temperature (21–24°C) in sealed Chemstrip bG vials (4 strips/vial) that contained a desiccant according to the manufacturer's recommendations. The vials were opened only for rereading of the reacted strips. Half of the strips were read daily for 5 days, and the remaining strips were read only

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**TABLE 1**
**Correlations for sample 1 Chemstrip bG versus reference plasma glucose determinations across days**

| | | Day | | | | |
|---|---|---|---|---|---|---|
| | *n* | 1 | 2 | 3 | 4 | 5 |
| Hypoglycemia | 44 | .83 | .74 | .58 | .77 | .78 |
| (<71 mg/dl) | | .79* | | | | .73 |
| Euglycemia | 50 | .90 | .81 | .81 | .81 | .76 |
| (71–199 mg/dl) | | .94* | | | | .87 |
| Hyperglycemia | 40 | .89 | .55 | .57 | .65 | .67 |
| (>199 mg/dl) | | .67* | | | | .50 |

All corrections were significant ($P < .01$).
*Samples were read on days 1 and 5.

initially and on day 5. The latter strips were stored in separate sealed vials and remained unexposed to light or air until day 5. A second sample of 60 reacted Chemstrips (sample 2) was tested in the exact same manner to validate the results observed with sample 1.

## RESULTS

There were no significant differences between blood glucose values obtained at day 5 with strips measured daily and with strips kept in sealed desiccator vials for 5 days for either sample 1 ($t = 0.31$, NS) or sample 2 ($t = 0.61$, NS). The remaining analyses were limited to data obtained from daily readings. Reference plasma glucose concentrations for sample 1 ranged from 31 to

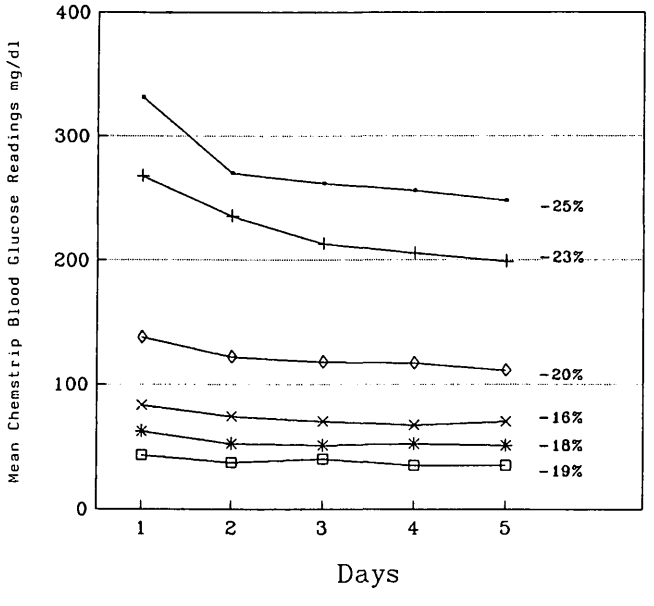


**FIG. 1. Decay of Chemstrip bG values are shown for 6 blood glucose ranges determined by day 1 Accu-Chek II readings: ≥300 mg/dl (●), 200–299 mg/dl (+), 100–199 mg/dl (◇), 71–99 mg/dl (x), 60–70 mg/dl (*), and <60 mg/dl (□).**

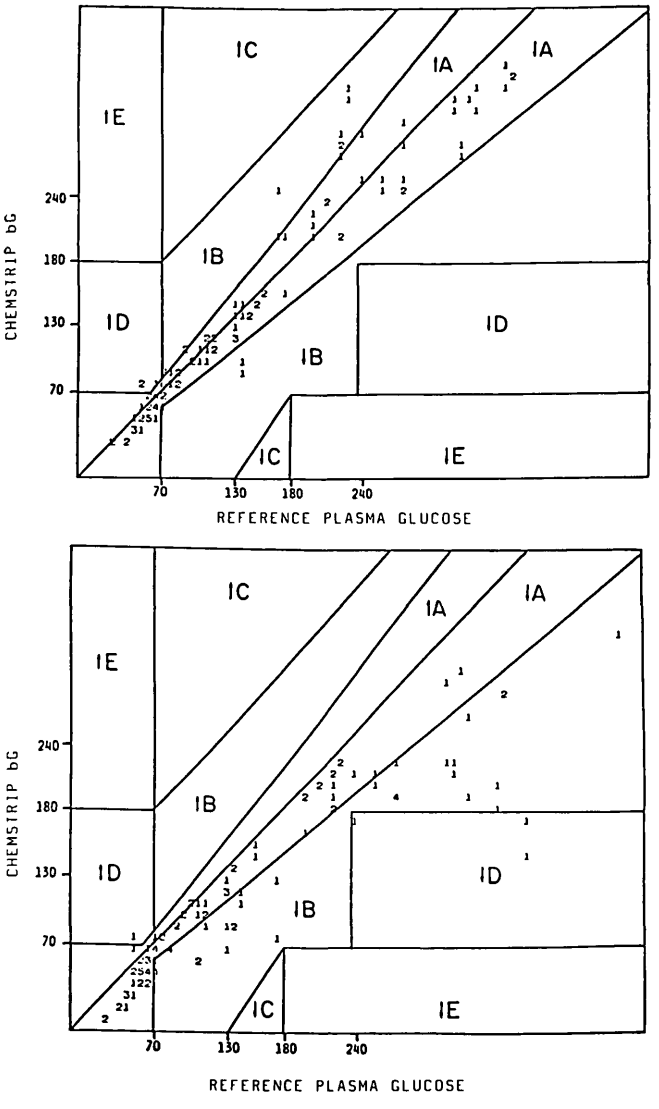


**FIG. 2. Error grid analyses of Chemstrip bG/Accu-Chek II readings relative to reference Beckman glucose analyzer readings for both day 1 (*top*) and day 5 (*bottom*) of sample 1.**

462 mg/dl. The mean coefficients of variation for reference plasma glucose values in the hypoglycemic (≤70 mg/dl), euglycemic (71–199 mg/dl), or hyperglycemic (>200 mg/dl) ranges were 1.3, 2.2, and 1.3%, respectively. The correlations between reference plasma glucose and Chemstrip bG values across days for sample 1 are shown in Table 1; all of these correlations were statistically significant. Table 1 illustrates that Chemstrip bG values in the hypoglycemic and the euglycemic ranges correlated relatively consistently with the reference values over time, whereas hyperglycemic plasma glucose values tended to deteriorate more over time (Figs. 1 and 2).

Figure 1 shows the decline in sample 1 Chemstrip bG readings relative to reference plasma glucose values. These readings reflect reference values in two hypo-

**TABLE 2**
**Daily correction factors, raw and adjusted mean errors, and standard deviations for samples 1 and 2**

| Day | Correction factors | Sample 1 | | Sample 2 | |
|---|---|---|---|---|---|
| | | Raw mean error | Adjusted mean error | Raw mean error | Adjusted mean error |
| 1 | .946 × STP + 8.09 | −.100 (24.019) | .001 (23.325) | −32.24 (29.929) | −32.24 (34.274) |
| 2 | 1.03 × STP + 18 | −21.246 (45.099) | .001 (45.042) | −38.93 (37.18) | −16.64 (34.89) |
| 4 | 1.17 × STP | −30.733 (43.472) | −10.947 (41.272) | −42.68 (43.06) | −20.13 (32.33) |
| 5 | 1.23 × STP | −34.15 (43.784) | −7.894 (39.847) | −41.15 (37.68) | −10.50 (26.11) |

Values are mean errors with SD in parentheses. STP, strip value. Error = (strip/adjusted strip) − standard.

glycemic ranges (<60 and 60–70 mg/dl), two euglycemic ranges (71–99 and 100–199 mg/dl), and two hyperglycemic ranges (200–299 and ≥300 mg/dl). Figure 1 illustrates that Chemstrip bG readings deteriorated over time, regardless of the initial reference plasma glucose value. Hyperglycemic values showed the greatest decay over 5 days [>300 mg/dl, $t(30) = 5.00$, $P < .01$; 200–299 mg/dl, $t(34) = 6.22$, $P < .001$]. There was a 20% decrease for glucose values between 100–199 mg/dl [$t(51) = 3.728$, $P < .05$], whereas there was an average decrease of 16% for glucose values between 71–99 mg/dl [$t(28) = 2.552$, $P < .05$]. Chemstrips at both hypoglycemic ranges also significantly dropped [60–70 mg/dl, $t(38) = 3.41$, $P < .01$; <60 mg/dl, $t(38) = 2.68$, $P < .02$].

To evaluate the clinical significance of Chemstrip bG readings, data from days 1 and 5 were evaluated by use of error grid analysis (EGA; Fig. 2). We have previously used EGA to analyze the clinical accuracy of patient-generated reflectance-meter measurements and patients' estimations of blood glucose levels (4–6). With EGA, Chemstrip bG readings fall into one of the following categories: *1*) accurate or within 20% of reference (A zones), *2*) benign errors that would not lead to inappropriate treatment decisions (B zones), *3*) potentially clinically dangerous errors that may lead to therapeutic overcorrection of euglycemic values (C zones), *4*) failure to detect hypo- or hyperglycemia errors (D zones), or *5*) erroneous treatment errors where hypo- or hyperglycemia are determined in the opposite range of the reference value (E zones).

On day 1 for sample 1, Chemstrip bG readings were clinically accurate (A zones) 94.3% of the time, resulted in clinically benign errors (B zones) 4.1% of the time, and resulted in clinically dangerous errors (D zones) 1.6% of the time. In contrast, on day 5, only 68.1% of the readings were clinically accurate (A zones), whereas 28.4% were clinically benign errors (B zones), and 3.5% were clinically dangerous errors (D zones).

Because there was a consistent deterioration in Chemstrip bG readings across all glucose ranges, post hoc correction factors were derived from sample 1 by use of simple β-weights from regression analyses. When applied to sample 1, the reduction in mean measurement error relative to uncorrected Chemstrip bG readings was 73% (Table 2).

Similar to sample 1, sample 2 data deteriorated an average of 18% over 5 days ($P < .01$). Day 1 Chemstrip bG readings included 98% zone A and 2% zone B values, compared to 68% zone A and 32% zone B values at day 5. When correction factors from sample 1 analysis were applied to sample 2, a 73% decrease in mean difference between initial and day 5 Chemstrip bG readings was observed (Table 2).

## DISCUSSION

These results demonstrate that Chemstrip bG test strips, when read immediately with an Accu-Chek II reflectance meter, yield highly accurate blood glucose readings. However, when properly stored in desiccator vials for as short as 1 day, these readings deteriorate substantially. These results are in contrast to those reported by Kubilis et al. (1) who only performed visual readings and reported results as average error.

The results of this study also disagree with a more recent report of the stability of Chemstrip bG read with Accu-Chek I (2). Freeman (2), using an identical method as that reported by Kubilis et al. (1), found that reacted strips with blood glucose values up to 320 mg/dl were stable for 7 days when properly stored. However, they tested only 30 reacted strips, and 20 of these were in the euglycemic range. In addition, the data were analyzed in terms of average error and were not examined separately across hypoglycemic, euglycemic, and hyperglycemic levels.

Our study also demonstrates, as reported previously (4–6), that statistically significant correlational analyses do not necessarily reflect clinical accuracy of blood glucose measurements. For example, correlations between Chemstrip bG and reference values in the hyperglycemic ranges were statistically significant, yet readings decreased an average of 24%, and accurate readings (A zones) decreased from 94 to 68%.

The consistent decay found in both samples 1 and 2 allowed the correction factors to be developed with sample 1 data. This reduced measurement error in sample 2. This indicates that the rate of Chemstrip bG decay over time is predictable and that simple correction factors can be applied to delayed Chemstrip bG readings to produce accurate results.

In conclusion, these results indicate that reacted Chemstrips cannot be accurately reread with Accu-Chek II after only 1 day of storage. The pattern of deterioration observed could lead to clinically significant treatment errors. Based on these results, delayed reading of Chemstrips with Accu-Chek II cannot be recommended for either clinical decision making or research purposes without appropriate correction.

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