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Assessing an Epidemic With the in2it[™]

the National Diabetes Information Clearinghouse (NDIC) reported that 23.6 million people, or 7.8 percent of the U.S. population, have diabetes. Of this group, 17.9 million are diagnosed; 5.7 million remain undiagnosed.² The incidence of diabetes continues to rise. According to the NDIC, between 2003 and 2006, 25.9 percent of U.S. adults age 20 years or older had impaired fasting glucose; by age 60 or older the percentage rose to 35.4 percent.

In 2006, Robert Steinbrook, MD published, "Facing the Diabetes Epidemic" in the *New England Journal of Medicine*. A very telling graph within that article reveals the dramatic rise in prevalence of diabetes: from six percent in 1980 to 15 percent in 2004.¹

Hemoglobin A1C is an indicator of longterm glycemic levels. Formed by glycation of the N-terminal valine of the β-chain of hemoglobin in the red blood cell, A1C is proportionate to the average glucose level over the preceding two to three months. Its measurement is therefore a window to an important overall diabetic perspective: average glycemic control. **Bio-Rad Laboratories** proudly offers the **in2it**[™] as a point-of-care diagnostic tool for this important measurement.

Point-of-care means an immediate ability to make objective decisions—based on solid data. Correlation between the A1C and patient-reported blood glucose levels gives additional insight into disease management choices; for example, whether a patient's



Bio-Rad Laboratories proudly offers the in2itTM as a point-of-care diagnostic tool for the measurement of hemoglobin A1C.

home blood glucose testing results sufficiently reflect the proper management of his/her diabetic condition.

The in2it is CLIA waived, fully automated, and easy to use. The CPT code for A1C testing at the point-of-care is 83037QW. The in2it uses a simple, three-step process employing a cartridge and sample collection key. The compact size of the in2it frees up valuable lab space, and its portability allows use at multiple sites—or even in the field. The instrument can process 20 samples using four rechargeable lithium batteries.

The in2it correlates closely to established HPLC laboratory methods. In four separate studies using four different HPLC instruments, the average correlation was 0.97. This level of correlation ensures that the results generated in your office will closely match laboratory results.

In a 2008 publication, Naomi Brewer, *et al.*, reported on the correlation between A1C

and mortality risk in a very large New Zealand population. Among nearly 48,000 participants, even those without a formal diagnosis of diabetes showed a direct correlation between the level of A1C and the risk of mortality. At \geq 7 percent, the risk ratio was 2.36.

The "Standards of Medical Care in Diabetes—2006" by the American Diabetes Association states specific recommendations for A1C testing.⁴ They are as follows:

- 1. Perform the A1C test at least two times a year in patients who are meeting treatment goals (and who have stable glycemic control);
- 2. Perform the A1C test quarterly in patients whose therapy has changed or who are not meeting glycemic goals;
- 3. Use of point-of-care testing for A1C allows for timely decisions on therapy changes, when needed.

The recommendations also state:

"By performing an A1C test, health providers can measure a patient's average glycemia over the preceding 2–3 months and, thus, assess treatment efficacy. A1C testing should be performed routinely in all patients with diabetes, first to document the degree of glycemic control at initial assessment and then as part of continuing care. Since the A1C test reflects mean glycemia over the preceding 2-3 months, measurement approximately every 3 months is required to determine whether a patient's metabolic control has been reached and maintained within the target range. Thus, regular performance of the A1C test permits detection of departures from the target in a timely fashion. For any individual patient, the frequency of A1C testing should be dependent on the clinical situation, the treatment regimen used, and the judgment of the clinician."

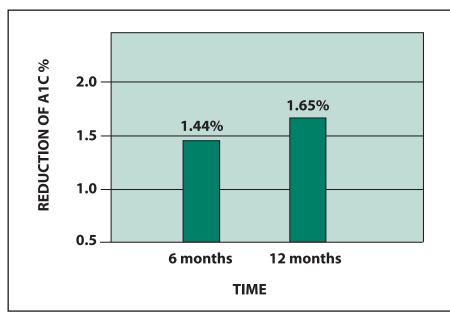
The time to make decisions efficiently is when the patient is in front of you. Rather than timeconsuming call-backs or delays for another visit, point-of-care testing of hemoglobin A1C offers the opportunity to have the patient leave the office with a definitive plan. Cagliero et al. showed that when A1C results were discussed with patients in real-time, A1C levels were reduced up to 1.44 percent HbA1C after six months and up to 1.65 percent HbA1C after 12 months in the immediate study group compared to the control group.5 Bio-Rad Laboratories is pleased to help you in your quest for excellent diabetic management.

To Learn More

For further information, call 1-800-224-6723. To request an on-site demo or to view a video of the **in2it**, please visit our product Web site www.in2itdemo.com.

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Studies show that discussing A1C results with patients at the point of care significantly improves glycemic control.⁵

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