

Glycohemoglobin Reagent Set

Intended Use

For the quantitative determination of Glycohemoglobin (HbA1) in blood by cation exchange resin. The test is to be used to monitor long-term glucose control in diabetes mellitus.

Summary and Explanation of Test

Throughout the circulatory life of the red cell, glycohemoglobin is formed continuously by the adduction of glucose to the N-terminal of the hemoglobin beta chain. This process, which is non-enzymatic, reflects the average exposure of hemoglobin to glucose over an extended period. In a classical study, Trivelli et al¹ showed glycohemoglobin in diabetic subjects to be elevated 2-3 fold over the levels found in normal individuals. Several investigators have recommended that glycohemoglobin serve as an indicator of metabolic control of the diabetic, since glycohemoglobin levels approach normal values for diabetics in metabolic control.^{2,3,4} Glycohemoglobin has been defined operationally as the "fast fraction" hemoglobins (HbA1a, A1b, A1c) that elute first during column chromatography with cation-exchange resins. The non-glycosylated hemoglobin, which consists of the bulk of the hemoglobin has been designated HbA0. The present glycohemoglobin procedure employs a weak binding cationexchange resin for the rapid separation of glycohemoglobin (fast fraction) from non-glycosylated hemoglobin. Over 80% of the labile fraction of glycohemoglobin is removed during the separation step in this procedure due to the inclusion of the borate buffer system.⁵

References

1. Trivelli, L.A., Ranney, H.M., and Lai, H.T., *New Eng. J. Med.* 284,353 (1971).
2. Gonen, B., and Rubenstein, A.H., *Diabetologia* 15, 1 (1978).
3. Gabbay, K.H., Hasty, K., Breslow, J.L., Ellison, R.C., Bunn, H.F., and Gallop, P.M., *J. Clin. Endocrinol. Metab.* 44, 859 (1977).
4. Bates, H.M., *Lab. Mang.*, Vol 16 (Jan. 1978).
5. PSI Records (8/84).

Monitoring blood glucose control in diabetes mellitus: a systematic review

Laboratory and near-patient testing

Results from the Diabetes Control and Complications Trial (DCCT) in type 1 DM and the UK Prospective Diabetes Study in type 2 DM have demonstrated the clinical effectiveness of using GHb estimations to monitor blood glucose control. Data from the DCCT suggest that the overall package of intervention employed would have acceptable cost-effectiveness. No unconfounded studies have addressed the optimal testing frequency for GHb, but current guidelines suggest from four tests per year in subjects with type 1 DM to two tests per year in subjects with stable type 2 DM. Standardisation of GHb assays between and within laboratories is an important objective being addressed by current work. Near-patient testing for GHb is being developed, but it is too early to judge its value.

Fructosamine estimations, which measure glycaemic control over shorter intervals than GHb, may be useful in diabetic pregnancy, but have not been shown to be better than GHb at this time. Fructosamine assays are less costly than GHb.