Evaluation of a new enzymatic HbA1c test for the diagnosis of diabetes

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BACKGROUND
Glycated Hemoglobin A1c (HbA1c) is a well-established parameter for long-term monitoring and diagnosis of diabetes. Here, we present a novel enzymatic HbA1c test (HbA1c net FS) for the highly specific detection of HbA1c, that eliminates interferences of common hemoglobin (Hb) variants of existing test systems. HbA1c net shows excellent precision resulting from the innovative application type (twin-test), linking 2 calibrations and 2 detections for Hb and HbA1c in only one determination. The test principle is based on Hb determination after sample hemolysis at 570 nm and subsequent H2O2 release after oxidative cleavage of fructosylated HbA1c-dipeptides in the same cuvette. H2O2 concentration is determined colorimetrically at 660 nm, where the delta absorbance is proportional to the HbA1c concentration.

METHODS
Assay adaption and performance verification have been carried out on a BioMajesty®JCA-BM 6010/C (BM) fully automated clinical chemistry analyzer system. All reagents, calibrators and controls were obtained from DiaSys Diagnostic Systems GmbH. Method comparisons were performed on BM and HPLC (ADAMS A1c HA 8160, Arkray) as reference system. Data have been evaluated by using regression analysis according to Passing/Bablok. Intra-assay imprecision was performed according to CCLI (EP5-A2). Determination of hemoglobin subtypes was carried out by recovery measurements of IFCC Hb-subtype evaluation samples.

RESULTS
A method comparison of HbA1c net FS against HPLC (figure 1) with 90 native samples demonstrated excellent correlation [r=0.9976; Passing/Bablok: y=0.980x – 0.645 mmol/mol HbA1c IFCC]. HbA1c net FS is highly precise with an intra-assay precision of CV<0.9% (for HbA1c values from 37 to 113 mmol/mol). (table 2). High accuracy of HbA1c net FS was demonstrated by recovery of IFCC controls (with varying Hb and HbA1c levels) within ± 3% of the target value (figure 2). Common Hb variants as e.g. HbAS, HbCC, HbEE, HbSC, HbSS, elevated HbF and β-Thalassemia showed no significant interference (table 1).

CONCLUSIONS
DiaSys HbA1c net FS assay reveals outstanding specificity and precision. This test correlates very well to HPLC (NGSP/DCCT) and IFCC reference material. The application of HbA1c net on the fully automated system BioMajesty®JCA-BM 6010/C allows on-board hemolysis of samples with optimized workflow and eliminates additional error-prone and time-consuming manual sample preparation steps.

REFERENCES