

Verification on site of a HPLC robot for the assay of glycosylated hemoglobin.

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Introduction

The glycosylated hemoglobin is a blood parameter which is used to follow the efficiency of type II diabetes treatments. Glycosylated hemoglobin is a normal fraction of hemoglobin in blood which increases in case of diabetes. Glycosylated hemoglobin is formed by non-enzymatical fixation of glucose on the β chain of globin. Normal rate of glycosylated hemoglobin is between 4 and 6 %, a more important fraction indicates the disease and a bad efficiency of treatment. The biological laboratory Trévoux Néolab performs the assay of glycosylated hemoglobin by cations exchange HPLC on a nonporous column with separation of different fractions of hemoglobin thanks to a gradient of increasing ionic strength on the G7 robot (Tosoh). The laboratory Néolab has decided to accreditate itself ISO EN 15189. They asked me to run checks on the machine used to carry out the assay of glycosylated hemoglobin in whole blood. The results have to correspond to the COFRAC recommendations, the official provider CV and also the Ricos variation coefficients (CV).

Experimental condition

The verification on site of the HPLC assay of hemoglobin in blood with this machine was based on a Technical Accreditation Guide delivered by the COFRAC in April 2011. To make sure that the robot HPLC-723-G7 (Tosoh) follows the recommended CV, we verified on selected patient blood samples the performance criteria defined by the COFRAC like repeatability tests, reproducibility tests, inter sample contamination tests... etc.

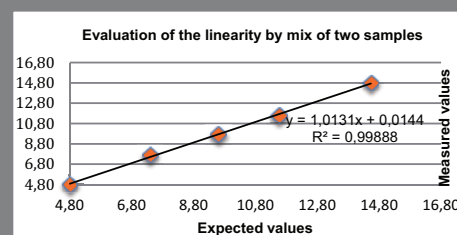
Results and discussion

The verification method on site of HPLC-723-G7 robot, which performed the glycosylated hemoglobin analysis in Trévoux Néolab Laboratory, yielded satisfactory results. The study of the different performance criteria referenced by the COFRAC, determined that this machine has often better performance than those recommended by Westgard. For the vast majority of parameters tested, the results obtained showed that CV were below optimal coefficients of variation defined by Ricos. It was however noted that this robot is more efficient for pathological level in assay of HbA_{1c}. The contamination study did not deliver satisfying results which in reality was not an issue as this test was not required for the certification.

Conclusion

The verification method on site of HPLC-723-G7 robot permitted to check that this robot respects the recommended Ricos CV and also the CV stated by the provider. This audit work was the first done at Néolab Laboratories and is going to be a pattern to the verification of the other robot used for patient analysis.

Example of tests done: Results of linearity test.



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