Evaluation of the qLabs® FIB system, a novel rapid and easy-to-use point-of-care system to quantify functional fibrinogen level using a single drop of citrated whole blood sample.

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INTRODUCTION

The qLabs® FIB system includes an electrometer (Fig. 1A) and a test strip (B) for a functional fibrinogen measurement from 1.0 to 4.0 g/L range in less than 10 minutes. After citrated blood drop deposition on the strip, the meter measures blood flow rate along microfluidic thrombin-coated channels and displays fibrinogen plasma concentration adjusted by sample hematocrit calculated simultaneously.

AIM

Analytical performances of the qLabs® FIB system were evaluated through a comparison study with the predicate STA® Liquid Fib assay on STA-R® Max (Stago), and a 3-sites precision study.

RESULTS

The one-site methods comparison study included 110 whole blood samples distributed over the qLabs FIB® measurement range [1 – 4 g/L]. 18% (20/110) were diluted whole blood samples (Fig. 2). For each sample, fibrinogen concentration was assessed using the qLabs® FIB and the STA® Liquid Fib assay on STA-R® Max (Stago).

A Bland & Altman and Passing Bablok distribution analyzes were applied to evaluate the substantial equivalence between qLabs FIB® and the predicate assay (EP09c directive) (Figures 3 and 4).

A 3-sites precision evaluation protocol was followed to assess the accuracy of qLabs® FIB using plasma quality controls (5 replicates/day, n=75 tests/level) (EP05-A3 directive). The precision types were expressed with both SD and CV, calculated with one (repeatability/within-lab precision) and two-way nested (reproducibility) ANOVA (Tables 1 and 2).

CONCLUSION

- The qLabs FIB® system provides a reliable and precise measurement of fibrinogen concentration from a single drop of citrated whole blood.
- Further clinical trials should confirm its ability to guide management of critical bleeding, especially in the evaluation of postpartum hemorrhage severity and eligibility for fibrinogen infusion.