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.

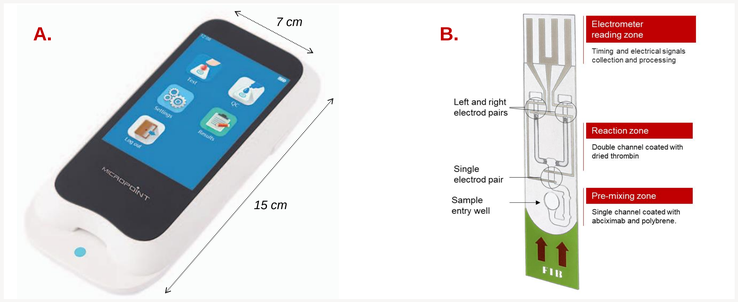
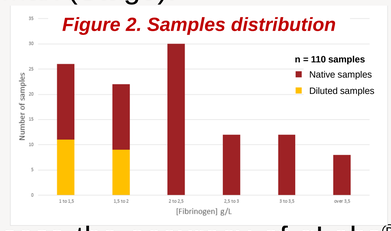


Figure 1. View of the qLabs® FIB system

MATERIAL & METHODS

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).

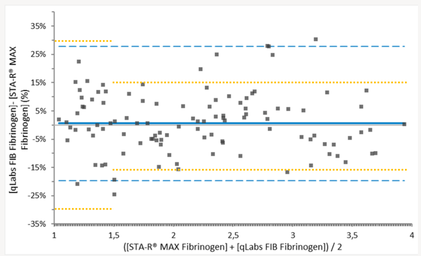
Figure 2. Samples distribution



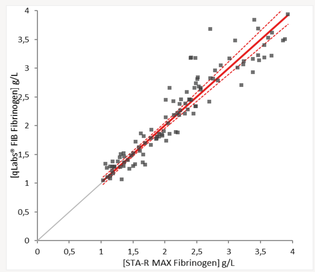
A Bland & Altman and Passing Bablok distribution analyzes were applied to evaluate the substantial equivalence between qLabs FIB® and the predicate assay (EP09c directive) (Figures 3 and 4).

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).

RESULTS



Median (0.63%)
95% LoA (-19.64% to 27.88%)
Acceptance criteria



Passing Bablok fit (y = 0.02 + 0.99 x)
95% CI

[Fib] (g/L)	< 1.5	[1,5 - 4.0]
Bias specifications	< 30 %	≤ 15 %
Comparison method study (n=110)	100% of samples within the specification	93% of samples within the specification

Figure 3. Bland and Altman analysis from the relative differences

Specifications	Passing Bablok regression fit		Correlation coefficient
	Slope (a) 1 ± 0.05	Intercept 0 ± 0.10	r ≥ 0.92
Comparison method study (n=110)	0.99	0.02	0.95

Figure 4. Passing Bablok regression – qLabs® FIB vs. STA® Liquid Fib on STA-R® Max

B&A and Passing Bablok results were compliant with specifications. Moreover, the Extreme Studentized Deviate test (ESD, Rosner 1983) did not statistically detect any outlier among the sample distribution (data not shown).

➔ The qLabs FIB assay was demonstrated as substantially equivalent to its predicate device, the STA® Liquid Fib assay on STA-R® Max (Stago).

RESULTS

Table 1. Within-site precision

	QC Control	Mean [Fib] (g/L)	Repeatability		Within Laboratory - Precision	
			SD	%CV	SD	%CV
Site # 1	Level 1	2.77	0.08	2.9%	0.08	2.9%
	Level 2	1.04	0.04	4.1%	0.04	4.1%
Site # 2	Level 1	2.67	0.08	2.9%	0.09	3.2%
	Level 2	0.99	0.03	2.7%	0.03	2.7%
Site # 3	Level 1	2.83	0.11	3.8%	0.11	3.8%
	Level 2	1.04	0.05	4.4%	0.05	4.6%

Table 2. Reproducibility

QC Control	Mean [Fib] (g/L)	Reproducibility (total 3 sites)	
		SD	%CV
Level 1	2.76	0.12	4.4%
Level 2	1.02	0.05	4.6%

➔ Repeatability/within-laboratory precision and reproducibility were satisfactory with CVs a ≤ 10% and ≤ 8% respectively, according to acceptance criteria.

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.

Stago