



Validation and Benchmarking of the new PoET Multiscreen Assay for Blood Donor Screening

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INTRODUCTION

Nucleic Acid Amplification Tests significantly improve the safety of blood donations by detecting viral infections earlier than serological tests.

Blood donation services face several key challenges and requirements:

- Rapid logistics to ensure timely release of blood products
- Testing with the highest possible sensitivity
- Cost efficiency, driving the adoption of laboratory automation.

Multiplex assays detecting multiple viral targets simultaneously are increasing cost efficiency and reduce turnaround time.

AIM

Since 2021, the CE-marked *PoET Instrument* (Figure 1) has been used to screen for transfusion-relevant viruses, including HCV, HBV, and HIV. To further improve throughput, new PCR assays and a software upgrade were introduced.



Figure 1. PoET Instrument

The latest additions to the PoET System are *PoET Multiscreen* (MSN) and *PoET Universal Positive Control* (UPC). *PoET Multiscreen* enables simultaneous real-time PCR detection of HCV, HBV, and HIV-1 and HIV-2, distinguishing viruses via fluorescent dyes.

Here we report on the general performance characteristics of *PoET Multiscreen* and the results of a benchmark comparison study with a comparator system¹.

METHOD

The PCR assay design covers three target amplicons for HIV-1, two amplicons each for HBV and HCV and one for HIV-2 and the Internal Control. This enhances safety, reliability and sensitivity at the same time.

PoET Multiscreen validation was performed in accordance with the Regulation (EU) 2017/746 (IVDR) and the Common Specifications (EU) 2022/1107² including a benchmark test with a comparator system to determine the “state-of-the-art”.

The sample set for the comparison of sensitivity and specificity included following sample types:

- reactive and non-reactive donor samples
- seroconversion panels from ZeptoMetrix and SeraCare
- specimens representing diverse viral genotypes respectively subtypes
- specimens with viral loads near the limit of detection

RESULTS

The 95% limit of detection (LoD) was 5.5 IU/ml (HCV), 1.5 IU/ml (HBV), 13.2 IU/ml (HIV-1) and 5.7 IU/ml (HIV-2) for *PoET Multiscreen* (tab. 1) The assays detect all relevant genotypes for HCV (genotypes: 1-8, 1b, 2a, 3a, 4a, 5a,,), HBV (A-H), HIV-1 (M (subtypes A-H, J, K), N and O + recombinant subtypes AB, AG, AE) and HIV-2 (A, B + recombinant AB).

	<i>PoET Multiscreen</i>	<i>comparator</i>
HCV	5.5 IU/mL	7.0 IU/mL
HBV	1.5 IU/mL	1.4 IU/mL
<HIV-1	13.2 IU/mL	25.7 IU/mL
HIV-2	5.7 IU/mL	4.0 IU/mL

Table 1. LoD95 of PoET Multiscreen and comparator

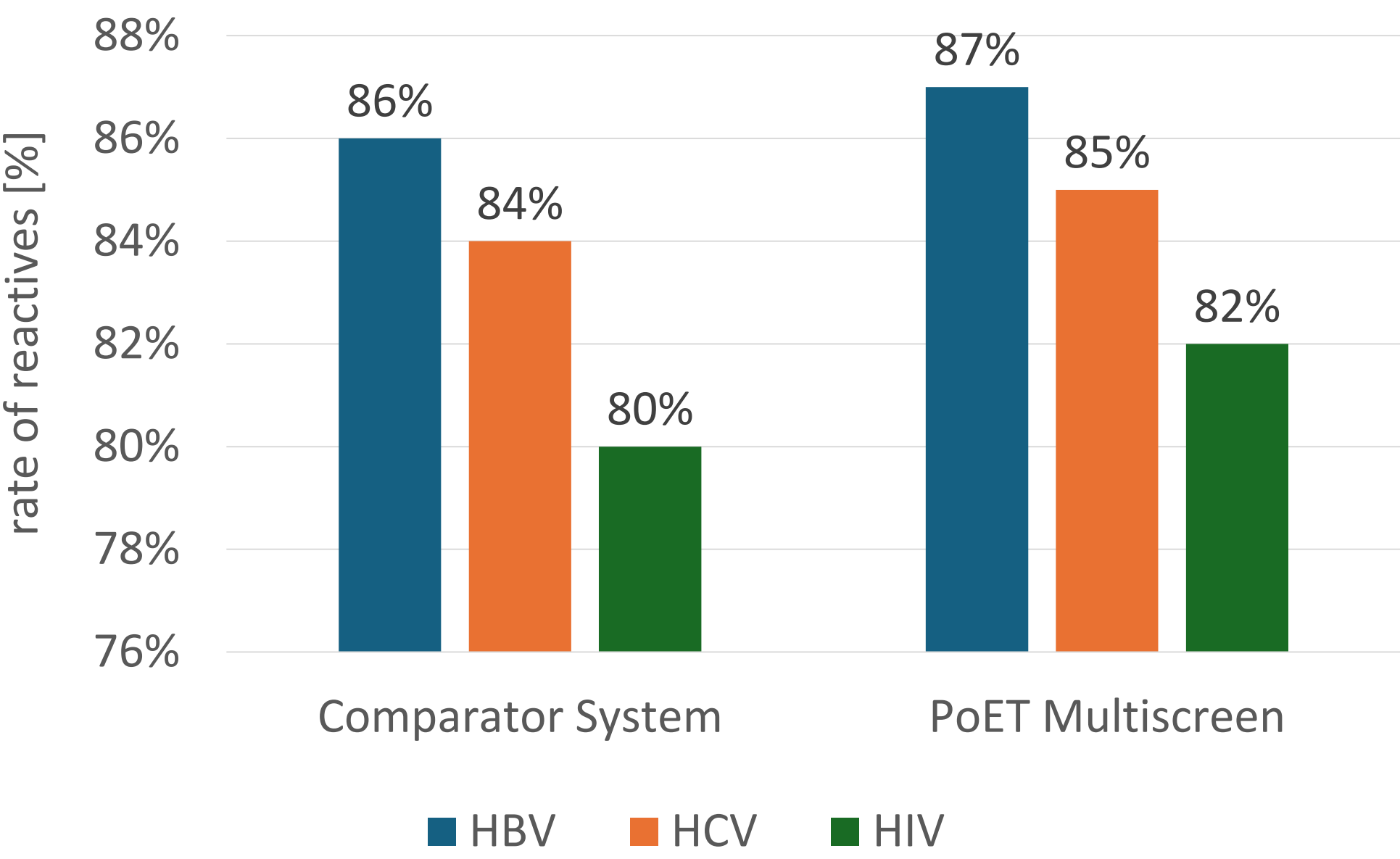


Figure 2. Success rates of PoET Multiscreen and the comparator

The benchmark testing was performed by directly comparing 267 samples tested with the *PoET System* and an established automated multiplex PCR system (comparator). The results showed a concordance rate of 96.7 % for HCV, 94.5 %, for HBV and 95.3 % for HIV-1 (tab. 2).

The reactivity rates indicate that both systems are overall comparable (Fig. 2).

		HBV		HCV		HIV		Total	
		PoET Multiscreen							
		positive	negative	positive	negative	positive	negative	positive	negative
Comparator	positive	83.5%	2.2%	82.4%	1.1%	78.8%	1.2%	81.6%	1.5%
	negative	3.3%	1.0%	2.2%	14.3%	3.5%	16.5%	3.0%	13.9%
concordance rate:		94.5%		96.7 %		95.3 %		95.5%	

Table 2. Concordance between PoET Multiscreen and the comparator.

The benchmark study used partly samples from seroconversion panels. In seroconversion samples in the early window phase of infection, slight differences in the success rate of both systems were observed, which may be due to viral loads close to the detection limit. Although the number of samples analyzed is limited, the results suggest that the PoET system has higher success rate.

The LoD comparison showed a close match to the comparator. This is supported by system comparison for the Hit Rate study and statistical concordance showed very similar performance.

CONCLUSIONS

In summary, *PoET Multiscreen* in combination with *PoET Instrument* resembles a state-of-the-art NAT assay.

The covering of the individual virus parameter by at least two PCR amplicons helps to ensure the safety of the test in regards to mutations³.

In addition, the assay design with multi virus detection contributes to the need of blood donation testing labs in regards to costs efficiency and turnaround time.

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