

Evaluating the sensitivity and specificity of Determine™ HIV-1/2 using a 0.01M phosphate-buffered saline (PBS) produced at the Medical Research Council Unit The Gambia for the diagnosis of HIV

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Introduction

RDTs are cheap, widely available, and easy to conduct. Nonetheless, packaging problems and buffer stock-outs have been reported(2,3,4). This leads to utilising non-approved liquid solutions, resulting in errors(5,6,7). HIV misdiagnosis can have significant consequences, including individual and social costs.

Material and methods

Paired Determine tests, one with commercial buffer and one with PBS, were performed on consecutive consenting individuals whose medical team requested a point-of-care test. Serum samples were sent for results confirmation through the local gold standard algorithm (Murex HIV Ag/Ab, Hexagon HIV +/- Geenius HIV 1/2). PBS was produced using commercial tablets. The buffer was sterilised, stored at room temperature, and kept in a safe space to avoid contamination. Then, the buffer was transferred into 5ml cleaned dropper bottles for clinical usage.

- **Inclusion criteria:** All adults and children above 18 months
- **Exclusion criteria:** Needle stick injuries

Results

173 individuals were screened for enrolment between 16/06/22 and 31/08/22. 167 (96.5%) agreed to participate. Of these, 127 PBS-Determine tests were negative and 40 positive. 137 individuals had a confirmatory test with the gold standard (Figure 1).

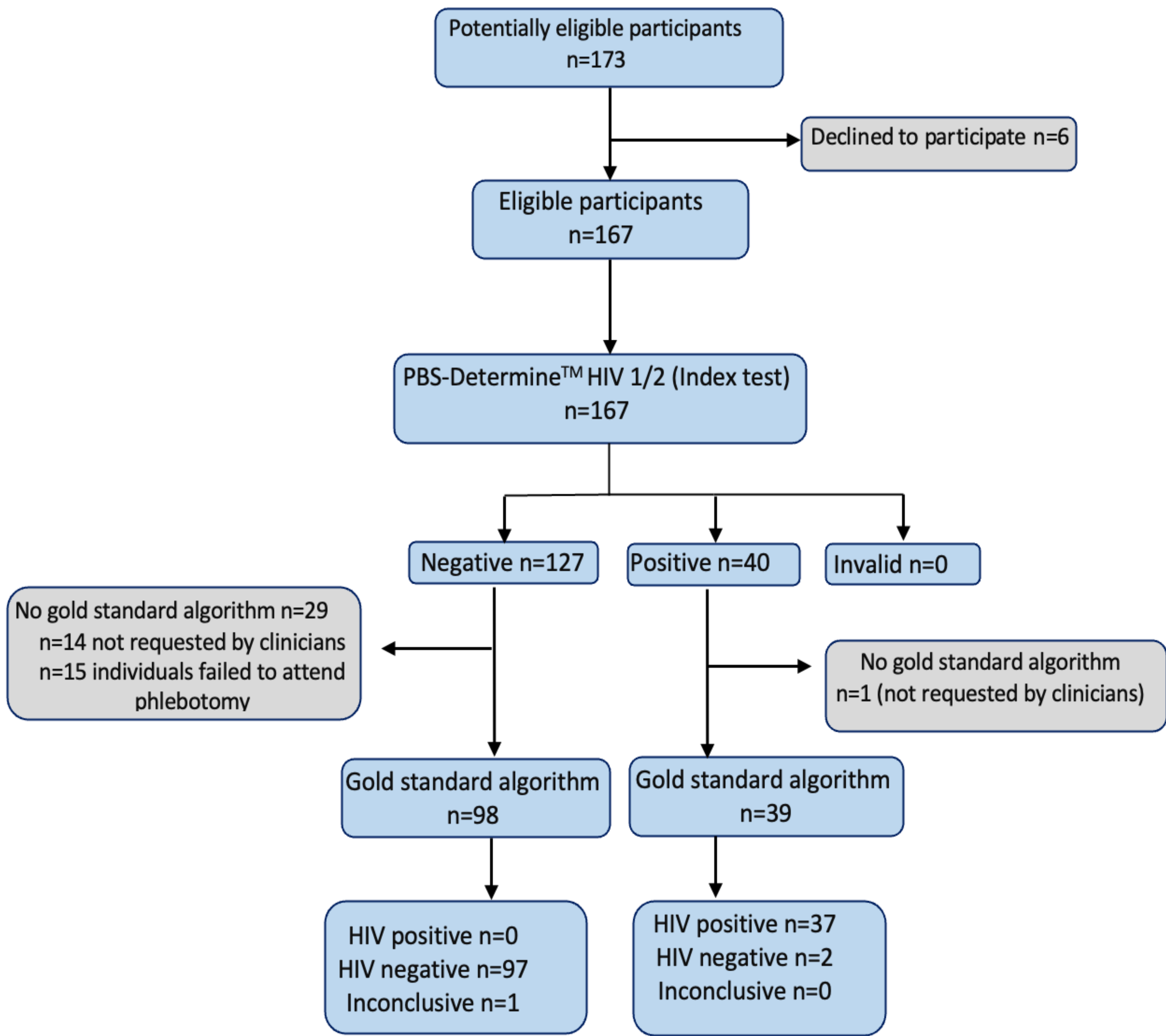


Figure 1. Study flow diagram

Results are presented in figure and table 1. The **sensitivity** of the Determine™ using PBS compared to the gold standard was **100%** (95% CI 90.5-100%), and the **specificity** was **98%** (95% CI 92.9-99.8%).

The **test agreement** between PBS-Determine and the gold standard algorithm or the commercial buffer was **high** (0.94 and 0.93). There was **insufficient evidence** against the null hypothesis to **conclude that the sensitivity and specificity** between Determine using PBS and manufacturer’s buffer (p=0.66) or the gold standard algorithm (p=0.22) **differ**.

The prevalence of HIV was 27.21% (37/136), considering only individuals with three positive results (RDT, Murex Ab/Ag and Hexagon) as confirmed diagnoses (WHO guidelines). The HIV-2 cohort prevalence was 0.74% (1/136).

Table 1. Performance of PBS-Determine compared to the gold standard algorithm

		Gold standard (Murex HIV Ag/Ab + Hexagon HIV)		Total
		Positive	Negative	
Determine™ HIV ½ (PBS)	Positive	37	2	39
	Negative	0	97	97
Total		37	99	136

Conclusions

Buffer stockouts and substitute liquid solutions are yet to be well studied. Ensuring all individuals requiring HIV rapid diagnostic tests can be tested and that correct buffer solutions are used when performing these is vital. The results of this study suggest that **0.01M phosphate buffer saline is an excellent alternative in the diagnosis of HIV using Determine™ HIV-1/2**. It is affordable, easy to produce and feasible in most settings.

Limitations

- Selection bias (missed demographic groups)
- Spectrum bias (health-seeking advise population)
- Verification bias (18% did not have confirmatory test)
- Misclassification bias (visual assay)
- Generalisability (specific brand, specific setting)

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