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## BACKGROUND

- HIV self-testing (HIVST) is a promising intervention for supporting community-based HIV service delivery; it has yet to be fully embraced by policymakers, in part, due to concerns about result misinterpretation and subsequent incorrect treatment decisions.
- Identifying tools that can support correct HIVST interpretation will likely be an important prerequisite to any large-scale incorporation of HIVST into national HIV service delivery programs.

**Objectives:** We sought to understand how well a cost-effective artificial intelligence (AI) algorithm could correctly interpret a common brand of blood-based HIVST kits.

## METHODS

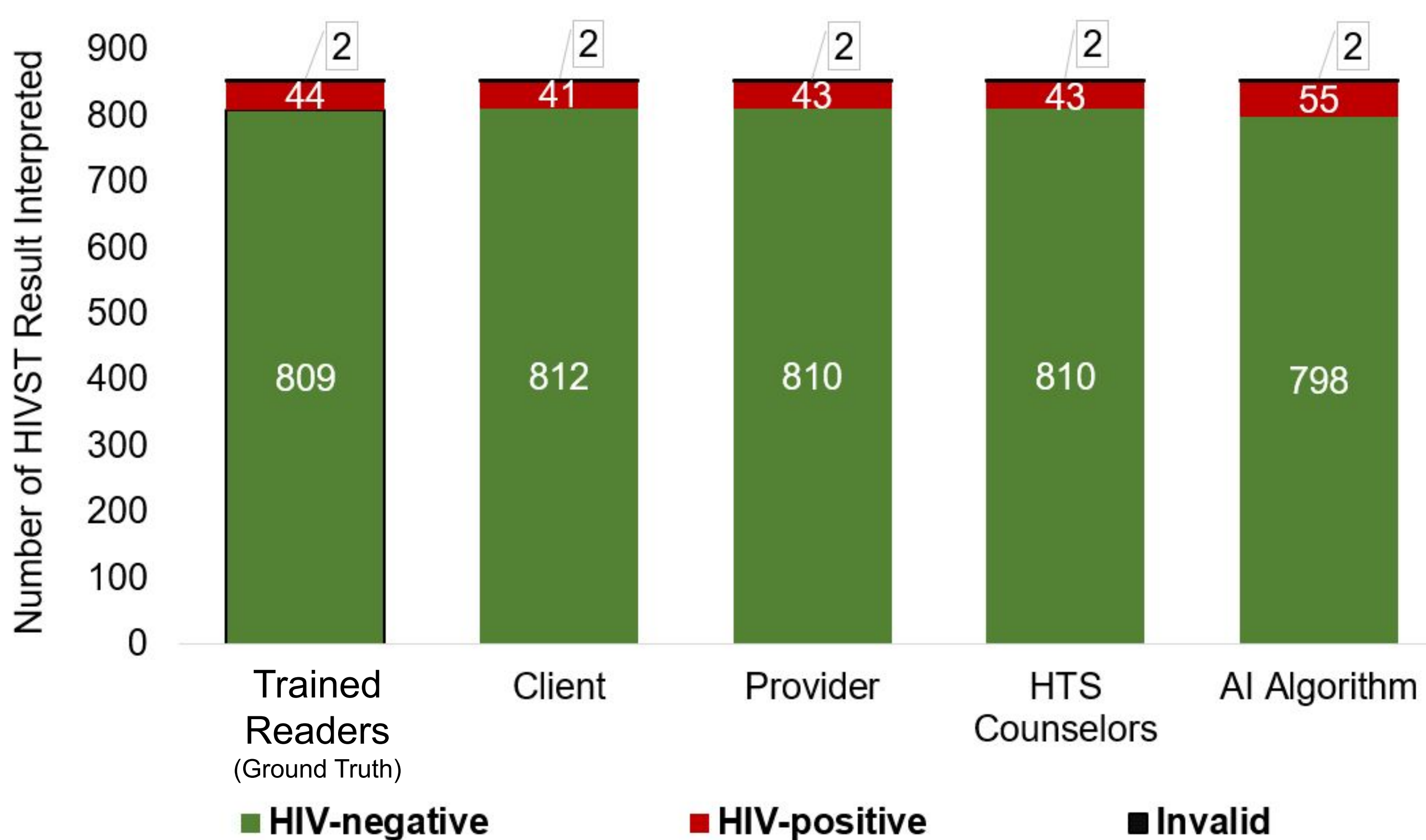
- At 20 private pharmacies in Kisumu, Kenya, we offered free blood-based HIVST to clients  $\geq 18$  years purchasing products indicative of sexual activity (e.g., condoms).
- Trained pharmacy providers assisted with testing, as needed. In real-time, each test was interpreted independently by (1) the client, (2) the pharmacy provider, and (3) a certified HIV testing service (HTS) counselor who then photographed the result.
- Each test image was subsequently interpreted by (4) an AI algorithm and (5) a panel of expert HIV rapid diagnostic test readers (n=3).
- Using the expert determination as the ground truth, we calculated the sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of each group's interpretation.

## RESULTS

- From March-June 2022, we screened 1691 pharmacy clients, enrolled 1500, and collected 855 test images, **Fig. 1**.
- Among clients with test images, 63% (540/855) were female, median age was 26 years (IQR 22-31), and 39% (335/855) reported casual sex partners.
- The AI algorithm correctly interpreted all positive tests as positive (100% sensitivity) and slightly outperformed HTS counselors and pharmacy providers (each 98% sensitivity; 95% CI 97%-99%) as well as pharmacy clients (93% sensitivity; 95% CI 91%-94%), **Table 1**.
- The AI algorithm correctly interpreted nearly all negative tests as negative (99% specificity; 95% CI 98%-99%), similar to the comparison groups, which all had 100% specificity.

An artificial intelligence algorithm interpreted images of HIV self-test results with high sensitivity and specificity, comparable to that of pharmacy clients, providers, and HTS counselors

**Fig 1. Interpretation of HIVST images by trained readers (ground truth), individuals at the pharmacy, and the AI algorithm**



**Table 1. Performance of HIVST result interpretation by AI, clients, providers, and HTS counselors, compared to trained readers**

	Pharmacy client interpretation	Pharmacy provider interpretation	HTS counselor interpretation	AI algorithm interpretation
<i>Performance analysis, n = 855 (Ref: Panel of trained HIVST readers)</i>				
<b>Sensitivity</b>	<b>93.2%</b>	<b>97.7%</b>	<b>97.7%</b>	<b>100.0%</b>
(95% CI)	(91.5%, 94.9%)	(96.7%, 98.7%)	(96.7%, 98.7%)	
<b>Specificity</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>98.6%</b>
(95% CI)				(97.9%, 99.4%)
<b>PPV</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>80.0%</b>
(95% CI)				(77.3%, 82.7%)
<b>NPV</b>	<b>99.6%</b>	<b>99.9%</b>	<b>99.9%</b>	<b>100.0%</b>
(95% CI)	(99.2%, 100.0%)	(99.6%, 100.0%)	(99.6%, 100.0%)	

## DISCUSSION

- The performance of the AI algorithm in interpreting HIVST results was comparable to that of pharmacy clients, pharmacy providers, and HTS counselors. The AI algorithm showed particularly good sensitivity and NPV, suggesting its potential value as a tool to support the delivery of prevention interventions, such as HIV PrEP.
- As differentiated models of HIV service delivery gain momentum, AI algorithms could potentially be used for quality control, timely validation of results, and disease surveillance. They could also provide reassurance to HIVST end-users and new providers who are being tasked with HIV service delivery, such as pharmacists, nurses, peer educators, and others.

**Funding:** Bill & Melinda Gates Foundation (INV-033052, INV-007492; INV-038498)

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