0966

False-Positive 4th Generation HIV Test Results in the Emergency Department

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BACKGROUND

- Universal opt-out HIV screening in low prevalence settings such as emergency departments (EDs) has increased identification of persons with HIV infection.
- False positive (FP) 4th generation HIV test results may impact the positive predictive value (PPV) and delay disclosure of HIV diagnosis and HIV treatment initiation.
- The objective of this analysis was to assess factors associated with false-positive test results.

METHODS

- Opt-out HIV screening was conducted in two EDs in San Diego (July 2017 - March 2019) and two EDs in Oakland (May 2017 - March 2019) using a 4th generation HIV Ag/Ab assay.
- Persons with a *positive* 4th generation HIV test result and a *negative* antibody differentiation confirmatory test and/or nucleic acid (NAT) test were defined as having a FP 4th generation test result.
- Demographics, clinical data, and HIV risk factors were extracted from electronic medical records and compared between persons with FP and true-positive (TP) test results using non-parametric statistical tests.

Table 1. Factors among individuals with FP 4th generation HIV test results compared to those with TP test results.

		FP N = 34	TP N = 104	*p* value
Age Median (SD)		42 (14)	38 (13)	0.10
Gender N (%)	Female	22 (64.7%)	20 (19.2%)	<0.001*
Race N (%)	White	21 (61.8%)	25 (24.0%)	<0.001*
	Black	2 (5.9%)	54 (51.9%)	<0.001*
	Asian	5 (14.7%)	3 (2.9%)	0.02*
	Other/Mixed	5 (14.7%)	21 (20.2%)	0.62
	Native American	0 (0%)	1 (0%)	1.0
	Unknown/Refused	1 (2.9%)	0 (0%)	-
Ethnicity N (%)	Hispanic/Latino	6 (17.6%)	18 (17.3%)	1.0
	Not Hispanic/Latino	28 (82.4%)	81 (77.9%)	-
	Unavailable/Declined	0 (0%)	5 (4.8%)	-
Pregnancy N (%)		3 (9.7%)	0 (0%)	0.047*
Obesity N (%)		8 (30.8%)	7 (6.9%)	0.003*
History of flu vaccination N (%)		19 (65.5%)	34 (38.2%)	0.02*
MSM N (%)		0 (0%)	44 (63.8%)	<0.001*
IDU N (%)		0 (0%)	12 (27.9%)	0.001*

*Statistically significant. MSM: men who have sex with men; IDU: injection drug use.

The ***false-positive rate*** of 4th generation HIV testing in the ED was **0.1%**. Persons who were ***female, White,*** and ***obese*** were more likely to have false-positive test results.

RESULTS

- 32,450 HIV tests were performed across four EDs using a 4th generation assay (Architect® and Roche Elecsys®) resulting in 104 TP cases and 34 FP cases and an overall FP rate of 0.1% (PPV: 75.4%).
  - When stratified by instrument, HIV testing with Architect gave a FP rate of 0.1% (PPV 80.4%) and testing with Roche Elecsys gave a FP rate of 0.2% (PPV 56.7%).
- In univariate analyses (**Table 1**), FP cases were significantly more likely than TP cases to be female (64.7% vs 19.2%, *p*<0.001), White (61.8% vs 24.0%, *p*<0.001), Asian (14.7% vs 2.9%, *p*=0.02), pregnant (9.7% vs 0%, *p*=0.047), obese (30.8% vs 6.9%, *p*=0.003) and flu-vaccinated (65.5% vs 38.2%, *p*=0.02).
  - FP cases were significantly less likely to be Black (5.9% vs 51.9%, *p*<0.001), MSM (0% vs 63.8%, *p*<0.001), and have IDU (0% vs 27.9%, *p*=0.001).
- After adjusting for covariates (**Table 2**), women were 4.3 times more likely (95%CI 1.3, 14.2; *p*=0.02) to have FP results than men, White persons were 6.1 times more likely (95%CI 1.5, 23.9; *p*=0.01) to have FP results than non-White persons, and obese persons were 6.7 times more likely (95%CI 1.4, 32.9; *p*=0.02) to have FP results than non-obese persons.

Figure 1. Predictors of FP 4th generation HIV test results.

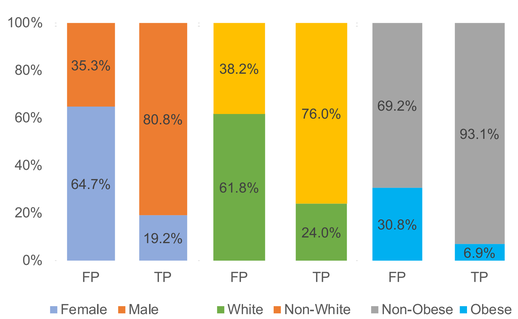


Table 2. Multivariable analysis of factors associated with FP 4th generation HIV test results.

Predictor	aOR (95% CI)	*p* value
Female Gender	4.3 (1.3, 14.2)	0.02*
White Race	6.1 (1.5, 23.9)	0.01*
Asian Race	7.6 (0.9, 66.5)	0.07
Obesity	6.7 (1.4, 32.9)	0.02*
History of flu vaccination	2.1 (0.5, 8.0)	0.30

*Statistically significant.

CONCLUSIONS

- The FP rate of the 4th generation HIV assay was 0.1%, resulting in a PPV of 75.4% during universal opt-out HIV screening in EDs at two medical centers in California.
- The Roche Elecsys had a higher FP rate and lower PPV than the Architect.
- In adjusted analyses, persons who were female, White, and obese were more likely to have FP test results.
- No persons with common behavioral risk factors for HIV acquisition had FP test results.
- Observations were consistent with the pre-test probability of having HIV given the low prevalence of HIV in the general population.
- FP 4th generation HIV test results may impact early disclosure of HIV diagnosis as well as initiation of antiretroviral treatment (ART), which is relevant in the context of universal HIV testing and rapid ART initiation.

ADDITIONAL KEY INFORMATION

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