

A photograph of the Golden Gate Bridge in San Francisco, California, taken from a high vantage point. The bridge's iconic orange-red towers and suspension cables are prominent against a soft, hazy sky at sunset or sunrise. The water of the bay is visible in the foreground and middle ground, with some distant hills and buildings in the background.

***Real-world performance
of the new US HIV
testing algorithm in
medical settings***

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HIV testing in medical settings

- Key access point for addressing HIV disparities
- Symptoms driven targeted testing
- Routine HIV testing as part of primary care or routine obstetrical care
- Documentation of HIV status upon entry to hospital care system

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- Symptoms driven targeted testing
- Routine HIV testing as part of primary care
- Routine HIV testing as public health screening
- **Documentation of HIV status upon entry to hospital care system**

ZSFG HIV Testing Program

- Zuckerberg San Francisco General (ZSFG)—formerly SFGH Clinical Laboratories
- 2,000 HIV tests per month
- 2-hourly rapid HIV testing, 7 days per week
- Until September 2015 (RT-IF): Unigold screening, immunofluorescence confirmation
- After September 1 2015 (AR-MS-VL): Architect screening with Multispot Ab confirmation-differentiation and viral load as needed

Case follow-up at ZSFG

- “Ward 86” HIV clinic at ZSFG
- PHAST-RAPID: a multidisciplinary team (NP, RN, CSW, PharmD) paged with every HIV+ test result at the ClinLab regardless of source clinic
 - **Track all new HIV results, ascertain prior HIV testing and care history, determine final HIV status and need for care**
 - Ensure linkage to care

Objectives

- Determine the real-world performance of the new algorithm (and algorithm components) in a medical setting
- Screening assay performance
- Detection of acute infections
- Ability of algorithm to resolve HIV status
- Turnaround time (preliminary & final)

Study Design

- Cross-sectional clinical laboratory performance evaluation using electronic medical record, laboratory administrative data and PHAST program logs
- Prior HIV testing status defined by detailed chart review on every HIV positive test result
- Final HIV infection status defined by algorithm results and all follow-up testing.

Study Design (2)

- Main analysis considered all consecutive HIV test records from January-November 2015 at ZSFG
- We compared ZSFG results under new algorithm (September-November 2015) with
 1. ZSFG results from Jan-Aug 2015
 2. consecutive CDC STOP study testers at SFDPH targeted MSM testing sites

HIV screening at ZSFG, Jan-Nov 2015

	No. Tests	No. HIV+	%
Total	21985	321	1.46%
Prev+	290	271	93.45%
Not prev+	21695	50	0.23%
Outpatient	3855	9	0.23%
OB	2526	3	0.12%
Jail	2444	7	0.29%
Inpatient	1774	7	0.39%
ED	1760	7	0.40%
Drop In	9028	17	0.19%

- 5 unresolved status infections; 0 acute cases

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Algorithm Performance: Turnaround Time

- The time to an initial positive result increased slightly from 114 minutes (Unigold RT) to 151 minutes (ARCHITECT)
- MS and Viral load results available in 1 and 5 days respectively
- The time to completion of the algorithm was substantially less (21 vs. 71 hours)
- Reduction in requirement for send out testing

Algorithm Performance: Resolution of Status

Algorithm	Samples	N	Confirmatory Ab			Unresolved
			+	-	ind	
RT-IF	15265	8	37	10	40	47.78%
AR-MS-VL	5430	2	11	16	0	22.22%

(-) tests

- Additional testing encounters confirmed 4/6 to be uninfected

HIV screening assay performance among HIV unknown status testers at ZSFG, 2015

Assay	Specs	Test+	HIV+	HIV-	unk	PPV	Sp
Unigold	15265	87	39	48	3	.45	99.7
ARCHI	5430	27	11	14	2	.44	99.7

- Specificity and PPV similar for Architect and Unigold screening assays
- No acute infections observed; sensitivity not evaluable

ZSFG vs. SF STOP sites

Characteristic	ZSFG		SF STOP
Algorithm	AR/MS/VL		AR/MS/VL
Prior HIV status	HIV+/-	HIV-	HIV-
Targeting	Medical	Medical	Risk based
N	21985	5430	29,335
HIV +	1.46%	0.23%	1.55%
Acute HIV+	0.00%	0.00%	0.22%
PPV (AR+)	0.77	0.44	0.93
PPV (AR+/MS-)	0.00	0.00	0.62
Sp (AR)	99.64	99.73	99.86

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PPV (AR+)	0.77	0.44	0.93
PPV (AR+/MS-)	0.00	0.00	0.62
Sp (AR)	99.64	99.73	99.86

Summary

- Implementation of the new HIV algorithm for high throughput 2 hourly testing was feasible in a large hospital based clinical laboratory.
- The number of infections that could be correctly classified without send out testing was improved
- Turnaround for negative and initial positive results was somewhat longer than under the rapid test based algorithm

Summary

- Using the 4th gen automated assay did not reduce the rate of false positive screening test results from using the manual rapid test
- *The positive predictive value of a **newly positive 4th gen result** was unexpectedly low (44%), reflecting low prevalence of undiagnosed HIV in medical settings and not lack of assay specificity.*

Discussion

- There are advantages for the lab, but
- Poor predictive value of positive 4th generation screening assay results in the new algorithm should be expected in medical settings
- HIV RNA viral load testing is still needed to diagnose acute HIV
- We will need rapid NAATs for rapid confirmation

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