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Background

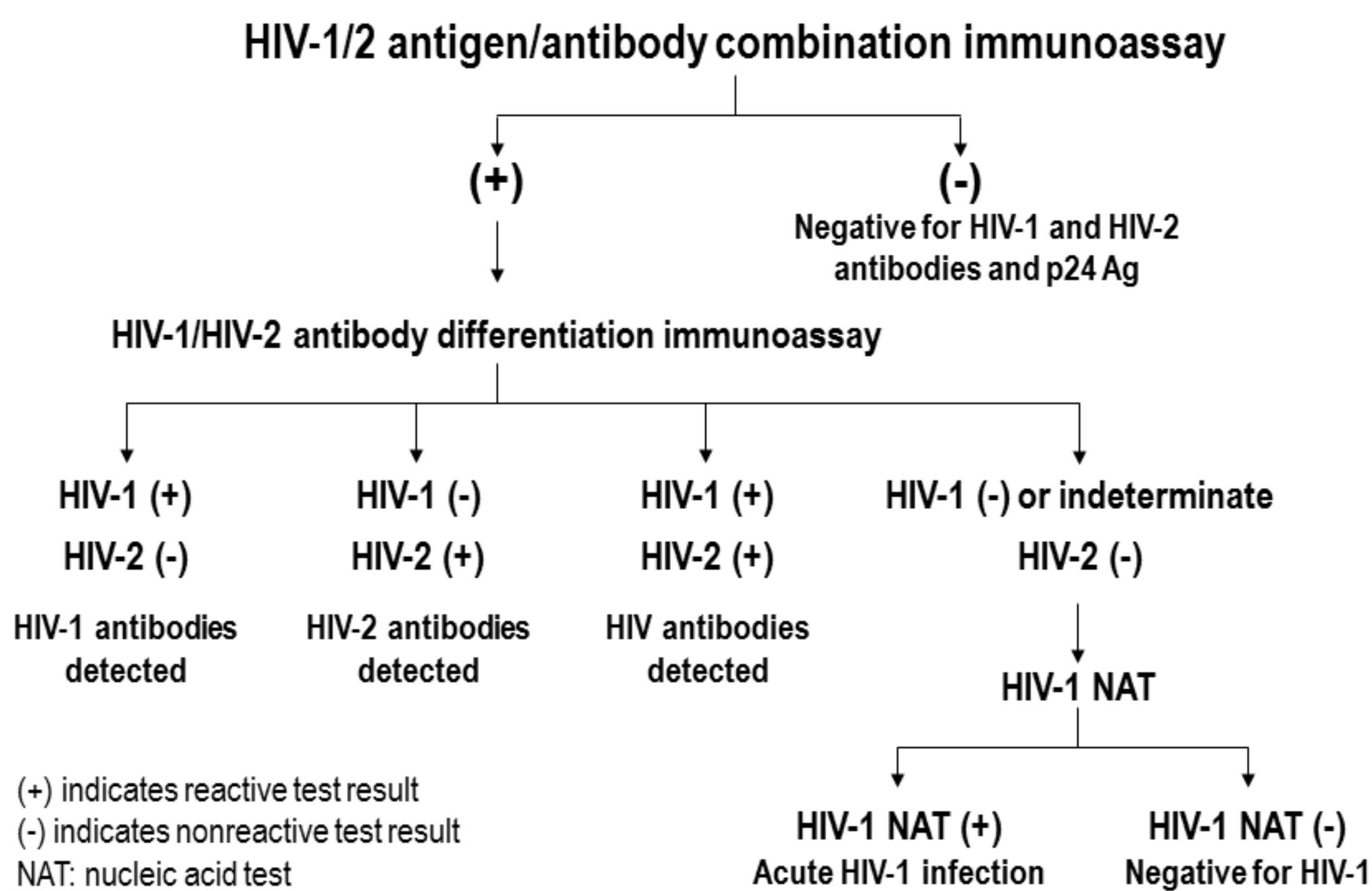
Harris Health System is the public safety net hospital system in the Houston area. Following the 2006 CDC recommendations, a routine HIV screening program has been running across Harris Health since 2008 in which patients 16 and older receiving blood draw for other reasons may be tested for HIV unless they opt out.¹

More than 502,000 HIV screening tests have been performed, including 6226 tests with a positive result (1.2% overall positivity rate), of which 1184 were new diagnoses (0.24% new positivity rate).

In October 2014, we implemented CDC's 4th generation HIV screening algorithm,² which is more sensitive at detecting acute HIV infection since the screening assay detects HIV antigen as well as antibody.

Objectives

To study the efficacy of 4th generation HIV screening algorithm (shown below) in detecting acute HIV infection and to evaluate the need for repeated HIV testing among HIV negative patients



Methods

This algorithm relies on a 4th generation screening test, with positive samples then tested with an HIV-1/HIV-2 antibody differentiation test (Multispot).

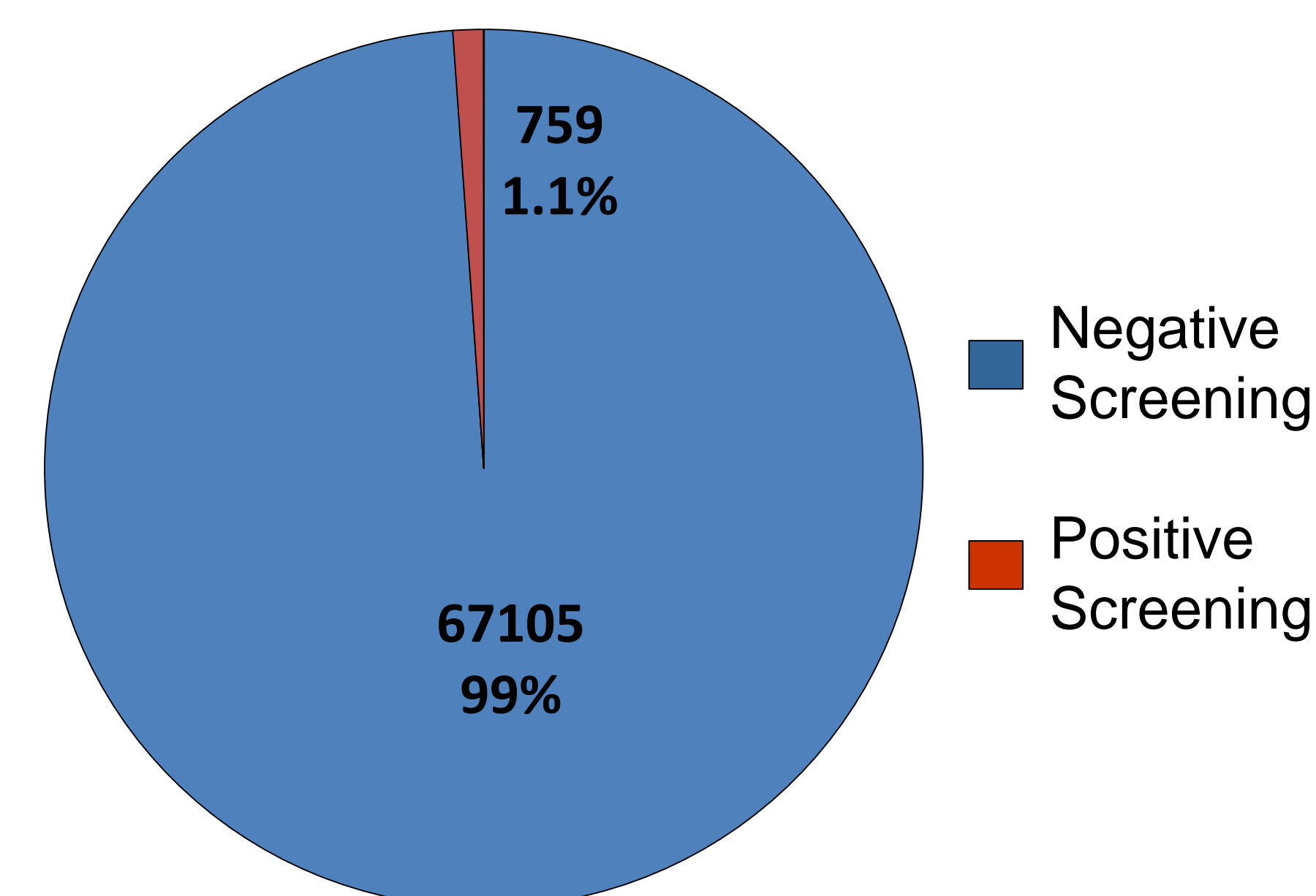
A positive screen followed by a negative Multispot is adjudicated with an HIV RNA viral load test (VL), which will distinguish between acute HIV infection and a false positive screening test.

We evaluated the number of acute HIV infections identified before and after implementation of the new algorithm.

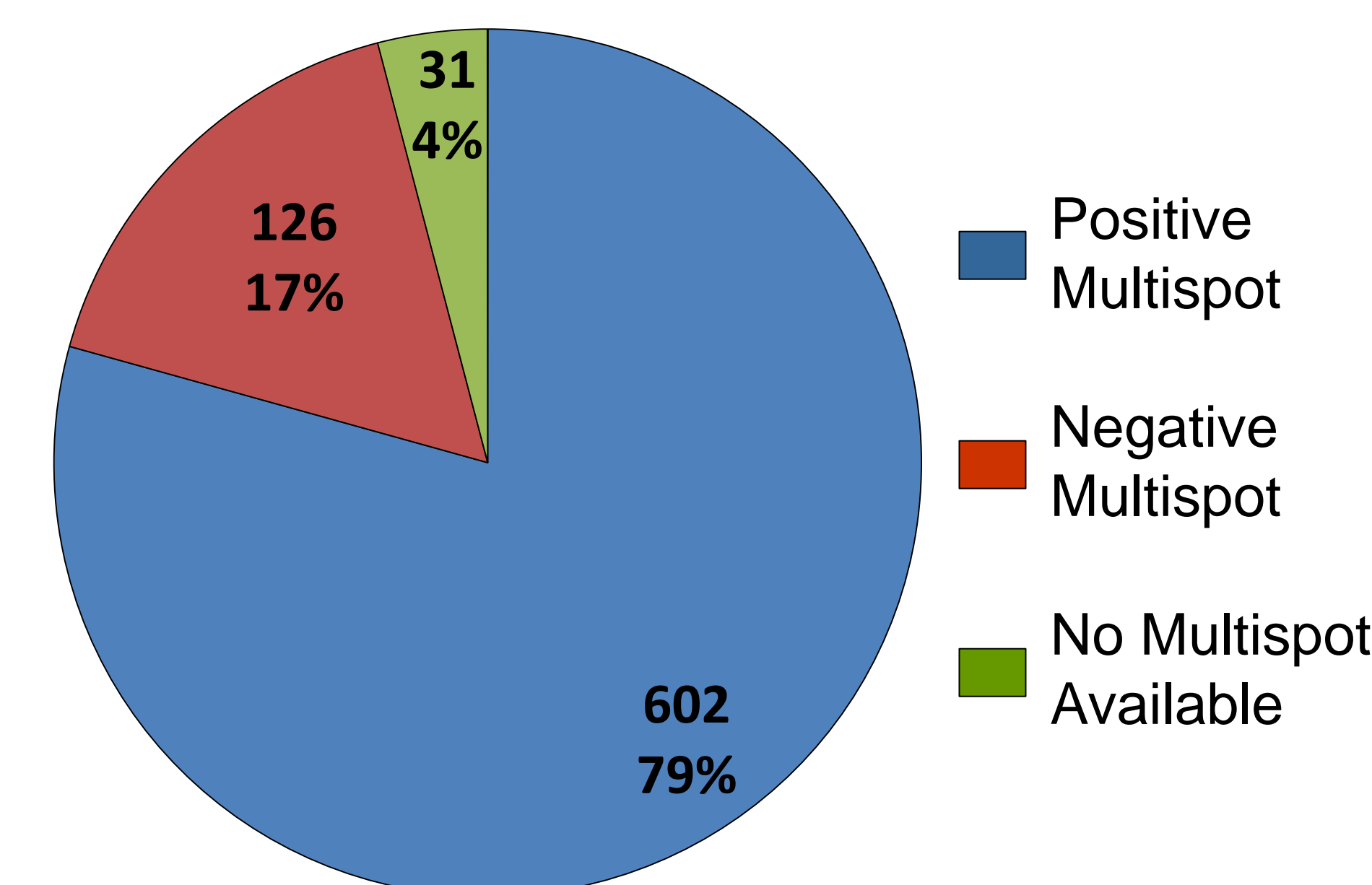
We also queried the electronic databases for newly diagnosed patients who had tested negative at least once prior to their diagnosis.

Results

4th Generation HIV Tests Performed (October 2014 – May 2015; N = 67,864)

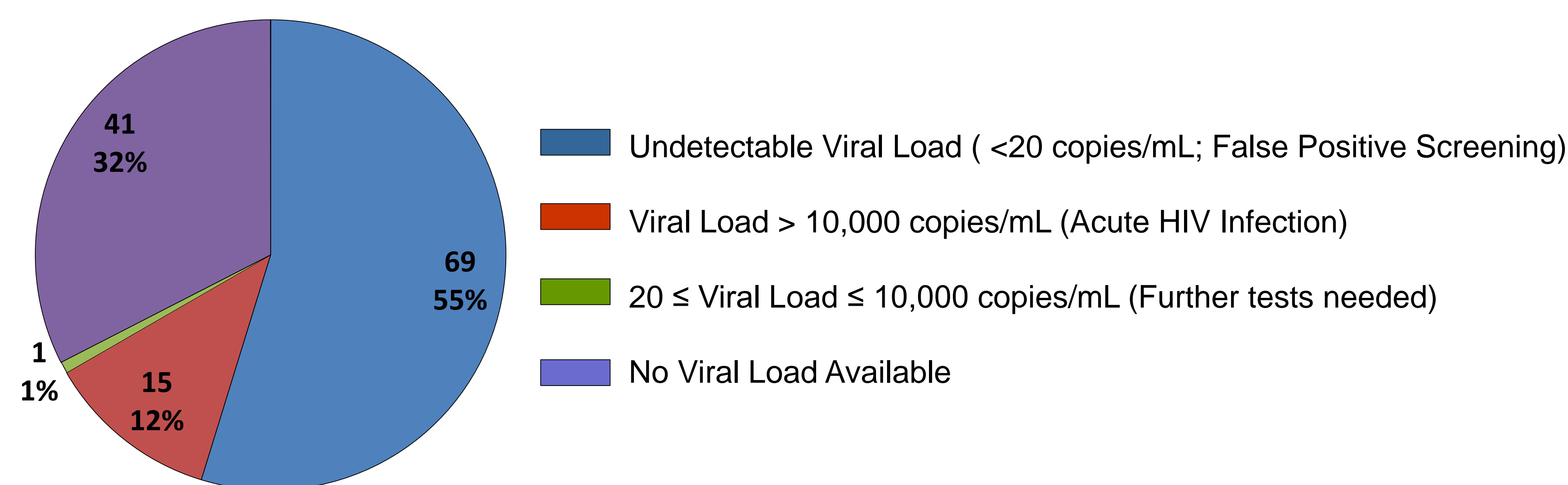


Tests With a Positive Initial Screening Result (N = 759)



- During the first seven months of the new algorithm 67,864 HIV screening tests were performed.
- 759 of the tests (1.1%) had a positive result.
- 126 of the positive screening tests (17%) were followed by a negative Multispot, indicating either a false positive screening or acute HIV infection.

Tests With a Discordant Multispot Result (Positive Screening, Negative Multispot; N = 126)



- We were able to perform Viral Load testing in 85 (67.4%) of the 126 patients with discordant results. 15 of these patients had a Viral Load >10,000 c/mL, indicating acute HIV infection (average 2.1 per month). These 15 patients had a median viral load of 1.5 million copies/mL and accounted for:
 - 18% of the patients with discordant screening and Multispot results who had a Viral Load test performed;
 - 12% of all discordant cases;
 - 2.0% of all patients with a positive screening test
 - 0.02% of all tests
- 69 of the 126 patients with a positive screen and negative Multispot had an undetectable Viral Load (<20), indicating a false positive screening result. These 69 patients accounted for:
 - 81% of the patients with discordant screening and Multispot results who had a Viral Load test performed;
 - 55% of all discordant cases;
 - 9% of all patients with a positive screening test
 - 0.1% of all tests
- One patient with a Viral Load between 20 and 10,000 is undergoing further tests.
- We were unable to obtain samples for Viral Load testing and thus could not confirm HIV status for 41 (33%) of the 126 patients with discordant results.

Results (Cont'd)

In the 6 years of routine screening prior to the new algorithm:

- 561,777 screening tests were performed
- 10,594 (1.9%) were initially positive
- 985 (9.3%) had a negative or indeterminate Western blot
- VL was available for 295 (29.9%) of the discordant cases of which 49 (16.7% of the discordant cases with a VL; average 0.7/month) were confirmed to be acute infection

Sero-Conversion:

- Among 1184 new diagnoses made since 2008 through conversion to the new algorithm, 132 (11.1%) had a negative HIV test in our system prior to diagnosis.
- The median time between the last negative test and diagnosis was 354 days.
- 8 of these patients were diagnosed during their acute infection phase (6 of which with the new algorithm).

Conclusions

Our program is identifying acute HIV infections with the 4th generation algorithm at 3-times the rate as it did with the previous algorithm.

Procedures need to be revised so that samples for viral load testing are readily available to discriminate false positive results from acute HIV infection.

The current CDC HIV testing algorithm should be implemented in areas with ongoing HIV transmission to more effectively detect acute HIV infection.

Consistent with modeling data,³ our data suggests that annual testing in high prevalence areas is likely beneficial.

References

- 1- Hoxhaj S. et al., "Using nonrapid HIV technology for routine, opt-out HIV screening in a high-volume urban emergency department." *Ann Emerg Med.* 2011.
- 2- Branson B. et al., "Laboratory Testing for the Diagnosis of HIV Infection: Updated Recommendations" *CDC*, 2014.
- 3- Lucas A. and Armbruster B., "The cost-effectiveness of expanded HIV screening in the United States" *AIDS*, 2013.

Acknowledgments

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