

# Shared Service Success

Six Years of HIV Nucleic Acid Testing  
for US Public Health Laboratories

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# Conflict of Interest

- Paid employee of Association of Public Health Laboratories
- APHL receives funding through a cooperative agreement with the Centers for Disease Control and Prevention
- I have no other conflicts to declare



# Acknowledgements

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# Acknowledgements

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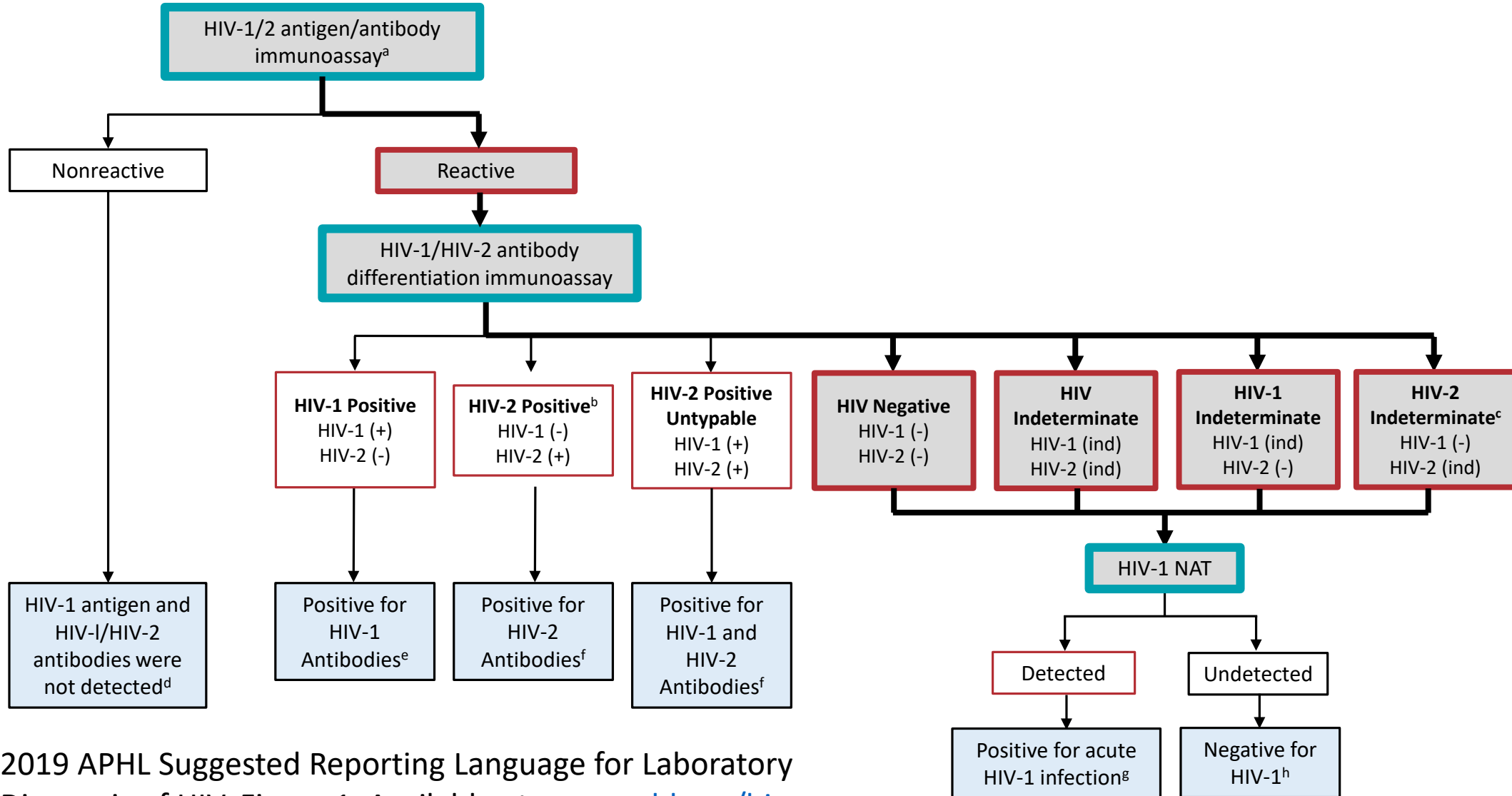


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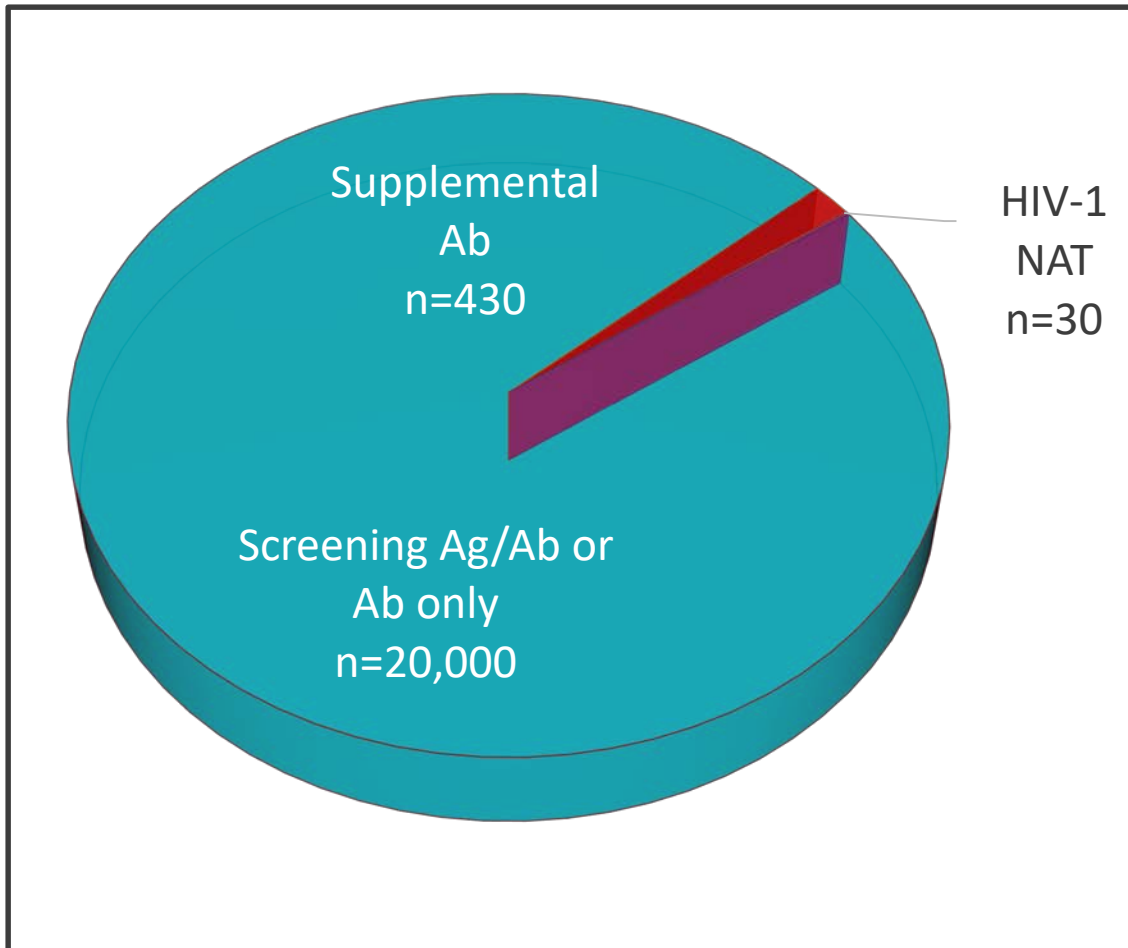
# HIV Laboratory Testing Algorithm in Serum/Plasma

(modified from 2014 algorithm figure and 2018 CDC Quick Reference Guide)



2019 APHL Suggested Reporting Language for Laboratory Diagnosis of HIV, Figure 1. Available at [www.aphl.org/hiv](http://www.aphl.org/hiv)

# The Case for Shared Service



- Maintaining HIV-1 NAT at every laboratory is prohibitive

AND

- Access to HIV-1 NAT is imperative to complete the recommended algorithm

# The Design

## Reference Laboratory (RL)

- 2 PHLs contracted to serve as reference laboratories
- FDA-approved HIV-1 NAT for diagnosis performed on eligible specimens
- Return results within 2 days of receipt

## Submitting Laboratory (SL)

- All US PHLs eligible to enroll
- Eligible specimens:
  - Reactive on Ag/Ab or Ab-only laboratory-based assay
  - Nonreactive or indeterminate on supplemental Ab assay

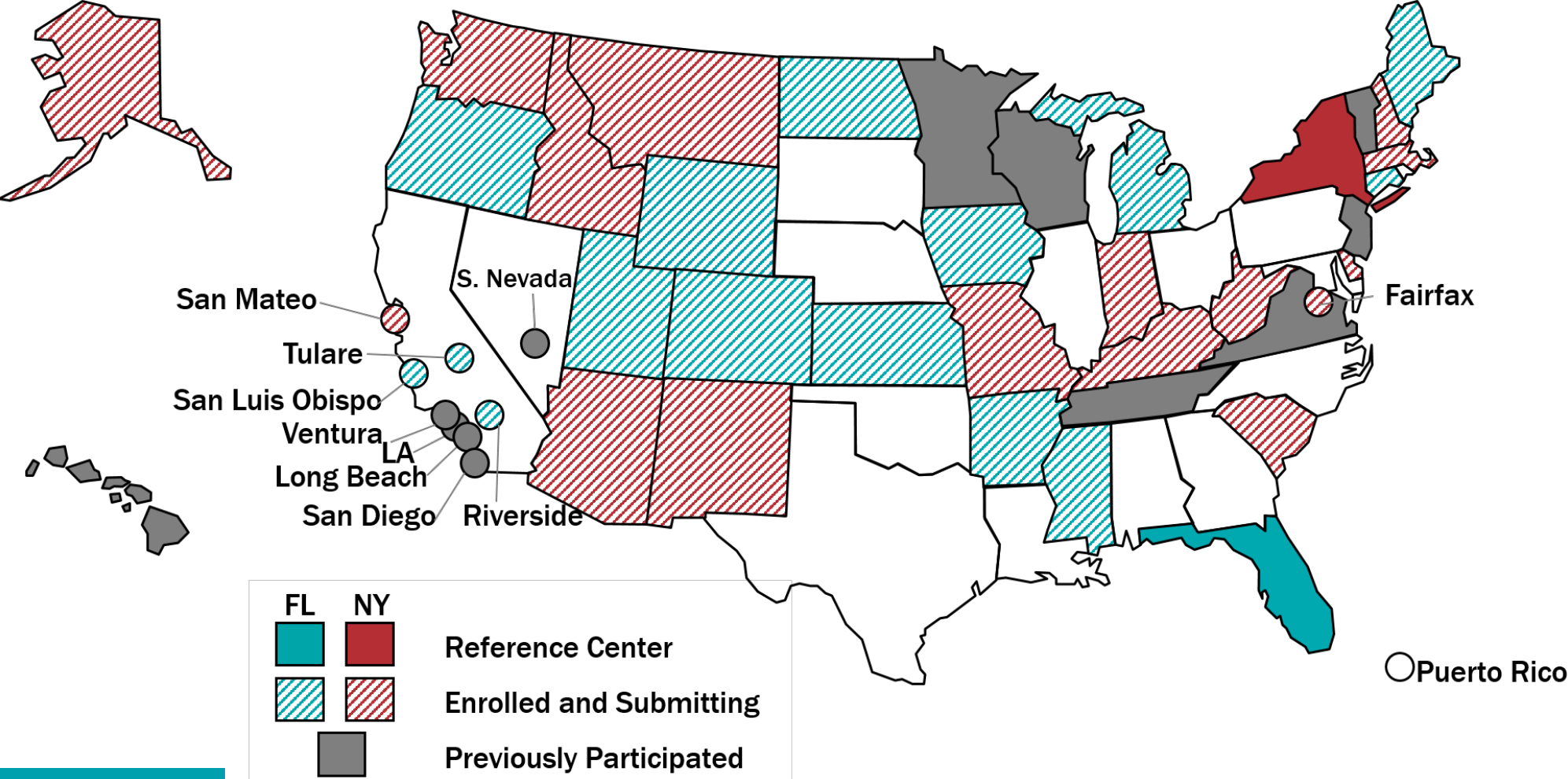
# The Numbers

- 6 years: 2012-2018
- 44 PHLs have enrolled
- 40 PHLs have submitted at least one sample
- 32 PHLs are actively participating





# The Map



# The Data

## Reference Laboratory (RL)

- De-identified Line listed data
  - Test manufacturer(s) and result(s)
  - Date(s) of specimen collection, receipt at SL, shipping, receipt at RL, tested at RL, reported to SL
  - HIV-1 NAT result

## Submitting Laboratory (SL)

- Aggregate Denominator Data
  - Number of Ag/Ab or Ab IA's performed
  - Number of Supplemental Ab tests performed and results
  - Number of eligible specimens for HIV-1 NAT and of those how many were sent for HIV-1 NAT



# The Method

- Number and Percentage of specimens that should receive HIV-1 NAT that are submitted for testing
- Number and Percent of specimens with algorithm defined Acute HIV-1 Infections
- Turnaround times
- Comparison of Supplemental Ab and HIV-1 NAT results



# Denominator Data-Specimens Requiring NAT

Year	Submitting Labs (SL)	Total HIV Ag/Ab or HIV Ab IA's performed at SLs	Total Supplemental Ab Tests Performed	Total Specimens Eligible for HIV-1 NAT <sup>a</sup>	Percentage (Number) of Eligible Specimens Submitted for HIV-1 NAT
2012-2013	22	288,713	Data not available	290	48% (140)
2013-2014	27	426,386	5,577	544	80% (437)
2014-2015	25	319,135	4,874	588	81% (478)
2015-2016	27	308,288	4,123	685	72% (491)
2016-2017	27	347,910	4,547	671	83% (556)
2017-2018	29	309,168	4,212	606	90% (544)

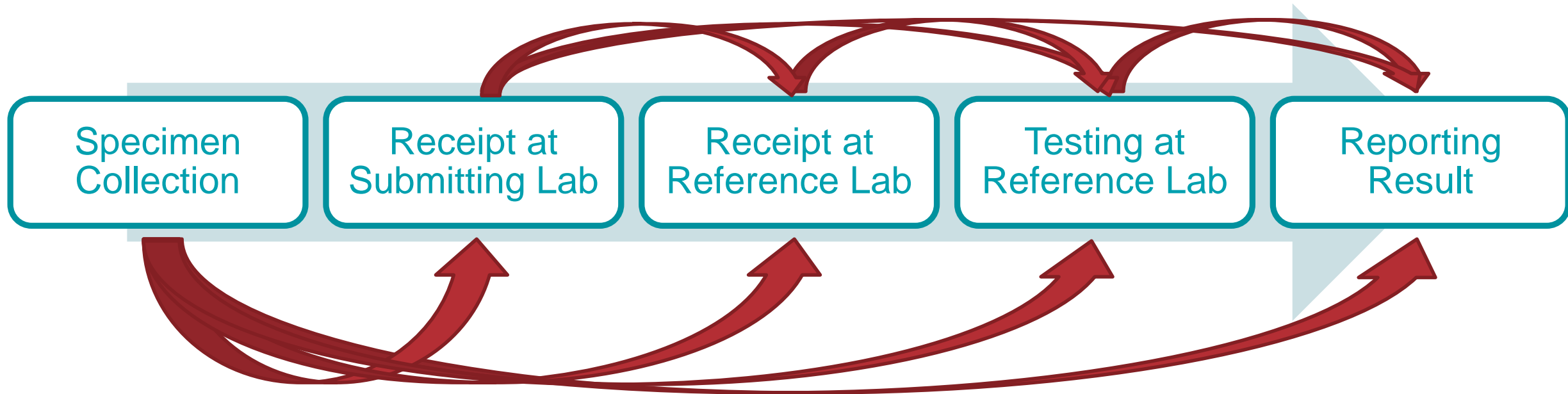
a. HIV Ag/Ab or HIV Ab reactive (repeatedly) and supplemental antibody negative or indeterminate.



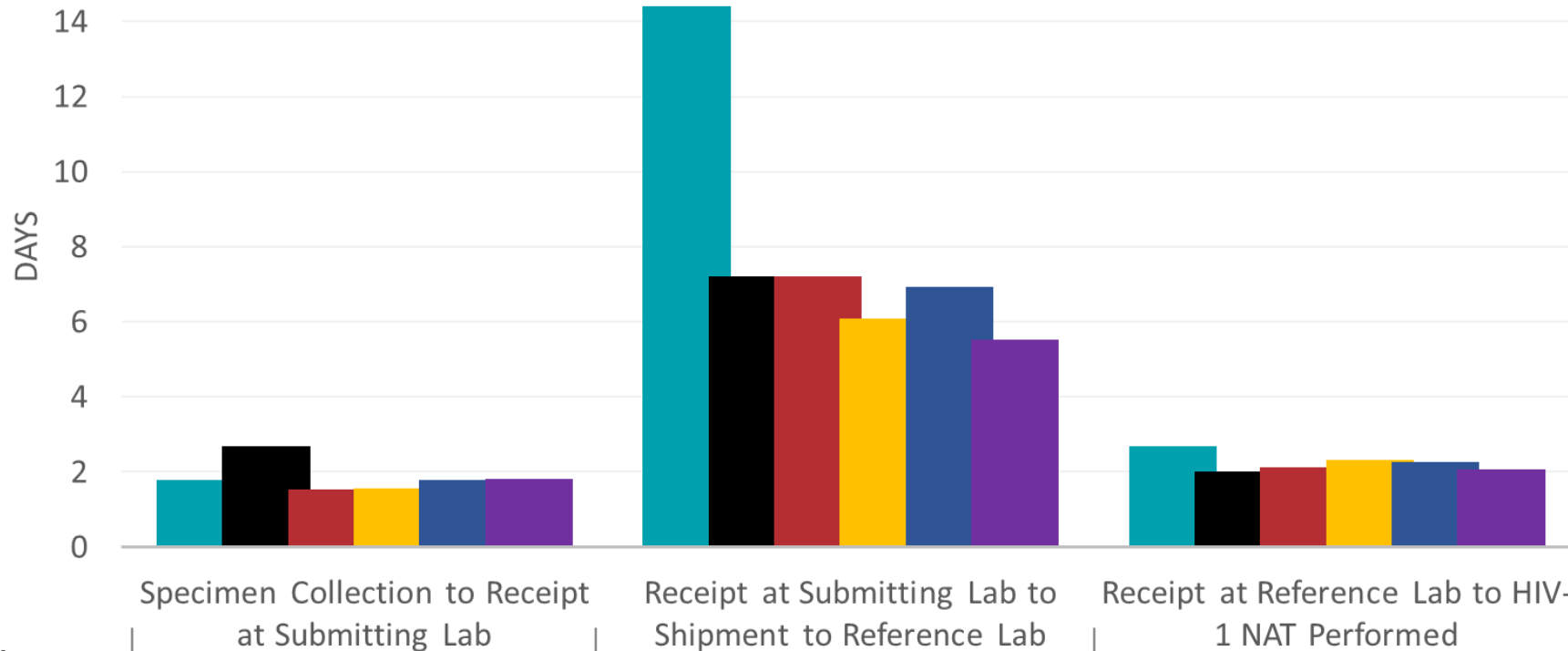
# Identification of Acute HIV-1 Infections

Year	Submitting Labs (SL)	HIV Ag/Ab or HIV Ab IA's performed at SL	Eligible Specimens Tested for HIV-1 NAT	Percentage of Acute HIV-1 Infections from Specimens submitted to RL (HIV-1 NAT Reactive)	Percentage of Acute HIV-1 Infections from all Specimens Screened at SL (HIV-1 NAT Reactive)
2012-2013	22	288,713	140	8.6% (12)	0.004%
2013-2014	27	426,386	415	14.9% (62)	0.015%
2014-2015	25	319,135	416	13.2% (56)	0.018%
2015-2016	27	308,288	476	18.9% (90)	0.029%
2016-2017	27	347,910	547	14.1% (77)	0.022%
2017-2018	29	309,168	530	15.8% (84)	0.027%

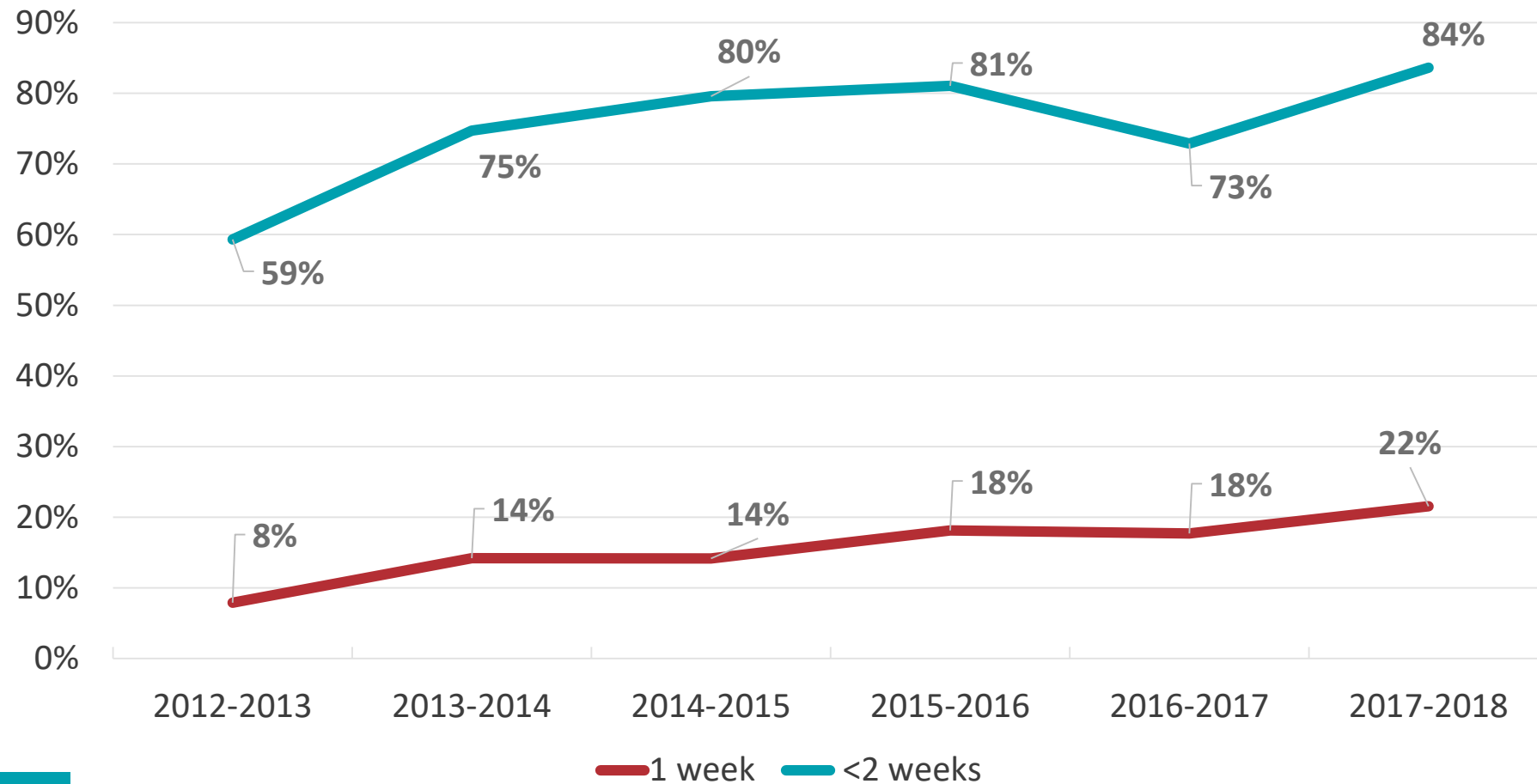
# Turnaround Times



# Mean (Median) TAT: Specimens submitted for HIV-1 NAT



# Average TAT: Collection to Result in 1-2 weeks





# Supplemental Testing Results-Ab and HIV-1 NAT

2016-2018

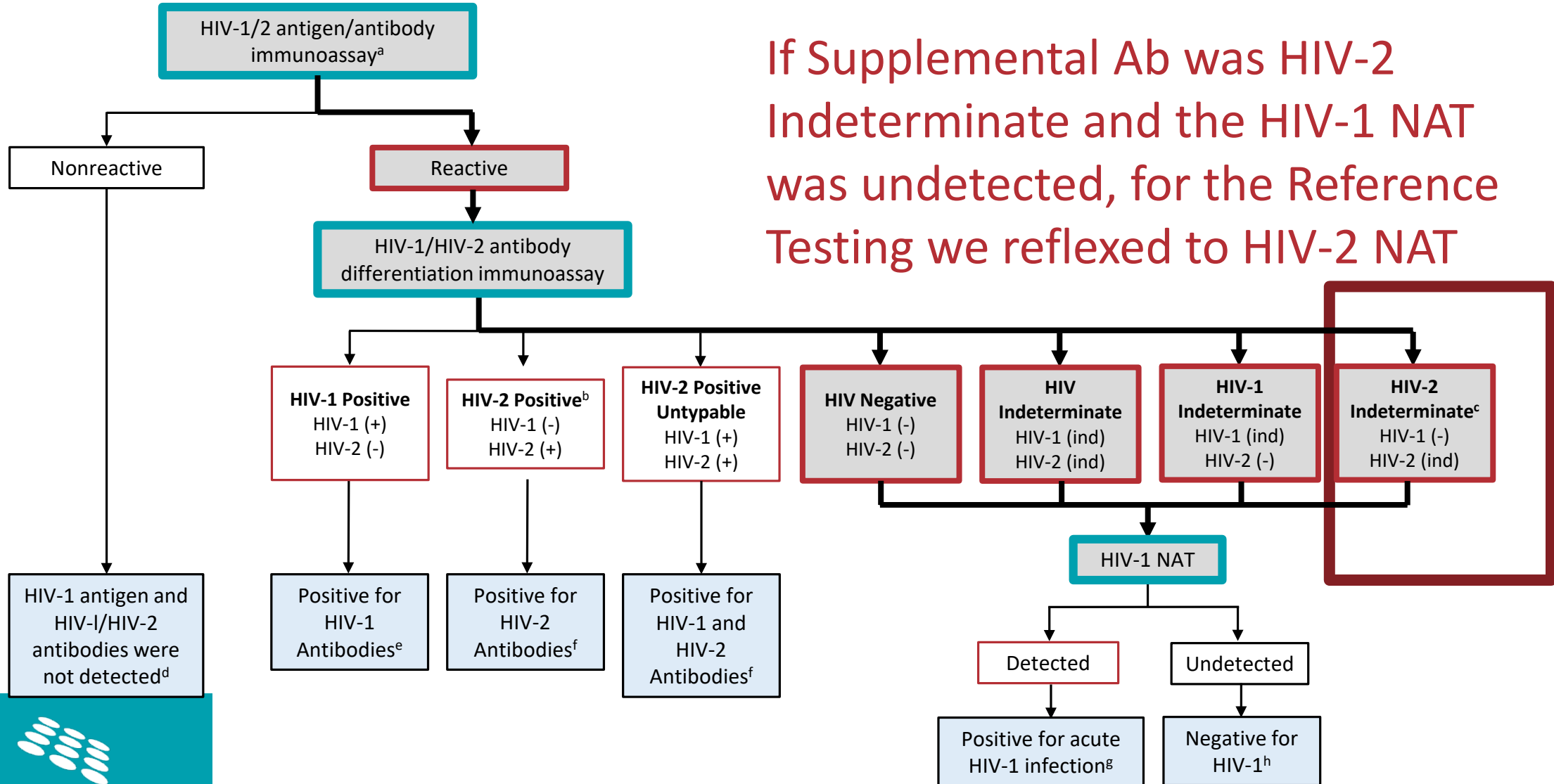
Supplemental Ab Test Result	n=	HIV-1 RNA Negative	HIV-1 RNA Positive	Percent HIV-1 RNA Positive
HIV indeterminate (Geenius/MS)	19	8	11	58%
HIV-1 indeterminate (Geenius)	59	24	35	59%
HIV-2 indeterminate (Geenius)	26	25	1	4%
Negative (All)	973	859	114	12%
TOTAL	1077	916	161	



# HIV Laboratory Testing Algorithm in Serum/Plasma

(modified from 2014 algorithm figure and CDC Quick Reference Guide)

If Supplemental Ab was HIV-2 Indeterminate and the HIV-1 NAT was undetected, for the Reference Testing we reflexed to HIV-2 NAT



# Conclusion

- A shared service model serves the needs of US PHLs needing access to timely and quality HIV-1 RNA testing
  - Identify Acute HIV-1 Infections (381)
  - HIV-1 NAT performed within 2 days on average
  - Access to HIV-2 NAT (NY)
    - Talk B3 at 11:00am today
- More timely testing is needed across the board to meet broader goals in HIV diagnosis and management



**THANKS!**

**Questions/Comments**

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