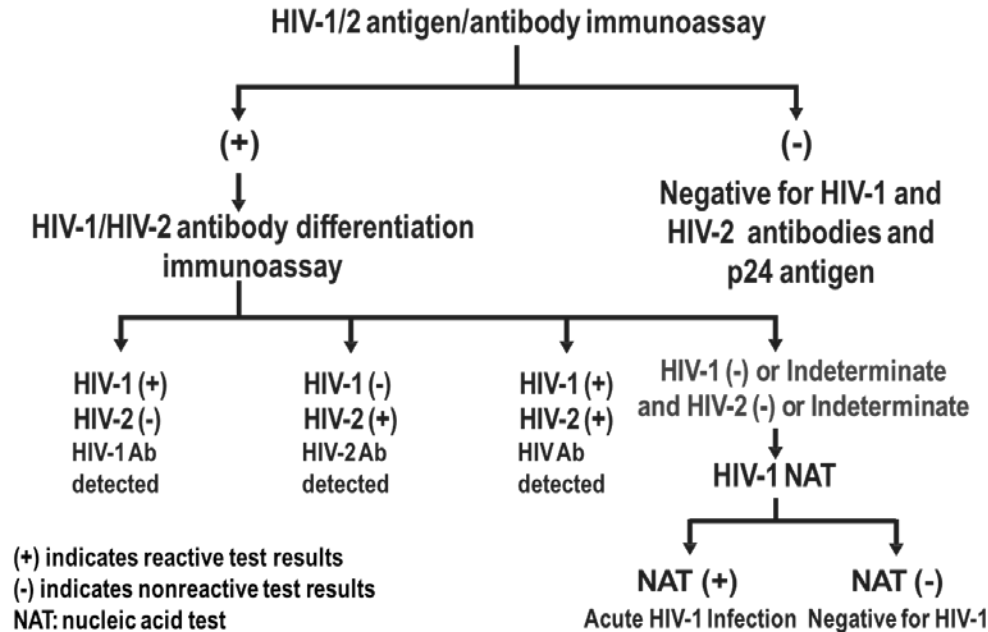# HIV-1/2 Differentiation in the United States HIV Testing Algorithm: High Burden, Low Yield

ANNE PERUSKI

MARCH 26, 2019

Recommended Laboratory HIV Testing Algorithm for Serum or Plasma Specimens

HIV-1/2 Differentiation Test

Geenius HIV-1/2 Supplemental
(differentiation) assay
Serum, plasma, whole blood
~ 30 min
FDA approved 2014

Multispot HIV-1/2 Supplemental
(differentiation) assay
Serum, plasma ~ 15 min
FDA approved 2004

Purpose

- **Develop a definition to categorize type of HIV diagnoses in the National HIV Surveillance System (NHSS)**

- **Evaluate the number of HIV-2 diagnoses**

- **Describe the demographics of HIV-1 and HIV-2 infections**

- **Evaluate the extent of the use of the HIV-1/2 differentiation test**

Data Source and Population

- **Data reported to the United States NHSS through June 2018**

- **Persons aged ≥13 years with HIV infection diagnosed during 2012-2016**

- **Persons residing in the 50 United States, Washington DC, or six dependent areas at time of diagnosis**

HIV diagnoses reported to the National HIV Surveillance System
2012-2016

Dual HIV-1 and HIV-2 diagnoses

HIV-2 diagnoses, confirmed

HIV-2 diagnoses, probable but not confirmed

HIV-1 diagnoses

Dual HIV-1 and HIV-2 diagnoses
HIV-2+ Ab or HIV-1+/HIV-2+ Ab
and
HIV-1+ RNA/DNA
and HIV-2+ RNA

HIV-2 diagnoses, confirmed
HIV-2+ RNA or HIV-2+ differentiating test
and
No HIV-1+ RNA/DNA

HIV-2 diagnoses, probable but not confirmed

HIV-2+ Ab

and

No HIV-1+ RNA/DNA

HIV-1 diagnoses
All remaining diagnoses

Type of HIV diagnoses for persons aged ≥13 years with HIV diagnosed during 2012- 2016—United States and 6 dependent areas

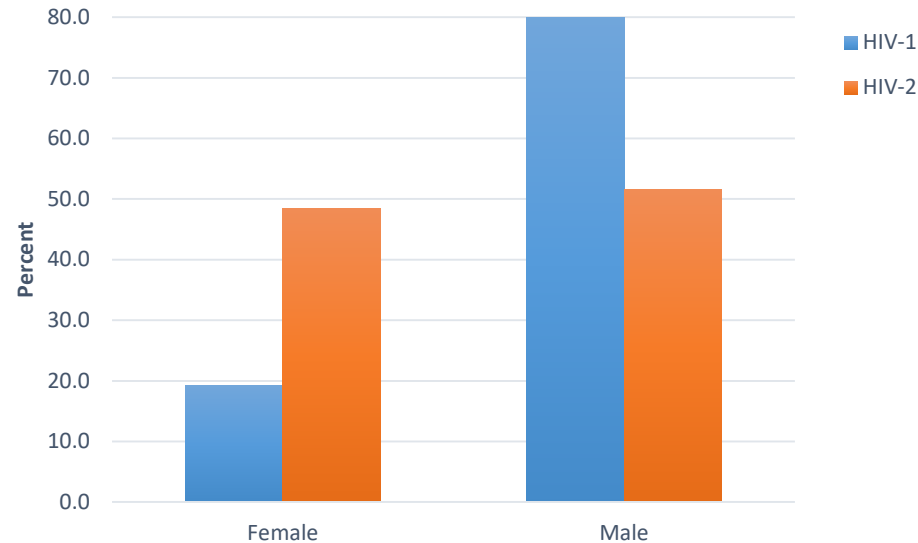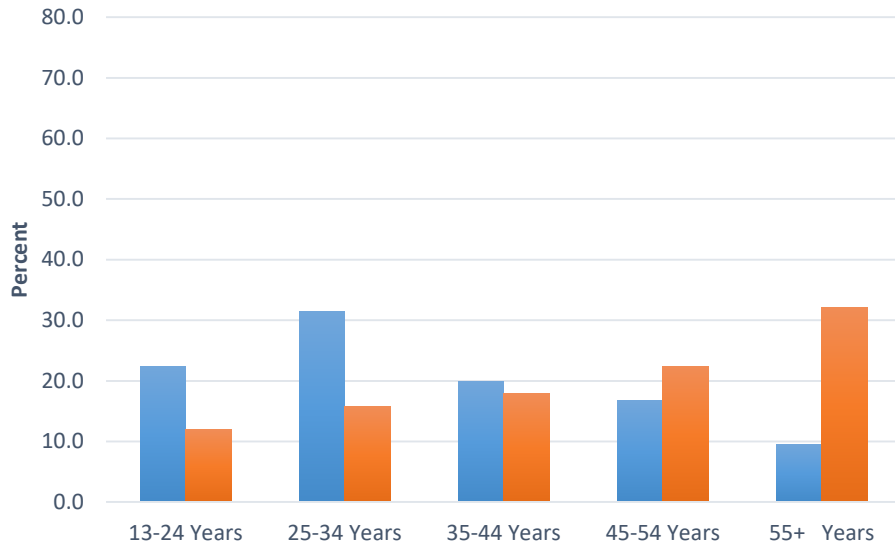|	Year of Diagnosis						EAPC*	95% CI**
	2012 N=41,701	2013 N=40,036	2014 N=40,708	2015 N=40,394	2016 N=40,012	Total N=202,851		
HIV-1 diagnoses	41,678	40,026	40,675	40,363	39,975	202,717	-0.01	(-0.01, -0.003)
Dual HIV-1/2 diagnoses	3	0	1	1	0	5	-42.6	(-72.7, 20.9)
HIV-2 diagnoses, confirmed	8	8	23	15	19	73	23.2	(4.4, 45.5)
HIV-2 diagnoses, probable but not confirmed	12	2	9	15	18	56	26.4	(4.5, 53.1)

*estimated annual percent change

**confidence interval

Type of HIV diagnoses for persons aged ≥13 years with HIV diagnosed during 2012- 2016—United States and 6 dependent areas

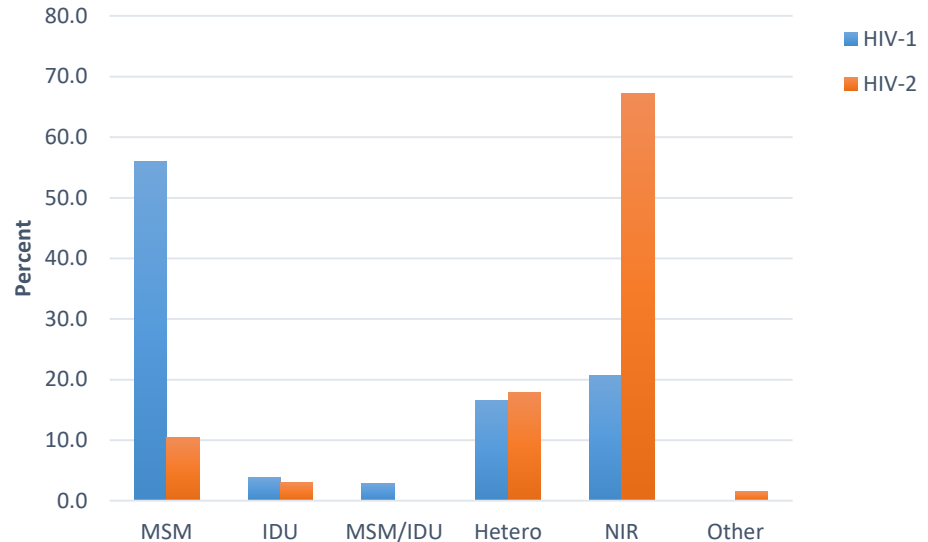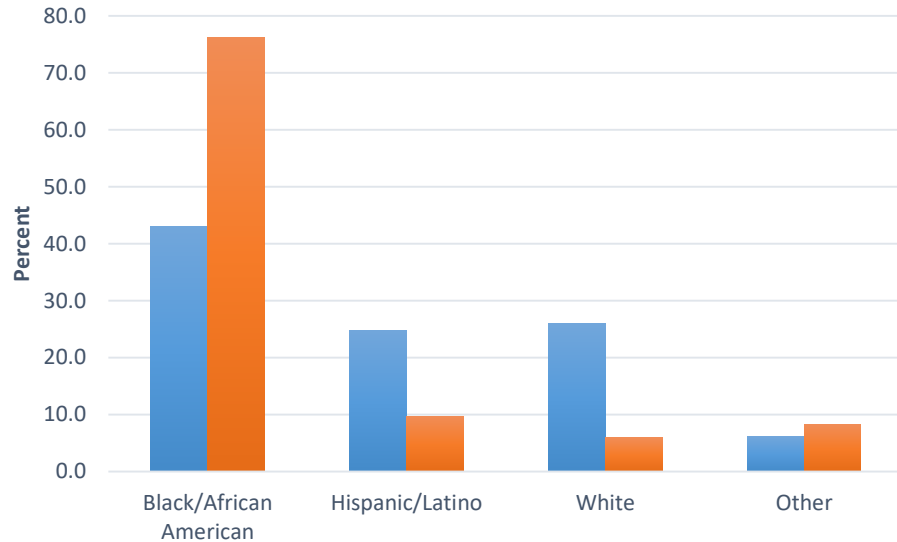|	Year of Diagnosis						EAPC*	95% CI**
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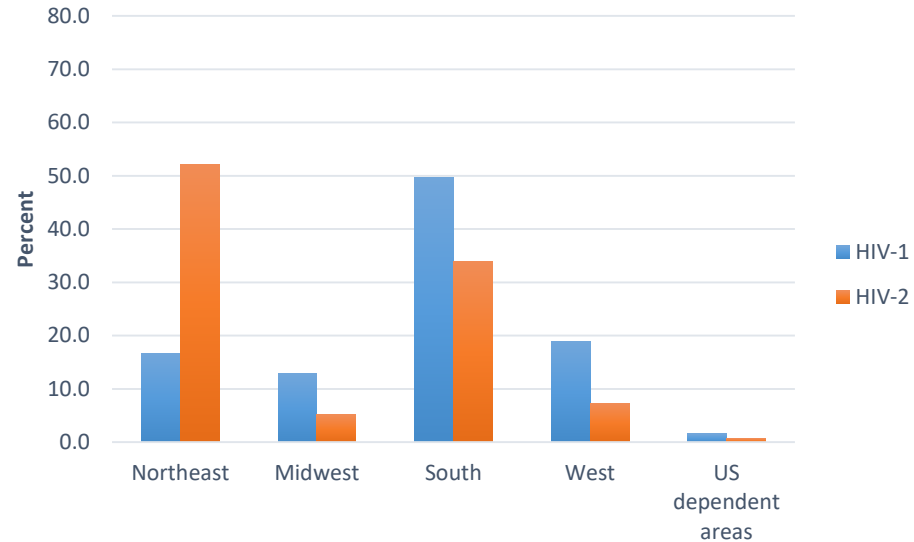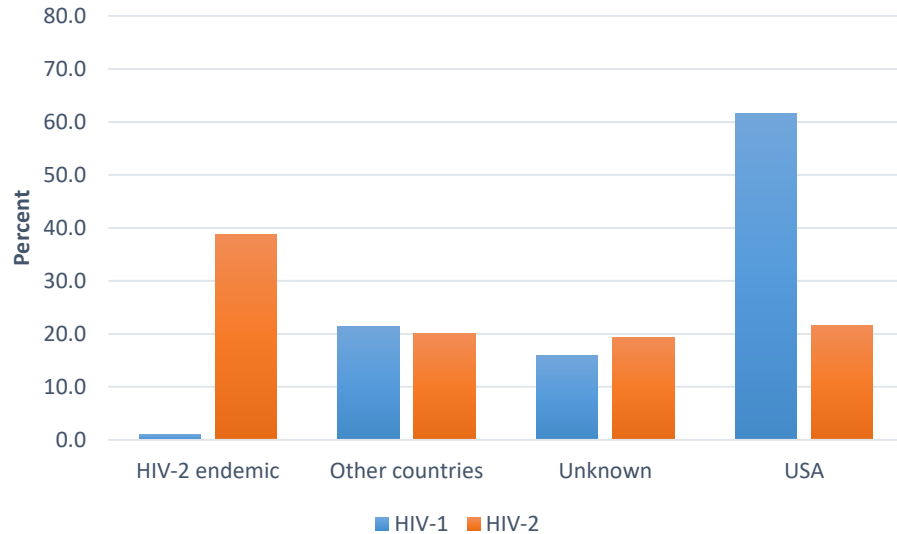
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Characteristics of persons aged ≥13 years with HIV diagnosed during 2012- 2016—United States and 6 dependent areas

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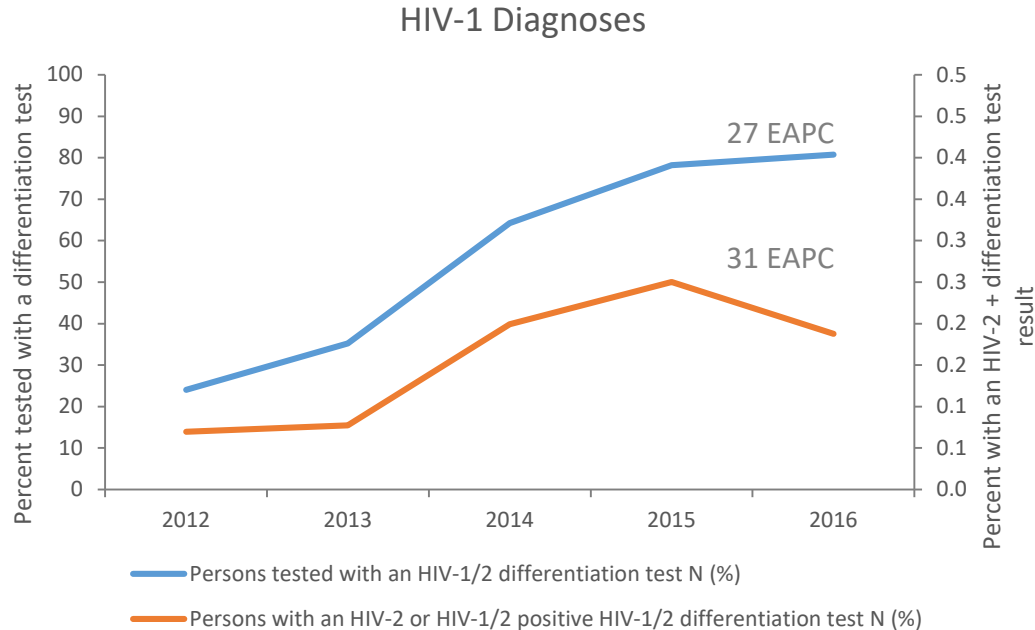
Characteristics of persons aged ≥13 years with HIV diagnosed during 2012- 2016—United States and 6 dependent areas

Differentiation testing among persons aged ≥13 years with <u>HIV</u> diagnosed during 2012-2016—United States and 6 dependent areas

	2012 N=41,701	2013 N=40,036	2014 N=40,708	2015 N=40,394	2016 N=40,012	Total N=202,851
Persons tested with an HIV-1/2 differentiation test N (%)	10,019 (24.0)	14,092 (35.2)	26,143 (64.7)	31,592 (80.7)	32,308 (80.7)	**114,154 (56.3)**
Persons with an HIV-2 or HIV-1 and HIV-2 positive differentiation test result N (%)	37 (0.1)	38 (0.1)	107 (0.3)	120 (0.3)	100 (0.2)	**402 (0.2)**

Differentiation testing among persons aged ≥13 years with <u>HIV-1</u> diagnosed during 2012-2016—United States and 6 dependent areas

	2012 N=41,701	2013 N=40,036	2014 N=40,708	2015 N=40,394	2016 N=40,012	Total N=202,851
Persons tested with an HIV-1/2 differentiation test N (%)	10,009 (24.0)	14,085 (35.2)	26,115 (64.2)	31,564 (78.2)	32,274 (80.7)	**114,047 (56.3)**
Persons with an HIV-2 or HIV-1 and HIV-2 positive differentiation test result N (%)	29 (0.1)	31 (0.1)	81 (0.2)	101 (0.3)	75 (0.2)	**317 (0.2)**

Trends in differentiation testing among persons aged ≥13 years with HIV-1 diagnosed during 2012-2016—United States and 6 dependent areas

HIV-1 Diagnoses

- Persons tested with an HIV-1/2 differentiation test N (%)
- Persons with an HIV-2 or HIV-1/2 positive HIV-1/2 differentiation test N (%)

Summary

- **Overall, 99.9% of all HIV infections diagnosed were HIV-1**
- **The number of HIV-2 diagnoses remained extremely low**
- **There has been a significant increase in the use of HIV-1/2 differentiation tests, which is consistent with the implementation of the new guidelines for the United States HIV testing algorithm**

Summary

- **Overall, during 2012-2016 there were 73 persons with confirmed HIV-2 diagnoses; considerably less than the 317 with confirmed HIV-1 diagnoses that had conflicting differentiation test results**

- **The demographics of persons with HIV-2 infection differ significantly from those with HIV-1 infection**
  - Persons with HIV-2 infection were more frequently older, female, black/African American, had no identified risk factor, were from HIV-2 endemic countries and resided in the northeast

Summary

- **The availability of additional FDA approved rapid and sensitive tests for diagnosis of HIV could lead to an improved HIV diagnostic algorithm**

Acknowledgements

DISCLAIMER

The findings and conclusions in this presentation are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

Questions?