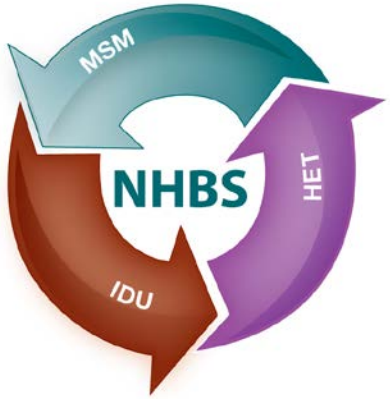
Evaluation of Different Rapid Testing Algorithms for Venue-based Anonymous HIV Testing among Men Who Have Sex with Men (MSM)



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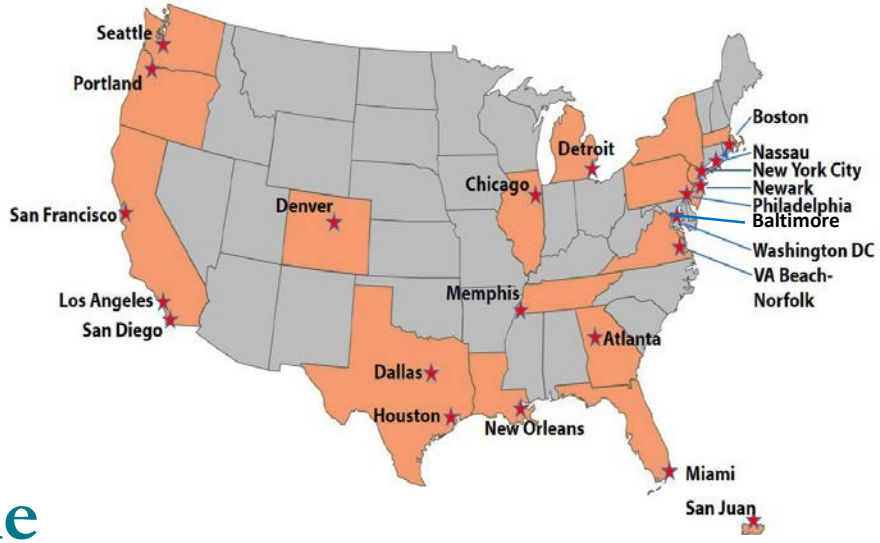
NHBS: Overall Strategy

- **Monitor prevalence and trends: HIV infection, HIV testing and use of prevention services, and risk behaviors (sex, drug use)**

- **NHBS conducted surveillance every three years among:**
  - Men who have sex with men (MSM)
    - Venue-based, time-space sampling
  - Persons who inject drugs(PWID) and Heterosexuals at increased risk of HIV infection (HET)
    - Respondent-driven sampling



- **In 2017, 23 cities participated in the MSM cycle**

2017 NHBS-MSM Rapid Testing Activities

- **Rapid-Rapid testing algorithm (RTA) was implemented**
  - A sequential RTA using two orthogonal rapid tests (RTs) was proposed
- **Adopted algorithms:**
  - 18 cities followed a sequential RTA
  - 1 city performed parallel rapid testing
  - 4 cities performed only one RT

- **All participants were offered anonymous HIV testing regardless of self-reported status via finger-stick or venous whole blood and counseling**
  - RT-preliminary positive are referred for care and treatment services
  - Based on self-report participants were HIV Positive or Non-HIV Positive (SRNH+)

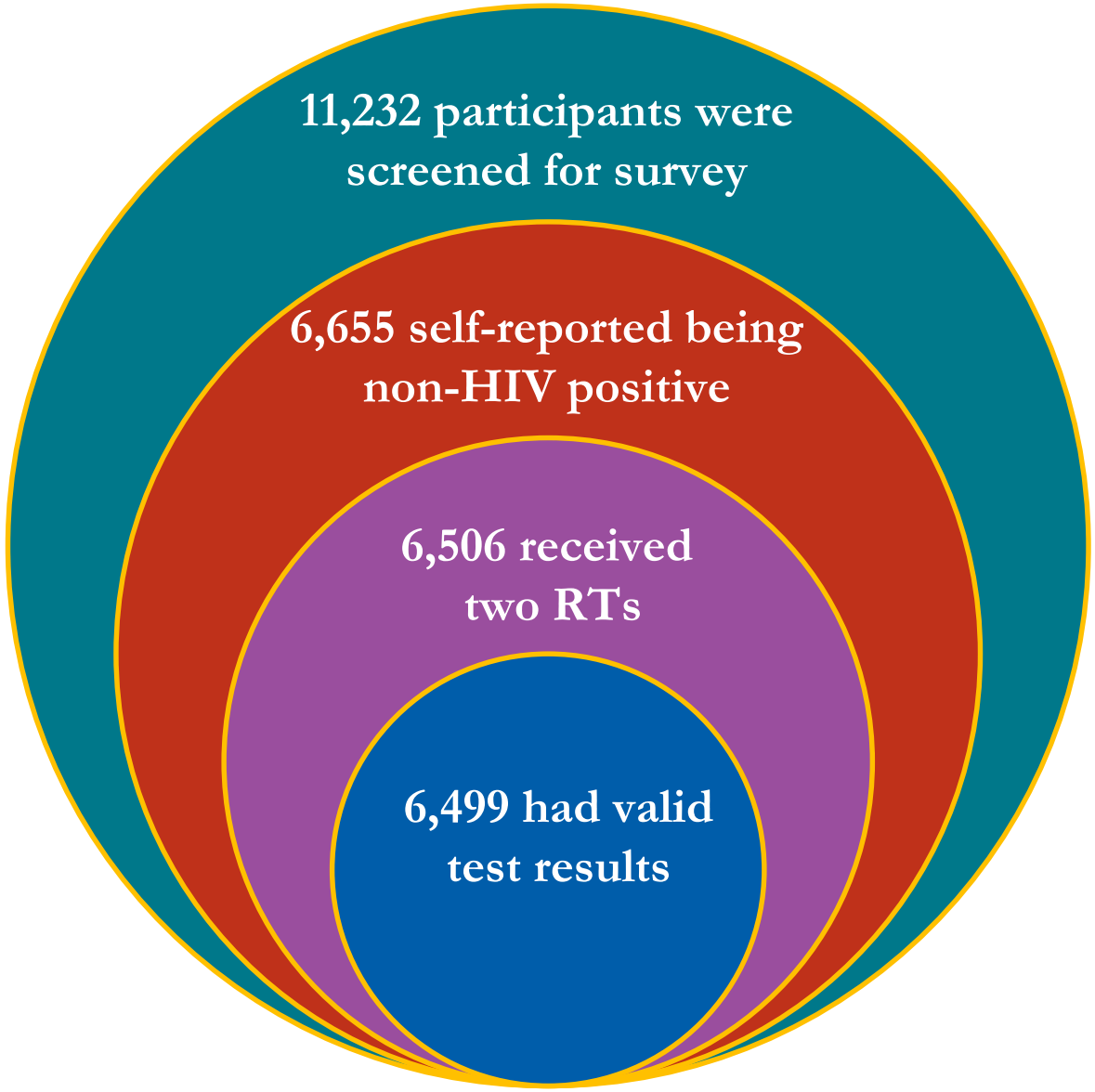
2017 NHBS MSM-DBS collection and testing

- **Dried and stored at ambient temperature**
- **Bagged and shipped weekly to CDC**
- **Checked for quality, repackaged and inventoried at CDC**
  - Stored at -20°C until testing
- **Testing performed:**
  - GS Bio-Rad HIV Combo Ag/Ab EIA (BRC) and Geenius HIV-1/2 supplemental assay (Geenius) for confirmation of HIV infection status
  - Abbott HIV-1 RealTime Viral Load (VL)
  - Mass Spectrometry for Antiretroviral drugs (ARVs)
    - Tenofovir (TFV), Lamivudine (3TC), Efavirenz (EFV), Dolutegravir (DTG), Emtricitabine (FTC), Elvitegravir (EVG), Ritonavir (RTV), Raltegravir (RAL), Abacavir (ABC)

OBJECTIVE:

To evaluate the performance of selected RTs used in the sequential and parallel rapid algorithms implemented among MSM who Self-Reported being Non-HIV Positive in 19 cities

Where do our results come from?



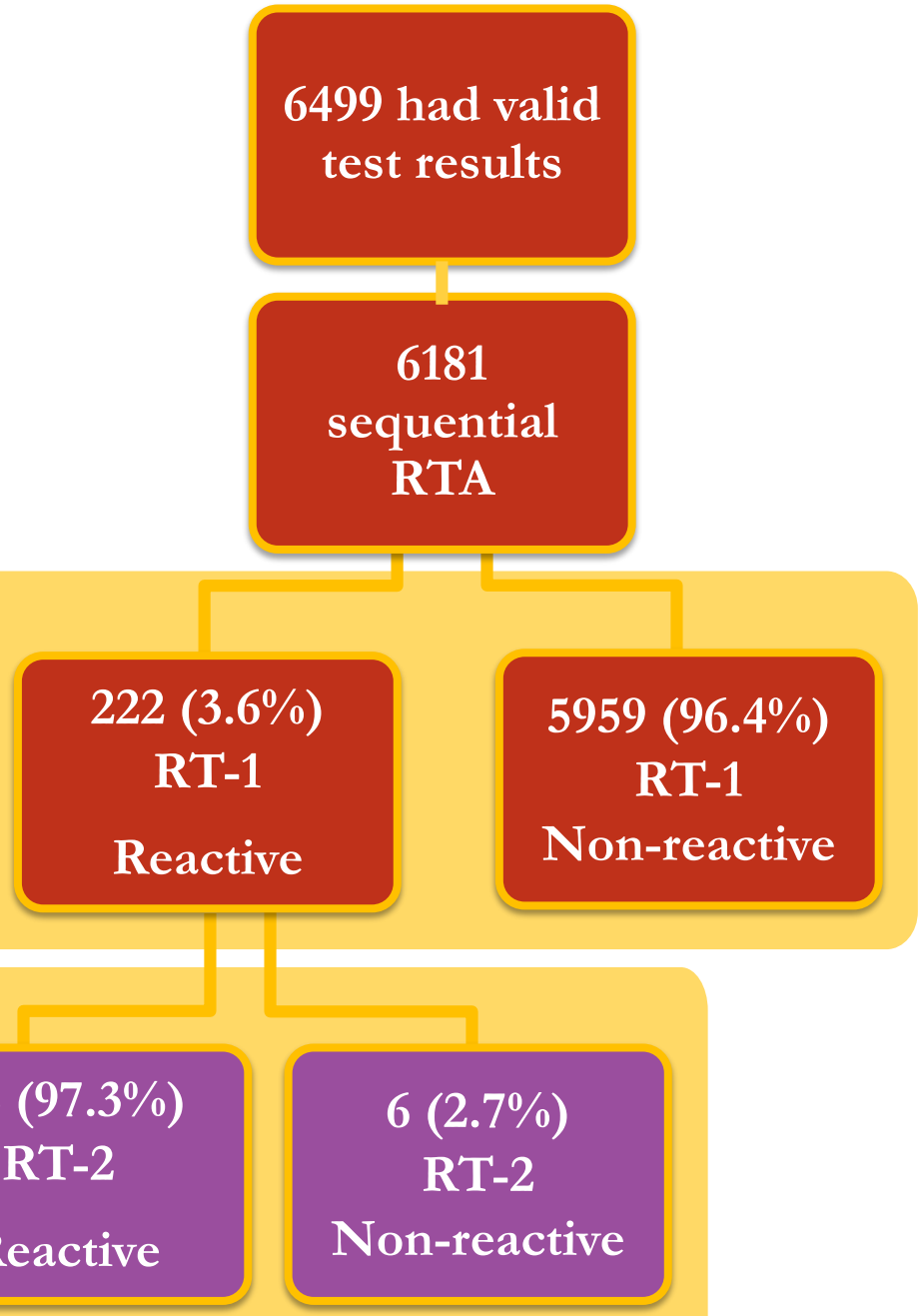
Variations of Sequential Rapid Testing Algorithm

Rapid Test 1

Alere Determine HIV-1/2 Ag/Ab Combo (DC)
bioLytical INSTI HIV-1 / HIV-2 Antibody Test (INSTI)
Chembio SURE CHECK HIV 1/2 Assay (Sure Check)
Uni-Gold Recombigen HIV-1/2 (Unigold)

Rapid Test 2

DC
INSTI
Sure Check
Unigold
OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test (OQ)



1- Sequential RTA starting with Determine Ag/Ab Combo

- Ag and Ab reactivity was not available from sites, DC was recorded either Reactive or Non-reactive
- 45.7% (2825/6181) of participants were initially screened with DC
  - 4.1% (115/2825) were DC-reactive

RTA	Number of participants tested according to RTA	DC results		RT-2 results	
		Nonreactive	Reactive	Reactive	Nonreactive
DC→ INSTI	2295 (81.2%)	2198	97	92 (94.8%)	5 (5.2%)
DC→ Sure Check	404 (14.3%)	389	15	15 (100%)	0
DC→ Unigold	126 (4.5%)	123	3	3 (100%)	0

- 95.6% overall DC/RT-2 concordance when used sequentially

2- Sequential RTA starting with INSTI

- 31.6% (1954/6181) of participants were initially screened with INSTI
  - 2.4% (47/1954) were INSTI-reactive

RTA	Number of participants tested according to RTA	INSTI results		Rapid Test 2	
		Nonreactive	Reactive	Reactive	Nonreactive
INSTI→ DC	1133 (58%)	1103	30	29 (96.7%)	1 (3.3%)
INSTI→ Unigold	352 (18%)	351	1	1 (100%)	0
INSTI→ Sure Check	469 (24%)	453	16	16 (100%)	0

- 97.9% overall INSTI/RT-2 concordance when used sequentially

3- Sequential RTA starting with Unigold

- 8.5% (528/6181) of participants were initially screened with Unigold
  - 5.7% (30/528) were Unigold- reactive

RTA	Number of participants tested according to RTA	Unigold results		Rapid Test 2	
		Nonreactive	Reactive	Reactive	Nonreactive
Unigold→ INSTI	528 (100%)	498	30	30 (100%)	0

- 100% overall Unigold/INSTI concordance when used sequentially

4- Sequential RTA starting with Sure Check

- 14.1% (874/6181) of participants were initially screened with Sure Check
  - 3.4% (30/874) were Sure Check- reactive

RTA	Number of participants tested according to RTA	Sure Check results		Rapid Test 2	
		Nonreactive	Reactive	Reactive	Nonreactive
Sure Check→ INSTI	851 (97.4%)	823	28	28 (100%)	0
Sure Check→ OQ	23 (2.6%)	21	2	2 (100%)	0

- 100% overall Sure Check/RT-2 concordance when used sequentially

Parallel Rapid Testing Algorithm

- 318 of participants were screened with Sure Check/OraQuick in parallel

OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test (OQ)

Chembio **SURE CHECK** HIV 1/2 Assay (Sure Check)

	Reactive	**Non-Reactive**
Reactive	15 (4.7%)	1 (0.3%)
Non-Reactive	0	302 (95%)

- 99.7% overall concordance when using Sure Check/OQ in parallel

Discordant results between rapid tests

Sample number	RT/ Results 1	RT/ Results 2	Comments/ local testing	Bio-Rad GS Ag/Ab Combo EIA	Bio-Rad Geenius HIV-1/2 Supplemental	Abbott RealTime HIV-1 RNA assay (copies/mL)	Antiretroviral drugs
1	DC-R	INSTI-NR		Non-Reactive		Target not detected	Not detected
2	DC-R	INSTI-NR		Non-Reactive		Target not detected	Not detected
3	DC-R	INSTI-NR		Non-Reactive		Target not detected	DTG (+/4)
4	DC-R	INSTI-NR	**DBS not sent**				Not done
5	DC-R	INSTI-NR	*WB HIV-negative* **DBS not sent**				Not done

- **Ag and Ab reactivity was not available from sites, DC was recorded either Reactive or Non-reactive**
- DTG: Dolutegravir

Discordant results between rapid tests

Sample number	RT/ Results 1	RT/ Results 2	Comments/ local testing	Bio-Rad GS Ag/Ab Combo EIA (BRC)	Bio-Rad Geenius HIV-1/2 Supplemental	Abbott RealTime HIV-1 RNA assay (copies/mL)	Antiretroviral drugs
1	DC-R	INSTI-NR		Non-Reactive		Target not detected	Not detected
2	DC-R	INSTI-NR		Non-Reactive		Target not detected	Not detected
3	DC-R	INSTI-NR		Non-Reactive		Target not detected	DTG (+/4)
4	DC-R	INSTI-NR	**DBS not sent**				Not done
5	DC-R	INSTI-NR	*WB HIV-negative* **DBS not sent**				Not done
6	**INSTI-R**	DC-NR		**Reactive (S/CO= 10.1)**	HIV-1 Antibody Negative	Target not detected	Not detected
7	**Sure Check-R**	OQ-NR	*WB HIV-negative*	Non-Reactive		Target not detected	Insufficient quantity

- **Geenius, VL, and drugs levels results may indicate false reactivity**
  - It could be an elite controller
  - Low viremia or drug levels may have been missed by the assays
- **WB, BRC, and VL indicate false reactivity in Sure Check**

Limitations

- **Participants who self-reported being Non-HIV Positive with RT-1 non-reactive results were considered HIV-negative**
  - Did not receive RT-2 except one site that tested in parallel
  - Not sent to CDC for Nucleic Acid Amplification testing
- **Abbott *Real*Time HIV-1 assay for DBS is less sensitive than plasma**
  - Low viral loads could have been missed
- **Use of Western blot for confirmation of screening test that detects p24 Ag**

Summary of results

- **Overall concordance**
  - Sequential - 216 (97.3%) had concordant-reactive results
    - 6 (2.7%) had discordant RT results
  - Parallel - 15 (4.7%) had concordant-reactive results
    - 302 (95%) had concordant-nonreactive results
    - 1 (0.3%) had discordant RT results
- **Low number of discordant RT results in RTAs**
  - 6181 following sequential: 5 DC->INSTI and 1 INSTI->DC
  - 318 performed in parallel: 1 Sure Check/OQ
- **Lab-based testing indicate false reactivity of Sure Check, INSTI, and DC**

Conclusions

- Discordant RT results were not associated with acute infection, but rather with false reactivity
- High RT-1/RT-2 concordance regardless of the order and RTs used
- RTAs work well in high-risk population and can confirm HIV infection status when laboratory follow up is not available
- Before choosing a RT or implementing a RTA in a particular setting target population prevalence, characteristics of RTs, and access to lab-based testing should be considered

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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.

Thank you for your attention!

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