

Alere: Meeting the Growing Demands

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Jeff Baker: General Manager: North America Virology Solutions

(Formally Director of New Product Development)

- Global leader in near-patient diagnostics with annual revenues in excess of \$2.5B.
- Global leader in near-patient diagnostics for the most prevalent infectious diseases.

Worlds Leader in POC Diagnostics

HIV Screening	Strep pneumo
Influenza	Legionella
Malaria	Strep A
C. difficile	Dengue

- We have several novel platforms launched or launching soon that will sustain this position well into the future:
 - Alere™ CD4 Analyzer... **PIMA** – provides absolute CD4 results to initiate and help manage antiretroviral therapy.
 - Alere™ iNAT – molecular platform for acute near-patient testing. First application expected in time for the 2013 – 14 US flu season.
 - Alere™ qNAT – HIV viral load testing, with applications for HCV and TB in development. Studies to support regulatory clearances currently underway in Africa.

ALERE'S MISSION

To empower individuals with the freedom to gain greater control over their own health, under the supervision of their healthcare providers.

RESULTS:

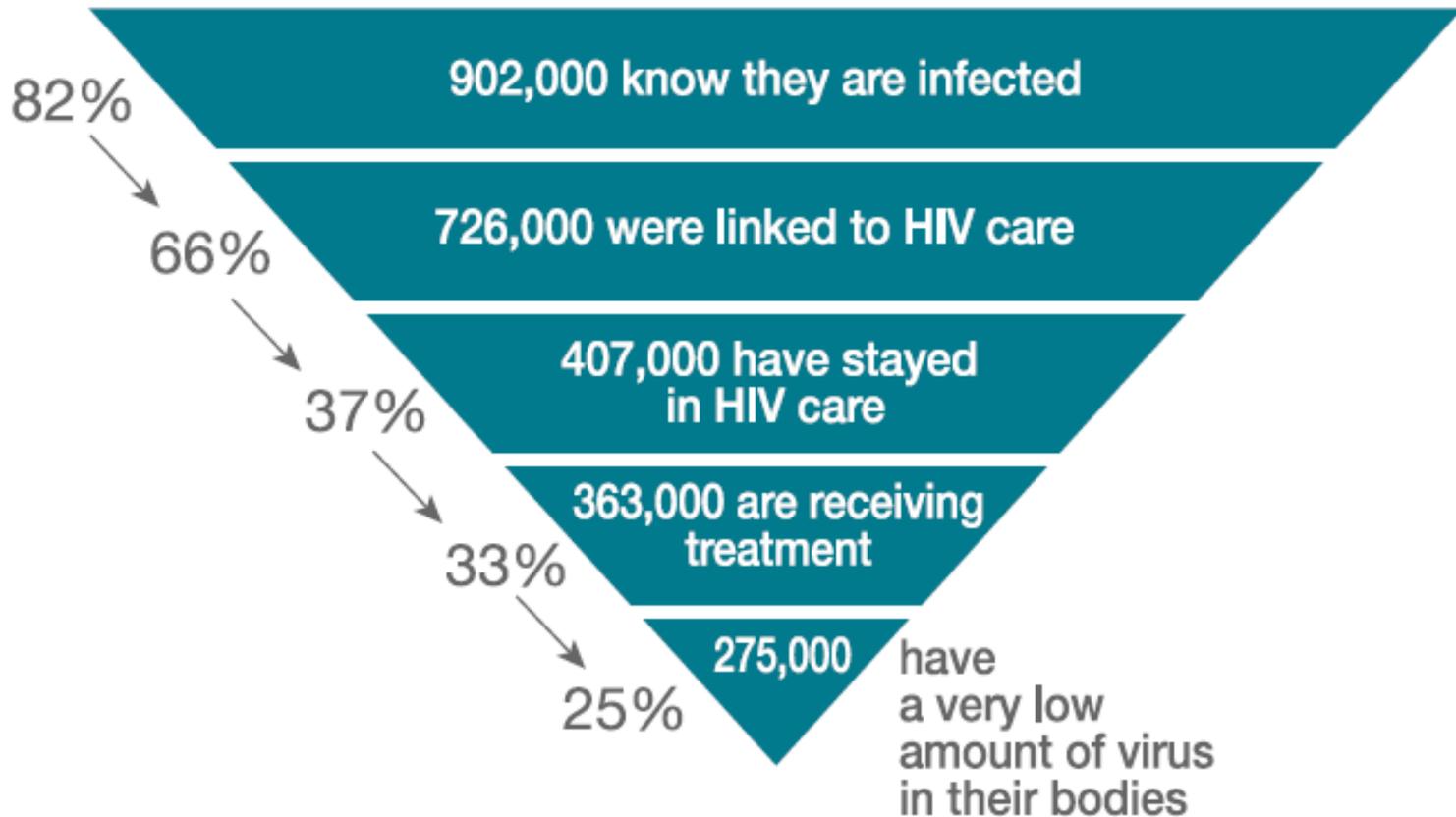
- Earlier interventions
- Personalized treatment
- Fewer hospitalizations
- Reduced healthcare costs
- Better quality of life





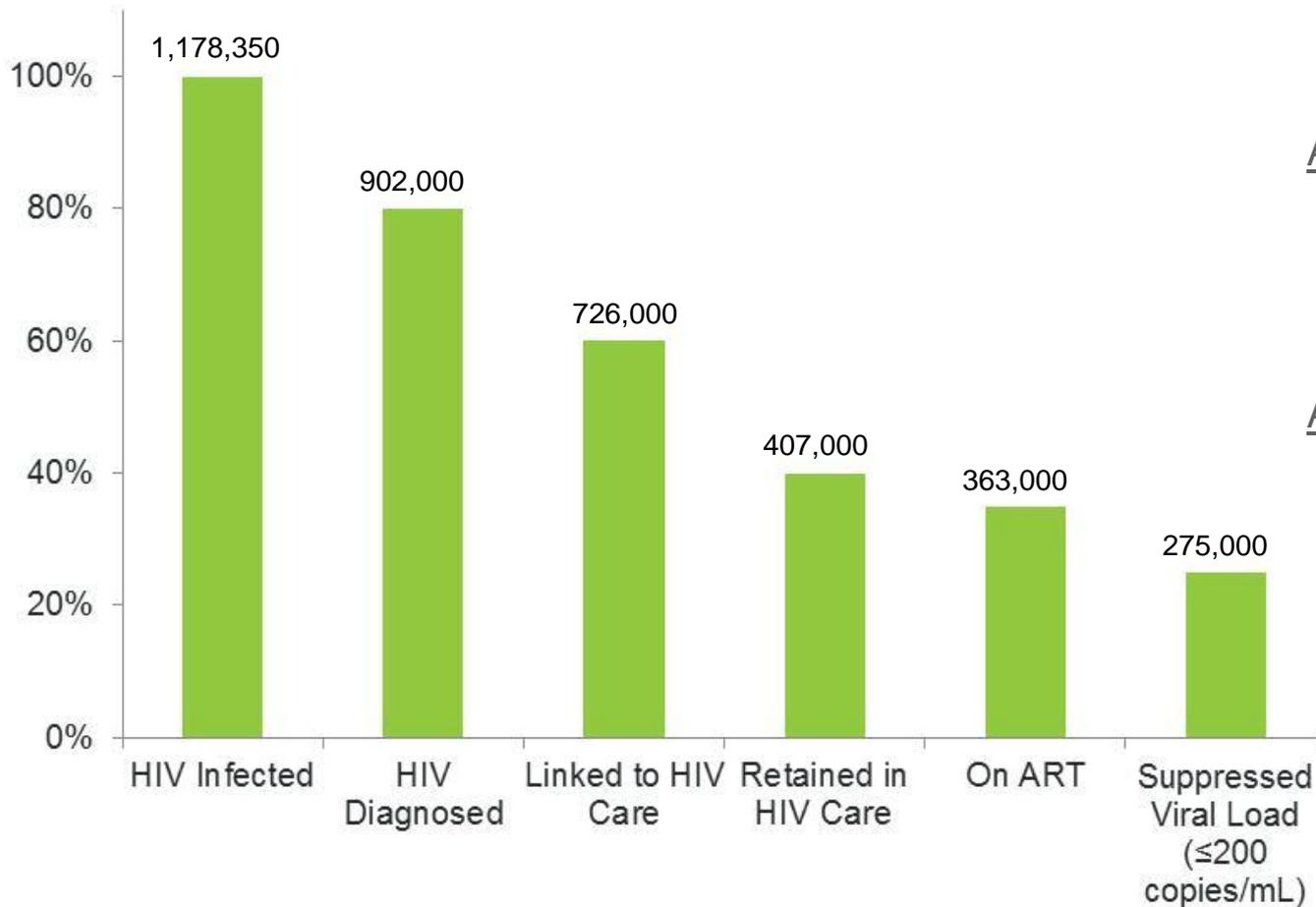
HIV Treatment Cascade

Out of the more than one million Americans with HIV:





US HIV Treatment Cascade



Alere Determine Combo

Rapid POC HIV testing

Earlier case ID

Alere CD4

Increasing access to care

Loss to patient follow-up

Knowing your #'s

Alere q HIV Viral Load

Knowing your #'s

Care Management

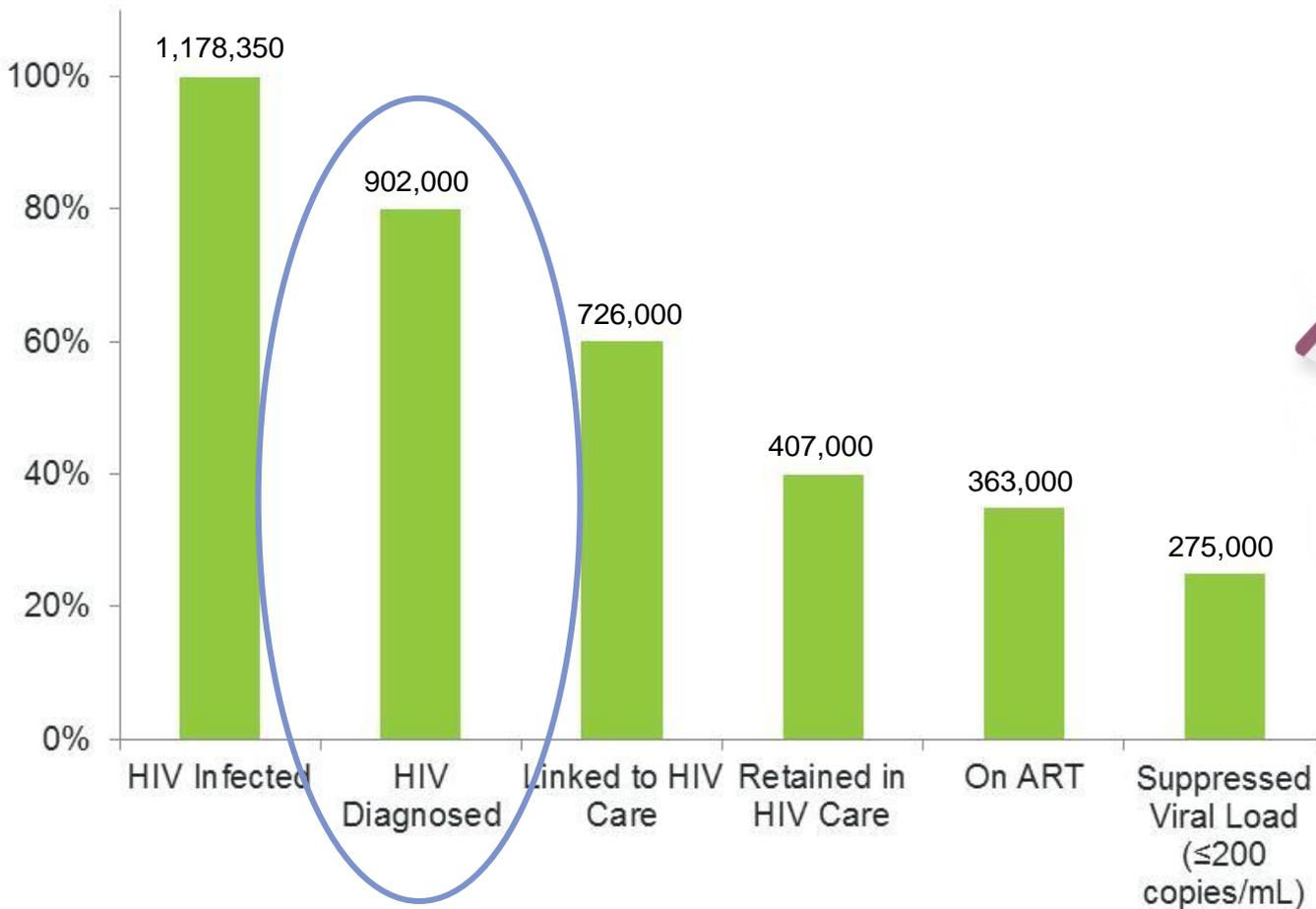
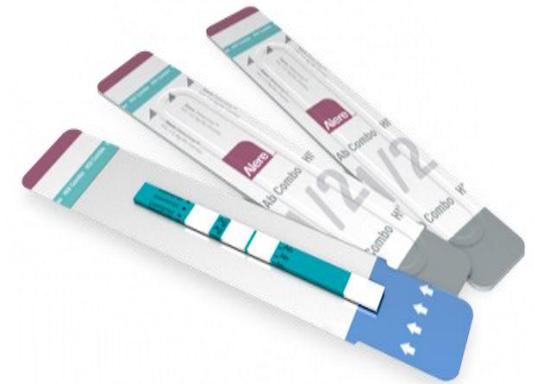


US HIV Treatment Cascade

Alere Determine Combo

Rapid POC HIV testing

Earlier case ID



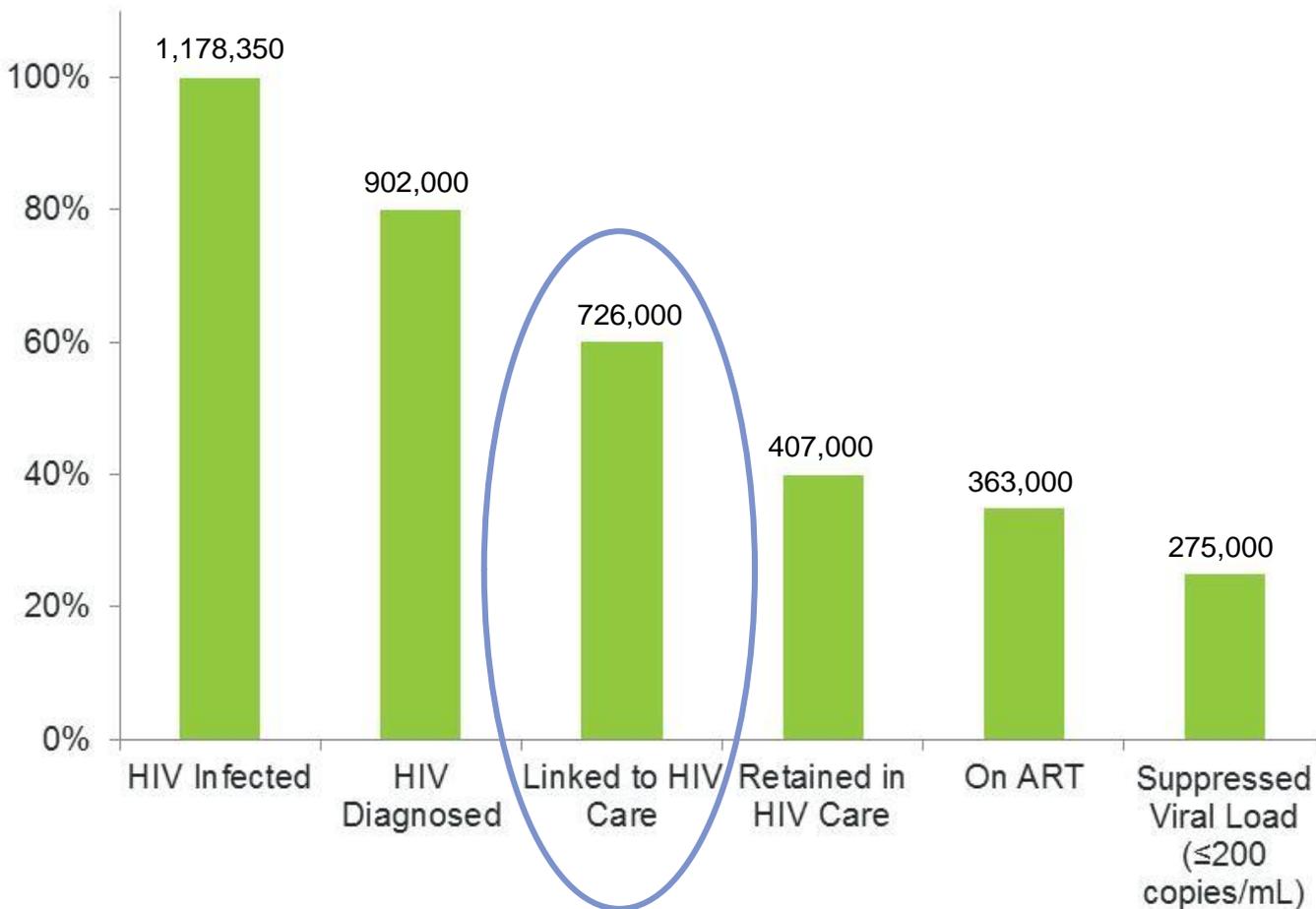


US HIV Treatment Cascade

Alere CD4

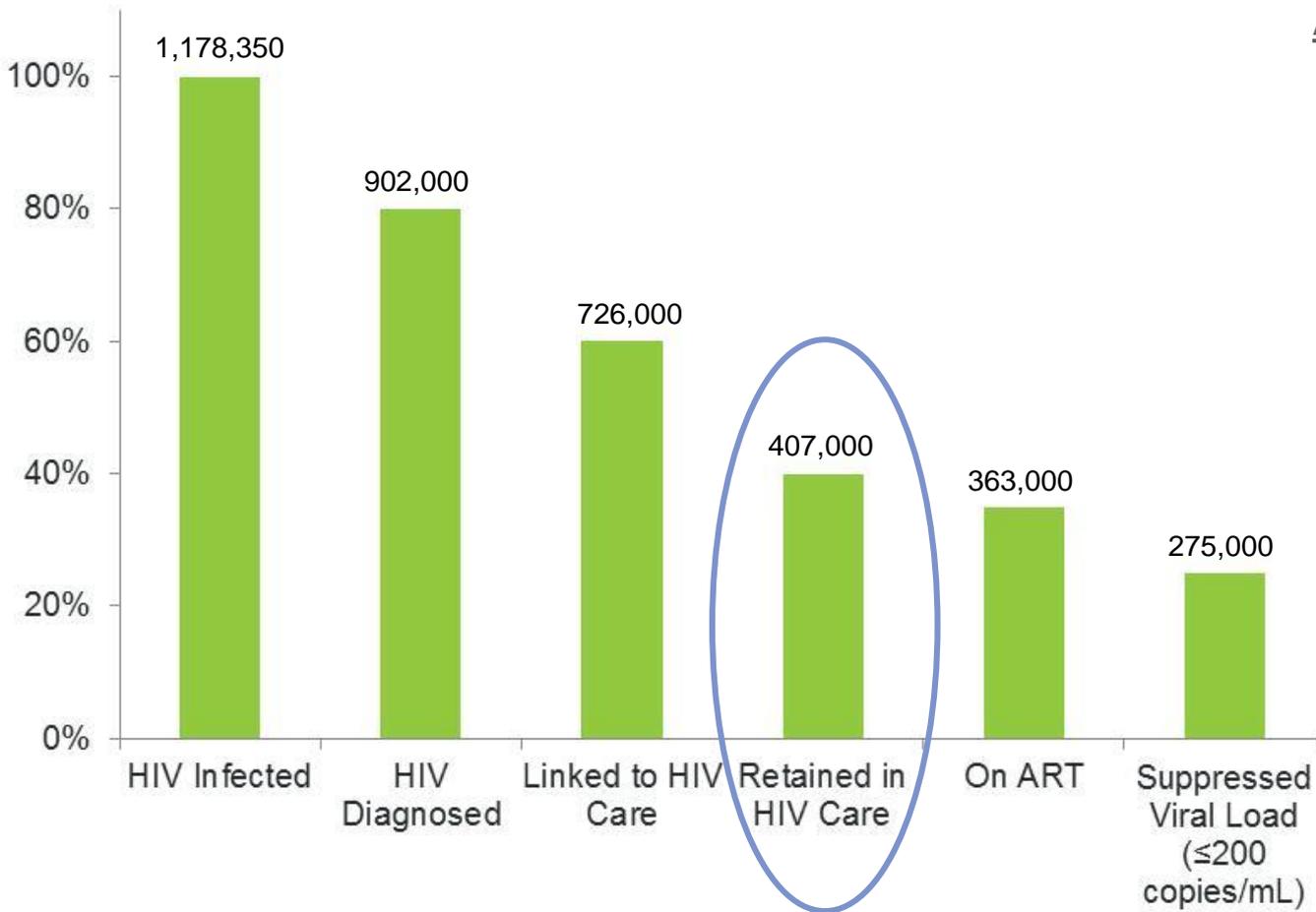
Increasing access to care

Loss to patient follow-up





US HIV Treatment Cascade



Alere CD4

Alere q HIV Viral Load

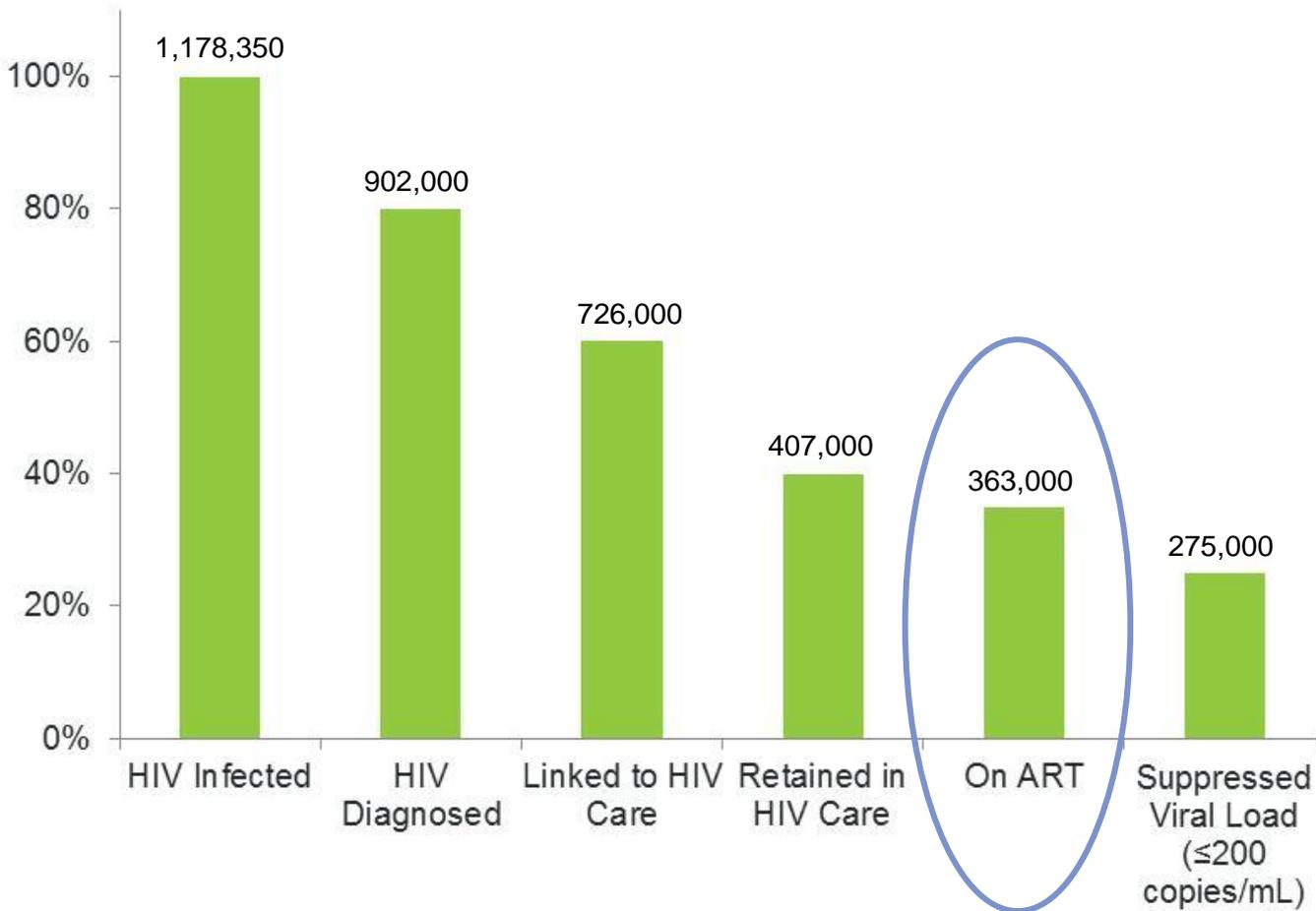
Knowing your #'s





US HIV Treatment Cascade

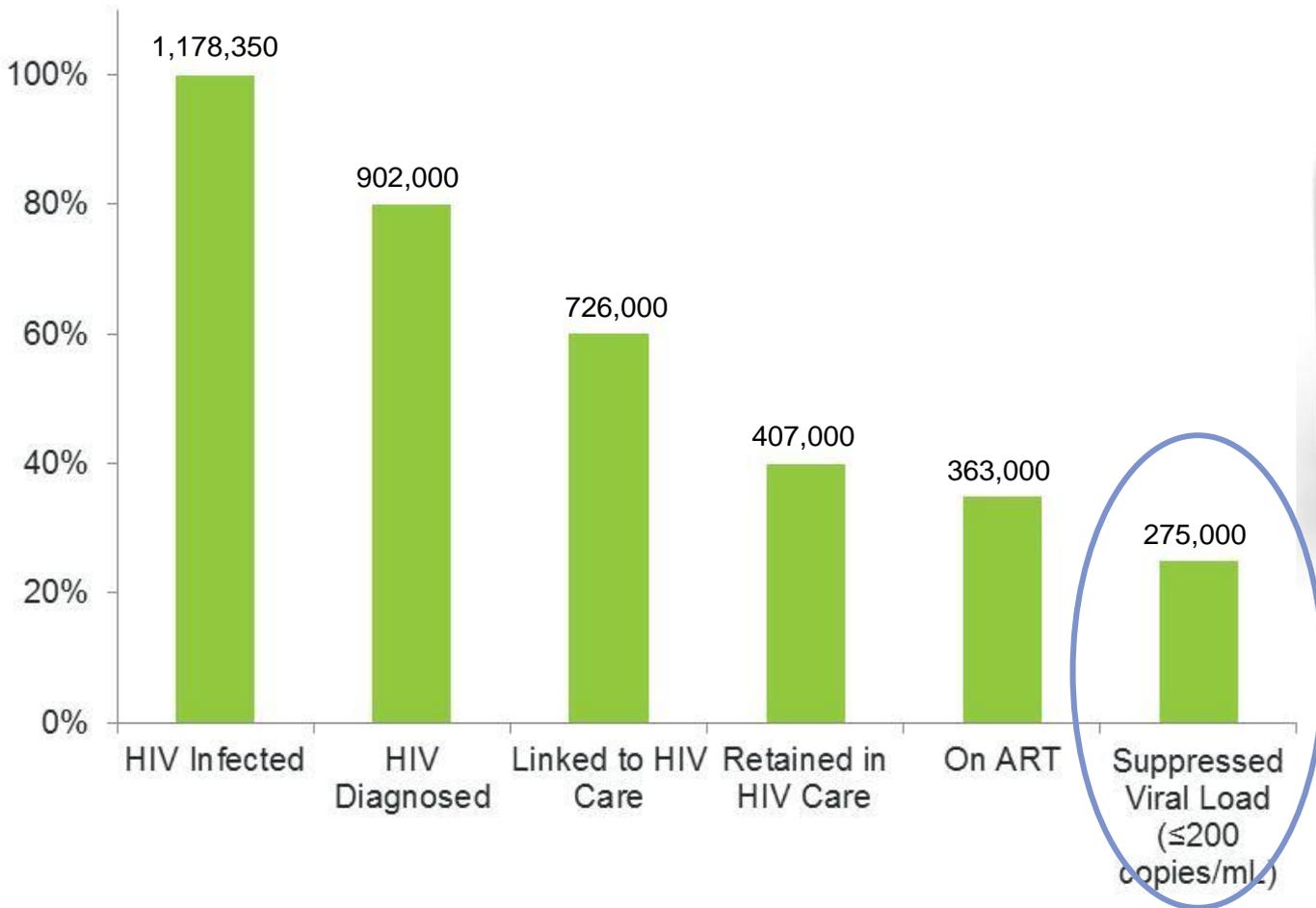
Alere q HIV Viral Load Care Management





US HIV Treatment Cascade

Alere q HIV Viral Load



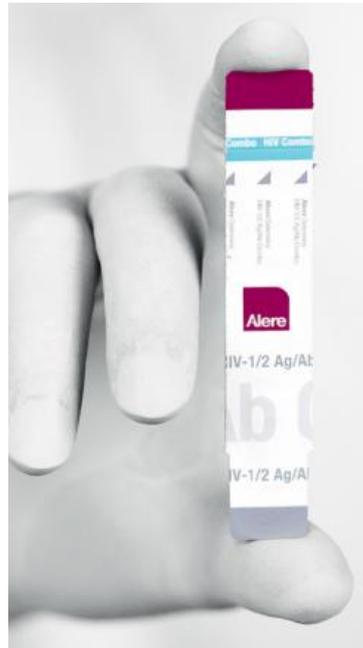


Capability & Capacity: *Meeting the Growing Demands*

Issues	Comments
1. Sustainable Solutions	<ul style="list-style-type: none">• Requires significant resources.<ul style="list-style-type: none">◦ Scale Up, Training, Supply logistics, Validation of new technologies.◦ Larger companies have the resources but often the time horizons for return on investment are misaligned with market realities, especially in the developing world.◦ Smaller companies struggle with this.
2. Complexity of Regulatory Processes and Duplication of Validation Procedures.	<ul style="list-style-type: none">• Requirements are variable and often specific to each individual country.<ul style="list-style-type: none">◦ There exists significant duplication of validation processes in the developing world.
3. Pricing	<ul style="list-style-type: none">• Massive downward pressure on pricing, due in part, the large scale tender in HIV screening in the dev. world. (Global Fund, US gov., Etc.)<ul style="list-style-type: none">◦ Numerous cases where huge tenders were filled at a loss.



Alere Infectious Disease POC Diagnostics



END... Tour of Britain





Back Up Slides

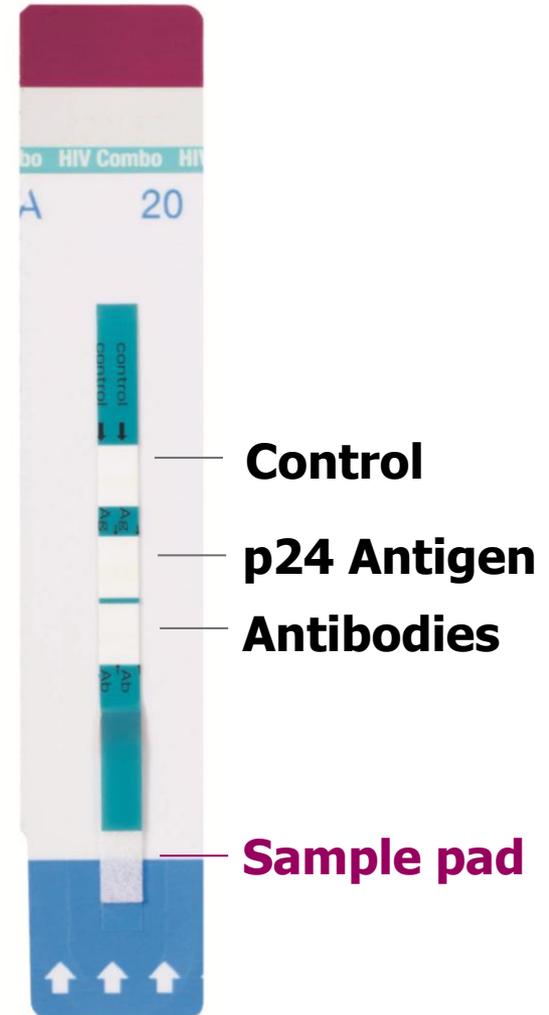


Alere Determine™ Combo

Product Information

Information Type	Product Detail
Method	Lateral flow
Time to results	20 minutes
Results window	20-30 minutes after starting test
Test lines	HIV-1 p24 antigen HIV-1/2 antibodies
Storage conditions	2-30 °C (36-86 °F)
Test shelf life	14 months
Sample type	Whole blood/serum/plasma

- Approved for Moderate Complexity
- Conducting CLIA Waiver Studies





Alere™ CD4 Analyzer



- The world's first point-of-care CD4 Analyzer
- Results <20 minutes
- No External calibration
- On-board data archive
- Disposable cartridge
- Dried reagents
- “Connectivity”



Alere™ q HIV-1/2 (In Development)



- The world's first point-of-care viral load assay for HIV-1 and HIV-2
- Viral load monitoring and molecular HIV diagnosis
- Exquisite Quantification
- “Connectivity”
- Currently in development.



Alere HIV Portfolio: Roadmap

Covering the full spectrum from prevention & wellness to diagnosis, staging, monitoring therapy and disease progression



PREVENTION & DIAGNOSIS 

Includes Health & Wellness, education, HIV Pre-exposure Prophylaxis (PrEP), screening, Early (acute) case detection



STAGING 

Disease & immune system staging for therapy initiation



MONITORING 

Management, optimization of therapies, Rx resistance indicators (genotyping/phenotyping), palliative care throughout care continuum



CO-MORBIDITIES 

Screening for co-morbidities, complications, opportunistic infections. Include, but not limited to, respiratory, gastro-intestinal, STDs, cardiovascular and cancers

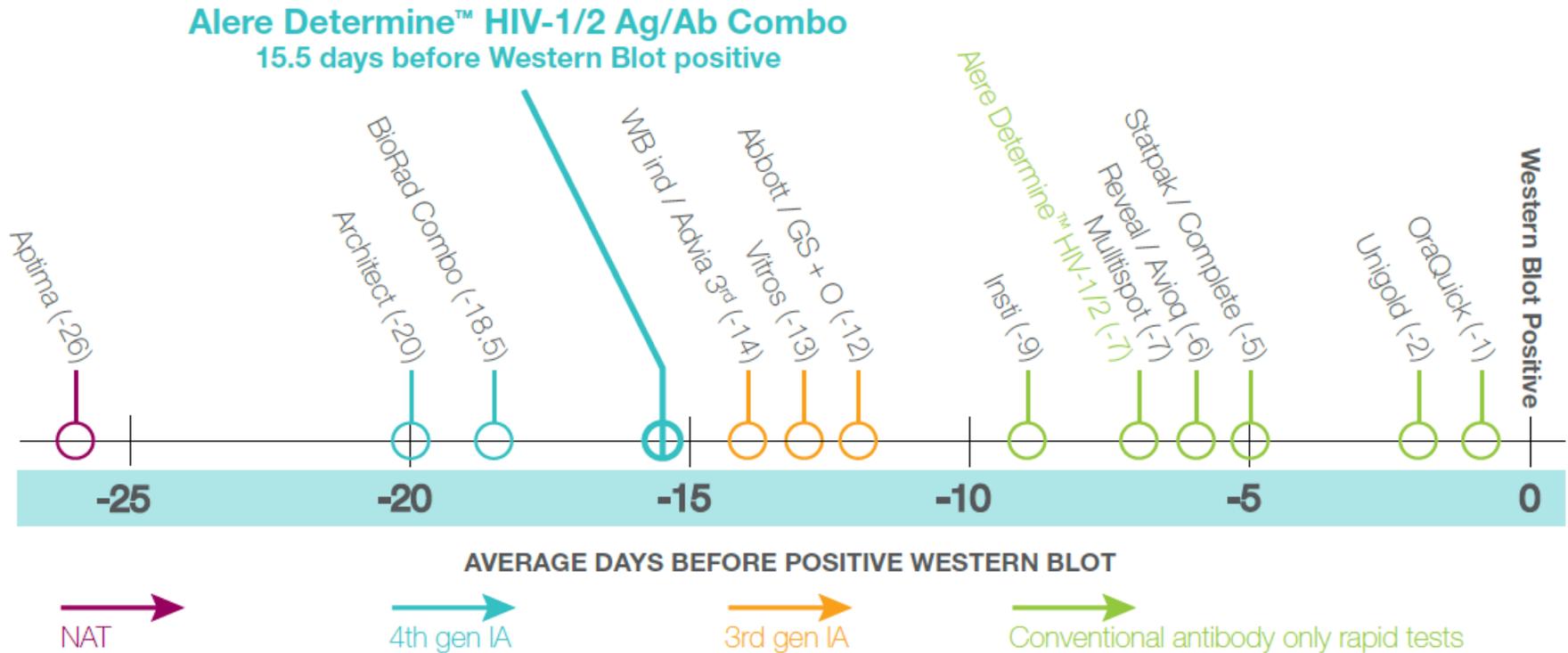


All Platforms (CD4, Alere q, Alere i) to deploy with connectivity and relevant Informatics/Data Management 

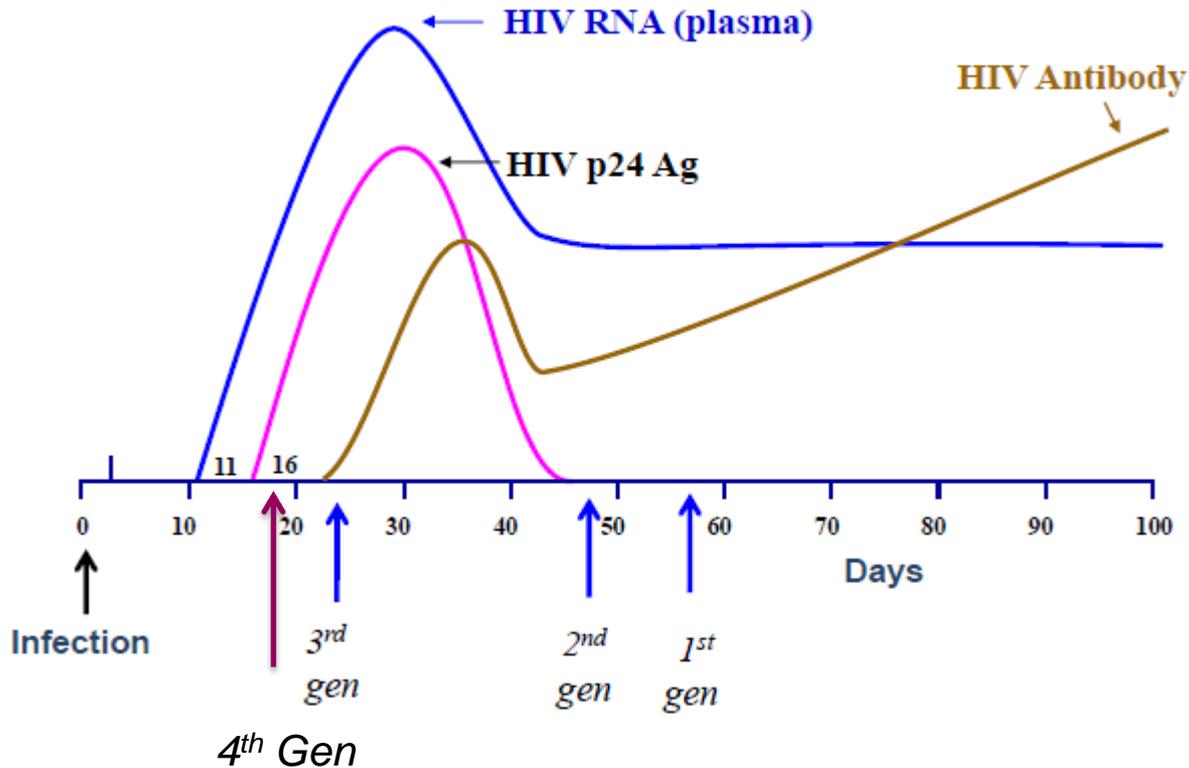


Changing Perception

Sensitivity of assay reactivity during early HIV-1 infections relative to number of days before first positive Western Blot



HIV Infection & Laboratory Markers

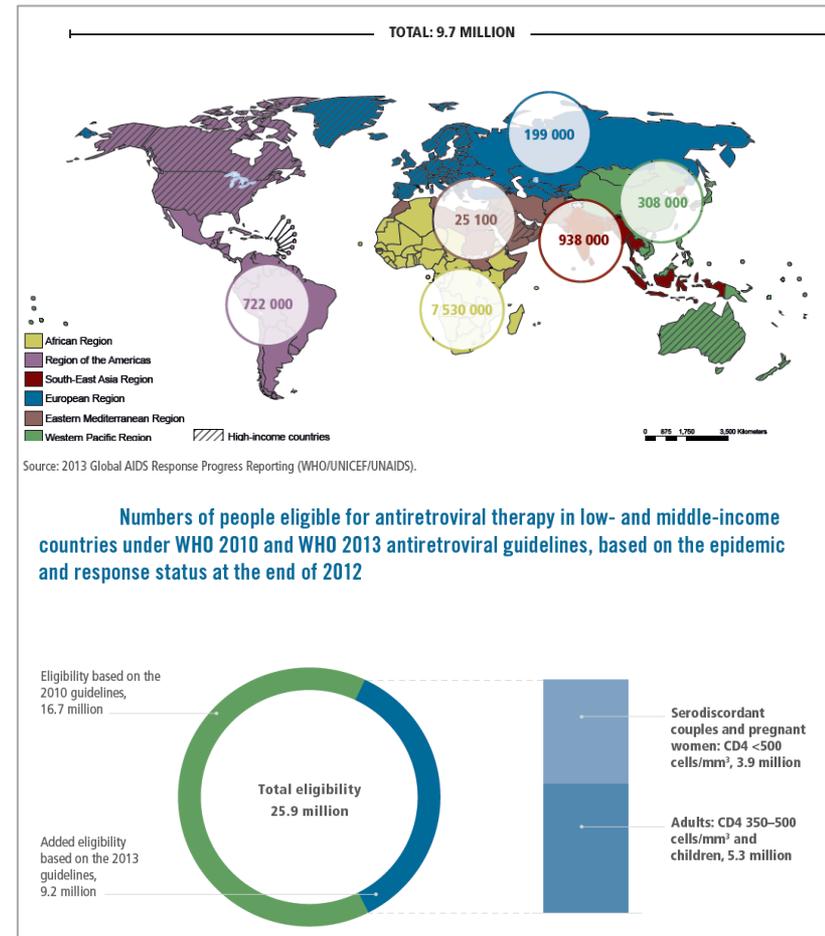


- Appearance of markers for HIV infection vary over time
- Viral RNA is first detectable marker
- Antibodies do not appear during early infection
- Antigen appears early (alone) and later complexed with antibodies

Modified after Busch et al. Am J Med. 1997

HIV/AIDS: Global Trends

- Globally, ~34.0 million people were living with HIV at the end of 2011.
 - Globally, the number of HIV+ individuals are expected to grow from 34M to 47M by 2020
 - Sub-Saharan Africa remains most severely affected, with nearly 1 in every 20 adults (4.9%) living with HIV and accounting for 69% of the people living with HIV worldwide.
 - ~5 million people are living with HIV in South, South-East and East Asia combined.
 - ~2.5M people are newly infected each year (declining)
- Antiretroviral therapy Guidelines updated by WHO (July 2013)
 - Currently 9.7M people on ART of 16.7M that would qualify – CD4 count <350 (2010 guidelines)
 - 2013 WHO Guidelines increased initiation threshold to a CD4 count of 500 = 25.9M now eligible for ART
- Acute HIV identification becoming increasingly important. Identifying persons with acute HIV infection is viewed as an effective HIV prevention strategy.
- Significant increase in HIV testing is expected due to availability of pre-exposure prophylaxis (PrEP) prevention interventions
 - TRUVADA received FDA Advisory Panel approval for use in PrEP in 2012.
 - The need for effective HIV-1 prevention has never been greater

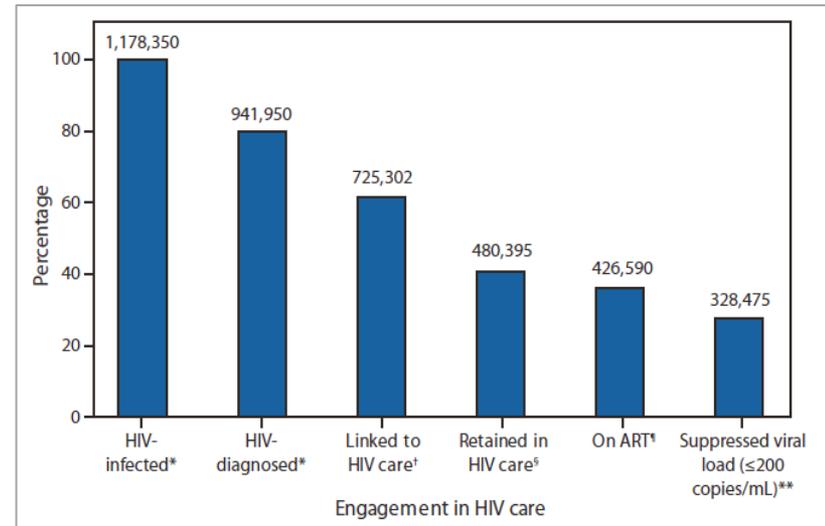




HIV/AIDS: United States Trends

- **Goals of the US National HIV/AIDS Strategy**

- Reducing New HIV infections ... (by 2015):
 - Lower the annual number of new infections by 25%
 - Reduce the HIV transmission rate by 30%
 - Increase the % of people living with HIV who know their serostatus from 79% to 90%
- Increasing Access to Care & Improving Health Outcomes for People Living with HIV... (by 2015):
 - Increase the proportion of newly diagnosed patients linked to clinical care within three months of their HIV diagnosis from 65% to 85%
 - Increase the proportion of Ryan White HIV/AIDS Program clients who are in continuous care from 73% to 80%
- Reducing HIV-Related Health Disparities ... (by 2015):
 - Improve access to prevention and care services for all Americans
 - By 2015, increase the proportion of HIV diagnosed gay and bisexual men, Blacks and Latinos with undetectable viral load by 20%



- **Loss to follow-up is one of the largest challenges to the US HIV care system**
 - This can occur at any one of the steps across a continuum of care
- According to the US CDC*, only 28% of all persons living with HIV infection in the US are virally suppressed (some studies put this as low as 15%)
- In the latest version of the US DHHS Guidelines...“Regardless of CD4 count, initiation of ART is strongly recommended...”
 - However, most KOLs will continue to use CD4 in disease staging and as a surrogate marker of disease progression.
- The recently released study findings of HPTN 052 demonstrated a 96% reduction in HIV transmission among serodiscordant couples attributable to viral load suppression
 - These findings have additional evidence support for the treatment as prevention paradigm