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U.S. President's Emergency Plan for AIDS Relief

Monitoring, Evaluation, and Reporting (MER) Guidance (v.2.4): LABORATORY

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Date: November 2019

Video Outline

- 1) **Section 1:** Overview of the technical area and related indicators
- 2) **Section 2:** Indicator changes in MER 2.4
- 3) **Section 3:** Review of numerator, denominator, and disaggregations.
 - What is the programmatic justification and intention for the data being collected?
 - How are program managers expected to use this data to make decisions that will improve PEPFAR programming?
 - How does it all come together? How should the data be visualized (e.g., cascades)? How do these indicators relate to other MER indicators?
- 4) **Section 4:** Overview of guiding narrative questions
- 5) **Section 5:** Data quality considerations for reporting and analysis
- 6) **Section 6:** Additional Resources and Acknowledgments

Section 1: Overview of the technical area and related indicators



Overview of Technical Area and Indicators

- Laboratories are essential for both diagnosing and monitoring patients with HIV and TB
- PEPFAR-supported laboratory activities aim to expand the availability of laboratory services and ensure testing quality
- Monitoring for PEPFAR-supported laboratory programs focuses on:
 - Engagement in continuous quality improvement (CQI)
 - Engagement in proficiency testing (PT)
 - Number of specimens received for testing

Program Area Group	Indicator Code	Indicator Name	Reporting Frequency	Reporting Level
Health Systems	LAB_PTCQI	<ul style="list-style-type: none"> • Number of PEPFAR-supported laboratory-based testing and/or Point-of-Care Testing (POCT) sites engaged in continuous quality Improvement (CQI) and proficiency testing (PT) activities. • Number of specimens received for testing at PEPFAR-supported laboratory-based testing and/or Point-of-Care Testing (POCT) sites 	Annual	Facility

Section 2: Indicator changes in MER 2.4



What's Changed?

- Removed the “Other” test category from the indicator.
- Added Rapid Test for Recent Infection (RTRI) test category.
- CQI and PT status, as well as the number of specimens received, will now be reported for RTRI

Section 3: Review of numerator, denominator, and disaggregations

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Numerator, Denominator, and Disaggregate Groups

LAB_PTCQI captures data on three metrics at two types of testing sites

↓
CQI engagement
PT engagement
of specimens received

↓
Laboratory-based
Point-of-care (POC)

of lab-based testing sites engaged in CQI by test category

of POCT sites engaged in CQI by test category

Numerator:

of lab-based testing sites engaged in PT by test category

of POCT sites engaged in PT by test category

of specimens received at lab-based testing sites by test category

of specimens received at POCT sites by test category

Denominator: N/A

Definitions of Disaggregates

- Engagement in CQI*

CQI participation: engaged in activities supported by a CQI or accreditation preparedness program

External audit: documented assessment conducted by a qualified external auditor

Accreditation: accreditation by a national, regional, or internationally-recognized accreditation body

- Engagement in PT*

PT participation: enrollment in a PT program

Passing PT: last scheduled and completed PT panel was scored as satisfactory by the PT provider

- # of Specimens Received

A specimen is received for testing if its arrival at the site was recorded in a register/log book and/or LIS within the reporting timeframe

*refer to the LAB_PTCQI indicator reference sheet for specifics and definitions for POCT sites

How to Count LAB_PTCQI

- PEPFAR-supported testing sites may receive:
 - DSD or TA from PEPFAR
 - Specimens from PEPFAR-supported clinics
 - PT panels via PEPFAR-support
- Testing sites may be laboratory-based or point-of-care



Laboratory-based testing sites:

- Dedicated laboratory infrastructure
- Laboratorians performing testing



POCT sites:

- At or near place of interaction with the patient
- No dedicated laboratory infrastructure
- May not have laboratorians performing testing

Facilities may have ≥ 1 laboratory-based testing sites, ≥ 1 POCT sites or both lab-based and POCT sites.

Disaggregates

(LAB_PTCQI, Laboratory, CQI)

Test Category	# of sites that perform test but do not participate in CQI	# of sites that perform test and participate in CQI, but have not been externally audited	# of sites that perform test, participate in CQI, and have been externally audited, but are not fully accredited	# of sites that perform test, participate in CQI, have been externally audited and are fully accredited
HIV Serology				
HIV IVT/EID				
HIV Viral Load				
TB Xpert				
TB AFB				
TB Culture				
CD4				
RTRI				

Disaggregates

(LAB_PTCQI, POCT, CQI)

Test Category	# of sites that perform test but do not participate in CQI	# of sites that perform test and participate in CQI, but have not been externally audited	# of sites that perform test, participate in CQI, and have been externally audited and achieved a score of 0-1 ($\leq 59\%$)	# of sites that perform test, participate in CQI, and have been externally audited and achieved a score of 2-3 (60%-89%)	# of sites that perform test, participate in CQI, and have been externally audited and achieved a score of 4-certified ($\geq 90\%$)
HIV Serology					
HIV IVT/EID					
HIV Viral Load					
TB Xpert					
TB AFB					
CD4					
RTRI					

Disaggregates

(LAB_PTCQI, Laboratory, PT)

Test Category	# of sites that perform test but do not participate in PT	# of sites that perform test and participate in PT, but did not pass last round	# of sites that perform test, participate in PT, and passed last round
HIV Serology			
HIV IVT/EID			
HIV Viral Load			
TB Xpert			
TB AFB			
TB Culture			
CD4			
RTRI			

Disaggregates

(LAB_PTCQI, POCT, PT)

Test Category	# of sites that perform test but do not participate in PT	# of sites that perform test and participate in PT, but did not pass last round	# of sites that perform test, participate in PT, and passed last round
HIV Serology			
HIV IVT/EID			
HIV Viral Load			
TB Xpert			
TB AFB			
CD4			
RTRI			

Disaggregates

(LAB_PTCQI, Laboratory, specimens received)

Test Category	# of specimens received for testing
HIV Serology	
HIV IVT/EID	
HIV Viral Load	
TB Xpert	
TB AFB	
TB Culture	
CD4	
RTRI	

Disaggregates

(LAB_PTCQI, POCT, specimens received)

Test Category	# of specimens received for testing
HIV Serology	
HIV IVT/EID	
HIV Viral Load	
TB Xpert	
TB AFB	
CD4	
RTRI	

How to use LAB_PTCQI

- For complex **laboratory-based** tests such as:
HIV Viral Load
HIV IVT/EID
TB Culture
100% of PEPFAR-supported sites should be enrolled in proficiency testing and working toward accreditation (have been audited or are fully accredited)
- All other laboratory-based and POC testing sites should strive to have all sites enrolled in PT and CQI.

Navigating the HSS Dossier

User must select "Lab" or "POCT" to view the appropriate data.

The screenshot displays the PEPFAR HSS Dossier interface. At the top, there are filters for PSNU, Fiscal Period (2018 Q4), Funding Agency, and Prime Partner. A dropdown menu for "Select a Lab Site Type (Required)" is highlighted with a red oval, showing options for "(All)", "Lab", and "POCT". Below this is a summary table of key metrics:

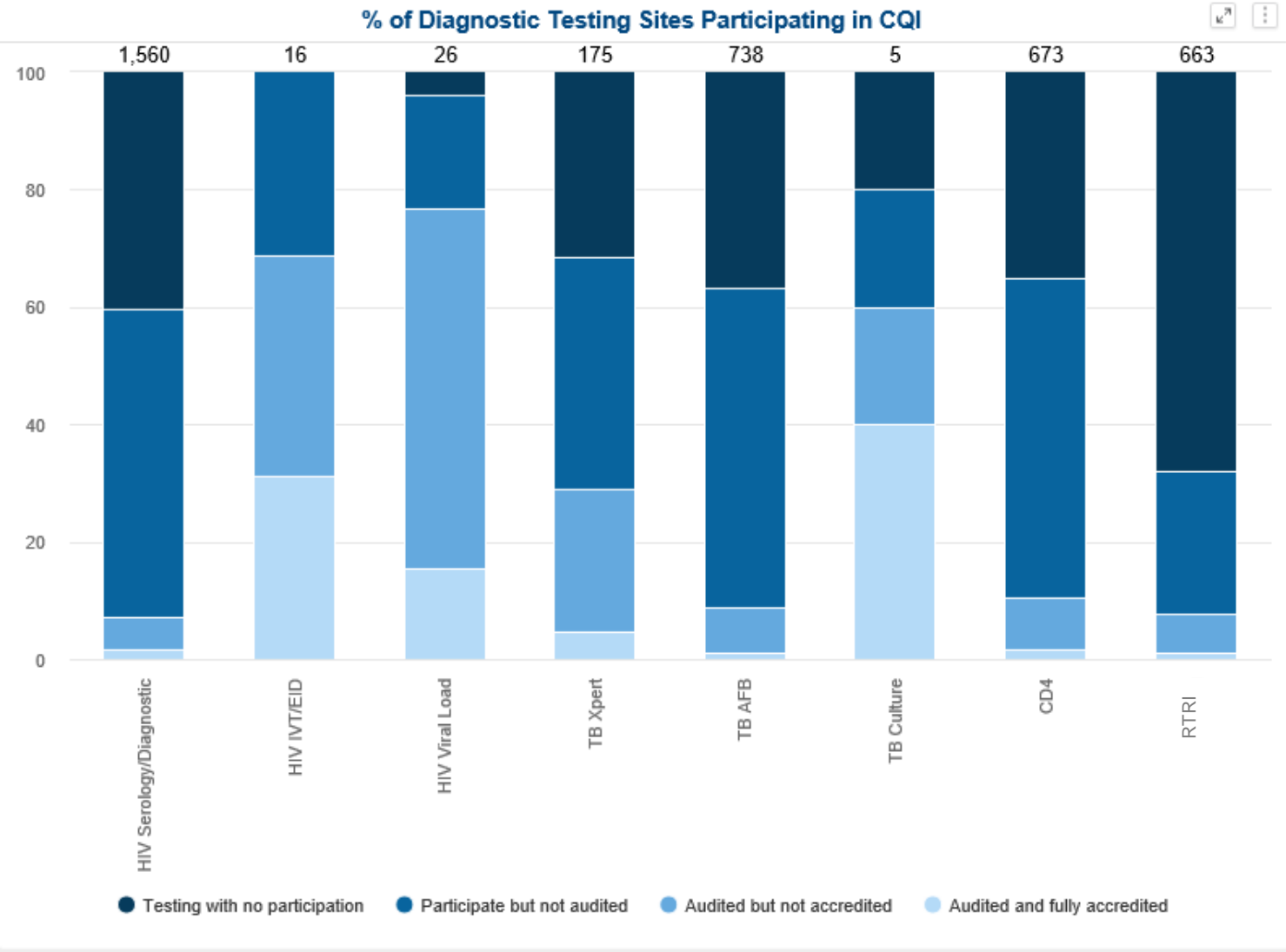
Total	HIV Serology/Diagnostic	IVT/EID	Viral Load	TB Xpert	TB AFB	TB Culture	CD4
1,506,875	111,235	31,270	205,716	101,884	172,721	4,362	594,047

Below the table are two bar charts showing the percentage of diagnostic testing sites participating in CQI and PT. The CQI chart shows participation levels for HIV Serology/Diagnostic, HIV VIT/EID, HIV Viral Load, TB Xpert, TB AFB, TB Culture, CD4, and RTRI. The PT chart shows participation levels for the same categories. A legend at the bottom of each chart indicates participation status: Testing with no participation (dark blue), Participate but not audited (medium blue), Audited but not accredited (light blue), and Audited and fully accredited (very light blue).

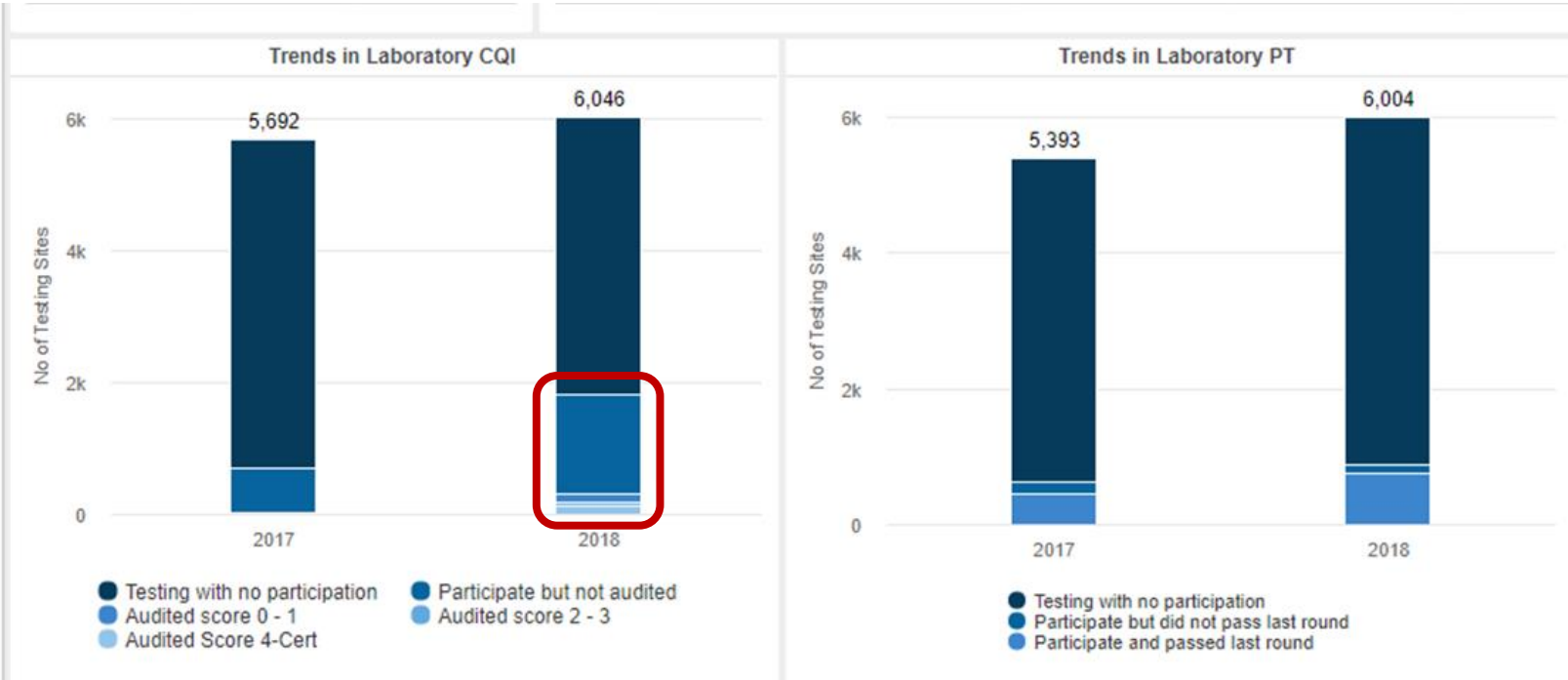
LAB_PTCQI Chapter

LAB_PTCQI
OU Lab Quality
Trends in LAB_PTCQI
Lab Quality by Partner and Region

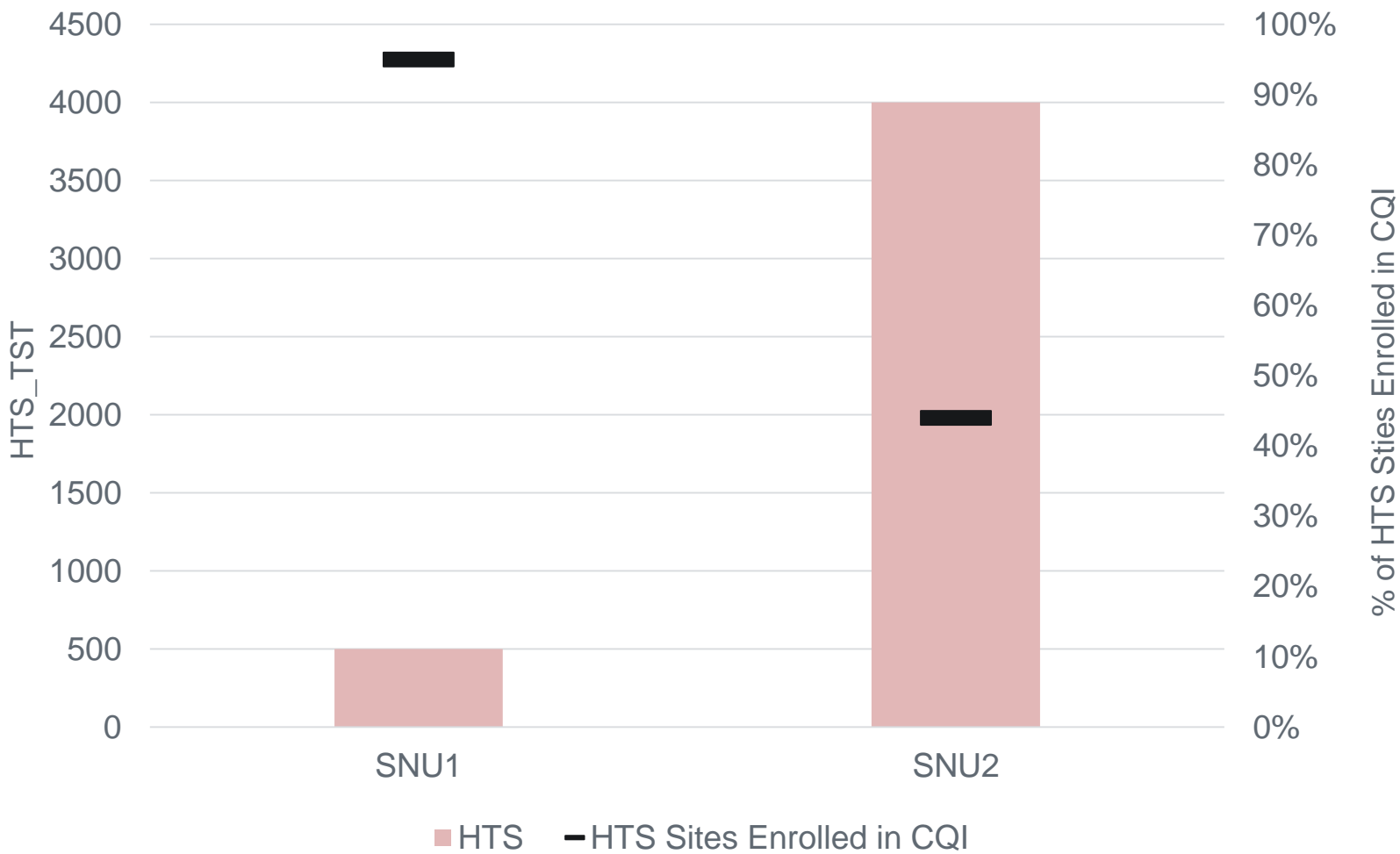
HSS Dossier: OU Lab Quality



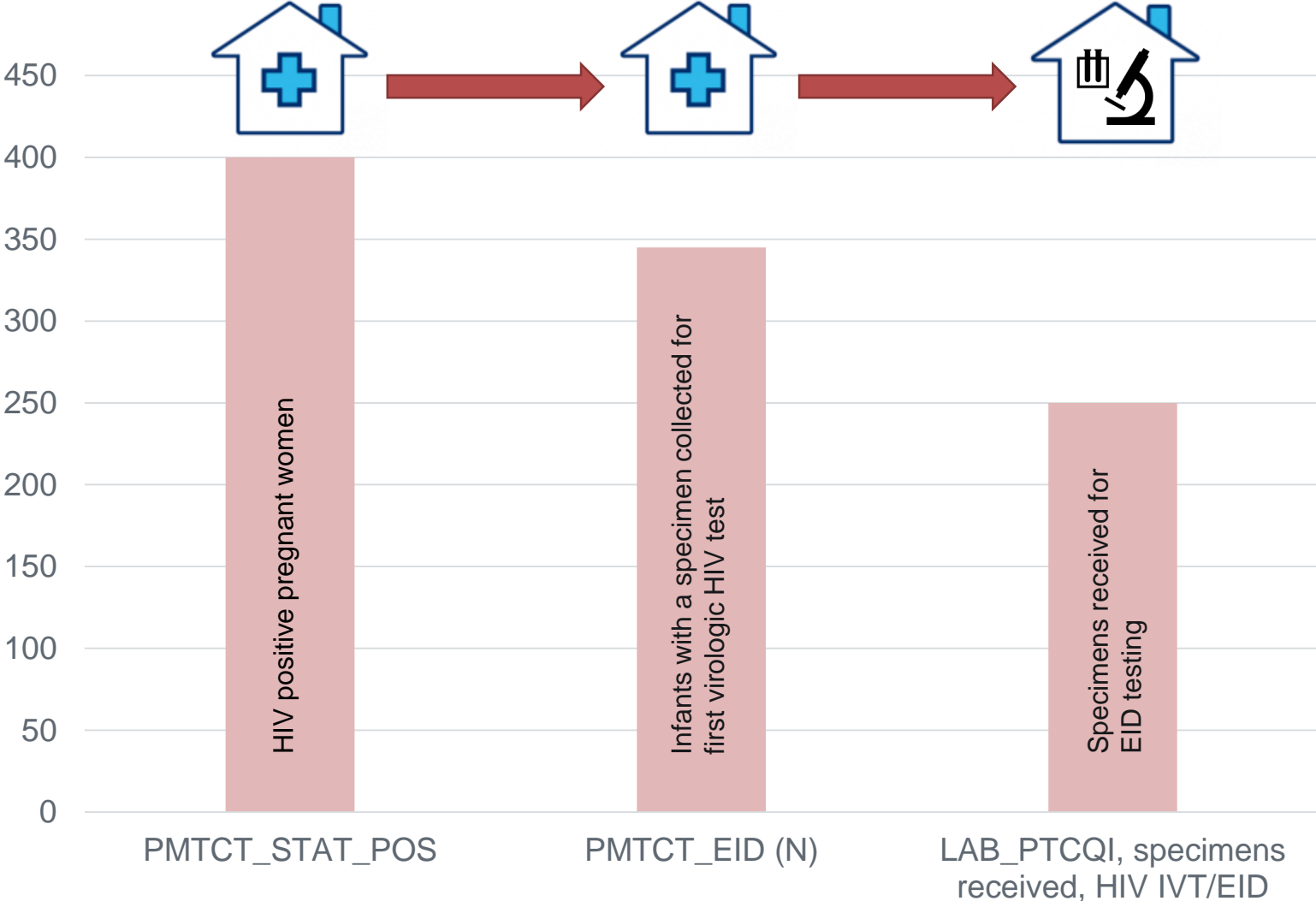
HSS Dossier: Trends in LAB_PTCQI



Context for HTS Results



Clinic-Lab Interface



Section 4: Overview of guiding narrative questions



Guiding Narrative Questions

- Take the opportunity to explain known or perceived gaps in laboratory quality.
- In the narrative, please define how the specimen volume was counted (i.e., specimen log, LIS, etc.).

Section 5: Data quality considerations for reporting and analysis

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Data quality considerations

- Sites conducting HIV rapid testing are POCT unless the testing is conducted in a laboratory by laboratorians.
- The numerator is automatically summed across CQI and PT data elements for each testing category. This sum should equal the total number of laboratory-based testing and/or POCT sites in each testing category at the facility.

LAB_PTCQI (Lab-based)					- Collapse
Required	Enter the number of PEPFAR supported laboratory based sites or blood bank/centers performing the following tests and their current CQI status at this facility.				
	How many sites perform this test but do not participate in CQI?	How many sites perform this test and participate in CQI, but have not been externally audited or accredited?	How many sites perform this test, participate in CQI, have been externally audited, but do not meet full accreditation standards?	How many sites perform this test, participate in CQI, have been externally audited & are fully Accredited?	Total number of sites performing this test supported at this Facility?
HIV Viral Load	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	Subtotal

Section 6: Additional Resources and Acknowledgments

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Acknowledgments

- These slides were adapted from slides originally developed by Peter Minchella.



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Thank you