

# Expanding Viral Load through Partnerships: Performance Evaluation of Cepheid GeneXpert HIV-1 Viral Load Assay in Botswana

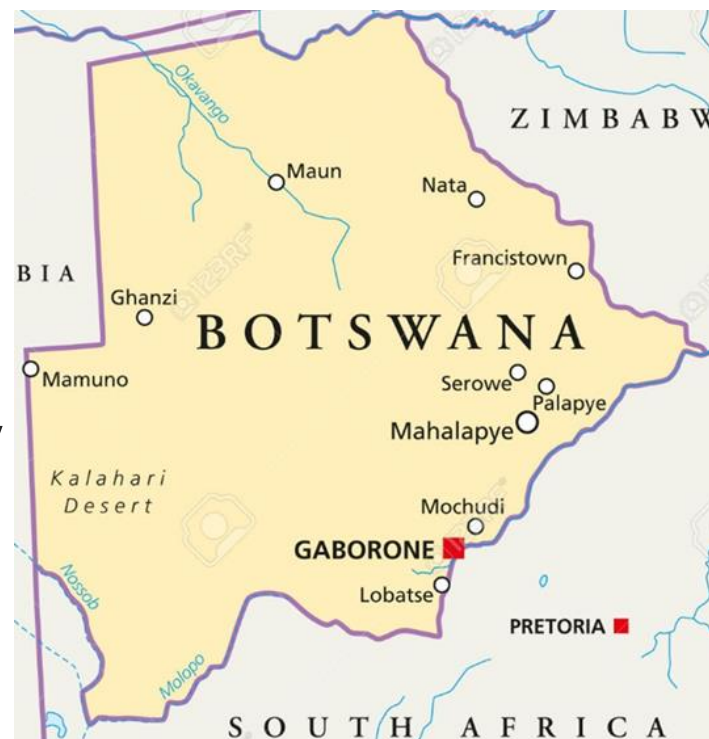
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# Botswana HIV Background Information

- ❑ Adults aged 15 to 49 prevalence - 22.2%
- ❑ The Botswana National ARV guidelines defines virologic failure as a viral load  $>400$  cp/mL
- ❑ 34 GeneXpert platforms currently in use for TB



# **Xpert Viral Load: Primary Objective**

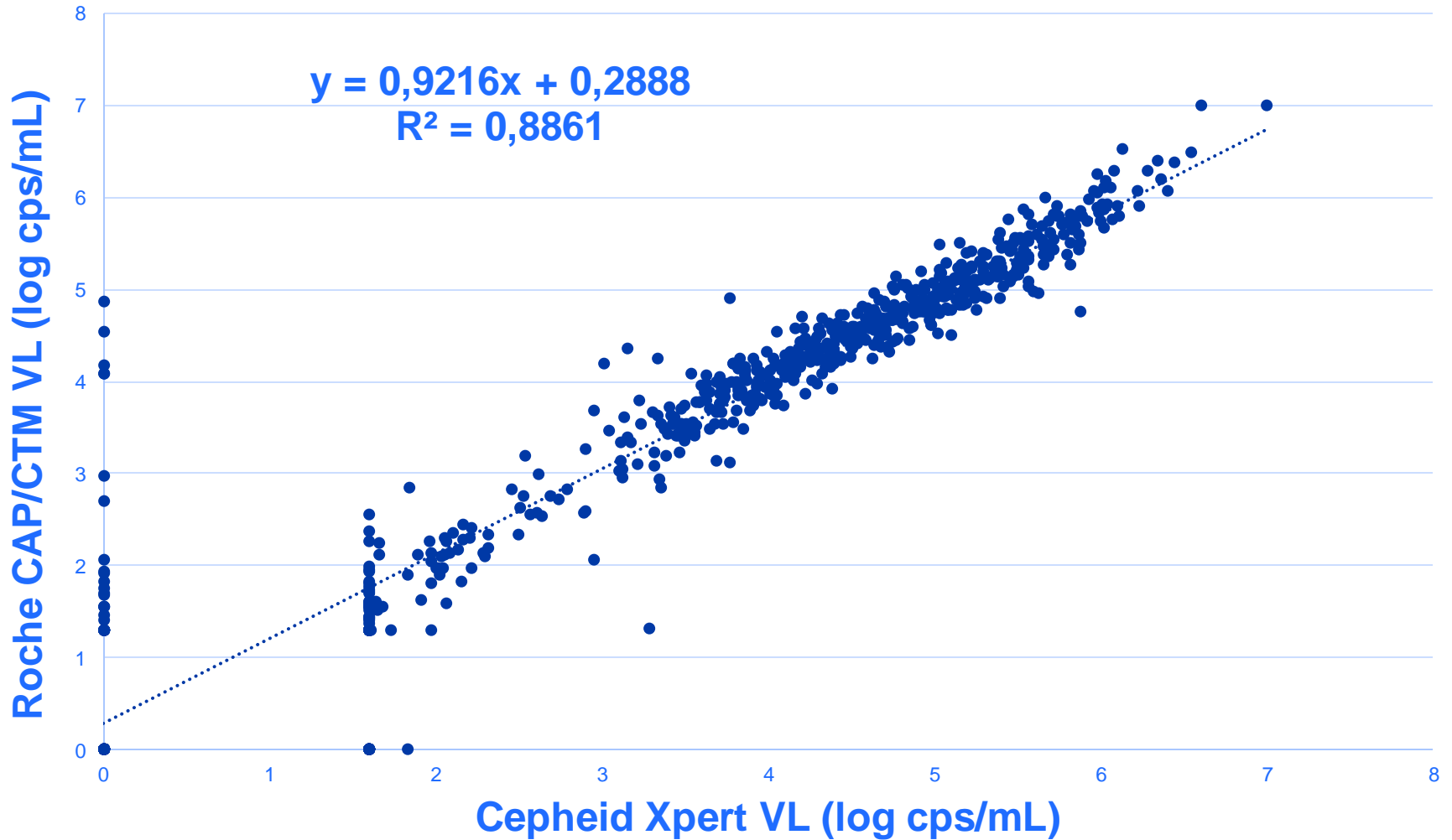
- ❑ **To evaluate the performance and quality of Cepheid's Xpert HIV-1 Viral Load plasma assay compared to a current gold standard test used in Botswana (Roche CAP/CTM HIV-1 V2.0) using clinical specimens from 4 clinical sites**
  - Agreement/concordance with reference standard
  - Misclassification rate
  - Sensitivity and specificity of the assay compared to the reference standard above and below the WHO cutoff and Botswana National guidelines for virological failure
  - Bias and the Standard Deviation of the mean difference between the Xpert VL test result and the reference standard will also be calculated

# Xpert Viral Load: Methods

- ❑ **Study population: HIV positive adults initiating ART or returning for 3,6,or 12 month VL visit or re-initiating ART after a default**
  
  - ❑ **During blood draw for baseline labs for ART initiation or follow-up labs on ART>3 months, draw 1 extra 10ml tube**
    - Centrifugation and processing at Xpert testing site
  
  - ❑ **Conduct VL testing using:**
    - Xpert HIV-1 VL assay
      - Area W Clinic Laboratory (Francistown)
      - National TB Reference Laboratory (Gaborone)
    - Roche (Reference Standard)
      - Botswana-Harvard National HIV Reference Laboratory (Gaborone)
      - Nyangabgwe Hospital HIV Reference Laboratory (Francistown)
- \*Note: results returned for all Roche tests



# Correlation of the Xpert and Roche Plasma VL n=746



# Sensitivity and Specificity at 400 and 1000 cps/mL

**400 cps/mL**

**1000 cps/mL**

<b>Sensitivity</b>	<b>97.80%</b>
<b>Specificity</b>	<b>97.00%</b>
<b>False Failures (upward)</b>	<b>3.00%</b>
<b>False Treatment Successful (downward)</b>	<b>2.20%</b>

<b>Sensitivity</b>	<b>98.50%</b>
<b>Specificity</b>	<b>98.12%</b>
<b>False Failures (upward)</b>	<b>1.88%</b>
<b>False Treatment Successful (downward)</b>	<b>1.50%</b>

## Cepheid Xpert VL Errors

- **Xpert instrument error rate 1.2% (9/746)**
  - 2037 (n=2)-Cartridge integrity test failed
  - 2123, 2124-Loss of connectivity/reconnection error
  - 2097 (n=3)-Incorrect specimen volume
  - 2008-Syringe pressure error
  - 2096-No specimen added

## Conclusions

- ❑ Data here suggest Xpert is suitable for VL testing but as with any POC instrumentation appropriate placement is important
  1. In-country discussions to determine effective use
  2. Which settings are most fitting given the population
  3. Quality assurance procedures are in place with documentation and corrective action taken when needed
- ❑ Ongoing study, as we continue to gather data on the use of Xpert we will update and disseminate our findings



# Who Are Our Partners?

- ❑ **Study is a true partnership**
  - Ministry of Health Botswana
  - University of Botswana
  - CDC Botswana, TB/HIV Research Unit
  - ASLM Laboratory Fellows



# Acknowledgements

## CDC Atlanta

- ❑ Steve Jadczyk
- ❑ Katrina Sleeman
- ❑ Karidia Diallo
- ❑ Guoqing Zhang
- ❑ Shon Nguyen
- ❑ Mireille Kalou
- ❑ John Nkengasong
- ❑ Linda Fleming
- ❑ Theresa NeSmith
- ❑ Mervi Detorio

## CDC Botswana

- ❑ Alyssa Finlay
- ❑ Rosanna Boyd
- ❑ Anikie Mathoma
- ❑ Unami Mathebula
- ❑ Joyce Basotli

## University of Botswana

- ❑ Prof Ishmael Kasvosve
- ❑ Naledi Nyepetsi
- ❑ Ritah Moathlodloga

## Botswana MOH

- ❑ Dr. Madisa Mine
- ❑ Julia Ngidi
- ❑ Sefetogi Ramaologa

## ASLM Fellows

- ❑ Charity Ralegoreng
- ❑ Otsile Msewele
- ❑ Monei Machailo
- ❑ Maruping Maruping