

# HIV Pre-Exposure Prophylaxis (PrEP) Quantitative HIV RNA Testing

**Joanne Stekler, MD MPH**  
**Professor of Medicine**  
**University of Washington**

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# Disclosures

Only FTC/TDF (Truvada), FTC/TAF (Descovy), and CAB-LA (Apretude) are approved by the U.S. Food and Drug Administration (FDA) and only for use in some, but not all, populations.

This talk may include discussion of non-FDA approved strategies for HIV prevention.

# Disclaimer

Funding for this presentation was made possible by U1OHA29296 from the Human Resources and Services Administration HIV/AIDS Bureau. The views expressed do not necessarily reflect the official policies of the Department of Health and Human Services nor does mention of trade names, commercial practices, or organizations imply endorsement by the U.S. Government. *Any trade/brand names for products mentioned during this presentation are for training and identification purposes only.*

# Case

“Hi Joanne, I wanted to check on a participant ... whose  
[lab] HIV RNA was 238  
POC RNA was >1000.

This pt reports good adherence and a fill schedule that matches...”

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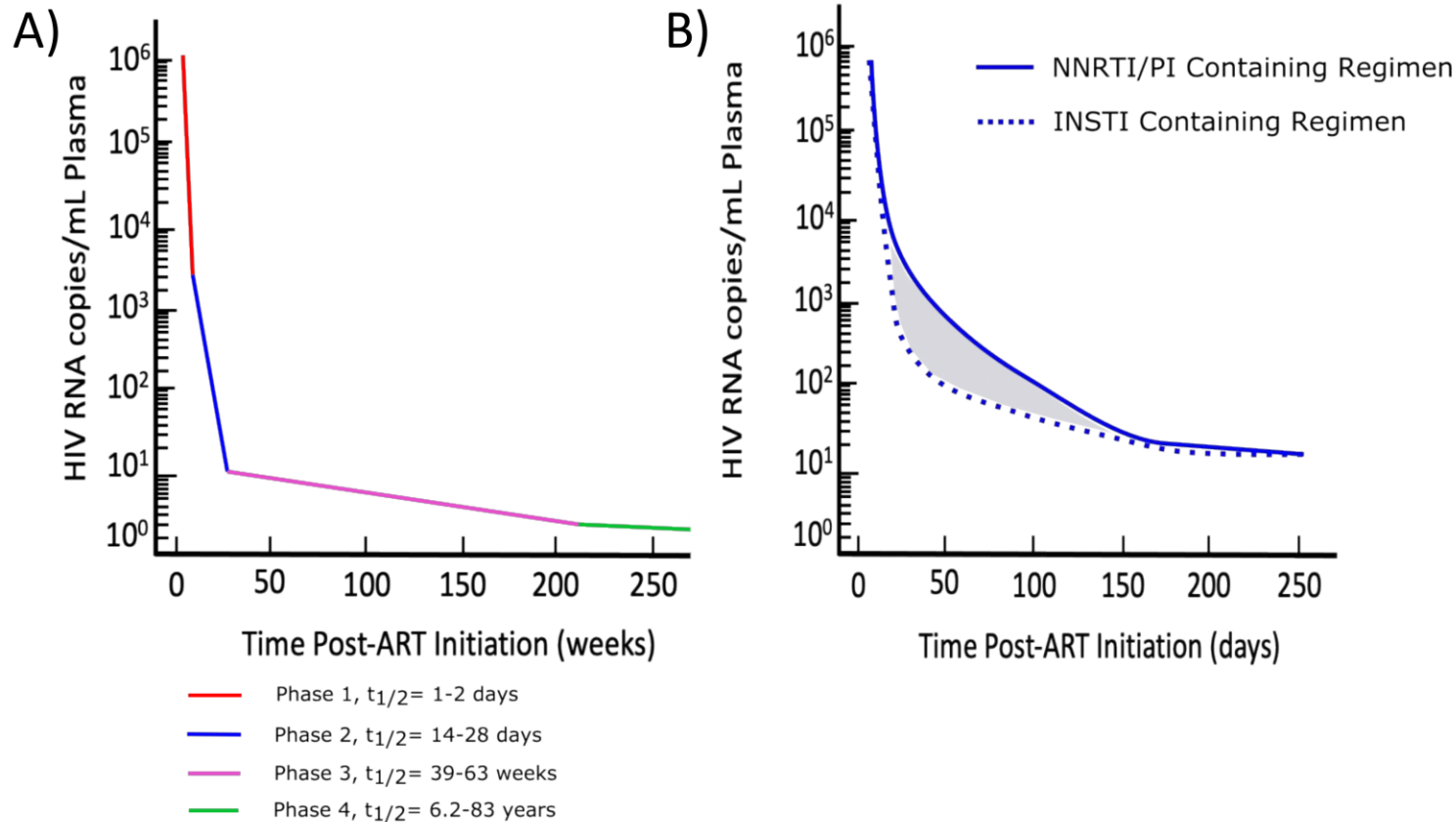
How do you interpret these test results?

# How do you interpret these test results? (poll)

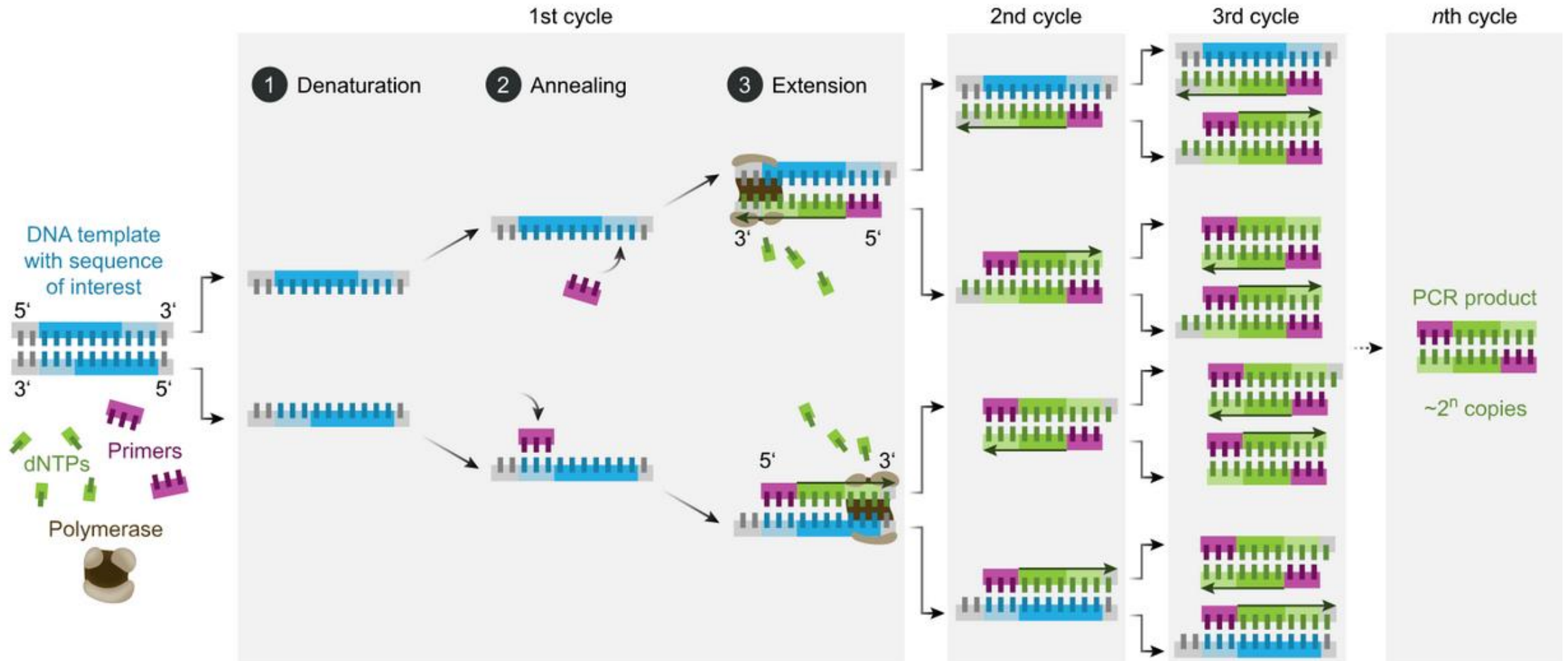
- A. One of these tests is a bad test.
- B. This is an example of that primer mismatch you always talk about.
- C. This is normal. HIV RNA tests can differ in results by up to 10-fold.
- D. You're trying to trick me. It won't work.

# What do “viral load” tests measure?

- “Viral load” tests measure HIV-1 RNA in blood plasma
  - From actively replicating virus
  - From cells that are releasing virus particles



# How do viral load tests work?



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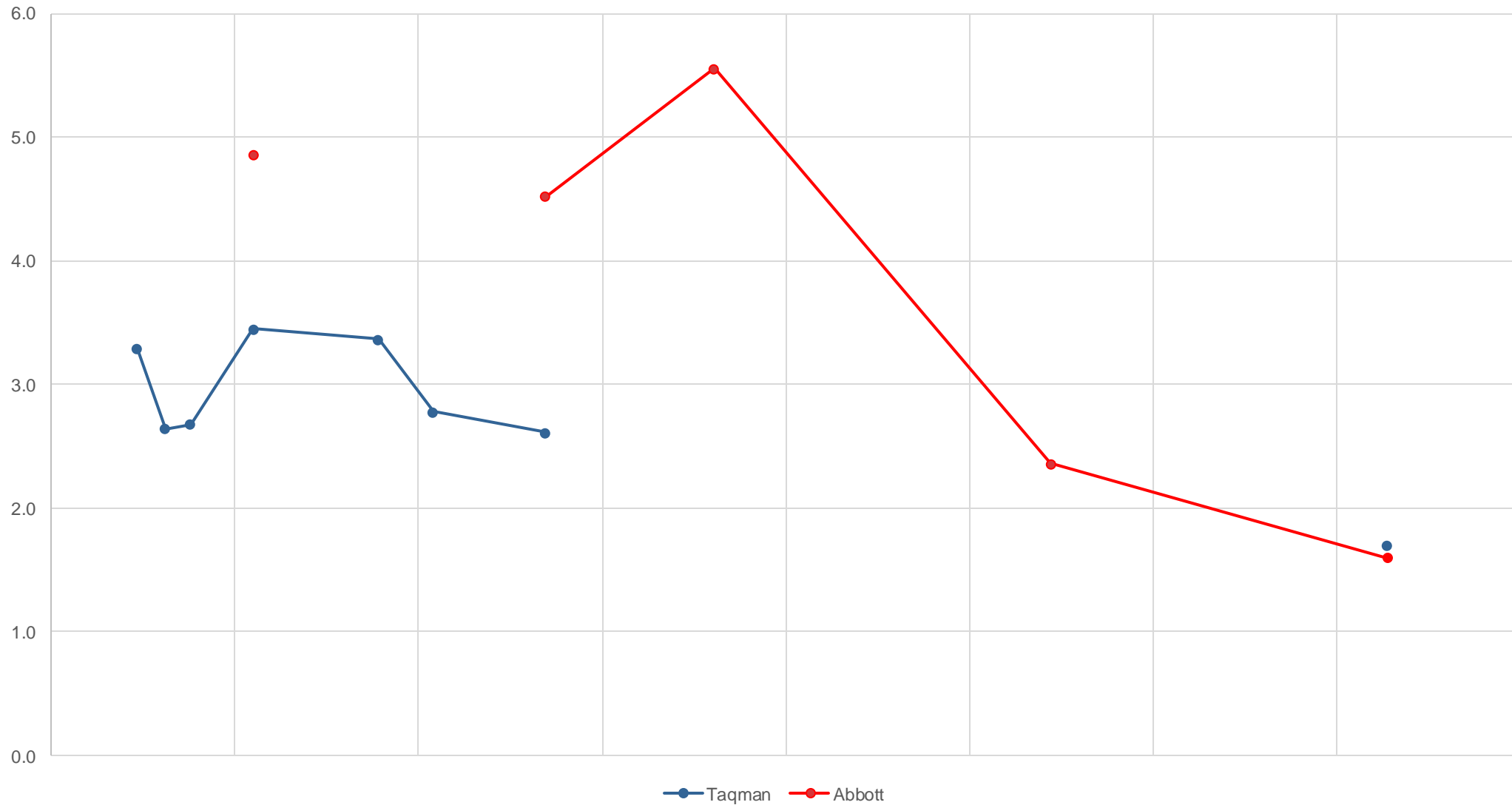
- Reverse transcription-polymerase chain reaction (RT-PCR)
  - Abbott RealTime HIV-1 Viral Load assay
  - Roche COBAS TaqMan HIV-1 test
  - Aptima HIV-1 Quant Dx Assay
- Branched DNA (bDNA) tests
  - VERSANT HIV-1 RNA 3.0 Assay
- Nucleic acid sequence-based amplification (NASBA) tests
  - NucliSens HIV-1 QT (bioMerieux)



# Why is HIV measured on a log scale

- The wide range of viral loads is easier to represent visually.
- Log-transformed data better approximate a normal distribution.
- Changes by factor of 10 are clinically significant.
  - Response from 100,000 to 10,000 is similar to 10,000 to 1000.

# Is primer mismatch real?



# Comparison of performance of viral load tests

## Example #1 (Kenya)

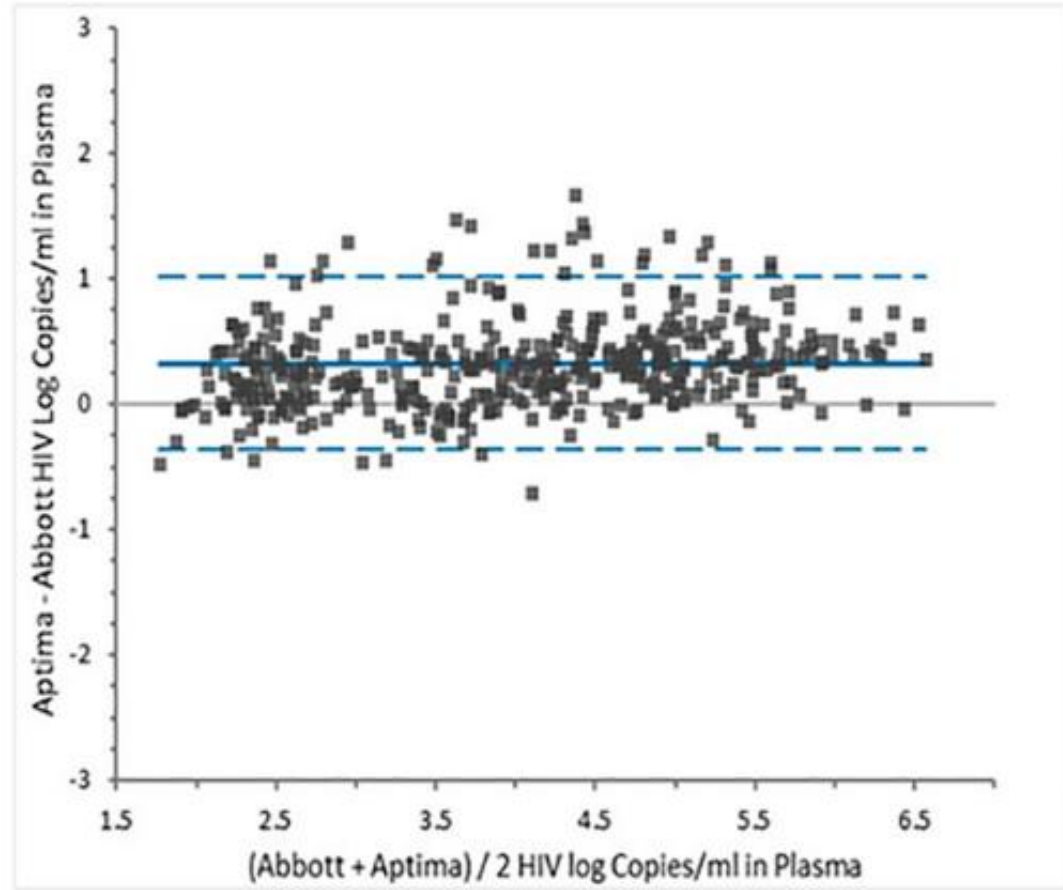
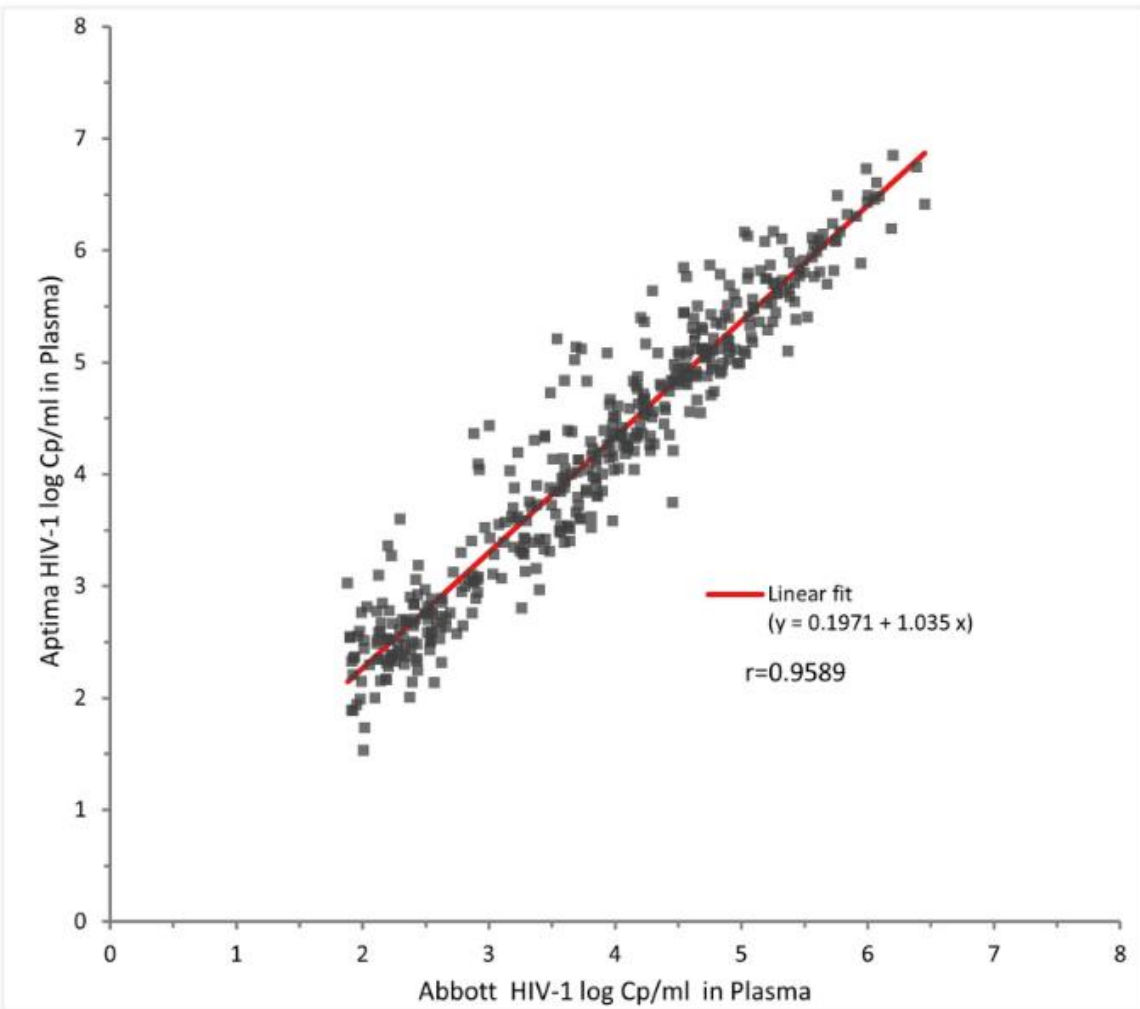
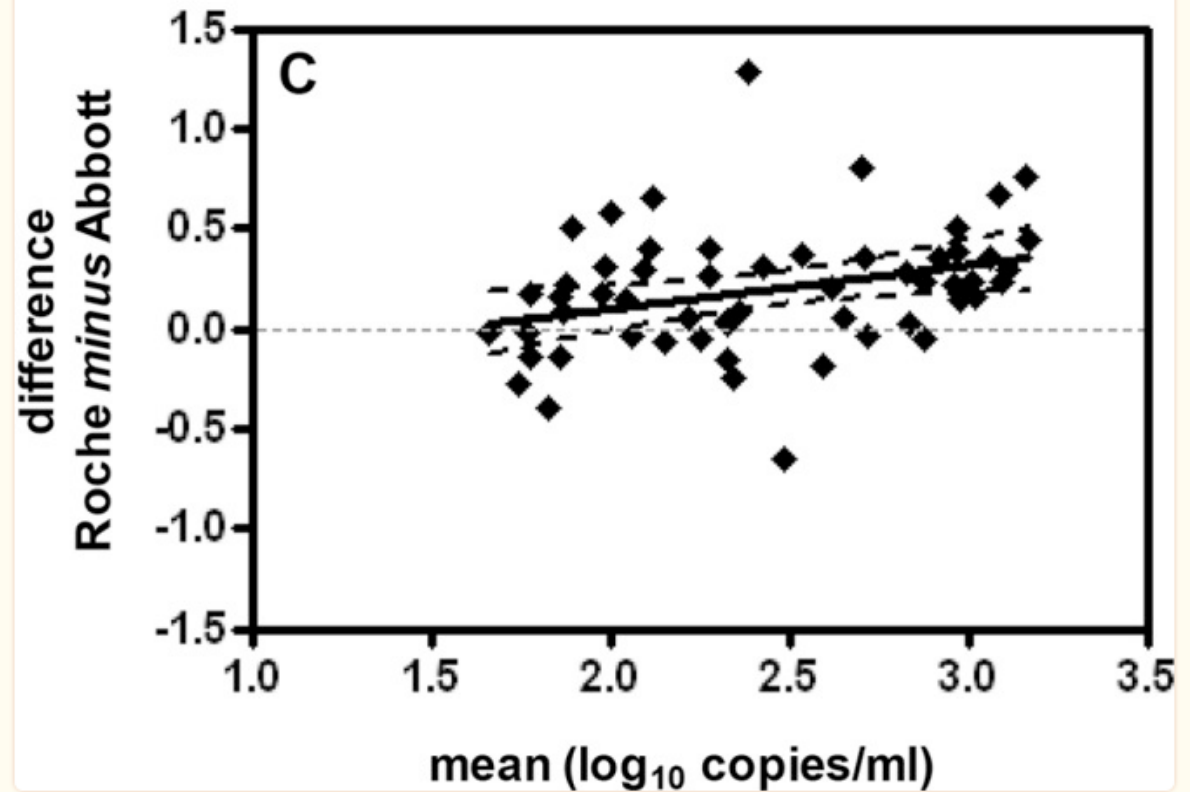
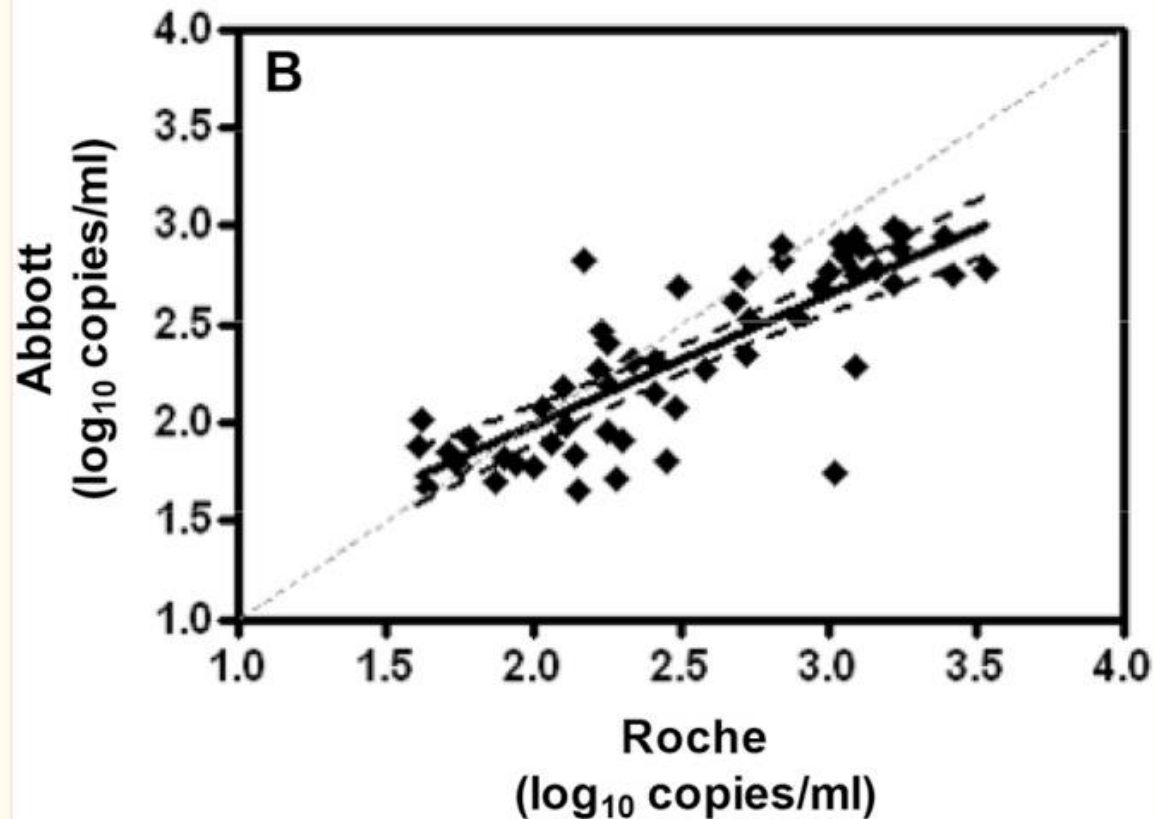


Fig 2. Bland Altman analysis of HIV VL results for 436 plasma samples tested in Aptima and Abbott RT assays.

Fig 1. HIV VL comparison for 436 plasma samples tested in Aptima and Abbott RT assays.

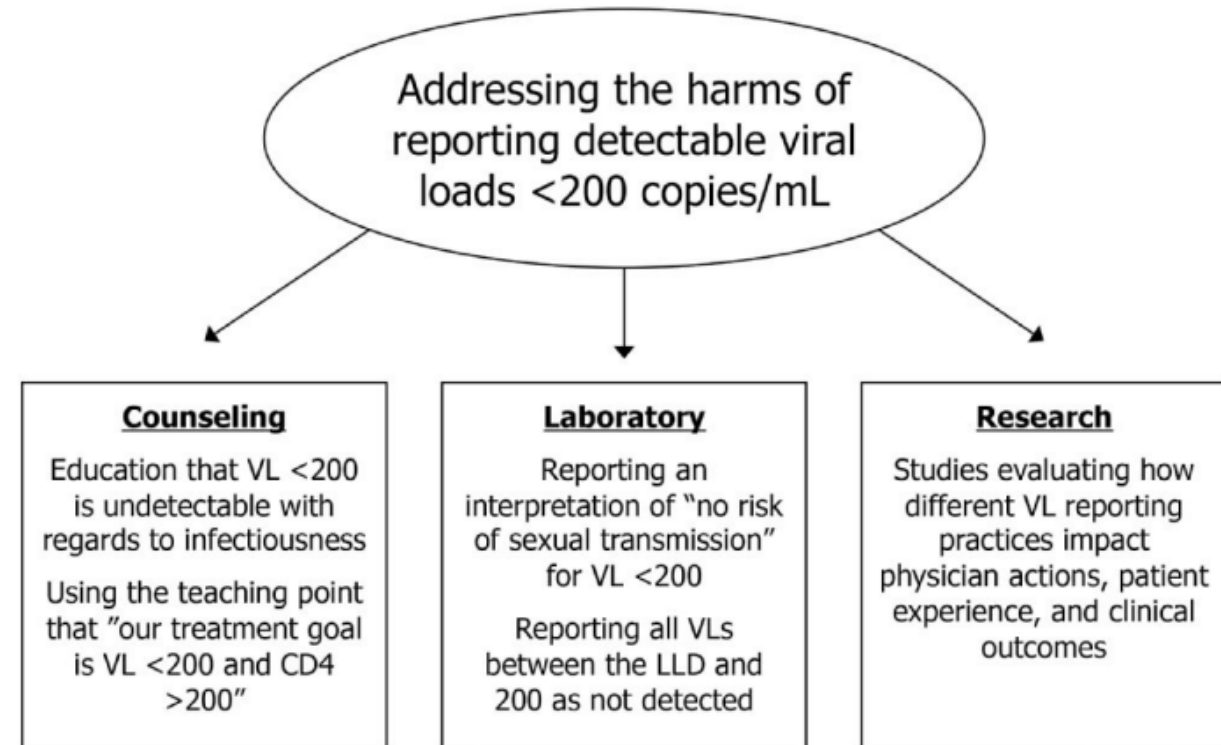
# Comparison of performance of viral load tests

## Example #2



# “The Perils of Overly Sensitive Viral Load Testing for Persons With Human Immunodeficiency Virus”

- Results
  - Not detected/target not detected
  - <X copies/mL
  - [Number]
- Discordance in messaging
  - What copy number is clinically relevant?
  - What copy number is relevant for U=U?



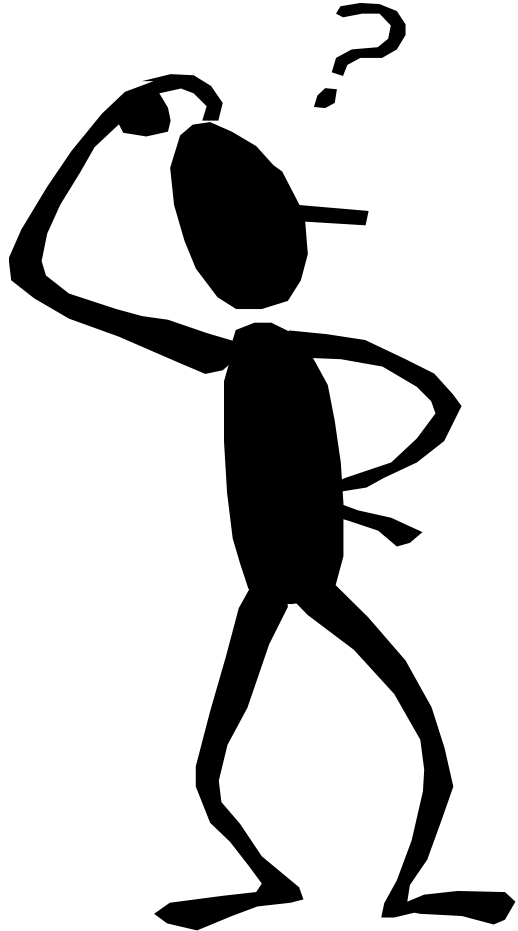
# Clinical question for discussion

Case: lab HIV RNA 238, POC RNA was >1000.

Testing 5 months earlier was undetectable.

- How would you counsel this patient with these results?
- What further testing would you do, if any?

# Questions?



# Acknowledgment

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