Clinical Samples with Delayed Processing Time are Associated with Lower HIV Viral Load Results in a High-Volume Regional Laboratory, Njombe Region, Tanzania (Oct 2024–Mar 2025)

Robert Baluhya
robertbaluhya@gmail.com
National Public Health Laboratory
Ally K. Hussein
Tanzania Field Epidemiology and Laboratory Training Program
Richard Buretta
Management and Development for Health
Peter Richard Torokaa
Ministry of Health
Robert Ndege
Ifakara Health Institute
Ritha Yodosi Masawe
Ministry of Health
Anthony Kavindi
Kilimanjaro Christian Medical University College
Esther Mwavika
National Public Health Laboratory
Ahmad Yusuf
Management and Development for Health
Joel Nikupala
Njombe Town Council Hospital
Perfecter Nchumbuka
Njombe Town Council Hospital
Ziada Chwaya
Njombe Town Council Hospital
Frank Msafiri
Muhimbili University of Health and Allied Sciences
Ambwene Mwakalobo
Ministry of Health
Alex S. Magesa
Ministry of Health
Mecky Isaac Matee
Muhimbili University of Health and Allied Sciences

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Abstract

Background

Accurate HIV viral load (VL) testing is essential for monitoring antiretroviral therapy (ART) and detecting treatment failure. In resource-limited settings such as Njombe Region, Tanzania, laboratories often face prolonged turnaround times (TAT) and suboptimal sample transport and storage. While RNA degradation during extended storage is well documented, its impact on routine, high-volume VL testing remains unclear. This study quantified the association between laboratory processing delays and reported HIV VL results.

Methods

We conducted a cross-sectional secondary analysis of VL data from Njombe Town Council Hospital Laboratory (October 2024–March 2025, N = 18,271). After excluding 244 records with missing dates, 18,025 samples were analyzed. Three TAT intervals—collection-to-reception (clinic to lab), reception-to-registration (lab receipt to system entry), and registration-to-testing (system entry to assay performance)—were categorized into quartiles. Multivariable multinomial logistic regression with predictive margins estimated associations between TAT delays and VL categories.

Results

Median total TAT was 22 days (IQR 13–36), exceeding the recommended ≤ 14 days. Only the slowest registration-to-testing quartile (Q4: ≥21 days) showed consistently fewer detectable VL results. Adjusted probability of Target Not Detected (TND) increased from 71.2% (fastest quartile) to 85.8% (slowest quartile) (RR = 1.205; 95% CI: 1.196–1.214; $p < 0.001$), while probabilities for all detectable VL categories declined significantly.

Conclusion

Prolonged registration-to-testing delays were strongly associated with lower reported HIV VL results, consistent with RNA degradation or pre-analytical bias. Such delays may compromise patient care and program monitoring. Therefore, interventions targeting workflow and laboratory system optimization are warranted—a conclusion likely generalizable to similar centralized HIV viral load laboratories across low- and middle-income countries.

Background

Accurate HIV viral load (VL) measurement is a cornerstone of antiretroviral therapy (ART) monitoring and essential for detecting treatment failure (Kippen et al. 2024). The accuracy of viral load testing is therefore fundamental to both clinical care and HIV prevention (WHO 2024; UNAIDS 2024). However, in resource-limited settings, which bear the highest global HIV burden, laboratory systems are frequently strained, leading to prolonged turnaround times (TAT) that often exceed the recommended 14 days (Mbiva et al. 2021; Mnzava et al. 2023). According to World Health Organization (WHO) guidance, plasma samples should be centrifuged and frozen within 24 hours (WHO 2024). For HIV VL testing kits and testing guidelines generally recommend storage and transport at room temperature (≤ 24 hours), 2–8°C (≤ 5 days), or − 20°C to − 80°C for up to six weeks (WHO 2024)

Furthermore, experimental evidence suggests that delays in sample transport or laboratory processing can lead to RNA degradation, potentially resulting in underestimated VL results (Gutema et al. 2022; Ethel et al. 2021). Laboratory stability studies and systematic review have reported substantial VL declines in stored plasma: 81.8% and 97.5% after 7 and 14 days at 30°C, and 52.6% and 25% after one month at − 20°C and − 80°C, respectively (Ethel et al. 2021; Hardie et al. 2024; Lesesa et al. 2025). While these experimental studies establish biological plausibility, they do not fully capture the complexity of routine laboratory workflows (Hardie et al. 2024). In HIV VL testing, delays may occur at multiple points under variable storage and handling conditions (Gutema et al. 2022). Evidence quantifying the real-world impact of such operational delays on reported VL results remains limited (Hardie et al. 2024).

When VL results are systematically underestimated, such errors may carry serious clinical and programmatic consequences, including delayed regimen switching, ongoing viral replication, and inaccurate ART program performance metrics (Lubega et al. 2022; NASHCOP 2024). Studies from sub-Saharan Africa indicate that over 50% of VL samples are processed beyond recommended timelines in many settings, highlighting the operational challenges facing high-burden regions (Mbiva et al. 2021; Moirana et al. 2022; Mnzava et al. 2023; Kippen et al. 2024; UNAIDS 2024).

Against this backdrop, we aimed to quantify the association between turnaround time and HIV viral load result distribution in a high-volume regional laboratory in mainland Tanzania. The novelty of this study lies in its ability to link routine operational delays to systematic shifts in VL result categories, thereby identifying actionable laboratory bottlenecks with direct clinical and programmatic relevance. Centralized VL monitoring systems in sub-Saharan Africa are known to face bottlenecks such as stockouts and testing backlogs that delay clinical decisions; nonetheless, there is a lack of quantitative data on how these delays systematically alter VL result distributions at the population level (Moirana et al. 2022; Hardie et al. 2024; Kippen et al. 2024).

Methodology

Study Design and Setting

We conducted a cross-sectional secondary analysis of HIV viral load (VL) monitoring data from the Njombe Town Council Hospital Laboratory. This facility serves as a regional referral laboratory for a population of approximately 889,946 across the Njombe Region, which spans 24,994 km² % (National Bureau of

Statistics [NBS] 2022). The region has an HIV prevalence of 12.7% (National Bureau of Statistics [NBS] 2022). The analysis included all individuals living with HIV whose samples were received and tested at the laboratory from October 2024 to March 2025 (N = 18,027). A total of 18,271 records were extracted from electronic laboratory records. No sampling was performed, minimizing selection bias at the data extraction stage.

Data Sources and Variables

Of the 18,271 records extracted, 244 (1.3%) were excluded due to missing critical date variables required for turnaround time calculation, resulting in a final analytic sample of 18,025 unique patient samples. Extracted data included VL results and dates for sample collection, laboratory receipt, sample registration, testing, and result authorization, as well as patient age and sex.

The primary exposure variables were three pre-analytical turnaround time intervals representing distinct operational stages within the testing pathway: Collection-to-reception (clinic to laboratory), Reception-to-registration (laboratory receipt to system entry), Registration-to-testing (system entry to assay performance). Each interval was categorized into quartiles (Q1–Q4), with Q4 representing the slowest and Q1 the fastest interval.

The primary outcome was the categorical VL result as reported by the assay, reflecting routine clinical interpretation. Categories included Target Not Detected (TND), < 40 copies/mL, 40–199 copies/mL, 200–999 copies/mL, and ≥ 1000 copies/mL.

Sample Storage and Handling During Turnaround Time Intervals

During the study period, HIV VL samples were managed according to national guidelines (URT, 2025) and manufacturers' instructions *(cobas® HIV-1 Test Nucleic acid test for use on the cobas® 4800 system IVD)*, which recommend storage and transport at room temperature for ≤ 24 hours, 2–8°C for up to 3 days, or − 20°C to − 80°C for up to six weeks (WHO 2024)

In routine practice at the study laboratory, samples awaiting testing after registration were stored within available laboratory cold-chain infrastructure, including refrigeration and freezer storage, in line with these standard operating procedures. However, this study did not directly measure actual storage temperatures, durations at each temperature level, or freeze–thaw cycles at the individual sample level. Consequently, while turnaround time intervals reflect operational delays within the testing pathway, they serve as proxy indicators of potential prolonged storage or delayed processing. Turnaround time intervals were therefore used as proxy indicators of potential prolonged storage or delayed processing, rather than as direct measures of RNA degradation or storage conditions.

Data Analysis

Data management and statistical analyses were performed using Stata/SE version 17.0 (StataCorp, College Station, TX, USA). Data visualizations and graphical representations were generated using R version 4.3.2 within the RStudio integrated development environment (Posit Software, PBC, Boston, MA, USA). Descriptive statistics were used to summarize sample and patient characteristics. Categorical variables were reported as frequencies and proportions, and distributions across VL categories were compared using Pearson's chi-square test. Associations between turnaround time components and VL categories were examined using multinomial logistic regression, with TND as the reference outcome. For each turnaround time component, quartiles Q2–Q4 were compared against the fastest quartile (Q1). Model results are presented as relative risk ratios (RRRs) with corresponding 95% confidence intervals (CIs).

Although VL categories are ordinal, the proportional odds assumption was not imposed because covariate effects were expected to differ across clinically distinct thresholds of viremia. Moreover, ART regimen and adherence were considered unlikely to satisfy the proportional odds assumption in routine programmatic settings (Dessie et al. 2020). Multinomial logistic regression was therefore selected to allow category-specific estimation of effects. Variables with a p-value < 0.20 in bivariable analyses, together with covariates identified a priori based on existing literature (age group, sex, ART regimen, and ART adherence), were included in multivariable models. Multicollinearity was assessed using variance inflation factors, with values < 5 considered acceptable (de Winter 2025).

Because ART regimen and adherence data were missing for approximately 38% of records, multiple imputation by chained equations was used under a missing-at-random assumption (Junaid et al. 2025). Twenty imputed datasets were generated and combined using Rubin's rules for pooling estimates and standard errors across imputations (Elasra et al. 2022). The number of imputations was selected based on methodological guidance indicating that 20 imputations are sufficient to achieve stable parameter estimates and standard errors, even with moderate to high levels of missingness (StataCorp LLC 2025). A complete-case analysis was conducted as a sensitivity analysis.

Adjusted predicted probabilities for each VL category were estimated using marginal standardization at the fastest (Q1) and slowest (Q4) turnaround time quartiles. Marginal estimates after multiple imputation were obtained using the *mimrgns* module in Stata, which extends the margins framework to multiply imputed datasets. Absolute differences (percentage points) and risk ratios with 95% CIs were calculated based on these predicted probabilities. Confidence intervals for the calculated risk ratios were estimated using the delta method.

Results

Turnaround Time and Sample Characteristics

A total of 18,025 HIV viral load (VL) results were included in the analysis after excluding 244 records (1.3%) with missing date variables. The median total turnaround time (TAT) from sample collection to result authorization was 22 days (IQR 13–36), while the median intra-laboratory TAT (receipt-to-authorization) was 19 days (IQR 10–31). The registration-to-testing interval showed the widest variability (IQR 1–20 days), indicating a major bottleneck in laboratory operations. Median durations for other intervals were: collection-to-receipt 2 days (IQR 1–4), receipt-to-registration 3 days (IQR 1–6), and testing-to-authorization 4 days (IQR 2–8).

Viral Load Result Distribution

Overall, 94.5% of results were virally suppressed (< 200 copies/mL). This included 13,339 (73.0%) TND results, 2,354 (12.9%) detectable VL < 40 copies/mL, and 1,575 (8.6%) low-level viremia (40–199 copies/mL). Among unsuppressed results, 392 (2.1%) were in the actionable viremia range (200–999 copies/mL) and 611 (3.3%) indicated virological failure (≥ 1000 copies/mL). Baseline characteristics across VL categories are shown in Suplimentary Table 1.

Associations Between Turnaround Time Intervals and Viral Load

The registration-to-testing interval was the strongest predictor of shifts in VL results (Fig. 1, Supplementary Table 2). Samples in the slowest quartile of registration-to-testing interval (Q4, ≥ 21 days) had a higher probability of TND results (85.8%) than the fastest quartile (Q1, ≤ 1 day, 71.2%), with concomitant reductions in all detectable VL categories (Fig. 2, Table 1). Collection-to-reception and reception-to-registration intervals showed weaker and less consistent effects, collection-to-reception delays were associated with slightly higher very low-level viremia (< 40 copies/mL) (Fig. 1, Supplementary Table 2)

Table 1
Adjusted probabilities and risk ratios of HIV viral load categories by registration-to-testing TAT quartile (Q1 ≤ 1 day vs Q4 ≥ 21 days).

Viral Load Category	(Q1, ≤1day days) Probability (95% CI)	(Q4, ≥ 21 days) Probability (95% CI)	Absolute Probability Difference	Risk Ratio Q4 vs Q1 (95% CI)	P-value
Target Not Detected	71.22% (70.77–71.67)	85.79% (85.46–86.13)	+ 14.57 pp	1.205 (1.196–1.214)	< 0.001
Detected < 40 cp/mL	14.54% (14.19–14.89)	5.09% (4.88–5.30)	-9.45 pp	0.350 (0.334–0.367)	< 0.001
Detected 40–199 cp/mL	7.99% (7.72–8.25)	5.68% (5.46–5.91)	-2.30 pp	0.712 (0.676–0.750)	< 0.001
Detected 200–999 cp/mL	2.77% (2.60–2.93)	1.40% (1.29–1.50)	-1.37 pp	0.505 (0.457–0.557)	< 0.001
Detected ≥ 1000 cp/mL	3.49% (3.30–3.68)	2.04% (1.91–2.17)	-1.45 pp	0.584 (0.537–0.635)	< 0.001

Sensitivity Analysis

A complete-case analysis (N = 11,050) confirmed the robustness of the inverse association between longer registration-to-testing intervals and viral load detectability. Effects remained consistent with primary analyses using multiple imputation (Supplementary Table 3).

Discussion

Key Findings and Interpretation

This study demonstrates a strong and consistent association between prolonged registration-to-testing intervals and systematically lower reported HIV viral load (VL) results. Samples processed after ≥ 21 days were significantly more likely to be classified as target not detected (TND) compared with those processed within one day, indicating an operational rather than biological effect (Ethel et al. 2021; Hardie et al. 2024). The most plausible explanation is **time-dependent degradation of HIV RNA** during extended pre-analytical and in-laboratory holding periods, particularly under high-throughput conditions with batching and workflow congestion. Although temperature and storage conditions were not directly measured, the observed dose-response across delay quartiles and persistence after adjustment for demographic and clinical covariates support a biologically credible, non-causal mechanism rather than confounding by patient factors (Hardie et al 2024).

Delays of five or more days between sample collection and laboratory reception were also associated with increased detection of very low-level viremia (< 40 copies/mL), likely representing a technical artifact rather than a true biological elevation in VL (Hardie et al. 2024). Notably, the downward effect of prolonged delays was substantially larger than any upward artifact from short pre-analytical delays (Fig. 1) underscoring the importance of timely sample processing to avoid underestimation of true viral burden (Hardie et al., 2024).

Clinical and Programmatic Implications

Systematic underestimation of VL may **delay recognition of low-level viremia** and early treatment failure, potentially postponing timely ART regimen adjustments (Rosen et al. 2022; Hardie et al. 2024). At the program level, this bias may artificially inflate viral suppression rates, affecting progress toward UNAIDS 95-95-95 targets (UNAIDS 2023). In high-burden regions such as Tanzania, even modest upward shifts in TND classification could overestimate

suppression rates by several percentage points, impacting thousands of individuals and masking early treatment failure signals (Moirana et al. 2022; Kathinzi et al. 2025). Patients in the slowest registration-to-testing quartile had an 85.8% probability of being classified as TND versus 71.2% in the fastest quartile, representing a 20% absolute increase and highlighting the magnitude of operational bias (Lemma et al. 2020; UNAIDS 2024).

Laboratory Bottlenecks in HIV Viral Load Testing

The registration-to-testing interval emerged as the dominant operational bottleneck, driven by equipment breakdowns, inadequate maintenance, reagent stock-outs, centralized testing, inefficient sample transport, staffing shortages, and high workloads (Mbiva et al. 2021; Kathinzi et al. 2025; Mnzava et al. 2023; Mpofu et al. 2024; Fonjungo et al.). These challenges underscore the need for targeted interventions to streamline workflows, improve equipment reliability, optimize human resources, and strengthen specimen logistics (Mnzava et al. 2023; Mpofu et al. 2024; Fonjungo et al).

Potential Interventions

A multi-pronged approach is required to address these delays. Automated sample tracking **systems** can flag bottlenecks in real time (Bowie et al. 2024). Decentralization of testing to peripheral or district-level laboratories can reduce transport-related delays and alleviate congestion at central labs (Mnzava et al. 2023). Ensuring adequate staffing, training, and workflow optimization, including sample triaging and prioritization protocols, can minimize backlogs (Cherie et al. 2024; Lubega et al.). Investment in equipment maintenance, backup instruments, forecasting and supply planning and clinical sample cold-chain monitoring reduces downtime and prevents RNA degradation (Williams et al. 2020; Fonjungo et al.). Finally, integrating these interventions with routine quality assurance and data-driven monitoring allows laboratories and HIV programs to continuously evaluate performance and improve turnaround times (WHO 2024).

Limitations

This study is subject to several limitations. The cross-sectional design limits causal inference (Savitz & Wellenius 2023). Storage temperature, plasma separation timing, and freeze–thaw cycles were not directly measured; turnaround time intervals were used as proxies for pre-analytical degradation (Moirana et al. 2022; Hardie et al. 2024). Residual confounding cannot be entirely excluded, including potential day-of-week effects, staff workload variations, or subtle differences in sample quality (Mesganaw et al. 2024; VanderWeele 2023). ART regimen and adherence data were missing for 38% of samples, though multiple imputation was applied. Despite these limitations, the large sample size, real-world setting, and robust sensitivity analyses enhance generalizability.

Conclusion

Prolonged in-laboratory processing delays, particularly between registration and testing, are associated with systematically lower HIV VL results, reflecting operational bias rather than true virological suppression. This bias can compromise patient management, obscure early detection of treatment failure, and distort national HIV program metrics. Implementing workflow optimization, adequate staffing, equipment maintenance, cold-chain monitoring, decentralization, and real-time sample tracking should be prioritized to ensure accurate viral load testing and reliable monitoring of HIV program performance.

Abbreviations

ART
Antiretroviral Therapy
CI
Confidence Interval
EDTA
Ethylenediaminetetraacetic Acid
HIV
Human Immunodeficiency Virus
IQR
Interquartile Range
MDH
Management and Development for Health
MI
Multiple Imputation
MOH
Ministry of Health
NACP
National AIDS Control Programme
NASHCOP
National AIDS Control Programme (Tanzania)
NBS
National Bureau of Statistics
PPT
Plasma Preparation Tube

Q1
First Quartile (Fastest Turnaround Time)
Q2
Second Quartile
Q3
Third Quartile
Q4
Fourth Quartile (Slowest Turnaround Time)
RNA
Ribonucleic Acid
RR
Risk Ratio
RRR
Relative Risk Ratio
SOP
Standard Operating Procedure
SSA
Sub–Saharan Africa
TAT
Turnaround Time
TND
Target Not Detected
UNAIDS
Joint United Nations Programme on HIV/AIDS
VL
Viral Load
WHO
World Health Organization

Declarations

Ethics approval and consent to participate

The study was approved by the Tanzania Ministry of Health as part of a data quality assessment exercise (Reference number Kumb.Na.MA.155/174/01/973). Ethical approval was waived in view of the retrospective nature of the study and because all procedures were performed as part of routine care. Client-identifying information was anonymized to safeguard privacy.

Consent for publication

Not applicable

Competing Interests

The authors declare no conflict of interest associated with this work.

Funding Statement

No formal funding was received for this work.

Author Contribution

RB led the conceptualization of the study, conducted data analysis, and prepared the original manuscript draft. E.M, R.B, A.Y, J.N, P.N, and Z.C curated and prepared the dataset for analysis, while R.BU, R.Y.M, A.Y, A.S.M, A.M, and M.M provided administrative coordination and oversight. The first draft underwent critical review by M.I.M, A.K.H, R.N, P.R.T, R.B.U, and F.M, who contributed substantial improvements. Further writing, critical review, and editorial revisions were carried out by R.B, A.K.H, R.N, R.BU, R.Y.M, A.K, P.R.T, F.M, A.M, A.S.M, and M.I.M. All authors approved the final manuscript.

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Data Availability

The datasets analyzed during the current study are not publicly available due to ethical restrictions but may be available from the corresponding author on reasonable request, subject to approval from the relevant ethics committee and data custodians. Baseline characteristics across VL categories; Supplementary table 1 and detailed regression results; Supplementary table 2 and Supplementary table 3, are provided as Supplementary Materials.

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Figures

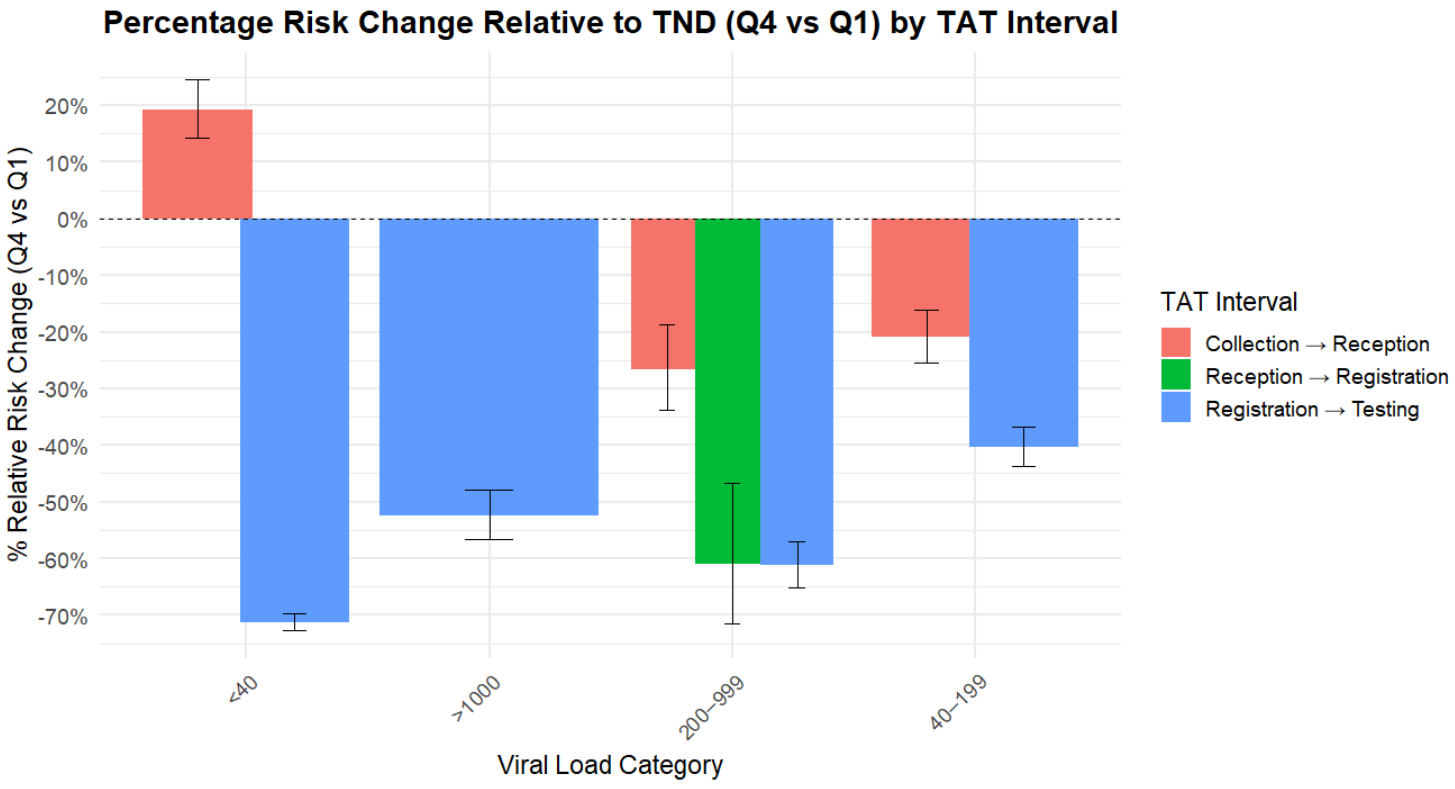

Figure 1

Percentage change in the relative risk ratio [(RRR-1) ×100%] for viral load categories from multiply imputed multinomial logistic regression, with target-not-detected (TND) as the base outcome category comparing slowest (Q4) to fastest (Q1) turnaround time.

Dashed line indicates no change (RRR = 1). Negative values: decreased relative risk of detectable VL relative to TND; positive values: increased relative risk relative to TND. Registration-to-testing interval shows the largest percentage reduction toward TND status.

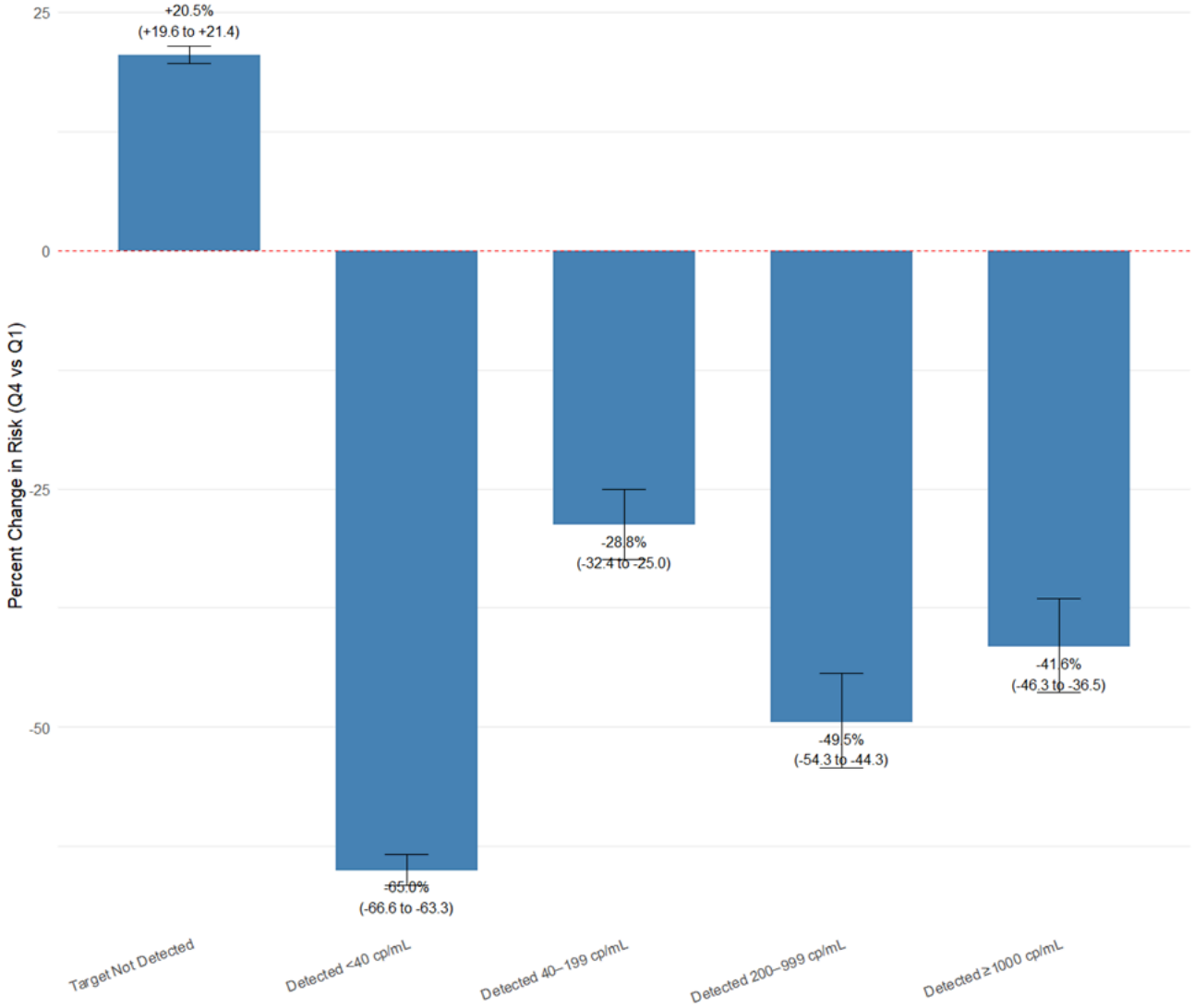

Figure 2

Percentage change in relative risk [(RR-1) ×100%] of each HIV viral load category comparing slowest (Q4, ≥21 days) to fastest (Q1, ≤1 day) registration-to-testing interval.

Dashed line indicates no change (RR = 1). Values>0 indicate increased likelihood; <0 indicate decreased likelihood. RRs were derived from adjusted predicted probabilities from multiply imputed multinomial logistic regression model. Error bars: 95% CI.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- SuplimentaryMaterialClinicalSampleswithDelayedProcessingTimeareAssociatedwithLowerHIVViralLoadResultsinaHighVolumeRegionalLaboratoryNjomb