

An overview of the effectiveness of the quality assurance programme for HIV point-of-care testing in South Africa

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Introduction

- In 2016, the South African National Health Laboratory Service (NHLS) implemented a quality management system for Human Immunodeficiency Virus (HIV) point-of-care testing (POCT).
- The NHLS Quality Assurance Department (QAD) provides continuing support to HIV rapid testing facilities across the country, ensuring that they have sufficient, high-quality supplies and are evaluated to increase accuracy of HIV POCT results.
- QAD is responsible for preparing HIV quality assurance panels consisting of HIV-positive and HIV-negative serum samples to be supplied to the facilities twice a year for proficiency testing (PT), as well as upon request for Internal Quality Control (IQC) and for training purposes.

Aim

- To determine the effectiveness of the HIV quality assurance program using HIV POCT data collected from January 2021 through October 2022.

NHLS Proficiency PT Scheme:

<https://www.nhls.ac.za/quality-assurance/proficiency-testing/>

Methods

- Between January 2021 and October 2022, more than 4,000 HIV rapid testing facilities participated in the NHLS HIV POC PT.
- Three survey batches consisting a total of 12636 PT sample panels were distributed to the facilities.
- Compliance was recorded indicating the total number of participating facilities that returned their results.
- Comparisons of the percentage scores for accuracy of the HIV PT results were calculated for HIV testing facilities against QAD results.
- A result score of $\geq 80\%$ was established as the acceptable threshold for evaluating the performance of the facilities.
- Further analysis of panels distributed for IQC and training purpose was conducted

Figure 1: Facilities participating in the NHLS HIV POC PT Scheme per survey between Jan 2021 to Oct 2022

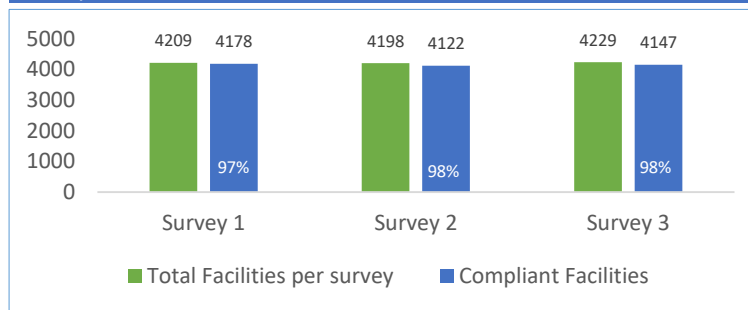


Table 1: NHLS HIV POC PT results for surveys 1, 2 and 3

| Survey | Total Compliant Facilities | Facilities with $\geq 80\%$ score | Facilities with $<80\%$ score | Non-Compliant Facilities |
|--------|----------------------------|-----------------------------------|-------------------------------|--------------------------|
| 1 | 4178 | 4090 (98%) | 88 (1%) | 31 (1%) |
| 2 | 4122 | 4055 (98%) | 67 (1%) | 76 (1%) |
| 3 | 4147 | 4077 (98%) | 70 (1%) | 82 (1%) |

Results

- Of the 12636 PT sample panels distributed, results for 12447 (98,5) were reported. This included 4178, 4122 and 4147 panels for surveys 1, 2 and 3, respectively (Table 1). This is equivalent to the average compliance of 98% for participating facilities and with the average mean score of 92%, across all the 3 surveys
- In all 3 surveys, an average of 95% of the facilities scored 100%, 98% scored $\geq 80\%$, and 1% did not respond.
- Additionally, a total of 365 samples for training and 6288 samples for IQC were distributed during the period.

Conclusion

The NHLS QAD has been efficient in assessing the HIV POC rapid testing quality in South Africa with the overall performance of facilities on PT assessments demonstrating excellent accuracy and compliance. Moreover, facilities are equipped with sufficient quality materials to conduct IQC and trainings.