

Performance of NGOs POCT participants in PNAEQ/Labquality HIV and Hepatitis B+C schemes in 2022



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Introduction

Point-of-care testing (POCT) is a diagnostic testing at/near the site of patient, performed by healthcare professionals (laboratories, primary healthcare settings or pharmacies) or personnel with no professional background in laboratory medicine (community health workers from NGOs).^{1,2}

However, to guarantee the reliability of results and the security of patient, POCT users must ensure External Quality Assurance (EQA). This is not an issue when healthcare professionals perform EQA schemes, but it implies a bigger responsibility to EQA provider when users have no healthcare education. This includes four moments: demonstrate to NGO's participants the importance of participation in EQA schemes; be able to distribute control materials with large submission time of results; elaborate comprehensible instructions and reports; provide help and guidance to participants when needed.²

POCT users in community perform POCT EQA schemes in sexual infections such as HIV and Hepatitis B+C. These EQA schemes are available in PNAEQ with collaboration of Labquality. NGO's order these schemes since 2018. This study focuses on their 2022 participation.

Aim

This work aims to evaluate the performance of NGO's POCT participants in PNAEQ/Labquality HIV and Hepatitis B+C schemes in 2022.

Methods

PNAEQ catalogue 2022 was distributed by email to all PNAEQ (historic and present) participants. NGO's POCT participants had also a dedicated divulgation where HIV and Hepatitis B+C POCT schemes were highlighted.

Three undiluted human plasma/serum from a single donor were sent in each survey: for HIVAb seven positive and five negative; for HBsAg six positive and six negative; for HCVAb four positive and eight negative.

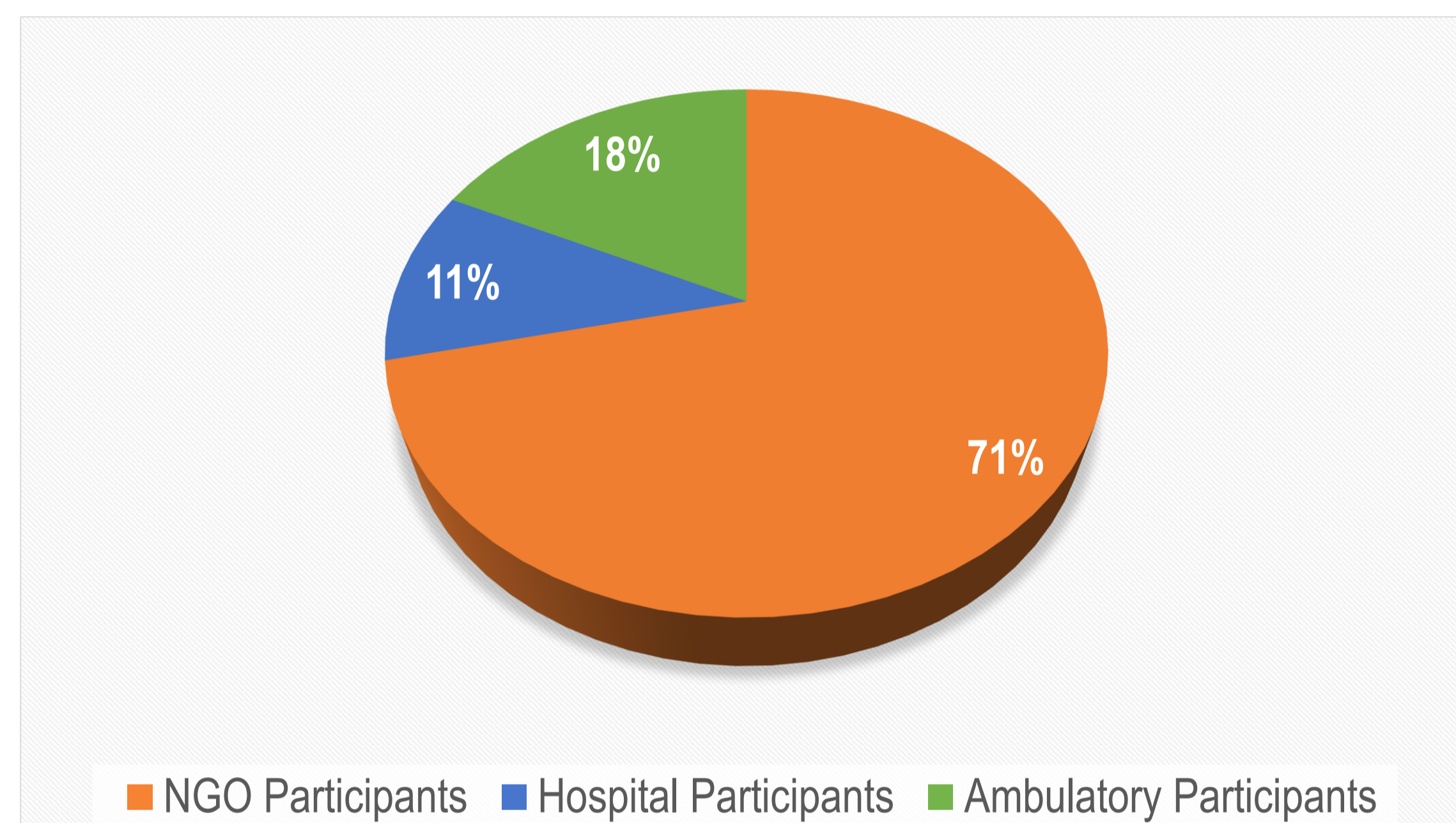
After receiving control samples, POCT participants performed each test as a routine procedure and submitted the results to Labquality's online platform.

Results evaluation were performed by Labquality, attending the pre-test results and the expert's comments. PNAEQ analyzed their reports and, in specific cases, contacted them, offering technical advice.

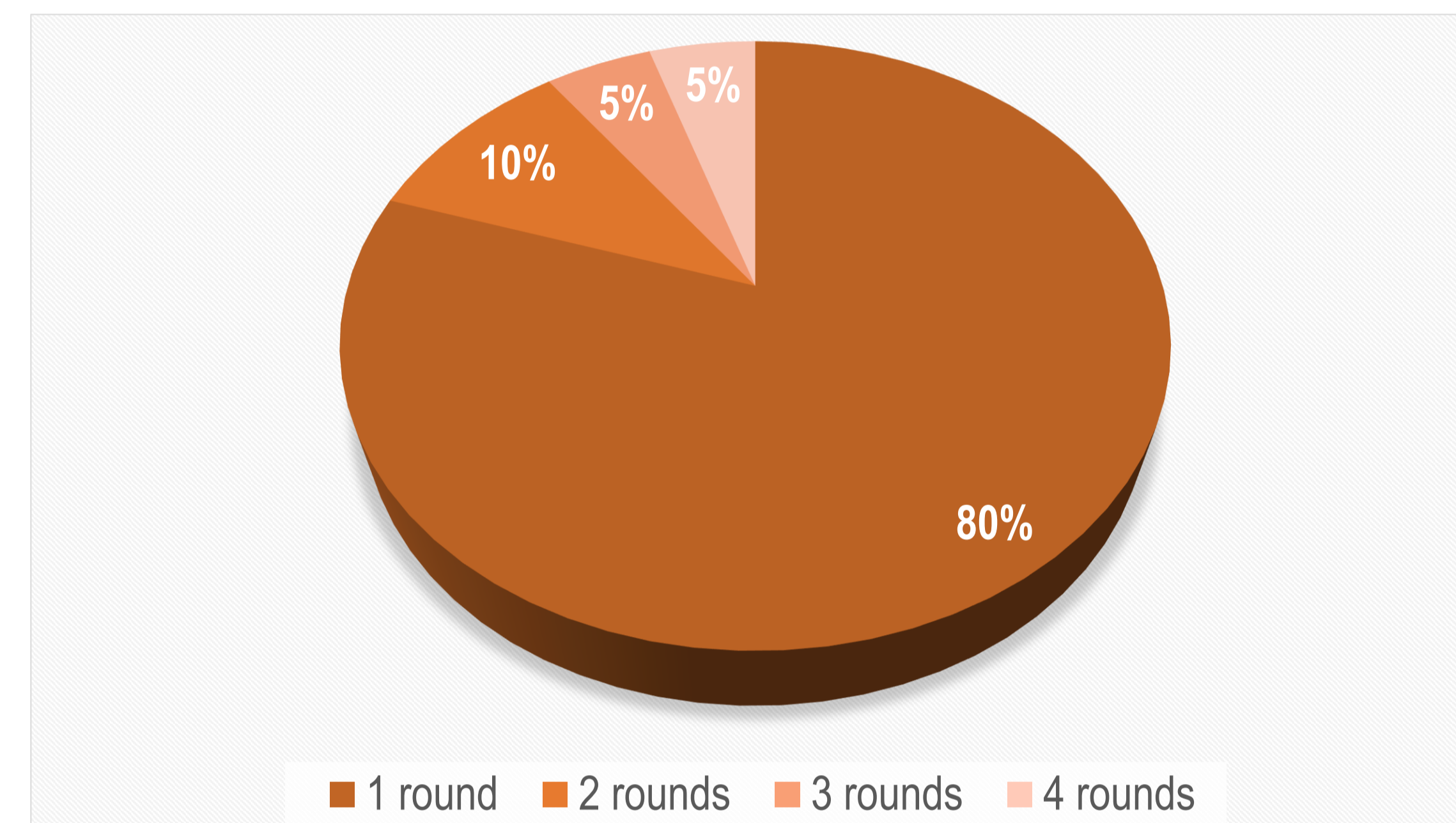
Results

In 2022, there were 28 participants enrolled in HIV and Hepatitis B+C schemes: 71% (N=20) were NGO's (Graphic 1).

All of them were registered in both schemes LQ-5090-HIV and LQ-5094-VHB+C: 80% (N=16) in one round each, 10% (N=2) in 2 rounds each and 5% (N=1) in 3 or 4 rounds each (Graphic 2).

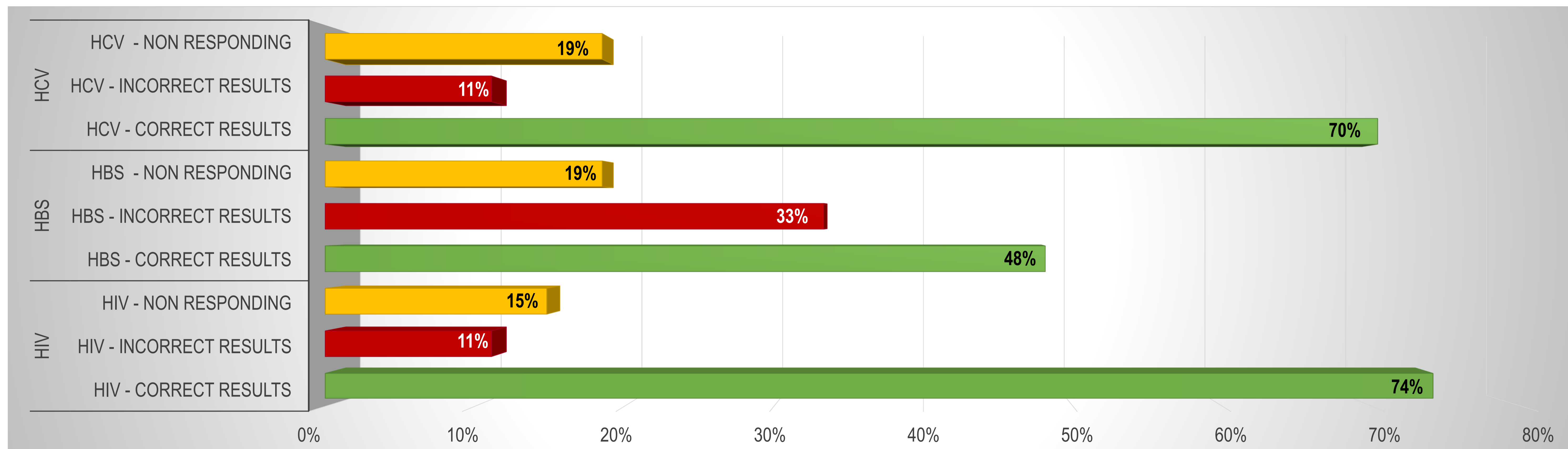


Graphic 1: Characterization of participants in PNAEQ/Labquality HIV and Hepatitis B+C schemes, in 2022.



Graphic 2: Distribution of NGO participation rounds in each PNAEQ/Labquality HIV and Hepatitis B+C scheme, in 2022.

Graphic 3 shows the results for all the 27 surveys for each test: HIV / HBs / HCV.



Graphic 3: Performance of NGO participants in HIV, HBs and HCV tests, respectively, in 2022.

For HIVAb were observed 11% of incorrect results (two false negatives and one unclear), for HBsAg were observed 33% of incorrect results (eight false negative and one borderline) and for HCVAb were observed 11% of incorrect results (two unclear and one borderline).

The average percentage of incorrect results for the three tests (HIV/HBs/HCV) was 19%. Of these, 4 participants (20%) were contacted by a PNAEQ team, who executed a presential audit with extra samples offered by Labquality. Three of them reported incorrect results in Round 2 – Sample 001 - HBsAg test (two false negative and one borderline) and one participant reported a false negative in Round 1 – Sample 003 – HIVAb test. In all these four re-tests, procedure was correctly performed by participants in the presence of the PNAEQ team and all samples were found positive or weakly positive.

Conclusion

- POCT plays an increasingly important role in screening infectious diseases. Individuals with very different educational backgrounds use POCT in community sites, underscoring the importance of quality results especially at NGO's.
- All negative samples for the three tests were correctly performed. For positive samples more actions must be done regarding education, verifying the practical procedure and eventually contact with suppliers.
- PNAEQ/Labquality EQA schemes in HIV and Hepatitis B+C pretend to be a helpful tool to guarantee reliable results to patient. Whenever this premise is not verified, PNAEQ contacts NGO's participants to assist in person with routine procedure.



References:

¹ Khan et al., Point-of-care testing in settings outside the hospital. Clin Chem Lab Med 2023; 61(9): 1572–1579.

² Anne Stavelin, Sverre Sandberg. Essential aspects of external quality assurance for point-of-care testing. Biochemia Medica. 2017;27(1):81–5.