Performance of PNAEQ participant's results for HIV and HCV infection in the First EQA round 2019

Ana Faria[1]; Silvia Viegas[1]; Catarina Ventura[1]; Helena Correia[1]; Ana Cardoso[1]; Edna Pereira[1]; Marsa Järvenpää[2]

(1) Programa Nacional de Avaliação Externa da Qualidade, Unidade de Avaliação Externa da Qualidade, Departamento de Epidemiologia, Instituto Nacional de Saúde Doutor Ricardo Jorge, Lisboa, Portugal
(2) Labquality Oy

Email: pnaeq@insa.min-saude.pt

Introduction

The Portuguese National External Quality Assessment Program (PNAEQ) has been collaborating with Labquality since 2002. One of the first schemes distributed to PNAEQ participants was for HIV laboratory tests, followed by HCV laboratory tests scheme in 2003. A suitable scheme for Point of Care Testing (POCT) is available for HIV since 2012 and for HCV since 2018.
Given the burden of HIV and HCV diseases, the Portuguese legislation allows, since 2018, that other locations than laboratories, such as pharmacies and Non-Governmental-Organizations (NGOs), perform tests for detect HIV and HCV infection. For this purpose, and in order to assure reliable results that leads to an early correct diagnostic and a timely treatment, leading to a decrease in the person-to-person transmission of HIV and HCV infection, a specific training to perform POCT for HIV and HCV is mandatory for these entities, as well as the participation in such EQA schemes, namely the PNAEQ-Labquality.

Objective

Evaluation of the performance of laboratory and POCT sites of the PNAEQ-Labquality participants for HIV and HCV infection in the first EQA round of 2019.

Material and Methods

PNAEQ distributed Labquality EQA schemes for HIV and HCV detection. For HIV there are two different schemes, one for laboratory tests (5091) and one for POCT users (5090). The control samples used in both HIV schemes are the same, with separate evaluation.
For HCV two schemes are available, 5094-5095, being the only difference the sample volume. For this scheme both laboratory tests and POCT results are evaluated.

- The first round of the two schemes for HIV detection (laboratory tests and POCT), were distributed in March 2019. Both schemes included the same sample controls: 4 human plasma (S001 anti-HIV-1 positive, HIVAg negative; S002 HIVAgAb negative; S003 HIVAgAb negative; S004 anti-HIV-1 positive, HIVAg negative). The anti-HIV positive specimens consisted of one single anti-HIV positive donation diluted in 1:10 with one single anti-HIV negative donation plasma. The anti-HIV negative specimens consisted of one single anti-HIV negative donator plasma.
- Fifteen participants performed laboratory tests (scheme 5091): 5 public hospitals and 10 public and private ambulatory laboratories used HIVAgAb (combo) test (9 different HIVAgAb Combo tests from 5 manufacturers).
- Twenty six participants performed POCT (scheme 5090): 1 public hospital laboratory, 1 private ambulatory laboratory, 3 NGO and 21 Pharmacies. All of them used POCT third generation immunochromatography (IC) (4 manufactures). The figure 1 shows the different type of participants that perform the HIV detection.

- The first round of the HCV detection scheme (laboratory tests and POCT) was distributed in March 2019 and included 3 human plasmas (S001 negative, S002 positive, S003 negative, each of which originated from a single separate donor).
- Forty participants performed HCV detection scheme: 6 public hospitals and 7 public and private ambulatory laboratories used HCVAb (chemi)electrochemiluminescence methodologies (4 manufacturers); 6 NGO and 21 Pharmacies used POCT (1 manufacturer). The figure 2 shows the different type of participants that perform the HCV detection.
- Training: In order to be in compliance with Portuguese legislation, all NGOs and pharmacies received EQA training from PNAEQ and Labquality team in 2018 and 2019.

Figure 1: *Participants of PNAEQ 1st round 2019 HIV tests*

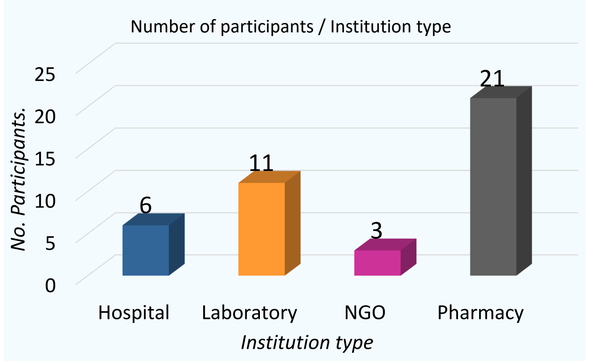
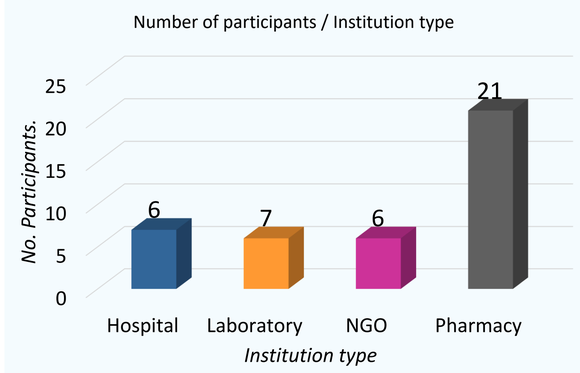


Figure 2: *Participants of PNAEQ 1st round 2019 HCV tests*

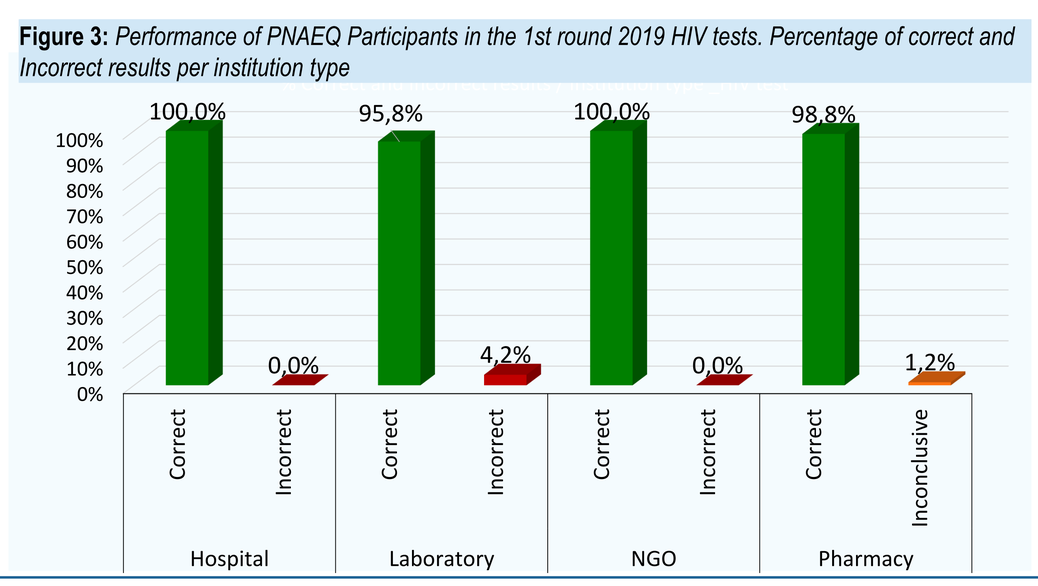


HIV Results

- For sample S001 (positive), one pharmacy reported undetermined result using POCT third generation. The participant requested a new sample for retest for confirmation.
- For sample S002 (negative), one ambulatory laboratory reported two results, one correct (negative) and one incorrect (positive), using different methodologies/manufactures.
- For sample S003 (negative), all results were reported correctly.
- For sample S004 (positive), one ambulatory laboratory reported an incorrect result (negative).
- The incorrect laboratory results were performed using HIVAgAb (combo) test from the same manufacturer.

The figure 3 shows the percentage of correct and incorrect results for HIV diagnosis.

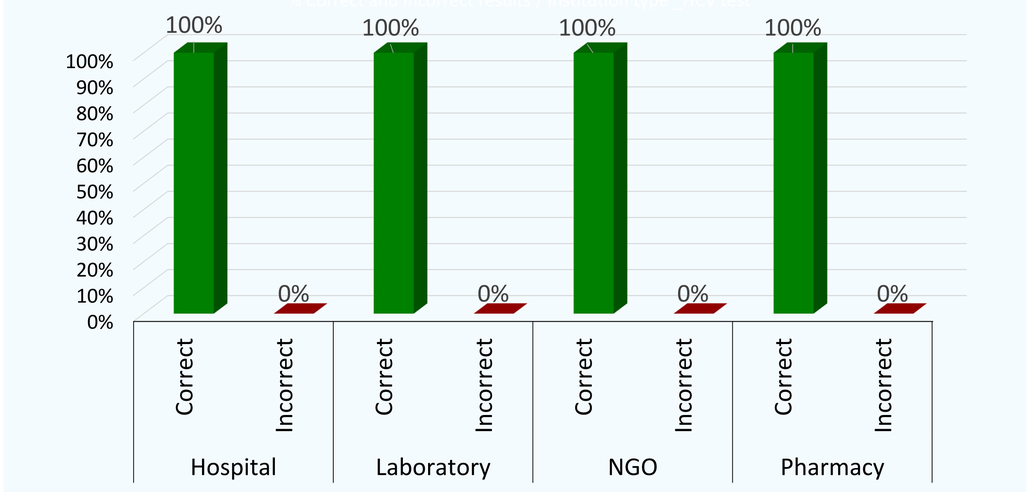
Figure 3: *Performance of PNAEQ Participants in the 1st round 2019 HIV tests. Percentage of correct and Incorrect results per institution type*



HCV Results

For HCV all results reported were correct in all samples. (Figure 4)

Figure 4: *Performance of PNAEQ Participants in the 1st round 2019 HCV tests. Percentage of correct and Incorrect results per institution type*



Conclusion

The performance of PNAEQ participants for HIV and HCV tests in the First EQA round 2019 was considered in general good. For HIV POCT, the user that reported an undetermined result proceeded correctly requesting a second sample for confirmation. Regarding the two incorrect results reported by laboratories, it is necessary to review the internal validation procedure and revalidation of the laboratory test, and implement corrective and preventive actions.

The training of participants that used POCT for the first time proved to be effective in acquiring skills to perform the tests properly.

PNAEQ will continue to provide education and training in quality control and motivate all the participants to continuously evaluate the results from the internal quality control and the reports from the external quality assessment.

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