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## Peruvian experience on the human immunodeficiency virus diagnostic flowchart

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## Peruvian experience on the human immunodeficiency virus diagnostic flowchart

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# PERUVIAN EXPERIENCE ON THE HUMAN IMMUNODEFICIENCY VIRUS DIAGNOSTIC FLOWCHART

## EXPERIENCIA PERUANA SOBRE EL FLUJOGRAMA DE DIAGNÓSTICO DEL VIRUS DE INMUNODEFICIENCIA HUMANA

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### Mr. Editor

The Joint United Nations Program on HIV/AIDS (UNAIDS) proposed as a goal that the countries reach 95-95-95 by the year 2030, in other words, that 95% of people living with HIV (PLH) are diagnosed and of these that 95% receive antiretroviral treatment (ART) and at least 95% have undetectable viral load or viral suppression<sup>(1)</sup>.

En el 2014 el Perú alcanzó la fórmula 64-46-36, por estas razones el Ministerio de Salud (MINSa) realiza numerosos esfuerzos para cerrar brechas y lograr este objetivo, es por ello que con base en la evidencia, periódicamente se modifican las fórmulas técnicas. estándares de salud para mejorar la cobertura y el abordaje de las PLH<sup>(2)</sup>.

In order to close the first gap, that is, the first 95, the MINSa began expanding the coverage of HIV diagnosis a few years ago through the use of rapid tests at all levels of care in the health system, as This is why the World Health Organization has recommended modifications in the diagnostic flowcharts, which shorten the time to define a person with HIV infection and that he or she can receive early treatment<sup>(3)</sup>.

The HIV diagnosis flowcharts for people over 18 months of age, which are contained in the three technical health standards currently in force, define a case of HIV infection as those people who have two reactive results to two screening tests from different manufacturers. or of a different principle, considering screening tests to be the Rapid Test (RT), Enzyme-Linked Immunosorbent Assay (ELISA), Chemiluminescence (CLIA) and Electrochemiluminescence (ECLIA). It is important to highlight the following cases as cases: a) two reactive results of two third-generation RPs from different manufacturers b) two reactive results of two RPs, one third-generation and one fourth-generation c) One third- or fourth-generation RP generation and an ELISA or equivalent with reactive results d) A third or fourth generation RP with a reactive result and a positive confirmatory test: viral load, indirect immunofluorescence (IIF) or immunoblot<sup>(4,6)</sup>.

In the novelty of these flowcharts, the consideration of two reactive results to two screening tests as a case of HIV infection is highlighted<sup>(4,5)</sup>; however, there is currently no relevant information on the experience of its applicability in the Peruvian population. For these reasons, the following objective was set: Identify the results of confirmatory HIV serological tests in Peruvian samples with two reactive results to two different screening tests.

An observational descriptive study was carried out during November 2021 at the National Reference Laboratory for Sexually Transmitted Viruses HIV/AIDS of the National Institute of Health (INS); Secondary data of diagnostic results were analyzed without access to patient identification, so it did not require the approval of an ethics committee since it was a necessity in national HIV surveillance to have information to provide technical guidance to the healthcare workers.

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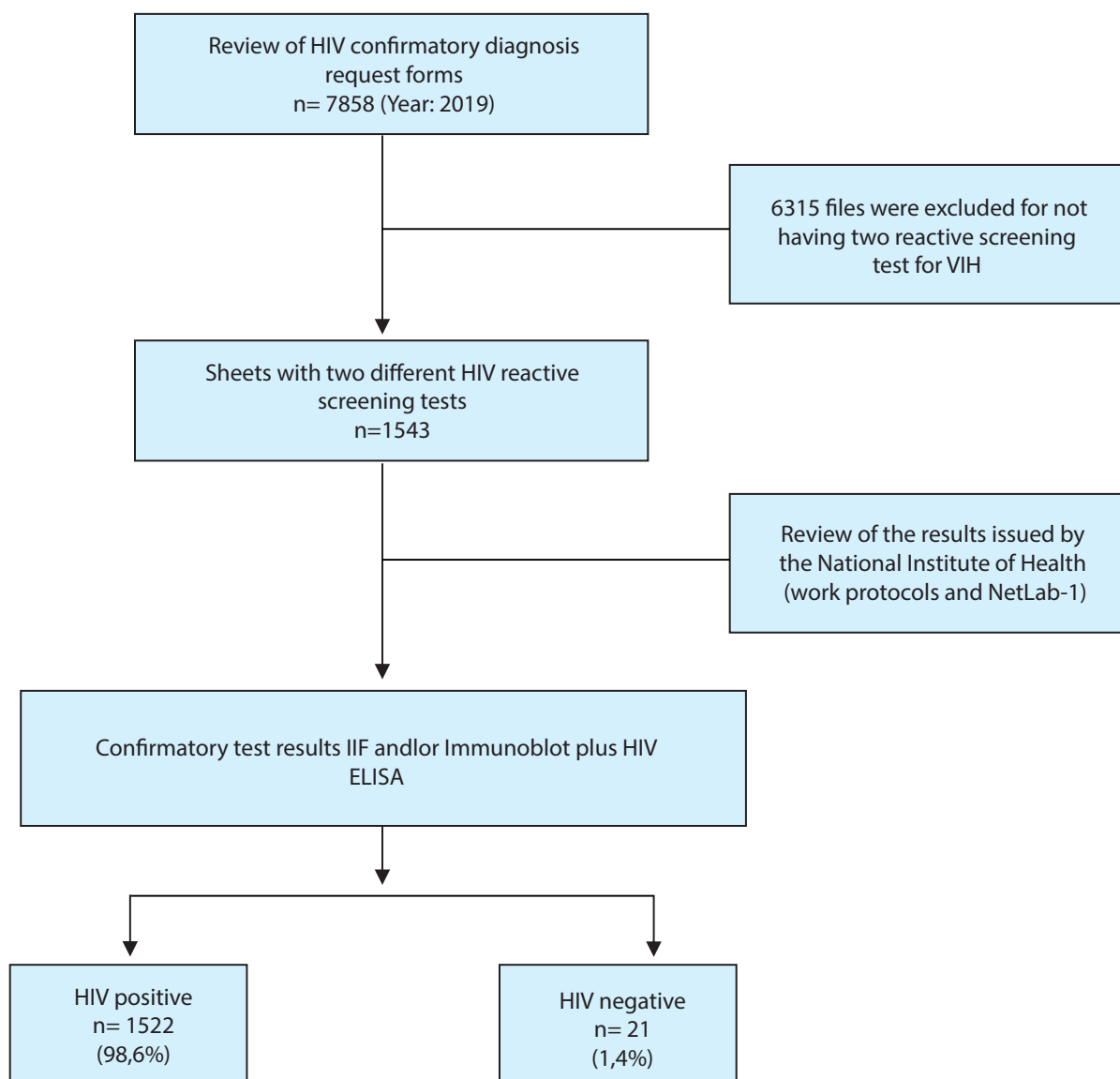




The search was carried out for the screening results recorded in the diagnostic files that were sent by the different health establishments in Peru to the INS for the confirmation of HIV in the period from January 1 to December 30, 2019. Likewise, the results of the confirmatory serological tests issued by the INS were obtained from the work protocols and the NetLab 1 laboratory information system.

Among the results, it was determined that of a total of 7,858 samples received, 1,543 had two reactive results to two different screening tests (age group: from eighteen months to thirteen years = 12; from fourteen to seventeen years = 39; years = 1492) at the same time it is evident among the main findings that 98.6% (1522/1543) had a concordant positive result by means of the confirmatory serological tests (IFI and Immunoblot) (See figure N° 1)

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**Figure 1.** Flowchart of samples incorporated into the study





It is important to highlight that only 1.4% (21/1543) had negative results for HIV, verifying that this small percentage that had the condition of defined case for HIV, showed to be false reagents. However, it is important to highlight that the diagnostic flowchart indicates that all cases with two reactive screening test results should immediately undergo the HIV viral load test (test considered confirmatory and baseline for the start of monitoring) before starting ART<sup>(4,5)</sup>. This fraction of cases could be identified as undetectable by the viral load test (viral RNA), so only these few samples should be referred to for serological confirmation, because there would be a risk of administering ART to patients who actually are HIV negative.

It should be noted that there are reports that HIV screening tests can generate false reactive results in hemolyzed, lipemic or contaminated samples, also in

people with anti-HLA antibodies, neoplasms, autoimmune diseases and in multiparous women<sup>(3)</sup>.

The high concordance demonstrated in the studied samples that were positive to the confirmatory serological tests (98.6%) allows us to show that the HIV diagnosis flowchart in the Peruvian population presents a high reliability in its application, consequently the results obtained allow us to indicate that samples with two reactive results to screening tests should not be referred for serological confirmation (IIF and Immunoblot) and should be sent directly for viral load analysis; in this way, patients would access timely ART.

This experience allows us to conclude that the HIV diagnosis flowchart in people older than 18 months works with high reliability in Peru.

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