

# Cerrahpaşa Medical Faculty Hospital HIV-1/-2 Serological Test Data: 2019-2022 Retrospective Evaluation

Harika Oyku Dinc<sup>1</sup> , Elif Keskin<sup>2</sup> , Banu Tufan Kocak<sup>3</sup> , Bekir Kocazeybek<sup>2</sup> 

<sup>1</sup>Department of Pharmaceutical Microbiology, Faculty of Pharmacy, Bezmialem Vakif University, Istanbul, Turkiye

<sup>2</sup>Department of Medical Microbiology, Cerrahpaşa Medical Faculty, Istanbul University-Cerrahpaşa, Istanbul, Turkiye

<sup>3</sup>T.C. Ministry of Health, Erenkoy Mental Health and Neurology Training and Research Hospital, Istanbul, Turkiye

ORCID ID: H.Ö.D. 0000-0003-3628-7392; E.K. 0000-0001-8264-0703; B.T.K. 0000-0002-6435-0785; B.K. 0000-0003-1072-3846

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## ABSTRACT

**Objective:** The aim of this study was to retrospectively discuss the human immunodeficiency virus (HIV) scanning and verification test results and demographics of patients who were admitted to the Istanbul University Cerrahpaşa Medical Faculty's Medical Microbiology Laboratory Center Serology/ELISA division with suspected HIV infection or pre-operative serologic screening. In addition, the study aimed to compare HIV seroprevalence with data from the center's previous period.

**Materials and Methods:** HIV-1/-2 antibody +P24 antigen (HIV-1/-2 Ab/Ag) was studied routinely using the chemiluminescent microparticle immunoassay (CMIA) method with the same method also being used as the second repeat test. The sera verifications of patients who showed repeated reactivity after the HIV Ab/Ag test were studied using the line immunoassay (LIA) method.

**Results:** The study retrospectively studied 156,542 cases between 2019-2022, of which 237 (0.17%) showed repeated anti-HIV-1/-2 reactivity. From the repeated reactivity serum samples, LIA testing was performed to confirm the remaining 181 serum samples after excluding the previously confirmed samples, with 175 (96.6%) coming back positive. All these samples showed *sgp120* and *gp41* band positivity, thus confirming HIV1 positivity.

**Conclusion:** These retrospective data from one center regarding HIV seroprevalence for the 2019-2022 period are in line with other national studies. However, due to the COVID-19 pandemic, HIV prevalence during this period may have been higher than detected. HIV prevalence in Istanbul, being a cosmopolitan city that receives immigrants, should be monitored in the future.

**Keywords:** HIV-1/-2, serological diagnostics, CMIA, LIA

## INTRODUCTION

In accordance with the World Health Organization (WHO) report published in July 2022, more than 34.8 million people live with the human immunodeficiency virus (HIV), with approximately 1.5 million people having been infected with HIV in 2021 globally (1). Through the intensive work of national and international health organizations and non-governmental organizations (NGOs), new HIV infections and HIV-related deaths respectively decreased by 39% and 51% between 2000-2019 (2). However, with only

approximately 81% of HIV-infected individuals knowing their own HIV status, the 90-90-90 treatment target of the Joint United Nations Program on HIV/AIDS (UNAIDS) has yet to be met (3). Therefore, HIV continues to be a serious public health problem. Antiretroviral therapy (ART) should be started immediately once a person is diagnosed with HIV, and these people should be monitored periodically using clinical and laboratory findings as well as blood tests that are performed to evaluate the viral load of HIV in blood. Diagnosing infected persons as soon as possible has great importance in this context.

**Corresponding Author:** Bekir Kocazeybek **E-mail:** bzeybek@iuc.edu.tr

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The present study aimed to retrospectively evaluate the test results and demographic data of patients who applied to the medical department's serology laboratory with suspected HIV infection or presurgical serological screening for the anti-HIV -1/-2 between January 2019-October 2022. In addition, the study evaluated the seroprevalence of HIV infections by comparing the data obtained in this period with the data from the previous period (January 2015-December 2018).

## MATERIALS AND METHODS

The study retrospectively evaluated the results from samples that had been sent to the laboratory for anti-HIV serology testing in line with presurgical screening or clinical suspicion between January 1, 2019-October 1, 2022. The patients' demographic information was obtained retrospectively from the ISHOP doctor and laboratory information system of the Istanbul University Cerrahpaşa Medical Faculty Hospital. The serological diagnosis of HIV infection at the center is based on the Republic of Türkiye Ministry of Health's HIV/AIDS Diagnostic Treatment Guide (6). Accordingly, once a serum sample arrives at the center with a request for the anti-HIV-1/-2 test, it is screened for the presence of HIV-1/-2 antibodies and p24 antigens using chemiluminescent microparticle immunoassay (CMIA) tests. Upon detecting reactivity with the first test, the test was then repeated two more times using the same kit,

(LIA) test (INNO-LIA® HIV I/II Score, Immunogenetics, Germany). In accordance with the recommendations from the Centers for Disease Control and Prevention (CDC) and WHO, the presence of at least two envelope proteins (sgp120/gp41 or sgp105, gp 36) or at least one envelope protein band (sgp120/gp41 or sgp105, gp36) together with the p24 antigen band was considered to confirm the WB/LIA test results for diagnosis (1, 5, 13). The detection of bands other than those specified was considered indeterminate, and the absence of the specified bands was considered negative.

### Statistical Analyses

The study analyzed the obtained data using the program SPSS (IBM Corp., 2012: IBM SPSS Statistics for Windows, Version 21.0; Armonk, NY). The study used the chi-square test as well as descriptive statistical analyses (i.e., frequencies, percentages) for the statistical evaluation of the results.

## RESULTS

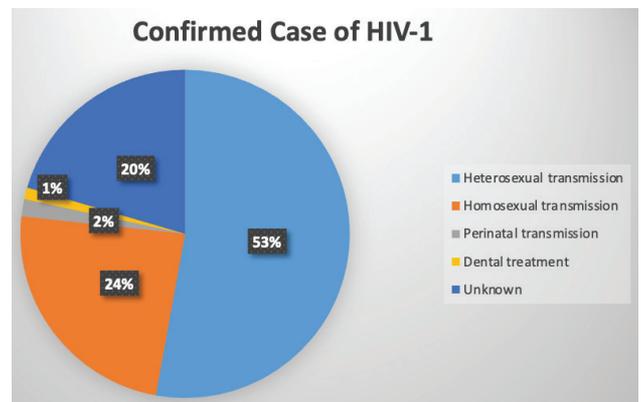
The retrospective evaluation requested the data from 160,194 HIV-1/-2 Ag+Ab tests, with the sera results from 4,697 patients unable to be accessed from the department for various reasons. During the evaluation period, 0.15% ( $n = 237$ ) of the 155,497 sera were repeatedly reactive to the HIV-1/-2 p24 Ag+Ab. Among these 237 patients, 90.7% ( $n = 215$ ) were male

**Table 1.** Frequency of HIV infection by years.

Years	Total Number of Tests	Recurrent HIV-1/-2 Ag+Ab Reactivity n (%)	HIV-1/-2 Confirmation Positive n (%)
January - December 2019	44.900	70 (0.15)	48 (0.1)
January - December 2020	30.974	44 (0.14)	38 (0.12)
January - December 2021	42.168	72 (0.17)	53 (0.13)
January - October 2022	38.500	51 (0.13)	36 (0.09)
<b>Total</b>	<b>156.542</b>	<b>237 (0.15)</b>	<b>175 (0.11)</b>

provided that one of the blood samples was the same as the first tested sample. A confirmatory test is performed when two of the three total tests were found to be reactive, and patients with a positive confirmatory test are informed.

As stated above, the presence of the HIV-1/-2 antibody and p24 antigen had been evaluated using the CMIA method (ARCHITECT HIV Ag/Ab Combo, Abbott Diagnostics, Abbott Park, IL, USA) on the serum samples. According to the manufacturer's instructions, the serum samples that yielded a reactive result were subjected to repeated testing using the same method. The results were obtained in terms of signal/cut-off (S/CO) units. After testing the repeated reactivity, blood was drawn a second time from the respective patient and the same CMIA test was performed again. For confirming the results of repeatedly reactive samples, the line immunoassay



**Figure 1.** Possible transmission routes of HIV-1 confirmed cases.

and 9.3% ( $n = 22$ ) were female, with a mean age of 38.7 years (Table 1, Figure 1). Six (2.5%) of the repeatedly reactive results to the anti-HIV belonged to patients under the age of 18. The confirmation test could not be performed with regard to 56 patients with repeated reactivity results for various reasons such as the patient interrupting the diagnosis/treatment process or the previous confirmation test being interrupted. As a result, the LIA test was performed on only 181 (76.3%) of the repeatedly reactive patients. The results came back positive for 175 (96.7%) and negative for six (3.3%) of these patients. LIA-positivity for HIV-1 was detected in all cases. When examining the transmission routes in the 175 cases with positive LIA results, 93 (53.1%) had had heterosexual intercourse, 42 (25.7%) had had homosexual intercourse, 3 (1.7%) had had a perinatal transmission, and 1 (0.5%) had had dental treatment. In 36 of the cases (20.5%), information about the possible transmission route could not be obtained (Figure 1). When examining the distribution of seropositive bands, the sgp120, gp41, p31, p24, and p17 bands were additionally found to be positive in 103 (58.8%) of the individuals (Table 2).

**Table 2.** Distribution of specific bands detected as reactive in HIV-1/-2 infected cases detected positive by LIA.

Bands	Number	Percentage (%) rate
<b>HIV-1</b>		
<b>Sgp 120, gp41, p31, p24, p17</b>	103	58.8
<b>Sgp 120, gp41, p31, p24</b>	41	23.5
<b>Sgp 120, gp41, p24, p17</b>	12	6.8
<b>Sgp 120, gp41, p31, p17</b>	5	2.9
<b>Sgp 120, gp41, p24</b>	4	2.3
<b>Sgp 120, gp41, p31</b>	7	4
<b>Sgp 120, gp41</b>	3	1.7

The age distribution of the 175 people who tested positive in the HIV confirmation tests was between 1-71 years old with an average age of 37.3 years. When considering the age distribution of patients with repeated reactivity regarding LIA

**Table 3.** Distribution of HIV-1/-2 positive cases according to age and gender.

Age Groups	GENDER	
	Female	Male
<b>0-18</b>	-	3
<b>18-35</b>	4	84*
<b>36-50</b>	11	43
<b>&gt;50</b>	3	27
<b>Total</b>	18	157

\* $p < 0.05$

positivity, HIV infection was most common in the 18-35 age group ( $p < 0.05$ ) (Table 3). Three cases occurred where the individuals were under the age of 18, and their transmission involved the parenteral route (Table 3). Of the positively infected cases, 89.7% (157) were male and 10.2% (18) were female. When statistically analyzing the positivity rate in terms of gender, the high positivity rate in males was found to be significant ( $p < 0.05$ ).

## DISCUSSION

HIV was identified in the mid-1980s, and more than 35 years have passed since the first case was reported in Türkiye. Within the scope of WHO and UNAIDS strategies for combatting HIV, the annual number of new cases in many countries has remained stable or tended to decrease over the last decade. However, Türkiye ranks at the top of the world in terms of the annual increase in the number of new cases alongside several Eastern European, Middle Eastern, and Asian countries (6, 7). One study that statistically examined HIV infection found that, while HIV infection was under control in Western European countries (e.g., Germany, France, England, Spain, and Italy), it had grown out of control in Central and Eastern European countries (e.g., Hungary, Poland, Türkiye, and Ukraine). Among these countries, Türkiye has been shown to have the highest incidence rate of 33 per 100,000 (8).

Türkiye has had 30,293 HIV-infected persons and 2,083 AIDS cases that were positively confirmed between 1985-December 31, 2021 (9). Of these cases 81.2% have been men and 18.8% women, with most cases occurring in the 25-29 and 30-34 age groups. According to data from the Republic of Türkiye's Ministry of Health, while the number of HIV-positive people had been 1,917 in 2014, this number was reported to be 2,922 in 2021 (9), with the infection trend being observed to have increased over the years. Once COVID-19 was declared a pandemic on March 11, 2020, the early detection process for HIV infections became disrupted as a result of the interruptions in surgery and health services, social restrictions, and other reasons. Although the number of test requests to the center under study here during the COVID-19 pandemic had decreased compared to previous periods, the positivity rate was found to be similar (10, 11).

During the 2019-2022 period, the HIV prevalence was retrospectively obtained to be 0.11%, which is a similar result compared to the 2015-2018 period at the laboratory center (10). In addition, the HIV seroprevalence was found to be 0.06 for the lab center's 2006-2009 period, which shows an almost 200% increase between 2006-2022 (11). When evaluating the HIV-1/-2 laboratory test results between 2010-2018 from Elazığ Province, 495 cases were detected to have been confirmed. However, that lab observed an increase in the mean age from 2010-2015, while a decrease was observed after 2015 (12). Another important point that draws attention during the HIV epidemic in Türkiye is that the age of newly diagnosed patients has begun to gradually decrease. This is clearly seen both in the official data from the Ministry of Health and in the real-life data.

The highest rate of new diagnoses was still seen in the 25-34 age group, with the rate of newly diagnosed persons in the 35-44 age group gradually decreasing and the rate in the 20-24 age group increasing (13, 14). One study in which 173 confirmed HIV cases were reported between January 2014-December 2018 determined the highest HIV positivity rate to be found in the 26-35 age group, with the 17-25 age group being the third highest age group (15). According to the data from the Ministry of Health regarding the cases reported in 2021, the number of new diagnoses in the 25-29 age group was reported to be greater than for any other age group. Similarly, although this study found the HIV positivity rate for persons between the ages of 18-35 to be significantly higher, positivity was more common in younger groups compared to previous periods.

When comparing our study's result with the previous results from the our and other centers that had been published in Türkiye, similar results are obtained (10-12). However, due to the restraints during the COVID-19 pandemic, limited access to healthcare services, and psychological and social problems, this study is of the opinion that more HIV-infected individuals exist than have been reported. However, Türkiye is estimated to be nearing the 90-90-90 targets of UNAIDS in terms of access to treatment and treatment success, but it still falls far behind the target regarding diagnosis (16, 17). In this context, monitoring HIV infections in populations such as Istanbul that receive immigrants and have a dense and complex urban life is thought to be able to assist in taking preventive measures and improving public health in Türkiye.

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