A STUDY ON THE USEFULNESS OF FOURTH GENERATION ELISA (p24 ANTIGEN AND ANTIBODY) FOR EARLY DETECTION OF HIV INFECTION IN THE HIGH RISK GROUP

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DERMATOLOGY,VENEREOLOGY AND LEPROSY

(BRANCH XX)

MADRAS MEDICAL COLLEGE

THE TAMILNADU DR. M.G.R. MEDICAL UNIVERSITY

APRIL 2015

CERTIFICATE

Certified that this dissertation titled "**A STUDY ON THE USEFULNESS OF FOURTH GENERATION ELISA ($_{P}$24 ANTIGEN AND ANTIBODY) FOR EARLY DETECTION OF HIV INFECTION IN THE HIGH RISK GROUP"** is a bonafide work done by Dr.G.Sukanya, Post graduate student of the Department of Dermatology, Venereology and Leprosy, Madras Medical College, Chennai – 3, during the academic year 2012 – 2015. This work has not previously formed the basis for the reward of any degree.

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I solemnly declare that the dissertation titled "**A STUDY ON THE USEFULNESS OF FOURTH GENERATION ELISA ($_P$24 ANTIGEN AND ANTIBODY) FOR EARLY DETECTION OF HIV INFECTION IN THE HIGH RISK GROUP"** is a bonafide work done by me at Madras Medical College during 2012 – 2015 under the guidance and supervision of **Prof.Dr.V.SUDHA.MD.D.V.,D.D.,** Director and Professor**,** Institute of Venereology and **Prof.Dr.R.VANAJA. M.D.(MICRO),** Associate Professor, Department of Serology, Institute of Venereology, Madras Medical College, Chennai -600003.

This dissertation is submitted to The Tamil Nadu Dr. M.G.R. Medical University, Chennai towards partial fulfillment of the rules and regulations for the award of M.D. Degree in Dermatology, Venereology and Leprosy (BRANCH XX).

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ABBREVIATIONS

HIV : Human Immunodeficiency Virus

AIDS : Acquired Immuno Deficiency Syndrome

MSM : Men having Sex with Men

TG : Transgender

HRG : High Risk Group

STD : Sexually Transmitted Diseases

ICTC : Integrated Counselling and Testing Centre

ART : Anti Retroviral Therapy

WHO : World Health Organisation

UNAIDS : United Nations programme on HIV and AIDS

NACO : National AIDS Control Organisation

NACP : National AIDS Control Programme

ANC : AnteNatal Cases

PPTCT : Prevention of Parent to Child Transmission

ELISA : Enzyme Linked ImmunoSorbent Assay

CSW : Commercial Sex Worker

FSW : Female Sex Worker

CRF : Circulating Recombinant Forms

RNA : RiboNucleic Acid

CD : Cluster of Differentiation

NAAT : Nucleic Acid Amplification Test

EIA : Enzyme Immuno Assay

IDU : Intravenous Drug Users

STI : Sexually Transmitted Infections

VDRL : Venereal Disease Research Laboratory

PCR : Polymerase Chain Reaction


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Within a span of four decades, it has established to become a global pandemic imposing a major threat to different walks of life. It has immense effect on social as well as economic perspectives of Nations. In 2006, there was a probable estimate of 2.9 million deaths from AIDS throughout the world.
Almost 95% cases hail from developing nations. An estimated 39.5 million people were believed to be living with HIV infection
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ABSTRACT

Introduction:

AIDS was postulated initially as an infective condition way back in 1981(Gotlieb et al). Worldwide there are forty million population living with Human Immunodeficiency Virus (HIV)/ Acquired ImmunoDeficiency Syndrome (AIDS). Within a span of four decades, it has established to become a global pandemic imposing a major threat to different walks of life. It has immense effect on social as well as economic perspectives of Nations. Projections of future mortality and morbidity due to HIV are a useful aid in deciding on priorities for health research, capital investment and training.

Aims and Objectives:

To detect HIV infection using Fourth Generation Enzyme Linked Immunosorbent Assay and to compare the results of Test 1 (Fourth Generation ELISA) with Test 2 (Rapid Assay)

Methodology:

200 patients consisting of High Risk Group and Contacts of High Risk Group attending the STI Out Patient Department, Institute of Venereology, Madras Medical College/RGGGH, Chennai were enrolled for the study.Fourth Generation ELISA for HIV infection was conducted on these selected patients along with routinely done Rapid Assay for HIV infection.

Results:

The percentage of patients tested Positive by Fourth Generation ELISA out of the 200 study group was 37% and Negative was 63%. The detection rate of HIV Positivity by Rapid Assay in High Risk Group was 11% ad Negative was 89%.

Conclusion:

In this study, in most of the categories, the percentage of HIV Positivity detected by Fourth Generation ELISA was higher than that detected by Rapid Assay showing that Fourth Generation ELISA is a more sensitive test than Rapid Assay. A late diagnosis of HIV infection can result in increased transmission, morbidity, mortality and cost to health care services. Hence,

early detection of HIV infection by Fourth Generation ELISA during the window period prevents transmission and above all improves the chances of early intervention.

Key Words: HIV, Fourth Generation ELISA, Rapid Assay

INTRODUCTION

AIDS was postulated initially as an infective condition way back in 1981(Gotlieb et al)[1] . The research for the identification and nomenclature of the agent continued till 1986 (Coffin, et.al., 1986). The International Committee on Taxonomy of viruses suggested the terminology "Human Immuno Deficiency Virus" (HIV) to the agent identified and named such by Montgainer and coworkers (1983) and HTLVIII isolated and recognised by Dr. Robert Gallo and associates (1984) and named as such (Gallo, et.al.,1984). So, it was in 1983-84 that the causative virus was isolated from victims of AIDS and was christened HIV in 1986[2].

Within a span of four decades, it has established to become a global pandemic imposing a major threat to different walks of life. It has immense effect on social as well as economic perspectives of Nations. In 2006, there was a probable estimate of 2.9 million deaths from AIDS throughout the world.

Almost 95% cases hail from developing nations. An estimated 39.5 million people were believed to be living with HIV infection in December 2006[3]. It accounted for nearly 2.5 million infected cases more than those reported in 2004.

REVIEW OF LITERATURE

Incidence

Worldwide there are forty million population living with Human Immunodeficiency Virus (HIV)/ Acquired Immuno Deficiency Syndrome (AIDS). Probable projections of future mortality and morbidity are a useful aid in deciding on priorities for health research, capital investment and training[(4)]. HIV stands first among the leading causes for morbidity and mortality.

In many parts of the world, new HIV cases are heavily concentrated among the youth population (15 -24 years of age), which accounted for 40% of it in the year 2006.

Number of people living with HIV all over the world in 2006:

Global prevalence of HIV infected	-	39.5 million
Adults Infected with HIV	-	37.2 million
Females Infected with HIV	-	17.7 million
Children less than 15 years infected by HIV	-	2.3 million

In Sub Saharan Africa, for every 10 adult men living with HIV, there are approximately 14 adult females infected (59%) with HIV. Almost 25

million people are living with HIV in Sub Saharan Africa, which accounts for 63% of total global HIV infection. Also, 2.1 million people succumbed to AIDS in Africa (ie 3/4th of global mortality). South Africa is the worst hit along with Mozambique and Swaziland, whereas Zimbabwe is the only Nation with declining HIV prevalence.

In Asia, South East zone remains the highest in HIV prevalence with case loads excessive in India, Pakistan, Nepal, Cambodia, Thailand and Vietnam due to MSM. In China, the incidence is on the ascending trend in females. The ethnic and racial minorities are disproportionately affected in United States of America. Among the Eastern European & Central Asian countries, HIV prevalence keeps escalating in Ukraine.

Hence, as per WHO and UNAIDS estimation in 2006, SubSaharan Africa leads the list in HIV prevalence, followed by Asia, Northern America, Western and Central Europe.

Indian Scenario

According to recent estimation based on National Family Health Survey (NFHS), released by (NACO) National AIDS Control Organization, the National HIV prevalence in India among the adult population is approximately 0.36% which corresponds to an estimated 2 to 3.1 million people living with HIV in our country. Out of these, 0.97 million (39.3%) are females and 0.09 million (3.8%) belong to paediatric population.

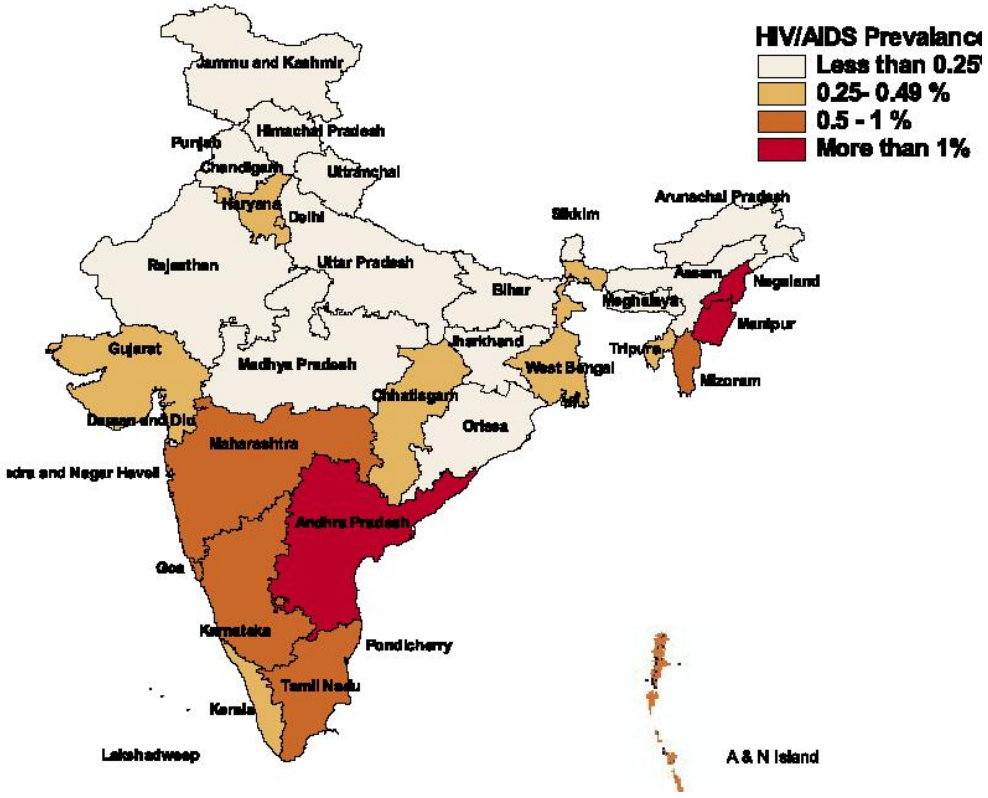
The high prevalence States are Tamilnadu, Karnataka, Maharashtra, Andhra Pradesh, Manipur and Nagaland. The epidemic in India is highly heterogenous due to the diverse modes of disease transmission in each state. Most of the earlier cases had occurred through heterosexual sex; but at the end of the 1980s, a quick spread of HIV was observed among injectable drug users in Manipur, Nagaland and Mizoram[(5)]. Even within the same State, the prevalence varies among districts. Hence, NACO has categorized districts.

1	>1% ANC/PPTCT prevalence at any time in a district in the previous 3 years	A
2	<1% ANC/PPTCT prevalence in all sites in the preceding 3 years associated with > 5% prevalence amongst HRGs	B
3	<1% ANC/PPTCT prevalence in the preceding 3 years in all sites furthermore associated with < 5% prevalence in all STD clinic attendees /HRG with recognized hot spots (migrant, tourists, truckers, large aggregation of factory workers, etc)	C
4	<1 % ANC prevalence in last 3 years in all areas with < 5% prevalence among STD clinic attendees / HRG / no or poor HIV data with no established hot spots	D

HIV prevalence was projected to be >1% among antenatal mothers in 95 districts, including 9 districts belonging to the low-prevalence States.

HIV prevalence has started to decline in Tamilnadu and other Southern States which have reportedly a high HIV burden. There has been feminization of this HIV epidemic with an estimated 38.4% of infected adults being women[6].

There are about 4000 integrated counselling and testing centers (ICTCs) in India. About 80,000 HIV infected people are accessing free antiretroviral treatment (ART) in 127 centers. PPTCT program has been scaled up in the county with Nevirapine as the drug of choice.



History of HIV in India

India's initial few cases of HIV were detected among sex workers in Chennai, Tamil Nadu. Intavenous drug users had contributed to a worse scenario in Manipur, Mizoram and Nagaland [(7)]. In 1987, a National AIDS Control Programme was launched to coordinate Nation level control activities. Its activities included surveillance, health education and blood screening [(8)]. In 1992, Indian Government formulated NACO (National AIDS Control Organisation), to oversee the formation and execution of policies, prevention work and control programs related to HIV and AIDS. In 2001, the Government adopted the National AIDS Prevention and Control Policy[(9)]. NACP III was launched officially on 6 th July 2007 [(10)] with a motto of halting or reversing the HIV epidemic in India by 2012. Whereas NACP IV launched in 2012 aimed at zero HIV incidence, zero stigmata, zero discrimination against HIV infected and zero AIDS related death . NACP has declared a 56% decline in HIV incidence in the last decade.

India housed 5.7 million HIV/AIDS patients (people aged between 15 and 49 years) way back in 2005, including the pediatric AIDS cases. The HIV/AIDS epidemic is affecting females and young girls more, especially where heterosexual sex is the main mode of transmission[(11)]. Out of the estimated adult population living with HIV, 38.4% were women[(12)].

The overall HIV prevalence among different sector of population in 2007 continues to picturise the concentrated epidemic in India, with a very high prevalence among High Risk Groups - IDU (7.2%), MSM (7.4%), FSW (5.1%) & STD (3.6%) and low prevalence among Antenatal clinic attendees (0.48%).

Table – 1.1: India and State-wise HIV Statistics 2010

State	Estimated Adult HIV Prevalence	
	Male (%)	Female (%)
Andaman & NicobarIslands	0.29	0.15
Andhra Pradesh	1.07	0.73
Arunachal Pradesh	0.2	0.12
Assam	0.1	0.06
Bihar	0.26	0.17
Chandigarh	0.46	0.29
Chhattisgarh	0.34	0.22
Dadra Nagar Haveli	0.17	0.12
Daman & Diu	0.18	0.13
Delhi	0.35	0.23
Goa	0.58	0.4
Gujarat	0.44	0.3
Haryana	0.17	0.07
Himachal Pradesh	0.23	0.16
Jammu & Kashmir	0.09	0.06
Jharkhand	0.16	0.1
Karnataka	0.75	0.51
Kerala	0.23	0.15
Madhya Pradesh	0.23	0.16
Maharashtra	0.64	0.45
Manipur	1.89	0.9
Meghalaya	0.1	0.07
Mizoram	0.97	0.64
Nagaland	0.94	0.61
Orissa	0.35	0.23
Puducherry	0.33	0.22
Punjab	0.37	0.26
Rajasthan	0.22	0.15
Sikkim	0.07	0.05
Tamil Nadu	0.39	0.27
Tripura	0.18	0.12
Uttar Pradesh	0.11	0.07
Uttarakhand	0.12	0.08
West Bengal	0.34	0.23
INDIA	**0.36**	**0.25**

HIV in Tamil Nadu

As per NACO study in 2004 -2006, amongst 32 districts, 22 fall under Category A. They include Coimbatore, Erode, Namakkal, Thoothukudi, Cuddalore, Kanyakumari, Karur, Madurai, Dharmapuri, Krishnagiri, Pudukottai, Perambalur, Ramanathapuram, Theni, Salem, Sivagangai, Nilgris, Vellore, Thiruvallur, Tiruchirapalli, Thiruvannamalai and Virudhunagar. Whereas, Chennai, Kanchipuram, Tirunelveli, Villupuram and Thanjavur districts were tabulated under Category B. Thiruvarur, Dindigul and Nagapattinam were assigned into Category C.

Table 12. Aids Cases in Tamil Nadu, No. Of Patients Currently on Anti Retroviral Treatment (Centre Wise Cumulative Reported Up to November 2009) (In Numbers)

Name of the ART Centre	Male	Female	TG	Children	Total
Govt. Hospital for Thorocic Medicine	3,713	2,353	28	325	6,419
Madurai	2,043	873	10	134	3,060
Madras Medical College	771	429	10	33	1,243
Namakkal	1,824	1,536	2	187	3,549
Salem	1,794	1,560	8	141	3,503
Tirunelveli	540	384	0	79	1,003
Kilpauk Medical College	318	233	7	102	660
Institute of Obseterics & Gynaecology	141	152	8	17	310
Thanjavur	805	546	0	139	1,498
Kanniyakumari	258	165	1	35	458
Vellore	852	731	1	131	1,715
CMC, Vellore	310	160	5	10	481
Coimbatore	1,033	830	5	140	2,008
Theni	741	583	0	149	1,478
Tiruchy	1,199	938	1	115	2,252
Karur	366	368	0	35	770
Dharmapuri	378	379	4	31	788
Villupuram	329	350	1	101	784
Virudhunagar	350	202	1	38	591
Krishnagiri	372	449	1	47	869
Dindigul	572	535	1	72	1,180
Perarnbalur	291	302	1	45	639
Cuddalore	267	223	1	62	553
Thoothukudi	238	188	0	15	442
Institute of Child Health	21	31	0	77	129
Tiruvallur	140	149	0	25	314
Tiruvannamalai	210	199	0	43	452
Chegalpattu	18	13	0	1	32
Stanley	47	26	0	0	73
Erode	395	310	0	9	714
The Nilgiri's	46	51	0	7	104
Ramanathapuram	99	63	0	3	165
Sivagangai	100	79	0	10	189
Pudukkottai	80	82	0	5	167
Thiruvarur	44	46	0	3	93
Nagapattinam	75	58	0	12	145
Total	20,780	15,576	96	2,378	38,830

The HIV prevalence at antenatal clinics in Tamilnadu was 0.88% in 2002 and 0.5% in 2005, though many districts still have rates above 1%. Prevalence among Intravenous drug users was 18% in 2005. Tamil Nadu had reported 52,036 AIDS cases to NACO by July 2005, which is by far the highest number reported by any State[(12)].

Also, there are cases of HIV 2 reported in Tamilnadu especially in southern districts especially Tirunelveli[13] .

Spread of HIV

The HIV pandemic has undergone four critical stages of evolution

1. Emergence - from remote rural areas
2. Dissemination to various parts of world due to population migration and world wide travel
3. Escalation - when transmission was increased by high risk groups
4. Stabilisation – In Australia, North America and Western Europe (LANCET)

The approximate risk of acquiring HIV infection after different types of exposure is less compared to risk of infection with HBV or HCV. Blood transfusion has the utmost chance of transmitting HIV of nearly 90 – 95%.

Mode of Exposure	**Chance of Transmission (in %)**
Blood and Blood product transfusion	90-95
Perinatal and Intranatal transmission	20-40
Mother to Child transmission	13 -48
Sexual intercourse	0.1 – 10
Vaginal intercourse	0.05 – 0.1

Anal intercourse	0.065 – 0.5
Oral intercourse	0.005 – 0.01
Intravenous drug use	0.67
Needle stick exposure	0.3
Mucosal splash to eye/ nose/mouth	0.09

Mode of exposure	**Cause of infection world wide in percentage**	**Cause of HIV infection in India- percentage**
Blood transfusion	5	2.5
Perinatal	10	
Sexual	75	86
Vaginal	60	85
Anal	15	0.548
Oral	Case reports only	
Intravenous drug use	10	7.3
Needle stick injury	0.1	0
Others		10.92

The above information concerning Indian statistics have been published in NACO website.

In contrary to common belief that saliva can transmit HIV, it is not so. Saliva contains some nonspecific inhibitory substances like fibronectins

and glycoproteins and salivary leukocyte protease inhibitor (SLPI) which could avert cell to cell transfer of virus. Thus, saliva is not a likely mode of transmission. Sweat, milk, tears, amniotic fluid, synovial fluid, broncho-alveolar lavage fluid, faeces and urine have been reported to yield zero to a few HIV particles. Hence, these vehicles are also not proposed to be important in virus transmission.

Breast milk at the time of primary acute HIV infection in a lactating mother has a high concentration of virus and may transmit the infection to the baby. Cerebrospinal fluid (CSF), on the other hand, also has a high viral concentration particularly in individuals with neurological involvement, but, CSF is not a natural source of virus transmission.

India's epidemic appears to follow the Type 4 pattern , initially postulated in Thailand.

High Risk Groups → Bridge population →General population

The shift in groups occurs when the prevalence in preceding group reaches 5%. The time lag between such a shift is around 2 -3 years.

High Risk Groups

They are the core groups including

- Commercial sex workers
- Partners of HIV/ VDRL reactive patients

- Transgenders / Homosexuals
- Victims of sexual abuse
- IV drug abusers
- H/o multiple blood transfusions
- Occupational exposure to blood products with exposure code 3 and risk code 2.

Commercial sex workers spread the infection to the bridge population with the transmission rate of 0.033 to 0.1%. The co existence of other STIs favour a quicker transmission of infection.

In transgenders and men having sex with men, unprotected anal intercourse puts the individual at a risk rate of 0.5 to 3% which is much higher than that of a male to female or female to male vaginal sex either way. Though open acceptance for Gay relationship is controversial, considerable number of men continue to be MSMs and keep it secretive. So limited is their knowledge of prevention and awareness of STIs and HIV. Alcoholics may also be included in this category due to higher unsafe sex practices prevalent among them[14] and higher chance of condom slippage and other risk factors.

In Vellore, a study indicates that the prevalence of HIV 1 antibodies among CSWs increased from 1.8% in 1986 to 28.6% in 1990. The prevalence of HIV infection among STD patients has increased from 0.19%

in 1986 to 3.9% in 1992. Also, the HIV incidence was 9.7 per 100 person years in men with recent exposure to CSWs without proper protection compared to 5.6 per 100 person years in men without such an exposure, as per a study conducted in Pune [15].

Co Factors involved in HIV transmission

The huge list of co factors can be enumerated which facilitate the transmission of HIV infection. They are

- Co existence of other STIs escalates the risk by 300 -400%
- Ignorance in the part of source as well as the victim
- Condom slippage/ tear
- Late marriage in men / women increasing incidence of pre marital sex
- Low socio economic status, financial burdens and human trafficking
- Lack of proper antenatal visits
- Alcoholism
- Recapping of needles
- Improper handling/ segregation of hospital wastes

Human Immunodeficiency Virus

HIV belongs to retroviridae family and lentivirinae subfamily. They are of 2 types namely HIV 1 and HIV 2. HIV 1 resembles SIV cpz isolated from chimpanzee subspecies Pan troglodytes troglodytes and is distributed world wide. HIV 2 resembles SIVsm isolated from Sooty Mangabey monkeys and is found to be virulent. HIV 2 was first isolated from West Africans.

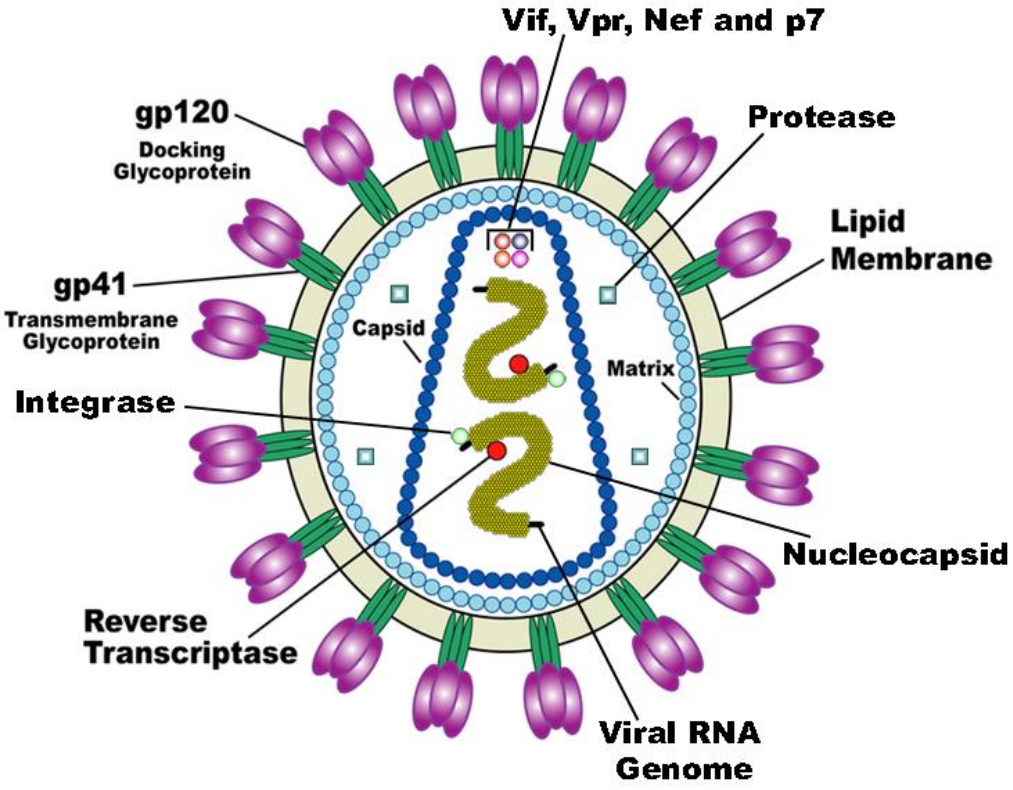
The strains of HIV 1 are divided into two groups as Major and Outlier indicated as M and O respectively. Furthermore, group N has been described in Cameroon. Group P has been isolated from Gorilla. The M group has nine subtypes called as clades A to K excluding E and I along with increasing major and minor circulating recombinant forms (CRFs).

India	-	Subtype C mainly, B and recombinant HIV (C and A).
Thailand	-	Sub type B and E.
United States and Europe	-	Sub type B.

CRFs are formed due to dual subtypes infection which recombine and create a virion with an added advantage. An example is AE form despite the fact that a pure parenteral E infection is yet to be detected. Furthermore, subtypes A and F are further classified into A1, A2, F1 and F2. The globally

most prevalent seven strains are HIV 1 subtype A, B, C, D, G, CRF01_AE and CRF02_AG. Of all these, subtype C is in the lead.

HIV 2 has further been subclassified into groups from A to G. In general, the group with utmost significance is HIV 1 Group M as this has contributed to the global pandemic. Whereas, HIV1 Group O and HIV 2 though found in many countries off late, contributes to localized epidemics.



It comprises of a central electron dense nucleoprotein core with two positive single stranded RNA copies, nucleocapsid and capsid proteins, viral enzymes integrase, protease and reverse transcriptase which are surrounded by an envelope. The capsid protein constitutes the icosohedral viral core

which is hydrophobic and is the major internal structural feature of the virion comprising the shell of viral core. On its outer surface lies a lipid bilayer constituting surface (gp120) and transmembrane (gp41) envelope glycoprotein[16]. The matrix protein lines the inner surface of the lipid bilayer.

The proviral DNA form of HIV 1 genome contains 8.5 to 9 kb of protein coding information flanked on either sides by long terminal repeats. The coding portion codes for 9 different genes

- Structural genes – gag, pol, env
- Regulatory genes – tat, rev, nef
- Accessory genes – vpu, vif, vpr

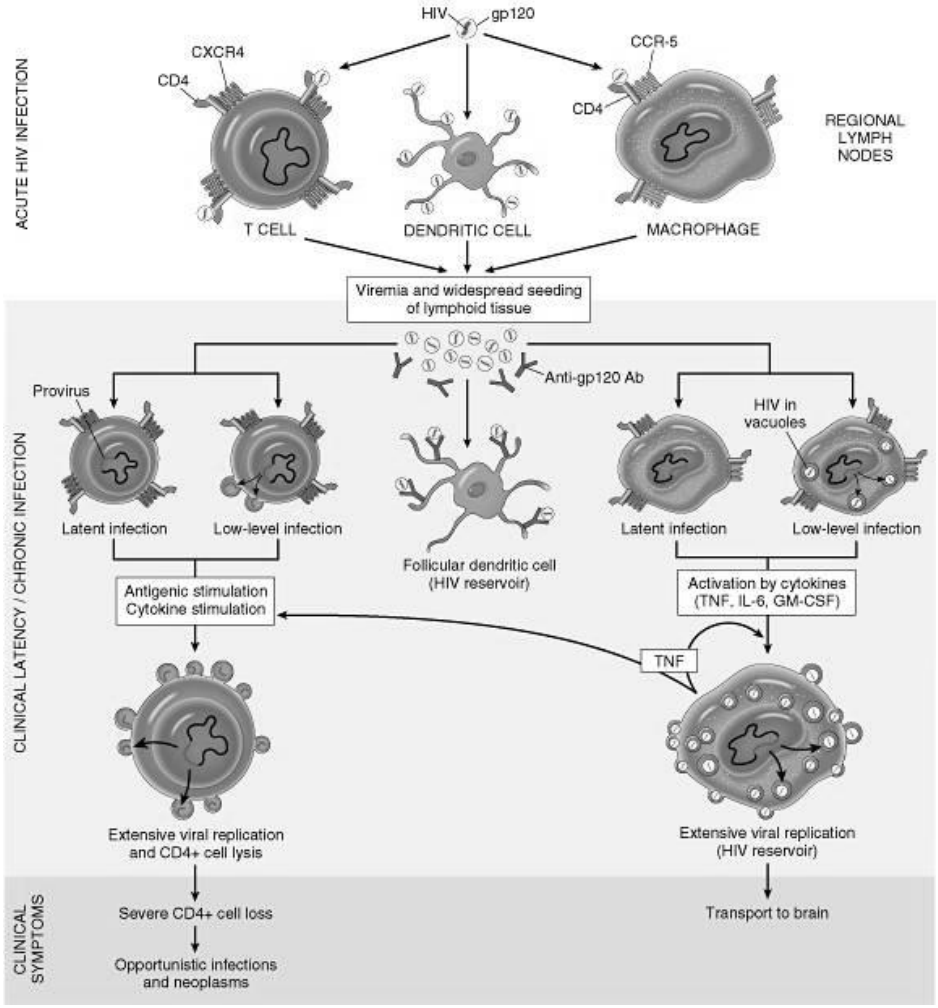
Gene	Type	Function
Env	Structural gene	Codes gp 160 (120 &41)
Gag	Structural gene	Codes internal proteins forming core of virion (p24,7,9)
Pol	Structural gene	Encodes (p7, 9, RNA, reverse transcriptase, integrase, protease)
Tat	Positive regulatory gene	Tansactivator of transcription
Nef	+/_ regulatory gene	Negative regulation factor
Rev	+/_ regulatory	Regulator of expression

	gene	
Vpr	Weak positive	Transcriptional activation ; Moderate activator of LATS
Vpu	?negative	Not found in HIV 2; If defective, virus replicates quickly
Vif	Infectivity	Virion infectivity factor

The main variation between HIV 1 and 2 is that HIV2 lacks vpu gene and has vpx instead. This vpx gene is absent in HIV 1. There are a lot of sequence diversities in HIV isolates, mainly clustered in the hypervariable regions.

Pathogenesis

The steps occurring in infection involve an interaction of HIV not only with the CD4 molecule on cells but also with other cellular receptors and antigen presenting cells[17] .



HIV can infect different types of cells such as CD4+ helper T-cells and macrophages that express the CD4 molecule on their surface.

Macrophage (M-tropic) strains of HIV-1 or the non-syncitia-inducing strains (NSI) utilise the beta-chemokine receptor CCR5 for entering the cell and are thus capable of replicating in macrophages and CD4+ T-cells[(18)]. These strains are now labelled as R5 viruses. This CCR5 co receptor is utilised by almost all primary HIV-1 isolates regardless of viral genetic subtype.

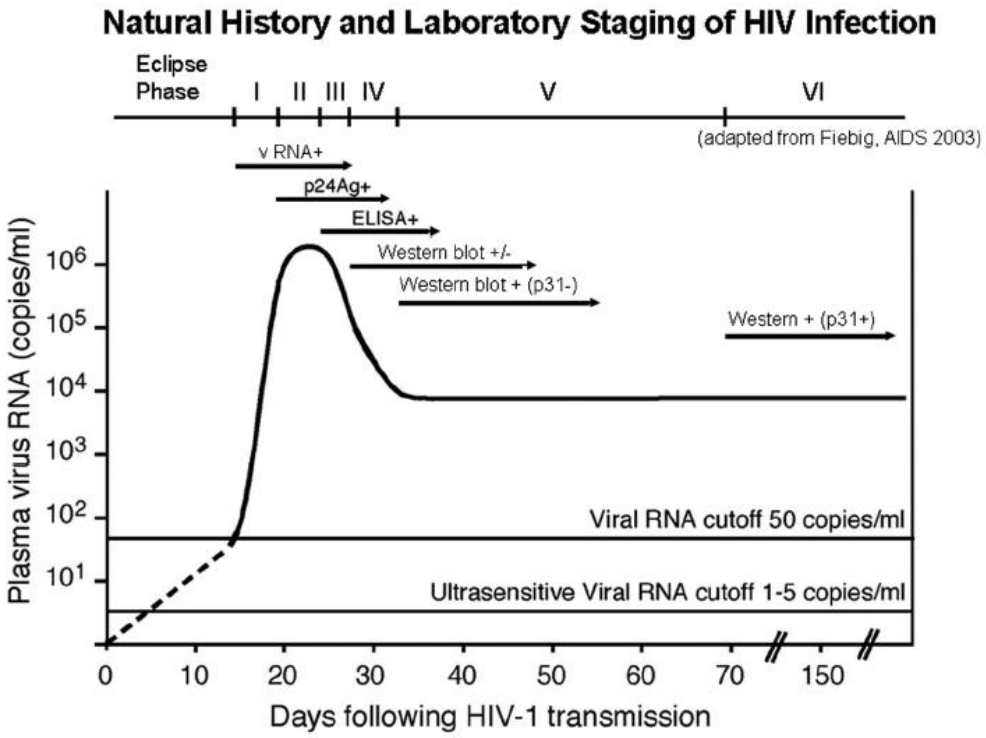
T-tropic isolates or the syncitia-inducing (SI) strains replicate in primary CD4+ T-cells as well as in macrophages and utilise the alpha-chemokine receptor, CXCR4, for gaining entry into the cell[19,20]. These strains are now labelled as X4 viruses. The alpha-chemokine, SDF-1, which is a ligand for CXCR4, suppresses the replication of T-tropic HIV-1 isolates.

Viruses that use only the CCR5 receptor are termed R5, those that only use CXCR4 are termed X4, and those that use both, X4R5. Apart from CD4 cells, the dendritic cells expressing C type Lectin named as DC sign.

HIV's replication cycle gets initiated with the high affinity binding of V1 region adjacent to N terminal of gp120 to CD4. This induces some conformational variations in gp120 which facilitates the binding to abovesaid coreceptors namely CCR5 and CXCR4. After the interaction of virus and the host cell receptor, fusion of viral as well as the cell membranes occur as gp41 penetrates the plasma membrane of the target cell and viral core ventures into target cell cytoplasm forming a pre integration complex consisting of viral nuclear material, its enzymes and capsid coat. By the action of reverse transcriptase, double stranded DNA is synthesised by having ssRNA as a template forming the proviral DNA. This stage is inhibited by APOBEC group of cellular proteins. These are counteracted by the viral protein vif factor by means of proteosomal degradation. It is followed by integration of viral DNA with host DNA within introns of active genes and their hot spots by the action of integrase enzyme.

RNA polymerase II aids in viral replication using integrated provirus as a template which is further converted into spliced and non spliced viral mRNA transcripts encoding regulatory and structural viral protein. Finally, they get assembled along with genomic length RNA and budding of virion from host cell surface from specialised regions in the lipid bilayer called as lipid rafts occurs releasing free infective virions. Proteases catalyse the gag pol precursor cleavage to finally release the mature virion.

Stages of HIV Infection



Following infection with HIV, there is a time period called as transmission bottle neck. It further leads to an initial eclipse phase where the

infection is localised to the tissue at that particular exposure site when there is no serological changes in blood. This phase exists for approximately 10 days. There is further spread to the regional lymphoid tissue and then into the systemic circulation with a viral replication time of 20 hours. A week after the stage of viremia, p24 Ag gets detected in blood. This p24 Ag detection occurs once HIV RNA copies exceeds 10000 copies/ml of blood[21].

During this period of time, the architecture of lymphoid tissues is profoundly altered, with dramatic depletion in CD4+ lymphocyte count, widespread immune stimulation and establishment of central nervous system infection. Finally, as cellular and humoral immune responses emerge, viral loads decline and stay at much lower levels associated with the initial set point[21,22]. The end of the phase of acute infection leads, in most cases, to the initiation of the long clinical latency of HIV infection.

The onset of symptoms of Acute HIV infection starts roughly a fortnight after acquisition of infection due to cytokine storm. Approximately, 5 -7 days following p24 Ag detection, anti HIV antibody reach levels detectable in blood[21].

Table 1. Fiebig Stage Classifications for Substages of Human Immunodeficiency Virus Type 1 Primary Infection, with Durations

Stage	Defining finding and/or marker	Duration, mean (range), days	
		Individual phase	Cumulative duration
Eclipse	…	10 (7–21)	10 (7–21)
I	vRNA positive	7 (5–10)	17 (13–28)
II	p24 antigen positive	5 (4–8)	22 (18–34)
III	ELISA positive	3 (2–5)	25 (22–37)
IV	Western blot positive or negative	6 (4–8)	31 (27–43)
V	Western blot positive, p31 antigen negative	70 (40–122)	101 (71–154)
VI	Western blot positive, p31 antigen positive	Open-ended	…

NOTE. ELISA, enzyme-linked immunoassay; vRNA, viral RNA.

A proper understanding of the phases in HIV infection is important in realizing the significance of detecting early cases of infection[23].The rate of HIV transmissibility per coital act was highest during the pre said early-stage of infection. This has implications and practical significance for HIV prevention and for projecting the effects of antiretroviral treatment on HIV transmission .

In a prospective study of patients attending STD clinics in India, screening for p24 antigen in HIV antibody negative people was found to be a reliable and effective research method for accessing recent risk behavior and clinching at the clinical signs of acute primary HIV infection [24].

From the initiation of infection, the level of HIV 1 in serum and semen seems to be directly proportional. But in the course of disease, the risk of transmission per coital act does not remain the same. It keeps

changing depending on altering viral load. These acute dynamics alone are sufficient to predict the increase in probability of heterosexual transmission by 8–10-fold between peak (day 20 after infection) and virologic set points (day 54 and later after infection) [25]. Depending on the frequency of sexual act, men with an average semen HIV-1 loads and without sexually transmitted diseases (STDs) would be predicted to infect 7%–24% of susceptible female sex partners during the first 2 months of infection. The risk of transmission is further increased with other co existing sexually transmitted infections[26].

A research conducted in Uganda projects that the average HIV transmission was 0.0082/ coital act within 2.5 months following seroconversion; 0.0015 /coital act within 6 to15 months following seroconversion; 0.007/coital act among HIV prevalent index partners and 0.0028/coital act few months before the death of the index partner. Early and late stages of infection, genital ulcer disease, higher viral load, and younger age of the index partner were significantly associated with higher rates of spread.

The rate of HIV transmission per coital act was thus assessed to be the highest during early stage of infection[27] .

HIV and other Sexually Transmitted Infections

The other co existing sexually transmitted infections act as augmentators or cofactors for transmission of HIV. This is termed epidemiological synergism[28]. Apart from the increased HIV shedding in most of the secretions, another common factor is sexual promiscuity.

Increased HIV spread is because of already broken mucosal barrier and a favourable environment with due to prior recruitment of HIV susceptible inflammatory cells like CD4+ T cells. On the other hand, in HIV infected, the cell mediated immunity is already compromised rendering the person more vulnerable to other STIs.

Odds ratio of the risk of acquiring HIV infection in association with other STIs are as follows:

Genital ulcer disease	:	3 -18
Chlamydial Urethritis	:	3 -6
Gonococcal Urethritis	:	3.5 to 9
Trichomoniasis	:	3
Genital Herpes	:	2

In HIV infected patients, other STIs presume an atypical presentation, prolonged course and a wide dissemination occurs with systemic involvement. Reactivation of a previous forgotten sexually transmitted

infection also occurs in HIV infected. Drug resistant strains both bacterial and viral are also another issue of concern in HIV infected people developing other STIs.

Destruction of HIV[29]

Sterilization

- Autoclaving at 121^0C, for 20 minutes under15 lbs pressure.
- Dry heat 170^0C for 60 minutes.
- Boiling for a time period of 20-30 minutes.

Chemical disinfection

- Sodium hypochlorite: 5gm/litre. (0.5 to 1% ordinarily, 5-10% for high organic matter content e.g. discarding tissues etc.)
- Calcium hypochlorite: 1.4 gm/litre
- Chloramine : 20gm/litre (Available chlorine 0.1%)
- Formalin : 3-4%
- Ethanol : 70%
- Povidone iodine (PVI)
- Glutaraldehyde : 2% for 30 minutes

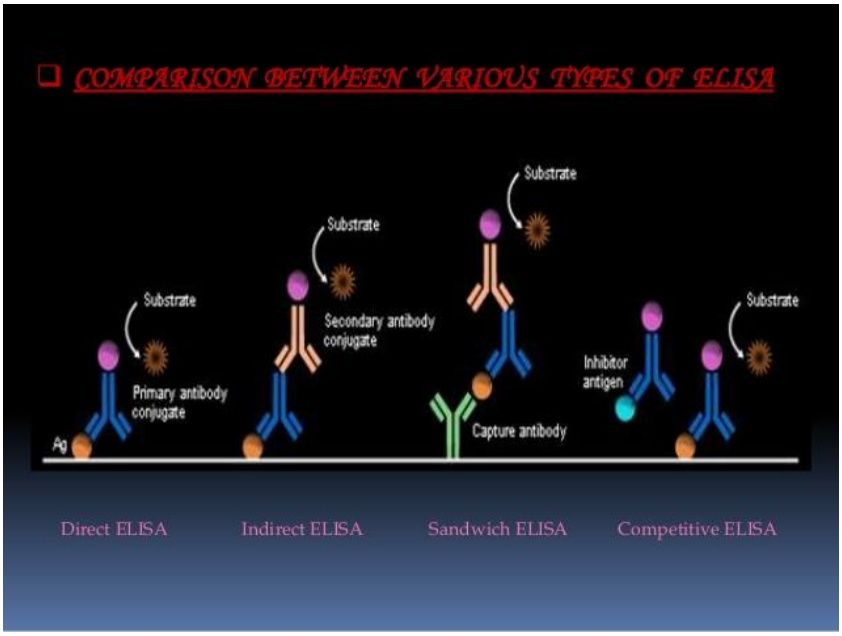
Diagnosis of HIV

The screening tests employed in detection of HIV are ELISA and Rapid assays.

Enzyme Linked ImmunoSorbent assay is a widely employed method for detecting HIV. Many samples are tested at the same time and results were obtained within four hours. In most of the people, detection of antibody in serum is possible within 6-12 weeks after infection using the previous generation of assays. This window period is decreased to 3-4 weeks when using the newer Third Generation ELISA. The additional advantage of detecting p24 Ag helps the latest Fourth-Generation ELISA to pick up infections 5 to 7 days prior. The total window period can be shrunken to two weeks using p24-antigen assay[30].

Enzyme Linked ImmunoSorbent Assay

The fundamental principle of ELISA is to utilise an enzyme to detect the antigen antibody complex formation. The enzyme transforms a colourless substrate to a coloured end product, indicating antigen and antibody binding. There are two main types namely Non competitive and Competitive ELISA. The Non competitive ELISA includes Indirect, Direct and Sandwich ELISA.



False Negative ELISA is predicted in the following conditions:

- Window period
- Terminal stage due to immune depletion
- Technical error
- Different subtype/ clades

False Positive ELISA occurs in

- Auto immunity
- Multiple transfusions
- Haemodialysis
- Multiple pregnancy
- Antibody to Class II HLA

- Acute Ebstein Barr virus infection
- Acute Cytomegalo virus infection
- Increased Immunoglobulin
- Vaccination for Hepatitis B/ Influenza
- Chronic alcoholic

There are four generations of ELISA[31]

First Generation : Crude antigen extracted from viral lysates was utilised. It could detect only HIV 1 and specifically IgG. It has increased sensitivity with lesser specificity.

Second Generation: Antigens are more refined and is a recombinant antigen extracted either from bacteria or fungi.

Third Generation: The antigen used is a synthetic polypeptide comprising of about 15 to 40 aminoacids. Detects both IgM and IgG of HIV 1 and 2. In this test, the window period is around 3 to 4 weeks following acquiring the infection.

Fourth Generation : It is the latest combo assay. It has an additional advantage of detecting p24 in addition to antibody detection due to coating of microtitre plate with both antigen and antibody.

Rapid assay has the immense advantage of quicker total reaction time of less than thirty minutes. It offers the opportunity to perform multiple assays at the same time with minimal cost. It also provides the additional advantage of not requiring any sophisticated or expensive modern equipment to perform the test or interpret the results .The other advantages are that test result read by naked eye and so do not need microscopic settings. The following methodologies are included in rapid tests

- Immunoblot technique
- Immunochromatography
- Red cell haemagglutination
- Membrane immuno concentration
- Particle agglutination
- Magnetic bead

Of all the above said methods, the most commonly employed one is dot blot assay[32,33] .

It utilizes nanogram quantities of HIV lysate, along with microliter amount of serum or culture supernatants for the detection of antibody. The microscopic sized particles are coated with a synthetic peptide which are then immobilized on a nitrocellulose membrane. To the patients serum (which supposedly contains anti HIV antibodies), conjugate, developer and

stop solutions are added in sequence after appropriate incubation time and washing. Colour develops in proportion to antibody level in serum.

The other supplementary tests are

Western Blot

This is a highly specific test with equal sensitivity as rapid assay and ELISA. The major crippling factor is the high cost incurred. The specific viral proteins derived from the whole viral lysate is run through gel electrophoresis. The various proteins are separated based on molecular weight and are blotted on nitrocellulose strip. The antibodies in blood get immobilized and attached to the proteins and a colorimetric reaction occurs on addition of enzyme, conjugate and substrate. The presence of coloured bands, confirms the sample positive for HIV.

Immunofluorescence test

Fluoroscein labeled anti human antibody is employed to detect the presence of anti HIV antibodies. A positive result is confirmed by development of an apple green fluorescence. Technical expertise is a major curbing factor in carrying out this otherwise inexpensive test.

Line Immuno assay

It bears lot of resemblance with Western blot except for the fact that a recombinant or synthetic peptide is used as an antigen.

Confirmatory tests

They include

Virus isolation

HIV virus is cultured by co cultivating HIV negative person´s peripheral blood mononuclear cell. It needs an average time of one week from acquisition of infection. There is also a microculture method described. Both methods picked up more than 75% of the positive cultures within a week and 100% of the positive cultures within a fortnight[(34)] . The main disadvantage is that a negative test does not rule out HIV, one week mean period required for detection and expertise needed.

p24 antigen – HIV specific core antigen detection:

Identifying cases in the acute stage of infection, particularly before detection of antibodies is very crucial in epidemiological, clinical and social point of view[(35)] .Understanding the intensity of transmission in the early infective period, the usefulness of psychological counselling and guidance regarding sexual abstinence or barrier methods need not be overemphasised.

Another noteworthy issue is mother to child transmission, which can also be prevented by intake of antiretroviral drugs after early detection of infection in a pregnant mother.

In 1985, in the United States of America, there was a study stating acquisition of HIV in recipients of blood transfusion whose donors were screened negative for HIV antibody at that point of time. Thus, it was then stressed that new assays which pick up HIV infection earlier should be evaluated for their effectiveness in screening donated blood [(36)].

By definition, antibody tests cannot generally identify cases of early acute HIV infection. Current rapid antibody tests detects HIV approximately during the fifth week of infection, after the occurrence of peak viremia [(37)]. A variety of tests exist that can pick up acute HIV infection before the currently employed standard EIAs and rapid antibody tests, including HIV p24 antigen immunoassays, Fourth-Generation immunoassays (which combine antibody and p24 antigen detection), and HIV NAATs.

Recognizing the limited ability of antibody tests to detect acute HIV infection, a number of large public testing systems in other countries have successfully implemented either p24 antigen tests alone, combined antibody and p24 antigen (Fourth-Generation immunoassay) [29] tests, or antibody and NAAT screening algorithms, to detect both acute and non acute HIV infections.

p24 antigen assay is useful not only in these early acute HIV infections, but also in newborn of reactive mothers where the maternal anti HIV antibodies misinterpret the other routine tests. Also, in HIV encephalopathy and dementia, a CSF p24 antigen can be searched for. p24 detection can be done by three methods namely

- Indirect ELISA
- Ultrasensitive p24 detection test – dissociation of immune complex before subjecting to ELISA
- RT – PCR

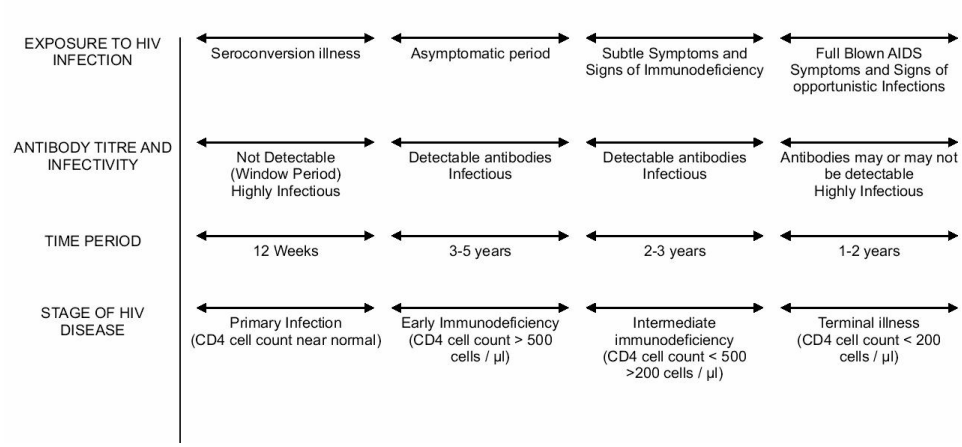
Polymerase Chain Reaction

It is the most sensitive test with the immense capacity to amplify even a single strand of proviral DNA. It aids in diagnosing cases earlier than viral culture.

The methods employed are

- RT PCR
- NASBA (Nucleic Acid Sequence Based Amplification)
- Branched DNA assay

National AIDS Control Organisation (NACO) Protocol:



The testing algorithms are based on prevalence of HIV in that area and the purpose of testing.

Testing algorithm - I

Purpose : Blood Transfusion

Done in : Zonal blood testing centre / Blood banks

Requirement : only one highly sensitive and reasonably specific test (ELISA) / anonymity maintained.

If positive, the blood is discarded.

Testing algorithm - II

Purpose : Serosurveillance

Tests : Two EIA are done, the first one very sensitive and the second test very specific.

Anonymity is maintained throughout. If serum is positive by first test, then a second test is done on the same sample. Only if positive by second test also, sample is considered positive and if not considered antibody negative.

Algorithm - III

Purpose : Diagnostic purpose

Number of tests done are three EIAs, with each one based on different antigen or principle.

In asymptomatic people, a positive first test is followed by second and third tests.

If positive by all three tests, sample is labelled positive

If negative by first or second test, again the sample is labelled negative

If positive by first and second test, but negative by third test, the sample is considered borderline or equivocal. Such samples are re tested with second and third test and also by Western blot for which sample is taken 2-3 weeks later.

In symptomatic, algorithm II holds good.

In a population with > 10% HIV prevalence, algorithm I is used in serosurveillance and algorithm II is used in asymptomatics.

Targeted Interventions by NACO

NACO states that the most effective means of controlling the spread of HIV in India is through the implementation of Targeted Interventions (TIs) among individuals who are more susceptible to HIV/AIDS, such as female sex workers (FSWs), men who have sex with men (MSM), transgenders (TGs) and injectable drug users(IDU). In addition, the bridge populations of truckers and migrants also require a more focussed intervention. Both NACO and the States gives a high priority upon full coverage of the States' FSWs, MSMs/TGs, IDUs and migrants/truckers with TIs.

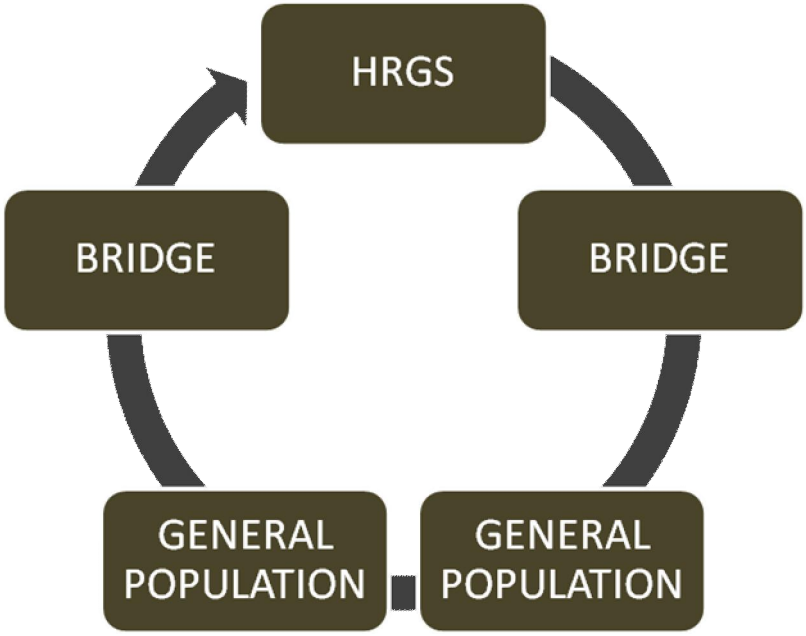
According to the framework of NACP III, prevention strategies will have a three pronged approach:

1. Core High Risk Groups (HRGs): There are three core HRGs — female sex workers (FSWs), high risk men who have sex with men and transgenders (MSM and TGs), and injecting drug users (IDUs).

2. Bridge populations: NACO gives prime focus on clients of sex workers: Clients benefit with a combination of services including condom promotion, referrals to clinical services for STI management and behavioural change

communication (BCC). Specific strategies have been outlined to approach two major populations within the bridge population: truckers and high risk migrants.

3. Other Vulnerable Populations: Risk groups in rural areas, HIV affected children, youth 15 - 19 years old and women receive a package of services delivered through a more extensive mechanism – that of link workers.



Studies state that in general a fulltime FSWs have at least one client per day, or at least 30 clients per month, and nearly 400 per annum. Some FSWs have 100 or more clients in a month. The higher risk of FSWs is reflected in a substantially higher prevalence of HIV among them than in the general population.

In India, Sentinel Surveillance data has shown that HIV prevalence among FSWs is generally 10 - 20% or more, which is more than ten times higher than among pregnant women attending antenatal clinics.

Within one year, 1,000 FSWs will have sexual contact with roughly 300,000 to 1,000,000 clients. In the contrary, 1,000 “high risk” men who have 6 - 12 sexual partners in a year will have a total of 6,000 -12,000 sexual partners per annum. Since the HIV prevalence is much higher among FSWs, a higher proportion of their sexual partnerships could result in HIV transmission more so in the stage of early acute HIV infection. The number of HIV positive sexual contacts for 1,000 FSWs is much greater than for the same number of high risk men. This demonstrates the strategic importance of focusing prevention programmes on FSWs.

MSMs and Transgenders

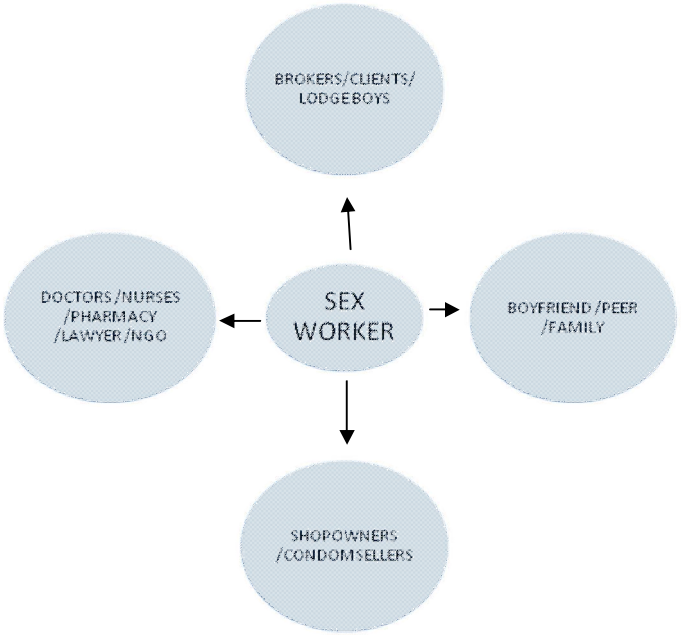
There are MSM subpopulations which do have high rates of change in partner as well as high number of concurrent sexual partners, and those who often engage in anal sex with multiple partners are at high risk and more vulnerable, since HIV is more transmissible through anal sex than by other sexual practices[38]. Members of the transgender population who have many male partners are also at high risk, since many of them engage in anal sex. Because many men who have sex with both high risk MSM as well as transgendered individuals also have other partners, both male and female,

targeted interventions for these HRGs are strategically critical to controlling the HIV epidemic.

Injecting Drug Users (IDUs)

IDUs are a third HRG for which targeted interventions are of critical importance. HIV is highly transmissible through the sharing of needles and other injection equipment, so it can spread very rapidly within the wide networks of IDUs who share injections and other equipments with each other. Once HIV prevalence is high in the IDU sector, it can extend quickly into their sexual networks too since sexual promiscuity is commonly present in the IDU sector. Some IDUs are also full fledged sex workers, which can rapidly link HIV spread in the IDU networks to transmission in the larger high risk sexual networks. The HIV prevalence among IDUs in Kolkatta was reported to be 1%[(39)].

It is important to understand that, like sexual transmission of HIV, HIV is essentially preventable among IDUs and their sex partners too. Interventions that are implemented early (HIV prevalence <5% among IDUs) are most efficient in decreasing the spread of the HIV epidemic among IDUs. HIV interventions targeting the majority of IDUs can stabilise and even reverse the escalating HIV epidemic among them.



The NACO strategies works on typology of female sex workers in to six categories and MSMs and IVU. They focus on reaching these HRGs in the field, forming a community based organizations, free condom supply and ensuring its availability, training and developing peer educators and propagating peer education .

Thus this study takes into account the magnitude of infection among the HRGs and the significance of earlier detection of HIV infection using p24 as well as the anti HIV antibodies.

AIM AND OBJECTIVES

1. To detect HIV infection using Fourth Generation Enzyme Linked Immunosorbent Assay

2. To compare the results of Test 1 (Fourth Generation ELISA) with Test 2 (Rapid Assay)

MATERIALS AND METHODS

Study Setting **:** Institute of Venereology
Madras Medical College /
Rajiv Gandhi Government General Hospital,
Chennai – 600003.

Study Period **:** One year (September 2013 – August 2014)

Study Observation : Prospective Observational Study

Sample Size: 200 patients consisting of High Risk Group and Contacts of High Risk Group attending the STI Out Patient Department, Institute of Venereology, Madras Medical College/RGGGH, Chennai were enrolled for the study.

The Ethics Committee approval was obtained and informed consent was taken from those patients who were enrolled in the study.

Study Population: High Risk Group and Contacts of High Risk Group

Inclusion Criteria

Patients attending STI Out Patient Department with high risk behaviours:

1. Commercial Sex Workers
   (including Female and Transgender Sex Workers)
2. Men with recent or recurrent exposure to Commercial Sex Workers
3. Females whose husbands were promiscuous and had multiple exposure to Commercial Sex Workers
4. Transgenders
7. Men with Homosexual Behaviour
5. Partners of HIV seropositive patients
6. Partners of VDRL reactive patients
8. Victims of Sexual Abuse
9. Intravenous Drug Abusers
10. H/o Multiple Blood Transfusions
11. Occupational Exposure to Blood Products with Exposure Code 3 and Risk Code 2

Exclusion Criteria

1. Known HIV positive patients
2. Patients who refuse to participate in the study
3. Patients less than 10 years

After fulfillment of the above inclusion criteria, patients were shortlisted and enrolled in the study.

Detailed clinical history which included age, gender, sexual orientation, occupational history, marital history, sexual history/ last contact, premarital and extramarital contact, HIV seropositivity in contacts, history related to present and past H/o sexually transmitted infections in patients as well as partners, followed by thorough clinical evaluation was done. Also, approach by the patient to STD department whether by self approach or referral from other medical fraternities or whether brought by NGO were recorded. Furthermore, willingness of the patient to give contact information including telephone number and contact address was noted which indirectly shows the approachability and accessibility to such patients.

History regarding the clinical complaints for which they approached STD department and other co morbid conditions like smoking, alcohol, Tuberculosis were documented. Furthermore, history regarding surgical intervention and blood transfusions were noted. History regarding intake of medications, previous treatments in STD clinic or any other health problems were sought.

Clinical Examination

In male patients, thorough genital examination was done with a speculative search for urethral discharge, balanoposthitis, phimosis, paraphimosis, genital ulcers or erosions, genital wart, genital molluscum contagiosum, genital scabies and genital scars.

In female patients, a routine gynaecological examination was done with Cusco`s self retaining bivalve speculum. Conditions like vulvovaginal candidiasis, genital herpes, genital wart, abnormal cervical discharge, abnormal vaginal discharge, genital ulcers or erosions were recorded if present. Urethral and cervical discharges were subjected to Gram staining, vaginal discharge was subjected to gram staining, KOH mount and saline mount and examined under microscope.

In Homosexuals with ororeceptive practices, throat swab for gonococcal culture was taken. Rectal swabs were taken for anoreceptive homosexuals and gonococcal culture was done. From genital ulcers, Tzanck smear, Gram staining and dark field microscopy was done to zero in on the cause.

Genital ulcers, if present were scraped from base to rule out herpetic lesions and serous discharge was subjected to dark ground examination.

A complete general examination to rule out any immunocompromised state or any coexistent diseases was done.

Investigations for other sexually transmitted infections like urine analysis for sugar, culture sensitivity, VDRL and TPHA for Syphilis, gonococcal culture were carried out.

Based on the above factors, Risk was assessed and High Risk patients recruited for the study.

After counselling and after recording their consent for the test, Fourth Generation ELISA for HIV infection was conducted on these selected patients along with routinely done Rapid Assay for HIV infection.

5 ml blood was withdrawn aseptically from the patient. The serum was separated and subjected to Fourth Generation ELISA as well as Rapid Assay for detection of HIV infection.

Study Principle

Test 1: It is Generation Four Solid Phase Enzyme Linked ImmunoSorbent Assay based on the principle of Double antigen/antibody sandwich technique for the detection of the IgM and IgG antibodies against HIV 1 and/or HIV 2 and p24 antigen in human serum or plasma.

Test 2: Dot ImmunoAssay employs the same principle as Enzyme Immuno Assay whereby the immobilized antigen antibody complex is visualized by means of colour producing (chromogenic) reaction. The coloured end point is developed by a Colloidal Gold Protein - A Signal Reagent.

Fourth Generation ELISA

The Fourth Generation ELISA is a Solid Phase Enzyme Linked Immunosorbent Assay. It utilizes the Double antigen antibody sandwich technique. It detects IgM and IgG Ab against HIV 1 & 2 and p24 Ag in human serum/plasma.

The kit used in this study employs monoclonal antibodies to p24 and highly purified antigens (recombinant) like gp41 (envelope glycoprotein) of HIV 1 and gp 36 (envelope glycoprotein) of HIV 2.

Mechanism

The microwells in the kit are coated with p24 antibodies, gp41 and gp36 antibodies of HIV 1 and 2 respectively. Samples along with both positive and negative controls were added into the wells. Antigen antibody complex forms. Then, the wells are washed to remove the unbound components. To the bound immune complexes adherent to the wells, biotinylated p24 antibodies were added which was followed by antigen HRP conjugate. Washing of wells was repeated. The reactions were stopped at a

specific time and absorbance was read at 450nm using an ELISA reader. Cut off value was then calculated and the results were compared. Samples with absorbance higher or equal to cut off value was considered positive or reactive.

Fourth Generation ELISA Kit

The kit consists of 96 microwells coated with monoclonal p24 antibodies and recombinant antigen of HIV 1 and 2.

Positive Control : Human serum reactive for HIV 1 which is stabilized and inactivated along with preservatives.

Negative Control : Stabilised, preserved, inactivated non reactive Human serum (non reactive to HIV 1,2, HBsAg and HCV).

Conjugate : Antigen HRP conjugate to be diluted with the given diluent. Antibody reagent : Biotinylated anti p24 Antibody (monoclonal).

Substrate : Tetramethyl benzidine and hydrogen peroxide.

Stop solution : Sulphuric acid (diluted).

Procedure

Samples taken were tested fresh or were short term refrigerated. Unheated samples were used. Sample, kit, diluents, conjugates and all reagents were brought to room temperature. 50 µl of sample diluent was

added in all wells. Further 100 µL of control or specimen were added in separate wells. This was incubated at 37degree centrigrade for thirty minutes. Each well was washed with wash buffer 350 µL giving 30 seconds soak time for six washes each. It was blot dried. After 100 µL of antibody reagent was added, the kit was again incubated at 37 degree centigrade for fifteen minutes. Blot dry the kit. 100 µl of diluted conjugate was added in each well and incubated for further fifteen minutes at 37 degree centigrade. The washing procedure as mentioned earlier was done six times. 100 µL of substrate was added in all wells, incubated at room temperature for thirty minutes. 100 µL of stop solution was added into each well in the same order as substrate was added. Finally, absorbance was read within half an hour of stopping the reaction at 450nm with reference range kept as 600 - 700nm.

Inference

Absorbance value of negative controls : < 0.1

Absorbance value of positive control : >1

If test run fails to meet the above criteria, it is invalid.

Procedure Flow Chart

50 µL of sample diluent in each well

⇩

100 µL control / specimen addition

⇩

Incubate at 37^0C for 30 minutes

⇩

100 µL antibody reagent added and incubate at 37^0C for 15 minutes

⇩

Blot dry

⇩

100 µL diluted conjugate added and incubated at 37^0C for 15 minutes

⇩

Wash six times

⇩

100 µL substrate added and incubated at room temperature for thirty minutes

⇩

100 µL stop solution added

⇩

Absorbance read at 450 nm (reference 600-700nm) within 30 minutes

The sensitivity of the kit used is 40pg/ml of HIV1 p24 antigen. The kit used has been stated to have a sensitivity of 100% and specificity of 99.71%.

Rapid Assay / Dot Immuno Assay

They are based on immunoconcentration method. HIV antigens both of HIV 1 and 2 are impregnated on comb shaped solid support. Sample used is diluted in specimen diluent and then added to the kit. Patient`s sera containing HIV antibody binds to the antigen in the kit and get immobilized. Protein A colloidal gold conjugate which is the signal reagent is then added to the kit. This protein A attaches to the Fc portion of anti HIV antibodies. A reddish spot proves the formation of immune complex, which further confirms the presence of anti HIV antibodies in the test serum.

Procedure

The sera and reagents are to be brought to room temperature before commencing the test procedure. Once started, the test should be carried out continuously without break. A positive and negative control should be done simultaneously.

Two drops of sample diluent is instilled in each well. 100 µL of sample or control kept in each well. They are mixed to ensure homogenization. Place the comb shaped solid support into each well.

Incubate the comb and sera with signal reagent for ten minutes. The signal reagent used is colloidal gold protein A. The combs are then placed with their reactive area facing upwards.

Reactive Sample **:** Pink or red dot of the same or little lesser colour intensity as that of positive control.

Non Reactive Sample **:** No colour development.

RESULTS

The study was conducted in the Institute of Venereology, Madras Medical College, Chennai. 200 patients including High Risk groups and contacts of High Risk groups were enrolled in the study.

Total Number of Patients in the Study Group – 200.

TABLE 1.1: PREVALENCE OF HIV POSITIVITY IN THE STUDY POPULATION BY FOURTH GENERATION ELISA

HIV FOURTH GENERATION ELISA	NUMBER OF PATIENTS	PERCENTAGE (%)
NEGATIVE	126	63
POSITIVE	74	37
TOTAL	100	100

FIG 1: HIV POSITIVITY AMONG STUDY GROUP BY FOURTH GENERATION ELISA

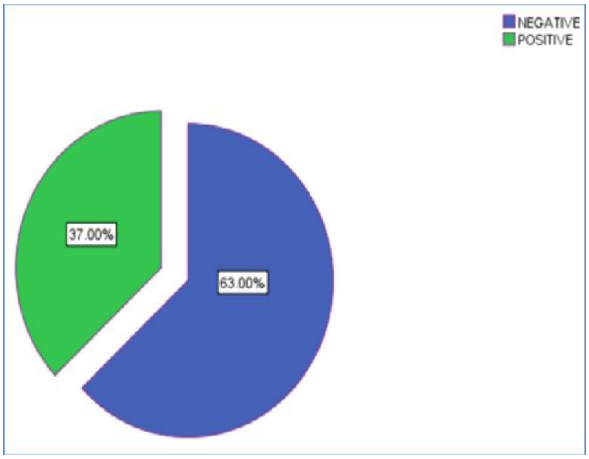


TABLE 1.2: PREVALENCE OF HIV POSITIVITY IN THE STUDY POPULATION BY RAPID ASSAY

HIV RAPID ASSAY	NUMBER OF PATIENTS	PERCENTAGE (%)
NEGATIVE	178	89
POSITIVE	22	11
TOTAL	100	100

FIG 2: HIV POSITIVITY AMONG STUDY GROUP BY RAPID ASSAY

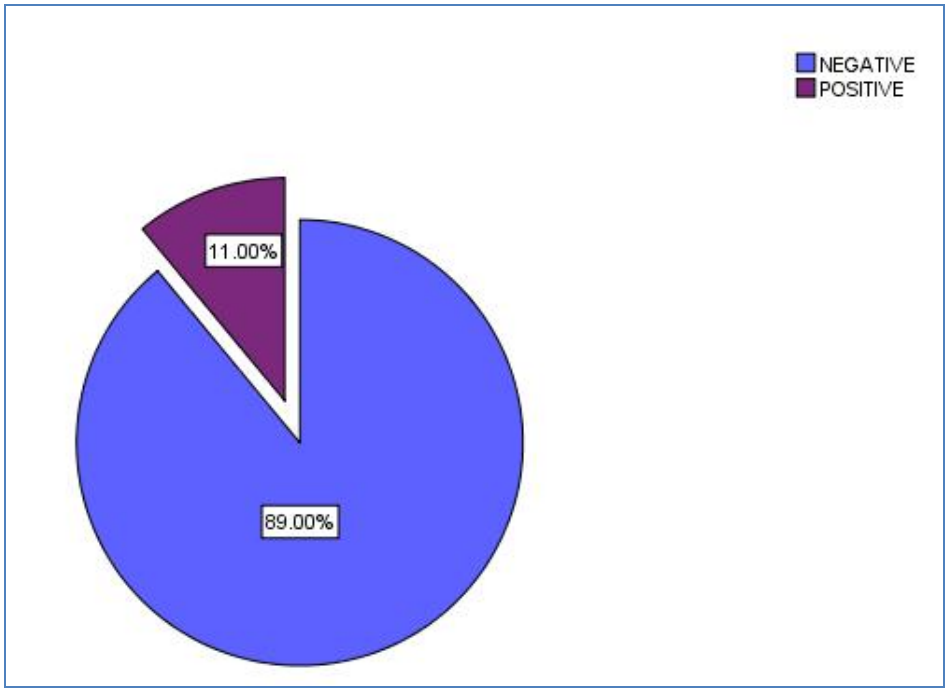


TABLE 1.3: PREVALENCE OF HIV AMONG THE VARIOUS GENDERS IN THE STUDY POPULATION BY FOURTH GENERATION ELISA

GENDER	NEGATIVE	POSITIVE	TOTAL
FEMALE	19 (63.3%)	11 (36.7%)	30 (100%)
MALE	97 (61.8%)	60 (38.2%)	157 (100%)
TRANSGENDER	10 (76.9%)	3 (23.1%)	13 (100%)
TOTAL	126 (63%)	74 (37%)	200 (100%)

FIG 3: HIV PREVALENCE AMONG VARIOUS GENDERS BY FOURTH GENERATION ELISA

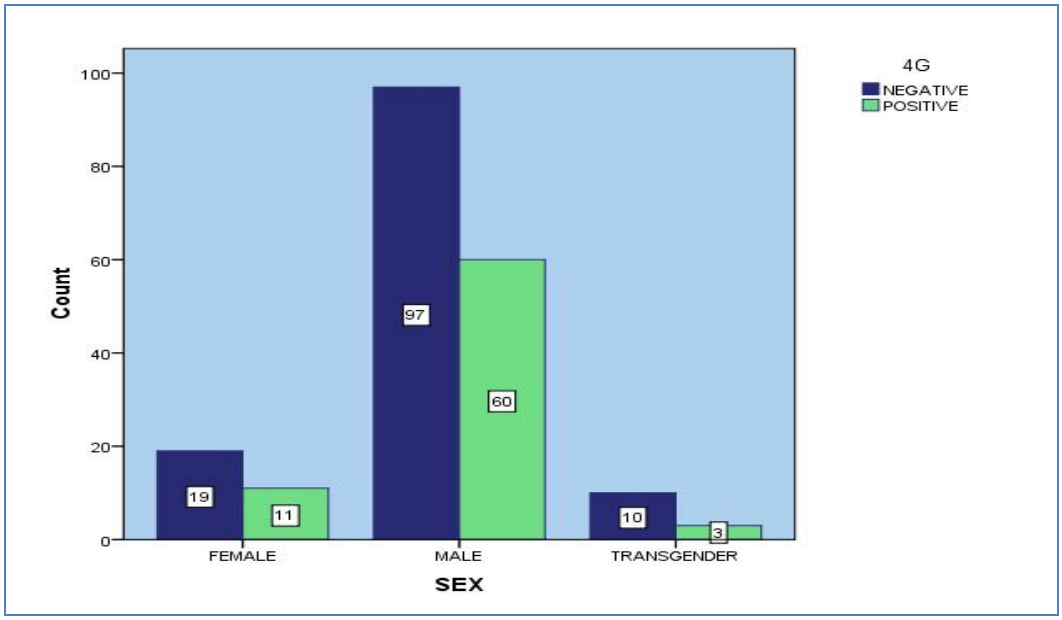


TABLE 1.4: PREVALENCE OF HIV AMONG THE VARIOUS GENDERS IN THE STUDY POPULATION BY RAPID ASSAY

GENDER	NEGATIVE	POSITIVE	TOTAL
FEMALE	26 (86.7%)	4 (13.3%)	30 (100%)
MALE	141 (89.8%)	16 (10.2%)	157 (100%)
TRANSGENDER	11 (84.6%)	2 (15.4%)	13 (100%)
TOTAL	178 (89%)	22 (11%)	200 (100%)

FIG 4: HIV PREVALENCE AMONG VARIOUS GENDERS BY RAPID ASSAY

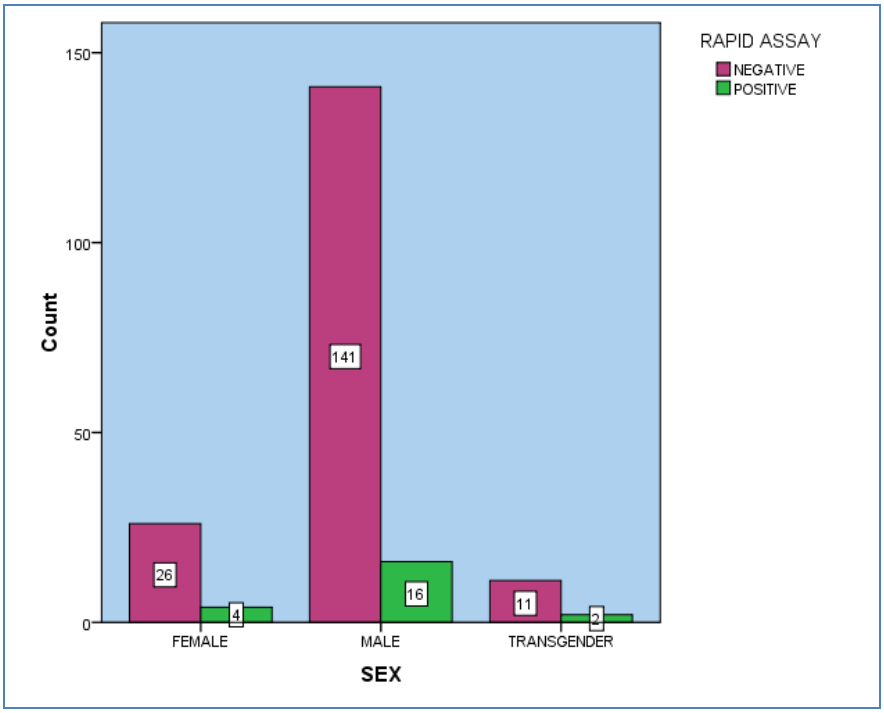
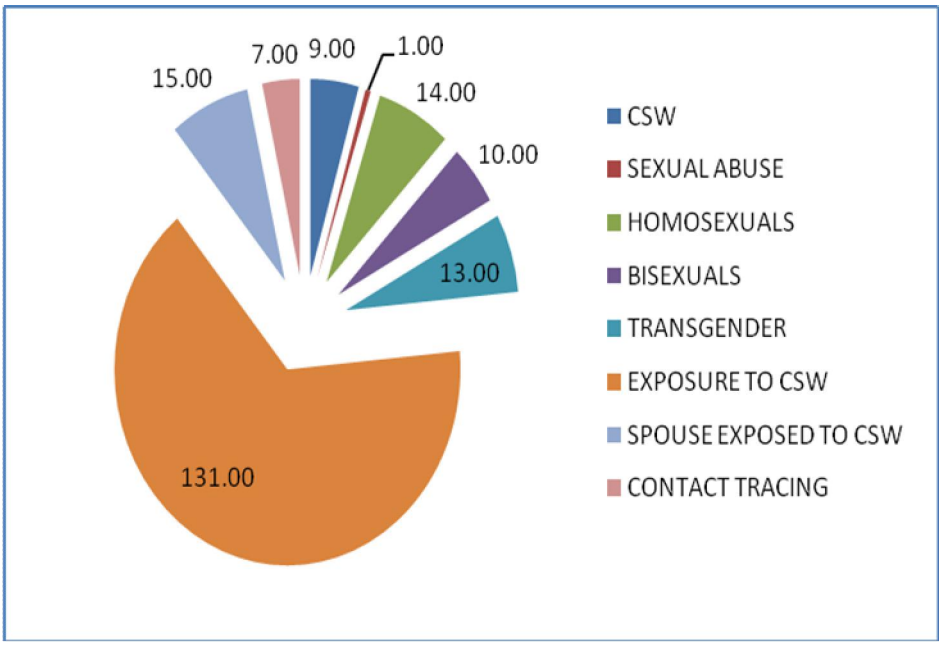


TABLE 1.5: HIGH RISK CATEGORISATION IN THE STUDY GROUP

HIGH RISK CATEGORY	NUMBER	PERCENTAGE (%)
CSW	9	4.5
SEXUAL ABUSE	1	0.5
HOMOSEXUALS (MSM)	14	7
BISEXUALS	10	0.5
TRANSGENDER	13	6.5
EXPOSURE TO CSW	131	65.5
SPOUSE EXPOSED TO CSW	15	7.5
CONTACT TRACING	7	3.5

FIG 5: HIGH RISK CATEGORISATION AMONG THE STUDY GROUP



SOCIODEMOGRAPHIC FEATURES

TABLE 2.1: PREVALENCE OF HIV AMONG VARIOUS AGE GROUPS BY FOURTH GENERATION ELISA

AGE IN YEARS	NEGATIVE	POSITIVE	TOTAL
<20	13 (76.5%)	4 (23.5%)	17 (100%)
21 – 30	49 (62.8%)	29 (37.2%)	78 (100%)
31 – 40	23 (47.9%)	25 (52.1%)	48 (100%)
>40	41 (71.9%)	16 (28.1%)	57 (100%)
TOTAL	126 (63%)	74 (37%)	200 (100%)

FIG 6 : PREVALENCE OF HIV IN VARIOUS AGE GROUPS BY FOURTH GENERATION ELISA

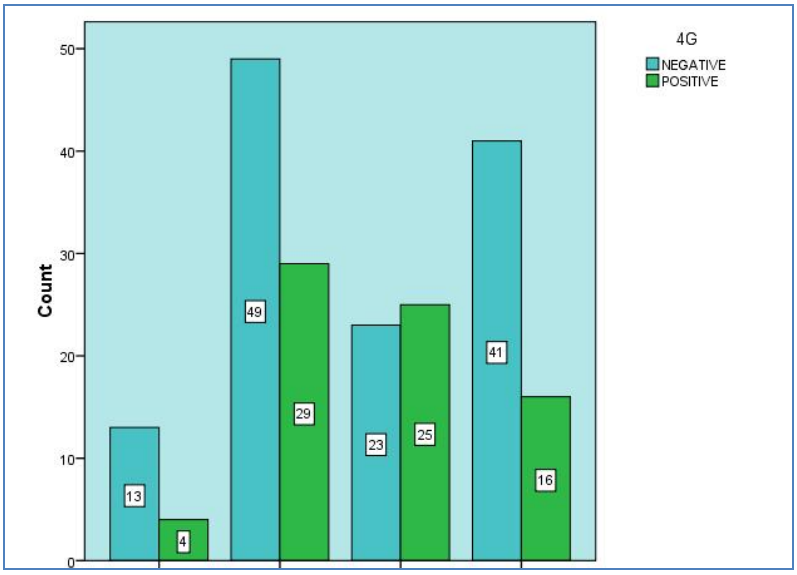
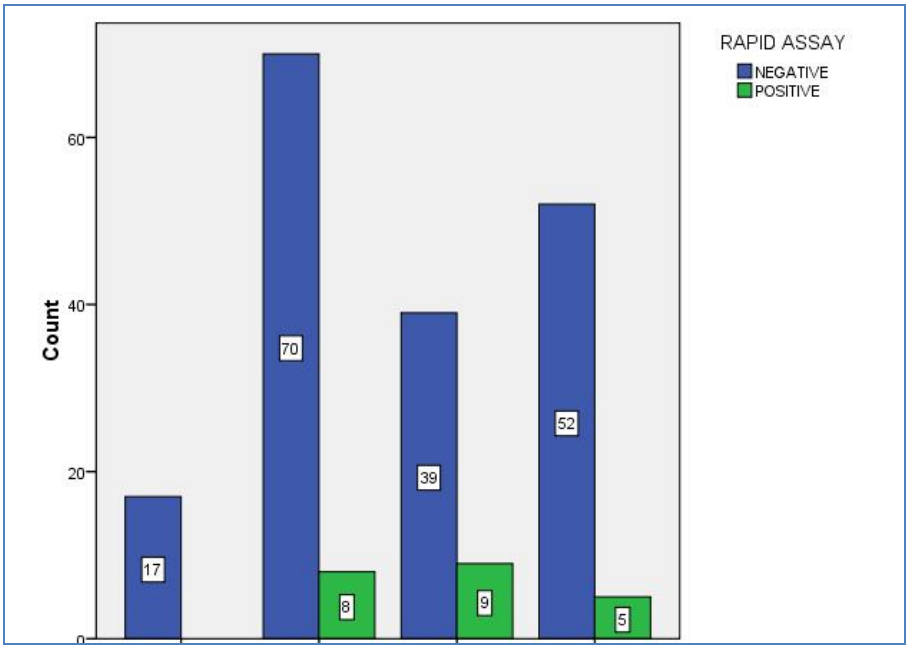


TABLE 2.2: PREVALENCE OF HIV AMONG VARIOUS AGE GROUPS BY RAPID ASSAY

AGE IN YEARS	NEGATIVE	POSITIVE	TOTAL
<20	17 (100%)	0 (0%)	17 (100%)
21 – 30	70 (89.7%)	8 (10.3%)	78 (100%)
31 – 40	39 (81.3%)	9 (18.7%)	48 (100%)
>40	52 (91.2%)	5 (8.8%)	57 (100%)
TOTAL	178 (89%)	22 (11%)	100 (100%)

FIG 7: PREVALENCE OF HIV IN VARIOUS AGE GROUPS BY RAPID ASSAY



<20 21 – 30 31-40 >40

AGE IN YEARS

TABLE 2.3: PREVALENCE OF HIV AMONG URBAN AND RURAL POPULATION IN THE STUDY GROUP BY FOURTH GENERATION ELISA

	NEGATIVE	POSITIVE	TOTAL
RURAL	51(63.8%)	29 (36.3%)	80 (100%)
URBAN	75 (62.5%)	45 (37.5%)	120 (100%)
TOTAL	126 (63%)	74 (37%)	200 (100%)

FIG 8: PREVALENCE OF HIV IN RURAL AND URBAN POPULATION IN THE STUDY GROUP BY FOURTH GENERATION ELISA

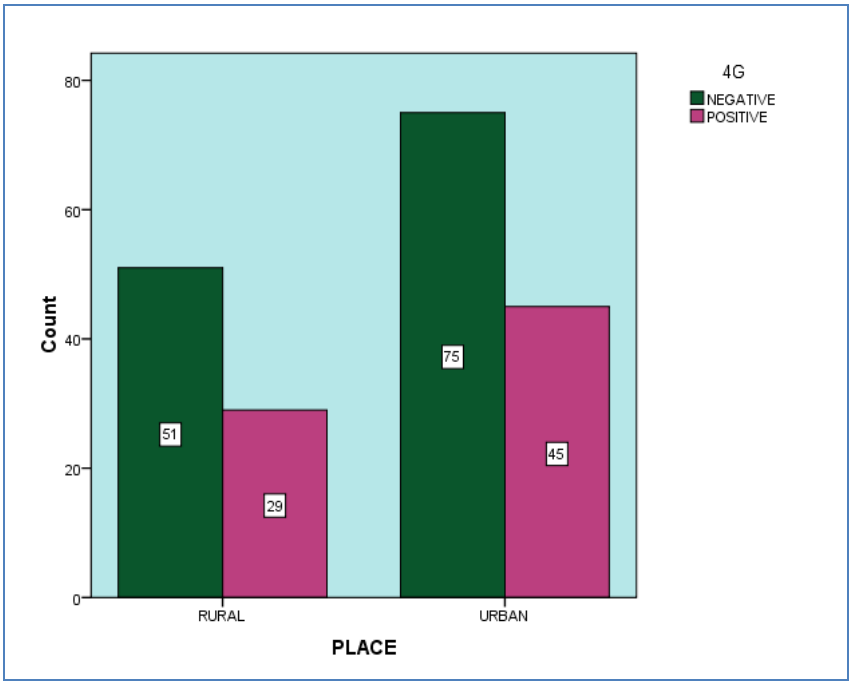


TABLE 2.4: PREVALENCE OF HIV AMONG URBAN AND RURAL POPULATION IN THE STUDY GROUP BY RAPID ASSAY

	NEGATIVE	POSITIVE	TOTAL
RURAL	69 (86.3%)	11 (13.8%)	80 (100%)
URBAN	109 (90.8%)	11 (9.2%)	120 (100%)
TOTAL	178 (89.0%)	22 (11.0%)	200 (100%)

FIG 9: PREVALENCE OF HIV AMONG URBAN AND RURAL POPULATION IN THE STUDY GROUP BY RAPID ASSAY

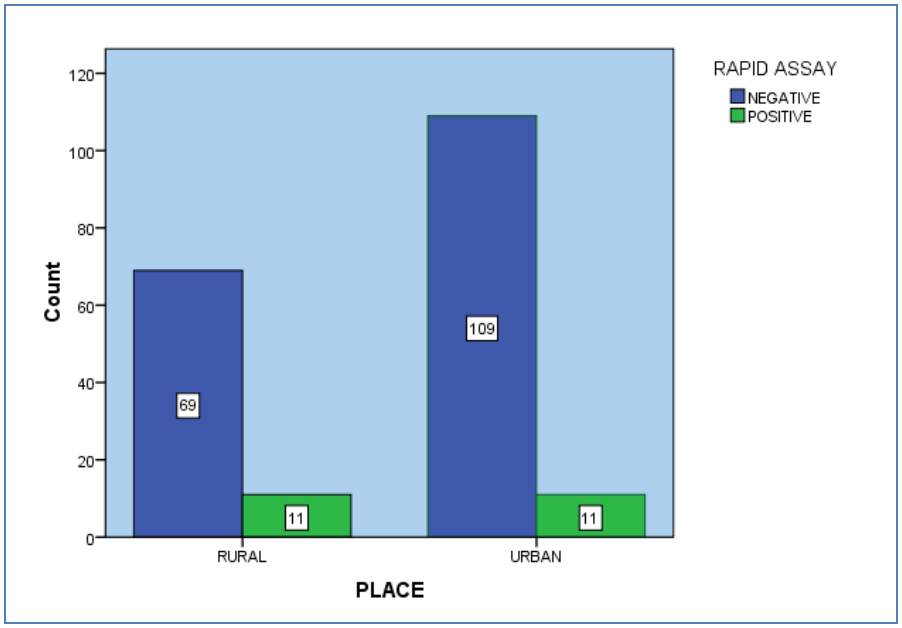


TABLE 2.5: HIV POSITIVITY BY FOURTH GENERATION ELISA AMONG PATIENTS WITH DIFFERENT EDUCATIONAL STATUS

	NEGATIVE	POSITIVE	TOTAL
GRADUATE	27 67.5%	13 32.5%	40 100%
HIGHER SECONDARY	8 44.4%	10 55.6%	18 100%
HIGH SCHOOL	27 60%	18 40%	45 100%
MIDDLE SCHOOL	17 70.8%	7 29.2%	24 100%
ILLITERATE	47 64.4%	26 35.6%	73 100%

FIG 10: HIV POSITIVITY BY FOURTH GENERATION ELISA AMONG PATIENTS WITH DIFFERENT EDUCATIONAL STATUS

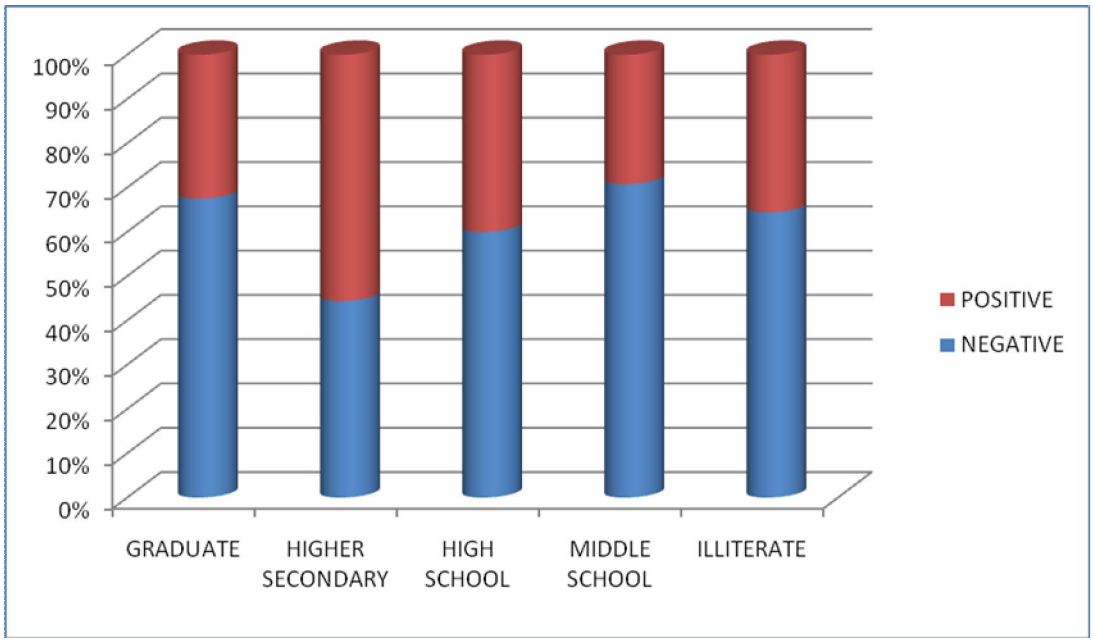


TABLE 2.6: HIV POSITIVITY BY RAPID ASSAY AMONG PATIENTS WITH DIFFERENT EDUCATIONAL STATUS

	NEGATIVE	POSITIVE	TOTAL
GRADUATE	38 95%	2 5%	40 100%
HIGHER SECONDARY	17 94.4%	1 5.6%	18 100%
HIGH SCHOOL	40 88.9%	5 11.1%	45 100%
MIDDLE SCHOOL	22 91.7%	2 8.3%	24 100%
ILLITERATE	61 83.6%	12 16.4%	73 100%

FIG 11: HIV POSITIVITY BY RAPID ASSAY AMONG PATIENTS WITH DIFFERENT EDUCATIONAL STATUS

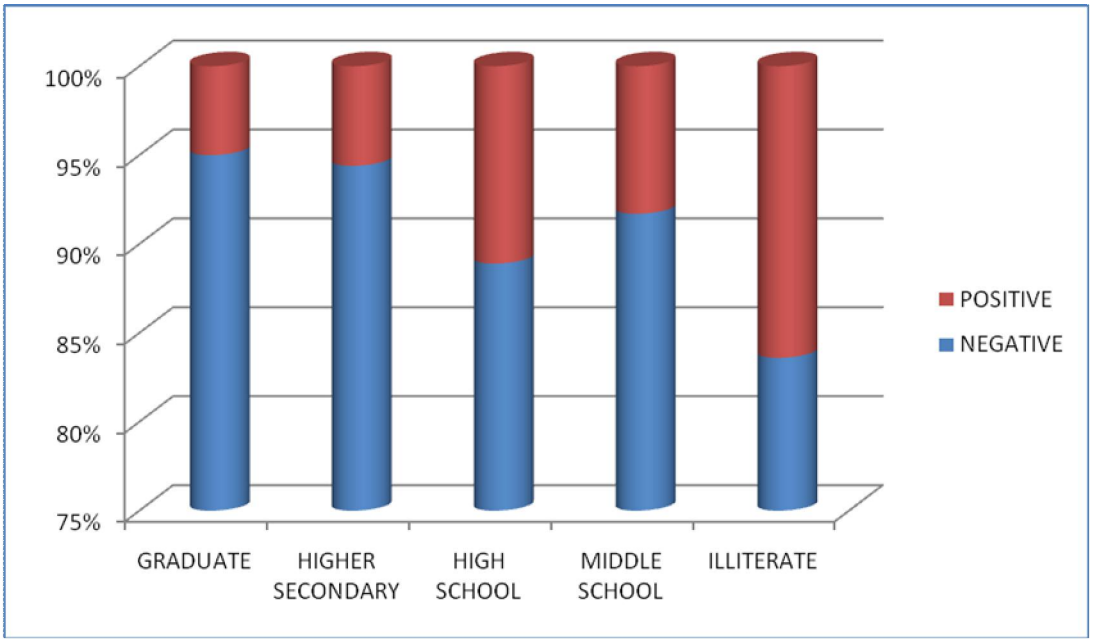


TABLE 2.7: HIV POSITIVITY BY FOURTH GENERATION ELISA AMONG VARIOUS OCCUPATIONS

OCCUPATION	NEGATIVE	POSITIVE	TOTAL
COOLEY	59 67.8%	28 32.2%	87 100%
CSW	6 66.7%	3 33.3%	9 100%
HOUSE WIFE	10 62.5%	6 37.5%	16 100%
NIL	3 75.0%	1 25.0%	4 100%
OTHERS	2 50%	2 50%	4 100%
PRIVATE	40 55.6%	32 44.4%	72 100%
PROFESSIONAL	0 0%	1 100%	1 100%
STUDENT	6 85.7%	1 14.3%	7 100%
TOTAL	126 63.0%	74 37.0%	200 100%

FIG 12: HIV POSITIVITY BY FOURTH GENERATION ELISA AMONG VARIOUS OCCUPATIONS

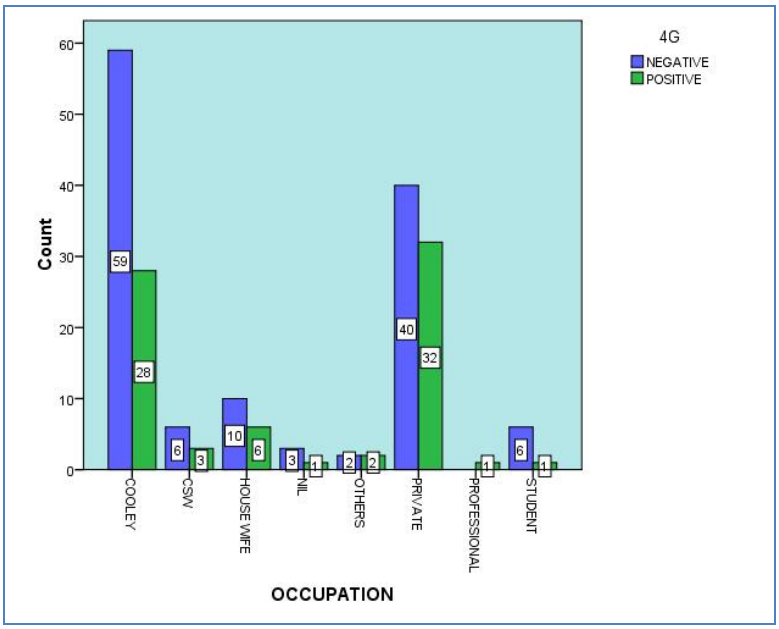


TABLE 2.8: HIV POSITIVITY BY RAPID ASSAY AMONG VARIOUS OCCUPATIONS

OCCUPATION	NEGATIVE	POSITIVE	TOTAL
COOLEY	78 89.7%	9 10.3%	87 100%
CSW	8 88.9%	1 11.1%	9 100%
HOUSEWIFE	13 81.2%	3 18.8%	16 100%
NIL	3 75%	1 25%	4 100%
OTHERS	3 75%	1 25%	4 100%
PRIVATE	66 91.7%	6 8.3%	72 100%
PROFESSIONAL	0 0%	1 100%	1 100%
STUDENT	7 100%	0 0%	7 100%
TOTAL	178 89%	22 11%	200 100%

FIG 13: DISTRIBUTION OF HIV POSITIVITY BY RAPID ASSAY AMONG VARIOUS OCCUPATIONS

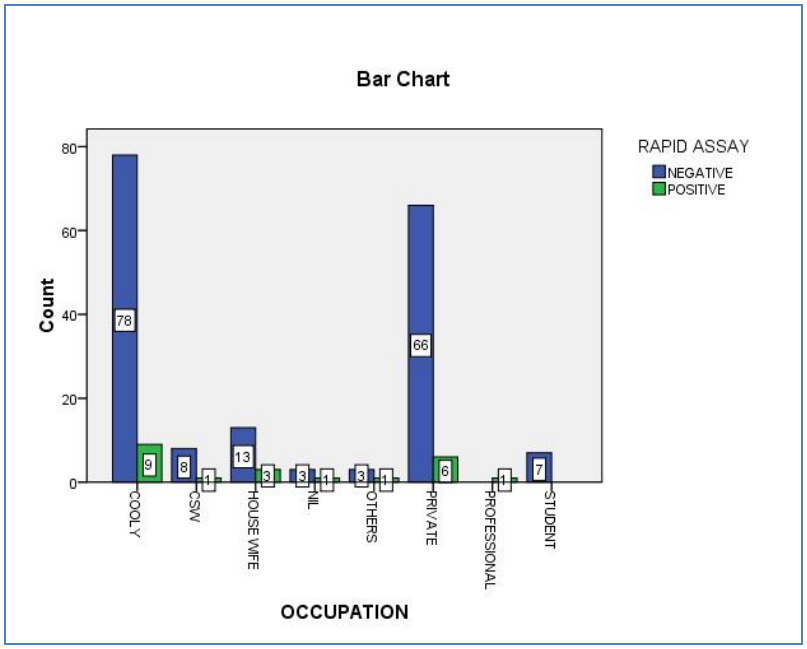


TABLE 2.9: HIV PREVALENCE BY FOURTH GENERATION ELISA IN RELATION TO SEXUAL ORIENTATION

	NEGATIVE	POSITIVE	TOTAL
HETEROSEXUAL	102 62.6%	61 37.4%	163 100%
HOMOSEXUAL	18 69.2%	8 30.8%	26 100%
BISEXUAL	6 54.5%	5 45.5%	11 100%
TOTAL	126 63%	74 37%	200 100%

FIG 14: HIV PREVALENCE BY FOURTH GENERATION ELISA IN RELATION TO SEXUAL ORIENTATION

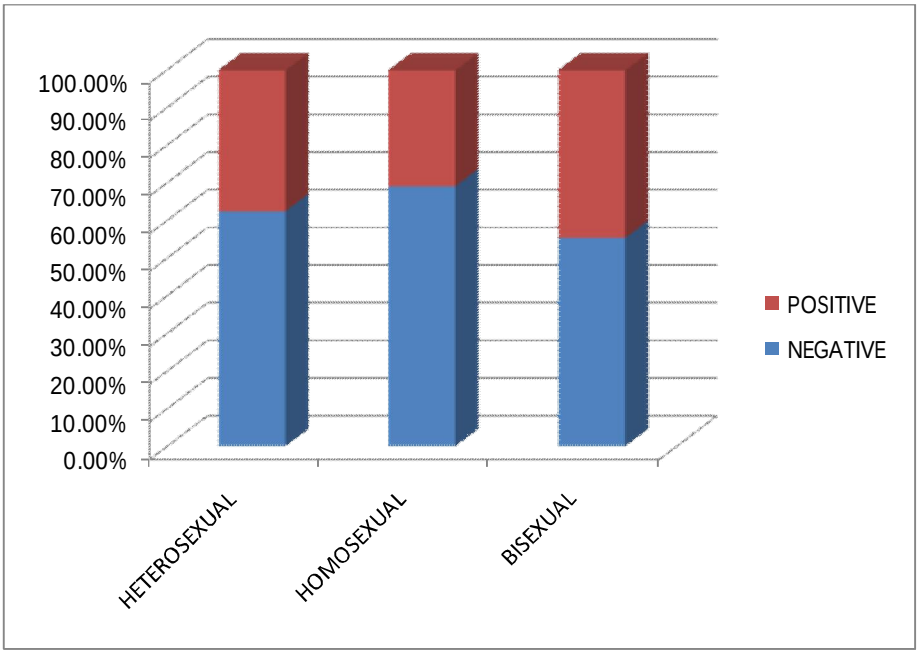


TABLE 2.10: HIV PREVALENCE BY RAPID ASSAY IN RELATION TO SEXUAL ORIENTATION

	NEGATIVE	POSITIVE	TOTAL
HETEROSEXUAL	145 89%	18 11%	163 100%
HOMOSEXUAL	23 88.5%	3 11.5%	26 100%
BISEXUAL	10 90.1%	1 9.9%	11 100%
TOTAL	178 89%	22 11%	200 100%

FIG 15: HIV PREVALENCE BY RAPID ASSAY IN RELATION TO SEXUAL ORIENTATION

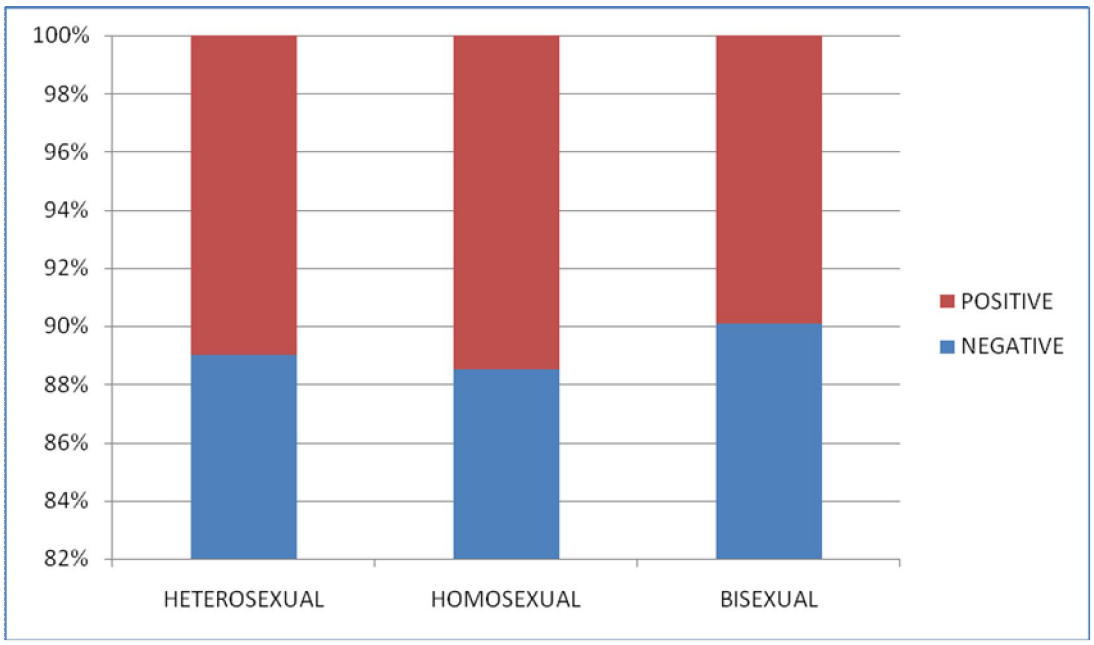


TABLE 2.11: DETECTION OF HIV BY FOURTH GENERATION ELISA IN RELATION TO MARITAL STATUS

	NEGATIVE	POSITIVE	TOTAL
MARRIED	64 59.3%	44 40.7%	108 100%
SINGLE	62 67.4%	30 32.6%	92 100%
TOTAL	126 63%	74 37%	200 100%

FIG 16: DETECTION OF HIV BY FOURTH GENERATION ELISA IN RELATION TO MARITAL STATUS

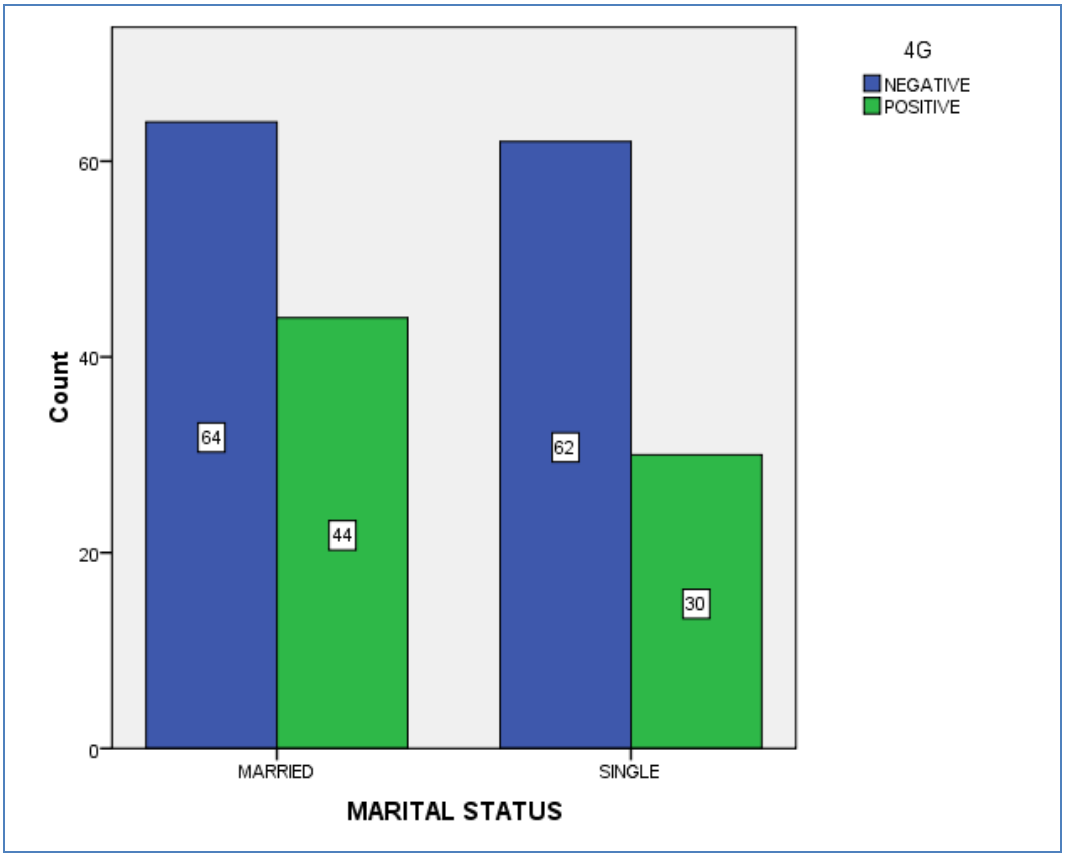
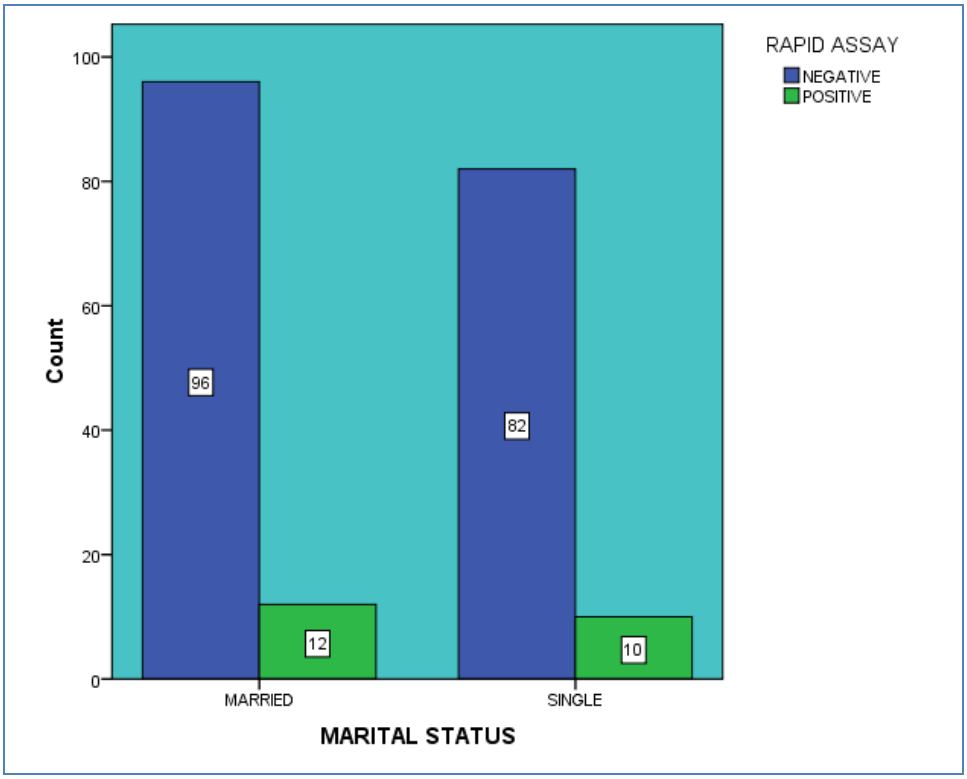


TABLE 2.12: DETECTION OF HIV BY RAPID ASSAY IN RELATION TO MARITAL STATUS

	NEGATIVE	POSITIVE	TOTAL
MARRIED	96 88.9%	12 11.1%	108 100%
SINGLE	82 89.1%	10 10.9%	92 100%
TOTAL	178 89%	22 11%	200 100%

FIG 17: DETECTION OF HIV BY RAPID ASSAY IN RELATION TO MARITAL STATUS



SEXUAL EXPOSURE

TABLE 3.1: HIV POSITIVITY DETECTED BY FOURTH GENERATION ELISA AMONG PATIENTS WITH AND WITHOUT EXTRAMARITAL EXPOSURE

EXTRAMARITAL CONTACT	NEGATIVE	POSITIVE	TOTAL
NIL	10 71.4%	4 28.6%	14 100%
YES	116 62.4%	70 37.6%	186 100%
TOTAL	126 63%	74 37%	200 100%

FIG 18: HIV POSITIVITY DETECTED BY FOURTH GENERATION ELISA AMONG PATIENTS WITH AND WITHOUT EXTRAMARITAL EXPOSURE

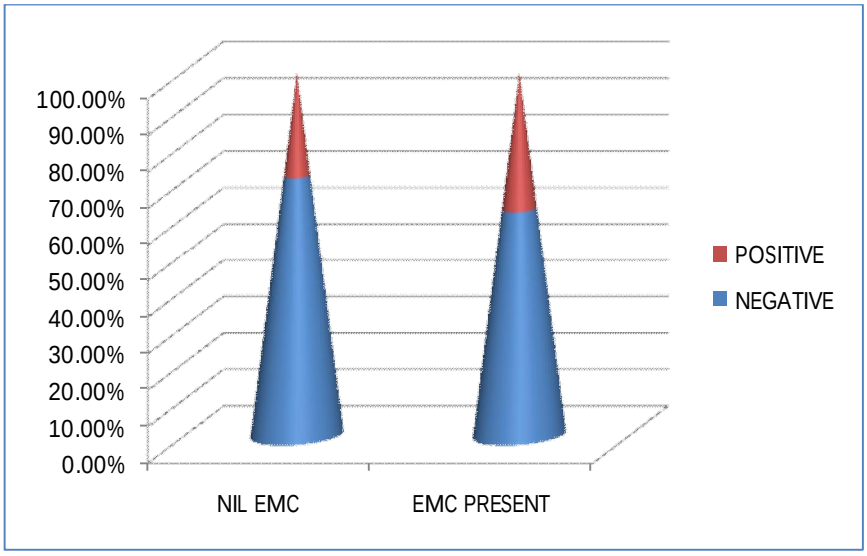


TABLE3.2: HIV POSITIVITY DETECTED BY RAPID ASSAY AMONG PATIENTS WITH AND WITHOUT EXTRAMARITAL EXPOSURE

EXTRAMARITAL CONTACT	NEGATIVE	POSITIVE	TOTAL
NIL	11 78.6%	3 21.4%	14 100%
YES	167 89.8%	19 10.2%	186 100%
TOTAL	178 89%	22 11%	200 100%

FIG 19: HIV POSITIVITY DETECTED BY FOURTH GENERATION ELISA AMONG PATIENTS WITH AND WITHOUT EXTRAMARITAL EXPOSURE

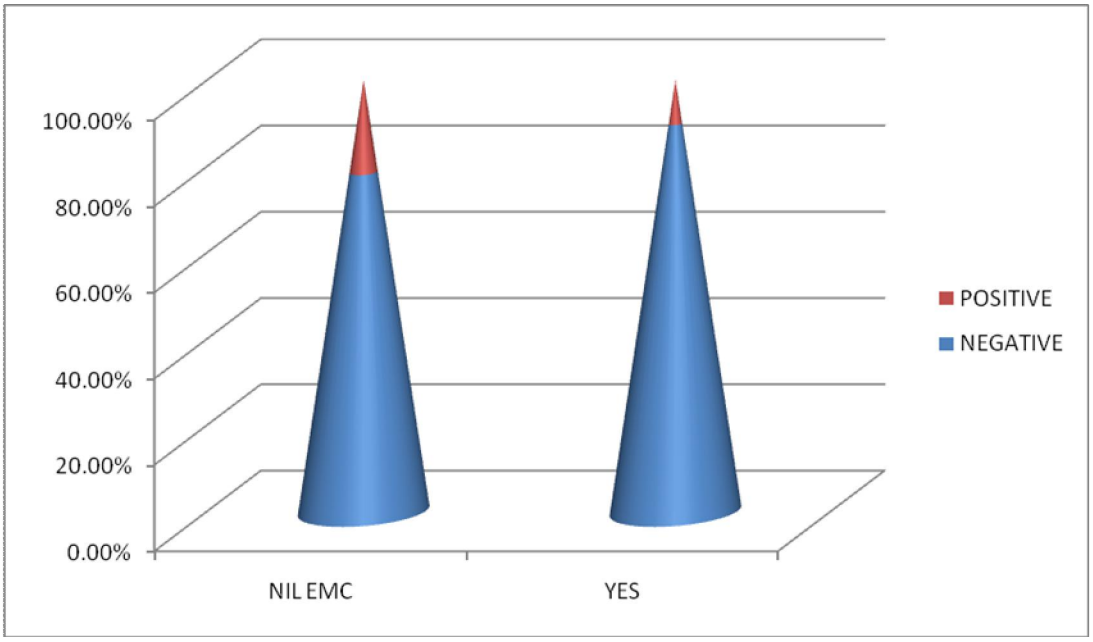


TABLE 3.3: HIV POSITIVITY BY FOURTH GENERATION ELISA IN RELATION TO NUMBER OF SEXUAL PARTNERS

NUMBER OF PARTNERS	NEGATIVE	POSITIVE	TOTAL
MULTIPLE	40 59.7%	27 40.3%	67 100%
NIL	10 71.4%	4 28.6%	14 100%
ONE	54 66.7%	27 33.3%	81 100%
TWO	22 57.9%	16 42.1%	38 100%
TOTAL	126 63%	74 37%	200 100%

FIG 20: HIV POSITIVITY BY FOURTH GENERATION ELISA IN RELATION TO NUMBER OF SEXUAL PARTNERS

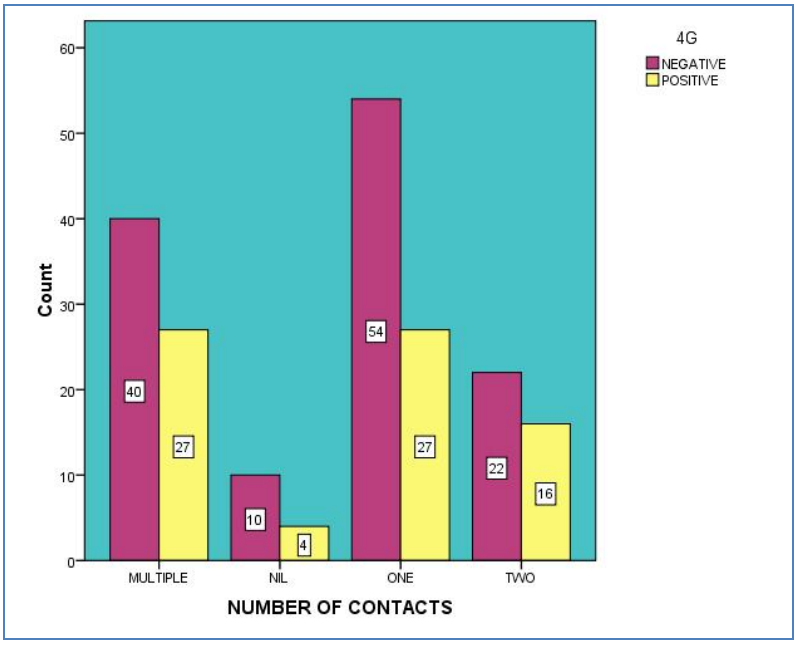


TABLE 3.4: HIV POSITIVITY BY RAPID ASSAY AND NUMBER OF SEXUAL PARTNERS

NUMBER OF PARTNERS	NEGATIVE	POSITIVE	TOTAL
	59	8	67
MULTIPLE	88.1%	11.9%	100%
	11	3	14
NIL	78.6%	21.4%	100%
ONE	73	8	81
	90.1%	9.9%	100%
TWO	35	3	38
	92.1%	7.9%	100%
	178	22	200
TOTAL	89%	11%	100%

FIG 21: HIV POSITIVITY BY RAPID ASSAY AND NUMBER OF SEXUAL PARTNERS

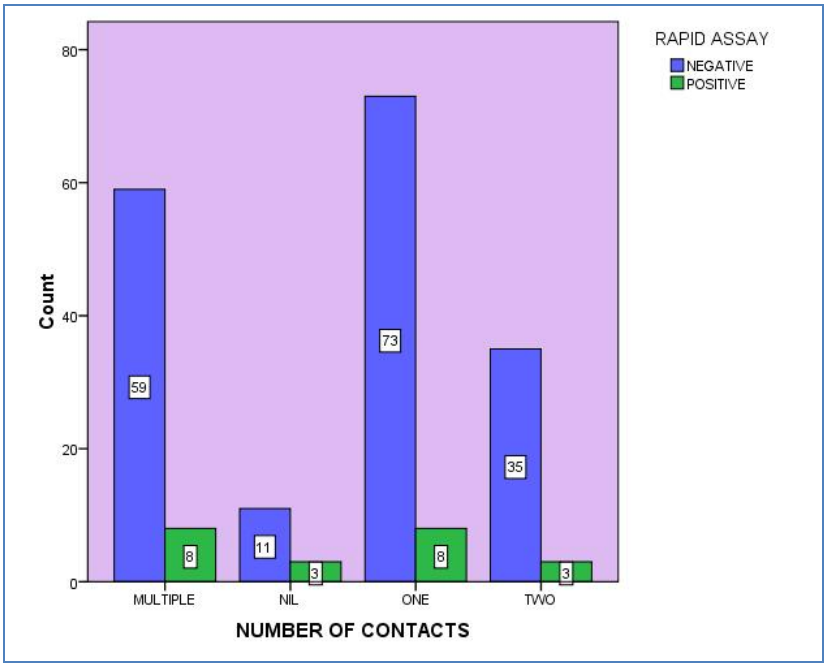


TABLE 3.5: HIV DETECTION BY FOURTH GENERATION ELISA IN RELATION TO TIME SINCE LAST EXPOSURE

TIME SINCE LAST EXPOSURE	NEGATIVE	POSITIVE	TOTAL
<2 WEEKS	36 66.7%	18 33.3%	54 100%
2 WEEKS – 2MONTHS	29 53.7%	25 46.3%	54 100%
2 – 6 MONTHS	18 64.3%	10 35.7%	28 100%
>6 MONTHS	33 66%	17 34%	50 100%
NIL EXPOSURE	10 71.4%	4 28.6%	14 100%

FIG 22: HIV DETECTION BY FOURTH GENERATION ELISA IN RELATION TO TIME SINCE LAST EXPOSURE

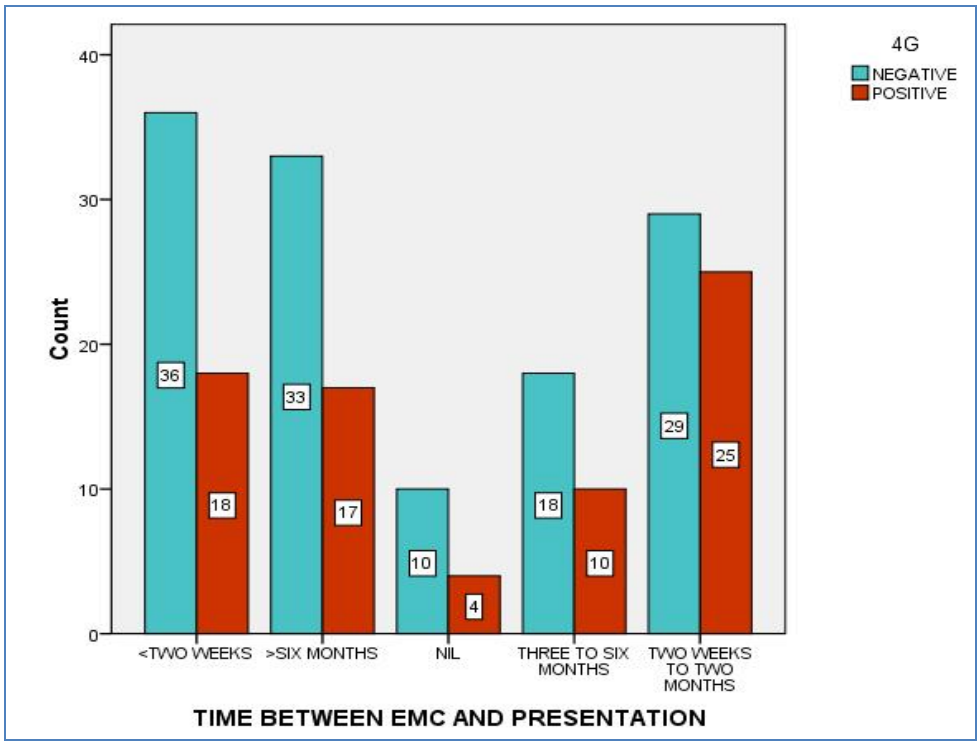


TABLE 3.6 : HIV DETECTION BY RAPID ASSAY IN RELATION TO TIME SINCE LAST EXPOSURE

TIME SINCE LAST EXPOSURE	NEGATIVE	POSITIVE	TOTAL
<2 WEEKS	50 92.6%	4 7.4%	54 100%
2WEEKS – 2MONTHS	50 92.6%	4 7.4%	54 100%
2-6 MONTHS	26 92.9%	2 7.1%	28 100%
>6 MONTHS	41 82%	9 18%	50 100%
NIL	11 78.6%	3 21.4%	14 100%

FIG 23: HIV DETECTION BY RAPID ASSAY IN RELATION TO TIME SINCE LAST EXPOSURE

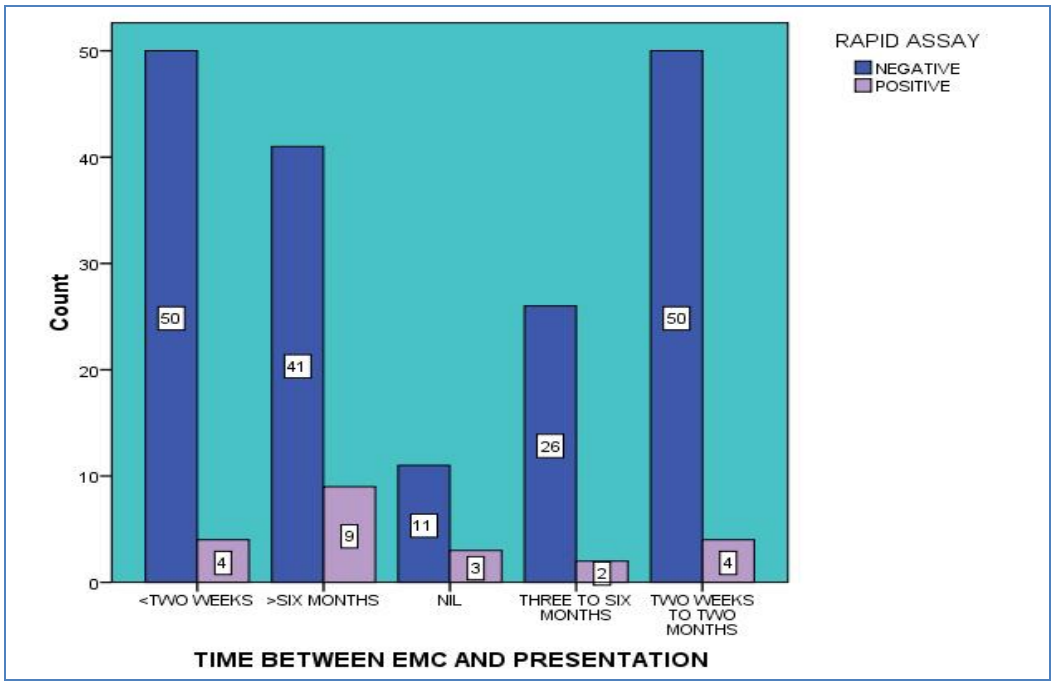


TABLE 3.7: HIV DETECTION BY FOURTH GENERATION ELISA IN RELATION TO PATIENT APPROACH TO VENEREOLOGY DEPARTMENT

	NEGATIVE	POSITIVE	TOTAL
SELF	48 53.3%	42 46.7%	90 100%
NGO	17 73.9%	6 26.1%	23 100%
REFERRAL	57 71.3%	23 28.7%	80 100%
CONTACT TRACING	4 57.1%	3 42.9%	7 100%

FIG 24: HIV DETECTION BY FOURTH GENERATION ELISA IN RELATION TO PATIENT APPROACH TO VENEREOLOGY DEPARTMENT

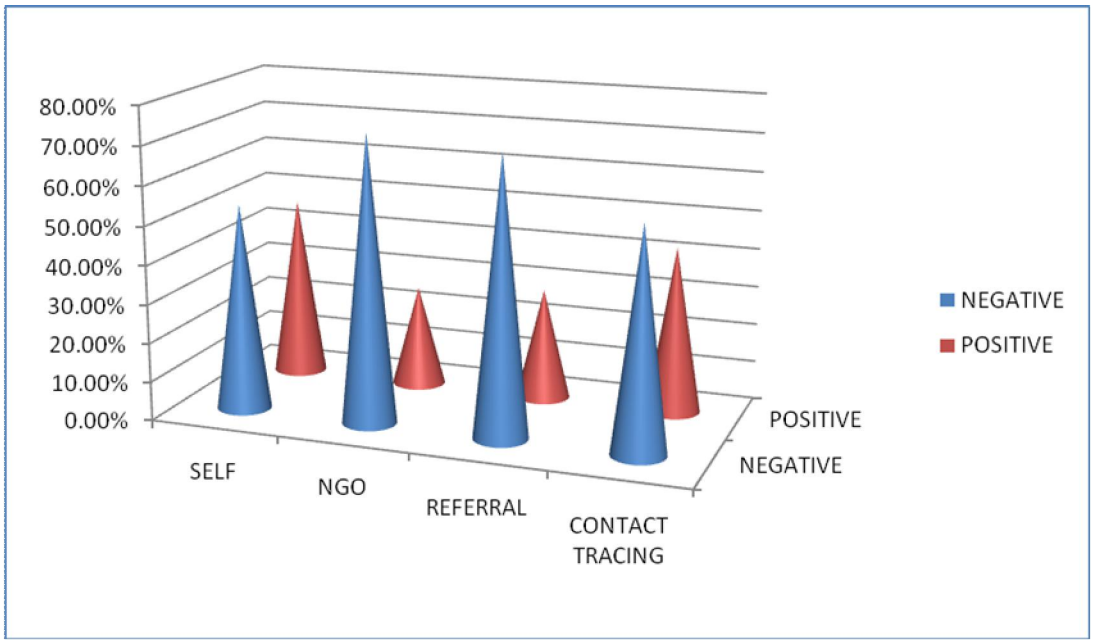


FIG 3.8: HIV DETECTION BY RAPID ASSAY IN RELATION TO PATIENT APPROACH TO VENEREOLOGY DEPARTMENT

	NEGATIVE	POSITIVE	TOTAL
SELF	78 86.7%	12 13.3%	90 100%
NGO	21 91.3%	2 8.7%	23 100%
REFERRAL	73 91.3%	7 8.7%	80 100%
CONTACT TRACING	6 85.7%	1 14.3%	7 100%

FIG 25: HIV DETECTION BY RAPID ASSAY IN RELATION TO PATIENT APPROACH TO VENEREOLOGY DEPARTMENT

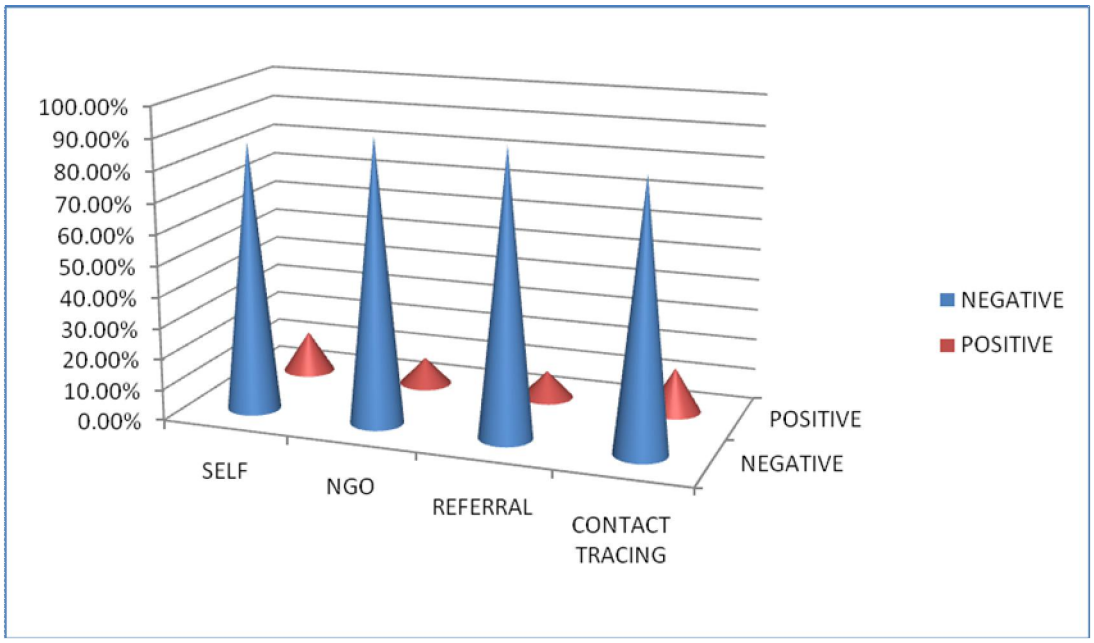


TABLE 3.9: HIV DETECTION BY FOURTH GENERATION ELISA IN PATIENTS WITH COMPLAINTS

COMPLAINTS	NEGATIVE	POSITIVE	TOTAL
NIL	66 65.3%	35 34.7%	101 100%
GENITAL	48 59.3%	33 40.7%	81 100%
NON SPECIFIC	10 62.5%	6 37.5%	16 100%
PARTNER ON ART	1 100%	0 0%	1 100%
SEXUALABUSE	1 100%	0 0%	1 100%

FIG 26: HIV DETECTION BY FOURTH GENERATION ELISA IN PATIENTS WITH COMPLAINTS

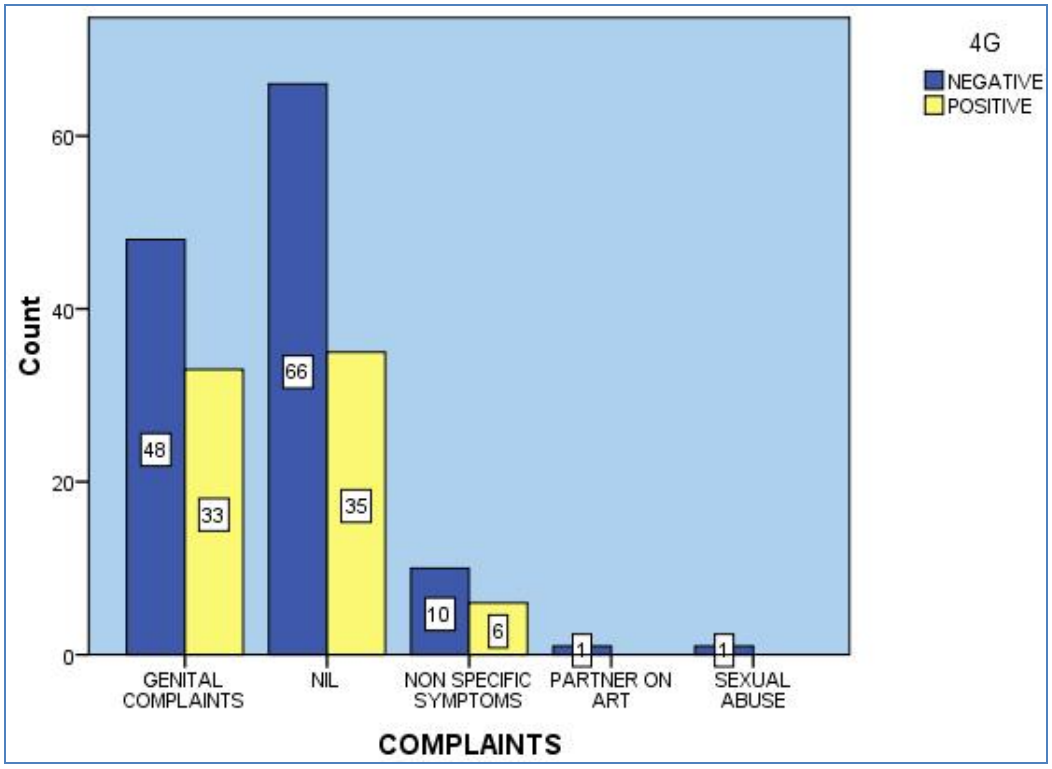


TABLE 3.10: HIV DETECTION BY RAPID ASSAY IN PATIENTS WITH COMPLAINTS

COMPLAINTS	NEGATIVE	POSITIVE	TOTAL
NIL	91 90.9%	10 9.1%	101 100%
GENITAL	72 88.9%	9 11.1%	81 100%
NON SPECIFIC	13 81.3%	3 18.8%	16 100%
PARTNER ON ART	1 100%	0 0%	1 100%
SEXUAL ABUSE	1 100%	0 0%	1 100%

FIG 27: HIV DETECTION BY RAPID ASSAY IN PATIENTS WITH COMPLAINTS

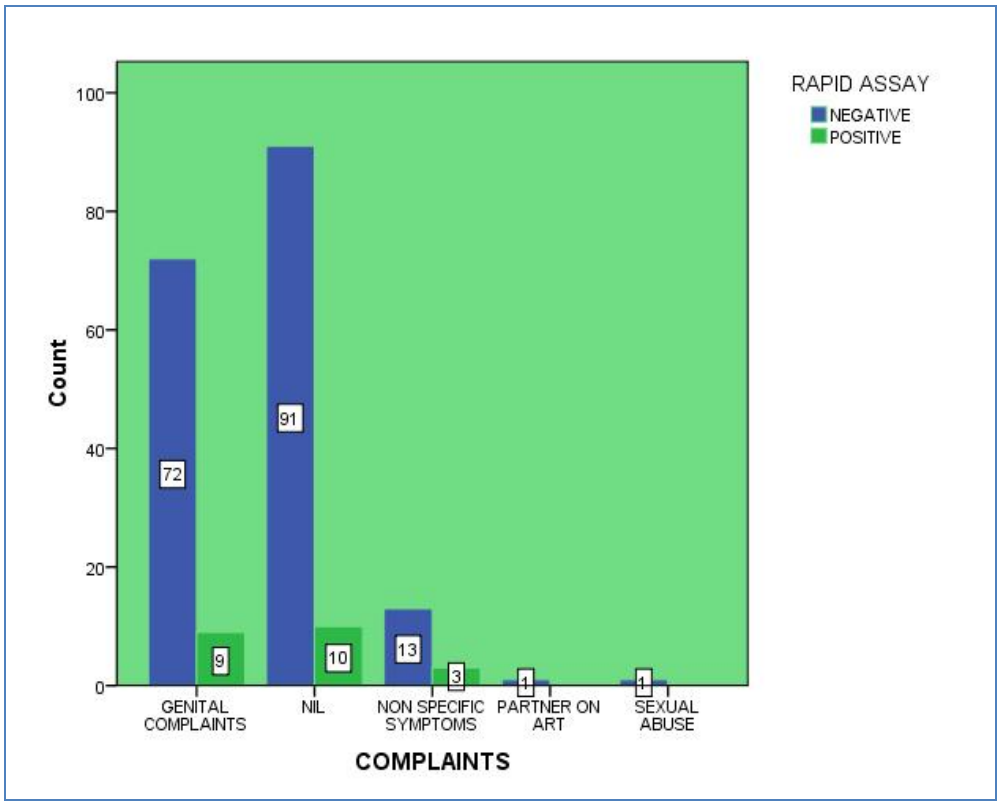


TABLE 3.11: HIV PREVALENCE BY FOURTH GENERATION ELISA IN PATIENTS WITH VARIOUS SEXUALLY TRANSMITTED INFECTIONS

	NEGATIVE	POSITIVE	TOTAL
BACTERIAL VAGINOSIS	4 66.7%	2 33.3%	6 100%
BALANOPOSTHITIS	6 75%	2 25%	8 100%
EPIDIDYMO ORCHITIS	0 0%	1 100%	1 100%
DERMATOPHYTOSIS	1 100%	0 0%	1 100%
GENITAL HERPES	2 100%	0 0%	2 100%
GENITAL MOLLUSCUM CONTAGIOSUM	1 33.3%	2 66.7%	3 100%
GENITAL SCABIES	2 66.7%	1 33.3%	3 100%
GENITAL WART	2 66.7%	1 33.3%	3 100%
GONOCOCCAL URETHRITIS	1 100%	0 0%	1 100%
NON GONOCOCCAL URETHRITIS	3 37.5%	5 62.5%	8 100%
HEPATITIS B	1 100%	0 0%	1 100%
NIL	75 60%	50 40%	125 100%
NON SPECIFIC GENITAL ULCER	5 83.3%	1 16.7%	6 100%
PERIANAL WART	1 100%	0 0%	1 100%
PROCTITIS	1 100%	0 0%	1 100%
SYPHILIS	20 71.4%	8 28.6%	28 100%
VULVOVAGINAL CANDIDIASIS	1 50%	1 50%	2 100%

FIG 28: HIV PREVALENCE BY FOURTH GENERATION ELISA IN PATIENTS WITH VARIOUS SEXUALLY TRANSMITTED INFECTIONS

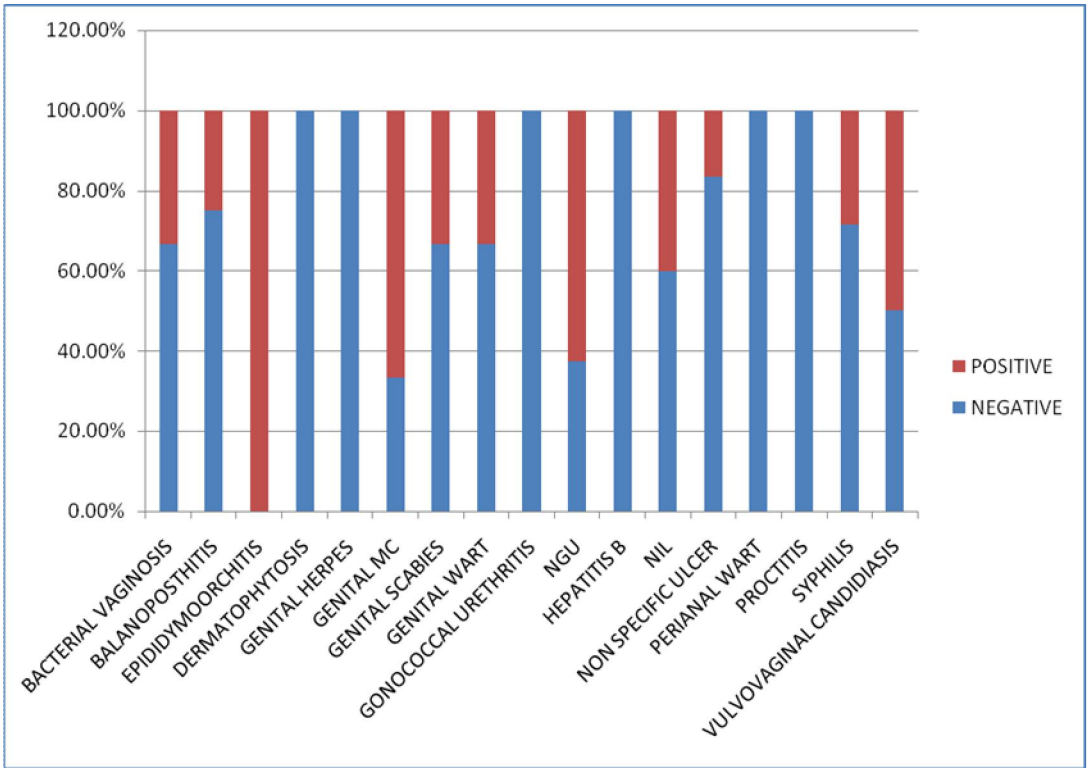


TABLE 3.12: HIV PREVALENCE BY RAPID ASSAY IN PATIENTS WITH VARIOUS SEXUALLY TRANSMITTED INFECTIONS

	NEGATIVE	POSITIVE	TOTAL
BACTERIAL VAGINOSIS	5 83.3%	1 6.7%	6 100%
BALANOPOSTHITIS	7 87.5%	1 12.5%	8 100%
EPIDIDYMO ORCHITIS	1 100%	0 0%	1 100%
DERMATOPHYTOSIS	1 100%	0 0%	1 100%
GENITAL HERPES	2 100%	0 0%	2 100%
GENITAL MOLLUSCUM CONTAGIOSUM	2 66.7%	1 33.3%	3 100%
GENITAL SCABIES	3 100%	0 0%	3 100%
GENITAL WART	2 66.7%	1 33.3%	3 100%
GONOCOCCAL URETHRITIS	1 100%	0 0%	1 100%
NON GONOCOCCAL URETHRITIS	6 75%	2 25%	8 100%
HEPATITIS B	1 100%	0 0%	1 100%
NIL	111 88.8%	14 11.2%	125 100%
NON SPECIFIC GENITAL ULCER	6 100%	0 0%	6 100%
PERIANAL WART	1 100%	0 0%	1 100%
PROCTITIS	1 100%	0 0%	1 100%
SYPHILIS	27 96.4%	1 3.6%	28 100%
VULVOVAGINAL CANDIDIASIS	1 50%	1 50%	2 100%

FIG 29 : HIV PREVALENCE BY RAPID ASSAY IN PATIENTS WITH VARIOUS SEXUALLY TRANSMITTED INFECTIONS

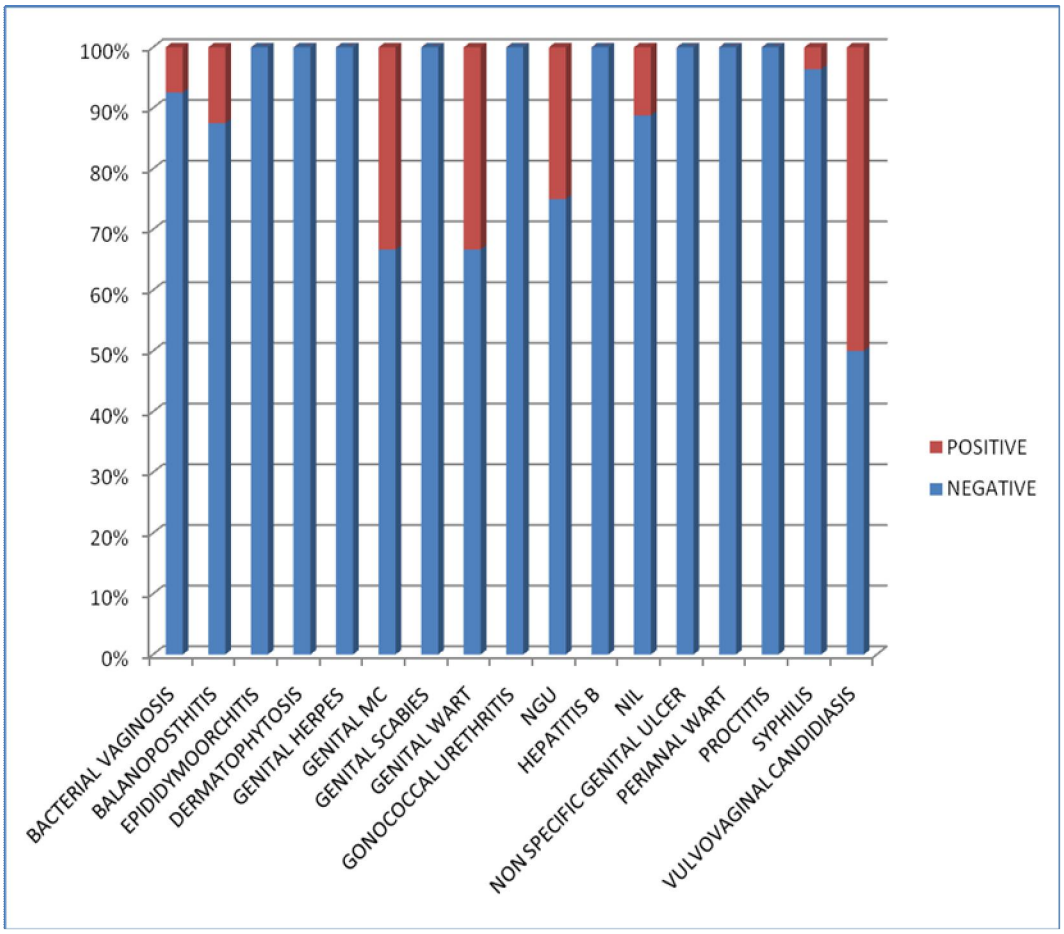


TABLE 3.13: DETECTION OF HIV BY FOURTH GENERATION ELISA IN PATIENTS WITH HISTORY OF PREVIOUS VENEREAL DISEASES

PREVIOUS VENEREAL DISEASE	NEGATIVE	POSITIVE	TOTAL
NIL	118 (62.1%)	72 (37.9%)	190 (100%)
GENITAL HERPES	4 (100%)	0 (0%)	4 (100%)
GENITAL SCABIES	1 (100%)	0 (0%)	1 (0%)
GENITALULCER	3 (60%)	2 (40%)	5 (100%)

FIG 30: DETECTION OF HIV BY FOURTH GENERATION ELISA IN PATIENTS WITH HISTORY OF PREVIOUS VENEREAL DISEASES

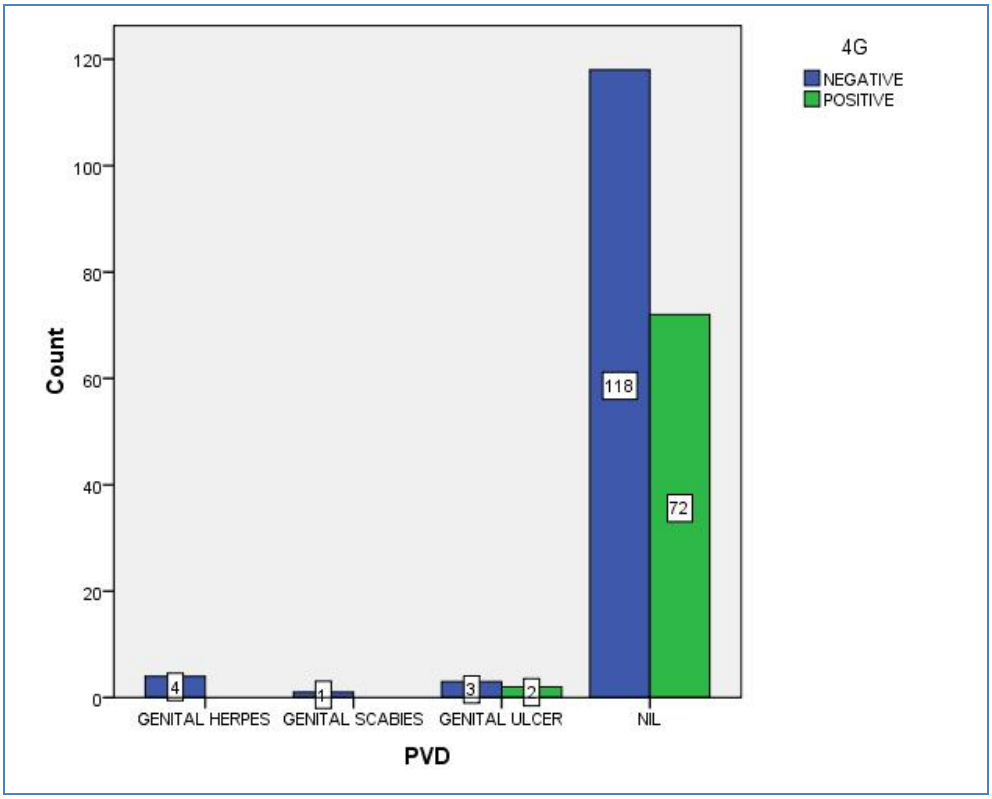
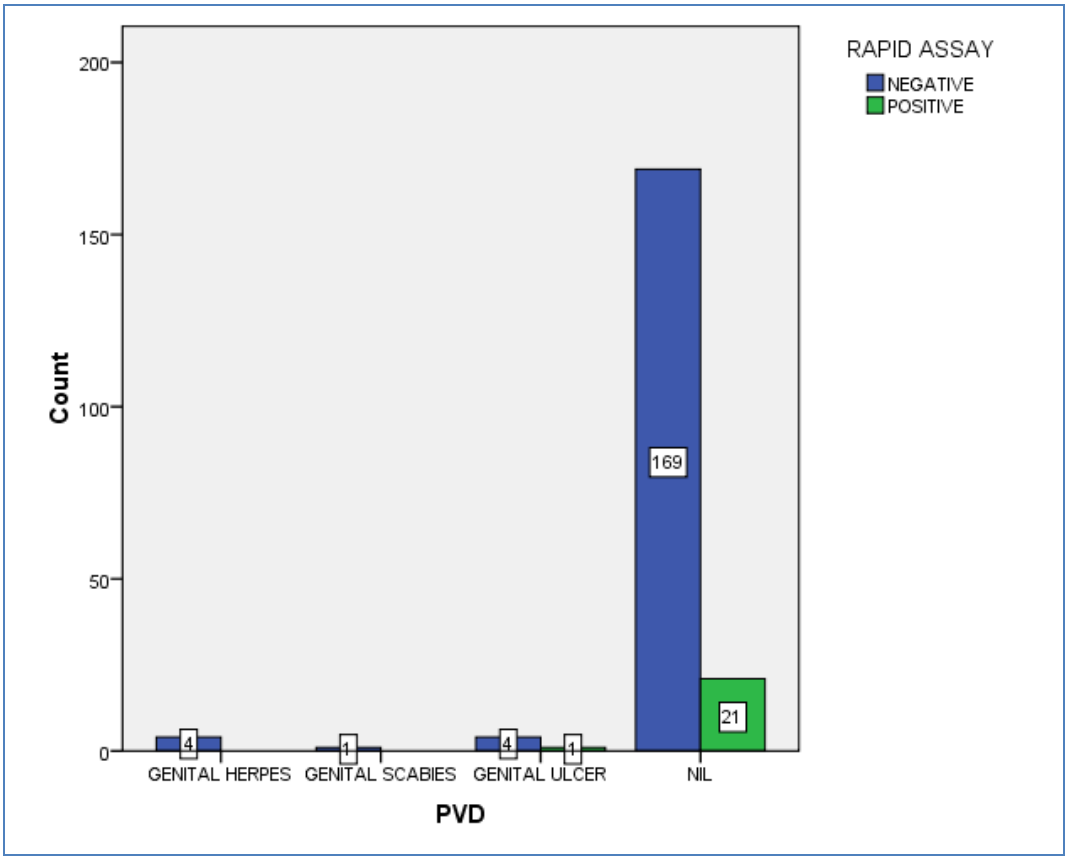


TABLE 3.14: DETECTION OF HIV BY RAPID ELISA IN PATIENTS WITH HISTORY OF PREVIOUS VENEREAL DISEASES

PREVIOUS VENEREAL DISEASE	NEGATIVE	POSITIVE	TOTAL
NIL	169 (88.9%)	21 (11.1%)	190 (100%)
GENITAL HERPES	4 (100%)	0 (0%)	4 (100%)
GENITAL SCABIES	1 (100%)	0 (0%)	1 (100%)
GENITAL ULCER	4 (80%)	1 (20%)	5 (100%)

FIG 31: DETECTION OF HIV BY RAPID ELISA IN PATIENTS WITH HISTORY OF PREVIOUS VENEREAL DISEASES



OTHER ASSOCIATIONS WITH HIV

TABLE 4.1: DETECTION OF HIV BY FOURTH GENERATION ELISA IN PATIENTS WITH TUBERCULOSIS

TUBERCULOSIS	NEGATIVE	POSITIVE	TOTAL
NIL	108 (61.4%)	68 (38.6%)	176 (100%)
YES	18 (75%)	6 (25%)	24 (100%)
TOTAL	126 (63%)	74 (37%)	200 (100%)

FIG 32: DETECTION OF HIV BY FOURTH GENERATION ELISA IN PATIENTS WITH TUBERCULOSIS

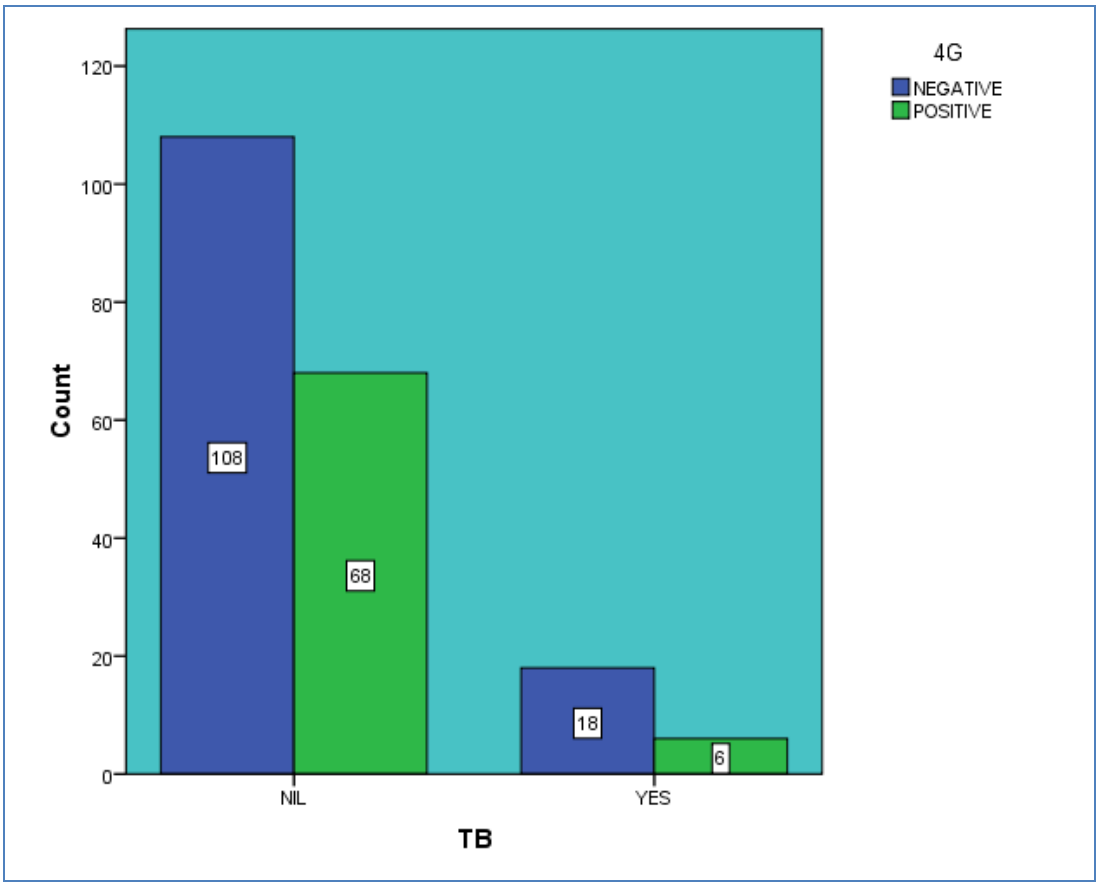


TABLE 4.2: DETECTION OF HIV BY RAPID ELISA IN PATIENTS WITH TUBERCULOSIS

TUBERCULOSIS	NEGATIVE	POSITIVE	TOTAL
NIL	157 (89.2%)	19 (10.8%)	176 (100%)
YES	21 (87.5%)	3 (12.5%)	24 (100%)
TOTAL	178 (89%)	22 (11%)	200 (100%)

FIG 33: DETECTION OF HIV BY RAPID ELISA IN PATIENTS WITH TUBERCULOSIS

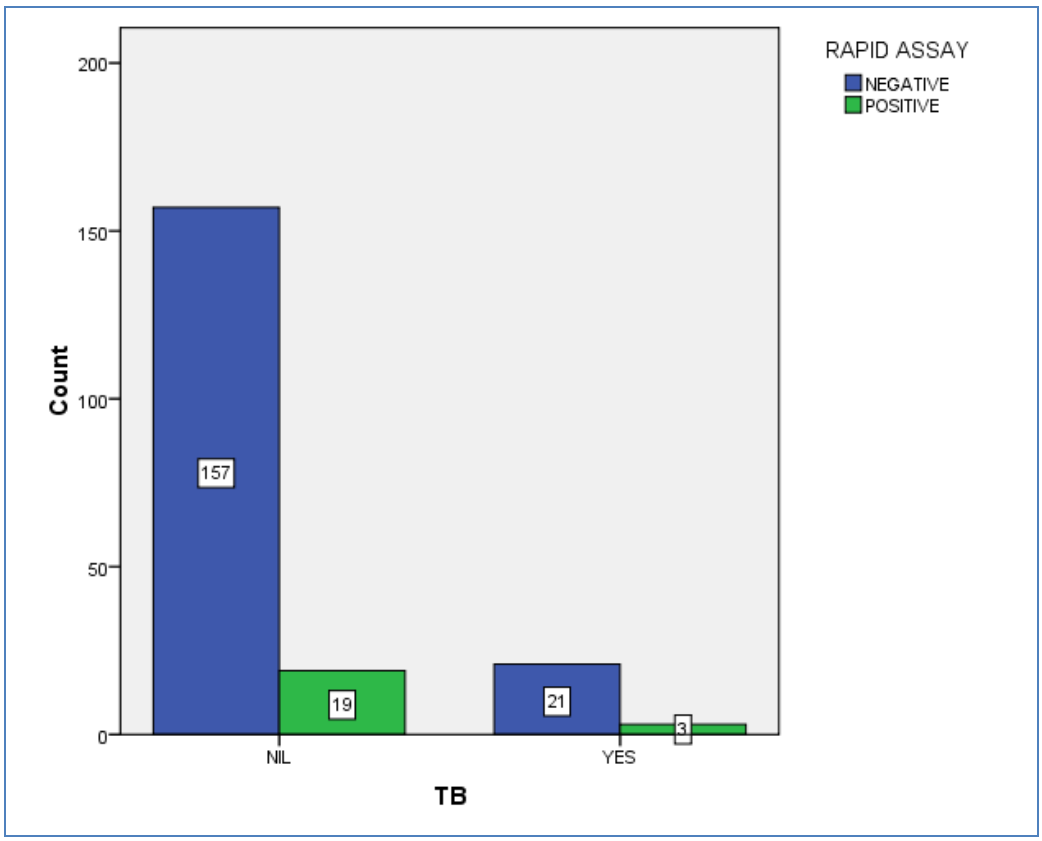


TABLE 4.3: DETECTION OF HIV BY FOURTH GENERATION ELISA IN INTRAVENOUS DRUG USERS

IVDU	NEGATIVE	POSITIVE	TOTAL
NO	126 (63%)	74 (37%)	200 (100%)
YES	0 (0%)	0 (0%)	0 (0%)
TOTAL	126 (63%)	74 (37%)	200 (100%)

FIG 34: DETECTION OF HIV BY FOURTH GENERATION ELISA IN INTRAVENOUS DRUG USERS

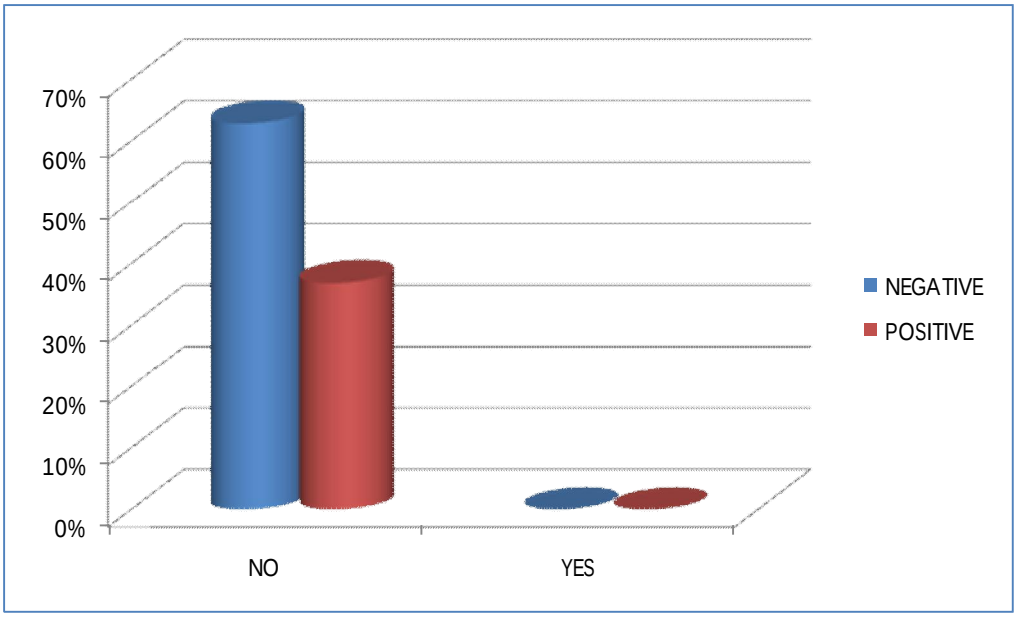


TABLE 4.4: DETECTION OF HIV BY RAPID ASSAY IN INTRAVENOUS DRUG USERS

IVDU	NEGATIVE	POSITIVE	TOTAL
NO	178 (89%)	22 (11%)	200 (100%)
YES	0 (0%)	0 (0%)	0 (0%)
TOTAL	178 (89%)	22 (11%)	200 (100%)

FIG 35: DETECTION OF HIV BY RAPID ASSAY IN INTRAVENOUS DRUG USERS

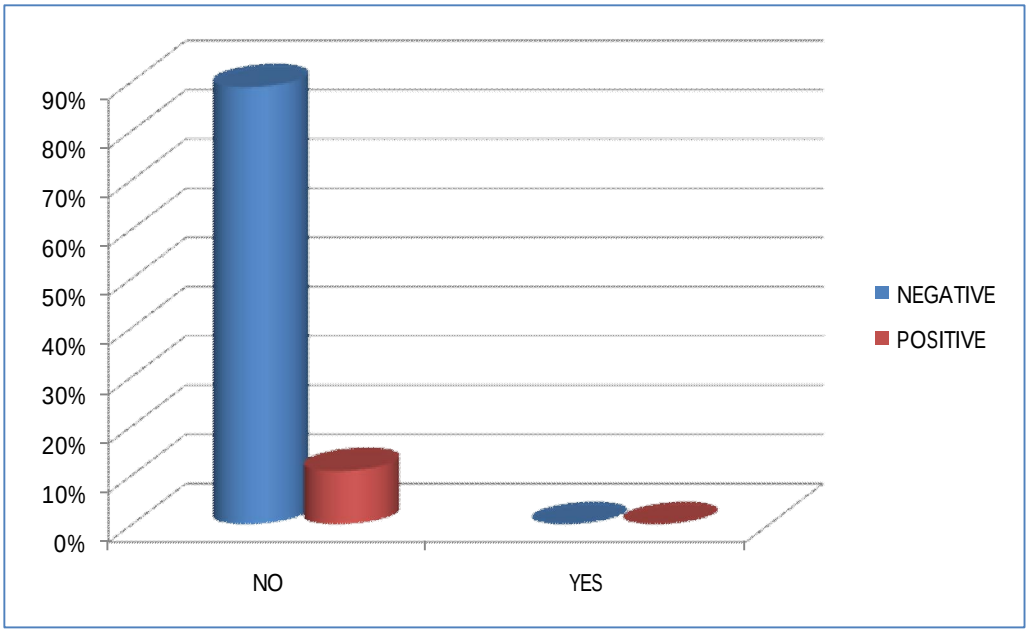


TABLE 4.5: DETECTION OF HIV BY FOURTH GENERATION ELISA IN ALCOHOLICS

ALCOHOLISM	NEGATIVE	POSITIVE	TOTAL
NO	72 (68.6%)	33 (31.4%)	105 (100%)
YES	54 (56.8%)	41 (43.2%)	95 (100%)

FIG 36: DETECTION OF HIV BY FOURTH GENERATION ELISA IN ALCOHOLICS

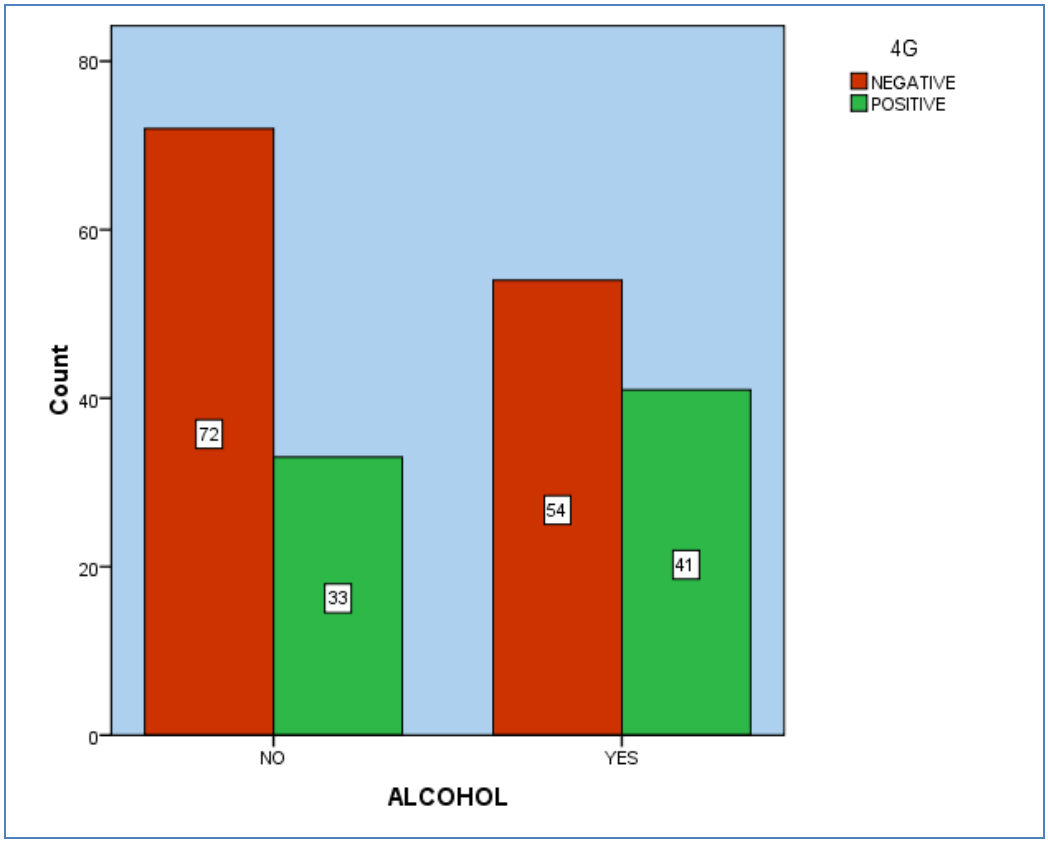


TABLE 4.6: DETECTION OF HIV BY RAPID ASSAY IN ALCOHOLICS

ALCOHOLISM	NEGATIVE	POSITIVE	TOTAL
NO	93 (88.6%)	12 (11.4%)	105 (100%)
YES	85 (89.5%)	10 (10.5%)	95 (100%)

FIG 37: DETECTION OF HIV BY RAPID ASSAY IN ALCOHOLICS

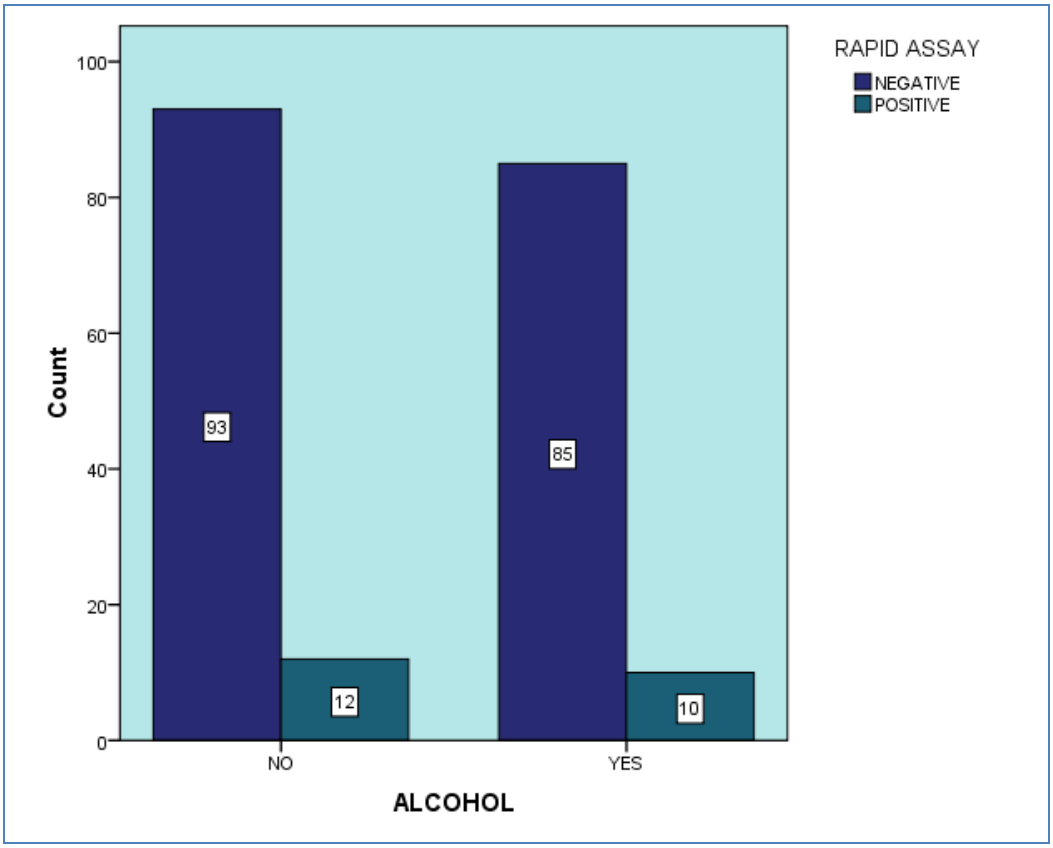


TABLE 4.7: DETECTION OF HIV BY FOURTH GENERATION ELISA IN SMOKERS

SMOKING	NEGATIVE	POSITIVE	TOTAL
NO	81 (66.4%)	41 (33.6%)	122 (100%)
YES	45 (57.7%)	33 (42.3%)	78 (100%)

FIG 38: DETECTION OF HIV BY FOURTH GENERATION ELISA IN SMOKERS

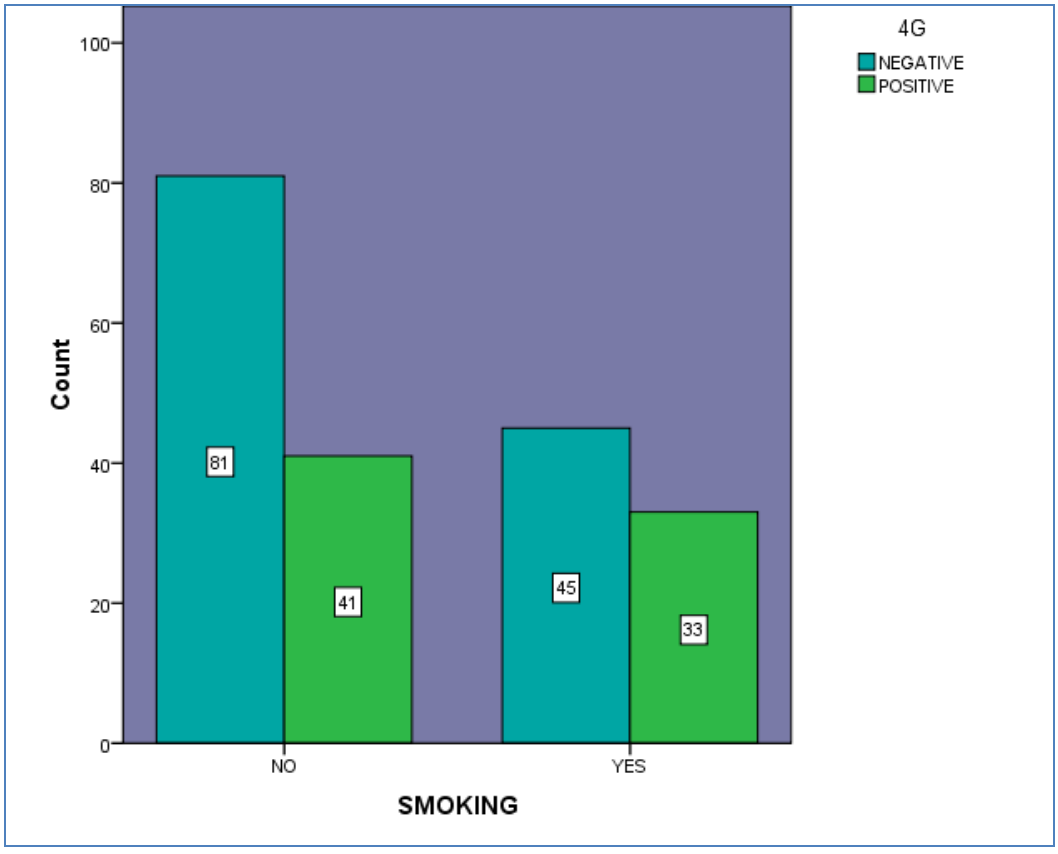
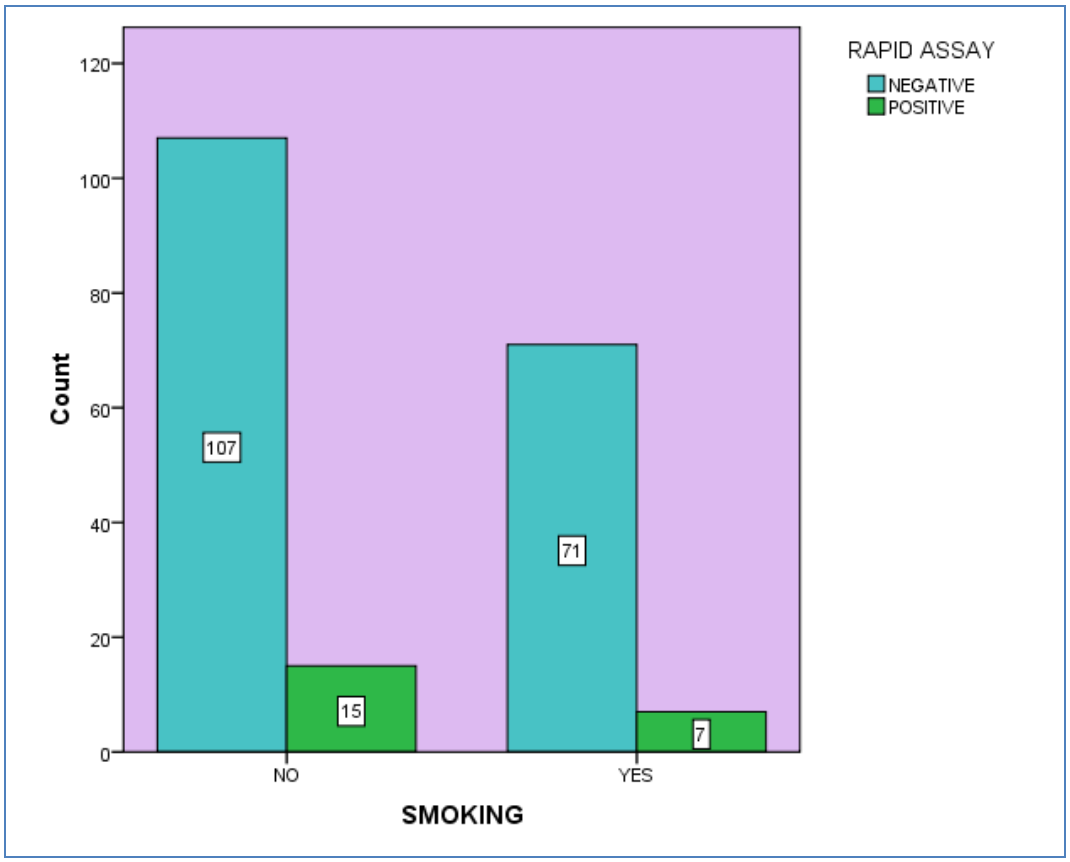


TABLE 4.8: DETECTION OF HIV BY RAPID ASSAY IN SMOKERS

SMOKING	NEGATIVE	POSITIVE	TOTAL
NO	107 (87.7%)	15 (12.3%)	122 (100%)
YES	71 (91%)	7 (9%)	78 (100%)

FIG 39: DETECTION OF HIV BY RAPID ASSAY IN SMOKERS



DISCUSSION

During the study period, 200 patients (High Risk Group and Contacts of High Risk Group) were enrolled for Fourth Generation ELISA test along with Rapid Assay (NACO protocol).

As per the observations in our study, the percentage of patients tested Positive by Fourth Generation ELISA out of the 200 study group was 37% and Negative was 63%. The detection rate of HIV Positivity by Rapid Assay in High Risk Group was 11% ad Negative was 89%.

This result is comparable with the observations by Adeola Folashi de Afolobi et al [33] who compared Rapid Assay and ELISA in High Risk Group in Nigeria. The study population both in terms of High Risk as well as number was comparable namely 356. They reported a 39.3% detection rate by Rapid Assay and 50% by ELISA (p24 Ag).

The prevalence of HIV in Nigeria as per 2012 statistics states it that as the second largest number of HIV incidence worldwide roughly about 3.7%. Their High Risk Groups mainly constitute CSW, MSM and IV Drug Abusers.

Age

The category with maximum patients were in 20 to 30 years age group in our study. The second largest category fell in more than 40 years age group. 39% (78 patients) were in 20 to 30 years category but the category with maximum tested Positive for HIV by Fourth Generation ELISA was in 31-40 years category (52.1%). The p value was 0.047 which is statistically significant.

A similar pattern was observed in Rapid Assay with maximum HIV Positivity of 18.7% in the same age group.

This is in contrast with the observations by Olufemi et al [(40)] where the maximum HIV Positive patients were in their second and third decade (age group).

Gender

In our study, the maximum population were men constituting 157 in number of whom 38.2% were tested Positive by Fourth Generation ELISA. Whereas, among 30 females, 36.7% and among the 13 Transgenders, 23.1% were tested Positive by Fourth Generation ELISA.

By Rapid Assay, among the 157 males, 10.2% (16 patients) were HIV Positive. 13.3% (4 patients) among the 30 females and 15.4% (2 patients) among the 13 Transgenders were also HIV Positive by Rapid Assay.

This is in contrast to Maninder Sing Setia et al [38] who studied focusing only Transgenders and MSMs involved in commercial sex where 68% of Transgenders were tested positive for HIV by Rapid Assay and ELISA.

Marital Status

108 patients **(**54%) of our study group (200) were married irrespective of their sexual orientation. Of these 108 patients, 44 were HIV Positive by Fourth Generation ELISA (40.7%). Among the 46% (92 patients) unmarried patients, 32.6% were HIV Positive. This is so because our selection of patients were patients with other risk factors like CSW exposure or other STIs.

Rapid Assay detected HIV Positive status in 11.1% of the married patients and 10.9% among the unmarried patients.

Pushpa Devi et al [41] reported a 6.5% HIV Positivity in married and 3.19% in unmarried patients.

The increase in HIV positivity rate in our population is mainly due to High Risk factors. A higher HIV positive status in married population is observed in both studies.

Socioeconomic Status

In our study, 37.5% of urban population and 36.3% of rural patients were tested HIV Positive by Fourth Generation ELISA. Thus, there was not much difference in these categories because of the high risk categorization. Whereas, there was a difference of 1.2 percentage among rural and urban population.

By Rapid Assay, 13.8% of the rural patients and 9.2% of the urban patients were HIV Positive. This can be explained by stressing on the fact that High Risk individuals in an urban set up have more awareness and so present early to STD department.

UNICEF[42] has also stated the same scenario in its Indian observation and the reduction in HIV prevalence as the literacy rate improves. Further more, urban slums constitute a major portion of urban HIV prevalence. This result is comparable with Kosambiya et al [43] who attributes the increased HIV prevalence in urban population to swelling of urban slums and metropolitanisation.

Approach to STD Department

In our study, there was slight dominance of patients who came for self screening mostly following exposure to commercial sex workers which was 90. Whereas, nearly comparable 80 patients came up as a referral from other

medical fraternities who presented with various complaints. Interestingly, 46.7% of the self screening patients turned out to be HIV Positive by Fourth Generation ELISA. Similiarly, 42.9% of patients with spouse infected by various sexually transmitted infections were reported HIV Positive. But, among the NGO referrals, who were expected to be more at risk only 26.1% were tested HIV Positive.

A similar trend was observed with Rapid Assay, except for the fact that the percentages were less. It was observed that these self screening patients mostly were frequent clients of commercial sex workers and came in for periodic screening.

This reinforces the increased case detection rates with improving awareness by counselling as suggested by Rochelle et al [(44)] in a study conducted in Massachusetts.

Presenting Complaints

The majority of patients 50.5% (101 patients) came without any complaints to our STD out patient department. Of which 34.7% (35 patients) were tested positive for HIV by Fourth Generation ELISA. 81 patients presented with genital complaints which were in the form of genital itching, ulcer, urethral discharge, vaginal discharge, genital lesions like genital wart. A couple of patients presented with difficulty and pain during defaecation, who on history taking revealed homosexual practice. Out of these 81

patients, 40.7% (33 patients) were HIV Positive. 16 patients presented with non specific symptoms like chronic cough, diarrhoea, fever or weight loss, and came either by self or by referrals. Of them, 6 were HIV Positive making it the second maximum percentage of HIV Positivity.

Whereas Rapid assay was able to detect HIV Positivity in 18.8% (3 patients) of patients with nonspecific symptoms. 11.1% (9 patients) among the patients with genital complaints were also HIV Positive. Interestingly, HIV positivity was detected in 9.1% (10 patients) in the sector of patients who presented without any complaints, but with only recent exposure to commercial sex worker. This category of patients may be the ones in the early phase of HIV in whom Rapid Assay lacked expertise.

This was in contrary to a Nigerian study by Olufemi et al[40] with a similar or comparable study of 218 patients where the foremost presentation observed was oral thrush. In our study, only one case presented with oral candidiasis.

Educational Status

In our study, there was not much significant difference in HIV Positivity among illiterates and literates. This probably might be due to cultural deviation and westernization among youngsters. Fourth Generation ELISA detected 35.6% (26 patients) HIV Positives among illiterates. Whereas Rapid Assay, detected only 16.4% (12 patients) among illiterates.

This explains the increased awareness and early presentation in case of educated youth.

Occupation

A maximum proportion of patients were cooley (87 patients) of whom 32.2% (28 patients) were HIV Positive by Fourth Generation ELISA. Of the 72 patients working in private sector which included clerical works, self employment, delivery boys, 44.4% (32 patients) were HIV Positive by Fourth Generation ELISA. The next highest category were house wives of whom 37.5% (6 patients) were HIV Positive. Most of their husbands were promiscuous with multiple exposure to commercial sex workers. Only one software professional came for self screening who turned out to be HIV Positive.

By Rapid Assay, 9 out of the 87 (10.3%) cooleys were HIV Positive. Among the private sector, 8.3% (6 patients) were HIV Positive by Rapid Assay. 18.8% (3 patients) of the house wives were also HIV Positive by Rapid Assay.

This higher HIV prevalence among house wives was comparable to study conducted by Nitya Vyas et al [(45)] in 2009 amounting to 33.6%. The second largest sector in their study were farmers and unskilled workers.

Sexual Practices

In our study, 81.5% (163 patients) were heterosexuals. Only 5.5% (11 patients) were bisexual, most of them married. 13% (26 patients) of the study group were homosexuals. The highest percentage of HIV Positives were in bisexuals nearly 45.5% (5 patients). A considerable 30.8% (8 patients) of the homosexuals were also HIV Positive by Fourth Generation ELISA.

In Rapid Assay, there was a higher positivity rate among homosexuals contributing to 11.5% (3 patients). One bisexual was HIV positive by Rapid Assay.

Our results have shown an increase in the HIV Positivity among MSM group. Vivian et al [(46)] who had conducted a study among 592 Chennai men way back in 2004, stated a HIV prevalence of 6.5%.

Contact History

In our study, 93% (186 patients) of the patients accepted one or more extramarital contact or exposure to commercial sex worker. Of these, 37.6% (70 patients) were HIV Positive by Fourth Generation ELISA. Whereas, in the remaining 7% (14 patients) who refused extramarital contact, 28.6% (4 patients) were HIV Positive.

By Rapid Assay, only 10.2% (19 patients) of whom accepted extramarital contact history were reported HIV Positive. In the contrary 21.4% (3 patients) of those who denied extramarital sexual exposure were HIV Positive by the same.

A study conducted by Dibua et al [47] quoted that the average age of first sexual act was around 15 to 20 years in Nigeria. Probably, in Indian set up the trend though not close still follows this.

Number of contacts

In our study, we observed that 40.3% (27 patients) of patients who had multiple extramarital exposures were HIV Positive by Fourth Generation ELISA. 42.1% (16 patients) of those with two sexual exposures to commercial sex workers were HIV Positive. Whereas 33.3% (27 patients) of those who had single extramarital exposure to CSW were also HIV Positive by Fourth Generation ELISA. This almost comparable result in all the above categories is because we included people with both multiple exposure to CSW and also those with recent exposure to CSW.

Whereas, Rapid Assay picked up more percentage of HIV Positivity in the multiple exposure group 11.9% (8 patients) rather than single or two exposures.

Wawer M J et al[27] has mentioned that the transmission rate per coital act increases with the number of exposure as well as the stage of HIV infection in the Reactive partner. It is stated that in early HIV infection the transmission rate is 0.0082/coital act whereas after 6 months of seroconversion the rate drops to 0.0015/ coital act. This further escalates to 0.0028/ coital act just months before death due to established Acquired Immuno Deficiency Syndrome.

Time period between Extramarital Exposure and Test

In our study, Fourth Generation ELISA was able to identify HIV Positivity in 46.3% (25 patients) of patients whose last extramarital sexual exposure was within two weeks and two months.33.3% (18 patients) who gave last extramarital contact within two weeks were reported HIV Positive by Fourth Generation ELISA.

Rapid Assay could only pick up HIV Positivity in 7.4% (4 patients) of the patients whose last extra marital contact fell within two weeks. A similar percentage of HIV Positivity was noted in the two weeks to two months category.

This supports the Fiebig`s HIV Staging and the serological parameters in each stage as given by Myron et al [21]. As per Fiebig`s Staging of Acute HIV infection, the detection of p24 Ag is from 13 to 28 days since the day of viral entry into the body. This advantage is picked up by our

Fourth Generation ELISA which detects both p24 Ag as well as Anti HIV antibody. Whereas, in Stage 3 of Fiebig`s classification ELISA positivity is expected from day 18 to 34 of vial entry into body. This four to eight days advantage that we get from p24 Ag detection is very crucial, the importance of which cannot be overemphasized.

There were some patients who refused extra marital sexual exposure and it was this group which showed more HIV Positivity in Rapid Assay. This might be due to patient apprehensive of stigmatization, spouse contribution to infection or due to other modes of spread.

Surgical Procedures in the Study Group:

36.6% (59 patients) of the patients who had never undergone surgery were HIV Positive by Fourth Generation ELISA. A slightly higher percentage 38.5% (15 patients) was HIV Positive in the category of patients who underwent surgeries in the past.

Rapid Assay detected HIV positivity in 11.8% (19 patients) among patients who had no previous surgeries. Whereas, 7.7% (3 patients) of patients with history of previous surgeries were HIV Positive by Rapid Assay.

William et al [48] refers to Spaulding`s segregation of medical items to critical, semicritical and non critical and has defined strict sterilization procedures. In most of our current hospital setups, autoclaving of instruments and fumigation of operation theatres is scrupulously done. So, the risk factor involved in surgical procedures is relatively less.

Blood Transfusion

Regarding blood transfusion, only 2 patients gave history of blood transfusion done 5 years back, of which one was reported to be HIV Positive by both Fourth Generation ELISA and Rapid Assay.

Jacob John et al [49] quotes NACO`s sentinel surveillance that in 2009, out of the new HIV infections, less than one percent was through blood and blood products.

This is consistent with our observation, which reports a 0.5% HIV positivity both by Fourth Generation ELISA as well as Rapid Assay.

Smoking

In our study, 39% (78 patients) were smokers. Of them, 42.3% (33 patients) were HIV Positive by Fourth Generation ELISA. Whereas, amongst the non smokers, 33.6% (41 patients) were only HIV Positive by Fourth Generation ELISA. Whereas, Rapid Assay detected 9% (7 patients) HIV Positivity among the 78 smokers.

This observation might be due to the fact that smoking weakens the mucosal barrier by acting on Human B defensin 2 and Interleukin 8 expression in oral / gingival mucosa which increases the propensity to acquire infections as mentioned by Mahonanda et al [50]. This is true more so in case of homosexuals with ororeceptive practices, cunnilingus and fellatio.

Alcoholism

In our study, 47.5% (95 patients) of the study group were alcoholics (taking alcohol more than twice a week). Of them, 43.2% (41 patients) were HIV Positive by Fourth Generation ELISA. Whereas, among nonalcoholics the HIV Positive percentage was 31.4% (33 patients).

By Rapid Assay, 10.5% (10 patients) of alcoholics and 11.4% (12 patients) among non alcoholics were HIV Positive.

This is comparable with the observations by Barbara et al [51] who observed that in alcoholics, lapse of judgement, increased frequency of sex, high risk behaviours, exposure to commercial sex workers and inconsistent condom use is much in vogue.

Sexually Transmitted Infections

According to our observations, 62.5% (125 patients) patients had no Sexually Transmitted Infections. But 40% (50 patients) of them, proved to be HIV Positive by Fourth Generation ELISA. In our study 37.5% of the

people had Sexually Transmitted Infections. Syphilis was the commonest Sexually Transmitted Infection documented in our study. 28.6% (8 patients) of these Syphilitics were HIV Positive.

8 patients presented with non gonococcal urethritis, of whom 5 were HIV Positive amounting to 62.5%. Bacterial vaginosis and Candidial Balanoposthitis were the subsequent groups with six patients each. 33.3% (2 patients) were HIV Positive in each group.

By Rapid Assay, only 11.2% (14 patients) of patients with no complaints were HIV Positive. 12.5% (1 patient) of Candidal Balanoposthitis were also Positive by Rapid Assay.

It is comparable with Hawkes et al [52] who reported 22% Sexually Transmitted Infection in the study group

Also, previous venereal diseases reported in our study group were genital herpes, genital scabies and genital ulcer. Of them, cases with history of genital ulcer were 5. Among these 2 patients were HIV Positive by Fourth Generation ELISA and 1 by Rapid Assay.

Tuberculosis

In our study, out of the 24 patients (12%) who presented with tuberculosis, 6 patients were HIV Positive by Fourth Generation ELISA which amounts to 25%.

Whereas, Rapid Assay could identify only 12.5% (3 patients) of HIV Positives amongst Tuberculosis patients.

India, perse is well known for it`s number of tuberculosis patients. Patients may present with tuberculosis as the first presentation or tuberculosis reactivation as part of Immune Reconstitution Inflammatory Syndrome (IRIS).

Sowmya et al [53] reports Tuberculosis - HIV coinfection of 50 to 80% in SubSaharan Africa and 5 to 24% elsewhere.

Intravenous Drug Abusers

Interestingly, not a single case gave a history of Intravenous Drug Abuse. This was in contrary to Chandra et al [54] who had studied 180 drug users in Chennai. It is reported that 69.4% of these patients were HIV Positive by ELISA and Western Blot.

Most probably, patients in our study group did not disclose drug abuse history or these sector of patients had different clinical array of presentation.

High Risk Categorisation

The majority of patients who can otherwise be termed as MARG (Most At Risk Group) were those exposed to CSWs. They contributed to 65.5% (131 patients) of the study group. The next highest group were those,

whose partners had multiple exposure to CSWs. There were 13 Transgenders in the study. The number of MSMs were 14. There was almost an equal distribution between Transgenders and MSMs among the homosexuals. Not a single female in this study, revealed a homosexual history. There were obvious overlap of categories, like Bisexuals or Transgenders or those whose spouse were exposed to Commercial Sex Workers and Sexually Transmitted Infections. There were also overlap between Commercial Sex Workers and patients with Sexually Transmitted Infections. Considerable number of patients had Multiple Risk factors.

Nitya Vyas et al [38] reported also reported an 86% High Risk sexual contact leading the risk categories which included Commercial Sex Workers, exposure to Commercial Sex Workers and Bisexuals.

SUMMARY

The study group consisted of MARG (Most At Risk Group) - those exposed to CSWs (65.5%), 13 Transgenders, 14 Homosexuals (MSM), 10 Bisexuals, 9 Commercial Sex Workers, 15 patients with spouse exposed to CSW, 7 cases of contact tracing and one case of sexual abuse.

In this study the following observations were made:

1. By Fourth Generation ELISA, out of the 200 High Risk group, the percentage of patients HIV Positivity was 37% and Negative was 63%.

2. By Rapid Assay, the percentage of HIV Positivity was 11% in the same study group.

3. The age group highly Positive by Fourth Generation ELISA was 31-40 years and the positive percentage was 52.1%. The p value was 0.047 which is statistically significant. In the same age group, by Rapid Assay the Positivity was 18.7%.

4. 36.7% among 30 females, 23.1% among the 13 Transgenders, and 38.2% among 157 men were HIV Positive by Fourth Generation ELISA.

5. 30.8% of the homosexuals were HIV Positive by Fourth Generation ELISA and 11.5% by Rapid Assay. The highest percentage of HIV Positives were in bisexuals nearly 45.5% by Fourth Generation ELISA.

6. 37.5% of urban population and 36.3% of rural population were HIV Positive by Fourth Generation ELISA. There was a difference of 1.2 percentage among rural and urban population.

7. 46.7% of the self screening patients were HIV Positive by Fourth Generation ELISA. Among the NGO referrals, who were expected to be more at risk only 26.1% were tested HIV Positive by Fourth Generation ELISA.

8. 34.7% of the patients with nil complaints were HIV Positive by Fourth Generation ELISA, 40.7% of the 81 patients with genital complaints were HIV Positive by Fourth Generation ELISA and among the 16 patients who presented with non - specific complaints - 6 were HIV Positive by Fourth Generation ELISA.

9. There was not much significant difference in HIV Positivity among illiterates and literates.

10. A maximum proportion of patients were cooley by occupation. The next highest category were patients working in private sector and then

house wives constituting 37.5% amongst which most of their husbands were promiscuous with multiple exposure to Commercial Sex Workers.

11. 40.3% of people with multiple extramarital exposures, 42.1% of patients with two sexual exposures to commercial sex workers and 33.3% of patients with single extramarital exposure to CSW were HIV Positive by Fourth Generation ELISA.

12. By Fourth Generation ELISA, HIV Positivity was detected in 46.3% of patients whose last extramarital sexual exposure was within two weeks and two months. 33.3% who gave last extramarital contact within two weeks were reported HIV Positive by Fourth Generation ELISA. By Rapid Assay, only 7.4% of the patients whose last extra marital contact fell within two weeks were HIV Positive.

13. 43.2% of alcoholics were HIV Positive by Fourth Generation ELISA and among non - alcoholics the positive percentage was 31.4%.

14. Of the 62.5% patients had no sexually transmitted infections, 40% of them proved to be HIV Positive by Fourth Generation ELISA. Syphilis tops the list of STIs in this study.

15. Among the Tuberculosis patients, 25% were reported HIV Positive by Fourth Generation ELISA and only 12.5% by Rapid Assay.

16. Higher HIV Positive status in married population is maintained in both Assays in this study.

17. In this study, in most of the categories, the percentage of HIV Positivity detected by Fourth Generation ELISA was higher than that detected by Rapid Assay showing that Fourth Generation ELISA is a more sensitive test than Rapid Assay.

CONCLUSION

The study group of 200 patients consisted of MARG (Most At Risk Group) - those exposed to CSWs, Transgenders, Homosexuals, Bisexuals, Commercial Sex Workers, patients with spouse exposed to CSW and cases of contact tracing.

- By Fourth Generation ELISA, out of the 200 High Risk group, the percentage of HIV Positivity was 37% and Negative was 63%.
- By Rapid Assay, the percentage of HIV Positivity was 11% in the same study group.
- In this study, in most of the categories, the percentage of HIV Positivity detected by Fourth Generation ELISA was higher than that detected by Rapid Assay showing that Fourth Generation ELISA is a more sensitive test than Rapid Assay.
- A late diagnosis of HIV infection can result in increased transmission, morbidity, mortality and cost to health care services.
- Hence, Early detection of HIV infection by Fourth Generation ELISA during the window period prevents transmission from mother to child, donor to recipient transmission in both blood and organ donations, transmission by sexual route and above all improves the chances of early intervention.

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PROFORMA

Serial no:

STD Op No:

Name:

Age:
1. 11-20
2.21-30
3. 31-40
4. >40

Gender:
1.Male
2.Female
3.Transgender

Address:
1.Urban
2.Rural

Occupation:
1.Cooley
2. CSW
3. Housewife
4 . Nil
5. Others
6. Private
7. Professional
8. Student

Educational Status:

1. Illiterate
2. Middle School
3. High School
4. Higher Secondary
5. Graduate

Presenting Complaints:

H/o present illness:

H/o vaginal / urethral discharge:

H/o abdominal pain:

H/o dyspareunia:

H/o genital itching / ulcer /lesions:

H/o pain or difficulty on defaecation: (for Homosexuals)

H/o Chronic fever / diarrhea /weight loss:

Menstrual history

Marital History:

1. Married
2. Single (divorced/ widow/ widower)

Sexual history:

Sexual orientation:
1. Heterosexual
2. Homosexual
3. Bisexual

Last marital contact :
Premarital contact :
Extra marital contact :
Number of extra marital contacts :
Duration since last contact :
Previous STI infections / treatments :

Obstetric history:

Past History:

Tuberculosis :

Diabetes :

Hypertension :

Bronchial asthma :

Previous surgeries :

Blood transfusions :

Jaundice:

Family History:

Personal History:

IV drug abuse:

Aberrant sexual practice:

General examination:

Built :

Pallor :

Jaundice :

Pedal edema :

Generalised lymphadenopathy :

Pulse:

BP:

Systemic examination:

CVS :

RS :

Abdomen :

CNS :

Local examination:

Female:

Any significant inguinal lymphadenopathy:

Inspection:

Vaginal discharge:

Any genital abnormalities:

Per vaginal examination: Position of cervix and uterus
Cervical motion tenderness

Per speculum examination:

Cervical discharge
Cervical erosion

Skin:

Mucosa:

Bones and Joints:

Male:

Inguinal lymphadenopathy:

Circumcised/ uncircumcised:

Phimosis:

Urethral discharge:

Subprepucial discharge:

Glans penis:

Testis/ scrotum:

Any ulcer/ erosion/ scars:

Skin:

Mucosa:

Bones and Joints:

Investigations

Urine routine:

Urethral/ vaginal / cervical discharge :
Grams stain/ wet mount with normal saline and KOH

Ulcers/erosions: Tzanck smear/ Dark field microscopy/ Grams stain

VDRL for syphilis:

Urine/ pharyngeal swab/ cervical culture for gonococci:

Fourth Generation ELISA for HIV:

Rapid assay for HIV:

Diagnosis:

Clinical:

Microbiological:

PATIENT CONSENT FORM

Title of the study: **"A Study On The Usefulness Of Fourth Generation ELISA ($_P$24 Antigen and Antibody) For Early Detection Of HIV Infection In The High Risk Group".**

Name of the participant :

Name of the principal investigator : Dr. G. Sukanya

Name of the Institution : Institute of Venereology, Madras Medical College & Rajiv Gandhi Government General Hospital, Chennai – 3.

Documentation of the informed consent:

I ---------- have read the information in this form (or it has been read to me). I was free to ask any questions and they have been answered. I am over 18 years of age and exercising my free power of choice, hereby consent to be included as a participant in the study.

1. I have read and understood this consent form and the information provided to me
2. I have had the consent document explained to me
3. I have been explained about the nature of the study
4. My rights and responsibilities have been explained to me by the investigator
5. I agree to co operate with the investigator and I will inform him/her immediately if I suffer unusual symptoms
6. I have not participated in any research study at any time
7. I am aware of the fact that I can opt out of the study at any time without having to give any reason and this will not affect my future treatment in this hospital

8. I hereby give permission to the investigator to release the information obtained from me as a result of participation in this study to the sponsors, regulatory authorities, Government agencies and institutional ethics committee. I understand that they are publicly presented.

9. My identity will be kept confidential if my data are publicly presented.

10. I am aware that if I have any question during the study, I should contact at one of the addresses listed above. By signing this consent form I attest that the information given in this document has been clearly explained to me and apparently understood by me, I will be given a copy of this consent document.

Participant initials:

For adult participants:

Name and signature/ thumb impression of the participant
(or legal representative if participant is incompetent)

_____ _____ ----------

Name Signature Date

Name and signature of impartial witness (required for illiterate patients):

_____ _____ _____

Name Signature Date

Address and contact number of the impartial witness:

Name and signature of the investigator or his representative obtaining consent:

_____ _____ _____

Name Signature Date

INFORMATION SHEET

Title of the study: **"A Study On The Usefulness Of Fourth Generation ELISA ($_P$24 Antigen and Antibody) For Early Detection Of HIV Infection In The High Risk Group".**

Name of the participant :

Name of the principal investigator : Dr. G. Sukanya

Name of the Institution : Institute of Venereology, Madras Medical College & Rajiv Gandhi Government General Hospital, Chennai – 3.

- Your specimen (Blood) has been accepted.
- We are conducting a study on HIV detection among patients attending Rajiv Gandhi Government General Hospital, Chennai and for that your specimen (blood) may be valuable to us.
- The purpose of this study is to diagnose early cases of HIV infection with the help of certain special tests.
- We are selecting certain cases and if your specimen is found eligible, we may be using your specimen to perform extra tests and special studies which in any way do not affect your final report or management.

- The privacy of the patients in the research will be maintained throughout the study. In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.
- Taking part in this study is voluntary. You are free to decide whether to participate in this study or to withdraw at any time; your decision will not result in any loss of benefits to which you are otherwise entitled.
- The results of the special study may be intimated to you at the end of the study period or during the study if anything is found abnormal which may aid in the management or treatment.

Signature of Investigator Signature of Participant

Date:

Serial no:	Age	Sex	Place	Approach to STD OP	Complaints	Education	Occupation	Contacts	No. of sexual partners	Time since last contact	Surgery	Transfusion	Smoking	Alcohol	Sexual orientaton	other STIs	TB	PVD	IVDU	Rapid assay result	4G resul	Marital status	HRG
1	2	3	1	2	1	3	6	1	1	1	1	1	1	1	2	12	1	1	1	NEGATIVE	NEGATIVE	2	5
2	3	3	1	2	1	3	6	1	1	1	1	1	1	1	2	12	1	1	1	POSITIVE	POSITIVE	2	5
3	3	1	1	1	2	5	6	2	3	5	2	1	1	1	1	12	1	1	1	NEGATIVE	NEGATIVE	2	6
4	2	1	1	1	1	4	6	2	4	3	1	1	2	2	1	12	1	1	1	NEGATIVE	POSITIVE	1	6
5	1	1	1	2	1	4	1	2	4	2	1	1	1	1	2	12	1	1	1	NEGATIVE	POSITIVE	2	3
6	3	1	1	2	1	2	1	2	2	2	1	1	2	2	2	12	1	1	1	NEGATIVE	POSITIVE	2	3
7	2	1	1	2	1	3	6	2	4	2	1	1	1	1	2	12	1	1	1	NEGATIVE	NEGATIVE	2	3
8	3	1	1	3	2	2	1	2	3	2	1	1	1	1	1	12	1	1	1	NEGATIVE	NEGATIVE	1	6
9	4	1	1	3	3	1	1	2	3	3	2	1	1	2	1	12	1	1	1	NEGATIVE	POSITIVE	1	6
10	4	1	1	3	1	5	1	2	2	4	2	1	1	1	1	12	1	1	1	NEGATIVE	NEGATIVE	2	6
11	3	1	1	3	1	1	1	2	2	2	2	1	2	2	1	12	2	1	1	NEGATIVE	NEGATIVE	1	6
12	4	1	2	3	2	3	6	2	3	5	1	1	2	2	1	2	2	1	1	NEGATIVE	POSITIVE	1	6
13	4	2	1	1	1	1	3	2	2	5	1	1	1	1	1	16	1	1	1	NEGATIVE	POSITIVE	1	7
14	3	1	2	1	1	4	6	2	4	3	1	1	2	2	1	12	1	1	1	NEGATIVE	POSITIVE	1	6
15	1	3	2	2	1	4	6	2	4	3	2	1	1	1	2	12	1	1	1	NEGATIVE	NEGATIVE	2	5
16	1	3	2	2	1	4	6	2	4	5	2	1	1	1	2	12	1	1	1	NEGATIVE	POSITIVE	2	5
17	1	3	2	2	1	4	6	2	4	2	2	1	1	1	2	12	1	1	1	NEGATIVE	NEGATIVE	2	5
18	2	1	1	1	2	5	6	2	2	2	1	1	2	1	1	13	1	1	1	NEGATIVE	NEGATIVE	2	6
19	4	1	2	1	2	3	5	2	4	4	1	1	1	1	1	12	1	1	1	NEGATIVE	NEGATIVE	1	6
20	3	1	1	3	1	3	6	2	2	5	2	1	2	2	1	12	1	1	1	NEGATIVE	POSITIVE	1	6
21	2	1	1	1	1	5	6	2	2	5	1	1	1	1	1	12	1	1	1	NEGATIVE	NEGATIVE	2	6
22	4	1	2	1	2	4	1	2	4	2	1	1	1	2	1	12	1	1	1	NEGATIVE	NEGATIVE	1	6
23	3	1	1	1	2	4	6	2	3	3	1	1	1	1	3	12	1	1	1	NEGATIVE	NEGATIVE	1	4
24	3	1	1	1	2	3	6	2	2	3	1	1	2	2	1	13	1	1	1	NEGATIVE	NEGATIVE	2	6
25	3	1	2	3	1	2	6	2	2	5	1	1	2	2	1	12	2	1	1	NEGATIVE	NEGATIVE	1	6
26	4	1	1	3	1	4	6	2	3	4	1	1	1	1	1	12	1	1	1	NEGATIVE	NEGATIVE	1	6

Serial no:	Age	Sex	Place	Approach to STD OP	Complaints	Education	Occupation	Contacts	No. of sexual partners	Time since last contact	Surgery	Transfusion	Smoking	Alcohol	Sexual orientaton	other STIs	TB	PVD	IVDU	Rapid assay result	4G resul	Marital status	HRG
27	3	1	1	3	1	5	6	2	3	2	1	1	2	2	2	12	1	1	1	NEGATIVE	NEGATIVE	1	3
28	2	1	1	2	1	5	6	2	4	2	1	1	1	1	2	12	1	1	1	NEGATIVE	NEGATIVE	2	3
29	4	1	2	3	1	1	1	2	2	5	2	1	2	2	1	16	1	1	1	NEGATIVE	NEGATIVE	1	6
30	3	2	2	1	1	1	3	2	4	4	1	1	1	1	1	16	1	1	1	NEGATIVE	NEGATIVE	1	1
31	2	1	1	1	1	3	6	2	4	2	1	1	1	1	1	12	1	1	1	NEGATIVE	POSITIVE	2	6
32	2	1	2	1	1	1	6	2	2	3	1	1	2	2	1	16	2	1	1	NEGATIVE	NEGATIVE	1	6
33	2	1	2	1	2	4	6	2	3	4	1	1	1	2	1	13	1	1	1	NEGATIVE	POSITIVE	2	6
34	2	1	2	3	2	5	6	2	4	3	2	1	1	2	1	10	1	1	1	NEGATIVE	NEGATIVE	1	6
35	2	1	1	1	1	2	6	2	2	3	1	1	2	2	1	12	1	1	1	NEGATIVE	POSITIVE	1	6
36	2	1	2	1	1	5	6	2	3	5	1	1	1	1	1	12	1	2	1	NEGATIVE	NEGATIVE	2	6
37	3	1	1	1	1	5	6	2	2	3	1	1	1	1	1	12	1	1	1	NEGATIVE	POSITIVE	2	6
38	4	1	1	3	1	2	1	2	3	5	1	1	2	2	1	12	1	1	1	NEGATIVE	POSITIVE	1	6
39	3	1	1	1	1	3	6	2	4	3	1	1	2	2	1	12	1	1	1	NEGATIVE	POSITIVE	2	6
40	4	1	1	1	2	1	1	2	3	3	1	1	2	2	1	12	1	1	1	NEGATIVE	POSITIVE	1	6
41	4	1	2	1	2	1	1	2	4	5	2	1	2	2	1	12	1	1	1	NEGATIVE	NEGATIVE	1	6
42	2	1	1	1	1	3	6	2	4	2	1	1	2	2	2	12	1	1	1	NEGATIVE	NEGATIVE	2	3
43	1	3	1	2	1	3	4	2	4	2	2	1	1	1	2	12	1	1	1	NEGATIVE	NEGATIVE	2	5
44	1	1	2	1	2	5	6	2	2	5	1	1	1	1	1	12	1	1	1	NEGATIVE	NEGATIVE	2	6
45	2	1	1	1	2	1	1	2	2	3	1	1	2	2	1	12	1	1	1	NEGATIVE	NEGATIVE	2	6
46	4	1	1	3	2	1	1	1	1	1	1	1	2	2	1	5	1	1	1	NEGATIVE	NEGATIVE	2	6
47	3	1	2	3	1	1	1	2	4	5	1	1	2	2	1	12	1	1	1	POSITIVE	POSITIVE	1	6
48	4	1	2	3	1	1	1	2	3	5	1	1	2	2	1	12	2	1	1	NEGATIVE	NEGATIVE	1	6
49	1	3	1	2	2	3	2	2	4	2	1	1	1	1	2	12	1	1	1	NEGATIVE	NEGATIVE	2	5
50	2	1	1	3	2	3	1	1	1	1	1	1	2	2	1	8	1	1	1	NEGATIVE	NEGATIVE	2	6
51	3	1	2	1	2	3	1	2	2	5	1	1	1	1	1	12	1	1	1	NEGATIVE	POSITIVE	2	6
52	3	1	1	3	1	1	1	2	2	4	1	1	1	1	1	12	2	1	1	NEGATIVE	NEGATIVE	1	6

Serial no:	Age	Sex	Place	Approach to STD OP	Complaints	Education	Occupation	Contacts	No. of sexual partners	Time since last contact	Surgery	Transfusion	Smoking	Alcohol	Sexual orientaton	other STIs	TB	PVD	IVDU	Rapid assay result	4G resul	Marital status	HRG
53	2	1	2	1	2	3	1	2	3	2	1	1	2	2	3	12	1	1	1	NEGATIVE	NEGATIVE	1	4
54	2	1	1	2	2	5	4	2	4	3	2	1	2	2	2	4	1	1	1	NEGATIVE	NEGATIVE	2	3
55	2	1	2	2	2	5	6	2	4	4	1	1	2	2	2	16	1	1	1	NEGATIVE	NEGATIVE	2	3
56	3	1	1	3	1	1	1	2	2	3	1	1	2	2	1	16	1	1	1	NEGATIVE	NEGATIVE	1	6
57	4	2	1	3	1	1	1	2	2	2	2	1	1	1	1	12	1	1	1	NEGATIVE	NEGATIVE	1	7
58	2	2	1	3	1	1	2	2	4	2	1	1	1	1	1	1	1	1	1	NEGATIVE	NEGATIVE	1	1
59	2	2	1	1	1	5	8	2	2	3	1	1	1	1	1	12	1	1	1	NEGATIVE	NEGATIVE	2	8
60	4	2	1	4	1	1	3	2	2	5	2	1	1	1	1	16	1	1	1	NEGATIVE	NEGATIVE	1	8
61	2	3	1	2	1	1	4	2	4	2	1	1	1	2	2	12	1	1	1	POSITIVE	POSITIVE	2	5
62	1	1	2	1	2	4	5	2	2	4	1	1	2	2	1	6	1	1	1	NEGATIVE	POSITIVE	2	6
63	2	1	2	1	1	5	6	2	4	3	1	1	1	2	1	12	1	1	1	NEGATIVE	POSITIVE	1	6
64	2	1	1	3	2	5	6	2	2	5	1	1	2	2	1	14	1	1	1	NEGATIVE	NEGATIVE	2	6
65	2	1	2	1	2	5	6	2	2	4	1	1	1	1	1	12	1	1	1	NEGATIVE	NEGATIVE	2	6
66	2	1	2	2	2	3	1	2	4	2	1	1	2	2	1	1	1	1	1	NEGATIVE	NEGATIVE	1	6
67	4	1	1	1	2	5	6	2	4	3	1	1	2	2	3	10	1	1	1	NEGATIVE	POSITIVE	1	4
68	3	1	1	3	1	1	1	2	3	3	2	1	2	2	1	12	1	1	1	NEGATIVE	POSITIVE	1	6
69	2	1	2	3	2	1	1	2	2	5	1	1	2	2	1	12	1	1	1	NEGATIVE	POSITIVE	1	6
70	2	1	2	1	2	4	1	2	4	5	1	1	2	2	1	16	1	1	1	NEGATIVE	NEGATIVE	2	6
71	4	1	1	3	3	1	1	2	4	5	1	1	2	2	1	12	2	1	1	NEGATIVE	NEGATIVE	1	6
72	2	1	2	1	1	2	1	2	2	4	1	1	2	2	1	12	1	1	1	NEGATIVE	NEGATIVE	2	6
73	2	3	1	2	2	2	1	2	4	5	1	1	1	1	3	12	1	1	1	NEGATIVE	NEGATIVE	1	5
74	1	3	1	2	1	3	1	2	4	2	2	1	1	1	2	12	1	1	1	NEGATIVE	NEGATIVE	2	5
75	2	3	1	2	1	3	1	2	4	2	2	1	1	2	2	12	1	1	1	NEGATIVE	NEGATIVE	2	5
76	2	3	1	2	1	5	8	2	4	2	1	1	1	2	2	12	1	1	1	NEGATIVE	NEGATIVE	2	5
77	4	1	1	3	1	1	1	2	2	5	2	1	1	2	1	16	2	1	1	NEGATIVE	NEGATIVE	1	6
78	4	1	1	2	1	1	1	2	4	3	1	1	1	1	2	16	1	1	1	NEGATIVE	NEGATIVE	2	3

Serial no:	Age	Sex	Place	Approach to STD OP	Complaints	Education	Occupation	Contacts	No. of sexual partners	Time since last contact	Surgery	Transfusion	Smoking	Alcohol	Sexual orientaton	other STIs	TB	PVD	IVDU	Rapid assay result	4G resul	Marital status	HRG
79	4	1	2	1	1	5	6	2	4	3	1	1	1	2	1	12	1	1	1	NEGATIVE	NEGATIVE	1	6
80	3	2	1	1	1	5	6	2	3	4	2	1	1	1	1	12	1	1	1	NEGATIVE	POSITIVE	1	7
81	2	1	2	3	3	5	6	1	1	1	1	1	1	1	1	16	1	1	1	NEGATIVE	NEGATIVE	2	6
82	2	1	1	1	2	5	6	2	4	2	1	1	1	1	2	12	1	1	1	NEGATIVE	POSITIVE	2	3
83	1	2	1	3	1	3	2	2	4	2	1	1	1	1	1	1	1	1	1	NEGATIVE	POSITIVE	1	1
84	3	1	2	1	2	1	1	2	4	3	2	1	2	2	1	7	1	1	1	NEGATIVE	POSITIVE	1	6
85	3	1	1	1	2	2	6	2	4	3	1	1	2	2	1	12	1	1	1	POSITIVE	POSITIVE	1	6
86	3	1	1	1	2	3	6	2	2	5	1	1	1	1	1	12	1	1	1	POSITIVE	POSITIVE	1	6
87	4	1	1	1	1	3	6	2	3	5	1	1	2	1	1	12	1	1	1	NEGATIVE	NEGATIVE	2	6
88	2	1	2	1	2	5	6	2	2	4	1	1	2	2	1	8	1	1	1	POSITIVE	POSITIVE	2	6
89	4	1	2	1	1	3	1	2	3	3	1	1	2	2	1	12	1	1	1	NEGATIVE	NEGATIVE	2	6
90	2	1	2	1	1	1	1	2	2	4	1	1	1	1	1	12	1	1	1	NEGATIVE	NEGATIVE	2	6
91	2	1	1	3	3	2	1	2	2	5	1	1	1	2	1	12	1	1	1	NEGATIVE	NEGATIVE	2	6
92	3	1	1	3	3	1	1	2	4	2	1	1	2	2	1	12	1	1	1	POSITIVE	POSITIVE	1	6
93	2	1	1	1	1	5	6	2	3	3	1	1	1	1	1	16	1	3	1	NEGATIVE	NEGATIVE	1	6
94	4	2	1	3	2	1	3	2	2	5	1	1	1	1	1	12	1	1	1	NEGATIVE	NEGATIVE	1	7
95	1	1	1	3	1	2	8	1	1	1	1	2	1	1	1	6	1	1	1	NEGATIVE	NEGATIVE	2	6
96	3	2	1	1	2	2	3	2	2	2	2	1	1	1	1	16	1	1	1	NEGATIVE	NEGATIVE	1	7
97	1	1	1	3	2	3	8	1	1	1	1	1	1	1	1	7	1	1	1	NEGATIVE	NEGATIVE	2	6
98	4	1	1	3	1	1	1	2	4	5	1	1	2	2	1	12	1	1	1	NEGATIVE	NEGATIVE	1	6
99	4	1	2	3	1	1	1	2	2	5	1	1	1	1	1	2	2	1	1	NEGATIVE	NEGATIVE	1	6
100	4	2	1	4	1	1	3	2	2	4	2	2	1	1	1	1	1	1	1	POSITIVE	POSITIVE	1	8
101	4	2	1	3	1	1	3	2	2	5	1	1	1	1	1	16	1	1	1	NEGATIVE	NEGATIVE	1	7
102	3	1	1	1	2	3	1	2	3	2	1	1	1	1	1	13	1	2	1	NEGATIVE	NEGATIVE	1	6
103	3	1	2	1	2	1	1	2	4	3	1	1	2	2	1	12	2	1	1	NEGATIVE	POSITIVE	1	6
104	4	1	1	1	2	1	1	2	4	2	1	1	1	1	1	12	1	1	1	NEGATIVE	NEGATIVE	1	6

Serial no:	Age	Sex	Place	Approach to STD OP	Complaints	Education	Occupation	Contacts	No. of sexual partners	Time since last contact	Surgery	Transfusion	Smoking	Alcohol	Sexual orientaton	other STIs	TB	PVD	IVDU	Rapid assay result	4G resul	Marital status	HRG
105	3	1	1	2	1	5	6	2	4	2	1	1	1	1	2	12	1	1	1	NEGATIVE	NEGATIVE	2	3
106	3	1	2	3	3	5	6	2	3	3	1	1	2	2	1	12	1	1	1	NEGATIVE	NEGATIVE	2	6
107	3	1	2	1	1	3	6	2	2	5	1	1	1	1	1	12	1	1	1	NEGATIVE	NEGATIVE	2	6
108	4	1	1	3	3	1	1	2	2	5	1	1	1	1	1	12	1	1	1	NEGATIVE	NEGATIVE	1	6
109	2	1	1	1	2	3	6	2	4	2	1	1	1	1	2	12	1	1	1	NEGATIVE	POSITIVE	2	3
110	2	1	1	1	2	5	6	2	2	4	1	1	2	2	1	12	1	2	1	NEGATIVE	NEGATIVE	2	6
111	2	1	2	1	1	5	6	2	2	2	1	1	2	2	1	12	1	1	1	NEGATIVE	POSITIVE	2	6
112	1	2	1	1	5	2	4	2	2	2	1	1	1	1	1	12	1	1	1	NEGATIVE	NEGATIVE	2	2
113	2	2	2	3	1	1	2	2	4	4	1	1	1	1	1	12	1	1	1	NEGATIVE	NEGATIVE	1	1
114	4	2	1	3	1	2	3	2	2	3	2	1	1	1	1	12	1	1	1	NEGATIVE	NEGATIVE	1	7
115	2	2	2	3	1	1	2	2	4	2	1	1	1	1	1	12	1	1	1	POSITIVE	POSITIVE	1	1
116	4	1	2	1	2	1	1	2	2	3	1	1	1	1	1	2	1	1	1	NEGATIVE	NEGATIVE	1	6
117	3	1	1	1	2	3	1	2	2	2	1	1	2	2	1	13	1	1	1	NEGATIVE	NEGATIVE	2	6
118	3	2	2	1	2	1	3	2	2	3	2	1	1	1	1	17	1	1	1	POSITIVE	POSITIVE	1	7
119	3	2	1	3	1	3	3	2	2	5	2	1	1	1	1	12	1	1	1	POSITIVE	POSITIVE	1	7
120	3	1	2	1	2	1	1	2	4	5	1	1	1	1	2	2	1	1	1	POSITIVE	POSITIVE	2	3
121	2	1	1	1	2	4	6	2	4	2	1	1	1	1	3	16	1	1	1	NEGATIVE	POSITIVE	1	4
122	3	1	2	3	2	1	1	2	3	3	2	1	2	2	1	16	1	1	1	NEGATIVE	POSITIVE	1	6
123	2	1	1	1	2	1	1	2	4	2	1	1	1	1	1	5	1	2	1	NEGATIVE	NEGATIVE	2	6
124	4	1	1	1	2	1	1	2	4	2	1	1	1	1	1	12	1	1	1	POSITIVE	POSITIVE	1	6
125	4	1	2	3	2	1	1	2	2	4	1	1	1	1	1	12	1	1	1	NEGATIVE	POSITIVE	1	6
126	4	1	1	3	3	3	6	2	2	4	2	1	1	1	1	12	1	1	1	NEGATIVE	POSITIVE	1	6
127	2	1	2	1	1	5	6	2	3	3	1	1	1	1	1	12	1	1	1	NEGATIVE	POSITIVE	1	6
128	2	1	2	1	2	5	6	2	2	4	1	1	2	1	1	12	1	1	1	NEGATIVE	NEGATIVE	2	6
129	4	1	1	3	2	3	6	2	3	4	2	1	2	2	1	2	1	1	1	NEGATIVE	NEGATIVE	1	6
130	4	1	1	1	3	1	1	2	2	5	1	1	1	1	1	12	2	1	1	POSITIVE	POSITIVE	1	6

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131	2	1	1	3	1	1	1	2	2	4	1	1	2	2	1	12	1	1	1	NEGATIVE	POSITIVE	1	6
132	4	1	2	3	3	1	1	1	1	1	1	1	2	2	1	12	2	1	1	POSITIVE	POSITIVE	2	6
133	4	1	1	1	2	3	6	2	2	4	1	1	1	1	1	10	1	1	1	NEGATIVE	POSITIVE	1	6
134	2	2	2	3	1	3	2	2	4	2	2	1	1	1	1	12	1	1	1	NEGATIVE	POSITIVE	1	1
135	2	2	2	3	1	1	2	2	4	3	1	1	1	1	1	1	1	1	1	NEGATIVE	NEGATIVE	1	1
136	2	1	1	2	1	3	6	2	4	3	2	1	1	1	2	16	1	1	1	NEGATIVE	NEGATIVE	2	3
137	2	1	2	1	1	3	1	2	2	5	1	1	1	1	1	12	1	1	1	POSITIVE	POSITIVE	2	6
138	2	1	2	1	1	5	6	2	2	3	1	1	1	1	1	12	1	1	1	NEGATIVE	NEGATIVE	2	6
139	4	2	1	4	1	1	3	2	2	5	1	1	1	1	1	12	1	1	1	NEGATIVE	NEGATIVE	1	8
140	2	1	2	1	2	3	1	2	3	5	1	1	1	2	1	10	1	1	1	POSITIVE	POSITIVE	1	6
141	4	1	2	1	2	1	1	2	3	4	1	1	2	2	1	2	1	1	1	NEGATIVE	NEGATIVE	1	6
142	2	1	2	3	1	5	6	2	4	3	1	1	1	1	3	12	1	1	1	NEGATIVE	NEGATIVE	1	4
143	3	2	1	3	1	1	1	2	2	2	1	1	1	1	1	16	1	1	1	NEGATIVE	NEGATIVE	1	7
144	3	1	1	3	2	1	6	2	2	3	1	1	1	2	1	10	1	1	1	POSITIVE	POSITIVE	2	6
145	2	1	1	2	2	3	1	2	4	4	1	1	1	2	3	16	1	1	1	NEGATIVE	POSITIVE	2	4
146	4	2	2	1	2	1	3	2	2	5	1	1	1	1	1	17	1	1	1	NEGATIVE	NEGATIVE	1	7
147	3	1	1	1	2	1	1	1	1	1	1	1	2	2	1	12	1	1	1	NEGATIVE	NEGATIVE	2	6
148	4	1	1	3	1	3	1	2	2	5	1	1	2	2	1	12	2	1	1	NEGATIVE	NEGATIVE	2	6
149	4	2	1	4	1	1	3	2	2	3	2	1	1	1	1	12	1	1	1	NEGATIVE	POSITIVE	1	8
150	2	1	1	1	2	5	6	2	2	4	2	1	2	2	1	12	1	4	1	NEGATIVE	NEGATIVE	2	6
151	3	1	2	3	1	2	1	1	1	1	2	1	2	2	1	12	2	1	1	NEGATIVE	NEGATIVE	2	6
152	2	1	2	3	1	1	1	2	2	3	1	1	1	2	1	10	2	1	1	NEGATIVE	NEGATIVE	1	6
153	2	1	1	4	2	4	6	2	2	3	1	1	1	1	1	12	1	4	1	NEGATIVE	POSITIVE	2	6
154	3	1	2	1	2	4	6	2	2	3	1	1	1	1	1	16	2	1	1	NEGATIVE	NEGATIVE	2	6
155	2	1	2	1	1	5	7	1	1	1	1	1	1	1	1	6	1	1	1	POSITIVE	POSITIVE	2	6
156	3	1	1	1	2	2	1	2	3	2	1	1	2	2	1	12	2	1	1	NEGATIVE	POSITIVE	1	6

Serial no:	Age	Sex	Place	Approach to STD OP	Complaints	Education	Occupation	Contacts	No. of sexual partners	Time since last contact	Surgery	Transfusion	Smoking	Alcohol	Sexual orientaton	other STIs	TB	PVD	IVDU	Rapid assay result	4G resul	Marital status	HRG
157	2	2	2	3	1	1	2	2	4	2	1	1	1	1	1	12	1	1	1	NEGATIVE	NEGATIVE	2	1
158	3	1	2	3	3	1	1	2	2	5	1	1	2	2	1	12	1	1	1	NEGATIVE	POSITIVE	1	6
159	4	1	1	3	1	1	1	2	3	5	1	1	2	2	1	12	2	1	1	NEGATIVE	NEGATIVE	1	6
160	4	1	2	1	2	1	1	2	4	5	1	1	2	2	1	12	1	4	1	NEGATIVE	NEGATIVE	1	6
161	4	1	1	3	1	1	6	2	3	5	1	1	1	2	1	12	1	1	1	NEGATIVE	NEGATIVE	1	6
162	2	1	2	1	1	4	6	2	3	5	1	1	1	1	1	12	1	4	1	POSITIVE	POSITIVE	2	6
163	4	1	1	1	2	3	1	2	2	4	1	1	2	1	1	16	1	1	1	NEGATIVE	NEGATIVE	1	6
164	2	1	1	1	2	2	1	2	4	3	1	1	2	2	3	16	1	1	1	POSITIVE	POSITIVE	2	4
165	2	2	1	3	1	2	3	2	2	2	2	1	1	1	1	12	2	1	1	NEGATIVE	NEGATIVE	1	7
166	1	3	1	1	2	1	1	2	4	2	1	1	2	2	2	15	1	4	1	NEGATIVE	NEGATIVE	2	5
167	4	1	2	3	2	3	6	2	4	3	1	1	2	2	1	10	2	1	1	NEGATIVE	NEGATIVE	1	6
168	2	1	2	1	1	5	6	2	2	2	1	1	1	1	1	12	1	1	1	NEGATIVE	NEGATIVE	2	6
169	3	2	1	1	1	1	3	2	2	2	2	1	1	1	1	16	1	1	1	NEGATIVE	POSITIVE	1	7
170	4	2	1	1	2	1	3	2	2	5	1	1	1	1	1	1	1	1	1	NEGATIVE	NEGATIVE	1	7
171	2	2	2	3	1	1	2	2	4	3	1	1	1	1	1	1	1	1	1	NEGATIVE	NEGATIVE	2	1
172	4	1	1	4	3	1	6	2	2	5	1	1	1	1	1	16	1	1	1	NEGATIVE	NEGATIVE	1	8
173	3	1	2	3	1	2	1	2	2	5	1	1	1	1	1	16	2	1	1	NEGATIVE	NEGATIVE	1	6
174	2	1	1	3	1	2	6	2	2	2	1	1	2	2	1	12	1	1	1	NEGATIVE	POSITIVE	1	6
175	4	1	2	3	1	1	6	2	3	5	1	1	2	2	1	12	2	1	1	POSITIVE	POSITIVE	1	6
176	2	1	1	1	1	3	1	2	4	2	1	1	1	1	3	12	1	1	1	NEGATIVE	NEGATIVE	1	4
177	4	1	1	3	3	1	1	2	2	4	2	1	1	2	1	2	1	1	1	NEGATIVE	NEGATIVE	2	6
178	2	1	2	3	2	1	1	2	2	2	1	1	1	1	1	12	1	1	1	NEGATIVE	NEGATIVE	1	6
179	4	1	1	4	4	2	1	2	3	2	1	1	1	2	1	12	1	1	1	NEGATIVE	NEGATIVE	1	8
180	4	1	1	3	3	3	6	2	3	2	1	1	2	1	1	12	1	1	1	NEGATIVE	NEGATIVE	1	6
181	4	1	2	3	3	1	1	2	2	3	1	1	2	2	1	12	2	1	1	NEGATIVE	NEGATIVE	1	6
182	2	1	1	3	2	5	5	2	4	3	1	1	2	2	1	12	1	1	1	NEGATIVE	POSITIVE	2	6

Serial no:	Age	Sex	Place	Approach to STD OP	Complaints	Education	Occupation	Contacts	No. of sexual partners	Time since last contact	Surgery	Transfusion	Smoking	Alcohol	Sexual orientaton	other STIs	TB	PVD	IVDU	Rapid assay result	4G resul	Marital status	HRG
183	2	1	1	1	2	3	1	2	4	3	1	1	1	2	1	12	1	1	1	NEGATIVE	POSITIVE	2	6
184	1	1	1	3	1	1	1	2	4	3	1	1	2	2	3	12	1	1	1	NEGATIVE	NEGATIVE	2	4
185	4	1	2	1	1	3	1	2	4	3	1	1	2	2	1	12	1	1	1	NEGATIVE	POSITIVE	2	6
186	2	1	2	3	2	5	8	1	1	1	1	1	1	2	1	7	1	1	1	NEGATIVE	NEGATIVE	2	6
187	3	1	1	1	2	2	1	2	2	2	1	1	1	1	1	13	1	1	1	NEGATIVE	NEGATIVE	1	6
188	2	1	1	1	1	5	6	2	3	2	1	1	1	1	3	12	1	1	1	NEGATIVE	POSITIVE	2	4
189	1	1	1	3	1	3	8	2	2	3	1	1	1	1	1	12	1	1	1	NEGATIVE	NEGATIVE	2	6
190	3	1	1	3	1	1	1	2	2	5	1	1	1	2	1	12	2	1	1	NEGATIVE	NEGATIVE	1	6
191	2	1	2	3	1	2	1	2	3	5	1	1	1	1	1	16	1	1	1	NEGATIVE	NEGATIVE	1	6
192	4	1	1	3	1	1	1	2	3	2	1	1	2	1	1	12	1	1	1	NEGATIVE	NEGATIVE	1	6
193	2	1	2	3	3	3	1	2	3	3	2	1	2	2	1	12	1	1	1	NEGATIVE	NEGATIVE	1	6
194	3	1	1	1	2	4	6	2	3	3	2	1	2	2	1	4	1	1	1	NEGATIVE	POSITIVE	1	6
195	1	1	2	3	1	4	1	1	1	1	1	1	1	1	1	11	1	1	1	NEGATIVE	NEGATIVE	2	6
196	2	1	2	1	2	2	1	2	4	4	1	1	1	2	1	8	1	1	1	NEGATIVE	NEGATIVE	2	6
197	2	1	1	1	2	5	8	2	2	2	1	1	2	2	1	16	1	1	1	NEGATIVE	POSITIVE	2	6
198	3	2	1	1	2	1	1	2	3	3	1	1	1	1	1	16	1	1	1	NEGATIVE	POSITIVE	1	7
199	2	1	2	3	2	2	1	2	2	3	1	1	1	2	1	2	1	1	1	NEGATIVE	NEGATIVE	2	6
200	2	1	2	3	2	5	5	1	1	1	1	1	2	2	1	10	1	1	1	NEGATIVE	POSITIVE	2	6

MASTER CHART KEY WORDS

GENDER

1	MALE
2	FEMALE
3	TRANSGENDER

PLACE

1	URBAN
2	RURAL

APPROACH TO STD OP

1	SELF
2	NGO
3	REFERRAL
4	CONTACT TRACING

HIGH RISK GROUP CATEGORISATION

1	CSW
2	SEXUAL ABUSE
3	HOMOSEXUALS
4	BISEXUALS
5	TRANSGENDER
6	EXPOSURE TO CSW
7	SPOUSE EXPOSED TO CSW
8	CONTACT TRACING

AGE

1	<20
2	21 -30
3	31-40
4	>40

EDUCATIONAL STATUS

1	ILLITERATE
2	MIDDLE SCHOOL
3	HIGH SCHOOL
4	HIGHER SECONDARY
5	GRADUATE

OCCUPATION

1	COOLEY
2	CSW
3	HOUSEWIFE
4	NIL
5	OTHERS
6	PRIVATE
7	PROFESSIONAL
8	STUDENT

SEXUAL ORIENTATION

1	HETEROSEXUAL
2	HOMOSEXUAL
3	BISEXUAL

MARITAL STATUS

1	MARRIED
2	SINGLE

EXTRAMARITAL EXPOSURE

1	NIL
2	YES

NUMBER OF SEXUAL PARTNERS

1	NIL
2	ONE
3	TWO
4	MULTIPLE (>2)

TIME SINCE LAST SEXUAL EXPOSURE

1	NIL
2	<2 WEEKS
3	2WEEKS - 2MONTHS
4	2 TO 6MONTHS
5	>6MONTHS

PRESENTING COMPLAINTS

1	NIL
2	GENITAL
3	NON SPECIFIC
4	PARTNER ON ART
5	SEXUAL ABUSE

STIs ASSOCIATED

1	BACTERIAL VAGINOSIS
2	BALANOPOSTHITIS
3	EPIDIDYMO ORCHITIS
4	DERMATOPHYTOSIS
5	GENITAL HERPES
6	GENITAL MOLLUSCUM
7	GENITAL SCABIES
8	GENITAL WART
9	GONOCOCCAL URETHRITIS
10	NONGONOCOCCAL URETHRITIS
11	HEPATITIS B
12	NIL
13	NON SPECIFIC GENITAL ULCER
14	PERIANAL WART
15	PROCTITIS
16	SYPHILIS
17	VULVOVAGINAL CANDIDIASIS

PREVIOUS VENEREAL DISEASES

1	NIL
2	GENITAL HERPES
3	GENITAL SCABIES
4	GENITAL ULCER

TUBERCULOSIS

1	NIL
2	YES

INTRAVENOUS DRUG ABUSE

1	NIL
2	YES

ALCOHOL

1	NIL
2	YES

SMOKING

1	NIL
2	YES

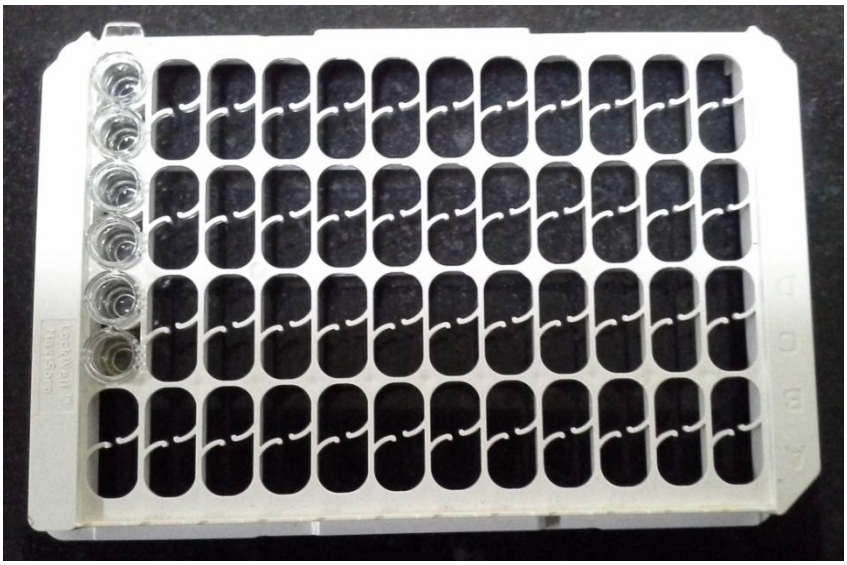
BLOOD TRANSFUSION

1	NIL
2	YES

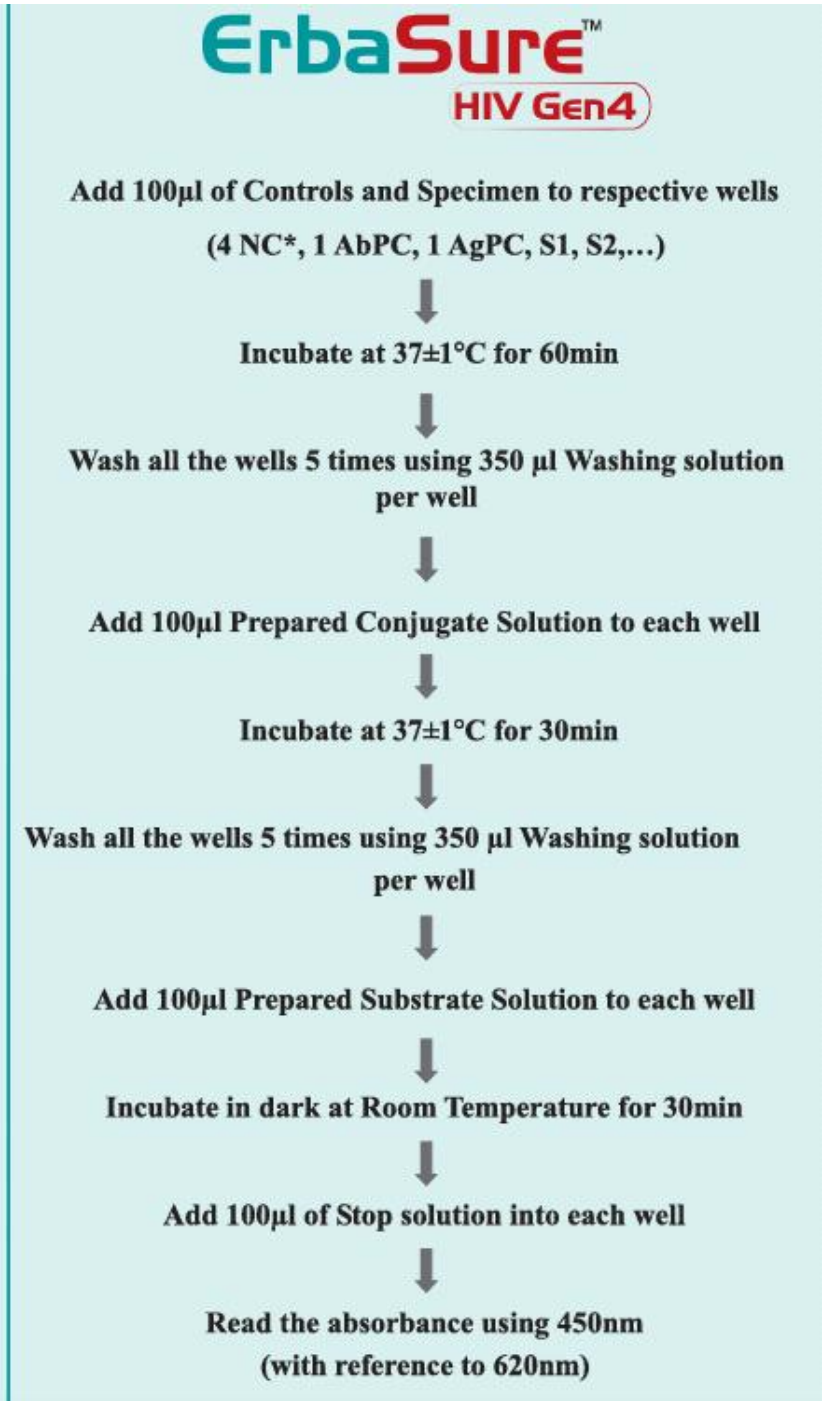
SURGERY

1	NIL
2	YES

FOURTH GENERATION ELISA KIT



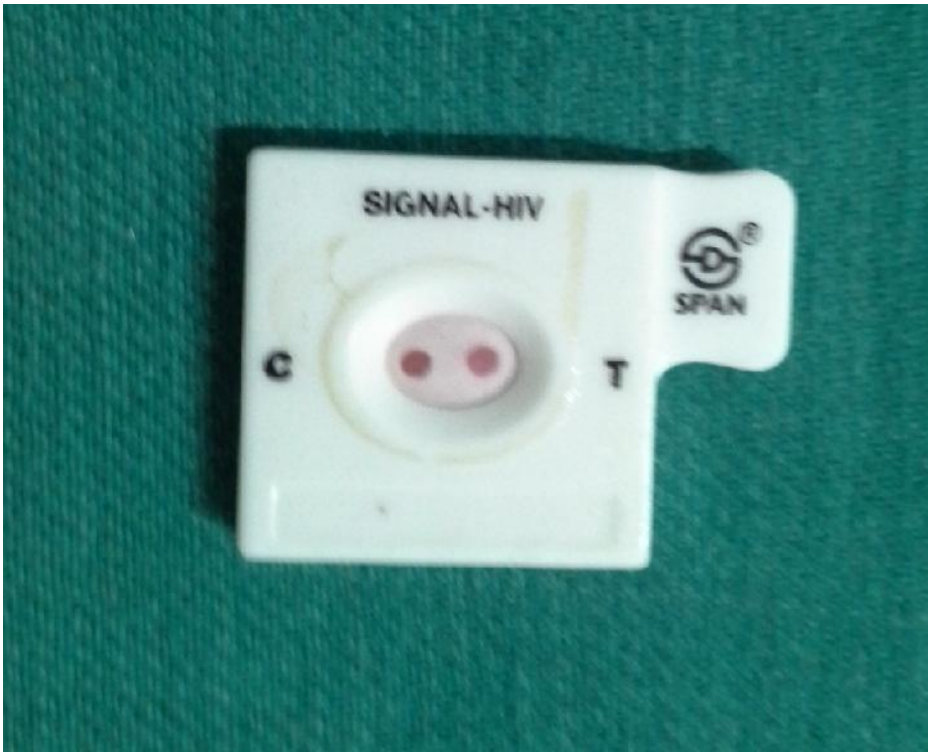
FOURTH GENERATION ELISA METHODOLOGY



RAPID ASSAY

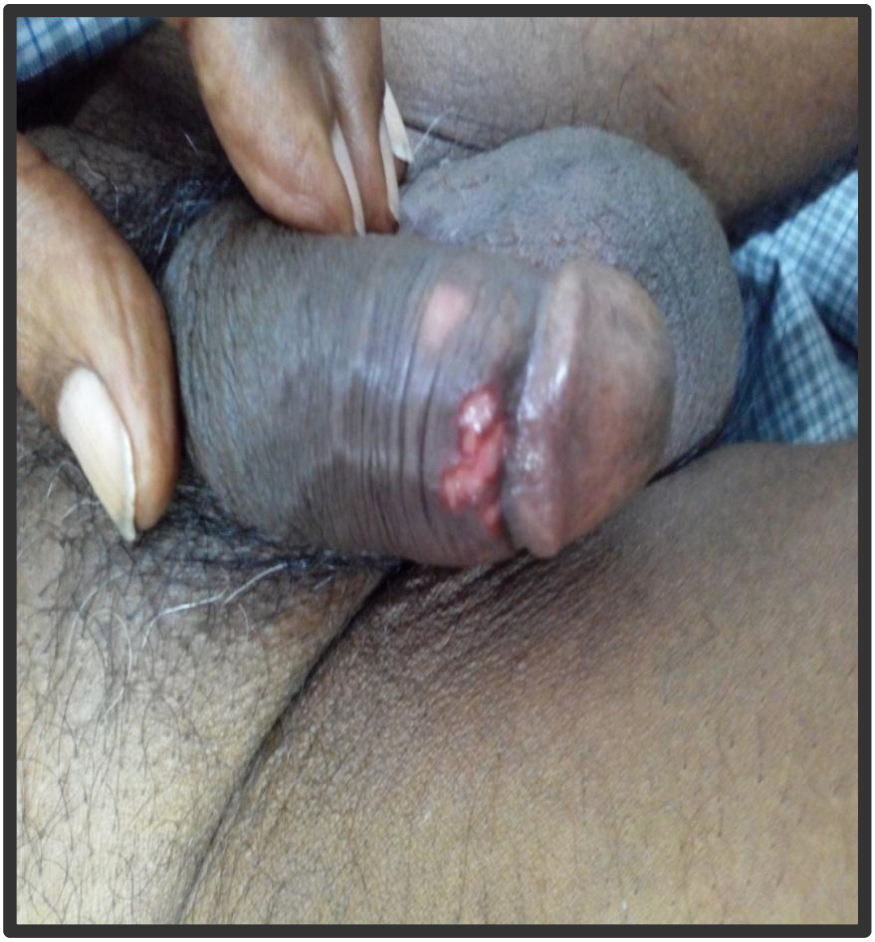

NACO
Comb Aids® RS
ADVANTAGE-ST
Recombinant Protein and Synthetic Peptides
6 ANTIGEN & CONTROL REAGENT COATED COMB
(HIV 1+2 Immunodot Test Kit)

DOT BLOT ASSAY KIT

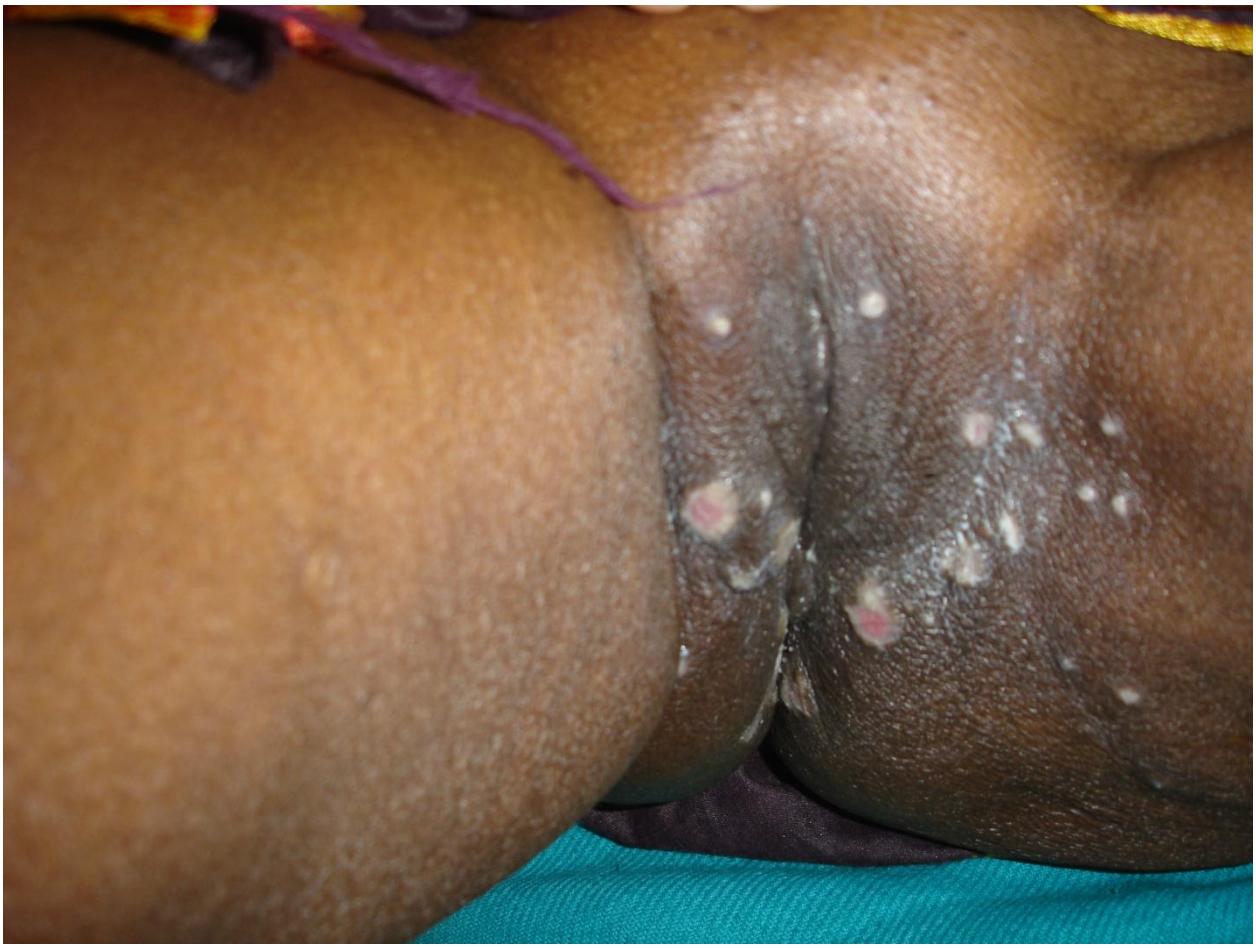


BALANOPOSTHITIS IN A HIV POSITIVE MALE PATIENT

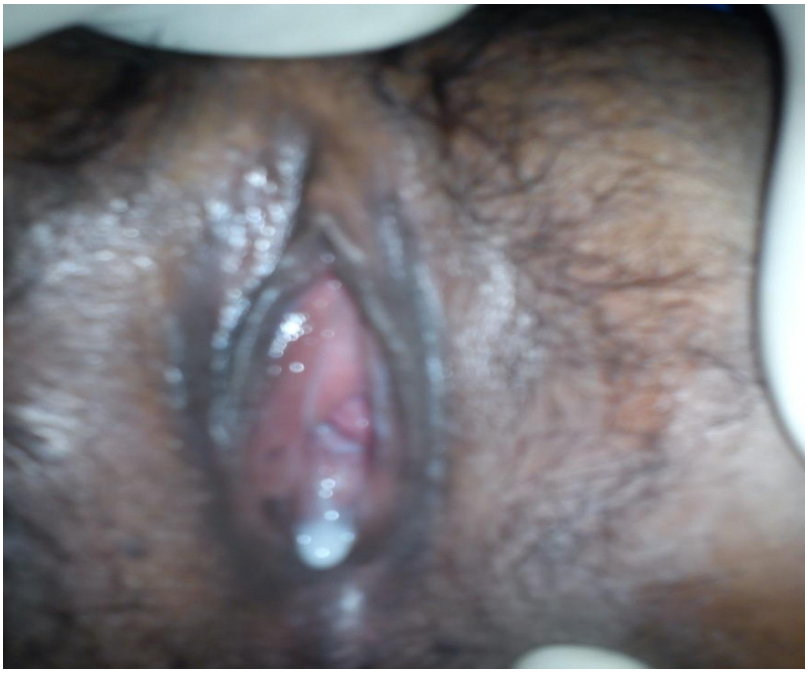
HERPETIC ULCER IN A HIV POSITIVE MALE PATIENT

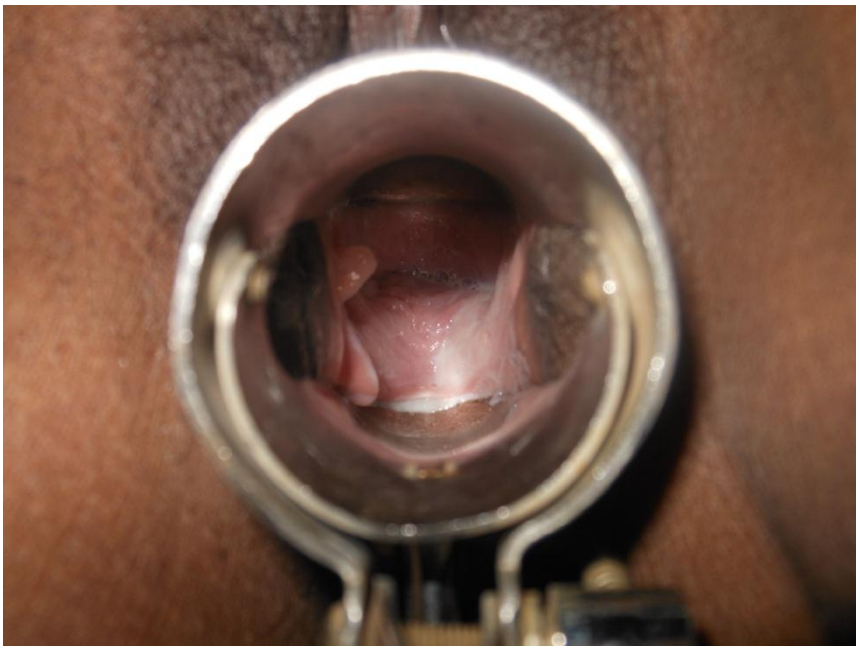


HERPETIC ULCER IN A HIV POSITIVE FEMALE PATIENT



VAGINAL DISCHARGE IN A HIV POSITIVE FEMALE PATIENT





GENITAL WART IN A HIV POSITIVE FEMALE PATIENT