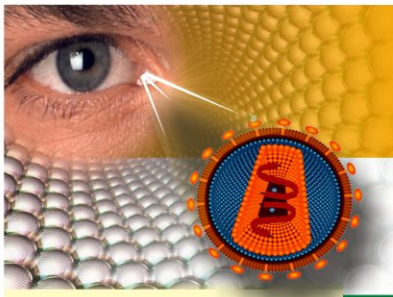
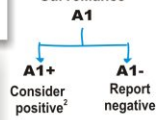


Eye on HIV Testing

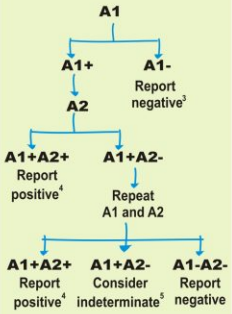
EVOLUTION & PRACTICAL ISSUES

UNAIDS / WHO HIV testing strategies*

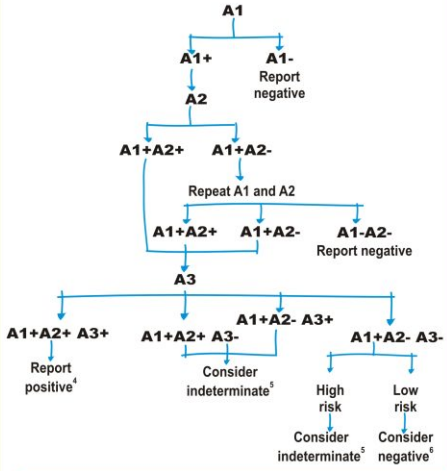
STRATEGY-I
Transfusion safety
Transplant safety
Surveillance



STRATEGY-II
Surveillance
Diagnosis



STRATEGY-III
Diagnosis



1. Assay A1, A2 and A3 represent three different assays.
2. Such a result is not adequate for diagnostic purposes: use strategy II or III. Whatever the diagnosis, donations which were earlier reactive should not be used for transfusion or transplant.
3. Report: result may be reported.
4. For newly diagnosed individuals a positive result should be confirmed on a second specimen.
5. Testing should be repeated on a second specimen taken after 14 days.
6. Result is considered negative in the absence of any risk of HIV infection.

Which Strategy to Follow Depends upon Prevalence*

Objective of testing	Prevalence of infection	Strategy applicable
Screening of blood & blood products	–	I
Surveillance	> 10	I
	< 10	II
Diagnosis		
Symptomatic	> 30	I
	< 30	II
Asymptomatic	> 10	II
	< 10	III

How to report HIV test results?*

Negative
If initial/screening test shows non-reactive result.

Positive
If the sample shows reactive results concordantly by the three screening tests.

Indeterminate (equivocal)
If the sample shows discordant results by the 3 screening tests, the follow up samples are required to retest at 2 weeks and at 3, 6 and 12 months before the final status of the test results should be conveyed. If the status remains indeterminate after 1 year, the person is considered to be HIV antibody negative.

Special Considerations
Pre-test, post-test counseling service should be provided and confidentiality should be maintained.

Causes of false-positive result

Flu, Herpes simplex , Upper respiratory tract infection, Recent viral infection, Exposure to viral vaccines, pregnancy in multiparous women, Malaria, Rheumatoid arthritis, Hepatitis B vaccination, Tetanus vaccination, Autoimmune diseases , Haemolyzed serum, Tuberculosis etc.

Generations & Detectability of HIV Assays

HIV assay	Antigen used	Detects	Can Detect by
1st Generation	Viral lysate	IgG antibody	6-12 weeks after exposure
2nd Generation	Recombinant antigens	IgG antibody	6-12 weeks after exposure
3rd Generation	Recombinant antigens / Synthetic peptides	Total HIV antibody	3-4 weeks after exposure
4th Generation	Recombinant antigens / Synthetic peptides / mono &/or polyclonal p24 antibody	Total HIV antibody & p24antigen	2-3 weeks after exposure
p24 antigen immunoassay	Mono &/or polyclonal p24 antibody	p24 antigen	2 weeks after exposure
Western Blot	Viral lysate/ recombinant	IgG antibody	Eq. to 1st/2nd generation
Nucleic Acid Technology (NAT)	-	HIV RNA	1 week after exposure

Duration of window period

Authorised body	Duration of window period
CDC, USA	2 weeks-1 year; Average: 3-6 months
The Canadian Medical Association	Within 6 months, 95% seroconvert within 3 months
WHO	6 weeks-3 months, unusual cases: 6 months or longer
NACO, India	3 weeks-3 months on an average, Can be longer sometimes

Factors influencing the duration of window period

- The host-virus interaction
- Immune status of the host
- Route of infection
- Type / subtype of infecting HIV strain
- Viral inoculum at the time of exposure

Causes of false-negative result

- **Performance and technical errors :**
  Pipetting error , mislabeling of samples, variability in test kits, powder from powdered gloves etc.
- **Biologic, pathologic, and pharmacologic determinants :**
  Window (pre-seroconversion) period, delayed antibody synthesis in infants, immunosuppressive therapy, Concurrent infection with EBV /CMV etc.
- **Congenital or drug-induced hypogammaglobulinemia :**
- **Sensitivity and specificity of the assay:**
  Sampling prior to immunoglobulin M to immunoglobulin G class switching (only if 2nd generation assay is used for testing), haemodilution, limited antigenic determinants etc.

Guidelines for HIV Diagnosis and Monitoring of Antiretroviral Therapy. WHO Project No: ICP BCT 001. WHO, July 2004.

Principles & Performance in the Claim Diagnosis
For the use of a registered medical practitioner or a Hospital or a laboratory only. Refer package insert before use.

Immunoassays for HIV Testing

QUALISA-HIV
ELISA to detect HIV 1 & 2 antibodies in human serum/plasma

RETROLISA 3.0
3rd generation ELISA to detect HIV 1 & 2 antibodies in human serum/plasma

RETROQUIC
Rapid immunoconcentration assay to detect & differentiate HIV 1 & 2 antibodies in human serum/plasma

RETROCHECK
3rd generation rapid ICT to detect HIV 1 & 2 antibodies in human serum/plasma/whole blood

RETROSCREEN
3rd generation ICT to detect & differentiate HIV 1 & 2 antibodies in human serum/plasma

PRACTICAL SOLUTIONS TO PRACTICAL ISSUES

QUALPRO DIAGNOSTICS

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