

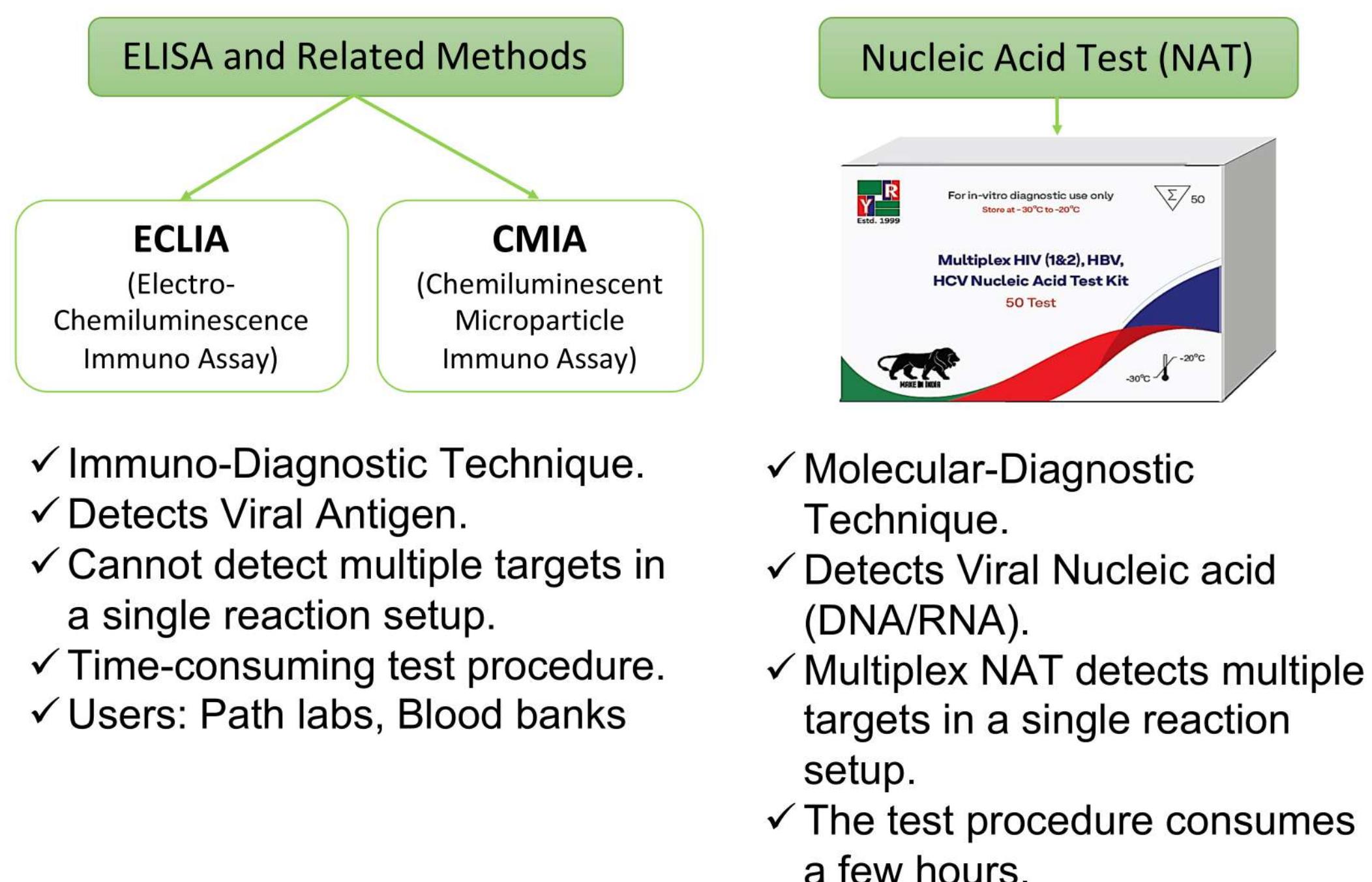
# Strengthening Blood Safety with the YBL's Multiplex HIV (1&2), HBV, HCV RT-PCR Kit: A Make in India Innovation

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## ABSTRACT

HIV-1, HIV-2, HBV and HCV are blood-borne pathogens that are highly contagious and transmitted through contaminated blood or bodily fluids. Early and accurate detection of these viruses is crucial for effective treatment and prevention of transmission through blood transfusion. According to the WHO report of June 02, 2023, it is mandatory that all blood donations be screened for HIV1/2, HBV, and HCV prior to use. The report highlights that 99.8% of the donations in high-income countries and 99.9% in upper-middle-income countries are screened following basic quality procedures. In contrast, only 83% of donations in lower-middle-income countries and 76% in low-income countries undergo such screening. Consequently, the rate of unsafe blood being transfused is as low as 0.001% to as high as 6% in high-income and low-income countries respectively. The WHO has expressed concern over the limitation of current detection systems and has emphasized the need of highly sensitive and selective early detection technologies. Real-time PCR (RT-PCR)-based Nucleic Acid Testing (NAT) has been recommended as a reliable method for early and accurate diagnosis. The HHH Kit developed by Yashraj Biotechnology Ltd. is an in-vitro RT-PCR assay designed for the simultaneous qualitative detection of HIV-1/2, HBV, and HCV from patient body fluid samples. It includes specific primers and probes for each virus and uses RNaseP as an internal control to validate sample preparation. This kit is compatible with open platforms using 4/5-channel RT-PCR instruments (detecting FAM, HEX, ROX, Cy5), enables efficient, multi-target detection. The LOD of YBL HHH kit for each targets are 30, 50, 25 and 30 copies for HIV1, HIV2, HBV and HCV, respectively. Developed indigenously by Yashraj Biotechnology Ltd. under the Make in India initiative, the kit has undergone validation through a CDSCO-approved laboratory on 210 samples. YBL HHH Kit demonstrated 96.19% sensitivity and 97.14% specificity when tested on an infective sample panel.

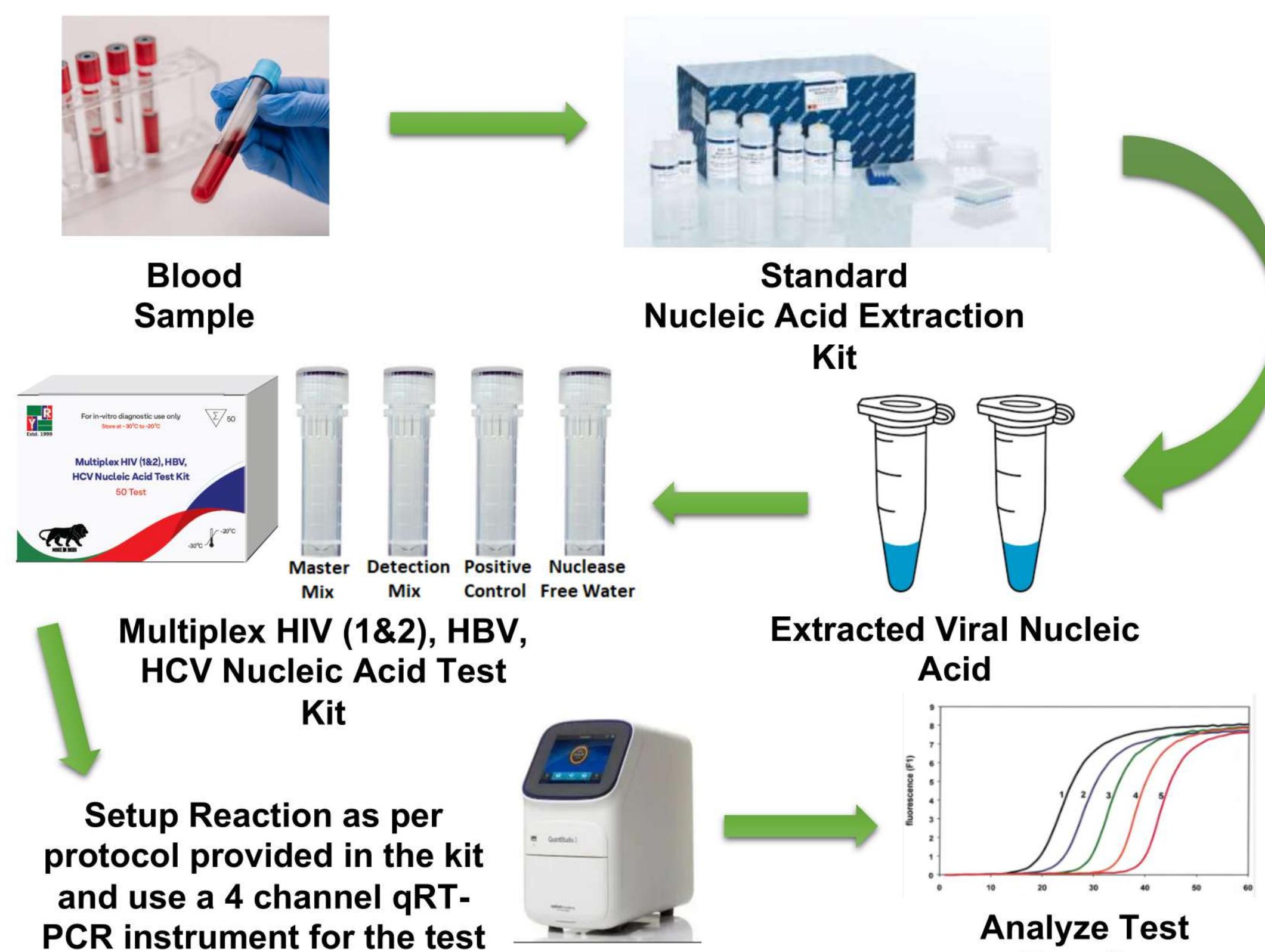
## ADVANTAGE of NAT



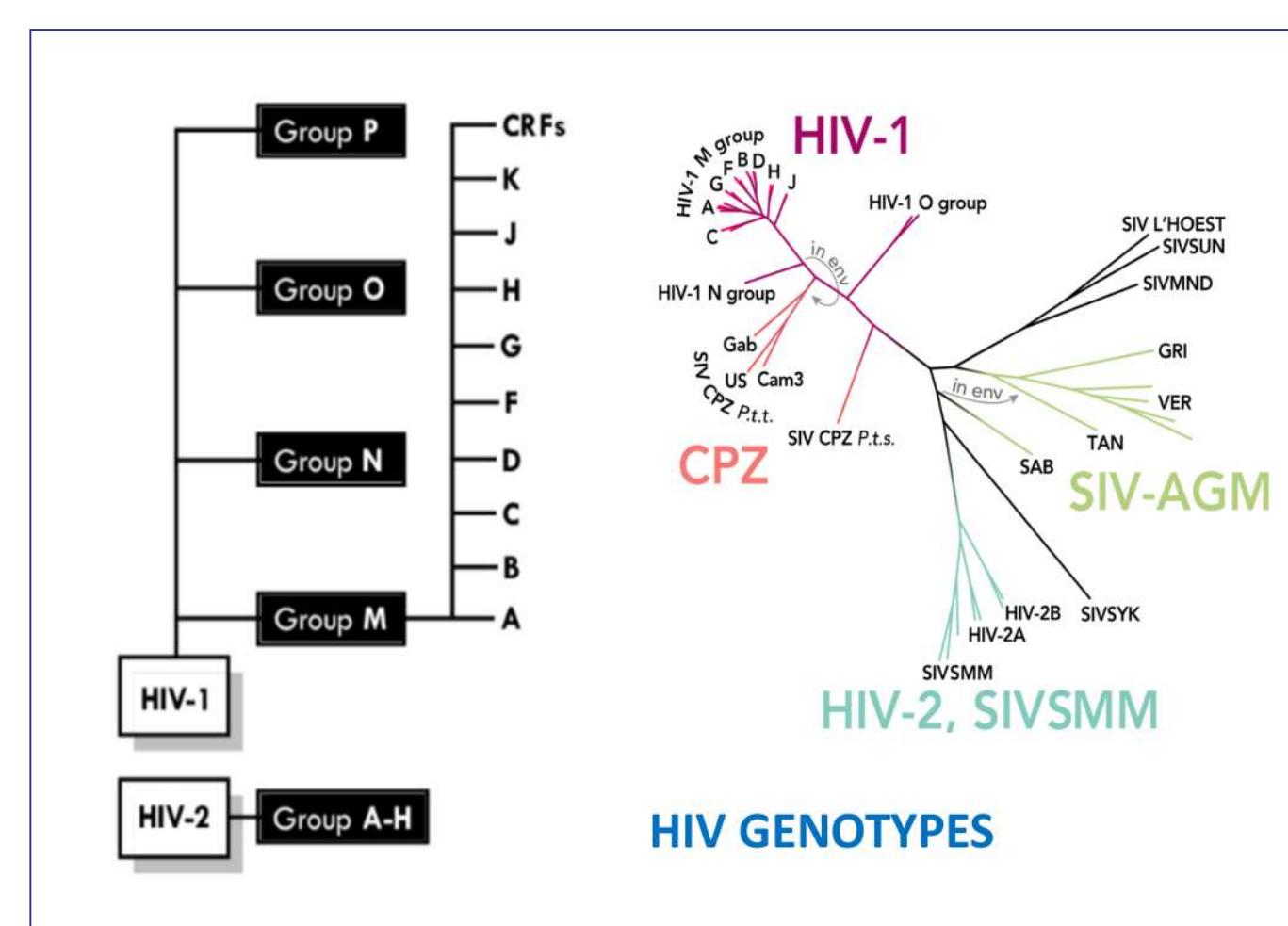
## Multiplex HIV (1&2), HBV, HCV Nucleic Acid Test Kit (A Qualitative Test):

- Only used for detecting the Absence/Presence of Target viruses.
- Faster Testing of samples for multiple infections simultaneously.
- Cost-effective preliminary test.
- Confirmatory for the live viral infective unit in the sample.
- Better sensitivity.
- Early detection of virus in patients.

## WORKING PRINCIPLE of the KIT

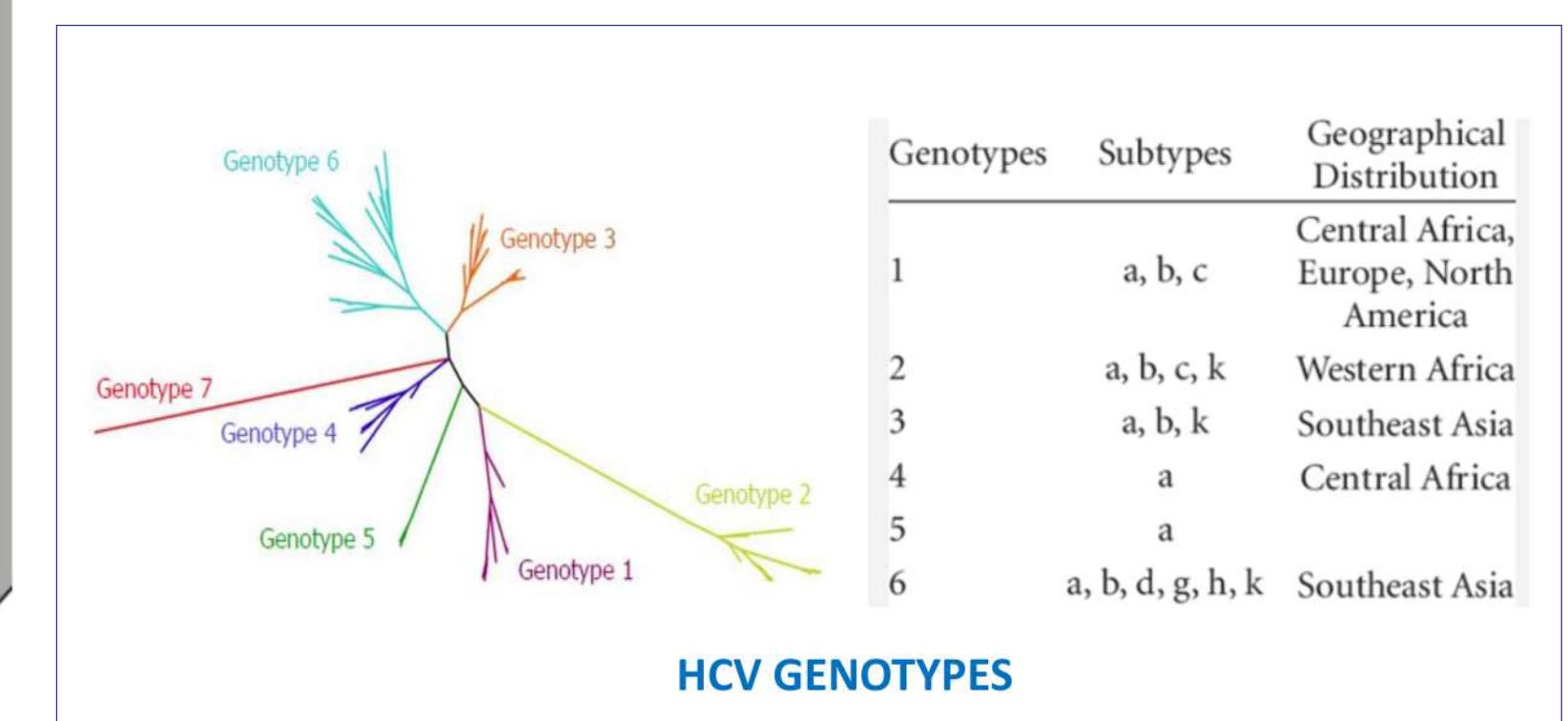
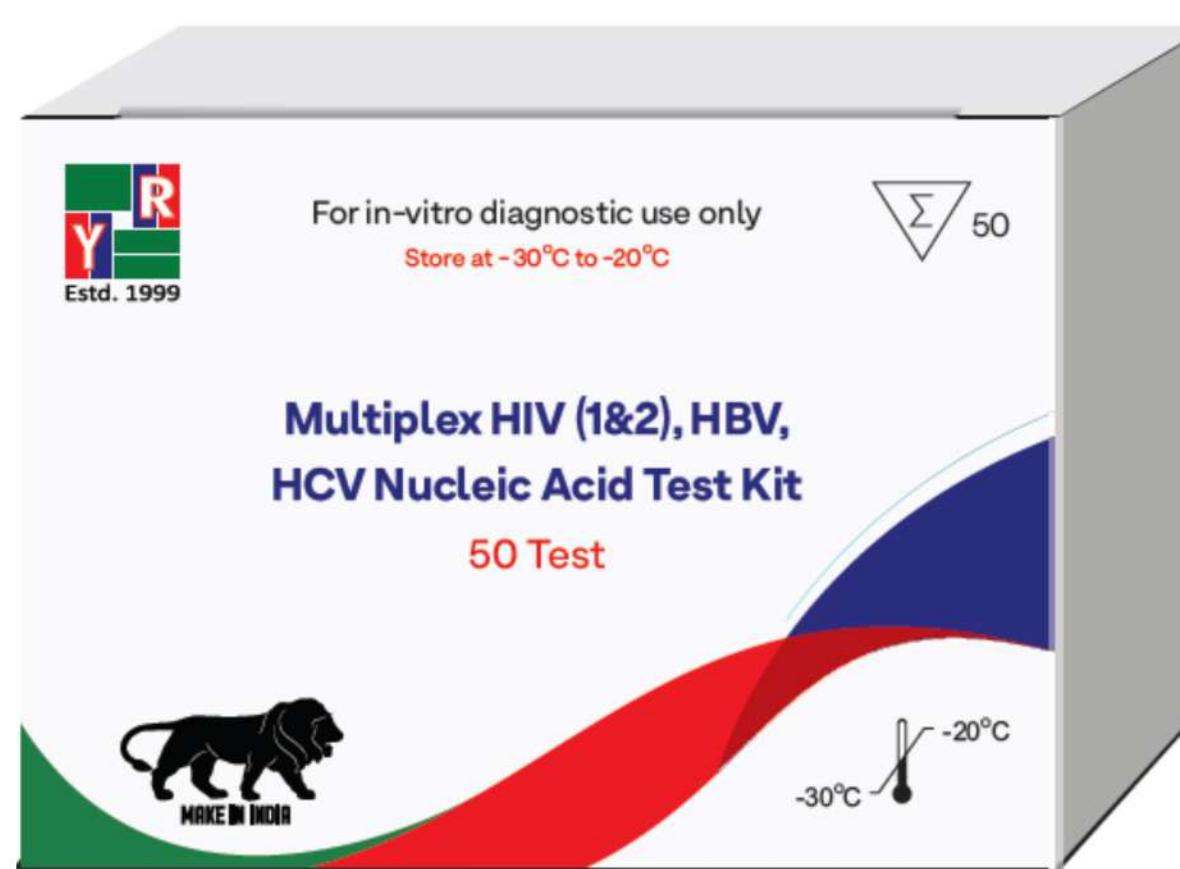


## YBL's MULTIPLEX RT-PCR Kit detects all Genotypes of HIV 1, HIV 2, HBV, and HCV

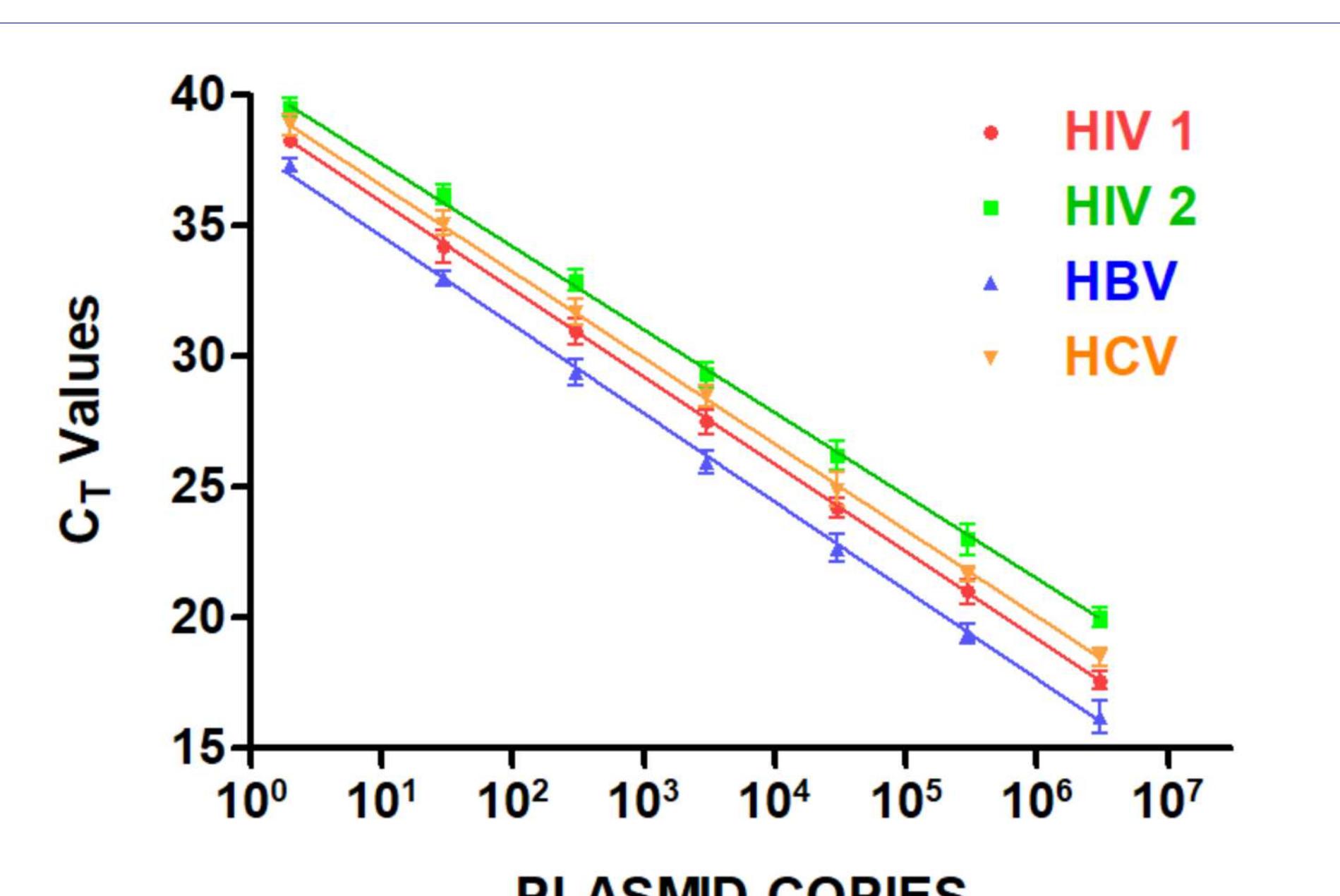


Genotype	Subtype	Geographic location
A	A1	Sub-Saharan Africa
	A2	Northern Europe
B	A3	Western Africa
	B1	Japan
B2-B5	B2-B5	Taiwan, China, Indonesia, Vietnam, Philippines
	B6	Alaska, Northern Canada, Greenland
C	C1-C3	Taiwan, China, Japan, Korea, Southeast Asia
	C4	Australia
D	C5	Philippines, Vietnam
	D1-D5	Africa, Europe, Mediterranean basin, India
E	E1	Restricted to West Africa
	F1-F4	Central and South America
G	G1	France, Germany, United States
	H1	Central America

**HIV GENOTYPES**



## KIT TESTING DATA



- KIT detected 3 plasmid copies and below for all targets. Standard Curve for all had a slope between -3.3 to -3.5 with efficiency between 95% to 105%.
- Tested Kit with NABL Accredited LAB on true clinical samples. Results were comparable to Singleplex kits available in market.

**YBL's Multiplex HIV (1&2), HBV, HCV Nucleic Acid Test Kit has been tested and approved by CDSCO. Testing was performed on clinical serum panel yielding a Sensitivity of 96.19% & Specificity of 97.14%.**

"Multiplex HIV (1&2), HBV, HCV Nucleic Acid Test Kit exhibit good performance across all evaluated parameters.

The Kit showed good clinical sensitivity and specificity, demonstrating it is reliable in detecting Human Immunodeficiency Virus (HIV-1 & HIV-2), Hepatitis B Virus (HBV), Hepatitis C Virus (HCV)."

.....CONCLUDED BY CDSCO TESTING LAB

