



Role of FDA in HIV Diagnosis

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The diagnosis of HIV infection has a major role to play in the prevention of the spread of HIV infection



Some of the roles played by different HHS agencies in HIV Diagnosis

- CDC:
 - Develops and recommends testing algorithms
 - Develops and distributes educational material
 - Tracks and maintains epidemiological data
- HRSA
 - Develops and distributes educational material
 - Provides some of the funding for testing
- CMS
 - Oversight of the testing labs
- FDA
 - Evaluates the performance and clinical utility of HIV diagnostic assays
 - Approves HIV diagnostic assays for use in the US

What is an In Vitro Diagnostic (IVD) Test?

IVD = Test Kit = Assay = Test = Device

IVD Medical Device: A device, whether used alone or in combination, intended by the manufacturer for the in vitro examination of specimens collected from the human body...

Why Do We Regulate IVDs?

- FDA regulates IVDs to ensure they are safe & effective for
 - their intended use
 - by intended user
 - in intended environment.

A test that is safe and effective will give you the correct answer, consistently and in a way that can be understood.

Why Do We Regulate IVDs?

Benefits to public health of safe and effective IVDs:

- Preventing spread of disease
- Informing and empowering people about their health
- Identifying individuals in need of health services
- Providing more timely and effective therapies

Why Do We Regulate IVDs?

Benefits to public health of safe and effective IVDs:

- Ensuring that the test kits are what they claim to be (traceability, version control)
- Ensuring that labeling language is suitable and that text is clear and unambiguous

Evaluation of HIV Tests: Performance

Performance evaluation

- Analytical studies
 - Ability to detect HIV analytes
- Performance in intended use setting
 - Performance in intended population
 - Performance by the operator (e.g., lab, untrained users)
- Evaluation of the instructions for use (appropriate for the intended users)
 - Clear instructions for use

Evaluation of HIV Tests: Manufacturing

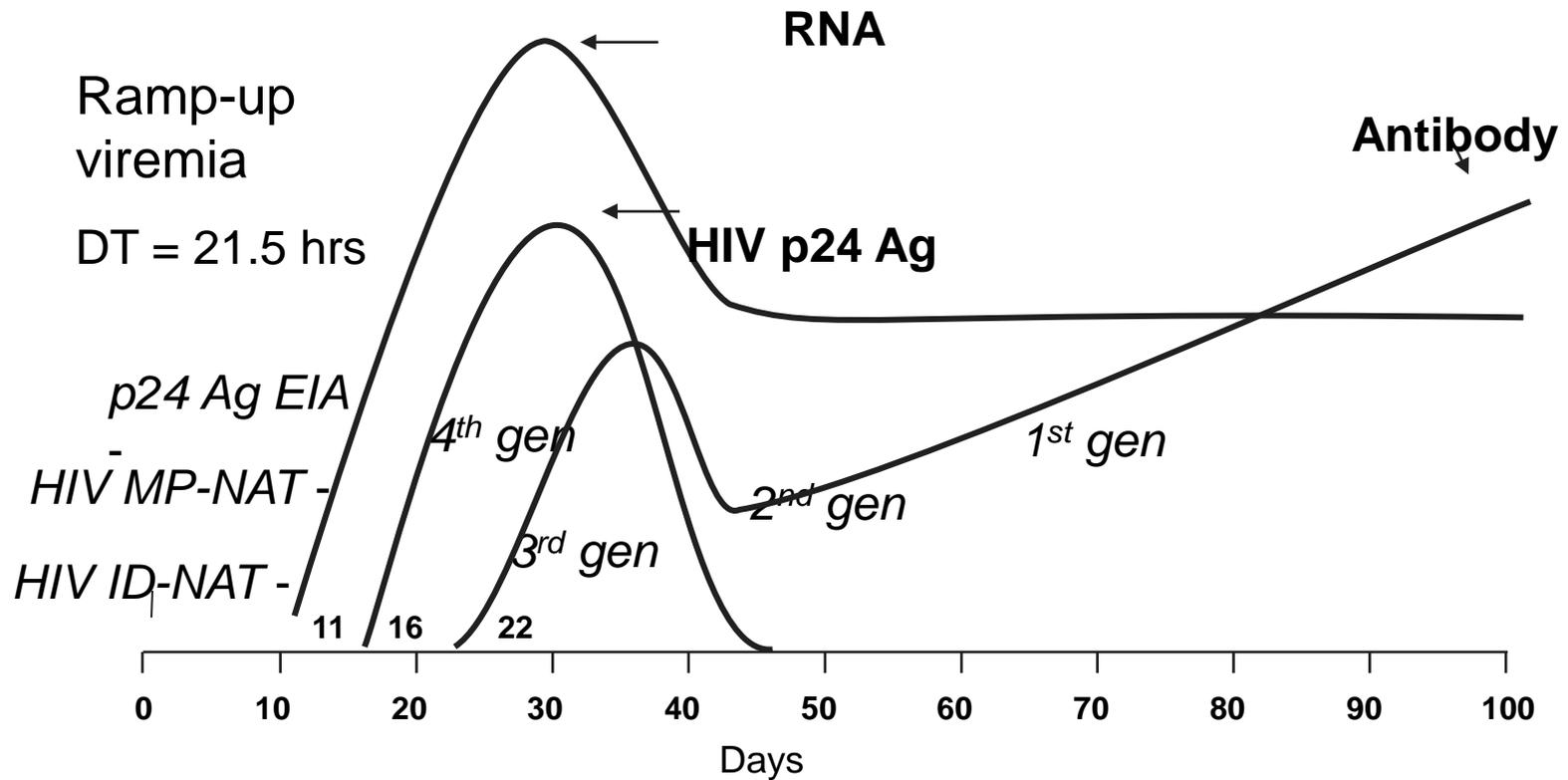
Manufacturing

- Review the Quality Management System
- Ensure ability to manufacture consistent product
- Evaluate complaint handling
- Implement Corrective and Preventive Action Plan (CAPA) as needed

Basis of HIV Testing

- Detection of antibodies to HIV
 - Primary detection
 - Confirmatory test
- Direct detection of HIV
 - Detection of HIV RNA (NAT)
 - Detection of HIV antigen (p24)

Appearance of the Markers During Course of HIV Infection



From: M. Busch

Types of HIV Tests

- Blood donor screening tests
- Aid in diagnosis tests
- Monitoring tests

HIV and Blood donor screening

- HIV can be transmitted through transfusion of blood and blood components
- To ensure the safety of the Nation's blood supply, every unit is tested for the evidence of HIV infection.

HIV Donor Screening Tests

Types of tests to screen donations of blood and blood components used for transfusion and further manufacturing

- Screening
 - HIV-1/HIV-2 Antibody test
 - HIV-1 NAT (Nucleic Acid Test)
- Confirmatory
 - HIV-1 Western blot (WB)
 - HIV-1 Immunofluorescence assay (IFA)
 - *HIV-1 NAT with limited supplemental claim*

Safety of Blood and Blood Components

- Individuals with risk for HIV infection are deferred from donating blood
- A unit that is positive on any HIV screening test is removed from the inventory and the donor is deferred
- A donor confirmed to be infected with HIV is deferred permanently from donating the blood or blood components

Residual Risk of HIV Transmission through Blood transfusion

The current estimated residual risk of transfusion transmitted HIV infection is approximately 1 in 1.47 million transfusions

Types of HIV Diagnostic Tests

- Preliminary diagnostic tests
 - Lab based tests
 - Point of care tests
 - In-home tests/collection device
- Confirmatory Tests
- Disease Progression/Monitoring
 - Viral load assays
 - Drug resistance assays

HIV Diagnostics: Lab Based Tests

Requires trained person to perform the test

- Provides repeatedly reactive results
- Requires confirmation
 - Antibody to HIV-1 and HIV-2
 - HIV Ag/Ab Combo Test

Confirmatory Tests

- Confirms the presence of antibodies to HIV
 - HIV-1 Western blot
 - HIV-1/HIV-2 Confirmatory/Differentiation Test

HIV Diagnostics: Point of Care Tests

Can be performed by users with little training

- Simple to perform and interpret results
- Provides preliminary positive results
- Requires confirmation
- Live counseling provided

HIV Diagnostic: In Home Collection Device

Can be performed by users with no training

- Users are provided with blood collection kit
- User collects specimens and sends to a testing lab
- Lab performs the test and provides the confirmed results
- Counseling provided via phone

HIV Diagnostic: Home Use HIV Tests

Can be performed by users with no training

- Test kit obtained over the counter
 - User collects the specimen
 - Performs the test and interpret the results
 - Requires confirmation
 - Counseling by phone is available (optional)

HIV Monitoring Test

HIV-1 Viral Load Assay

- Provides the viral load in infected individual
- Used for clinical management of the patient
- Monitor the effectiveness of the therapy
- Not for primary diagnosis of HIV infection

HIV Drug Resistance Test

Drug Resistance assay

- Used when the therapy fails
- Determines the resistance to various antiretroviral drugs

Summary

- HIV diagnosis is important to contain the spread of HIV infection
- HIV diagnosis is important for timely medical treatment
- Several DHHS agencies have roles in the diagnosis of HIV
- FDA regulates and approves the HIV tests for use in the US
- FDA evaluates the performance of the assay based on the intended use and population
- FDA approves different types of HIV tests

FDA Resources for HIV Diagnostic Tests

Donor Screening Assays for Infectious Agents and HIV Diagnostic Assays

<http://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/LicensedProductsBLAs/BloodDonorScreening/InfectiousDisease/ucm080466.htm>

Consumer updates

<http://www.fda.gov/forconsumers/consumerupdates/ucm310545.htm>



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