

# Recent FDA-approved HIV qualitative nucleic acid tests in HIV diagnostic testing

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# Recently Approved Diagnostic HIV Qualitative Nucleic Acid Tests

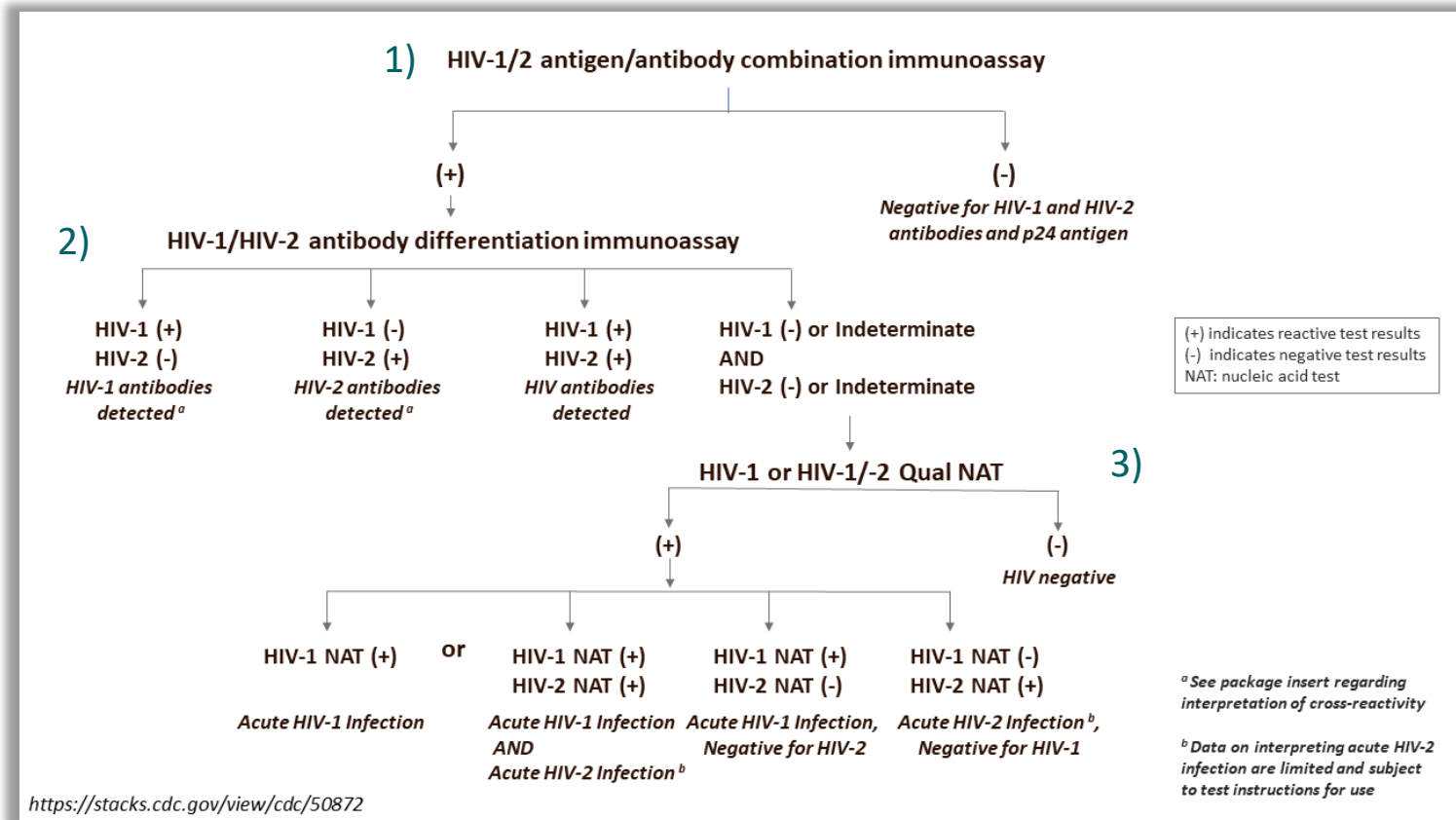
- **Two automated HIV nucleic acid tests (NATs) were approved in 2020 by the U.S. Food and Drug Administration (FDA) for diagnostic use:**
  - cobas® HIV-1/HIV-2 Qualitative test (Roche Molecular Systems Inc., Branchburg NJ)
  - Aptima® HIV-1 Quant Dx Assay (Hologic Inc., San Diego, CA)
- **Proposed uses of *these* diagnostic HIV qualitative NATs in the recommended HIV diagnostic algorithm for persons not on PrEP and considerations for their use in alternative algorithms**

# Potential use in the Recommended HIV Diagnostic Algorithm

Clinical Settings

# Recommended HIV Diagnostic Algorithm

Remains 1) Combo IA (+) → 2) Ab Diff IA (-/IND) → 3) Qual RNA

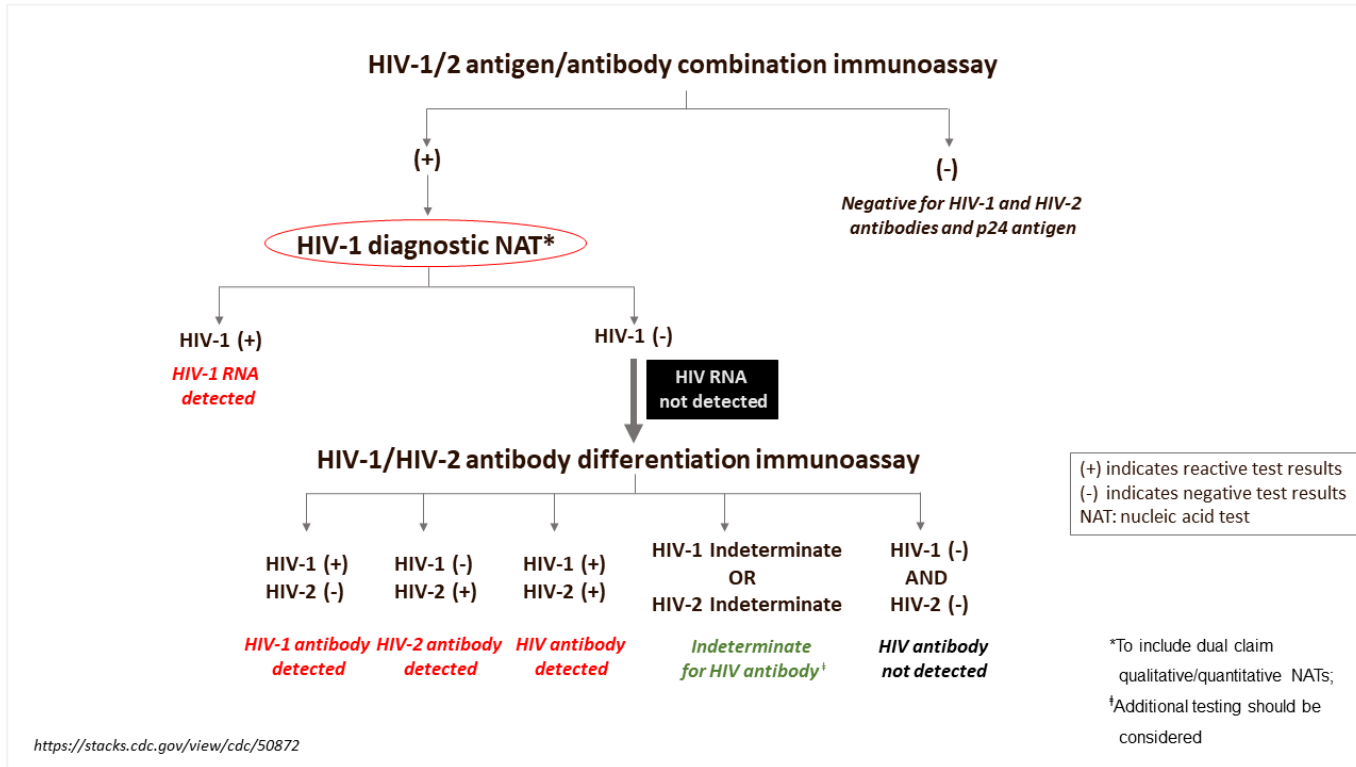


# Potential use of Diagnostic NATs as the second-step test

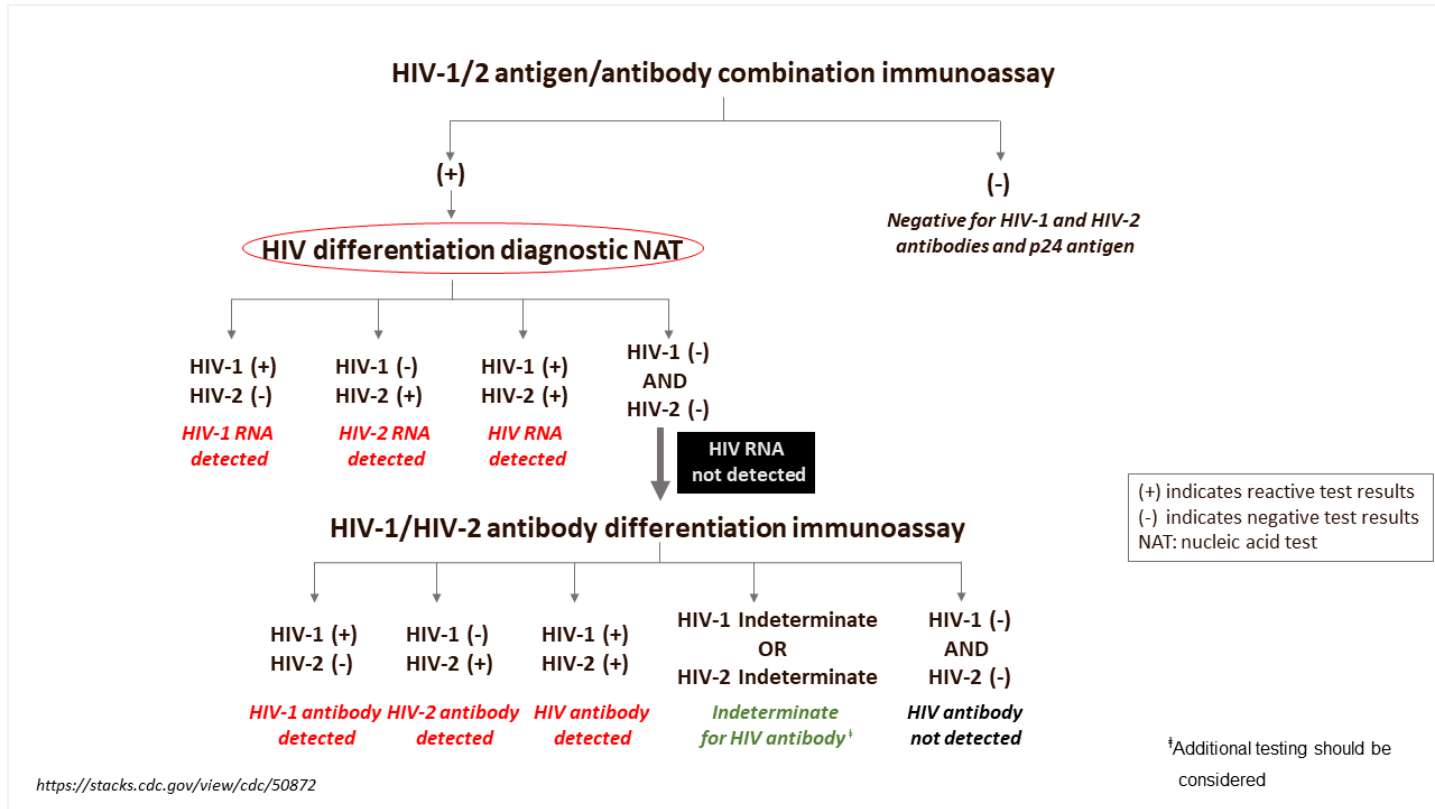
Alternative Algorithms

# Alternative use of an HIV-1 NAT at the Second Step of an HIV Diagnostic Algorithm

- Includes dual claim Qual/Quant NATs



# Alternative use of an HIV Differentiation NAT at the Second Step of an HIV Diagnostic Algorithm



# Recently Approved Diagnostic HIV Qualitative Nucleic Acid Tests - Considerations

- Individual patient management vs PHL resources
- NAT costs and turn-around-time for small/medium vs large capacity labs; local HIV prevalence
- Impact of recommended PrEP monitoring on NAT volume for labs
- Appropriate follow-up testing for discordant serology / NAT results
- Inability to determine if infection is acute using 2nd-step NAT



*More discussion to come!*

For more information, contact CDC  
1-800-CDC-INFO (232-4636)  
TTY: 1-888-232-6348 [www.cdc.gov](http://www.cdc.gov)

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

