FDA-Approved RNA Tests for HIV Diagnosis

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Dr. Branson has no financial relationships to disclose.

He will moderate a roundtable on Wednesday sponsored by Hologic discussing HCV, HIV, and *N. gonorrhoeae* resistance testing.

RNA as Second Test in HIV Algorithm?

- 2 exploratory studies with stored specimens:
  - Excellent performance in absence of ART
  - Reduced overall number of 3rd tests
  - Subsequent antibody test required
- Model: possible clinical and cost benefits from viral load as 2nd test
  - Reduced turnaround time to initiation of ART
  - Often, additional specimen is not submitted for algorithm-indicated NAT test
- Cost, specimen type, collection, storage and transport: challenges for clinical studies and implementation

- Masciotra et al Sex Transm Diseases 2020
- Pitasi et al Sex Transm Diseases 2020

RNA Tests for HIV Diagnosis

- APTIMA HIV-1 RNA Qualitative Assay: FDA approved 2006
  - Intended use: Aid in diagnosis of acute HIV-1 infection or supplemental test for confirmation after repeatedly reactive EIA
  - Initially approved for plasma; subsequent indication added for serum
  - Limit of Detection: 30 copies/mL

- Whole blood, plasma or serum may be stored at ≤ 25°C for up to 72 hours (not to exceed 30°C acceptable for up to 24 hours), and additional 5 days at 2°C to 8°C following centrifugation.
  - Longer term storage of plasma at <-20°C after separation from cells; long-term storage of serum has not been evaluated

**Final lot expires 7/15/2022*

RNA Tests for HIV Diagnosis

- cobas HIV-1/HIV-2 Qualitative test: FDA approved August 2020
  - Intended use: qualitative detection and differentiation of HIV-1 and HIV-2 RNA in serum or plasma as aid in diagnosis of acute HIV-1 or HIV-2 infection or supplemental test for confirmation of repeatedly reactive Ag/Ab test
  - Limit of detection (plasma): 12.8 copies/mL HIV-1, 35.4 copies/mL HIV-2
  - Limit of detection (serum): 12.8 copies/mL HIV-1, 26.3 copies/mL HIV-2

- Whole blood in PPT tubes, SST tubes or EDTA tubes may be stored and/or transported for up to 24 hours at 2°C to 25°C prior to centrifugation.
- After separation, plasma or serum samples may be stored in secondary tubes for up to 24 hours at 30°C followed by up to 5 days at 2°C to 8°C or up to 6 weeks at ≤ -20°C.

RNA Tests for HIV Diagnosis and Monitoring

- Aptima HIV-1 Quant Dx Assay: FDA approved November 2020
  - Intended use: Detection and quantitation of HIV-1 as an **aid in diagnosis** of acute HIV-1 infection or as a supplemental test for confirmation of HIV-1 infection after a reactive screening assay. **Aid in monitoring** the effects of antiretroviral treatment, as measured by changes in plasma HIV-1 RNA levels.
  - Limit of detection: 12 copies/mL (plasma), 8.9 copies/mL (serum)
  - Lower limit of quantitation: 30 copies/mL

- Qualitative results have been evaluated with both plasma and serum. Quantitative results of the Aptima HIV-1 Quant Dx assay have been evaluated with plasma. Serum may not be used to obtain quantitative results.

Specimens for Aptima HIV-1 Quant Dx Assay

- For quantitative measurements: whole blood collected in tubes with EDTA or ACD anticoagulants or in PPTs.
- For qualitative determination: whole blood collected in tubes with EDTA or ACD anticoagulants, PPTs, serum tubes, or SSTs.
- Whole blood can be stored at 2°C to 30°C and must be centrifuged within 24 hours of specimen collection.
  - After 24 hours, **plasma** may be stored in the primary collection tube at 2°C to 8°C for up to 3 days, in a secondary tube at 2°C to 8°C for up to 5 days, or in a secondary tube at -20°C or -70°C for up to 90 days.
  - After 24 hours, **serum** may be stored in the serum tube or secondary tube at 2°C to 8°C for up to 5 days, or in the secondary tube at -20°C for up to 90 days.

Challenges for Laboratories

- Comparing quantitative results from plasma and serum
- Validating specimen stability with more stringent specimen handling, storage, and transport requirements
- Submission of plasma specimens for HIV testing and transport alternatives for specimens collected off-site