

# The ultrasensitive p24 antigen assay is comparable to DNA PCR for early infant diagnosis, Ho Chi Minh City, Vietnam

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## Background

- Early diagnostic testing of HIV-exposed infants facilitates referral to care and can provide major psychosocial benefits to families living with HIV
- Standard molecular testing, such as DNA and RNA PCR, requires high-level laboratory infrastructure
- The ultrasensitive p24 antigen (Up24) assay is an ELISA-based test that has been shown to provide reliable results
  - Requires mid-level technical capacity and less equipment to perform
  - HIV-exposed infants in Ho Chi Minh City (HCMC) were enrolled in a study to compare the Up24 to DNA PCR

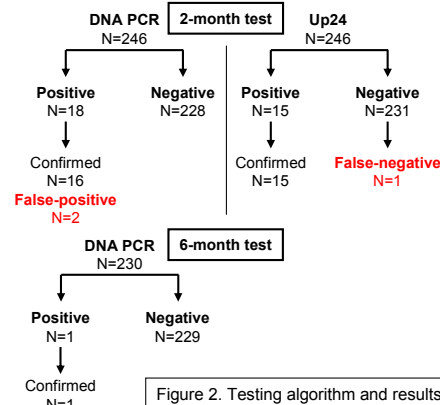
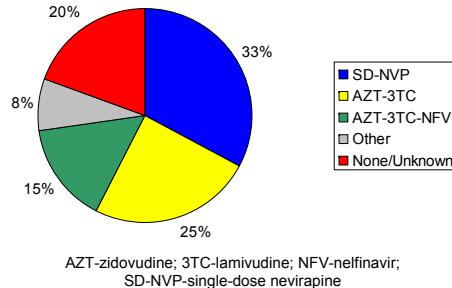
## Methods

- Patients
  - Inclusion criteria: infants  $\geq 36$  weeks gestation and  $\leq 2$  months of age without AIDS-defining illnesses
  - Formula for breast milk replacement offered
    - Provided through 6-12 months
- Testing protocol
  - DNA PCR and Up24 testing beginning at 2 months
  - Confirmation of positive tests by DNA PCR
  - Diagnostic criteria:  $\geq 2$  correlating DNA PCR results
- Laboratory
  - DNA PCR: in-house, three-gene amplification test
  - Up24: standard quantitative protocol (HIV-1 Ultra Ag Assay, PerkinElmer Life Sciences)

## Results

- 246 infants with  $\geq 2$  DNA PCR and  $\geq 1$  Up24 results included in the analysis
  - Enrolled from February 2005 – May 2006
- Perinatal PMTCT antiretroviral (ARV) exposure
  - To both mother and infant: 80.5% (N=198)
    - Maternal regimen: median 14 (range 1-273) days
    - Infant regimen: median 1 (range 1-7) days
  - No ARVs or unknown: 7.72% (N=19)
- Ever breastfed: 8.13% (N=20)
  - Duration: median 5.5 (range 1-70) days

Figure 1. Maternal PMTCT ARV regimens, N=246



- HIV transmission rates
  - At 2 months of age: 6.50% (N=16)
  - By 6 months of age: 6.91% (N=17)
  - Mother + infant perinatal ARVs: 5.56% (N=11)
  - None/unknown perinatal ARVs: 2.6% (N=5)
  - Ever breastfed: 3.5% (N=7)

- Test performance at 2 months
  - DNA PCR: 2 false-positive results
    - Sensitivity 100%, specificity 99%
  - Up24: 1 false-negative result
    - Sensitivity 94%, specificity 100%
    - Median p24 level in positive samples: 62,349 (range 14,556-544,511) fg/ml

## Conclusions

- The Up24 test was comparable to DNA PCR in diagnosing HIV-exposed infants at 2 months of age
  - Low rate of breastfeeding and short post-natal ARV exposure may be factors in results
  - Available 6-month Up24 tests were consistent with 2-month results (N=189)
- Reduced technical requirements make the Up24 an attractive assay for use in resource-limited settings

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