

Performance of Rapid HIV testing using Determine® HIV-1/2 for Diagnosis of HIV infection during Pregnancy in Tijuana, Baja California, Mexico

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Background

- The rapid HIV test Determine® HIV-1/2 has good sensitivity and specificity, however most studies were done in predominately white men.
- There is a paucity of information on the performance of the rapid HIV test Determine HIV-1/2 in pregnant women

Objective

- To evaluate the sensitivity, specificity, positive and negative predictive value of Determine HIV-1/2, using HIV EIA and Western blot as confirmatory tests.
- To determine the timing of antiretroviral intervention at delivery based on the rapid test results

Methods

- Pregnant women with unknown HIV status seeking prenatal care or admitted in labor at Tijuana General Hospital
- Counseling and rapid HIV testing with Determine® HIV-1
- All samples positive and negative were confirmed with EIA and Western blot

Methods

- Sensitivity, specificity, positive and negative predictive values were evaluated
 - Sensitivity: $a/a+c \times 100 = \%$
 - Specificity: $d/b+d \times 100 = \%$
 - PPV: $a/a+b \times 100 = \%$
 - NPV: $d/c+d \times 100 = \%$
- Time from blood collection to diagnosis and antiretroviral administration was recorded

Determine® HIV-1/2 Performance

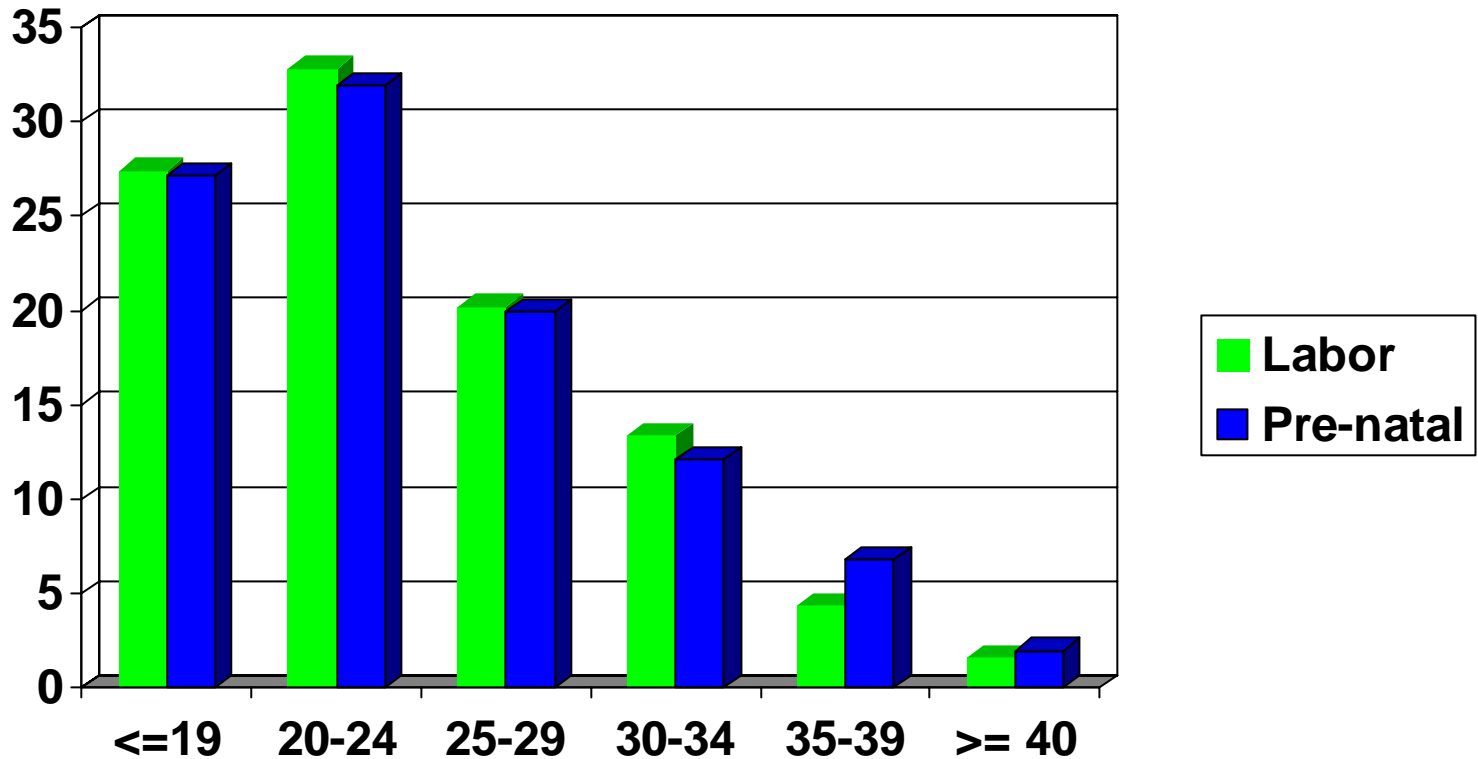
| | EIA + | EIA - |
|-------------|-------|-------|
| Determine + | a | b |
| Determine - | c | d |

Results

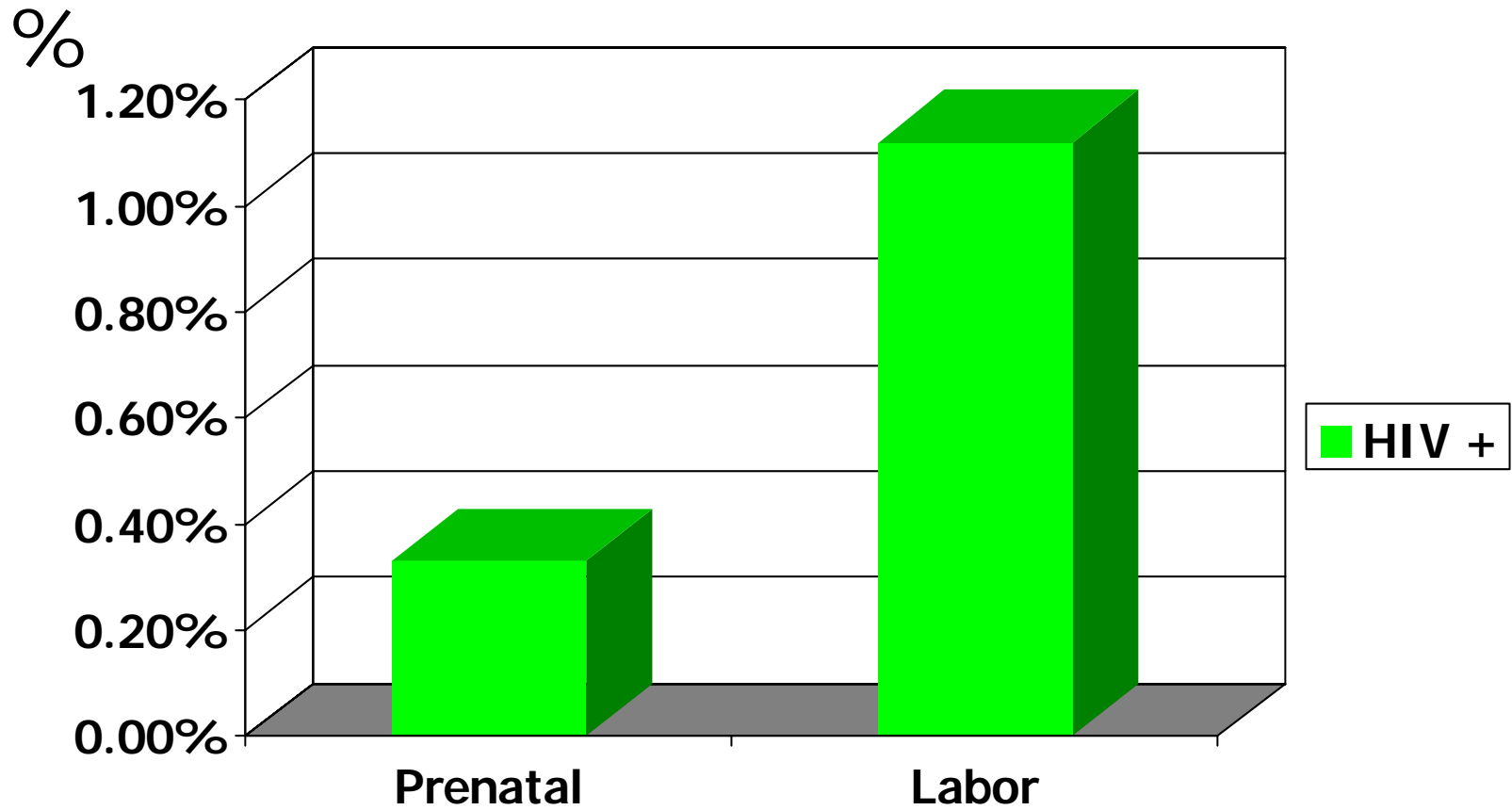
- Between March and November 2003, 1,529 women who sought pre-natal care and 1,068 women in labor received counseling and testing
- HIV seroprevalence was higher among women screened during labor (12/1068; 1.12%) compared to women seeking prenatal care (5/1529; 0.33%)

Results: Age Distribution of Pregnant Women

%



HIV-1 Infection Rate



Labor Group

| | EIA + | EIA - |
|-------------|-------|-------|
| Determine + | 12 | 3 |
| Determine - | 0 | 1053 |

Labor Group

- Sensitivity: $12/12 \times 100 = 100\%$
- Specificity: $1053/1056 \times 100 = 99.71\%$
- Positive Predictive Value (PPV):
 - PPV: $12/15 \times 100 = 80\%$
- Negative Predictive Value (NPV):
 - NPV: $1053/1053 \times 100 = 100\%$

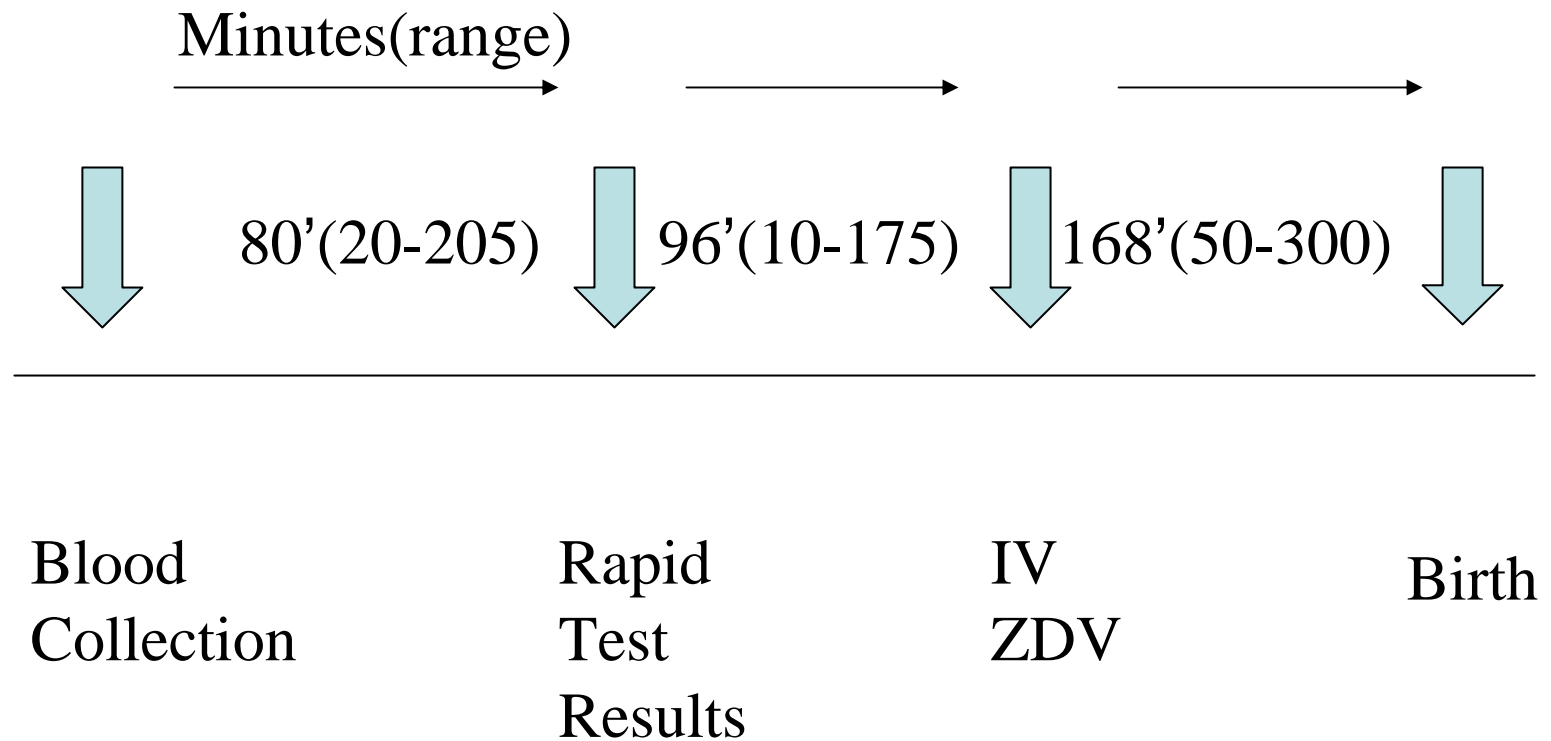
Prenatal Care Group

| | EIA + | EIA - |
|-------------|-------|-------|
| Determine + | 5 | 2 |
| Determine - | 0 | 1522 |

Prenatal Care Group

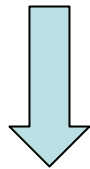
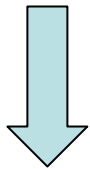
- Sensitivity: $5/5 \times 100 = 100\%$
- Specificity: $1522/1524 \times 100 = 99.8\%$
- Positive Predictive Value (PPV):
 - PPV: $5/7 \times 100 = 71.4\%$
- Negative Predictive Value (NPV):
 - NPV: $1522/1522 \times 100 = 100\%$

Time to Diagnosis and to Intervention: Labor Group

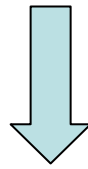
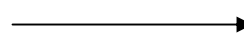


Time to Diagnosis and to Intervention: Labor Group

33 hours (range:6-120)



7 h(2-16)



Blood
Collection

Birth

Neonate
Oral
ZDV

Maternal
EIA
Results

Results

- Delivery:
 - Vaginal: 78.4%
 - C-section: 21.6%
- 17 women had a + Determine® HIV-1
- All confirmed + by EIA/Western blot

Results: Neonatal Outcome

- Labor Group: 11 alive, 1 stillbirth
- Mean Birth Weight: 2.82 Kg (1.9-3.4 Kg)
 - 2 HIV + infants; HIV DNA + at 1 & 12 days.
 - Mother-to-Child Transmission Rate: 18%
- Among the transmitter mothers:
 - None had PNC
 - None received IV AZT
 - 1 vaginal delivery, 1 C-section; both in labor
 - Both mothers used drugs

Results: Neonatal Outcome

- Prenatal Care Group: 5 alive
 - Mean Birth Weight: 3.01 Kg (2.54-3.90 Kg)
 - No HIV infected infants.
 - Maternal Transmission Rate: 0%
 - All had PNC and received AZT, 3TC & NFV
 - All women received IV AZT
 - All newborns received oral AZT
 - All born by C-section

Conclusion

- The rapid test Determine HIV-1/2 has a high sensitivity and specificity when used during prenatal care and in labor
- Rapid HIV testing during pregnancy diminishes the time to diagnosis and enables prompt intervention with zidovudine in labor and delivery

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