

## 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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### Product Evaluated

Determine HIV-1/2 (Inverness Medical)

Within this study, a cross-sectional study of women with unknown HIV status seeking prenatal care or who were admitted to the labour and delivery unit with an estimated gestational age >28 weeks was conducted at Tijuana General Hospital, Baja California, Mexico, between March and November 2003.

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

### Abstract

*The aim of this study was to evaluate the performance of the rapid antibody test Determine HIV-1/2, in pregnant women in Tijuana General Hospital. Pregnant women seeking prenatal care or admitted in labour had blood drawn for a rapid HIV test (Determine HIV-1/2), enzyme immunoassay (EIA) and Western blot. Between March and November 2003, 1068 women in labour and 1529 women in prenatal care were enrolled. The sensitivity, specificity, positive and negative predictive values were 100%, 99.8%, 77% and 100% respectively. For women in labour, the mean time between blood collection and rapid test results was 92 minutes (range: 20-205 minutes) compared with 41 hours (range: 24-120 hours) for HIV EIA (P = 0.012). All HIV-exposed infants received oral zidovudine. These findings indicate that the rapid test Determine HIV-1/2 has a high sensitivity and specificity in pregnant women. Rapid HIV testing greatly diminishes the time to diagnosis and enables a prompt intervention with antiretrovirals at delivery.*

### Results

Below is a summary of the data reported in the paper.

Sensitivity, specificity and predictive value of Determine HIV-1/2 test in pregnant women, Tijuana General Hospital, 2003.

HIV +:	Labour (n=1068)	Prenatal (n=1529)	Combined (n=2597)
Determine HIV-1/2	15	7	22
Confirmatory EIA/ Western blot	12	5	17
Sensitivity (%)	100	100	100
Specificity (%)	99.7	99.8	99.8
Positive predictive value (%)	80	71	77
Negative predictive value (%)	100	100	100

### Discussion

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