# Added-value of a Novel Dual Treponemal/Non-Treponemal Rapid Diagnostic Test for Syphilis among Pregnant Women

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## Background

- In resource-limited settings, syphilis rapid diagnostic tests (RDTs) aid in the prevention of congenital syphilis. However, most syphilis RDTs detect only treponemal antibodies which persist after treatment. Consequently, treatment may be provided unnecessarily to pregnant women with past infection, their neonate(s) and their partner.
- A new immunochromatographic rapid point-of-care test, Dual Path Platform Syphilis Screen and Confirm assay (DPP test, CHEMBIO Diagnostic System, Inc, USA) combines simultaneous detection of treponemal (T) and non-treponemal (NT) antibodies.

## Objectives

- **Main objective :** to estimate the potential reduction of over-treatment of pregnant women using DPP test compared to T-RDT (SD Bioline Syphilis Test).
- **Secondary objectives :**
  - to estimate the proportion of treatment misclassification (over-treatment or under-treatment) comparing different algorithms to the reference tests;
  - to estimate the prevalence of presumptive active syphilis;
  - to estimate inter-user agreement between medical staff and laboratory technician.

## Methods

- **Study design :** Prospective study
- **Study area** : Maternity of Deou, Oudalan, Burkina Faso
- **Inclusion criteria :**
  - Pregnant woman
  - Attending antenatal consultations in study site
  - Eligible for routine syphilis screening according to routine practices in the maternity
  - Consent to participate to the study
- **Interventions** :

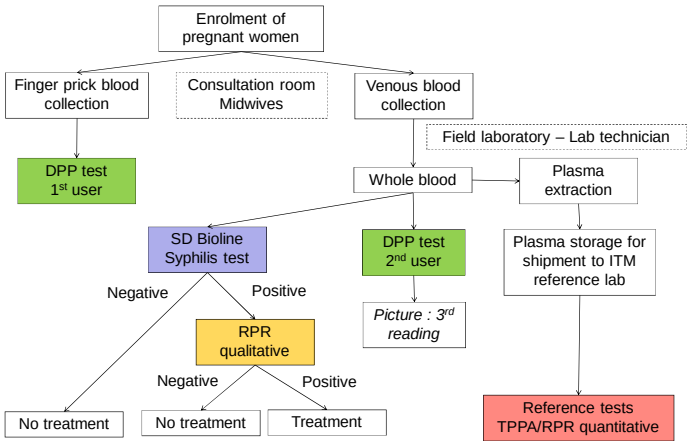


**Figure 1:** Description of study activities

- **Analysis** :

Primary endpoints : DPP results by midwives and laboratory technician; SD Bioline results by laboratory technician; reference tests results (TPPA and RPR) done at the Institute of Tropical Medicine (ITM), Antwerp, Belgium.

Presumptive active syphilis : detection of T and NT antibodies.

McNemar test for paired samples : compare proportions of falsely treated cases or falsely non treated cases between different algorithms (significance level p = 0.05).

- **Ethical considerations** : Ethics approval was granted by the National Ethical Committee of Mali, ITM-Ethical Review Board and the Comité de Protection des Personnes in France.

## Results

- 242 pregnant women were included from May to August 2014.
  - Median age = 25y
  - No history of syphilis or current clinical symptoms of syphilis
- **Prevalence** of presumptive active syphilis = **37.6%** (half with RPR titre ≥ 1:8)
- DPP **inter-user agreement** : T-line = 0.95; NT-line = 0.75.
- 4% of women who were **not to be treated** would have been using T-RDT only against 0.0% using DPP (p=0.2). But, 48.4% of women who **had to be treated** would have not been using DPP against 2.2% using T-RDT (p<0.001) (Figure 2).
- The **sensitivity** of DPP test was almost 52% but increased up to 85% for RPR titre ≥ 1:8 (Table 1).

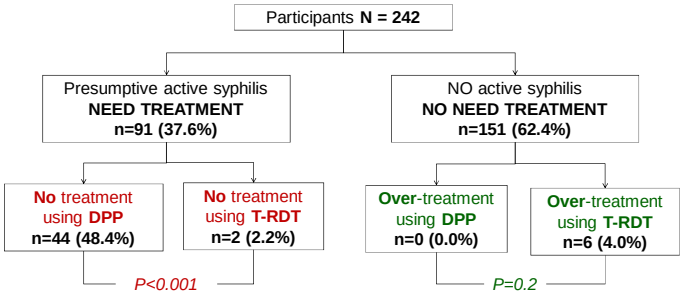


**Figure 2**. Impact on treatment according to diagnostic algorithms

**Table 1**. Performances of DPP test.

| | Sensitivity % (95%CI ) | Specificity % (95%CI) | PPV % (95%CI) | NPV % (95%CI) |
|---|---|---|---|---|
| **T-line vs TPPA** | 95.0 (88.8-98.4) | 97.9 (93.9-99.6) | 97.0 (91.4-99.4) | 96.5 (92.0-98.9) |
| **NT-line vs RPR any titre** | 46.1 (36.2-56.2) | 100.0 (97.4-100.0) | 100.0 (92.5-100.0) | 71.8 (64.9-78.0) |
| RPR ≥1:8 | 85.4 (72.2-93.9) | - | - | 95.2 (90.4-98.1) |
| **T+NT lines vs TPPA+RPR any titre** | **51.6 (40.9-62.3)** | 100.0 (97.4-100.0) | 100 (97.5-100) | 77.4 (70.9-83.1) |
| RPR ≥1:8 | **85.4 (72.2-93.9)** | - | - | 95.2 (90.4-98.1) |

Legend: PPV: positive predictive value, NPV: negative predictive value, CI: confidence interval.

## Discussion

- DPP test showed no added value in reducing the proportion of unnecessarily treated women. Conversely, DPP underestimated women needing treatment.
- We found a high prevalence of presumptive active syphilis. However, this could suggest that non-venereal treponematoses are endemic in the study area as previously shown in the 80's.
- The overall sensitivity of the DPP test lower compared to other studies performed in behavioral high risk groups or symptomatic patients.

## Conclusion

This study was the first evaluation of DPP test in pregnant women.
Additional studies are required to evaluate the potential benefits of the DPP tests for preventing congenital syphilis in resource-limited settings.

## Acknowledgements

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