1 — Abstract

Background: The identification of acute HIV infection is important for early treatment initiation and to control the risk of the spread of the disease, in particular in high risk populations. Since the window period between the infection and the identification of antigen/antibodies in HIV is still a limitation of serology-based screening tests, a high quality molecular approach is crucial.

Methods: Commercially available serocconversion panels were tested with the cobas HIV-1/2 Qual test and with the Bio-Rad Geenius® HIV-1/2 Confirmatory Assay. The assay was performed in the Nuremberg and Vienna laboratories. The percentage of positive results in the Geenius was determined on an additional 10 HIV-1 and HIV-2 subtypes and subgroups.

Results: cobas HIV-1/2 Qual detected all HIV-1/2 subtypes and subgroups. For the serocconversion panel, the assay detected HIV an average of 18.9 days earlier than the serology based test. The limit of detection for cobas HIV-1/2 Qual was verified at 12.0 copies/ml for plasma and 12.1 copies/ml for serum and 17.5 copies/ml for plasma, and 24.8 copies/ml for serum, for HIV-1.

Conclusion: The results indicate that the cobas HIV-1/2 Qual test is highly sensitive and suitable for diagnosing HIV-1 and HIV-2. The assay may detect and discriminate HIV infections over weeks earlier than serology based test, enabling earlier HIV treatment and prevention of ongoing HIV transmission.

2 — Sequential appearance of different laboratory markers

3 — CDC HIV Diagnostic Algorithm

4 — Analytical performance including Limit of Detection (LOD)

5 — Inclusivity Using 2nd WHO HIV Inclusivity International Reference Panel for NAT

6 — Evaluation of each assay’s relative effectiveness in relation to pre–seroconversion window period using serocconversion panels (ZepBioMetrix, SeraCare)

6a) cobas HIV-1/2 Qual Test Clinical Agreement (as Compared to CoA) by Serocconversion Panels and Overall. (Seroconversion Panels Calculated as Mediated by Subject)

6b) Geenius HIV-1/2 Confirmatory Assay Clinical Agreement (as Compared to CoA) by Serocconversion Panels and Overall. (Seroconversion Panels Calculated as Mediated by Subject)

7 — Assay Correlation using Clinical Specimens

— HIV-1 Clinical Specimens: EDTA plasma or serum specimens provided by the testing site from patients undergoing HIV management. These specimens may be HIV detectable (<100) or non-detectable (<40) depending on response to treatment.

— HIV-2 Clinical Specimens: Approximately 30 EDTA plasma or serum specimens previously determined to be HIV-2 positive. Provided to the testing site.

— HIV Negativity Specimens: 51 EDTA plasma or serum specimens negative for HIV, provided by the testing site.

8 — Conclusions

— cobas HIV-1/2 Qual test enables accurate and sensitive diagnosis of HIV-1 and HIV-2 across sample types.

— cobas HIV-1/2 Qual test detected and discriminated HIV infections over two weeks compared to the serology-based test, that could help prevent transmission during acute HIV infection, expand access to NAT HIV testing for adults and lead to simplification of HIV diagnostic algorithms.

— cobas HIV-1/2 Qual test could make a substantial contribution to reaching the ‘first 90’ UNAIDS goal, the testing of 90% of the infected population.