Abstract #33

Evaluation of the Trinity Uni-Gold™ Recombigen Rapid HIV-1 Assay in a Pediatric Cohort

Abstract Category:	Point of Care Algorithms Using Combinations of Rapid Tests
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BACKGROUND

The use of rapid HIV Tests is expanding because of waived status and perinatal screening recommendations. Published evaluations of FDA-approved rapid HIV-1 tests typically examine samples from adult cohorts. Studies on the feasibility of these tests in children were not done and at least one of these FDA-approved assays specifically excluded subjects under 13 years of age.

METHODS

In the current study, we examined 128 samples from children less than 13 years of age stratified into three groups.
Group 1 (N=28) included low risk children, 3-<13 years old.
Group 2 (N=26) included known, confirmed HIV infected children 0.5-13 years old.
Group 3 (N=66) included HIV exposed children 0-<3 years further stratified into sub-groups to assess the Trinity Uni-Gold performance when maternal antibody level is declining.
Serum and Plasma samples were tested on the patients using the Abbott EIA Antibody, Trinity Uni-Gold™ Recombigen Rapid HIV-1 Assay, and the Bio-Rad Western Blot Assay.
All Samples were blinded and the data was combined after all testing was completed.

RESULTS

The Trinity Uni-Gold assay showed a sensitivity and specificity of 95.5% and 100% respectively, with positive and negative predictive values of 100% and 97.6% respectively. These assay results with the pediatric cohorts were similar to those reported in larger adult studies. Two of 22 samples from HIV exposed children between 7 and 4 months of age were negative on the Uni-Gold Rapid test, but were positive by standard EIA and Western Blot testing. Of interest, 10 of 17 concordant negative EIA and Trinity Rapid HIV results were western blot indeterminate. All 22 children in this group were fully seronegative by 18 months.

CONCLUSIONS

The Trinity Uni-Gold Rapid HIV test is acceptable for use in pediatric patients. Testing HIV exposed children when maternal antibodies are declining may be problematic. Further studies of this Rapid HIV test are in the progress to determine if the assay can be used as an earlier predictor of seroreversion than western blot in HIV exposed children.