EVALUATION OF THE MEDMIRA REVEAL G4 RAPID HIV ANTIBODY TESTS WITH WHOLE BLOOD AND PLASMA SPECIMENS

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BACKGROUND

- Sensitive and accurate rapid tests performed in point of care (POC) settings can help increase access to testing and awareness of HIV status, thus would help decrease transmission of HIV
- The MedMira Reveal G4 Rapid HIV-1 Antibody Test (G4 POC) is a 2-minute rapid test
- FDA-approved for use in laboratory settings for HIV-1 IgG antibody detection with plasma and serum (LAB/SP format) and whole blood (POC format) specimens
- CE-marked for use in POC and laboratory settings for detection of both HIV-1 and HIV-2 antibodies
- IgG is present early after HIV infection, so the use of antibody-based HIV tests may miss detection of acute infections

OBJECTIVE

To evaluate the performance of the G4 POC using simulated whole blood (wb) and LAB/SP using plasma for detecting early and established HIV-1 and HIV-2 infections

HIV SAMPLES AND METHODS

183 commercial seroconversion panels (SCP) (n=183) were used to prepare simulated wb and plasma specimens. They may include samples, so based on measurement of the drop 30 µL fingerstick blood

DATA COLLECTION

- 3 SCPs (n=39) that initiated antiretroviral therapy (ART) were tested for viral load to measure viral suppression and 15 SCP (n=144) were ART-naïve

RESULTS 1- Performance of G4 LAB/SP and POC HIV tests

Reveal G4 Rapid HIV: PROTOCOL and LIMITATIONS

B- Test Results of Seroconversion Plasma Panels

- Seven panels (38.9%, 90 samples) showed discordant reactivity in POC-wb compared to LAB/SP-plasma (nine samples)
- Ten panels (55.6%, 85 samples) showed no difference in reactivity with LAB/SP-plasma and POC-wb, including 3 panels that initiated early ART

Results of other FDA-Approved diagnostic assays from 9 discordant seroconversion samples

Both tests were 100% R with samples Fiebig Stage V when HIV-1 Western blot and Geenius HIV-1/2 Supplemental assay were HIV-1 positive (-p31-)

G4 showed 54% reactivity of plasma specimens from F-IV in LAB/SP when HIV-1 Western blot is indeterminate (evidence of IgG response)

Reactivity with simulated wb with POC was inferior compared to plasma with LAB/SP

RESULTS 2- Reactivity of G4 LAB/SP and POC HIV tests in early HIV-1 infections

A- Results of Early Infection characterized by Fiebig Stages

- Reactivity with simulated wb was compared to plasma with LAB/SP

- G4 showed 54% reactivity of plasma specimens from F-IV in LAB/SP when HIV-1 Western blot is indeterminate (evidence of IgG response)

- Both tests were 100% R with samples Fiebig Stage V when HIV-1 Western blot and Geenius HIV-1/2 Supplemental assay were HIV-1 positive (-p31-)

B- Test Results of Seroconversion Plasma Panels

- Of 18 SCP (n=183):

  - Ten panels (55.6%, 85 samples) showed no difference in reactivity with LAB/SP-plasma and POC-wb, including 3 panels that initiated early ART
  - Seven panels (38.9%, 90 samples) showed discordant reactivity in POC-wb compared to LAB/SP-plasma (nine samples)
  - One never became Reactive with POC-wb for up to 14 days follow-up when LAB/SP-plasma became Reactive

B-2 Delayed Reactivity of LAB/SP compared to POC from first available HIV-1 NAT-positive

- The overall median numbers of days following first NAT+ result was 13 for LAB/SP plasma and 14 for POC-wb

- For the 6 SCP with delayed reactivity in wb, the median number of days to cutoff on the basis of measurement on LAB/SP plasma was 11.5 days for POC-wb

- Delayed reactivity was seen in wb, but plasma results at time points ranging from 11-17 days after follow up

- One panel became Reactive after first Reactive tests (plasma and wb) likely due to secondary negative phase of reactivity

SUMMARY

- Reveal G4 shows reliable performance in different sample sets and various stages of infection for various subsets of HIV-1 and HIV-2
- Based on the Fiebig stages of infection and the seroconversion results, the test performs well for its ability to detect IgG antibodies
- Viral suppression did not appear to influence the performance of the test
- Overall, there were nine out of 429 invalid results (2%)

- One sample was invalid/invalid for wb, one sample was invalid/NR for plasma and seven samples were invalid/invalid for plasma

CONCLUSIONS

- Reveal G4 reacts strongly against good agreement in whole blood and plasma, with overall sensitivity in early HIV-1 infections delayed by one day in wb compared to plasma

- For plasma, the G4 POC test using fingerstick wb is a sensitive and less (0.2 to 0.4) test option when screening for IgG in HIV-1/HIV-2 infections even in presence of long-term antiretroviral suppression

CONTACT INFORMATION

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18 commercial seroconversion panels (SCP) (n=183)

7 SCP (38.9%) that initiated antiretroviral therapy (ART) were tested for viral load to measure viral suppression and 15 SCP (83.3%) were ART naïve

Days after first available HIV-1 NAT-positive (NAT+) result was calculated for 15 SCP (n=129), range of 5-28 samples in each panel followed up for a median of 42 days for plasma (LAB/SP) and wb (POC) and results compared

McKinnon's paired analysis was done to compare results in plasma and wb

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