Introduction of Experienced Rapid Testers to a New Multiplex Rapid Test

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INTRODUCTION

In the US, 16% of all syphilis patients and 28% of men infected with syphilis have coinfection with HIV. It is estimated that syphilis infection increases the chance of getting a HIV infection by 2.4 fold and HIV by 2.0 fold. Detection of both HIV and syphilis can play a critical role in reducing the incidences of transmission.

A rapid multiplex test will not only reduce workflow and sample volume problems but also increases access to test especially in low-resource and rural settings.

Designing a new Point-of-Care test for test operators with limited or no hands-on training is a challenge and comparing it with existing tests provides valuable feedback.

OBJECTIVE

Errors in rapid diagnostics tests can be reduced by designing tests where chances of operational missteps and data misinterpretation are low. DPP® HIV-Syphilis Assay System (DPP® HIV-SYP) is a multiplex RT utilizing a microreader that simultaneously measures both HIV and Treponema (TP) antibodies. Our intent was to gauge user response to the microreader and to a multiplexed rapid test.

METHOD

22 experienced RT users, naïve to both products, read the QRI and completed the test to gauge user response to the QRI, assess reaction to a microreader that simultaneously measures both HIV and Treponemal antibody.

RESULTS

The DPP® HIV-SYP device is designed to be read ONLY with a microreader. The DPP® Micro Reader is supplied with the rapid test kits and will perform up to 20 tests before it automatically needs to be powered. By the rapid tests, the reader which utilizes an internal algorithm to interpret the test results as shown below.

INTERPRETING THE RESULTS

- **TP Non-Reactive Results**
  - HIV Non-Reactive Result
  - HIV Reactive Result
  - HIV & TP Reactive Results

- **TP Reactive Results**
  - HIV Non-Reactive Result
  - HIV Reactive Result
  - HIV & TP Reactive Results

- **TP Low Reactive**
  - HIV Non-Reactive Result
  - HIV Reactive Result
  - HIV & TP Reactive Results

- **TP High Reactive**
  - HIV Non-Reactive Result
  - HIV Reactive Result
  - HIV & TP Reactive Results

LIMITATIONS

1. Fixed volume pipettes were used to apply specimens
2. TP specimens were chosen to provide a challenging range of reactivity

DISCUSSION

Multiplex testing has many potential distinct advantages:
- Improve diagnostic efficiency – allowing one to test 2 or more biomarkers simultaneously
- Improve diagnostic precision – by testing confirmatory biomarkers to generate a meaningful conclusion
- Reduces the diagnostic expense of a rapid screening event
- Reduces manufacturing cost
- Improves Rapid Test Operator productivity (tests/operator)

Why use a digital reader?
- Rapid tests are often used in rural settings under sub-optimal conditions including:
  - Varying light conditions: low light to intense light
  - Vision of rapid testers can range from Ted Williams sharp (20/5) to blind as a bat (20/200). Many testers in CLIA-waived settings are not tested for their visual acuity or potential color blindness
  - Not all rapid tests produce sharp, defined lines
  - Multiple lines on a rapid test cassette can be confusing

A digital reader provides an engineered solution minimizing reporting errors and designed to:
- Produce consistent lighting on every read event
- Support multiple biomarkers on the same device without confusion
- Reduce transcription errors by automating data transmission

CONCLUSIONS

- Clearly of instruction, simplicity of test design, and the role of a standardized result interpretation were key features appreciated by operators.
- Users strongly preferred the DPP® HIV-SYP to the SHC because of the ease of test interpretation and ability to simultaneously screen for two diseases.
- Given the role of RTs in CLIA-waived settings, micro readers could significantly reduce in 11 false interpretations.

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