A Multiplex Point-of-Care for Detection of HIV-1/HIV-2 and Hepatitis C Infection

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**Introduction**

There are over 3 million people chronically infected with Hepatitis C virus (HCV) and over 1 million infected with Human Immunodeficiency Virus (HIV) in the United States. 1 The expansion and improvement of HIV testing and linkage programs to high-risk groups, including those who abuse injectable drugs and men who have sex with men, are important for treatment on prevention of co-infections. 2 The ability to diagnose HIV and HCV infections simultaneously can lead to more effective treatment decisions and improved linkage to care. 3 Prevention, education, and treatment are important because HIV and HCV coinfection is associated with higher rates of morbidity due to accelerated liver disease compared to those with only HCV monoinfection. 4

Currently, the diagnosis of HIV infection requires a testing algorithm which begins with an antibody and/or antigen test, followed by a HIV RNA detection test. For HCV testing, an antibody test is required and positive, a nucleic acid test that detects HCV RNA. Generally, HCV is diagnosed by laboratory-based methods, including rapid tests. Rapid tests can advantageously provide same-day results and do not require highly-trained personnel. Many of the HIV point-of-care rapid tests do not distinguish between HIV-1 and HIV-2 infections. Positive results at point-of-care is only preliminary and require supplemental testing to confirm HIV or HCV. 5

Testing is a challenge as resources may be limited. Maxims objective is to develop and evaluate a multiplex HIV and HCV which may offer convenient, quick, cost-effective, point-of-care screening for high-risk populations at health departments and substance abuse treatment facilities.

**Methods**

- Using lateral flow dispensing equipment, Control antibody, HCV-2 Antigens, and HCV Care Antigens were dispensed onto nitrocellulose membrane. The positions are illustrated in Figure 1.
- Detection antibody was conjugated to colloidal gold and dispensed onto the conjugate pad.
- The processed nitrocellulose membrane, gold conjugate, wick and sample pad were then assembled onto a backing card, cut into strips and assembled into cassette.
- Well-characterized, commercially available human plasma/serum specimens that are HIV/HCV negative, HIV monoinfected, HCV monoinfected, and the six genotypes (Genotype 1-6) of HCV were tested.
- Specimens were processed at ambient temperature (23-29°C) on the benchtop. Serum/plasma specimens were diluted 1:200 in Running Buffer with 75% of the diluted sample was added to the sample well. The strip was assayed for 20 minutes then read visually.

**Results**

Figure 2 and 3 provides photographic results from the test. The strip was removed from cassette for photographic purposes. Table 1 and 2 lists the specimens tested and their visual results. This multiplex assay was able to correctly identify the specimens as Negative, only HIV positive, only HCV positive. Figure 4 shows initial testing results at 20 minutes with Running Buffer only, a negative specimen, HIV monoinfected specimen, HCV monoinfected specimen, and HCV/HIV coinfected specimen. In addition, this assay was able to detect the six genotypes of HCV, which are illustrated in Figure 5. Refer to Table 1 and 2 for the list of corresponding specimens tested and their serological status.

**Lessons Learned**

The HIV-1 and HIV-2 antigens have been evaluated on lateral flow in over 1800 serum/plasma specimens with the CDC Approved Maxim Swift™ HIV Recent Infection Assay (RIA). The same antigens used for Maxim Swift™ RIA were used in the HIV-1/HIV-2 Test line. The sensitivity of the HIV-1 and HIV-2 Test line is 99.5% and specificity is 99.4%.

Based on initial evaluation, multiplex lateral flow for HIV-1/HIV-2 and HCV coinfection screening appears promising, but further testing is needed to evaluate sensitivity, specificity, cross-reactivity and interference. In addition, other sample types such as dried blood spots (DBS) and Oral Fluid will be evaluated.

**References**

2. Centers for Disease Control and Prevention. “HIV Testing.” Test kit line. The sensitivity of the HIV-1 and HIV-2 Test line is 99.5% and specificity is 99.4%.

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