Performance of the Determine HIV-1/2 Combo rapid test for detection of acute/early HIV-1 infection

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Background

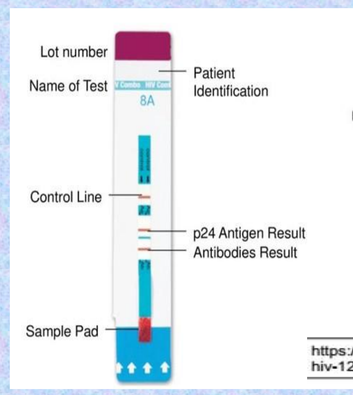
The new guideline from CDC for HIV testing recommended use of fourth generation assays as the primary screening test in the algorithm to avoid late of diagnosis and to shorten the window period. The first point-of-care HIV assay, namely, Determine HIV Combo was used in high prevalence setting. The capacity of this assay detects HIV infection more rapid than IgM/IgG laboratory-based assays. Sensitivity of HIV-1 p24 antigen (Ag) detection was lower than those of laboratory-based fourth generation assays. However, the capacity to detect acute/early HIV-1 infection in high risk subjects is needed to evaluate.

Objective

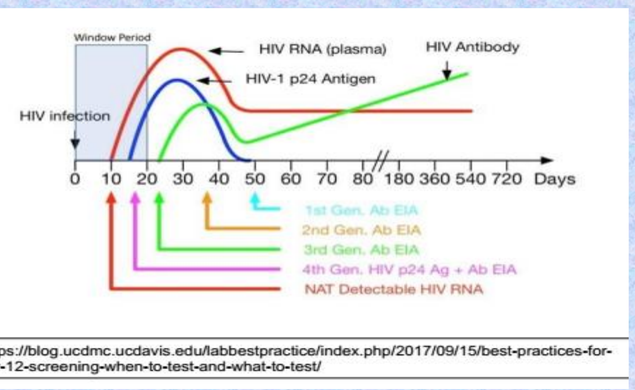
To evaluate the performance of Determine HIV Combo in plasma Seroconversion plasma specimens from acute/early HIV-1 patients

Materials/Methods

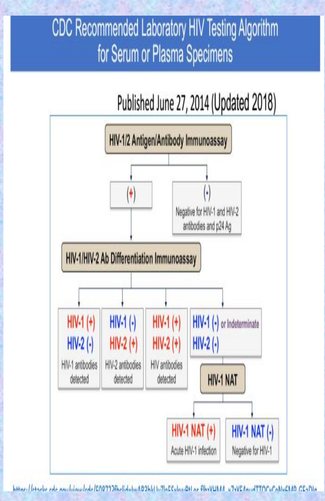
Study design: We selected the 12 seroconversion plasma specimens from 5 acute/ early patients diagnosed by Elecsys HIV Ag, 4th generation ECLIA (Elecsys HIV Combi PT) and supplemented by NAAT (viral load) from our previous study to evaluate the performance of Determine HIV Combo sensitivity. McNemar's exact test was used to compare the difference in reactivity during acute/early infection between tests. The specificity was evaluated with 96 HIV-1 negative plasma specimens.

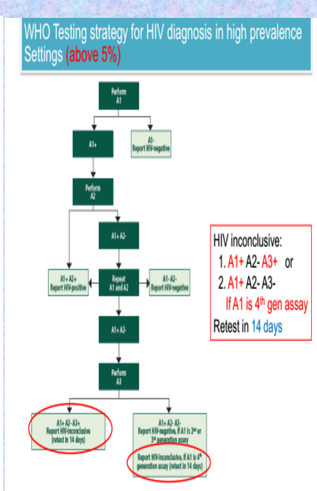


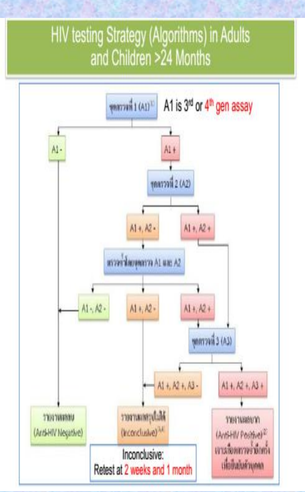
Determine Combo



Time Couse of HIV Detection following infection





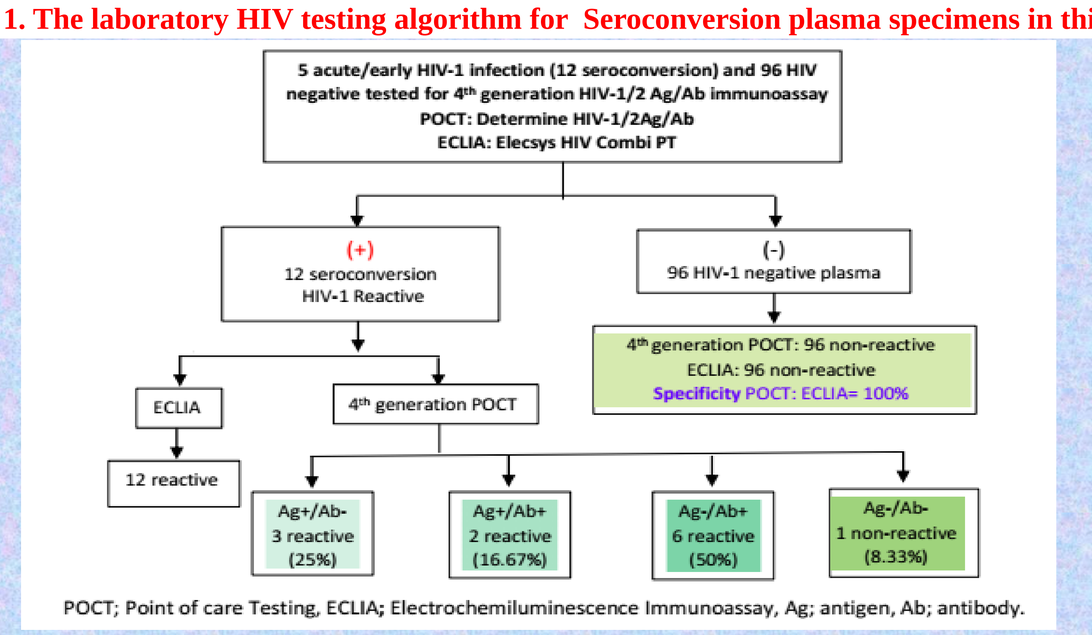


Result and Discussion

Seroconversion sensitivity of Determine HIV Combo was 91.67% (p=0.32) when compared to 4th generation ECLIA and Elecsys HIV Ag results. There were 3 discordant results with 3rd generation HIV POCT (p=0.14). The reactivity of HIV p24 Ag detection, which compared to Elecsys HIV Ag, were 41.67% (p=0.0021). Determine HIV Combo had 8.33% false negative result and 100% specificity. The first positive HIV p24 Ag and antibody results from Determine HIV Combo were found on 14 days and 21 days, respectively. Data in this study evidenced that the time to reactivity for Determine HIV Combo is 7 days earlier than 3rd generation assays (POCT) in one MSM subject (Table 1)

Our data suggest that when active HIV case finding in high risk, hard to reach populations, such as MSM and FSW, need non-laboratory based HIV testing in field, non-instrument based and rapid turnaround time. The 4th generation POCT assay seems to be appropriated for the first HIV screening test after sexual exposure more than 13 days. Therefore when less than 14 days, when reporting negative results by Determine HIV Combo, high risk population should be performed supplement tests such as HIV Ag, 4th generation laboratory-based HIV tests and/or HIV

Figure 1. The laboratory HIV testing algorithm for Seroconversion plasma specimens in this



POCT; Point of care Testing, ECLIA; Electrochemiluminescence Immunoassay, Ag; antigen, Ab; antibody.

Table 1. Days after exposure and temporal trend of HIV testing in 12 Seroconversion specimens

No.	Risk group	Days after sexual exposure	4th generation: Determine HIV Combo Ag	4th generation: Determine HIV Combo Ab	4th generation: Elecsys HIV Combi PT (S/CO) Positive>1	3rd generation POCT: Alere Determine HIV-1/2 Ab	3rd generation POCT: Double CheckGold Ultra HIV1&2	3rd generation POCT: SD Bioline HIV-1/2	Elecsys HIV Ag (S/CO) Positive≥0.9	HIV RNA (copies/ml)
1	MSM	14	+	-	+(111.3)	-	-	-	+*wp (4.9)	>10,000,000
2		19	+(pale)	-	+(338.4)	-	-	-	+(11.9)	Not done
3		21	-	+(pale)	+(443.2)	+(pale)	+(pale)	+(Pale)	+ (8.3)	Not done
4	MSM	22	+	+	+(504.4)	+	+(pale)	+(pale)	+*(8.7)	474,000
5		32	-	+	+(646.8)	+	+	+	+(11.1)	Not done
6	MSM	22	-	+	+(431.2)	+	+	+	+*(9.6)	291,000
7		27	-	+	+(332.2)	+	+	+	+wp(5.8)	Not done
8		35	-	+	+(713.8)	+	+	+	+wp(3.8)	Not done
9	MSM	25	+	+	+(88.4)	+ (pale)	+ (pale)	+(pale)	+*(7.3)	380,000
10		33	-	+	+(423.0)	+	+	+	+wp(5.4)	Not done
11	FSW	13	-	-	+(59.9)	-	-	-	+*(5.7)	117,800
12		16	+(pale)	-	+(89.8)	-	-	-	+(9.1)	7,480,000

+ (pale) = reactive with pale color of band, wp= weakly positive. +* Elecsys HIV Ag positive (specimen no.1,4,6,9 and 11) confirmed HIV Ag positive by HIV Ag neutralization test.

Conclusion

Our finding indicated the poor antigen sensitivity compare with HIV Ag and viral load performance, p24 Ag of Determine Combo can detect acute/early HIV-1 infection at more than 13 days after sexual exposure, improve HIV rapid test to decrease the window period, expand access to HIV testing and prevent HIV transmission.

Acknowledgement

We thank the owner of plasma specimens, NGO staffs (PPAT, SWING, FAR) and HIV care center.