

Implementation of HIV Combo Ag/Ab EIA in a Public Health Laboratory

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ABSTRACT

Objective: HIV Combo Ag/Ab EIA was validated and implemented for routine screening test for detection of HIV-1 and HIV-2 at the Texas Department of State Health Services (DSHS).

UPDATED ABSTRACT

Study Design: Beginning September 2012, sera submitted for routine HIV testing were screened with the Bio-Rad GS HIV Combo Ag/Ab EIA for repeated reactivity and confirmed with WB. All WB reactive, indeterminate, and nonreactive sera were tested with MS for the comparison study. WB indeterminate and nonreactive sera were also sent to Dallas for NAAT if enough volume was available for the testing.

Results: Serum samples routinely submitted to the DSHS laboratory for HIV testing were screened with Bio-Rad HIV Combo Ag/Ab EIA. Among the 11,964 sera screened, 150 were initially reactive. Among these, 138 were repeatedly reactive and 12 (0.1%) initially reactive were nonreactive when retested in duplicate. Repeatedly reactive 138 (1.15%) sera were confirmed with WB and 121 reported as reactive. Among the 121 WB reactive sera, 118 were tested with MS and the results were in 100% agreement for HIV-1 and 3 samples could not be tested with MS due to QNS for testing. 12 of the 14 WB-NR samples were also tested MS-NR; 1 QNS serum could not be tested and one was undifferentiated when tested diluted sample. Among the 14 WB nonreactive sera, 9 eligible samples were sent to Dallas for NAAT and 5 QNS sera could not be tested. Of the 9 NAAT samples, 3 were reactive and 6 were reported nonreactive. 2 or 3 WB-IND samples were tested nonreactive with MS and NAAT and one was QNS for both.

Assay Validation

HIV Combo Ag/Ab EIA Validation

Tested 470 positive and negative specimens for HIV-1, HIV-2, and HIV-1 p24 Ag for performance specifications

Accuracy

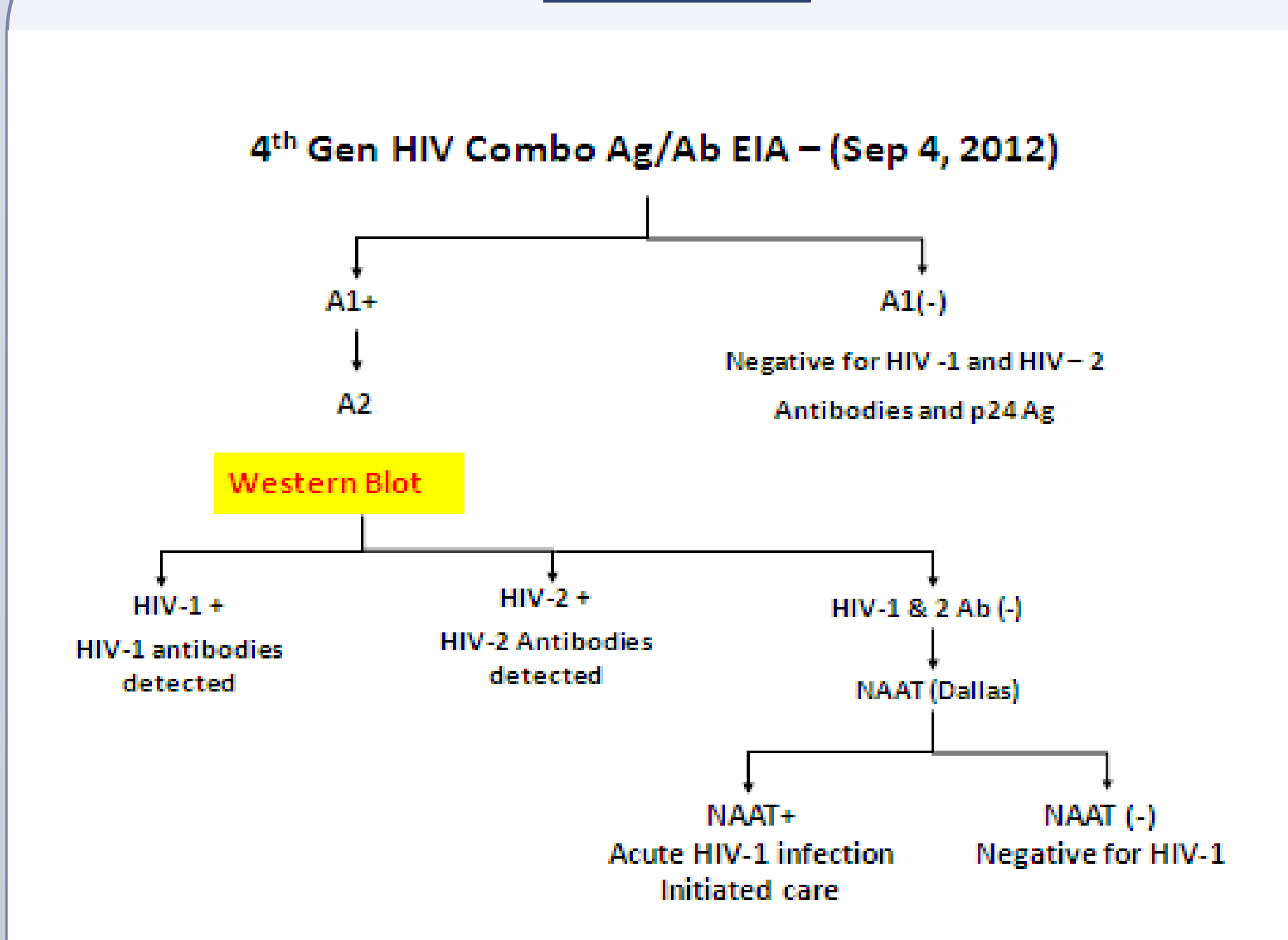
Precision

Intra-assay – (within run)
Inter-assay – (between run)

Reportable range of the test results

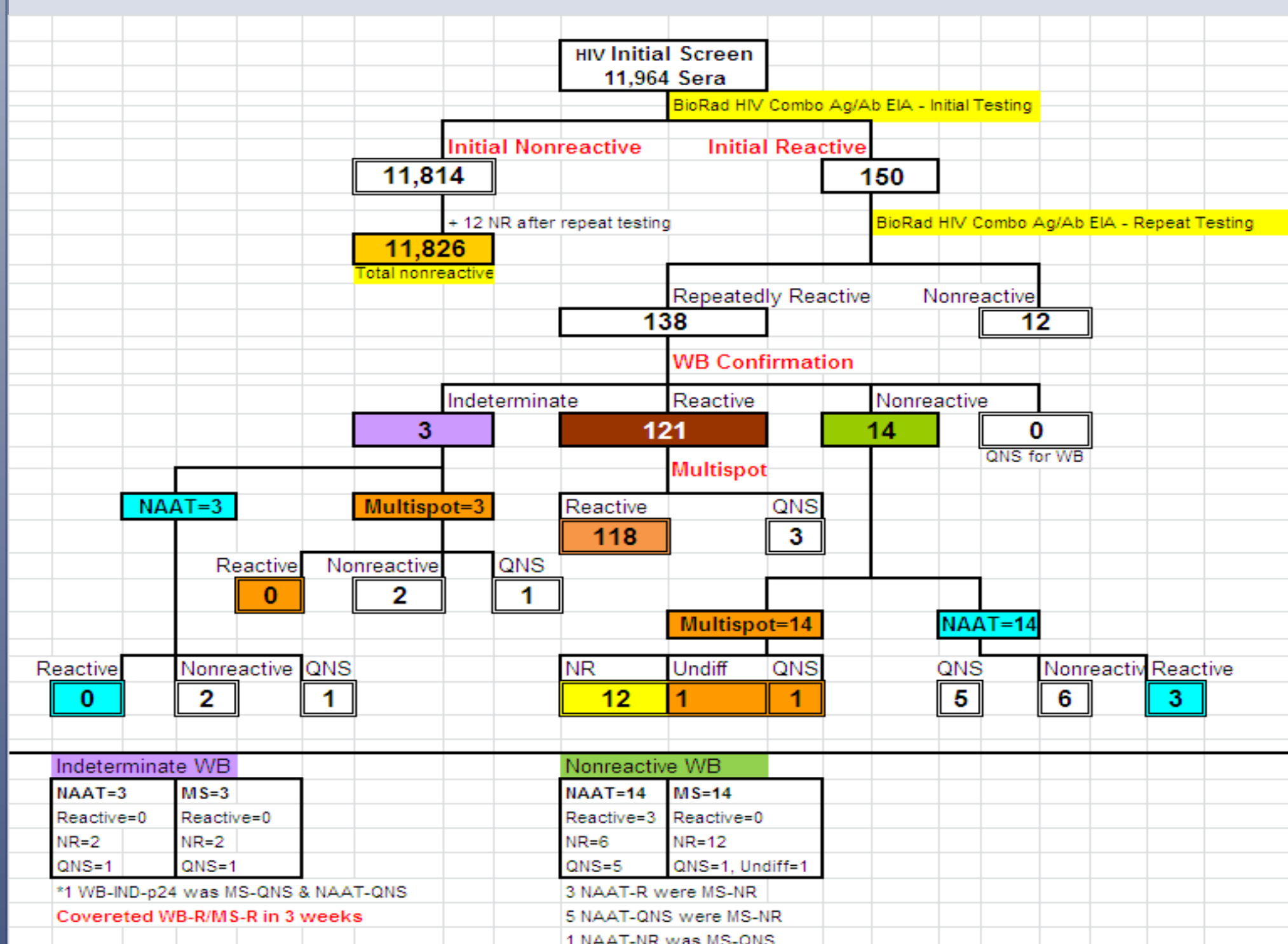
Implemented in September 2012

METHODS



RESULTS

	OD and S/C values of initial-R Final-NR EIA Results									
	OD-1	S/c-1	Inter	OD-2	S/c-2	Inter	OD-3	S/c-3	Inter	Final EIA
1	0.380	1.290	R	0.055	0.196	NR	0.055	0.196	NR	NR
2	0.520	1.816	R	0.050	0.171	NR	0.057	0.195	NR	NR
3	0.699	2.221	R	0.066	0.212	NR	0.073	0.235	NR	NR
4	0.413	1.466	R	0.049	0.166	NR	0.052	0.176	NR	NR
5	2.811	9.465	R	0.053	0.182	NR	0.056	0.193	NR	NR
6	0.527	1.691	R	0.067	0.219	NR	0.065	0.213	NR	NR
7	0.314	1.005	R	0.060	0.201	NR	0.055	0.184	NR	NR
8	3.193	10.632	R	0.063	0.211	NR	0.055	0.184	NR	NR
9	0.331	1.130	R	0.063	0.211	NR	0.055	0.184	NR	NR
10	2.453	8.204	R	0.072	0.241	NR	0.071	0.238	NR	NR
11	0.407	1.454	R	0.058	0.196	NR	0.060	0.202	NR	NR
12	0.639	2.104	R	0.055	0.195	NR	0.086	0.283	NR	NR
13	3.208	11.011	R	3.240	11.224	R	3.392	11.751	R	R



RESULTS

Serum samples routinely submitted to the DSHS laboratory for HIV testing were screened with Bio-Rad HIV Combo Ag/Ab EIA. A total of 11,964 specimens were tested from September to November, 2012. Among the 11,964 sera screened, 150 sera were initially reactive. Among these, 138 were repeatedly reactive and 12 (0.1%) initially reactive were nonreactive when retested in duplicate.

Repeatedly reactive 138 (1.15%) sera were confirmed with WB and 121 (1.01%) reported as reactive. Among the 121 WB reactive sera, 118 were tested with MS and the results were in 100% agreement for HIV-1 and 3 samples could not be tested with MS due to 'quantity not sufficient (QNS)' for testing. One WB-R, MS-R, was also tested NAAT-R and was not considered as acute case and the follow-up was not initiated.

Among the 14 WB nonreactive sera, 9 eligible samples were sent to Dallas for NAAT and 5 QNS sera could not be tested. Of the 9 NAAT samples, 3 were reactive and 6 were reported nonreactive. Two of the three WB-IND samples were tested nonreactive with MS and NAAT and one was QNS for both. Among the 14 WB nonreactive sera tested by MS, 12 were found nonreactive; 1 QNS serum could not be tested and one was undifferentiated when tested diluted sample.

Among the 3 WB indeterminate sera, 2 samples were tested nonreactive by MS and 1 QNS serum could not be tested. Among the 3 WB indeterminate sera, 2 eligible samples were tested nonreactive for NAAT at Dallas and 1 QNS sera could not be tested.

****WB-IND with p-24 band/MS-QNS/NAAT-QNS was converted to WB-R/MS-R in 3 weeks.**

27 yrs./male, DOC 9/27, EIA-R/WB-R/MS-R/NAAT-R, 10/6, Not followed up

Followed up with NAAT reactive cases

Case # 1: 31 yrs., male, DOC 10/4, EIA-R, WB-NR, MS-NR, NAAT-R, 10/19

Initiated care – Confirmed case, found source
5 partners – tested
One – reactive, 4 – nonreactive

Case # 2: 25 yrs., male, DOC 10/15, EIA-R, WB-NR, MS-NR, NAAT-R, 10/26

Case investigation initiated – 11/12/12, No info yet

Case # 3: 18 yrs., male, DOC 10/17, EIA-R, WB-NR, MS-NR, NAAT-R, 10/31, No record found initially

Case investigation initiated 11/30/12

Followed up with WB-Ind / NAAT-QNS case

Case # 1: 22 yrs./male, DOC 11/7, EIA-R/WB-p24/MS-QNS/NAAT-QNS, 11/27

Case investigation initiated – redrawn 11/28/12

HIV Combo EIA – 12/3/12 – Reactive

WB – R (gp160/p24) / MS-R / NAAT-R (12/6/12)

HIV 1/2+O EIA – 10/21/2010 - nonreactive

Follow-up

Followed up with WB-NR/MS-NR/NAAT-QNS case

- Case # 1: 28 yrs./female, DOC 9/25, EIA-R/WB-NR/MS-NR/NAAT-QNS, 10/6
 - Case investigation NOT initiated - Case WB-R 4/11/2011?
 - 1/28/2011 - HIV 1/2+O EIA - R / WB-NR
 - 2/11/2011 - HIV 1/2+O EIA - R / WB-NR
 - 4/11/2011 - HIV 1/2+O EIA - R / WB-R, all bands present
 - 9/22/2011 - HIV 1/2+O EIA - R / WB-NR, NAAT-NR
 - 9/25/2012 - Amplified RNA Probe for CTGC - Negative
 - 10/25/2012 - Amplified RNA Probe for CTGC - Negative
 - 10/25/2012 - HBsAg - Nonreactive
 - 10/25/2012 - Rubella IgG - Negative
 - 10/25/2012 - Syphilis RPR - Nonreactive

CONCLUSIONS

Preliminary results of three months data demonstrated that Bio-Rad HIV Combo Ag/Ab EIA detected acute HIV cases that were nonreactive by WB. Comparison of WB and multispot rapid test (MS) suggests that MS can be used for confirmation of HIV-1 and HIV-2 in the HIV testing algorithm replacing expensive and labor intensive WB.

