

Performance of an Alternative HIV Diagnostic Algorithm Including HIV-1 RNA Viral Load Compared to the CDC/APHL Laboratory Diagnostic Algorithm

Marc Pitasi

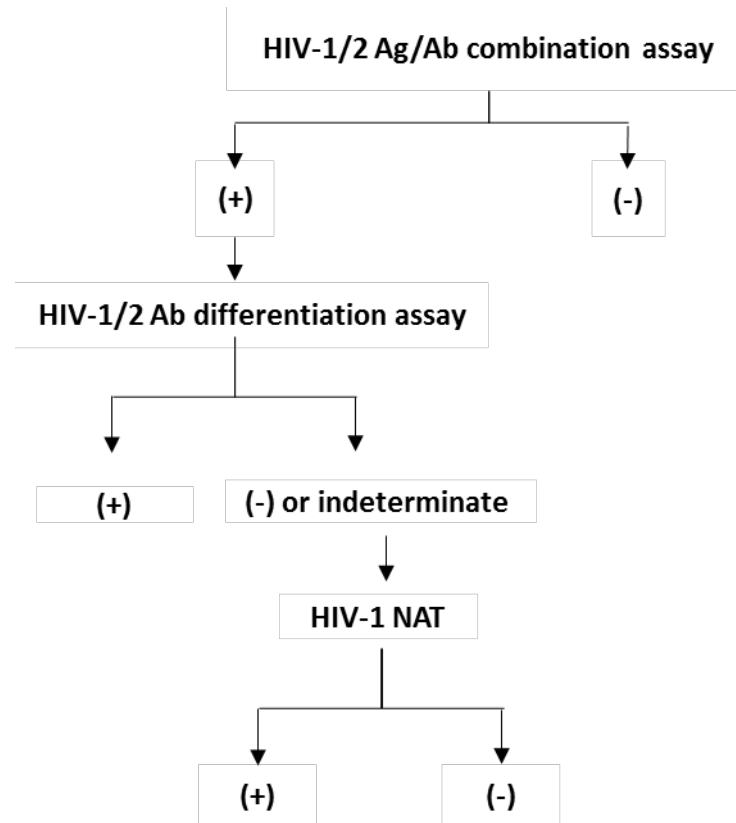
March 26, 2019



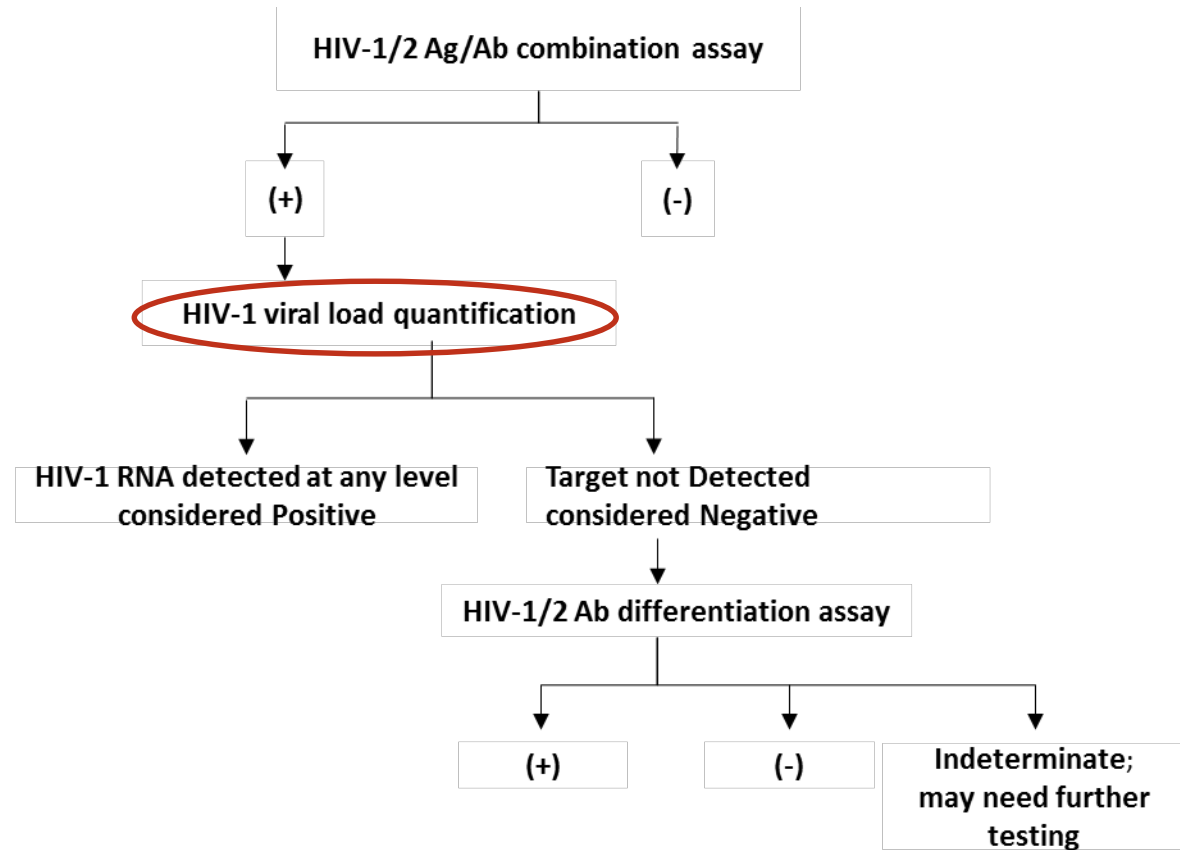
No conflicts of interest



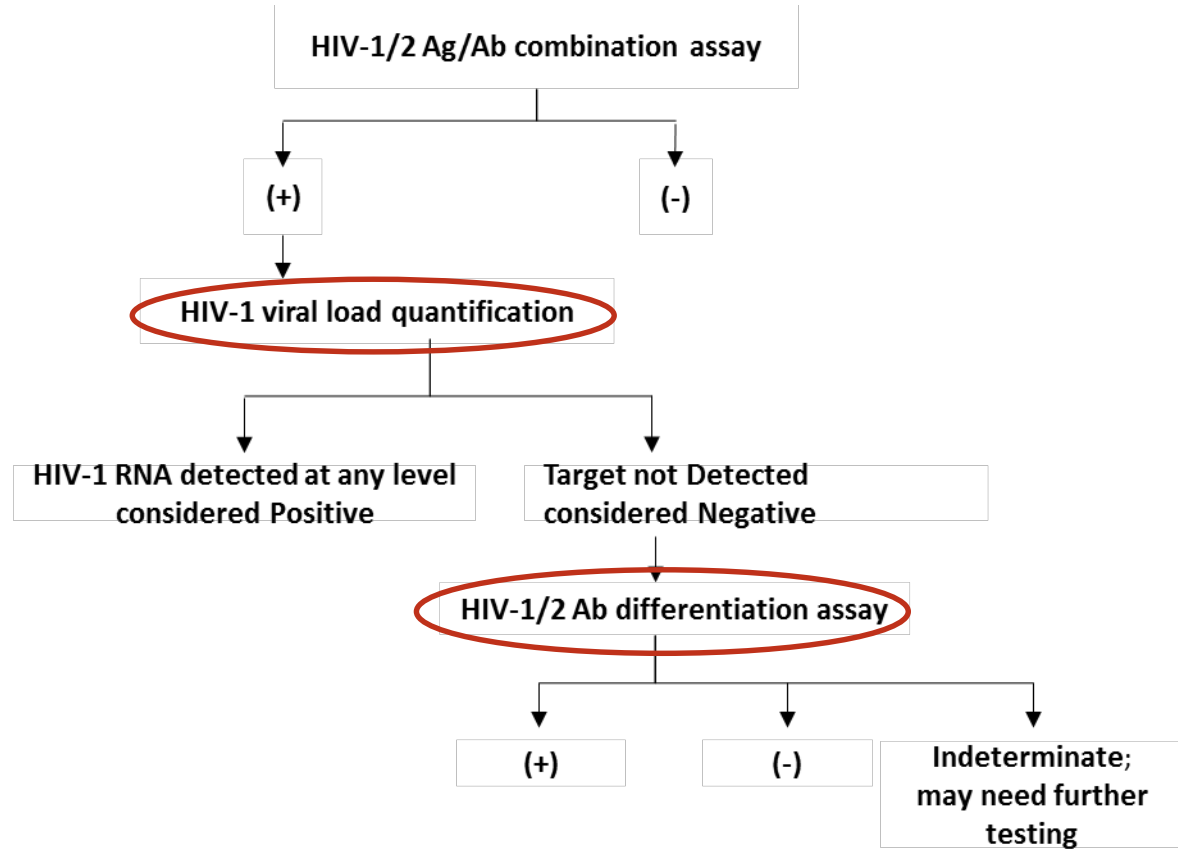
Recommended Laboratory Testing Algorithm



An Alternative Laboratory Testing Algorithm



An Alternative Laboratory Testing Algorithm



Objective

Evaluate performance of specimens tested with 5 Ag/Ab screening tests and 2 viral load tests in alternative and recommended algorithms



Sample Description

- **Serum and plasma collected from >6,000 patients at high risk for HIV infection seeking testing at 2 clinics in Los Angeles during 2003–2005**
- **Stored specimens subsequently tested with Ag/Ab assays and viral load tests**

Analysis

- **Evaluated specimens testing positive on any Ag/Ab screening test**
 - Abbott ARCHITECT HIV Ag/Ab Combo
 - Bio-Rad GS HIV Combo Ag/Ab EIA
 - Siemens ADVIA Centaur[®] HIV Ag/Ab Combo
 - Bio-Rad BioPlex[®]2200 HIV Ag-Ab
 - Alere Determine[™] HIV-1/2 Ag/Ab Combo

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 - Alere Determine[™] HIV-1/2 Ag/Ab Combo
- **Viral load tests used as algorithm second step**
 - Roche Amplicor HIV-1 Monitor
 - Hologic Aptima HIV-1 Quant Assay

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 - Abbott ARCHITECT HIV Ag/Ab Combo
 - Bio-Rad GS HIV Combo Ag/Ab EIA
 - Siemens ADVIA Centaur® HIV Ag/Ab Combo
 - Bio-Rad BioPlex®2200 HIV Ag-Ab
 - Alere Determine™ HIV-1/2 Ag/Ab Combo
- **Viral load tests used as algorithm second step**
 - Roche Amplicor HIV-1 Monitor
 - Hologic Aptima HIV-1 Quant Assay
- **Geenius™ HIV-1/2 Supplemental Assay used as third step**

Analysis

- **Classified specimens according to recommended algorithm:**
 - 5 early infection (nonreactive/indeterminate Ab, reactive NAT)
 - 152 established infection (reactive Ab)
 - 38 false positive screening (nonreactive/indeterminate Ab, nonreactive NAT)

Analysis

- **Classified specimens according to recommended algorithm:**
 - 5 early infection (nonreactive/indeterminate Ab, reactive NAT)
 - 152 established infection (reactive Ab)
 - 38 false positive screening (nonreactive/indeterminate Ab, nonreactive NAT)
- **Calculated percentages and 95% confidence intervals of specimens correctly classified by Ag/Ab screening followed by viral load testing relative to recommended algorithm**
 - by each Ag/Ab test and viral load test
 - overall

Performance of Ag/Ab Screening Tests

Test	Sensitivity, Early Infection	Sensitivity, Established Infect.	Specificity
Abbott Architect	53% (27–79)	100.0% (98.7–100)	98.3% (97.3–99.0)
Bio-Rad Ag/Ab Combo	60% (32–84)	100.0% (98.7–100)	98.9% (98.0–99.4)
Siemens ADVIA Centaur	60% (32–84)	100.0% (98.7–100)	98.3% (97.3–99.0)
Bio-Rad BioPlex	60% (32–84)	100.0% (98.7–100)	98.6% (97.6–99.2)
Determine Ag/Ab Combo	40% (16–68)	99.6% (98.0–100)	98.9% (98.0–99.4)

Similar Sensitivity During Early Infection

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Determine Ag/Ab Combo	40% (16–68)	99.6% (98.0–100)	98.9% (98.0–99.4)

Similar, High Sensitivity for Established Infection

Test	Sensitivity, Early Infection	Sensitivity, Established Infect.	Specificity
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Performance of VL tests after Ag/Ab screening

	Roche Amplicor			Aptima Quant*	
	Early	Established	False Positive	Early	Established
Abbott Architect	5/5	144/152	13/13	4/4	110/110
Bio-Rad Ag/Ab Combo	5/5	144/152	11/11	4/4	110/110
Siemens ADVIA Centaur	5/5	144/152	11/11	4/4	110/110
Bio-Rad BioPlex	5/5	144/152	13/13	4/4	110/110
Determine Ag/Ab Combo	4/4	144/151	3/3	3/3	110/110

*False positive specimens were not tested with Aptima Quant

Roche VL identified all early infections

	Roche Amplicor			Aptima Quant*	
	Early	Established	False Positive	Early	Established
Abbott Architect	5/5	144/152	13/13	4/4	110/110
Bio-Rad Ag/Ab Combo	5/5	144/152	11/11	4/4	110/110
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Bio-Rad BioPlex	5/5	144/152	13/13	4/4	110/110
Determine Ag/Ab Combo	4/4	144/151	3/3	3/3	110/110

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Roche VL identified most established infections

	Roche Amplicor			Aptima Quant*	
	Early	Established	False Positive	Early	Established
Abbott Architect	5/5	144/152	13/13	4/4	110/110
Bio-Rad Ag/Ab Combo	5/5	144/152	11/11	4/4	110/110
Siemens ADVIA Centaur	5/5	144/152	11/11	4/4	110/110
Bio-Rad BioPlex	5/5	144/152	13/13	4/4	110/110
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Any screening test followed by Roche Amplicor

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Any screening test	5/5	144/152	38/38	4/4	110/110

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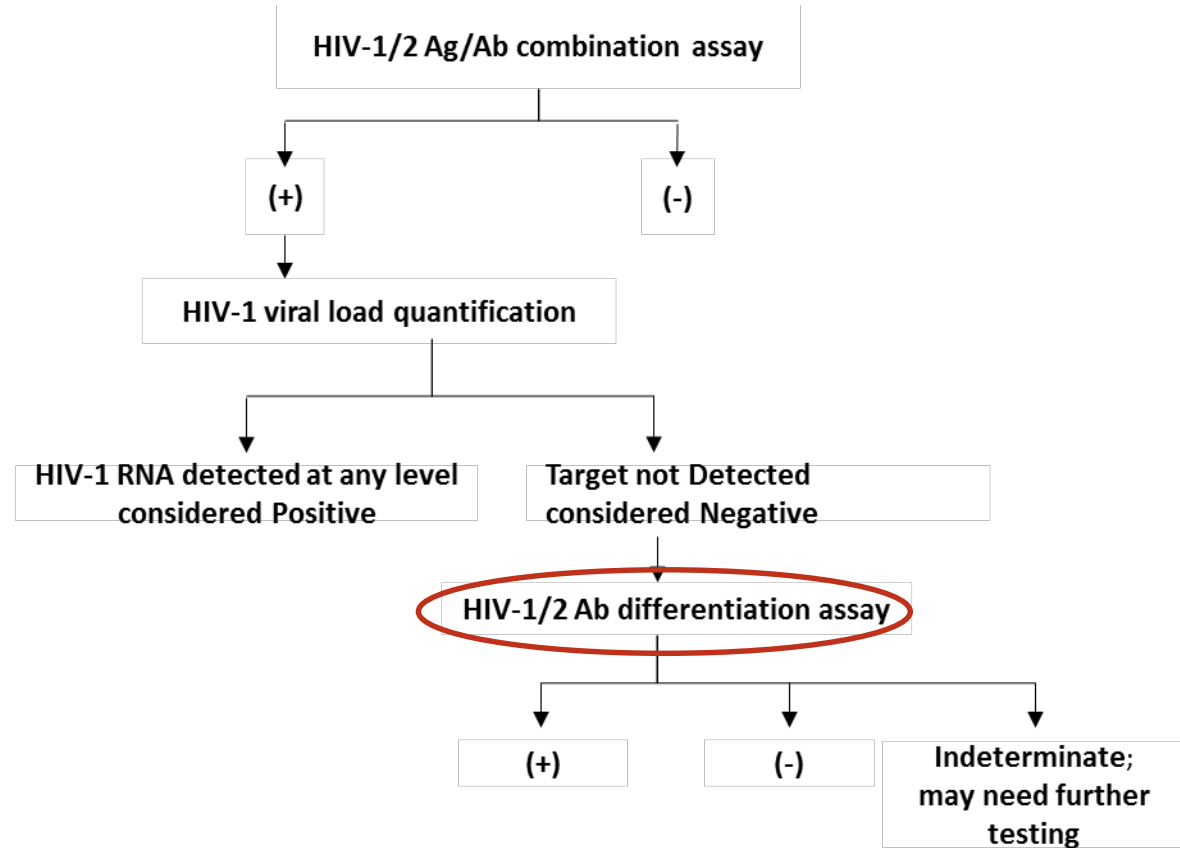
94.7% (89.9-97.7%)

Any screening test followed by Aptima Quant

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8 Specimens with TND result on Roche VL



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ID	Architect S/CO	BRC S/CO	ADVIA S/CO	BioPlex Index	Determine (Ag/Ab)	Geenius	Geenius bands	Aptima Qual	Roche VL
1	274.71	15.21	12.00	>200	(-) / (+)	HIV-1+	gp160, gp41	P	TND
2	522.83	15.38	12.00	>200	(-) / (+)	HIV-1+	gp140, p31, gp160, p24, gp41	P	TND
3	460.38	15.51	12.00	>200	(-) / (+)	HIV-1+	gp160, gp41	N	TND
4	373.27	15.64	12.00	>200	(-) / (+)	HIV-1+	gp160, gp41	N	TND
5	242.05	15.23	12.00	>200	(-) / (+)	HIV-1+	p31, gp160, p24, gp41	N	TND
6	296.79	15.60	12.00	>200	(-) / (+)	HIV-1+	p31, gp160, p24, gp41	N	TND
7	91.88	15.37	12.00	>200	(-) / (+)	HIV-1+	gp160, gp41	P	TND
8	25.19	15.41	12.00	99.89	(-) / (-)	HIV-1+	gp160, p24, gp41	N	TND

7 Specimens Reactive on Every Screening Test

ID	Architect S/CO	BRC S/CO	ADVIA S/CO	BioPlex Index	Determine (Ag/Ab)	Geenius	Geenius bands	Aptima Qual	Roche VL
1	274.71	15.21	12.00	>200	(-) / (+)	HIV-1+	gp160, gp41	P	TND
2	522.83	15.38	12.00	>200	(-) / (+)	HIV-1+	gp140, p31, gp160, p24, gp41	P	TND
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8	25.19	15.41	12.00	99.89	(-) / (-)	HIV-1+	gp160, p24, gp41	N	TND

1 Specimen False Reactive on Determine

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8 Specimens with TND result on Roche VL

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Geenius Detected Each TND Specimen

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7	91.88	15.37	12.00	>200	(-) / (+)	HIV-1+	gp160, gp41	P	TND
8	25.19	15.41	12.00	99.89	(-) / (-)	HIV-1+	gp160, p24, gp41	N	TND

8 Specimens False Reactive on >1 Ag/Ab Test

ID	Architect S/CO	BRC S/CO	ADVIA S/CO	BioPlex Index	Determine (Ag/Ab)	Geenius	Aptima Qual	Roche VL
1	11.58	6.76	12.00	163.06	(-) / (-)	HIV-1 ind.	N	TND
2	8.92	13.03	12.00	24.93	(-) / (+)	HIV negative	N	TND
3	3.44	8.73	0.44	0.33	(-) / (-)	HIV negative	N	TND
4	0.23	0.10	2.07	3.49	(-) / (-)	HIV negative	N	TND
5	0.17	0.19	1.95	0.10	(+) / (+)	HIV negative	N	TND
6	0.10	0.10	1.59	4.21	(-) / (-)	HIV negative	N	TND
7	0.09	1.64	0.87	1.75	(-) / (-)	HIV negative	N	TND
8	0.07	1.16	0.09	0.01	(-) / (+)	HIV negative	N	TND

All negative using recommended algorithm

ID	Architect S/CO	BRC S/CO	ADVIA S/CO	BioPlex Index	Determine (Ag/Ab)	Geenius	Aptima Qual	Roche VL
1	11.58	6.76	12.00	163.06	(-) / (-)	HIV-1 ind.	N	TND
2	8.92	13.03	12.00	24.93	(-) / (+)	HIV negative	N	TND
3	3.44	8.73	0.44	0.33	(-) / (-)	HIV negative	N	TND
4	0.23	0.10	2.07	3.49	(-) / (-)	HIV negative	N	TND
5	0.17	0.19	1.95	0.10	(+) / (+)	HIV negative	N	TND
6	0.10	0.10	1.59	4.21	(-) / (-)	HIV negative	N	TND
7	0.09	1.64	0.87	1.75	(-) / (-)	HIV negative	N	TND
8	0.07	1.16	0.09	0.01	(-) / (+)	HIV negative	N	TND

All TND on Roche VL test

ID	Architect S/CO	BRC S/CO	ADVIA S/CO	BioPlex Index	Determine (Ag/Ab)	Geenius	Aptima Qual	Roche VL
1	11.58	6.76	12.00	163.06	(-) / (-)	HIV-1 ind.	N	TND
2	8.92	13.03	12.00	24.93	(-) / (+)	HIV negative	N	TND
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7 of 8 negative on Geenius

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1	11.58	6.76	12.00	163.06	(-) / (-)	HIV-1 ind.	N	TND
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3	3.44	8.73	0.44	0.33	(-) / (-)	HIV negative	N	TND
4	0.23	0.10	2.07	3.49	(-) / (-)	HIV negative	N	TND
5	0.17	0.19	1.95	0.10	(+) / (+)	HIV negative	N	TND
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7	0.09	1.64	0.87	1.75	(-) / (-)	HIV negative	N	TND
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7 of 8 negative on Geenius

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5	0.17	0.19	1.95	0.10	(+) / (+)	HIV negative	N	TND
6	0.10	0.10	1.59	4.21	(-) / (-)	HIV negative	N	TND
7	0.09	1.64	0.87	1.75	(-) / (-)	HIV negative	N	TND
8	0.07	1.16	0.09	0.01	(-) / (+)	HIV negative	N	TND

ID	HIV-1/2 Ag/Ab combination assay					Geenius	Aptima Qual	Roche VL
1	HIV-1/2 Ag/Ab combination assay (+)					HIV-1 ind.	N	TND
2	HIV-1 viral load quantification HIV-1 RNA detected at any level considered Positive					HIV negative	N	TND
3	HIV-1 viral load quantification Target not Detected considered Negative					HIV negative	N	TND
4	HIV-1/2 Ab differentiation assay					HIV negative	N	TND
5	HIV-1/2 Ab differentiation assay (+)					HIV negative	N	TND
6	HIV-1/2 Ab differentiation assay (-)					HIV negative	N	TND
7	HIV-1/2 Ab differentiation assay Indeterminate; may need further testing					HIV negative	N	TND
8	0.07	1.16	0.09	0.01	(-) / (+)	HIV negative	N	TND

...but some S/COs are inconsistent

ID	Architect S/CO	BRC S/CO	ADVIA S/CO	BioPlex Index	Determine (Ag/Ab)	Geenius	Aptima Qual	Roche VL
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5	0.17	0.19	1.95	0.10	(+) / (+)	HIV negative	N	TND
6	0.10	0.10	1.59	4.21	(-) / (-)	HIV negative	N	TND
7	0.09	1.64	0.87	1.75	(-) / (-)	HIV negative	N	TND
8	0.07	1.16	0.09	0.01	(-) / (+)	HIV negative	N	TND

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4	0.23	0.10	2.07	3.49	(-) / (-)	HIV negative	N	TND
5	0.17	0.19	1.95	0.10	(+) / (+)	HIV negative	N	TND
6	0.10	0.10	1.59	4.21	(-) / (-)	HIV negative	N	TND
7	0.09	1.64	0.87	1.75	(-) / (-)	HIV negative	N	TND
8	0.07	1.16	0.09	0.01	(-) / (+)	HIV negative	N	TND

...but some S/COs are inconsistent

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3	3.44	8.73	0.44	0.33	(-) / (-)	HIV negative	N	TND
4	0.23	0.10	2.07	3.49	(-) / (-)	HIV negative	N	TND
5	0.17	0.19	1.95	0.10	(+) / (+)	HIV negative	N	TND
6	0.10	0.10	1.59	4.21	(-) / (-)	HIV negative	N	TND
7	0.09	1.64	0.87	1.75	(-) / (-)	HIV negative	N	TND
8	0.07	1.16	0.09	0.01	(-) / (+)	HIV negative	N	TND

Other False Positive Specimens

- **Of 30 specimens that were false positive on only 1 Ag/Ab test:**
 - 4 were HIV-2 Indeterminate on Geenius, but
 - 3 were false positive on Abbott Architect with low S/CO
 - 1 false positive on BioPlex with low index value

Limitations

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Conclusions

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- **Moving Ab supplemental test to third step would have eliminated need for Ab supplemental testing in 149/195 specimens**
 - However, indeterminate Geenius results might have required additional testing in 5/46 specimens

Public Health Implications

- **The alternative algorithm may reduce the total number of tests performed, reduce overall turnaround time to result, and expedite availability of VL results for patient care**
 - But what about cost? Availability? Other barriers?

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Disclaimer

The findings and conclusions in this presentation are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.