

# Performance of the Abbott Architect HIV Ag/Ab Combo assay in the US Army HIV Diagnostic Algorithm

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# HIV Diagnosis in US Military

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- DODI 6485.01: *Human Immunodeficiency Virus (HIV) in Military Service Members*
- AR 600-110: *Identification, Surveillance, and Administration of Personnel Infected with Human Immunodeficiency Virus, 2014*



# Rationale

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- Protect the blood supply during urgent donation setting from the “walking blood bank”
- Prevent potentially fatal complications from administration of military required live vaccines
- Monitor HIV infected personnel for continuing physical qualification for duty



# HIV Diagnostics and Reference Laboratory

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- Technical oversight and final authority for HIV diagnosis
  - Army Active Duty, Army Reserve, Army National Guard
  - 1 M HIV serological screening tests annually – contract screening laboratory (enzyme immunoassay only)
  - HIV serological tests for European and Central Commands, Medical Entrance Processing Commands, 51 Medical Treatment Facilities
- Conduct all HIV confirmatory testing and infection status determination for Army personnel
- Provide HIV infection status resolution testing and diagnostic consultation for US Navy/Marines and US Air Force by request

# Current HIV Test Requirements

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- Medical Entrance Processing Command: Accession into US military service – must screen **Non Reactive**
- Active Duty Surveillance – every 2 years
- USAR/USNG Surveillance – every 2 years
- Overseas assignment – deployment/TDU > 30 days
  - Pre-deployment test within 120 days of deployment
  - Post-deployment test within 30 days return from Area of Operation

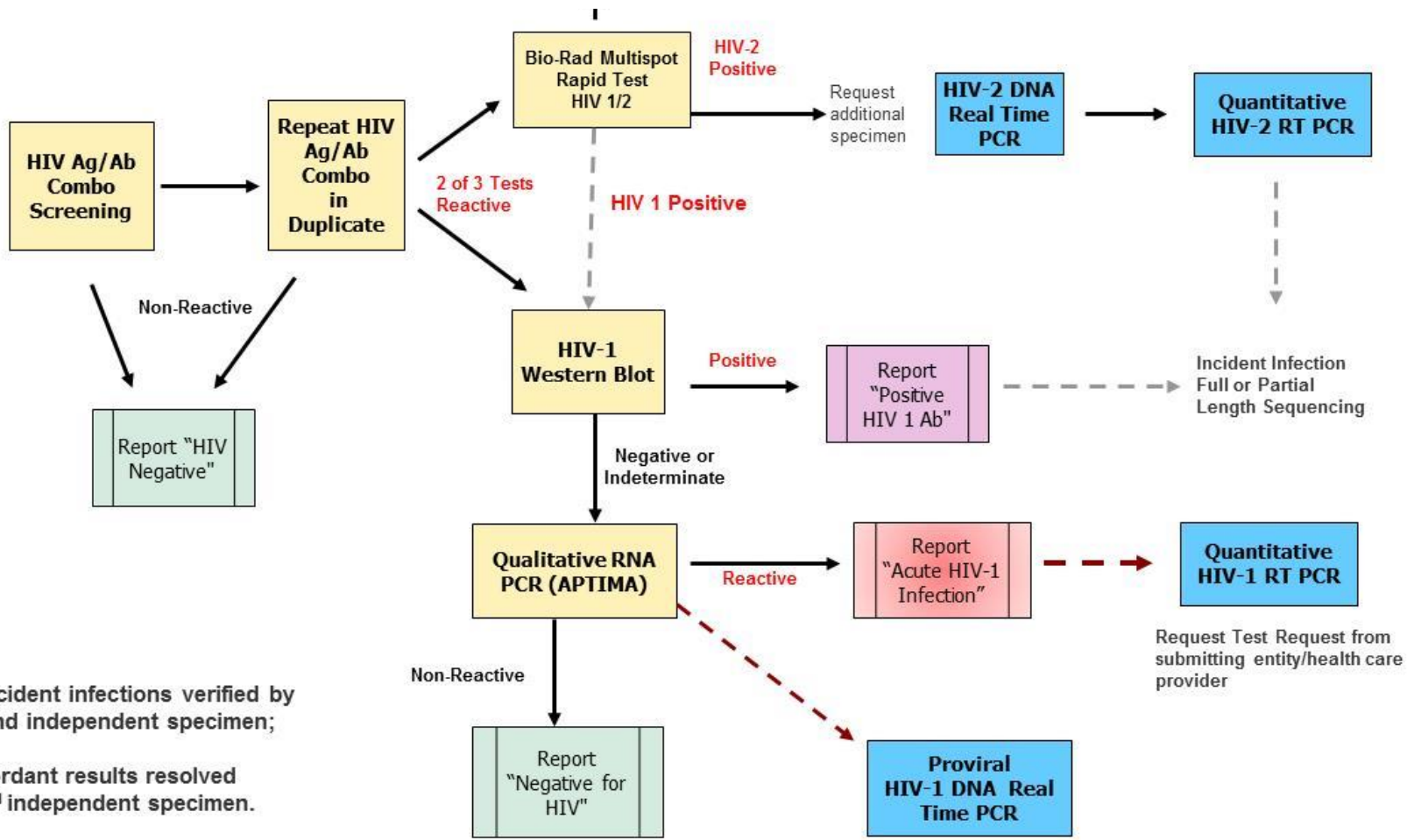
# HIV Testing Requirements Cont'd

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- Suspicious Illness
  - ARS
- STD infection
  - Follow-up at 3, 6, 12 months (if the initial test is NR)
- Sexual partners of HIV-infected individuals
- Injecting Drug Use (IDU)
- Voluntary Screening – per initiated Soldier request



# US Army Surveillance HIV Algorithm



All incident infections verified by second independent specimen;

Discordant results resolved by 3<sup>rd</sup> independent specimen.

WB IND/NEG, Aptima Reactive cases Reflex to HIV-1 viral load, Health care Provider contacted for test request

Whole blood specimen Confirmation; Special Cases



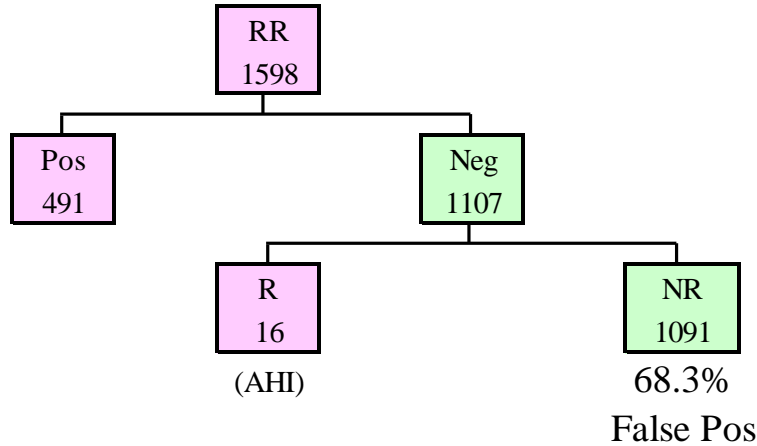
# Case Detection – SOT Code

Test Indication (SOT Code)	4th Gen	
	# Pos	Pos per 100,000
Physical Exam	206	28.2
Force Testing	4	0.5
Clinically Indicated	5	0.7
STI Clinic	1	0.1
Pre-Deployment	1	0.1
Requested by Individual	2	0.3
Post-Deployment	1	0.1
Redraw (EIA Pos)	1	0.1
Other	1	0.1
Not classified	22	3.0
<b>Total Positive</b>	<b>244</b>	<b>33.5</b>

The highest percentage of cases coded Physical Examination, followed by Force Test.

# 4<sup>th</sup> Gen Assay Performance

N = 987,947



Algorithm

Confirmation

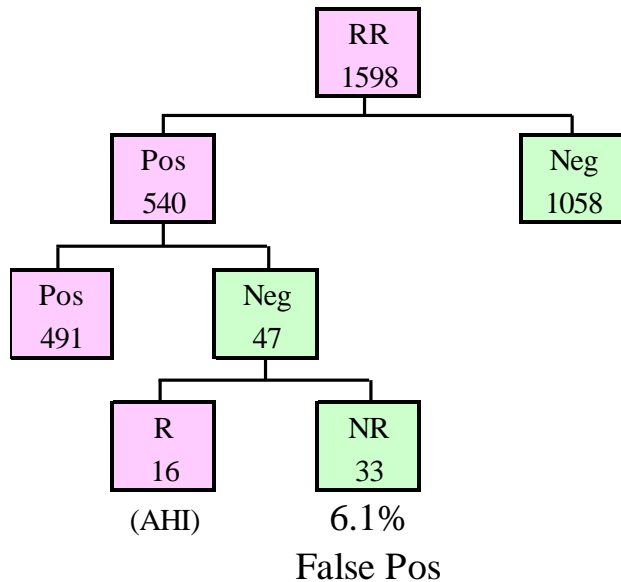
Western Blot

1,598

Aptima RNA

1,107

## Revised Algorithm



Bio-Rad Ag/Ab

1,598

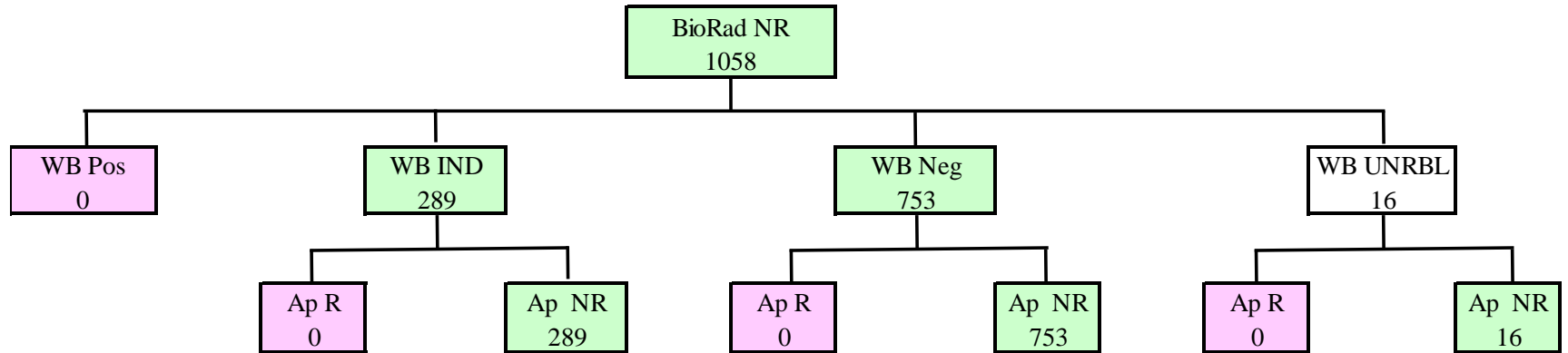
Western Blot

540

Aptima RNA

47

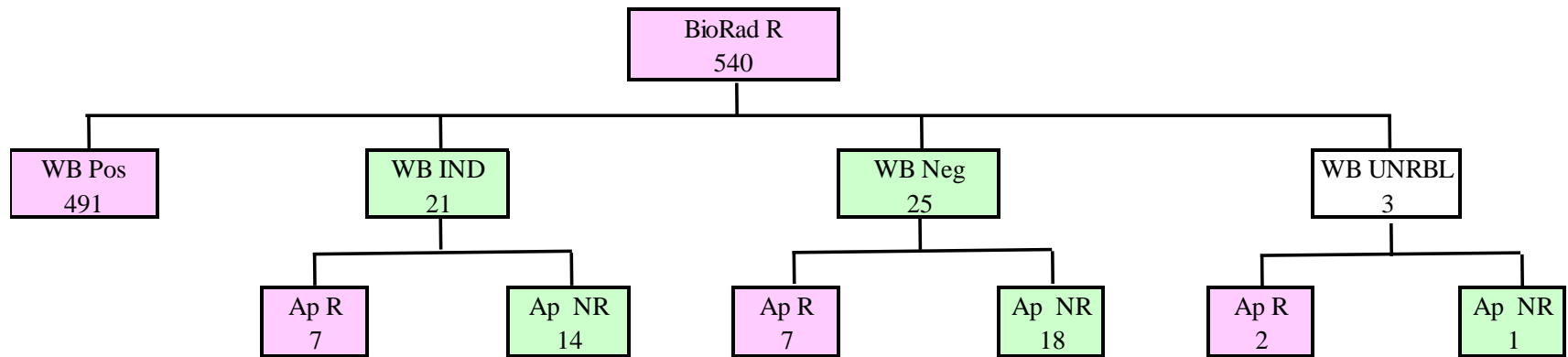
# Architect Ag/Ab Combo RR Tested by Bio-Rad Ag/Ab Combo



Of 1,058 RR specimens (Architect) and NR by Bio-Rad

- No WB Positive specimens identified
- No Aptima Reactive specimens
- No False Negative specimens

# Architect Ag/Ab Combo RR Tested by Bio-Rad Ag/Ab Combo



Of 540 specimens RR by both Architect and RR by Bio-Rad

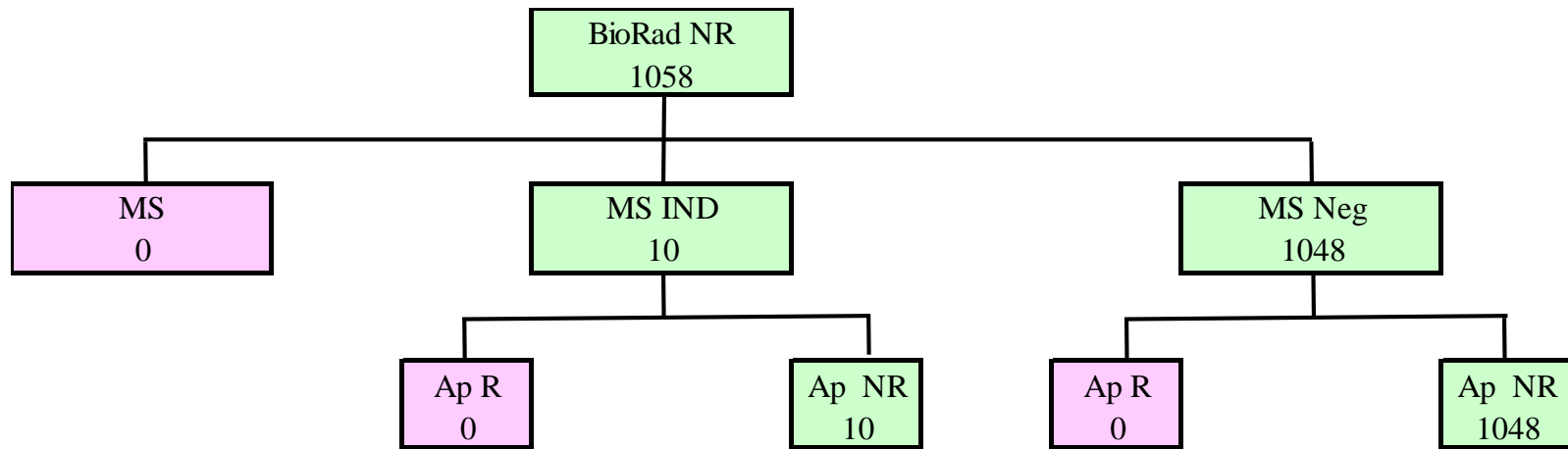
- 491 (90.9%) are confirmed WB Pos

Of 49 WB Neg/IND

- 14 are Aptima R (Acute HIV Infection)
- 33 of 540 (6.1%) are False Positives

# Architect Plus Bio-Rad Ag/Ab Combo RR MultiSpot Confirmation

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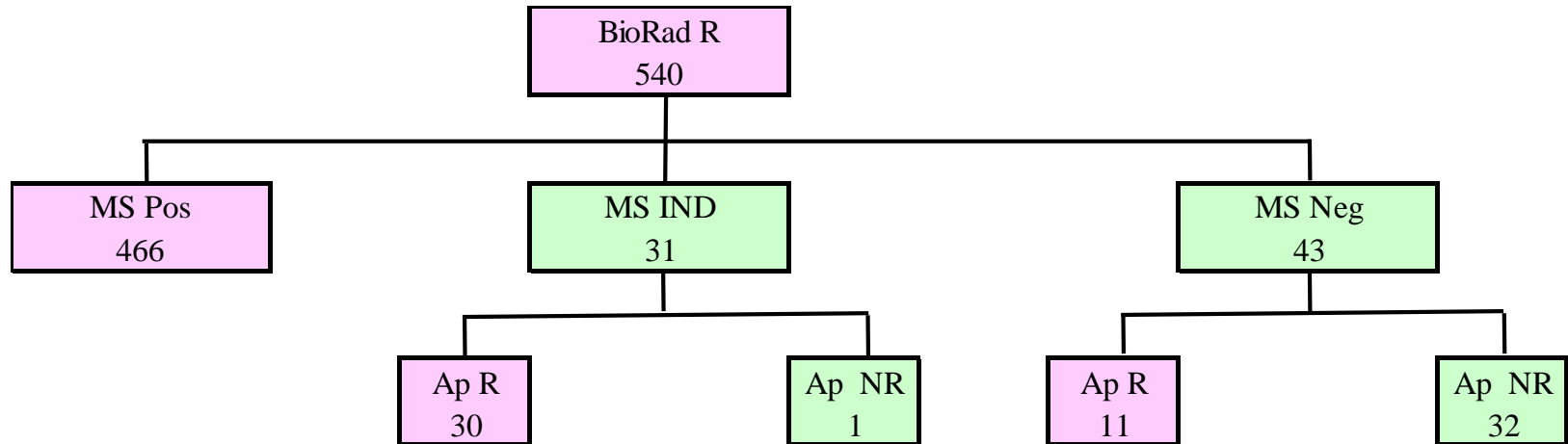


1058 specimens RR by both Architect and NR by Bio-Rad

- No MS Positive specimens
- No Aptima Reactive specimens
- No False Negative Specimens

# Architect Plus Bio-Rad Ag/Ab Combo RR MultiSpot Confirmation

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540 RR specimens by both Architect and Bio-Rad Combo

- 466 (86.3%) were MS positive
- 491 (90.9%) were WB Positive

74 Neg or IND MS specimens

- 41 were Aptima R (Acute HIV Infection)
- 33/540 (6.1%) were False Positive

# HIV Detection by 4<sup>th</sup> Gen Ag/Ab Combo

Screening Assay	Abbott Ag/Ab Combo	Abbott + BioRad Combo
Dates	Jan 2015 - Dec 2015	Jan 2015 - Dec 2015
# Screened	987,947	987,947
EIA RR	1,598	540
% Initial Pos	0.162%	0.055%
WB or RNA Confirmed	507	507
% Pos	0.051%	0.051%

EIA RR	1,598	540
% Conf	31.7%	93.9%

Addition of Bio-Rad Combo as a secondary repeat reactive screen would reduce the number of specimens reflexed to supplemental confirmatory testing



# Sensitivity, Specificity, Positive Predictive Value

		Resolved HIV Status		
		+	-	
Abbott	+	507	1,091	1,598
	-	0	986,349	986,349
		507	987,440	987,947

		Resolved HIV Status		
		+	-	
Abbott + BioRad	+	507	33	540
	-	0	987,407	987,407
		507	987,440	987,947

		95% CI
Sensitivity	100%	99.3 - 100%
Specificity	99.9%	99.9 - 99.9%
Pos Likelihood Ratio	905	853 - 960
Neg Likelihood Ratio	0	0%
Prevalence	0.05%	0.05 - 0.06%
<b>PPV</b>	<b>31.8%</b>	<b>29.5 - 34.1%</b>
NPV	100%	100%

		95% CI
Sensitivity	100%	99.3 - 100%
Specificity	100%	100%
Pos Likelihood Ratio	29,938	21,284 - 421,120
Neg Likelihood Ratio	0	0%
Prevalence	0.05%	0.05 - 0.06%
<b>PPV</b>	<b>93.9%</b>	<b>91.5 - 95.8%</b>
NPV	100%	100%

# Conclusions

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- Transition to Architect Ag/Ab: slight increase in number (3) HIV cases detected
- Increased the number of specimens which required further testing: 67.2% False Positive
- Secondary screen by Bio-Rad Ag/Ab significantly reduced number supplemental confirmatory tests: WB (67.2%); Aptima (95.8%)
- BioRad Ag/Ab repeat reactive secondary screen increased PPV from 31.8% to 93.9%

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