Comparison of Turn-around Time and Total Cost of HIV Testing Before and After Implementation of the 2014 CDC / APHL Laboratory Testing Algorithm for Diagnosis of HIV Infection

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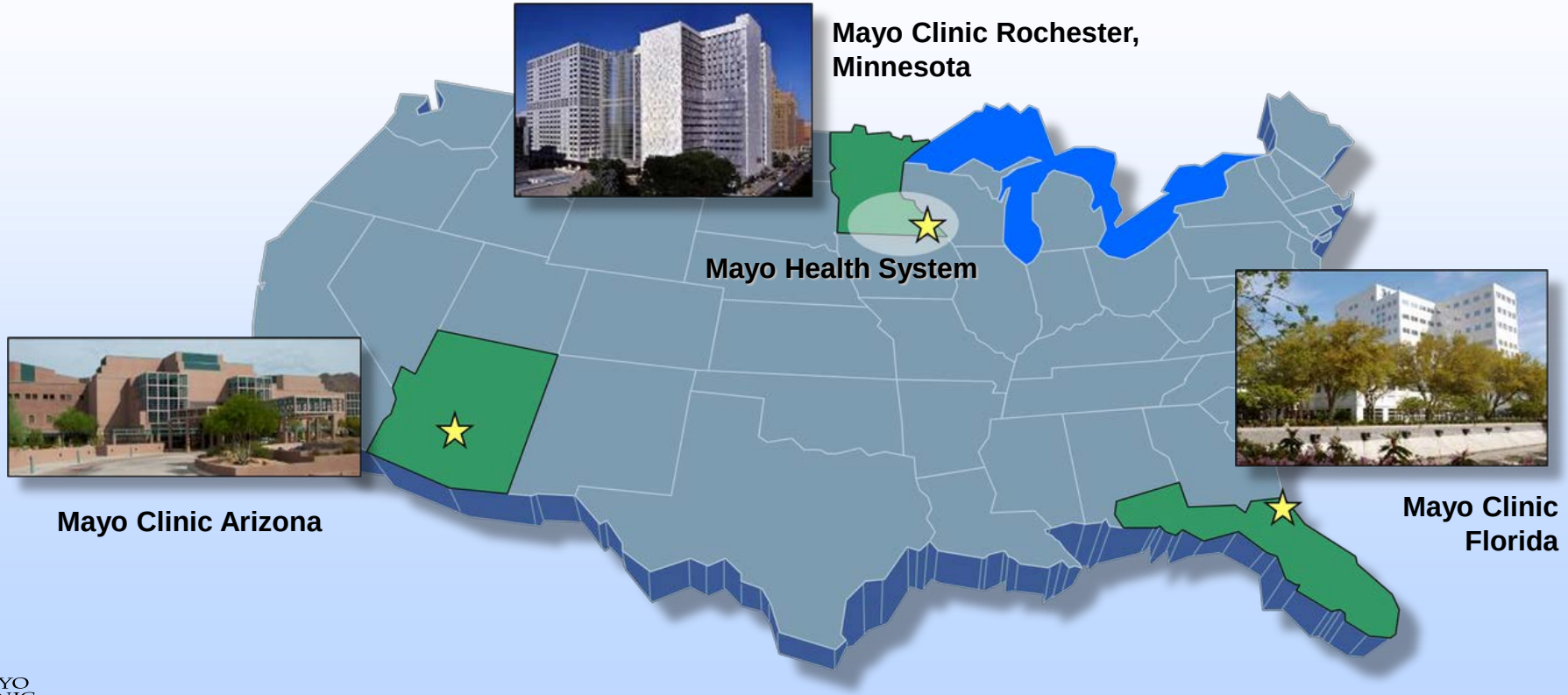
Mayo Clinic Patient Care Sites



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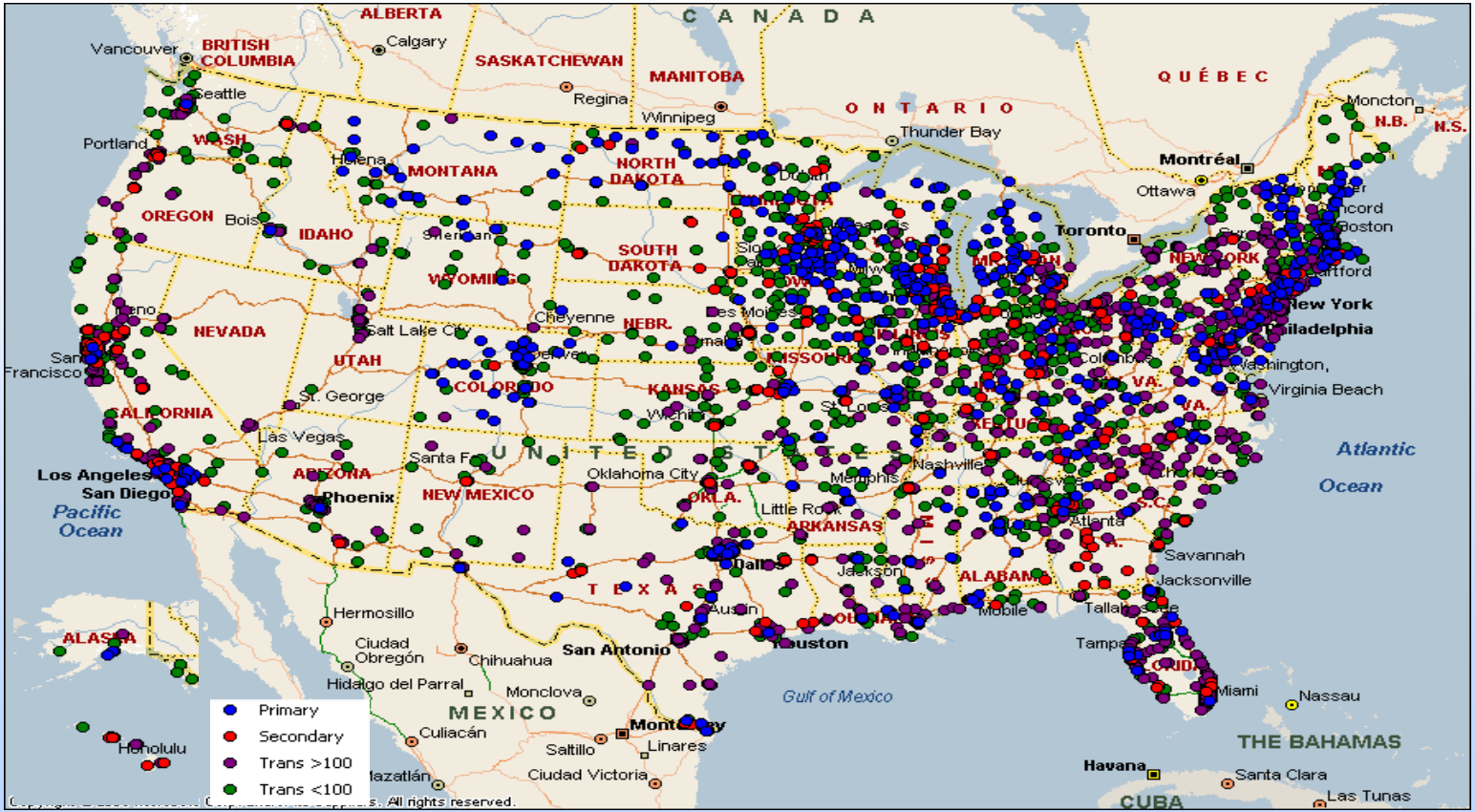
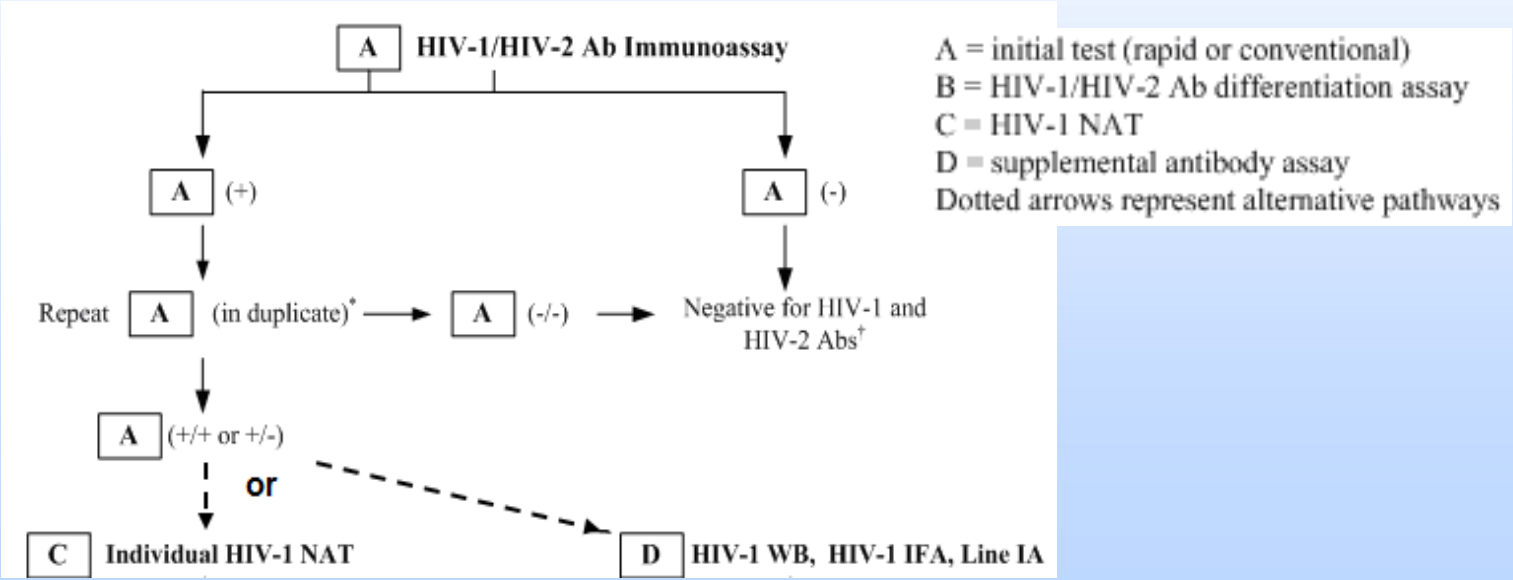
~4,000 Academic medical centers, hospitals, and clinics



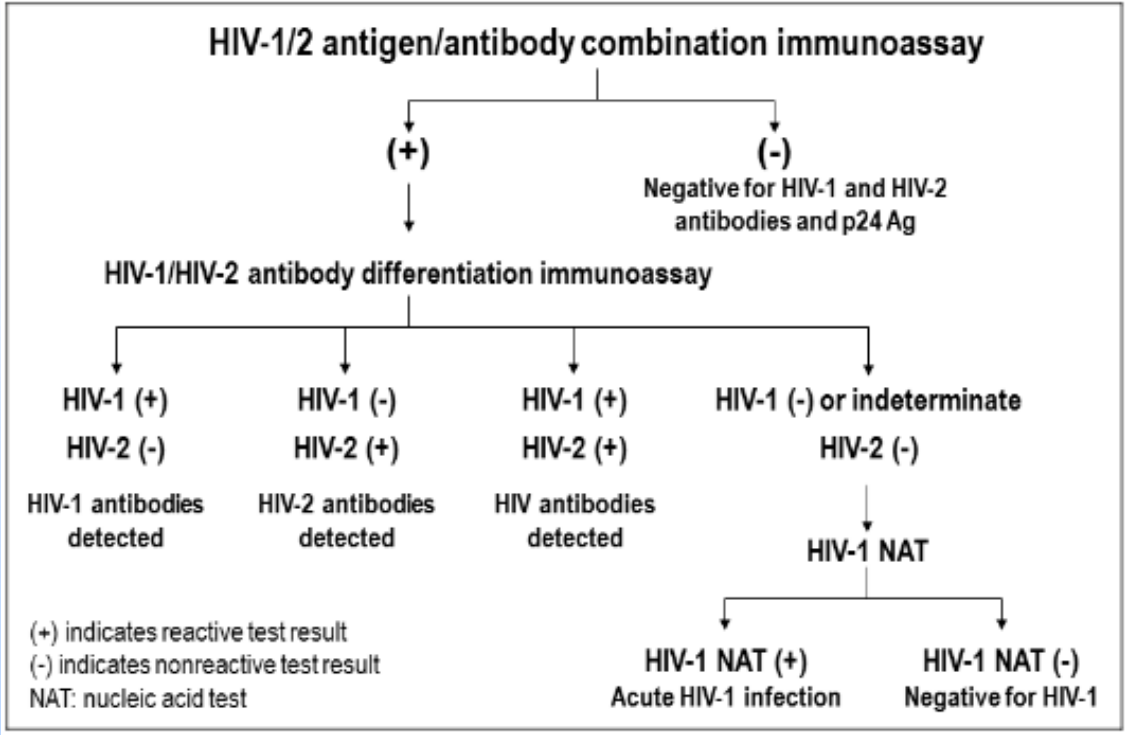
Background

- Prior to June 2014: MML performed HIV testing using 3rd generation HIV immunoassays (Ortho Vitros CIA; GS HIV-1/-2 Plus O EIA) with reflex to GS HIV-1 Western blot (Bio-Rad) ± GS HIV-2 EIA (Bio-Rad) ± INNO-LIA HIV I/II Score (Innogenetics)



Background (2)

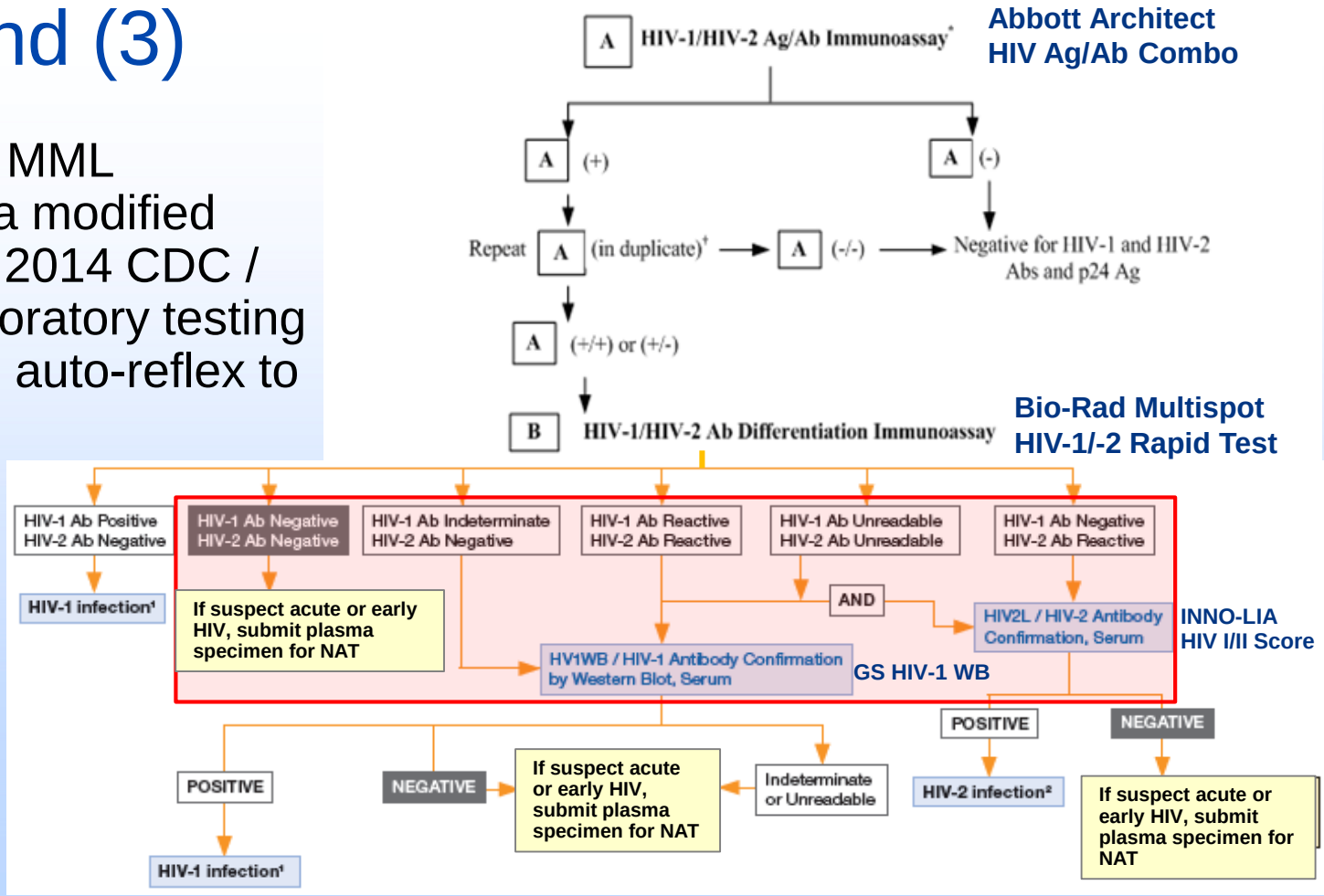
- June 2014: U.S. CDC and APHL issued updated recommendations on HIV laboratory testing algorithm, based on the use of 4th generation HIV immunoassays as initial testing for early detection of HIV infection



Background (3)

- In May 2014: MML implemented a modified version of the 2014 CDC / APHL HIV laboratory testing algorithm, w/o auto-reflex to HIV NAT *

* Concerns for possible sample-to-sample contamination during testing with automated Abbott Architect system



Study Objectives

1. Compare reactivity rates of initial HIV serologic tests and positivity rates of HIV supplemental tests before and after implementation of 2014 CDC / APHL recommended HIV testing algorithm;
2. Determine and compare the test turn-around time, total direct and indirect cost of the test result profiles between the 2 test periods.

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Method

- All HIV test results were retrieved retrospectively from MML lab information system (LIS) during the following study periods before and after implementation of modified 4th gen HIV testing algorithm:
  - Nov 2012 through May 2014 (18 months): 3rd gen algorithm
  - May 2014 through Nov 2015 (18 months): 4th gen algorithm
- Test results for each patient were grouped according to various result profiles
- Test turn-around time (TAT), total direct and indirect testing costs were determined for each result profile

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Results

Algorithm (Period)	Total initial HIV serologic tests (*N*)	"Reactive" initial results (%)	"Positive" supplemental results (%)
3rd Gen (11/2012 – 5/2014)	76,584	534 (0.70%)	112 (21.0%)
4th Gen (5/2014 – 11/2015)	78,998	595 (0.75%)	173 * (29.1%)

** 54.4% increase in (+) rate (multifactorial)*

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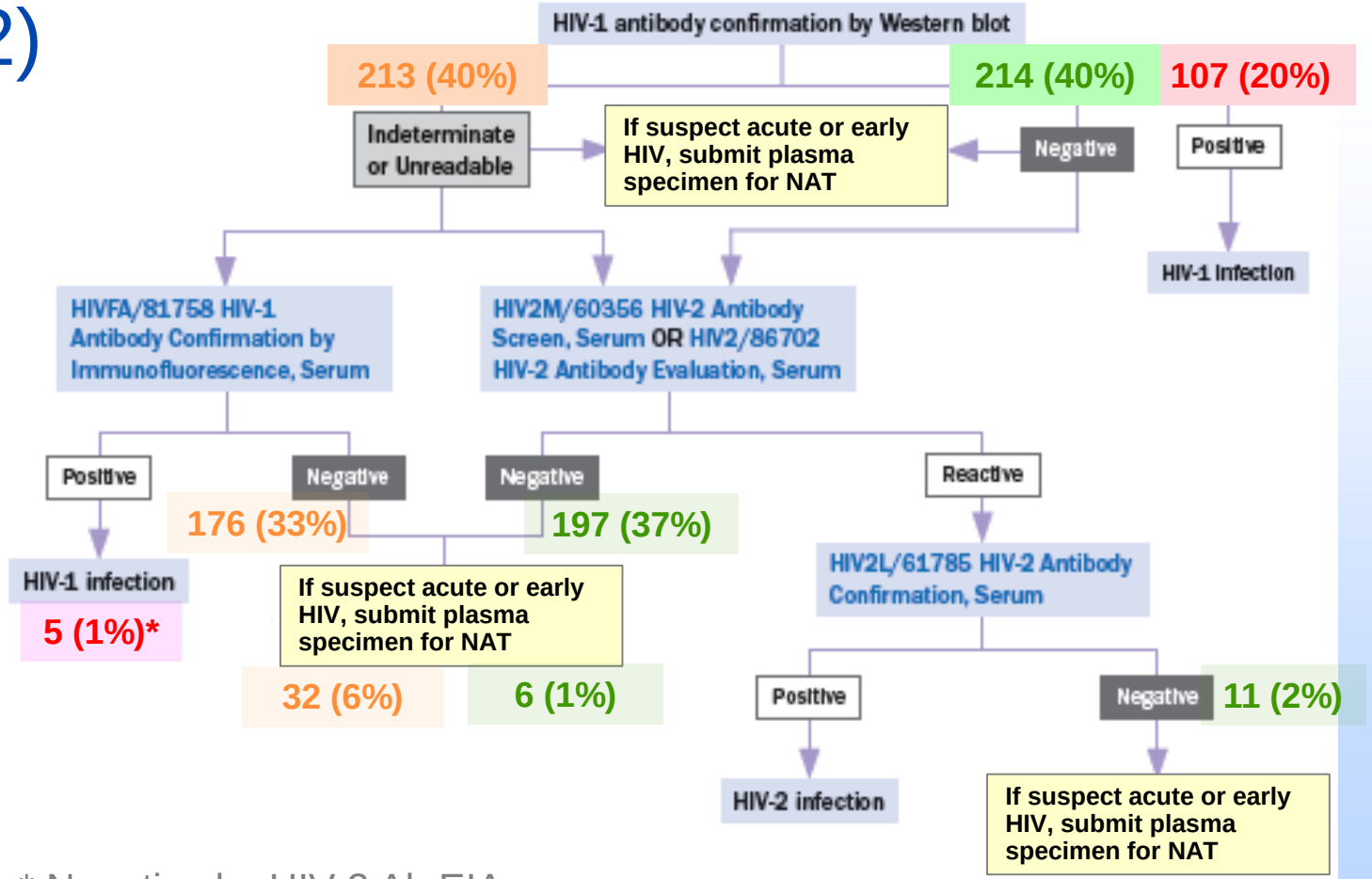
Results (2)

Distribution of result profiles for 3rd generation algorithm 11/2012 – 5/2014

N = 534

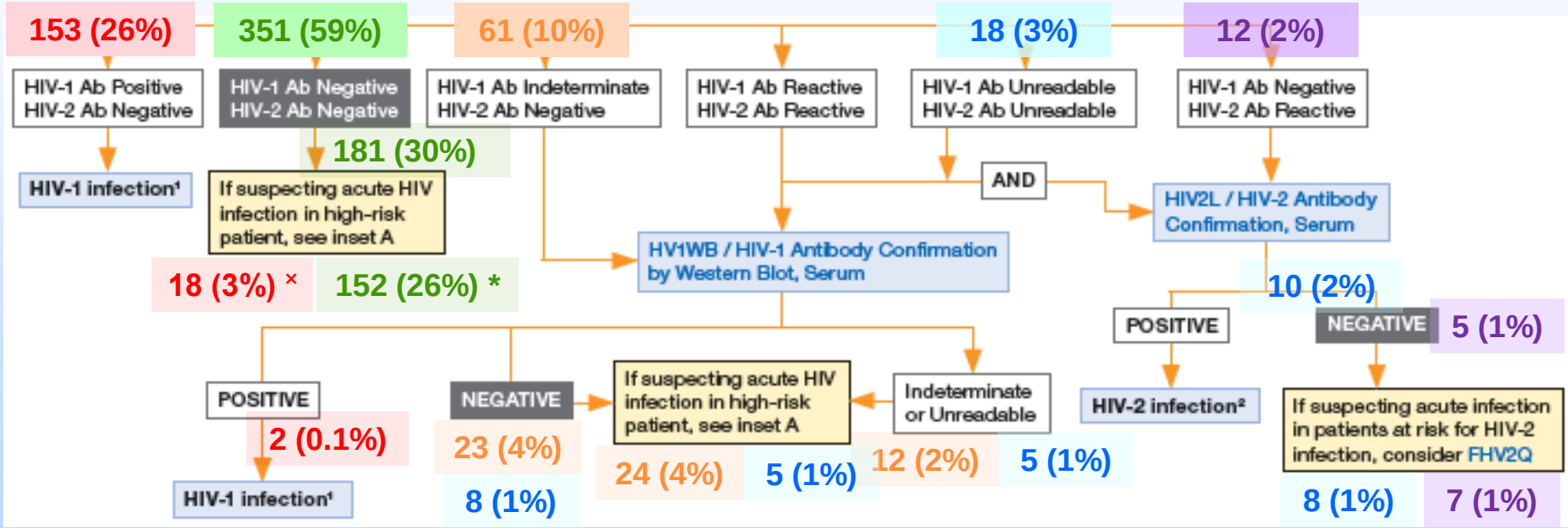


* Negative by HIV-2 Ab EIA

Results (3)

Distribution of result profiles for 4rd gen algorithm, 5/2014 – 11/2015

N = 595



× All are HIV-1 NAT(+); *1 patient had negative HIV-1 and HIV-2 NAT.

Results (4)

Algorithm / Result profile	TAT Median (hr)	TAT Range (hr)	Total cost
3rd Gen			
WB(+)	27.1	6.9 – 89.3	$75.04
WB(-), HV2 EIA(-)	52.4	27.4 – 125.2	$103.91
WB ind, HV1 IFA(-), HV2 EIA(-)	52.4	27.4 – 125.2	$167.81
WB ind, HV1 IFA(±), HV2 EIA(R), HV2 LIA(±)	103.0	71.9 – 241.8	$224.02
WB ind, HV1 IFA(-), HV2 EIA(-), HV1 NAT	293.0	151.9 – 2,011.8	$277.50
4th Gen			
Diff (-) or Diff HV1 (+)	17.4	1.0 – 94.6	$41.52
Diff HV1 ind, WB(±, ind)	95.0	25.5 – 125.5	$101.39
Diff HV1 ind, WB(- or ind), HV1 NAT	175.5	49.1 – 1,782.6	$211.08
Diff HV1 ind, WB ind, HV1 & 2 NAT	374.1	277.5 - 1,810.1	$437.08

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Conclusions

- 54.4% increase in positivity rate during 4th gen algorithm testing period, including 3% by HIV NAT (acute HIV-1 infection);
- No HIV-2 infection detected during 3rd and 4th gen algorithm testing periods;
- 4th gen algorithm testing provided shorter TAT (median of 10 hr less) and less expensive (45% less total costs) Dx of “presumptive” HIV-1 infection than 3rd gen algorithm testing;
- MML modified 4th gen algorithm detected 2 cases (0.1%) of HIV-1 infection by HIV-1 WB among Multispot-indeterminate specimens

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