

# Supplementary Appendix

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## 1 ***Materials and Methods***

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3 This cost model was built on our recent cost-model that compared the same four  
4 algorithms with regard to costs per acute HIV infection (AHI) diagnosis in community based  
5 screening algorithms (1). In short, the cost model used risk data and annual testing and HIV  
6 prevalence [i.e. 3000 HIV tests performed per year, resulting in an overall HIV prevalence of  
7 2.9% (n=87), with 0.7% [n=21] diagnosed with AHI and 2.2% [n=66] with established  
8 infection] observed in MSM undergoing community-based AHI screening in San Diego  
9 between 2006 and 2014. Basic demographics, risk behaviors and frequency of repeat HIV  
10 testing from this cohort of MSM have been published previously (2-6). In the following  
11 section of this supplement we will concisely summarize the methods of the previous model on  
12 costs per AHI diagnosis. More detailed descriptions of the methods, cost items, costs per test  
13 result, annual costs of the four algorithms (calculated for the year 2014) and comparative cost  
14 analysis per AHI diagnosis can be found elsewhere (1).

## 15 ***Excerpt of Methods for Calculation of the previous Model on Costs per Test*** 16 ***Results (1)***

### 17 ***Algorithms***

18 This model compared four community-based HIV screening algorithms: 1.) the San  
19 Diego Early Test, which provides routine HIV nucleic-acid-amplification testing (NAT;  
20 Procleix Ultrio, Hologic, Bedford, MA) in all Ab negative persons, 2.) Architect algorithm,  
21 which provides HIV p24 antigen (Ag) detection via Architect™ (Abbott Diagnostics, Abbott  
22 Park, IL) in all Ab negative persons (in the community setting initial POC Ab testing ensures  
23 that persons with newly diagnosed established HIV get informed about their diagnosis), and  
24 3.) Determine algorithm, which differentiates HIV Ab and p24 Ag detection via the rapid  
25 Determine™ HIV-1/2 Ag/Ab Combo test (Alere Inc, Waltham, MA). These testing

1 approaches were also compared to: 4) point-of-care HIV Ab-testing (INSTI™ HIV-1  
2 Antibody Test, bioLytical Laboratories Inc., Richmond, Canada) alone. All four algorithms  
3 are displayed in Figure S1.

4 Test performances of Architect™, Determine™, and INSTI™ INSTI for diagnosing AHI  
5 and established HIV infection were calculated using published data, as described previously (1). In  
6 algorithms that do not provide POC positive results for AHI (i.e. EarlyTest and Architect  
7 algorithm) a 5% (95%CI 1%-9%) loss of follow up (i.e. clients not informed about AHI  
8 diagnosis) was estimated, based on data observed in the San Diego EarlyTest.

### 9 ***Costs per Test Result***

10 Work-time estimates (measured by our testing personnel) and compensation information  
11 in our screening program were combined to estimate the personnel costs associated with each  
12 of the different testing and counseling procedures (pretest counseling, specimen collection  
13 and test processing, and post-test counseling for persons with negative or positive Ab results,  
14 and additional post-test counseling during a second visit in those with AHI). The cost analyses  
15 were conducted from an established HIV testing program perspective, assuming that there is  
16 an existing data system for delivery of negative results (therefore only maintenance cost were  
17 calculated for the data system), and further assuming that space for HIV counseling and  
18 testing is already available (the cost analysis did therefore not account for costs of space,  
19 electricity etc.). Where possible (e.g. work time) 95%CIs were added. The cost analysis used  
20 actual costs of tests as well as miscellaneous disposable items (95%CI calculated for the  
21 latter, as well as test controls) in our 2014 testing program. For Architect and Determine  
22 algorithms, work-time estimates were performed by testing personnel that had performed both  
23 assays as part of study proposals. Time estimates were therefore performed by testers who actually  
24 performed those tests. Costs for Architect and Determine assays reflect actual prices in our setting.  
25 Cost items used to calculate costs per test result have been published previously (1) and are depicted in

1 Table S1.

2 ***Total annual costs***

3 Costs per test results and test performances were combined to calculate total annual  
4 costs per testing program. Major focus of these total annual costs was cost-items that varied  
5 between the four algorithms, as differences between the algorithms and not total costs  
6 presented the objected outcome of this analysis. Results were expressed in 2014 USD.

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1           References

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13 screening for acute and early HIV infection in san diego. *Medicine (Baltimore)* 94(41): e1830.

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17 score to predict acute and early HIV infection risk in men who have sex with men. *Clin Infect*  
18 *Dis* 61(3): 468-475.

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Cost Items / Diagnosis (in 2014 USD) <i>(test outcomes for which cost items are applicable)</i>	Algorithms				Details
	I Dual Early Test ( <b>EarlyTest</b> )	II Archit ect Combo ( <b>Architect</b> )	III Deter mine Combo ( <b>Determin</b> e)	IV POC Ab alone (Antibody)	
Personnel costs: Pre-test counseling and Testing related procedures <i>(Negative, Established HIV, Acute HIV)</i>	7.90 (95%CI 5.79 – 10.53)	7.90 (95%CI 5.79 – 10.53)	5.26 (95%CI 3.68-6.32)	5.26 (95%CI 3.68-6.32)	Basis: SRA-1 level (31.58USD per hour); phlebotomy for EarlyTest and Architect , total 15 minutes (i.e. 10 minutes pretest counseling, plus 5 minutes sample collection),95%CI 11-20 minutes; blood obtained from fingertip for Determine and Antibody algorithms , total 10 minutes (i.e. 9 minutes pretest counseling, 1 minute sample collection includes test processing), 95% CI 7-12 minutes
Costs for POC/Rapid Ab Test (INSTI™ HIV 1 Antibody Test / Alere Determine™ HIV-1/2 Combo Test) <i>(Negative, Established HIV, Acute HIV)</i>	8.33 (95%CI 8.10-8.56)	8.33 (95%CI 8.10-8.56)	18.22 (95% CI 18.18- 18.26)	8.33 (95%CI 8.10-8.56)	Determine™ p24 Ag/Ab used instead of INSTI™ in Determine algorithm  Costs of INSTI™: 6.99 USD (test) + 1.34 USD (costs per test for controls; assumption one vial set [i.e. 5 USD] per month)  Costs of Determine™: 18.00 USD (test) + 0.22 USD (costs per test for controls; assumption one set of controls [i.e. 55 USD] per month)  Test costs are actual costs provided by manufacturer. 95%CI calculated for costs of controls only.
Costs for further investigations in false positive INSTI™ / Determine™ Combo Test results (i.e. supplemental Ab Test [ Uni-Gold™ Recombigen® HIV Antibody Test ] plus counseling for all four algorithms, plus costs for phlebotomy, ID NAT and second visit for DT and Ab algorithms only) <i>(Negative)</i>	0.06 (95%CI 0.05-0.06)	0.07 (95%CI 0.06-0.08)	0.69 (95%CI 0.57-0.86)	0.43 (95%CI 0.35-0.53)	Calculation based on specificities of 99.5% (i.e. 15 false positives per year) for INSTI™ and 99.2% (i.e. 24 false positives per year) for Determine™  For all 4 algorithms costs of Uni-Gold™: 8.25 USD (test) + 0.09 USD (costs per test for controls; assumption one set of controls [i.e. 23 USD] per month [250 tests per month]); 95% CI 8.32-8.37 USD plus costs of 5 minute pretest counseling and test performance (95%CI 3-7 minutes) by SRA-1 were added.

					<p>Additional costs for performing ID NAT instead of ARCHITECT have been included in Architect algorithm.</p> <p>For false positive Determine™ or INSTI in Determine or Antibody algorithm in addition costs of phlebotomy, ID NAT, second visit and counseling have been included for false positive Ab results. In contrast costs for ID NAT/ Architect, second visit and counseling are already included for all cases in EarlyTest and Architect algorithm (see below).</p>
<p>Costs for further investigations in true positive INSTI™ / Determine™ Combo Test results I Additional Personnel costs for phlebotomy and supplemental Ab test in those with established HIV (Uni-Gold™ Recombigen® HIV Antibody Test/ INSTI™ HIV 1 Antibody): Pre-test counseling and Testing (Established HIV)</p>	<p>2.63 (95%CI 1.58-3.68)</p>	<p>2.63 (95%CI 1.58-3.68)</p>	<p>5.26 (95%CI 3.68-7.37)</p>	<p>5.26 (95%CI 3.68-7.37)</p>	<p>Basis: SRA-1 level (31.58USD per hour); 5 minutes for EarlyTest and Architect algorithms (pretest counseling and performance of Unigold), 95%CI 3-7 minutes; 10 minutes for Determine and Antibody algorithms (5 minutes for sample collection using phlebotomy- needed for further supplemental testing with e.g. Western Blot, plus 5 minutes pretest counseling and performance of Unigold), 95%CI 7-14 minutes</p>
<p>Costs for further investigations in true positive INSTI™ / Determine™ Combo Test results II Costs for supplemental Ab Test (Uni-Gold™ Recombigen® HIV Antibody Test) (Established HIV)</p>	<p>8.34 (95% CI 8.32-8.37)</p>	<p>8.34 (95% CI 8.32-8.37)</p>	<p>8.34 (95% CI 8.32-8.37)</p>	<p>8.34 (95% CI 8.32-8.37)</p>	<p>Costs of Uni-Gold™: 8.25 USD (test) + 0.09 USD (costs per test for controls; assumption one set of controls [i.e. 23 USD] per month [250 tests per month]). Test costs are actual costs provided by manufacturer. 95%CI calculated for costs of controls only.</p>
<p>Costs for further investigations in true positive Determine™ Combo Test results (Acute HIV)</p>	<p>-</p>	<p>-</p>	<p>26.46 (95%CI 24.45- 29.01)</p>	<p>-</p>	<p>Contains costs for UniGold™ Antibody Test to rule out established HIV (8.34 USD) plus costs for pretest counseling plus phlebotomy (5.26 USD personnel costs for sample collection plus 12.86 for disposable items)</p>
<p>Cost of miscellaneous disposable items (Negative, Acute HIV)</p>	<p>12.86 (95%CI 12.45- 13.27)</p>	<p>12.86 (95%CI 12.45- 13.27)</p>	<p>10.41 (95%CI 10.05- 10.77)</p>	<p>10.41 (95%CI 10.05- 10.77)</p>	<p>Includes: latex gloves, sterile wipes and gauze pads, adhesive bandages, phlebotomy equipment (needles, holders, blood tubes), absorbent workspace covers, biohazard waste-disposal bags, and laboratory supplies (pipettes, tubes). Items and costs differ between Determine and Antibody algorithms, where blood is obtained from fingertip and EarlyTest and Architect algorithms where phlebotomy is performed.</p>

Cost of miscellaneous disposable items (Established HIV)	12.86 (95%CI 12.45- 13.27)	12.86 (95%CI 12.45- 13.27)	23.27 (95%CI 22.50- 24.04)	23.27 (95%CI 22.50- 24.04)	Includes: latex gloves, sterile wipes and gauze pads, adhesive bandages, phlebotomy equipment (needles, holders, blood tubes), absorbent workspace covers, biohazard waste-disposal bags, and laboratory supplies (pipettes, tubes). Items and costs differ between Determine and Antibody algorithms, where blood is obtained primarily from fingertip, and then later again from phlebotomy, and EarlyTest and Architect algorithms where phlebotomy is performed primarily.
Costs for room (Negative, Established HIV, Acute HIV)	0	0	0	0	Cost analyses conducted from an HIV testing program perspective assuming that there is no extra cost for rooms of HIV counseling and testing.
Post-test counseling (Negative)	5.26 (95%CI 3.16-7.90)	5.26 (95%CI 3.16-7.90)	5.26 (95%CI 3.16-7.90)	5.26 (95%CI 3.16-7.90)	Basis: SRA-1 level (31.58USD per hour); 10 minutes for negative results (95%CI 6 minutes-15 minutes).
Post-test counseling (Established HIV)	15.79 (95%CI 10.53- 26.32)	15.79 (95%CI 10.53- 26.32)	15.79 (95%CI 10.53- 26.32)	15.79 (95%CI 10.53- 26.32)	Basis: SRA-1 level (31.58USD per hour); 30 minutes for positive results (95%CI 20 minutes-50 minutes)-
Post-test counseling POC results (Acute HIV)	5.26 (95%CI 3.16-7.90)	5.26 (95%CI 3.16-7.90)	15.79 (95%CI 10.53- 21.05)		Basis: SRA-1 level (31.58USD per hour); 10 minutes for negative results in EarlyTest and Architect algorithm,(95%CI 6 minutes-15 minutes); 30 minutes(95%CI 20 minutes-40 minutes) for positive result in Determine algorithm (which still needs to be confirmed by NAT).
Sending samples with FEDEX to St. Louis for HIV-1/HCV/HBV qualitative NAT Testing (American Red Cross National testing lab in St. Louis, MO) (Negative)	1.97 (95% CI 1.90-2.04)	0	-	-	Costs calculated assuming 246 tests per month and shipments 3 times per week (i.e. 13 shipments per month); i.e. 19 samples per shipment; cost per shipment USD 27.43 + 10 USD per case (case costs 50 USD and it was assumed that every case is reused 5 times). For Architect algorithm no costs for shipping of samples as ARCHITECT testing assumed available "in house"
Sending samples with FEDEX to St. Louis for HIV-1/HCV/HBV qualitative NAT Testing (American Red Cross National testing lab in St. Louis, MO) (Acute HIV)	1.97 (95% CI 1.90-2.04)	0	1.97 (95% CI 1.90-2.04)	-	



Costs for HIV-1/HCV/HBV qualitative NAT Testing (Procleix™ Ultrio™ Assay) or ARCHITECT testing ( <i>Negative</i> )	21.00	20.00	-	-	Actual test costs at UCSD /provided by manufacturer. NO 95%CI calculated.
Costs for HIV-1/HCV/HBV qualitative NAT Testing (Procleix™ Ultrio™ Assay) or ARCHITECT testing ( <i>Acute HIV</i> )	21.00	20.00	21.00	-	Actual test costs at UCSD /provided by manufacturer. NO 95%CI calculated.
Data System Maintenance Costs (for delivering negative results) ( <i>Negative</i> )	13.60 (95%CI 13.00- 14.20)	13.60 (95%CI 13.00- 14.20)	-	-	Assumption Data system is available. Basis for costs salary of technician maintaining data system (i.e. 3318 USD per month) divided through 244 (i.e. number of negative tests per month)
Costs for calling in those with positive NAT results (phone calls, messages) ( <i>Acute HIV</i> )	7.90 (95%CI 1.58-15.80)	7.90 (95%CI 1.58-15.80)	7.90 (95%CI 1.58-15.80)	-	Basis: SRA-1 level (31.58USD per hour); 15 minutes (95%CI 3 minutes-30 minutes) Estimation: 5% of positives can't be reached EarlyTest and Architect algorithms; all clients reached in Determine algorithm (more extensive posttest counseling after positive Determine POC result).
Transportation money for necessary second visit ( <i>Acute HIV</i> )	10.00	10.00	10.00	-	
Post-test counseling ( <i>Acute HIV</i> )	15.79 (95%CI 10.53- 26.32)	15.79 (95%CI 10.53- 26.32)	15.79 (95%CI 10.53- 26.32)		Basis: SRA-1 level (31.58USD per hour); 30 minutes for positive results (95%CI 20 mintes-50 minutes).
<b>TOTAL BASE COSTS PER NEGATIVE TEST RESULT</b>	<b>70.98</b>	<b>68.02</b>	<b>39.84</b>	<b>29.69</b>	
<b>TOTAL COSTS PER NEGATIVE TEST RESULT IN PROBABILISTIC SENSITIVITY ANALYSIS (MEAN, SD)</b>	<b>71.47 (2.02)</b>	<b>68.51 (2.02)</b>	<b>39.89 (1.61)</b>	<b>29.73 (1.61)</b>	
<b>TOTAL BASE COSTS PER ESTABLISHED HIV DIAGNOSIS</b>	<b>55.85</b>	<b>55.85</b>	<b>76.14</b>	<b>66.25</b>	
<b>TOTAL COSTS PER ESTABLISHED HIV DIAGNOSIS IN PROBABILISTIC SENSITIVITY ANALYSIS (MEAN, SD)</b>	<b>58.78 (4.68)</b>	<b>58.78 (4.68)</b>	<b>78.93 (4.59)</b>	<b>69.03 (4.58)</b>	
<b>TOTAL BASE COSTS PER ACUTE HIV DIAGNOSIS BUT LOST TO FOLLOW UP (i.e. not informed about diagnosis)</b>	<b>65.22</b>	<b>62.25</b>	<b>-</b>	<b>-</b>	<b>Loss of follow up only in algorithms that do not provide POC positive results for AHI (i.e. EarlyTest and Architect algorithm)</b>

<b>TOTAL COSTS PER ACUTE HIV DIAGNOSIS ACUTE HIV DIAGNOSIS BUT LOST TO FOLLOW UP IN PROBABILISTIC SENSITIVITY ANALYSIS (MEAN, SD)</b>	<b>66.59 (4.57)</b>	<b>63.63 (4.57)</b>	<b>-</b>	<b>-</b>	
<b>TOTAL BASE COSTS PER ACUTE HIV DIAGNOSIS</b>	<b>91.01</b>	<b>88.04</b>	<b>132.80</b>	<b>-</b>	<b>Acute HIV diagnosed in EarlyTest , Architect and Determine algorithms only.</b>
<b>TOTAL COSTS PER ACUTE HIV DIAGNOSIS IN PROBABILISTIC SENSITIVITY ANALYSIS (MEAN, SD)</b>	<b>95.11 (6.33)</b>	<b>92.14 (6.33)</b>	<b>136.51 (6.80)</b>	<b>-</b>	

4        **Table S 1:** Base costs as well as costs in probabilistic sensitivity analysis per negative test, per established HIV diagnosis and per acute HIV  
5 diagnosis in the Dual EarlyTest (POC AB+ID NAT), the Architect combo, the Determine combo, and the POC Antibody (Antibody) alone  
6 algorithms. Uniformly distributed 95%CI were calculated for applicable cost items and used for probabilistic sensitivity analyses on costs per test  
7 result. Adapted from (1).

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1 **Figure S 1:** The four algorithms that were evaluated in this cost-analysis. EarlyTest, Architect, Determine, and Antibody only. White shade are  
2 point-of-care results, grey shade results that require a second visit. Adapted from (1).  
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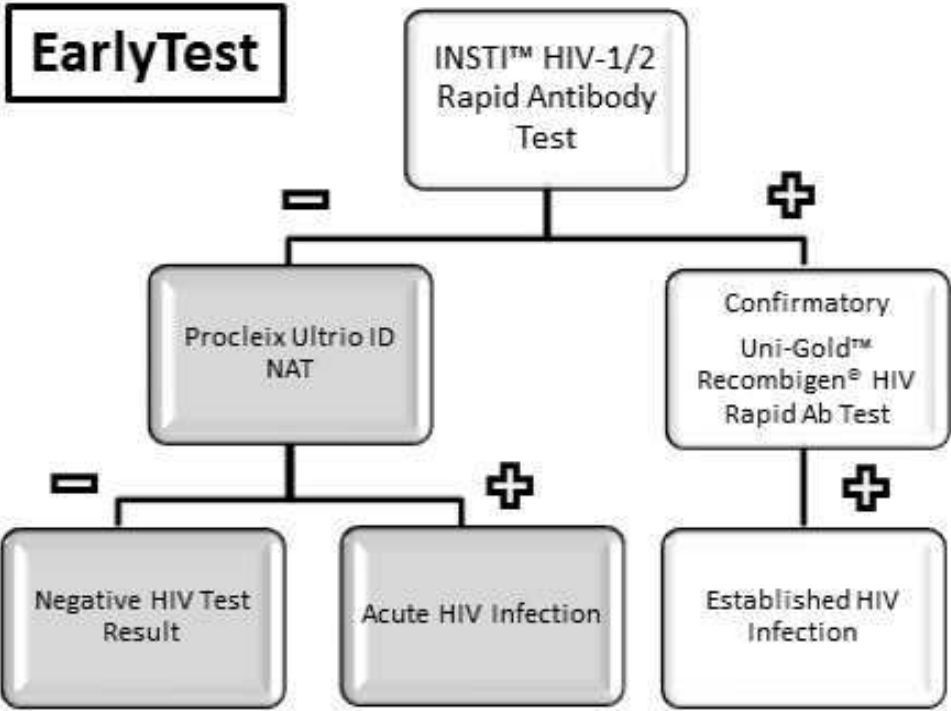
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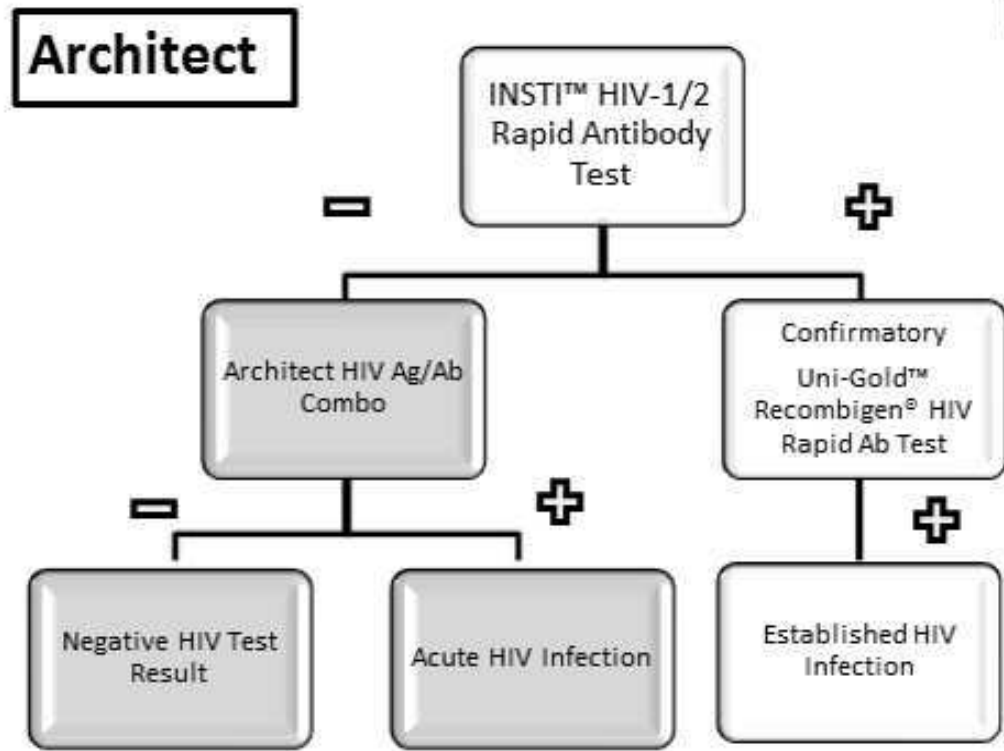
7



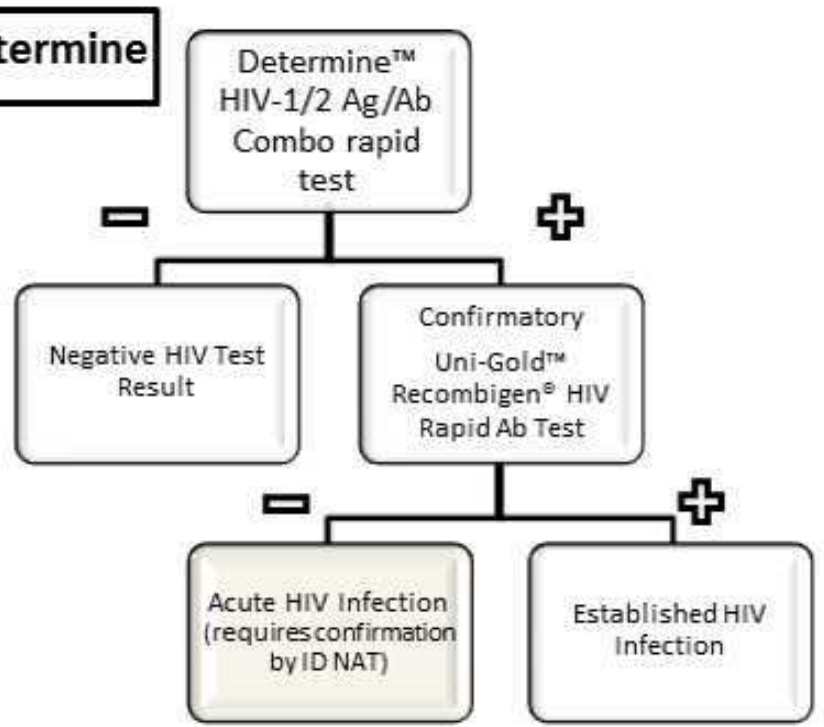
# EarlyTest



# Architect



# Determine



# Antibody

