

ARCHITECT HIV Ag/Ab Combo: Acute HIV and the value of 4th generation
testing

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Architect HIV Ag/Ab Combo

Acute HIV and the value of 4th generation testing



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Intended Use and Important Safety Information

The ARCHITECT HIV Ag/Ab Combo assay is a chemiluminescent microparticle immunoassay (CMIA) for the simultaneous qualitative detection of human immunodeficiency virus (HIV) p24 antigen and antibodies to HIV type 1 (HIV-1 group M and group O) and/or type 2 (HIV-2) in human serum and plasma (EDTA and heparin). The ARCHITECT HIV Ag/Ab Combo assay is intended to be used as an aid in the diagnosis of HIV-1/HIV-2 infection, including acute or primary HIV-1 infection. The assay may also be used as an aid in the diagnosis of HIV-1/HIV-2 infection in pediatric subjects (i.e., children as young as two years of age) and in pregnant women. An ARCHITECT HIV Ag/Ab Combo reactive result does not distinguish between the detection of HIV p24 antigen, HIV-1 antibody, or HIV-2 antibody.

The ARCHITECT HIV Ag/Ab Combo is not intended for use in screening blood or plasma donors. The effectiveness of ARCHITECT HIV Ag/Ab Combo for use in screening blood or plasma donors has not been established. However, this assay can be used as a blood donor screening assay in urgent situations where traditional licensed blood donor screening tests are unavailable or their use is impractical.

This product requires the handling of human specimens. Human sourced materials should be considered potentially infectious and handled in accordance with the OSHA Standards. This product contains sodium azide: material and its container must be disposed of in a safe way. Assay results should be interpreted in conjunction with the patient's clinical presentation, history, and other laboratory results. If the results are inconsistent with clinical evidence, additional testing is suggested to confirm the result. The performance of this assay has not been established for individuals younger than two years of age.



Terms and Conditions

This is an interactive presentation intended for use in commercial discussions regarding Abbott's ARCHITECT HIV Ag/Ab Combo assay. The calculations quantify the potential impact of fourth-generation HIV testing as an alternative to 3rd-generation testing for HIV in the United States, including an estimated number of patients correctly identified or missed in certain scenarios, and cost-effectiveness.

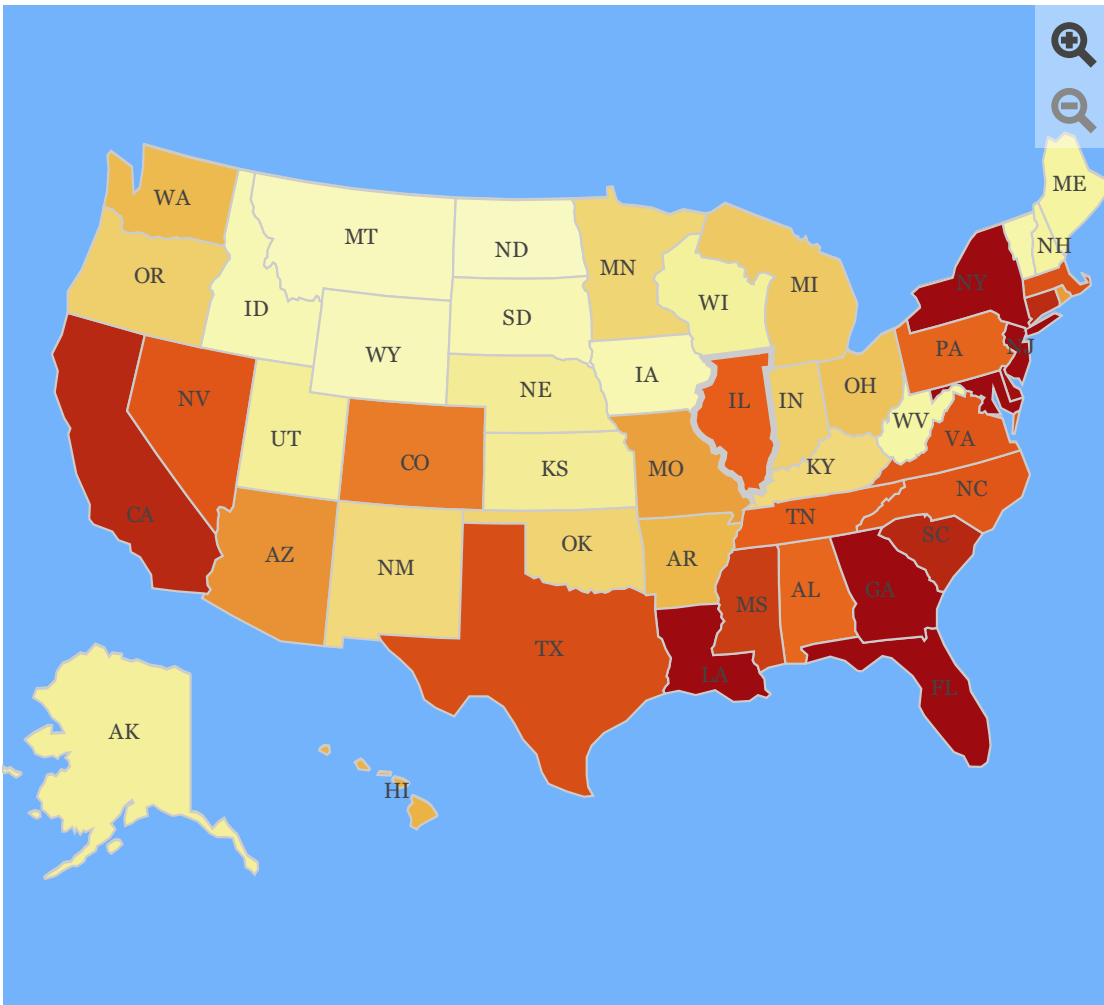
The calculations within this tool are based upon data from the scientific literature, commercially available data sets, data provided by the customer, and various external sources. Estimates resulting from the tool are merely for educational purposes. It is not intended nor necessarily suitable for any other purpose.

It should be recognized that because future events do not occur exactly as expected, there are usually differences between cost estimates and the actual results. Abbott does not take responsibility for any such discrepancies.

This tool is expressly not to be distributed to third parties.

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HIV infection affects patients throughout the United States



Persons Living with an HIV Diagnosis, 2010¹

In Illinois:

an estimated 300 of every 100,000 people live with an HIV diagnosis.

Given the population size, this translates into 31,884 cases.¹



And closer to home ...

Health System:

State:

County:

Patient population served (est.): 

In Cook County, Illinois

an estimated 559 of every 100,000 people are living with HIV.¹

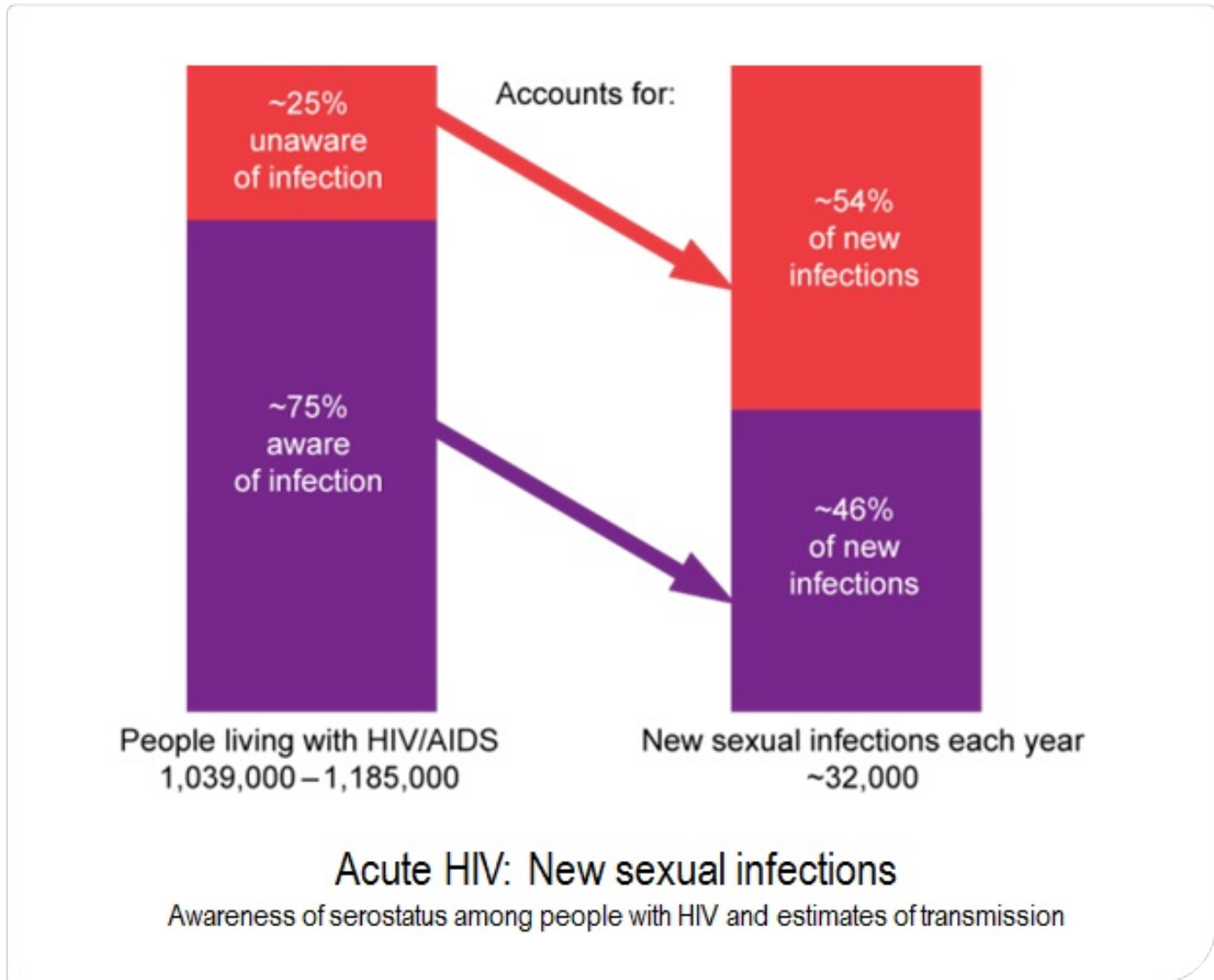
For Example Health System, this infection rate could translate into 1,118 cases of HIV, with 225 cases (20.1%²) potentially undiagnosed.

[Calculation detail](#)

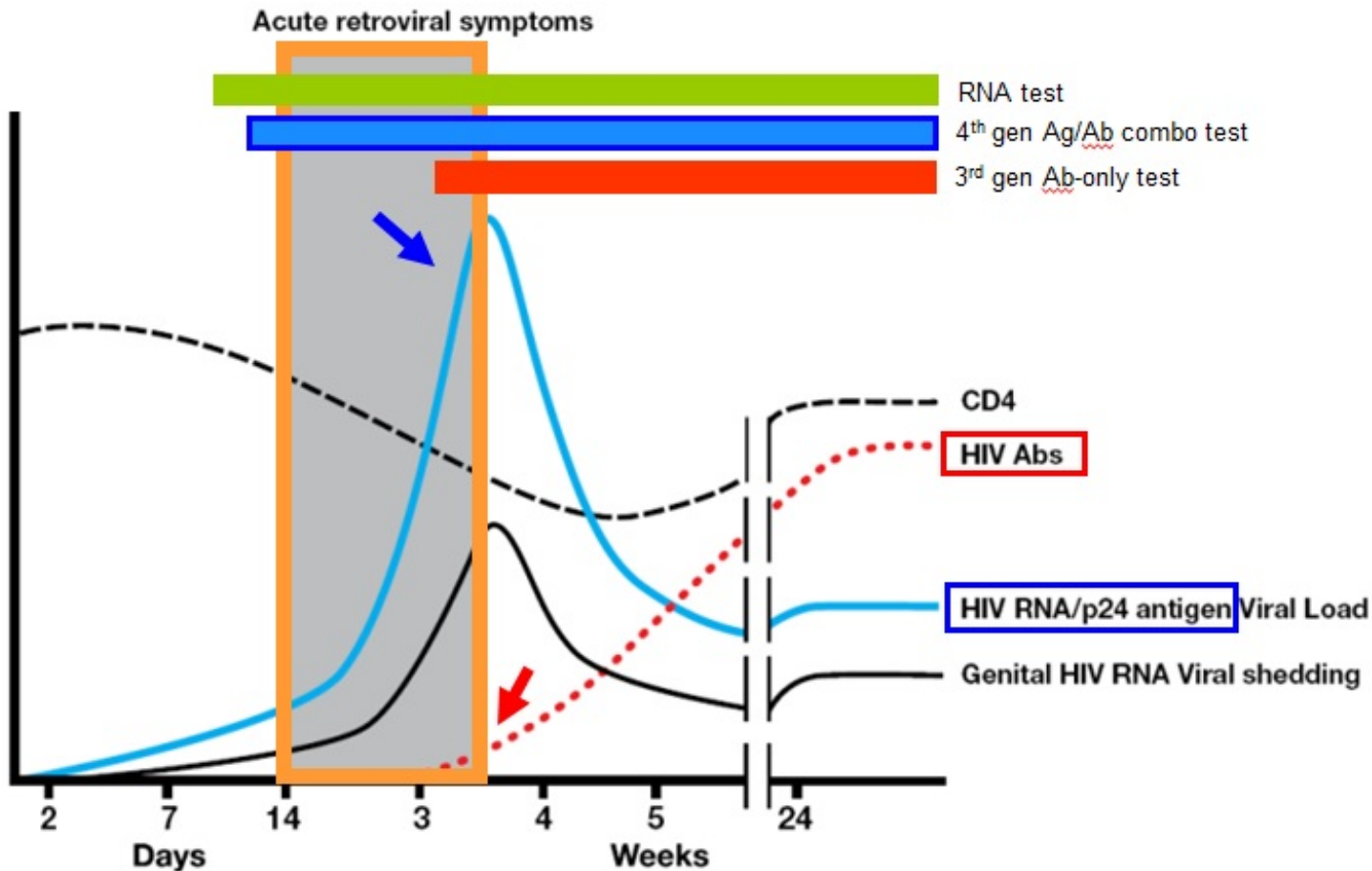
Stopping HIV transmission is key to achieving an AIDS-Free Generation 3

More than half of new infections

Are caused by those unaware of their HIV infection 4, 5



Fourth-generation laboratory tests can detect HIV earlier, when it is highly infectious



Fourth-generation immunoassay tests can:

Identify HIV up to 20 days earlier than other test methods

6

7



How many people might be identified earlier in your health system?

Studies have found up to 10% of all HIV infections in a tested population are in the acute phase, where an antibody-only assay would not likely identify them. 8-10

In Example Health System's estimated population of 225 undiagnosed cases of HIV

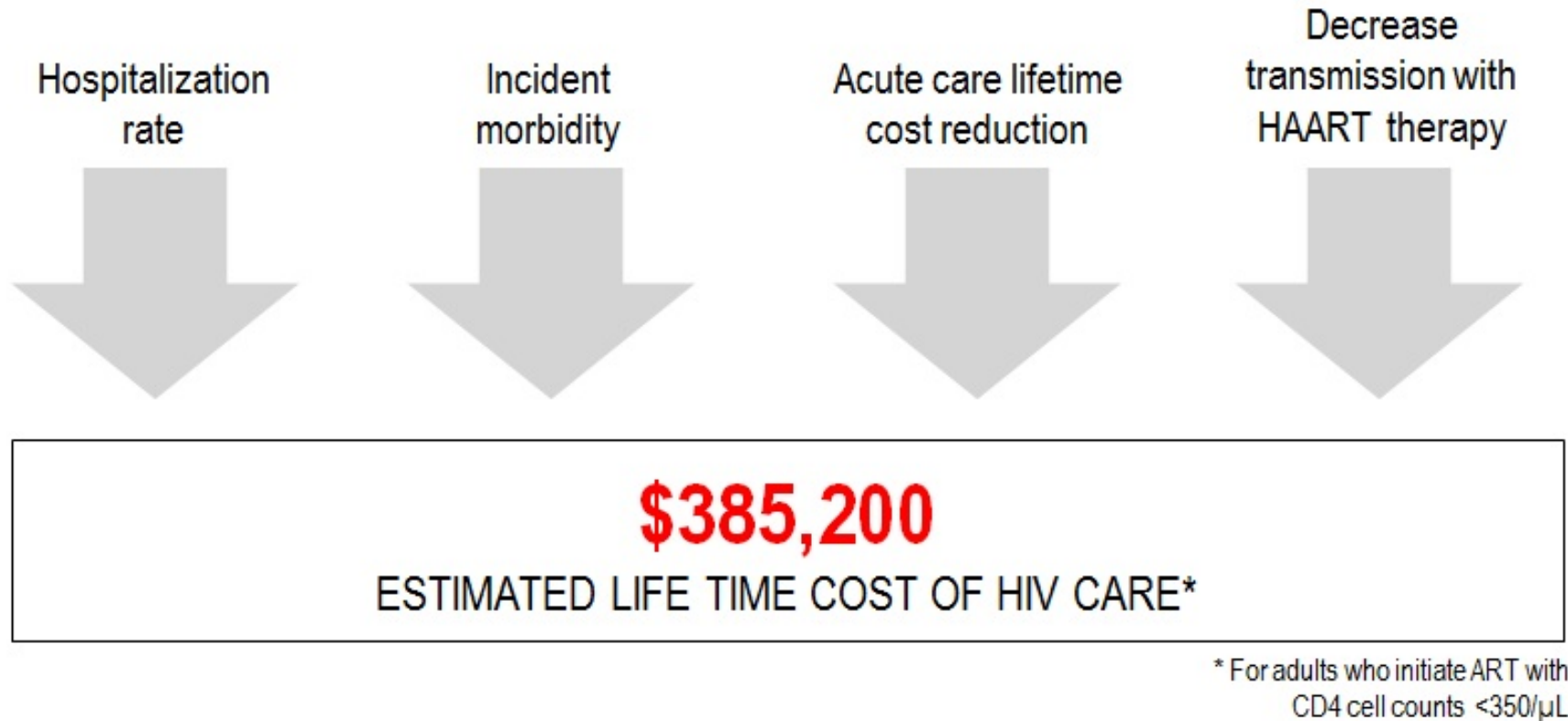
10% acute cases could translate into up to 23 HIV-positive patients which might be missed with antibody-only testing

% acute HIV cases: 10%



What about cost-effectiveness?

Timely diagnosis and treatment of HIV can lead to health economic benefits 11-14



What about cost-effectiveness versus 3rd-generation HIV testing?



[HIV Clin Trials](#). 2012 Jan-Feb;13(1):11-22. doi: 10.1310/hct1301-011.

Cost-effectiveness of a fourth-generation combination immunoassay for human immunodeficiency virus (HIV) antibody and p24 antigen for the detection of HIV infections in the United States.

[Cragin L](#)¹, [Pan F](#), [Peng S](#), [Zenilman JM](#), [Green J](#), [Doucet C](#), [Chalfin DB](#), [de Lissovoy G](#).

Cost-effectiveness of 4th-generation testing arises from 15

- an increased number of correctly identified cases
- earlier detection and treatment

Combined with patient behavior modifications, this may lead to

- fewer transmissions
- longer life expectancy
- higher quality of life



In the scenario we discussed for 200,000 people seen by Example Health System

- **An estimated 1,118 people are living with HIV, with 225 who may be undiagnosed and contagious**
- **10 percent of the 225 undiagnosed may be in the acute (early) stage of HIV infection, which can be missed if 4th-generation HIV testing is not used**
- **Early diagnosis and treatment may be cost-effective due to improved patient outcomes and reduced transmissions**



Assumptions and Limitations

- Exact costs and budget impact are different for every customer setting. This analysis is for general discussion purposes only. These numbers are not a guarantee of savings, and represent an example of potential outcomes.
- Population and prevalence numbers are based on 2010 data as published by the U.S. Centers for Disease Control and Prevention. Where county data is unavailable, state data is used.
- Estimated acute HIV cases are calculated based on customer input for the population size, and a range of percentages of acute infection based on case examples.
- Assumptions for cost-effectiveness are based on Cragin et al's publication, which details a patient microsimulation model.
- Cost-effectiveness varies by scenario. Key variables identified by Cragin et al include prevalence, test cost, time to correctly identify HIV infection if the original test result is false negative, and other variables listed in the publication.





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