

ARCHITECT HIV Ag/Ab COMBO

BACKGROUND

- HIV infection affects more than 1.2 million people in the U.S.¹
- Nearly 1/3 of transmissions are caused by those unaware of their HIV infection¹
- HIV Ag/Ab Combo tests identify HIV infections earlier than antibody-only test method which can lead to reduced transmissions²
- Center for Disease Control guidelines recommend the use of HIV Ag/Ab Combo as first line of testing³

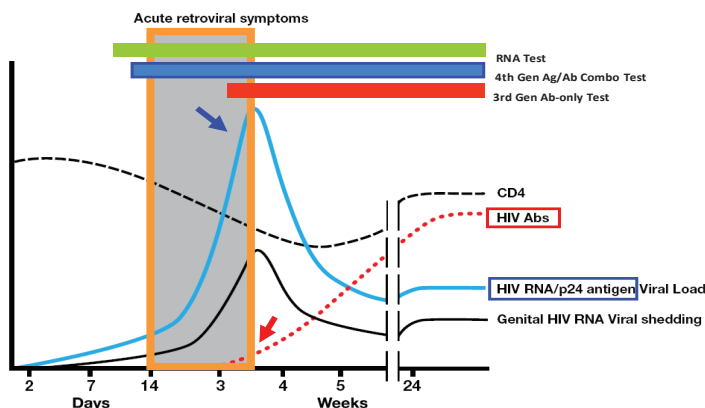
VALUE TO YOUR LAB

Abbott ARCHITECT HIV Ag/Ab Combo Assay aids in the early and accurate diagnosis of HIV:

- Excellent clinical sensitivity leading to fewer false negatives
- Excellent clinical specificity leading to fewer false positives and reduced confirmatory testing²
- Excellent turnaround time among automated platforms for 4th generation tests

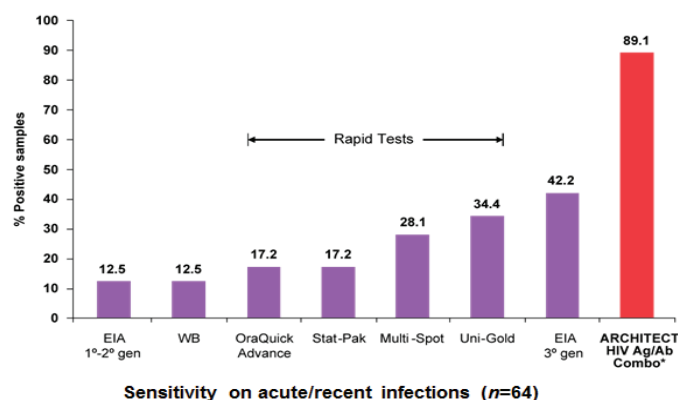
Abbott global surveillance program is continuously monitoring HIV variants

4TH GENERATION PROVIDES EARLIER DETECTION⁴



Adapted from: Marquez, MLO February 2008. "HIV Testing: An Update."

SENSITIVITY ON ACUTE/RECENT INFECTIONS⁵



*ARCHITECT HIV Ag/Ab Combo data generated using reagents not available for sale in the US (LN 4J27).

Adapted from: Pandori, et al. *J Clin Microbiol.* 2009;47:2639-2642.

INTENDED USE AND IMPORTANT SAFETY INFORMATION

For In Vitro Diagnostics Use

Intended Use: 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.

See Important Safety Information on Reverse

SPECIFICATIONS^{2,6-7}

METHOD & FORMAT	Two-step chemiluminescence microparticle immunoassay (CMIA)
THROUGHPUT / TIME TO FIRST RESULT	Up to 200 tests per hour / 29 minutes
REAGENT ON-BOARD / CALIBRATION STABILITY	30 days / 30 days
INTERPRETATION OF RESULTS	S/CO ≥ 1.00 Reactive S/CO < 1.00 Non-Reactive
SAMPLE VOLUME	Single test – 150 μ L Each additional test – 100 μ L
SAMPLE TYPE	Human serum and plasma
ASSAY SENSITIVITY*	100%
HIV-1 P24 ANTIGEN ANALYTICAL SENSITIVITY*	18.39 pg/mL
ASSAY SPECIFICITY*	99.77%

*Representative data; Results in individual laboratories may vary from this data.

ORDERING INFORMATION

PRODUCT DESCRIPTION	LIST NUMBER	CONFIGURATION
Reagent (tests): 100 500	2P36-25 2P36-35	Each test kit contains: 1 bottle each (microparticles, conjugate, and diluent)
Calibrator	2P36-01	1 Calibrator
Control	2P36-10	5 Controls (1 negative and 4 positive)

AVAILABILITY ON SYSTEM
ARCHITECT i1000SR, i2000, i2000SR

REFERENCES:

1. Morbidity and Mortality Weekly Report (MMWR). 2015;64 (24); 657-662 (June 26, 2015).
2. ARCHITECT HIV Ag/Ab Combo Package Insert G2-6108/R02.
3. Bernard M. Branson, S. Michele Owen, Laura G. Wesolowski, et al. Laboratory Testing for the Diagnosis of HIV Infection.
4. Marquez, MLO February 2008. "HIV Testing: An Update."
5. Pandori, et al. *J Clin Microbial*. 2009;47:2639-2642.
6. ARCHITECT Operations Manual 96211-116.
7. Data on file at Abbott.

INTENDED USE AND IMPORTANT SAFETY INFORMATION (continued)

Important Safety Information: Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in the package insert. This product contains sodium azide. Contact with acids liberates very toxic gas. This material and its container must be disposed of in a safe way.

Caution: United States Federal Law restricts this device to sale and distribution by or on the order of a physician, or to a clinical laboratory; and use is restricted to, by, or on the order of a physician. This product contains human-sourced and/or potentially infectious components and must be handled in accordance with the OSHA Standard on Bloodborne Pathogens.