

TEST CHANGE

Human Immunodeficiency Virus (HIV) Combo Antigen/Antibody (HIV-1/O/2) by CIA with Reflex to HIV-1/HIV-2 Antibody Differentiation, Supplemental

2013333, HIVAGABGE

Specimen Requirements:

Patient Preparation: N/A

Collect: Serum separator tube (SST). Also acceptable: Lavender (EDTA) or pink (K2EDTA).

Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 1.5 mL serum **or plasma** into an ARUP standard transport tube. (Min: 0.75 mL) Remove particulate material.

Transport Temperature: ~~Frozen~~ Refrigerated.

Unacceptable Conditions: Specimens containing particulate material. Severely hemolyzed or heat-inactivated specimens.

Remarks:

Stability: After separation from cells: Ambient: 24 hours; Refrigerated: 7 days; Frozen: 8 months (avoid repeated freeze/thaw cycles)

Methodology: Qualitative Chemiluminescent Immunoassay (CLIA)/Qualitative Immunoassay

Performed: Sun-Sat

Reported: 1-2 days

Note: The fourth-generation screen test is for the simultaneous qualitative detection of human immunodeficiency virus type 1 (HIV-1) p24 antigen and antibodies to HIV type 1 (HIV-1 groups M and O) and HIV type 2 (HIV-2). Results of the screen cannot be used to distinguish between the presence of HIV-1 p24 antigen, HIV-1 antibody, or HIV-2 antibody. The reflexed HIV-1/ HIV-2 antibody differentiation test discriminates between HIV-1 and HIV-2 antibodies. Results for each type are reported. If the HIV-1,2 combo antigen/antibody screen is repeatedly reactive, then the HIV-1/ HIV-2 antibody differentiation test will be performed. Additional charges apply. A recommendation to order further testing on a separate specimen for HIV-1/**HIV-2** nucleic acid will be made for certain results. This multitest algorithm is recommended by the Centers for Disease Control and Prevention (CDC) and was adopted by the Clinical

Laboratory Standards Institute (CLSI) for the diagnosis of HIV.

CPT Codes: 87389; if reflexed, add 86701; 86702

New York DOH Approval Status: This test is New York DOH approved.

Interpretive Data:

This test should not be used for blood donor screening, associated reentry protocols, or for screening human cell, tissues, and cellular- and tissue-based products (HCT/P).

Reference Interval:

| Test Number | Components | Reference Interval |
|-------------|--------------------------------|--------------------|
| | HIV 1,2 Combo Antigen/Antibody | Negative |