

TEST CHANGE

Human Immunodeficiency Virus (HIV) Combo Antigen/Antibody (HIV-1/O/2) by CIA, Reflexive Panel

2012674, HIV PANEL

Specimen Requirements:

Patient Preparation:

Collect: ~~Serum separator tube (SST), lavender~~ **Lavender** (EDTA) or pink (K2EDTA).

Specimen Preparation: Separate from cells within 24 hours of collection. Transfer 3 mL ~~serum or~~ plasma into an ARUP standard transport tube. (Min: ~~2.3~~ mL) Remove particulate material. This test requires a dedicated transport tube submitted only for **the HIV PANEL assay** testing.

Transport Temperature: Frozen.

Unacceptable Conditions: ~~Serum~~-Heparinized or citrated plasma specimens. **Plasma preparation tube**. Specimens containing particulate material. Severely hemolyzed or heat-inactivated specimens.

Remarks:

Stability: After separation from cells: Ambient: 24 hours (CRITICAL: SHIP FROZEN); Refrigerated: ~~5 days~~ **72 hours**; Frozen: ~~6 weeks~~ **3 months** (avoid repeated freeze/thaw cycles)

Methodology: Qualitative Chemiluminescent Immunoassay (CLIA)/Qualitative Immunoassay/**Qualitative Polymerase Chain Reaction (PCR)**~~Quantitative Transcription-Mediated Amplification (TMA)~~

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 (Ab), or HIV-2 Ab. If the HIV-1,2 combo antigen/Ab screen is repeatedly reactive, then the HIV-1/2 Ab differentiation immunoassay will be performed. Additional charges apply. The HIV-1/2 Ab differentiation immunoassay confirms and discriminates between HIV-1 and HIV-2 Abs. Results for each type are reported. If the HIV-1/2

Ab differentiation immunoassay is Negative or Indeterminate, then the Human Immunodeficiency Virus 1 and 2 (HIV-1/HIV-2) by Qualitative NAAT, Plasma will be added. Additional charges apply. 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 (refer to <http://arupconsult.com/content/human-immunodeficiency-virus>). Refer to the following tests for additional information regarding Performed or Reported times, Interpretive Data, and Notes for the reflex tests of this panel: Human Immunodeficiency Virus Types 1 and 2 (HIV-1/2) Antibody Differentiation, Supplemental with Reflex to HIV-1/HIV-2 Qualitative ~~Quantitative~~ NAAT, Plasma (ARUP test code 2012669); Human Immunodeficiency Virus 1 and 2 (HIV-1/HIV-2) by Qualitative NAAT, Plasma (ARUP test code 3017779~~3000867~~).

CPT Codes: 87389; if reflexed, add 86701 and 86702; if reflexed, add 87535~~6~~

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 cells, tissues, and cellular- and tissue-based products (HCT/P).

Reference Interval:

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

Effective November 12, 2018