Lab Dept:	**Serology**
Test Name:	**HIV-1,2 COMBO EVALUATION REFLEX (ANTI-HIV-1,2)**

General Information

Lab Order Codes:	HIVI
Synonyms:	Human Immunodeficiency Virus Types 1 and 2 (combined) Antibodies; Anti-HIV-1,2; Anti-HIV; HIV Screen; HIV Combo; HIV Ag/Ab Screen
CPT Codes:	87389 – HIV-1 antigen, with HIV1/2 antibodies, single result 86701 – HIV-1 antibody (if appropriate) 86702 – HIV antibody-type 2 (if appropriate)
Test Includes:	HIV-1,2 Ag/Antibody reported as non-reactive or reactive. If HIV-1,2 ag/antibody is reactive, then HIV-1,2 antibody differentiation is performed and referred to Mayo at an additional charge.

Logistics

Test Indications:	In pediatrics age 2 and older, for qualitative deletion of Human Immunodeficiency Virus (HIV) p24 antigen, antibodies to HIV1 groups MTO, and/or antibodies to HIV2. Assay does not distinguish between HIV-1 antibody, HIV-2 antibody or p24 antigen.
Lab Testing Sections:	Serology – Performed on Minneapolis Campus
Referred to:	Mayo Medical Laboratories (Test: HVDIP) if appropriate
Phone Numbers:	MIN Lab: 612-813-6280 STP Lab: 651-220-6550
Test Availability:	Daily, 24 hours
Turnaround Time:	Performed daily. Confirmatory testing may increase turnaround times.
Special Instructions:	N/A

Specimen

Specimen Type:	Blood
Container:	Lavender (EDTA) tube

Draw Volume:	4.5 mL (Minimum: 3 mL) blood
Processed Volume:	1.5 mL (Minimum 1 mL) plasma Note: Minimum does not allow for repeat testing.
Collection:	Routine blood collection
Special Processing:	Lab Staff: Centrifuge specimen within 24 hours, remove serum aliquot into screw-capped round bottom plastic vial. Store at room temperature up to 3 days once separated. Freeze specimen for reflex testing to Mayo. Outside clinics: Refrigerate specimens for testing in Minneapolis. Forward promptly.
Patient Preparation:	None
Sample Rejection:	Specimens other than plamsa; mislabeled or unlabeled specimens

Interpretive

Reference Range:	Non-reactive (HIV1, p24 Ag and HIV1/HIV2 Abs not detected. If reactive, reflex testing at an additional charge will be performed if the specimen is reactive. Refer to Test Includes:
Critical Values:	N/A
Limitations:	Heterophile antibodies may interfere with immunoassay testing. Human anti-mouse antibody positive patients may present falsely elevated or depressed results. The performance of this assay has not been established for individuals younger than 2 years of age. Nearly all infants born to HIV-infected mothers passively acquire maternal antibody, and in some cases, will test antibody positive until age 18 months regardless of whether they are infected. Definitive diagnosis in early infancy require other assays, including HIV nucleic tests or viral culture. A non-reactive result does not exclude the possibility of exposureto or infection with HIV due to antigen or antibody levels that are below the limit of detection of this assay. If results are inconsistent with clinical evidence, additional testing is suggested to confirm the result.

Methodology:

HIV-1, Ag/Ab Screen and HIV-2 Aby: Chemoluminescenct particle assay
HIV-1 Differentiation: Rapid Immunographic method
HIV-2 Differentiation: Rapid Immunographic method

References:

Abbott Architect HIV ½ Combo Reagent Package Insert (April 2012) Abbott Laboratories Diagnostics Division, Abbott Park, IL, 60064, USA

Abbott Alinity HIV Ag/Ab Combo Calibrator Package Insert (September 2019) Abbott Laboratories Diagnostics Division, Abbott Park, IL, 60064, USA

Abbott Alinity HIV Ag/Ab Combo Controls Package Insert (September 2019) Abbott Laboratories Diagnostics Division, Abbott Park, IL, 60064, USA

Abbott Alinity HIV Ag/Ab Combo Reagent Package Insert (September 2019) Abbott Laboratories Diagnostics Divison, Abbott Park, IL, 60064, USA

Updates:

4/6/2004: Test moved from Memorial Blood Center of Minneapolis to Mayo Medical Laboratories. Note: Test now reflexes to supplemental/confirmatory testing (with additional charges) when indicated by reactive findings.
11/18/2008: Method change, previously listed as Enzyme Immunoassay
3/13/2012: EDTA no longer appropriate tube type.
3/1/2013: HIV-2 confirmation now preformed by immunoassay at Mayo.
5/19/2014: Method change previously listed as HIV1/2 Aby Scn by Chemoluminescence (EIA). Now also screen for HIV-1 antigen. CPT code change for screening test. Previously listed as 86709.
5/15/2018: Qualitative test moved to inhouse test, updated method.
8/14/2018: Tube type, previously SST, and volume update.
12/8/2020: Updated for method Abbott Alinity.